SIEMENS

ACUSON S1000 ACUSON S2000 ACUSON S3000 Diagnostic Ultrasound System Instructions for Use



Complies with IMDA Standards DA107142



ACUSON S1000 ACUSON S2000 ACUSON S3000 Product Version VE10

©2008-2017 Siemens Medical Solutions USA, Inc.

All Rights Reserved.

February 2017

3-Scape, AcuNav, ACUSON, ACUSON AcuNav, ACUSON S1000, ACUSON S2000, ACUSON S3000, ACUSON S Family, Advanced fourSight, Advanced SieClear, Axius, Cadence, Clarify, Color SieScape, Contrast Dynamics, DTI, DTO, Dynamic TCE, ElastoGrip, ErgoDynamic, eSieCalcs, eSieCrypt, eSieFusion, eSieImage, eSieLink, eSieScan, eSie Touch, Evolve Package, fourSight, HELX, microCase, Multi-D, MultiHertz, SieClear, Siemens Remote Service, SieScape, SpaceTime, SuppleFlex, SwiftLink, TCE, TEQ, Vector, Velocity Vector Imaging, and Virtual Touch are trademarks of Siemens Medical Solutions USA, Inc.

 \emph{syngo} is a trademark of Siemens Healthcare GmbH.

All other product names are references to third-party products and are trademarks of their respective companies. Siemens includes references to third-party products in the user documentation for informational purposes only. Siemens does not endorse third-party products referenced in the user documentation. Siemens does not assume responsibility for the performance of third-party products.

Siemens reserves the right to change its products and services at any time. In addition, this publication is subject to change without notice.

Legal Manufacturer

Siemens Medical Solutions USA, Inc. Ultrasound 685 East Middlefield Road Mountain View, CA 94043 U.S.A. Phone: +1-888-826-9702 siemens.com/healthcare

CE Declaration

This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. The CE marking only applies to medical devices that have been put on the market according to the above referenced Council Directive.

Unauthorized changes to this product are not covered by the CE marking and the related Declaration of Conformity.

EU Authorized Representative

Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany

Siemens Healthcare Headquarters

Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany Phone: +49 9131 84-0

Phone: +49 9131 84-0 siemens.com/healthcare

Contents

Chapter 1 Introduction

General overview of the diagnostic ultrasound imaging system.

Chapter 2 Safety and Care

Detailed information on system safety and how to care for and maintain the system, transducers, and transducer accessories.

Chapter 3 System Setup

Detailed descriptions of how to transport, set up, and prepare the system for use, including transducer connection and system startup procedures.

Chapter 4 Examination Fundamentals

Information on starting an examination, including instructions for entering and editing patient data and selecting an exam type, imaging mode, and transducer.

Chapter 5 Transducer Accessories and Biopsy

Attachment procedures for transducer accessories and an explanation of the biopsy (puncture) function, including a procedure for needle path verification.

Chapter 6 Transesophageal Transducer

Description of the transesophageal transducer, including cleaning and care information for the transducer.

Chapter 7 Specialty Transducers

Description of the following specialty transducers:

9EVF4

Chapter 8 Physiologic Function

Explanation of the Physiologic function.

Chapter 9 eSieFusion Imaging

Explanation of eSieFusion imaging for viewing real-time ultrasound images aligned with reference data acquired using another imaging modality. Includes procedures for setting up the tracking system for eSieFusion imaging and procedures for cleaning, disinfecting, and care of the tracking system.

Chapter 10 Virtual Touch Applications

Explanation of the following feature and options:

- Virtual Touch imaging
- Virtual Touch quantification
- Virtual Touch IQ

Appendix A Technical Description

Technical description of the ultrasound system.

Appendix B Control Panel and Touch Screen

Description of the controls on the control panel including the special keys on the alphanumeric keyboards.

See also: An overview and example of the control panel is located in Chapter 1 of this manual.

Appendix C Control Panel

(For systems without a touch screen)

Explanation of all controls and keys on the control panel, alphanumeric keyboard, and optional footswitch.

Appendix D On-screen Controls

Explanation of the on-screen controls for imaging, review, measurements, and patient data management.

Appendix E Advanced Feature Controls

Explanation of the on-screen controls for advanced imaging features and clinical application programs.

Appendix F Acoustic Output Reference

Acoustic output reporting tables.

Note: Not all features and options described in this publication are available to all users. Please check with your Siemens representative to determine the current availability of features and options.

ii Instructions for Use

About the User and Reference Manuals

The user and reference manuals contain descriptions for the following ultrasound systems:

- ACUSON S1000 diagnostic ultrasound system
- ACUSON S2000 diagnostic ultrasound system
- ACUSON S3000 diagnostic ultrasound system

Features and options unique to an ultrasound system are identified in Chapter 1 and Appendix A of the Instructions for Use.

The user and reference manuals consist of the following publications.

Publication	Includes
Instructions for Use	Conventions and typographical conventions used in the manuals
	 Intended Audience
	 Technical description of the ultrasound system
	 Safety and care information for the system and compatible transducers
	 Procedures for system setup, examination fundamentals, and the biopsy function
	Procedures and descriptions of specialty transducers, the physiologic function, and the following imaging features:
	 eSieFusion imaging
	 Virtual Touch applications
	 Descriptions of system controls
	Acoustic output data
Features and Applications Reference*	 Descriptions of image acquisition and optimization, including optional imaging features
	 General and exam-specific measurements and calculations
	Data management
	 Explanation of the clinical software programs for use on the ultrasound system
System Reference*	 Description of customizable system settings
	 Information about DICOM connectivity, network capabilities, and external devices
	 Clinical references
Electromagnetic Emissions and Immunity: Guidance and Manufacturer's Declaration*	 Information regarding the electromagnetic compatibility (EMC) testing of this system

^{*}Languages supported by the user interface include a translation of this publication.

Instructions for Use iii

Conventions

Take a moment to familiarize yourself with these conventions.

The user and reference manuals include procedures and descriptions for ultrasound systems with and without a touch screen. Except where noted in the manuals, descriptions apply to both systems.

The following bullet symbols indicate procedures or descriptions for systems with and without a touch screen:

- This bullet symbol indicates a procedure specific to systems with a touch screen.
- o This bullet symbol indicates a procedure specific to systems without a touch screen.
- This bullet symbol indicates a procedure or description for systems with and without a touch screen.
 - This bullet symbol indicates a procedure or description for systems with and without a touch screen.

Except where noted in the manuals, numbered steps apply to both systems.

Warnings, Cautions, and Notes	▲ WARNING: Warnings are intended to alert you to the importance of following the correct operating procedures where risk of injury to the patient or system user exists.		
	Caution: Cautions are intended to alert you to the importance of following correct operating procedures to prevent the risk of damage to the system.		
	Note: Notes contain information concerning the proper use of the system and/or correct execution of a procedure.		
Cross-References	Examples: See also: Biohazards, Safety and Care, Chapter 2, Instructions for Use See also: Documentation Devices, Chapter 2, System Reference		
	See also: Alphanumeric Keyboard, p. 26		
Customizable System	System settings available for customization are depicted as shown.		
Settings	Example:		
	Use the system configuration menu to customize the registration form.		
	System Config > Patient Registration		

iv Instructions for Use

Examples of Interacting with the Control Panel

The following conventions are used in this manual to provide you with a description of how to identify and use the controls and keys located on the control panel, including the alphanumeric keyboard.

Push Controls, Press Controls, and Press or Rotate Controls

The labels on the control panel are depicted in this manual with text in upper case, boldface type, as shown below.

Example	Convention	
Depth	Push DEPTH .	
E	Press E to access the advanced imaging features.	
	Rotate the FORWARD/BACKWARD control to skip the current view in a protocol.	
	Press TEQ to activate or deactivate tissue equalization optimization.	
ABC	To insert a body marker, press ANNOTATION and then select the required body marker.	
	Rotate 2D to adjust the 2D gain.	
(C2D)	Press M to activate the M cursor (line) on the 2D image.	
M		

Keys on the Alphanumeric Keyboard

The labels on the alphanumeric keyboard are depicted in this manual with text in boldface type, as shown below.

Convention

- Press Delete.
- Press **Help** on the keyboard.
- o For systems without a touch screen, press F1.

Touch Screen Controls

The six controls directly below the touch screen are not labeled on the control panel. In this manual, you can identify the function assigned to the control by the text in boldface type within brackets, as shown below.

Example	Convention	
	Press or rotate [El Color] to select a color map.	

Other Controls

These controls do not have labels on the control panel. In this manual, you can identify the function assigned to the control with descriptive text.

Example	Convention
	Slide the DGC sliders to adjust the depth gain compensation.
	Roll the trackball to adjust the size of the field of view.

LED Controls

(For systems without a touch screen)

The six controls directly below the LED panel are not labelled on the control panel. In this manual, you can identify the function assigned to the control by the text in boldface type within brackets, as shown below.

Example	Convention	
	Press or rotate [El Color] to select a color map.	

Soft Key Controls and Scroll Wheel

(For systems without a touch screen)

Soft key controls are located above the trackball with corresponding selections on the image screen. In this manual, the on-screen labels are depicted with boldface type, as shown below.

Example	Convention	
Soft keys	Press the THI soft key.	
Scroll wheel	Rotate the scroll wheel to select Resize Full.	

vi Instructions for Use

Examples of Interacting with On-screen Objects

In this manual, the following conventions are used to provide you with a description of how to identify and use menu selections and other software selections, including on-screen icons and objects.

Toolbar Controls

Controls located on the toolbar are indicated by boldface type, as shown below.

Example	Convention
•	Click Patient Registration on the toolbar.

Touch Screen Controls

Except for the labels on the lowest row, the labels on the touch screen are depicted in this manual with text in boldface type, as shown below.

In this manual, procedures describe how to interact with objects on the touch screen.

Example	Convention
TEQ Set	Select TEQ Set .
	To change the orientation of the transducer marker, drag the dot around the circle on the touch screen.

The labels on the lowest row of the touch screen are depicted in this manual with text in boldface type within brackets, as shown below. Press or rotate the control directly below the label to activate the function assigned to the control.

Example
Press or rotate [El Color] to select a color map.

Procedures

In this manual, procedures include the following conventions to describe user actions.

Note: Press POINTER to display the cursor on the image screen, if necessary.

Term	Description	
Press	The action of pressing a control on the control panel.	
Rotate	The action of rotating a control on the control panel.	
Select	• The action of highlighting an on-screen object, making a selection from a list, or enabling an on-screen selection.	
	The action of rolling the trackball to position the pointer on an on-screen selection in a list or menu and then pressing the left or right key on either side of the trackball.	
	Also, the action of tapping the touch screen.	
Click	The action of rolling the trackball to position the pointer on an on-screen control or object and then either pressing the left or right key on either side of the trackball.	
Double-click	The action of pressing the left or right key on either side of the trackball twice quickly.	
Drag	The action of rolling the trackball to position the pointer on an on-screen object and then pressing and holding the left key next to the trackball to move the object around the screen.	
	The action of using your finger to touch and position or resize an object on the touch screen.	

Instructions for Use vii

Intended Audience

The intended audience for the user and reference manuals includes the following users.

User	Interaction with Ultrasound Equipment	Expected Experience and Other Characteristics
Sonographer	 Acquires diagnostic views of anatomy, blood flow, and related pathology Performs measurements and analysis of the acquired images Prepares exam data for review and interpretation by a qualified physician 	 Ranges from novices (for example, students) to advanced practitioners with certification in multiple subspecialties Educated in anatomy, physiology, patient care, and identification of pathology in ultrasound images Many sonographers have a Bachelor's degree; some have advanced degrees in related health care subjects
Cardiologist	 Performs invasive and non-invasive ultrasound exams Interprets exam data, including echocardiography exam data Writes and assembles exam findings in a report 	 Medical doctor Expert in diagnostic imaging, including computed tomography (CT), magnetic resonance imaging (MRI), X-ray, ultrasound, and nuclear medicine Advanced training in imaging physics with typically four to six years of post-doctoral training in the field of cardiology
Maternal-fetal Medicine Obstetrician/ Perinatologist Radiologist and Internist	 Performs ultrasound exams Interprets exam data Writes and assembles exam findings in a report Performs ultrasound exams Interprets exam data Writes and assembles exam findings in a report 	 Medical doctor Manages high-risk obstetrical patients for the safe and successful delivery of the fetus Skilled in interpreting ultrasound exam data Medical doctors Expert in diagnostic imaging, including CT, MRI, X-ray, ultrasound, and nuclear medicine Advanced training in imaging physics with typically two to six years of post-doctoral training in the field of radiology
System Administrator and Customer Service Engineer	Configures the ultrasound system for use in a networked environment	 A System Administrator is an individual within your organization who is designated to set up system parameters to connect the ultrasound system or workstation to a picture archiving and communication system (PACS). Customer Service Engineers are Siemens representatives who configure the ultrasound system or workstation during software installation and support troubleshooting activities.

viii Instructions for Use

1 Introduction

System Overview	3
System Review	
Control Panel	7
Example of Control Panel	7
Intended Use	9
Contraindications	9
ACUSON S1000 Ultrasound System	9
Indications for Use Statement	10
ACUSON S2000 Ultrasound System	11
Indications for Use Statement	11
ACUSON S3000 Ultrasound System	12
Indications for Use Statement	12
Transducers and Intended Applications	13
Image Screen Layout	19
Screen Saver	
Sample Image Screens	20

1 Introduction

1 - 2 Instructions for Use

System Overview

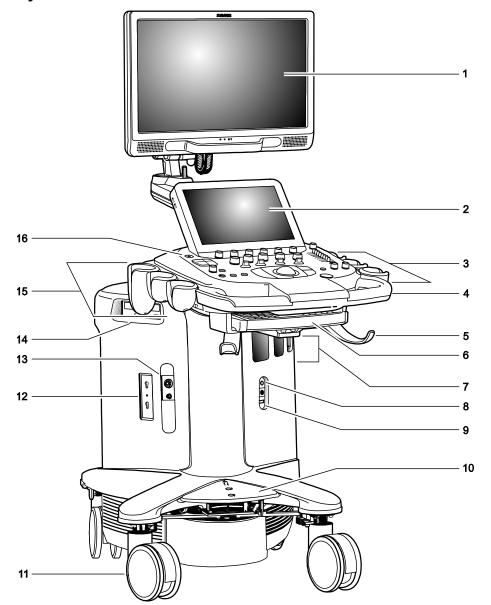
The ACUSON S Family ultrasound systems are designed to streamline clinical workflow from image acquisition to archival in a diagnostic setting for general imaging, vascular, and cardiac applications. The system supports software-based applications, exam-specific imaging presets, measurements, body markers, annotations, patient reports, and system diagnostics. The system design is based upon image quality, knowledge-based workflow, adaptive ergonomics, and innovative applications.

Operating modes for the system include:

- 2D-mode
- 2D-mode with THI (Tissue Harmonic Imaging)
- Dual mode
- 2D/M-mode
- M-mode with THI
- M-mode with CDV
- Pulsed Wave Doppler
- Color Doppler Energy (CDE)
- Color Doppler Velocity (CDV)
- Steerable Continuous Wave Doppler
- Auxiliary Continuous Wave Doppler

See also: Technical Description, Appendix A, Instructions for Use

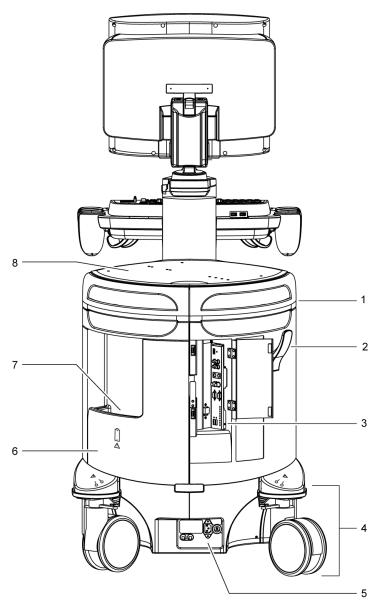
System Review



Example of the ultrasound system.

1 - 4 Instructions for Use

- 1 User-adjustable high-resolution flat panel monitor with two forward-facing speakers
- 2 Touch screen
 - For systems without a touch screen, this is the location of the alphanumeric keyboard
- 3 User-adjustable control panel (height and swivel)
- 4 Front handle
- 5 Cable hanger
- 6 Retractable alphanumeric keyboard (for systems with a touch screen)
- 7 Transducer ports
- 8 Auxiliary continuous wave Doppler transducer port
- 9 Footswitch connector
- 10 Central brakes
- 11 Front swivel wheels
- 12 Parking port for transducers
- 13 Physio panel
- 14 CD/DVD-RW drive
- 15 Transducer and gel holders
- 16 Power ON/OFF () (Standby)



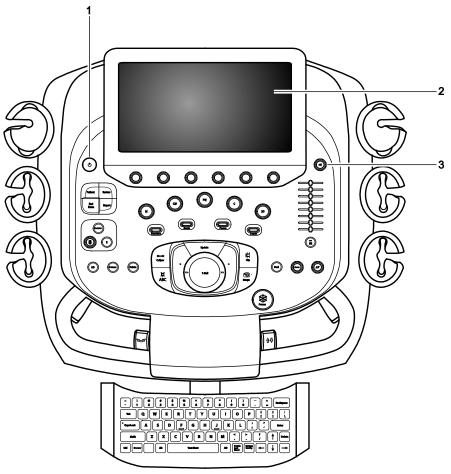
Example of the ultrasound system, back view.

- 1 Rear handle
- 2 Cable hanger
- 3 Input/output panel with audio and video connections
- 4 Rear swivel wheel with brake
- 5 AC tray panel
- 6 Back panel
- 7 Storage bin
- 8 Shelf

Control Panel

The ultrasound imaging system has a combination of keys, rotary knobs, push and rotate controls, and toggle controls. A trackball provides access to on-screen objects. The keys and controls are logically arranged to require a minimum number of hand and eye movements.

Example of Control Panel



Example of the control panel and touch screen on the ultrasound system.

1 Power on/off

For systems without a touch screen, the power on/off control, the backlighting and task lighting control, the volume control and microphone control, and transmit power control are located above the alphanumeric keyboard.

- 2 Touch screen with selections for each operating mode's optimization parameters and functions, measurement labels and tools, review selections, and selections for exam types and transducers. You can tap the touch screen to make a selection.
 - Six controls are located on the control panel with corresponding selections on the touch screen. Press, rotate, or press and then rotate these controls to select a setting.
 - For systems without a touch screen, six controls on the control panel have corresponding selections on the LED panel. Additionally, the image menu includes the mode-specific optimization parameters and functions, measurement labels and tools, review selections, and the access to exam types and transducers
 - For systems without a touch screen, this location includes soft key selections available for the active mode or function. Soft key selections correspond to the controls and scroll wheel on the control panel directly above the trackball.
- 3 Doppler audio volume control
 - For systems without a touch screen, this control includes a microphone and is located above the alphanumeric keyboard.

1 - 8 Instructions for Use

Intended Use



⚠ **WARNING:** The analysis of results from an ultrasound examination requires that you are trained in the interpretation of diagnostic ultrasound studies and are qualified to make clinical diagnoses.



△ Caution: In the United States of America, federal law restricts this device to sale or use by, or on the order of, a physician.

⚠ Caution: Ultrasound is used as an imaging aid, but may have further restrictions specific to in-vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.

Contraindications

The ultrasound system is not intended for ophthalmic use or any ophthalmic application causing the acoustic beam to pass through the eye.

ACUSON S1000 Ultrasound System

The ACUSON S1000 ultrasound system supports the following applications:

- Abdominal (Renal)
- Obstetrics (Fetal Echo)
- Gynecology
- Small Parts (Breast, Testicle, Thyroid)
- Musculoskeletal
- Pediatric (Abdomen, Infant Hip, and Neonatal Cephalic)
- Cardiac
- Vascular (Arterial and Venous)
- Digital
- Urology (Penile, Pelvis, Prostate)

Indications for Use Statement

Product	Indications for Use Statement
ACUSON S1000 Ultrasound System	The S1000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.
	The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, transesophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
syngo Arterial Health Package (AHP)	The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.
	This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging."
ACUSON AcuNav Ultrasound Catheter	The catheter is intended for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

1 - 10 Instructions for Use

ACUSON S2000 Ultrasound System

The ACUSON S2000 ultrasound system supports the following applications:

- Abdominal (Renal)
- Obstetrics (Fetal Echo)
- Gynecology
- Small Parts (Breast, Testicle, Thyroid)
- Musculoskeletal
- Pediatric (Abdomen, Infant Hip, and Neonatal Cephalic)
- Cardiac
- Vascular (Arterial and Venous)
- Digital
- Urology (Penile, Pelvis, Prostate)

Indications for Use Statement

Product	Indications for Use Statement
ACUSON S2000 Ultrasound System	The S2000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.
	The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, transesophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
syngo Arterial Health Package (AHP)	The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.
	This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging."
ACUSON AcuNav Ultrasound Catheter	The catheter is intended for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

ACUSON S3000 Ultrasound System

The ACUSON S3000 ultrasound system supports the following applications:

- Abdominal (Renal)
- Obstetrics (Fetal Echo)
- Gynecology
- Small Parts (Breast, Testicle, Thyroid)
- Musculoskeletal
- Pediatric (Abdomen, Infant Hip, and Neonatal Cephalic)
- Cardiac
- Vascular (Arterial and Venous)
- Digital
- Urology (Penile, Pelvis, Prostate)

Indications for Use Statement

Product	Indications for Use Statement
ACUSON S3000 Ultrasound System	The S3000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.
	The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, transesophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
syngo Arterial Health Package (AHP)	The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.
	This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging."
ACUSON AcuNav Ultrasound Catheter	The catheter is intended for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

1 - 12 Instructions for Use

Transducers and Intended Applications

Refer to the table below for transducers compatible with these ultrasound systems:

- ACUSON S1000 ultrasound system
- ACUSON S2000 ultrasound system
- ACUSON S3000 ultrasound system

Only the following transducers from Siemens are compatible with your ultrasound system.

EMC Note: Operating the transducer in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations, may lead to temporary degradation or interference visible on the monitor screen. A lightening of image background may be noticed while visualizing hypoechoic structures, or color spectral interference, or jitter, or horizontal lines in the image screen may occur. The transducer and the system have been designed and tested to withstand such interference and will not be permanently damaged.

See also: Electromagnetic Emissions and Immunity: Guidance and Manufacturer's Declaration

⚠ WARNING: In accordance with Canadian law, the 14L5 SP transducer is not licensed for use with the ACUSON S1000 ultrasound system or the ACUSON S3000 ultrasound system.

Transducer Name	Operating Frequency ¹	Modes of Operation ²	Intended Applications
	Curved a	nd Linear Array Transd	lucers
(Available on	the ACUSON S1000 syst	em, ACUSON S2000 sy	stem, and ACUSON S3000 system)
4C1	2D-mode:	2D, C, D, M	■ Fetal
	2.0 MHz-4.5 MHz		Abdominal
	Doppler:		
	2.0 MHz-3.5 MHz		
6C2	2D-mode:	2D, C, D, M	■ Fetal
	2.5 MHz-6.0 MHz		■ Abdominal
// /18	Doppler:		■ Pediatric
	2.5 MHz-3.75 MHz		Peripheral Vessel
9L4	2D-mode:	2D, C, D, M	■ Fetal
	4.0 MHz-9.0 MHz		Pediatric
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Doppler:		Small Organ
Com	4.0 MHz-6.75 MHz		Neonatal Cephalic
			Peripheral Vessel
			Musculo-skeletal Conventional
12L4	2D-mode:	2D, C, D, M	Pediatric
	6.0 MHz-12.0 MHz		Small Organ
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Doppler:		Peripheral Vessel
	4.0 MHz–7.5 MHz		Musculo-skeletal Conventional

Transducer Name	Operating Frequency ¹	Modes of Operation ²	Intended Applications
	Curved a	nd Linear Array Transd	lucers
(Available or	the ACUSON S1000 syst	em, ACUSON S2000 sy	stem, and ACUSON S3000 system)
14L5	2D-mode:	2D, C, D, M	Small Organ
	6.0 MHz-14.0 MHz		Peripheral Vessel
	Doppler:		Musculo-skeletal Conventional
	5.5 MHz–7.5 MHz		
14L5 SP	2D-mode:	2D, C, D, M	Intraoperative
Λ	6.0 MHz-14.0 MHz		Small Organ
WE	Doppler:		Peripheral Vessel
600	5.5 MHz-9.0 MHz		Musculo-skeletal Conventional
18L6 HD	2D-mode:	2D, C, D, M	■ Small Organ
	7.0 MHz–17.0 MHz		Peripheral Vessel
1	Doppler:		Musculo-skeletal Conventional
	5.5 MHz-10.0 MHz		Musculo-skeletal Superficial
	Curved a	nd Linear Array Transd	lucers
(Ava	ilable only on the ACUSC	N S2000 system and th	ne ACUSON S3000 system)
6C1 HD	2D-mode:	2D, C, D, M	■ Fetal
	1.5 MHz-5.5 MHz		Abdominal
1 19	Doppler:		
	2.0 MHz-3.5 MHz		
8C3 HD	2D-mode:	2D, C, D, M	■ Fetal
S	3.0 MHz-8.0 MHz		Abdominal
	Doppler:		■ Pediatric
	2.85 MHz-3.75 MHz		Small Organ
			■ Peripheral Vessel

1 - 14 Instructions for Use

Transducer Name	Operating Frequency ¹	Modes of Operation ²	Intended Applications
	Pha	ased Array Transducers	3
(Available on	the ACUSON S1000 syst	em, ACUSON S2000 sy	stem, and ACUSON S3000 system)
4V1	2D-mode:	2D, C, D, M	■ Fetal
	2.0 MHz-4.5 MHz		Abdominal
	Doppler:		
	2.0 MHz-3.5 MHz		
4V1c	2D-mode:	2D, C, D, M, CW	Abdominal
√ 18 N	1.75 MHz-4.64 MHz		Pediatric
	Doppler:		Adult Cephalic
	1.8 MHz-3.5 MHz		■ Cardiac
			Other (Neonatal Cardiac)
8V3	2D-mode:	2D, C, D, M, CW	■ Fetal
	4.0 MHz-8.0 MHz		Pediatric
	Doppler:		Neonatal Cephalic
	2.5 MHz-5.0 MHz		■ Cardiac
			Other (Neonatal Cardiac)
10V4	2D-mode:	2D, C, D, M, CW	■ Fetal
[II]	4.0 MHz-10.0 MHz		Abdominal
	Doppler:		Pediatric
	4.5 MHz-6.0 MHz		Neonatal Cephalic
			■ Cardiac
			Peripheral Vessel
4P1	2D-mode:	2D, C, D, M, CW	■ Fetal
	1.75 MHz-4.64 MHz		Abdominal
	Doppler:		Adult Cephalic
	2.0 MHz-3.5 MHz		Cardiac

Transducer Name	Operating Frequency ¹	Modes of Operation ²	Intended Applications
	Pha	sed Array Transducers	
(Available on	the ACUSON S1000 syst	em, ACUSON S2000 sy	stem, and ACUSON S3000 system)
V5Ms	2D-mode:	2D, C, D, M, CW	 Transesophageal
	4.0 MHz-7.0 MHz		
)	Doppler:		
	3.5 MHz-4.0 MHz		
V7M	2D-mode:	2D, C, D, M, CW	 Transesophageal
	4.0 MHz-8.0 MHz		
	Doppler:		
	3.5 MHz-4.75 MHz		
AcuNav 8F	2D-mode:	2D, C, D, M, CW	Pediatric
	4.0 MHz-10.0 MHz		■ Cardiac
	Doppler:		Intracardiac
	4.0 MHz–6.5 MHz		Other (Intraluminal)
AcuNav 10F	2D-mode:	2D, C, D, M, CW	Pediatric
	4.0 MHz-10.0 MHz		■ Cardiac
	Doppler:		Intracardiac
	4.0 MHz–6.5 MHz		Other (Intraluminal)
	<u> </u> 	l ndocavity Transducers	
(Available on			stem, and ACUSON S3000 system)
EV-8C4	2D-mode:	2D, C, D, M	■ Fetal
	4.0 MHz-9.0 MHz		Abdominal
	Doppler:		Transvaginal
	4.2 MHz–6.75 MHz		
EC9-4	2D-mode:	2D, C, D, M	■ Fetal
	4.0 MHz-8.0 MHz		Abdominal
	Doppler:		Small Organ
	3.75 MHz-6.75 MHz		Neonatal Cephalic
			 Transrectal
			Transvaginal
MC9-4	2D-mode:	2D, C, D, M	■ Fetal
	4.0 MHz–8.0 MHz		Abdominal
	Doppler:		Small Organ
	3.75 MHz–6.75 MHz		Neonatal Cephalic
			Transrectal Transrectal
			Transvaginal

1 - 16 Instructions for Use

Transducer Name	Operating Frequency ¹	Modes of Operation ²	Intended Applications
	fou	urSight 4D Transducers	
(Available on	the ACUSON S1000 syst	tem, ACUSON S2000 sy	stem, and ACUSON S3000 system)
7CF1	2D-mode:	2D, C, D, M	■ Fetal
	3.0 MHz-7.0 MHz		Abdominal
a a b b	Doppler:		
	2.5 MHz-3.75 MHz		
7CF2	2D-mode:	2D, C, D, M	■ Fetal
	3.0 MHz-7.0 MHz		Abdominal
	Doppler:		
	2.5 MHz-3.75 MHz		
9EVF4	2D-mode:	2D, C, D, M	■ Fetal
	4.0 MHz-9.0 MHz		Neonatal Cephalic
	Doppler:		Transvaginal
	4.0 MHz-7.5 MHz		

Transducer Name	Operating Frequency ¹	Modes of Operation ²	Intended Applications
	Continuous Wave Transducers		
(Available on	the ACUSON S1000 syst	tem, ACUSON S2000 sy	stem, and ACUSON S3000 system)
CW2	2.0 MHz	CW	Adult Cephalic
0 0			Cardiac
			Peripheral Vessel
CW5	5.0 MHz	CW	Adult Cephalic
			Cardiac
			Peripheral Vessel

¹ Operating Frequency	Range of selectable operating frequencies for:
2D-mode	Fundamental and harmonic imaging, not including contrast
Doppler	Pulsed wave, continuous wave, and color imaging

² Modes of Operation	Includes one or more of the following system operating modes
2D (brightness mode)	2D-mode, 2D-mode with Tissue Harmonic Imaging (THI)
C (color flow Doppler)	Color Doppler Velocity (CDV), Color Doppler Energy (CDE)
D (Doppler)	Pulsed Wave Doppler, 2D/Doppler, 2D/Doppler with CDV, 2D/Doppler with CDE
M (motion mode)	M-mode, M-mode with THI, 2D/M-mode, 2D/M-mode with CDV, 2D/M-mode with CDE
CW (continuous wave Doppler)	Steerable Continuous Wave Doppler (for phased array transducers), Auxiliary Continuous Wave Doppler (for continuous wave [pencil] transducers)

1 - 18 Instructions for Use

Image Screen Layout

The monitor on the ultrasound system displays clinical images together with important operating parameters and patient data.

You can hide the thumbnail panel to increase the space available on the screen for the image.

For systems without a touch screen, you can also hide the soft key selections and menu located on the left side of the screen.

Use the system configuration menu to customize the location of information within the patient banner.

System Config > Patient Banner

Use the system configuration menu to configure the parameter settings in the imaging parameters section of the screen.

System Config > Image Text Editor

Screen Saver

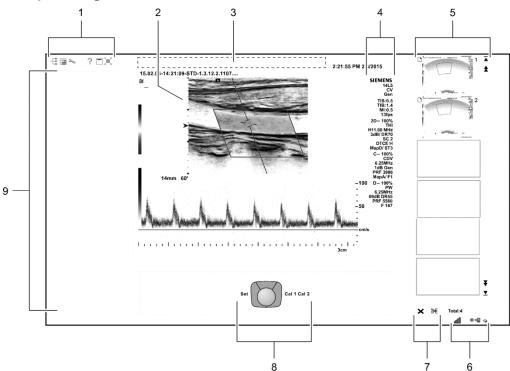
The screen saver feature automatically freezes the system and replaces the active display with a screen-saver display after the system has been inactive for a specified number of minutes. Exit the active screen saver display by pressing any key, adjusting any control, or rolling the trackball. When the security package is activated on the ultrasound system, a user name and password are required to exit the active screen-saver display and access the system.

Use the system configuration menu to select the duration of operational inactivity needed to activate the screen saver.

System Config > Basic System

Note: The screen saver feature is not available when the system is in external video playback or during the Biopsy function.

Sample Image Screens



Example of a typical image screen.

- 1 Toolbar buttons. Displays controls for system functions, for example, displaying or hiding the menu, accessing the patient browser, and displaying information about using the ultrasound system.
 - Displays the security icon when the security package is activated.
- 2 Measured Results. Displays values for measurements and calculations.
 - Drag the measured results to the required location.
- 3 Patient banner. Customizable information for identifying the patient, operator, institution, date, and time.
- 4 *Imaging Parameters*. Displays a list of imaging parameter settings for each active mode. Displays a clip icon when the clip store function is activated.
- 5 Thumbnail Display. Displays reference images (reduced-size images) of stored clips, images, and volumes. Use the arrows on either end of the thumbnail panel to scroll the thumbnails.
- 6 Displays information about the network connection and network job status.
- 7 Controls for printing and deleting thumbnails.

- 8 Trackball status. Indicates the function currently assigned to the trackball and the controls adjacent to the trackball
 - For systems without a touch screen, this location includes soft key selections available for the active mode or function. Soft key selections correspond to the controls and scroll wheel on the control panel directly above the trackball.
- 9 Image menu. Displays controls and functions of the optional software programs available during review. Use the trackball pointer to expand or collapse the display of selections for each section in the menu. For systems without a touch screen, this location includes mode-specific optimization parameters and functions, measurement labels and tools, review selections, and access to exam types and transducers.

1 - 20 Instructions for Use

2 Safety and Care

Operating Safety and Environment	3
System Symbols	3
Labels	11
Biohazard Considerations	13
Note on Fetal Examinations	14
Acoustic Output — Mechanical and Thermal Indices	15
Mechanical and Thermal Indices	16
Transmit Power Control	16
Transmit Power Display	17
Imaging Functions that Change Acoustic Output	18
Transducer Surface Temperature Limits	19
Electrical Safety	20
Level of Protection Against Electrical Shock — System	21
Level of Protection Against Electrical Shock — Transducers	21
Defibrillators	
Defibrillator Use and the ACUSON AcuNav Ultrasound Catheter	
Implantable Devices	22
Possible Combinations with Other Equipment	23
Maintaining Data Integrity	23
Data Compression	
Caring for the Ultrasound System	24
Daily Checklist	
Maintenance	
Repair	
Siemens Authorized Care	
Caring for Documentation and Storage Devices	
Caring for the Battery Pack	
Recharging the Battery Pack	
Battery Pack Replacement	
Battery Pack Location	
Removing the Battery Pack	
Installing a Battery Pack	
Recycling the Battery Pack	
Cleaning and Disinfecting	
Cleaning Ultrasound System Surfaces	
Approved Disinfectant Wipes for the Ultrasound System Surfaces.	
Cleaning the Air Filter	

Caring for Transducers3	36
Methods for Cleaning and Disinfecting Transducers3	38
Examples of Transducer Components	39
Cleaning and Disinfecting Transducers4	12
Approved List of Cleaners4	14
Approved List of Disinfectants4	15
Sterilizing Transducers — 14L5 SP4	16
Caring for Transducer Accessories4	17
Transducer Sheaths4	1 7
Storage4	1 7
Gel Pad4	18
Storage4	18
Needle Guide Bracket Kits4	18
Storage and Transportation4	18
Cleaning, Disinfecting, and Sterilizing Transducer Accessories4	19
Needle Guide Bracket Kits4	19
Environmental Protection5	51
Product Recycling and Disposal5	51
Hazardous Substances5	51
Caring for Batteries5	51
Recycling Batteries5	52
Disposing of the Packaging Materials5	52
Disposing of Components and Accessories5	53
Energy Conservation5	53

Operating Safety and Environment

Do not operate the ultrasound imaging system until you fully understand the safety considerations and procedures presented in this manual.

System Symbols

The table below is provided for your identification of important symbols located on the ultrasound imaging system and transducers:

Symbol	Explanation
AP	Danger: Risk of explosion if used in the presence of flammable anesthetics.
À	Caution: Risk of electric shock.
	Do not open. Refer servicing to qualified service personnel.
Ţ <u>i</u>	Consult instructions for use
	It is mandatory you refer to the manual.
	(blue illustration)
\wedge	Caution
<u> </u>	(black illustration)
	Note: For systems and transducers shipped from the factory prior to 1 October 2010, the symbol means "Caution, consult accompanying documents."
\wedge	General Warning
<u> </u>	(yellow and black illustration)
ம்	Standby — ON
	ON only for MAINS control
	OFF only for MAINS control
•	Monitor Tint
- XX	Monitor Brightness
•	USB Connection
₽	Ethernet Connection

Symbol	Explanation
-\rac{\triangle}{\triangle}-	Control Panel Light or Indicator Light
-\[\bar{\pi}\]	Yellow Indicator Light
- © -	Status Indicator for DC Power Good (Green) or Green Indicator Light
	Printer Connection
4 *	Type BF Defibrillator-proof Patient Connection
⚠	Type BF Applied Part
*	Type B Patient Connection
	Continuous Wave Transducer Port
	Transducer Port
	ECG Signal Connection
ECG	Electrocardiogram (EKG)
€	Signal Input
\rightarrow	Signal Output

2 - 4 Instructions for Use

Symbol	Explanation
2	Footswitch Connector
A	Equipotential Connection
<u></u>	Protective Earth Ground
⊗	Do not install wet
⋧ ⋮∷	Location of Air Filter
11	Insert this way
+	Battery
NI-MH	Recycle Ni-MH battery
	Do not dispose of by burning
	The product must be properly disposed of in accordance with local, state, and regional laws and regulations. Products bearing this symbol are subject to the European Community directive 2002/96/EC on waste electrical and electronic equipment (WEEE), amended by directive 2003/108/EC. For collection and disposal of the product, its components, or its accessories, contact your local Siemens representative.
&	Do not dispose of by flushing down lavatory

Symbol	Explanation
	Pinch hazard.
DO NOT LEAN	Do not lean against the monitor.
XX kg MAX XX lbs MAX	Shelf Weight Restriction
O	Brake Engaged
<u>()</u>	Brake Released
	Direction/Steer Lock
C € 0123	Manufacturer's declaration of product compliance with applicable EEC directive(s) and the European notified body
(D)	DEMKO-Denmark approval mark
c Sus us xxxxxxx	UL symbol for listing as recognized components for Canada and United States of America
C UL US	UL classified symbol for Canada and United States of America
	EAC (Eurasian Conformity mark)
EHL	The Eurasian Conformity mark is a product marking to indicate that the product conforms to all Technical Regulations of the Customs Union assessment procedures
Complies with IMDA Standards DAXXXXXX	Equipment complies with the standard and specifications published by IMDA (Info-communications Media Development Authority of Singapore)
	"XXXXXX" represents the dealer's license number
Segurança COP 0004 Compulsório METRO	TÜV Rheinland INMETRO Certification Mark (Brazil)
EC REP	Authorized representative in the European community

2 - 6 Instructions for Use

Symbol	Explanation
MADE IN USA	Location of device manufacturing: United States of America
MADE IN KOREA	Location of device manufacturing: Republic of Korea
MADE IN JAPAN	Location of device manufacturing: Japan
MADE IN NETHERLANDS	Location of device manufacturing: Netherlands
System	(System Installierte Volumen Komponente)
IVK	Identifies the system for product traceability at Siemens Healthcare
	(Installierte Volumen Komponente)
IVK	Identifier of selected system components or parts for product traceability
€	Gost-R symbol indicates that this product is certified for conformity to the safety requirements of Russian state standards
R ONLY	Caution: In the United States of America, federal law restricts this device to sale or use by, or on the order of, a physician.
	Safe working load
57 <xxxkg< th=""><th>"XXX" represents the weight of the system unpacked and ready for operation with documentation devices installed</th></xxxkg<>	"XXX" represents the weight of the system unpacked and ready for operation with documentation devices installed
LI VAXAIDS	Additional objects or devices on the system cannot exceed the safe working load
√-60°C	Transducer storage temperature range (example)
-40°C -	System storage temperature range (example)
6 ← 6	Unlock (left) and lock (right) positions
IPX7	Protected against the effects of temporary immersion in water
IPX8	Protected against the effects of continuous immersion in water
	Barcode
	Barcode with product identification information according to the following barcode specification: GS1 128 2D

Symbol	Explanation			
GTIN	Global Trade Item Number			
Rev	Model revision			
REV				
Serial	Serial number			
SERIAL				
Count	Quantity of product			
COUNT				
Model	Siemens model number			
MODEL				
REF	Device part number			
Origin US	Manufacturer country of origin: United States of America			
ORIGIN US				
Origin KR	Manufacturer country of origin: Republic of Korea			
ORIGIN KR				
Origin JP	Manufacturer country of origin: Japan			
ORIGIN JP				
Origin NL	Manufacturer country of origin: Netherlands			
ORIGIN NL				
\sim	Date of Manufacture symbol with the date below			
20XX				
***	Manufacturer			

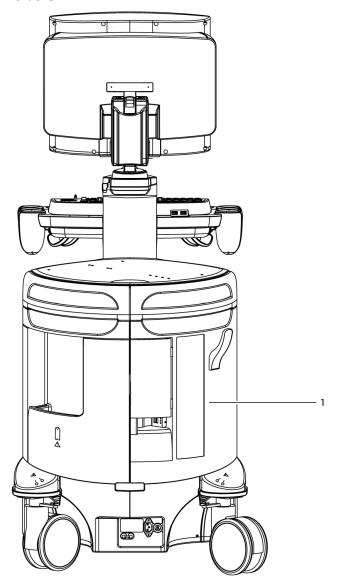
2 - 8 Instructions for Use

Symbol	Explanation
V~	AC (alternating current) voltage source
100V~ 50/60Hz 15A	Identifies voltage, frequency, and current rating of system configuration for MAINS. 100V~, 50/60 Hz, 15A maximum draw, 15A MAINS breaker.
100V~ 50/60Hz MAINS 15A	
115V~ 50/60Hz 12A	Identifies voltage, frequency, and current rating of system configuration for MAINS. 115V~, 50/60 Hz, 12A maximum draw, 15A MAINS breaker.
115V~ 50/60Hz MAINS 15A 12A	
230V~ 50/60Hz 6.5A	Identifies voltage, frequency, and current rating of system configuration for MAINS. 230V~, 50/60 Hz, 6.5A maximum draw, 7.5A MAINS breaker.
230V~ 50/60Hz MAINS 7.5A	
Mains 100V~ 15A 115V~ 15A 230V~ 7.5A	Identifies voltage and circuit breaker current.

Symbol	Explanation
	Weight and size
_ >XXX kg	"XXX" represents the weight of the system packaged for shipping
>XX" x XX" x XX"	"XX" represents the size of the box in inches
P	Do not stack
É	Recycle
Too sp. in.	Storage atmospheric pressure range (example)
2	Storage humidity range (example)
<u> </u>	Indicates this side up
1	Do not stack
367 kg	Shipping weight (example)
+	Do not allow to get wet
Ţ	Fragile. Handle with care.
	Refer to the operator's manual for information about compatible needle guides.
50	Environmentally friendly use period
$((\bullet))$	Intentional transmitter of non-ionizing radiation.

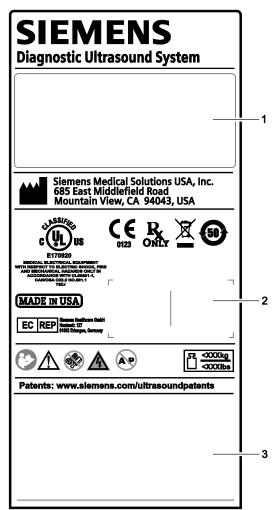
2 - 10 Instructions for Use

Labels



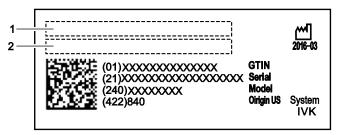
Location of labels on the ultrasound system (example).

System warning label with certification labels



- 1 Identification label
- 2 Country-specific labels
- 3 Country-specific labels

Example of system label.



Example of identification label.

- 1 Product name
- 2 System input power requirement

2 - 12 Instructions for Use

Biohazard Considerations

⚠ WARNING: With the exception of systems licensed to use the ACUSON AcuNav catheter, this equipment is not suitable for intracardiac use or direct cardiac contact.

See also: For additional information on the AcuNav catheter, refer to the user manual for the catheter.



▲ WARNING: This equipment is not suitable for intracardiac use or direct cardiac contact.



⚠ **WARNING**: For neonatal head imaging, Siemens recommends that you exercise special care during neonatal cephalic scanning to avoid possible damage to the posterior region of the eye. The ultrasound energy emitted by the transducer easily penetrates the fontanels of the infant.



⚠ **WARNING:** Siemens makes every effort to manufacture safe and effective transducers. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, and during endocavity or intraoperative scanning; during biopsy or puncture procedures; or when scanning patients with open wounds.



⚠ WARNING: To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, always dispose hazardous or infectious materials according to local, state, and regional laws and regulations.



MARNING: Transducer sheaths: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.



⚠ **WARNING**: Ultrasound energy is transmitted more effectively through water than through tissue. When using a standoff device of any kind, for example, a waterpath or gel pad, the actual mechanical and thermal indices, MI and/or TI, may be higher than indicated in the output display on the ultrasound system.

The assessment of the biological effects of diagnostic ultrasound on humans is a subject of ongoing scientific research. This ultrasound system, and all diagnostic ultrasound procedures, should be used for valid reasons, for the shortest possible period of time, and at the lowest mechanical and thermal indices necessary to produce clinically acceptable images.

According to the principles of ALARA (As Low As Reasonably Achievable), the acoustic output should be the lowest level required to satisfactorily perform the examination.

The ultrasound imaging system complies with the standards of the American Institute of Ultrasound in Medicine (AIUM) and the National Electrical Manufacturer's Association (NEMA), the guidelines of the United States Food and Drug Administration (FDA) and the standards of the International Electrotechnical Commission (IEC) in terms of safety and acoustic output levels. The ultrasound output levels are stated to permit the user to critically evaluate the ultrasound system settings in the event of new research findings being announced.

Note on Fetal Examinations

The following recommendation is excerpted from the National Institute of Health in the United States of America. *Consensus Statement on the Use of Ultrasound Imaging During Pregnancy*, Volume 5, No. 1, based on the recommendation issued at the Health Consensus Development Conference, February, 1984:

Ultrasound examination in pregnancy should be performed for a specific medical indication. The data on clinical efficacy and safety do not allow a recommendation for routine scanning at this time.

Ultrasound examination performed solely to satisfy the family's desire to know the fetal sex, to view the fetus, or to obtain a picture of the fetus should be discouraged. In addition, visualization of the fetus solely for educational or commercial demonstrations without medical benefit should not be performed.

In August 1994, the Food and Drug Administration (FDA) notified the medical community and the ultrasound industry regarding its concerns about the misuse of diagnostic ultrasound equipment for non-medical purposes, and to discourage patients from having sonograms for non-medical reasons.

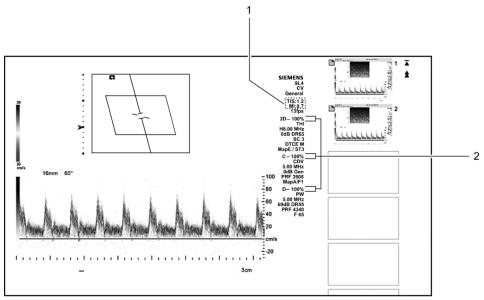
The American Institute of Ultrasound in Medicine (AIUM) has also advocated the responsible use of diagnostic ultrasound for all fetal imaging (August 2005).

2 - 14 Instructions for Use

Acoustic Output — Mechanical and Thermal Indices

⚠ WARNING: Ultrasound procedures should be used for valid reasons, for the shortest period of time, and at the lowest mechanical/thermal index setting necessary to produce clinically acceptable images.

The ultrasound system incorporates an output display of Mechanical and Thermal Indices to allow you to monitor, and to limit, the amount of ultrasound energy that is transferred to the patient.



Example of the mechanical and thermal indices and the transmit power display on the image screen.

- Mechanical and thermal indices
- Transmit power display

Note: For ultrasound systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM that is shipped with the system.

2 - 15 Instructions for Use

Mechanical and Thermal Indices

The ultrasound system displays the Mechanical and Thermal Indices during real-time imaging, in all imaging modes, when the Mechanical Index or the Thermal Indices are equal to or exceed a value of 0.4.

Note: During exams using contrast agent imaging, the system always displays values for the Mechanical Index (MI) and the Maximum of Mechanical Indices measured at the active focal zones (MIF).

Indices display in the abbreviated form shown below:

- MI: Mechanical Index
- MIF: Maximum of the Mechanical Indices measured at the active focal zones (displayed during contrast agent imaging exams only)
- TIB: Bone Thermal Index (fetal application)
- TIS: Soft Tissue Thermal Index
- TIC: Cranial Thermal Index

Transmit Power Control

Adjust the transmit power and the corresponding acoustic pressure delivered through the transducer to the patient by using the designated control on the ultrasound system. It is the main system function that determines the transmitted intensity of ultrasound for all transducers and imaging modes during real-time imaging, though it is not the only function that affects the mechanical and thermal indices. The range and especially the maximum level of the mechanical and thermal indices differ depending on the transducers. In addition, each diagnostic exam type has preset values for mechanical and thermal indices.

Note: Maximum transmit acoustic intensity and the mechanical index for each exam type is limited in accordance with the United States Food and Drug Administration's (FDA) recommendations and guidelines. System default transmit intensity and mechanical index values are always below the FDA recommendations for each exam type. Although some exam types may default to a condition of maximum allowable transmit power, there are other system controls or functions that could raise acoustic output levels.

To increase the transmit power during real-time imaging:

- Rotate the [Transmit Power] control located below the touch screen clockwise to increase transmit power.
- For systems without a touch screen, press the TX POWER control on the control panel upward to increase transmit power.

To decrease the transmit power during real-time imaging:

- Rotate the [Transmit Power] control located below the touch screen counterclockwise to decrease transmit power.
- For systems without a touch screen, press the TX POWER control on the control panel downward to decrease transmit power.

2 - 16 Instructions for Use

Adjusting the Transmit Power during Contrast Agent Imaging

During contrast agent imaging, you can also increase or decrease the transmit power. The transmit power range is from 0.10% to 100% for contrast agent imaging.

- Rotate the [Power] control located below the touch screen clockwise to increase transmit power. Rotate the [Power] control counterclockwise to decrease transmit power.
- For systems without a touch screen, rotate the [Power] LED panel control clockwise to increase transmit power. Rotate the [Power] control counterclockwise to decrease transmit power.

Transmit Power Display

The transmit power range is from 0% to 100%. Selecting 100%, in combination with other ultrasound system controls or functions, generates the maximum acoustic intensity and mechanical index for each transducer, where:

 $I_{SPTA.3}$: \leq 720 mW/cm² and MI \leq 1.9

Imaging Functions that Change Acoustic Output

MARNING: Observe the real-time display of mechanical and thermal indices (MI/TI) at all times.

■ Marning: Observe the real-time display of mechanical and thermal indices (MI/TI) at all times.

In addition to the adjustment of the transmit power, adjustment of the following imaging functions and/or controls may affect the acoustic output:

- Automatic Time-out
- Color Ensemble Size
- Color ROI Position
- Color ROI Size
- Doppler Gate Position
- Doppler Color PRF
- Doppler Gate Size
- Exam Type
- Field of View (Scan Angle)
- Focus
- Frame Rate
- Freeze
- Image Depth

- Imaging Mode
- Line Density/Resolution
- M-mode ROI Position
- Multi-Frequency
- Power On/Off 🖰
- Presets
- Reset
- Transducer
- Transmit Power
- Update
- Gel Pad
- Zoom

2 - 18 Instructions for Use

Transducer Surface Temperature Limits

The following table provides the maximum surface temperature of the transducers compatible with the system.

Maximum surface temperatures are in accordance with IEC 60601-2-37.

	Maximum Temperature	
Transducer	TMM	Still Air
4C1	≤ 38.6°C	≤ 35.9°C
6C1 HD	≤ 41.0°C	≤ 38.0°C
6C2	≤ 40.1°C	$\leq 40.0^{\circ}C$
8C3 HD	≤ 41.0°C	≤ 42.5°C
9L4	≤ 39.4°C	≤ 38.1°C
12L4	≤ 42.5°C	≤ 47.0°C
14L5	≤ 41.7°C	≤ 41.1°C
14L5 SP	≤ 40.7°C	≤ 40.5°C
18L6 HD	≤ 42.9°C	≤ 43.0°C
4P1	≤ 40.9°C	≤ 42.6°C
4V1	≤ 40.3°C	≤ 40.8°C
4V1c	≤ 42.3°C	≤ 46.0°C
8V3	≤ 41.4°C	≤ 41.0°C
10V4	≤ 37.7°C	≤ 36.5°C
V5Ms	≤ 36.4°C	≤ 39.4°C
V7M	≤ 42.6°C	≤ 40.3°C
EV-8C4	≤ 38.9°C	≤ 39.6°C
EC9-4	≤ 36.0°C	≤ 36.7°C
MC9-4	≤ 42.5°C	≤ 45.3°C
7CF1	≤ 38.6°C	≤ 45.0°C
7CF2	≤ 36.7°C	≤ 37.2°C
9EVF4	≤ 38.4°C	≤ 38.3°C
CW2	≤ 36.9°C	≤ 37.7°C
CW5	≤ 35.3°C	≤ 37.7°C
AcuNav 8F	≤ 41.1°C	NA
AcuNav 10F	≤ 39.6°C	NA

TMM = Tissue Mimicking Material

NA = not applicable (not tested)

Electrical Safety

A

⚠ WARNING: To avoid electric shock, use a protective earth connection to connect the ultrasound system to the mains power supply. The protective earth connection ensures that the mains circuit breaker will disconnect the power supply in the event of a short circuit.

WARNING: For 115V ultrasound systems: To ensure grounding reliability, only connect the system to a hospital-grade power outlet.

★ WARNING: The AC power connector plug for the ultrasound system is a three-prong grounded plug (in the U.S.A.) and should never be adapted to any two-prong (non-grounded) outlet, either by modifying the plug or by using an adapter. In the U.S.A., proper grounding requires the AC power connector plug to be plugged into a hospital-grade power outlet.

⚠ WARNING: To avoid electrical shock, never modify the ultrasound system AC power connector plug, as doing so may overload your facility's power circuits. To ensure grounding reliability, connect the system only to an equivalent outlet.

⚠ WARNING: To avoid electrical shock, never use equipment or a mains power cord that shows signs of wear or tampering, or that has a ground plug which has been bypassed by using an adapter.

★ WARNING: Equipment connected to the ultrasound system and in the patient zone must be powered from a medically-isolated power source or must be a medically-isolated device. Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the ultrasound system.

⚠ WARNING: Using an extension cord or multi-socket outlet setup to provide power to the
ultrasound system, or to the system's peripheral devices may compromise the system grounding
and cause your system to exceed leakage current limits.

⚠ **WARNING:** To avoid electrical shock and damage to the ultrasound system, power off and unplug the equipment from the AC power outlet before cleaning and disinfecting.

WARNING: To avoid electrical shock and damage to the control panel resulting from ingress of liquid, place the gel bottle and gel warmer on the side of the system closest to the patient.

⚠ WARNING: To prevent excessive leakage current from contacting the patient, do not touch a user-accessible connector on the system while touching or scanning the patient. User-accessible connectors include the ECG connector, a USB connector, and any other audio, video, or data transmission connectors.

▲ WARNING: Connecting peripheral devices to accessory outlets on the ultrasound system effectively creates a medical electrical system, resulting in a reduced level of safety.

▲ WARNING: Do not modify this equipment without authorization from Siemens.

2 - 20 Instructions for Use

△ Caution: To avoid the possibility of static shock and damage to the system, avoid the use of aerosol spray cleaners on the monitor screens.



Caution: Do not use spray cleaners on the ultrasound system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.



△ Caution: Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.



Caution: To ensure proper grounding and leakage current levels, it is the policy of Siemens to have an authorized Siemens representative or Siemens approved third party perform all on-board connections of documentation and storage devices to the ultrasound system.



△ Caution: To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 24 months. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.

EMC Note: Proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

Level of Protection Against Electrical Shock — System

According to EN 60601-1 and IEC 60601-1, the system provides a "Level of Protection Against Electrical Shock" of "Type B."



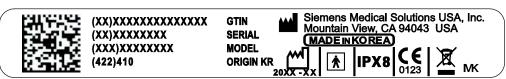
The Type B icon is located on the system.

Level of Protection Against Electrical Shock — Transducers

According to EN 60601-1 and IEC 60601-1, the assemblies for the endocavity transducer and the linear, curved, and phased array transducers provide a "Level of Protection Against Electrical Shock" of "Type BF."



The Type BF icon is located on the transducer label.



Example of a transducer label.

Defibrillators

▲ WARNING: The ECG function is designed to withstand the effects of defibrillation. However, when possible, disconnect the ECG leads during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.

For patient safety, be sure to use defibrillators that do not have grounded patient circuits.

Defibrillator Use and the ACUSON AcuNav Ultrasound Catheter



▲ WARNING: The catheter is designed to withstand the effects of defibrillation. However, when possible, disconnect the connector from the ultrasound system during defibrillation because a malfunction of the safety controls could otherwise result in electrical burns for the patient.

The catheter is designed to withstand the effects of defibrillation. There are no exposed conductive surfaces distal to the handle. Within the flexible shaft, a chassis ground shield covers all active circuits and conductors.

Recovery Time After Defibrillation During a Catheter Procedure

If you disconnect the SwiftLink catheter connector from the ultrasound system before defibrillation, the recovery time after defibrillation is equal to the time required to reconnect the connector to the ultrasound system.

The recovery time after defibrillation for the ultrasound system:

Three (3) minutes if defibrillation is performed with the ultrasound system on.

Implantable Devices



⚠ WARNING: Ultrasound systems, like other medical equipment, use high-frequency electrical signals that can interfere with implantable devices such as pacemakers and implantable cardioverter-defibrillators (ICDs). If the patient has such an implantable device, you should be aware of any interference in its operation and immediately power off the ultrasound system.

2 - 22 Instructions for Use

Possible Combinations with Other Equipment

MARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Anyone who connects additional equipment to any of the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards IEC 60601-1. Siemens can only guarantee the performance and safety of the devices listed in the Instructions for Use. If in doubt, consult the Siemens service department or your local Siemens representative.

The ultrasound system supports a maximum of three documentation devices connected to the system. Depending on how your system is configured, certain documentation devices will maintain power when the system is powered off. Although this will not cause harm to your documentation device. Siemens recommends that you power off each device whenever the system is powered off.

Some on-board peripheral devices must be installed by an authorized Siemens representative or by a Siemens-approved third party. Devices installed by other people will be at the user's risk and may void the system warranty.

Maintaining Data Integrity

Important Information

To ensure data integrity:

- To prevent the loss of data that results from power failures and other system "down" occurrences, you must archive important data, such as patient records, onto an external recording media, such as a CD or a network.
- Loss of data is to be expected and its retrieval is not normally possible under the following conditions: loss of power to the ultrasound system, hard disk failure, CPU failure, system lockup, and other similar causes.
- Should an abnormal system shutdown occur, retrieval of data not saved to the hard disk or not archived to an external recording media is not normally possible.
 - An abnormal system shutdown occurs if you do not power off the ultrasound system using the green partial power on/off switch (\circlearrowleft) located on the front of the system. Other examples of abnormal system shutdown include: equipment malfunction, loss of power, or pressing and holding the green partial power on/off switch longer than 4 seconds.
- Should an abnormal system shutdown occur, the system may initially require additional time to reboot or to respond to user input. This is due to the operating system performing a background scan of the hard disk to detect and segregate any truncated or corrupted files.

Data Compression



⚠ WARNING: This product uses JPEG Lossy compression that is irreversible and can result in the loss of image quality. All compressed images contain information about the compression ratio and compression type. This product conforms to the DICOM standard. DICOM conformance statements for ultrasound products are available at www.siemens.com/dicom.

Caring for the Ultrasound System

It is the responsibility of the user to verify that the ultrasound system is safe for diagnostic operation on a daily basis. Each day, prior to using the system, perform each of the steps in the Daily Checklist.

All exterior parts of the ultrasound system, including the control panel, keyboard, transducers, and biopsy devices, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect components to destroy pathogens and other microorganisms.

The ultrasound system has removable, washable air filters. The filters must be cleaned regularly to maintain proper system cooling. Check the air filters weekly, and clean as needed.

Daily Checklist



▲ WARNING: To minimize the risk of cross-contamination and infectious diseases, a sterile, non-pyrogenic transducer sheath must be in place during procedures requiring sterility.



⚠ WARNING: To avoid electrical shock, you must visually inspect a transducer prior to use. Do not use a transducer that has a cracked, punctured, or discolored casing or a frayed cable.

Discoloration Exception: The use of approved cleaners and disinfectants may cause discoloration of the transducer. You can continue to use a transducer discolored due to the use of approved cleaners and disinfectants only.

Perform the following each day before using the ultrasound system:

- Visually inspect all transducers. Do not use a transducer that has a cracked, punctured, or discolored casing or a frayed cable.
- Visually inspect all power cords. Do not power on the ultrasound system if a cord is frayed or split, or shows signs of wear.
- Visually inspect the ECG connector and the cable. Do not use the ECG function if the connector or cable is damaged or broken.
- Verify that the trackball, DGC slide controls, and other controls on the control panel appear clean and free from gel or other contaminants.

Once the ultrasound system is powered on:

- Visually check the on-screen displays and lighting.
- Verify that the monitor displays the current date and time.
- Verify that the transducer identification and indicated frequency are correct for the active transducer.

2 - 24 Instructions for Use

Maintenance

▲ Caution: To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 24 months. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.

Repair

For questions regarding repair or replacement of any equipment parts on your system, contact your Siemens service representative.

Siemens Authorized Care

Installers and operators must observe any statutory regulations that govern the installation. operation, inspection, and maintenance of this equipment.

To ensure the safety of patients, operators, and third parties, the equipment must be inspected every 24 months, and the replacement of parts is performed as necessary. This maintenance must be performed by a qualified Siemens authorized representative. It is important to inspect the equipment more frequently if it is operated under extraordinary conditions.

Perform inspections and maintenance at the prescribed intervals to avoid worn and hazardous parts due to wear. Contact the Siemens service department for information regarding the required maintenance.

As manufacturers and installers of ultrasound equipment, Siemens cannot assume responsibility for the safety properties, reliability, and/or performance of the equipment, if:

- Installations, extensions, readjustments, modifications, additions, or repairs are carried out by persons not specifically authorized by Siemens.
- Components that affect the safe operation of the system are replaced by parts not authorized by Siemens.
- The electrical installation of the room where the equipment is located does not meet the power and environmental requirements stated in this manual.
- The equipment is not used in accordance with the operating instructions.
- The system is operated by personnel not adequately educated or trained.

Siemens suggests that you request any person who performs maintenance or repairs to provide you with a certificate showing:

- The nature and extent of the work performed
- Changes in rated performance
- Changes in working ranges
- Date of service
- Name of person or firm performing the service
- Signature of person performing the service

Technical documentation pertinent to the ultrasound system is available at an additional charge. However, this does not in any way constitute an authorization to conduct repairs or maintenance. Siemens refuses all responsibility whatsoever for repairs that are performed without the express written consent of the Siemens service department.

Caring for Documentation and Storage Devices

For information on the care of an optional documentation or storage device, refer to the manufacturer's operating instructions that accompanied the device.

Caring for the Battery Pack

Recharging the Battery Pack

See also: Hazardous Substances, p. 2-51

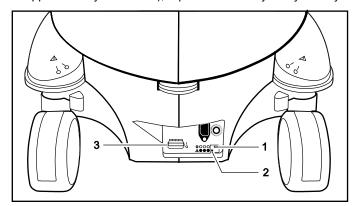
The battery pack is designed to maintain system memory for a minimum of four hours.

AC Tray Panel	Typical Time to Recharge	Maximum Time to Recharge
20 1 2 3 □ COX	1.8 hours	2 hours

Battery Pack Replacement

Replace the battery pack when it is no longer able to hold a charge.

- When the system is disconnected frequently from the AC power (for a duration of greater than four to eight hours), replace the battery every 12 to 18 months.
- When the system is only occasionally disconnected from the AC power (for a duration of approximately four hours), replace the battery every three years.



- Battery pack charge indicator LED
- 2 AC OK indicator LED
- 3 Mains ON-OFF circuit breaker

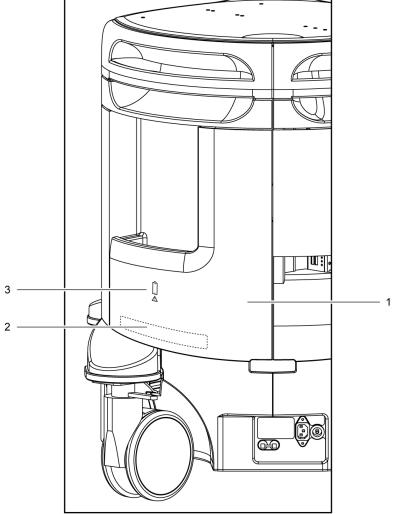
Example of an AC Tray panel with the battery pack charge indicator LED.

The battery pack charge indicator LED is located at the rear of the system, on the AC Tray panel. A green blinking LED indicates that the battery is actively charging. A solid green LED indicates that the battery pack is fully charged. If the LED is not illuminated, then there is a problem with the battery pack, or the battery pack may be missing.

2 - 26 Instructions for Use

Battery Pack Location

The battery pack is located under the storage bin cover, within a recess on the right rear panel of the ultrasound system. The storage bin cover must be removed to access the battery pack.



- 1 Storage bin cover
- 2 Battery pack location
- Battery symbol

Battery pack location.

To remove the storage bin cover:

- 1. Grasp the cover by the top right edge, above the battery location, and gently pull to unsnap the first of four fastener pins from its receptacle.
- 2. Support the cover near each fastener as you pull, working downward and toward the left, until the cover is removed.

Removing the Battery Pack

Caution: When removing the battery pack, be careful not to pull or otherwise strain the wires in the cable connecting the battery to the ultrasound system because doing so can damage the battery pack and the ultrasound system.

To remove the battery pack:

- 1. With the storage bin cover removed, locate the battery pack within the recess on the right rear panel. The battery pack is attached to the ultrasound system by a connector at the end of a cable. The battery is also secured within the recess by hook and loop fastener.
- Grasp the battery pack within the recess and gently pull the battery pack to release the hook and loop fastener.
- Support the connector housing attached to the battery cable and pull the connector straight out of the connector receptacle to disconnect the battery.

Installing a Battery Pack

⚠ Caution: There is only one correct orientation for attaching the battery connector. Do not force or twist the connector because doing so can damage the battery pack and the ultrasound system.

To install a battery pack:

- Orient the battery pack connector at the end of the battery cable with the receptacle on the ultrasound system, located within the battery recess. Firmly push them together.
- Turn the battery pack so that the hook and loop fastener on the battery pack is toward the battery recess in the right rear panel, and press the battery pack into the recess, connecting the hook and loop fastener on the battery pack with the hook and loop fastener in the recess.
- 3. Position the battery wires so they are neatly stored within the battery recess.

To replace the storage bin cover:

Working from the lower left toward the upper right of the storage bin cover, align the fastener pins with the pin receptacles and press to snap the storage bin cover into place on the right rear panel.

Recycling the Battery Pack

See also: Recycling Batteries, p. 2-52

2 - 28 Instructions for Use

Cleaning and Disinfecting

You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. Use universal precautions when cleaning and disinfecting. You should treat all portions of the ultrasound system that come in contact with human blood or other body fluids as if they were known to be infectious.

All exterior parts of the ultrasound system, including the control panel, keyboard, transducers, and biopsy devices, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect components to destroy pathogens and other microorganisms.

Cleaning Ultrasound System Surfaces



⚠ **WARNING:** To avoid electric shock and damage to the ultrasound system, power off and unplug the equipment from the AC power outlet before cleaning and disinfecting.



⚠ WARNING: Disinfectants and cleaning methods listed are recommended by Siemens for compatibility with product materials, not for biological effectiveness. Refer to disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.



⚠ WARNING: The use of any disinfectants other than those specified in the instructions for use may damage the ultrasound system and accessory surfaces and, as a result, may create electrical hazards for the patients and/or users.



Caution: To avoid the possibility of static shock and damage to the ultrasound system, avoid the use of aerosol spray cleaners on the monitor screens.



△ Caution: Do not clean the ultrasound system with chlorinated or aromatic solvents, acidic or basic solutions, isopropyl alcohol or strong cleaners such as ammoniated products, as these can damage the surface of the system. Use the recommended cleaning procedure.



△ Caution: Do not use spray cleaners on the ultrasound system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.



△ Caution: Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.



△ Caution: Prior to cleaning or disinfecting the system, you must disconnect and remove transducers from the ultrasound system. Unintended contact with disinfectants approved only for use with the system can result in damage to the transducers.

The following instructions describe cleaning the surface of the ultrasound system, including the trackball and transducer holder.

To Do This		
Clean and disinfect the	1. Power off the ultrasound system and unplug the power cord from the power outlet.	
surface of the ultrasound system	2. Use a clean gauze pad or lint-free cloth, lightly moistened with a mild detergent, to wipe the surface of the ultrasound system.	
	If your system has a touch screen, take care to gently wipe the surface of the touch screen.	
	Take particular care to clean the areas near the trackball and the slide controls. Ensure these areas are free of coupling agent (gel) and any other visible residue.	
	Ensure that cleaning solution does not seep into the control panel, keyboard, or any other openings.	
	3. After cleaning, use a clean, lint-free cloth to dry the surface.	
	4. As required, use an approved disinfectant wipe to disinfect the ultrasound system and accessories.	
	5. Reconnect the ultrasound system power cord into the power outlet.	
Clean and disinfect the	Remove the holder from the ultrasound system.	
holders for transducers and coupling gel	 Reach under the holder to locate the tab on the holder. The tab extends below the point of attachment to the ultrasound system. 	
	b. Squeeze the tab towards the holder and pull the holder downward.	
	Clean the holder under running water, using a mild detergent and dry with a lint-free cloth.	
	3. As required, use an approved disinfectant wipe to disinfect the holder.	
	4. Reattach the holder to the ultrasound system.	
	Align the support on the holder directly below the point of attachment on the ultrasound system and firmly push upwards until the holder snaps into place.	

2 - 30 Instructions for Use

To Do This

Clean and disinfect the gel

 \triangle

Caution: To avoid damage to the gel warmer, do not immerse the gel warmer in water or any solution.

Note: To facilitate cleaning, remove the cap at the bottom of the gel warmer. Rotate the cap counterclockwise to remove the cap; rotate the cap clockwise to secure the cap.

- 1. Remove the gel warmer from the ultrasound system.
 - a. Unplug the power cable attached to the gel warmer from the ultrasound system. The connector on the ultrasound system is located on the right or left side of the control panel, just behind the point of attachment for the gel warmer.
 - b. Reach under the gel warmer to locate the tab on the gel warmer. The tab extends below the point of attachment to the ultrasound system.
 - c. Squeeze the tab towards the gel warmer and pull the gel warmer downward.
- 2. Unplug the power cable from the gel warmer.
- 3. Clean and disinfect the gel warmer using an approved disinfectant wipe.
- 4. Reattach the gel warmer to the ultrasound system.
 - a. Attach one end of the power cable accompanying the gel warmer to the connector on the back of the gel warmer and then attach the other end of the power cable to the connector on the ultrasound system.
 - b. Align the support on the gel warmer directly below the point of attachment on the ultrasound system and firmly push upwards until the gel warmer snaps into place.

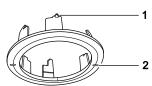
То

Do This

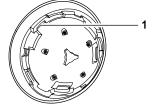
Clean and disinfect the



Caution: Do not drop or place foreign objects inside the trackball assembly because doing so may affect the trackball operation and damage the ultrasound system.



Example of the trackball ring.



Example trackball assembly.

- Tab for inserting into the trackball assembly
- 2 Raised markings on either side of the ring
- 1 Point of attachment for the trackball ring
- Rotate the ring around the trackball counterclockwise and then carefully lift up the ring to remove the ring and trackball.
- Clean the ring and trackball with a cotton swab or lint-free pad moistened with mild detergent solution.
- Clean the inside of the trackball assembly with a cotton swab or lint-free pad moistened with mild detergent solution.
- 4. As required, use an approved disinfectant wipe to disinfect the ring, trackball, and trackball assembly.
- 5. Allow the trackball components to completely dry before reassembly.
- 6. Reinstall the ring and trackball.
 - a. Place the trackball inside the trackball assembly.
 - b. Place the ring over the trackball, taking care to align the tab with the point of attachment on the trackball assembly.
 - Rotate the ring clockwise until the ring snaps into place and the ridges of the ring are in a horizontal position.

2 - 32

Approved Disinfectant Wipes for the Ultrasound System Surfaces

The following matrix provides a list of approved disinfectant wipes for use on the ultrasound system and surfaces of the listed accessories.

	Sani-Cloth	Sani-Cloth Bleach Wipe*	Sani-Cloth HB	Sani-Cloth Plus	Super Sani-Cloth
Ultrasound System	✓	✓	✓	✓	✓
Transducer Holders	✓	✓	✓	✓	✓
Trackball Assembly	✓	✓	✓	✓	✓
Gel Warmer	✓	✓	✓	✓	✓

^{*}or any bleach wipe with <1% sodium hypochlorite and no other active ingredients

NA = not approved

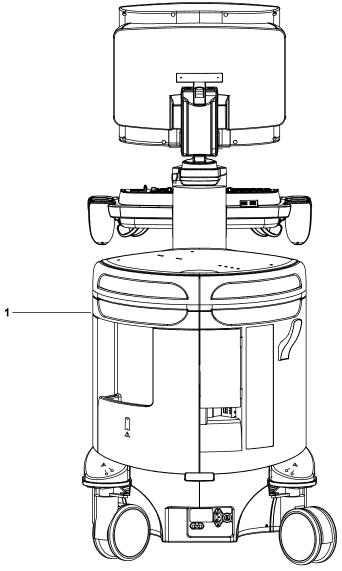
^{√ =} approved

Cleaning the Air Filter



The filter location is marked with the air filter symbol.

The ultrasound system has one removable, washable air filter. This air filter must be cleaned regularly to maintain proper system cooling. Check the air filter weekly, and clean as needed. Clean and reinstall the air filter according to the following instructions.



1 Location of back panel air filter

Example of the location of the air filter.

2 - 34 Instructions for Use

To remove and clean the back panel air filter:

△ Caution: Do not scrub, stretch, or bend the filter, or apply heat to the filter, as doing so could damage the filter.

- 1. Power off and unplug the power cord from the power outlet.
- 2. Locate the air filter tray in the back panel and pull the tray out of the ultrasound system.
- 3. Remove the air filter from the tray.
- Rinse the air filter with running water and allow the filter to completely dry.
 To hasten drying, you may gently shake the filter, or blot the filter with a clean, lint-free cloth.
- ⚠ Caution: Do not insert a wet filter as this can damage the system.
- 5. Replace the air filter into the tray, positioning the filter flat side down, with the angled corners fitting into the back of the tray. The filter will fit into the back corners of the tray only if the filter is positioned flat side down.
- 6. Press the filter against the hook and loop fasteners on the tray.
- 7. Slide the air filter tray back into the ultrasound system.
- 8. Plug the power cord into the power outlet.

Caring for Transducers



▲ WARNING: To minimize the risk of cross-contamination and infectious diseases, clean and high-level disinfect endocavity transducers after each use; clean and sterilize intraoperative transducers after each use.



⚠ **WARNING**: During neurosurgical procedures, if a transducer becomes contaminated with tissue or fluids of a patient known to have Creutzfeldt-Jacob disease, the transducer should be destroyed as it cannot be sterilized.



⚠ WARNING: When using an endocavity or intraoperative transducer with a BF or CF type applied part, the patient leakage currents may be additive.



⚠ **WARNING:** Prior to each use, inspect the endocavity or intraoperative transducer for signs of mechanical damage such as cracks, cuts, tears, perforations, or protrusions. Do not use the transducer if the transducer appears damaged in any way. Any damage could cut the patient and compromise the electrical safety of the transducer, causing possible patient or user injury. Contact your local Siemens representative.



△ Caution: Transducers are sensitive instruments — irreparable damage may occur if they are dropped, knocked against other objects, cut, or punctured. Do not attempt to repair or alter any part of a transducer, contact your local Siemens representative.



△ Caution: To avoid cable damage, do not roll the ultrasound system over transducer cables.



△ Caution: To avoid damage to the transducer, do not use transducer sheaths containing an oil-based coating or petroleum- or mineral oil-based ultrasound coupling agents. Use only a water-based ultrasound coupling agent.



△ Caution: Follow all instructions provided by manufacturers of sterile goods (transducer sheaths) to ensure proper handling, storage, and cycling of all sterile goods.

Take extreme care when handling or storing transducers. They must not be dropped, jarred, or knocked against other objects. Do not allow transducers to come into contact with any sharp-edged or pointed object.

2 - 36 Instructions for Use

Protective Case

Due to the mechanical sensitivity of transducers, Siemens recommends that you always use the transducer case when you ship a transducer or transport it from one place of examination to another. The case is specially designed to protect the sensitive parts of the transducer. Be sure that all parts of the transducer are properly placed inside the case before you close the lid.

Storage

Store transducers in a clean and dry environment. Extreme temperatures or humidity may damage a transducer.

See also: Technical Description, Appendix A, Instructions for Use.

Repair

Do not attempt to repair or alter any part of the transducer. Contact your service representative at Siemens immediately if a transducer appears to be damaged or malfunctions in any way.

Methods for Cleaning and Disinfecting Transducers

You must observe the required methods for cleaning and disinfecting or cleaning and sterilization before the first use and after each use of a transducer.

Siemens defines the methods for cleaning and disinfecting or cleaning and sterilization by classifying the use of the transducer according to the Spaulding Classification scheme observed by the United States Food and Drug Administration (FDA).

Example of Transducers	Use	Required Method	Classification	
 Intraoperative 	Sterile body tissue	Cleaning and sterilization	Critical	
Laparoscopic				
Endocavity	Intact mucous membranes	Cleaning and high-level	Semi-critical	
 Transesophageal 		disinfection		
Non-invasive	Non-intact skin	Cleaning and high-level disinfection	Semi-critical	
 Non-invasive 	Intact skin	Cleaning and low-level disinfection	Noncritical	

Important Information

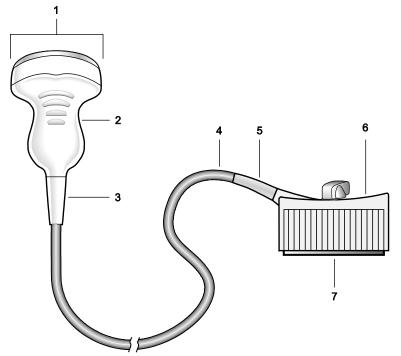
The ACUSON S1000, ACUSON S2000, and ACUSON S3000 ultrasound systems do not support the following transducers:

Laparoscopic

See also: For information on cleaning and disinfecting transesophageal transducers, refer to Chapter 6 in this manual.

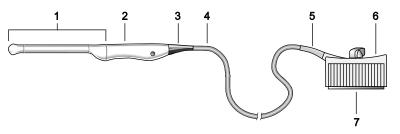
2 - 38 Instructions for Use

Examples of Transducer Components



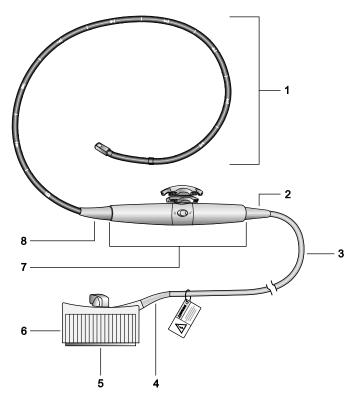
- I Transducer surface in contact with the patient
- 2 Handle
- 3 Strain relief for the transducer
- 4 Cable
- 5 Strain relief for the connector
- 6 Connector
- 7 Electrical component on the connector

Example of transducer components.



Example of endocavity transducer components.

- 1 Transducer surface in contact with the patient
- 2 Handle
- 3 Strain relief for the transducer
- 4 Cable
- 5 Strain relief for the connector
- 6 Connector
- 7 Electrical component on the connector



Example of transesophageal transducer components.

- Transducer surface in contact with the patient (flexible shaft with depth markings, articulating section, and distal tip)
- 2 Strain relief for the handle
- 3 Cable
- 4 Strain relief for the connector
- 5 Electrical component on the connector
- 6 Connector
- 7 Handle with controls
- 8 Strain relief for the handle

2 - 40 Instructions for Use

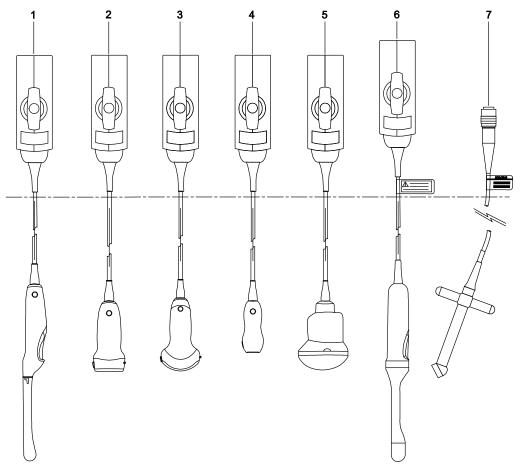
Immersion Levels

⚠ Caution: To avoid damage to the transducer, observe the immersion levels indicated for each transducer type.

⚠ Caution: Do not immerse the label located on the cable of the CW transducer.

Note: Transducers meet Ingress Protection level IPX8 of EN 60529 and IEC 60529 to the depth of the immersion line shown in the illustration. Endocavity transducers exceed minimum Ingress Protection level IPX7 of IEC 60601-2-18 to the depth of the immersion line shown in the illustration.

Note: Intraoperative transducers are immersible up to the strain relief on the connector.



Example of immersion levels.

- Endocavity
- 2 Linear
- Curved 3
- 4 Phased
- 5 fourSight 4D
- fourSight 4D (endocavity)
- 7 Continuous Wave (CW)

⚠ WARNING: To avoid electrical shock and damage to the system, disconnect the transducer prior to cleaning or disinfecting.



▲ WARNING: Disinfectants and cleaning methods listed are recommended by Siemens for compatibility with product materials, not for biological effectiveness. Refer to disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.



Caution: Do not sterilize transducers using hot steam, cold gas, or Ethylene Oxide (EO) methods. Before applying any other methods that might be recommended by manufacturers of sterilization equipment, please contact your Siemens representative.



△ Caution: To avoid damage to the transducer, observe the immersion levels indicated for each transducer type. Do not immerse or allow the connector of a transducer or the strain relief on the connector to become wet.



△ Caution: The transducers have been designed and tested to be able to withstand disinfection as recommended by the manufacturer of the disinfectant product. Carefully follow the disinfectant manufacturer's instructions. Do not immerse for more than one hour.



△ Caution: Do not use abrasive cleaners, organic solvents such as benzene, isopropyl alcohol, or phenol-based substances, cleaners, or disinfectants containing organic solvents to clean or disinfect transducers. These substances can damage the transducers.



△ Caution: Do not use an abrasive sponge or brush. These materials can damage the transducer.



△ Caution: The use of a spray cleaner or disinfectant may force fluid inside the transducer and the ultrasound system. To avoid damage, first remove the transducer from the system and then carefully spray the transducer. Never spray the transducer connector.



⚠ Caution: Prior to cleaning or disinfecting a transducer, you must disconnect and remove the transducer from the ultrasound system. Do not clean or disinfect the transducer on or near the ultrasound system. Unintended contact with approved transducer cleaners and disinfectants can result in severe damage to the ultrasound system components.

2 - 42 Instructions for Use

Required Task	Location in This Manual
Read and understand the biohazard considerations.	p. 2-13
Perform the steps in the daily checklist.	p. 2-24
Read and understand the cleaning and disinfecting information for the ultrasound system.	p. 2-24
Read and understand all transducer-specific warnings and cautions.	p. 2-36
Disconnect the transducer.	Chapter 3
Clean and disinfect the transducer after each use.*	p. 2-43
Select an approved disinfectant.	p. 2-45
Dry and store the transducer in its protective carrying case.	p. 2-37

^{*}Information on cleaning and disinfecting transesophageal transducers is located in Chapter 6 in this manual

To clean and disinfect a transducer:

- 1. Wipe visible gel or particles from the transducer with a soft cloth.
- 2. Remove any transducer accessories from the transducer.
- 3. Disconnect and remove the transducer from the ultrasound system.
- 4. To remove existing particles from the transducer prior to disinfection, moisten a clean gauze pad or cloth with water or an approved cleaner and then wipe the transducer. Avoid touching the electrical components on the connector.

See also: For a list of approved cleaners, refer to p. 2-44.

5. Select an approved disinfectant for low-level or high-level disinfection. Follow the disinfectant manufacturer's instructions for the required level of disinfection.

See also: For a list of approved disinfectants, refer to p. 2-45.

- a. Moisten a clean gauze pad with the disinfectant, if necessary.
- b. Carefully wipe the transducer from the connector to the surface which was in contact with the patient. Avoid touching the electrical components on the connector.

Note: If immersion is required, keep the transducer connector and connector strain relief dry while immersing the transducer in an approved disinfectant to the immersion level indicated on p. 2-41.

6. Follow the disinfectant manufacturer's instructions for drying the transducer.

Note: If the disinfectant manufacturer does not provide drying instructions, dry the transducer with a clean, lint-free, soft cloth.

Instructions for Use 2 - 43

Approved List of Cleaners

Note: Gigasept FF may discolor the transducer. There is no associated degradation of imaging performance or transducer reliability. You can use Gigasept FF as a cleaner and a disinfectant.

	ENZOL	Gigasept FF	Transeptic
4C1	✓	✓	✓
6C1 HD	✓	✓	NA
6C2	✓	✓	✓
7CF1	✓	✓	✓
7CF2	✓	✓	✓
8C3 HD	✓	✓	NA
EV-8C4	✓	✓	✓
EC9-4	✓	✓	✓
MC9-4	✓	✓	✓
9EVF4	✓	✓	✓
9L4	✓	NA	✓
12L4	✓	NA	NA
14L5	NA	✓	NA
14L5 SP	NA	✓	NA
18L6 HD	✓	✓	NA
4P1	NA	✓	NA
4V1	✓	✓	✓
4V1c	✓	✓	✓
8V3	✓	✓	✓
10V4	✓	✓	✓
V5Ms	✓	✓	✓
V7M	✓	✓	✓
CW2	✓	✓	✓
CW5	✓	✓	✓

^{√ =} approved

NA = not approved

2 - 44 Instructions for Use

Approved List of Disinfectants

Note: CIDEX OPA and Gigasept FF may discolor the transducer. There is no associated degradation of imaging performance or transducer reliability. You can use Gigasept FF as a cleaner and a disinfectant.

