HITACHI
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DIAGNOSTIC ULTRASOUND SYSTEM

F37

Instruction Manual

Safety Instruction

⚠CAUTION

Instruction manuals consist of this manual, Power Data Book, How to Use and Measurement.

Before using this system, please read this manual.

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Introduction

This is an instruction manual for F37, a diagnostic ultrasound system.

Read the manual carefully before using the system. Take special note of the items in Chapter 1, "Safety Precautions" of Safety Instruction manual.

Keep this manual securely for future reference.

Symbols Used in this Document

The following items are important in preventing harm or injury to the operator of the equipment and the patient. There are 4 levels of harm/damage that can be caused by ignoring instructions or displays and using the equipment incorrectly: "Danger", "Warning", "Caution", and "Note".

These types are indicated by the following symbols.

⚠DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in the death or serious injury of the operator of the equipment.
⚠WARNING	Indicates a hazardous situation which, if not avoided, may result in death or serious injury.
⚠CAUTION	Indicates a hazardous situation which, if not avoided, may result in slight or moderate injury, or property damage.
⚠NOTE	Indicates a request concerning an item that must be observed in order to prevent damage or deterioration to the equipment and also to ensure effective use.

Cautions of cautions shows the following graphics.

	This mark means the corresponding item is "alerted".
	This mark means the corresponding item is "prohibited".
	This mark means the corresponding item is "required".

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About the F37

The F37 is intended to be used by doctors and other qualified personnel in fracture diagnostics and hemodynamic diagnostics.

However, this equipment is not designed to be used in ophthalmic ultrasound diagnosis, as its sound intensity is not compliant with ophthalmic restrictions established by the FDA.

Only physicians and other qualified personnel should operate this equipment for diagnostic purposes. Read section 1-1 of the Safety Instruction manual.

1) PRECAUTIONS Concerning the Use/Management of the F37

- Do not disassemble, repair or remodel this equipment or optional features without our consent.

  NOTE: Disassemble is removing the parts or options from the equipment using tools.

  NOTE: Remodel is installing or connecting the unspecified parts or equipment, including replacement of power cord.

- Assemble of the equipment or optional accessories shall be performed by our third party certified. Please contact one of our offices