	CIDEX	CIDEXPLUS	CIDEX OPA	Gigasept FF	Milton	PI-Spray II	Rely+On Virkon	Revital Ox RESERT HLD	Sani-Cloth AF3	Sani-Cloth HB	Super Sani-Cloth
4C1	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6C1 HD	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓	NA
6C2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7CF1	✓	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓
7CF2	✓	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓
8C3 HD	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓	NA
EV-8C4	✓	✓	✓	✓	✓	✓	✓	✓	NA	NA	NA
EC9-4	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓	✓
MC9-4	✓	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓
9EVF4	✓	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓
9L4	✓	✓	✓	NA	NA	✓	NA	NA	✓	✓	✓
12L4	✓	✓	✓	NA	NA	✓	✓	✓	NA	NA	NA
14L5	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓	✓
14L5 SP	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓	✓
18L6 HD	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓	NA
4P1	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓	✓
4V1	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4V1c	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8V3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10V4	✓	✓	✓	✓	✓	✓	✓	NA	✓	✓	✓
V5Ms	✓	✓	✓	✓	✓	✓	NA	NA	NA	✓	✓
V7M	✓	✓	✓	✓	✓	✓	✓	NA	NA	NA	NA
CW2	✓	✓	✓	✓	✓	✓	✓	NA	NA	✓	✓
CW5	✓	✓	✓	✓	✓	✓	✓	NA	NA	✓	✓

^{√ =} approved

NA = not approved

Instructions for Use 2 - 45

Sterilizing Transducers — 14L5 SP

△ Caution: The transducers have been designed and tested to be able to withstand sterilization as recommended by the manufacturer of the sterilization system. Carefully follow the sterilization manufacturer's instructions.

The STERRAD[®] sterilization system, a hydrogen peroxide gas plasma sterilization system, is approved for use with the listed intraoperative transducer(s).

14L5 SP

To sterilize a transducer with the STERRAD system:

Note: This procedure applies to the 14L5 SP transducer only.

- 1. Disconnect the transducer from the system.
- 2. Thoroughly clean, rinse, and dry the transducer.
- 3. Carefully follow the manufacturer's instructions for sterilization.

2 - 46 Instructions for Use

Caring for Transducer Accessories

Instructions are provided for the following accessories for transducers:

- Transducer Sheaths
- Gel Pads
- Needle Guide Bracket Kits

See also: Transducer Accessories and Biopsy, Chapter 5, Instructions for Use

Transducer Sheaths



▲ WARNING: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.



MARNING: To minimize the risk of cross-contamination and infectious diseases, a sterile, non-pyrogenic transducer sheath must be in place during procedures requiring sterility.



⚠ **WARNING:** Only a sterile transducer sheath provides the sterile barrier required for surgical procedures. To ensure sterility of a procedure, always place a sterile sheath on a transducer, as transducers cannot be sterilized using hot steam, cold gas, or Ethylene Oxide (EO) methods.



△ Caution: Siemens recommends that you follow all instructions provided by manufacturers of sterile goods (transducer sheaths) to ensure proper handling, storage, and cycling of all sterile

Using a disposable latex transducer sheath on a transducer reduces the possibility of cross-contamination. Always use a protective transducer sheath for endocavity exams, and when scanning an open wound or an area where the skin is not intact.

Storage



⚠ **WARNING:** Before use, examine sterile goods, such as sheaths, for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.



Caution: Do not store transducer sheaths in direct sunlight, as ultraviolet damage can result.

Latex products have a limited shelf life, and should be stored in a cool, dry, dark place with an ambient temperature between -5°C and +40°C and up to 80% relative humidity at +40°C. Before use, examine these products for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.

Instructions for Use 2 - 47

Gel Pad

Before use, examine the gel pad for any material flaws. Thinning, bulging, or brittleness of the material indicates damage. Any product showing flaws should not be used.

Storage

Do not store the gel pads below 40°F (5°C) nor above 135°F (57°C). Gel pads have a limited shelf life. Before use, examine these products for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.

Needle Guide Bracket Kits



⚠ **WARNING**: If a needle guide becomes contaminated with tissue or fluids of a patient known to have Creutzfeldt-Jacob disease, then the needle guide should be destroyed. Sterilization is not effective against Creutzfeldt-Jacob contamination.

Needle guide bracket kits are available for biopsy and puncture procedures for specific transducers.

Storage and Transportation

Always clean and sterilize or high-level disinfect components used in a needle puncture or biopsy procedure after each use.

Refer to the in-box instructions for storage and transportation information for all needle guide accessories except as noted below.

Storing or Transporting the EC-1 Bracket Kit

- Do not use the carrying case for storing the bracket assembly. If the carrying case is used for storage, it may become a source of infection.
- The bracket assembly must be stored and transported under the following environmental conditions:

Ambient temperature: -10°C to 60°C

Relative humidity: 30% to 95% (no condensation)

700 hPa to 1060 hPa Atmospheric pressure:

- Between examinations, keep the bracket assembly in a sterile environment.
- When the biopsy adapter is transported to a different hospital or clinic or is sent to your Siemens representative for repair, be sure to sterilize it and keep it in the carrying case for transportation to prevent infection.

2 - 48 Instructions for Use

Cleaning, Disinfecting, and Sterilizing Transducer Accessories

⚠ **WARNING**: Ensure the accessories for a transducer are properly cleaned, sterilized, or disinfected as appropriate before each use to avoid possible patient contamination.

Needle Guide Bracket Kits

Needle guide bracket kits are available for specific transducers. Instructions follow for the cleaning, disinfecting, and sterilization of each kit. Bracket assemblies should be cleaned and sterilized or high-level disinfected after each use.

See also: For a list of transducers compatible with the needle guide accessories, refer to Chapter 5 in this manual.

EC-1 Needle Guide Bracket Kit for Endocavity Transducers



⚠ WARNING: The EC-1 Needle Guide Bracket kit is packaged non-sterile. Sterilize this product prior to its first use.

Prior to sterilization, clean the bracket assembly.

To clean the bracket assembly:

- Rinse the bracket under water and remove all debris. Avoid using a brush as it may damage the needle guide bracket.
- 2. Visually inspect the guide to make sure all debris is removed.
- 3. Wipe off water on the bracket assembly using a sterile cloth or sterile gauze.

To sterilize the bracket assembly:

Use sterile technique to perform this procedure.

- Sterilize assembly using high-pressure steam sterilization (130°C [266°F] for an exposure time of 10 minutes), EO (ethylene oxide) sterilization, or hydrogen peroxide plasma sterilization.
- 2. Perform one of the gas sterilization methods listed below:

Sterilization	Gas	Procedure					
Method	Concentration	Temperature	Humidity	Pressure	Time		
Ethylene Oxide Gas	10%	50°C (122°F)	50%	Maximum operating pressure 980 hPa (1.0 kgf/cm²)	7 hours		
Hydrogen Peroxide Plasma	STERRAD	For details, refer to the operation manual for the STERRAD® sterilization system.			RRAD [®]		

3. After gas sterilization, thoroughly degas (aerate) the biopsy adapter to remove all gas residues.

Instructions for Use 2 - 49

CH4-1, C7F2/C5F1, 7CF1, 18L6 HD, 8C3 HD, SG-2, SG-3, SG-4, SG-5 and VF12-4 **Bracket Assemblies**

▲ WARNING: The needle guide is packaged sterile and is a single-use item. Do not use if the packaging indicates signs of tampering or if the expiration date has passed.

The needle guides for use with the CH4-1, C7F2/C5F1, 7CF1, 18L6 HD, 8C3 HD, SG-2, SG-3, SG-4, SG-5, and VF12-4 brackets are single-use items. Refer to the in-box instructions for disposal instructions.

The brackets are reusable items. Refer to the in-box instructions for cleaning and high-level disinfecting procedures for the bracket.

MC9-4, EC9-4 and EV-8C4 Disposable Endocavity Needle Guides

⚠ WARNING: The needle guide is packaged sterile and is a single-use item. Do not use if the packaging indicates signs of tampering or if the expiration date has passed.

The disposable endocavity needle guide is a single-use item. Refer to the in-box instructions for disposal instructions.

MC9-4, 9EVF4 and EV-8C4 Stainless Steel Endocavity Needle Guide Kits

⚠ WARNING: Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use.

The stainless steel endocavity needle guide is a reusable item. Refer to the in-box instructions for attachment and care procedures, including cleaning and sterilization.

Tracking Brackets and Needle Guides for eSieFusion Imaging

⚠ WARNING: The needle guide is packaged sterile and is a single-use item. Do not use if the packaging indicates signs of tampering or if the expiration date has passed.

The needle guides for use with eSieFusion imaging are single-use items. Refer to the in-box instructions for disposal instructions.

Refer to the in-box instructions for cleaning and high-level disinfecting procedures for the tracking brackets.

See also: For a list of tracking brackets and needle guides compatible with eSieFusion Imaging, see Technical Description, Appendix A, Instructions for Use.

2 - 50 Instructions for Use

Environmental Protection

Siemens recognizes its responsibility to minimize the environmental impacts of services, operations, and products. For more information, contact your local Siemens representative.

Product Recycling and Disposal

Dispose of this product according to local, state, and regional laws and regulations.

Batteries and electrical and electronic equipment can contain hazardous substances. If released, the hazardous substances can harm people and the environment.

Siemens provides disassembly instructions to treatment facilities for the safe and proper removal and recycling of electrical and electronic components in this product. For more information, contact your local Siemens representative.

To the extent required by local, state, and regional laws and regulations, Siemens has programs for the return of used products. For more information, contact your local Siemens representative.

Hazardous Substances

The 54.5 cm (21.5 inch) flat panel display monitor does not contain mercury.

Caring for Batteries



▲ WARNING: Do not strike or drop batteries, allow batteries to contact water or other fluids, disassemble batteries, allow conductive object to contact a battery's terminals, cause a battery to become short circuited, heat batteries, or expose batteries to fire. Any of these actions can compromise the structural integrity of a battery. Compromising the structural integrity of a battery can result in battery leakage, heat generation, fire, or explosion, causing possible personal injury.



MARNING: Do not use a battery if it leaks fluid or has changed shape. If skin or clothing comes in contact with fluid from the battery, thoroughly wash the area immediately with clean water. If any fluid comes in contact with a user's eyes, immediately flush their eyes with water and seek medical attention.



⚠ **WARNING**: Replace batteries with the same or equivalent type. Use of incompatible batteries can result in battery leakage, heat generation, fire, or explosion, causing possible personal injury.



MARNING: Do not attempt to recharge non-rechargeable batteries, such as the batteries included on printed circuit boards. Recycle non-rechargeable batteries according to local, state, and regional laws and regulations.

For maximum battery life, do both of the following when the system is not in use:

- Keep the system plugged into the power outlet.
- Ensure the mains circuit breaker is in the on position (I = ON).

Instructions for Use 2 - 51

Recycling Batteries

⚠ WARNING: Never dispose of batteries by burning or by flushing into any waste water system, for example, a lavatory. Compromising the structural integrity of a battery can result in leakage or explosion and the potential for personal injury.

⚠ WARNING: Do not throw batteries into the trash. Collect and recycle used batteries separate from other waste.

Item	Handling Instructions
lithium batteries	See also: Caring for Batteries, p. 2-51
	The battery is expected to hold a sufficient charge for 1.5 years from the start of service if:
	 the system is never plugged into the power outlet
	 the system is plugged into the power outlet, but the mains circuit breaker is in the off position (O = OFF) for the entire 1.5 years
	If the system clock no longer keeps time, it could be time to replace the battery. Contact your local Siemens representative.
battery packs (nickel-metal hydride [Ni-MH] battery)	See also: Caring for the Battery Pack, p. 2-26
, i i i i i i i i i i i i i i i i i i i	The battery is rechargeable.

Recycle batteries according to local, state, and regional laws and regulations. Use a battery collection program available in your country to recycle batteries.

To the extent required by local, state, and regional laws and regulations, Siemens will collect and recycle batteries for this product at no charge. Contact your local Siemens representative for battery shipment instructions.

Disposing of the Packaging Materials

Dispose of or recycle the packaging materials according to local, state, and regional laws and regulations.

To the extent required by local, state, and regional laws and regulations, Siemens will collect and dispose of packaging materials for this product. For more information, contact your local Siemens representative.

2 - 52 Instructions for Use

Disposing of Components and Accessories

⚠ WARNING: Observe local, state, and regional laws and regulations for the disposal of the ultrasound system components and accessories.

⚠ WARNING: Bodily fluids on used needles and needle guides can transmit infectious diseases. To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, always dispose of the needle and the needle guide according to local, state, and regional laws and regulations.

Component or Accessory	Handling Instructions
air filter	See also: Cleaning the Air Filter, p. 2-34
	The air filter is reusable.
	Replace the air filter if the air filter is damaged in any way. For example, the air filter has a hole or will not fit in the air filter slot.
CH4-1, C7F2/C5F1, 18L6 HD, 8C3 HD, 7CF1, SG-2, SG-3,	The needle guides for use with the brackets are single-use items. Refer to the in-box instructions for disposal procedures.
SG-4, SG-5 and VF12-4 needle guide bracket assemblies	The brackets are reusable items. Refer to the in-box instructions for attachment and care procedures, including cleaning, and high-level disinfection procedures for the brackets. Refer to the in-box instructions for guidance regarding when to dispose of a damaged needle guide.
MC9-4, EC9-4 and EV-8C4 disposable endocavity needle guides	The disposable endocavity needle guide is a single-use item. Refer to the in-box instructions for disposal procedures.
MC9-4, 9EVF4 and EV-8C4 needle guide bracket kits	The stainless steel endocavity needle guide is a reusable item. Refer to the in-box instructions for attachment and care procedures, including cleaning, disinfection, and sterilization. Refer to the in-box instructions for guidance regarding when to dispose of a damaged needle guide.
	Refer to the in-box instructions for disposal procedures for the single-use components.
EC-1 needle guide bracket kit	If the biopsy bracket assembly becomes damaged or compromised in any way, dispose of it only after sterilizing. The assembly is made of polyetherimide resin. When disposing of the assembly, be sure to comply with all applicable laws or regulations.
Needle guides for eSieFusion imaging	The needle guides for use with eSieFusion imaging are single-use items. Refer to the in-box instructions for disposal procedures.

Energy Conservation

See also: Mobile QuikStart for Portable Studies (Standby), Chapter 3, Instructions for Use

See also: Supplying Power to the System, Chapter 3, Instructions for Use

For moderate energy conservation when the system is not in use, place the system in standby status.

For improved energy conservation when the system is not in use, power off the system. Keep the system plugged into the power outlet. Ensure the mains circuit breaker is in the on position (I = ON).

For maximum energy conservation when the system is in storage, power off and unplug the system from the power outlet or switch the mains circuit breaker to the off position (O = OFF).

Note: Unplugging the system from the power outlet or switching the mains circuit breaker to the off position (O = OFF) for long periods of time can shorten the life of the system batteries.

Instructions for Use 2 - 53 2 Safety and Care

2 - 54 Instructions for Use

3 System Setup

Initial Setup	3
Moving the System	3
Using the Front Brakes	
Using the Rear Brakes	
Securing the Monitor	
Prior to the Move	
During the Move	
After the Move	
Shipping the System	
System Startup	7
AC Tray Panel	7
Plugging in the System	7
Supplying Power to the System	
Mobile QuikStart for Portable Studies (Standby)	9
Adjusting the Screen Brightness	10
Connecting and Disconnecting Transducers	11
Array Transducers	12
Continuous Wave Transducers	13
Protective Transducer Holder	13
Transducer Cable Management	14
Connecting System Accessories	15
Footswitch	15
Physio Cables	15
Gel Warmer	16
Virtual Communication for Remote Assistance	18
Connecting the Ultrasound System to a Network	19
Wired Connection	19
Wireless Connection	19
Network Connection Icons	20
System Security	21
Restricting User Access and Permissions	21
Tracking User Activities	21
Disk Space Security Indicators	21
Input/Output Panel Connections	22
Connecting Peripheral Equipment	23
On-Board vs. Off-Board Documentation Devices	25
System Ergonomics	26
Inotalling System Undates	27

3 System Setup

3 - 2 Instructions for Use

Initial Setup

⚠ WARNING: Do not tip the system in any direction more than 10 degrees. This action can cause the system to tip over and create a risk for injury to the user or patient and damage to the

⚠ **WARNING**: Do not lean on or apply excessive force to the control panel or monitor. These actions can cause the system to tip over and create a risk for injury to the user or patient and damage to the system.

The ultrasound imaging system is initially unpacked and installed by a Siemens representative. Your Siemens representative will verify the operation of the system. Any transducers, documentation devices, accessories, and options delivered with your system are also connected and installed for you.

Moving the System

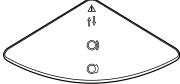


⚠ WARNING: Preparations before moving the system are important to minimize potential damage to sensitive components and to avoid safety hazards. Review the moving instructions before moving the system.

⚠ WARNING: Do not park, or leave unattended, on a slope. Even when the rear brakes are engaged, the system may slide down a ramp.

The ultrasound system is designed to be a mobile unit. Before moving the system to another location, you must prepare for the move by powering off and securing the system.

Using the Front Brakes



Front Brake.

The front brakes (on the wheels nearest you when you face the control panel on the ultrasound system) are set differently from the rear brakes.

The front brakes are set simultaneously from a foot pedal in the central section of the system front bumper as either unlocked, locked swivel, or locked.



- Locked swivel (wheels only roll straight forward or backward)
- Unlocked (wheels can swivel and roll)
- Locked (wheels cannot swivel or roll)

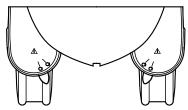
Positions of the front brake.

Instructions for Use 3 - 3

Task	Procedure
To set the front brakes:	 Press the center section of the front bumper down firmly with your foot until the brakes lock into place. This is the lowest position for the front bumper.
To release the front brakes:	 Lift the center section of the front bumper from underneath until it clicks once, using the top of your foot. This is the center position for the front bumper.
To set the swivel brakes:	 Lift the center section of the front bumper from underneath firmly until the wheels are locked in a forward position, using the top of your foot. This is the highest position for the front bumper.
To release the swivel brakes:	 Press the center section of the front bumper down with your foot until it clicks once. This is the center position for the front bumper.

Using the Rear Brakes

The rear brakes are set individually as either unlocked or locked.

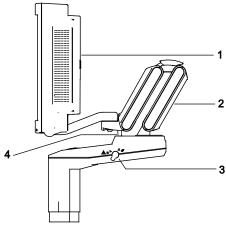


Rear Brakes.

Task	Procedure
To set the rear brakes:	 Using your foot, move lever to the Lock position until you hear a click.
To release the rear brakes:	 Using your foot, move lever to the Unlock position until you hear a click.

3 - 4 Instructions for Use

Securing the Monitor



- 1 Flat panel monitor
- 2 Articulating arm
- 3 Transport lock
- 4 Locking pin

Example of monitor in locked position.

To lock the position of the flat panel monitor for transport:

- Ensure the directional swivel of the wheels (swivel brakes) on the ultrasound system is locked.
- 2. Align the flat panel monitor to the front, center of the ultrasound system.
- 3. Gently tip the monitor toward the front of the system to increase visibility during transport.
- 4. Push and rotate the transport lock into the locked position. Ensure the locking pin engages with the hole on the articulating arm.

Prior to the Move

- 1. **Power OFF:** Briefly press and then release the power on/off switch ($^{(\!\!\!)}$) to power off the ultrasound system. The power on/off switch is located to the right of the CD-R drive.
- 2. *Unplug cord:* Unplug the power cord from the wall outlet. Pull on the plug, NOT the cord. If applicable, also unplug the Ethernet cable.
- Secure components: The following components must be secured or transported separately:
 - Power cord: Secure the power cord to avoid rolling the system wheels over the cord.
 - Transducers: To ensure that the transducers are transported safely, remove each transducer and place it in its protective carrying case.
 - Gel, videotapes, and CD-R disks: Transport separately.
 - Control panel: Ensure the control panel is in the center position.
 - Flat panel monitor: Lock the flat panel monitor.
- Release brakes: Release both the front and rear brakes.

Instructions for Use 3 - 5

During the Move

△ Caution: When moving the ultrasound system, protect it from environmental changes including: moisture, winds, dirt and dust, and extreme heat or cold exposure.



Caution: Avoid moving the ultrasound system on outside surfaces with loose dirt, contaminates, or standing liquids.



△ Caution: Care should be taken to minimize shock and vibration of the ultrasound system. Avoid uneven surfaces that contain an abrupt height change or jarring surface irregularities.

You can move the ultrasound system from room to room within a facility and easily reposition the system during an examination. Be careful on inclines and uneven surfaces. The ultrasound system can be moved across pavement and other hardened parking lot surfaces.

Note: The wheels of the ultrasound system must be locked when transporting by vehicle. The ultrasound system must be sufficiently anchored to the vehicle floor or walls such that it does not shift or move during transport.

After the Move



△ Caution: Make sure the ultrasound system has proper ventilation during operation. Do not position the system against walls or hard surfaces that would impede free ventilation around the system.



⚠ Caution: Do not allow linens, bedding, and/or hanging curtain partitions to block the ultrasound system's ventilation.



△ Caution: Obstructed fans can cause potential system overheating, system performance degradation, or failure.



△ Caution: Brakes are most effective on a level surface. Never park the system on an incline greater than five degrees.

- Position system: Make sure the system is not placed against walls or fabrics that obstruct perimeter air flow to the system cooling fans.
- Set brakes: Set the front and rear brakes.
- Unlock the flat panel monitor.
- Plug in cord: Plug the power cord into a hospital-grade or local equivalent wall outlet. If applicable, also plug the Ethernet cable into an appropriate connector.
- Power ON: Power on ($^{\circlearrowleft}$) the ultrasound system.
- Check display: After the boot-up sequence is complete, verify that the image display is stable, that you can select a transducer, and that selections made on the control panel respond to your selection.

3 - 6 Instructions for Use

Shipping the System

When shipping the system, perform the following tasks, as appropriate.

To prepare the system for shipment over long distances or rough terrain:

- Repack the system in the factory packaging and crate according to the instructions shown on the container.
- 2. Load the system into a vehicle using a lift gate.
 - To prevent lateral movement of the system, secure the system with cargo straps.
 - To prevent sudden jarring of the system during transport, provide shock cushions beneath the system.

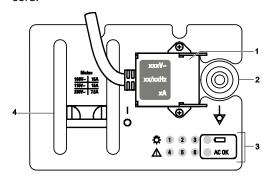
System Startup

⚠ WARNING: Operating the ultrasound system in close proximity to other equipment can cause reciprocal interference. You should observe and ensure normal operation of the ultrasound system and other equipment.

The first step to operating the ultrasound system is to connect the system to a power source.

AC Tray Panel

The AC tray panel on your system may have a connector cover for protection of the power cord.



- 1 Power cord connector
- 2 Equipotential connector
- 3 Service diagnostic lights
- 4 MAINS circuit breakerI = ONO = OFF

Example of AC Tray panel with a connector cover.

Plugging in the System

⚠ **WARNING:** Before connecting the ultrasound system to a power supply, you must read and understand the Electrical Safety section of Chapter 2, Instructions for Use.

The ultrasound system has a non-detachable power cord.

To plug in the system:

- Connect the power cord plug to the MAINS supply in the following manner:
 - 230V systems to a 230V standard MAINS, i.e., "Schuko" receptacle (CEE 7-7 standard).
 - 115V systems to a hospital-grade MAINS receptacle.
 - 100V systems to a standard 100V MAINS receptacle.

Instructions for Use 3 - 7

Supplying Power to the System

The ultrasound system is powered on and off using the green partial power on/off switch (⁽⁾) located on the control panel.

Siemens recommends powering off the system every 24 hours to maintain optimal performance.

Note: This switch does not completely shut down or disconnect the system from the power mains. This switch only powers on, or off, a portion of the ultrasound system. To completely disconnect the system from the power mains, the circuit breaker located on the back panel must be switched from the I to O position.

△ Caution: Wait approximately 20 seconds between powering the system off and then on again. This allows the system to complete its shutdown sequence.

To power on the system:

- Before using the system, perform the Daily Checklist.
 See also: Daily Checklist, Safety and Care, Chapter 2, Instructions for Use
- 2. Verify the power cord is plugged into the system and then into the power supply.
- 3. Power on ($^{\circlearrowleft}$) the ultrasound system.

Note: Only power on the system when the power on/off switch is flashing green and when the system is plugged into the power supply. Ensure the MAINS circuit breaker is in the on position (I = ON).

When the system is powered on, it runs through a series of self-diagnostic and calibration tests, after which the system is ready for use.

Note: The system will not run through the complete power-on routine if a problem occurs. Instead, an error code or message appears on the screen to indicate the problem. Please note the message and call your local Siemens service representative.

If you selected the **Standby** button during system power off, then the system is ready for use within approximately 60 seconds.

The system restarts the transfer of images if a network connection is detected upon system power on from a standby status. This restart occurs only for images that could not be transferred when the system was placed in a standby status. For example, a network connection did not exist when the system was placed in a standby status.

4. Visually check the on-screen displays and lighting indicated in the Daily Checklist.

To power off the system:

- 1. Briefly press and then release the power on/off switch $({}^{(\!\!\!)}\!\!)$ to power off the ultrasound system.
- Select the Shut Down button on the displayed System Shut Down dialog box.
 If the system is transferring images, then it will wait until the transfer is complete to power off.

Wait approximately 20 seconds after the system powers off before powering on $(^{\c U})$ the ultrasound system.

3 - 8 Instructions for Use

Mobile QuikStart for Portable Studies (Standby)

The QuikStart feature for portable studies decreases the time required to power the system on or off by using the installed battery to place the ultrasound system in a standby status.

The system can maintain the standby status for approximately four hours when the system's power cord is not plugged into the power supply.

To place the system in a standby status:

- Briefly press and then release the power on/off switch (⁽⁾) to power off the ultrasound system.
- Select the Standby button on the displayed System Shut Down dialog box.
 Note: If the system detects errors that require a system shutdown, then the Standby button is not available. You can either select Cancel or power off the system.

If the system is transferring images, then it will wait until the transfer is complete to power off.

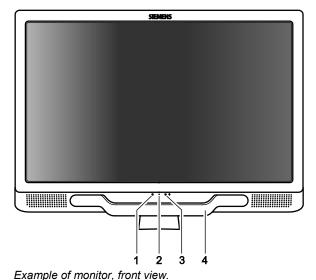
Wait approximately 20 seconds after the system powers off before powering on $({}^{(\!\!\! \ \!\!\!)})$ or unplugging the ultrasound system.

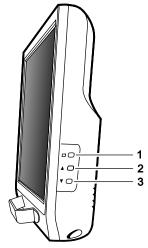
Note: Only power on the system when the power on/off switch is flashing green and when the system is plugged into the power supply. Ensure the MAINS circuit breaker is in the on position (I = ON).

Instructions for Use 3 - 9

Adjusting the Screen Brightness

Note: Factory-defined imaging presets were created using default settings of the brightness and contrast controls of the monitor. Adjusting the brightness and tint controls on the monitor may affect the image optimization intended by the factory-defined imaging presets.





Example of monitor, side view.

- 1 Monitor On/Off LED
- 2 Microphone
- 3 Microphone On/Off LED
- 4 Monitor handle

- 1 Monitor Menu Control
- 2 ▲ Up (increase brightness)
- B ▼ Down (decrease brightness)

For consistency in image reproduction, adjustments to the brightness of the viewing monitor should be made prior to adjusting the print quality of installed documentation devices.

To adjust the screen brightness with the monitor controls:

1. Press the menu control on the monitor.

The system displays the menu for approximately ten seconds.

Note: To immediately dismiss the menu, press the menu control.

- 2. Adjust the screen brightness.
 - To increase the screen brightness, press the up control.
 - To decrease the screen brightness, press the down control.
 - To restore the default screen brightness, simultaneously press the up and down controls.
- 3. Press the menu control to confirm the setting.

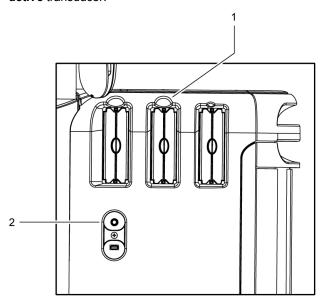
Note: If you press an unsupported key combination, the screen displays a message indicating the menu is locked. To dismiss the message, press the menu control. Or, wait a few seconds for the message to automatically close.

3 - 10 Instructions for Use

Connecting and Disconnecting Transducers

⚠ Caution: Ensure that the system is in freeze before connecting and disconnecting transducers. If a transducer is disconnected before the image is frozen, the system will display an error message. Select another transducer before continuing to use the system.

You can connect multiple transducers to the ultrasound system, with one transducer being the active transducer.



Transducer ports.

- 1 Three micro-pinless (MP) ports for array transducers
- 2 Continuous wave transducer

Instructions for Use 3 - 11

Array Transducers

Connect an array transducer to any of the three available array ports.

⚠ Caution: You must freeze the system before connecting or disconnecting a transducer.

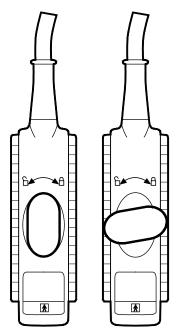
Note: When transducer connectors are being attached to or disconnected from the system, resistance may be encountered due to the special shielding material inside the connectors. This is normal for these transducers.

To connect an array transducer:

- 1. Hold the transducer connector with the cable extending upward from the connector.
- 2. Insert the connector into the system port and turn the lock on the transducer connector clockwise until it locks in position.

This secures the connector in position and ensures the best possible contact.

3. Place the transducer in the transducer holder.



Example of locked (left illustration) and unlocked (right illustration) positions of the transducer connector.

To disconnect an array transducer:

⚠ **Caution:** To avoid damaging the transducer cable, do not pull on the cable to disconnect the transducer. Use the following instructions.

- 1. Turn the lock on the connector housing counterclockwise until it unlocks.
- 2. Firmly grasp the transducer connector and carefully remove it from the system port.
- 3. Store each transducer in its protective carrying case.

3 - 12 Instructions for Use

Continuous Wave Transducers



Continuous wave transducer port.

△ Caution: You must freeze the system before connecting or disconnecting a CW transducer.

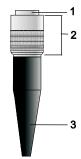
To connect a continuous wave transducer:

- 1. Align the connector key until it fits smoothly into the receptacle.
- 2. Insert the connector into the system port until it locks in position.

To disconnect a continuous wave transducer:

△ Caution: To avoid damaging the transducer cable, do not pull on the cable to disconnect the transducer. Use the following instructions.

- 1. Pull on the connector housing ring to disengage the locking mechanism. Continue pulling on the ring to remove the connector from the system port.
- Store each transducer in its protective carrying case.



- Connector
- 2 Retractable connector housing
- 3 Transducer cable

Example of CW transducer connector.

Protective Transducer Holder

△ Caution: Transducer holders have variable sizes, both in depth and diameter. To avoid transducer damage, you must use the holder or insert provided for transducers that have small or large diameter handles or for specialty transducers, such as endocavity transducers.

After connecting a transducer to the system, place the transducer in the protective holder attached to the control panel platform. There is also a holder for the coupling agent (gel).

Transducer Holders

The transducer holders on the sides of the control panel are interchangeable and replaceable.

Instructions for Use 3 - 13

Transducer Cable Management

★ WARNING: To avoid injury from tripping over a transducer cable, use the cable hooks on the ultrasound system to keep the transducer cable from contact with the floor.

After you have connected and secured a transducer, drape the transducer cable through one of the cable hooks located on the ultrasound system. These hooks provide support for the transducer cables, keep cables off the floor, and help to prevent tangling of the cables when more than one transducer is connected to the system.

3 - 14 Instructions for Use

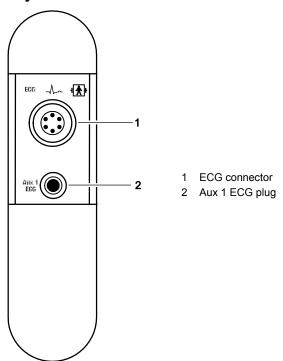
Connecting System Accessories

The ultrasound system has connections for system accessories.

Footswitch

Attach the optional footswitch connector into the corresponding socket located on the front system panel.

Physio Cables



Example of Physio panel.

Attach the optional Physio leads and auxiliary connectors to the Physio panel, located on the left front of the system.

The optional Physio feature allows the system to display a scrolling ECG waveform on the image screen.

Note: The Physio inputs are Defibrillation Proof. However, in the event of defibrillation while using the Physio function, the Physio inputs may become saturated (overloaded). An ECG pattern may not be visible for up to 30 seconds. After this time, the Physio function should return to normal operation.

To connect the Physio cables:

Connect the six-pin Physio cable to the socket labeled ECG on the front of the system.

Instructions for Use 3 - 15

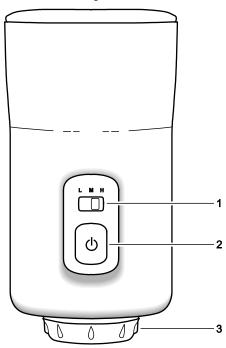
(Available only on systems with a touch screen)

⚠ WARNING: To avoid electrical shock and damage to the control panel resulting from ingress of liquid, place the gel bottle and gel warmer on the side of the ultrasound system closest to the patient.

△ Caution: Do not attempt to repair or alter the gel warmer. Contact your local Siemens service representative immediately if your gel warmer appears to be damaged or malfunctions in any

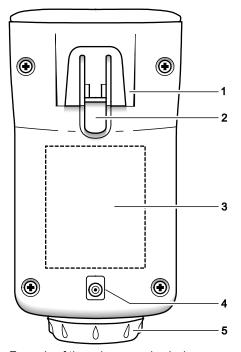
See also: Refer to the cleaning and disinfecting procedures in Chapter 2 in this manual.

When the ultrasound system is powered on, the gel warmer continuously heats the bottle of gel inserted into the gel warmer.



Example of the gel warmer, front view.

- Temperature control
- 2 Power control
- Cap for collecting gel spilled from the inverted gel bottle



Example of the gel warmer, back view.

- Support
- 2 Tab
- Label
- Power cable connector
- 5 Cap

To attach the gel warmer to the ultrasound system:

- Remove the transducer holder on the side of the ultrasound system closest to the patient and farthest from the front of the system.
 - a. Reach under the holder to locate the tab on the holder. The tab extends below the point of attachment to the ultrasound system.
 - b. Squeeze the tab towards the holder and pull the holder downward.
- 2. Attach the gel warmer to the ultrasound system.
 - a. Attach one end of the power cable accompanying the gel warmer to the connector on the back of the gel warmer and then attach the other end of the power cable to the connector on the ultrasound system.
 - b. Align the support on the gel warmer directly below the point of attachment on the ultrasound system and firmly push upwards until the gel warmer snaps into place.

To use the gel warmer:

1. Press the power on/off control ($^{(\)}$) on the front of the gel warmer to power on the gel warmer, if necessary.

The gel warmer power control illuminates when the gel warmer is powered on.

Note: A blinking light indicates there is a problem with the device. Check the cable connector on the gel warmer and on the ultrasound system. If you continue to experience a problem with the device, contact your Siemens service representative.

2. Slide the temperature control on the front of the gel warmer to adjust the temperature of the gel warmer.

Selection	Setting	Temperature
L	Lowest	31°C
М	Medium	34°C
Н	Highest	37°C

3. Invert the bottle of gel, and insert the bottle into the gel warmer.

Instructions for Use 3 - 17

Virtual Communication for Remote Assistance

(Available only for ultrasound systems with the service option for remote assistance)

⚠ **WARNING**: To maintain patient confidentiality, do not use the camera and headset within the patient environment. You must remove the camera from the ultrasound system after the conclusion of a remote service session.

You can use the optional camera and headset from Siemens for virtual communication with a Siemens service representative.

To begin a remote service session:

Note: If the camera attachment is not installed on the ultrasound system, inform your service representative.

- 1. Locate the camera and headset for use with the ultrasound system.
- 2. Initiate the remote assistance session using the phone number provided by your Siemens representative.
- 3. Follow the instructions provided by your service representative to set up the session of virtual communication, including connections of the camera and headset.

The following ports on the input/output panel of the ultrasound system are compatible with the camera and headset:

- J4A, J4B
- J5A, J5B
- 4. Conclude the remote service session as directed by your representative.

Note: If you do not disconnect from the remote service session, the session ends after 30 minutes of inactivity.

5. Disconnect the camera and headset from the ultrasound system and then store the camera and headset in a location designated by your department.

3 - 18 Instructions for Use

Connecting the Ultrasound System to a Network

The ultrasound system can connect to a local area network (LAN) through a wired or a wireless connection. When both wired and wireless connections are configured and available, the ultrasound system assigns priority to the wired connection.

If you are in the process of saving a study to a network location when you disconnect from the LAN or change the connection to the LAN, the ultrasound system pauses the process of saving the study and resumes saving the study when you reconnect the system to the LAN through a wired or wireless connection.

See also: Network Configuration, Chapter 4, System Reference

Wired Connection

To connect the ultrasound system to a network through a wired connection:

Prerequisite: The network administrator has configured the required wired connection on the ultrasound system.

- Connect the network cable to the Ethernet port located on the inside of the input/output panel door.
- 2. Connect the network cable to the hospital network port.

If the ultrasound system is connected to a wireless network, the ultrasound system disconnects from the wireless network. The system then connects to the LAN through the wired connection and displays an icon at the bottom of the image screen indicating a wired connection.



Example of the icon displaying two monitors to indicate a wired connection. (The icon displaying one monitor indicates a data transfer job.)

Wireless Connection



Caution: Do not connect a wireless adapter or network card to any USB ports on the ultrasound system.



⚠ Caution: Maintain a radius of at least 25 cm between the adapter located near the CD/DVD drive and possible sources of interference for the wireless connection. Possible sources of interference can be other medical devices and systems, including devices and systems in compliance with CISPR emission standards.

⚠ Caution: Ultrasound systems operate in the range of radio frequencies (RF) and are susceptible to electromagnetic interference generated by other RF energy sources. To prevent this interference, increase the distance between the ultrasound system and the interfering RF energy source.

Instructions for Use 3 - 19

To connect the ultrasound system to a network through a wireless connection:

1. Disconnect the network cable from the ultrasound system, if necessary.

The ultrasound system connects to the most recently used wireless network, if the wireless network is secured and detected. An icon indicates the strength of the wireless connection.



Example of the icon indicating the signal strength of a wireless connection.

- To connect to another detected wireless network, manually connect to the required wireless network.
 - a. Press System Config on the keyboard. Or, click the System Config icon on the toolbar.
 - b. Select DICOM / Wireless.
 - c. Click the Wireless tab.

То	Do This
Connect to a wireless network with a network profile	 Click the Available Networks tab, select the required wireless network, and then click Connect.
	 Click the Network Profiles tab, select the required wireless network, and then click Connect.
Connect to a wireless network without a network profile	Click the Network Profiles tab.
	2. Under the Profile Names list, click Add.
	The tab displays the selections for configuring a new network profile.
	In the network profile selections, enter the required settings for the wireless network and then click Save.
	Note: Consult your network administrator for the required settings.
	4. Select the required wireless network and then click Connect .

The ultrasound system connects to the wireless network. An icon indicates the strength of the wireless connection.

d. To view the details of the wireless connection, click the **Status** tab.

Network Connection Icons

When connected to a LAN, the ultrasound system displays a network connection icon at the bottom of the image screen.

Icon	Description
	Status: Wired Network Connected
	Connected to a local area network (LAN) through a wired connection
<u> </u>	Connected to: <network name=""> Speed: Mbps</network>
чЦШ	Connected to a wireless network.
	The network speed is indicated in megabits per second (Mbps).
	Status: Not Connected
	Not connected to a wireless network

3 - 20 Instructions for Use

System Security

The ultrasound system includes features to protect patient confidentiality, for example, removing or hiding patient-identifying information from ultrasound studies or transferring encrypted DICOM communication from the system to a DICOM-compatible device.

Your Siemens service representative can configure additional security features on your ultrasound system, for example, encrypting the system hard disk and restricting access to the system by requiring a user account and password.

Note: Hard drive encryption requires the eSieCrypt hard disk encryption software option.

Use the system configuration menu to select encrypted transfer of DICOM communication.

System Config > DICOM / Wireless

See also: For information about hiding patient-identifying information from ultrasound studies, refer to Chapter C2 in the Features and Applications Reference manual.

Restricting User Access and Permissions

When the security package is activated, you can restrict access to the ultrasound system by requiring a user account and password. You can also restrict access to the following tasks on the system:

- Viewing studies stored on the ultrasound system
- Connecting to printers within the patient environment
- Backing up or restoring ultrasound system data
- Changing or applying new ultrasound system settings

Tracking User Activities

When the security package is activated, the ultrasound system tracks user activities, including access to patient data, and saves the information to a security log file. The log file is stored on the system hard disk or a network location.

For information about the user activities contained in the log file, contact your ultrasound system administrator.

Disk Space Security Indicators

The system displays an icon on the image screen when the disk space allocation for the security log file is low. Contact your ultrasound system administrator to archive the log file of the audit trail.

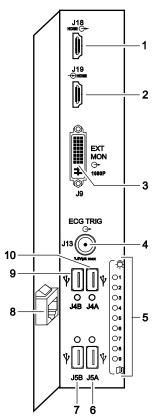
Icon	Description
	Low disk space warning icon (yellow)
	Indicates the system disk space is low and the ultrasound system administrator must archive the ultrasound system's log file. Failure to archive the log file will result in a loss of system functionality.
	Full disk warning icon (red)
	Indicates the system disk space is full. The ultrasound system will be locked from further access and no further actions may be taken on the system until the log file is archived.
	Contact the ultrasound system administrator immediately.

Instructions for Use 3 - 21

Audio and video connections are located on the Input/Output (I/O) panel. An Ethernet (network) port is located on the inside of the input/output panel door. Two additional USB ports are located on the back of the control panel.

▲ WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Anyone who connects additional equipment to any of the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards IEC 60601-1. Siemens can only guarantee the performance and safety of the devices listed in the Instructions for Use. If in doubt, consult the Siemens service department or your local Siemens representative.

△ Caution: To ensure proper grounding and leakage current levels, it is the policy of Siemens to have an authorized Siemens representative or approved third party perform all on-board connections of documentation and storage devices to the ultrasound system.



- HDMI port, J18: video recorder (video and audio output)
- HDMI port, J19: video recorder (video and audio input) 2
- DVI port, J9: external monitor (digital or analog output)
- BNC-type port, J13: ECG trigger (output)
- System status LEDs
- USB-A port, J5A: printer or USB storage device
- USB-A port, J5B: printer, SIE1 data transmission, or USB storage device
- RJ-45 port: Ethernet (10BaseT/100BaseT/1000BaseT)
- USB-A port, J4B: video recorder (remote control) or USB storage device
- 10 USB-A port, J4A: USB storage device

Example of input/output panel ports and connections.

Connecting Peripheral Equipment

Marning: Equipment connected to the ultrasound system and in the patient environment must be powered from a medically-isolated power source or must be a medically-isolated device. Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the ultrasound system.



▲ WARNING: Non-medical grade report printers cannot be used within a patient environment.



⚠ WARNING: During use of a non-medical grade report printer or when a non-medical grade report printer is connected to the ultrasound system, the ultrasound system cannot in any way be in contact with a patient.

On-board peripheral devices must be installed by an authorized Siemens representative or by a Siemens approved third party. Any use of other devices with the system will be at the user's risk and may void the system warranty.

In order to fulfill EN 60601-1 and IEC 60601-1 (Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance) requirements, connection of peripheral equipment to your ultrasound system must adhere to one of the following conditions:

- The peripheral equipment itself is a medical device approved according to EN 60601-1 and IEC 60601-1, or
- Non-medical peripheral equipment approved according to any other EN or IEC standard (EN XXXXX or IEC XXXXX, e.g., equipment complying with EN 60348 and IEC 60348, EN 60950 and IEC 60950, etc.) must use the following setup for connection:



Equipotential connector located on AC tray panel of the ultrasound system.

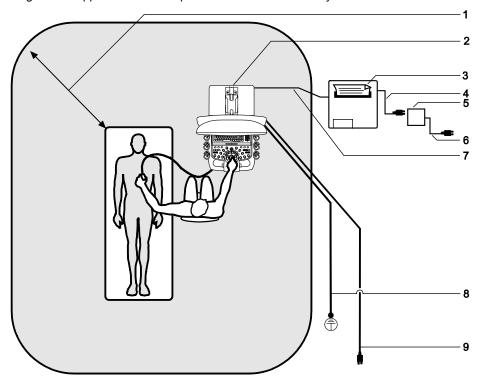
- Connect the ultrasound system to an independent protective ground terminal, with a ground wire connection to the ultrasound systems equipotential connector. Ensure that the protective ground wire is connected to a qualified protective ground connection independent of the existing system's ground connection (via the power cable).
- The peripheral equipment is located at least 1.5 meters (1.8 meters [6 feet] in Canada and the U.S.A.) outside of the patient environment. A patient environment is defined as the area in which medical examination, monitoring, or treatment of the patient takes
- The peripheral equipment is connected to a main outlet outside the patient environment but still within the same room as the ultrasound system.

For additional information and other possible combinations, please refer to the Medical Electrical Equipment Standard EN 60601-1 or IEC 60601-1, Annex I.

Note: The above information is based on current EN 60601-1 and IEC 60601-1 standards. If your country's regulatory standards for medical equipment do not correspond to EN 60601-1 and IEC 60601-1, your local requirements may be different.

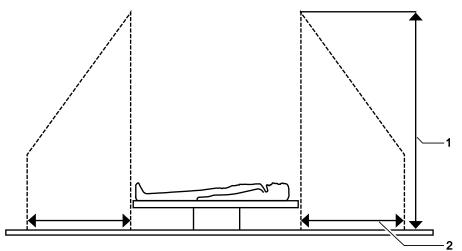
Instructions for Use 3 - 23 During normal operation, the ultrasound system is designed to display ultrasound images without noise, artifacts, or distortion that cannot be attributed to physiological effects.

Observe the peripheral equipment connections and patient environment shown in the following diagram to support the normal operation of the ultrasound system.



Example of a peripheral equipment connection and patient environment.

- 1 Patient environment represented by shading, extending exactly 1.5 meters (1.8 meters [6 feet] in Canada and in the U.S.A.) around patient and ultrasound system
- 2 Ultrasound system
- 3 Peripheral equipment (EN XXXXX and IEC XXXXX)
- 4 Peripheral equipment power cord
- 5 Medically-approved isolation transformer
- 6 Medically-approved isolation transformer power cord
- 7 Printer data cable
- 8 Additional protective ground
- 9 Ultrasound system power cord



Example of a peripheral equipment connection and patient environment.

- 1 2.5 meters (typical)
- 2 1.5 meters (1.8 meters [6 feet] in Canada and the U.S.A.)

3 - 24 Instructions for Use

On-Board vs. Off-Board Documentation Devices

⚠ **WARNING:** Do not connect any off-board device to an AC outlet on the ultrasound system. Doing so will cause the ultrasound system to be out of compliance and may create a safety

Note: Only authorized Siemens representatives are permitted to install documentation devices on-board the ultrasound system.

On-board documentation devices must be installed by authorized Siemens representatives.

Off-board documentation devices are user installable.

An off-board documentation device has a data cable connecting it to the ultrasound system, but is connected to AC power separate from the ultrasound system. An off-board documentation device is located separately, for example: on a table next to the ultrasound system.

Up to three documentation devices in total may be connected to the ultrasound system. All installed documentation devices may be controlled from the ultrasound system.

The following configurations are supported:

- One off-board device and two on-board devices.
- Up to two off-board devices and one on-board device.
- Up to three off-board devices when there are no on-board devices.

You can make the following adjustments to the system:

Monitor. You can tilt and swivel the monitor for optimal viewing while scanning. The sides of the monitor provide a general hand hold for tilting and swiveling the monitor.

Height and Swivel. The height adjustment control and the swivel control are on the front handle of the ultrasound system.

Adjust the height of the monitor, control panel, and keyboard by pressing and holding the height adjustment control and pulling upward or pushing downward on the handle.



Example of the icon on the height adjustment control.

Note: When two on-board peripheral devices are installed, you may not be able to adjust the height of the control panel.

Rotate the control panel by pressing and holding the swivel control and rotating the control panel to the left or right.



Example of the icon on the swivel control.

Installing System Updates

If Remote Update Handling is enabled, Siemens can remotely update your ultrasound system. The system notifies you that updates are available for installation by displaying an icon at the bottom of the image screen and an installation dialog box when you restart the system.

Note: Siemens recommends that you install a system update within one week after the update is downloaded.

To install or defer system updates:

 Click the system updates icon at the bottom of the image screen. Or, restart the ultrasound system.



То	Do This	
Install the system update	Click Install.	
	Note: Do not power off the ultrasound system while the installation is in progress.	
	The installation requires up to 40 minutes depending on the size of the system update. The system restarts when the installation is complete.	
	If multiple system updates are ready for installation, the system installs the first update and then prompts you to continue installation of the next update.	
Postpone installation of the system	Click Defer.	
update	If multiple system updates are ready for installation, the ultrasound system postpones the first update and then prompts you to continue installation of the next update.	
Postpone installation of all system updates	(Available only if multiple system updates are ready for installation) Click Defer All.	

3 System Setup

3 - 28 Instructions for Use

4 Examination Fundamentals

Preventing Unauthorized Access	3
Logging In to the Ultrasound System	4
Patient Registration	5
Registering or Pre-registering a Patient	
Selecting a Scheduled Procedure for Registration	8
Patient Registration Form Selections	9
Patient/Procedure Worklist	9
Patient Data	10
Institution	11
Exam	11
History (OB or GYN)	13
Changing the Exam, Transducer, Protocol, or Patient Information	14
Imaging Overview	16
Priority Mode	18
2D-Mode Overview	18
M-Mode Overview	18
Color Flow Overview	19
Acoustic Streaming with Cysts	19
Doppler	20
Selecting an Operating Mode	20
Optimizing Images	20
Examples of Imaging Parameter Settings	20
Working with Mode-Specific Menus	23
Performing Measurements and Calculations	25
Reviewing Images and Clips	25
Creating and Viewing Thumbnails	26
Recording and Playing Back with a Digital Video Recorder (DVR)	28
Examination Completion	30

4 - 1

4 Examination Fundamentals

4 - 2 Instructions for Use

Preventing Unauthorized Access

Prerequisite: A Siemens service representative has activated the security package on the ultrasound system to restrict user access.

The security package on the ultrasound system protects patient information from unauthorized access by requiring a user account and password to access the ultrasound system. It is the responsibility of the ultrasound system administrator at your facility to observe local security policies and implement security settings and policies for the ultrasound system.

When the security package is activated, you can lock the screen to prevent unauthorized access to patient information. An active screen saver display also locks the screen. A locked screen requires a user name and password to access the system.

See also: For information about the screen saver, refer to Chapter 1 in this manual.

The ultrasound system administrator also assigns permissions for each user account. Permissions establish data access rights (either no access or full access) that determine whether a user can view studies stored on the system. To understand the permissions assigned to your user account, or if you do not have a user name and case-sensitive password, contact your ultrasound system administrator.

Use the system configuration menu to review the permissions assigned to the currently logged-in user account.

System Config > Service > Security Settings > Security View

Logging In to the Ultrasound System

When the security package is activated, all users are required to log in to the ultrasound system prior to use.

To log in to the ultrasound system:

1. Enter your user name and password on the log in screen.

2. Click **OK**.

То	Do This		
Prevent unauthorized	1. Click Security.		
access to the ultrasound system			
	2. Select Lock Computer.		
	The ultrasound system displays the lock screen.		
Begin a study without a password	(Available only when enabled in the system configuration menu)		
	Prerequisite: Obtain the emergency access user name from your ultrasound system administrator.		
	1. Enter the emergency access user name on the log in screen.		
	2. Click OK .		
	The ultrasound system enables limited access to patient data.		
Change your password	(Available only when enabled for the currently logged-in user account in the system configuration menu)		
	1. Click Security.		
	2. Select Change Password.		
	3. Enter the password information on the change password screen.		
	4. Click OK .		
Log in as a different user	1. Click Security.		
	2. Select Log in Different User.		
	ÁÁ		
	3. Enter your user name and password.		
	4. Click OK .		
Log off the ultrasound system	Note: You can log off the ultrasound system only after an exam is completed.		
	1. Click Security.		
	2. Select Log Off <user name=""> (where User Name is your assigned user name).</user>		
	Land		

4 - 4 Instructions for Use

Patient Registration

Note: You can schedule a patient and procedure(s) using a connected Hospital Information System/Radiology Information System (HIS/RIS) server. Use the patient browser to retrieve patient data for scheduled patients.

Registering or Pre-registering a Patient

To register a patient:

• Click Patient Registration on the toolbar.



Patient Registration toolbar button.

То	Do This
Select the type of registration	Click Short Form to display the fields defined for the short form.
form	 Click Long Form to display the fields defined for the long form.
Enter registration information for	1. If necessary, click New Patient on the patient registration form.
a new patient	2. Enter the required information in the form.
Edit information in the patient	Click Correct on the patient registration form.
registration form during an active examination	2. Enter or edit the required information in the form.
Access data for an existing or preregistered patient	 In the patient registration form, select the required database from the database list.
	2. Enter the patient's name or other known information in the Search field.
	3. Select the required patient from the displayed list.
	The system populates the patient registration form with data for the selected patient.
Access patient data from a connected server or storage media	 Click Patient Browser on the toolbar and then select the required server or storage media.

То	Do This	
Retrieve data entered for a previous patient or a pre-registered patient	Use the system configuration menu to define search options, such as the locations for stored patient data and the type of data to display in the search results.	
	System Config > Basic System > Registration Configuration > Searching	
	Note: Use an asterisk (*) to indicate partially known values. For example, to search for the last name "Miller," you can enter "Mil*" or "*ler" in the Patient Name field.	
	1. Enter known information in the Patient section of the patient registration form.	
	2. Click Search.	
	The system lists matching patient data.	
	3. Select a patient and then click OK .	
	The system populates the patient registration form with the data for the selected patient.	
Pre-register a patient (store	1. Enter the required information in the patient registration form.	
patient data in the Scheduler)	Note: You must enter at least the patient's last name, an identification code for the patient, and date of birth to pre-register a patient.	
	2. Click Preregister.	
	The system stores the entered registration data in the Scheduler and clears the entries in the patient registration form.	
	Note: If an HIS/RIS server is not connected to the system, the system automatically removes the patient data for the pre-registered patient from the Scheduler after the patient is pre-registered.	
Store the entered registration data as an image and begin the examination	Press the control panel key assigned to the store function.	
Select a study type during patient	Use the system configuration menu to customize study type selections.	
registration	System Config > Basic System 2	
	 Select the required study type from the Study list on the patient registration form. 	

4 - 6 Instructions for Use

То	Do This	
Select a transducer during patient	• Select a transducer from the Transducer list on the patient registration form.	
registration	If a transducer is not selected, the system activates the default transducer for the selected study type if it is connected to the system.	
	Note: If you choose an unsupported study type for the selected transducer during patient registration, the system activates the default study type during imaging.	
Select a workflow protocol during	Select a protocol from the Protocol list on the patient registration form.	
patient registration	The system activates the first view of the protocol when you begin the examination.	
Start a study using the entered registration data	Click Start Study.	
Start a new study for the current	Click New Study.	
patient	The system closes the current study and begins a new study.	
Update the displayed list of studies	Click Refresh List.	
Add images, clips, and volumes	1. Click Append Study.	
to a closed study	2. Acquire new images, clips, and volumes to append to the current study.	
Cancel patient registration	Click Cancel.	

Selecting a Scheduled Procedure for Registration

You can select a scheduled procedure step in the patient browser to enter information in the patient registration form.

Note: For scheduled procedures to be available, the ultrasound system must be connected to a HIS/RIS (Worklist) server configured for MPPS (Modality Performed Procedure Step).

To select a scheduled procedure:

- 1. Click Patient Browser on the toolbar.
- 2. Select Scheduler to display scheduled procedures.
- 3. Select a procedure step and then press **SELECT** twice. Or, select a procedure step and then select **Register** on the **Patient** menu in the patient browser.
 - The system displays the patient information from the selected procedure step in the patient registration form.
- 4. Enter or edit data, if required.
 - Note: The system disables editing of entries that contain data from the HIS/RIS server.
- 5. Click **Start Study** to register the patient and begin the examination.
- 6. If the system displays a message requesting confirmation to end the current study, confirm the operation.

4 - 8 Instructions for Use

Patient Registration Form Selections

Use the system configuration menu to customize the layout of the patient registration form.

System Config > Patient Registration

Control	Description	
New Patient	Enables entry of new patient data.	
New Study	Retains the existing data in the patient form and allows you to select a new study type.	
Correct	Enables editing of the existing patient data.	
Short Form	Changes the displayed patient registration form to the short form.	
Long Form	Changes the displayed patient registration form to the long form.	
Browser	Opens the patient browser and enables access to patient data on a connected server or storage media.	
Start Study	Accepts the patient information and begins the examination.	
Append Study	Enables addition of new images, clips, and volumes to an existing study.	
Preregister	Pre-registers the patient.	
Cancel	Deletes any entered patient information and closes the patient registration form.	

Patient/Procedure Worklist

Selection	Description	
Database/Scheduler	(Available only for studies saved to the ultrasound system hard drive)	
	Displays the current database. You can select a different database or the patient scheduler.	
Search	Enables entry of a patient's name or partial name with an asterisk (*), or other known information to locate a preregistered patient.	
Patient/Procedure Worklist	Displays a list of all preregistered patients matching the specified criteria.	
Load To Review	(Available only when Local Database is selected)	
	Loads the selected patient's images to the review screen after the study has been completed.	
Refresh List	Updates the information in the patient/procedure worklist.	
Hide	Hides the worklist.	
Show	Displays the worklist.	

Patient Data

Selection	Enter	
Last Name	Patient's last name.	
	If a last name is not entered, then the system generates the name "Unknown."	
	Note: The patient name (first, middle, and last combined) is limited to 60 characters.	
First Name	Patient's first name.	
Middle Name	Patient's middle name.	
Patient ID	Identification code for the patient.	
	If an identification (ID) code is not entered, then the system generates a unique identifier starting with the system date and time.	
	This ID code displays on the image screen. If there is not enough space for the entire code to display on the image screen, a portion of the code is displayed followed by three dots ().	
Date of Birth	Patient's date of birth using the date format selected in the system configuration menu	
	When you enter or change this value, the system calculates and displays the patient's age.	
	If a date of birth is not entered before the examination is completed, then the system generates the date of birth 11/18/1858, but does not display this date on the form.	
Age	The system automatically calculates and displays the patient's age based on the patient's date of birth, if entered.	
Sex (gender)	Patient's gender.	
	If Male or Female is not selected, then the system assigns the gender based on the study selected, for example, OB displays Female and Abdomen displays Other .	
Height	Patient's height using the measurement system (metric or feet/inches) selected in the system configuration menu.	
Weight	Patient's weight using the measurement system (metric or pounds) selected in the system configuration menu.	
BP [mmHg]	Patient's blood pressure.	
BSA [m ²]	(Applies only to cardiac exams)	
	Patient Body Surface Area (BSA) in m ² . The system automatically calculates the BSA (based on height and weight entries) and transfers the value to the patient report.	

4 - 10 Instructions for Use

Institution

Note: The system automatically adds a new institution entry to the registration configuration list on the system configuration menu (if the maximum number of entries has not been exceeded).

Selection	Enter	
Institution Name Note: Information retrieved from a HIS/RIS (Worklist) server does not over if Use first entry as default is selected in the system configuration menu.		
	Name of the institution.	
Performing Physician	Physician's name.	
Referring Physician	Referring physician's name.	
Operator	Your initials or other identifying code.	

Exam

Selection	Description		
Transducer	Lists the connected to	Lists the connected transducers.	
Study	Lists the system and	user-defined exam types.	
	Abdomen	Abdomen	
	Abdomen-New	Abdomen New	
	Breast	Breast	
	CV	Cerebrovascular	
	Digital	Digital	
	Adult Echo	Adult Echo	
	Fetal Echo	Fetal Echo	
	Gyn	Gynecology	
	Int-op Abd	Intraoperative Abdomen	
	Int-op Vas	Intraoperative Vascular	
	MSK	Musculoskeletal	
	Neo Echo	Neonatal Echo	
	Neo Head	Neonatal Head	
	ОВ	Obstetrics	
	Ped Abd	Pediatrics Abdomen	
	Ped Echo	Pediatrics Echo	
	Ped Hip	Pediatric Hip	
	Pelvis	Pelvis	
	Penile	Penile	
	Prostate	Prostate	
	PV-Art	Peripheral Vascular Arterial	
	PV-Ven	Peripheral Vascular Venous	
	Renal	Renal	
	TCD	Transcranial Doppler	
	Testis	Testis	
	Thyroid	Thyroid	

Selection	Description	
Protocol	Lists the eSieScan workflow protocols. A protocol is a pre-defined checklist that guides you through a clinical workflow.	
	Breast	
	Cardiac	
	OB	
	Vascular	
	User-defined protocols	
Requested Procedure	Displays the requested MPPS (Modality Performed Procedure Step) from an HIS/RIS server.	
Request ID	Identification code for the procedure in the imaging service request. An imaging service request identifies attributes that are common among the requested procedures. Typically generated by an HIS/RIS server.	
Accession No	Identification code indicating the sequence of the current study as related to other studies for this patient. Used for billing purposes. Typically generated by an HIS/RIS server.	
	Note: An accession number is required for sending data to a Nuance report template.	
Indication	Information describing the symptom or particular circumstance that indicates the advisability or necessity of a specific medical procedure.	

4 - 12 Instructions for Use

History (OB or GYN)

Selection	Enter	ОВ	Gyn
Date LMP/IVF	The start date of the patient's last menstrual period (LMP) or the date of in-vitro fertilization (IVF), using the date format selected in the system configuration menu.	✓	✓
	When you enter or change this date, the system calculates and displays the estimated fetal age and estimated date of confinement (EDC).		
EDC	Calculates and displays the estimated date of confinement (EDC), using the date format selected in the system configuration menu, based on entries for LMP or IVF and/or estimated fetal age.	✓	
	When you enter or change this date, the system calculates and displays the estimated LMP/IVF and estimated fetal age.		
Age [wks days]	Calculates and displays the estimated fetal age in weeks and days if you entered dates for LMP or IVF.	✓	
	When you enter or change the estimated fetal age (in weeks and days), the system calculates and displays values for LMP or IVF and EDC.		
No. Fetuses	If more than one fetus is present, enter the number of fetuses (up to four) to enable the multiple gestation analysis capability (Fetus A, B, C, D).	✓	
Gravida	Patient's history of pregnancies.	✓	✓
Para	The entries in these fields are transferred to the patient report, but do not		
Aborta	display on the image screen.		
Ectopics			
Additional Info.	Any additional data or comments that relate to the patient.	✓	✓
OB History	Displays a screen for manual entry of growth data for use in the growth analysis graph (growth curves) on the OB report.	✓	
Interval Growth Rate	Calculates and displays the growth rate since the previous examination for BPD (biparietal diameter), AC (abdominal circumference), and FL (femur length), based on values entered in the OB History screen.	✓	
Interval Growth Percentile	Calculates and displays the percentage of growth since the previous examination for BPD (biparietal diameter), AC (abdominal circumference), and FL (femur length), based on values entered in the OB History screen.	✓	

Changing the Exam, Transducer, Protocol, or Patient Information

During an examination, you can correct patient registration information or select a different exam type, protocol, or transducer. If a transducer is not selected in the patient registration form, the system activates the default transducer for the selected study type if it is connected to the system.

Note: The study types supported by each transducer will vary.

Use the system configuration menu to customize study type selections.

System Config > Basic System 2

То	Do This
Correct registration data during an examination	Note: Images stored before you correct registration data may contain incorrect text (such as the original, incorrect patient name).
	Display the patient registration form.
	Press PATIENT on the control panel.
	 For systems without a touch screen, press Patient Registration on the keyboard. Or, click Patient Registration.
	The system displays the patient registration form for the current patient.
	2. Click Correct.
	3. Update your entries.
	4. To save the changes, click OK .
	5. To exit the patient registration form without saving changes, click Cancel .
Change the exam type during	Display a list of the supported exam types for the selected transducer.
an examination	Select the current exam.
	 For systems without a touch screen, click the arrow next to the current exam type on the image menu. Or, press MENU.
	2. Select the required exam type from the list.
Change the transducer	Connect the required transducer to the ultrasound system, if necessary.
during an examination	2. Select the transducer.
	 Select the transducer name on the touch screen.
	 For systems without a touch screen, select the current transducer name on the image menu and then select the transducer from the list.

4 - 14 Instructions for Use

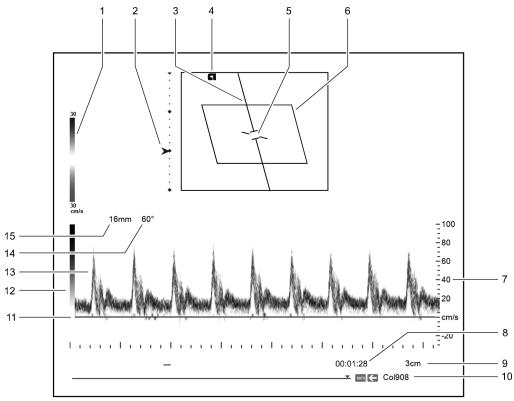
То	Do This
Begin a new study during an	Display the patient registration form.
examination	 Press PATIENT on the control panel.
	 For systems without a touch screen, press Patient Registration on the keyboard. Or, click Patient Registration.
	The system displays the patient registration form for the current patient.
	2. Click New Study.
	3. If necessary, update the Study and Transducer entries.
	4. Select a protocol from the Protocol drop-down list.
	5. Click Start Study.
	The system ends the study in progress, begins the new study, and displays the image menu for the current patient.
Select a pre-defined workflow	Note: You must register a patient to select a workflow protocol on the image menu.
protocol during an examination	Select the required protocol.
	• Select More , select eSieScan™ Protocols , and then select a protocol name.
	 For systems without a touch screen, select a protocol name from the image menu.
	Note: The image menu displays eSieScan™ Workflow Protocols when a workflow protocol has not been selected.
	2. Select the required protocol from the list of available workflow protocols.
	The system activates the first view of the protocol.
Skip the current view in a	Display the next view or the previous view.
protocol	Rotate the FORWARD/BACKWARD control.
	 For systems without a touch screen, click the Next or Previous arrow on the image screen.

Use the system configuration menu to customize workflow protocols.

System Config > eSieScan™ Protocols

Imaging Overview

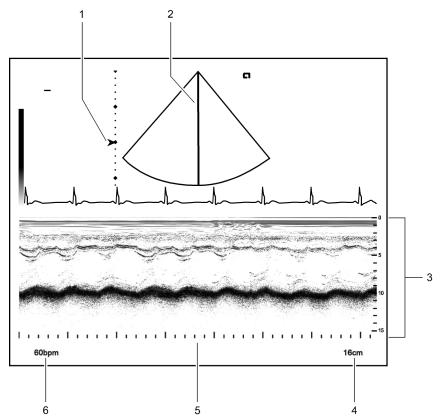
You can activate each mode of operation using the mode controls located on the control panel. Mode-specific menus and selections display during imaging.



Example of 2D-mode with Doppler and color imaging.

- 1 Color bar
- 2 Focal point markers
- 3 Doppler cursor
- 4 Transducer orientation indicator
- 5 Doppler gate and Doppler angle indicator
- 6 Color ROI
- 7 Doppler Scale
- 8 Timer

- 9 Depth
- 10 CINE bar
- 11 Doppler baseline
- 12 Gray bar
- 13 Doppler spectrum
- 14 Doppler angle
- 15 Pulsed wave Doppler gate depth



Example of 2D-mode with M-mode imaging.

- 1 Focal zone markers
- 2 M-mode cursor
- 3 M-mode sweep with depth scale
- 4 Depth
- 5 Time scale
- 6 Heart rate

Priority Mode

A mode must have visibility or priority over any other activated modes for you to adjust the controls or make menu selections for that mode. During combined mode imaging, more than one mode may be activated at any given time, but only one mode is the priority mode. When a mode is activated, the previous mode with priority remains activated, but it is no longer the priority mode.

To change the priority mode during combined mode imaging:

- Activate the required mode.
 - Press the control for the required mode. Or, select the tab for the required mode on the touch screen.
 - o For systems without a touch screen, press PRIORITY.

The image menu and the trackball status area indicate the current priority mode.

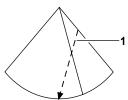
2D-Mode Overview

2D-mode is the default imaging mode for the ultrasound system. It indicates brightness or two-dimensional (2D) gray scale imaging. You can display dual 2D-mode images, select transducer-dependent image formats, and adjust imaging parameters for the active image.

M-Mode Overview

M-mode displays a 2D image and an M-mode sweep. The cursor represents the acoustic line along which the M-mode information is gathered.

During cardiac exams, use Anatomical M-mode to view an M-mode sweep based on the patient's anatomy and independent of transducer orientation. You can rotate and reposition the anatomic M-mode cursor to align with the patient's anatomy.



1 Example of Anatomic M-mode cursor.

Color Flow Overview

During Color imaging, the system applies color to indicate velocities of blood flow in a defined region of interest (ROI) within a 2D image. Color is supported by all imaging transducers.

- Color Doppler Velocity (CDV) applies color to the velocities and directions of blood flow within the ROI.
- Color Doppler Energy (CDE), or Power mode, applies color to the energy measurement generated by the blood flow within the ROI.

Acoustic Streaming with Cysts

★ WARNING: Acoustic streaming may occur in fluid filled cysts under certain conditions, for example, when it is necessary to repetitively image a fluid filled cyst with long ultrasound pulses. To verify that flow inside of a cyst is actually acoustic streaming, use spectral Doppler with a large gate and low scale and filter settings and move the sample volume around the inside of the cyst.

Acoustic streaming is a well-known physical phenomenon that can occur while imaging fluid filled cysts. Under typical imaging conditions, the color flow and Doppler scale and filter settings are set too high to see the low velocity acoustic streaming, however, physical artifacts may be generated under the following conditions:

- Long ultrasound pulses are repetitively used to image a fluid filled cyst about 1 centimeter or larger.
- The fluid in the cyst has low viscosity.
- The center of the cyst is located near the elevation focus of the transducer.
- The PRF setting is low. (Acoustic streaming flow is typically visible between 1 to 2 centimeters per second.)
- The wall filter setting is low. (Acoustic streaming velocities are usually set by filters.)

You can confirm the flow inside of a cyst is acoustic streaming by using a large gate and low scale and filter settings and then moving the sample volume inside the cyst.

Note: Flow away from the transducer is visible at multiple locations throughout the center of the cyst if it is acoustic streaming. It is more difficult to generate acoustic streaming near the edge of the cyst.

Doppler

Doppler displays a 2D image and a Doppler spectrum. The cursor represents the acoustic line along which the sample volume or the Doppler gate is placed for gathering Doppler information. The system supports both pulsed wave and continuous wave Doppler.

Note: Auxiliary continuous wave Doppler is supported with a pencil transducer.

Selecting an Operating Mode

Mode	Selection
2D-mode	■ Press 2D .
M-mode	■ Press M.
Pulsed wave Doppler	■ Press PW .
Continuous wave Doppler	■ Press CW.
Color (Color Doppler Velocity)	■ Press C.
Power	1. Press C .
	2. Activate Color Doppler Energy:
	Select CDE.
	 For systems without a touch screen, press the CDE soft key.

Optimizing Images

During imaging, the system displays mode-dependent parameters that you can use to optimize images. Some parameters, such as depth, gain, focus, and zoom, are changed using the controls on the control panel. Other parameters, such as edge enhancement, maps, and tint, are adjusted using on-screen controls.

The system provides pre-defined image optimization presets to accommodate different tissue types. The image preset adjusts the settings for a group of imaging parameters, specific to the active mode. You can also create user-defined image optimization presets when 2D-mode is activated.

See also: User-Defined Image Presets, Imaging Functions, Chapter A2, Features and Applications Reference

Examples of Imaging Parameter Settings

Each imaging mode has mode-dependent parameters used to adjust imaging settings. The current imaging settings are displayed on the right side of the screen.

Use the system configuration menu to enable or disable the display of the imaging parameter settings.

System Config > Image Text Editor

Settings

Example	Parameter
4C1	Transducer name
Abdomen	Exam
General	Image optimization preset for the active priority mode.
	During contrast agent imaging, indicates the balance of the image shown on the right side of the screen:
	 2D displays only the 2D image
	 CA displays only the image with the contrast agent
	 MIX displays a combination of the 2D image and the image with contrast agent
DVR Track 1 0:00:08	(Displayed only when the DVR and media are ready for recording)
	DVR track and time
TIS: 0.4	Soft tissue thermal index
TIB: 0.4	(Displayed only for fetal applications)
	Bone thermal index
TIC: 1.0	Cranial thermal index
MI: 1.2	Mechanical index
MIF: 0.02	(Displayed only when contrast agent imaging is activated)
	Maximum of the mechanical indices measured at the active focal zones
16fps	Frame rate
2D-mode Settings	
Example	Parameter
2D - 100%	Imaging mode / transmit power
THI	Submode:
	THI indicates tissue harmonic imaging
	GEN indicates fundamental imaging
	 Contrast indicates contrast agent imaging
	 CCAI indicates contrast agent imaging (for systems without a touch screen)
H5.50 MHz	Transmit frequency
	Note: The transmit frequency is preceded by an H (harmonic) or HC (harmonic compounding) when THI is activated. The transmit frequency is preceded by CPS or CH during contrast agent imaging when contrast pulse sequence or contrast harmonic imaging is activated. ADI indicates the agent detection imaging technique is enabled.

Example	Parameter
9dB DR65	Gain / dynamic range
CTI1	Optimization setting applied during Custom Tissue Imaging
CPS 0 db	Gain during contrast agent imaging
ASC 3	Level of SieClear or Advanced SieClear spatial compounding
DTCE M	Level of Dynamic Tissue Contrast Enhancement
MapE / ST4	Gray scale map / SpaceTime
E1 / P3	Edge enhancement / persistence
T3 / B1	Tint / Balance (available only during contrast agent imaging)
ClarifyVE 1	Level of Clarify Vascular Enhancement
El Map 2	Gray scale or color map for elasticity imaging
SW Velocity/Elasticity	Image display setting applied to shear wave velocity and elasticity data in the region of interest (available only for Virtual Touch IQ)

Color Settings

Example	Parameter
CDV	Color mode, for example, Color Doppler Velocity (CDV) or Color Doppler Energy (CDE)
7.3 MHz	Transmit frequency
2 dB Gen	Gain / image optimization preset for Color, for example, Gen, Low, or High
P3 / ST2	Persistence / SpaceTime
PRF 5580	Pulsed repetition frequency
MapA / F 2	Map / wall filter
S 3 / Pr 2	Smoothing / priority
T 2	Tint
6cm/s	Maximum velocity
Display OFF	Color display off (color (CDV) or power (CDE) information is removed from the region of interest)

4 - 22 Instructions for Use

Doppler Settings

Example	Parameter	
PW	Pulsed wave Doppler (PW) or continuous wave Doppler (CW)	
5.3 MHz	Transmit frequency	
68 dB DR 55	Gain / dynamic range	
Map F	Мар	
GS 1.5	Size of gate	
PRF 7102	Pulsed repetition frequency	
F 320	Wall filter	

M-mode Settings

Example	Parameter
GEN	2D-mode image optimization, for example, general imaging (GEN) or tissue harmonic imaging (THI)
8.00 MHz	Transmit frequency
2 dB DR 55	Gain / dynamic range
MapB / E1	Map / edge enhancement
T 2	Tint

Working with Mode-Specific Menus

When you activate an imaging mode, the system displays the related settings for the selected mode on the touch screen. For systems without a touch screen, the system displays the related settings on the left side of the image screen.

Note: Not all settings can be changed using all methods.

To work with mode-specific menus:

- Press the control for the required mode. Or, select the tab for the required mode on the touch screen.
- For systems without a touch screen, click the Hide or Show Menu icon in the toolbar to display the image menu on the left side of the screen.



То	Do This	
Expand or hide menu selections	Rotate MENU to highlight a menu heading, such as Protocol .	
using MENU	2. Press MENU to expand or hide the selections under the heading.	
Expand or hide a menu using the trackball controls	Note: If the trackball is assigned to a tool on the image area of the screen, press SELECT to assign the trackball to the pointer function.	
	1. Roll the trackball to position the cursor on the menu heading.	
	2. Press SELECT to expand or hide the selections under the heading.	
Adjust a setting using a dedicated or LED control	Rotate the control on the control panel.	
Adjust a setting using MENU	1. Rotate MENU to highlight the selection on the menu.	
	2. Press MENU to activate the selection.	
	3. Rotate MENU to adjust the setting.	
	4. Press MENU to confirm the setting.	
Adjust a setting using the trackball	Note: If the trackball is assigned to a tool on the image area of the screen, press SELECT to assign the trackball to the pointer function.	
	 Roll the trackball to position the cursor to the selection on the image menu and then press SELECT. 	
	2. Rotate MENU to adjust the setting.	
	3. Press MENU to confirm the setting.	
Modify a group of imaging parameters by selecting an image optimization preset	Note: The available image optimization presets depend on the active priority mode.	
optimization preset	Choose a method:	
	 Rotate IMAGE to select the image optimization preset, for example, Penetration or Soft. 	
	 Press IMAGE to display the available system and user-defined image optimization presets, rotate IMAGE to select the image preset, and press IMAGE to confirm the selection of the image preset. 	
	The system adjusts the image and the display of settings in the imaging parameters section of the screen.	
	Note: An image optimization preset does not change the depth or gain values.	

4 - 24 Instructions for Use

Performing Measurements and Calculations

The measurement function includes the measurements and calculations available for each exam type and imaging mode. You can use the measurement function during a patient examination or with stored images.

The ultrasound system contains measurements and calculations that are either standard for all applications or particular to one application, such as OB. Calculations use formulas that require specific measurements. The system automatically performs a calculation when the required measurements have been completed.

To perform measurements:

- Activate the measurement function.
 - Press CALIPER.
 - For systems without a touch screen, press CALCS.

See also: For more information about measurements and calculations, refer to the Features and Applications Reference manual.

Reviewing Images and Clips

You can review images stored during the current examination or previous examinations. All of the stored images can be viewed, deleted, flagged for attention, and printed.

When you activate the review feature, the system displays all images stored for the current study, including images stored and printed during previous examinations that are in the study folder.

The patient name and patient ID for the currently displayed images are always displayed at the top of the screen. During an examination (when a patient is registered), the system also displays the current date and time at the top of the screen. During a review session (when reviewing previous examinations), the system displays the study date and time instead of the current date and time.

To activate the review function:

Press REVIEW.

Creating and Viewing Thumbnails

Thumbnails are reduced-size representations of clips, volumes, or a single frame. The system automatically creates thumbnails when you complete a store operation.

Use the system configuration menu to enable or disable thumbnails.



To create and view thumbnails:

- Display the thumbnail panel.
 - Select Full Screen. Or, click the Enable or Disable Full Screen icon on the toolbar.
 - For systems without a touch screen, click the Enable or Disable Full Screen icon on the toolbar.



То	Do This	Control	Tool Tip
Create a thumbnail	Store an image.		
	Press IMAGE.		
	 For systems without a touch screen, press the key assigned to the store function. 		
	The system creates a thumbnail, assigns a number, and displays the thumbnail in the thumbnail panel at the bottom of the screen. The icon on the upper left of the thumbnail indicates the item referenced by the thumbnail (image, clip, or volume).		
Scroll through thumbnails	 Click the double-arrow icon to display the next six thumbnails. Or, use the scroll bar to view thumbnails not currently visible on the screen. 		
	 Click the single-arrow icon to display the next thumbnail, one at a time. 		
View an image, clip, or volume referenced by a thumbnail	Note: Thumbnails are highlighted with a blue box when selected.		
	 Position the cursor on a thumbnail and double-click UPDATE. 		
	The review screen displays the image, clip, or volume in full-screen format.		

4 - 26 Instructions for Use

То	Do This	Control	Tool Tip
Copy a thumbnail to a film sheet	Note: You can select multiple consecutive or non-consecutive thumbnails.	}	Copy to Film Sheet
	1. Select a thumbnail from the thumbnail panel.		Onoot
	2. Click Copy to Film Sheet on the image screen.		
	During review, select the control assigned to the copy function.		
	Select Copy To Film.		
	 For systems without a touch screen, press the Copy to Film soft key. 		
Copy a thumbnail to a	Display a patient report.		
patient report	 Press REPORT. 		
	 For systems without a touch screen, press Report on the keyboard. 		
	2. Click Images to access the image section of the report.		
	Select the required thumbnail from the thumbnail panel displayed at the bottom of the report.		
	Roll the trackball to position the image in the report and then press SELECT.		
	Note: Images marked for deletion in imaging or review are not removed from the patient report.		
Delete a thumbnail	Note: You can select multiple consecutive or non-consecutive thumbnails.	×	Delete
	1. Select a thumbnail from the thumbnail panel.		
	2. Click Delete on the image screen.		
	The system places a deletion icon on each marked thumbnail.		
	Note: If the selected thumbnail displays a stress echo icon, all stress echo images are marked for deletion. The system displays a dialog box to confirm deletion of the stress echo images.		
	To keep a thumbnail currently marked for deletion, select the thumbnail and then press Delete again.		
	Thumbnails marked for deletion remain in the thumbnail panel until you end the current exam or enter new patient information.		
Play back a thumbnail clip	Press SELECT twice in quick succession (double-click).		
	The system displays the clip in the review screen in full-screen format.		

Recording and Playing Back with a Digital Video Recorder (DVR)

You can use a DVR to record a patient study on media for later playback. When you start and then stop a recording session, the DVR creates a *title*. Each time you pause and then resume recording during a session, the DVR creates a *chapter*. A title can consist of multiple chapters. The DVR assigns a title using the patient's last name and the exam type.

The controls for the DVR recording and playback are located on the ultrasound system control panel and screen. The ultrasound system also displays DVR status messages on the image menu and in the list of imaging parameters.

Note: The DVR supports only BD-R and BD-RE disk media. Siemens has qualified media only from Panasonic and TDK.

To record a patient study:

Prerequisite: Power on the DVR before powering on the ultrasound system. Otherwise, the ultrasound system cannot detect the DVR.

Ensure formatted media is inserted in the DVR.

Note: Refer to the manufacturer's instructions for information about formatting new media.

- 2. Begin recording.
 - Select Record/Pause.
 - For systems without a touch screen, press DVR (F12) on the ultrasound system keyboard.

The ultrasound system displays the video recording selections on the menu.

- 3. To pause or resume recording:
 - Select Pause or Record.
 - For systems without a touch screen, press DVR (F12).
- To stop recording:
 - Select Stop Recording.
 - For systems without a touch screen, click End Exam.
- 5. To finalize the recording:
 - Select Finalize Disk.
 - o For systems without a touch screen, click Finalize.
- To eject the media from the DVR, select Eject.

To play back a recorded patient study:

Prerequisite: The media with the recorded study is in the DVR and the DVR is powered on before powering on the ultrasound system.

- 1. Play back a recording.
 - Select Play.
 - $\circ \quad \text{For systems without a touch screen, click $\textbf{View Disk}$.}$
- 2. To pause or resume playback:
 - Select Pause or Play.
 - For systems without a touch screen, press GAIN FREEZE/CINE.
- 3. To fast forward or rewind playback:
 - Select Fast Forward or Rewind.
 - o For systems without a touch screen, rotate GAIN FREEZE/CINE.
- 4. To stop playback:
 - Select Exit.
 - For systems without a touch screen, press DVR (F12).
- 5. To select a different title or chapter for playback:
 - Rotate [Title] or [Chapter] and then select Play.
 - For systems without a touch screen, rotate [Title] and then press [Title], or rotate [Chapter] and then press [Chapter].
- 6. To eject the media from the DVR, select **Eject**.

Examination Completion

You can end an examination from the review screen or the patient registration screen.

▲ WARNING: If the Nuance data transfer feature is enabled, the ultrasound system transfers measured results from the patient report to the configured destination device when you end an exam. If measured results are deleted from the patient report on the ultrasound system after the measurements are successfully transferred, the measurements are not deleted on destination device.

See also: Transferring Reports, Measurements and Calculations, Chapter B1, Features and Applications Reference

To end the current patient examination, choose a method:

- Click **End Exam** on the review menu.
- Begin a new patient examination.
- Click End Exam on the patient report screen.

4 - 30 Instructions for Use

5 Transducer Accessories and Biopsy

Transducer Accessories	3		
Transducer Sheaths	5		
General Information — Sheaths	5		
Application — Sheaths	5		
Disposal — Sheaths Gel Pad Preparation for Use Needle Guide Brackets	6		
		EC-1 Needle Guide Bracket Kit	
		Biopsy (Puncture) Guideline Function	10
		Activating the On-screen Guidelines	10
System Biopsy Safeguards	11		
Needle Path Verification	12		

5 Transducer Accessories and Biopsy

5 - 2 Instructions for Use

Transducer Accessories

⚠ WARNING: Before using the transducer accessories, you must read and understand the Caring for Transducer Accessories section of Chapter 2, Instructions for Use.

Attachment procedures for the following accessories are presented in this chapter or shipped separately with the device. Accessories for each transducer are listed in the following table.

See also: For a list of tracking brackets and needle guides compatible with eSieFusion Imaging, see Technical Description, Appendix A, Instructions for Use.

Accessory	Curved Array	Linear Array	Phased Array	Endocavity	fourSight 4D
Transducer Sheath	All	All	All	All	All
Gel Pad	4C1	9L4	4P1		
	6C2	14L5	4V1		
			10V4		
Needle Guide Bracket	4C1				
Kits, CH4-1	6C1 HD				
Needle Guide Bracket Kits, C7F2/C5F1					7CF2
Needle Guide Bracket Kits, 7CF1					7CF1
Needle Guide Bracket Kits, SG-2			4V1		
Needle Guide Bracket Kits, SG-3		9L4			
Needle Guide Bracket Kits, SG-4		14L5			
Needle Guide Bracket Kits, SG-5	6C2				
Needle Guide Bracket Kit, VF12-4		12L4			
Needle Guide Bracket Kit, EV-8C4				EV-8C4	
Needle Guide Bracket					9EVF4
Kit, 9EVF4					(endocavity)

5 - 3 Instructions for Use

Accessory	Curved Array	Linear Array	Phased Array	Endocavity	fourSight 4D
Needle Guide Bracket Kits, EC-1				EC9-4	
Needle Guide Bracket Kits, MC9-4				MC9-4	
Needle Guide Bracket Kits, MC9-4 (Disposable Endocavity Needle Guide)				MC9-4	
Needle Guide Bracket Kits, EC9-4 (Disposable Endocavity Needle Guide)				EC9-4	
Needle Guide Bracket Kits, EV-8C4 (Disposable Endocavity Needle Guide)				EV-8C4	
Needle Guide Bracket Kit, 8C3 HD	8C3 HD				
Needle Guide Bracket Kit, 18L6 HD		18L6 HD			

5 - 4 Instructions for Use

Transducer Sheaths

Siemens makes every effort to manufacture safe and effective transducers. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, and during endocavity or intraoperative scanning; during biopsy or puncture procedures; or when scanning patients with open wounds.

General Information — Sheaths

Transducer sheaths are single-use items used to ensure proper acoustic coupling and provide a prophylactic barrier for the intended ultrasound application. Sheaths are available for all transducers. Siemens recommends the use of market-cleared transducer sheaths.

Application — Sheaths



MARNING: After placing the sheath over the transducer, visually inspect the sheath to ensure there are no defects. Do not use the sheath if it has any holes or tears.

Step-by-step instructions are provided for both non-sterile and sterile procedures.

To place the transducer in a sheath for non-sterile use:

Before applying any coupling agent (gel) to the sheath, remove any powder in the sheath by rinsing with water.

- Remove the packaging and unfold the transducer sheath.
- Apply a water-based coupling agent (gel) to the inside of the sheath and onto the face of the transducer.
- Hold the transducer by the cable relief and unroll the sheath onto the transducer.
- Pull the transducer sheath tightly over the face of the transducer to remove wrinkles.
- Secure the sheath to the transducer housing or cable relief with the adhesive tapes or elastic bands.

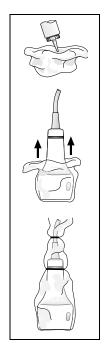
To place the transducer in a sheath for sterile use:

Before applying any sterile coupling agent (gel) to the sheath, remove any powder in the sheath by rinsing with sterile water.

- Using sterile technique, remove the packaging and unfold the transducer sheath.
- Taking care not to contaminate the sheath, apply a sterile water-based coupling agent (gel) to the inside of the sheath and onto the face of the transducer.
- Using sterile technique, hold the transducer by the cable relief and unroll the sheath onto the transducer and cable.
- Pull the transducer sheath tightly over the face of the transducer to remove wrinkles.
- 5. Secure the sheath to the transducer cable with the adhesive tapes or elastic bands.

Disposal — Sheaths

While wearing protective gloves, remove the transducer sheath from the transducer. Dispose of the transducer sheath according to local, state, and regional laws and regulations for biohazardous waste.



Instructions for Use 5 - 5 The gel pad is a disposable bacteriostatic standoff. It is used when superficial imaging requires an appropriate standoff for utilizing the focal zone of the transducer. The gel pad provides a fixed distance between the transducer face and the body surface.



MARNING: Ultrasound energy is transmitted more efficiently through the gel pad than through tissue. When using a standoff device of any kind (for example a waterpath or gel pad), the actual mechanical and thermal indices, MI and/or TI, may be higher than indicated in the output display on the system.

Preparation for Use

Before use, examine the gel pad for any material flaws. Any product showing flaws should not be used.

Needle Guide Brackets



⚠ **WARNING**: Percutaneous procedures always involve heightened risk to the patient and to the operator handling biopsy needle guides. Clinicians using Siemens recommended biopsy devices under ultrasound guidance should be trained and must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomfort and unnecessary risk and injury to the patient.

Refer to the in-box instructions for attachment and care procedures for all needle guide accessories except as noted below.

See also: EC-1 Needle Guide Bracket Kit, p. 5-7

5 - 6 Instructions for Use

EC-1 Needle Guide Bracket Kit

The EC-1 Needle Guide Bracket Kit consists of a biopsy guide cover, three biopsy guide plates (15G/16G, 17G/18G, 19G/20G/21G), an operation manual, and a carrying case. You can use the needle guide with needle sizes ranging from 14 to 22 gauge (2.11 to 0.64 mm). The biopsy bracket has a fixed angle.

Biopsy Guide Cover

Biopsy Guide Plate

Example of the EC-1 needle guide bracket assembly.

Preparation for Use — EC-1 Needle Guide Bracket Kit

⚠ **WARNING:** Do not attempt to use the Needle Guide Bracket Kit until you have read the following instructions. The needle guide should only be used after proper training and after verifying the path of the needle.

★ WARNING: The needle guide is packaged non-sterile. Sterilize this product prior to its first use.

⚠ **WARNING:** Ensure that the needle guide is properly cleaned and sterilized before each use to avoid possible patient contamination.

⚠ **WARNING:** Before attaching the needle guide to the transducer, place the transducer in a sterile transducer sheath.

▲ WARNING: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

⚠ Caution: Use only a water-based ultrasound coupling agent (gel) with this kit. Petroleum- or mineral oil-based materials can harm the transducer.

Instructions for Use 5 - 7

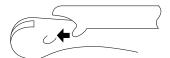
To attach the needle guide to the transducer:

⚠ **WARNING:** Care must be taken to ensure that the needle guide is properly positioned. When properly positioned, the bracket will cover the colored ring on the transducer handle and the hook will be firmly against the transducer tip.

1. Place a sterile transducer sheath over the transducer.

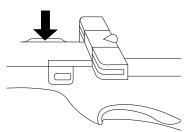
To ensure an accurate scan, there should not be any air bubbles or wrinkles between the transducer face and the transducer sheath.

- 2. Select the correct biopsy guide plate.
- 3. Slide the biopsy guide plate into the biopsy guide cover until the plate locks.
- 4. Engage the biopsy adaptor fixing hook into the biopsy adaptor fixing slot at the tip of the transducer.



Example of fixing the biopsy bracket assembly to the transducer tip.

Insert the fixing hook at the other end into the fixing slot in the transducer grip section until it clicks.



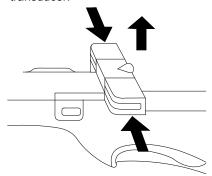
Example of fixing the biopsy bracket assembly to the transducer grip.

Note: For illustration purposes only, the transducer is shown without a transducer sheath. Always place a sterile transducer sheath over the transducer.

6. Before performing any patient procedure, verify the needle path.

Detachment

 Hold the biopsy adapter firmly on the sides and pull it upwards to remove it from the transducer.



Example of Bracket disassembly.

2. Remove the biopsy guide plate from the biopsy guide cover.

Disposal

Dispose of the needle and the transducer sheath according to local, state, and regional laws and regulations for biohazardous waste.

If the biopsy bracket assembly becomes damaged or compromised in any way, dispose of it only after sterilizing. The assembly is made of polyetherimide resin. When disposing of the assembly, be sure to comply with all applicable laws or regulations.

Instructions for Use 5 - 9

⚠ **WARNING**: Percutaneous procedures always involve heightened risk to the patient and to the operator handling biopsy needle guides. Clinicians using Siemens recommended biopsy devices under ultrasound guidance should be trained and must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomfort and unnecessary risk and injury to the patient.

⚠ **WARNING**: The system displays biopsy guidelines to indicate an anticipated needle path. The guidelines do not account for a bent or deflected needle and are not intended as an absolute reference. It is the user's responsibility to verify correct positioning of the needle during a biopsy or puncture procedure.

You can display on-screen guidelines for use with transducers compatible with needle guide attachments.

Activating the On-screen Guidelines

The biopsy function is activated only during real-time imaging in the following modes:

2D-mode full FOV

2D/Doppler

2D/M-mode

2D-mode with color

2D-mode with power

2D/Doppler with color

2D/Doppler with power

2D/Clarify

Should you attempt to activate the biopsy function from an incompatible mode, the system displays a message to indicate which corrective action the system will take to allow you to activate the biopsy function.

- Select **OK** to enter the biopsy function.
- Select Cancel to leave the system as it is. The system will not display the biopsy guidelines on the screen.

To display guidelines on the image screen:

- 1. Activate the biopsy function.
 - Select Biopsy and then select A or B.
 - For systems without a touch screen, select Biopsy A or Biopsy B on the image

Note: The selection corresponds to the track on the needle guide attachment. For fixed-angle needle guides, always use the Biopsy A selection.

The system displays the following message as a precaution:

Please verify that the physical needle guide matches your angle selection.

- 2. Ensure the selected angle (Biopsy A or Biopsy B) corresponds to the needle guide attached to the transducer and then click **OK**.
- 3. To remove the biopsy guidelines from the screen:
 - Select the active biopsy and then select Off.
 - For systems without a touch screen, select **Biopsy Off** on the image menu.

5 - 10Instructions for Use

System Biopsy Safeguards

⚠ **WARNING**: To reduce the risk of injury to the patient, conduct a biopsy procedure during real-time imaging. When an image is frozen, the correct positioning of the needle cannot be

While using the biopsy function, you can switch to a different acceptable mode or freeze the image. When you freeze the image, the color of the guidelines change from yellow to white.

Should you request an action that is not allowed during the biopsy function, the system displays a message indicating that the action is not allowed.

Disconnecting the active transducer while in biopsy causes the system to exit the biopsy function. The system displays a message prompting you to connect a transducer and then it displays a message indicating that the biopsy function has ended.

5 - 11 Instructions for Use

Needle Path Verification

Before performing any patient procedure using a needle guide, you must verify that the path of the needle is accurately indicated by the on-screen guidelines.

The needle guide is ready for patient use only after the path of the needle has been verified.

Checklist of Items Required for Needle Path Verification:

- Transducer with attached needle guide
- Water-based coupling agent (gel)
- Sterile transducer sheath
- New, straight, biopsy needle
- Sterilized container of sterilized and degassed water

To verify the path of the needle:

⚠ WARNING: The system displays biopsy guidelines to indicate an anticipated needle path. The guidelines do not account for a bent or deflected needle and are not intended as an absolute reference. It is the user's responsibility to verify correct positioning of the needle during a biopsy or puncture procedure.

▲ WARNING: Do not use a needle guide if the path of the needle is not accurately indicated by the on-screen guidelines. The path of the needle must display within the guideline. Contact your Siemens service representative if the needle path is not accurately indicated.

- 1. Attach the needle guide to the transducer.
- 2. Connect the transducer to the system and activate the transducer.
- 3. Set the system to the depth of the intended puncture procedure.
- 4. Activate the biopsy function to display the guidelines on the image screen.
 - Select Biopsy and then select A or B.
 - For systems without a touch screen, select Biopsy A or Biopsy B on the image menu.
- Ensure the selected angle (Biopsy A or Biopsy B) corresponds to the needle guide attached to the transducer.
- Immerse the head of the transducer into the degassed water and insert the needle into the needle guide.
- Verify that the path of the needle displays according to the guidelines shown on the image screen.

After verification, the needle guide is ready for use.

5 - 12 Instructions for Use

6 Transesophageal Transducer

Introduction to the Transesophageal Transducers	3
About the V5Ms Transducer	4
Transducer Articulation Controls (V5Ms)	5
Array Rotation Control (V5Ms)	5
Flex Controls (V5Ms)	6
Friction Brakes (V5Ms)	7
About the V7M Transducer	9
Transducer Articulation Controls (V7M)	10
Friction Brake (V7M)	11
Array Rotation Control (V7M)	11
Flex Control (V7M)	12
Neutral Position (V7M)	12
Preparation for Use	13
Prior to First Use	13
Prior to Each Use	13
Inspecting the Transducer	
Using a Transducer Sheath	
Using Protective Drapes	
Electrical Safety Considerations	
Implantable Devices	
Defibrillators	15
Punctures or Cracks	
Electrosurgical Units	16
Exam Considerations	16
Bite Guards	16
Exam Procedures	17
Imaging with the V5Ms Transducer	19
Changing the Imaging Scan Plane (V5Ms)	20
Temperature Controls and Safeguards (V5Ms)	21
Managing the Lens Surface Temperature (V5Ms)	22
Temperature Sensor Failure (V5Ms)	23
Imaging with the V7M Transducer	24
Changing the Imaging Scan Plane (V7M)	25
Selecting an Estimated Patient Temperature Setting (V7M)	26
Temperature Controls and Safeguards (V7M)	27
Managing the Lens Surface Temperature (V7M)	28
Temperature Sensor Failure (V/7M)	20

Caring for the Transesophageal Transducer	30
Cleaning and Storage	30
Approved Cleaning and Disinfection Agents for the Transesophageal Transducer	30
Cleaning and Disinfecting the Transducer	31
Storing and Handling	34
Service and Repair	34
Preventing Injury and Equipment Damage	35
V5Ms Transducer Technical Description	37
V7M Transducer Technical Description	39

6 - 2 Instructions for Use

Introduction to the Transesophageal Transducers

⚠ **WARNING:** Do not use this transducer unless you are thoroughly trained in transesophageal echocardiography and are familiar with the orientation of cardiac images obtained through a TEE procedure. The transesophageal transducer should be used only by a licensed physician.

⚠ **WARNING:** Before attempting to use this transducer, you should be thoroughly familiar with the safe operation of the ultrasound system and this transducer. Refer to the content of this chapter and to the Safety and Care chapter in the Instructions for Use manual for ultrasound system and transducer-related safety information.

⚠ **WARNING**: The leakage current test for transesophageal transducers must be done prior to each use in order to reduce the likelihood of harm to the patient. Refer to the manufacturer's instructions included with the tester.

See also: Safety and Care, Chapter 2, Instructions for Use

The transesophageal transducer can be introduced into the esophagus of the patient to obtain images of the heart structure. This procedure, known as transesophageal echocardiography (TEE), can provide virtually unobstructed views of the heart and surrounding tissue.

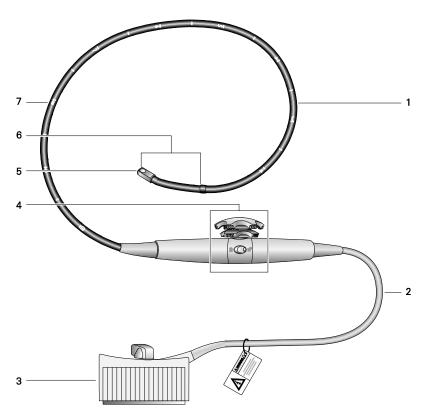
Instructions for Use 6 - 3

About the V5Ms Transducer

The V5Ms is a multi-frequency, multi-plane, phased sector array transducer.

The V5Ms transducer supports the following modes:

- 2D-mode
- M-mode
- Pulsed Wave Doppler
- Steerable Continuous Wave Doppler
- Color Doppler
- Color DTI
- Pulsed Wave DTI
- Anatomical M-mode



Example of the V5Ms transducer.

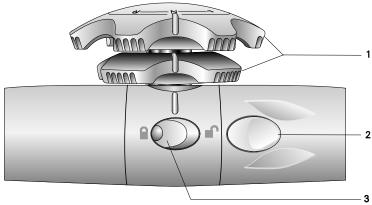
- 1 Flexible shaft
- 2 Cable
- 3 Transducer connector
- 4 Transducer controls
- 5 Distal tip (contains rotating array)
- 6 Articulating section
- 7 Depth markings (in centimeters)

6 - 4 Instructions for Use

Transducer Articulation Controls (V5Ms)

⚠ Caution: Do not use your hands or fingers to bend or manipulate the articulating section of the transesophageal transducer. To avoid severe damage to the articulating mechanism, use only the transducer controls to change the articulation angle.

The Array Rotation Control, Flex Controls, and Friction Brakes are located on the handle of the transducer.



Example of V5Ms transducer controls.

- Flex Controls
 - Bend the articulating section of the transducer shaft
- 2 Array Rotation Control
 - Rotates the transducer crystal within the distal tip of the transducer
- 3 Friction Brakes (one on each side of the transducer) Locks the flex controls

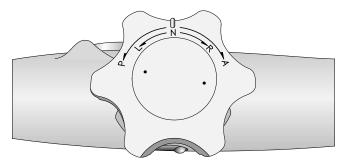
Array Rotation Control (V5Ms)

The array rotation control rotates the transducer crystal within the distal tip of the transducer. The position of the array corresponds to the imaging scan plane. The scan plane is adjustable from 0° to 180°.

Instructions for Use 6 - 5

Flex Controls (V5Ms)

The flex controls manipulate the movement of the distal tip.



Example of flex controls located on the handle of the V5Ms transducer.

Anterior/Posterior Deflection

For anterior deflection (anteflexion) of the distal tip, rotate the anterior/posterior flex control toward the **A** marking to move the tip anteriorly.

For posterior deflection (retroflexion) of the distal tip, rotate the anterior/posterior flex control toward the **P** marking to move the tip posteriorly.

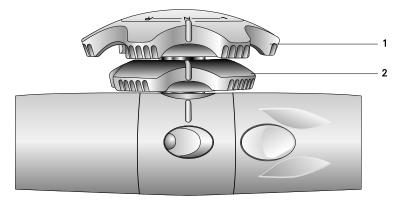
Right/Left Deflection

For right deflection of the distal tip, rotate the left/right flex control toward the **R** marking to move the tip right.

For left deflection of the distal tip, rotate the left/right flex control toward the ${\bf L}$ marking to move the tip left.

Neutral Position

To place the distal tip in the neutral position, rotate the anterior/posterior flex control and the right/left flex control to align the ${\bf N}$ marking and raised reference lines with the raised reference line on the handle of the transducer.



Example of flex controls in the neutral alignment.

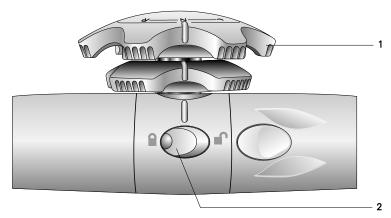
- 1 Anterior/Posterior flex control
- 2 Left/Right flex control

6 - 6 Instructions for Use

Friction Brakes (V5Ms)

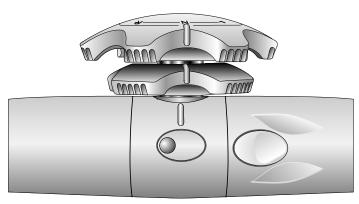
The friction brakes lock the deflection positions of the distal tip. When the brakes are engaged, you can change the imaging scan plane without losing acoustical contact.

A friction brake is located on each side of the transducer handle. The friction brakes are color-coded to match their corresponding flex control.



Example of V5Ms transducer with locked/unlocked icons. Brake for Anterior/Posterior flex control is in the locked position.

- 1 Anterior/Posterior flex control (light gray)
- 2 Brake for Anterior/Posterior flex control (light gray)



Example of V5Ms transducer without locked/unlocked icons. Brake for Anterior/Posterior flex control is in the unlocked position.

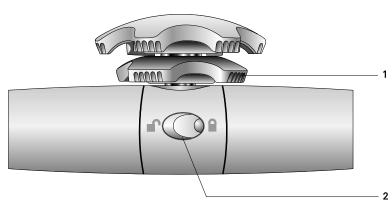
To lock the anterior/posterior deflection position of the distal tip:

Press the raised tactile indicator located on the button of the corresponding brake.

To unlock a brake:

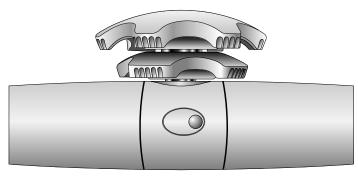
Press the flat portion on the button of the corresponding brake.

Instructions for Use 6 - 7



Example of V5Ms transducer with locked/unlocked icons. Brake for Left/Right flex control is in the locked position.

- 1 Left/Right flex control (dark gray)
- 2 Brake for Left/Right flex control (dark gray)



Example of V5Ms transducer without locked/unlocked icons. Brake for Left/Right flex control is in the unlocked position.

To lock the left/right deflection position of the distal tip:

Press the raised tactile indicator located on the button of the corresponding brake.

To unlock a brake:

Press the flat portion on the button of the corresponding brake.

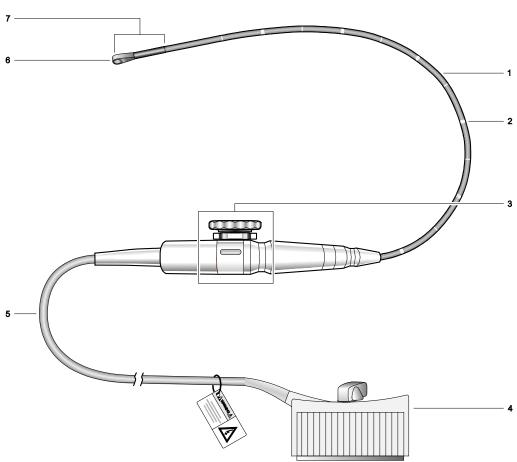
6 - 8 Instructions for Use

About the V7M Transducer

The V7M is a multi-frequency, multi-plane, phased sector array transducer.

The V7M transducer supports the following modes:

- 2D-mode
- M-mode
- Pulsed Wave Doppler
- Steerable Continuous Wave Doppler
- Color Doppler Velocity
- Color DTI
- Pulsed Wave DTI
- Anatomical M-mode

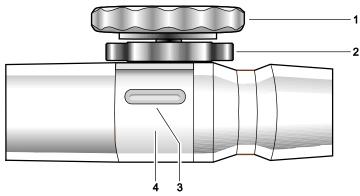


Example of the V7M transducer.

- 1 Flexible shaft
- 2 Depth markings (in centimeters)
- 3 Transducer controls
- 4 Transducer connector
- 5 Cable
- 6 Distal tip (contains rotating array)
- 7 Articulating section

⚠ Caution: Do not use your hands or fingers to bend or manipulate the articulating section of the transesophageal transducer. To avoid severe damage to the articulating mechanism, use only the transducer controls to change the articulation angle.

The Array Rotation Control, Flex Control, and Friction Brake are located on the handle of the transducer.



Example of V7M transducer articulation controls.

1 Array Rotation Control

Rotates the transducer crystal within the distal tip of the transducer

2 Flex Control

Bends the articulating section of the transducer shaft

3 Friction Brake Lock Indicator

Red lock indicator means the friction brake is locked. White lock indicator means the friction brake is unlocked.

4 Friction Brake

Locks the flex control

6 - 10

Friction Brake (V7M)

The friction brake locks the deflection position of the distal tip. When the brake is engaged, you can change the imaging scan plane without losing acoustical contact.

To lock the friction brake:

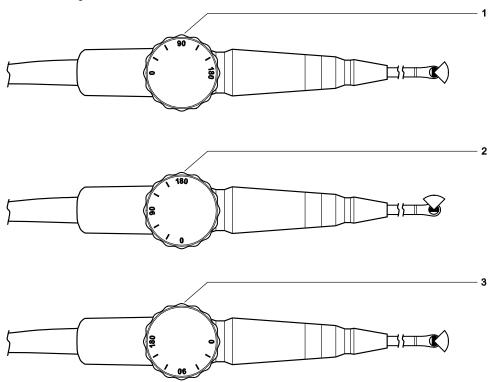
 With the distal tip pointed away from you, rotate the metal barrel located on the handle clockwise until the friction brake lock indicator changes from white to red.

To unlock the friction brake:

 With the distal tip pointed away from you, rotate the metal barrel located on the handle counterclockwise until the friction brake lock indicator changes from red to white.

Array Rotation Control (V7M)

The array rotation control rotates the transducer crystal within the distal tip of the transducer. The position of the array corresponds to the imaging scan plane. The scan plane is adjustable within the range of -12° to 192°.



Example of V7M transducer array rotation control.

- 1 0° array rotation angle, transverse plane
- 2 90° array rotation angle, longitudinal plane
- 3 180° array rotation angle, transverse plane, left/right inverted

Instructions for Use 6 - 11

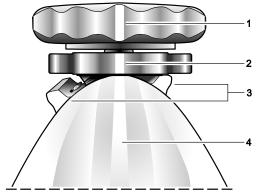
Flex Control (V7M)

The flex control manipulates the movement of the distal tip.

Anterior/Posterior Deflection

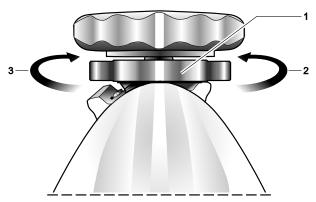
For anterior deflection (anteflexion) of the distal tip, rotate the flex control clockwise. Clockwise rotation moves the distal tip anteriorly.

For posterior deflection (retroflexion) of the distal tip, rotate the anterior/posterior flex control counterclockwise. Counterclockwise rotation moves the tip posteriorly.



Example of a V7M transducer in the neutral position as viewed from the handle near the connector cable.

- 1 Array rotation control (90° array rotation angle position indicator)
- 2 Flex control neutral position indicator
- 3 Flex control lock in the unlocked position
- 4 V7M handle near the connector cable



Example of movement of the V7M transducer flex control as viewed from the handle near the connector cable.

- 1 Flex control
- 2 Rotate the flex control counterclockwise to move the distal tip down
- 3 Rotate the flex control clockwise to move the distal tip up

Neutral Position (V7M)

To place the distal tip in the neutral position:

- 1. Unlock the friction brake.
- 2. Rotate the flex control until the neutral position indicator is aligned with the handle portion that is near the connector cable.

6 - 12 Instructions for Use

Preparation for Use

⚠ WARNING: When using an endocavity or intraoperative transducer with a BF or CF type applied part, the patient leakage currents may be additive.



⚠ WARNING: The leakage current test for transesophageal transducers must be done prior to each use in order to reduce the likelihood of harm to the patient. Refer to the manufacturer's instructions included with the tester.



⚠ **WARNING:** Prior to each use, inspect the endocavity or intraoperative transducer for signs of mechanical damage such as cracks, cuts, tears, perforations, or protrusions. Do not use the transducer if the transducer appears damaged in any way. A damaged transducer could cut the patient or user and compromise the electrical safety of the transducer, causing possible patient or user injury. Contact your local Siemens representative.



⚠ **WARNING:** (V7M only) Prior to each use, confirm the maximum deflection angle range of the distal tip is 90° to 120° upward and 60° to 90° downward. If the up/down deflection exceeds the maximum deflection angle range, do not use the transesophageal transducer. The distal tip could fold over in the esophagus, causing possible patient injury. Contact your local Siemens representative.

Prior to First Use

Proper precautions reduce risks to the patient and the equipment.

- Review the Safety and Care section.
- Thoroughly understand the features and operation of the transesophageal transducer, particularly the use of the flex controls and friction brakes.
- Clean and high-level disinfect the transesophageal transducer prior to its first use.
- Perform a leakage current test on the transducer. Refer to the manufacturer's instructions included with the tester.

Prior to Each Use

Review this checklist before each use of the transesophageal transducer to ensure patient safety, comfort, and confidence.

- Review patient history to ensure contraindications do not apply.
- Thoroughly inspect the transducer for mechanical damage.
- Familiarize yourself with the articulation controls.
- Ensure that the transducer has been properly cleaned and has been high-level disinfected, if disinfection is necessary.
- Perform a leakage current test on the transducer. Refer to the manufacturer's instructions included with the tester.
- Place a sheath on the transducer, if indicated.
- If necessary, place a drape over the transducer handle, cable, connector and the ultrasound system.

See also: Safety and Care, Chapter 2, Instructions for Use

Instructions for Use 6 - 13

Inspecting the Transducer

To inspect the transducer before use:

- 1. Examine by look and touch the entire surface of the flexible shaft all the way to the distal tip for cuts, scrapes, protrusions, holes, dents, or cracks.
 - If you discover the surface of the transducer has been compromised, do not use the transducer. Contact your local Siemens representative.
- 2. Test the array rotation control to ensure a smooth rotation.
- 3. Rotate the flex controls through the full range of motion and observe that the control movement is smooth and easy.
 - If the range of motion is tight or binding, or if the transducer controls make an unusual noise, do not use the transducer. Contact your local Siemens representative.

If the distal tip appears to sag slightly when the flex controls are in the neutral position, this may be a sign of stretched or damaged control cables. Do not use the transducer. Contact your local Siemens representative.

(V7M only) Confirm the maximum deflection angle range of the distal tip is 90° to 120° upward and 60° to 90° downward. If the up/down deflection exceeds the maximum deflection angle range, do not use the transesophageal transducer. Contact your local Siemens representative.

- 4. Test the brakes:
 - (V5Ms only) Engage the brakes (deflection locking mechanism) by pressing each ratchet button.
 - The brakes hold the distal tip at the appropriate articulation angle when locked.
 - (V7M only) Engage the brake (deflection locking mechanism) by rotating the metal barrel located on the handle.

The brake holds the distal tip at the appropriate articulation angle when locked.

Using a Transducer Sheath

See also: Transducer Sheaths, Safety and Care, Chapter 2, Instructions for Use

▲ WARNING: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

For greatest patient and operator safety, cover a transducer with a transducer sheath. Siemens recommends that you use market-cleared transducer sheaths specifically designed for TEE applications. Follow the instructions provided by the manufacturer of the transducer sheath.

Disposal

While wearing protective gloves, remove the transducer sheath from the transducer. Dispose of the transducer sheath according to local, state, and regional laws and regulations for biohazardous waste.

Using Protective Drapes

Follow your hospital's guidelines regarding equipment use in the presence of infectious disease.

6 - 14 Instructions for Use

Electrical Safety Considerations

For safe use of this device, ensure an electrical safety procedure is in place for periodically inspecting the grounding system in the examination area and that this procedure is performed routinely.

Implantable Devices



⚠ **WARNING:** Ultrasound systems, like other medical equipment, use high-frequency electrical signals that can interfere with implantable devices such as pacemakers and implantable cardioverter-defibrillators (ICDs). When using a transesophageal transducer on a patient who has an implantable device, pay special attention to the performance of the implantable device. Stop the examination if there is interference.

Defibrillators



▲ WARNING: The transesophageal transducer is designed to withstand the effects of defibrillation. However, disconnect the transducer during defibrillation because a malfunction of the safety controls could otherwise result in electrical burns for the patient.

The transesophageal transducer is designed to withstand the effects of defibrillation. There are no exposed conductive surfaces distal to the handle. Within the flexible shaft, a chassis ground shield covers all active circuits and conductors. The shield runs along the entire length of the transducer.

Transesophageal transducers with this label are certified as type BF defibrillator proof per IEC 60601-1 Standard for Safety of Medical Equipment:



Type BF Defibrillator-proof Patient Connection.

Transesophageal transducers with this label are not certified as defibrillation proof:



Type BF Applied Part.

Instructions for Use 6 - 15

Punctures or Cracks

Punctures or cracks in the outer layer of the transducer could expose the patient's esophagus to chassis leakage current and cause the patient to be at the chassis ground potential. If this occurs, the transducer will no longer meet the requirements of a type BF classification. The transducer would no longer be a "floating" part and would fail a dielectric test. Provided that the internal grounding mechanism within the ultrasound system's power cord is intact and the cord is connected to a properly grounded wall outlet, there is little hazard to the user or patient from the system's leakage current. However, since the patient would now be at ground potential, leakage currents from other devices within the patient's environment could travel through the patient, compromising the safety to the patient or operator. If punctures or cracks in the outer layer of the transducer are observed, contact your local Siemens representative.

Electrosurgical Units



▲ WARNING: Use only isolated output electrosurgical units with the transesophageal transducer and disconnect the transducer when it is not in use. Failure to follow these procedures can result in esophageal burns for the patient, damage to the equipment, and unreliable data.

Use only electrosurgical units that have isolated outputs. If possible, use return-fault/ground-fault detection circuits, which provide extra protection.

Electrosurgical units and other operating room devices that do not have isolated outputs can introduce radio frequency electromagnetic fields or currents into the patient. The transducer is susceptible to these radio frequencies, which can interfere with the 2D-mode image and can completely override the color flow image, making it useless for diagnostic purposes.

In addition, any failure to an electrosurgical unit or other device, including the transesophageal transducer, could cause electrosurgical currents to return along the transducer's conductors. As a result, the patient could suffer from burns to the esophageal membranes. This arcing could also damage the transducer. To reduce the risk of leakage currents and electrosurgical interference, disconnect the transesophageal transducer from the ultrasound system when it is not in use.

Where isolation of electrosurgical units is in question, consult the manual for each electrosurgical unit or contact the biomedical engineering group.

Exam Considerations

Bite Guards



⚠ WARNING: Follow the bite guard manufacturer's instructions to clean, disinfect, and rinse the bite guard if you use a reusable bite guard. Any disinfectant remaining on the reusable bite guard can burn the patient's mouth.

Bite guards are provided with the transducer for use with patients who will be awake during the exam. These guards are also available from third-party providers.

Do not use the provided bite guard with anesthetized patients. Use a separately purchased bite guard that has a space for taping an endotracheal tube to the guard.

6 - 16Instructions for Use

Exam Procedures

⚠ WARNING: (V5Ms only) Ensure that the friction brakes are unlocked and the flex controls are in the neutral alignment position when you insert or withdraw the transducer. Advancing or withdrawing the transducer while the transducer tip is bent and/or rigid can result in patient injury or death.



⚠ WARNING: (V7M only) Ensure that the friction brake is unlocked and the flex control is in the neutral alignment position when you insert or withdraw the transducer. Advancing or withdrawing the transducer while the transducer tip is bent and/or rigid can result in patient injury or death.



⚠ WARNING: Do not use excessive force to advance or withdraw the transducer. Using excessive force to advance or withdraw the transducer can result in patient injury or death. If you encounter strong resistance during transducer articulation, discontinue the procedure. Identify and address the cause of the resistance before resuming the procedure. Withdraw and redirect the transducer as needed.



⚠ **WARNING:** To reduce the risk of pressure necrosis, put the transducer in the neutral position when inserting or withdrawing it. Minimize pressure applied to the articulating section and distal tip. Do not let the distal tip displace tissue for more than five minutes.



⚠ **WARNING**: Do not use the transesophageal transducer for any procedure requiring hyperextension of the neck. Improper patient positioning can cause paralysis of the vocal cord.



⚠ **WARNING:** Always use a bite guard to prevent damage to the transducer from the patient's teeth, which could, as a result, create potential mechanical and electrical hazards for the patient. Using a bite guard also protects the patient's teeth.

Exam Procedures (V5Ms)

To use the V5Ms transducer during a transesophageal echocardiogram:

- 1. Remove dentures, if present, and place them in a protected area until after the procedure.
- 2. Place a transducer sheath on the transducer, if needed.
- 3. Place a bite guard around the distal end of the transducer.
- Ensure that both friction brakes are unlocked and both flex controls are in the neutral alignment position before inserting the transducer so that the transducer can bend to accommodate the path of the esophagus.
- 5. Place the transducer in the patient's mouth, and secure the bite guard into place before further advancing the transducer.
- 6. When the transducer has been inserted, press the array rotation control to change the imaging scan plane.
- 7. As necessary, adjust the anterior/posterior and the left/right deflection using the flex controls. Position the transducer for optimal acoustical contact and the required viewing
- 8. When the required scan plane is achieved and good acoustical contact is made, engage both the anterior/posterior and the left/right friction brakes.
- Unlock both friction brakes and move both flex controls to the neutral position to acquire new echocardiographic views, which necessitate further advancement or withdrawal of the transducer, or change in the deflection.
- 10. Unlock both friction brakes and move both flex controls to the neutral position to remove the transducer.

Instructions for Use 6 - 17

Exam Procedures (V7M)

To use the V7M transducer during a transesophageal echocardiogram:

- 1. Remove dentures, if present, and place them in a protected area until after the procedure.
- 2. Place a transducer sheath on the transducer, if needed.
- 3. Place a bite guard around the distal end of the transducer.
- 4. Ensure that the friction brake is unlocked and the flex control is in the neutral position before inserting the transducer so that the transducer can bend to accommodate the path of the esophagus.
- 5. Place the transducer in the patient's mouth, and secure the bite guard into place before further advancing the transducer.
- 6. As necessary, adjust the anterior/posterior deflection using the flex control. Position the transducer for optimal acoustical contact and for viewing the required scan plane.
- 7. When good acoustic contact is made, engage the friction brake.
- 8. Rotate the array rotation control to adjust the imaging scan plane.
- 9. Unlock the friction brake and move the flex control to the neutral position:
 - to acquire new echocardiographic views that require advancing or withdrawing the transducer.
 - to change the deflection.
- Unlock the friction brake and move the flex control to the neutral position to remove the transducer.

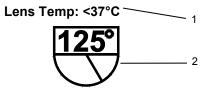
6 - 18 Instructions for Use

Imaging with the V5Ms Transducer

When you connect a transesophageal transducer to the system, the system displays a transducer-specific message.

Transducer	Message	Displays When	Recommended Action
V5Ms	Safety Instructions Review the warnings and precautions as cited in the user's manual for safety leakage current testing, proper use, inspection, and disinfection prior to each use in order to reduce the likelihood of harm to the patient.	The V5Ms transducer is selected.	Click Close .

During imaging with the transesophageal transducer, information displays on the image screen regarding the rotation angle of the transducer array and regarding an indication of temperature at the lens surface of the transducer array.



The Scan Plane Icon indicates the approximate rotation angle of the imaging scan plane.

1 Temperature Indicator

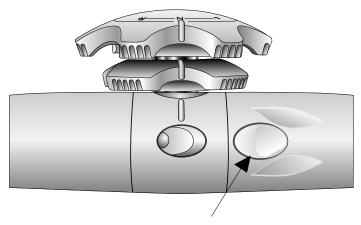
Displays as <37°C until the temperature rises above 37°C

2 Rotation Angle of the transducer array

Instructions for Use 6 - 19

Changing the Imaging Scan Plane (V5Ms)

You can change the imaging plane of the V5Ms transducer by using the array rotation control to rotate the transducer crystal within the distal tip of the transducer in a 0° to 180° range. The starting position for the transducer is 0° .



Example of the array rotation control is located on the handle of the V5Ms transducer.

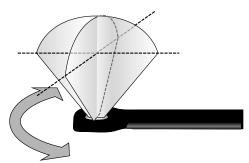
As the array orientation changes, the on-screen scan plane icon updates to indicate the relative direction of the array and the numerical value of the rotation angle.

The angle of 0° is equivalent to the transverse imaging scan plane.	The angle of 90° is equivalent to the longitudinal imaging scan plane.	The angle of 180° provides the mirrored transverse imaging scan plane.
Lens Temp: <37°C	Lens Temp: <37°C	Lens Temp: <37°C
0°	90°	180°

Examples of the **scan plane icon**. The array rotation angle is displayed numerically at the top of the icon.

To change the array orientation:

 Press the array rotation control to increase or decrease the array rotation angle. Press and hold the control to rapidly change the angle.



Example of array rotation on the V5Ms transducer.

6 - 20 Instructions for Use

Temperature Controls and Safeguards (V5Ms)

▲ WARNING: Disconnect the transducer if the system displays the message indicating that the maximum thermal limit is exceeded. (The transducer temperature is 43°C or higher.) Failure to disconnect a transesophageal transducer that has exceeded the maximum thermal limit can burn the patient's esophagus. Reconnect the transducer after the transducer has cooled. Or, use a different transducer.

Because some concerns have been raised about possible thermal injury to the esophagus due to the local buildup of heat during transesophageal echocardiography, the transesophageal transducer incorporates a shut-off mechanism in the interest of patient safety in the unlikely event overheating should occur. For additional information on temperature limitation, refer to EN 60601-2-37 and IEC 60601-2-37.

A temperature sensor mounted in the distal tip of the transducer monitors the temperature of the scanning array and displays the temperature on the screen.

- When the temperature is 37°C or below, the temperature indicator displays <37°C.
- When the temperature is above 37°C, the system displays the actual temperature. When the temperature reaches 40°C, the temperature indicator is highlighted.

Lens Temp: 40°C



Example of temperature indicator displayed above scan plan icon.

When the temperature reaches 41°C and you choose to override the software and continue to scan the patient, OVERRIDE displays next to the scan plane icon.

Lens Temp: 41°C





Example of temperature indicator displayed above scan plan icon.

Instructions for Use 6 - 21

Managing the Lens Surface Temperature (V5Ms)

You can reduce the acoustic output to lower the lens surface temperature.

See also: Imaging Functions that Change Acoustic Output, Safety and Care, Chapter 2, Instructions for Use

To reduce the acoustic output:

- Lower the transmit power.
- Change the scanning mode.

Follow the instructions included in the on-screen messages if the lens surface temperature approaches, reaches, or exceeds the thermal limit.

Message	Displays When	Recommended Action
Thermal Limit	The lens surface	1. Click Close to remove the message.
Near thermal limit. Advise lower output setting.	temperature approaches 40°C.	2. Reduce the acoustic output.
Thermal Limit	The lens surface	1. Click Override.
At thermal limit.	temperature reaches 41°C (the thermal limit).	2. Reduce the acoustic output.
System frozen. Press Override to continue.	47 6 (the thermal limit).	Note: You can click Override and continue to scan the patient when the temperature indicator displays 41°C or higher without lowering the acoustic output. If the acoustic output is not reduced, the lens surface of the transducer array may reach 43°C during imaging. If this happens, the system automatically freezes the image and turns off the transmitted power to the transducer.
Thermal Limit	The lens surface	Note: When the lens surface temperature reaches 43°C, the
Maximum thermal limit exceeded. Disconnect	ded. Disconnect lucer to continue. ore instructions, 43°C (the maximum thermal limit is exceeded).	system stops imaging and turns off the transmitted power to the transducer.
For more instructions,		1. Click Close to remove the message.
see user's manual.		2. Disconnect the transducer.
		Reconnect the transducer after the transducer has cooled. Or, use a different transducer.
		Note: If the original transducer is left in place, it will not be operable until the lens surface of the transducer array has cooled sufficiently (typically less than one minute).

6 - 22 Instructions for Use

Temperature Sensor Failure (V5Ms)

⚠ **WARNING**: Disconnect the transducer if the system displays the message indicating a temperature monitor failure. Remove the transducer from the patient. Failure to disconnect and remove a transesophageal transducer with faulty temperature sensor can burn the patient's esophagus. Contact your Siemens service representative.

Follow the instructions included in the on-screen message if the system detects a temperature monitor failure:

Message	Displays When	Recommended Action
Temperature Monitor Failure	The system detects a	Click Close to remove the message.
Temperature monitor failure.	temperature sensor failure.	Disconnect the transducer.
Disconnect transducer.		3. Remove the transducer from the patient.
		Contact your Siemens service representative.

Instructions for Use 6 - 23

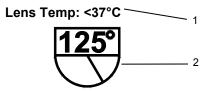
Imaging with the V7M Transducer

⚠ **WARNING**: You must be aware of the patient's core temperature and select the appropriate patient temperature setting when using the V7M transducer. Select the Normal patient temperature setting if the patient's core temperature is between 37.0°C and 37.9°C to reduce the likelihood that the transducer will exceed the thermal limit and burn the patient's esophagus. Select the **Hyperthermic** patient temperature setting if the patient's core temperature is between 38.0°C and 39.4°C to reduce the likelihood that the transducer will reach the thermal limit and stop imaging during the exam.

When you connect a transesophageal transducer to the system, the system displays a transducer-specific message.

Transducer	Message	Displays When	Recommended Action
V7M	Safety Instructions Review the warnings and	The V7M transducer is selected.	From the list box in the on-screen message:
	precautions as cited in the user's manual for safety leakage current testing, proper use, inspection, and disinfection prior to each use in order to reduce the likelihood of		Select the estimated patient temperature setting:
			 If the patient temperature is between 37.0°C and 37.9°C, select Normal.
	harm to the patient. Estimated Patient Temperature: Normal		 If the patient temperature is between 38.0°C and 39.4°C, select Hyperthermic.
	Hyperthermic		2. Click Close.
	Note: Normal is the default setting.		Note: N (normal) or H (hyperthermic) displays in the imaging parameters after you select the estimated patient temperature setting.

During imaging with the transesophageal transducer, information displays on the image screen regarding the rotation angle of the transducer array and regarding an indication of temperature at the lens surface of the transducer array.



The Scan Plane Icon indicates the approximate rotation angle of the imaging scan plane.

- Temperature Indicator Displays as <37°C until the temperature rises above 37°C
- 2 Rotation Angle of the transducer array

6 - 24 Instructions for Use

Changing the Imaging Scan Plane (V7M)

You can change the imaging plane of the V7M transducer by rotating the array rotation control.

As the array orientation changes, the on-screen scan plane icon updates to indicate the relative direction of the array and the numerical value of the rotation angle.

Note: The V7M transducer scan plane is adjustable within the range of -12 $^{\circ}$ to 192 $^{\circ}$. The angle indicator in the scan plan icon does not display when the angle is less than 0 $^{\circ}$ (-1 $^{\circ}$ to -12 $^{\circ}$) or greater than 180 $^{\circ}$ (181 $^{\circ}$ to 192 $^{\circ}$).

The angle of 0° is equivalent to the transverse imaging scan plane.	The angle of 90° is equivalent to the longitudinal imaging scan plane.	The angle of 180° provides the mirrored transverse imaging scan plane.	
Lens Temp: <37°C	Lens Temp: <37°C	Lens Temp: <37°C	
0°	90°	180°	

Examples of the scan plane icon. The array rotation angle is displayed numerically at the top of the icon.

Instructions for Use 6 - 25

Selecting an Estimated Patient Temperature Setting (V7M)

▲ WARNING: The V7M transesophageal transducer can exceed 43°C in the event of a system malfunction, which can harm the patient. Disconnect the V7M transducer from the system during periods of poor perfusion or circulatory arrest or during the hypothermic phase of open heart surgery. Using the V7M transducer in the event of a system malfunction under any of these conditions could harm the patient.



⚠ WARNING: When you are using the Hyperthermic patient temperature setting on a patient whose core temperature is between 38.0°C and 39.4°C, there is a risk the transducer will reach the maximum thermal limit during the exam. At the maximum thermal limit, the transducer will stop imaging. Reduce the transmit power to minimize the possibility of reaching the maximum thermal limit.



⚠ WARNING: When you are using the Normal patient temperature setting on a patient whose core temperature is between 37.0°C and 37.9°C, there is a risk the transducer will exceed the maximum thermal limit. Above the maximum thermal limit, the transducer can burn the patient's esophagus. Reduce the transmit power to minimize the possibility of exceeding the maximum thermal limit.



⚠ **WARNING**: The V7M transducer is not intended for use in patients whose core temperature is below 37.0°C. If the core temperature of the patient is below 37.0°C, the V7M thermal sensor will not prevent the transducer from overheating in the event of a malfunction. If the core temperature of the patient is below 37.0°C, disconnect the transducer from the system until the core temperature of the patient returns to 37.0°C.

When you connected the V7M transducer to the system you selected the estimated patient temperature setting. You can change the estimated patient temperature setting in the image menu if the core temperature of the patient has changed.

To change the patient temperature setting:

Based on the core temperature of the patient, click the required Pt Temp: setting on the image menu.

Estimated Patient Temperature Setting	Core Temperature of the Patient
Normal	37.0°C to 37.9°C
Hyperthermic	38.0°C to 39.4°C

6 - 26Instructions for Use

Temperature Controls and Safeguards (V7M)

▲ WARNING: Disconnect the transducer if the system displays the message indicating that the maximum thermal limit is exceeded. (The transducer temperature is 43°C or higher.) Failure to disconnect a transesophageal transducer that has exceeded the maximum thermal limit can burn the patient's esophagus. Reconnect the transducer after the transducer has cooled. Or, use a different transducer.

Because some concerns have been raised about possible thermal injury to the esophagus due to the local buildup of heat during transesophageal echocardiography, the transesophageal transducer incorporates a shut-off mechanism in the interest of patient safety in the unlikely event overheating should occur. For additional information on temperature limitation, refer to EN 60601-2-37 and IEC 60601-2-37.

A temperature sensor mounted in the distal tip of the transducer monitors the temperature of the scanning array and displays the temperature on the screen.

- When the temperature is 37°C or below, the temperature indicator displays <37°C.
- When the temperature is above 37°C, the system displays the actual temperature. When the temperature reaches 40°C, the temperature indicator is highlighted.

Lens Temp: 40°C



Example of temperature indicator displayed above scan plan icon.

When the temperature reaches 41°C and you choose to override the software and continue to scan the patient, **OVERRIDE** displays next to the scan plane icon.

Lens Temp: 41°C





Example of temperature indicator displayed above scan plan icon.

Instructions for Use 6 - 27

Managing the Lens Surface Temperature (V7M)

You can reduce the acoustic output to lower the lens surface temperature.

See also: Imaging Functions that Change Acoustic Output, Safety and Care, Chapter 2, Instructions for Use

To reduce the acoustic output:

- Lower the transmit power.
- Change the scanning mode.

Follow the instructions included in the on-screen messages if the lens surface temperature approaches, reaches, or exceeds the thermal limit.

Message	Displays When	Recommended Action
Thermal Limit	The lens surface temperature approaches 40°C .	Click Close to remove the message.
Near thermal limit.		2. Reduce the acoustic output.
Advise lower output setting.	approacties 40 C.	Note: If you are using the Normal patient temperature setting for a hyperthermic patient, change the estimated patient temperature setting to Hyperthermic to prevent the system from prematurely reaching the thermal limit. Reselect Normal if you determine the core temperature of the patient has returned to 37.9°C or less.
Thermal Limit	The lens surface	Click Override.
At thermal limit. Acoustic output setting reduced. System frozen. Press Override to continue.	temperature reaches 41°C (the thermal limit).	Note: If you are using the Normal patient temperature setting for a hyperthermic patient, change the estimated patient temperature setting to Hyperthermic to prevent the system from prematurely reaching the thermal limit. Reselect Normal if you determine the core temperature of the patient has returned to 37.9°C or less.
Thermal Limit Maximum thermal limit exceeded. Disconnect	The lens surface temperature reaches 43°C (the maximum thermal limit is exceeded).	Note: When the lens surface temperature reaches 43°C, the system stops imaging and turns off the transmitted power to the transducer.
transducer to continue. For more	thermal militio exoceded).	Click Close to remove the message.
instructions, see user's manual.		2. Disconnect the transducer.
		Reconnect the transducer after the transducer has cooled. Or, use a different transducer.
		Note: If the original transducer is left in place, it will not be operable until the lens surface of the transducer array has cooled sufficiently (typically less than one minute).

6 - 28 Instructions for Use

Temperature Sensor Failure (V7M)

⚠ **WARNING**: Disconnect the transducer if the system displays the message indicating a temperature monitor failure. Remove the transducer from the patient. Failure to disconnect and remove a transesophageal transducer with faulty temperature sensor can burn the patient's esophagus. Contact your Siemens service representative.

Follow the instructions included in the on-screen message if the system detects a temperature monitor failure:

Message	Displays When	Recommended Action
Temperature Monitor Failure	The system detects a	Click Close to remove the message.
Temperature monitor failure. Disconnect transducer.	temperature sensor failure.	2. Disconnect the transducer.
		3. Remove the transducer from the patient.
		Contact your Siemens service representative.

Instructions for Use 6 - 29

Caring for the Transesophageal Transducer

See also: Caring for Transducers, Safety and Care, Chapter 2, Instructions for Use

Cleaning and Storage

Each time the transducer is used, it must be properly cleaned and disinfected.

Approved Cleaning and Disinfection Agents for the Transesophageal Transducer

▲ WARNING: The use of any disinfectants other than those specified here may damage the transducer and, as a result, may create electrical hazards for patients and/or users.



⚠ **WARNING**: Disinfectants and cleaning methods listed are recommended by Siemens for compatibility with product materials, not for biological effectiveness. Refer to disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.

⚠ **WARNING**: Refer to the disinfectant manufacturer's instructions for guidance on proper rinsing of the disinfectant from the transesophageal transducer. Any disinfectant remaining on the transesophageal transducer can burn the patient's mouth or esophagus.

Transducer	Approved Cleaners	Approved Disinfectants	
V5Ms	ENZOL	CIDEX	
	Gigasept FF	CIDEXPLUS	
	Transeptic	CIDEX OPA	
		Gigasept FF	
		Milton	
		PI-Spray II	
		Super Sani-Cloth	
V7M	ENZOL	CIDEX	
	Gigasept FF	CIDEXPLUS	
	Transeptic	CIDEX OPA	
		Gigasept FF	
		Milton	
		Rely+On Virkon	

6 - 30Instructions for Use

Cleaning and Disinfecting the Transducer

WARNING: To avoid electrical shock and damage to the system, disconnect the transducer prior to cleaning or disinfecting.

⚠ WARNING: Never use hot steam or Ethylene Oxide (EO) for disinfecting the transesophageal transducer. These disinfection methods may damage the jacketing material, the transducer array, or the articulation controls, making the device unsafe to use on a patient.

⚠ WARNING: Never use iodine or solutions containing iodine for cleaning or disinfecting the transesophageal transducer. Iodine will cause degradation of the shaft material and of the distal tip resulting in a dangerous electrical hazard.

⚠ Caution: Never clean the transducer with bleach. Cleaning with bleach will damage the flexible shaft jacketing material, which will invalidate the manufacturer's warranty and could increase leakage current.

⚠ Caution: The distal tip is very sensitive to pressure. Care must be taken not to damage the tip while cleaning it.

⚠ Caution: Do not bend the flexible shaft into a curve of less than 30.5 cm in diameter.

△ Caution: The transducers have been designed and tested to be able to withstand high-level disinfection as recommended by the manufacturer of the disinfectant product. Carefully follow the disinfectant manufacturer's instructions.

⚠ Caution: Never immerse the entire transesophageal transducer in any solution. Immersion of the transducer handle could introduce fluid into the housing and cause damage to the controls or steering cables.

△ Caution: Do not clean the transducer with ethanol or methanol. Ethanol and methanol can damage the transducer.

△ Caution: (V5Ms only) Do not immerse the transducer above 100 cm from the distal tip; doing so may damage the controls.

△ Caution: (V7M only) Do not immerse the transducer above 70 cm from distal tip; doing so may damage the controls.

Instructions for Use 6 - 31

To clean the transesophageal transducer:

- 1. Disconnect and remove the transducer from the ultrasound system.
- While wearing protective gloves, remove the transducer sheath, if any. Dispose of the transducer sheath according to local, state, and regional laws and regulations for biohazardous waste.
- 3. Clean the distal tip and flexible shaft of the transducer.
 - (V5Ms only) Clean the distal tip and flexible shaft with gauze pads that have been soaked in an approved cleaner or immerse the tip and shaft up to the 100-cm mark in an approved cleaner.

See also: For a list of approved cleaners, refer to p. 6-30.

- (V7M only) Clean the distal tip and flexible shaft with gauze pads soaked in mild soapy lukewarm tap water (below 26°C).
- 4. Use clean gauze pads to wipe the parts of the transducer that cannot be immersed, including the cable, handle, articulation controls, and connector. Avoid touching the electrical components on the connector.
 - (V5Ms only) Dip gauze pads in a mild, soapy solution.
 - (V7M only) Dampen gauze pads with tap water.
- 5. Rinse the distal tip and flexible shaft of the transducer.
 - (V5Ms only) Rinse the distal tip and flexible shaft up to the 100-cm mark with warm tap water.
 - (V7M only) Rinse the distal tip and flexible shaft up to the 70-cm mark with lukewarm tap water (below 26°C).
- (V5Ms only) Clean the transducer handle with a pad moistened in 70% isopropyl alcohol. Do not use ethanol.
- 7. Disinfect the transducer.

6 - 32 Instructions for Use



V5Ms: Submerge only to the 100-cm mark. V7M: Submerge only to the 70-cm mark.

To disinfect the transesophageal transducer:

Note: If using a disinfectant wipe, thoroughly wipe the distal tip and flexible shaft of the transducer.

- Immediately after cleaning, submerge the distal tip and the flexible shaft in an approved disinfectant. You must observe the restrictions for immersion of the transducer.
 - **Note:** Keep the transducer connector, connector strain relief, transducer handle, and articulation controls dry while immersing the transducer in an approved disinfectant to the level indicated.
 - (V5Ms only) Do not immerse the transducer more than 100 cm above the distal tip.
 - (V7M only) Do not immerse the transducer more than 70 cm above the distal tip. Do not immerse the transducer in the disinfectant agent for more than one hour.

See also: For a list of approved disinfectants, refer to p. 6-30.

- 2. Carefully follow the disinfectant manufacturer's instructions for high-level disinfection.
- 3. Dry the transducer with gauze pads. Do not use heated air.
- 4. Store the disinfected transducer in the original shipping case only after disinfecting. The transesophageal transducer is fragile and should not be stored in the transducer holders on the system.

Instructions for Use 6 - 33

Storing and Handling

The transesophageal transducer is a mechanically sensitive device. The distal tip is especially sensitive to bumps, scrapes, and jarring. Take extreme care when handling and storing the transducer. Never move the distal tip by hand. Always use the flex controls.

When you store the transesophageal transducer, ensure that the friction brakes are off, the distal tip is straight, and the cables and flexible shaft are free of kinks.

Store the disinfected transducer in the original shipping case only after disinfecting. The transesophageal transducer is fragile and should not be stored in the transducer holders on the system.

Transporting the Transducer

Use the case for shipping or for moving the transducer from one site to another. Take care that the distal tip is straight and that the cable is free of kinks as you carefully place the transducer in the foam padding. Before you close the lid, ensure that nothing protrudes from the case.

Service and Repair

Do not attempt to repair or alter any part of the transesophageal transducer. Contact your local Siemens service representative office immediately if your transducer appears to be damaged or malfunctions in any way.

6 - 34 Instructions for Use

Preventing Injury and Equipment Damage

Following the preventive measures outlined below will help ensure patient safety.

Preventive Measure	Problem	Potential Harm to Patient/Potential Damage
Place both V5Ms flex controls in the neutral alignment position, without the friction brakes applied, when you insert or withdraw it. Do not force the transducer.	Improper insertion or withdrawal	Esophageal cuts, bruising, bleeding, ligament damage, perforations
Place the V7M flex control in the neutral alignment position, without the friction brake applied, when you insert or withdraw it. Do not force the transducer.	Improper insertion or withdrawal	Esophageal cuts, bruising, bleeding, ligament damage, perforations
Inspect the transesophageal transducer prior to each use to ensure that it is functioning properly and that it has no cuts, tears, fraying, loose parts, or rough edges.	Mechanical damage, electrical damage, leakage current	Severe trauma, esophageal cuts, bleeding, perforation, electrical burns, serious electrical hazards
Use only isolated output electrosurgical units with the transesophageal transducer. Disconnect the transducer when it is not in use.	Non-isolated electrosurgical units	Electrical burns
Adjust the Transmit Voltage (dB or %) as low as clinically useful. Observe the on-screen temperature warning messages and respond accordingly.	Improper transducer temperature and/or acoustic output	Esophageal burns
For maximum safety, disconnect the transesophageal transducer from the system prior to defibrillation rather than relying on the transducer's built-in safeguards.	Defibrillation	Electrical burns
Maintain a regimen of electrical safety checks.	Electrical damage, leakage current	Esophageal burns, electrical damage
Put the transducer in the neutral position, without either friction brake applied, when inserting or withdrawing it. Minimize pressure applied to the articulating section and distal tip. Do not let the distal tip displace tissue for more than five minutes.	Pressure necrosis	Permanent damage to esophageal lining

Instructions for Use 6 - 35

Preventive Measure	Problem	Potential Harm to Patient/Potential Damage
Do not use the transesophageal transducer if a patient has esophageal varices or masses or strictures are present.	Esophageal Varices	Excessive bleeding
Do not use the transesophageal transducer for any procedure requiring hyperextension of the neck.	Improper patient position	Paralysis of the vocal cord
Be aware that a patient with a loose tooth could lose the tooth in a TEE procedure.	Improper assessment of dental risk	Tooth loss
Use a bite guard.	No dental protection, leakage current	Dental damage, electrical damage
Follow the bite guard manufacturer's instructions to clean, disinfect and rinse the bite guard if you use a reusable bite guard.	Disinfectant residue on the bite guard and transesophageal transducer	Burns in the mouth and esophagus
Refer to the disinfectant manufacturer's instructions for guidance on proper rinsing of the disinfectant from the transesophageal transducer.		
Never use Steam Heat or Ethylene Oxide for disinfecting the transesophageal transducer.	Improper cleaning resulting in electrical damage	Esophageal burns
Do not use any disinfectants other than those specified.		
Do not use iodine or solutions containing iodine for cleaning or disinfecting the transesophageal transducer.		
Immerse the transesophageal transducer no longer than the time required by the manufacturer for high-level disinfection. Never immerse transducer controls or the system connector in liquids.	Improper disinfection, exposing electrical workings to liquids	Nosocomial infection, electrical damage affecting image quality, electrical safety, or mechanical operation
Do not force distal tip articulation. Always use the controls to alter articulation.	Forcing the deflection control	Stretching or breaking deflection controls
When the transesophageal transducer is not in use, store it in the original case or suspend it from a wall rack. Do not store the transducer in a tight coil.	Improper storage	Damage to array elements, cuts and abrasions to the flexible shaft

6 - 36 Instructions for Use

V5Ms Transducer Technical Description

Transducer Type: Phased Array, multiplane

Elements: 64

Array Rotation Angle: 0° to 180°

Distal Tip Articulation: 120° anterior, 90° posterior

45° right, 45° left

Maximum insertion length: 1080 mm

Maximum insertion width: 15 mm

2D-mode Transmit

Frequencies: 4.0 MHz, 5.0 MHz, 6.0 MHz, 7.0 MHz

Color mode Transmit Frequencies, including

CDV, Color DTI: 3.5 MHz, 3.75 MHz, 4.0 MHz

Doppler Transmit

Frequencies, including PW,

SCW, Aux CW,

Pulsed Wave DTI: 3.5 MHz, 3.75 MHz, 4.0 MHz

Imaging Modes: 2D-mode, PW Doppler, Steerable CW Doppler, Color mode, M-mode, Color DTI,

Pulsed Wave DTI, Anatomical M-mode

Maximum Image

Field of View: 90°
Image: Sector

Operating Environment

Temperature: 10°C to +40°C **Relative Humidity:** 10% to 80%

Storage Environment

Temperature: -10°C to +50°C Relative Humidity: 10% to 95%

Degree of protection against electrical shock:



V5Ms transducers with this label are certified as type BF defibrillator proof per IEC 60601-1 Standard for Safety of Medical Equipment



V5Ms transducers with this label are certified as type BF (not defibrillator proof) per IEC 60601-1 Standard for Safety of Medical Equipment

Degree of protection against ingress of fluid:

IPX8

Instructions for Use 6 - 37

Measurement Accuracy

Rotation angle of the transducer array:

Temperature:

≤3°	
Temperature	Accuracy
>41°C	40.1 ≤ 41°C
>=41°C	40.1 ≤ 41°C
>=42°C	41.1 ≤ 42°C
>=42°C and system freeze	41.9 ≤ 43°C

EMC Note: Operating the transducer in close proximity to sources of electromagnetic fields, such as radio transmitters, may lead to temporary degradation or interference visible on the image monitor screen. A lightening of image background may be noticed while visualizing hypoechoic structures, or color spectral interference, or jitter, or horizontal lines in the image screen may occur. The transducer and system have been designed and tested to withstand such interference and will not be permanently affected.

6 - 38 Instructions for Use

V7M Transducer Technical Description

Transducer Type: Phased Array, multiplane

Elements: 48

Range of Array Rotation

Angle: -12° to 192°

Distal Tip Articulation: 120° anterior, 90° posterior

Minimum Patient Weight: 3.5 kg (7.7 lbs) and above

Maximum insertion length: 700 mm

Maximum insertion width: 10.7 mm

2D-mode Transmit

Frequencies: 4.0 MHz, 5.0 MHz, 6.0 MHz, 7.0 MHz, 8.0 MHz

Color mode Transmit Frequencies, including

CDV, Color DTI: 3.5 MHz, 3.75 MHz, 4.0 MHz, 4.75 MHz

Doppler Transmit

Frequencies, including PW,

SCW, Aux CW,

Pulsed Wave DTI: 3.5 MHz, 3.75 MHz, 4.0 MHz

Imaging Modes: 2D-mode, PW Doppler, Steerable CW Doppler, Color mode, Color DTI,

Pulsed Wave DTI, M-mode, Anatomical M-mode

Maximum Image

Field of View: 90° Image: Sector

Operating Environment

Temperature: 0°C to +45°C Relative Humidity: 10% to 95%

Storage Environment

Temperature: -10°C to +45°C Relative Humidity: 10% to 95%

Degree of protection against electrical shock:

★

V7M transducers with this label are certified as type BF (not defibrillator proof) per IEC 60601-1 Standard for Safety of Medical Equipment

Degree of protection against ingress of fluid:

IPX8

Instructions for Use 6 - 39

Measurement Accuracy

Rotation angle of the transducer array:

Temperature:

N/A

Temperature	Accuracy	
40°C	-0.6°C to +0.4°C	
41°C	-0.5°C to +0.5°C	
42°C	0.0°C to +1.0°C	
43°C	+0.4°C to +1.4°C	

EMC Note: Operating the transducer in close proximity to sources of electromagnetic fields, such as radio transmitters, may lead to temporary degradation or interference visible on the image monitor screen. A lightening of image background may be noticed while visualizing hypoechoic structures, or color spectral interference, or jitter, or horizontal lines in the image screen may occur. The transducer and system have been designed and tested to withstand such interference and will not be permanently affected.

6 - 40 Instructions for Use

7 Specialty Transducers

9EVF4 Transducer	3
Transducer Markings	
Imaging with the 9EVF4 Transducer	
Technical Data	5

Instructions for Use 7 - 1

7 Specialty Transducers

7 - 2 Instructions for Use

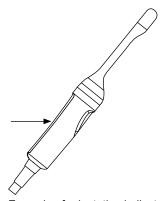
9EVF4 Transducer

⚠ **WARNING**: Before attempting to use endocavity transducers, you should be trained in ultrasonography and endocavity scanning techniques, and you should be thoroughly familiar with the safe operation of the ultrasound imaging system.

The 9EVF4 transducer is a fourSight 4D (curved array) transducer. The 9EVF4 transducer is designed for endovaginal imaging of the general pelvic region, such as during the early stages of pregnancy, for detection of ectopic pregnancies, and for examination of the follicles, ovaries, fallopian tubes, inner cavities, bladder, and uterus.

Transducer Markings

The 9EVF4 transducer is designed with an orientation indicator on the handle of the transducer.



Example of orientation indicator on transducer handle.

Instructions for Use 7 - 3

Imaging with the 9EVF4 Transducer

The 9EVF4 transducer supports all of the functions and controls that are available in 2D-mode, M-mode, Color, Power, Pulsed Doppler, and during volume acquisition.

The 9EVF4 transducer samples a 173° maximum sector angle. You can select a structure of interest between 18° and 173° within the scan plane. You can also adjust the scan angle.

To

Do This

Select a steering angle for the 9EVF4 transducer

- Adjust the steering angle.
 - Rotate Steer to select the required angle.
 - For systems without a touch screen, select Steer and then rotate MENU to select the required angle.

The steering angle increases or decreases in increments of 5° for each rotation. An on-screen graphic indicates the steering angle of the transducer when the steering angle is greater or less than 0° .



Example of the on-screen symbol for the 9EVF4 transducer during 2D-mode imaging.



Example of the on-screen symbol for the 9EVF4 transducer during volume acquisition.

Note: During *four*Sight imaging or 3-Scape imaging (when using **Auto Sweep**), the range of settings depends on the selected angle.

Select a scan angle (to determine the amount of data for volume acquisition) for the 9EVF4 transducer

- During volume acquisition setup or during volume acquisition, adjust the scan angle.
 - Select Angle and then select the required angle.
 - For systems without a touch screen, select Angle and then rotate MENU to select the required angle.

During 3-Scape imaging, the system computes the scan duration based on the selected angle, acquisition speed, and the current frame rate and displays the steering angle and acquisition time on the image menu.

Instructions for Use

Set the steering angle back to zero

- Reset the steering angle.
 - Select Reset Angle.
 - o For systems without a touch screen, select Reset Steer Angle.

7 - 4

Technical Data

Transducer type: Mechanically-driven curved array

Number of Elements: 192

Frequency range:

2D-Mode 4.0 MHz, 7.0 MHz, 9.0 MHz

Doppler and Color 4.0 MHz, 5.5 MHz, 7.5 MHz

THI 5.0 MHz, 7.0 MHz, 9.0 MHz

Focus: 24 mm $\pm 10\%$

Minimum Depth: 3 cm

Maximum Depth: 16 cm

Operating modes: 2D-mode, M-mode, 2D/M-mode, 2D/Doppler, Color, Power, Pulsed Doppler

Maximum displayable

field of view: 173°

Maximum scan angle

(wobble angle): 90°

Radius of Curvature: 13 mm

Orientation: On-screen graphical icon indicates steering angle

Operating environment: +20°C to +40°C

Storage: -5°C to +50°C

Humidity: Up to 80% relative humidity (non-condensing)

Instructions for Use 7 - 5

7 Specialty Transducers

7 - 6 Instructions for Use

8 Physiologic Function Physiologic Function

Physi	iologic Function	3
Α	ctivating the ECG Feature	4
Е	CG Troubleshooting Guide	6

Instructions for Use 8 - 1

8 Physiologic Function

8 - 2 Instructions for Use

Physiologic Function

⚠ **WARNING:** Use ECG for timing purposes only. It is not intended for diagnostic usage or patient monitoring.



▲ WARNING: Do not use the ECG feature in conjunction with electrosurgery or diathermy equipment.



⚠ WARNING: To reduce the risk of electric shock and burns, use only the cable and patient leads supplied with the ECG feature. Use of other ECG cables could defeat the current-limiting and electrical safety features of the ECG.



⚠ Caution: To avoid possible damage to the ECG cable, do not pull on the cable when disconnecting the ECG connector. Always grasp the connector housing.

The Physio module consists of the ECG feature.

The ECG feature includes three leads attached to a six-pin ECG cable, along with a start-up kit of ECG electrode patches.

The electrical activity controlling the heart muscle is detected by placing ECG electrode patches in specific locations on the patient and amplifying the electrical signals that produce the ECG trace display on the system monitor.

EMC Note: Operating the ultrasound imaging system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations, may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

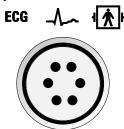
Instructions for Use 8 - 3

Activating the ECG Feature

Note: The ECG inputs are defibrillation proof. However, in the event of defibrillation while using the ECG function, the ECG inputs may become saturated (overloaded). An ECG pattern may not be visible for up to 30 seconds. After this time, the ECG function should return to normal operation.

To activate ECG:

 Connect the six-pin ECG cable to the connector labeled "ECG" on the left front of the system.



ECG connector.

- 2. Attach the ECG electrode patches to the patient in the locations specified below.
- 3. Connect each lead to the appropriate patch.

The ECG trace is activated when you connect the ECG cable.

Note: The system cannot display a trace unless all three leads are connected to a patient.

4. To dismiss the message that displays when an ECG lead becomes disconnected, click **Close**. Or, reconnect the disconnected ECG lead.

In keeping with existing international standards, the ECG leads for systems that operate at 115V (for example, North and South America) are red, white, and black. They are labeled RA (right arm), LA (left arm), and LL (left leg). Leads for systems that operate at 230V (for example, Europe) are green, red, and yellow. They are labeled R (right arm), L (left arm), and F (left leg).

Patient Location	100V	115V	230V	
Left leg	Green	Red	Green	
Right arm	Red	White	Red	
Left arm	Yellow	Black	Yellow	

8 - 4 Instructions for Use

To adjust the ECG trace:

- Select More and then select Physio.
- For systems without a touch screen, press Physio on the keyboard.

Do this (Available only when Manual Gain is enabled on the system configuration menu) Adjust the wave amplitude of the trace System Config > Physio System Increase or decrease the wave amplitude. • Rotate [Gain] to select Gain Min or Gain Max. Gain **Ž** Gain. For systems without a touch screen, select Increase Gain or Decrease Gain on the image menu. Decrease Gain Increase Gain. Position the trace up or Reposition the trace. down on the image Rotate [Position] to select Position Min or Position Max. screen Position × Position. o For systems without a touch screen, select Move ECG Up or Move ECG Down. Move ECG Up. Move ECG Down. Adjust the scrolling (Available during 2D-mode only) speed of the trace Select a setting. • Rotate [Sweep Speed]. o For systems without a touch screen, rotate [Menu]. Note: During Doppler or M-mode, the trace has the same scrolling speed as the Doppler spectrum or M-mode sweep.

Instructions for Use 8 - 5

То	Do this
Display or hide a trace on an image	Select ECG.
Enable trigger markers	Enable the first ECG trigger.
at specific points in the cardiac cycle	Press the first Delay control.
cardiac cycle	 For systems without a touch screen, select T1 on the image menu.
	Enable the second ECG trigger.
	 Press the second Delay control.
	 For systems without a touch screen, select T2 on the image menu.
	The system displays a trigger as a blue vertical line on each cycle of the ECG trace. The first trigger is twice the length of the second trigger.
	Each trigger defines the time when the system updates (refreshes) the 2D-mode image. If multiple 2D-mode images are displayed, the system updates only the real-time image. For example, if Dual format is selected with only the left image displayed in real-time, the system updates only the left image.
	Note: If you activate a mixed imaging mode that includes M-mode or Doppler, the system deactivates the trigger function.
Set the trigger delay(s)	Set a trigger delay for Trigger 1.
	Rotate the first Delay control.
	 For systems without a touch screen, select Delay and then rotate [Menu].
	2. Set a trigger delay for Trigger 2.
	Rotate the second Delay control.
	 For systems without a touch screen, select Delay and then rotate [Menu].
	Each trigger delay setting determines the position of the related trigger. The system retains the trigger delay setting(s) until the system is powered off.
	Note: Increasing the trigger delay positions the trigger farther to the right of the QRS complex.

ECG Troubleshooting Guide

Symptom	Possible Cause
ECG trace is not present, or	 The ECG cable is not properly attached to the system.
displays as a flat line	 All three leads are not connected to the patient.
	 Leads are poorly connected to the cable.
	 Leads are poorly connected to the patient.
	 Leads are incorrectly placed on the patient. Remove the ECG patch, clean the skin, and attach a new ECG patch to the patient.
	 Gain is set too low.
Cannot position a trigger	No R-wave present.
	 Too much movement by the patient.
ECG trace is noisy, ragged, or erratic	 A lead or leads may be detecting muscle movement. Inspect the ECG patch placement and reposition the lead(s) on the patient as necessary.
	 The conductive gel pad of an ECG patch has evaporated (dried out). Replace the ECG patch with a new one (check the expiration date of the new patch).
Trigger is not visible on the trace	A trigger may be superimposed on the R-wave.

8 - 6 Instructions for Use

9 eSieFusion Imaging

eSieFusion Overview	3
Terminology Used in This Chapter	5
Activating and Deactivating eSieFusion	6
Quality Indicators	7
Loading the Reference Data	8
eSieFusion Functions	8
eSieFusion Navigator	9
eSieFusion Navigator Controls	9
Working with eSieFusion	11
Real-time Imaging	14
Supported Imaging Functionality	14
Interventional Procedures	15
Planning Data	17
Image Alignment	21
Adjusting the Image Alignment	22
Troubleshooting	
Setting up the Tracking System for eSieFusion Imaging	25
Connecting the Electronics Unit to the Ultrasound System	25
Connecting the Transmitter	26
Repositioning the Transmitter	26
Attaching the Sensors to the Electronics Unit	27
Attaching Sensors to the Transducer or Needle	27
Troubleshooting the Tracking System	27
Maintenance, Cleaning, and Care for eSieFusion Imaging	28
Daily Checklist	28
Cleaning and Disinfecting the Tracking System Equipment	28
Cleaning and Disinfecting the Sensors	28

9 eSieFusion Imaging

9 - 2 Instructions for Use

eSieFusion Overview

▲ WARNING: This feature uses reference data collected using other imaging modalities. Variability in system performance, operator technique, patient characteristics, patient movement, and other factors may affect image alignment and sensor tracking data. At all times, the clinician is advised to carefully review the on-screen data and confirm the information presented with clinical judgment.



⚠ **WARNING**: The tracking system generates magnetic fields that can interfere with implantable devices such as pacemakers and implantable cardioverter-defibrillators (ICDs). If the patient has such an implantable device, you should be aware of any interference in its operation and immediately power off the ultrasound system.



⚠ **WARNING**: Percutaneous procedures always involve heightened risk to the patient and to the operator. Clinicians using biopsy or ablation devices under ultrasound guidance should be trained and must observe proper procedures when attaching tracking sensors to the transducer or the needle to avoid inaccurate tracking or alignment.

eSieFusion imaging enables viewing of a real-time ultrasound image aligned with reference data acquired using another imaging modality, such as computed tomography (CT) or magnetic resonance imaging (MRI). You can use the blended image for visualization during diagnostic ultrasound exams, ultrasound-quided ablation procedures, and ultrasound-quided biopsy procedures.

The eSieFusion feature is compatible with the following transducers and exam types.

Transducer	Exam Types
6C1 HD	Abdomen, Renal
4V1	Abdomen, Renal
4C1	Abdomen, Renal
6C2	Abdomen, Renal
9L4	Musculoskeletal

The eSieFusion feature requires the following tracking system equipment.

Equipment	Description
Electronics unit	Provides connections to the transmitter, the transducer sensors, and the needle sensor.
Transmitter	Connected to the electronics unit. Generates a magnetic field for determining the location of the transducer or needle.
Transducer sensor	Attached to the transducer and the electronics unit. Provides location and orientation information to the tracking system.
Needle tracking sensor	Inserted into the needle and attached to the electronics unit. Provides location and orientation information to the tracking system.

See also: Equipment, eSieFusion Imaging, Technical Description, Appendix A, Instructions for Use

Instructions for Use 9 - 3

Example of eSieFusion screen during real-time imaging.

- 1 Blended image
- 2 Tracking quality indicator
- 3 Orientation indicator
- 4 Navigator

For systems without a touch screen, the system displays the eSieFusion menu selections on the left side of the image screen, above the Navigator.

9 - 4 Instructions for Use

Terminology Used in This Chapter

Term	Definition	
blended image	An overlay of reference data on a real-time ultrasound image.	
electronics unit	Component of the tracking system that provides connections to the transmitter, the transducer sensors, and the needle sensor.	
fuse	To align reference data with the same anatomy or area of interest in a real-time ultrasound image.	
image	In this chapter, the term <i>image</i> refers to an ultrasound image, reference data, or a blended image. When a function applies only to specific type(s) of images, the images types are explicitly named.	
landmark	A marker on a displayed image used to indicate a point of interest on the patient anatomy.	
level	The midpoint of the range of values displayed in the reference data. Adjusting the window and level settings for reference data is similar to adjusting contrast in an ultrasound image.	
multiplanar reconstruction (MPR)	A rendered view of a single plane (axial, sagittal, or coronal) of a volume.	
Navigator	A list of all planning data and alignments.	
needle path	A guideline drawn on the reference data for use during an interventional procedure.	
planning data	Landmarks, segmentations, and needle paths created for use as references during an interventional procedure.	
reference data	A previously acquired data set, for example computed tomography (CT) or magnetic resonance imaging (MRI), saved in DICOM format.	
segmentation	The process of identifying the anatomy of interest (foreground) on the reference data.	
	 Line segmentation identifies the foreground using a line drawn through the anatomy of interest. 	
	 Seed segmentation identifies the foreground (for example, a lesion) and background (for example, surrounding tissue) using landmarks (seed points). 	
tracking system	The eSieFusion hardware and software that detects the location and orientation of the transducer and needle.	
window	The range of values displayed in the reference data. Adjusting the window and level settings for reference data is similar to adjusting brightness in an ultrasound image.	

Instructions for Use 9 - 5

The tracking system must be powered on and a transmitter and at least one transducer sensor must be connected to the electronics unit before you activate eSieFusion.

See also: Setting up the Tracking System for eSieFusion Imaging, p. 9-25

To activate or deactivate eSieFusion:

Prerequisite: You must have a data set in the local database before activating eSieFusion. Register the patient through the patient browser and then select a compatible transducer and exam type before activating eSieFusion.

- 1. Select the control assigned to activating the feature.
 - Select More and then select eSie Fusion.
 - For systems without a touch screen, click eSie Fusion on the image menu.



The ultrasound system displays a message while the tracking system initializes and then activates real-time imaging and displays selections for eSieFusion.

2. To exit eSieFusion, press 2D.

During color imaging, press **2D** once to exit Color. Press **2D** twice to exit eSieFusion imaging.

When you exit eSieFusion, the transmitter is deactivated.

Note: eSieFusion retains all saved planning data and alignments until you end the exam or register a new patient.

9 - 6 Instructions for Use

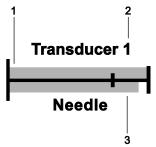
Quality Indicators

After the tracking system is initialized, the ultrasound system displays graphical tracking quality indicators for the transducer sensor and the needle tracking sensor. The indicator displays a green bar across the width of the indicator when tracking quality is high. If the indicator displays a yellow bar, move the transmitter closer to the patient.

The system displays a message if the transducer or needle is not detected:

Sensor 1 Unplugged

Needle Unplugged



Example of the tracking quality indicators.

- 1 Tracking quality indicator for the transducer sensor
- 2 The port number on the tracking system for the active transducer sensor
- 3 Tracking quality indicator for the needle sensor

Instructions for Use 9 - 7

Loading the Reference Data

You must import reference data to the local database (system hard drive) before you load reference data to an exam.

See also: Importing Patient Data, Patient Data Management, Chapter C2, Features and Applications Reference

To load reference data to eSieFusion:

Note: If you manually entered the patient name, patient ID, date of birth, and gender on the patient registration form, the entries are case sensitive and must match the corresponding information for the reference data.

- Click Tree on the View menu in the patient browser and then select and register the patient, if necessary.
- 2. Activate eSieFusion.
- 3. Double-click the series for the reference data to load. When the data is loaded, the system closes the patient browser and displays the reference data on the image screen.

eSieFusion Functions

eSieFusion provides tools for the following primary functions.

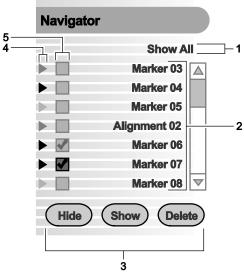
Function	Description	
Real-time imaging	Use the Scan tools to acquire images, optimize images, make measurements, or perform interventional procedures.	
	See also: Real-time Imaging, p. 9-14	
Planning data	Use the Plan tools to identify the anatomy of interest and draw planned needle paths for an interventional procedure.	
	See also: Planning Data, p. 9-17	
Image alignment	Use the Fuse tools to initialize and adjust the alignment of the ultrasound image and reference data.	
	See also: Image Alignment, p. 9-21	

9 - 8 Instructions for Use

eSieFusion Navigator

The Navigator lists all planning data and alignments created for the displayed image. Planning data includes landmarks, segmentations, and needle paths. Each time you create planning data, the system displays a unique marker on the image and updates the Navigator with a corresponding entry. The color of the on-screen marker matches the color of the entry marker in the Navigator.

Note: Alignments do not display a corresponding on-screen marker.



Example of eSieFusion Navigator.

- 1 Menu to limit the list of entries displayed in the Navigator
- 2 List of entries
- 3 Controls to display, hide, or delete planning data or alignments on the image
- 4 Entry marker
- 5 Check boxes to select the entries to hide, display, or delete

eSieFusion Navigator Controls

Type of Planning Data	Example of Navigator Label	Example Marker on the Image
Landmark	Marker 01	MK01
Pair of corresponding points (identified using the point alignment method)	Pair Markers 03	PtC03
Needle path guideline	Needle Path 01	Pink outline
Segmentation (outline of an area of interest)	Segmentation 04	Segmentation dots or outline
Alignment	Alignment 02	

Instructions for Use 9 - 9

То	Do this
Rename an entry in the Navigator	Double-click the entry text in the list.
	2. Enter the new name in the text box and then press Enter on the keyboard.
	The system updates the name in the Navigator and on the image.
	Note: If the new name exceeds the available space, the system displays an ellipsis () at the end of the name.
Permanently remove planning data or alignments from the image	Select the check box for the required entries and then click Delete .
	The system removes the markers for the selected entries from the image and removes the corresponding entries from the Navigator.
Temporarily remove selected	 Select the check boxes for the required entries and then click Hide.
planning data on the image	The system removes the markers on the image for the selected entries.
	 To redisplay hidden planning data, select the check boxes for the required entries and then click Show.
Limit the list of entries in the Navigator	Click the current Filter Navigator List selection and then select the entries to include in the Navigator:
	 Show All displays all entries for planning data and alignments.
	 Show Segmentation displays only the entries for outlines created using line segmentation or seed segmentation.
	 Show Needle Path displays only the entries for planned needle paths.
	 Show Marker displays only the entries for landmarks.
	 Show Point Correspondence displays only the entries for pairs of alignment markers. (Available only when point alignment is activated.)
	 Show Alignment displays only the entries for saved alignments.
	 The Navigator displays only the selected entries in the list.
	2. To redisplay all entries in the Navigator, click Show All.

9 - 10 Instructions for Use

Working with eSieFusion

То	Do this
Change the display format	(Available only when a blended image is displayed. Biopsy controls are available in 1:1, 2:1 and 1:3 display formats.)
	1. Use the control assigned to changing the display format.
	Rotate [Layout].
	 For systems without a touch screen, press the Layout soft key.
	2. Select the required display format:
	 1:1 displays the blended image in a full screen format.
	 2:1 displays the reference data on the left side of the screen and the ultrasound image on the right side of the screen.
	 1:3 displays the blended image on the left side of the screen. The right side of the screen displays multiplanar reconstructions (MPRs) and a volume rendering.
	 4:1 displays the sagittal MPR in the upper left quadrant, the coronal MPR in the upper right quadrant, the axial/transversal MPR in the lower left quadrant, and a volume rendering in the lower right quadrant. This layout does not support biopsy.
Measure a distance	(Available only for 2D images during real-time imaging or planning)
	Note: The measurement units setting in system configuration does not apply to eSieFusion. The system always displays measured results in millimeters (mm) when eSieFusion is activated.
	1. Select Distance .
	2. Position and then anchor the first marker.
	3. Position and then anchor the second marker.
	The system displays the measured results on the image screen.
	4. To temporarily hide the measured results, select Measured Results .
	5. To delete the most recent measurement performed:
	Press DELETE.
	 For systems without a touch screen, press the Delete soft key.
	You can delete all completed measurements in reverse sequence.
	6. To exit the measurement function, select Distance .

Instructions for Use 9 - 11

То	Do this	
Position a landmark	(Not available during system freeze or image alignment)	
	Note: If you position landmarks on the ultrasound image before you load the reference data, the system deletes the landmarks when the reference data is loaded.	
	1. Activate the landmark tool.	
	Select Landmark.	
	 For systems without a touch screen, press UPDATE to activate the landmark tool. 	
	Pointer for positioning a landmark.	
	2. Click the required location for the landmark.	
	The system displays a marker and a unique label on the image and updates the Navigator with a corresponding entry.	
Display or hide all planning	(Available only when reference data is displayed)	
data	Select Structures.	
Adjust the size or position of	1. Select 2D FOV .	
the FOV	2. Select Size or Position.	
	3. Roll the trackball to resize or reposition the FOV.	
	4. Press SELECT.	
Activate color and adjust the	1. Press C and then select the color region of interest.	
size or position of the color	2. Select Size or Position.	
region of interest (C ROI)	3. Roll the trackball to resize or reposition the C ROI.	
	4. Press SELECT.	
Deactivate color imaging	■ Press 2D .	
	 To exit eSieFusion, press 2D again. 	
Change the image orientation	To change the direction of the image horizontally (right-to-left or left-to-right):	
	Select L/R Flip.	
	 For systems without a touch screen, select L/R Flip On or L/R Flip Off. 	
	 To change the direction of the image vertically (top-to-bottom or bottom-to-top): 	
	Select U/D Flip.	
	 For systems without a touch screen, select U/D Flip On or U/D Flip Off. 	
Reset the image orientation	 Select Reset Orientation. 	
Zoom a blended image	Press and then rotate ZOOM.	
Pan a blended image	a. Activate the pan function.	
	Select Pan.	
	 For systems without a touch screen, press NEXT to select Pan. 	
	b. Select the blended image.	
	c. Roll the trackball to reposition the image.	
	d. Click the blended image to anchor the position of the image.	
	e. To restore the previous position of the blended image, select Reset Pan .	

9 - 12 Instructions for Use

То	Do this		
Apply predefined optimization	(Available only during planning)		
settings to the displayed reference data	Note: If the volume quadrant is selected, the system applies the setting to the volume data. If an MPR quadrant is selected, the system applies the setting to all MPRs.		
	 Select the optimization setting. 		
	Rotate [Preset].		
	 For systems without a touch screen, select a Presets setting on the image menu. 		
	Note: CTA is a computed tomography angiogram. T1 and T2 are types of magnetic resonance imaging (MRI) scans.		
Adjust the range of values	(Available only during planning)		
displayed in the reference data	Note: If the volume quadrant is selected, the system applies the setting to the volume data. If an MPR quadrant is selected, the system applies the setting to all MPRs.		
	 Select the value range setting. 		
	 Drag the Window and Level icon on the touch screen to adjust the setting. 		
	 For systems without a touch screen, select a Window setting on the image menu. 		
Adjust the midpoint of values	(Available only during planning)		
displayed in the reference data	Note: If the volume quadrant is selected, the system applies the setting to the volume data. If an MPR quadrant is selected, the system applies the setting to all MPRs.		
	Select the value setting.		
	Drag the Window and Level icon on the touch screen to adjust the setting.		
	 For systems without a touch screen, select a Level setting on the image menu. 		
Adjust the opacity of the	(Available only when a blended image is displayed)		
displayed reference data	 Select an opacity setting. 		
	Rotate [Transparency].		
	 For systems without a touch screen, select a Transparency setting on the image menu. 		
	The following transparency settings are available when a blended image is displayed.		
	0% - The reference data is not visible.		
	Less than 50% - More of the ultrasound image and less of the reference data is visible.		
	50% - Both the ultrasound image and the reference data are equally visible.		
	More than 50% - More of the reference data and less of ultrasound image is visible.		
	100% - The reference data is fully visible and the ultrasound image is less visible.		

Instructions for Use 9 - 13

Real-time Imaging

Use the Scan tools to perform real-time imaging before you load the reference data. After the reference data has been aligned with the ultrasound image, you can capture additional images and clips of the blended image. You can also use the blended image, including any planning data, as a reference during an interventional procedure.

To acquire real-time images when eSieFusion is activated:

- Activate the Scan function.
 - Select Scan.
 - o For systems without a touch screen, click Scan on the image menu.

If you have not loaded reference data, the system displays a real-time ultrasound image in full-screen display format. If reference data has been fused with the ultrasound image, the system displays the blended image.

Supported Imaging Functionality

During real-time imaging, eSieFusion supports 2D imaging features, including CINE and the following imaging functionality:

- Tissue Equalization (TEQ)
- Tissue Harmonic Imaging (THI)
- Color Imaging
- Biopsy
- Contrast Agent Imaging

See also: Imaging Functions, Chapter A2, Features and Applications Reference

See also: Transducer Accessories and Biopsy, Chapter 5, Instructions for Use

See also: Contrast Agent Imaging, Chapter A6, Features and Applications Reference

9 - 14 Instructions for Use

Interventional Procedures

⚠ **WARNING**: Percutaneous procedures always involve heightened risk to the patient and to the operator handling biopsy needle guides. Clinicians using Siemens recommended biopsy devices under ultrasound quidance should be trained and must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomfort and unnecessary risk and injury to the patient.

You can perform interventional procedures, including ultrasound-guided ablation and biopsy procedures, using the blended image as a reference. Biopsy controls are available only when Scan is activated.

See also: Transducer Accessories and Biopsy, Chapter 5, Instructions for Use

Before you perform an interventional procedure, you can create planning data such as landmarks, segmentations, and planned needle paths.

See also: Planning Data, p. 9-17

To track the position of the needle:

Prerequisite: You must connect a needle-tracking sensor to port 4 on the tracking system and a transducer sensor to the port associated with the active transducer.

See also: Attaching the Sensors to the Electronics Unit, p. 9-27

- 1. Select **Scan** to display the blended image.
- 2. To view both the reference image and the ultrasound image select the required display format (1:1, 2:1, or 1:3).

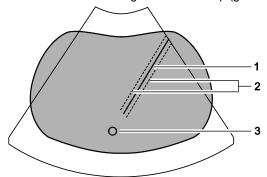
The system displays the reference data on the left side of the screen and the ultrasound image on the right side of the screen.

Select Track Needle.

The system displays the tracked needle on the ultrasound image. Red indicates the part of the needle on the right side or above the ultrasound image plane, depending on the orientation of the transducer. Blue indicates the part of the needle on the left side or below the ultrasound image plane, depending on the orientation of the transducer.

The system displays an indicator (green circle) when the needle is more than 5° outside the imaging plane. The needle tip is pointing to the location identified by the green circle (indicator). The circle decreases in size to a point as the needle tip nears the image plane.

Instructions for Use 9 - 15 4. To enable or disable tracking of the needle tip (green circle), select **Needle Tip Graphics**.



Example of the eSieFusion screen with needle tracking.

- 1 Indicates the position of the needle (solid line)
- 2 Indicates 5 mm on each side of the position of the needle (dotted line)
- 3 Indicates that the needle tip position is outside the image plane

The system displays a graphical indicator of tracking quality for the transducer sensor and the needle tracking sensor.

5. Use the pan function to view the entire needle path in selected display formats.

See also: Quality Indicators, p. 9-7

Planning Data

You can create landmarks and segmentations on the reference data to identify areas of interest. You can also draw planned needle paths for use during an interventional procedure.

An on-screen indicator identifies the orientation of the patient. The system displays the orientation indicator whenever reference data is displayed.

Label	Description
Α	Anterior
Р	Posterior
R	Right
L	Left
Н	Head
F	Feet



Example of the on-screen orientation indicator.

Instructions for Use 9 - 17

To create planning data on the reference data:

Prerequisite: If you manually entered the patient name, patient ID, date of birth, and gender on the patient registration form, the entries are case sensitive and must match the corresponding information for the reference data.

1. Load the reference data, if necessary.

See also: Loading the Reference Data, p. 9-8

The system activates the tools for creating planning data.

2. Adjust the display to optimize positioning of planning data.

То	Do this
Change the display format	Select a setting.
	 Rotate [Layout] to select a full-screen format (1:1) or rotate [Quadrant] to select a quadrant (4:1) display format.
	 For systems without a touch screen, press the soft key to select a full-screen (1:1) or quadrant (4:1) display format.
Display multiplanar reconstruction	(Available only for a 4:1 display format)
(MPR) with or without a volume	 Select a display setting for the volume.
rendering (VR)	 Select MPR + VR and then select MPR + VR or MPR Only.
	 For systems without a touch screen, select MPR + VR or MPR Only.
	Note: When you select MPR Only , the volume quadrant displays only the planning data.
Change the active view	■ Select a view.
	 Rotate [X], [Y], or [Z] to select the coronal, sagittal, or axial view, respectively.
	 For systems without a touch screen, rotate the scroll wheel to select the required view.
Pan a multiplanar reconstruction	a. Activate the pan function.
(MPR)	Select Pan.
	 For systems without a touch screen, press NEXT to select Pan.
	b. Select the required MPR.
	c. Roll the trackball to reposition the image.
	d. Click the MPR to anchor the position of the image.
	e. To restore the previous position of the MPR, select Reset Display .

9 - 18 Instructions for Use

То	Do this
Pan the volume	a. Activate the pan function.
	Select Pan.
	 For systems without a touch screen, press NEXT to select Pan.
	b. Drag the volume to the required location.
	 To restore the previous position of the volume, select Reset Display o the image menu.
Cycle through the slices of an	a. Choose a method:
MPR	 Rotate [X], [Y], or [Z] on the control panel to cycle through the coronal, sagittal, or axial MPR, respectively.
	 Drag the required axis on the image.
	b. To restore the previous display, select Reset Display .
Change the active plane view	Select a plane.
	 Rotate [X], [Y], or [Z] to select the coronal, sagittal, or axial view, respectively.
	 For systems without a touch screen, rotate the scroll wheel to rotate the selected plane.
dentify an area of interest.	
То	Do this
Identify an area of interest by	a. Activate the drawing tool.
drawing a line	Select Line Segmentation.
	 For systems without a touch screen, click Line Segmentation on the image menu.
	 b. Click the image to position the starting and ending points of a line across the area of interest.
	The system displays an outline around the area identified by the line segmentation and updates the Navigator with a corresponding entry.

Instructions for Use 9 - 19

Do this

Identify an area of interest by positioning seeds

- a. Activate the seed placement tool.
 - Select Seed Segmentation.
 - For systems without a touch screen, click Seed Segmentation on the image menu.



Pointer to place segmentation seeds.

- b. Select a Seed Size setting.
- c. To position the foreground seeds:
 - Press SELECT-R to select Foreground and then click the required location(s) on the image.
 - For systems without a touch screen, press NEXT to select Foreground, if necessary, and then click the required location(s) on the image.
- d. To position the background seeds:
 - Press SELECT-R to select Background and then click the required location(s) on the image.
 - For systems without a touch screen, press **NEXT** to select **Background** and then click the required location(s) on the image.
- e. To remove foreground or background seeds:
 - Select Clear Foreground Seeds or Clear Background Seeds.
 - For systems without a touch screen, click Clear Foreground Seeds or Clear Background Seeds on the image menu and then press UPDATE.

The system displays an outline around the area identified by the foreground and background seeds and updates the Navigator with a corresponding entry.

- 4. Draw a planned needle path.
 - a. Select Needle Path.

The system activates the needle path tool.

- b. Click the starting point of the needle path on an MPR.
- c. Click the ending point of the needle path on an MPR.

Note: You can position the starting and ending points of the needle path on different MPRs.

The system displays a pink outline on the image to mark the planned needle path and updates the Navigator with a corresponding entry.

9 - 20

Image Alignment

eSieFusion provides tools to align the reference data and an ultrasound image. An on-screen indicator identifies the orientation of the reference data during alignment.

See also: Planning Data, p. 9-17

To initialize the alignment of reference data with an ultrasound image:

- 1. Select Fuse.
 - If the reference data has not been previously aligned with the ultrasound image, the system displays the reference image and the ultrasound image in a split-screen format. Proceed to step 3.
 - If the reference data has been previously aligned with the ultrasound image, the system displays the blended image. Proceed to step 2 to reinitialize the alignment or follow the procedures for performing fine adjustments.
- 2. Select Reset Alignment.
- 3. Select Supine or Prone.
- 4. Select Coronal, Sagittal, or Axial.
- 5. Select Manual to drag and drop the image.

Or, select **Point** to set a point first on the ultrasound image and then scroll on the reference image to select the second point.

- 6. To initialize alignment:
 - Rotate [Scroll Plane] to select the required plane and then press UPDATE.
 - For systems without a touch screen, rotate the scroll wheel and then press UPDATE.

The system activates a full-screen display format and aligns the the reference data with the ultrasound image.

Note: You can alternatively position the transducer at the midline of the patient in a transverse plane and then initialize alignment.

Instructions for Use 9 - 21

You can use the alignment tools in any combination to perform fine adjustments of the image alignment with the reference data.

То	Do this
Acquire an ultrasound clip and	(Available only for CT reference data)
automatically align the ultrasound image with the reference data	Note: The system does not support automatic alignment with contrast agent imaging.
	1. Select a setting.
	Select Auto.
	 For systems without a touch screen, press PRIORITY to select Auto.
	Press UPDATE to begin acquiring a clip and then press UPDATE again to end the acquisition.
	Note: The system supports clip lengths up to 60 seconds.
	The system aligns the reference data with the ultrasound data in the acquired clip.
	3. To save the current alignment, click Save Alignment.
	The system updates the Navigator with an entry for the saved alignment.
Manually align the ultrasound	Select a setting.
image with the reference data	Select Manual.
	 For systems without a touch screen, press PRIORITY to select Manual.
	2. Select the method of manual alignment.
	Select Move, Z, or Y.
	 For systems without a touch screen, press NEXT to select Move, Z, or Y.
	The system changes the pointer based on the method you select:
	 Move positions the reference data in the plane of the ultrasound image.
	 Z rotates the reference data in the plane of the ultrasound image.
	Y rotates the reference data around the vertical axis of the ultrasound image
	 Click the blended image and then roll the trackball to position the reference data in the required location on the ultrasound image.
	4. Click the blended image to anchor the position of the reference data.
	5. To save the current alignment, click Save Alignment.

9 - 22 Instructions for Use

The system updates the Navigator with an entry for the saved alignment.

То	Do this
Align the ultrasound image and	Activate the point function.
the reference data using	Select Point.
corresponding points	 For systems without a touch screen, press PRIORITY to select Point.
	The system displays the reference data and ultrasound image in a side-by-side format. When you position the pointer on the reference data, the system displays a bull's-eye (target) marker at the corresponding position on the ultrasound image.
	+
	Bull's-eye marker.
	2. Click a location on the ultrasound image.
	The system displays an aqua marker on the ultrasound image, calculates the optimal alignment of the two points, and updates the Navigator with a corresponding entry.
	Note: The entry markers in the Navigator for pairs of corresponding points are always green.
	3. Click a location on the reference data.
	The system displays a green marker on the reference data. When you position the pointer on the ultrasound image, the system displays a bull's-eye marker at the corresponding position on the reference data.
	4. Repeat steps 2 and 3 to position additional pairs of corresponding points on the reference data and the ultrasound image.
	The system recalculates the optimal alignment of all corresponding pairs each time you position a pair of corresponding points.
	Note: The system removes corresponding points from the image and the Navigator when you exit point alignment.
	5. Select Reset Alignment.
	6. To recalculate the optimal alignment, press UPDATE .
	7. To save the current alignment, select Save Alignment .
	The system updates the Navigator with an entry for the saved alignment.
Cancel the most recent	Select Undo.
adjustment made to the alignment	You can cancel all adjustments performed in reverse sequence.
Display a previously saved	Select the required alignment in the Navigator and then click Show.
alignment	The evetem restores the positions of the reference date and ultreasund image

alignment

The system restores the positions of the reference data and ultrasound image when the selected alignment was saved.

9 - 23 Instructions for Use

Troubleshooting

Symptom	Possible Cause	Recommend Action
System indicates poor transducer tracking quality	The tracking sensor is not properly attached to the transducer.	Verify that the sensor has been attached to the transducer as described in the manufacturer's instructions.
	 The magnetic field (transmitter) is causing interference with the electronics unit. 	 Verify that the transmitter is at least 24 inches (61 cm) from the electronics unit.
	 Metal objects or electromagnetic field emissions near the tracking field are causing magnetic field distortion. 	 Remove potential sources of magnetic field distortion or reposition the tracking system or patient.
System indicates that the transducer sensor is unplugged	The transducer sensor is not connected to the electronics unit or is connected to the wrong port on the electronics unit.	Verify that the transducer sensor is connected to the correct port on the electronics unit.
		See also: Attaching the Sensors to the Electronics Unit, p. 9-27
System indicates that needle sensor is unplugged	The needle sensor is not connected to the electronics unit or is connected to the wrong port on the electronics unit.	Verify that the needle sensor is connected to port 4 on the electronics unit.
No data is displayed	Transmitter or sensor is disconnected or the connection is faulty.	Verify that the transmitter and sensor cables are securely connected to the electronics unit.
Data is too noisy (for example, random changes in the position and orientation of	 Excessive electrical noise from other electrical and magnetic devices is interfering with the tracking system. 	Power off the electrical equipment operating near the electronics unit to determine the source of the noise.
the tracking data)		Remove the equipment (source of the noise) from the area.
		If the equipment is critical, increase the distance between the equipment and the sensor, or decrease the distance between the sensor and the transmitter.
	 Power line frequency is set incorrectly. 	 Verify that the correct power line frequency (50 Hz or 60 Hz) is configured.
		System Config > Service
Poor data accuracy (for example, the tracking system does not accurately depict the position and orientation of the transducer)	Metal near the tracking system is causing magnetic distortion.	Remove or reduce the amount of metal near the tracking system, including areas around the transmitter and the area between the sensor and the transmitter.
System indicates inability to initialize alignment or perform sweep acquisition	The tracking sensor is too far from the transducer.	Verify that the sensor has been attached to the transducer as described in the manufacturer's instructions.

9 - 24 Instructions for Use

Setting up the Tracking System for eSieFusion Imaging

The tracking system consists of the following components:

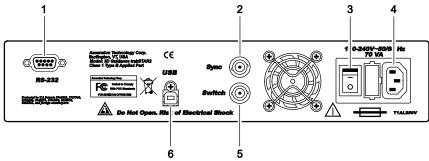
- electronics unit
- transmitter
- transducer sensors
- needle tracking sensor

Connecting the Electronics Unit to the Ultrasound System

Note: The electronics unit must be installed by an authorized Siemens representative or by a Siemens-approved third party.

The electronics unit must be connected to a USB port on the input/output panel of the ultrasound system.

See also: Input/Output Panel Connections, System Setup, Chapter 3, Instructions for Use



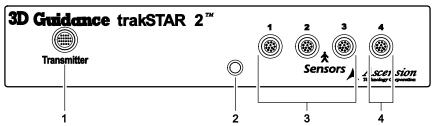
Example of the trakSTAR2 electronics unit, back view.

- 1 RS-232 connection (not used)
- 2 Multi-unit synchronization connection (not used)
- 3 Power on/off switch
- 4 Power cord connection
- 5 Connection for analog switch (not used)
- 6 USB connection from ultrasound system

Instructions for Use 9 - 25

Connecting the Transmitter

Connect the transmitter cable to the connector on the front of the electronics unit.



Example of the electronics unit for the trakSTAR2 tracking system, front view.

- Connection for the transmitter
- Status indicator
- Ports for connecting transducer sensors
- 4 Port for connecting needle tracking sensor

Repositioning the Transmitter

Note: If you reposition the transmitter, ensure that the transmitter is at least 24 inches (61 cm) from the electronics unit.

When the mid-range transmitter is mounted on a rolling stand, it is designed to be mobile. When the transmitter is in use, be sure to engage the brakes located on two of the wheels. You can also adjust the height of the transmitter by repositioning the arm on the rolling stand.

To adjust the position of the transmitter on the transmitter stand:

- Support the arm with one hand and rotate the knob counterclockwise.
- Slowly move the arm up or down the pole to the required position.
- Continue to support the arm and rotate the knob clockwise to secure the arm.

To use the brakes on the rolling stand:

- To engage the brakes, push down the brake lever on each wheel.
- To release the brakes, push up on the brake lever on each wheel.

Attaching the Sensors to the Electronics Unit

Ports for sensors on the electronics unit are associated with a specific transducer port on the ultrasound system.

Sensor Port	Transducer Port
1	Left
2	Center
3	Right

Port 4 on the electronics unit is reserved for the needle sensor.

To connect a sensor to the electronics unit:

 Insert the sensor connector in the corresponding port on the electronics unit until you hear an audible click.

Attaching Sensors to the Transducer or Needle

Refer to the manufacturer's instructions included with the device.

Troubleshooting the Tracking System

An LED on the front panel of the electronics unit provides status information for troubleshooting the tracking system. The LED slowly blinks green when the tracking system is fully functional and the transmitter is not activated. The LED displays solid green when the tracking system is fully functional and the transmitter is activated.

Symptom	Possible Cause	Recommend Action
Front panel LED is not illuminated	No power.	 Check the power cord connection to the electronics unit and to the power source (outlet).
		 Cycle power to the electronics unit.
Front panel LED blinks red and yellow	A valid transmitter is not connected to the electronics unit or is not connected properly.	 Attach a transmitter to the electronics unit.
		 Check the connection from the transmitter to the electronics unit.
Front panel LED slowly blinks green and orange	The tracking system has not fully initialized.	 Wait a few minutes for the tracking system to complete its initialization process. The LED will then slowly blink green.
The tracking system is unable to communicate using the USB connection	USB cable is not properly connected.	 Disconnect and reconnect the USB cable to the electronics unit.
		 Cycle power to the electronics unit.

Instructions for Use 9 - 27

Maintenance, Cleaning, and Care for eSieFusion Imaging

Daily Checklist

Note: In addition to the daily checklist for eSieFusion, you must also perform each of the steps in the Daily Checklist for the ultrasound system.

See also: Caring for the Ultrasound System, Safety and Care, Chapter 2, Instructions for Use

Perform the following steps before each use of eSieFusion:

- Visually inspect the cables for the transmitter and sensors. Do not use a cable with nicks or cuts in the insulation.
- Inspect both the connectors and connections. Do not use a cable with bent or damaged
- Inspect the transmitter. Do not use a transmitter with cracks or exterior damage. If the interior of the transmitter is exposed in any way, the component should be replaced after proper disposal.

Cleaning and Disinfecting the Tracking System Equipment

⚠ **WARNING**: To avoid electrical shock and damage to the ultrasound system, power off and unplug the equipment from the AC power outlet before cleaning and disinfecting.

Follow this procedure to clean the tracking system equipment (electronics unit, transmitter, and cables).

To clean the tracking system equipment:

Note: If the equipment comes in contact with biological fluid or tissue, follow your organization's procedures for proper cleaning and disinfection. Do not subject the electronics units or transmitters to autoclaving or gamma radiation. Do not immerse the electronics unit, transmitter, or cables in liquids.

Wipe the equipment with a cloth dampened with a cleaning solution such as a mild soap and water or a similar solution.

Cleaning and Disinfecting the Sensors

Refer to the manufacturer's instructions included with the device.

9 - 28 Instructions for Use

10 Virtual Touch Applications

Acoustic Radiation Force Impulse Technology	3
Virtual Touch Imaging	4
Virtual Touch Imaging Measurements	
Virtual Touch Quantification	6
Virtual Touch Quantification Measurements	8
Virtual Touch Quantification Patient Report	10
Virtual Touch Quantification Scanning Technique Hints	12
Scanning Techniques to Mitigate Technical Limitations of Virtual Touch Quantification	12
Shear Wave Velocity and Elasticity Measurements in Liver Assessment	14
Virtual Touch IQ	15
Virtual Touch IQ Measurements	19
Virtual Touch IQ Patient Report	21
Virtual Touch IQ Technique Hints	22

Instructions for Use 10 - 1

10 Virtual Touch Applications

10 - 2 Instructions for Use

Acoustic Radiation Force Impulse Technology

▲ WARNING: To prevent the possibility of inadvertently heating tissue, avoid repeated image acquisitions near the interface of bone and tissue within a short period of time.

The following features use acoustic radiation force impulse (ARFI) technology to obtain qualitative visualizations or quantitative measurements of tissue stiffness:

- Virtual Touch Imaging
- Virtual Touch Quantification
- Virtual Touch IQ

ARFI technology uses a time-controlled sequence of "push pulses" from the transducer, rather than manual compression or palpation cycles, to induce a small displacement of tissue. The image qualitatively depicts the relative stiffness of tissue within a selected region of interest compared to surrounding tissue. The system can also provide a quantitative measurement of shear velocity (Vs) or elasticity (E) at a specific anatomical location.

During acquisition, ARFI technology combines a period of pulse sequences with a temporary freeze period of no transmit power. A timer indicates the remaining time in seconds until the transducer is available for imaging. This duration is typically a few seconds depending on the transducer and imaging conditions. The cooling timer prevents possible heating of the transducer surface from the momentary shear wave generation pulses.

Cooling 5

Example of Virtual Touch timer.

The system uses an optimization algorithm to ensure acceptable levels for the I_{SPTA.3}, the Mechanical Index (MI), and the Thermal Index (TI) during use. When imaging is activated, you cannot adjust imaging parameters that affect the transmit power output until the acquisition is complete.

Instructions for Use 10 - 3

Virtual Touch Imaging

Use Virtual Touch imaging to qualitatively visualize tissue stiffness for a selected region of interest.

Virtual Touch imaging supports the following transducers and exam types:

- 4C1 (abdominal exam)
- 4V1 (abdominal exam)
- 9L4 (breast or thyroid exam)
- 6C1 HD (abdominal exam)

To activate Virtual Touch imaging:

- During 2D-mode or 2D-mode with THI active, select the control assigned to activating the feature:
 - Press E and then select Virtual Touch Imaging, if necessary.
 - o For systems without a touch screen, select Virtual Touch Imaging.



Virtual Touch imaging button.

The system activates a dual display format with a region of interest (ROI) box on the left image. The right image is blank.

- 2. To display the full field of view:
 - Select Full.
 - For systems without a touch screen, double-click UPDATE.

10 - 4 Instructions for Use

То	Do This
Reposition or resize the region of interest (ROI)	Activate the positioning or sizing function:
	Press SELECT.
	 For systems without a touch screen, press NEXT.
	2. Roll the trackball to reposition or resize the ROI.
	The software restricts the depth of the ROI.
Begin acquisition	Note: You cannot adjust the ROI during acquisition.
	 Press UPDATE.
	An audible tone indicates when volume acquisition begins and when acquisition is complete.
	When acquisition is complete, the system automatically freezes. During system freeze, a cooling timer indicates the remaining time (in seconds) until the transducer is available for image acquisition.
	 In dual display format, the system displays relative tissue stiffness within the ROI on the right image.
	 In full-screen display format, the system displays the relative tissue stiffness as a transparent color overlay on the 2D image.
	The system also activates CINE. The last frames of CINE include the Virtual Touch imaging acquisition.
Reactivate Virtual Touch	1. Unfreeze the image.
imaging after the automatic freeze period ends	2. Adjust the ROI size and position, if necessary.
	3. Press UPDATE to begin acquisition.
Activate dual display	Activate a dual format.
	Select Dual.
	 For systems without a touch screen, double-click UPDATE.
	2. Press UPDATE .
Select a different color map	Rotate [VTI Map].
Exit Virtual Touch imaging	■ Press 2D.

Virtual Touch Imaging Measurements

Virtual Touch imaging supports basic measurements, including area ratio and distance ratio. You can perform all basic measurements (such as distance, ellipse, and trace) on either dual image.

When the shadow function is active, the system displays the measurements on both the measured image and the shadow image.

То	Do This
Activate the shadow function during measurements in a dual-screen format	1. Select Shadow .
	2. Perform a measurement, such as distance, trace, or ellipse, on either image.
	When the measurement is completed, the measured image displays the measurement markers and the dotted measurement line; the shadow image displays only the dotted measurement line.
Exit the shadow function	Select Shadow again.

Instructions for Use 10 - 5

Virtual Touch Quantification

Use Virtual Touch quantification to measure tissue for a selected region of interest as shear velocity (Vs) or elasticity (E).

Note: Because shear waves do not propagate through fluid, do not use Virtual Touch quantification to measure fluids.

Virtual Touch quantification supports the following transducers and exam types:

- 4C1 (abdominal exam)
- 4V1 (abdominal exam)
- 9L4 (breast or thyroid exam)
- 6C1 HD (abdominal exam)

Use the system configuration menu to display shear wave measurements as velocity (m/s) or elasticity (kPa) units in the image screen and patient report.

System Config > System-wide Meas. Tools > Shear Wave Measurements Units

To activate Virtual Touch quantification:

- During 2D-mode or 2D-mode with THI active, select the control assigned to activating the feature:
 - Press E and then select Virtual Touch Quantification, if necessary.
 - o For systems without a touch screen, select Virtual Touch Quantification.



Virtual Touch quantification button.

The system displays a region of interest (ROI) box on the image.

10 - 6

То	Do This
Reposition the region of interest	Roll the trackball to reposition the ROI.
	The software restricts the depth of the ROI.
	Note: You cannot adjust the ROI size.
Begin acquisition	■ Press UPDATE .
	An audible tone indicates when volume acquisition begins and when acquisition is complete.
	When acquisition is complete, the system automatically freezes and displays the tissue shear velocity (Vs) or elasticity (E) and ROI depth in the measured results.
	During system freeze, a cooling timer indicates the remaining time (in seconds) until the transducer is available for image acquisition.
	Note: If the system displays the measurement values as x.xx, the confidence interval threshold for measurement quality was not reached. Repeat the acquisition until the system displays a numerical value instead of x.xx.
	The system also activates CINE. The last frames of CINE include the Virtual Touch quantification acquisition.
Reactivate Virtual Touch	Unfreeze the image.
quantification after the automatic freeze period ends	2. Adjust the ROI position, if necessary.
	3. Press UPDATE to begin acquisition.
Exit Virtual Touch quantification	■ Press 2D.

Instructions for Use 10 - 7

Virtual Touch Quantification Measurements

Virtual Touch quantification provides a set of shear velocity and elasticity measurement labels for abdomen exams:

- Up to four sites for generic locations
- Up to four lesions
- Up to 9 liver segments based on the Couinaud segmentation system

After each measurement, the system displays a counter below the image to indicate the number of valid measurements and the total number of all measurements assigned to each liver assessment measurement label. A valid measurement is any measurement that displays a numerical value in the measured results.

Lesion 1: 8 Valid / 10 Total

Example of Virtual Touch quantification measurement counter.

To label then measure shear velocity or elasticity:

- 1. Display the liver assessment measurement labels:
 - Select Liver Assessment.
 - For systems without a touch screen, press SELECT and then click Liver Assessment. Or, rotate MENU to select Liver Assessment.
- 2. Select the required measurement label from the list.
- 3. Press UPDATE.

The system displays the measurement in the measured results.

10 - 8 Instructions for Use

To measure then label shear velocity or elasticity:

1. Press **UPDATE**.

The system displays the measurement in the measured results.

- 2. Display the liver assessment measurement labels:
 - Select Liver Assessment.
 - For systems without a touch screen, press **SELECT** and then select **Liver Assessment**. Or, rotate **MENU** to select **Liver Assessment**.
- 3. Select the required label from the list.

То	Do This
Save a measurement to the abdomen patient report	Press SELECT.
Perform another measurement with the current label	 After the automatic freeze period ends, unfreeze the image and then press UPDATE.
Perform another measurement with a different measurement label	1. After the automatic freeze period ends, unfreeze the image.
	2. Select a label:
	 Select Measurement and then select the required label from the list.
	 For systems without a touch screen, select the required label from the Liver Assessment list.
	3. Press UPDATE .
	4. Press SELECT to copy the measurements to the report.
Perform an unlabeled measurement	Select Liver Assessment and then select No Label from the list.
	2. Press UPDATE .

Instructions for Use 10 - 9

Virtual Touch Quantification Patient Report

When you have made Virtual Touch quantification measurements, the abdomen patient report lists measurements for each liver assessment measurement label.

Measurement Data	Description
Vs (m/s)	Shear velocity
E (kPa)	Elasticity
Depth (cm)	Depth of the region of interest
Median	Median calculation for all measurements associated with the assigned label
Mean	Mean calculation for all measurements associated with the assigned label
Std Dev	Standard deviation calculation for all measurements associated with the assigned label
IQR	Interquartile range (the distance between the 75th percentile and the 25th percentile) for all measurements associated with the assigned label
IQR/Median	Ratio of the interquartile range to the median calculation for all measurements associated with the assigned label
Overall Statistics	
Median	Median calculation for all measurements included in the report
Mean	Mean calculation for all measurements included in the report
Std Dev	Standard deviation calculation for all measurements included in the report
IQR	Interquartile range calculation for all measurements included in the report
IQR/Median	Ratio of the interquartile range to the median calculation for all measurements included in the report

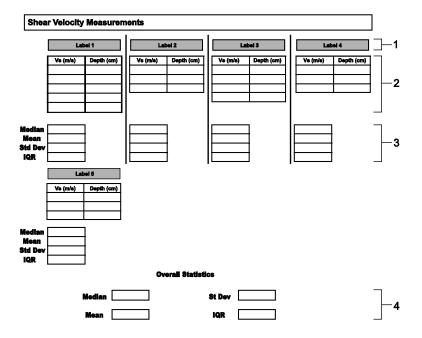
The abdomen report also includes a liver assessment section.

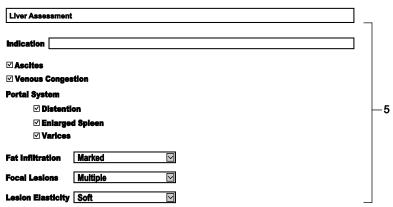
Liver Assessment Field	Selection
Indications	(text entry)
Ascites	(check box)
Venous Congestions	(check box)
Portal System	
Distension	(check box)
Enlarged Spleen	(check box)
Varices	(check box)
Fat Infiltration	(blank)
	Marked
	Mild
	Moderate
Focal Lesions	(blank)
	Multiple
	Single
Lesion Elasticity	(blank)
	Hard
	Isoelastic
	Soft

To delete a measurement:

• Click **Delete** next to the required measured result and then confirm the deletion.

10 - 10 Instructions for Use





Example of abdomen patient report with location of Virtual Touch quantification measurements and liver assessment data.

- 1 Measurement labels
- 2 Shear velocity or elasticity and depth measurements associated with the selected labels
- 3 Mean, median, standard deviation, interquartile range, and the ratio of the interquartile range to the median calculation for all measurements associated with the assigned label
- 4 Overall mean, median, standard deviation, interquartile range, and the ratio of the interquartile range to the median calculation for all measurements included in the report
- 5 Liver assessment fields

Instructions for Use 10 - 11

Virtual Touch Quantification Scanning Technique Hints

Scanning Techniques to Mitigate Technical Limitations of Virtual Touch Quantification

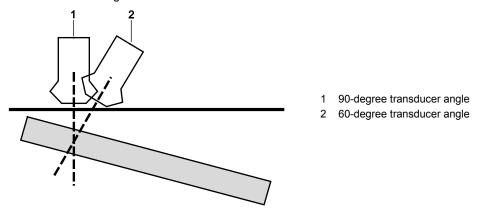
- During breast imaging with Virtual Touch quantification, shear wave velocity and elasticity measurements may frequently display "x.xx" in the measured results with certain breast cancers. This result is typically caused by a low shear wave signal-to-noise ratio (SNR) due to high tissue stiffness where the excitation pulse from the transducer cannot generate sufficient shear wave magnitude.
 - When frequent "x.xx" results are encountered in focal lesions, Siemens recommends evaluating the elevated shear wave velocities in the periphery of the lesion.
- To obtain reproducible results in the liver with Virtual Touch quantification, take measurements in the right lobe of the liver using an intercostal scanning approach. Advise the patient to breathe normally and to momentarily stop breathing and then take measurements. Avoid taking measurements during deep inspiration and breath hold as the literature cites that this action increases central venous pressure. Elevated central venous pressure can artificially elevate shear wave velocity and elasticity measurements.
 - Siemens recommends maintaining a measurement region of interest (ROI) depth between 3 cm and 6 cm to minimize the effects of depth on shear wave velocity and elasticity measurements.
- To obtain reliable and repeatable results with Virtual Touch quantification, apply the appropriate amount of scanning pressure.
 - Siemens recommends using minimal to mild compression for optimal results. Applying excessive pressure with the transducer on the body may artificially elevate shear wave velocities and result in unreliable shear wave velocity and elasticity.
- Measurement values for shear wave velocity, elasticity, and other image display settings are relative indexes intended only for the purpose of comparison with other measurements performed using the ACUSON S2000 ultrasound system and the ACUSON S3000 ultrasound system. Absolute values for shear wave velocity and elasticity measurements may vary among different manufacturers due to multiple system-dependent factors, including shear wave frequency, excitation beam (push beam) frequency, shear wave detection techniques, and shear wave velocity and elasticity estimation methods.

Note: The system displays the following message on the screen during Virtual Touch quantification and in the report if shear wave speed measurements are saved to the report: "Shear wave speed and elasticity values may vary among manufacturers!"

10 - 12 Instructions for Use

 In general, use a transducer angle of 90 degrees to the skin surface for the highest measurement accuracy.

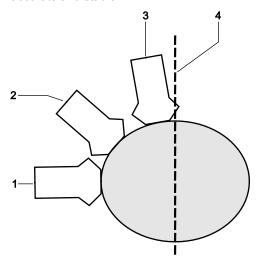
An out-of-plane transducer angle less than 50 degrees to the skin surface can result in artificially low shear wave velocities and elasticity values due to loss of transducer contact with the flat scanning surface.



Transducer angle on a flat surface.

 Maintain adequate contact and be aware of the effects of the transducer angle relative to the contact surface.

When the transducer surface is in continuous contact with the skin surface and follows the contour of the curved surface, shear wave velocity and elasticity measurements are accurate and stable.



Transducer angle on a curved surface.

- 1 90-degree transducer angle
- 2 50-degree transducer angle
- 3 10-degree transducer angle
- 4 Vertical axis

Instructions for Use 10 - 13

Shear Wave Velocity and Elasticity Measurements in Liver Assessment

Virtual Touch quantification can provide a reliable measure of shear wave velocity and elasticity in the liver when proper technique is used.

The following factors can result in abnormally high values in the liver:

- Excessive transducer pressure on the liver, such as in subcostal scanning where transducer pressure is used to displace intervening bowel gas
- Elevated central venous pressure due to heart failure or valsalva maneuvers (including deep inspiration and breath hold)
- Significant portal hypertension
- Poor contact with the skin surface or oblique transducer angles relative to the liver
- Elevated aminotransferase levels
- Food intake less than 2 to 3 hours prior to examination
- Liver location (liver segment measured)
- Liver fibrosis

The following techniques should be used in liver assessment to ensure measurements using Virtual Touch quantification in liver assessment are reliable:

- Measurements are most reliable at least 1 cm to 2 cm deep to the liver capsule using the intercostal scanning approach along a mid-axial line in liver segments 5 and/or 8.
- The patient should breathe normally with measurements taken after the patient is asked to momentarily suspend respiration.
- Multiple measurements in the same location should be taken to ensure measurement repeatability with the median shear wave velocity and elasticity value representing the most reliable single measure when there are measurement outliers.
- The Virtual Touch quantification measurement region of interest (ROI) should be maintained between 3 cm and 6 cm depth whenever possible to minimize the effect of depth on measurements. Values can be higher at depths less than 3 cm and lower at depths greater than 6 cm.
- An IQR/median shear wave velocity and elasticity ratio less than 0.3 is indicative of reliable liver assessment with Virtual Touch quantification. A higher ratio indicates significant variability in the measurements, decreasing the reliability of measurement results.

10 - 14 Instructions for Use

Virtual Touch IQ

△ Caution: Using the appropriate amount of scanning pressure is an important factor in achieving reliable and repeatable results with Virtual Touch IQ. Minimal to mild compression is recommended for best results. Excessive pressure on the body with the transducer may artificially elevate shear wave velocities and result in unreliable measurements.



△ Caution: In breast applications of Virtual Touch IQ, shear wave imaging may have limitations in adequately visualizing regions of very high stiffness, for example, in certain breast cancers. Siemens recommends using the Quality image display setting to verify that the shear wave velocity and elasticity image represents adequate shear wave formation. Shear wave velocity and elasticity measurements should be made only in regions with high shear wave quality, represented in green when the Quality image display setting is selected.



△ Caution: In lesions where multiple or extensive areas of low shear wave quality are encountered, shear wave velocity and elasticity estimates in the lesion should be interpreted with caution

Note: Measurement values for shear wave velocity, elasticity, and other image display settings are relative indexes intended only for the purpose of comparison with other measurements performed using the ACUSON S2000 ultrasound system and the ACUSON S3000 ultrasound system. Absolute values for shear wave velocity and elasticity measurements may vary among different manufacturers due to multiple system-dependent factors, including shear wave frequency, excitation beam (push beam) frequency, shear wave detection techniques, and shear wave velocity and elasticity estimation methods. The system displays the following message on the screen during Virtual Touch IQ imaging and in the report if measurements are saved to the report: "Shear wave speed and elasticity values may vary among manufacturers!"

Virtual Touch IQ quantitatively depicts tissue stiffness for a selected region of interest and provides a quantitative measurement of shear wave velocity (Vs) or elasticity (E) for any point within the region of interest. You can adjust the size and depth of the region of interest (ROI) where shear wave information will be acquired. The maximum depth for the ROI is 6 cm, the effective limit to acquire shear wave images in the intended applications under normal scanning conditions.

- In a full-screen format, the system displays the shear velocity or elasticity data as a transparent color overlay on the 2D image.
- In a dual-screen format, the system displays the 2D image on the left side and the ROI with the shear velocity or elasticity data on the right side.

Instructions for Use 10 - 15 In either full-screen or dual-screen format, you can apply one of the following image display settings to the shear wave velocity and elasticity data: **Velocity** or **Elasticity**, **Quality**, **Time**, or **Displacement**. Each of these settings provides additional context for evaluating and interpreting the shear wave velocity and elasticity and measured results.

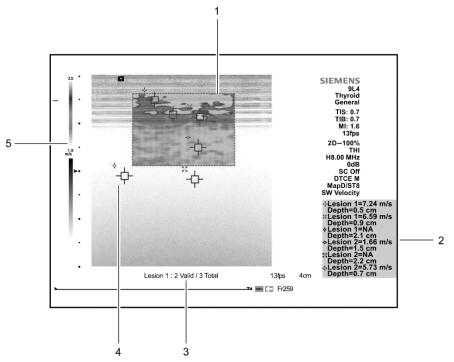
Note: If the shear wave velocity and elasticity within the region of interest is not detectable (for example, a fluid-filled cyst) or the shear wave velocity and elasticity is non-determinant, the selected image display setting (except quality) displays only the 2D-mode data in that area (no color is displayed).

Basic measurements, including area ratio and distance ratio, are also available. You can perform all basic measurements, such as distance, ellipse, and trace, on either side of a dual display format.

Virtual Touch IQ supports the following transducers and exam types:

9L4 (breast or thyroid exam)

10 - 16 Instructions for Use



Example of Virtual Touch IQ screen.

- 1 Virtual Touch IQ region of interest
- Measured results for shear wave velocity or elasticity. If you perform a measurement within the region of interest (ROI) that exceeds the current maximum velocity setting, the measured results display HIGH for the shear velocity value. If you perform a measurement within the ROI that is lower than the current minimum velocity setting, the measured results display LOW. The measured results display NA if the shear wave was not detected within the ROI or if you perform a measurement outside of the ROI.
- 3 Measurement counter
- 4 Measurement marker with unique identifier. Each measurement displays the corresponding identifier in the measured results.
- 5 Color bar depicts the range of values displayed in the region of interest for the selected image display setting: velocity or elasticity, quality, time, or displacement.

Note: For systems without a touch screen, Virtual Touch measurement labels and measurement tools are displayed on the left side of the image screen.

Use the system configuration menu to display shear wave measurements as velocity (m/s) or elasticity (kPa) units in the image screen and patient report.

System Config > System-wide Meas. Tools > Shear Wave Measurements Units

Instructions for Use 10 - 17

To activate Virtual Touch IQ:

- 1. During 2D-mode imaging, select the control assigned to activating the feature:
 - Press E and then select Virtual Touch IQ.
 - o For systems without a touch screen, select Virtual Touch IQ.



Virtual Touch IQ button.

The system activates a full-screen format and displays a region of interest (ROI).

- 2. To activate a dual display format:
 - Select Dual.
 - For systems without a touch screen, double-click **UPDATE**.

The left image displays the ROI. The right image is blank.

То	Do This
Adjust the size or position of the region of interest (ROI) prior to acquisition	Activate the positioning or sizing function:
	Press SELECT.
	 For systems without a touch screen, press NEXT.
	2. Roll the trackball to reposition or resize the ROI.
Begin acquisition	Note: You cannot adjust the ROI during acquisition.
	■ Press UPDATE .
	The system acquires a single image frame and then freezes the image and applies the velocity image display setting. During system freeze, a timer indicates the remaining time (in seconds) until the transducer is available for image acquisition.
Change the image display	Rotate [Shear Wave] to select the required setting:
setting	 Velocity depicts the range of shear wave velocity or elasticity values from minimum to maximum. Shear wave velocity is slower in soft tissue and faster in stiff tissue. Elasticity is higher in soft tissue and lower in stiff tissue. The color bar displays the minimum and maximum range of the shear wave velocity and elasticity measurement.
	 Quality depicts the combination of shear wave displacement magnitude and the signal-to-noise level from low (LO) to high (HI). A low displacement magnitude and high noise level are depicted as low quality. A high displacement magnitude and low noise level are depicted as high quality.
	 Time indicates the travel time of the shear wave from slow (S) to fast (F).
	 Displacement indicates the magnitude of the shear wave displacement of tissue from low (LO) to high (HI). Displacement is higher in soft tissue and lower in stiff tissue.
Reactivate Virtual Touch IQ acquisition after the automatic freeze period ends	Unfreeze the image.
	2. Adjust the ROI size and position, if necessary.
	3. Press UPDATE to begin acquisition.
Exit Virtual Touch IQ	■ Press 2D.

10 - 18 Instructions for Use

Virtual Touch IQ Measurements

You can measure the shear wave velocity or elasticity anywhere within the region of interest. You can perform multiple measurements on a single acquisition. Virtual Touch IQ supports both measure-then-label and label-then-measure methods and includes a set of measurement labels:

- Up to four sites for generic locations
- Up to four lesions

Note: The 2D-mode thyroid measurement labels are also available during Virtual Touch IQ.

After each labeled measurement using the label-then-measure method, the system displays a counter below the image to indicate the number of valid measurements and the total number of all measurements for the active measurement label. A valid measurement is any measurement that displays a numerical value in the measured results.

To measure shear wave velocity or elasticity:

Note: You can perform shear wave velocity or elasticity measurements only when the [**Shear Wave**] setting is **Velocity**.

- Activate the measurement function, if necessary, and select the shear velocity measurement tool:
 - Press CALIPER and then select Shear Velocity or Elasticity.
 - For systems without a touch screen, press CALCS and then click Shear Velocity or Elasticity on the measurement menu.



Note: When you use the label-then-measure method, the system automatically activates the shear velocity measurement tool when you select a shear velocity measurement label.

Position the measurement caliper and then press SELECT.

The system displays the measured results for shear velocity in meters per second (m/s). Measured results for elasticity display in kiloPascals (kPa).

Note: If you perform a measurement within the region of interest (ROI) that exceeds the current maximum velocity or elasticity setting, the measured results display **HIGH** for the shear velocity and elasticity value. If you perform a measurement within the ROI that is lower than the current minimum velocity and elasticity setting, the measured results display **LOW**. The measured results display **NA** if the shear wave was not detected within the ROI or if you perform a measurement outside of the ROI.

То	Do This
Adjust the range of velocities or elasticity displayed in the region of interest	To change the maximum velocity or elasticity:
	Rotate [Max Velocity] or [Max Elasticity].
	 For systems without a touch screen, press and then rotate [Max Velocity].
	2. To change the minimum velocity:
	Rotate [Min Velocity] or [Min Elasticity].
	 For systems without a touch screen, press and then rotate [Min Velocity] or [Min Elasticity].
	The system updates the shear wave velocities in the region of interest and the color or gray bar to depict the velocities within the selected range. The selected maximum and minimum velocity values display above and below the gray bar or color bar. The selected maximum and minimum elasticity values display in blue.
Activate the shadow function in a dual-screen format	1. When the measurement function is active, select Shadow .
	2. Perform a measurement on either image.
	When the system completes a shear velocity measurement, both images display the measurement marker. When the system completes a 2D-mode measurement, the measured image displays the measurement markers and the dotted line; the shadow image displays only the dotted line.
	3. To exit the shadow function, select Shadow .

10 - 20 Instructions for Use

Virtual Touch IQ Patient Report

When you have made Virtual Touch IQ measurements during a breast or thyroid exam, the patient report lists measurements for each measurement label.

Measurement Data	Description
Vs (m/s)	Shear velocity
E (kPa)	Elasticity
Depth (cm)	Depth
Median	Median calculation for all measurements associated with the assigned label
Mean	Mean calculation for all measurements associated with the assigned label
Std Dev	Standard deviation calculation for all measurements associated with the assigned label
IQR	Interquartile range (the distance between the 75th percentile and the 25th percentile) for all measurements associated with the assigned label
IQR/Median	Ratio of the interquartile range to the median calculation for all measurements associated with the assigned label
Overall Statistics	
Median	Median calculation for all measurements included in the report
Mean	Mean calculation for all measurements included in the report
Std Dev	Standard deviation calculation for all measurements included in the report
IQR	Interquartile range calculation for all measurements included in the report
IQR/Median	Ratio of the interquartile range to the median calculation for all measurements included in the report

To delete a measurement:

Click **Delete** next to the required measured result and then confirm the deletion.

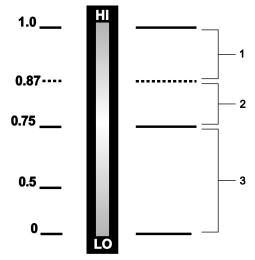
Virtual Touch IQ Technique Hints

Virtual Touch IQ provides a two-dimensional display (map) of shear wave velocity or elasticity, quality, travel time, and displacement information. Each of these maps represents a parameter of the system-generated shear waves to assist in the interpretation of Virtual Touch IQ images.

Use the Quality map to confirm that shear wave formation was adequate and identify regions of the shear wave image where shear wave velocity or elasticity estimations may be artificially low due to poor shear wave signal quality. For example, in some exceptionally stiff breast cancers, it can be difficult to adequately visualize and measure shear wave velocities because of high tissue attenuation. Shear wave velocity or elasticity measurements are reliable in locations of high signal quality and these locations are represented in green; measurements are unreliable in locations of low signal quality and these locations are represented in yellow/orange. When the shear wave quality is orange/red, shear wave velocities cannot be estimated and the Velocity or Elasticity, Time, and Displacement maps display only 2D-mode information.

The following illustration depicts the use of color to represent shear wave quality. The color indications in the Quality map help identify locations in the Velocity map where shear wave velocity and elasticity estimations are reliable, may be unreliable, or could not be estimated. The values in the left column indicate the quality index calculated by the system software. Index values of 0 and 1.0 represent the minimum and maximum quality. A threshold of 0.75 is used to determine that estimates of shear wave velocity or elasticity are not possible. When the quality index is below 0.75, the system displays only 2D-mode information.

△ Caution: In lesions where multiple or extensive areas of low shear wave quality are encountered, shear wave velocity or elasticity estimates in the lesion should be interpreted with caution.



Example of the color bar for the Quality map.

- Reliable shear wave velocity or elasticity estimate (green to yellow-green)
- Shear wave velocity or elasticity estimate may be unreliable (yellow-green to yellow-orange)
- Shear wave velocity or elasticity estimate not possible (yellow-orange to red)

10 - 22 Instructions for Use

- Use the Time map to improve boundary definition in structures with elevated shear wave velocities or elasticity values. The time map represents the relative travel time differences of shear waves within the image.
- Use the Displacement map to improve visualization of structural boundaries where large differences in shear wave amplitude can occur. The Displacement map indicates the relative differences of shear wave magnitude in the image and are represented in shades of blue. The lightest blue represents the highest relative displacement magnitude. Shear wave displacement is typically lower in very stiff tissue compared to softer tissues. You can correlate the Displacement map to the Quality map to understand if poor shear wave quality may be related to low shear wave displacement. In general, high shear wave velocity and elasticity (stiffness) are for low shear wave displacement.

10 Virtual Touch Applications

10 - 24 Instructions for Use

Appendix A Technical Description

Technical Description	3
Standard Features	3
Operator Control Panel	3
System Operating Software	3
Monitor	4
Mobility	4
Transducer Technology and Design Attributes	5
User-Accessible Connections	6
CD/DVD Combination Drive	6
Disk Media	6
Operating Modes	6
Single Modes	6
Combined Modes	6
Formats	7
General (2D) Imaging Features	7
Pulsed Wave Doppler Features	8
Steerable Continuous Wave Doppler	
Continuous Wave Doppler (Auxiliary CW)	9
Color Doppler Velocity (CDV) Features	
Color Doppler Energy (CDE) Features	
M-Mode Features	
Tissue Harmonic Imaging	
Clips	
eSieScan Workflow Protocols	11
Accessories and Options	12
Language-Specific Operating System	12
Options	13
Transducer Options	26
Digital Documentation Devices	28
Measurements and Reports	29
General Functions	29
General 2D-mode Measurements	29
General M-mode Measurements	29
General Doppler Measurements	29
Application enecific Measurements	30

Measurement Range and Accuracy	33
Clinical Measurements: Range and Accuracy	33
2D-Mode Measurements	33
Doppler Measurements	34
M-Mode Measurements	35
Mixed Mode Measurements	35
Virtual Touch Quantification	36
Clinical Measurements: Range and Accuracy	36
Virtual Touch IQ	36
Clinical Measurements: Range and Accuracy	36
System Requirements	37
Power Supply Requirements	37
Possible Combinations with Other Equipment	37
Leakage Currents	37
Audio, Video, and Data Transmission Connections — Input and Output Signals	38
Wireless Network Connections	
Environmental Requirements	
Protective Measures	
Maximum Physical Dimensions	
System Classifications	41
Standards Compliance	42
Quality Standards	42
Design Standards	42
Acoustic Output Standards	42
Radio and Telecommunications Standards	
CE Declaration	43

Technical Description

Except as noted, the content of this chapter applies to the following ultrasound systems:

- ACUSON S1000 ultrasound system
- ACUSON S2000 ultrasound system
- ACUSON S3000 ultrasound system

Standard Features

- System operating software
- Power cordset
- Biopsy software
- DICOM software
- High-density hard disk
- Recordable disk drive (DVD)
- Coupling Agent (Gel), 0.25 liters
- Security package
 - Restricts access to the ultrasound system by adding user accounts and passwords
 - Tracks user activities and saves the information to a security log file
 - Encrypts DICOM communication transferred from the system to a DICOM compatible device

Note: The available features depend on the licenses purchased for your system.

Operator Control Panel

- Task lighting and backlit controls and keys
- Control panel height adjustment for standing and sitting positions
 - Left/right swivel: ±38°
 - Range of height: 85 cm to 100 cm
- Control panel text in English, German, French, Spanish, or Italian
- Language-specific alphanumeric keyboard
- Control panel layout supports ambidextrous operation
- Five locking positions

System Operating Software

- Image screen text in English, German, French, Spanish, or Italian
- Customizable system settings
- User-Defined exam type feature for defining up to 10 specific exam, transducer, and image parameter settings per exam type
- Supports DICOM file format
- Supports PC file format

Monitor

- 54.5 cm (21.5 inch) High-resolution Flat Panel Display (Monitor)
- 16:9 wide screen format
- 256 shades of gray
- 8 bit (16.7 million colors)
- Recordable image area of 800 by 600 pixels (clips)
- Recordable image area of 1024 by 768 (static image)
- IPS (in-plane switching) technology
- 1920 x 1080 resolution, progressive scan, flicker-free monitor
- Brightness controls
- Built-in microphone
- Reduced glare in all working environments
- Variable positioning adjustments:
 - Range of height: 176 cm to 140 cm; folds down for transport or portable exams to 115 cm
 - Left and right swivel: ±180°
 - Extended wide-angle viewing angle (rotation at the base of the monitor): ±178°
 - Tilt front (+90°) and back (-10°)
- Articulating arm adjustments (independent of control panel):
 - Left and right swivel: ±180°
 - Vertical: up to 12.7 cm

Mobility

- The Mobile QuikStart feature for portable studies decreases the time required to power the system on or off by using the installed battery to place the ultrasound system in a standby status.
 - Startup from standby in approximately 30 seconds
 - Shutdown to standby in approximately 10 seconds
- Central braking system and individual caster lock system
- Swivel casters with shock attenuation features
- Compact and lightweight industrial design
- Large steering handle for portability and maneuvering
- Transducer holders and cable management
- Tilt-down flat panel
- Locking arm for flat-panel monitor

A - 4 Instructions for Use

Transducer Technology and Design Attributes

- Multi-D array transducer technology
- fourSight 4D transducer technology
- Wideband MultiHertz multiple frequency transducer technology
- Hanafy Lens transducer technology
- Virtual Format Imaging feature allows linear displays in a trapezoidal format
- 2.0 to 17.0 MHz imaging range capability
- Three array transducer ports
- One auxiliary continuous wave transducer port
- Parking port for transducer storage
- Transducer holder for all transducer designs and gel bottle storage
- Micro-pinless connectors
- Electronic transducer selection
- Lightweight, ergonomic transducer design with SuppleFlex cables
- Image depth (maximum)

Transducer	Maximum Display Depth (cm)	
4C1	30	
6C1 HD	30	
6C2	30	
8C3 HD	30	
7CF1	24	
7CF2	24	
EV-8C4	14	
EC9-4	14	
MC9-4	14	
9EVF4	16	
9L4	14	
12L4	14	
14L5	8	
14L5 SP	8	
18L6 HD	8	
4V1	30	
4V1c	30	
8V3	18	
4P1	30	
10V4	14	
V5Ms	18	
V7M	18	
CW2	N/A	
CW5	N/A	
AcuNav 8F	18	
AcuNav 10F	18	

User-Accessible Connections

Note: The ultrasound system does not support the U3 USB device type.

- USB modem port for user or service network connectivity
- USB ports on back of control panel for importing and exporting protocols, archiving, and serviceability (quantity 2)
- USB ports on left side of touch screen for importing and exporting protocols, archiving, and serviceability (quantity 2)*
- DC power socket for optional gel warmer*

CD/DVD Combination Drive

Note: The DVD recordable media supported by the CD/DVD combination drive is DVD-R or DVD-RW only. The CD/DVD combination drive does not support DVD+R or DVD+RW formatted media.

 Recordable disk (DVD) drive and hardware for storage, review, and archival of patient and image data

Disk Media

A

⚠ Caution: Use only disk media brands that have been qualified by Siemens. You may have problems saving data to or retrieving data from disk media that has not been qualified by Siemens

Only use CD-Rs (recordable compact disks) or DVD-Rs (recordable digital video disks) with the ultrasound system. The following disk media brands have been qualified by Siemens for use with the system: JVC, Sony, TDK, Verbatim, and Maxell.

Operating Modes

Single Modes

- 2D-modeM-mode
- Color Doppler Velocity (CDV)
- Color Doppler Energy (CDE)
- Pulsed Doppler
- Continuous Wave Doppler

Combined Modes

- 2D/M-mode
- 2D/Doppler
- 2D-mode with CDV
- 2D-mode with CDE
- 2D/M-mode with CDV
- 2D/M-mode with CDE
- 2D/Doppler with CDV
- 2D/Doppler with CDE

A - 6 Instructions for Use

^{*}Not available for systems without a touch screen

Formats

- Dual, Seamless Dual image display
- Live dual image display format
- Virtual Format Imaging: linear, sector, steered, or trapezoidal format
- Curved-sector, linear, and phased-sector data acquisition and display formats

General (2D) Imaging Features

- Field of view (FOV) format adjustment
- Up to 16 choices for magnification in frozen, CINE, or real-time imaging
- 0.5 cm to 30 cm depth of view display
- CINE memory capacity: Up to 30 seconds of CINE capture
- Acquired 2D-mode frame rates up to 500 fps
- Up to six 2D-mode transmit frequencies per transducer
- Quad signal parallel processing
- Linear array transducer beam steering
- 2D/Doppler Refresh, Update, and Triplex functions
- Gain of -20 dB to 20 dB in one decibel increments
- Dynamic range of 30 dB to 90 dB in five decibel increments
- Multi-frequency Ensemble Tissue Harmonic Imaging feature
- Three levels of Dynamic Tissue Optimization (DTO)

Pulsed Wave Doppler Features

- Doppler measurements and calculations available for all linear, curved, and phased array transducers
- Fast Fourier Transformation (FFT) processing of 32 to 256 points
- FFT speed up to 1,920 FFTs per second at the highest sweep speed
- Up to four user-selectable transmit frequencies per transducer
- Simultaneous 2D-mode and Doppler display and 2D/Doppler with color (Triplex)
- User-selectable Doppler update mode
- User-adjustable Doppler scale and position controls
- Angle correction of 0° to 89° in one degree increments
- Transmit frequencies of 2 to 7.5 MHz
- Downshift frequency and high-PRF Doppler
- Doppler grayscale and colorization (tint) maps
- Spectral invert
- User-selectable frequency (kHz) or velocity (m/s) display format
- Wall filter selections: 20 Hz to 1,600 Hz
- Adjustable Doppler Gate size from 0.1 cm up to 4.0 cm, depending on the transducer
- Flow angle correction on real-time or frozen images, with velocity readout update
- PRF range from 100 Hz to 52,000 Hz
- Doppler signal processing that enables automatic calculation of waveform statistics during real-time imaging
- Derived waveform Doppler trace function analyzes frozen Doppler spectrum for mean and maximum velocity information. Waveform may be set to trace above baseline, below baseline, or both.
- Doppler audio output while in Doppler cursor mode
- Doppler CINE control feature up to 30 seconds of Doppler data can be stored
- Five sweep speed selections
- Gain of 0 dB to 90 dB in one decibel increments

Steerable Continuous Wave Doppler

Steerable continuous wave Doppler for phased array transducers

A - 8 Instructions for Use

Continuous Wave Doppler (Auxiliary CW)

(Requires the Cardiac Application Module option or the Continuous Wave Doppler Interchangeability Option)

Activates the port for Continuous Wave Doppler (pencil) transducers

Color Doppler Velocity (CDV) Features

- 2D/Color display
- User-adjustable color region of interest (ROI), size, and position
- Independent controls for color gain, PRF, invert, baseline, space/time, persistence, priority, and smoothing
- Up to four user-selectable transmit frequencies
- Color On/Off invert and baseline shift functions
- Three user-selectable color flow states: low, general, and high
- Color-adaptive wall filter
- PRF range of 100 Hz to 19,500 Hz
- Six color velocity maps (three velocity maps and three velocity + variance maps (VV))
- Up to 512 color samples per color data line
- Up to 512 2D-mode lines plus 256 color lines

Color Doppler Energy (CDE) Features

- Power mode On/Off control
- Background Power Doppler on and off selection
- Power Gain from -20 dB to 20 dB in one decibel increments
- Independent controls for power gain, PRF, invert, baseline, resolution/frame rate, persistence, priority, and smoothing
- Up to four user-selectable transmit frequencies
- Up to eight user-selectable Power map selections
- Up to five persistence levels (0 to 4)
- Up to four levels of Power smoothing (0 to 3)
- PRF range from 100 Hz to 19,500 Hz
- Adaptive wall filter
- Three user-selectable flow states: low, general, high

M-Mode Features

- Independent controls for M-mode gain, and sweep speed
- Dynamic range display from 30 dB to 70 dB in five decibel increments
- M-mode gain from -17 dB to 20 dB in one decibel increments
- Five sweep speed selections
- Up to five user-selectable transmit frequencies
- Up to four user-selectable Edge Enhancement selections
- Six M-mode grayscale maps and up to 12 colorization maps
- 25-second CINE capability for measurements
- Anatomical M-mode for cardiac exams supports visualization of an M-mode sweep by rotating the M-mode cursor off axis

Tissue Harmonic Imaging

- Available for all imaging transducers
- Up to five THI transmit frequencies per transducer

A - 10 Instructions for Use

Clips

(Standard with system)

- Prospective capture of motion image data
- Retrospective capture of motion image data
- Variable clip length (1 second to 10 minutes)
- Compressed JPEG Lossy format
- Uncompressed Clips
- Acoustic Clip Capture
- AVI and JPEG format
- DICOM format
- Supports storing of individual images within clips

eSieScan Workflow Protocols

An eSieScan protocol is a pre-defined checklist that guides you through a clinical workflow.

- Define protocol steps (views) that include an image, volume, or clip with measurements, body markers, and annotations
- Change the sequence of views during a protocol
- Pause and resume a protocol
- Activate a clinical application program during a protocol
- Create new workflow protocols or modify existing protocols
- Import or export protocols using a USB storage device

Accessories and Options



▲ WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Anyone who connects additional equipment to any of the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards IEC 60601-1. Siemens can only guarantee the performance and safety of the devices listed in the *Instructions for Use*. If in doubt, consult the Siemens service department or your local Siemens representative.



⚠ WARNING: You must only use the transducers, accessories, cables, and replacement parts for internal components specified by Siemens to reduce the risk of increased RF (radio frequency) emissions or decreased immunity of the ultrasound system.

The Siemens-authorized accessories and options for your ultrasound system are listed in this chapter.

Note: To ensure compliance with the Medical Device Directive, use only the devices listed in this chapter with your ultrasound system.

Language-Specific Operating System

Includes the operating and general imaging system software, language-specific keyboards, and system Operating Instructions.

- **English Language Operating System**
- International English Language Operating System
- German Language Operating System
- French Language Operating System
- Spanish Language Operating System
- Italian Language Operating System

A - 12 Instructions for Use

Options

Note: For information about the combinations of options available for purchase, contact your Siemens representative.

Tissue Equalization (TEQ) Technology Option

- Optimizes the overall field of view (FOV) image brightness uniformity by changing the DGC and overall gain
- Supports 2D and spectral Doppler imaging

eSielmage Multiparametric Optimization

eSielmage optimization continuously applies the Tissue Equalization (TEQ) technology to your 2D-mode image. This feature optimizes the overall field of view (FOV) image brightness uniformity by changing the DGC and overall gain.

- Requires the Tissue Equalization (TEQ) Technology Option
- Compatible transducer: 6C1 HD
 - Supported studies: Abdomen, Fetal Echo, Gyn, OB, Pelvis, Renal
- Compatible transducer: 8C3 HD
 - Supported studies: Gyn, OB, Pediatric Abdomen, Fetal Echo
- Compatible transducer: MC9-4
 - Supported studies: Gyn, OB, Prostate, Neonatal Head
- Compatible transducer: 12L4
 - Supported studies: Breast, Cerebrovascular, Digital, Musculoskeletal, Penile, Peripheral Vascular, Testicle, Thyroid, Pediatric Abdomen, Pediatric Hip
- Compatible transducer: 18L6 HD
 - Supported studies: Breast, Cerebrovascular, Digital, Musculoskeletal, Penile, Peripheral Vascular, Testicle, Thyroid

Note: eSielmage optimization is active when you select a compatible transducer and supported exam.

Advanced SieClear Spatial Compounding Option

- 2D image optimization technique for enhanced viewing of tissue differences by detection of subtle lesions and enhanced tissue differentiation
- Works with Tissue Contrast Enhancement (TCE) to provide detail in complex masses

Advanced SieClear Spatial Compounding with Color Option

- Requires the Advanced SieClear Spatial Compounding (ASSC) option
- Supports ASSC for 2D images when Color is activated

Dynamic TCE Tissue Contrast Enhancement Option

 Reduces speckle and enhances contrast to provide a realistic tissue presentation and patient-specific processing that adapts to differences in tissue

Clarify Vascular Enhancement (Clarify VE) Technology Option

- Available in combination with 2D-mode, the 2D-mode image in Doppler, SieClear compounding, and THI
- Clarify vascular enhancement technology (Clarify VE) is an optional feature that can decrease artifacts in the 2D-mode image, resulting in an improved view of anatomical structures. Decreased artifacts can enhance definition of both tissue and vessel walls by increasing contrast resolution and improving boundary detection. Clarify VE uses flow information to eliminate noise and reverberation from vessels.
- Compatible with the Advanced SieClear Spatial Compounding (ASSC) option

Custom Tissue Imaging Option

Optimizes the 2D image by adjusting the speed of sound.

A - 14 Instructions for Use

eSieFusion Imaging

(Available only on the ACUSON S3000 system)

- eSieFusion imaging aligns reference data with a real-time ultrasound image for diagnosis and interventional procedures
- Supported reference data: computed tomography (CT), magnetic resonance imaging (MRI)
- Compatible transducers: 6C1 HD, 4V1, 4C1, 6C2

Supported studies: Abdomen, Renal

Compatible transducer: 9L4

Supported studies: Musculoskeletal

Equipment

eSieFusion supports the following components:

- Ascension Technologies Corporation trakSTAR2 electromagnetic tracking system
- Ascension Technologies Corporation Mid-range Transmitter (for the trakSTAR2)
- GCX pole to support mid-range transmitter
- CIVCO General Purpose 8 mm sensors
- CIVCO eTrax Needle Sensor Starter Kit
- Transducer-specific tracking brackets without needle guides
- Transducer-specific tracking brackets with needle guides

Note: For information on the installation, care, and operation of hardware components, refer to the manufacturer's operating instructions that accompanied the device.

eSie Touch Elasticity Imaging Option

- Provides a qualitative representation of relative tissue stiffness for the region of interest
- Requires the 18L6 HD, 14L5, 12L4, 9L4, 6C2, 4C1, 6C1 HD, MC9-4, or EC9-4 transducer

eSie Strain Ratio Option

- At the time of publication, eSie Strain Ratio was not cleared for use by the U.S. Food and Drug Administration. This feature is not enabled or available for use in systems sold in the U.S.A.
- Requires the eSie Touch Elasticity Imaging Option
- Provides a quantifiable method to compare the relative stiffness of tissue within two userselectable regions of interest

Virtual Touch Imaging Option

(Available only on the ACUSON S2000 system and the ACUSON S3000 system)

Compatible transducer: 4C1
 Supported studies: Abdomen
 Compatible transducer: 4V1
 Supported studies: Abdomen
 Compatible transducer: 9L4

Supported studies: Breast, Thyroid
Compatible transducer: 6C1 HD
Supported studies: Abdomen

Supports all basic measurements on either image in dual screen format

Virtual Touch Quantification Option

(Available only on the ACUSON S2000 system and the ACUSON S3000 system)

Compatible transducer: 4C1
 Supported studies: Abdomen
 Compatible transducer: 4V1
 Supported studies: Abdomen
 Compatible transducer: 9L4

Supported studies: Breast, Thyroid
Compatible transducer: 6C1 HD
Supported studies: Abdomen

- Use Virtual Touch quantification to measure tissue shear velocity (Vs) and elasticity (E) for a selected region of interest. Virtual Touch quantification uses acoustic radiation force impulse (ARFI) technology of diagnostic ultrasound to induce tissue displacement. A timecontrolled sequence of "push pulses" from the transducer induces a small displacement of tissue. The ultrasound system measures shear wave velocity and elasticity at the region of interest.
- Provides measurement labels for sites, lesions, and liver segments, which display in the liver assessment section of the abdomen report

A - 16 Instructions for Use

Virtual Touch IQ Option

(Available only on the ACUSON S2000 system and the ACUSON S3000 system)

Compatible transducer: 9L4

Supported studies: Breast, Thyroid

- Uses acoustic radiation force impulse (ARFI) technology of diagnostic ultrasound to induce tissue displacement
- Qualitatively depicts shear velocity for a selected region of interest on a 2D image
- Provides quantitative measurements of shear velocity (Vs) and elasticity (E) for selected points within the region of interest
- Provides shear velocity and elasticity measurement labels for the breast and thyroid exams
- Supports all basic measurements in either a full-screen format or a dual-screen format

3-Scape Real-Time 3D Imaging Option

A MARNING To select the least of the select of the select

⚠ **WARNING:** To avoid technique-related artifacts, you must be thoroughly familiar with the techniques of 3D and 4D imaging. Read the entire 3D and 4D imaging chapter before using the 3-Scape real-time 3D imaging or *four*Sight 4D ultrasound imaging technology.

- The 3D imaging feature is a system option that allows the acquisition of three-dimensional ultrasound images. MultiPlanar Rendering (MPR) provides a view of each segment of the volume as an arbitrary slice.
- Real-time reconstruction after free-hand acquisition
- MultiPlanar Rendering demonstrates imaging planes not accessible with normal scanning techniques

Advanced four Sight Technology Option

- ▲ WARNING: To avoid technique-related artifacts, you must be thoroughly familiar with the techniques of 3D and 4D imaging. Read the entire 3D and 4D imaging chapter before using the 3-Scape real-time 3D imaging or *four*Sight 4D ultrasound imaging technology.
- Requires 3-Scape 3D Imaging Option
- Requires the 9EVF4, 7CF1, or 7CF2 transducer
- fourSight 4D imaging ultrasound technology provides a comprehensive real-time image of anatomical structures and pathological conditions displayed simultaneously in all spatial dimensions
- MultiPlanar Rendering demonstrates imaging planes not accessible with normal scanning techniques

Amnioscopic Render Method Option

- Requires the 3-Scape 3D Imaging and Advanced fourSight Technology Options
- Provides detailed and near photorealistic views of the fetus

Fetal Skeletal Rendering Option

- Requires the 3-Scape 3D Imaging Option
- Optimizes visualization of the fetal spine from volume data

Fetal Heart Spatial-Temporal Image Correlation (STIC) Option

- Requires the Advanced OB/Gyn Visualization Package
 - or -
- Requires the 3-Scape 3D Imaging and Advanced fourSight Technology Options
- Requires the 7CF1 or 7CF2 transducer
- Automatic volume acquisition records a 3D dataset of 2D images of the fetal heart.
 Resulting cine shows the beating heart over multiple heart cycles.

A - 18 Instructions for Use

Black and White SieScape Panoramic Imaging Option

⚠ **WARNING:** To avoid technique-related artifacts and measurement inaccuracies, read the entire SieScape imaging chapter before using the SieScape feature.

⚠ **WARNING:** To ensure accuracy, measurements should only be made on SieScape images that are acquired in a single scan plane.

▲ WARNING: Technique-related artifacts unique to SieScape imaging can occur. Before using the SieScape imaging feature, be sure to read and understand the technique tips in the SieScape imaging chapter.

- SieScape images may be created up to 60 cm in length and up to 360° when the depth is less than the radius of the target area being scanned
- CINE display of frame-by-frame review of individual data frames within the SieScape image
- On-screen reference and speed indicators enhance imaging technique
- Reverse during acquisition
- Zoom and pan capabilities
- Compatible with the Dynamic TCE tissue contrast enhancement technology option

Color SieScape Panoramic Imaging Option

⚠ **WARNING:** To avoid technique-related artifacts and measurement inaccuracies, read the entire SieScape imaging chapter before using the SieScape feature.

⚠ **WARNING:** To ensure accuracy, measurements should only be made on SieScape images that are acquired in a single scan plane.

▲ WARNING: Technique-related artifacts unique to SieScape imaging can occur. Before using the SieScape imaging feature, be sure to read and understand the technique tips in the SieScape imaging chapter.

- Requires the Black and White SieScape Panoramic Imaging Option
- Color SieScape imaging is a combination of real-time SieScape imaging and real-time Power mode acquisition (Color Doppler Energy (CDE)). All Power information is preserved during image acquisition, and the peak of the signal is saved for the Color SieScape image.

Contrast Agent Imaging Option

⚠ **WARNING:** Carefully follow the manufacturers' instructions for use, including indications and contraindications, when administering ultrasound contrast agents.

Compatible transducer: 4C1

Supported studies: Abdomen, Renal, Gynecology, Pelvis

Compatible transducer: 9L4

Supported studies: All except Fetal Echo, Obstetrics, Pediatric Abdomen, and Pediatric Hip

Compatible transducer: EC9-4, MC9-4

Supported studies: Prostate

Compatible transducer: 6C1 HD

Supported studies: Abdomen, Renal

- Supports the following acquisition techniques: Contrast Pulse Sequencing (CPS), Agent Detection Imaging (ADI)
 - CPS is a low Mechanical Index continuous real-time, non-linear imaging technique that provides contrast-to-tissue specificity.
 - ADI is a high Mechanical Index imaging technique that uses the emission properties of contrast agents to characterize their presence or absence in the tissue.
- Supports the following contrast agent destruction techniques: Burst, Micro-Bubble Destruction (MBD)
 - Burst is a high Mechanical Index technique designed to rapidly destroy the injected contrast agent bubbles for a view of re-perfusion immediately afterwards.
 - MBD is a high Mechanical Index non-imaging mode technique for rapid destruction of contrast agent.

A - 20 Instructions for Use

Contrast Harmonic Imaging (CHI)

Requires the Contrast Agent Imaging option

Compatible transducer: 4C1

Supported studies: Abdomen, Renal

Compatible transducer: 9L4

Supported studies: Thyroid, Peripheral Vascular

Compatible transducer: 6C1 HD
 Supported studies: Abdomen, Renal

 A low Mechanical Index harmonic imaging technique that improves contrast image resolution and frame rate compared to fundamental imaging techniques

VueBox Option

- Requires clips acquired during Contrast Pulse Sequencing and stored in DICOM format
- Compatible transducers: 6C1 HD, 4C1, 9L4, MC9-4, EC9-4
- Enables compatibility with the VueBox software application from Bracco. The software is
 used to perform qualitative and quantitative analysis of linear data. For information
 regarding the software application, refer to the manufacturer's instructions.

Multi-Modality Review

Note: Reference images displayed on the ultrasound system are informational only and not intended for diagnosis.

- Displays images from a previous exam side-by-side with images from the current exam.
- Supported modalities for previous exams:
 - Mammography
 - Computed tomography (CT)
 - Magnetic resonance imaging (MR)
 - Ultrasound

Stress Echo Option

- Requires the Cardiac Application Module
- Captures and reviews cardiac loops for multiple-phase (multiple-stage) Stress Echo protocols

syngo eSieCalcs Option

- Provides area, volume, and maximum diameter measurements using a border detection algorithm
- User defines the region of interest
- Can be used wherever manual trace is available

syngo Auto OB Measurements Option

- Provides automatic measurements of crown rump length (CRL), bi-parietal diameter (BPD), head circumference (HC), abdomen circumference (AC), femur length (FL), humerus length (HL), and occipital frontal diameter (OFD)
- Supports BPD outer-to-outer or outer-to-inner measurements

syngo Auto Left Heart Analysis Option



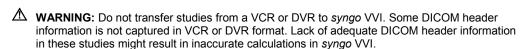
MARNING: This application utilizes ultrasound data collected prior to analysis. The quality of the data collected and used as input could have an effect on the output of this application. Variability in ultrasound system performance, operator technique, patient characteristics, and other factors may affect the output. At all times, the clinician is advised to carefully review the output and confirm the information presented with clinical judgment and any other relevant sources of data.

- Requires the Cardiac Application Module
- Automatically traces an outline of the endocardial border of the left ventricle or the left atrium for the end-diastolic and end-systolic images on an apical two-chamber or four-chamber view of the heart
- Generates calculation data and measurements for end-diastolic volume and end-systolic volume, ejection fraction, and heart rate

syngo Velocity Vector Imaging Option



MARNING: This application utilizes ultrasound data collected prior to analysis. The quality of the data collected and used as input could have an effect on the output of this application. Variability in ultrasound system performance, operator technique, patient characteristics, and other factors may affect the output. At all times, the clinician is advised to carefully review the output and confirm the information presented with clinical judgment and any other relevant sources of data.



- Tracks and estimates tissue velocity and other motion and deformation parameters at selected points on a user-defined outline of a structure
- Assists analysis of rotation, displacement, and radial strain of the left ventricle
- Assists evaluation of fetal to adult cardiac contraction by analyzing the systolic and diastolic ventricular strain and rotation

A - 22Instructions for Use

Contrast Dynamics Software Option

- At the time of publication, the Contrast Dynamics software option was not cleared for use by the U.S. Food and Drug Administration. This feature is not enabled or available for use in systems sold in the U.S.A.
- Compatible with all clips
- Contrast Dynamics software is a quantification application used with contrast agent imaging technology
- Illustrates contrast agent enhancement by displaying graphs indicating changes of intensity over time within defined regions of interest (ROIs)
- Measures the average value and curve-fitted value for each ROI on each image frame

syngo Arterial Health Package (AHP)

- Compatible with clips or images that contain only 2D-mode data and clips or images acquired with a linear transducer
- Provides a method of quantifying Carotid Intima-Media Thickness (CIMT)
- Uses semi-automated border detection to determine the maximum and average thickness
 of the intima-medial layer of the carotid artery

Wireless Data Transfer Option

(Standard on the ACUSON S3000 system; available as an option on the ACUSON S1000 system and ACUSON S2000 system)

Enable wireless capabilities on the ultrasound system.

eSieCrypt Hard Disk Encryption Software Option

⚠ Caution: Hard disk encryption on your ultrasound system requires a USB storage device with the recovery key for recovering encrypted data in the event of a system failure. The ultrasound system administrator must keep the recovery key in a secure location.

The software option protects the information stored on ultrasound system by preventing unauthorized access.

- Protection of patient information and system settings
- A USB storage device with the recovery key for recovering encrypted data

AcuNav ICE (Intracardiac Echo) Option

- Compatible with AcuNav 8F and AcuNav 10F transducers
- SwiftLink catheter connector (includes instructions for use)
- Sterile sheaths

SwiftLink Catheter Connector

Connects the AcuNav ultrasound catheter to the ultrasound system

Footswitch Option

- Configurable 3-pedal footswitch
- Attaches to the ultrasound system with a USB connector

Gel Warmer Option

Attaches to the ultrasound system with a power cable

A - 24 Instructions for Use

Physio Module Option

Includes the ECG function, which contains the ECG cable and leads

ECG Option

- ECG leads, standard U.S.A.
- ECG leads, standard European
- Disposable ECG (EKG) electrodes (50 count)

Cardiac Application Module option

- Cardiac measurements and reports
- Color DTI (Doppler tissue imaging) capability
- Pulsed Wave DTI (Doppler tissue imaging) capability

Continuous Wave Interchangeability Option

Enables functionality for auxiliary continuous wave Doppler

Virtual Communication for eSieLink Remote Assistance

- Enables virtual communication for remote assistance with a Siemens representative.
- Requires using the phone number provided by your Siemens representative to initiate remote assistance. The representative guides you through the setup of each communication session.
- Includes a headset, camera, and camera attachment

Transducer Options

Refer to the following table to identify transducers compatible with your ultrasound system.

Options	Description
Transducers, Curved Array	4C1 (Hanafy Lens)
	• 6C2 (Hanafy Lens)
Transducers, Curved Array	(Available only on the ACUSON S2000 system and the ACUSON S3000 system)
	6C1 HD (Hanafy Lens)
	8C3 HD (Hanafy Lens)
Transducers, Linear Array	■ 9L4
	■ 12L4
	■ 14L5
	■ 14L5 SP
	 18L6 HD (requires a license on the ACUSON S1000 system)
Transducers, Phased Array	■ 4P1
	■ 4V1
	■ 4V1c
	■ 8V3
	■ 10V4
	 V5Ms
	(includes the Leakage Current Tester)
	■ V7M
	(includes the Leakage Current Tester)
	 AcuNav 8F
	 AcuNav 10F
Transducers, Endocavity	■ EV-8C4
	■ EC9-4
	■ MC9-4
Transducers, fourSight 4D	■ 7CF1
(Require 3-Scape Real-Time 3D Imaging Option)	■ 7CF2
	■ 9EVF4
Transducers, Continuous Wave	■ CW2
(Require the CW Interchangeability Module or the Cardiac Application Module)	• CW5
Transducer Components	MP SwiftLink Catheter Connector

A - 26 Instructions for Use

Options	Description
Transducer Accessories	Transducer Sheaths:
	 Non-sterile, EC9-4, MC9-4
	Sterile, EC9-4, MC9-4
	 Aquasonic Gel
	 Contact Gel
	 Disposable Standoff Gel Pads
	 CH4-1 Needle Guide Set, 4C1, 6C1 HD
	 C7F2/C5F1 Needle Guide Set, 7CF2
	 7CF1 Needle Guide Set, 7CF1
	 EC-1 Needle Guide Set, EC9-4
	 MC9-4 Needle Guide Set, MC9-4
	 MC9-4 Disposable Needle Guide Set, MC9-4
	 EC9-4 Disposable Needle Guide Set, EC9-4
	 EV-8C4 Needle Guide Set, disposable, EV-8C4
	 EV-8C4 Needle Guide Set, EV-8C4
	 9EVF4 Needle Guide Set, 9EVF4
	 SG-2 Needle Guide Set, 4V1
	 SG-3 Needle Guide Set, 9L4
	 SG-4 Needle Guide Set, 14L5
	 SG-5 Needle Guide Set, 6C2
	 VF12-4 Needle Guide Set, 12L4
	 8C3 HD Needle Guide Set, 8C3 HD
	 18L6 HD Needle Guide Set, 18L6 HD
	See also: For a list of transducers compatible with the needle guide accessories, refer to Chapter 5 in this manual.
Transducer Accessories, eSieFusion Imaging	■ Tracking bracket without needle guides, 6C1 HD, 4C1
	 Tracking bracket without needle guides, 4V1
	 Tracking bracket without needle guides, 6C2
	 Tracking bracket (multi-angle) with needle guides, 6C1 HD, 4C1
	 Tracking bracket (multi-angle) with needle guides, 4V1
	 Tracking bracket (single angle) with needle guides, 6C2
	 Tracking bracket (dual angle) with needle guides, 9L4
	 Tracking bracket (dual angle) without needle guides, 9L4

Digital Documentation Devices

- On-Board Digital Video Recorder (DVR), UR-50BD, TEAC
- On-Board Black and White Printer Assembly, P-93DW, Mitsubishi
- On-Board Black and White Printer Assembly, P-95DW, Mitsubishi
- On-Board Color Printer Assembly, UP-D23MD, Sony*
- On-Board Color Printer Assembly, UP-D25MD, Sony
- On-Board Color Printer Assembly, UP-D55MD, Sony
- On-Board Color Printer Assembly, CP30DW, Mitsubishi
- External Digital Video Recorder (DVR), UR-50BD, TEAC
- External Black and White Printer Assembly, P-93DW, Mitsubishi
- External Black and White Printer Assembly, UP-897, Sony
- External Black and White Printer Assembly, UP-898, Sony
- External Color Printer Assembly, UP-D23MD, Sony*
- External Color Printer Assembly, UP-D25MD, Sony
- External Color Printer Assembly, UP-D55MD, Sony
- External Color Printer Assembly, CP30DW, Mitsubishi

Consumables

- Black and White Paper, P-93DW Printer
- Black and White Paper, P-95DW Printer
- Print Media, UP-D23MD Printer
- Print Media, UP-D25MD Printer
- Cleaning Sheets, Black and White P-93DW Printer
- Cleaning Sheets, Black and White P-95DW Printer
- 650 MB CD-R Disks (box of 5)
- 25 GB BD-R Blu-ray Disks (box of 5)
- 25 GB BD-RE Blu-ray Disks (box of 5)

A - 28 Instructions for Use

^{*}Not available for sale.

Measurements and Reports

Measurements are available during all examinations on real-time, frozen, and CINE images.

Note: Images saved in the ultrasound image output format (with or without overlays) can be recalled for measurements after the examination ends.

General Functions

- 2D-mode and M-mode have unlimited sets of calipers per image for distance measurements
- Doppler has unlimited sets of calipers per image for velocity or frequency measurements
- 2D measurement tools on frozen/CINE and real-time images include distance, ellipse, and trace
- 2D measurement packages include distance, area, circumference, volume, stenosis, and volume flow
- Label then Measure or Measure then Label workflow

General 2D-mode Measurements

- Distance/Depth
- Circumference (using a Trace or Ellipse method)
- Area (using an Ellipse or Trace method)
- Volume and Stenosis
- Volume Flow (using an Area or Diameter method with a Doppler measurement)

General M-mode Measurements

- Distance/Depth
- Heart Rate
- Slope
- Time

General Doppler Measurements

- Measurements on a frozen or CINE image including velocity/frequency, HR (heart rate), S/D (systolic/diastolic ratio), RI (resistive index), PI (pulsatility index), TAMx (time-average maximum), TAMn (time-average mean), Slope (Acceleration/Deceleration), Volume Flow, A/B ratios, Time
- Automatic Doppler statistics (automatic waveform trace) for real-time and CINE display of Doppler spectral measurements and calculations, including PS, ED, S/D, PI, RI, TAMx, TAMn

Application-specific Measurements

The ACUSON S1000 ultrasound system includes only the application-specific measurements purchased for your system.

The ACUSON S2000 ultrasound system includes all application-specific measurements.

The ACUSON S3000 ultrasound system includes all application-specific measurements.

The following applications (exam types) include general measurements and exam-specific measurement labels, body markers, annotations, and an editable report:

Abdomen, Adult Echo, Breast, Cerebrovascular, Digital, Fetal Echo, Gynecology, Musculoskeletal, Neonatal Echo, Neonatal Head, OB, Pediatric Abdomen, Pediatric Echo, Pediatric Hip, Pelvis, Penile, Prostate, PV-Arterial, PV-Venous, Renal, Testicle, Thyroid, Transesophageal, and Transcranial.

Application	Application-Specific Measurements and Calculations
Abdomen	Ratio of the peak systolic velocity (PSV) of the renal artery to the PSV of the aorta
	 Ratio of the interquartile range to the median calculation for all measurements associated with the assigned label
	 The patient report includes a liver evaluation section that displays shear wave velocity and elasticity measurements from the Virtual Touch quantification function
Breast	 The patient report includes shear wave velocity and elasticity measurements from Virtual Touch IQ
Cerebrovascular	 The patient report includes selections for the Internal Carotid Artery/Common Carotid Artery (ICA/CCA) ratio
Fetal Echo	 Cardiothoracic Area Ratio: Fetal Heart Area/Fetal Thoracic Cross-Sectional Area
	 Fetal Echo measurement ratios for 2D-mode LV percentage of fractional shortening and for Doppler mitral valve E/A and Tei Index
Gynecology	Micturated volume
Pelvis	
Pediatric	 Hip Angle 2D-mode measurement labels for % coverage or Graf method
Prostate	Prostate volume calculation
	 Prostate-specific gravity: user preset for 1.0 or 1.05
Renal	 Ratio of the peak systolic velocity (PSV) of the renal artery to the PSV of the aorta
Thyroid	Thyroid volume
	 Ratio of the interquartile range to the median calculation for all measurements associated with the assigned label
	 The patient report includes shear wave velocity or elasticity measurements from Virtual Touch IQ
Transcranial	 Middle Cerebral Artery/Internal Carotid Artery (MCA/ICA) Ratio

A - 30 Instructions for Use

Application

Application-Specific Measurements and Calculations

Cardiac

- 2D-mode measurement labels include specific labels for Mitral Valve Function, Aortic Valve Function, Pulmonary Valve Function, Proximal Isovelocity Surface Area (Mitral Regurgitation), Proximal Isovelocity Surface Area (Mitral Stenosis), Left Ventricular Dimensions, Left Ventricular (Truncated Ellipse), Left Ventricular Mass (Area and Length), Cardiac Output
- 2D-mode calculation labels including: Cardiac Index, Cardiac Output, End Diastolic Velocity and End Systolic Velocity, Ejection Fraction, Fractional Shortening, Stroke Index, Stroke Volume, thickness of the myocardium (t), short-axis radius (b), Aortic Root/Left Atrium, Left Ventricular Mass Index, Left Ventricular Mass (Truncated Ellipse), Left Ventricular Mass (Area and Length), Left Atrial Volume (Area and Length, Simpson Bi-Plane, Ellipsoid), Right Atrial Volume (Area and Length, Simpson Single Plane)
- M-mode measurement labels include specific labels for Aortic Valve/Left Atrium (M-mode), Mitral Valve, Right Ventricular Dimensions, and Left Ventricular Dimensions
- M-mode calculation labels including Cardiac Index, Cardiac Output, End Diastolic Velocity and End Systolic Velocity, Ejection Fraction, Aortic Root/Left Atrium, Heart Rate, Stroke Index, Stroke Volume, Left Ventricular Mass, Left Ventricular Mass (corrected), Left Ventricular Mass Index, M-mode Velocity of circumferential fiber shortening
- Doppler measurement labels and calculation include Aortic Valve Function, Mitral Valve Function, Tricuspid Valve Function, Pulmonary Valve Function, Pulmonary Vein Function, Aortic Regurgitation, Tricuspid Regurgitation, Pulmonary Regurgitation, Mitral Regurgitation, Proximal Isovelocity Surface Area (Mitral Regurgitation), Proximal Isovelocity Surface Area (Mitral Stenosis), and Doppler Tissue Imaging
- Left Ventricular Function Assessment, including: Simpson Single Plane, Simpson Bi-Plane, Cubed Formula, Teichholz Formula
- Patient report and worksheet

Application

Application-Specific Measurements and Calculations

Obstetric

- Gestational age and estimated date of confinement (EDC) by last menstrual period (LMP) or in-vitro fertilization (IVF)
- Gestational age by single parameter:

Biparietal Diameter (BPD), Head Circumference (HC), Occipital Frontal Diameter (OFD), Abdominal Circumference (AC), Femur Length (FL), Crown Rump Length (CRL), Binocular distance, Gestational Sac Diameter (GSD), Humerus Length (HL), tibia length, ulna length, clavicle length, foot length, and fetal trunk area

- Gestational age by multiple parameters
- Interval Growth Rate
- Estimated Date of Confinement by ultrasound age
- Estimated Fetal Weight (EFW)
- Standard Deviation (SD) of measurements and EFW Calculations
- Singleton, twin, triplet or quadruplets
- User-defined Obstetrical tables
- User-defined fetal and maternal assessment checklist
- Serial (historical) growth trending import up to 20 previous exams
- Export of data with serial cable to Windows file share location using DICOM Structured Reporting*
- Growth Evaluation
- Ratios: Cephalic Index (CI), HC/AC, FL/AC, FL/HC, FL/BPD, Left Ventricular Width/Hemispheric Width (LVW/HW), Transcerebellar Diameter/Abdominal Circumference (TCD/AC)
- Curves: AC, BPD, CRL, EFW, FL, Fetal Trunk Area (FTA), GSD, HC/AC, HC, HL, Occipital-Frontal Diameter (OFD), Transabdominal Diameter (TAD), APADxTAD, MCA, Umb A
- Percentile display on report
- 2D-mode Measurement Labels
- PW Doppler Measurement Labels
- M-mode Measurement Labels
- Fetal heart rate
- Biophysical Profile

A - 32 Instructions for Use

^{*}The RS-232 port is enabled on systems manufactured before February 2011. For more information, contact your Siemens representative.

Measurement Range and Accuracy

The following tables describe the variability in accuracy for clinical measurements.

Clinical Measurements: Range and Accuracy

Direct Measurement	Range	Tolerance Symbol	Tolerance Function or Value (Accuracy)
Distance*	0 – 36 cm	Tol(D)	3% of the distance or 1.5 mm; whichever is greater assuming 1,540 m/sec speed of sound. Does not apply to trace tool. Distance tolerance using trace tool is user-dependent.
Distance using SieScape extended field of view	0 – 60 cm	Tol(D)	Linear transducer: 5% of the distance or 2.5 mm; whichever is greater assuming 1,540 m/sec speed of sound.
			Curved transducer: 8% of the distance or 2.5 mm; whichever is greater assuming 1,540 m/sec speed of sound.
Trace Area*	0 – 560 cm ²	Tol(A)	6% of the area or 1.5 cm ² ; whichever is greater, assuming minimal operator error in tracing the desired object and assuming 1,540 m/sec speed of sound.
Time @	0 – 9.4 sec	Tol(T) @	15 msec
Slow Sweep		Slow Sweep	
Time @	0 – 4.7 sec	Tol(T) @	7.5 msec
Med Sweep		Med Sweep	
Time @	0 – 2.4 sec	Tol(T) @	3.8 msec
Fast Sweep		Fast Sweep	
Velocity	10 – 600 cm/sec	Tol(V)	10% of the velocity or 5 cm/s; whichever is greater using a J J & A string phantom at 45 degrees ±1 degree.

^{*} Also applies to measurements on MPR (slice) quadrants from acquired volumes.

2D-Mode Measurements

2D-mode			
Measurements	Range or Formula	Minimum Value	Maximum Value
Distance	0 – 34 cm	D-Tol(D)	D + Tol(D)
Distance Ratio	D1/D2	(D1-Tol(D1))/(D2+Tol(D2))	(D1+Tol(D1))/(D2-Tol(D2))
Mean Distance	(D1+D2+D3)/3	(D1-Tol(D1)+D2-Tol(D2)+ D3-Tol(D3))/3	(D1+Tol(D1)+D2+ Tol(D2)+D3Tol(D3))/3
Ellipse Circumference	$\pi \{1/2[D1^2+D2^2]\}^{1/2}$	π {1/2[(D1-Tol(D1)) ² + (D2-Tol(D2)) ²]} ^{1/2}	π {1/2[(D1+Tol(D1)) ² + (D2+Tol(D2)) ²]} ^{1/2}
Ellipse Area	π(D1)(D2)/4	π(D1-Tol(D1))(D2-Tol(D2))/4	π(D1+Tol(D1)) (D2+Tol(D2))/4
Ellipse Volume	(π/6)(D1)(D2) ²	(π/6)(D1-Tol(D1))(D2- Tol(D2)) ²	(π/6)(D1+Tol(D1)) (D2+Tol(D2)) ²
(D1 = axis of rotation)		101(D2))	(BZ: 101(BZ))
Trace Circumference	0 – 85 cm	D-Tol(D)	D+Tol(D)
Trace Area	$0 - 450 \text{ cm}^2$	A-Tol(A)	A+Tol(A)

2D-mode Measurements	Range or Formula	Minimum Value	Maximum Value
% Stenosis by Area	100(A1-A2)/A1	100(A1-Tol(A1)-A2- Tol(A2))/(A1+Tol(A1))	100(A1+Tol(A1)- A2+Tol(A2))/(A1-Tol(A1))
% Stenosis by Diam.	100(D1-D2)/D1	100(D1-Tol(D1)-D2- Tol(D2))/(D1+Tol(D1))	100(D1+Tol(D1)- D2+Tol(D2))/(D1-Tol(D1))
Amniotic Fluid Index*	AFI=D1+D2+D3+D4	D1-Tol(D1)+D2-Tol(D2)+ D3-Tol(D3)+D4-Tol(D4)	D1+Tol(D1)+D2+Tol(D2)+ D3+Tol(D3)+D4+Tol(D4)
Bi-plane Volume	(D1)(D2)(D3)(0.52)	(D1-Tol(D1))(D2-Tol(D2)) (D3-Tol(D3))(.52)	(D1+Tol(D1))(D2+Tol(D2)) (D3+Tol(D3))(.52)
Strain Ratio	M _{ROI1} /M _{ROI2}		
	M _{ROI} =Mean strain in a region of interest		

^{*} Values are adjusted for fewer than four distances (quadrants). For example, if the second and fourth quadrants are measured, then the formula is "AFI=D2+D4." The minimum value is "D2-Tol(D2)+D4-Tol(D4)" and the maximum value is "D2+Tol(D2)+D4+Tol(D4)."

Doppler Measurements

Doppler Measurements	Range or Formula	Minimum Value	Maximum Value
Velocity	20 - 600 cm/sec	V-Tol(V)	V+Tol(V)
Frequency	2F ₀ Vcosθ/1540 F ₀ =Carrier Frequency	2F ₀ cosθ(V-Tol(V))/1540	$2F_0\cos\theta(V+Tol(V))/1540$
Delta Velocity	V1 - V2	V1-Tol(V1)-V2-Tol(V2)	V1+Tol(V1)-V2+Tol(V2)
Delta Frequency	2F ₀ cosθ(V1-V2)/1540	2F ₀ cosθ(V1-Tol(V1)- V2-Tol(V2))/1540	2F ₀ cosθ(V1+Tol(V1)- V2+Tol(V2))/1540
Time @ Slow Sweep	0 – 11.2 sec	T-Tol(T)@ Slow Sweep	T+Tol(T)@ Slow Sweep
Time @ Med Sweep	0 – 5.6 sec	T-Tol(T)@ Med Sweep	T+Tol(T)@ Med Sweep
Time @ Fast Sweep	0 – 2.8 sec	T-Tol(T)@ Fast Sweep	T+Tol(T)@ Fast Sweep
Time Averaged Maximum Velocity; TAMx	(MxVel ¹ +MxVel ² ++ MxVel ^N)/N	(MxVel ¹ -Tol(MxVel ¹)+MxVel ² - Tol(MxVel ²)++MxVel ⁿ - Tol(MxVel ⁿ))/N	(MxVel ¹ +Tol(MxVel ¹)+ MxVel ² +Tol(MxVel ²)++ MxVel ⁿ +Tol(MxVel ⁿ))/N
	N=Number of Velocities Averaged		
Time Averaged Mean Velocity; TAMn	(MnVel ₁ +MnVel ₂ + +MnVel _N)/N	(MnVel ₁ -Tol(MnVel ₁) +MnVel ₂ -Tol(MnVel ₂)+	(MnVel ₁ +Tol(MnVel ₁)+ MnVel ₂ +Tol(MnVel ₂)++
	N=Number of Velocities Averaged	+MnVel _n -Tol(MnVel _n))/N	$MnVel_n+Tol(MnVel_n))/N$
Time Averaged Minimum Velocity;	(MinVel ₁ +MinVel ₂ + +MinVel _N)/N	(MinVel ₁ -Tol(MinVel ₁)+ MinVel ₂ -Tol(MinVel ₂)++	(MinVel ₁ +Tol(MinVel ₁)+ MinVel ₂ +Tol(MinVel ₂)++
TAMin	N=Number of Velocities Averaged	MinVel _n -Tol(MinVel _n))/N	MinVel _n + Tol(MinVel _n))/N

A - 34 Instructions for Use

Doppler Measurements	Range or Formula	Minimum Value	Maximum Value
Time Averaged Mode Velocity; TAMd	(MnVel ₁ +MnVel ₂ ++ MnVel _N)/N	(MdVel ₁ -Tol(MdVel ₁)+ MdVel ₂ -Tol(MdVel ₂)++	(MdVel ₁ +Tol(MdVel ₁)+ MdVel ₂ +Tol(MdVel ₂)++
	N=Number of Velocities MdVel _n -Tol(MdVel _n))/N Averaged	MdVel _n -Tol(MdVel _n))/N	MdVel _n +Tol(MdVel _n))/N
Resistivity Index	(PS-ED)/PS	(PS-Tol(PS)-ED- Tol(ED))/(PS+Tol(PS))	(PS+Tol(PS)-ED+Tol(ED))/(PS- Tol(PS))
Pulsatility Index	(PS-ED)/TAV	(PS-Tol(PS)-ED- Tol(ED))/(TAV+Tol(TAV))	(PS+Tol(PS)-ED-Tol(ED))/(TAV- Tol(TAV))
Slope	(V1-V2)/T	(V1-Tol(V1)-V2-	(V1+Tol(V1)-V2+ Tol(V2))/(T-
(Acceleration)		Tol(V2))/(T+Tol(T))	Tol(T))
Systolic/Diastolic	S/D	(PS-Tol(PS))/(ED+Tol(ED))	(PS+Tol(PS))/(ED-Tol(ED))
Ratio			

M-Mode Measurements

M-Mode Measurements	Range or Formula	Minimum Value	Maximum Value
Distance	0 – 24 cm	D-Tol(D)	D+Tol(D)
Time @	0 – 11.2 sec	T-Tol(T) @ Slow Sweep	T+Tol(T) @ Slow Sweep
Slow Sweep			
Time @	0 – 5.6 sec	T-Tol(T) @ Med Sweep	T+Tol(T) @ Med Sweep
Med Sweep			
Time @	0 – 2.8 sec	T-Tol(T) @ Fast Sweep	T+Tol(T) @ Fast Sweep
Fast Sweep			
Heart Rate	60 – 240 bpm	N/Time for N beats - N/(Time for N beats+Tol(T))	N/Time for N beats - N/(Time for N beats-Tol(T))
		N = 1, 2, 3, 4, or 5	N = 1, 2, 3, 4, or 5

Mixed Mode Measurements

Mixed-mode Measurements	Range or Formula	Minimum Value	Maximum Value
Volume Flow by Area	(TAMn)(Area)(0.06)	(TAMn-Tol(TAMn))	(TAMn+Tol(TAMn))
(TAMn is in cm/s, Area is in cm ²)	*I/min	(Area-Tol(A))(0.06)	(Area+Tol(A))(0.06)
Volume Flow by Diameter	(TAMn)(πD²/4)(0.06) *I/min	(TAMn-Tol(TAMn)) ($\pi * (D-Tol(D))^2/4)(0.06)$	(TAMn+Tol(TAMn)) ($\pi * (D+Tol(D))^2/4)(0.06)$
(TAMn is in cm/s, Area is in cm ²)	Where TAMn is in cm/s and the area is in cm ²	Where TAMn is in cm/s and the area is in cm ²	Where TAMn is in cm/s and the area is in cm ²

Virtual Touch Quantification

Clinical Measurements: Range and Accuracy

Direct Measurement	Range	Tolerance Symbol	Tolerance Function or Value (Accuracy)
Shear Velocity (Vs)	0.8 – 3.65 m/s	Tol(Vs)	(Applies to the 4C1, 4V1, and 6C1 HD transducers)
			$\pm 20\%$ of the velocity over the depth range of 0.5 - 8.0 cm
	3.65 – 5.0 m/s	Tol(Vs)	(Applies to the 4C1, 4V1, and 6C1 HD transducers)
			$\pm 30\%$ of the velocity over the depth range of 3.0 - 6.0 cm
Shear Velocity (Vs)	0.8 – 6.1 m/s	Tol(Vs)	(Applies to the 9L4 transducer)
			$\pm 20\%$ of the velocity over the depth range of 0.5 - 4.0 cm
	6.1 – 8.4 m/s	Tol(Vs)	(Applies to the 9L4 transducer)
			$\pm 40\%$ of the velocity over the depth range of 0.5 - 2.0 cm
Elasticity (E)	1.9 – 40.0 kPa	Tol(E)	(Applies to the 4C1, 4V1, and 6C1 HD transducers)
			$\pm 20\%$ of the elasticity over the depth range of 0.5 - 8.0 cm
	40.0 – 75.0 kPa	Tol(E)	(Applies to the 4C1, 4V1, and 6C1 HD transducers)
			$\pm 30\%$ of the elasticity over the depth range of 3.0 - 6.0 cm
Elasticity (E)	1.9 – 111.6 kPa	Tol(E)	(Applies to the 9L4 transducer)
			$\pm 20\%$ of the elasticity over the depth range of 0.5 - 4.0 cm
	111.6 – 211.7 kPa	Tol(E)	(Applies to the 9L4 transducer)
			$\pm 40\%$ of the elasticity over the depth range of 0.5 - 2.0 cm

Virtual Touch IQ

Clinical Measurements: Range and Accuracy

Direct Measurement	Range	Tolerance Symbol	Tolerance Function or Value (Accuracy)
Shear Velocity (Vs)	0.5 – 10.0 m/s	Tol(Vs)	$\pm 20\%$ of the velocity over the range of 0.5 – 10.0 m/s
Elasticity (E)	0.8 – 300.0 kPa	Tol(E)	$\pm 20\%$ of the elasticity over the range of 0.8 $-$ 300.0 kPa

A - 36 Instructions for Use

System Requirements

Power Supply Requirements

MAINS V	Range	Max. Current	Frequency	Freq. Range
230V~	196V to 264V	6.5 amps	50/60 Hz	47 to 63 Hz
115V~	98V to 132V	12 amps	50/60 Hz	47 to 63 Hz
100V~	90V to 110V	15 amps	50/60 Hz	47 to 63 Hz

Possible Combinations with Other Equipment

Only the peripheral devices listed in this chapter are approved for use with the ultrasound system. Any use of other devices with the system will be at the user's risk and may void the system warranty.

On-board peripheral devices may need to be installed by an authorized Siemens representative or approved third party. Check with your sales representative.

▲ WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Anyone who connects additional equipment to any of the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards IEC 60601-1. Siemens can only guarantee the performance and safety of the devices listed in the *Instructions for Use*. If in doubt, consult the Siemens service department or your local Siemens representative.

Leakage Currents

Connecting peripheral products and accessories from non-isolated sources may result in chassis leakage current exceeding safe levels.

Audio, Video, and Data Transmission Connections — Input and Output Signals

Port	Location	Example of Connection	Signal
RJ-45	Inside the input/output panel door	Ethernet (10BaseT/100BaseT/1000BaseT)	Bi-directional
HDMI (J18)	Input/output panel	Video recorder (video and audio)	Output
HDMI (J19)	Input/output panel	Video recorder (video and audio)	Input
USB-A (J4A, J4B, J5A, J5B)	Input/output panel	Printer, video recorder (remote control), eSieFusion electronics unit, SIE1 data transmission, headset and camera for virtual communication with a Siemens service representative	Bi-directional
DVI (J9)	Input/output panel	External monitor (digital or analog)	Output
BNC-type (J13)	Input/output panel	ECG trigger	Output
USB-A	Control panel	USB storage device	Bi-directional
USB-A	Front system panel	Footswitch	Bi-directional
ECG connector (ECG)	Physio panel	ECG leads	Input
Phone jack (Aux 1 ECG)	Physio panel	ECG external DC input	Input

Wireless Network Connections

The ultrasound system supports the following options for connections to wireless networks.

Network standard:	■ 802.11a
	■ 802.11b
	■ 802.11g
	■ 802.11n
	Mixed
Frequency bandwidth:	■ 2.4 GHz
	■ 5 GHz
Authentication:	WPA
	■ WPA2
	WPA-PSK
	WPA2-PSK
	Open
	Shared
Encryption:	None
	WEP
	 TKIP
	AES
Extensible Authentication Protocol (EAP):	■ PEAPv0 (PEAP-MSHCAPV2)

Environmental Requirements

EMC Note: Operating the ultrasound imaging system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

	During Operation	Ambient (During Storage or Transportation)
Relative humidity:	10% to 80%, non-condensing	10% to 95%, non-condensing
Temperature:		
System	+10°C to +40°C*	-20°C to +60°C
Array Transducers (except 7CF2, 9EVF4)	+10°C to +40°C	-10°C to +50°C
7CF2, 9EVF4	+20°C to +40°C	-5°C to +50°C
Pencil CW Transducers CW2, CW5	+10°C to +40°C*	-40°C to +60°C
Maximum Altitude:	Operation up to 3,050 meters (10,000 feet)	5,050 meters (18,000 feet)

^{*}For systems with documentation devices installed.

Protective Measures

Explosion protection: This product is not designed for operation in areas subject to explosion

hazards.

Maximum Physical Dimensions

Width: 623 mm

Height:

(For systems with a 1,630 mm

touch screen) 1,330 mm (minimum)

(For systems without 1,540 mm

a touch screen) 1,275 mm (minimum)

Depth: 1,103 mm

Weight: Not to exceed 170 kg (375 lbs)

The weight of the system is based on the system unpacked and ready

for connecting transducers and using in a patient examination.

The weight includes documentation devices, such as printers, installed

on the system.

A - 40 Instructions for Use

System Classifications

- Type of protection against electrical shock:
 - Class I, external powered
- Degree of protection against electrical shock:
 - Type BF applied part for ECG and endocavity, linear, curved, and phased array transducers
 - Type B applied part for eSieFusion transducer sensors and needle tracking sensors
 - Type CF applied part for ACUSON AcuNav ultrasound catheters
 - Defibrillation-proof applied part for ECG and ACUSON AcuNav ultrasound catheters
- Degree of protection against harmful ingress of water:
 - Ordinary equipment
- Degree of safety of application in the presence of a flammable anesthetic material with air or with oxygen or nitrous oxide:
 - Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
- Mode of operation:
 - Continuous operation

Standards Compliance

The ultrasound system is in compliance with the following standards, including all applicable amendments at the time of product release.

Quality Standards

- FDA QSR 21 CFR Part 820
- ISO 13485
- ISO 9001

Design Standards

- UL 60601-1
- CSA C22.2 No. 601.1
- EN 62304 and IEC 62304
- EN 62366 and IEC 62366
- EN 60601-1 and IEC 60601-1
- EN 60601-1-2 and IEC 60601-1-2 (Class B)

Note: The system is a Class A device when the ACUSON AcuNav ultrasound catheter is in use.

Note: The system is a Class A device when the ACUSON S2000 Automated Breast Volume Scanner is in use.

Note: The ultrasound system is a Class A device when the eSieFusion is in use.

- EN 60601-1-6 and IEC 60601-1-6
- EN 60601-2-18 and IEC 60601-2-18
- EN 60601-2-37 and IEC 60601-2-37
- ISO 14971

Acoustic Output Standards

- IEC 62359
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

Radio and Telecommunications Standards

- CFR 47 FCC Part 15.247
- CFR 47 FCC Part 15.107
- CFR 47 FCC Part 15.109
- ETSI EN 300 328
- ETSI EN 301 489-1
- ETSI EN 301 489-17
- ETSI EN 301 893

CE Declaration

This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. The CE marking only applies to medical devices that have been put on the market according to the above referenced Council Directive.

Unauthorized changes to this product are not covered by the CE marking and the related Declaration of Conformity.

EU Authorized Representative

Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany

A - 44 Instructions for Use

ppendix B Control Panel and T	
ontrol Panel	
Lighting and Audio	
Touch Screen Controls	
Symbols on the Touch Screen	
Trackball Controls	5
Trackball Functions	
Update	
Select, Select-R	
Operating Mode Controls	
2D (2D-Mode)	8
C (Color)	
PW (Pulsed Wave Doppler)	
CW (Continuous Wave Doppler)	9
M (M-Mode)	9
Image Optimization Controls	10
Depth	10
Focus	10
Scale	10
Baseline	11
TEQ	11
DGC Slider Controls	11
Image Format Controls	12
Dual	12
Zoom	12
Annotation and Measurement Controls	13
Annotation	13
Caliper	13
Delete	13
Freeze and Archive Controls	14
Freeze	14
Clip	15
Image	15
Specialty Controls	16
UD (User-Defined)	
Pointer	
Forward/Backward	

	Advanced Controls	17
	3D/4D	17
	E (Elasticity)	18
	Contrast	18
	Workflow Controls	19
	Patient	19
	Review	19
	Report	19
	End Exam	19
Fc	ootswitch	20
ΑI	lphanumeric Keyboards	20
	Retractable Keyboard	20
	Touch Screen Keyboard	20
	Special Keys	21
	Special Keys on the Retractable Keyboard	21
	Special Keys on the Touch Screen Keyboard	22
	Special Characters	23

Control Panel

(Available only for systems with a touch screen)

See also: Descriptions of controls for the following functions or features are available in dedicated chapters within this manual.

- Transmit Power, Chapter 2
- Biopsy, Chapter 5
- Transesophageal transducers, Chapter 6
- Specialty transducers, Chapter 7
- Physiologic function, Chapter 8
- eSieFusion imaging, Chapter 9
- Virtual Touch applications, Chapter 10
- Imaging, review, measurements, and patient data management, Appendix D
- Advanced imaging features and clinical application programs, Appendix E

The control panel includes a touch screen, push controls, press controls, press or rotate controls, and a retractable keyboard. A trackball provides access to objects on the image screen.



When the ultrasound system is in use, most controls on the control panel and touch screen are supported by context-sensitive lighting. Exceptions are noted in this chapter.

Color of Lighting	Status
Blue	The control or selection is in use (active).
White	The control or selection is available for use, but inactive.
No illumination (dimmed)	The control is not available during the active function.

Lighting and Audio

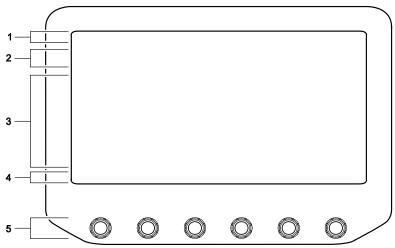
Use the selections on the touch screen to adjust the backlighting for the control panel, the touch screen, and the retractable keyboard. You can also activate or deactivate the microphone.

See also: For more information, refer to Appendix D in this manual.

Note: Use the volume control on the control panel to adjust Doppler audio volume.

Touch Screen Controls

The touch screen has selections for use during an exam for each operating mode and during review.



Example of the touch screen layout.

- Selections for the exam type and for transducers connected to the ultrasound system.
 During measurements and annotations, the touch screen displays the name of the active function.
- 2 Tabs for operating modes, features, or functions.
- 3 Touch selections for the active mode, feature, or function. Tap the touch screen to make a selection.
- 4 Selections for the press and rotate controls directly below the selections.
- 5 Controls correspond to the touch screen selections directly above the controls.Press, rotate, or press and then rotate a control to make a selection or change a setting.

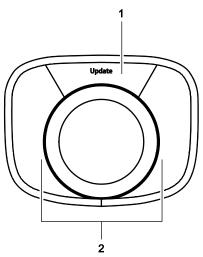
Symbols on the Touch Screen

Symbol	Description
•	Indicates a port is available for connecting an array transducer to the system.
a	Indicates a port is available for connecting a continuous wave (pencil) transducer to the system.
•••	Accesses additional pages of selections or selections for additional features and advanced imaging, including selections for lighting adjustment and for the digital video recorder.
	Accesses additional selections.
	Indicates a selection assigned to a control with both push and rotate functions.
•	The box is solid when the selection is activated.
	A rectangular outline indicates the selection currently assigned to a dual-function control.

B - 4 Instructions for Use

Trackball Controls

Use the trackball to position objects, such as the color ROI (region of interest), Doppler cursor, and measurement markers, and to interact with controls on the image screen.



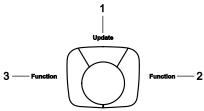
Example of trackball controls.

- 1 **UPDATE** control
- 2 Unlabeled trackball controls: the SELECT (left side) and SELECT-R (right side) controls

Note: Unless otherwise indicated, the SELECT and SELECT-R controls have the same functionality.

Trackball Functions

The function of all trackball controls depends on the active task. The active functions for trackball controls are indicated by on-screen labels displayed at the bottom of the image screen.



Example of on-screen labels indicating the active trackball function.

- 1 Task assigned to the **UPDATE** control
- 2 Task assigned to the SELECT-R (right) control
- 3 Task assigned to the SELECT (left) control

Update

Note: Press the control once to activate the selection in the description. Double-click describes the action of pressing the control twice in rapid succession.

Active Function	Description	
Dual imaging	Selects the active image.	
Doppler	 Displays the real-time 2D image or real-time Doppler spectrum in a full-screen format. 	
	 Activates pulsed wave (PW) Doppler. 	
	 Displays either a Doppler spectrum in a full-screen format or displays a 2D image and Doppler spectrum in a split-screen format when you double-click the control. 	
M-mode	 Displays either a real-time 2D image in a full-screen format or a real-time M-mode sweep in a full-screen format. 	
	 Displays either an M-mode sweep in a full-screen format or a 2D image and M-mode sweep in a split-screen format when you double-click the control. 	
SieScape or 3D imaging	Starts, pauses, or continues the acquisition process.	
eSie Touch Elasticity Imaging	Starts the acquisition process and displays either a dual-screen format or a full-screen format.	
Virtual Touch Imaging	 Starts the acquisition process. 	
Virtual Touch IQ	 Displays either a dual-screen format or a full-screen format prior to acquisition when you double-click the control. 	
Virtual Touch Quantification	Starts the acquisition process.	
3D/4D	Starts or cancels 3D/4D image acquisition.	
	 Displays either the selected screen format or a full-screen format when you double-click the control. 	
Review	Displays either the selected screen format or a full-screen format when you double-click the control.	
Stress Echo Review	Redisplays the stress echo image screen.	
	 Loads the stress echo exam to the stress echo review screen when you double-click the control. 	

B - 6 Instructions for Use

Select, Select-R

Interacts with controls in the patient browser, patient registration form, patient report, system configuration menu, and on the image screen.

Note: Press the control once to activate the selection in the description. Double-click describes the action of pressing the control twice in rapid succession.

Active Function	Description	
Imaging	 Assigns control of the trackball to an object or a tool on the image screen when you click the object or a tool, for example, the 2D field of view. 	
	 Selects a menu item, control, marker, or other object on the image screen. 	
	 Displays the selected thumbnail in review in a full-screen format when you double-click the control. 	
Measurements	 SELECT anchors a measurement marker and either generates the next marker for positioning or completes the measurement. 	
	 SELECT-R activates previous measurement markers for repositioning. 	
Review	Highlights any type of image or thumbnail on the review screen.	
System freeze	Plays or pauses a clip during CINE.	
Patient browser	Displays the contents of the selected series object in a 4:1 display format when you double-click the control.	
Annotation	Activates the last annotation or anchors the position of the current annotation text, body marker, or arrow.	

See also: For information about the **SELECT** control for the eSieFusion feature, refer to Chapter 9 in this manual.

Operating Mode Controls

Note: Press the control once to activate the function. Rotate the control to adjust the gain. The description for each control includes any additional actions. For example, double-click describes the action of pressing a control twice in rapid succession.



2D (2D-Mode)



- Activates 2D-mode gray scale imaging except during 3D or 4D imaging.
- During zoom, restores a magnified image to the original size.
- During system freeze, reactivates image acquisition.
- During 3D or 4D, displays the 3D or 4D setup screen.
- During 4D, cancels acquisition and redisplays the setup selections.
- During stress echo, pauses the stress echo protocol.

C (Color)



Activates or exits Color Doppler.

Note: Use the touch screen to activate either Color Doppler Velocity (CDV) or Color Doppler Energy (CDE).

 During 3D or 4D, rotates the selected quadrant around the x-axis when you rotate the control.

B - 8 Instructions for Use

PW (Pulsed Wave Doppler)



Activates pulsed wave Doppler for linear, curved, and phased array transducers.

Depending on the configuration settings, the system simultaneously displays the Doppler gate on the 2D image and a Doppler spectrum. Or, you can adjust the position and size of the Doppler gate on the 2D image before pressing **PW** a second time to display a Doppler spectrum.

Use the system configuration menu to select the Doppler gate display, select the display format for the Doppler spectrum, and enable the audible Doppler signal.

System Config > Doppler / M-Mode Setup

 During 3D or 4D, rotates the selected quadrant around the y-axis when you rotate the control.

CW (Continuous Wave Doppler)



- Activates steerable continuous wave (SCW) Doppler for phased array transducers.
- During 3D or 4D, rotates the selected quadrant around the z-axis when you rotate the control.

M (M-Mode)



Activates M-mode and displays the M-mode sweep and 2D image according to the image screen format selected in the system configuration menu.

Depending on the configuration settings, the system simultaneously displays the M-mode cursor on the 2D image and an M-mode sweep. Or, you can adjust the position of the M-mode cursor on the 2D image before pressing **M** a second time to display the M-mode sweep.

Use the system configuration menu to select the M-mode cursor display and the display format for 2D/M-mode imaging.

System Config > Doppler / M-Mode Setup

Image Optimization Controls



Depth



- Increases or decreases depth.
- Steps through the slices during 4D imaging or 3D/4D system freeze when the slice function is available.

Focus



Repositions the focal zone markers on the image.

Scale



Adjusts the scale factor of the Pulsed Repetition Frequency (PRF). During combined mode imaging, affects only the active priority mode.

B - 10 Instructions for Use

Baseline



Adjusts the position of the spectral or color baseline. During combined mode imaging, affects only the active priority mode.

TEQ



Note: When TEQ is active, the TEQ icon displays on the image screen. The TEQ icon is the symbol shown on the control. When eSielmage optimization is active, the system displays the TEQ icon in gold.

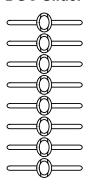
(In combined mode imaging, TEQ affects only the active priority mode)

- Activates TEQ (Tissue Equalization technology).
- Deactivates TEQ when you double-click the control.
- Activates eSielmage Multiparametric Optimization when scanning with a compatible transducer and supported exam.

See also: For information about this feature, refer to Appendix A in this manual.

 Disables eSielmage Multiparametric Optimization when you double-click the control. You can then manually adjust the gain.

DGC Slider Controls



Adjusts the depth gain compensation.

Use the system configuration menu to specify a default setting of maximum depth or current depth and to enable or disable the display of the DGC curve graphic on the image screen.

System Config > Basic System

Image Format Controls



Dual



- Activates or deactivates dual imaging.
- Activates or deactivates the live dual display format during contrast agent imaging.

Use the system configuration menu to select the dual format when you activate dual imaging.

System Config > Basic System

Zoom



- Changes the image magnification (zoom) when you rotate the control.
 - The system displays a ${\bf Z}$ on the image screen when zoom is activated.
- Activates the zoom function and displays a zoom box for a specific region of interest when you press the control once.
- Activates the high-density zoom function with enhanced resolution when you press the control twice.
 - The system displays \mbox{HD} on the image screen when high-density zoom is activated.
- Deactivates the zoom function when you press the control once.

B - 12 Instructions for Use

Annotation and Measurement Controls



Annotation



Activates or deactivates the annotation function including text, body markers, and arrows.

Caliper



Activates or deactivates the measurement function.

Delete

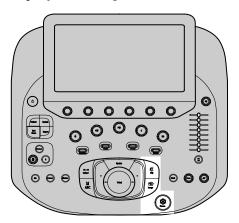


- Deletes one word at a time in reverse chronological order.
- Deletes the measurement in progress.
- Deletes a body marker.
- Deletes arrows in reverse chronological order.
- Clears the screen of all text, body markers, arrows, and measurement calipers when you
 press and hold the control.

Freeze and Archive Controls

Use the system configuration menu to assign print and/or store functions to the ${\bf CLIP}$ and ${\bf IMAGE}$ controls.

System Config > Print/Store



Freeze



- Freezes or unfreezes acquisition of an image, sweep, or spectrum.
- During clip capture, ends the capture.
- During data entry, closes the form and redisplays the image screen.
- During review, activates an assigned function. For example, exits review or a clinical application program, or plays and pauses CINE data.

Use the system configuration menu to select the function assigned to the freeze function during review.

Clip



- Acquires and then saves a clip or volume to the system's hard disk. The system displays saved data in the thumbnail panel, if enabled.
- Ends clip capture while capturing a clip.
- Starts playing CINE data from the current frame and stores the data from the current location to the end of the clip during system freeze.

Image



Activates the function assigned to this control.

Specialty Controls



UD (User-Defined)



Activates the function assigned to this control.

Use the system configuration menu to assign functionality to this control.

System Config > Footswitch and UD Key

Pointer



Press the pointer control to enable text entry or access to the controls on the image screen or the thumbnails on the right side of the image screen.

Note: If a tool is activated and the trackball pointer (cursor) is not visible, press **POINTER** to redisplay the pointer.

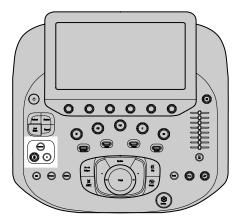
Forward/Backward



- During an eSieScan protocol or a stress echo protocol, pauses or resumes the protocol when you press the control.
- Activates the next or previous page of images when you rotate the control.

B - 16 Instructions for Use

Advanced Controls



3D/4D



- Activates or deactivates 3D/4D setup, depending on the active transducer and exam type.
- Displays the 3D/4D setup screen.
- Adjusts the 3D/4D brightness during system freeze when you rotate the control.
- Adjusts the volume gain during real-time imaging when you rotate the control.

E (Elasticity)



Activates or exits the following features:

- Virtual Touch IQ
- Virtual Touch Quantification
- Virtual Touch Imaging
- eSie Touch Elasticity

Contrast



Activates the selected contrast imaging technique and provides access to other contrast imaging techniques.

Use the system configuration menu to select the contrast clip capture protocol when you activate contrast imaging.

System Config > Basic System 2

Workflow Controls



Patient

Opens or closes the patient registration form.

Review

- Activates the review function to view, evaluate, measure, and annotate the results of the current examination or a previous examination stored in the local database.
- Provides access to clinical software programs:
 - syngo Arterial Health Package
 - syngo Velocity Vector Imaging
 - syngo Auto Left Heart
 - syngo Contrast Dynamics

Report

Opens or closes a patient report.

End Exam

Activates the following functions:

- Ends the exam
- Closes the current patient study
- Closes images
- Saves a report
- Initiates any actions queued to occur at the end of an exam. For example, printing or archiving images to a storage device.

Footswitch

You can use the footswitch as an alternative to using the controls on the control panel.

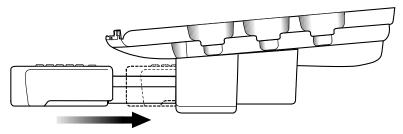
Use the system configuration menu to assign functionality to each pedal on the footswitch.

System Config > Footswitch and UD Key

Alphanumeric Keyboards

Retractable Keyboard

The retractable alphanumeric keyboard attaches below the control panel.



- To extend the keyboard, pull gently on the keyboard.
- To retract the keyboard, gently push the keyboard backward toward the ultrasound system.

Touch Screen Keyboard

The system displays a customized alphanumeric keyboard on the touch screen when you use the following forms or functions:

- Patient registration form or report
- Text annotation
- System configuration menu

The on-screen keyboard displays only alphanumeric keys and special function keys related to the active feature. For example, when text annotation is activated, only keys specific to text annotation display on the on-screen keyboard.

B - 20 Instructions for Use

Special Keys

These special keys are available on the retractable keyboard and the touch screen keyboard.

Key Name	Description
Arrows (Left, Right,	 Annotates anatomy or areas of interest on the image when the annotation function is active.
Up, and Down)	 Pages through online Help.

Special Keys on the Retractable Keyboard

Key Name	Description
Blank	Accesses special characters located on the alphanumeric keyboard.
	Note: This key is blank on English keyboards.
Text Start	Activates the annotation function.
(Space Bar)	When the Annotation function is active, inserts a blank space at current position of the text cursor.
Alt	Provides access to special characters required for some languages when used in combination with the alphanumeric keys.
	Note: This key is labeled Alt Gr on non-English keyboards.
Alt Gr	(Available only on non-English keyboards)
	Accesses special characters located on the alphanumeric keyboard.
Delete Last Word	Deletes the last word or annotation.
Browser	Opens or closes the patient registration browser.
	Use the patient browser to retrieve patient data and to enter information in the patient registration form.
System Config	Opens or closes the system configuration menu.
	Use the system configuration menu to modify and customize general ultrasound system settings, image annotation, and calculation settings.

Special Keys on the Touch Screen Keyboard

These special keys are available only while using the text annotation function.

Key Name	Description
Home	Places the text cursor in the Home position (as defined with the Set Home key) when the annotation function is active.
Set Home	Changes the default Home position to the current position of the text cursor when the annotation function is active.
	To reset the Home position, press and hold Home for a few seconds.
Clear Screen	Removes all text, arrows, and body markers from the image screen.
Delete Line	Deletes the line currently containing the cursor or the word most recently entered.
Hide Words	Displays or hides any text added to the image screen.
	The "off" setting shows text, and the "on" setting hides text.
Page	Displays the next or previous page, when available.
Keyboard	Hides the touch screen keyboard.
Application	Displays the currently selected exam.
Previous Annotation	Activates on-screen text in reverse chronological order.
Overwrite	(Available only in review)
	Covers all or part of an existing text annotation with new text.

B - 22 Instructions for Use

Special Characters

The system supports special characters for some languages through the use of a combination of keys on the retractable keyboard.

German		French	French	
Character	Key Combination Character Key Combinatio		Key Combination	
Ä	Alt+p	Ç	Alt+n	
ä	Alt+-	ç	Alt+j	
Ö	Alt+0 (zero)	à	Alt+z	
Ü	Alt+[è	Alt+x	
ü	Alt+=	é	Alt+s	
ß	Alt+'	ù	Alt+b	
Spanish		Italian		
Character	Key Combination	Character	Key Combination	
i	Alt+1	à	Alt+z	
ن	Alt+/	è	Alt+x	
Ñ	Alt+I	é	Alt+s	
ñ	Alt+9	ì	Alt+c	
á	Alt+a	ò	Alt+v	
é	Alt+s	ù	Alt+b	
í	Alt+d			
ó	Alt+f			
ú	Alt+g			
Scandinavian		Other	Other	
Character	Key Combination	Character	Key Combination	
Æ	Alt+m	Œ	Alt+u	
æ	Alt+k	œ	Alt+8	
Ø	Alt+. (period)	α	Alt+q	
Ø	Alt+;	β	Alt+w	
Å	Alt+,	μ	Alt+e	
å	Alt+I	θ	Alt+r	

B - 24 Instructions for Use

Appendix C Control Panel

Control Panel	3
Control Panel Lighting	3
Example of Control Panel	4
Trackball Controls and Soft Keys	5
UPDATE	6
SELECT	7
PRIORITY	8
NEXT	8
Gain Freeze/Cine	9
Imaging Mode Controls	9
Image Optimization Controls	11
Transmit Power	13
Power, Lighting, Sound, and Special Function Controls	13
Other Imaging Controls	13
Archive Controls	14
LED Panel Controls	14
Alphanumeric Keyboard	15
Special Characters	15
Function Keys	16
Other Alphanumeric Keys	17

C - 1

C - 2 Instructions for Use

Control Panel

(For systems without a touch screen)

The ultrasound imaging system has a combination of keys, rotary knobs, push and rotate controls, and toggle controls. A trackball provides access to on-screen objects. The keys and controls are logically arranged to require a minimum number of hand and eye movements. The control panel also includes customizable keys.

Use the system configuration menu to assign the function of the customizable keys.

System Config > Print/Store

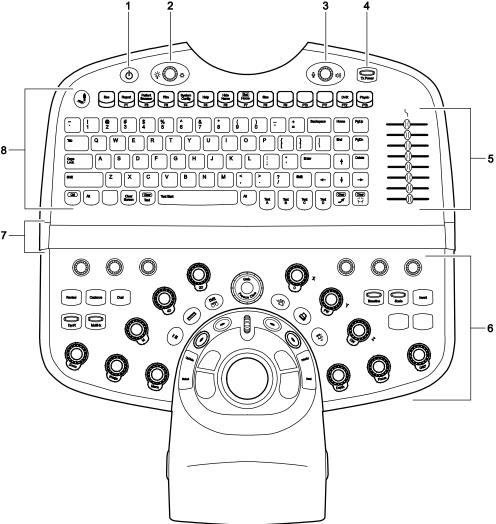
Control Panel Lighting

When the ultrasound system is in use, most controls on the main control panel are supported by backlighting. Exceptions are noted in this chapter.

Color of Lighting	Status
Green	The control is active (in use).
White	The control is inactive, but available for use.
No illumination	The control is not available during the active function.

The alphanumeric keyboard on the control panel is also illuminated.

Example of Control Panel



Example of the control panel and alphanumeric keyboard on the ultrasound system.

- 1 Power on/off
- 2 Backlighting and task lighting
- 3 Volume control / Microphone on/off
- 4 Transmit power
- 5 DGC controls
- 6 Control panel
- 7 LED panel
- 8 Alphanumeric keyboard

C - 4 Instructions for Use

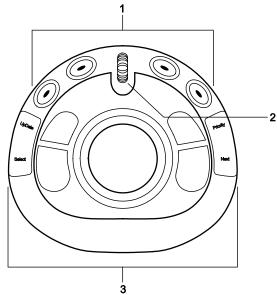
Trackball Controls and Soft Keys

Use the trackball to position on-screen objects, such as the color ROI (region of interest), Doppler cursor, and measurement calipers, and to make selections from the on-screen menus.

The function of all trackball controls and soft keys depends on the active task. The active functions for trackball controls are indicated by on-screen labels displayed at the bottom of the screen. The active functions for the soft keys and scroll wheel are displayed above the trackball control labels and above the thumbnail panel.

See also: For information about the use of trackball controls during eSieFusion Imaging, refer to Chapter 9 in this manual.

Note: The scroll wheel does not support backlighting.



Example of trackball controls and soft keys.

- 1 Soft keys
- 2 Scroll wheel
- 3 Trackball and trackball controls: Select, Update, Next, and Priority

UPDATE

When a function is assigned to double-clicking the $\mbox{\bf UPDATE}$ key, the on-screen labels display the available function in parentheses.

Active Function	Description
Dual imaging	Selects the active image.
Doppler	In a full-screen format, displays either the real-time 2D image or the real-time Doppler spectrum. Double-click UPDATE to display either the Doppler spectrum in a full-screen format or the 2D image and Doppler spectrum in a split-screen format.
M-mode	In a full-screen format, displays either the real-time 2D image or the real-time M-mode sweep. Double-click UPDATE to display either the M-mode sweep in a full-screen format or the 2D image and M-mode sweep in a split-screen format.
SieScape or 3D imaging	Starts, pauses, or continues the acquisition process.
Elasticity Imaging	Displays either a dual-screen format or a full-screen format.
Virtual Touch Imaging	Starts the acquisition process. Prior to acquisition, double-click UPDATE to display either a dual-screen format or a full-screen format.
Virtual Touch	Starts the acquisition process.
Quantification	Displays the shear velocity measurement in the measured results.
Virtual Touch IQ	Starts the acquisition process. Prior to acquisition, double-click UPDATE to display either a dual-screen format or a full-screen format.
4D	Displays either the volume in a full-screen format or the volume and multiplanar renderings (MPRs) in the previously selected screen format.
Review	Double-click UPDATE to display either the selected screen format or a full-screen format.
Review	When a Stress Echo image is selected, double-click UPDATE to load the Stress Echo exam to the Stress Echo Review screen.
Stress Echo	Redisplays the stress echo imaging screen after stopping acquisition to review acquired loops.
Contrast agent imaging	Reserved for future use.

C - 6 Instructions for Use

SELECT

Active Function	Description
	Selects on-screen menu items and assigns trackball control to on-screen tools (for example, Doppler gate or distance measurement tools).
	When a tool is active, the trackball pointer (cursor) is not visible. Press SELECT to redisplay the pointer.
	When the trackball is assigned to the pointer function, the SELECT key is equivalent to the left mouse button on a personal computer.
Imaging	When the cursor is positioned over the image area, activates the pointer or the default tool for the active mode (for example, 2D FOV).
	When the cursor is positioned over the image menu, activates a menu selection.
	Press SELECT twice to display the selected thumbnail in review in a full-screen format.
Measurement	When the cursor is positioned over the image area, anchors a measurement caliper and generates the next caliper for positioning.
	When the cursor is positioned over the measurement menu, selects a measurement tool (for example, Distance, Volume, or Velocity), measurement label, or body marker.
Review	Selects images or tools.
	Select an image and press SELECT to activate the clinical software program compatible with the selected image.
Patient browser	Press SELECT twice to display the selected series object (subfolder within a study folder) in review in a 4:1 display format.
Annotation	Anchors the position of the directional arrow or annotation.
Body Marker	Anchors the position of the body marker or transducer marker.

PRIORITY

Active Function	Description
Imaging	Cycles trackball control through the imaging modes. For example, during Doppler and 2D-mode, press PRIORITY to assign trackball control to the Doppler gate (D Gate) or the 2D-mode field of view (2D FOV).
3D or 4D	Activates the 2D FOV tool or the ROI/VOI tool. Cycles through the available tools for the current task. For example, when working with volumes, displays the Slice tool and when using the amnioscopic rendering method, displays the Light tool.
Measurement Cycles through the available caliper sets.	
Body Marker	

NEXT

Active Function	Description
	Cycles through the imaging mode tools currently controlled by the trackball. For example, during Doppler, press NEXT to activate the Doppler gate positioning function or the Doppler gate steering function.
	When the trackball is assigned to the pointer function, the NEXT key is equivalent to the right mouse button on a personal computer.
SieScape	Activates the rotate function or the pan function.
Measurement	Cycles through the caliper end points.
Ellipse	Anchors the end point for the major axis.
eSie Calcs Auto Volume	Repositions the measurement region of interest.
3D or 4D	Activates the rotate function or the pan function. In 4D, cycles through the active tool functions and polygon markers.
Review of 4D volumes	When a quadrant is not selected, activates the measurement function.
Patient Browser Filming screen	Displays a shortcut menu of available selections.
Velocity Vector Imaging	Anchors the last marker, for example, to complete a trace or freeform drawing.

C - 8 Instructions for Use

Gain Freeze/Cine



Control	Active Function	Description
GAIN FREEZE/CINE	Imaging	Rotate GAIN FREEZE/CINE to adjust the gain for the active priority mode.
		Note: The Gain label does not illuminate.
		Press GAIN FREEZE/CINE to freeze an image, sweep, or spectrum or restore real-time imaging.
		The Freeze/Cine label is illuminated white during real-time imaging and illuminated green when the system is frozen.
	Review	Depending on system configuration, press GAIN FREEZE/CINE to play or pause clip playback or to exit review.
		Use the system configuration menu to select the function assigned to pressing GAIN FREEZE/CINE during review.
		System Config > Basic System 2
		Rotate GAIN FREEZE/CINE to view a clip frame-by-frame.

Imaging Mode Controls



Control	Name	Active Function	Description
2D	2D-mode		Press 2D to activate 2D-mode grayscale imaging, except during live 4D or 3D/4D imaging.
			Rotate 2D to adjust the gain.
		Imaging (frozen 2D-mode)	Activates real-time imaging.
		Live 4D or 3D	Displays the live 4D or 3D preview screen.
		4D	Cancels acquisition and displays the 4D setup selections on the image menu.
		Stress Echo	Pauses the stress echo protocol.

Control	Name	Active Function	Description
4D	3D or 4D		Press 4D to activate 3D or 4D setup. The system activates 4D setup or 3D setup, depending on the active transducer and exam type.
			During system freeze, rotate 4D to adjust the brightness.
		4D	During live imaging, rotate 4D to adjust the volume gain.
M	M-mode	Imaging	Press M to activate M-mode and display the M-mode sweep and 2D image according to the format selected in the system configuration menu.
			Rotate M to adjust the gain.
			Use the system configuration menu to select the default action of the M control for cursor display.
			System Config > Doppler / M-Mode Setup
C, X	Color		Press C to activate or exit Color Doppler imaging.
			Note: Use the soft keys to activate either Color Doppler Velocity (CDV) or Color Doppler Energy (CDE).
		Color	Rotate C to adjust the gain.
		3D or 4D	Rotate X to rotate the selected MPR (multi-planar reformatting) quadrants around the x-axis.
PW, Y	Pulsed Wave	Doppler	Press PW to activate the pulsed wave (PW) Doppler function for linear, curved, and phased array transducers.
			Rotate PW to adjust the gain.
		3D or 4D	Rotate Y to rotate the selected MPR (multi-planar reformatting) quadrants around the y-axis.
			Use the system configuration menu to specify Doppler settings, including cursor on/off and cursor audio mode, when you first activate pulsed wave Doppler.
			System Config > Doppler / M-Mode Setup
CW, Z	Continuous Wave	Doppler	Press CW to activate the steerable continuous wave (SCW) Doppler function for phased array transducers.
			Rotate CW to adjust the gain.
		3D or 4D	Rotate Z to rotate the selected MPR (multi-planar reformatting) quadrants around the z-axis.
			Use the system configuration menu to specify Doppler settings, including cursor on/off and cursor audio mode, when you first activate continuous wave Doppler.
			System Config > Doppler / M-Mode Setup

C - 10 Instructions for Use

Image Optimization Controls

Key	Name	Description
A STATE OF THE STA	ZOOM	Rotate ZOOM to activate or deactivate the zoom function and change the image magnification. The system displays a Z on the image screen when zoom is activated.
)	Press ZOOM to activate or deactivate the zoom function with enhanced resolution. The system displays HD on the image screen when high-density zoom is activated.
COOM J		Press ZOOM and then roll the trackball to reposition or resize the region of interest (ROI). Press NEXT to alternate the resizing function with the repositioning function.
	IMAGE	Press IMAGE to view a list of all currently available image optimization presets or to create a user-defined image preset.
Image of the second	•	Rotate IMAGE to select the required optimization presets. The imaging parameters are updated as you rotate the control. During combined mode imaging, the selected setting affects the active priority mode.
	MENU	Press MENU to activate or deactivate a selection.
	\	Rotate MENU to cycle through the menu selections.
Menu	ļ	This control illuminates white when available and does not illuminate when not available.
		Rotate MENU during a protocol to select the PREVIOUS or NEXT control for scrolling the thumbnail panel. Press MENU to scroll the thumbnail panel.
	DEPTH	Rotate DEPTH to change the imaging depth.
)	When the slice function is activated during 3D imaging or during 4D system freeze, rotate DEPTH to step through the slices.
Depth		Use the system configuration menu to assign the direction (clockwise or counterclockwise) for increase or decrease.
		System Config > Basic System 2
	FOCUS	Press FOCUS to display the focal zone marker selections. Rotate FOCUS to cycle through the selections. Press FOCUS to select the required number of focal zones.
	1	Rotate FOCUS to reposition the focal zone markers.
Focus		Use the system configuration menu to assign the rotation direction (clockwise or counterclockwise) to increase or decrease.
		System Config > Basic System 2
	0/60°	Press 0/60° to cycle through the angle correction selections (60, 0, -60).
)	Rotate 0/60° to adjust angle correction values in one degree increments between 60 and -60 degrees.
0/60°		During cardiac exams with M-mode imaging, rotate 0/60° to activate anatomical M-mode and adjust the angle of the anatomical M-mode cursor.
		When anatomical M-mode is activated, press 0/60° to exit anatomical M-mode.

Key	Name	Description
	TEQ	(In combined mode imaging, affects only the active priority mode)
(")		Press TEQ to activate TEQ (Tissue Equalization technology). Press TEQ twice to deactivate the feature.
		Note: When TEQ is active, the TEQ icon displays on the image screen.
		Press the TEQ key twice to disable continuous optimization and manually adjust the gain for the image. Press TEQ once to re-activate eSielmage optimization.
		Note: When eSieImage optimization is active, the system displays the TEQ icon in gold.
	CALCS	Press to activate or deactivate the measurement function.
	MULTIHZ	(In combined mode imaging, affects only the active priority mode)
MultiHz		Push MULTIHZ up or down to adjust the transmit frequency of the active multi-frequency transducer.
	DYN R	(In combined mode imaging, affects only the active priority mode)
DynR		Push DYN R to adjust the overall contrast resolution of an image, sweep, or spectrum.
	BASELINE	(In combined mode imaging, affects only the active priority mode)
		Push BASELINE up or down to adjust the position of the spectral or color baseline.
Baseline		This control illuminates white when available and does not illuminate when not available.
	SCALE	(In combined mode imaging, affects only the active priority mode)
Scale		Push SCALE up or down to adjust the scale factor of the Pulsed Repetition Frequency (PRF).
		This control illuminates white when available and does not illuminate when not available.
	INVERT	(In combined mode imaging, affects only the active priority mode)
Invert		Vertically flips the Doppler spectrum on the baseline (negative values display above the baseline) and inverts the Doppler audio.
		Vertically flips the colors depicting forward and reverse flow in the color ROI and in the color bar.
<u> </u>		Push the sliders to the right or left to adjust the gain.
		Use the system configuration menu to specify the default image depth setting for depth-gain compensation and select the on, off, or fade display setting.
		System Config > Basic System

C - 12 Instructions for Use

Transmit Power



Press **TX POWER** up or down to adjust the transmit power for the active priority mode.

Power, Lighting, Sound, and Special Function Controls

Control	Description
(Powers the ultrasound system on or off.
	Press the control to activate back lighting or task lighting.
(*O*)	Rotate the control to adjust the lighting level.
	Note: When you activate the microphone function, the system disables Doppler audio.
	Press the control to activate the microphone function during video recording.
	Rotate the control to adjust the Doppler signal volume.
	Use the footswitch as an alternative to operating keys on the control panel.
	Use the system configuration menu to assign functions to the footswitch pedals.
	System Config > Footswitch/UD

Other Imaging Controls

Key	Name	Description
Cadence	CADENCE	Press CADENCE to activate the default contrast imaging modes and provide access to other contrast imaging modes.
	DUAL	Press DUAL to activate or deactivate dual imaging.
Dual		During contrast agent imaging, the DUAL key activates or deactivates live dual display format.
		Use the system configuration menu to select the dual format that displays when you activate dual imaging.
		System Config > Basic System
Review	REVIEW	Press REVIEW to activate or deactivate the Review screen. Use the review function to view previously saved images and clips during the active exam or from a previous exam.
		(Left blank key) Hides or redisplays the menu located on the left side of the screen. (Right blank key) Hides or redisplays the thumbnail panel and the soft key selections to increase or decrease the space available on the screen for the image.

Archive Controls

Key	Name	Description	
DIR.	DVR	Starts or pauses video recording.	
	CLIP STORE	Acquires and saves a clip or volume to the system's hard disk. The saved data displays in the thumbnail panel, if enabled.	
(PRINT	Use the system configuration menu to assign print and/or store functions to this key. System Config > Print/Store Press PRINT to activate the function assigned to this key.	
1	STORE	Use the system configuration menu to assign print and/or store functions to this key. System Config > Print/Store Press STORE to activate the function assigned to this key.	

LED Panel Controls

The LED panel provides functions based on the current system state or operating mode. Each selection displayed on the LED panel corresponds to the control immediately below it on the control panel. The functions assigned to LED controls depend on the current imaging mode or active function.

See also: On-screen Controls, Appendix D, Instructions for Use

C - 14 Instructions for Use

Alphanumeric Keyboard

Special Characters

The system supports special characters for some languages through the use of a combination of keys on the keyboard.

German		French	
Character	Key Combination	Character	Key Combination
Ä	Alt+p	Ç	Alt+n
ä	Alt+-	ç	Alt+j
Ö	Alt+0 (zero)	à	Alt+z
Ü	Alt+[è	Alt+x
ü	Alt+=	é	Alt+s
ß	Alt+'	ù	Alt+b
Spanish		Italian	
Character	Key Combination	Character	Key Combination
i	Alt+1	à	Alt+z
Ċ	Alt+/	è	Alt+x
Ñ	Alt+I	é	Alt+s
ñ	Alt+9	ì	Alt+c
á	Alt+a	ò	Alt+v
é	Alt+s	ù	Alt+b
ĺ	Alt+d		
ó	Alt+f		
ú	Alt+g		
Scandinavian		Other	
Character	Key Combination	Character	Key Combination
Æ	Alt+m	Œ	Alt+u
æ	Alt+k	œ	Alt+8
Ø	Alt+. (period)	α	Alt+q
Ø	Alt+;	β	Alt+w
Å	Alt+,	μ	Alt+e
å	Alt+l	θ	Alt+r

Function Keys

Key	Name	Description
	Patient Registration	Opens or closes the patient registration form.
Esc	Esc	Closes on-screen items, such as dialog boxes, lists, and menus.
Report F1	Report	Opens or closes the patient report.
Patient	Patient	Opens or closes the patient browser.
Browser F2	Browser	Use the patient browser to search for patient records and view patient data.
	Film	Opens or closes a print preview screen.
Film F3		Use the film screen to preview images prior to sending them to an external documentation device.
System	System	Opens or closes the system configuration menu.
Config F4	Config	Use the system configuration menu to modify and customize the system, including general settings, image annotation, and calculation settings.
Help F5	Help	Opens or closes information about using the ultrasound system.
Hide Name F6	Hide Name	Hides or displays patient-identifying information on the patient banner on the image screen.
Set	Home,	Repositions the text cursor to the predetermined Home position.
Home F7	Set Home	To change the default Home position of the text cursor, roll the trackball to the new position and press Ctrl+Set Home . Or, hold Home (F7) for two seconds.
Size F8	Size	During 2D imaging, changes the size of the 2D image.
DVR F12	DVR	Displays or hides the video recording selections on the menu.
Physio F13	Physio	Displays or hides the Physio selections on the menu.

C - 16 Instructions for Use

Other Alphanumeric Keys

Key	Name	Description
Backspace	Backspace	Deletes one character at a time from right to left during text entry.
Home	Home	Places the text cursor in the Home position (as defined with the Set Home key) when the annotation function is active.
PgUp	PgUp	Reserved for future use.
PgDn	PgDn	Reserved for future use.
<u></u>	End	Repositions text cursor to the end of the active text entry.
End		Highlights the last selection in a drop-down list.
Delete	Delete	Deletes one character at a time from left to right during text entry.
+++	Arrows	Repositions the text cursor in the direction shown on the arrow key.
Enter	Enter	Positions the cursor at the beginning of the next line of text or field and accepts entered data.
Tab	Tab	Positions the cursor to the beginning of the next available entry field in the patient registration form or patient report.
Caps Lock	Caps Lock	Locks all keyboard letter keys in upper case.
Shift	Shift	Accesses the uppercase letters and the character located on the upper half of a number or punctuation key.
	Ctrl	Accesses special characters or functions.
Ctrl		When used in combination with a key that contains a label enclosed in a circle, activates the related function. For example, if you press Ctrl+Clear Text , the system removes the selected text.

Key	Name	Description
Ait	Alt	Accesses special characters located on the alphanumeric keyboard.
		Note: This key is labeled Alt Gr on non-English keyboards.
	Blank	Accesses special characters located on the alphanumeric keyboard.
		Note: This key is blank on English keyboards.
Clear Screen	Clear Screen	Removes all text, arrows, and body markers from the screen.
	Text, Clear Text	Enables or disables the annotation function.
(Clear) Text		Press Ctrl+Clear Text keys to remove all text displayed in the image area. Pressing this key does not delete arrows or body markers.
Text Start	Text Start	Inserts a blank space when used during text entry.
	(Space Bar)	
	Alt Gr	(Available only on non-English keyboards)
Alt Gr		Accesses special characters located on the alphanumeric keyboard.
Text A	Text A, Text B, Text C, Text D	System-defined annotation keys. Places text on the image screen at the cursor location.
Close	Arrow Up	Displays an annotation arrow. Press Ctrl+Arrow Up keys to
Clear	(Annotation)	clear the annotation arrow. Or, hold Arrow Up for two seconds.
Clear	Body Marker, Clear Body Marker	Displays the default body marker for the current exam type and assigns the transducer marker to the trackball.
14		Press Ctrl+Body Marker keys to clear the pictogram and transducer marker. Or, hold Body Marker for two seconds.

C - 18 Instructions for Use

Appendix D On-screen Controls

On-screen Controls Overview	3
Toolbar	4
Informational Icon	4
Thumbnail Panel	5
Light and Audio Settings	6
Imaging Parameters	7
eSieScan Workflow Protocol Controls	10
2D-Mode Parameter Selections	12
M-Mode Parameter Selections	15
Color Flow Imaging Parameter Selections	16
Doppler Parameter Selections	19
Clip Capture Selections	22
CINE Graphics	23
Annotation Selections	23
Basic Measurement Tools	26
2D Measurement Tools	26
Doppler Measurement Tools	27
M-Mode Measurement Tools	28
Patient Report Screen Controls	29
Selections for Cardiac Measurements	30
Basic Cardiac Measurement Tools	30
Cardiac Report Controls	31
DVR Menu Selections and Status Indicators	32
Recording Icons	32
Review Controls	33
Review Clip Bar Graphics	38
Filming Screen Controls	39
Filming Screen Tab Card	40
Layout Tab	40
Images Tab	40
Camera Tah	40

Patient Browser Screen	41
Icon Selections	41
Menu Selections	42
Patient Menu Selections	42
Transfer Menu Selections	43
Edit Menu Selections	45
View Menu Selections	46
Filter Menu Selections	47
Sort Menu Selections	48
Options Menu Selections	49
Help Menu Selections	49

On-screen Controls Overview

See also: Descriptions of controls for the following functions or features are available in dedicated chapters within this manual.

- Biopsy, Chapter 5
- Transmit Power, Chapter 2
- Transesophageal transducers, Chapter 6
- Specialty transducers, Chapter 7
- Physiologic function, Chapter 8
- eSieFusion imaging, Chapter 9
- Virtual Touch applications, Chapter 10
- Imaging, review, measurements, and patient data management, Appendix D
- Advanced imaging features and clinical application programs, Appendix E

The controls displayed on the screen depend on the currently active imaging mode or function. For example, a specific set of selections displays during 2D imaging and a different set of selections display during the measurement function. Certain controls, such as the toolbar or the thumbnail panel, are always available unless they are disabled using the system configuration menu.

Note: The image screen does not support touch technology. Use the trackball and **SELECT** controls on the control panel to interact with the selections on the image screen.

Toolbar

Note: To access the toolbar on systems with a touch screen, press **POINTER** on the control panel to activate the trackball pointer.

Selection	Description
	Patient Browser
世	Opens or closes the patient browser.
	Film Sheet
Hell	Opens or closes a print preview screen.
	System Config
	Opens or closes the menu for customizing system settings.
	Help
?	Opens or closes information about using the ultrasound system.
	Hide Name
	Hides or redisplays patient-identifying information on the patient banner on the image screen.
5-2	Enable or Disable Full Screen
1	Hides or redisplays the thumbnail panel and the soft key selections to increase or decrease the space available on the screen for the image.
	Security
	(Available only on systems with the security package activated)
	Opens or closes the dialog box for locking the screen on the ultrasound system, logging off the system, logging in as a different user, and changing the user account password.
F	(Available only on systems without a touch screen)
◀ ■	Hide or Show Menu
	Hides or redisplays the menu located on the left side of the screen.
•	Patient Registration
T	Opens the patient registration form.
	(Available only on systems without a touch screen)
	Reports
	Opens or closes the patient report.

Informational Icon

Icon	Description
	(Available only when creating a growth curve or an eSieScan protocol)
(!)	Displays a message indicating an incomplete or an invalid entry of information in a text box that requires correction.
	(Available only when a remote system update is ready for installation)
	Displays an installation dialog box to install or defer system updates.

D - 4 Instructions for Use

Thumbnail Panel

Button/Icon	Description
	Copy to Film Sheet
}	Copies the image represented by the thumbnail to the filming screen for printing.
—	Delete
•	Marks the thumbnail image for deletion when you exit the exam.
	If the selected thumbnail displays the stress echo icon, marks all stress echo images for deletion.
Total	Indicates the total number of thumbnail images captured for the exam.
Icon	Description
	Indicates the thumbnail represents an image.
Ħ	Indicates the thumbnail represents a clip.
3D	Indicates the thumbnail represents a volume.
4D	Indicates the thumbnail represents a 4D volume.
4D CINE	Indicates the thumbnail represents a 4D clip.
∅	Indicates the thumbnail represents a stress echo exam.
STIC	Indicates the thumbnail represents a STIC volume.

Light and Audio Settings

(Available only on systems with a touch screen)

To adjust the settings for the control panel and system:

- 1. Select More and then select Settings on the touch screen.
- 2. Rotate the required controls to adjust the brightness of the lighting or to activate the microphone.

Selection	Description
Blue Light	Adjusts the brightness of the blue lighting when a control or selection is in use.
White Light	Adjusts the brightness of the white lighting when a control or selection is available, but not in use.
Keyboard	Adjusts the brightness of the backlighting for the retractable keyboard.
Touch Screen	Adjusts the brightness of the touch screen.
Microphone	Activates or deactivates the microphone during recording.
Down Light	Adjusts the brightness of the insignia on the front of the system.

D - 6 Instructions for Use

Imaging Parameters

Each imaging mode has mode-dependent parameters used to adjust imaging settings. The current imaging settings are displayed on the right side of the screen.

Selection	Description
(current selection)	Transducer
	Activates a connected transducer.
(current selection)	Exam
	Selects a system or user-defined exam type. The exam type consists of a configuration of image optimization settings and a compatible transducer.
	Note: The system uses the study type selected during patient registration for patient records.
(current selection)	(Available only on systems with a touch screen)
	Static CW Transducer Port
	Activates a connected continuous wave pencil transducer.
2D	2D Mode
	Displays selections for 2D-mode imaging.
M	M-Mode
	Displays selections for M-mode.
С	Color
	Displays selections for Color (CDV) and Power (CDE) modes.
D	Doppler
	Displays selections for Doppler.
3D	3D/4D
	Displays selections to acquire three dimensional images, using the 3-Scape real-time 3D imaging feature.
4D	3D/4D
	Displays selections to acquire and simultaneously view three-dimensional ultrasound images in real-time, using the <i>four</i> Sight Imaging feature.
TEQ Set	TEQ Overall Gain Set
	Saves a TEQ gain offset for the current imaging mode.
L/R Flip	Left/Right Flip
	Horizontally flips the image (right-to-left or left-to-right).
U/D Flip	Up/Down Flip
	Vertically flips the image (top to bottom or bottom to top).
Live Dual	Live Dual
	Enables or disables the display of two real-time images originating from the same acquisition in a side-by-side format.

Selection	Description
ASC Dual	(Available only when Advanced SieClear is enabled)
	Advanced SieClear Dual
	Enables or disables the display of two real-time images originating from the same acquisition in a side-by-side format. The right side displays the 2D image with Advanced SieClear enabled and the left side displays the 2D image with Advanced SieClear disabled.
Transmit Power	Adjusts the transmit power during real-time imaging.
	Note: For systems without a touch screen, this selection is assigned to TX POWER.
Frequency	MultiHz
	(In combined mode imaging, affects only the active priority mode)
	Adjusts the transmit frequency of the active multi-frequency transducer.
	Note: For systems without a touch screen, this selection is assigned to MULTIHZ.
DR	Dynamic Range
	(In combined mode imaging, affects only the active priority mode)
	Adjusts the overall contrast resolution of an image, sweep, or spectrum.
	Note: For systems without a touch screen, this selection is assigned to DYN R .
DVR	Displays a control on the touch screen for recording images during imaging when a digital video recorder is connected and configured for use with the system.
SieScape	SieScape
	Displays selections to acquire two-dimensional ultrasound images with a composite, extended field of view, using the SieScape Panoramic Imaging feature.
E	Elasticity Imaging
	Provides access to features used to detect the relative stiffness of tissue: eSie Touch elasticity imaging, Virtual Touch Imaging (VTI), Virtual Touch IQ (VTIQ), and Virtual Touch Quantification (VTQ).
El Color	Elasticity Imaging Color
	Displays selections in color to detect the relative stiffness of tissue, using the eSie Touch elasticity imaging feature.
eSie Touch	eSie Touch
	Displays selections to detect the relative stiffness of tissue, using the eSie Touch elasticity imaging feature.
	Note: For systems without a touch screen, the selection is assigned to a button:
	EI

D - 8 Instructions for Use

Selection	Description
VTI	Virtual Touch Imaging
	Displays selections for a qualitative view of tissue stiffness, using the Virtual Touch imaging feature.
	Note: For systems without a touch screen, the selection is assigned to a button:
VTQ	Virtual Touch Quantification
	Displays selections for a quantitative measure of shear velocity and elasticity, using the Virtual Touch quantification feature.
	Note: For systems without a touch screen, the selection is assigned to a button:
	ф
VTIQ	■ Virtual Touch IQ
	Activates or deactivates the Virtual Touch IQ feature to depict a qualitative view of tissue stiffness and provide a quantitative measurement of shear velocity and elasticity.
	Note: For systems without a touch screen, the selection is assigned to a button:
	ф
eSieScan™ Protocols	Displays a list of the available workflow protocols. A protocol is a pre-defined checklist that guides you through a clinical workflow. When a workflow protocol is selected, the image menu displays the name of the selected protocol:
	■ Breast
	■ Cardiac
	■ OB
	 Vascular
	(user-defined protocols)
Biopsy	Biopsy
	Activates on-screen guidelines for use with the biopsy function.
Cine	Review CINE data in a continuous loop.
	 Play starts CINE playback
	 Pause stops CINE playback
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Full Screen	Displays the image in full-screen format.

eSieScan Workflow Protocol Controls

Use the system configuration menu to customize protocols.

System Config > Basic System 2 > Default Protocol Settings

System Config > eSieScan™ Protocols

Selection	Description
	Next/Previous
	Selects the next or previous view within a protocol.
	Note: For systems without a touch screen, the selections are assigned to buttons:
(current selection)	Protocol
	Selects a protocol.
(current selection)	View Name
	Selects a view.
Show All Views	Show All Views
	Displays up to 30 views for the active protocol.
Pause Protocol	Pause Protocol/Resume
Resume	Temporarily pauses or resumes the protocol.
End Protocol	End Protocol
	Saves all data, ends the active protocol, and displays a message if any protocol views are not complete.
Add View	Add View
	Inserts a new view immediately before the active view.
Rename View	Rename View
	Displays a dialog box to enter a new name for the view.
Delete	Delete Image
	Marks the selected view for deletion and removes the image and any measurements from the view.
	Note: The view marked for deletion is still available in the patient report and in review.
Append Paused Images	When a protocol is paused, inserts a newly saved image at the current location or at the end of the protocol list.

D - 10 Instructions for Use

Selection	Description
Remain Frozen	(Available only when acquisition is frozen)
	When enabled and a view is selected, displays the view, the predefined annotations, starts the predefined measurements, and then remains frozen.
	Applications
	Lists the software programs available to review the clip. The system returns to the protocol when you exit the program.
syngo AHP	syngo AHP – Arterial Health Package
	Activates the syngo Arterial Health Package (AHP) software program.
	Note: For systems without a touch screen, the selection is assigned to a button:
syngo VVI	syngo VVI – Velocity Vector Imaging
	Activates the syngo Velocity Vector Imaging (syngo VVI) software program.
	Note: For systems without a touch screen, the selection is assigned to a button:
syngo Auto LHA	syngo Auto LHA
	Activates the syngo Auto Left Heart software program.
	Note: For systems without a touch screen, the selection is assigned to a button:
Contrast Dyn	Contrast Dynamics(TM) software
	Activates the syngo Contrast Dynamics software program.
	Note: For systems without a touch screen, the selection is assigned to a button:

2D-Mode Parameter Selections

Selection	Description
Trapezoid	Trapezoid/Linear
	Enables linear or trapezoid image format for linear transducers.
	 On displays a trapezoid image.
	Off displays a linear image.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Space Time	Adjusts the balance between the image line density (resolution) and the frame rate.
	• 0 to 3
	Note: For systems without a touch screen, the selection is on the LED panel.
Maps	Selects a processing curve that assigns echo amplitudes to gray levels.
	• A, B, C, D, E, F
	Note: For systems without a touch screen, the selection is on the LED panel.
Tint	Changes the color of the image by adding blue, red, yellow, or green to the gray in a gray map.
	 Available settings: transducer-dependent
	Note: For systems without a touch screen, the selection is on the LED panel.
Edge	Edge Enhancement
	Distinguishes the contours of a structure during imaging.
	■ 0 (none)
	■ 1 to 4
	Note: For systems without a touch screen, the selection is on the LED panel.
Persist	Persistence
	Creates a visible smoothing effect by maintaining lines of image data for each frame of imaging. A higher setting includes more frames in the image data.
	 Available settings depend on the transducer and exam type
ТНІ	Tissue Harmonic Imaging
	 Enables or disables the Tissue Harmonic Imaging feature, used to enhance contrast resolution.
	Note: For systems without a touch screen, the selection is assigned to a soft key.

D - 12 Instructions for Use

Selection	Description
ClarifyVE	Clarify vascular enhancement technology, used to reduce artifacts in 2D-mode images.
	 Press the control to enable or disable Clarify VE.
	 Rotate the control to set the Clarify VE level of flow information to add to the image.
	Note: For systems without a touch screen, press the soft key to enable or disable Clarify VE and rotate the scroll wheel to set the level of flow.
SieClear/ Advanced	Activates SieClear/Advanced SieClear multi-view spatial compounding, used to reduce speckle and enhance tissue differentiation in 2D-mode images.
SieClear	 Available settings: Transducer-dependent
	Note: If you activate color when Advanced SieClear is enabled, the system changes the compounding level to 3 if the current setting is higher than 3.
	Note: For systems without a touch screen, the selection is on the LED panel.
DTCE	Dynamic Tissue Contrast Enhancement
	Reduces speckle from the image. The selected DTCE level determines the amount of enhancement the system performs.
	 Off
	Low
	 Medium
	High
	Note: For systems without a touch screen, the selection is on the LED panel: Dynamic TCE
DTO	Dynamic Tissue Optimization
	Adjusts levels of gain compensation for cardiac applications.
	■ Off
	1 , 2, 3
СТІ	Custom Tissue Imaging
	Optimizes the 2D image by adjusting the speed of sound.
	0 , 1, 2, 3, 4

Selection	Description
Balance	Image Optimization Preset
	Applies the selected image optimization settings for 2D-mode images.
	Available settings depend on the transducer and exam type.
	Note: The system displays CA, Mix, or 2D when contrast agent imaging is activated.
	- Contrast
	Detail
	 Penetration
	 Soft
	General
	• LVO
	Fetal Echo
	1st Trimester
	 User-Defined
	(user-defined image presets)
	Note: The User-Defined setting is available only when a user-defined exam is selected. Use this setting to save a customized image optimization preset.
	Note: For systems without a touch screen, the selection is on the LED panel.
Timer	Start Timer/Stop Timer
	Activates or deactivates the on-screen timer.
Focus Points	Focus
	Selects the required number of focal zones.
Size	Size
	Changes the size of the 2D image.

D - 14 Instructions for Use

M-Mode Parameter Selections

Selection	Description
Sweep Speed	Sweep Speed
	Adjusts the scrolling speed of the M-mode sweep.
	■ NTSC: 1, 2, 4, 6, 8
	■ PAL: 1, 2, 5, 7, 8
	Note: For systems without a touch screen, the selection is on the LED panel.
Edge	Edge Enhancement
	Distinguishes the contours of a structure during imaging.
	■ 0 (none)
	• 1 to 3
Maps	Selects a processing curve that assigns echo amplitudes to gray levels.
	• A, B, C, D, E, F, G
Tint	Changes the color of the M-mode sweep by adding blue, red, yellow, or green to the gray in a gray map.
	 Available settings: transducer-dependent
THI	Tissue Harmonic Imaging
	Enables or disables the Tissue Harmonic Imaging feature, used to enhance contrast resolution.
Full Screen Trace	Full Screen Trace
	Activates a full-screen format for the M-mode sweep.
	Note: For systems without a touch screen, the selection is assigned to a button:
	√
Split Screen	Split Screen
	Displays both the 2D-mode image and the M-mode sweep.
	Note: For systems without a touch screen, the selection is assigned to a button:
Full Screen 2D	Full Screen 2D
	Activates a full-screen format for the 2D-mode image.
	Note: For systems without a touch screen, the selection is assigned to a button:

Color Flow Imaging Parameter Selections

Selection	Description
CDV/CDE/DTI	Cycle the available color modes:
	 CDV (Color Doppler Velocity) — Applies colors to the velocities and directions of blood flow within the region of interest.
	 CDE (Color Doppler Energy) — Applies colors to the energy measurement generated by the blood flow within the region of interest.
	 DTI (Doppler Tissue Imaging) — Applies colors to the Doppler shift information of moving tissue within the region of interest.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Image	(Available settings depend on the transducer and exam type)
	Image Optimization Preset
	Optimizes hemodynamic flow conditions.
	 Low — Provides maximum sensitivity to low velocity flows by incorporating the lowest possible filter settings and lower PRFs. You may experience increased flash (motion artifacts).
	 General, Gen — Produces an optimal balance between flash suppression and maximum sensitivity by using an adaptive wall filter.
	 High — Optimizes the system for the high arterial flow common to pulsatile vessels and stenotic conditions.
	 Fetal Echo — Optimizes the system for viewing the blood flow in a fetal heart.
	Note: For systems without a touch screen, this selection is assigned to IMAGE .
Priority	Tissue Reject (Priority)
	When CDV is activated, adjusts the threshold for overlaying color pixel information on the 2D-mode image.
	When CDE is activated, adjusts the threshold for the amplitude of the power display.
	• 0 to 4
	Note: For systems without a touch screen, the selection is on the LED panel.
Filter	Wall Filter
	When CDV is activated, adjusts the level of motion discrimination during live imaging.
	When CDE is activated, balances low flow sensitivity with flash suppression.
	■ 0 to 3
	Note: For systems without a touch screen, the selection is on the LED panel.

D - 16 Instructions for Use

Selection	Description
Space Time	Adjusts the balance between the image line density (resolution) and the frame rate. Increasing the line density increases resolution and decreases frame rate.
	• 0 to 5
	Note: For systems without a touch screen, the selection is on the LED panel.
Persist	(Available only when Advanced SieClear is disabled)
	Persistence
	When CDV is activated, adjusts the time that the colors corresponding to blood flow velocity remain in the region of interest before decaying or being replaced by another color.
	When CDE is activated, adjusts the time that power data is processed in calculating the power amplitude display.
	• 0 to 4
	Note: For systems without a touch screen, the selection is on the LED panel.
Smooth	Spatial Averaging (Smoothing)
	Adjusts the level of spatial (both axial and lateral) averaging used to smooth the flow pattern display.
	• 0 to 3
	Note: For systems without a touch screen, the selection is on the LED panel.
Maps	When CDV is activated, selects a processing curve that assigns the velocity range to a range of colors.
	■ A, B, C, D, E, F
	When CDE is activated, selects a processing curve that assigns flow amplitudes to color levels.
	■ A, B, C, D, E, F, G, H
	Note: For systems without a touch screen, the selection is on the LED panel.
C Display	Activates and deactivates the color (CDV) or power (CDE) information and the region of interest.
	• On
	- Off
	Note: For systems without a touch screen, the selection is assigned to the Display soft key.

Selection	Description
C Background	(Available only when CDE is activated)
	Adds or removes a background enhancement of solid color. The solid background color changes, depending on the power map selected.
	■ On
	• Off
	Note: For systems without a touch screen, the selection is assigned to the Background sof key.
DTA/DTV/DTE	(Available only when DTI is activated)
	Selects a presentation method for color:
	 DTV — Presents the mean velocities of tissue in the sample area.
	 DTE — Presents the Doppler signal energies returning from the tissue.
	 DTA — Presents the rate of change of velocities (acceleration) in the sample area.
	Note: For systems without a touch screen, this selection is assigned to IMAGE.
Invert	(Affects only the active priority mode)
	Vertically flips the Doppler spectrum on the baseline (negative values display above the baseline) and inverts the Doppler audio.
	Vertically flips the colors depicting forward and reverse flow in the color ROI and in the color bar.
	Note: For systems without a touch screen, this selection is assigned to INVERT.
Steering Angle	(Available only for linear transducers)
	Change the steering angle within the transducer's array.

D - 18 Instructions for Use

Doppler Parameter Selections

Unless otherwise specified, the following selections are available for pulsed wave Doppler and continuous wave Doppler.

Selection	Description
Filter	Wall Filter
	Rejects low frequency signals, for example, signals generally caused by tissue clutter.
	 Available settings depend on the transducer and exam type
	Note: For systems without a touch screen, the selection is on the LED panel.
Gate	(Available only for pulsed wave Doppler)
	Gate Size
	Adjusts the size of the Doppler gate.
	 Available settings: Dependent on transmit frequency
	Note: For systems without a touch screen, use the scroll wheel to adjust the settings.
Sweep Speed	Sweep Speed
	Adjusts the horizontal speed of the Doppler spectrum.
	• NTSC: 1, 2, 4, 6, 8
	PAL: 1, 2, 5, 7, 8
	Note: For systems without a touch screen, the selection is on the LED panel.
Steer Reverse	(Available only for pulsed wave Doppler)
	(Available only for linear array transducers)
	Steer Reverse
	Reverses the Doppler angle, gate axis, and Doppler spectrum.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Maps	Selects a processing curve that assigns echo amplitudes to gray levels.
	■ A, B, C, D, E, F, G, H
	Note: For systems without a touch screen, the selection is on the LED panel.
Tint	Changes the color of the Doppler spectrum by adding blue, red, yellow, or green to the gray in a gray map.
	 Available settings: transducer-dependent
	Note: For systems without a touch screen, the selection is on the LED panel.
T/F Res	Time/Frequency Resolution
	Adjusts time/frequency resolution.
	■ A, B, C, D, E, F, G, H, I

Selection	Description
DTI	Enables or disables Doppler Tissue Imaging, which illustrates movement of tissue.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Trace Update	Trace Update Styles
Styles	Selects an update style or simultaneous display for the 2D-mode image and the Doppler spectrum. An update style pauses the Doppler spectrum and refreshes the 2D-mode image at the selected interval.
	2D-Lv/D-Lv
	2D-Lv/D-Frz
	 D-Lv/2D-Frz
	D-Lv/2D-Lv
	 D-Lv/2D-EOS (end of sweep)
	 D-Lv/2D-2s (every two seconds)
	 D-Lv/2D-4s (every four seconds)
	 D-Lv/2D-8s (every eight seconds)
	Note: The selections available depend on the active image.
Auto Stats	Auto Statistics
	Enables or disables the display of Doppler statistics.
	■ On
	• Off
Auto Stats On	(Available only for pulsed wave Doppler)
	Selects the trace settings to use data above the baseline, below the baseline, or on both sides of the baseline.
	Only Above Baseline
	Only Below Baseline
	 Above and Below
Full Screen Trace	Full Screen Trace
	Activates a full-screen format for the Doppler spectrum.
	Note: For systems without a touch screen, the selection is assigned to a button:

Selection	Description
Split Screen	Split Screen
	Displays both the 2D-mode image and the Doppler spectrum.
	Note: For systems without a touch screen, the selection is assigned to a button:
	2
Full Screen 2D	Full Screen 2D
	Activates a full-screen format for the 2D image with cursor mode Doppler gate displayed.
	Note: For systems without a touch screen, the selection is assigned to a button:
Live/Live	Acquires both images simultaneously in a split screen display.
Invert	(In combined mode imaging, affects only the active priority mode)
	Vertically flips the Doppler spectrum on the baseline (negative values display above the baseline) and inverts the Doppler audio.
	Vertically flips the colors depicting forward and reverse flow in the color ROI and in the color bar.
Steering Angle	(Available only for pulsed wave Doppler)
	(Available only for linear transducers)
	Change the steering angle within the transducer's array to the left, center, or right position.
Angle Correct	(Available only for pulsed wave Doppler)
60/0/60	Cycles through the angle correction selections (60, 0, -60).
	Rotate to adjust angle correction values in one degree increments between 60 and -60 degrees.
	Note: For systems without a touch screen, this selection is assigned to 0/60 .

Clip Capture Selections

A protocol is a capture definition that contains a group of settings for storing and reviewing clips.

Use the system configuration menu to change the default clip capture for an exam type.

System Config > Basic System 2 > Default Protocol Settings

Selection	Description
Stress Echo	Launch Stress Echo
	Activates the Stress Echo exam.
(current setting)	Change Capture Definition
	Specifies the clip length. The settings are available based on the protocol selected in system presets.
	(Time)
	■ 3 sec
	■ 2 sec
	• 5 sec
	■ 10 sec
	(R-wave)
	3 beats
	■ 1 beat
	■ 2 beats
	4 beats
	■ 5 beats
	■ 10 beats

CINE Graphics

During CINE playback, the system displays a CINE bar that represents the status of the CINE memory buffer.



- 1 Indicates the beginning of the CINE data
- 2 Indicates the location of the frame within the loop of CINE data
- 3 Indicates the end of the CINE data
- 4 Adjusts the playback speed during imaging
- 5 Reverses the direction the CINE data is moving (available only during imaging)
- 6 Indicates the number of the active frame

Selection	Description
Playback Speed	Adjusts the playback speed during imaging.
Cine Direction	Reverses the direction the CINE data is moving (available only during imaging).
Left Margin	Indicates the beginning of the CINE data.
Right Margin	Indicates the end of the CINE data.

Annotation Selections

Selection	Description
Keyboard	Shows or hides the touch screen keyboard.
Text (Tab)	Selects application-specific text annotations for an image.
Body Marker (Tab)	Displays a body marker on the screen and activates body marker selection.
Arrow (Tab)	Displays an arrow on the screen and activates arrow selection.
Set Home	Changes the default position of the annotation cursor.
Home	Repositions the annotation cursor to the default position.
Position/Rotate Area	An interactive area on the touch screen for changing the size, location, and direction of transducer markers, and arrows.
Page	Displays the next or previous page, when available.
Previous Annotation	(Available only on systems with a touch screen)
	Activates on-screen text in reverse chronological order.
Overwrite	(Available only in review)
	Creates text to replace an existing text annotation. The new text is an overlay on the existing text.

Selection	Description
Delete Word	(Available only on systems without a touch screen)
	Deletes one word
	Deletes the current word or the first word to the left of the cursor. Pressing the key again deletes previous words in reverse chronological order.
Delete Line	Deletes one line
	Deletes the current line of text.
Clear Screen	Clear entire screen
	Deletes all text, arrows, and body markers on the image screen.
Hide Words	Enables or disables display of text on the image screen.
	Note: If an image is annotated, annotations are still displayed in the image screen when Hides Words Off is activated.
Text	(Available only on systems without a touch screen)
	Adds the selected annotation (term) to the screen.
A	(Available only on systems without a touch screen)
	Add Text A text
	Displays the first annotation (term) in the "A" list, then cycles through the selections in the list.
В	(Available only on systems without a touch screen)
	Add Text B text
	Displays the first annotation (term) in the "B" list, then cycles through the selections in the list.
С	(Available only on systems without a touch screen)
	Add Text C text
	Displays the first annotation (term) in the "C" list, then cycles through the selections in the list.
D	(Available only on systems without a touch screen)
	Add Text D text
	Displays the first annotation (term) in the "D" list, then cycles through the selections in the list.
T	(Available only on systems without a touch screen)
_	Turn on Text cursor
	Activates the text cursor.

D - 24 Instructions for Use

Selection	Description
Body Marker	(Available only on systems without a touch screen)
	Body Marker
	Displays a body marker on the screen and activates body marker selection.
	Note: The selection is assigned to a button:
	77
Delete Body Marker	Delete current Body Marker
	Removes the currently displayed body marker from the screen.
	Note: For systems without a touch screen, the selection is assigned to a button:
Transducer Marker	Transducer Marker
	Adds or removes a transducer marker for the currently displayed body marker.
	Note: For systems without a touch screen, the selection is assigned to a button:
	M
Move/Set	Repositions and anchors the body marker.
7	(Available only on systems without a touch screen)
	Add Arrow
	Changes the text cursor into an arrow for placement of an arrow on the image screen.
Delete Arrow	Delete last Arrow
	Deletes the current arrow.
Length	Changes the length of the arrow and indicates the length in pixels.
Angle	(Available only on systems with a touch screen)
	Changes the direction of the arrow tip and indicates the angle of the direction.
Rotate	(Available only on systems without a touch screen)
	Changes the direction of the arrow tip and indicates the angle of the direction.

Basic Measurement Tools

Selection	Description
Delete	Removes the measurement from the image and measured results.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Undo	Edits a trace measurement.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
APAD/TAD	(Available only for measurements derived from an abdominal circumference)
	Switches the measured results for the anterior-posterior abdominal diameter with the measured results for the transabdominal diameter.
	Note: For systems without a touch screen, the selection is assigned to a soft key.

2D Measurement Tools

Selection	Description
Distance	Depth/Distance
	Calculates the length of a straight line.
Ellipse	Ellipse
	Determines area, diameter, and circumference.
2D Trace	Trace
(*)	Calculates the circumference of an irregular shape inside a manual trace.
Open Trace	Open Trace
(* .)	Calculates the diameter of an irregular shape inside open manual trace.
eSieCalcs	eSieCalcs
(* <u>*</u> .* <u>*</u>	Calculates the circumference of an automatically traced irregular shape inside a rectangle.
Angle	Angle
	Determines the degree of the acute angle.
Auto Volume	Auto Volume
	Calculates the volume and maximum distance of an automatically traced irregular shape.
Shear Velocity/	Shear Velocity/Elasticity
Elasticity	(Available only when Virtual Touch IQ is activated)
•	Measures the shear wave velocity and elasticity.

D - 26 Instructions for Use

Doppler Measurement Tools

Selection	Description
Velocity/Frequency	Velocity/Frequency
1	Calculates velocity or frequency on a real-time or frozen image.
Heart Rate	Heart Rate
	Determines the heart rate between two delimiters.
D-Trace	Trace
*:>	Performs a manual waveform trace.
RI-S/D	Resistive Index - Systolic/Diastolic
RI	Calculates the RI and SD ratios on a frozen Doppler spectrum.
Acceleration	Slope
	Measures acceleration or deceleration of speed over time.
Time	Time
	Measures time between two delimiters.
Heart Cycle	Heart Cycle
H	Measures the velocities, means, maximums, and ratios for one heart cycle.
Velocity Ratio	Velocity Ratio
(V _{/v})	Calculates the ratio of two velocity markers.
Auto Stats	Auto Statistics
	Measures the heart cycle automatically.

M-Mode Measurement Tools

Selection	Description
Distance	Distance
	Calculates the length of a vertical line.
Heart Rate	Heart Rate
	Defines the number of heart cycles between two delimiters.
Acceleration	Slope
	Measures the change in distance over time.
Time	Time
	Measures time on an M-mode sweep.

D - 28 Instructions for Use

Patient Report Screen Controls

Selection	Description
Patient Information	Displays information from the patient registration form.
Study	Displays all studies with a labeled measurement for a patient.
Fetus	(Available only for the obstetric exam)
	Displays images and measurements for each fetus.
Growth Curves	(Available only for the obstetric exam)
	Displays the fetal growth patterns according to the selected reference for a measurement or calculation label.
Side by Side	(Available only for the obstetric exam)
	Displays multiple fetuses to compare measured gestational age values.
Comments	Displays a text box for comments.
Images	Displays the images saved to the report. Thumbnails of all images in the current study display at the bottom of the screen.
New Patient	Ends the current exam and displays the patient registration form.
Edit Report	(Available only for the cardiac exam)
	Displays a version of the cardiac report that you can edit.
End Exam	Ends the current exam.
OB History	Displays previous fetal biometry when entered.
Transfer Report	(Available for the following exams: Breast, obstetric, cardiac, gynecology, and vascular)
	Sends the patient report to the network path specified in system configuration.
Store Report	Saves images (screenshots) of the patient report to the patient exam.
Print Report	Prints all sections of the report to a connected printer.
Remove Image	Enables the removal of images from the patient report.
Quit Remove	Disables the removal of images from the patient report.
Format	Selects a display format:
	• 1:1
	• 2:1
	• 4:1
	• 6:1
	• 9:1
	■ 16:1
Delete	(Available only for shear wave velocity and elasticity measurements from Virtual Touch Quantification and Virtual Touch IQ)
	Deletes the measured result from the report.
	Note: For systems without a touch screen, the selection is assigned to a button:

Selections for Cardiac Measurements

Basic Cardiac Measurement Tools

Selection	Description
2D-Mode	
Distance	Distance
	Calculates the length of a straight line.
LV Dist	LV Dist
	Measures the distance between four points on a line to determine IVS (interventricular septum), LVID (left ventricular internal diameter) and LVPW (left ventricular posterior wall).
Angle	Angle
	Determines the angle by intersecting lines (PISA and MS).
Spline	Spline
	Measures the circumference and area of a structure established with three or more markers.
Ellipse	Ellipse
	Determines the area, diameter, and circumference.
Trace	Trace
	Calculates the circumference of an irregular shape.
Vol MOD	Vol MOD
	Determines the circumference, area, long axis length, and volume of a structure.
Doppler	
Time	Time
	Measures the change in time between two points.
Velocity	Velocity
	Determines velocity (V) and pressure gradient (PG).
HR	HR (Heart Rate)
	Measures the heart rate using one heart cycle.
Acceleration	Accel (Acceleration)
	Measures the change of velocity over time, using a slope formula.
PHT	PHT (Pressure Half Time)
	Determines a valve area from a peak velocity and a diastolic slope and calculating the time takes for the pressure to drop by one half.
VTI manual	VTI manual
	Determines velocity and pressure gradients using a manual trace of a Doppler spectrum.
VTI Mean (auto)	VTI Mean (auto)
	Determines velocity and pressure gradients using an automatic trace of a Doppler spectrum.

D - 30 Instructions for Use

Selection	Description
Above Baseline	Above Baseline, Below Baseline
Below Baseline	Determines if the data required for the automatic trace is obtained from above or below the baseline.
	Note: For systems without a touch screen, the selection is assigned to the scroll wheel.
AR/DR Rate	AR/DR Rate
	Measures rate and time for acceleration and deceleration.
M-Mode	
Distance	Distance
	Calculates the length of a straight line.
Time	Time
	Measures the change in time between two points.
Slope	Slope
	Measures the change in distance over time.
LV Dist	LV Dist
	Measures the distance between four points on a line to determine IVS, LVID and LVPW.
HR	HR (Heart Rate)
	Determines heart rate using one heart cycle.

Cardiac Report Controls

Selection	Description
Edit Report	Opens a version of the report that you can edit.
Page	Displays the page number and total number of pages.
Prev	Displays the previous page of the selected group of measurements.
Next	Displays the next page of the selected group of measurements.
Delete All	Removes the data from the selected page.
Delete Line	Removes the data from the selected row.
Delete Cell	Removes the data from the selected cell.
Result is	Selects the display of the most recent value or the average value:
	 Last
	 Average
	■ Minimum
	■ Maximum
	■ 1st, 2nd, 3rd, 4th, or 5th
Close	Exits the cardiac edit report page and displays the cardiac exam.
Final Report	Displays the cardiac report.

DVR Menu Selections and Status Indicators

See also: For information about playback controls for this feature, refer to Chapter 4 in this manual.

Selection	Description
(current status)	Displays the current status of the media:
	 Ready indicates the device and media are ready for recording.
	 Recording indicates the device is currently recording images.
	 Finalized indicates the media can be played on another device, such as an external DVD player or computer equipped with a DVD drive. New recordings cannot be saved to the media.
(current time remaining on media)	Displays the estimated time (in hours and minutes) remaining for recording before media space is filled.
(current space used on media)	Displays the percentage of space used on the media.
View Disk	Displays the viewer screen for playback.
Finalize	Prepares the contents of the media for playback on other devices.
Eject	Ejects the media from the recording device.

Recording Icons

The ultrasound system displays the following icons in the image menu.

Icon	Description
	Indicates the device is recording.
	Storage Space Warning
	Indicates the media is nearly filled.
	Disk is full. Insert new DVR media.
	Indicates the media is filled. To continue recording, you must insert new media.
⊗	Disk is finalized. Unable to record.
	Indicates the media is finalized. New recordings cannot be saved to the media.

D - 32 Instructions for Use

Review Controls

Selection	Description
syngo AHP	syngo AHP – Arterial Health Package
	Activates the syngo Arterial Health Package (AHP) software program.
	Note: For systems without a touch screen, the selection is assigned to a button:
syngo VVI	syngo VVI – Velocity Vector Imaging
	Activates the syngo Velocity Vector Imaging (syngo VVI) software program.
	Note: For systems without a touch screen, the selection is assigned to a button:
syngo Auto LHA	syngo Auto LHA
	Activates the syngo Auto Left Heart software program.
	Note: For systems without a touch screen, the selection is assigned to a button:
Contrast Dyn	Contrast Dynamics(TM) software
	Activates the syngo Contrast Dynamics software program.
	Note: For systems without a touch screen, the selection is assigned to a button:
Page # of #	Selects a page of images.
	Note: For systems without a touch screen, use the scroll wheel or the LED panel controls to adjust the settings.
Format	Selects a display format:
	• 1:1
	2:1
	4:1
	• 6:1
	• 9:1
	• 16:1
	Note: For systems without a touch screen, the selection is on the LED panel.
	Note: To alternate full-screen display format and the last selected display format, position the cursor over an image and then press UPDATE twice.

Selection	Description
Protocol Text	(Available only for images captured during a workflow protocol)
	Displays or hides the view name:
	 On displays the view names on the review screen and the thumbnail panel.
	 Off hides view names.
Sort Mode	(Available only for images captured during a workflow protocol)
	Sorts the protocol views by the selected criterion:
	 Time displays images in the sequence they were captured.
	 View displays images in the sequence that the views were displayed in the thumbnail panel when the protocol was activated.
	Note: Images captured before the protocol was activated are displayed before the sorted protocol views. Images captured after the protocol was activated, including images captured while the protocol was paused, are displayed after the sorted protocol views.
	Use the system configuration menu to specify the sequence that views are displayed in the thumbnail panel.
	System Config > eSieScan Workflow Protocols
Compare	Compare Mode
	Displays only the selected images (static images, clips, or volumes) in the sequence the images were selected.
# of #	Displays the number of images selected for comparison and the total number of images in the study.
Remove image(s)	Remove Image(s)
	Hides the selected image from the displayed images currently selected for comparison.
Synchronization	
Synchronization	Synchronization
Synchronization	
Synchronization	Synchronization
Synchronization	Synchronization Selects the playback synchronization for the displayed clips:
Synchronization	 Synchronization Selects the playback synchronization for the displayed clips: None or No Synchronization disables synchronization of clip playback. Sync Start begins playback for all clips at the same time. For example, begins playback for a long and short clip at the same time. Does not begin playback again until the long clip has

D - 34 Instructions for Use

Selection	Description
Speed	Replay Speed
	Selects the playback speed, a percentage of the speed during acquisition, for the displayed clips:
	12.5%
	25 %
	■ 33%
	■ 50%
	■ 66%
	• 100%
	200%
	400 %
Play Forward	Replay Forward/Backward
Backward	Changes the direction of clip playback.
Jump to First	Jump to First Frame
Frame	Displays the first frame of the displayed clips.
	Note: For systems without a touch screen, the selection is assigned to a button:
Step Backward	Step Backward
•	Displays the previous frame of the displayed clips.
	Note: For systems without a touch screen, the selection is assigned to a button:
Play	Play/Pause Replay
	Begins playback of the displayed clips.
	Note: For systems without a touch screen, the selection is assigned to a button:

Selection	Description
Pause Replay	Play/Pause Replay
	Stops playback of the displayed clips.
	Note: For systems without a touch screen, the selection is assigned to a button:
Step Forward	Step Forward
•	Displays the next frame of the displayed clips.
	Note: For systems without a touch screen, the selection is assigned to a button:
Jump to Last Frame	Jump to Last Frame
rrame	Displays the last frame of the displayed clips.
	Note: For systems without a touch screen, the selection is assigned to a button:
	▶ I
Single Select	Single Select
	Selects an image and cancels selection of any previously selected image.
	Note: For systems without a touch screen, the selection is assigned to a button:
Multiple Select	Multiple Select
	Selects an image and retains the selection of any previously selected image.
	Note: For systems without a touch screen, the selection is assigned to a button:
Select All	Select All
	Selects all available images.
	Note: For systems without a touch screen, the selection is assigned to a button:
Select None	Select None
	Cancels selection of any selected images.
	Note: For systems without a touch screen, the selection is assigned to a button:

Selection	Description
Flag	Flag
	Activates or deactivates a flag mark at the top of the selected image(s). The flag marker is visible every time you review the image on the review screen.
	Note: For systems without a touch screen, the selection is assigned to a button:
	4
Copy to Film	Note: Multiple-frame images, such as clips and volumes, cannot be printed or copied to the filming screen.
	Copies the selected image(s) to the filming screen for printing.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Delete	Activates or deactivates a deletion mark at the top of a selected image to indicate that the image is tagged for deletion.
	For active exams, the system deletes the tagged images from the patient study when you end the examination. For previously saved exams, the system deletes the tagged images when you end the review session.
	For active exams, if the selected image displays a stress echo icon, all stress echo images are marked for deletion.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Selected	Indicates the number of currently selected images.
Copy to Film	Indicates the number of images copied to the filming screen.
Deleted	Indicates the number of images that are tagged for deletion.
Flagged	Indicates the number of images that are marked with a flag.
Total	Indicates the total number of images and clips displayed on the review screen (all pages).
Images	Indicates the number of images displayed on the review screen (all pages).
Clips	Indicates the number of clips displayed on all pages of the review screen.
SE Clips	Stress Echo Clips
	Indicates the number of stress echo clips displayed on all pages of the review screen.
End Exam	Ends the current examination.
Exit Review	Ends the review session.
3D/4D	When a volume is the only item selected, loads the volume and displays the 3D visualization tools.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Calcs/Text	When an image or clip is the only item selected, loads the selected item to review in 1:1 format, displays the measurement menu, and provides access to the annotation menu.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Layout	Changes the number of images displayed on each page.
Review 3D Data	Begins 3D data review.

Review Clip Bar Graphics



Example of clip bar.

- 1 Beginning of the clip
- 2 Location of the currently displayed frame
- 3 End of the clip
- 4 Playback speed
- 5 Current frame number



Example of the expanded clip bar.

- 1 Frame number of the starting margin of the clip
- 2 Frame number of the current frame
- 3 Frame number of the ending margin of the clip

Filming Screen Controls

You can preview images before printing, customize print settings for images, and print images. Images printed from the current examination are available for preview and printing from the filming screen when automatic printing is disabled.

Selection	Description
	Page corner icon
	Displays the next or previous page of images.
	Copies
	Sets the number of copies to print for the selected film job.
Selection	Description
%	Film Task Status
4	Displays film job information.
	Delete
	Deletes the selected image(s) or the selected film job from the filming screen.
□ → \$	Expose Film Task
	Immediately sends all images in the film job to the selected printer.

Filming Screen Tab Card

The filming screen has three tabs where you can prepare images for printing.

Layout Tab

Select from a choice of pre-configured layouts for your printed images on the **Layout** tab. The more images you choose per film sheet, the smaller your images will print.

Images Tab

Image text tools affect the display of patient name and imaging parameters while graphic tools affect the display of regions of interest (ROIs) and color bars. Use the system presets to customize image text (designate categories of image text for display).

Note: Image text and graphics can be hidden and displayed on images that were saved as ultrasound images with graphic overlays only.

Selection	Description
7	All Text
	Displays image text for the selected image(s).
73	Customized Text
	Displays customized image text for the selected image(s).
	No Text
	Hides image text for the selected image(s).
₹7	Show Graphics
7	Displays graphics for the selected image(s).
\bigcirc	Hide Graphics
7	Hides graphics for the selected image(s).
	Fit to Segment
K . A	Displays the selected image(s) as large as possible (without clipping) given the size of their segment(s).
<u> </u>	Original Image
W	Do not change the image display format from the factory default Fit to Segment (the only valid setting). Changing this selection from the factory default may cause errors during printing.
	Clip Document
	Do not change the image display format from the factory default Fit to Segment (the only valid setting). Changing this selection from the factory default may cause errors during printing.

Camera Tab

You can override the default printer selected in system presets by selecting from available printers on the **Camera** tab. You can also select film size.

D - 40 Instructions for Use

Patient Browser Screen

The patient browser displays patient data stored on the following storage locations: Local database, the connected Hospital Information System/Radiology Information System (HIS/RIS) server (if any), and the inserted media.

Note: Use the **Browser Configuration** dialog box to configure the display of status indicators and headings.

The organization of the patient data within the navigation section or the content section depends on the selected layout (tree view or single view). The tree view layout is the default setting.

Icon Selections

Icon	Selection	Description
	Local Database (storage location)	Displays patient data stored on the local database.
	Scheduler (storage location)	Displays pre-registered patients (data entered on the ultrasound system) and scheduled patients (data retrieved from a connected HIS/RIS server).
	CD-DVD (storage location)	Displays patient data stored on the inserted disk.
	Patient Folder (Local Database or CD-DVD)	Displays study folders within the patient folder. This icon is displayed in tree view only for patient data in the local database or on an inserted disk.
	Study Folder	Displays series objects within the study folder. This icon is displayed in tree view only for patient data in the local database or on an inserted disk.
	Series Object	Displays images within the series object. This icon is displayed in tree view only for patient data in the local database or on an inserted disk.
	Patient Folder (Scheduler)	Displays procedure folders within the patient folder. This icon is displayed in tree view only for patient data in the Scheduler.
P	Procedure Folder	Displays procedure steps within the procedure folder. This icon is displayed in tree view only for patient data in the Scheduler.
	Procedure Step	Displays action items within the procedure step. This icon is displayed in tree view only for patient data in the Scheduler.

Menu Selections

 $\textbf{Note:} \ \ \textbf{Use the Browser Configuration} \ \ \text{dialog box to configure display of toolbar buttons for frequently used menu selections.}$

 $\textbf{Note:} \ \mathsf{Images} \ \mathsf{displayed} \ \mathsf{in} \ \mathsf{the} \ \mathsf{patient} \ \mathsf{browser} \ \mathsf{may} \ \mathsf{represent} \ \mathsf{clips}, \ \mathsf{volumes}, \ \mathsf{or} \ \mathsf{other} \ \mathsf{multiple-frame} \ \mathsf{images}.$

Patient Menu Selections

Menu Selection	Button	Description
Register		Patient Registration
		Displays the patient registration form. If a patient folder or study folder was selected, copies the patient data to the patient registration form.
Load to Review	}	(Available only for patient data stored on the local database)
	₽.■	Load to Review
		Exits the patient browser and displays the images in the selected study folder or series object on the review screen.
De-Identify		Displays the De-Identify dialog box to enter non-identifying text for the patient name.
Upload to Siemens		Displays the De-Identify dialog box and then transmits the study to the Siemens FTP site.
Show MPPS		(Available only for patient data stored on the local database)
		Show MPPS
		Displays the Modality Performed Procedure Step dialog box, which lists MPPS data for the selected study.
		Note: When you select a patient folder, the system automatically selects the most recent study folder; when you select Local Database , the system automatically selects the first patient folder.
Film Task Status	\$	Film Task Status
		Displays the Film Task Status dialog box, which lists film jobs.
Expose Film Task		Expose Film Task
		If a film job exists in the filming screen, then the system immediately sends all of its images to the default printer. If more than one film job exists in the filming screen, then the system displays the Select Film Job dialog box, which lists film jobs you can select for printing.
Copy to Film Sheet]*[(Available only for patient data stored on the local database)
	TI.	Copy to Film Sheet
		Copies the selected images to the filming screen for manual formatting and exposure. If you select a patient folder, the system copies all images for all study folders within the selected patient folder.

D - 42 Instructions for Use

Menu Selection	Button	Description	
Print Preview		Displays a preview of the patient data for printing. This selection is available only for a selected storage location, patient folder, or procedure (Scheduler).	
Print List		Prints the patient data displayed in the content section of the patient browser.	
Print		Displays the Print dialog box, listing available printers and their configuration options.	
Search 2		Open "Patient Search" dialog	
		Displays the Patient Search dialog box to enter criteria to search for patient information in the local database, Scheduler, or inserted disk.	
Search Selected		Search Selected	
		Displays the Patient Search dialog box with data for the selected patient.	
Close Browser		Exits the patient browser.	

Transfer Menu Selections

Menu Selection	Description	Button
Import	Copies the selected patient data to the local database. This selection is available only for patient data on the inserted disk.	
Archive to ""	Archives the selected patient data to the indicated archive device.	₽
	This menu selection indicates the currently configured default archive device.	3 4
Archive to	Displays the Archive To dialog box, which lists destinations (archive devices) for archival of the selected patient data. When the archival is complete, the system updates the work status of the patient data to "Archived." This selection is available only for patient data on the local database.	
Send to ""	Sends the selected patient data to the indicated storage device.	₽→1
	This menu selection indicates the currently configured default storage device. For example, if a workstation named "MV300" is the default storage device, then the menu selection is Send to MV300 .	= 1
Send to	Displays the Send To dialog box, which lists destinations (storage devices) for storing the selected patient data. When the transfer is complete, the system updates the work status of the patient data to "Sent." This selection is available only for patient data on the local database.	
Export to	Displays the Export To dialog box, which lists destinations (offline devices) for storing of the selected patient data. When the transfer is complete, the system updates the work status of the patient data to "Exported." This selection is available only for patient data on the local database.	

Menu Selection	Description	Button
Eject from CD-DVD	Ejects the inserted disk.	1 2
Eject from	Displays the Eject From dialog box. The system ejects the disk when you select the disk and confirm the operation.	
Finalize Medium	Completes writing to the inserted disk and ejects the disk.	T
and Eject from CD-DVD	Note: Finalizing the disk prepares it for playback on other devices.	↓ ✓
Nuance Data Transfer Status	Displays a dialog box, which lists pending transfers of measured results to a Nuance report template.	
Local Job Status	Displays the Local Job Status dialog box, which lists transfers of patient data to the inserted disk or to other local destinations.	3
Network Job Status	Displays the Network Job Status dialog box, which lists transfers of patient data to the network.	? [
Import from Off-line	Displays the Import from Off-line dialog box, which lists patient data files and their locations on the system's hard disk or supported external media. The system imports the selected patient data files to the local database.	
	Note: You can also enter a location and press Enter on the keyboard to display the contents of the entered location.	
Export to Off-line	Displays the Export to Off-line dialog box, which lists locations on the system's hard disk or supported external media and export options for the selected patient data. The system exports the selected patient data files to the selected location on the system's hard disk. This selection is available only for patient data on the local database.	
	Note: You can also enter a location.	
Export to CD in PC Format	Copies the selected images and clips to the inserted disk. Images are stored in JPEG format. Clips are stored in AVI (audio-video interleave) format. Patient data and DICOM information are not copied with the transferred images and clips.	
Export to USB in PC Format	Copies the selected images and clips to the inserted USB storage device. Images are stored in JPEG format. Clips are stored in AVI (audio-video interleave) format. Patient data and DICOM information are not copied with the transferred images and clips.	
Record Off-line Files	Records selected data files to local storage media.	

D - 44 Instructions for Use

Edit Menu Selections

Menu Selection	Description	Button
Cut	Places a copy of the selected item of patient data onto the clipboard for future removal.	*
Delete	Removes the selected patient data from a storage location.	
Paste	Removes the patient data currently on the clipboard (that is, the item of patient data that was most recently "copied" using the Cut selection) from its original location and inserts it into the selected item of patient data.	
Protect	Assigns protection to the selected patient data. Protection on any objects in the lower or higher data levels prevents deletion. For example, protection assigned to a series object prevents deletion of the related patient folder. However, an unprotected, unrelated series object within this same patient folder can be deleted.	-0
Remove Protection	Removes protection from the selected patient data.	76
Restore	Removes all modifications and restores the data to the previously saved state.	
Clear Scheduler	Removes all pre-registered patients and scheduled patients.	
Empty Recycle Bin	Permanently removes deleted items from the recycle bin.	
Find	Locates data on the system based on specified parameters.	
Mark	Assigns "mark" (bookmark) work status to the selected patient data. Marked items of patient data can be filtered for display.	
Unmark	Removes "mark" work status from the selected patient data.	
Set State▶	Indicates completion of the selected process.	
	Note: This selection is not available for patient data in the Scheduler.	
Completed	Indicates completion of the Completed process for the selected patient data.	
Read	Indicates completion of the Read process for the selected patient data.	₩
QA Verified	Indicates completion of the Verified process for the selected patient data.	4
Correct	Displays the Correct dialog box, which lists information about the selected patient data. The system applies any entered corrections (such as a revised study comment) to the selected patient data.	
History	Displays the Correct & Rearrange History dialog box, which lists information about past corrections.	

View Menu Selections

Menu Selection	Description	Button
Open Subtree	Displays all series objects for the selected patient folder. A series object may contain multiple images.	#
Close Subtree	Hides all series objects for the selected patient folder.	
Refresh	Manually updates the display of patient data.	Ø
	Note: The system automatically updates patient data at regular intervals.	V •
	Note: This selection does not update the Worklist.	
Patient based worklist query	Displays the Patient Worklist Query dialog box to enter criteria to search for patient data in a worklist.	
Update Worklist	For systems connected to a HIS/RIS server, manually updates the Scheduler display of data for scheduled patients.	
Tree	When checked, displays patient data according to the pre-selected format options for tree view layout.	
	When not checked, displays patient data according to the pre-selected format options for single view layout.	
	Note: Use the Browser Configuration dialog box to configure the format options for tree view or single view layout.	
Image Stamps	When checked, displays miniature representations of the images within the selected series object, according to the pre-selected format options for image presentation.	
	When not checked, displays information about the images within the selected series object, according to the pre-selected headings for images.	
	Note: Use the Browser Configuration dialog box to configure the format options for tree view or single view layout.	
	Note: This selection is not available for the single view display format.	
Toolbar	When checked, displays the pre-selected toolbar buttons.	
	Note: Use the Browser Configuration dialog box to configure toolbar buttons.	

D - 46 Instructions for Use

Menu Selection	Description	Button
Info Area	When checked, displays information above the content section depending on the level of selected patient data:	
	 Patient folder — patient name, date of birth, patient ID 	
	 Study folder — study description and study date, in addition to patient folder information 	
	 Series object or image — modality, in addition to study folder information 	
Source▶		
1 Scheduler	When checked, displays the Scheduler icon for viewing of pre-registered and scheduled patients.	
2 Local Database	When checked, displays the Local Database icon for viewing of patient data stored on the local database.	
3 CD-DVD	When checked, displays the icon for viewing of patient data stored on an inserted disk.	

Filter Menu Selections

Menu Selection	Description	Button
Off	Disables any activated filter and displays all patient data.	\mathbf{Z}
Not Archived	Displays only patient data without an archived work status.	201
Not Printed	Displays only patient data without a printed work status.	
Not Sent	Displays only patient data without a sent work status (for sending over the network).	₹ □
Not Marked	Displays only patient data without a "marked" work status.	
Marked	Displays only patient data with a "marked" work status.	
(user-defined filter)	Displays only patient data that meets the criteria specified for the selected user-defined filter.	
Not Exported	Displays patient data not exported.	

Sort Menu Selections

The sorting function is available only in the tree view layout. The selections available depend on the level of patient data selected (storage location, patient folder, study folder, series object, or image). The system sorts data in the next lower data level.

Note: Sorting is restricted to the list of patients for the Scheduler.

Sort Selections for Storage Location Icons

Note: You can also sort patient data by the patient ID, planned examination date, and scheduled procedure.

Selection	Sorts Patient Folders by
Patient Name	Patient name.
DB Date and Time	Date and time that the patient folder was created on the local database.
Patient ID	Identification code for the patient.
Patient Latest Exam Date	Most recent exam date for the patient.
Work Status▶	
1 Printed	Printed work status. Not available for the Scheduler.
2 Archived	Archived work status. Not available for the Scheduler.
3 Sent	Sent work status. Not available for the Scheduler.
Reverse Order	Reverse order in the selected sorting option.

Sort Selections for Patient Folders

Selection	Sorts Study Folders by
Study Description	Study description.
Study Date and Time	Study date and time.
Work Status▶	
1 Printed	Printed work status.
2 Archived	Archived work status.
3 Sent	Sent work status.
4 Workflow	Workflow work status.
Multiple	Displays the Image Display Order dialog box, which lists multiple sorting options.
Reverse Order	Reverse order in the selected sorting option.

Sort Selections for Study Folders

Selection	Sorts Series Objects by
Series Number	Series number.
Series Description	Series description.
Series Date and Time	Series date and time.
Modality	Modality.
Performing Physician	Physician's name.
Work Status▶	
1 Printed	Printed work status.
2 Archived	Archived work status.
3 Sent	Sent work status.
4 Workflow	Workflow work status.
Multiple	Displays the Image Display Order dialog box, which lists multiple sorting options.
Reverse Order	Reverse order in the selected sorting option.

D - 48 Instructions for Use

Sort Selections for Series Objects or Images

Selection	Sorts Images by
Instance Number	Instance (image) number.
Instance Date and Time	Instance (image) date and time.
Slice Position	Slice position (transversal-coronal-sagittal).
Modality Specific Data►	Data specific to the exam modality, for example, anatomical orientation, image slice position, or time of acquisition.
Work Status▶	
1 Printed	Printed work status.
2 Archived	Archived work status.
3 Sent	Sent work status.
Multiple	Displays the Image Display Order dialog box, which lists multiple sorting options.
Reverse Order	Reverse order in the selected sorting option above.

Options Menu Selections

Selection	Description
Configure Browser	Displays the Browser Configuration dialog box, which contains options for customizing the display of the patient browser.
Filter Settings	Displays the Filter Specification dialog box, which lists criteria for the selected filter.
Drag and Drop for Rearrange	Enables the drag and drop method to arrange patient data for the currently registered patient.

Help Menu Selections

Selection	Description
Contents and Index	Displays the online information about using the patient browser.

D - 50 Instructions for Use

Appendix E Advanced Feature Controls

Advanced Feature Controls Overview	3
eSieFusion Controls	3
eSie Touch Elasticity Imaging (EI) Selections	4
Elasticity Measurement Tools	4
Virtual Touch Controls	5
3-Scape and fourSight Imaging Controls	5
Selections for 3D and 4D Setup	5
Selections for 3D and 4D Imaging	6
Selections for 3D and 4D Visualization	11
3-Scape and fourSight Editing Controls	13
SieScape Controls	14
Speed Indicator	
Contrast Agent Imaging Selections	16
Multi-Modality Review On-screen Controls	18
Reference Images Screen	21
Physiologic Function Controls	21
Selections Used in the Stress Echo Feature	22
Select Protocol Dialog Box	22
Acquisition Selections	22
Stress Echo Screen	23
Toolbar Buttons	23
Select Mode Selections	25
Review Mode Selections	26
Wall Motion Scoring Mode Selections	
LV Mode Selections	
Indication Dialog Box	
Select Text to Insert Dialog Box	
Maintenance Dialog Box	29
Protocol Editor Dialog Box	32

syngo Auto Left Heart Controls	34
Example of View Selection Screen	34
Example of syngo Auto Left Heart Screen	35
Calculation Data and Measurements	37
syngo VVI (Velocity Vector Imaging) Controls	38
Strain/Velocity Measurement Window	40
3D Window and Magnification Window	40
Global Measurements Window	41
M-mode, R-waves, Crop Window	41
Dyssynchrony Analysis Window	42
Contrast Dynamics Software Controls	44
Contrast Dynamics Software Controls Contrast Dynamics Context Menus	
-	46
Contrast Dynamics Context Menus	46
Contrast Dynamics Context Menus Select Destination and File Format Dialog Box	46 46
Contrast Dynamics Context Menus Select Destination and File Format Dialog Box Select Destination Dialog Box	46 46 46
Contrast Dynamics Context Menus Select Destination and File Format Dialog Box Select Destination Dialog Box syngo Arterial Health Package (AHP) Controls	46 46 46 47
Contrast Dynamics Context Menus Select Destination and File Format Dialog Box Select Destination Dialog Box syngo Arterial Health Package (AHP) Controls AHP Screen — Navigation Panel	46 46 47
Contrast Dynamics Context Menus Select Destination and File Format Dialog Box Select Destination Dialog Box syngo Arterial Health Package (AHP) Controls AHP Screen — Navigation Panel Image Quality Panel	46 46 47 47 47

Advanced Feature Controls Overview

This appendix provides a description of the controls available for advanced features. The system displays controls for the active feature on the touch screen and on the image screen.

Note: The image screen does not support touch technology. Use the trackball and **SELECT** controls on the control panel to interact with the on-screen controls.

To view additional controls on the touch screen, you can rotate the **Page** control, select **More**, or select **Next Page** or **Previous Page**, depending on the currently active function.

For systems without a touch screen, the system displays the controls on the on-screen menu, except as noted in this appendix.

eSieFusion Controls

See also: For information about controls for this feature, refer to Chapter 9 in this manual.

eSie Touch Elasticity Imaging (EI) Selections

Description
Elasticity Imaging
Activates or deactivates the eSie Touch elasticity imaging feature.
Note: For systems without a touch screen, the selection is assigned to a button:
Adjusts the size of the live, dual image as a percentage.
• 50% to 100%
Cycles through the map index selections for gray scale and color maps.
0 is the standard map
Map index 0 is the natural result of the strain estimation from the echo signal without compensation for pre-compression (stress) or non-uniform stress applied by the user.
1 is the normalized map
Map index 1 compensates for the potential that non-uniform stress is applied with the transducer during scanning.
2 is the inverse map
Note: For systems without a touch screen, use the scroll wheel and the LED panel controls to adjust the settings.
Activates or deactivates the color map.
Off deactivates the color map.
 1 applies a range of color to depict tissue stiffness from soft to hard.
 2 applies blue to depict harder tissue and red to depict softer tissue.
Note: For systems without a touch screen, the selection is on the LED panel.
(Available only for systems with a touch screen)
Displays a 2D image and an elastogram.
(Available only for systems with a touch screen)
Displays a full screen image.
(Available only for systems without a touch screen)
When On is selected, displays a 2D image and an elastogram. When Off is selected, displays a full screen image.

Elasticity Measurement Tools

Selection	Description
Shadow	When the shadow function is active, you can make a measurement on either the left image or the right image. The system then duplicates and displays the measurement on the other image.
Strain Ratio	Calculates the ratio of average strain (stiffness of tissue) within two user-selectable regions of interest.
ROI 1	
ROI 2	

E - 4 Instructions for Use

Virtual Touch Controls

See also: For information about controls for this feature, refer to Chapter 10 in this manual.

3-Scape and fourSight Imaging Controls

Selections for 3D and 4D Setup

Selection	Description
3D/4D	Enables 3D or 4D setup.
	Note: For systems without a touch screen, press 4D to activate 3D or 4D setup.
Scan Method	Scan Method
	Selects the scan method for volume acquisition.
	Linear
	 Rocked
	 Auto Sweep
	• STIC
Length	Scan Length
	Selects the scan length for volume acquisition.
	 Available settings: transducer-dependent
Angle	Scan Angle
	Selects the scan angle for volume acquisition.
	 Available settings: transducer-dependent
Speed	Scan Speed
	Selects the scan speed for volume acquisition.
	■ Fast
	Medium
	• Slow
Scan Time	Scan Time
	Selects the time of acquisition (in seconds) for Spatial Temporal Image Correlation (STIC).
	• 7 to 18
Quality	Quality Factor
	Selects the quality setting for volume acquisition.
	■ 1 to 6
3D ROI	3-Scape Region of Interest
	Activates or deactivates the display of the 3-Scape ROI.
	■ Off
	■ On
4D ROI	fourSight Region of Interest
	Activates or deactivates the display of the fourSight ROI.
	■ Off
	■ On

Selections for 3D and 4D Imaging

Description
(Available only when VOI is enabled)
Rotates the volume to the selected angle.
• 0°, 90°, 180°, 270°
Note: For systems without a touch screen, the selection is assigned to a soft key.
(Available settings depend on the transducer, exam type, and the active imaging mode)
Image Optimization Preset
Applies the selected image optimization settings for 3D or 4D images.
 Amnioscopic
Fetal Brain
Fetal Heart
■ Spine
1st Trimester
2nd/3rd Trimester
Endometrium
 Uterus
 Adnexa
Note: For systems without a touch screen, this selection is assigned to IMAGE .
Selects the required slice or volume.
Note: For systems without a touch screen, this selection is assigned to the scroll wheel.
Changes the view from plane view to slice view.
Note: For systems without a touch screen, press the scroll wheel.
Steps through the slices in the volume.
Note: For systems without a touch screen, this selection is assigned to the scroll wheel.

E - 6 Instructions for Use

Selection Description **Render Mode** Renders the volume using the selected rendering method: Opacity — Smoothes image contours, creating a soft, sculptured appearance for highlighting surface features. Uses the selections for opacity percentage, thresholds, and smoothing. MinIP (Minimum Intensity Projection) — Limits the display to minimum-value pixels by selecting pixels with the lowest value along each projection of the volume. May be helpful in visualizing hypo-echoic lesions and large vascular structures. MaxIP (Maximum Intensity Projection) — Limits the display to maximum-value pixels by selecting pixels with the highest value along each projection of the volume. May be helpful in visualizing hyper-echoic structures and fetal skeletons. MeanIP (Mean Intensity Projection) — Limits the display to average-value pixels by selecting pixels with the arithmetic mean (average) value along each projection of the Gradient Light — Simulates the reflection of light off a surface, resulting in improved depth perception. Amnioscopic — Simulates scattering of directed light within an object, producing translucency and shadowing effects. **Surf. Shading** — Heightens contrast, creating a textured appearance for highlighting internal features. Uses the selected shading, opacity percentage, and thresholds. Note: Surf. Shading is available only when CDE is activated. Note: Only Opacity, Gradient Light, and Amnioscopic rendering modes are available when skeletal rendering is activated. Note: For systems without a touch screen, the selection is on the LED panel. **Format** Selects a display format: 1:1 — Displays only the selected quadrant, in full-screen display format. 4:1 — Displays all four quadrants. 2:1 — Displays the acquisition plane on the left of the screen and the volume on the right. • 1:3 — Displays the volume on the left of the screen and the three MPRs on the right. Note: For systems without a touch screen, the selection is assigned to a soft key. VOI 3-Scape Volume of Interest Activates or deactivates the volume of interest. On Off **Low Thresh** Low Threshold Sets the low threshold for the opacity curve. Removes 2D-mode data (voxels) from the volume that have values lower than the selected threshold. **Note:** For systems without a touch screen, the selection is on the LED panel.

Selection	Description
Opacity	Adjusts the percentage of opacity in the volume to smooth image contours.
	■ 0 to 100
	Note: For systems without a touch screen, the selection is on the LED panel.
Smooth	Smoothing
	Adjusts the percentage of smoothing to smooth the data in the volume quadrant.
	■ 0 to 100
	Note: For systems without a touch screen, the selection is on the LED panel.
Contrast	Adjusts the percentage of contrast.
	• 0 to 100
	Note: For systems without a touch screen, the selection is on the LED panel.
Light	Lighting
	Adjusts the lighting effects used in gradient light and amnioscopic rendering.
	■ 0 to 100 (in increments of 5)
	Note: For systems without a touch screen, the selection is on the LED panel.
Shading	Adjusts the shading effects used in surface shading rendering.
	• 0 to 100 (in increments of 5)
	Note: For systems without a touch screen, the selection is on the LED panel.
Priority	Tissue Reject (Priority)
	Adjusts the threshold for displaying 2D versus color or power data in any pixel. For example, increasing the color priority results in more color pixel information overlaying the 2D image.
	• 0 to 15
	Note: For systems without a touch screen, the selection is on the LED panel.
Dynamic TCE	Dynamic Tissue Contrast Enhancement
	Adjusts levels of Dynamic Tissue Contrast Enhancement for 3D images.
	■ Off
	■ Low
	■ Med
	■ High
Tint	Applies the selected tint to the 2D-mode data and the volume rendering.
	 Available settings: transducer-dependent
	Note: For systems without a touch screen, the selection is on the LED panel.

E - 8 Instructions for Use

Selection	Description
Plane	(Available only when VOI is disabled)
	Cut plane
	Enables or disables the specified cut plane for the volume.
	• Off
	1 , 2
Maps	(Applies only to MPRs)
	Selects a processing curve that assigns echo amplitudes to gray levels.
	• A, B, C, D, E, F, G, H, I, J, K, L
	Note: The settings ${\bf J}$, ${\bf K}$, and ${\bf L}$ are available only for volumes acquired using contrast agent imaging.
Reset All	Restores the default orientation and display format for all quadrants; also restores the default (or user-defined) settings of other parameters for all quadrants. User-defined settings are those that were in effect when the current volume was first displayed.
Reset Orientation	Restores the default orientation for all quadrants.
Sync	Aligns the MPR and volume orientation. When the selected quadrant is an MPR, the system aligns the orientation of the volume to that of the MPR.
	Note: If the VOI is displayed when you select an MPR quadrant and then click Sync , the system redefines the render direction to match the selected MPR.
Center	On each slice, repositions the focal point to the center of the quadrant.
Flip	Reverses the render direction.
Bright	Brightness
	Adjusts the percentage of brightness in 2D-mode data included in the volume. An increase in brightness increases the saturation of voxels that have a higher voxel value and increases the brightness of voxels that have a lower voxel value.
	• 0 to 100
Blend	Blend Color
	When enabled, combines (blends) 2D-mode and power data displayed within the volume quadrant.
	When disabled, superimposes (overlays) power data on the 2D-mode data displayed within the volume quadrant.
	• On
	• Off
Trace	Activates or deactivates the trace editing tool.

Selection	Description
Advanced	
MultiSlice	MultiSlice
	Displays tools for viewing multiple cross-sectional slices at the same time in any plane.
	Note: For systems without a touch screen, the selection is assigned to a button:
Thick Slice	Thick Slice Imaging
Imaging	Displays tools to adjust the thickness of an individual slice to improve contrast resolution.
	Note: For systems without a touch screen, the selection is assigned to a button:
Curved MPR	Curved MPR
	Displays tools for drawing a curved MPR (multiplanar rendering) to straighten curved anatomy.
	Note: For systems without a touch screen, the selection is assigned to a button:

Selections for 3D and 4D Visualization

Selection	Description
Volume Display	Volume Display Type
Type	Selects a display method for the quadrants.
	 MPR Only — Displays only the MPR quadrants.
	 3 Slice — Displays the slices and indicates their positions in the volume quadrant.
	 MPR + VR — Displays the MPRs and the volume.
Display	(Available only when the volume includes acquired power Doppler data)
	Limits the display to the selected set of data: 2D-mode data and/or Doppler power data. The display available depends on the quadrant selected. If an MPR quadrant is selected, 2D or 2D + C affects only the MPRs. If the volume is selected, 2D, 2D + C, or C affects only the volume rendering.
	■ 2D, 2D + C, C
	(Available only when VOI is disabled)
	Wireframe
	Enables or disables the display of the wireframe in the volume quadrant.
A	Automatic Rotation
	Automatically rotates the volume according to the selected range, speed, and axis.
	Note: The system dithers the editing selections while the volume is automatically rotating.
Rotation Range	Rotation Range
	Selects rotation range (in degrees). For the 360 selection, the volume continuously rotates in one direction around the selected axis (for Axial , to the right; for Lateral , downward). For other selections, the volume rotates in both directions around the selected axis (for Axial , left and right motions; for Lateral , downward and upward motions).
	3 0, 60, 90, 120, 180, 240, 300, 360
Rotation Speed	Rotation Speed
·	Selects rotation speed.
	Slow
	 Medium
	■ Fast
Rotation Axis	Rotation Axis
	Selects rotation axis.
	Axial
	 Lateral

Selection	Description
Inversion	Reverse dark and bright areas of the rendered volume.
	• On
	• Off
Render Direction	(Available only when a volume of interest (VOI) is activated)
	Render Direction
	Select the orientation of the volume of interest.
Skeletal	Skeletal Rendering
Rendering	Activates or deactivates optimization of the fetal spine.
Bone Enhance	(Available only when fetal skeletal rendering is activated)
	Bone Enhancement
	Adjusts the percentage of contrast in a skeletal rendering.
	• 0 to 100

E - 12 Instructions for Use

3-Scape and four Sight Editing Controls

Selection	Description
	Polygon
	Defines an irregular area from a drawn outline and then removes all the voxels inside or outside of that area.
	Trace
	Defines an area from a free-form drawn outline and then removes all the voxels inside or outside that area.
	Parallel Cut
	Selects a plane (layer) within the volume and then removes all the voxels outside the selected plane.
	Note: This selection is not available when VOI is enabled.
	Niche
	Removes all the voxels from the nearest corner of the volume to a selected depth inside the volume.
	Note: This selection is not available when VOI is enabled.
	Large Eraser
4	Displays the large eraser cursor for editing.
	Small Eraser
4	Displays the small eraser cursor for editing.
Undo Last Edit	Undo Last Edit
	Removes the most recent edit. You can repeatedly select Undo Last Edit to sequentially remove several previous edits.
Undo All Edits	Undo All Edits
	Removes all edits.
	Note: Edits on a volume of interest (VOI) cannot be removed.

SieScape Controls

Selection	Description
Scan Start	Scan Start
	Begins acquisition of the composite image.
	Note: For systems without a touch screen, the selection is assigned to a button:
)
Pause	Pause
	Pauses image acquisition without exiting the acquisition process.
	Note: For systems without a touch screen, the selection is assigned to a button:
Scan End	Scan End
	Ends image acquisition.
	Note: For systems without a touch screen, the selection is assigned to a button:
Redisplay	Displays the full screen SieScape image or CINE.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Restore	Scales the SieScape image to the original display of the frozen image.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Resize	Adjusts the size of the image.
	• Full (full acquisition size)
	Fit (fits the image area)
	 1, 2, 3, 4, and 5 incrementally scale the image between Fit and Full.
	Note: For systems without a touch screen, the selection is assigned to the scroll wheel.
Best Fit	Scales the image to fit the image area.
	Note: For systems without a touch screen, the selection is assigned to a soft key.

Selection	Description
Flex Ruler	Displays a flexible ruler along the length of acquisition.
Display	Enables or disables the display of color information on the region of interest.
	• Off
	■ On
Background	Enables or disables a background enhancement of solid color.
	Off
	■ On
AllPwr	All Power
	Activates or deactivates the display of power data in the region of interest. When On , power data is visible in the real-time image. When Off , power data is captured and displays in the SieScape image.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Col Cap	Color Capture
	Enables continuous capture of power data without transducer movement.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Flow	Activates or deactivates power data without stopping image acquisition.
	Note: For systems without a touch screen, the selection is assigned to a soft key.
AcqFrac	Acquisition Fraction
	Displays power data in the region of interest during SieScape image acquisition. When On , displays 100 percent of the power data. When Off , displays 30 percent of the power data.
	Note: For systems without a touch screen, the selection is assigned to a soft key.

Speed Indicator

The speed of scanning is depicted by the shading of the speed indicator.

Shading	Scan Speed
	Below optimum scan rate — increase scan speed slightly.
	Optimum scan rate.
	Above optimum scan rate, nearing "tear" speed — decrease scan speed slightly.

Contrast Agent Imaging Selections

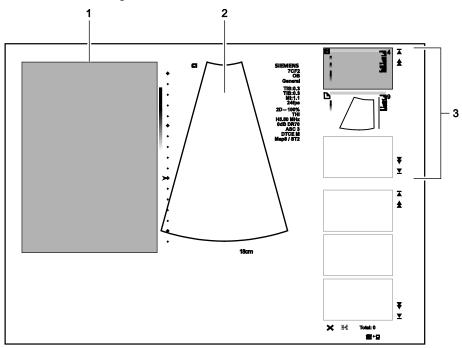
Note: For systems with a touch screen, press **CONTRAST** on the control panel. For systems without a touch screen, press **CADENCE** on the control panel.

Selection	Description
Start Timer /	StopWatch
Stop Timer	Activates and displays or deactivates and removes the on-screen timer. The timer displays the time elapsed since the timer was started. When the image is frozen, the system also displays the time when freeze occurred.
	• Off
	• On
	Note: For systems without a touch screen, the selection is assigned to a soft key.
Reset Timer	Reset Timer
	Sets the timer to zero and automatically starts the timer.
	• 00.00.00
FR Control	(Not available during Doppler or M-mode)
	Frame rate control
	Limits the frame rate to the selected maximum value.
	Available Settings: Transducer-dependent
Start Burst	Rotate:
	Selects the number of frames (fr) for the burst process. The number of frames determines the duration of the burst process.
	1 , 3, 5, 7, 10, 15, 20, 30, 50
	Press:
	Starts the burst process.
	Note: For systems without a touch screen, the selection is on the LED panel.
MBD	Rotate:
	Selects the duration of MBD in seconds (sec).
	<1, 1, 2, 3, 4
	Press:
	Enables Micro-Bubble Destruction (MBD).
	Note: For systems without a touch screen, the selection is on the LED panel.

E - 16 Instructions for Use

Selection	Description
CPS Capture	(Available only for systems without a touch screen)
	Starts or stops the acquisition for the contrast pulse sequence (CPS) or contrast harmonic imaging (CHI) technique.
Duration	Rotate:
	Selects the duration of CPS acquisition in seconds (sec).
	■ 1, 2, 3, 5, 10, 15, 20, indefinite
	Note: For systems without a touch screen, the selection is assigned to the scroll wheel.
	Press:
	Starts or stops the acquisition for the contrast pulse sequence (CPS) or contrast harmonic imaging (CHI) technique.
Power	Adjusts the transmit power during contrast imaging.
	0.10% to 100% dependent on exam type
	Note: For systems without a touch screen, the selection is on the LED panel.
	See also: Transmit Power Control, Safety and Care, Chapter 2, Instructions for Use
Protocol	Selects the clip capture duration in seconds (sec).
	■ 30, 45, 60, 90, user-defined
ADI	Enables the Agent Detection Imaging (ADI) technique during contrast agent imaging.
	■ On
	• Off
CPS/CHI	(Available only when ADI is disabled)
	Enables the contrast pulse sequence (CPS) or contrast harmonic imaging (CHI) technique.
	• CPS
	• CHI
	Note: For systems without a touch screen, the selection is on the LED panel.
2D/CA/Mix	Displays the 2D image (2D), the contrast agent image (CA), or a combination (Mix) of the contrast agent image with the 2D image.
	Note: For systems without a touch screen, the selection is on the LED panel.
Live Dual	Live Dual
	Enables or disables the display of two real-time images originating from the same acquisition in a side-by-side format.
	• On
	■ Off

Multi-Modality Review On-screen Controls



Example of the Multi-Modality Review in wide screen format.

- 1 Reference data
- 2 Ultrasound image
- 3 Multi-Modality Review thumbnail panel

Note: For systems without a touch screen, the controls for multi-modality review are located on the image menu on the left side of the screen and soft key selections are located at the bottom of the screen.

E - 18 Instructions for Use

Control	Description
Multi-Modality	Multi-Modality Review
Review	Activates Multi-Modality Review and displays the reference images screen.
	Note: For systems without a touch screen, the selection is assigned to a button:
Select Images	Select Multi-Modality Review Images
	Displays the Reference Images screen to select additional images to review.
Image	Next Image, Previous Image
	Displays the next or previous reference image in the thumbnail panel.
	Note: For systems without a touch screen, the selection is assigned to a button:
	><
Zoom	Zoom
	Increases or decreases the magnification of the reference image.
	10% , 15%, 25%, 35%, 50%, 75%, 100%, 125%, 150%, 200%
	Note: For systems without a touch screen, the selection is assigned to a button:
	Zoom 100%
Pan	Repositions the reference image and displays a box indicating the visible part of the reference data on the image screen.
	Note: For systems without a touch screen, the selection is assigned to a button:
	Pañ
Frame	(Available only for systems with a touch screen)
	(Available only when the reference image is a clip)
	Cycles through each frame of a reference clip.

Control Description Frame-by-Frame (Available only for systems without a touch screen) Clip Review (Available only when the reference image is a clip) Cycles through each frame of a reference clip. Note: For systems without a touch screen, the selection is assigned to an on-screen slider control: Frame 1 Window and Level (Available only for static gray scale images) Window/Level Adjusts the contrast and brightness of a static, gray scale reference image. Available settings depend on the type of reference data Note: For systems without a touch screen, the selection is assigned to the trackball. L 40 **Apply To All** Apply to All Applies the current window (contrast) and level (brightness) settings to all static gray scale reference images. Note: For systems without a touch screen, the selection is assigned to a button: **Restore Image Restore Image** Cancels the most recent changes to the window and level settings for the displayed reference Note: For systems without a touch screen, the selection is assigned to a button: Delete Delete Removes the selected image from the MMR thumbnail panel.

Note: For systems without a touch screen, the selection is assigned to a button:



Cine

(Available only when the ultrasound image is frozen)

Starts or stops clip playback in the active view.

Note: For systems without a touch screen, the selection is assigned to the **GAIN FREEZE/CINE** control.

Reference Images Screen

Selection	Description
Studies	Lists the following information for all studies stored on the local database for the registered patient:
	 Date
	Study Description
	 Series
(thumbnail preview)	Displays an enlarged preview of the selected image.
Images	Displays thumbnails for all images in the selected study.
Select All	Selects all of the displayed thumbnails.
Select None	Clears the selection of all thumbnails.
ОК	Closes the Reference Images screen and displays the first selected thumbnail in a side-by-side format with the ultrasound image during an active exam. In review, displays the selected images in the MMR thumbnail panel.
Cancel	Closes the Reference Images screen without loading any of the selected images to the exar

Physiologic Function Controls

See also: For information about controls for this feature, refer to Chapter 8 in this manual.

Selections Used in the Stress Echo Feature

(Requires the Cardiac Application Module option)

Select Protocol Dialog Box

The **Select Protocol** dialog box lists all the available protocols. The default list includes the following protocols:

- Dobutamine Stress Echo Auto Review
- Dobutamine Stress Echo
- Ergometric Stress Echo Auto Review
- Ergometric Stress Echo Continuous
- Treadmill Stress Echo Prospective
- Treadmill Stress Echo Retrospective

Acquisition Selections

Continuous stages display views on the menu only if the View control is enabled in the Stress Echo system configuration dialog box. For non-continuous stages, or phases, the menu lists the phases and views of the selected protocol. At the beginning of acquisition, the system expands the first phase to list its constituent views; all other phases are contracted. The system expands the next phase in the sequence once images have been acquired for each view in the current phase.

Selection	Description
Start Acquisition	Starts stress echo acquisition for non-continuous stages.
End Acquisition	Stops stress echo acquisition when the last stage is completed.
Pause	Temporarily stops continuous acquisition. If the Show View control is enabled in the Stress Echo configuration dialog box, the system displays Paused above the scroll wheel on the image screen.
Resume	Restarts continuous acquisition after it has been paused.
<view name=""></view>	Starts acquisition of the selected view in the current continuous stage.
	Note: For systems without a touch screen, the selection is assigned to the scroll wheel.
End Protocol	Saves Stress Echo data and closes the Stress Echo program.
<view stage=""></view>	Starts acquisition of the selected stage in the current view.
	Note: For systems without a touch screen, the selection is assigned to the scroll wheel.

E - 22 Instructions for Use

Stress Echo Screen

Toolbar Buttons

Button	Description
	Acquire Mode
	Exits the Stress Echo screen and redisplays the imaging screen. This button is available only when acquisition of Stress Echo loops is not yet complete.
66	Select Mode
	Enables Select Mode.
	Review Mode
	Enables Review Mode.
DD	Wall Motion Scoring Mode
DD	Enables Wall Motion Scoring Mode.
	LV Mode
	Enables LV Mode.
	Indication
	Displays the Indication dialog box.
	Save Examination
	Saves the Stress Echo data with all loops (all loops acquired for each view or continuous stage).
	Save Examination (only selected loops)
	Saves the Stress Echo data with loops selected as "preferred" only (one representative loop for each view).
	Report Preview
	Displays the report for the current mode when available. Reports are available for Wall Motion Scoring Mode and LV Mode .
	Print
	Prints the report for the current mode when available. Reports are available for Wall Motion Scoring Mode and LV Mode .
	Record/Pause
●II	Records Stress Echo data to external media.
<u>Ata</u>	Maintenance
%	Displays the Maintenance dialog box.
	Exit
	Displays a dialog box to save or discard changes and then closes the Stress Echo screen and exits the Stress Echo feature.
	Toggle Play
	When enabled (highlighted), plays back the loops. When disabled (not highlighted), displays one frame for each loop.
K	Start of Sequence
	Displays the first frame of each loop.
	Step Backward
	Displays the previous frame of each loop.
	Step Forward
	Displays the next frame of each loop.

End of Sequence Displays the last frame of each loop. Decrease Speed Decreases the speed of loop playback. Increase Speed	
Decrease Speed Decreases the speed of loop playback.	
Decreases the speed of loop playback.	
Increase Speed	
Increases the speed of loop playback.	
Sweeping Play	
Plays back loops in both directions, forward, then reversed. The displayed loops in one direction. When the last frame is played, playback direction. You can change the beginning and end point	the system reverses the
A Labels On/Off	
Hides and re-displays labels from loops.	
Playback Synchronization	
Selects the synchronization for loop playback:	
 Loop Align begins and ends playback for all loops at the sar each loop, if necessary. 	me time, adjusting speeds for
 Same Start begins playback for all loops at the same time. S the longest loop completes playback. 	Shorter loops do not restart until
 Free Form begins playback for all loops at the same time and loop completes playback. 	d restarts each loop when that
Loop segment	
Specifies the loop segment for display. Drop-down list. Available	e settings:
 Systole — Displays the systole segment only (all loops) 	
 User-defined — Allows manual repositioning of review marked frames from review (selected loop only) 	ers on the loop bar to exclude
 Fixed range — Displays the – and + buttons for repositioning bar to exclude frames from review (all loops) 	g of review markers on the loop
Decrement left marker position	
(Displayed when you select Fixed range from the Loop Segme the left review marker on the loop bar one frame to the left.	ent drop-down list.) Repositions
Increment left marker position	
(Displayed when you select Fixed range from the Loop Segme the left review marker on the loop bar one frame to the right.	ent drop-down list.) Repositions
Decrement right marker position	
(Displayed when you select Fixed range from the Loop Segme the right review marker on the loop bar one frame to the left.	ent drop-down list.) Repositions
Increment right marker position	
(Displayed when you select Fixed range from the Loop Segme the right review marker on the loop bar one frame to the right.	ent drop-down list.) Repositions
(text box)	
(Displayed when you select Fixed range from the Loop Segme the frame number of the review marker.	ent drop-down list.) Indicates

E - 24 Instructions for Use

Select Mode Selections

Note: For a continuous stage, the **Home**, **To Left**, **To Right**, and **End** buttons display loops saved for the stage (not the view).

Note: For a continuous stage, the **Scroll Up** and **Scroll Down** buttons display the preferred loop for the view. If no loop is designated as preferred for the selected view, then these buttons have no effect

Button	Description
	Scroll Up
	Displays loops in the previous view.
	Scroll Down
<u> </u>	Displays loops in the next view.
I	Home
	Selects the first loop in the currently displayed view.
	To Left
	Selects the previous loop in the currently displayed view.
	To Right
	Selects the next loop in the currently displayed view.
▶ 1	End
· •	Selects the last loop in the currently displayed view.

Review Mode Selections

Note: Phases are stages.

Button	Description
	Shuffle Mode
(4)	Displays all loops that represent the selected stage.
	This button is available only when the Display Selected Loops button is disabled.
	Show previous page
	Displays loops for the previous view in the displayed stage.
	Show next page
	Displays loops for the next view in the displayed stage.
	Shuffle Back
	Displays the previous view when that view is not deselected.
	This button is available only when the Display Selected Loops button is disabled.
	Shuffle Forward
	Displays the next view when that view is not deselected.
	This button is available only when the Display Selected Loops button is disabled.
	Comparison Mode
4	Activates or deactivates the display of a comparison loop from the first stage and reference loops from another stage.
	Display Selected Loops
	Displays the selected phases side by side for each selected view.
	This button is available only when the Shuffle Mode button is disabled.
Accept	When automatic review is enabled, saves the loop for the current stage and activates acquisition for the next view in the stage. Sets the second to last loop as the preffered loop and saves all loops for reference.
Reject	When automatic review is enabled, reactivates acquisition for the current view and replaces the previously acquired views.
Zoom	soft key
	Enables or disables magnification of the region of an image displayed within a zoom box.
Zoom All	(Available only when Zoom soft key is activated)
	soft key
	Enables or disables magnification of the region of all displayed images within a zoom box.
1,⊕	Pointer to mark the first point of the zoom box when the Zoom soft key is activated.
t _⊙	Pointer to mark the second point of the zoom box when the Zoom soft key is activated. If the zoom box is complete, deactivates zoom function.
	Cycles through acquired loops in forward or reverse sequence.

E - 26 Instructions for Use

Wall Motion Scoring Mode Selections

Note: Phases are stages.

Button	Description
X, 1, 2, 3, 4, 5, 6, 7	Designates the score to be used for assignment when you select a portion of the WMS graphic. The numbers displayed correspond to the WMS Type selected in the Maintenance dialog box.
(R)	Selected Loop Normal
R D	Assigns the "Normal" score to the selected view.
	All Visible Loops Normal
KK	Assigns the "Normal" score to all displayed views.
EE	Toggle Display
	Toggles placement of views with placement of WMS graphics. At first selection, the system displays the views (reduced in size) on the lower right of the screen and displays the corresponding WMS graphics (magnified) on the review section of the screen. At second selection, the system displays the views and WMS graphics in their original sizes and locations.
	Enter WMS Comment
	Displays the WMS Comment dialog box and then saves the entered text to the WMS-Report.

WMS Comment Dialog Box — Stress Echo

Selection	Description
(text box)	Text box for entry of comments.
Insert text	Displays the Select text to insert dialog box for selection of predefined terms.
ОК	Saves changes and closes the dialog box.
Cancel	Discards changes and closes the dialog box.

LV Mode Selections

Button	Description	
	Delete Contour	
	Erase the last trace line created.	
	Enter LV Comment	
	Displays the LV Function Comment dialog box and then saves the entered text to the LV-Report .	

LV Function Comment Dialog Box

Selection	Description	
(text box)	Text box for entry of comments.	
Insert text	Displays the Select text to insert dialog box for selection of predefined terms.	
ОК	Saves changes and closes the dialog box.	
Cancel	Discards changes and closes the dialog box.	

Indication Dialog Box

Selection	Description	
Interpreter	Text box for entry of the reviewer's name. Also contains a drop-down list of previously entered names.	
Indication	Text box for entry of information describing the symptom or particular circumstance that indicates the advisability or necessity of a specific medical procedure.	
Insert text	Displays the Select text to insert dialog box for selection of predefined terms.	
ок	Saves changes and closes the dialog box.	
Cancel	Discards changes and closes the dialog box.	

Select Text to Insert Dialog Box

Selection	Description		
(list of predefined terms)	Factory default terms and user-defined terms.		
Edit	Displays the Edit text dialog box for revising the selected term.		
New	Displays the Create new text dialog box for entering a new term.		
Delete	Removes the selected term from the list.		
Defaults	Restores the factory default list of terms.		
Insert text at position	Specifies the location within the Indication text box for the selected term. Available settings are:		
	 Beginning 		
	• End		
	- Current		
Insert in separate line	When enabled (checked), places the selected term on a separate line within the Indication text box.		
ОК	Saves changes and closes the dialog box.		
Cancel	Discards changes and closes the dialog box.		

E - 28 Instructions for Use

Maintenance Dialog Box

Note: Phases are stages.

Maintenance Dialog Box			
Selection	Description		
Acquire Mode			
Manual ROI	Enables display of ROI (region of interest) after the Stress Echo protocol is selected. The ROI can be resized and/or repositioned as required. The ROI determines the portion of the image area to be saved.		
Fixed ROI	Implicitly sets the ROI to a system defined size and position. The size and position cannot be changed during the exam.		
Fullscreen	For each image saved, the system captures the entire image area and the gray bar. No ROI is displayed after the Stress Echo protocol is selected.		
Image Compression	n		
High	Sets image compression during acquisition to High (12:1).		
Medium	Sets image compression during acquisition to Medium (8:1).		
Overlay			
Name of level	Displays the phase label on the loop in the Stress Echo screen.		
Name of view	Displays the view label on the loop in the Stress Echo screen.		
Heartrate	Displays the heart rate at which the loop was acquired on the loop in the Stress Echo screen.		
Time stamp acquisition	Displays the time of acquisition on the loop in the Stress Echo screen.		
Timespan since start of level	Displays the time elapsed from the beginning of the phase to this loop's acquisition on the loop in the Stress Echo screen. This value can be used in an exercise-based stress echo protocol to indicate the time elapsed since the patient began exercising.		
Compression Ratio	Displays the compression ratio of the corresponding loops on the loop in the Stress Echo screen.		
Loop ID	Displays a sequence identifier number on the upper left of each loop to indicate the sequence of loop acquisition within the view. For example, the first acquired loop for each view is labeled "[1]."		
	Note: Sequence identifier numbers are displayed when Select Mode is enabled only.		
Frame slider	Displays the loop bar to indicate the location of the displayed frame and the beginning and ending review markers within the loop.		
	Note: The loop bar is not displayed when LV Mode is enabled.		

Maintenance		
Dialog Box Selection	Description	
WMS Type	2000.	
ASE 16 – 4 Scores or	Configures the system to display the indicated type of WMS graphics (16-segment or 17-segment) and the following wall motion scores for assignment:	
ASE 17 – 4 Scores	X — Cannot evaluate 1 — Normal	
	2 — Hypokinetic 3 — Akinetic	
	4 — Dyskinetic	
ASE 16 – 5 Scores or	Configures the system to display the indicated type of WMS graphics (16-segment or 17-segment) and the following wall motion scores for assignment:	
ASE 17 - 5	X — Cannot evaluate	
Scores	1 — Normal	
	2 — Hypokinetic	
	3 — Akinetic	
	4 — Dyskinetic	
	5 — Aneurysmal	
ASE 16 – 7 Scores or	Configures the system to display the indicated type of WMS graphics (16-segment or 17-segment) and the following wall motion scores for assignment:	
ASE 17 - 7	X — Cannot evaluate	
Scores	1 — Normal	
	2 — Hypokinetic	
	3 — Akinetic	
	4 — Dyskinetic	
	5 — Aneurysmal	
	6 — Akinetic with scar	
	7 — Dyskinetic with scar	

E - 30 Instructions for Use

Maintenance		
Dialog Box Selection	Description	
Auto-adjust segments	Enables the assignment of a different score to the same segment (view) in each stage.	
Print colored	Prints the report in color when checked.	
LV Trace Line		
Solid Line	Configures the system to display a solid line when you create an LV trace.	
Dotted Line	Configures the system to display a dotted line when you create an LV trace.	
Printer	Select a printer from the drop-down box.	
QT-Time Table		
Heartrate	Allows you to enter a heart rate. When a heart rate and systolic duration are both entered, you can add this pair of values to the QT-Time Table .	
Syst. Duration	Allows you to enter a systolic duration. When a heart rate and systolic duration are both entered, you can add this pair of values to the QT-Time Table .	
Reset table	Restores the default values in the QT-Time Table.	
Update	Adds the entered heart rate and systolic duration to the QT-Time Table.	
Delete	Removes the selected heart rate and systolic duration pair from the QT-Time Table.	
Beep during acquisition	When checked, indicates with an audible tone that acquisition is complete during a continuous stage.	
Show View control	When checked, enables selection with the scroll wheel of another view in a continous stage.	
Factory Settings	Applies factory defaults for systolic durations and heart rates.	
Save	Saves changes.	
Protocol Editor	Displays the Protocol Editor dialog box.	
Quit	Exits the Maintenance dialog box.	

Protocol Editor Dialog Box

Note: Phases are stages.

Protocol Editor			
Dialog Box Selection	Description		
Protocol Name	When the Load button is selected, displays the name of the loaded protocol.		
	When the New button is selected, allows you to enter a new protocol name.		
Stage			
Q	When selected for a non-continuous stage, activates review after acquiring clips for the current view.		
	When selected, displays a timer for the corresponding stage during acquisition and stress echo review.		
Description	When the Load button is selected, displays the name of the first phase (or selected phase).		
	When the New button is selected, allows you to enter a new phase name.		
Clip Capture	Designates the stage as Retrospective, Prospective, or Continuous.		
Loops	When a phase is selected in the Stage list, allows you to select the number of loops to be acquired for each view in the selected phase.		
	Note: This selection is not available for continuous stages.		
View			
First	Specifies the first view to acquire when the selected stage is activated. If no views are selected, the first view acquired is the view at the top of the list.		
	Note: Subsequent views are acquired in the sequence displayed in the list, beginning with the view immediately below the selected first view and then continuing from the top of the list.		
Standard Views	Lists the standard views available for selection to be included in the protocol. The selected views are displayed for every phase in the protocol.		
	You can also use the keyboard to enter a user-defined view name.		
	Note: Wall Motion Scoring Mode selections are not available for views with user-defined names.		

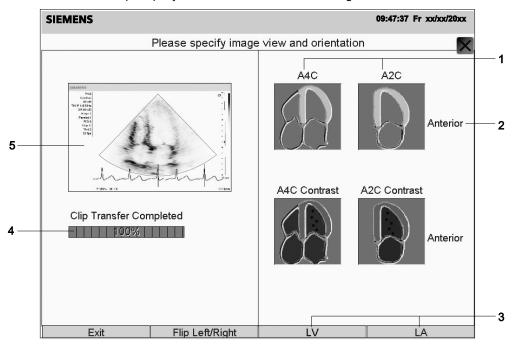
E - 32 Instructions for Use

Protocol Editor			
Dialog Box Selection	Description		
Start Stage	Specifies when stage timers are activated for all stages configured to display the timer.		
Timers	at beginning of Stage		
	Starts the timer when the stage is activated.		
	upon Clip Capture		
	Starts the timer when acquisition of the first image for the stage begins.		
Trigger	Specifies the heart cycle portion(s) captured by the protocol.		
	R-R Systolic captures only the systolic portion of the heart cycle.		
	R-R Full captures the full heart cycle (systolic and diastolic portions).		
	Note: The captured heart cycle segments (portions) can be edited. You can select loop segments for display or you can reposition the review markers.		
WMS model	Lists the WMS models available for selection to be used by default in the protocol.		
New	Clears the Protocol Name selection and allows you to create a new protocol.		
Load	Displays the Select Protocol to load dialog box and then displays information about the selected protocol within the Protocol Editor dialog box.		
Save	Saves changes.		
Delete	Removes the protocol from memory.		
Quit	Exits the Protocol Editor dialog box.		

syngo Auto Left Heart Controls

Example of View Selection Screen

The program displays the view selection screen when you activate *syngo* Auto Left Heart. The view selection screen prompts you to select a chamber and image view.



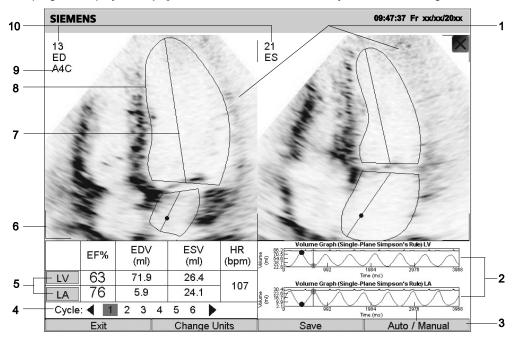
- 1 A4C and A2C view selections
- 2 Anterior or inferior left ventricular or left atrial wall indicator for A2C view only
- 3 LV and LA chamber selections
- 4 Clip Transfer progress indicator
- 5 Image from a clip

Note: The contrast view buttons do not display when LA is selected.

E - 34 Instructions for Use

Example of syngo Auto Left Heart Screen

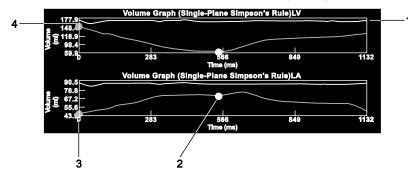
The program displays the syngo Auto Left Heart screen when you select the image view.



- 1 Image display area
- 2 Volume graphs
- 3 Location of buttons
- 4 Heart Cycle indicator
- 5 Calculation data
- 6 Frame corner indicating the active image
- 7 Long axis
- 8 Outline of the structure
- 9 Current view and image orientation
- 10 Frame number

Example of Volume Graph

For non-contrast studies, the program displays a volume graph. The volume graph depicts the values for volume (ml or ml/m^2) over time (ms), using a Single-Plane Simpson's Rule.



- 1 ECG trace
- 2 Inactive ED or ES frame (indicated by gray dot)
- 3 Current frame (indicated by vertical line)
- Active ED or ES frame (indicated by green dot)

When both the left ventricle and the left atrium are assessed, *syngo* Auto Left Heart displays two volume graphs, one for each chamber.

Selection	Description		
Flip Left/Right	Reorients the image view selection from left-to-right to right-to-left to match the orie of the clip.		
LV	Selects the left ventricle as the active chamber.		
LA	Selects the left atrium as the active chamber.		
A4C	Selects the apical four-chamber image view (non-contrast) for the displayed clip.		
A2C	Selects the apical two-chamber image view (non-contrast) for the displayed clip.		
A4C Contrast	Selects the contrast apical four-chamber image view for the displayed clip.		
A2C Contrast	Selects the contrast apical two-chamber image view for the displayed clip.		
F8 function key or	(Available only for systems without a touch screen)		
GAIN FREEZE/CINE	Starts or stops playback of the clip in the active view (ED or ES).		
Left or right arrow key	Displays prior or next frame of the clip.		
	Note: For systems without a touch screen, the selection is assigned to the GAIN FREEZE/CINE control.		
Stop	Stops playback of the clip.		
	Note: For systems without a touch screen, the selection is assigned to the GAIN FREEZE/CINE control.		
1 2 3 4 : :	Indicates the selected heart cycle from multiple-cycle clips.		

Selection	Description	
Up or down arrow key	Changes the gamma curve (brightness) of the active image.	
ZOOM	Toggles between zoom factors for the 2D images.	
Show Trace or F9	(Available only for systems without a touch screen)	
function key	Hides or displays the outlines and their long axes, including any markers on the images. Calculation data and measurement values continue to display at the bottom of the screen.	
Auto/Manual	Alternates the automatic trace method and the manual trace method for generating an outline.	
	Note: If you create a trace and toggle between Auto and Manual before saving the trace, the program deletes the trace so you can start over.	
Guided/Manual	(Available for contrast studies only)	
	Alternates the guided trace method and the manual trace method for generating an outline.	
	Note: If you create a trace and toggle between Guided and Manual before saving the trace, the program deletes the trace so you can start over.	
Apply	(Available for non-contrast studies only)	
	When a trace is displayed on both the ED and ES frames and after changes to the border are made, applies the <i>syngo</i> Auto Left Heart algorithm to all frames in the clip.	
SET ED	Selects the currently displayed frame as the representative frame for the End Diastole image.	
SET ES	Selects the currently displayed frame as the representative frame for the End Systole image.	
Backup	Erases the most recent segment or marker of a user-created outline. Available during tracing of a new outline and before the outline is complete.	
Mark	Activates the mark function for creating an outline from positioned points along the border.	
Draw	Activates the trace drawing function for creating an outline.	
End Trace	Completes the manual marking of LV or LA border points and calculates the results.	
Change Units	Changes the units displayed in calculations and the volume graph. Units available are ml and ml/m².	
Close	Exits the Volume Range Selector or BSA Calculator dialog box without saving changes.	
Save&Close	Exits the Volume Range Selector or BSA Calculator dialog box and saves changes.	
Save	Saves the calculation data and measurements to a findings record.	
Exit	Exits syngo Auto Left Heart.	

Calculation Data and Measurements

Measurement	Unit	Description
EF	%	Ejection Fraction calculated for the selected view.
HR	bpm	Heart rate detected by the program for the selected view.
EDV	ml or ml/m ²	End-diastolic volume calculated for the selected view.
ESV	ml or ml/m ²	End-systolic volume calculated for the selected view.

syngo VVI (Velocity Vector Imaging) Controls

Control	Description
Exit	Exits the module.
4	Strain/Velocity Measurement Window
	Displays velocity, strain, and strain rate information in the Strain/Velocity Measurement window.
②	Global Measurements Window
	Displays ejection fraction (EF), Dmin, Dmax, volume, and segmental volume information in the Global Measurement window.
	Note: This selection may not be available for traces processed using the Generic Curve processing algorithm.
	Dyssynchrony analysis
	Displays peak and timing information (such as time-to-peak values) related to strain, strain rate, velocity, or displacement in the Dyssynchrony window.
	Note: This selection may not be available for traces processed using the Generic Curve processing algorithm.
Long Axis	Selects the Long Axis algorithm for processing the trace.
Short Axis	Selects the Short Axis algorithm for processing the trace.
Generic Curve	Selects the Generic Curve algorithm for processing the trace.
Average Heart Cycle	When selected (enabled), calculates and displays the motion parameters for the average heart cycle by averaging the values from the multiple R-R intervals.
	Note: This selection is available for multiple-cycle clips, after processing only.
Endo+Epi	When selected (enabled), displays a second trace outside the endocardium trace. Required to calculate radial strain and radial strain rate.
(>)	Restores the original gamma image setting.
Gamma	Adjusts the gamma image setting (changes both brightness and contrast).
P	Process Images
	Calculates velocity vector data for the selected trace.
	New Trace
	Activates the tracing (outlining) function and removes the displayed trace (if any) from the window.
△	Increases or decreases the distance between the endo/epi traces. Only visible when creating or editing endo/epi traces.
*	Bkg MMode display
	Adds or removes the M-mode display from graphs.
	Toggle Pan/Zoom
	Changes the size of the displayed clip.

E - 38 Instructions for Use

Control	Description
(Alexander)	Edit trace
\$ \\ \\$	Activates or deactivates the editing function. When the editing function is active, points within the trace are available for repositioning.
	Shorter Arrows
	Decreases the length of the velocity vectors in two-pixel increments.
	No Arrows
	Cycles through display settings for velocity vectors:
	 Display velocity vectors
	 Hide velocity vectors
	 Display trajectory of segments of tissue over time
	 Hide velocity vectors and trace (contour)
<u> </u>	Longer Arrows
	Increases the length of the velocity vectors in two-pixel increments.
	Restore the Graphs Aspect
	Displays all curves on the curve plot.
<u> </u>	Toggle Original Border Points to Equispaced Points x4
	Toggles display of the user-defined trace points with display of the program-generated trace points.
	M-mode, R-waves, Crop
	Displays the M-mode, R-Waves, Crop window where you can:
	 View clip in M-mode
	 Add, move, or delete R-wave indicators
	 Crop long clips
	Toggle Filtered/Unfiltered Plots
	Adjusts the smoothing in curves on all curve plots (all windows).
<u></u>	Export
	Exports an image or clip to a storage device, network destination, or to the computer's hard disk.
Slow	Slows playback of a clip.
	Play/Stop
	Starts and stops playback of a clip. This is a toggle control.
N	Next Frame
	Displays the next frame of a clip.
	Previous Frame
K	Displays the previous frame of a clip.
History	Displays a button for each trace.
Delete	Removes the displayed trace from the window.

Strain/Velocity Measurement Window

Control	Description
Row by Row	Displays curves for all points in the parametric M-mode graphs.
Delete Stored Points	Removes all selected points from the parametric M-mode graphs and associated curves.
Pan/Zoom	Magnifies the selected curve plots to a full-screen display.
Velocity	Selects the velocity curve plot for magnification.
Strain	Selects the strain curve plot for magnification.
Strain Rate	Selects the strain rate curve plot for magnification.
3D	Displays the 3D window including the 3D rendering of information in the related parametric M-mode graph.
	Toggle Filtered/Unfiltered Plots
	Adjusts the smoothing in curves on all curve plots (all windows).
	Export
	Saves an image or clip to a storage device, network destination, or to the computer's hard disk.
Close	Exits the displayed window and redisplays the VVI window.

3D Window and Magnification Window

The following selections are displayed on the 3D window and the magnification window accessed from the Strain/Velocity Measurement window.

Control	Description
Export	Exports an image or clip to an external USB-compatible storage device.
Close	Exits the displayed window and redisplays the VVI window.

E - 40 Instructions for Use

Global Measurements Window

Control	Description
All the Curves	When selected (enabled), displays curves for all traces. When unselected, displays curves for the current trace only.
	Toggle Filtered/Unfiltered Plots
	Adjusts the smoothing in curves on all curve plots (all windows).
	Export
	Exports an image or clip to an external USB-compatible storage device.
	Play/Stop
	Starts and stops playback of a clip. This is a toggle control.
M	Next Frame
	Displays the next frame of a clip.
K	Previous Frame
	Displays the previous frame of a clip.
LAX Calc Area	Displays only if Long Axis is select on the VVI window. When selected (enabled), calculates the area enclosed by the trace.
Close	Exits the displayed window and redisplays the VVI window.

M-mode, R-waves, Crop Window

Control	Description
Gamma	Adjusts the gamma image setting (changes both brightness and contrast).
⟨⟩	Restores the original gamma image setting.
Reset	Removes the currently displayed free-form M-mode trace.
Reverse Colors	Toggles black-on-white display with white-on-black display.
Bpm	Displays beats per minute. Changes as you add or delete an R-wave.
Period Selector	Displays R-waves. Displays selected M-mode background for viewing on plots, behind curves. Time bars on either end are used to crop the clip.
Close	Exits the displayed window and redisplays the VVI window.

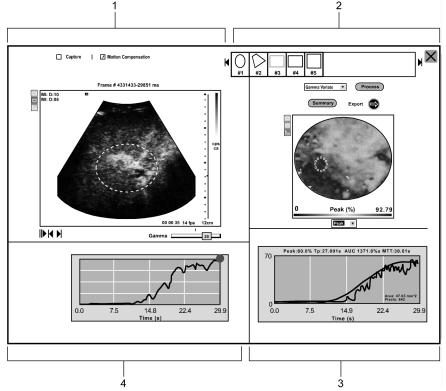
Dyssynchrony Analysis Window

Control	Description
Time To Peak	Identifies the highest point on each curve for all parameters except strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential.
	Identifies the lowest point on each curve for these parameters: strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential.
Time to 75%	Identifies the point that is 75% of the highest point on each curve for all parameters except strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential
	Identifies the point that is 75% of the lowest point on each curve for these parameters: strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential.
Time to 50%	Identifies the point that is 50% of the highest point on each curve for all parameters except strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential
	Identifies the point that is 50% of the lowest point on each curve for these parameters: strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential.
Reverse Peak	For all parameters except strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential, identifies the lowest point, the point that is 75% of the lowest point, or the point that is 50% of the lowest point as determined by the "Time To" selection.
	For parameters strain longitudinal, strain circumferential, strain rate longitudinal, and strain rate circumferential, identifies the highest point, the point that is 75% of the highest point, or the point that is 50% of the highest point as determined by the "Time To" selection.
R-R	Moves from beat to beat with each click in a continuous cycle. Disabled if only one beat is captured.
Velocity	Computes and displays values for the selected parameter:
	 Longitudinal (longitudinal velocity). Long axis and generic curve views only.
	 Rotation (rotation rate). Counterclockwise rotation is positive. Short axis views only.
	Radial (radial velocity).
Strain	Computes and displays values for the selected parameter:
	 Longitudinal (strain longitudinal). Long axis and generic curve views only.
	 Circumferential (strain circumferential). Short axis views only.
	 Radial (radial strain). Requires endo/epi traces.
Strain Rate	Computes and displays values for the selected parameter:
	 Longitudinal (strain rate longitudinal). Long axis and generic curve views only.
	 Circumferential (strain rate circumferential). Short axis views only.
	 Radial (radial strain rate). Requires endo/epi traces.

E - 42 Instructions for Use

Control	Description
Displacement	Computes and displays values for the selected parameter:
	 Longitudinal (longitudinal displacement). Long axis and generic curve views only.
	 Rotation (Rotation). Short axis views only.
	Radial (radial displacement).
All Curves	When selected (enabled), displays all curves. When cleared (disabled), displays selected curves only.
	Note: Data on the window includes values for the displayed curves only.
	Toggle Filtered/Unfiltered Plots
	Adjusts the smoothing in curves on all curve plots (all windows).
Zoom	Magnifies the graph. Click Close to return to the Dyssynchrony Analysis window.
	Export
	Exports an image or clip to a storage device, network destination, or to the computer's hard disk.
Close	Exits the displayed window and redisplays the VVI window.

Contrast Dynamics Software Controls



- 1 Clip Review quadrant
- 2 Parametric Display quadrant
- 3 Intensity Curve quadrant
- 4 Time Window quadrant

Example of Contrast Dynamics screen.

Control	Description
Gamma	Adjusts the brightness of the image.
	Activates the selected drawing tool.
	 Rectangle
	 Ellipse
	 Trace
Motion Compensation	Compensates for patient movement to stabilize the image in the region of interest.
	On, Off
Process	Activates parametric analysis.

E - 44 Instructions for Use

Control	Description
<drop-down list=""></drop-down>	Parametric Fitting
	Displays a list of parametric analyses available.
	Gamma Variate
	 Exponential
<drop-down list=""></drop-down>	Displays a list of parameters to use during analysis. The parameters available depend on the type of analysis selected.
	Gamma Variate:
	• Peak (Peak %)
	■ Tp (Time-to-peak)
	AUC (Area under curve)
	MTT (Mean transit time)
	Exponential:
	■ Peak
	■ Beta
	■ Slope
Capture	Enables capture and integration of contrast agent data over time to improve vascular detail
	On, Off
	Note: If the contour region is not defined, the program captures the entire clip image. If the contour region is defined, the program captures only the defined region of interest.
	Play/Stop
	Starts or ends playback of the clip.
N	Next Frame
	Displays the next frame in the clip.
Tu	Previous Frame
	Displays the previous frame in the clip.
Export	Export Data
	Saves the results data to the selected USB location.

Contrast Dynamics Context Menus

Selection	Description
Save Image to USB	Saves the image in the selected quadrant in .bmp or .jpg format.
Save AVI File	Saves the clip displayed in the Clip Review quadrant in .avi format.
Show/Hide ROIs	Displays or hides the ROIs in the selected quadrant (Clip Review or Parametric Display).
New ROI	Enables the tool to draw a new region of interest on the parametric image.
Copy ROI	Copies the currently selected ROI on the parametric image to memory.
Paste ROI	Displays the ROI previously copied to memory on the parametric image.
Delete ROI	Deletes the selected region of interest.
Set Bounds	Displays a dialog box to select the range of values for each parameter displayed by the color map. A color scale displays below the parametric image with the selected range.
Toggle Real/ Calculated Curves	Displays real curves (unsmoothed data), calculated curves (smoothed data), or both in the Intensity Curve quadrant.

Select Destination and File Format Dialog Box

Selection	Description
Select USB drive	Specifies the location of the USB storage device.
Image Format	Specifies the file format to save the selected image:
	 Jpeg
	■ Bmp

Select Destination Dialog Box

Selection	Description
USB drive	Specifies the location of the USB storage device.

E - 46 Instructions for Use

syngo Arterial Health Package (AHP) Controls

Controls consist of on-screen selections and keys on the alphanumeric keyboard.

AHP Screen — Navigation Panel

The navigation panel displays on the upper right of the AHP screen.

Icon	Description
	CIMT Border
ununu	Displays the Carotid Intima-Media Thickness (CIMT) screen with the Image Quality Panel and the CIMT Editing Tools Panel.
	Reports
2 F	Displays the CIMT report and report selections.
	Setup
[[list	Displays the AHP Setup screen.
$\overline{\mathbf{V}}$	Exit
	Exits the AHP program.

Image Quality Panel

The image quality panel displays on the right of the screen.

Icon	Description
K	Prior
	Displays the previous frame of the clip.
	Run
	Starts playback of the displayed clip.
П	Stop
	Stops playback of the displayed clip.
M	Next
	Displays the next frame of the clip.
lacktriangle	Zoom +
	Magnifies the current clip or frame.
Q	Zoom –
	Minimizes the current clip or frame.
4	Pan
	Positions the current clip or frame in the window.
	Contrast (slider)
	Adjusts the difference between the light and dark shades.
*	Brightness (slider)
7MT	Lightens or darkens shades.

CIMT Editing Tools Panel

Tools for editing the borders of the Carotid Intima-Media Thickness (CIMT) display on the right of the screen and are available after establishing the CIMT region of interest (ROI).

Far Wall Tools

Button	Description
	Edit lumen-intima
	Activates the edit function for the far lumen-intima boundary.
50	Edit media-adventitia
	Activates the edit function for the far media-adventitia boundary.
20	Manual trace lumen-intima
7	Activates the manual trace function for the far lumen-intima boundary.
	Manual trace media-adventitia
7	Activates the manual trace function for the far media-adventitia boundary.

Trace Editing Tools

Button	Description
	Clear borders
	Deletes the current border and the CIMT ROI (region of interest).
	Toggle exclude frame
	Exclude or include a specific frame from analysis and quantification.
M	Undo Edit
K 7	Discards the most recent edit.
(A)	Zoom to ROI
	Magnifies the selected ROI (region of interest).
	Save CIMT
	Saves data into the report.

E - 48 Instructions for Use

Appendix F Acoustic Output Reference

Display Accuracy and Measurement Uncertainty	3
Default Displayed MI and TI Values by Transducer	
Track 3, FDA 510(k) and IEC 60601-2-37 Acoustic Output Reporting	6
Summary Table for Acoustic Output	6
Definitions	8
Legend	9

F - 2 Instructions for Use

Display Accuracy and Measurement Uncertainty

When a transducer is capable of exceeding a mechanical index (MI) or thermal index (TI) of 1.0, the ultrasound imaging system displays indices starting from 0.4 in increments of 0.1 for all displayed values.

A number of factors contribute to the estimation error for the displayed index. Variations among the following factors contribute to the index display error: transducers and systems, assumptions and approximations for real-time index calculations, and measurement uncertainty. The MI and TI display values should be interpreted as relative information and only used to assist the operators to implement the ALARA (As Low As Reasonably Achievable) principle for patient examinations; the acoustic output should be the lowest level required to satisfactorily perform the examination.

Measurement uncertainty for acoustic pressure, acoustic intensity, power, and center frequency is within 12%, 25%, 10% and 5% respectively assessed by considering both the systematic and random uncertainties. The total estimated display accuracy is $\pm 25\%$ for MI and $\pm 50\%$ for TI. Definitions for these parameters can be found in the IEC 62359, "Ultrasonics – Field Characterization – Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields."

Default Displayed MI and TI Values by Transducer

(Per transducer/mode that exceeds default MI or TI value of 0.4)

Refer to the Chapter 1 and Appendix A in this manual to identify transducers compatible with your ultrasound system.

General Imaging

		Mode											
	В			М		PWD	S	CW	(Color		CWD	
Transducer	MI	TI	MI	TI	MI	TI	MI	TI	MI	TI	MI	TI	
4C1	1.2	-	1.4	2.2(B ²)	8.0	3.4(B ²)	-	-	1.1	0.5(S ¹)	-	-	
6C1 HD	1.4	0.5(S ¹)	1.4	1.6(B ²)	1.1	4.0(B ²)	-	-	1.4	0.8(S ¹)	-	-	
6C2	1.0	0.5(S ¹)	1.4	1.2(B ²)	0.7	3.1(B ²)	-	-	1.0	0.8(S ¹)	-	-	
8C3 HD	0.6	-	0.7	-	0.7	1.4(B ²) 0.4(S ¹)	-	-	0.8	-	-	-	
9L4	1.0	-	1.0	-	1.4	1.3(B ²)	-	-	0.9	1.9(S ¹)	-	-	
12L4	0.8	-	0.8	-	1.3	0.6(B2) 0.6(S1)	-	-	0.8	0.6(B2) 0.6(S1)	-	-	
14L5	1.0	-	0.9	-	1.1	1.8(B ²)	-	-	0.9	1.2(S ¹)	-	-	
14L5 SP	0.8	-	0.9	-	0.6	1.0(B ²)	-	-	1.3	0.8(S ¹)	-	-	
18L6 HD	1.0	-	0.7	-	1.0	1.2(B ²)	-	-	1.0	0.6(S ¹)	-	-	
4P1	1.2	1.0(S ¹)	1.4	1.9(B ²)	1.0	3.8(B ²)	-	-	1.2	1.2(S ¹)	-	-	
4V1	0.8	0.4(S ¹)	1.1	1.4(B ²)	0.9	4.3(B ²)	-	-	8.0	0.8(S ¹)	-	-	
4V1c	1.4	0.9(S ¹)	1.4	1.4(B ²)	1.0	3.7(B ²)	-	-	1.4	1.1(S ¹)	-	-	
8V3	0.6	0.5(S ¹)	1.2	0.4(B ²)	1.4	2.5(B ²)	-	-	0.7	0.9(S ¹)	-	-	
10V4	0.8	1.0(S ¹)	1.5	0.4(B ²)	0.6	1.9(B ²)	-	-	8.0	1.2(S ¹)	-	-	
EV-8C4	0.9	0.5(S ¹)	1.3	$0.7(B^2)$	1.2	2.0(B ²)	-	-	1.0	0.6(S ¹)	-	-	
EC9-4	0.4	-	0.4	-	0.6	1.0(B ²)	-	-	8.0	0.4(S ¹)	-	-	
MC9-4	8.0	-	0.8	-	1.0	1.8(B ²) 0.9(S ¹)	-	-	0.7	-	-	-	
7CF1	1.0	-	1.2	0.9(B ²) 0.5(S ¹)	0.5	1.7(B ²) 0.8(S ¹)	-	-	0.9	0.5(B ²) 0.5(S ¹)	-	-	
7CF2	1.1	-	1.1	0.8(B ²)	0.5	1.8(B ²)	-	-	1.2	0.5(S ¹)	-	-	
9EVF4	0.5	-	0.5	-	0.9	1.4(B ²)	-	-	0.8	-	-	-	
CW2	-	-	-	-	-	-	-	-	-	-	0.1	4.9(B ²)	
CW5	-	-	-	-	-	-	-	-	-	-	0.1	3.0(B ²)	

S¹: Soft Tissue Thermal Index, B²: Bone Thermal Index, C³: Cranial Thermal Index

F - 4 Instructions for Use

Cardiac Imaging

		Mode										
		в м			PWD		SCW		Color	CMD		
Transducer	МІ	TI	MI	TI	MI	TI	MI	TI	MI	TI	MI	TI
4C1	1.2	-	1.4	2.2(B ²)	0.8	3.4(B ²)	-	-	1.1	0.5(S ¹)	-	-
6C1 HD	1.4	0.5(S ¹)	1.4	1.6(B ²)	1.1	4.0(B ²)	-	-	1.4	0.8(S ¹)	-	-
6C2	1.0	0.5(S ¹)	1.4	1.2(B ²)	0.7	3.1(B ²)	-	-	1.0	0.8(S ¹)	-	-
9L4	1.0	-	1.0	-	1.4	1.3(B ²)	-	-	0.9	1.9(S ¹)	-	-
14L5	1.0	-	0.9	-	1.1	1.8(B ²)	-	-	0.9	1.2(S ¹)	-	-
14L5 SP	8.0	-	0.9	-	0.6	1.0(B ²)	-	-	1.3	0.8(S ¹)	-	-
18L6 HD	1.0	-	0.7	-	1.0	1.2(B ²)	-	-	1.0	0.6(S ¹)	-	-
4P1	1.2	1.2(S ¹)	1.4	1.0(B ²)	0.7	3.3(B ²)	0.1	3.4(B ²)	1.1	1.4(S ¹)	-	-
4V1	0.8	0.4(S ¹)	1.1	1.4(B ²)	0.9	4.3(B ²)	-	-	0.8	0.8(S ¹)	-	-
4V1c	1.1	1.1(S ¹)	1.4	1.3(B ²)	0.7	3.6(B ²)	0.1	3.5(B ²)	1.3	1.1(S ¹)	-	-
8V3	1.0	0.9(S ¹)	1.2	-	0.7	2.4(B ²)	0.1	2.0(B ²)	1.1	0.9(S ¹)	-	-
10V4	0.5	1.0(S ¹)	0.7	-	0.3	2.1(B ²)	0.1	2.2(B ²)	0.7	1.2(S ¹)	-	-
V5Ms	0.3	-	0.7	-	0.2	$0.7(B^2)$	0.1	1.3(B ²)	0.5	-	-	-
V7M	0.3	-	0.5	-	0.3	$0.9(B^2)$	-	0.6(B ²)	0.6	-	-	-
EV-8C4	0.9	0.5(S ¹)	1.3	$0.7(B^2)$	1.2	2.0(B ²)	-	-	1.0	0.6(S ¹)	-	-
EC9-4	0.4	-	0.4	-	0.6	1.0(B ²)	-	-	8.0	0.4(S ¹)	-	-
7CF2	1.1	-	1.1	0.8(B ²)	0.5	1.8(B ²)	-	-	1.2	0.5(S ¹)	-	-
9EVF4	0.5	-	0.5	-	0.9	1.4(B ²)	-	-	8.0	-	-	-
CW2	-	-	-	-	-	-	-	-	-	-	0.1	4.9(B ²)
CW5	-	-	-	-	-	-	-	-	-	-	0.1	3.0(B ²)
AcuNav 8F	1.1	-	1.1	-	0.3	1.5(B ²)	0.1	0.7(B ²)	0.7	-	-	-
AcuNav 10F	1.2	0.7(S ¹)	1.2	-	0.3	3.0(B ²)	0.1	-	1.0	1.1(S ¹)	-	-

S¹: Soft Tissue Thermal Index, B²: Bone Thermal Index, C³: Cranial Thermal Index

Track 3, FDA 510(k) and IEC 60601-2-37 Acoustic Output Reporting

Data presented in Track 3 and IEC 60601-2-37 format represents the average MI/TI values of each transducer model measured under worst-case acoustic output conditions. The on-screen MI/TI values are based on measurements on one transducer rounded up to the nearest display increment. It is possible that the values displayed on screen may exceed the MI/TI values presented in the Track 3 and IEC 60601-2-37 format.

Summary Table for Acoustic Output

An "X" indicates that either the MI index or TI indices is greater than 1.0 for each transducer/mode. A Track 3 and IEC 60601-2-37 format acoustic output table is supplied for each transducer/mode combination marked with an "X."

	Operating Mode									
Transducer Model	B-mode (2D)	2D-mode (THI)	M-mode	Pulsed Doppler	Color Flow or Power	SCW Doppler	CW Doppler			
(Availab	le on the ACU	SON S1000 sys	tem, ACUSON	N S2000 syster	m, and the ACU	SON S3000 sy	/stem)			
4C1	Х	Х	Х	Х	Х					
6C2	х	Х	Х	Х	Х					
9L4	Х	Х	X	Х	Х					
12L4	X	X	X	Х	X					
14L5	X	X	X	Х	X					
14L5 SP	Х	Х	Х	Х	Х					
18L6 HD	Х	Х	X	Х	Х					
4P1	X	X	X	Х	X	X				
4V1	х	Х	Х	Х	Х					
4V1c	Х	Х	Х	Х	Х	Х				
8V3	х	Х	Х	Х	Х	Х				
10V4	х	Х	Х	Х	Х	Х				
V5Ms	х		Х	Х	Х	Х				
V7M	х		X	Х	Х	X				
EV-8C4	X	Х	X	Х	Х					
EC9-4	х	Х	Х	Х	Х					
MC9-4	х	х	Х	Х	Х					
7CF1	х	х	Х	Х	Х					
7CF2	Х	Х	Х	Х	Х					
9EVF4	х	х	Х	Х	Х					
CW2							Х			
CW5							Х			
AcuNav 8F	Х		Х	Х	х	Х				
AcuNav 10F	Х		Х	Х	х	Х				
	(Available o	nly on the ACU	SON S2000 sy	stem and the	ACUSON S3000	0 system)				
6C1 HD	Х	Х	Х	Х	Х					
8C3 HD	Х	Х	Х	Х	Х					

F - 6 Instructions for Use

The following rules apply to the summary table:

B-mode (2D)	No other mode active.
	Only MI (when larger than 1.0) is reported for this mode.
M-mode	May include simultaneous B-mode.
PW-Doppler / SCW-Doppler	In duplex modes, the largest displayed TIS (scanned or non-scanned) is reported if it is larger than 1.0.
Color Flow or Power	May include simultaneous color flow M-mode, B-mode, and Doppler.
	In combined modes, the largest displayed TIS (scanned or non-scanned) is reported if it is larger than 1.0.
Combined modes	The output is reported as a separate mode if the largest formulation of TIS, TIB, or TIC (if an intended use) is greater than the corresponding value reported for all constituent modes.
Other	TIC is reported if the transducer is intended for transcranial or neonatal cephalic use.

Definitions

Symbol		Definition						
FDA	IEC	FDA	IEC	Units				
MI	MI	Mechanical Index	Same as FDA	n/a				
TIS _{scan}	TIS Scan	Soft Tissue Thermal Index in autoscanning mode	Same as FDA	n/a				
TIS _{non-scan}	TIS Non-scan	Soft Tissue Thermal Index in non-autoscanning mode	Same as FDA	n/a				
TIB	TIB	Bone Thermal Index	Same as FDA	n/a				
TIC	TIC	Cranial Thermal Index	Same as FDA	n/a				
A _{aprt}	A _{aprt}	Area of the active aperture	-12dB output beam area	cm ²				
P _{r.3}	p _{ra}	Derated peak rarefactional pressure	Attenuated peak-rarefactional acoustic pressure	MPa				
Wo	P	Ultrasonic power, except for TIS _{scan} in which case it is the ultrasonic power passing through a one centimeter window	Output power	mW				
W _{.3} (z ₁)	$P_{\alpha}(z_{\rm s})$	Derated ultrasonic power at axial distance z ₁	Attenuated output power at z _s	mW				
I _{TA.3} (z ₁)	$I_{\mathrm{ta}, \alpha}(z_{\mathrm{s}})$	Derated spatial-peak, temporal-average intensity at axial distance z ₁	Attenuated temporal-average intensity at <i>z</i> _s	mW/cm ²				
Z ₁	z _s	Axial distance corresponding to the location of the max [min ($W_{.3}(z)$, $I_{TA.3}(z)$ x 1 cm ²)], where $z > z_{bp}$	Depth for TIS	cm ²				
Z _{bp}	Z _{bp}	1.69 (A _{aprt}) ^{1/2}	Break-point depth	cm				
Z _{sp}	z_{b}	Axial distance at which TIB is a maximum (i.e., $z_{sp} = z_{B.3}$)	Depth for TIB	cm				
z@PII _{.3max}	z at max. I _{pi,α}	The axial distance corresponding to the maximum of the derated spatial-peak pulse intensity integral (megapascals).	Depth at the point where the free-field, attenuated pulse intensity integral is a maximum	cm				
d _{eq} (z)	$d_{ m eq}(z)$	Equivalent beam diameter as a function of axial distance z, and is equal to $ \left[\left(\frac{4}{\pi} \right) \left(\frac{W_o}{I_{TA}(z)} \right) \right]^{0.5} $ where $I_{TA}(z)$ is the temporal-average intensity as a function of z	Equivalent beam diameter at axial distance z	cm				
f _c	f_{awf}	Center frequency	Acoustic working frequency	MHz				
Dim. of A _{aprt}	Dim. of A _{aprt}	Active aperture dimensions for the azimuth and elevational planes	Same as FDA	cm				
PD	t _d	Pulse duration	Same as FDA	μs				
PRF	prr	Pulse repetition frequency	Pulse repetition rate	Hz				
p _r @PII _{max}	p _r at max. I _{pi}	Peak rarefactional pressure at the point where the free- field, spatial-peak pulse intensity integral is a maximum	Same as FDA	MPa				
d _{eq} @PII _{max}	$d_{\rm eq}$ at max. $I_{\rm pi}$	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum	Same as FDA	cm				
FL	FL	Focal Length, or azimuthal and elevational lengths, if different	Same as FDA	cm				
I _{PA.3} @MI _{max}	I _{pa,α} at max. MI	Derated pulse-average intensity at the point of global maximum reported MI	Same as FDA	W/cm ²				

Note: Pulse-average intensity (I_{pa}) is the ratio of the pulse-intensity integral (I_{pi}) to the pulse duration (I_{d}).

F - 8 Instructions for Use

Legend

English	Translations for languages other than English
Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37	n/a
(Per transducer/mode that exceeds MI or TI value of 1.0)	n/a
Transducer Model	n/a
Operating Mode	n/a
Associated Acoustic Parameters	n/a
Index label	n/a
scan	n/a
non-scan	n/a
At surface	n/a
Below surface	n/a
units	n/a
Maximum Value	n/a
Other Information	n/a
Operator Control	n/a
TX Level (transmit level)	n/a
Focal length	n/a
Focus	n/a
Gate Size	n/a
Sample Rate	n/a
Res/Speed	n/a
Ensemble Size	n/a
Frequency	n/a
PRF (Pulsed Repetition Frequency)	n/a
a This Index is not relevant to this operating mode.	n/a
b This transducer is not intended for transcranial or neonatal cephalic uses.	n/a
c This formulation for TIS is less than that for an alternate formulation in this mode.	n/a
# No data is provided for this operation condition since the maximum index value is not reported for the reason listed.	n/a

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4C1 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan		-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.29	0.29	-	-	-	1.04
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	1.84					
sters	Wo	P	(mW)		132.03	-		-	132.03
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
: Б	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. Ι _{ρί,α}	(cm)	1.60					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.05	2.03	-	-	-	2.03
4	Dim. of A _{aprt}		X (cm)		4.01	-	-	-	2.86
			Y (cm)		1.40	-	-	-	1.40
	PD	t _d	(µsec)	1.27					
ijon	PRF	prr	(Hz)	39.98					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.09					
Jē.	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
erl	Focal Length	FLx	(cm)		18.00	-	-		18.00
Oth		FLy	(cm)		4.88	-	-		4.88
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	101.60					·
to	Focus (cm)	•		2.00	18.00	-	-	-	18.00
Operator Control	Frequency (MHz)	•		2.00	2.00	-	-	-	2.00
90	Res/Speed	•		3	3	-	-	-	3

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4C1

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Non	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.32	0.39	-	-	-	1.54
	FDA	IEC	Units						
ø	P _{r.3}	p _{ra}	(MPa)	1.84					
eter	Wo	P	(mW)		203.01	-		-	203.01
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i E	z_1	Z _S	(cm)				-		
snc	Z _{bp}	Z _{bp}	(cm)				-		
Ä	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.90					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Assı	f _c	f _{awf}	(MHz)	1.98	2.15	-	-	-	2.15
	Dim. of A _{aprt}		X (cm)		6.11	-	-	-	4.37
			Y (cm)		1.40	-	-	-	1.40
	PD	$t_{\sf d}$	(µsec)	0.79					
tion	PRF	prr	(Hz)	39.97					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.20					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
er	Focal Length	FLx	(cm)		18.00	-	-		18.00
ㅎ		FLy	(cm)		4.88	-	-		4.88
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	108.09					
Operator Control	Focus (cm)			4.00	18.00	-	-	-	18.00
ontr	Frequency (MHz)	Frequency (MHz)			4.50	-	-	-	4.50
ÖÖ	Res/Speed			3	3	-	-	-	3

This Index is not relevant to this operating mode.

F - 10 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **4C1** Operating

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.31	0.67	-	-	-	2.75
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	1.80					
ter	Wo	P	(mW)		73.73	-		-	356.62
Associated Acoustic Parameters	min of [W $_3$ (z $_1$), I $_{TA.3}$ (z $_1$)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
E	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.20					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	1.89	3.33	-	-	-	1.88
_	Dim. of A _{aprt}		X (cm)		1.19	-	-	-	5.34
			Y (cm)		1.40	-	-	-	1.40
	PD	t_{d}	(μsec)	2.28					
tion	PRF	prr	(Hz)	8.02					
шa	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.34					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		5.01	-	-		28.59
₽		FLy	(cm)		4.88	-	-		4.88
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	157.55					
_	Focus (cm)			5.02	5.01	-	-	-	28.59
rato	Res/Speed			5	5	-	-	-	5
Operator Control	Ensemble Size			12	12	-	-	-	12
0	Frequency (MHz)			2.00	3.50	-	-	-	2.00

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4C1

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.31		-	1.42	3.56	3.25
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	1.80					
ters	Wo	P	(mW)		-	-		185.50	397.25
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				156.22		
ic P	Z ₁	Z _S	(cm)				4.50		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				3.68		
Acc	Z _{sp}	Z _b	(cm)					6.40	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.2					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.51	
\ssc	f _c	f _{awf}	(MHz)	1.89	1	-	1.91	1.90	1.88
_	Dim. of A _{aprt}		X (cm)		1	-	3.39	2.00	5.25
			Y (cm)		-	-	1.40	1.40	1.40
	PD	$t_{\sf d}$	(µsec)	2.28					
tion	PRF	prr	(Hz)	610.35					
шa	Pr@ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.34					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.48	
er	Focal Length	FLx	(cm)		•	-	14.04		26.39
o ₽		FLy	(cm)		•	-	4.88		4.88
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	157.60					
_	Frequency (MHz)			2.00	•	-	2.00	2.00	2.0
rato	Focus (cm)			5.01	1	-	14.04	8.36	26.39
Operator Control	Gate Size (cm)			0.3	1	-	0.30	0.30	0.30
0	Sample Rate (Hz)			610.35	-	-	24083	22321	24083

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4C1

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.32	-	-	0.74	1.69	1.45
	FDA	IEC	Units						
ro.	P _{r.3}	p _{ra}	(MPa)	1.87					
ter	Wo	P	(mW)		-	-		131.15	131.15
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				80.14		
으	Z ₁	Z _S	(cm)				3.60		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				3.38		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					4.10	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	5.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.01	
Assc	f _c	f _{awf}	(MHz)	2.02	-	-	1.94	1.94	2.03
1	Dim. of A _{aprt}		X (cm)		-	-	2.86	2.86	2.86
			Y (cm)		-	-	1.40	1.40	1.40
	PD	$t_{\sf d}$	(µsec)	1.17					
tion	PRF	prr	(Hz)	600					
na E	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.65					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					31.26	
ē	Focal Length	FLx	(cm)		-	-	18.00		18.00
ğ		FLy	(cm)		-	-	4.88		4.88
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	199.32					
Ψ.	Frequency (MHz)			2.00	-	-	2.00	2.00	2.00
Operator Control	Focus (cm)			6.00	-	-	18.00	18.00	18.00
g S	Gate Size (cm)			1.03	-	-	1.03	1.03	1.03
	Sample Rate (Hz)			600.00	-	-	600	600	600
	This Index is not rel	avant to this anare	tina mada						

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C1 HD

Operating mode: 2D-Mode

			MI		TIS		TIB	TIC
Ind	ex Label			Scan	Non-	scan	Non-scan	
					A _{aprt} ≤1	A _{aprt} >1		
Maximum Value			1.40	5.18	-	-	-	4.34
FDA	IEC	Units						
P _{r.3}	p _{ra}	(MPa)	1.98					
Wo	P	(mW)		444.00	-		-	444.00
min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Z ₁	Z _S	(cm)				-		
Z _{bp}	Z _{bp}	(cm)				-		
Z _{sp}	Z _b	(cm)					-	
z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	5.90					
$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
f _c	f _{awf}	(MHz)	1.99	3.43	-	-	-	3.43
Dim. of A _{aprt}		X (cm)		5.14	-	-	-	3.67
		Y (cm)		1.40	-	-	-	1.40
PD	t _d	(μsec)	1.22					
PRF	prr	(Hz)	39.98					
P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.99					
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
Focal Length	FLx	(cm)		23.00	-	-		23.00
	FLy	(cm)		7.00	-	-		7.00
I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	118.40					
Focus (cm)			14.00	23.00				23.00
Frequency (MHz)	Frequency (MHz)			0.00				0.00
Res/Speed			3	3				3
	Maximum Value FDA	FDA IEC Pr₃ pr₃ W₀ P min of [W₃(z₁), I₁x₃(z₁)] Min. of [P₀(z₅), I₂a₀(z₅)] z¹ z₅ Z₀p Z₀p Z₅p z₀ Z₀PII₃max z @ max. Ipi, G d₀q(z₅p) d₀q(z♭) f₀ f₃wd Dim. of A₃prt Pr@ max. Ipi PRF prr P₁@ PIImax P₁@ max. Ipi d₀q@ PIImax d₀c@ max. Ipi Focal Length FLx FLy Ip₃,a@ Mimax Ip₃a,@ max. MI Focus (cm) Frequency (MHz) Res/Speed Res/Speed	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{ l l l l l l l l l l l l l l l l l l l$	$\begin{array}{ c c c c c } \hline \textbf{Maximum Value} & 1.40 & 5.18 \\ \hline \textbf{FDA} & \textbf{IEC} & \textbf{Units} \\ \hline P_{\Gamma,3} & p_{\Gamma a} & (MPa) & 1.98 \\ \hline W_o & P & (mW) & 444.00 \\ \hline \min \ of \ [W_3(z_1), \\ I_{TA,3}(z_1)] & Min. \ of \ [P_a(z_s), \\ I_{1a,a}(z_s)] & (cm) \\ \hline Z_1 & Z_s & (cm) \\ \hline Z_0p & Z_{0p} & (cm) \\ \hline Z_0p & Z_{0p} & (cm) \\ \hline Z_0p & Z_0 & (cm) \\ \hline Z_0p & Z_0p & (cm) \\ \hline Z_0p & Z$	$ \begin{array}{ c c c c c } \hline & & & & & & & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & & & & \\ \hline \textbf{FDA} & & & & & & & & & \\ \hline \textbf{FDA} & & & & & & & & & \\ \hline \textbf{P}_{r,3} & & & & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & & & \\ \hline \textbf{FDA} & & & & & & & & & \\ \hline \textbf{P}_{r,3} & & & & & & & & & \\ \hline \textbf{P}_{r,3} & & & & & & & & & \\ \hline \textbf{W}_{o} & & & & & & & & & \\ \hline \textbf{W}_{o} & & & & & & & & & \\ \hline \textbf{Min of } [W_3(z_1), & & & & & & & & \\ \hline \textbf{Min. of } [P_{o}(z_s), & & & & & & & & \\ \hline \textbf{Min. of } [P_{o}(z_s), & & & & & & & \\ \hline \textbf{Min. of } [P_{o}(z_s), & & & & & & & \\ \hline \textbf{Min. of } [P_{o}(z_s), & & & & & & & \\ \hline \textbf{Min. of } [W_3(z_1), & & & & & & & \\ \hline \textbf{Min. of } [P_{o}(z_s), & & & & & & & \\ \hline \textbf{Min. of } [P_{o}(z_s), & & & & & & \\ \hline \textbf{MWV} & & & & & & & \\ \hline \textbf{J}_{1a,o}(z_1)] & & & & & & & \\ \hline \textbf{Min. of } [P_{o}(z_s), & & & & & & \\ \hline \textbf{MWV} & & & & & & & \\ \hline \textbf{J}_{1a,o}(z_s)] & & & & & & \\ \hline \textbf{MWV} & & & & & & & \\ \hline \textbf{J}_{1a,o}(z_s)] & & & & & & \\ \hline \textbf{MWV} & & & & & & & \\ \hline \textbf{J}_{1a,o}(z_s)] & & & & & & \\ \hline \textbf{MWV} & & & & & & & \\ \hline \textbf{MWV} & & & & & & & \\ \hline \textbf{J}_{1a,o}(z_s)] & & & & & & \\ \hline \textbf{MWV} & & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & \\ \hline \textbf{Maximum Value} & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Meq. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline \textbf{Min. of } & & & & & & \\ \hline $	$ \begin{array}{ c c c c c c c c } \hline \text{Indivibule} & & & & & & & & & & & & & & & & & & &$	Index Label Scan Non-scan Non-scan Maximum Value 1.40 5.18 - - - FDA IEC Units - - - - $P_{r,3}$ p_{ra} (MPa) 1.98 - - - - W_0 P (mW) 444.00 - - - - W_0 P (mW) 444.00 - - - - W_0 P (mW) - 444.00 - - - - W_0 P (mW) -

This Index is not relevant to this operating mode.

F - 12 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C1 HD

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.36	1.39	-	-	-	2.01
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	1.81					
ter	Wo	P	(mW)		175.92	-		-	175.92
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	1.77	2.32	1	-	-	2.32
1	Dim. of A _{aprt}		X (cm)		3.74	-	-	-	2.67
			Y (cm)		1.40	-	-	-	1.40
	PD	t _d	(µsec)	1.50					
Other Information	PRF	prr	(Hz)	39.97					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.23					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
erl	Focal Length	FLx	(cm)		8.00	-	-		8.00
g		FLy	(cm)		7.00	1	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	71.46					
tor	Focus (cm)	•		14.00	8.00				8.00
Operator Control	Frequency (MHz)	Frequency (MHz)			0.00				0.00
90	Res/Speed	•		3	3				3

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C1 HD

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.40	1.30	-	-	-	4.13
	FDA	IEC	Units						
·/o	P _{r.3}	p_{ra}	(MPa)	1.92					
sters	Wo	P	(mW)		122.66	-		-	515.47
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S P	Z ₁	Z _s	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	8.30					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	1.88	3.32	-	-	-	2.50
_	Dim. of A _{aprt}		X (cm)		0.95	-	-	-	5.14
			Y (cm)		1.40	-	-	-	1.40
	PD	$t_{\sf d}$	(μsec)	2.20					
tion	PRF	prr	(Hz)	7.74					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.19					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
ē	Focal Length	FLx	(cm)		4.00	-	-		23.00
£		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	125.37					
	Focus (cm)			11.00	4.00				23.00
rato	Res/Speed			3	3				3
Operator Control	Ensemble Size	•		12	12				12
0	Frequency (MHz)			2.00	3.50				2.50

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C1 HD

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.33	-	-	1.36	4.21	4.06
	FDA	IEC	Units						
ro.	P _{r.3}	p _{ra}	(MPa)	1.83					
ter	Wo	P	(mW)		-	-		240.29	501.33
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				146.65		
. <u>S</u>	Z ₁	Z _S	(cm)				4.30		
nst	Z _{bp}	Z_{bp}	(cm)				3.28		
Acc	Z _{sp}	$Z_{\rm b}$	(cm)					7.30	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	4.30					
<u>cia</u>	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.48	
SSC	f _c	f _{awf}	(MHz)	1.89	1	-	1.95	1.94	2.50
_	Dim. of A _{aprt}		X (cm)			-	2.69	2.31	5.36
			Y (cm)			-	1.40	1.40	1.40
	PD	$t_{\sf d}$	(µsec)	2.35					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.33					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.43	
ē	Focal Length	FLx	(cm)		1	-	11.06		29.85
₽		FLy	(cm)		1	-	7.00		7.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	100.81					
_	Frequency (MHz)	•	•	2.00	1	-	2.00	2.00	2.50
rato	Focus (cm)			4.00	-	-	11.06	9.58	29.85
Operator Control	Gate Size (cm)	-		0.25	-	-	0.25	0.25	0.25
0	Sample Rate (Hz)			100.16	1	-	7440	9765	11160

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C1 HD

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.40	-	-	0.73	1.55	1.79
	FDA	IEC	Units						
	P _{r.3}	p _{ra}	(MPa)	2.67					
ters	Wo	P	(mW)		-	-		148.68	183.69
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				76.54		
i.	Z ₁	Z _s	(cm)				4.80		
nst	Z _{bp}	Z _{bp}	(cm)				3.83		
Acc	Z _{sp}	Z _b	(cm)					4.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.70					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					1.19	
SSC	f _c	f _{awf}	(MHz)	3.63	-	-	2.00	2.00	3.43
4	Dim. of A _{aprt}		X (cm)		-	-	3.67	3.67	3.67
			Y (cm)		-	-	1.40	1.40	1.40
	PD	$t_{\sf d}$	(μsec)	0.46					
Other Information	PRF	prr	(Hz)	600.00					
maj	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.30					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					33.40	
erl	Focal Length	FLx	(cm)		1	-	23.00		23.00
o ₽		FLy	(cm)		1	-	7.00		7.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	318.16					
_	Frequency (MHz)			2.50	-	-	1.50	1.50	2.50
Operator Control	Focus (cm)	•		2.00	1	-	23.00	23.00	23.00
Spel	Gate Size (cm)	•		1.00	-	-	1.00	1.00	1.00
0 -	Sample Rate (Hz)			600.00	-	-	600	600	600
а	This Index is not rele	evant to this oners	ting mode					•	

This Index is not relevant to this operating mode.

F - 14 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **6C2** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.35	0.81	-	-	-	1.83
	FDA	IEC	Units						
m	P _{r.3}	p _{ra}	(MPa)	2.25					
eter	Wo	P	(mW)		201.35	-		-	201.35
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Б	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted /	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.60					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.79	2.77	-	-	-	2.77
4	Dim. of A _{aprt}		X (cm)		3.86	-	-	-	2.76
			Y (cm)		1.20	-	-	-	1.20
	PD	t _d	(µsec)	0.87					
ion	PRF	prr	(Hz)	39.98					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.48					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		12.00	-	-		12.00
듐		FLy	(cm)		6.90	-	-		6.90
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	249.78					
o t	Focus (cm)			6.00	12.00	-	-	-	12.00
Operator Control	Frequency (MHz)				2.50	-	-	-	2.50
ర్ధిర	Res/Speed			3	3	-	-	-	3

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C2 Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Non	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.50	2.04	-	-	-	2.05
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	2.59					
eter	Wo	P	(mW)		172.23	-		-	172.23
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.20					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Asso	f _c	f _{awf}	(MHz)	2.98	2.98	-	-	-	2.98
_	Dim. of A _{aprt}		X (cm)		4.02	-	-	-	2.87
			Y (cm)		1.20	-	-	-	1.20
	PD	$t_{\sf d}$	(µsec)	0.42					
tion	PRF	prr	(Hz)	9.28					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.99					
ufo	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
er	Focal Length	FLx	(cm)		12.00	-	-		12.00
ㅎ		FLy	(cm)		6.90	-	-		6.90
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	289.36					
Operator Control	Focus (cm)			4.00	12.00	-	-	-	12.00
ontr	Frequency (MHz)			6.00	6.00	-	-	-	6.00
ÖÖ	Res/Speed			3	3	-	-	-	3

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C2

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.27	0.90	-	-	-	1.57
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	2.05					
ter	Wo	P	(mW)		120.19	-		-	132.93
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.90					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	2.61	3.55	-	-	-	3.07
*	Dim. of A _{aprt}		X (cm)		1.19	-	-	-	1.19
			Y (cm)		1.20	-	-	-	1.20
	PD	$t_{\sf d}$	(μsec)	1.52					
tion	PRF	prr	(Hz)	8.05					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.85					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		5.00	-	-		5.00
£		FLy	(cm)		6.90	-	-		6.90
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	270.55					
ب	Focus (cm)	•	•	5.00	5.00	-	-	-	5.00
rato	Res/Speed			4	4	-	-	-	4
Operator Control	Ensemble Size			12	12	-	-	-	12
0	Frequency (MHz)			2.50	3.75	-	-	-	3.25

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 6C2

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.27	1	-	1.00	3.69	4.01
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.05					
ter	Wo	P	(mW)		1	-		132.86	486.67
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				81.60		
i P	z_1	Z _S	(cm)				2.70		
onst	Z _{bp}	Z _{bp}	(cm)				2.22		
Acc	Z _{sp}	Z _b	(cm)					4.70	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.90					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.35	
ASSC	f _c	f _{awf}	(MHz)	2.61		-	2.57	2.57	3.10
_	Dim. of A _{aprt}		X (cm)		1	-	1.44	1.44	6.03
			Y (cm)		1	-	1.20	1.20	1.20
	PD	t _d	(μsec)	1.52					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.85					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.27	
e	Focal Length	FLx	(cm)		1	-	6.02		25.02
o₩		FLy	(cm)		1	-	6.90		6.90
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	270.67					
	Frequency (MHz)			2.50		-	2.50	2.50	3.25
Operator Control	Focus (cm)			5.01		-	6.02	6.02	25.02
g S	Gate Size (cm)			0.20		-	0.20	0.20	0.20
0	Sample Rate (Hz)			100.16	•	-	19531	19531	19531
а	This Index is not rel	evant to this oners	ting mode						

This Index is not relevant to this operating mode.

F - 16 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **6C2** Operating mode: **M-Mode**

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.20	-	-	0.95	1.59	2.18
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	1.99					
ter	Wo	P	(mW)		-	-		182.79	182.79
Associated Acoustic Parameters	min of $[W_3(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				73.68		
iS P	Z ₁	Z _S	(cm)				4.20		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				3.14		
Acc	Z _{sp}	z_{b}	(cm)					3.90	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.00					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.25	
\ssc	f _c	f_{awf}	(MHz)	2.78	-	-	2.71	2.71	2.71
_	Dim. of A _{aprt}		X (cm)		-	-	2.87	2.87	2.87
			Y (cm)		-	-	1.20	1.20	1.20
	PD	$t_{\sf d}$	(μsec)	0.78					
tion	PRF	prr	(Hz)	600.00					
i.	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.87					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					37.54	
ē	Focal Length	FLx	(cm)		-	-	20.00		20.00
£		FLy	(cm)		-	-	6.90		6.90
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	277.59					
_	Frequency (MHz)			2.50	-	-	2.50	2.50	2.50
rato	Focus (cm)			4.00	-	-	20.00	20.00	20.00
Operator Control	Gate Size (cm)			3.00	-	-	3.00	3.00	3.00
	Sample Rate (Hz)			600.00	-	-	600	600	600

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **8C3 HD** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.18	0.76	-	-	-	1.14
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	2.60					
ters	Wo	P	(mW)		45.13	-		-	78.66
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	z_1	Z _S	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSO	f _c	f _{awf}	(MHz)	4.83	4.25	-	-	-	3.44
4	Dim. of A _{aprt}		X (cm)		3.03	-	-	-	1.93
			Y (cm)		1.20	-	-	-	1.20
	PD	t _d	(μsec)	0.37					
ţion	PRF	prr	(Hz)	13.91					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.17					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		16.00	-	-		8.00
o₩		FLy	(cm)		6.90	-	-		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	259.76					
Operator Control	Focus (cm)		•	2.00	16.00				8.00
era	Frequency (MHz)		•	0.00	0.00				0.00
90	Res/Speed		•	3	3				3

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

 $^{{\}tt c} \quad \ \ {\tt This formulation for TIS is less than that for an alternate formulation in this mode.}$

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 8C3 HD

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Non-	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1	İ	
	Maximum Value			1.50	0.63	-	-	-	0.78
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.25					
ters	Wo	P	(mW)		41.41	-		-	56.88
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
:S	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
fed	z@PII.3max	z @ max. Ι _{ρί,α}	(cm)	4.00					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.23	3.85	-	-	-	2.27
1	Dim. of A _{aprt}		X (cm)		3.03	-	-	-	2.17
			Y (cm)		1.20	-	-	-	1.20
	PD	t _d	(µsec)	0.87					
ion	PRF	prr	(Hz)	10.37					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.97					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
erl	Focal Length	FLx	(cm)		16.00	-	-		8.00
듐		FLy	(cm)		6.90	-	-		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	125.34					
lo o	Focus (cm)			4.00	16.00				8.00
era	Frequency (MHz)			0.00	0.00				0.00
ဝီပိ	Res/Speed			3	3				3
Operator	Focus (cm) Frequency (MHz)			4.00 0.00	0.00				0.

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 8C3 HD

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non-	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.41	0.82	-	-	-	1.23
	FDA	IEC	Units						
"	P _{r.3}	p ra	(MPa)	2.71					
ters	Wo	P	(mW)		54.87	-		-	50.98
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.19					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Assc	f _c	f _{awf}	(MHz)	3.68	3.69	-	-	-	3.70
_	Dim. of A _{aprt}		X (cm)		0.47	-	-	-	0.24
			Y (cm)		1.20	-	-	-	1.20
	PD	$t_{\sf d}$	(μsec)	1.05					
tion	PRF	prr	(Hz)	5.08					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.62					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
er	Focal Length	FLx	(cm)		2.00	-	-		1.00
ㅎ		FLy	(cm)		6.90	-	-		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	322.89					
	Focus (cm)			3.50	2.00				1.00
Operator Control	Res/Speed			2	2				2
g S	Ensemble Size			12	12				12
	Frequency (MHz)			3.75	3.75				3.75
2	This Index is not rela	evant to this opera	ting mode						

This Index is not relevant to this operating mode.

F - 18 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 8C3 HD

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.41		0.81	-	2.23	1.89
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	2.41					
ter	Wo	P	(mW)			45.44		45.44	45.44
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
E	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\rm bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					1.00	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.50					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.36	
\ssc	f _c	f _{awf}	(MHz)	2.93		3.72	-	3.72	3.72
_	Dim. of A _{aprt}		X (cm)			0.24	-	0.24	0.24
			Y (cm)			1.20	-	1.20	1.20
	PD	$t_{\sf d}$	(μsec)	1.43					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.46					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.34	
Other Information	Focal Length	FLx	(cm)			1.00	-		1.00
₽		FLy	(cm)			6.90	-		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	230.88					
_	Frequency (MHz)			2.85		3.75		3.75	3.75
rato	Focus (cm)			4.50		1.00		1.00	1.00
Operator Control	Gate Size (cm)			0.15		0.10		0.10	0.10
٠	Sample Rate (Hz)			100.06		24083		24083	24083

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 8C3 HD

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Inde	x Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.92	-	-	0.20	0.39	0.33
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	1.83					
ters	Wo	P	(mW)		-	-		15.83	23.75
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				11.66		
i P	Z ₁	Z _S	(cm)				2.80		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				2.73		
Acc	Z _{sp}	z_{b}	(cm)					2.50	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.20					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.52	
\ss(f _c	f _{awf}	(MHz)	3.93	1	-	3.68	3.41	3.68
_	Dim. of A _{aprt}		X (cm)		1	-	2.17	1.45	2.17
			Y (cm)		1	-	1.20	1.20	1.20
	PD	t _d	(µsec)	0.58					
tion	PRF	prr	(Hz)	600.00					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.12					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					13.07	
er	Focal Length	FLx	(cm)			-	20.00		20.00
o ₽		FLy	(cm)			-	6.90		6.90
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	135.56					
_	Frequency (MHz)			3.00	1	-	3.00	3.00	3.00
Operator Control	Focus (cm)			2.00	1	-	20.00	6.00	20.00
Sp	Gate Size (cm)			1.00	1	-	1.00	1.00	1.00
0	Sample Rate (Hz)			600.00	1	-	600	600	600

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 9L4 Operating mode: 2D-Mode

	•		·	MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.21	0.83	-	-	-	1.94
	FDA	IEC	Units						
m	P _{r.3}	p _{ra}	(MPa)	2.52					
ters	Wo	P	(mW)		162.90	-		-	162.94
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S. P	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Aco	Z _{sp}	$Z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.60					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	4.32	4.21	-	-	-	4.01
٩	Dim. of A _{aprt}		X (cm)		3.86	-	-	-	2.76
			Y (cm)		0.90	-	-	-	0.90
	PD	t_{d}	(µsec)	0.43					
ion	PRF	prr	(Hz)	47.77					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.20					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
Other Information	Focal Length	FLx	(cm)		9.00	-	-		9.00
g		FLy	(cm)		2.00	-	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	415.59					
<u> </u>	Focus (cm)			2.00	9.00	-	-	-	9.00
Operator	Frequency (MHz)	Frequency (MHz)			4.00	-	-	-	4.00
50	Res/Speed				3	-	-	-	3

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 9L4

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.36	1.31	-	-	-	1.55
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	2.83					
eter	Wo	P	(mW)		79.51	-		-	122.98
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is P	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.90					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Asso	f _c	f _{awf}	(MHz)	4.31	4.18	-	-	-	4.11
_	Dim. of A _{aprt}		X (cm)		1.51	-	-	-	2.76
			Y (cm)		0.90	-	-	-	0.90
	PD	$t_{\sf d}$	(μsec)	0.23					
tion	PRF	prr	(Hz)	17.56					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.30					
ugu	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
le l	Focal Length	FLx	(cm)		3.00	-	-		12.00
윰		FLy	(cm)		2.00	-	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	280.60					
Operator Control	Focus (cm)			1.00	3.00	-	-	-	12.00
ontr	Frequency (MHz)			9.00	9.00	-	-	-	9.00
ÖÖ	Res/Speed			0	3	-	-	-	3

This Index is not relevant to this operating mode.

F - 20 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 9L4

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.27	2.19	-	-	-	2.50
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.83					
ter	Wo	P	(mW)		105.79	-		-	207.85
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	4.98	5.01	-	-	-	5.01
1	Dim. of A _{aprt}		X (cm)		0.48	-	-	-	3.28
			Y (cm)		0.90	-	-	-	0.90
	PD	t_{d}	(µsec)	0.74					
Other Information	PRF	prr	(Hz)	6.13					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.57					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
erl	Focal Length	FLx	(cm)		2.00	-	-		13.75
Oth		FLy	(cm)		2.00	-	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	309.25					
_	Focus (cm)			2.01	2.00	-	-	-	13.75
rato	Res/Speed			0	5	-	-	-	5
Operator Control	Ensemble Size			14	14	-	-	-	14
0 ,	Frequency (MHz)			5.00	5.00	-	-	-	5.00

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 9L4

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.20	-	2.19	-	2.19	2.80
	FDA	IEC	Units						
·0	P _{r.3}	p _{ra}	(MPa)	2.70					
ters	Wo	P	(mW)		-	176.82		176.82	176.82
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i D	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	Z b	(cm)						
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.60					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)						
ASSC	f _c	f _{awf}	(MHz)	4.99	1	5.08	-	5.08	5.08
_	Dim. of A _{aprt}		X (cm)		1	2.17	-	2.17	2.17
			Y (cm)		1	0.90	-	0.90	0.90
	PD	$t_{\sf d}$	(μsec)	0.73					
tion	PRF	prr	(Hz)	100.16					
ща	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.55					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)						
e	Focal Length	FLx	(cm)		-	6.49	-		6.49
o₩		FLy	(cm)		-	2.00	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	357.12					
_	Frequency (MHz)	•	•	5.00	-	5.00	-	5.00	5.00
Operator Control	Focus (cm)	•	•	2.00	-	6.49	-	6.49	6.49
g S	Gate Size (cm)	•	•	0.15	-	0.15	-	0.15	0.15
O '	Sample Rate (Hz)			100.16	-	28409	-	28409	28409

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 9L4 Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.21	-	0.47	-	0.71	0.83
	FDA	IEC	Units						
Ø	P _{r.3}	p _{ra}	(MPa)	2.52					
ter	Wo	P	(mW)		-	58.74		30.59	58.74
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					3.70	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.60					
<u>G</u>	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.33	
SSC	f _c	f _{awf}	(MHz)	4.32	-	4.16	-	4.26	4.21
4	Dim. of A _{aprt}		X (cm)		-	2.76	-	1.44	2.76
			Y (cm)		-	0.90	-	0.90	0.90
	PD	t_{d}	(µsec)	0.43					
Other Information	PRF	prr	(Hz)	600.00					
mai	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.20					
Jē.	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					10.14	
e	Focal Length	FLx	(cm)		-	9.00	-		9.00
g		FLy	(cm)		-	2.0	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	415.59					
_	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
ato	Focus (cm)	' ' '			-	9.00	-	4.00	9.00
Operator Control	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
0	Sample Rate (Hz)			600.00	-	600	-	600	600

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 12L4 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Non-	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1	prt >1	
	Maximum Value			1.36	0.58	-	-	-	1.30
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.08					
ters	Wo	P	(mW)		83.73	-		-	111.07
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _s	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.50					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\SS(f _c	f _{awf}	(MHz)	5.13	5.27	-	-	-	5.27
4	Dim. of A _{aprt} X (cm)		X (cm)		3.34	-	-	-	2.39
			Y (cm)		0.70	-	-	-	0.70
	PD	t _d	(µsec)	0.32					
Other Information	PRF	prr	(Hz)	29.96					
ma	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.48					
uţo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		10.00	-	-		10.00
oth		FLy	(cm)		2.50	-	-		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	300.48					
ğ p	Focus (cm)	Focus (cm)			10.00				10.00
ontr	Frequency (MHz)	Frequency (MHz)			0.00				6.15
Operator Control	Res/Speed	•	·	0	3				3

This Index is not relevant to this operating mode.

F - 22 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 12L4 Operating mode: 2D-Mode (THI)

						TIS		TIB	TIC
	Inc	dex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.50	0.50	-	-	-	1.12
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	3.22					
ter	Wo	P	(mW)		68.66	-		-	96.14
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.67					
<u>S</u>	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	4.60	6.07	-	-	-	4.95
_	Dim. of A _{aprt}		X (cm)		4.01	-	-	-	2.86
			Y (cm)		0.70	-	-	-	0.70
	PD	t _d	(μsec)	0.30					
tion	PRF	prr	(Hz)	18.36					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.81					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
e	Focal Length	FLx	(cm)		10.00	-	-		10.00
윰		FLy	(cm)		2.50	-	-		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	410.05					
o to	Focus (cm)			3.50	10.00				10.00
Operator Control	Frequency (MHz)			0.00	0.00				4.00
ర్ధిర	Res/Speed	•		0	1				3

a This Index is not relevant to this operating mode.

- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 12L4

Operating mode: Color / Power

				MI		TIS		TIB Non-scan	TIC
	Inde	ex Label			Scan	Non-	scan		
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.21	1.01	-	-	-	1.45
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.75					
ters	Wo	P	(mW)		109.30	-		-	109.30
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.09					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	5.19	5.17	-	-	-	5.17
4	Dim. of A _{aprt}		X (cm)		2.67	-	-	-	2.67
	Y		Y (cm)		0.70	-	-	-	0.70
	PD	$t_{\sf d}$	(μsec)	0.69					
tion	PRF	prr	(Hz)	5.54					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.02					
ufoi	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
ē	Focal Length	FLx	(cm)		8.00	-	-		8.00
듈		FLy	(cm)		2.50	-	-		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	344.11					
_	Focus (cm)				8.00				8.00
rato	Res/Speed			5	0				0
Operator Control	Ensemble Size	Ensemble Size			14				14
	Frequency (MHz)			5.50	5.50				5.50

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 12L4

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.55	1	1.21	-	2.00	1.52
	FDA	IEC	Units						
ø	P _{r.3}	p_{ra}	(MPa)	3.52					
ate	Wo	P	(mW)		-	70.10		35.06	70.10
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					1.11	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.25					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.26	
\ssc	f _c	f_{awf}	(MHz)	5.18	1	5.44	-	5.39	5.44
*	Dim. of A _{aprt}		X (cm)		1	1.50	-	0.51	1.50
			Y (cm)		-	0.70	-	0.70	0.70
	PD	$t_{\sf d}$	(µsec)	0.73					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	5.00					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.21	
er	Focal Length	FLx	(cm)		1	4.50	-		4.50
£		FLy	(cm)		1	2.50	-		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	465.98					
	Frequency (MHz)			5.50	-	5.50	-	5.50	5.50
rato	Focus (cm)			2.75	-	4.50	-	1.50	4.50
Operator Control	Gate Size (cm)	Gate Size (cm)			-	0.15	-	0.15	0.15
	Sample Rate (Hz)			100.16	-	24083	-	26042	24083

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 12L4

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.38	-	0.29	-	0.40	0.41
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	3.10					
sters	Wo	P	(mW)		-	19.16		19.16	19.16
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is F	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					1.76	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.60					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.60	
\ss(f _c	f _{awf}	(MHz)	5.05	-	4.88	-	4.88	4.88
_	Dim. of A _{aprt}		X (cm)		-	1.55	-	1.55	1.55
			Y (cm)		-	0.70	-	0.70	0.70
	PD	t _d	(µsec)	0.33					
tion	PRF	prr	(Hz)	600.00					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.61					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					17.75	
er	Focal Length	FLx	(cm)		-	6.50	-		6.50
o ₽		FLy	(cm)		-	2.50	-		2.50
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	278.75					
_	Frequency (MHz)			6.00	-	6.00	-	6.00	6.00
rato	Focus (cm)			3.50	-	6.50	-	6.50	6.50
Operator Control	Gate Size (cm)	Gate Size (cm)			-	1.00	-	1.00	1.00
0	Sample Rate (Hz)	•	•	600.00	-	600	-	600	600

This Index is not relevant to this operating mode.

F - 24 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **14L5** Operating mode: **2D-Mode**

						TIS			TIC
	Inc	dex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.21	1.63	-	-	-	2.04
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	3.34					
eter:	Wo	P	(mW)		53.38	-		-	40.76
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				-		
:S	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.40					
<u>cia</u>	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	7.53	7.53	-	-	-	7.53
4	Dim. of A _{aprt}		X (cm)		0.90	-	-	-	0.32
			Y (cm)		0.30	-	-	-	0.15
	PD	t_{d}	(µsec)	0.24					
tion	PRF	prr	(Hz)	61.60					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.71					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
er	Focal Length	FLx	(cm)		2.28	-	-		0.75
듐		FLy	(cm)		1.10	-	-		1.10
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	476.16					
d o	Focus (cm)		0.50	2.28	-	-	-	0.75	
Operator Control	Frequency (MHz)		•	6.00	6.00	-	-	-	6.00
ర్ధిర	Res/Speed			3	3	-	-	-	3

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 14L5 Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.35	0.98	-	-	-	1.11
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.59					
sters	Wo	P	(mW)		33.16	-		-	32.49
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is P	z_1	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.90					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	7.07	7.07	-	-	-	7.07
1	Dim. of A _{aprt}		X (cm)		0.50	-	-	-	0.32
			Y (cm)		0.30	-	-	-	0.30
	PD	$t_{\sf d}$	(µsec)	0.21					
tion	PRF	prr	(Hz)	28.39					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.48					
Je i	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
erl	Focal Length	FLx	(cm)		1.00	-	-		0.75
듈		FLy	(cm)		1.10	-	-		1.10
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	608.32					
to	Focus (cm)			1.00	1.00	-	-	-	0.75
Operator Control	Frequency (MHz)			14.00	14.00	-	-	-	14.00
90	Res/Speed	•		0	0	-	-	-	0
2			4:						

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 14L5

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.45	2.27	-	-	-	2.34
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	3.66					
je:	Wo	P	(mW)		30.66	-		-	30.83
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
.S	z ₁	Z _S	(cm)						
onst	Z _{bp}	$z_{\sf bp}$	(cm)				ı		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Assc	f _c	f _{awf}	(MHz)	6.35	6.36	-	1	-	6.36
_	Dim. of A _{aprt} X (cm)		X (cm)		0.12	-	-	-	0.12
			Y (cm)		0.3	-		-	0.30
	PD	$t_{\sf d}$	(µsec)	0.61					
Other Information	PRF	prr	(Hz)	7.57					
ä	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.26					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
ē	Focal Length	FLx	(cm)		0.51	-	ı		0.51
듈		FLy	(cm)		1.10	-	ı		1.10
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	556.62					
_	Focus (cm)	Focus (cm)			0.51	-	ı	-	0.51
Operator Control	Res/Speed	Res/Speed			3	-		-	3
g S	Ensemble Size			12	12	-		-	12
	Frequency (MHz)			6.25	6.25	-	-	-	6.25
	This Index is not re	lavant to this anare	tina mada						

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 14L5

Operating mode: Pulsed Doppler

						TIS		TIB	TIC
	Index Label				Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.22	1	2.91	-	2.91	2.22
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	3.09					
ter	Wo	P	(mW)		1	82.07		82.07	89.11
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)						
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.10					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)						
SSC	f _c	f _{awf}	(MHz)	6.32	-	7.43	-	7.43	6.34
•			X (cm)		-	2.63	-	2.63	2.63
			Y (cm)		-	0.30	-	0.30	0.30
	PD	t _d	(µsec)	0.62					
Other Information	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.93					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)						
e	Focal Length	FLx	(cm)		1	7.93	-		7.93
o₩		FLy	(cm)		1	1.10	-		1.10
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	435.76					
_	Frequency (MHz)			6.25	-	7.50	-	7.50	6.25
Operator Control	Focus (cm)	Focus (cm)			•	7.93	-	7.93	7.93
g S	Gate Size (cm)			0.10		0.10	-	0.10	0.10
	Sample Rate (Hz)			100.16	•	24083	-	24083	24083
а	This Index is not rel	nis Index is not relevant to this operating mode							

This Index is not relevant to this operating mode.

F - 26 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **14L5** Operating mode: **M-Mode**

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.22	1	0.83	-	0.83	0.79
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	3.37					
ters	Wo	P	(mW)		-	23.92		23.92	23.92
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S.	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)						
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.50					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)						
SSC	f _c	f _{awf}	(MHz)	7.54	'n	7.28	-	7.28	7.28
_	Dim. of A _{aprt}		X (cm)		•	1.51	-	1.51	1.51
			Y (cm)		•	0.30	-	0.30	0.30
	PD	t _d	(µsec)	0.24					
tion	PRF	prr	(Hz)	600.00					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.79					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)						
er	Focal Length	FLx	(cm)		-	5.26	-		5.26
g		FLy	(cm)		-	1.10	-		1.10
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	456.68					
_	Frequency (MHz)			6.00	-	6.00	-	6.00	6.00
rato	Focus (cm)			0.75	-	5.26	-	5.26	5.26
Operator Control	Gate Size (cm)			1.0	-	1.00	-	1.00	1.00
	Sample Rate (Hz)	1		600.00	-	600	-	600	600

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 14L5 SP Operating mode: 2D-Mode

		•		MI		TIS	•	TIB	TIC
	Ind	lex Label			Scan	Non	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.55	0.59	-	-	-	1.20
	FDA	IEC	Units						
'n	P _{r.3}	p _{ra}	(MPa)	4.30					
ters	Wo	P	(mW)		43.49	-		-	43.49
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.60					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\SS(f _c	f _{awf}	(MHz)	7.70	7.34	-	-	-	7.34
٩	Dim. of A _{aprt}		X (cm)		1.60	-	-	-	1.14
			Y (cm)		0.25	-	-	-	0.25
	PD	t _d	(µsec)	0.25					
ion	PRF	prr	(Hz)	43.17					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.70					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		4.00	-	-		4.00
Other Information		FLy	(cm)		0.75	-	-		0.75
-	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	764.83					
Operator Control	Focus (cm)			0.75	4.00	-	-	-	4.00
	Frequency (MHz)			6.00	6.00	-	-	-	6.00
3 ŏ	Res/Speed				3	-	-	-	3

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 14L5 SP

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.16	0.48		-	-	1.02
	FDA	IEC	Units						
ဟ	P _{r.3}	p _{ra}	(MPa)	3.14					
eter	Wo	P	(mW)		36.75	-		-	36.75
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
.ii	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Asso	f _c	f _{awf}	(MHz)	7.31	7.07	-	-	-	7.07
	Dim. of A _{aprt}		X (cm)		1.20	-	-	-	0.86
			Y (cm)		0.25	-	-	-	0.25
	PD	$t_{\sf d}$	(µsec)	0.19					
Other Information	PRF	prr	(Hz)	21.58					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.51					
ug.	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
e	Focal Length	FLx	(cm)		3.00	-	-		3.00
듐		FLy	(cm)		0.75	-	-		0.75
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	415.81					
to o	Focus (cm)			1.50	3.00	-	-	-	3.00
Operator Control	Frequency (MHz)			14.00	14.00	-	-	-	14.00
ర్ధిర	Res/Speed			3	3	-	-	-	3
a .	This Index is not re	lovant to this apar	ating mode						

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 14L5 SP

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.45	1.15	-	-	-	1.51
	FDA	IEC	Units						
·0	P _{r.3}	p _{ra}	(MPa)	3.94					
ters	Wo	P	(mW)		40.15	-		-	44.62
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is P	Z ₁	Z _S	(cm)				•		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.60					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	7.34	7.35	-	-	-	6.38
~	Dim. of A _{aprt}		X (cm)		0.72	-	-	-	0.72
			Y (cm)		0.25	-	•	-	0.25
	PD	t _d	(µsec)	0.49					
tion	PRF	prr	(Hz)	6.43					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.58					
JQ.	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
ē	Focal Length	FLx	(cm)		3.00	-	1		3.00
듈		FLy	(cm)		0.75	-	1		0.75
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	672.67					
_	Focus (cm)			1.00	3.00	-	-	-	3.00
Operator Control	Res/Speed	•	•	5	5	-	•	-	5
a S	Ensemble Size	•	•	14	14	-	•	-	14
	Frequency (MHz)			7.50	7.50	-	-	-	6.25
2	This Index is not rel	nis Index is not relevant to this operating mode							

This Index is not relevant to this operating mode.

F - 28 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 14L5 SP

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.41	-	1.84	-	1.96	2.07
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	3.56					
eters	Wo	P	(mW)		-	59.95		46.75	46.75
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					0.90	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.36	
\ssc	f _c	f _{awf}	(MHz)	6.33	-	6.45	-	6.46	6.36
*	Dim. of A _{aprt}		X (cm)		-	1.96	-	1.00	1.00
			Y (cm)		-	0.25	-	0.25	0.25
	PD	t_{d}	(μsec)	0.63					
tion	PRF	prr	(Hz)	610.35					
ma	Pr@ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.77					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.21	
ē	Focal Length	FLx	(cm)		-	5.91	-		3.00
£		FLy	(cm)		-	0.75	-		0.75
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	452.02					
	Frequency (MHz)			6.25	-	6.25	-	6.25	6.25
rato	Focus (cm)			2.00	-	5.91	-	3.00	3.00
Operator Control	Gate Size (cm)			0.10	-	0.10	-	0.10	0.10
	Sample Rate (Hz)			610.35	-	31250	-	34722	34722

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 14L5 SP

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.31	-	0.41	-	0.46	0.43
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.61					
ters	Wo	P	(mW)		-	11.89		11.89	8.91
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.00	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.80					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.35	
SSC	f _c	f _{awf}	(MHz)	7.45	-	7.25	-	7.45	7.48
_	Dim. of A _{aprt}		X (cm)		-	1.14	-	1.14	0.86
			Y (cm)		-	0.25	-	0.25	0.25
	PD	t _d	(µsec)	0.30					
ţio	PRF	prr	(Hz)	600.00					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.44					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					11.16	
er	Focal Length	FLx	(cm)		-	4.00	-		3.00
o ₽		FLy	(cm)		-	0.75	-		0.75
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	462.29					
_	Frequency (MHz)			6.00	-	6.00	-	6.00	6.00
rato	Focus (cm)			1.50	-	4.00	-	4.00	3.00
Operator Control	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
	Sample Rate (Hz)			600.00	-	600	-	600	600

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **18L6 HD** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.26	0.22	-	-	-	0.35
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	3.50					
eter	Wo	P	(mW)		13.12	-		- 1	24.22
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S P	Z ₁	Z _s	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Aco	Z _{sp}	$z_{\rm b}$	(cm)						
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.30					
<u>S</u>	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	7.67	6.12	-	-	-	6.12
4	Dim. of A _{aprt}		X (cm)		1.93	-	-	-	1.38
			Y (cm)		0.40	-	-	-	0.40
	PD	t _d	(µsec)	0.17					
ţion	PRF	prr	(Hz)	29.96					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.93					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)						
ē	Focal Length	FLx	(cm)		5.26	-	-		5.26
g		FLy	(cm)		1.80	-	-		1.80
J	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	427.14					
o t	Focus (cm)	•		1.50	5.26				5.26
Operator Control	Frequency (MHz)			10.00	14.00				14.00
ర్ధిర	Res/Speed			0	3				3

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 18L6 HD Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.28	0.17	-	-	-	0.29
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.31					
ters	Wo	P	(mW)		18.29	-		-	18.29
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _s	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	1.10					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	fc	f _{awf}	(MHz)	6.72	6.43	-	-	-	6.43
4	Dim. of A _{aprt}		X (cm)		1.93	-	-	-	1.38
			Y (cm)		0.40	-	-	-	0.40
	PD	t _d	(µsec)	0.18					
lion	PRF	prr	(Hz)	21.64					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.10					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
erl	Focal Length	FLx	(cm)		5.26	-	-		5.26
g		FLy	(cm)		1.80	-	-		1.80
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	421.70					
o to	Focus (cm)		1.50	5.26				5.26	
Operator Control	Frequency (MHz)			0.00	0.00				0.00
90	Res/Speed			3	3				3

a This Index is not relevant to this operating mode.

F - 30 Instructions for Use

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 18L6 HD

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.36	0.95	-	-	-	0.99
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	3.39					
ter	Wo	P	(mW)		41.02	-		-	43.68
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.00					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f_{awf}	(MHz)	6.26	7.23	-	-	-	6.29
_	Dim. of A _{aprt}		X (cm)		1.31	-	-	-	1.31
			Y (cm)		0.40	-	-	-	0.40
	PD	$t_{\sf d}$	(µsec)	0.60					
tion	PRF	prr	(Hz)	6.34					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.21					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
ē	Focal Length	FLx	(cm)		5.50	-	-		5.50
윰		FLy	(cm)		1.80	-	-		1.80
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	523.28					
	Focus (cm)			1.50	5.50				5.50
rato	Res/Speed	•		5	5				5
g S	Res/Speed Ensemble Size			14	14				14
	Frequency (MHz)			6.25	7.50				6.25

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- ${\tt c} \quad \ \ {\tt This formulation for TIS is less than that for an alternate formulation in this mode.}$
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 18L6 HD

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.50		1.92	-	1.92	1.40
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	3.73					
ters	Wo	P	(mW)		-	55.53		55.53	55.53
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)						
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)						
SSC	f _c	f _{awf}	(MHz)	6.15	-	7.26	-	7.26	7.26
_	Dim. of A _{aprt}	Dim. of A _{aprt}			1	1.93	-	1.93	1.93
			Y (cm)		1	0.40	-	0.40	0.40
	PD	t _d	(µsec)	0.60					
tion	PRF	prr	(Hz)	100.16					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.68					
ugu	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)						
er	Focal Length	FLx	(cm)		•	5.90			5.90
o ₽		FLy	(cm)		•	1.80			1.80
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	565.94					
_	Frequency (MHz)			6.25	•	7.50	-	7.50	7.50
Operator Control	Focus (cm)			2.01	-	5.90	-	5.90	5.90
Sp	Gate Size (cm)			0.10	1	0.10	-	0.10	0.10
	Sample Rate (Hz)			100.16	-	31250	-	31250	31250

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 18L6 HD Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.50	-	0.14	-	0.26	0.14
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	3.97					
ter	Wo	P	(mW)		-	4.68		2.87	4.68
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
E	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\rm bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					1.60	
ted	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	1.20					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.12	
\ssc	f _c	f_{awf}	(MHz)	6.97	-	6.48	-	6.78	6.48
_	Dim. of A _{aprt}		X (cm)		-	1.38	-	1.08	1.38
			Y (cm)		-	0.40	-	0.40	0.40
	PD	$t_{\sf d}$	(µsec)	0.27					
tion	PRF	prr	(Hz)	600.00					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.78					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					3.70	
er	Focal Length	FLx	(cm)		-	3.00	-		3.00
₽		FLy	(cm)		-	1.80	-		1.80
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	603.46					
_	Frequency (MHz)			8.00	-	8.00	-	8.00	8.00
rato	Focus (cm)	•	•	1.50	-	3.00	-	2.00	3.00
Operator Control	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
	Sample Rate (Hz)			600.00	-	600	-	600	600

a This Index is not relevant to this operating mode.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4P1

Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.18	0.74	-	-	-	2.80
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	1.75					
ter	Wo	P	(mW)		221.13	-		-	221.13
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	z_1	z _s	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.40					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	2.19	2.16	-	1	-	2.16
_	Dim. of A _{aprt}		X (cm)		1.92	-	-	-	1.92
			Y (cm)		1.60	-	-	-	1.60
	PD	t_{d}	(µsec)	0.89					
tion	PRF	prr	(Hz)	84.69					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	1.96					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)						
e	Focal Length	FLx	(cm)		10.00	-	-		10.00
g		FLy	(cm)		5.00	-	-		5.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	146.06					
o ţ	Focus (cm)			4.30	10.00	-	-	-	10.00
Operator Control	Frequency (MHz)	•	•	2.00	2.25	-	-	-	2.25
ဝီပိ	Res/Speed	•		4	4	-	-	-	4
	Tit is a second of the second								

a This Index is not relevant to this operating mode.

- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4P1

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.38	0.96	-	-	-	3.14
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	2.00					
ters	Wo	P	(mW)		155.95	-		-	155.95
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.06	2.06	-	-	-	2.06
_	Dim. of A _{aprt}		X (cm)		0.74	-	-	-	0.74
			Y (cm)		1.60	-	-	-	1.60
	PD	$t_{\sf d}$	(μsec)	1.22					
tion	PRF	prr	(Hz)	61.24					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.33					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		3.00	-	-		3.00
듈		FLy	(cm)		5.00	-	-		5.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	157.13					
tor	Focus (cm)			3.00	3.00	-	-	-	3.00
Operator Control	Frequency (MHz)			4.00	4.00	-	-	-	4.00
ÖÖ	Res/Speed			5	5	-	-	-	5
2	This Index is not rel	august to this angre	ting made						

a This Index is not relevant to this operating mode.

- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 4P1

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.34	1.16	-	-	-	2.73
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	1.91					
ter	Wo	P	(mW)		142.99	-		-	142.99
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
E	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.70					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	2.01	2.48	-	-	-	2.48
_	Dim. of A _{aprt}		X (cm)		0.94	-	-	-	0.94
			Y (cm)		1.60	-	-	-	1.60
	PD	t_{d}	(μsec)	2.06					
tion	PRF	prr	(Hz)	13.57					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.23					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		4.00	-	-		4.00
₽		FLy	(cm)		5.00	-	-		5.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	146.54					
_	Focus (cm)			4.00	4.00	-	-	-	4.00
rato	Res/Speed			5	5	-	-	-	5
Operator Control	Ensemble Size			7	7	-	-	-	7
0	Frequency (MHz)			2.00	2.50	-	-	-	2.50

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4P1

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.34	-	-	1.12	2.77	2.15
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	1.91					
ters	Wo	P	(mW)		-	-		164.91	164.91
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				69.98		
ic P	Z ₁	Z _S	(cm)				3.70		
onst	Z _{bp}	Z _{bp}	(cm)				2.87		
Acc	Z _{sp}	Z _b	(cm)					6.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.70					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.31	
Assc	f _c	f _{awf}	(MHz)	2.01	-	-	3.36	3.36	3.36
1	Dim. of A _{aprt}		X (cm)		'n	-	1.80	1.80	1.80
			Y (cm)		-	-	1.60	1.60	1.60
	PD	t _d	(µsec)	2.06					
Other Information	PRF	prr	(Hz)	1220.70					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.23					
ufo	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.28	
ē	Focal Length	FLx	(cm)		-	-	7.65		7.65
₽		FLy	(cm)		-	-	5.00		5.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	146.54					
_	Frequency (MHz)			2.00	'n	-	3.50	3.50	3.50
Operator Control	Focus (cm)	•		4.00	-	-	7.65	7.65	7.65
g S	Gate Size (cm)	•		0.30	-	-	0.30	0.30	0.30
٠	Sample Rate (Hz)			1220.7	-	-	8223	8223	8223
а	This Index is not rel	evant to this oners	ating mode						

This Index is not relevant to this operating mode.

F - 34 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4P1

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.24	-	-	0.46	0.93	1.03
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	1.86					
ter	Wo	P	(mW)		-	-		61.56	69.13
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				43.89		
ic P	Z ₁	Z _S	(cm)				3.00		
nst	Z _{bp}	$z_{\sf bp}$	(cm)				2.50		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					4.50	
ted	z@PII _{.3max}	z @ max. I _{pi,α}	(cm)	2.30					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.78	
SSC	f _c	f _{awf}	(MHz)	2.20	-	-	2.19	2.11	3.05
4	Dim. of A _{aprt}		X (cm)		-	-	1.37	1.37	1.37
			Y (cm)		-	-	1.60	1.60	1.60
	PD	t _d	(µsec)	0.88					
Other Information	PRF	prr	(Hz)	600.00					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.21					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					22.68	
ler l	Focal Length	FLx	(cm)		-	-	16.00		16.00
oth		FLy	(cm)		-	-	5.00		5.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	164.06					
_	Frequency (MHz)			2.00	-	-	3.00	2.00	3.00
rato	Focus (cm)			2.80	-	-	16.00	16.00	16.00
Operator Control	Gate Size (cm)			1.00	-	-	1.00	1.00	1.00
0 -	Sample Rate (Hz)			600.00	-	-	600	600	600

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4P1

Operating mode: SCW Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.09	-	1.25	-	2.67	2.77
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	0.13					
ter	Wo	P	(mW)		'n	148.23		111.80	148.23
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Si	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					4.20	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.80					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.53	
ASSC	fc	f _{awf}	(MHz)	2.00	'n	2.50	-	2.00	2.50
_	Dim. of A _{aprt}		X (cm)		'n	0.88	-	0.88	0.88
			Y (cm)		'n	1.60	-	1.60	1.60
	PD	t _d	(μsec)						
ţio	PRF	prr	(Hz)						
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	0.16					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.52	
er	Focal Length	FLx	(cm)		•	14.56	-		14.56
o ₽		FLy	(cm)		•	5.00	-		5.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.45					
	Frequency (MHz)			2.00	-	2.50	-	2.00	2.50
rato	Focus (cm)			6.02	-	14.56	-	14.56	14.56
Operator Control	Gate Size (cm)			-	-	-	-	-	-
0 -	Sample Rate (Hz)			-	-	-	-	-	-

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- Wo data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **4V1** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.19	0.92	-	-	-	2.16
	FDA	IEC	Units						
m	P _{r.3}	p _{ra}	(MPa)	1.84					
eter	Wo	P	(mW)		132.74	-		-	173.18
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Б	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted /	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.70					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ss(f _c	f _{awf}	(MHz)	2.37	2.57	-	-	-	2.32
4	Dim. of A _{aprt}		X (cm)		2.00	-	-	-	2.01
			Y (cm)		1.35	-	-	-	1.35
	PD	$t_{\sf d}$	(µsec)	0.94					
tion	PRF	prr	(Hz)	33.01					
.ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.08					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
ē	Focal Length	FLx	(cm)		4.00	-	-		7.00
듈		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	114.22					
ᅙᅙ	Focus (cm)			2.00	4.00	-	-	-	7.00
Operator Control	Frequency (MHz)			2.00	3.00	-	-	-	2.00
90	Res/Speed			3	3	-	-	-	3

a This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.50	1.11	-	-	-	2.86
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	2.16					
ters	Wo	P	(mW)		187.41	-		-	228.67
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.20					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	2.07	2.19	-	-	-	2.18
_	Dim. of A _{aprt}		X (cm)		2.00	-	-	-	2.01
			Y (cm)		1.35	-	-	-	1.35
	PD	t _d	(µsec)	0.62					
tion	PRF	prr	(Hz)	17.81					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.92					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
er	Focal Length	FLx	(cm)		4.00	-	-		7.00
듈		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	147.39					
tor	Focus (cm)			4.00	4.00	-	-	-	7.00
Operator Control	Frequency (MHz)			4.00	4.50	-	-	-	4.50
90	Res/Speed			2	3	-	-	-	3

a This Index is not relevant to this operating mode.

F - 36 Instructions for Use

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	M	laximum Value		1.18	0.88	-	-	-	3.27
	FDA	IEC	Units						
ø	P _{r.3}	p_{ra}	(MPa)	1.68					
eter	Wo	P	(mW)		114.10	-		-	281.64
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	Z ₁	Z _S	(cm)				ı		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				ı		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.70					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Assc	f _c	f _{awf}	(MHz)	2.03	2.04	-	ı	-	2.04
1	Dim. of A _{aprt}		X (cm)		1.01	-	•	-	2.82
			Y (cm)		1.35	-	•	-	1.35
	PD	$t_{\sf d}$	(μsec)	2.06					
tion	PRF	prr	(Hz)	8.07					
na.	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.04					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
Other Information	Focal Length	FLx	(cm)		4.02	-			29.41
g		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	102.39					
	Focus (cm)			4.02	4.02	-		-	29.41
Operator Control	Res/Speed			5	5	-	•	-	5
Spe	Ensemble Size			12	12	-	•	-	12
0	Frequency (MHz)			2.00	2.75	-	1	-	2.00

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.29	-	-	1.44	3.76	3.65
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	1.85					
sters	Wo	P	(mW)		-	-		297.14	320.88
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				146.73		
i P	Z ₁	Z _S	(cm)				4.6		
nst	Z _{bp}	Z _{bp}	(cm)				3.11		
Acc	Z _{sp}	Z _b	(cm)					7.90	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.20					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.58	
\ss(f _c	f _{awf}	(MHz)	2.05	-	-	2.05	2.05	2.05
_	Dim. of A _{aprt}		X (cm)		-	-	2.51	2.51	2.82
			Y (cm)		-	-	1.35	1.35	1.35
	PD	t _d	(μsec)	2.64					
ţion	PRF	prr	(Hz)	610.35					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.44					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.54	
er	Focal Length	FLx	(cm)			-	10.03		12.03
o₩		FLy	(cm)			-	7.00		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	130.54					
_	Frequency (MHz)			2.00	-	-	2.00	2.00	2.00
rato	Focus (cm)	•	•	5.01	-	-	10.03	10.03	12.03
Operator Control	Gate Size (cm)	•	•	0.40	-	-	0.40	0.40	0.40
J	Sample Rate (Hz)	•	•	610.35	-	-	26042	26042	22321

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

 $^{{\}tt c} \quad \ \ {\tt This formulation for TIS is less than that for an alternate formulation in this mode.}$

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 4V1

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.56	-	-	0.99	1.65	2.02
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.63					
iter:	Wo	P	(mW)		-	-		150.52	150.52
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				79.05		
.인	Z ₁	Z _S	(cm)				3.50		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				2.79		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					3.90	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.70					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					1.02	
\ssc	f _c	f _{awf}	(MHz)	2.83	-	-	2.62	2.62	2.62
_	Dim. of A _{aprt}		X (cm)		-	-	2.01	2.01	2.01
			Y (cm)		-	-	1.35	1.35	1.35
	PD	t _d	(µsec)	0.64					
Other Information	PRF	prr	(Hz)	600.00					
ma.	Pr@ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.05					
ug.	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					30.34	
ē	Focal Length	FLx	(cm)		-	-	10.00		10.00
₽		FLy	(cm)		-	-	7.00		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	384.55					
- a	Frequency (MHz)			3.00	-	-	3.00	3.00	3.00
Operator Control	Focus (cm)	·		2.00	-	-	10.00	10.00	10.00
g S	Gate Size (cm)			1.00	-	-	1.00	1.00	1.00
	Sample Rate (Hz))		600.00	-	-	600	600	600

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1c

Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.40	0.70	-	-	-	1.85
	FDA	IEC	Units						
ro.	P _{r.3}	p _{ra}	(MPa)	2.03					
ters	Wo	P	(mW)		73.44	-		-	103.52
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i D	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.10					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	2.02	3.05	-	-	-	1.99
^	Dim. of A _{aprt}		X (cm)		1.63	-	-	-	1.17
			Y (cm)		1.31	-	-	-	1.31
	PD	$t_{\sf d}$	(µsec)	0.90					
tion	PRF	prr	(Hz)	15.61					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.60					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		4.30	-	-		10.00
o₩		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	177.87					
Operator Control	Focus (cm)			4.30	4.30	-	-	-	10.00
era	Frequency (MHz)		•	2.00	3.00	-	-	-	2.00
80	Res/Speed			5	5	-	-	-	5

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

F - 38 Instructions for Use

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1c

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	In	dex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.37	0.90	-	-	-	3.26
	FDA	IEC	Units						
ø	P _{r.3}	p_{ra}	(MPa)	1.83					
ite:	Wo	P	(mW)		215.31	-		-	215.31
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.10					
<u>S</u>	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	1.78	1.88	-	-	-	1.88
4	Dim. of A _{aprt}		X (cm)		1.63	-	-	-	1.63
			Y (cm)		1.31	-	-	-	1.31
	PD	t _d	(µsec)	0.57					
Other Information	PRF	prr	(Hz)	7.32					
in a	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.35					
ufo.	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		10.00	-	-		10.00
듐		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	112.02					
o to	Focus (cm)			4.00	10.00	-	-	-	10.00
Operator Control	Frequency (MHz)	, ,			4.00	-	-	-	4.00
రిర	Res/Speed				5	-	-	-	5

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1c

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.36	0.93	-	-	-	2.61
	FDA	IEC	Units						
(n	P _{r.3}	p _{ra}	(MPa)	1.92					
eter	Wo	P	(mW)		148.86	-		-	160.98
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	z_1	Z _S	(cm)				-		
nost	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.60					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	1.97	2.49	-	-	-	1.98
_	Dim. of A _{aprt}		X (cm)		1.63	-	-	-	1.63
			Y (cm)		1.31	-	-	-	1.31
	PD	$t_{\sf d}$	(μsec)	1.95					
tion	PRF	prr	(Hz)	13.58					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.36					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
er_	Focal Length	FLx	(cm)		19.99	-	-		20.00
횽		FLy	(cm)		7.00	-	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	155.34					
- a	Focus (cm)			4.00	19.99	-	-	-	20.00
Operator Control	Spacetime			5	5	-	-	-	5
Sol	Ensemble Size			7	7	-	-	-	7
)	Frequency (MHz)			2.00	2.50	-	-	-	2.00

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 4V1c

Operating mode: Pulsed Doppler

			MI		TIS		TIB	TIC
Ind	ex Label			Scan	Nor	n-scan	Non-scan	
					A _{aprt} ≤1	A _{aprt} >1		
Maximum Value			1.24	-	-	1.47	4.51	2.87
FDA	IEC	Units						
P _{r.3}	p _{ra}	(MPa)	1.74					
Wo	P	(mW)		-	-		207.73	189.26
min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				121.05		
Z ₁	Z _S	(cm)				2.50		
Z _{bp}	Z _{bp}	(cm)				2.47		
Z _{sp}	$Z_{\rm b}$	(cm)					5.90	
z@PII.3max	z @ max. I _{pi,α}	(cm)	4.30					
$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.45	
f _c	f _{awf}	(MHz)	1.97	1	-	2.54	2.06	2.42
Dim. of A _{aprt}		X (cm)		-	-	1.63	1.63	1.63
		Y (cm)		-	-	1.31	1.31	1.31
PD	$t_{\sf d}$	(μsec)	1.89					
PRF	prr	(Hz)	100.16					
P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.31					
d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.40	
Focal Length	FLx	(cm)		1	-	10.00		15.01
	FLy	(cm)		1	-	7.00		7.00
I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	138.23					
Frequency (MHz)			2.00	-	-	2.00	2.00	2.50
Focus (cm)			6.00	-	-	10.00	12.01	15.01
Gate Size (cm)			0.15	-	-	0.15	0.15	0.15
Sample Rate (Hz)			100.16	-	-	12019	11160	9191
	Maximum Value FDA Pr.3 Wo min of [W.3(Z1), Int.3(Z1)] Z1 Zbp Zsp Z@PII 3max deq(Zsp) fc Dim. of Aaprt PD PRF Pr@ PIImax deq@ PIImax Focal Length Ipa.3@ MImax Frequency (MHz) Focus (cm) Gate Size (cm) Sample Rate (Hz)	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{ c c c c c } \hline \textbf{Maximum Value} & 1.24 & - \\ \hline \textbf{FDA} & \textbf{IEC} & \textbf{Units} \\ \hline P_{r.3} & p_{ra} & (MPa) & 1.74 \\ \hline W_o & P & (mW) & - \\ \hline \min \text{ of } [W_3(z_1), & Min. \text{ of } [P_o(z_s), I_{la,a}(z_s)] & (cm) \\ \hline Z_{bp} & Z_{bp} & (cm) & \\ \hline Z_{bp} & Z_{bp} & (cm) & \\ \hline Z_{eq}PII_{3max} & z @ max. I_{pi,a} & (cm) & 4.30 \\ \hline d_{eq}(z_{pp}) & d_{eq}(z_{p}) & (cm) & \\ \hline Dim. \text{ of } A_{aprt} & X & (cm) & - \\ \hline PD & t_d & (\musec) & 1.89 \\ \hline PRF & prr & (Hz) & 100.16 \\ \hline P_{r}@ PII_{max} & P_{r}@ max. I_{pi} & (cm) & 2.31 \\ \hline d_{eq}@ PII_{max} & d_{eq}@ max. I_{pi} & (cm) & \\ \hline P_{rocus} & PII_{max} & I_{pa,3}@ MI max & (W/cm^2) & 138.23 \\ \hline Frequency & (MHz) & 0.15 & - \\ \hline Sample Rate & (Hz) & 100.16 & - \\ \hline \end{array} $	$ \begin{array}{ c c c c c c c } \hline \textbf{Maximum Value} & 1.24 & - & - \\ \hline \textbf{FDA} & \textbf{IEC} & \textbf{Units} & & & & \\ \hline P_{r.3} & p_{ra} & (MPa) & 1.74 & & & \\ \hline W_o & P & (mW) & - & - & - \\ \hline \min \text{ of } [W_3(z_1), & Min. \text{ of } [P_o(z_6), I_{1a.a}(z_2)] & & & \\ \hline Z_1 & Z_5 & (cm) & & & \\ \hline Z_{bp} & Z_{bp} & Z_{bp} & (cm) & & \\ \hline Z_{gp} & Z_{b} & (cm) & & & \\ \hline Z_{gp} & Z_{b} & (cm) & & & \\ \hline Z_{gp} & Z_{gp} & Z_{gp} & (cm) & & \\ \hline Z_{gp} & Z_{gp} & Z_{gp} & Z_{gp} & (cm) & & \\ \hline Z_{gp} & Z_{gp} & Z_{gp} & Z_{gp} & Z_{gp} & \\ \hline Z_{gp} & Z_{gp} & Z_{gp} & Z_{gp} & Z_{gp} & \\ \hline Z_{gp} & Z_{gp} & Z_{gp} & Z_{gp} & Z_{gp} & Z_{gp} & \\ \hline Z_{gp} & Z_{g$	$ \begin{array}{ c c c c c c c } \hline \textbf{Naximum Value} & & & & & & & & & & & & & & \\ \hline & & & &$	$ \begin{array}{ c c c c c c c c } \hline \textbf{Maximum Value} & & & & & & & & & & & & & & & & & & &$

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 4V1c

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.80	-	-	0.41	1.20	1.02
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	1.16					
ter	Wo	P	(mW)		-	-		67.27	67.27
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				46.27		
S.	Z ₁	Z _S	(cm)				2.90		
onst	Z _{bp}	Z _{bp}	(cm)				2.47		
Acc	Z _{sp}	Z _b	(cm)					5.70	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.10					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.61	
ASSC	f _c	f _{awf}	(MHz)	2.02	-	-	1.87	1.87	1.75
_	Dim. of A _{aprt}		X (cm)		-	-	1.63	1.63	1.63
			Y (cm)		-	-	1.31	1.31	1.31
	PD	$t_{\sf d}$	(μsec)	0.86					
Other Information	PRF	prr	(Hz)	600.00					
ща	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	1.49					
ugu	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					18.71	
ē	Focal Length	FLx	(cm)		-	-	16.00		16.00
₽		FLy	(cm)		-	-	7.00		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	51.95					
	Frequency (MHz)			1.75	-	-	1.75	1.75	1.75
Operator Control	Focus (cm)			4.30	-	-	16.00	16.00	16.00
g S	Gate Size (cm)			1.00	-	-	1.00	1.00	1.00
	Sample Rate (Hz)			600.00	-	-	600	600	600
а	This Index is not rel	evant to this oners	ating mode						

This Index is not relevant to this operating mode.

F - 40 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **4V1c** Operating mode: **SCW Doppler**

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.08	-	0.79	-	3.29	2.10
	FDA	IEC	Units						
ro.	P _{r.3}	p _{ra}	(MPa)	0.11					
je:	Wo	P	(mW)		-	98.05		98.05	98.05
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iSi F	z_1	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					3.00	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.30					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.46	
\ssc	f _c	f _{awf}	(MHz)	1.80	-	1.80	-	1.80	1.80
~	Dim. of A _{aprt}		X (cm)		-	0.82	-	0.82	0.82
			Y (cm)		-	1.31	-	1.31	1.31
	PD	t_{d}	(µsec)						
ţion	PRF	prr	(Hz)						
шa	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	0.13					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.45	
e	Focal Length	FLx	(cm)		-	10.51	-		10.51
듐		FLy	(cm)		-	7.00	-		7.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.37					
_	Frequency (MHz)			1.80	-	1.80	-	1.80	1.80
rato	Focus (cm)			4.01	-	10.51	-	10.51	10.51
Operator Control	Gate Size (cm)			-	-	-	-	-	-
0 2	Sample Rate (Hz)			-	-	-	-	-	-
	T1: 1 1 1 1 1 1			ı	ı	1			

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **8V3** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.23	0.88	-	-	-	1.31
	FDA	IEC	Units						
ro.	P _{r.3}	p _{ra}	(MPa)	2.42					
ters	Wo	P	(mW)		61.37	-		-	41.16
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i D	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.80					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	3.80	3.79	-	-	-	3.85
^	Dim. of A _{aprt}		X (cm)		1.92	-	-	-	0.54
			Y (cm)		0.90	-	-	-	0.90
	PD	$t_{\sf d}$	(μsec)	0.48					
tion	PRF	prr	(Hz)	32.12					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.27					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		9.00	-	-	-	1.50
o₩		FLy	(cm)		4.00	-	-	-	4.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	297.58					
Operator Control	Focus (cm)			3.00	9.00	-	-	-	1.50
era	Frequency (MHz)			4.00	4.00	-	-	-	4.00
80	Res/Speed			5	5	-	-	-	5

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

 $^{{\}tt c} \quad \ \ {\tt This formulation for TIS is less than that for an alternate formulation in this mode.}$

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 8V3

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.53	0.88	-	-	-	1.59
	FDA	IEC	Units						
ø	P _{r.3}	p_{ra}	(MPa)	2.53					
eter	Wo	P	(mW)		69.83	-		-	49.86
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i E	z_1	Z _S	(cm)				ī		
Snc	Z _{bp}	$z_{\sf bp}$	(cm)				ī		
Ä	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.90					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Assı	f _c	f _{awf}	(MHz)	2.74	3.32	-	ī	-	3.27
`	Dim. of A _{aprt}		X (cm)		1.92	-	-	-	0.54
			Y (cm)		0.90	-	-	-	0.90
	PD	t _d	(µsec)	0.58					
ţion	PRF	prr	(Hz)	32.38					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.20					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		9.00	-	-		1.50
듐		FLy	(cm)		4.00	-	-		4.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	223.41					
o to	Focus (cm)			3.00	9.00	-	-	-	1.50
Operator Control	Frequency (MHz)			5.00	7.00	-	-	-	6.00
ဝီပိ	Res/Speed			5	5	-	-	-	5
_	This Indovis not re							•	

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 8V3

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.49	1.15	-	-	-	2.36
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.39					
ters	Wo	P	(mW)		92.05	-		-	138.51
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S.	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.60					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	2.59	2.59	-	-	-	2.57
_	Dim. of A _{aprt}		X (cm)		1.00	-	-	-	1.92
			Y (cm)		0.90	-		-	0.90
	PD	t _d	(µsec)	1.67					
tion	PRF	prr	(Hz)	13.74					
шa	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.29					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
erl	Focal Length	FLx	(cm)		4.01	-			9.00
ㅎ		FLy	(cm)		4.00	-	-		4.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	167.78					
	Focus (cm)			5.00	4.01	-	-	-	9.00
Operator Control	Res/Speed			5	5	-	1	-	5
g S	Ensemble Size			7	7	-	1	-	7
0	Frequency (MHz)			2.50	2.50	-		-	2.50
9	This Index is not rel	levant to this opera	ting mode				·		,

This Index is not relevant to this operating mode.

F - 42 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 8V3

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.49	-	-	1.17	3.96	2.36
	FDA	IEC	Units						
ø	P _{r.3}	p _{ra}	(MPa)	2.40					
ter	Wo	P	(mW)		-	-		131.27	139.73
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				93.31		
. <u>S</u>	Z ₁	Z _s	(cm)				2.30		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				2.22		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					5.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.60					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.28	
Assc	f _c	f _{awf}	(MHz)	2.60	-	1	2.68	2.68	2.57
1	Dim. of A _{aprt}		X (cm)			-	1.92	1.75	1.92
			Y (cm)		-	-	0.90	0.90	0.90
	PD	$t_{\sf d}$	(μsec)	1.72					
tion	PRF	prr	(Hz)	1775.57					
na.	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.94					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.29	
Other Information	Focal Length	FLx	(cm)		-	1	8.01		8.01
g		FLy	(cm)		-	1	4.00		4.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	138.31					
	Frequency (MHz)			2.50	-	-	2.50	2.50	2.50
Operator Control	Focus (cm)			3.00	-	-	8.01	7.01	8.01
Con	Gate Size (cm)			0.30	-	-	0.30	0.30	0.30
0	Sample Rate (Hz)			1775.57	-	-	15625	17361	15625

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 8V3

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.56	-	0.40	-	0.69	0.56
	FDA	IEC	Units						
(n	P _{r.3}	p_{ra}	(MPa)	3.03					
ter	Wo	P	(mW)		-	27.90		27.90	27.90
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					3.10	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.80					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.42	
SSO	f _c	f _{awf}	(MHz)	3.80	-	3.70	-	3.61	3.76
4	Dim. of A _{aprt}		X (cm)		-	1.37	-	1.37	1.37
			Y (cm)		-	0.90	-	0.90	0.90
	PD	t _d	(µsec)	0.49					
tion	PRF	prr	(Hz)	600.00					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.11					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					11.67	
er	Focal Length	FLx	(cm)		-	10.50	-		10.50
₽		FLy	(cm)		-	4.00	-		4.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	454.07					
L	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
rato	Focus (cm)				-	10.50	-	4.50	10.50
Operator Control	Gate Size (cm)			1.02	-	1.02	-	1.02	1.02
ا ا	Sample Rate (Hz)	1		600.00	-	600	-	600	600

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 8V3 Operating mode: SCW Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.09	-	0.49	-	2.21	1.98
	FDA	IEC	Units						
S	P _{r.3}	p_{ra}	(MPa)	0.15					
ate.	Wo	P	(mW)		-	41.54		41.54	41.54
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	z_1	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					0.80	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.80					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.37	
Assc	f _c	f _{awf}	(MHz)	2.50	-	2.50	-	2.50	2.50
_	Dim. of A _{aprt}		X (cm)		-	0.24	-	0.24	0.24
			Y (cm)		-	0.90	-	0.90	0.90
	PD	$t_{\sf d}$	(µsec)						
Other Information	PRF	prr	(Hz)						
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.16					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.37	
e	Focal Length	FLx	(cm)		-	2.01	-		2.01
듈		FLy	(cm)		-	4.00	-		4.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.34					
_	Frequency (MHz)	•	•	2.50	-	2.50	-	2.50	2.50
Operator Control	Focus (cm)	•	•	2.01	-	2.01	-	2.01	2.01
Spel	Gate Size (cm)	•	•	-	-	-	-	-	-
0 -	Sample Rate (Hz)			-	-	-	-	-	-
	This Index is not rel	avant to this apare	ting made						

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 10V4 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.16	0.83	-	-	-	1.05
	FDA	IEC	Units						
m	P _{r.3}	p _{ra}	(MPa)	2.87					
ter	Wo	P	(mW)		32.44	-		-	32.44
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.00					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSO	f _c	f _{awf}	(MHz)	5.81	5.82	-	-	-	5.82
٩	Dim. of A _{aprt}		X (cm)		1.32	-	-	-	0.94
			Y (cm)		0.50	-	-	-	0.50
	PD	$t_{\sf d}$	(µsec)	0.24					
ion	PRF	prr	(Hz)	24.92					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.29					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		3.00	-	-		3.00
Ö ₽		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	308.11					
Operator Control	Focus (cm)		•	2.00	3.00	-	-	-	3.00
era	Frequency (MHz)	Frequency (MHz)			6.00	-	-	-	6.00
90	Res/Speed			5	5	-	-	-	5

This Index is not relevant to this operating mode.

F - 44 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **10V4** Ope

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.16	0.65	-	-	-	1.00
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.57					
ters	Wo	P	(mW)		31.90	-		-	31.90
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.90					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	4.69	4.65	-	-	-	4.65
•	Dim. of A _{aprt}				1.32	-	-	-	0.94
			Y (cm)		0.50	-	-	-	0.50
	PD	t_{d}	(µsec)	0.25					
ijon	PRF	prr	(Hz)	23.91					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.34					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
er	Focal Length	FLx	(cm)		4.41	-	-		4.41
g		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	206.96					
o to	Focus (cm)			2.00	4.41	-	-	-	4.41
Operator Control	Frequency (MHz)			10.00	10.00	-	-	-	10.00
ర్ధిర	Res/Speed			3	3	-	-	-	3
	This Indovis not so								

a This Index is not relevant to this operating mode.

- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 10V4

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.48	1.29	-	-	-	1.74
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	3.35					
sters	Wo	P	(mW)		47.20	-		-	53.77
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.80					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Asso	f _c	f _{awf}	(MHz)	5.03	5.60	-	-	-	4.66
_	Dim. of A _{aprt}		X (cm)		1.00	-	-	-	1.00
			Y (cm)		0.50	-	-	-	0.50
	PD	$t_{\sf d}$	(μsec)	0.66					
tion	PRF	prr	(Hz)	12.20					
шa	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.85					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
Other Information	Focal Length	FLx	(cm)		4.01	-	-		4.01
g		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	437.62					
_	Focus (cm)			1.50	4.01	-	-	-	4.01
rato	Res/Speed	Res/Speed			5	-	-	-	5
Operator Control	Ensemble Size	Ensemble Size			7	-	-	-	7
	Frequency (MHz)		•	5.00	6.00	-	-	-	4.50

a This Index is not relevant to this operating mode.

- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 10V4

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.05		1.75	-	2.52	2.02
	FDA IEC Units								
ø	P _{r.3}	p_{ra}	(MPa)	2.24					
eter	Wo	P	(mW)		-	63.73		60.76	73.90
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					2.90	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.70					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.21	
\ssc	f _c	f _{awf}	(MHz)	4.49	1	5.78	-	4.64	4.66
_	Dim. of A _{aprt}		X (cm)			1.32	-	0.92	1.32
			Y (cm)		-	0.50	-	0.50	0.50
	PD	$t_{\sf d}$	(µsec)	0.75					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.84					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.21	
ē	Focal Length	FLx	(cm)		1	7.01	-		7.01
윰		FLy	(cm)		-	3.00	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	232.32					
_	Frequency (MHz)			4.50	1	6.00	-	4.50	4.50
Operator Control	Focus (cm)			2.50	-	7.01	-	3.67	7.01
g S	Gate Size (cm)			0.15	-	0.15	-	0.15	0.15
	Sample Rate (Hz)			100.16	-	17361	-	14204	17361

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 10V4

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.50	-	0.48	-	0.48	0.71
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.32					
ter	Wo	P	(mW)		-	21.96		21.96	21.96
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)						
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.80					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)						
Asso	f _c	f _{awf}	(MHz)	4.82	-	4.61	-	4.61	4.61
~	Dim. of A _{aprt}		X (cm)		-	0.94	-	0.94	0.94
			Y (cm)		-	0.50	-	0.50	0.50
	PD	t _d	(µsec)	0.46					
tion	PRF	prr	(Hz)	600.00					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.79					
JQ.	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)						
e	Focal Length	FLx	(cm)		-	9.52	-		9.52
o ₽		FLy	(cm)		-	3.00	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	419.57					
	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
Operator Control	Focus (cm)			1.00	-	9.52	-	9.52	9.52
a S	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
	Sample Rate (Hz)			600.00	-	600	-	600	600
а	This Index is not rel	evant to this oners	ating mode						·

This Index is not relevant to this operating mode.

F - 46 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 10V4 Operating mode: SCW Doppler

Index I abel	MI		TIS		TIB	TIC		
Ind	ex Label			Scan	Non	ı-scan	Non-scan	
					A _{aprt} ≤1	A _{aprt} >1		
Maximum Value			0.07	-	0.62	-	2.40	1.33
FDA	IEC	Units						
P _{r,3}	p_{ra}	(MPa)	0.15					
Wo	P	(mW)		-	32.44		32.44	33.69
min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Z ₁	Z _S	(cm)				-		
Z _{bp}	$z_{\sf bp}$	(cm)				-		
Z _{sp}	z_{b}	(cm)					1.90	
z@PII.3max	z @ max. I _{pi,α}	(cm)	1.90					
$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.18	
f _c	f _{awf}	(MHz)	4.00	1	4.00	-	4.00	4.00
Dim. of A _{aprt}		X (cm)		-	0.62	-	0.62	0.63
		Y (cm)		-	0.50	-	0.50	0.50
PD	$t_{\sf d}$	(μsec)						
PRF	prr	(Hz)						
P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	0.19					
d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.17	
Focal Length	FLx	(cm)		-	4.99	-		6.00
	FLy	(cm)		-	3.00	-		3.00
I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.50					
Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
Focus (cm)			3.00	-	4.99	-	4.99	6.00
Gate Size (cm)			-	-	-	-	-	-
Sample Rate (Hz)			-	-	-	-	-	-
	$\begin{tabular}{ll} Maximum Value \\ FDA \\ P_{r,3} \\ W_o \\ min of [W_{.3}(z_1), $	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{ c c c c c c c }\hline \textbf{Maximum Value} & 0.07 & -\\ \hline \textbf{FDA} & \textbf{IEC} & \textbf{Units} \\ \hline P_{r,3} & p_{ra} & (MPa) & 0.15 \\ \hline W_o & P & (mW) & -\\ \hline \min \ of \ [W_3(z_1), & Min. \ of \ [P_o(z_s), \\ I_{1a,o}(z_s)] & I_{1a,o}(z_s)] & (mW) \\ \hline z_1 & z_s & (cm) & \\ \hline z_bp & z_{bp} & (cm) & \\ \hline z_{bp} & z_{bp} & (cm) & \\ \hline z_{gp} & z_{b} & (cm) & \\ \hline z_{gp} & z_{gp} & z_{gp} & z_{gp} & \\ \hline z_{gp} & z_{gp} & z_{gp} & z_{gp} & \\ \hline z_{gp} & z_{gp} & z_{gp} & z_{gp} & z_{gp} & \\ \hline z_{gp} & z_{gp} & z_{gp} & z_{gp} & z_{gp} & z_{gp} & \\ \hline z_{gp} & $	$ \begin{array}{ c c c c c c c c c } \hline \textbf{Maximum Value} & 0.07 & - & 0.62 \\ \hline \textbf{FDA} & \textbf{IEC} & \textbf{Units} & & & & & & & & \\ \hline P_{r,3} & p_{ra} & (MPa) & 0.15 & & & & & & & \\ \hline W_o & P & (mW) & & - & 32.44 & & & \\ \hline min of [W_3(z_1), & Min. of [P_a(z_s), I_{la.a}(z_s)] & (mW) & & - & 32.44 & & \\ \hline min of [W_3(z_1), & Min. of [P_a(z_s), I_{la.a}(z_s)] & (mW) & & - & & & \\ \hline I_{TA,3}(z_1)] & I_{la.a}(z_s)] & (cm) & & & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & & & & \\ \hline Z_{bp} & z_b & (cm) & $	$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	$\begin{array}{ c c c c c c c c c c c c c c c c c c c$

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: V5Ms Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.83	0.55	-	-	-	0.67
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	1.65					
ters	Wo	P	(mW)		19.99	-		-	27.44
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				-		
i.	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.90					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	3.84	5.92	-	-	-	3.79
•	Dim. of A _{aprt}		X (cm)		0.96	-	-	-	0.96
			Y (cm)		0.85	-	-	-	0.85
	PD	$t_{\sf d}$	(µsec)	0.50					
ion	PRF	prr	(Hz)	90.46					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.13					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e –	Focal Length	FLx	(cm)		2.00	-	-		2.00
oth		FLy	(cm)		5.50	-	-		5.50
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	125.60					
tor o	Focus (cm)			2.00	2.00	-	-	-	2.00
Operator Control	Frequency (MHz)	Frequency (MHz)			6.00	-	-	-	4.00
ర్ధిర	Res/Speed			0	0	-	-	-	5

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: V5Ms

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.12	0.52	-	-	-	0.66
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	2.21					
ter	Wo	P	(mW)		23.64	-		-	23.64
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
.S	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.30					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Assc	f _c	f _{awf}	(MHz)	3.84	3.82	-	-	-	3.82
_	Dim. of A _{aprt}		X (cm)		0.96	-	-	-	0.96
			Y (cm)		0.85	-	-	-	0.85
	PD	$t_{\sf d}$	(µsec)	0.97					
Other Information	PRF	prr	(Hz)	13.03					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.99					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
ē	Focal Length	FLx	(cm)		4.00	-	-		4.00
£		FLy	(cm)		5.50	-	-		5.50
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	208.84					
_	Focus (cm)			3.00	4.00	-	-	-	4.00
Operator Control	Res/Speed			0	5	-	-	-	5
g S	Ensemble Size			7	7	-	-	-	7
	Frequency (MHz)			4.00	4.00	-	-	-	4.00
2	This Index is not re	lovant to this oper	ting mode					•	

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: V5Ms

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.12	-	0.55	-	0.88	0.73
	FDA	IEC	Units						
·0	P _{r.3}	p _{ra}	(MPa)	2.22					
ters	Wo	P	(mW)		-	29.34		21.12	15.39
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S.	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	z _b	(cm)					1.30	
eq	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.50					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.38	
SSC	f _c	f _{awf}	(MHz)	3.85	-	3.96	-	3.95	3.92
٩	Dim. of A _{aprt}	-	X (cm)		-	0.96	-	0.51	0.25
			Y (cm)		-	0.85	-	0.85	0.85
	PD	t _d	(µsec)	0.93					
Other Information	PRF	prr	(Hz)	100.16					
mat	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.96					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.35	
ē	Focal Length	FLx	(cm)		-	4.01	-		1.01
₽		FLy	(cm)		-	5.50	-		5.50
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	196.78					
_	Frequency (MHz)	-		4.00	-	4.00	-	4.00	4.00
Operator Control	Focus (cm)			4.00	-	4.01	-	2.01	1.01
Spel	Gate Size (cm)			0.15	-	0.15	-	0.15	0.15
0 -	Sample Rate (Hz)			100.16	-	11160	-	11160	11160
а	This Index is not rel	evant to this opera	iting mode.			•		•	

This Index is not relevant to this operating mode.

F - 48 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: V5Ms

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.16	-	0.41	-	0.55	0.55
	FDA	IEC	Units						
(n	P _{r.3}	p _{ra}	(MPa)	2.29					
ter	Wo	P	(mW)		-	22.50		13.63	22.50
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				1		
: <u>S</u>	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					1.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.40	
Asso	f _c	f _{awf}	(MHz)	3.83	-	3.87	-	3.93	3.77
1	Dim. of A _{aprt}		X (cm)		-	0.96	-	0.66	0.96
			Y (cm)		-	0.85	-	0.85	0.85
	PD	$t_{\sf d}$	(µsec)	0.47					
tion	PRF	prr	(Hz)	600.00					
na H	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.07					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					11.80	
ē	Focal Length	FLx	(cm)		-	9.00	1		9.00
g		FLy	(cm)		-	5.50	1		5.50
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	258.25					
_	Frequency (MHz)			4.00	-	4.00	1	4.00	4.00
rato	Focus (cm)			3.00	-	9.00		1.00	9.00
Operator Control	Gate Size (cm)			1.00	-	1.00		1.00	1.00
0	Sample Rate (Hz)			600.00	-	600	1	600	600

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: V5Ms

Operating mode: SCW Doppler

Index Label			MI		TIS		TIB	TIC
Inde	ex Label			Scan	Nor	ı-scan	Non-scan	
					A _{aprt} ≤1	A _{aprt} >1		
Maximum Value			0.05	-	0.39	-	1.25	0.94
FDA	IEC	Units						
P _{r.3}	p _{ra}	(MPa)	0.08					
Wo	P	(mW)		-	24.80		24.80	19.83
min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
z_1	Z _S	(cm)				-		
Z _{bp}	$Z_{ m bp}$	(cm)				-		
Z _{sp}	Z _b	(cm)					1.10	
z@PII.3max	z @ max. I _{pi,α}	(cm)	1.10					
$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.35	
f _c	f _{awf}	(MHz)	3.31	-	3.31	-	3.31	3.82
Dim. of A _{aprt}		X (cm)		-	0.42	-	0.42	0.25
		Y (cm)		-	0.85	-	0.85	0.85
PD	t _d	(µsec)						
PRF	prr	(Hz)						
P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.09					
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.35	
Focal Length	FLx	(cm)		-	2.01	-		1.01
	FLy	(cm)		-	5.50	-		5.50
I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.22					
Frequency (MHz)			3.50	-	3.50	-	3.50	3.50
Focus (cm)				-	2.01	-	2.01	1.01
Gate Size (cm)			-	-	-	-	-	-
Sample Rate (Hz)			-	-	-	-	-	-
	$\begin{tabular}{ll} \textbf{Maximum Value} \\ \hline \textbf{FDA} \\ P_{r,3} \\ W_o \\ min of [W_{:3}(z_1), 1, 1, 2, 3, 2, 1]] \\ Z_1 \\ Z_{bp} \\ Z_{sp} \\ Z_{gp} \\ Z_{gp} \\ Dim. of A_{apt} \\ Dim. of A_{apt} \\ PD \\ PRF \\ P_{f}@ PII_{max} \\ d_{eq}@ PII_{max} \\ Focal Length \\ \hline I_{pa,3}@ MI_{max} \\ Frequency (MHz) \\ Focus (cm) \\ Gate Size (cm) \\ \hline \end{tabular}$		$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{ c c c c c } \hline \textbf{Maximum Value} & 0.05 & - \\ \hline \textbf{FDA} & \textbf{IEC} & \textbf{Units} \\ \hline P_{\Gamma.3} & p_{\Gamma a} & (MPa) & 0.08 \\ \hline W_o & P & (mW) & - \\ \hline \min of [W_3(z_1), & Min. of [P_a(z_s), I_{1a.a}(z_s)] & (cm) \\ \hline Z_1 & Z_s & (cm) & \\ \hline Z_{bp} & Z_{bp} & (cm) & \\ \hline Z_{0p} & Z_{0p} & Z_{0p} & \\ \hline Z_{0p} & Z_{0p} & (cm) & \\ \hline Z_{0p} & Z_{0p} & Z_{0p} & Z_{0p} & \\ \hline Z_{0p} & Z_{0p} & Z_{0p} & Z_{0p} & \\ \hline Z_{0p} & Z_{0p} & Z_{0p} & Z_{0p} & \\ \hline Z_{0p} & Z_{0$	$ \begin{array}{ c c c c c c } \hline & & & & & & & & & & & & & \\ \hline & & & &$	$ \begin{array}{ c c c c c c c } \hline \text{Index Label} & Scan & No-scan \\ \hline & A_{aprt} \leq 1 & A_{aprt} \geq 1 \\ \hline & A_{aprt} \leq 1 & A_{aprt} \leq 1 \\ \hline & A_{aprt} \leq 1 & A_{aprt} \leq 1 \\ \hline & A_{aprt} \leq 1 & A_{aprt} \leq 1 \\ \hline & P_{f.3} & P_{fra} & (MPa) & 0.08 & & & & & & & \\ \hline & W_o & P & (mW) & & - & 24.80 & & & & & \\ \hline & min of [W_3(z_1), & Min. of [P_0(z_5), & (mW) & & - & 24.80 & & & & \\ \hline & min of [W_3(z_1)], & Min. of [P_0(z_5), & (mW) & & - & 24.80 & & & & \\ \hline & V_{f.a,3}(z_1)], & Min. of [P_0(z_5), & (mW) & & - & 24.80 & & & & \\ \hline & V_{f.a,3}(z_1)], & Min. of [P_0(z_5), & (mW) & & - & 24.80 & & & \\ \hline & M_{f.a,a}(z_5)], & Min. of [P_0(z_5), & (mW) & & - & 24.80 & & & \\ \hline & V_{f.a,3}(z_1)], & V_{f.a,a}(z_5), & (mW) & & - & 24.80 & & & \\ \hline & V_{f.a,3}(z_1)], & V_{f.a,a}(z_5), & (mW) & & - & 24.80 & & & \\ \hline & V_{f.a,3}(z_1)], & V_{f.a,a}(z_5), & (mW) & & - & 24.80 & & \\ \hline & V_{f.a,3}(z_1)], & V_{f.a,a}(z_5), & (mW) & & - & 2.01 & & \\ \hline & V_{f.a,3}(z_1)], & V_{f.a,a}(z_5), & (mW) & & - & 2.01 & & -\\ \hline & V_{f.a,3}(z_1)], & V_{f.a,a}(z_1), & V_{f.a,a$	$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$

- a This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: V7M

Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.94	0.32	-	-	-	0.49
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	1.89					
je:	Wo	P	(mW)		16.69	-		-	16.69
Associated Acoustic Parameters	min of [W $_3$ (z $_1$), I _{TA.3} (z $_1$)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iSi F	z_1	z _s	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.10					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	4.09	4.07	-	1	-	4.07
_	Dim. of A _{aprt}		X (cm)		0.67	-	-	-	0.67
			Y (cm)		0.73	-	-	-	0.73
	PD	t_{d}	(µsec)	0.52					
tion	PRF	prr	(Hz)	26.10					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.21					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
e	Focal Length	FLx	(cm)		1.00	-	-		1.00
듐		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	172.02					
ᅙ	Focus (cm)	•		1.00	1.00	-	-	-	1.00
Operator Control	Frequency (MHz)			4.00	4.00	-	-	-	4.00
ဝီပိ	Res/Speed			5	5	-	-	-	5
	T1: 1 :								

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: V7M

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$				Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.06	0.35	-	-	-	0.53
	FDA	IEC	Units						
·0	P _{r.3}	p_{ra}	(MPa)	2.10					
ters	Wo	P	(mW)		15.24	-			9.77
Associated Acoustic Parameters		Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S.	Z ₁	Z _s	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.00					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	3.91	3.98	-	-	-	3.95
~	Dim. of A _{aprt}		X (cm)		0.75	-	-	-	0.25
			Y (cm)		0.73	-		-	0.73
	PD	t _d	(µsec)	1.01					
Other Information	PRF	prr	(Hz)	11.92					
E a	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.45					
JQ.	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
ē	Focal Length	FLx	(cm)		3.00	-			1.00
듈		FLy	(cm)		3.00	-			3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	157.74					
	Focus (cm)			2.00	3.00	-	-	-	1.00
Operator Control	Res/Speed			5	5	-	1	-	5
g S	Ensemble Size			7	7	-	1	-	7
0	Frequency (MHz)			4.00	4.00	-		-	4.00
2	This Index is not rel	levant to this opera	ting mode						

This Index is not relevant to this operating mode.

F - 50 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: V7M

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.48	-	0.45	-	1.48	0.71
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	2.94					
ter	Wo	P	(mW)		-	23.57		23.57	23.57
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.90	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.80					
<u>cia</u>	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.21	
\ssc	f _c	f _{awf}	(MHz)	3.92	-	4.00	-	4.00	3.98
_	Dim. of A _{aprt}		X (cm)			0.75	-	0.75	0.75
			Y (cm)		-	0.73	-	0.73	0.73
	PD	$t_{\sf d}$	(μsec)	1.00					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.67					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.21	
ē	Focal Length	FLx	(cm)		-	3.00	-		3.00
£		FLy	(cm)		-	3.00	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	405.85					
	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
Operator Control	Focus (cm)			3.01	-	3.00	-	3.00	3.00
g S	Gate Size (cm)			0.15	-	0.15	-	0.15	0.15
	Sample Rate (Hz)			100.16	-	15625	-	15625	15625

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: V7M

Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.16	-	0.34	-	0.72	0.46
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	2.30					
ster	Wo	P	(mW)		1	17.84		17.24	17.84
Associated Acoustic Parameters	min of [W $_{.3}(z_1)$, I $_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is F	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					2.10	
ted	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	2.20					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.30	
\ss(fc	f _{awf}	(MHz)	3.92	1	3.98	-	4.00	4.00
_	Dim. of A _{aprt}		X (cm)		1	1.02	-	1.02	1.02
			Y (cm)		1	0.73	-	0.73	0.73
	PD	$t_{\sf d}$	(μsec)	0.47					
tion	PRF	prr	(Hz)	600.00					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.05					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					9.58	
er	Focal Length	FLx	(cm)		-	11.00	-		11.00
₽		FLy	(cm)		-	3.00	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	232.41					
	Frequency (MHz)	•		4.00	-	4.00	-	4.00	4.00
rato	Focus (cm)	•		3.00	-	11.00	-	7.00	11.00
Operator Control	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
0	Sample Rate (Hz)	•		600.00	-	600	-	600	600

- a This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: V7M Operating mode: SCW Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.04	-	0.27	-	0.68	0.52
	FDA	IEC	Units						
ro.	P _{r.3}	p _{ra}	(MPa)	0.07					
ter	Wo	P	(mW)		-	15.39		10.16	10.16
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
.ii	z_1	Z _S	(cm)				-		
net	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.00	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.00					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.26	
\ssc	f _c	f _{awf}	(MHz)	3.62	-	3.62	-	3.62	3.98
1	Dim. of A _{aprt}		X (cm)		-	0.45	-	0.25	0.25
			Y (cm)		-	0.73	-	0.73	0.73
	PD	$t_{\sf d}$	(µsec)						
ţion	PRF	prr	(Hz)						
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.08					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.26	
e	Focal Length	FLx	(cm)		-	2.00	-		1.01
듐		FLy	(cm)		-	3.00	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.15					
_	Frequency (MHz)		3.75	-	3.75	-	3.75	3.75	
rato	Focus (cm)			1.01	-	2.00	-	1.01	1.01
Operator Control	Gate Size (cm)			-	-	-	-	-	-
0 -	Sample Rate (Hz)			-	-	-	-	-	-
	Sample Rate (Hz)			1		l			

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EV-8C4** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.55	0.73	-	-	-	0.92
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.42					
ters	Wo	P	(mW)		37.18	-		-	37.18
arame	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
nsti	Z _{bp}	Z _{bp}	(cm)				-		
Associated Acoustic Parameters	Z _{sp}	Z _b	(cm)					-	
	Z _{sp}	z @ max. I _{pi,α}	(cm)	1.40					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	4.84	4.72	-	-	-	4.72
٩	Dim. of A _{aprt}				1.24	-	-	-	0.89
			Y (cm)		0.50	-	-	-	0.50
	PD	t _d	(μsec)	0.30					
ion	PRF	prr	(Hz)	28.76					
ma	P _r @ PII max	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.32					
Other Information	d _{eq} @ PII max	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		9.52	-	-		9.52
Oth		FLy	(cm)		3.50	-	-		3.50
	I _{pa.3} @ MI max	I _{pa.3} @ MI max	(W/cm ²)	443.55					
Operator Control	Focus (cm)			1.50	9.52	-	-	-	9.52
	Frequency (MHz)	Frequency (MHz)			4.00	-	-	-	4.00
5 0	Res/Speed				3	-	-	-	3

a This Index is not relevant to this operating mode.

F - 52 Instructions for Use

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: EV-8C4

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	
	Inc	dex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.47	0.80	-	-	-	1.03
	FDA	IEC	Units						
ø	P _{r.3}	p_{ra}	(MPa)	3.17					
eter	Wo	P	(mW)		38.89	-		-	38.89
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i F	Z ₁	Z _S	(cm)				-		
snc	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.80					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Assı	f _c	f _{awf}	(MHz)	4.61	4.32	-	-	-	4.32
_	Dim. of A _{aprt}		X (cm)		1.96	-	-	-	1.40
			Y (cm)		0.50	-	-	-	0.50
	PD	$t_{\sf d}$	(µsec)	0.28					
tion	PRF	prr	(Hz)	19.24					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.11					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
e	Focal Length	FLx	(cm)		4.41	-	-		4.41
듐		FLy	(cm)		3.50	-	-		3.50
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	406.64					
o to	Focus (cm)		2.00	4.41	-	-	-	4.41	
Operator Control	Frequency (MHz)		9.00	9.00	-	-	-	9.00	
ဝီပိ	Res/Speed			3	3	-	-	-	3

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: EV-8C4

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.48	0.96	-	-	-	1.32
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.02					
ters	Wo	P	(mW)		47.57	-		-	50.76
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	Z _{sp}	z @ max. I _{pi,α}	(cm)	1.30					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Asso	f _c	f _{awf}	(MHz)	4.20	4.78	-	-	-	4.76
1	Dim. of A _{aprt}		X (cm)		1.17	-	-	-	1.29
			Y (cm)		0.50	-	-	-	0.50
	PD	$t_{\sf d}$	(μsec)	0.83					
tion	PRF	prr	(Hz)	8.00					
ma	P _r @ PII max	P _r @ max. I _{pi}	(MPa)	3.65					
nfor	d _{eq} @ PII max	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
Other Information	Focal Length	FLx	(cm)		6.50	-	-		13.50
g		FLy	(cm)		3.50	-	-		3.50
	I _{pa.3} @ MI max	I _{pa.3} @ MI max	(W/cm ²)	361.82					
_	Focus (cm)			2.01	6.50	-	-	-	13.50
Operator Control	Res/Speed				5	-	-	-	5
Spe	Ensemble Size		•	12	12	-	-	-	12
0	Frequency (MHz)			4.20	5.00	-	-	-	5.00

a This Index is not relevant to this operating mode.

This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: EV-8C4 Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.08	-	1.24	-	2.08	1.53
	FDA	IEC	Units						
·0	P _{r.3}	p_{ra}	(MPa)	2.25					
ters	Wo	P	(mW)		-	52.47		36.37	52.47
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					2.10	
ted	Z _{sp}	z @ max. I _{pi,α}	(cm)	2.40					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.21	
\ssc	f _c	f_{awf}	(MHz)	4.35	-	4.95	-	4.35	4.76
_			X (cm)		-	1.15	-	0.81	1.15
			Y (cm)		-	0.50	-	0.50	0.50
	PD	$t_{\sf d}$	(μsec)	0.88					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII max	P _r @ max. I _{pi}	(MPa)	3.10					
Other Information	d _{eq} @ PII max	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.19	
ē	Focal Length	FLx	(cm)		-	9.03	-		9.03
₽		FLy	(cm)		-	3.50	-		3.50
	I _{pa.3} @ MI max	I _{pa.3} @ MI max	(W/cm ²)	234.64					
_	Frequency (MHz)			4.20	-	5.00	-	4.20	5.00
Operator Control	Focus (cm)		2.00	-	9.03	-	3.36	9.03	
Spel	Gate Size (cm)			0.15	-	0.15	-	0.15	0.15
0	Sample Rate (Hz)			100.16	-	20833	-	28409	20833

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: EV-8C4 Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.89	-	0.23		0.37	0.35
	FDA	IEC	Units						
·0	P _{r.3}	p _{ra}	(MPa)	3.98					
ters	Wo	P	(mW)		-	10.62		10.62	10.62
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i D	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					1.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.50					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.44	
ASSC	f _c	f _{awf}	(MHz)	4.43	-	4.51	-	4.51	4.72
_	Dim. of A _{aprt} X (cm)		X (cm)		-	0.89	-	0.89	0.89
			Y (cm)		-	0.50	-	0.50	0.50
	PD	$t_{\sf d}$	(μsec)	0.44					
tion	PRF	prr	(Hz)	600.00					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.84					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					13.36	
e	Focal Length	FLx	(cm)			9.52	-		9.52
o₩		FLy	(cm)			3.50	-		3.50
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	765.92					
_	Frequency (MHz)		4.00	-	4.00	-	4.00	4.00	
Operator Control	Focus (cm)			2.00	-	9.52	-	9.52	9.52
Spel	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
U	Sample Rate (Hz)			600.00	-	600	-	600	600

This Index is not relevant to this operating mode.

F - 54 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.11	0.36	-	-	-	0.94
	FDA	IEC	Units						
v	P _{r.3}	p_{ra}	(MPa)	2.20					
ter	Wo	P	(mW)		27.08	-		-	47.81
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iS T	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.70					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	3.89	3.74	-	-	-	3.74
_	Dim. of A _{aprt}	Dim. of A _{aprt}			1.83	-	-	-	1.31
			Y (cm)		0.60	-	-	-	0.60
	PD	t _d	(µsec)	0.56					
tion	PRF	prr	(Hz)	21.22					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.76					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		9.52	-	-		9.52
듐		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	223.91					
to.	Focus (cm)			1.50	9.52	-	-	-	9.52
Operator Control	Frequency (MHz)			4.00	6.00	-	-	-	6.00
ဝီပိ	Res/Speed				3	-	-	-	3

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: EC9-4 Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.31	0.26	-	-	-	0.71
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.65					
sters	Wo	P	(mW)		19.94	-		-	35.78
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.80					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	4.11	3.74	-	-	-	3.74
1	Dim. of A _{aprt}		X (cm)		1.83	-	-	-	1.31
			Y (cm)		0.60	-	-	-	0.60
	PD	$t_{\sf d}$	(µsec)	0.30					
Other Information	PRF	prr	(Hz)	14.16					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.43					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
er	Focal Length	FLx	(cm)		9.52	-	-		9.52
듈		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	272.03					
Operator Control	Focus (cm)			1.50	9.52	-	-	-	9.52
ontr	Frequency (MHz)			8.00	7.00	-	-	-	7.00
ರ್ಣಿ	Res/Speed	Res/Speed			3	-	-	-	3
2									

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: EC9-4

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.26	0.59	-	-	-	0.68
	FDA	IEC	Units						
w	P _{r.3}	p_{ra}	(MPa)	2.81					
ter	Wo	P	(mW)		29.12	-		-	29.12
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iS T	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.60					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	4.85	4.81	-	-	-	4.81
_	Dim. of A _{aprt}		X (cm)		0.99	-	-	-	0.99
			Y (cm)		0.60	-	-	-	0.60
	PD	$t_{\sf d}$	(µsec)	0.72					
tion	PRF	prr	(Hz)	7.91					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.67					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
Other Information	Focal Length	FLx	(cm)		4.00	-	-		4.00
듈		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	299.39					
_	Focus (cm)		2.00	4.00	-	-	-	4.00	
rato	Res/Speed		3	5	-	-	-	5	
Operator Control	Ensemble Size			12	12	-	-	-	12
	Frequency (MHz)			5.00	5.00	-	-	-	5.00

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: EC9-4

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Non	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.98	-	1.14	-	1.20	1.25
	FDA	IEC	Units						
	P _{r.3}	p _{ra}	(MPa)	2.19					
	Wo	P	(mW)		-	47.23		27.78	47.23
	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
	z_1	Z _S	(cm)				-		
60	Z _{bp}	Z _{bp}	(cm)				-		
neters	Z _{sp}	Z _b	(cm)					1.90	
Paran	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.00					
Associated Acoustic Parameters	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.27	
Ago	f _c	f _{awf}	(MHz)	5.05	-	5.06	-	5.05	4.85
ciatec	Dim. of A _{aprt}	Dim. of A _{aprt} X (cm			-	1.17	-	0.48	1.17
Asso			Y (cm)		-	0.60	-	0.60	0.60
	PD	t _d	(μsec)	0.74					
	PRF	prr	(Hz)	100.16					
	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.07					
c	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.29	
Other Information	Focal Length	FLx	(cm)		-	10.02	-		10.02
- Infor		FLy	(cm)		-	3.00	-		3.00
Othe	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	238.97					
-	Frequency (MHz)				-	5.00	-	5.00	5.00
Sontro	Focus (cm)			2.00	-	10.02	-	2.00	10.02
Operator Control	Gate Size (cm)			0.15	-	0.15	-	0.15	0.15
Open	Sample Rate (Hz)	•	•	100.16	-	17361	-	20833	17361

This Index is not relevant to this operating mode.

F - 56 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4** Operating mode: **M-Mode**

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.18	-	0.21	-	0.39	0.28
	FDA	IEC	Units						
S	P _{r.3}	p_{ra}	(MPa)	2.35					
eter	Wo	P	(mW)		-	11.21		10.76	11.21
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i E	Z ₁	$z_{\rm s}$	(cm)				-		
nst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					1.70	
ted	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	1.70					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.40	
Asso	f _c	f _{awf}	(MHz)	3.89	-	3.92	-	3.88	3.92
1	Dim. of A _{aprt}		X (cm)		-	1.31	-	1.20	1.31
			Y (cm)		-	0.60	-	0.60	0.60
	PD	$t_{\sf d}$	(μsec)	0.56					
tion	PRF	prr	(Hz)	600.00					
.ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.95					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					11.74	
ē	Focal Length	FLx	(cm)		-	9.52	ı		9.52
g		FLy	(cm)		-	3.00	ı		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	266.47					
_	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
rato	Focus (cm)			1.50	-	9.52	-	4.41	9.52
Operator Control	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
0	Sample Rate (Hz)			600.00	-	600	1	600	600

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: MC9-4 Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.30	0.97	-	-	-	1.21
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.68					
ter	Wo	P	(mW)		48.16	-		-	48.16
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
S. P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z bp	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.81					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					- 1	
SSV	f _c	f _{awf}	(MHz)	4.23	4.24	-	-	-	4.24
٩	Dim. of A _{aprt}		X (cm)		1.83	-	-	-	1.31
			Y (cm)		0.60	-	-	-	0.60
	PD	t _d	(µsec)	0.58					
ion	PRF	prr	(Hz)	29.96					
maj	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.37					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		9.50	-	-		9.50
O H		FLy	(cm)		2.00	-	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	288.36					
Operator Control	Focus (cm)			2.00	9.50				9.50
ontr	Frequency (MHz)			0.00	0.00				0.00
ర్ధిర	Res/Speed			0	4				4

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: MC9-4

Operating mode: 2D-Mode (THI)

				МІ		TIS		TIB	TIC
	Inc	lex Label			Scan	Non-	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.31	0.88	-	-	-	1.11
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	2.69					
ters	Wo	P	(mW)		44.41	-		-	44.41
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.54					
<u>S</u>	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	4.18	4.18	-	-	-	4.18
4	Dim. of A _{aprt}		X (cm)		1.83	-	-	-	1.31
			Y (cm)		0.60	-	-	-	0.60
	PD	t _d	(µsec)	0.42					
ţion	PRF	prr	(Hz)	19.07					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.36					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		9.50	-	-		9.50
듐		FLy	(cm)		2.00	-	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	341.89					
ol for	Focus (cm)			1.50	9.50				9.50
Operator Control	Frequency (MHz)			0.00	0.00				0.00
ర్ధి	Res/Speed			0	4				4
	This Indovisionst vo			1					

This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: MC9-4

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Non-	-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.30	0.99	-	-	-	1.34
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.19					
ters	Wo	P	(mW)		44.17	-		-	26.26
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
.i	z_1	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.79					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Assc	f _c	f _{awf}	(MHz)	6.01	4.91	-	-	-	5.06
_	Dim. of A _{aprt}		X (cm)		1.00	-	-	-	0.12
			Y (cm)		0.60	-	-	-	0.60
	PD	t_{d}	(μsec)	0.73					
tion	PRF	prr	(Hz)	7.91					
шa	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.48					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
erl	Focal Length	FLx	(cm)		4.00	-	-		0.50
£		FLy	(cm)		2.00	-	-		2.00
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	326.62					
_	Focus (cm)			2.00	4.00				0.50
Operator Control	Res/Speed			5	3				3
g S	Ensemble Size			12	12				12
0	Frequency (MHz)			6.75	5.00				5.00
	This Indov is not role		At a second a						

This Index is not relevant to this operating mode.

F - 58 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: MC9-4

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.36	-	0.96	-	1.81	2.16
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	3.01					
ter	Wo	P	(mW)		-	47.08		22.84	25.7
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					0.71	
ted	z@PII.3max	z @ max. $I_{pi,\alpha}$	(cm)	1.59					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.22	
\ssc	f _c	f_{awf}	(MHz)	4.93	1	5.05	-	5.03	5.06
_	Dim. of A _{aprt}		X (cm)		-	1.18	-	0.23	0.12
			Y (cm)		-	0.6	-	0.6	0.6
	PD	$t_{\sf d}$	(µsec)	0.66					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.95					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.14	
Other Information	Focal Length	FLx	(cm)		-	9	-		0.51
₽		FLy	(cm)		-	2	-		2
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	449.4					
_	Frequency (MHz)			5	-	5	-	5	5
rato	Focus (cm)	•		2.01	-	9	-	1	0.51
Operator Control	Gate Size (cm)			0.1	-	0.15	-	0.15	0.25
0	Sample Rate (Hz)			100.16	-	1085	-	28409	28409

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table — Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: MC9-4 Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Inde	ex Label			Scan	Non-	scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.4	-	0.41	-	0.82	0.99
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	2.85					
ters	Wo	P	(mW)		-	27.6		27.6	40.13
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta,\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.59	
eq	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.71					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.48	
SSC	f _c	f _{awf}	(MHz)	4.14	-	4.21	-	4.21	5.06
•	Dim. of A _{aprt}		X (cm)		-	1.34	-	1.34	1.34
			Y (cm)		-	0.6	-	0.6	0.6
	PD	t _d	(µsec)	0.57					
Other Information	PRF	prr	(Hz)	600					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.64					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					15.41	
er	Focal Length	FLx	(cm)		-	9.5	-		9.5
o₩		FLy	(cm)		-	2	-		2
	I _{pa.3} @ MI _{max}	I _{pa,α} @ max. MI	(W/cm ²)	321.65					
_	Frequency (MHz)			4	-	4	-	4	8
Operator Control	Focus (cm)			2	-	9.5	-	9.5	9.5
Sp	Gate Size (cm)			1	-	1	-	1	1
0	Sample Rate (Hz)			600	-	600	-	600	1200
а	This Index is not rele	evant to this opera	ting mode.						

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **7CF1** Operating mode: **2D-Mode**

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.38	0.88	-	-	-	3.94
	FDA	IEC	Units						
ø	P _{r.3}	p _{ra}	(MPa)	2.39					
eter	Wo	P	(mW)		58.9	-		-	223.67
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i F	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.34					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	2.97	3.45	-	-	-	3.45
_	Dim. of A _{aprt}		X (cm)		2.02	-	-	-	1.44
			Y (cm)		1.1	-	-	-	1.1
	PD	$t_{\sf d}$	(µsec)	0.83					
tion	PRF	prr	(Hz)	13.78					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.23					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
Other Information	Focal Length	FLx	(cm)		6	-	-		6
윰		FLy	(cm)		5	-	-		5
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	235.19					
o to	Focus (cm)			4	6	-	-	-	6
Operator Control	Frequency (MHz)	1		0	0	-	-	-	0
ဝီပိ	Res/Speed			3	3	-	-	-	3

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **7CF1** Operating mode: **2D-Mode (THI)**

	•			MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.36	0.7	-	-	-	1.04
	FDA	IEC	Units						
'n	P _{r.3}	p_{ra}	(MPa)	2.07					
sters	Wo	P	(mW)		54.13	-		-	83.82
arame	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iсР	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z b	(cm)					-	
Associated Acoustic Parameters	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.82					
	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ss(f _c	f _{awf}	(MHz)	2.33	3.01	-	-	-	3
_	Dim. of A _{aprt}		X (cm)		2.02	-	-	-	2.91
			Y (cm)		1.1	-	-	-	1.1
	PD	t_{d}	(µsec)	0.94					
tion	PRF	prr	(Hz)	8.37					
щ	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.78					
ug.	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
Other Information	Focal Length	FLx	(cm)		4	-	-		20
ğ		FLy	(cm)		5	-	-		5
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	180.64					
ᅙᅙ	Focus (cm)			4	4	-	-	-	20
Operator Control	Frequency (MHz)			0	0	-	-	-	0
ÖÖ	Res/Speed		·	3	3	-	-	-	3

a This Index is not relevant to this operating mode.

F - 60 Instructions for Use

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **7CF1** Operating mode: **Color / Power**

1.84
160.85
3.1
2.91
1.1
12
5
12
2
12
3.25

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- ${\tt c} \quad \ \ {\tt This formulation for TIS is less than that for an alternate formulation in this mode.}$
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **7CF1** Operating mode: **Pulsed Doppler**

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.37	-	-	1.2	2.3	2.18
	FDA	IEC	Units						
m	P _{r.3}	p _{ra}	(MPa)	2.39					
ters	Wo	P	(mW)		-	-		67.67	176.46
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				81.33		
S P	Z ₁	z _s	(cm)				3.62		
nst	Z _{bp}	Z _{bp}	(cm)				3.02		
Acc	Z _{sp}	Z _b	(cm)					3.59	
ted	z@PII _{.3max}	z @ max. Ι _{ρί,α}	(cm)	4.13					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.31	
SSC	f _c	f _{awf}	(MHz)	3.04	-	-	3.1	3.14	3.1
1	Dim. of A _{aprt}		X (cm)		-	-	2.91	1.02	2.91
			Y (cm)		-	-	1.1	1.1	1.1
	PD	t _d	(μsec)	1.27					
Other Information	PRF	prr	(Hz)	100.16					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.37					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.43	
e	Focal Length	FLx	(cm)		-	-	12		12
O#		FLy	(cm)		-	-	5		5
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	240.07					
Ī	Frequency (MHz)			3.25	-	-	3.08	3.25	3.25
ator	Focus (cm)			6	-	-	12	4.25	12
Operator Control	Gate Size (cm)			0.20	-	-	0.4	0.4	0.4
	Sample Rate (Hz)			100.16	-		3125	24083	3125

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 7CF1 Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.27	-	-	0.59	0.99	1
	FDA	IEC	Units						
S	P _{r.3}	p _{ra}	(MPa)	2.22					
eter	Wo	P	(mW)		-	-		51.38	77.09
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				42.56		
E	Z ₁	Z _S	(cm)				2.98		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				2.88		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					3.25	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.4					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.61	
\ssc	f _c	f _{awf}	(MHz)	3.04	-	-	2.89	2.92	2.89
1	Dim. of A _{aprt}		X (cm)		-	-	2.63	1.44	2.63
			Y (cm)		-	-	1.1	1.1	1.1
	PD	$t_{\sf d}$	(µsec)	0.73					
Other Information	PRF	prr	(Hz)	600					
шa	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	2.57					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					16.27	
ē	Focal Length	FLx	(cm)		-	-	20		20
듈		FLy	(cm)		-	-	5		5
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	191.69					
_	Frequency (MHz)	•		3	-	-	3	3	3
rato	Focus (cm)	•		2	-	-	20	6	20
Operator Control	Gate Size (cm)			1	-	-	1	1	1
J .	Sample Rate (Hz)			600	-	-	600	600	600

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 7CF2 Operating mode: 2D-Mode

			MI		TIS		TIB	TIC	
Inc	lex Label			Scan	Nor	n-scan	Non-scan		
					A _{aprt} ≤1	A _{aprt} >1			
Maximum Value			1.27	0.18	-	-	-	0.86	
FDA	IEC	Units							
P _{r.3}	p _{ra}	(MPa)	2.19						
Wo	P	(mW)		19.19	-		-	87.52	
min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-			
Z ₁	Z _s	(cm)				-			
Z _{bp}	Z _{bp}	(cm)				-			
Z _{Sp}	Z _b	(cm)					-		
z@PII _{.3max}	z @ max. Ι _{ρί,α}	(cm)	3.40						
$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-		
f _c	f _{awf}	(MHz)	3.00	4.40	-	-	-	2.97	
Dim. of A _{aprt}		X (cm)		1.32	-	-	-	2.58	
		Y (cm)		1.10	-	-	-	1.10	
PD	t _d	(µsec)	0.76						
PRF	prr	(Hz)	29.13						
P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.06						
d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-		
Focal Length	FLx	(cm)		4.00	-	-		20.00	
	FLy	(cm)		6.00	-	-		6.00	
I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	205.50						
Focus (cm)			4.00	4.00	-	-	-	20.00	
Frequency (MHz)			3.00	4.50	-	-	-	3.00	
Res/Speed			0	3	-	-	-	3	
	Maximum Value FDA	FDA IEC Pr₃ pr₃ W₀ P min of [W₃(z₁), I₁x₃(z₁)] Min. of [P₀(z₅), I₂a₀(z₅)] Z¹ z₅ Z₀p Z₅p Z₅p z₀ Z@PII ₃max z @ max. Ipi.a deq(z₅p) deo(z₀) fc f₃wd Dim. of A₃prt Pr PRF prr Pr@ PII max Pr@ max. Ipi deq@ PIImax deo@ max. Ipi Focal Length FLx FLy Ip₃₃@ MI max Focus (cm) Frequency (MHz)	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{ c c c c c } \hline \textbf{Maximum Value} & 1.27 & 0.18 \\ \hline \textbf{FDA} & \textbf{IEC} & \textbf{Units} \\ \hline P_{r,3} & p_{ra} & (MPa) & 2.19 \\ \hline W_o & P & (mW) & 19.19 \\ \hline \min \text{ of } [W_3(z_1), & Min. \text{ of } [P_0(z_5), \\ I_{TA,3}(z_1)] & I_{Ia,a}(z_5)] & (cm) \\ \hline z_1 & z_5 & (cm) \\ \hline z_{0p} & z_{0p} & (cm) \\ \hline z_{0p} & z_{0} &$	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Index Label Scan Non-sean Maximum Value 1.27 0.18 - FDA IEC Units P _{r,3} p _{ra} (MPa) 2.19 - W _o P (mW) 19.19 - Union [W _a (V _a)] (mW) 19.19 - Z _b (cm) 3.40 - - Z _b (cm) 3.40 - - Q _a Q B M _a (MHz) 3.00 4.40 <th c<="" td=""><td>$\begin{array}{ c c c c c c c c c c c c c c c c c c c$</td></th>	<td>$\begin{array}{ c c c c c c c c c c c c c c c c c c c$</td>	$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$

This Index is not relevant to this operating mode.

F - 62 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **7CF2** Operating mode: **2D-Mode (THI)**

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.20	0.19	-	-	-	0.50
	FDA	IEC	Units						
v	P _{r.3}	p_{ra}	(MPa)	1.84					
ter	Wo	P	(mW)		28.47	-		-	50.28
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iS T	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.80					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	2.45	3.20	-	-	-	2.82
_	Dim. of A _{aprt}		X (cm)		0.97	-	-	-	2.42
			Y (cm)		1.10	-	-	-	1.10
	PD	$t_{\sf d}$	(µsec)	0.62					
tion	PRF	prr	(Hz)	14.53					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.47					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		2.00	-	-		10.00
듐		FLy	(cm)		6.00	-	-		6.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	113.11					
to o	Focus (cm)			4.00	2.00	-	-	-	10.00
Operator Control	Frequency (MHz)	Frequency (MHz)			7.00	-	-	-	5.50
ဝီပိ	Res/Speed			0	3	-	-	-	3

- a This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **7CF2** Operating mode: **Color / Power**

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.23	0.81	-	-	-	1.62
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	1.98					
sters	Wo	P	(mW)		63.74	-		-	160.26
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.00					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	2.58	3.62	-	-	-	2.58
_	Dim. of A _{aprt}		X (cm)		1.16	-	-	-	3.83
			Y (cm)		1.10	-	-	-	1.10
	PD	$t_{\sf d}$	(µsec)	1.53					
tion	PRF	prr	(Hz)	8.09					
щa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.55					
ugu	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
Other Information	Focal Length	FLx	(cm)		5.00	-	-		16.00
듈		FLy	(cm)		6.00	-	-		6.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	178.36					
	Focus (cm)			4.01	5.00	-	-	-	16.00
rato	Res/Speed	Res/Speed			5	-	-	-	5
Operator Control	Ensemble Size	•		12	12	-	-	-	12
0	Frequency (MHz)	•		2.50	3.75	-	-	-	2.50

- a This Index is not relevant to this operating mode.
- b This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 7CF2

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.16	-	-	0.86	2.35	2.04
	FDA	IEC	Units						
m	P _{r.3}	p _{ra}	(MPa)	1.86					
ter	Wo	P	(mW)		-	-		81.64	194.73
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				69.30		
. <u>S</u>	Z ₁	Z _S	(cm)				4.40		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				2.98		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					3.60	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	4.00					
<u>S</u>	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.41	
\ssc	f _c	f _{awf}	(MHz)	2.62	-	-	2.61	2.62	2.58
_	Dim. of A _{aprt}		X (cm)		-	-	2.83	1.16	4.08
			Y (cm)		-	-	1.10	1.10	1.10
	PD	t _d	(µsec)	1.75					
Other Information	PRF	prr	(Hz)	100.16					
na H	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.63					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.38	
ē	Focal Length	FLx	(cm)		-	-	11.96		16.95
듐		FLy	(cm)		-	-	6.00		6.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	176.99					
_	Frequency (MHz)		•	2.50	-	-	2.50	2.50	2.50
rato	Focus (cm)			5.00	-	-	11.96	5.02	16.95
Operator Control	Gate Size (cm)			0.20	-	-	0.20	0.20	0.20
	Sample Rate (Hz)			100.16	-	-	20833	22321	19531
_	This Indovis not rol								

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 7CF2 Operating mode: M-Mode

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.34	-	-	0.55	0.96	1.07
	FDA	IEC	Units						
,n	P _{r.3}	p_{ra}	(MPa)	2.30					
ters	Wo	P	(mW)		-	-		55.13	81.49
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				39.54		
Si P	Z ₁	Z _s	(cm)				3.50		
onst	Z _{bp}	Z _{bp}	(cm)				2.85		
Acc	Z _{sp}	Z _b	(cm)					3.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	3.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.66	
SSO	f _c	f _{awf}	(MHz)	3.01	-	-	2.94	2.92	2.97
4	Dim. of A _{aprt}		X (cm)		-	-	2.58	1.41	2.58
			Y (cm)		-	-	1.10	1.10	1.10
	PD	t _d	(µsec)	0.77					
ion	PRF	prr	(Hz)	600.00					
Other Information	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.21					
JQ.	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					18.17	
e	Focal Length	FLx	(cm)		-	-	20.00		20.00
₽		FLy	(cm)		-	-	6.00		6.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	225.96					
	Frequency (MHz)			3.00	-	-	3.00	3.00	3.00
rato	Focus (cm)				-	-	20.00	6.00	20.00
Operator Control	Gate Size (cm)			1.00	-	-	1.00	1.00	1.00
	Sample Rate (Hz)	1		600.00	-	-	600	600	600

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

F - 64 Instructions for Use

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 9EVF4

Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.47	0.42	-	-	-	0.52
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	3.28					
ters	Wo	P	(mW)		18.49	-		-	18.49
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	z_1	Z _S	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.30					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	5.01	4.85	-	-	-	4.85
4	Dim. of A _{aprt}		X (cm)		0.97	-	-	-	0.69
			Y (cm)		0.60	-	-	-	0.60
	PD	t _d	(μsec)	0.46					
lion	PRF	prr	(Hz)	18.79					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.95					
Je J	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		10.53	-	-		10.53
g		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	455.61					
ᅙ	Focus (cm)			1.50	10.53	-	-	-	10.53
Operator Control	Frequency (MHz)			4.00	4.00	-	-	-	4.00
ဝီပိ	Res/Speed			3	3	-	-	-	3
	This Indovis not re				•				

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 9EVF4

Operating mode: 2D-Mode (THI)

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.28	0.33	-	-	-	0.45
	FDA	IEC	Units						
(n	P _{r.3}	p_{ra}	(MPa)	2.74					
sters	Wo	P	(mW)		15.51	-		-	15.51
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{Sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	4.66	4.57	-	-	-	4.57
1	Dim. of A _{aprt}		X (cm)		0.87	-	-	-	0.63
			Y (cm)		0.60	-	-	-	0.60
	PD	t _d	(µsec)	0.40					
Other Information	PRF	prr	(Hz)	4.70					
щa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.18					
lg.	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
erl	Focal Length	FLx	(cm)		4.56	-	-		4.56
듐		FLy	(cm)		3.00	-	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	306.87					
to o	Focus (cm)			1.50	4.56	-	-	-	4.56
Operator Control	Frequency (MHz)			9.00	9.00	-	-	-	9.00
ဝီပိ	Res/Speed			3	3	-	-	-	3
2	This Indovis not re	ev is not relevant to this operating mode							

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: 9EVF4

Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.34	0.70	-	1	-	0.79
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	3.07					
ter	Wo	P	(mW)		32.84	-		-	32.84
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Б	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				ı		
Acc	Z _{sp}	z_{b}	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
\ssc	f _c	f _{awf}	(MHz)	5.24	5.15	-	ı	-	5.15
1	Dim. of A _{aprt}		X (cm)		1.13	-	1	-	1.13
			Y (cm)		0.60	-	-	-	0.60
	PD	t _d	(μsec)	0.70					
Other Information	PRF	prr	(Hz)	7.97					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	3.84					
nfor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
erl	Focal Length	FLx	(cm)		10.03	-	-		10.03
oth		FLy	(cm)		3.00	-	ı		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	368.49					
ڀ	Focus (cm)	•		2.00	10.03	-	ı	-	10.03
rato	Res/Speed			5	5	-	-	-	5
Operator Control	Ensemble Size			12	12	-	ı	-	12
0 '	Frequency (MHz)			5.50	5.50	-	-	-	5.50

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: 9EVF4

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	No	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.34	-	0.85	-	1.01	0.91
	FDA	IEC	Units						
w	P _{r.3}	p _{ra}	(MPa)	3.07					
ter	Wo	P	(mW)		-	33.66		31.70	33.66
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	Z ₁	Z _S	(cm)				1		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.60	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.39	
ASSC	f _c	f _{awf}	(MHz)	5.24	-	5.31	-	5.30	5.31
_	Dim. of A _{aprt}		X (cm)		-	1.12	1	1.00	1.12
			Y (cm)		-	0.60	-	0.6	0.60
	PD	t _d	(μsec)	0.70					
Other Information	PRF	prr	(Hz)	976.56					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.84					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.26	
er	Focal Length	FLx	(cm)		-	9.02	-		9.02
o#		FLy	(cm)		-	3.00	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	367.95					
_	Frequency (MHz)			5.50	-	5.50	-	5.50	5.50
Operator Control	Focus (cm)	•		2.00	-	9.02	-	4.03	9.02
Se	Gate Size (cm)			0.15	-	0.15	-	0.15	0.15
0	Sample Rate (Hz)			976.56	-	20833	-	24083	20833
а	This Index is not rel	evant to this onera	ting mode						

This Index is not relevant to this operating mode.

F - 66 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **9EVF4** Operating mode: **M-Mode**

				MI		TIS		TIB	TIC
	Inc	dex Label			Scan	Nor	ı-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.49	-	0.31	-	0.51	0.46
	FDA	IEC	Units						
m	P _{r.3}	p_{ra}	(MPa)	3.34					
ter	Wo	P	(mW)		-	13.47		13.47	13.47
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Б	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					1.40	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.50					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.37	
\ssc	f _c	f _{awf}	(MHz)	5.05	'n	4.85	-	4.85	4.85
1	Dim. of A _{aprt}		X (cm)		-	0.69	-	0.69	0.69
			Y (cm)		-	0.60	-	0.60	0.60
	PD	t _d	(µsec)	0.49					
tion	PRF	prr	(Hz)	600.00					
ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	4.16					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					11.31	
ē	Focal Length	FLx	(cm)		'n	10.53	-		10.53
듐		FLy	(cm)		-	3.00	-		3.00
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	460.79					
_	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
rato	Focus (cm)				•	10.53	-	10.53	10.53
Operator Control	Gate Size (cm)	Gate Size (cm)			-	1.00	-	1.00	1.00
0 -	Sample Rate (Hz))	·	600.00	-	600	-	600	600

a This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: CW2 Operating mode: CW Doppler

				MI		TIS		TIB	TIC
	Ind	ex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.08	-	1.60	-	4.89	4.29
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	0.12					
ter	Wo	P	(mW)		-	167.65		167.65	167.65
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Si	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.50	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	2.70					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.63	
ASSC	f _c	f _{awf}	(MHz)	2.00	-	2.00	-	2.00	2.00
_	Dim. of A _{aprt}		X (cm)		-	0.54	-	0.54	0.54
			Y (cm)		-	1.38	-	1.38	1.38
	PD	t _d	(μsec)						
tion	PRF	prr	(Hz)						
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.14					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.55	
e	Focal Length	FLx	(cm)		-	9.10	-		9.10
o₩		FLy	(cm)		-	4.50	-		4.50
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.45					
	Frequency (MHz)			2.00	-	2.00	-	2.00	2.00
rato	Focus (cm)	•	•	9.10	-	9.10	-	9.10	9.10
Operator Control	Gate Size (cm)	•	•	-	-	-	-	-	-
J	Sample Rate (Hz)	•	•	-	-	-	-	-	-

a This Index is not relevant to this operating mode.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

[#] No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

b This transducer is not intended for transcranial or neonatal cephalic uses.

c This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: CW5

Operating mode: CW Doppler

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			0.05	-	1.64	-	1.64	2.16
	FDA	IEC	Units						
S	P _{r.3}	p _{ra}	(MPa)	0.12					
ter	Wo	P	(mW)		-	68.94		68.94	68.94
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
. <u>S</u>	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)						
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.90					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)						
\ssc	f _c	f _{awf}	(MHz)	5.00	-	5.00	-	5.00	5.00
_	Dim. of A _{aprt}		X (cm)		-	0.44	-	0.44	0.44
			Y (cm)		-	1.13	-	1.13	1.13
	PD	$t_{\sf d}$	(μsec)						
tion	PRF	prr	(Hz)						
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.16					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)						
ē	Focal Length	FLx	(cm)		-	9.10	-		9.10
듈		FLy	(cm)		-	4.50	-		4.50
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.39					
_	Frequency (MHz)			5.00	-	5.00	-	5.00	5.00
rato	Focus (cm)			9.10	-	9.10	-	9.10	9.10
Operator Control	Gate Size (cm)			-	-	-	-	-	-
	Sample Rate (Hz)			-	-	-	-	-	-
_	This Indov is not rol								

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 8F

Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.35	0.86	-	-	-	2.64
	FDA	IEC	Units						
ro.	P _{r.3}	p _{ra}	(MPa)	2.78					
ters	Wo	P	(mW)		43.65	-		-	43.65
Associated Acoustic Parameters	min of [W _{.3} (z ₁), $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
.i	z_1	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	4.23	4.12	-	-	-	4.12
4	Dim. of A _{aprt}		X (cm)		0.70	-	-	-	0.70
			Y (cm)		0.19	-	-	-	0.19
	PD	t _d	(μsec)	0.45					
ţio	PRF	prr	(Hz)	47.83					
Other Information	Pr@ PII _{max}	P _r @ max. I _{pi}	(MPa)	2.99					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
e	Focal Length	FLx	(cm)		2.00	-	-		2.00
o₩		FLy	(cm)		1.30	-	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	234.00					
Operator Control	Focus (cm)			1.00	2.00	-	-	-	2.00
era	Frequency (MHz)			4.00	4.00	-	-	-	4.00
90	Res/Speed			5	5	-	-	-	5

- This Index is not relevant to this operating mode.
- This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

F - 68 Instructions for Use

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 8F

Operating mode: Color / Power

	Index Label			MI		TIS		TIB	TIC
	Inc			Scan	Nor	ı-scan	Non-scan		
					A _{aprt} ≤1	A _{aprt} >1			
	Maximum Value			1.62	0.88	-	-	-	2.50
	FDA	IEC	Units						
"	P _{r.3}	p_{ra}	(MPa)	4.02					
ters	Wo	P	(mW)		40.61	-		-	40.81
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
.인	Z ₁	Z _S	(cm)				-		
nst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.40					
<u>S</u>	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	6.16	4.44	-	-	-	4.42
4	Dim. of A _{aprt}		X (cm)		0.70	-	-	-	0.70
			Y (cm)		0.19	-	-	-	0.19
	PD	t _d	(µsec)	0.57					
ion	PRF	prr	(Hz)	132.63					
mai	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	4.37					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
ē	Focal Length	FLx	(cm)		5.00	-	-		3.00
g		FLy	(cm)		1.30	-	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	568.27					
_	Focus (cm)			1.00	5.00	-	-	-	3.00
rato	Res/Speed			0	5	-	-	-	5
Operator Control	Ensemble Size			7	7	-	-	-	7
ر ا	Frequency (MHz)			6.50	4.50	-	-	-	4.50

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 8F

Operating mode: Pulsed Doppler

				MI		TIS		TIB	TIC
	Inc		Scan	Nor	n-scan	Non-scan			
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.55	-	0.97	-	2.79	2.71
	FDA	IEC	Units						
"	P _{r.3}	p _{ra}	(MPa)	3.46					
ters	Wo	P	(mW)		-	44.66		41.81	44.66
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is P	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					1.30	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.40					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.23	
ASSC	f _c	f _{awf}	(MHz)	5.00	1	4.54	-	4.54	4.63
_	Dim. of A _{aprt}		X (cm)		1	0.70	-	0.63	0.70
			Y (cm)		1	0.19	-	0.19	0.19
	PD	t _d	(µsec)	0.52					
Other Information	PRF	prr	(Hz)	390.63					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.71					
ufor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.22	
er	Focal Length	FLx	(cm)		-	7.01	-		7.01
o ₽		FLy	(cm)		-	1.30	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	429.52					
_	Frequency (MHz)	•	•	5.00	-	4.50	-	4.50	4.50
Operator Control	Focus (cm)	•	•	1.02	-	7.01	-	2.51	7.01
Sp	Gate Size (cm)	•	•	0.15	-	0.15	-	0.15	0.15
0	Sample Rate (Hz)			390.63	-	17361	-	15625	17361
_	This Index is not rel	ovent to this energ	ting mode			•		•	

This Index is not relevant to this operating mode.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: AcuNav 8F

Operating mode: M-Mode

	Index Label			MI		TIS		TIB	TIC
	Ind		Scan	No	n-scan	Non-scan			
					A _{aprt} ≤1	A _{aprt} >1			
	Maximum Value				1	0.23	-	0.59	0.68
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	2.62					
ter	Wo	P	(mW)		-	11.28		11.28	11.28
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
ic P	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					0.70	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	1.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.35	
\ssc	f _c	f _{awf}	(MHz)	4.13	1	4.23	-	4.23	4.18
_	Dim. of A _{aprt}		X (cm)			0.70	-	0.70	0.70
			Y (cm)			0.19	-	0.19	0.19
	PD	$t_{\sf d}$	(μsec)	0.47					
tion	PRF	prr	(Hz)	600.00					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.13					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					11.27	
erl	Focal Length	FLx	(cm)		1	7.00	-		7.00
g		FLy	(cm)		1	1.30	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	243.93					
_	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
rato	Focus (cm)			2.00	-	7.00	-	7.00	7.00
Operator Control	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
	Sample Rate (Hz)			600.00	-	600	-	600	600

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37 (Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 8F

Operating mode: SCW Doppler

				MI		TIS		TIB	TIC
	Inc	lex Label			Scan	Nor	n-scan	Non-scan	
					A _{aprt} ≤1	A _{aprt} >1			
	Maximum Value			0.06	-	0.08	-	0.59	0.51
	FDA	IEC	Units						
ers	P _{r.3}	p _{ra}	(MPa)	0.12					
ters	Wo	P	(mW)		-	3.94		3.94	3.94
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
is P	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$Z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					0.40	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.40					
ocia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.13	
SSC	f _c	f _{awf}	(MHz)	4.44	-	4.44	-	4.44	4.44
1	Dim. of A _{aprt}		X (cm)		-	0.15	-	0.15	0.15
			Y (cm)		-	0.19	-	0.19	0.19
	PD	t _d	(μsec)						
ţio	PRF	prr	(Hz)						
mai	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	0.13					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.13	
e	Focal Length	FLx	(cm)		-	3.00	-		3.00
₽		FLy	(cm)		-	1.30	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.24					
	Frequency (MHz)			4.50	-	4.50	-	4.50	4.50
rato	Focus (cm)			3.00	-	3.00	-	3.00	3.00
Operator Control	Gate Size (cm)		•	-	-	-	-	-	-
	Sample Rate (Hz)			-	-	-	-	-	-

This Index is not relevant to this operating mode.

F - 70 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 10F Operating mode: 2D-Mode

				MI		TIS		TIB	TIC
	Inc			Scan	Nor	ı-scan	Non-scan		
					A _{aprt} ≤1	A _{aprt} >1			
	Maximum Value			1.38	1.31	-	-	-	2.77
	FDA	IEC	Units						
v	P _{r.3}	p_{ra}	(MPa)	3.10					
ter	Wo	P	(mW)		52.45	-		-	52.45
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iS P	Z ₁	Z _s	(cm)				-		
nst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.80					
cia	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
SSC	f _c	f _{awf}	(MHz)	5.09	5.26	-	-	-	5.26
_	Dim. of A _{aprt}		X (cm)		0.70	-	-	-	0.70
			Y (cm)		0.25	-	-	-	0.25
	PD	$t_{\sf d}$	(µsec)	0.28					
tion	PRF	prr	(Hz)	62.49					
Other Information	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.57					
nfor	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					-	
er	Focal Length	FLx	(cm)		5.00	-	-		5.0
듐		FLy	(cm)		1.30	-	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	508.27					
to o	Focus (cm)			1.00	5.00	-	-	-	5.00
Operator Control	Frequency (MHz)			5.00	5.00	-	-	-	5.00
gö	Res/Speed			5	5	-	-	-	5

a This Index is not relevant to this operating mode.

- This transducer is not intended for transcranial or neonatal cephalic uses.
- c This formulation for TIS is less than that for an alternate formulation in this mode.
- # No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 10F Operating mode: Color / Power

				MI		TIS		TIB	TIC
	Ind	lex Label			Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.53	1.26	-	-	-	3.04
	FDA	IEC	Units						
S	P _{r.3}	p _{ra}	(MPa)	3.41					
eter	Wo	P	(mW)		55.68	-		-	55.68
Associated Acoustic Parameters	min of [W _{.3} (z_1), I _{TA.3} (z_1)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					-	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					-	
Asso	f _c	f _{awf}	(MHz)	4.95	4.51	-	-	-	4.51
_	Dim. of A _{aprt}		X (cm)		0.70		-	-	0.70
			Y (cm)		0.25		-	-	0.25
	PD	$t_{\sf d}$	(μsec)	0.71					
tion	PRF	prr	(Hz)	12.07					
щa	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.84					
ufor	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					-	
Other Information	Focal Length	FLx	(cm)		5.00	-	-		5.00
£		FLy	(cm)		1.30	-	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	429.16					
_	Focus (cm)		1.51	5.00	-	-	-	5.00	
rato	Res/Speed			5	5	-	-	-	5
Operator Control	Ensemble Size			7	7	-	-	-	7
J	Frequency (MHz)			5.00	4.50	-	-	-	4.50

a This Index is not relevant to this operating mode.

- b This transducer is not intended for transcranial or neonatal cephalic uses.
- This formulation for TIS is less than that for an alternate formulation in this mode.
- Who data is provided for this operation condition since the maximum index value is not reported for the reason listed.

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 10F

Operating mode: Pulsed Doppler

	Index Label			MI		TIS		TIB	TIC
	Inc			Scan	Nor	n-scan	Non-scan		
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value			1.51	-	1.38	-	2.58	3.26
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	3.36					
ter	Wo	P	(mW)		-	50.94		56.62	61.71
Associated Acoustic Parameters	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
Ö	z ₁	$z_{\rm s}$	(cm)				-		
onst	Z _{bp}	$z_{ m bp}$	(cm)				-		
Acc	Z _{sp}	$z_{\rm b}$	(cm)					0.80	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.70					
cia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.38	
\ssc	f _c	f _{awf}	(MHz)	4.94	1	5.70	-	4.68	4.54
_	Dim. of A _{aprt}		X (cm)		-	0.70	-	0.70	0.70
			Y (cm)		-	0.25	-	0.25	0.25
	PD	$t_{\sf d}$	(μsec)	0.55					
tion	PRF	prr	(Hz)	100.16					
шa	P _r @ PII _{max}	P _r @ max. I _{pi}	(Mpa)	3.78					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					0.29	
ē	Focal Length	FLx	(cm)		1	6.41	-		13.00
£		Fly	(cm)		1	1.30	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	374.69					
_	Frequency (MHz)			5.00	1	6.00	-	4.50	4.50
rato	Focus (cm)			1.50	-	6.41	-	4.01	13.00
Operator Control	Gate Size (cm)	·		0.10	-	0.10	-	0.10	0.10
0	Sample Rate (Hz)	1		100.16	-	19531	-	13020	15625

This Index is not relevant to this operating mode.

Acoustic Output Reporting Table – Track 3, FDA 510(k) and IEC 60601-2-37

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: AcuNav 10F

Operating mode: M-Mode

	Index Label			MI		TIS		TIB	TIC
Index Label					Scan	Noi	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value				-	0.24	-	0.53	0.58
	FDA	IEC	Units						
·0	P _{r.3}	p _{ra}	(MPa)	3.09					
ters	Wo	P	(mW)		-	10.97		10.97	10.97
Associated Acoustic Parameters	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
i P	z_1	Z _S	(cm)				1		
onst	Z _{bp}	Z _{bp}	(cm)				-		
Acc	Z _{sp}	Z _b	(cm)					0.80	
eq	z@PII.3max	z @ max. Ι _{ρί,α}	(cm)	0.80					
cial	d _{eq} (z _{sp})	$d_{\rm eq}(z_{\rm b})$	(cm)					0.36	
SSC	f _c	f _{awf}	(MHz)	4.26	-	4.50	-	4.50	4.50
^	Dim. of A _{aprt}		X (cm)		-	0.70	-	0.70	0.70
			Y (cm)		-	0.25	-	0.25	0.25
	PD	t _d	(µsec)	0.49					
io	PRF	prr	(Hz)	600.00					
ma	P _r @ PII _{max}	P _r @ max. I _{pi}	(MPa)	3.64					
Other Information	d _{eq} @ PII _{max}	d _{eq} @ max. I _{pi}	(cm)					11.12	
e	Focal Length	FLx	(cm)		-	9.00	-		9.00
∯ E		FLy	(cm)		-	1.30	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	296.16					
_	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
Operator Control	Focus (cm)			3.00	-	9.00	-	9.00	9.00
Spel	Gate Size (cm)			1.00	-	1.00	-	1.00	1.00
0 -	Sample Rate (Hz)			600.00	-	600	-	600	600
а	This Index is not rel	evant to this opera	iting mode.						

This Index is not relevant to this operating mode.

F - 72 Instructions for Use

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Transducer model: AcuNav 10F Operating mode: SCW Doppler

				MI		TIS		TIB	TIC
	Index Label				Scan	Nor	n-scan	Non-scan	
						A _{aprt} ≤1	A _{aprt} >1		
	Maximum Value				1	0.04	-	0.40	0.22
	FDA	IEC	Units						
ro.	P _{r.3}	p_{ra}	(MPa)	0.10					
je:	Wo	P	(mW)			1.99		1.99	1.99
Associated Acoustic Parameters	min of [W $_{.3}(z_1)$, $I_{TA.3}(z_1)$]	Min. of $[P_{\alpha}(z_s), I_{ta.\alpha}(z_s)]$	(mW)				-		
iS T	Z ₁	Z _S	(cm)				-		
onst	Z _{bp}	$z_{\sf bp}$	(cm)				-		
Acc	Z _{sp}	z_{b}	(cm)					0.40	
ted	z@PII.3max	z @ max. I _{pi,α}	(cm)	0.40					
ocia	$d_{eq}(z_{sp})$	$d_{\rm eq}(z_{\rm b})$	(cm)					0.10	
Assc	f _c	f _{awf}	(MHz)	4.00	-	4.00	-	4.00	4.00
_	Dim. of A _{aprt}		X (cm)		-	0.15	-	0.15	0.15
			Y (cm)		-	0.25	-	0.25	0.25
	PD	$t_{\sf d}$	(μsec)						
tion	PRF	prr	(Hz)						
.ma	P _r @ PII _{max}	$P_{\rm r}$ @ max. $I_{\rm pi}$	(MPa)	0.11					
Other Information	d _{eq} @ PII _{max}	$d_{\rm eq}$ @ max. $I_{\rm pi}$	(cm)					0.10	
ē	Focal Length	FLx	(cm)		1	2.01	-		2.01
ğ		FLy	(cm)		1	1.30	-		1.30
	I _{pa.3} @ MI _{max}	I _{pa.3} @ MI max	(W/cm ²)	0.28					
	Frequency (MHz)			4.00	-	4.00	-	4.00	4.00
rato	Focus (cm)		2.01	-	2.01	-	2.01	2.01	
Operator Control	Gate Size (cm)			-	-	-	-	-	-
	Sample Rate (Hz)			-	1	-	-	-	-

This Index is not relevant to this operating mode.

This transducer is not intended for transcranial or neonatal cephalic uses.

This formulation for TIS is less than that for an alternate formulation in this mode.

No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

F - 74 Instructions for Use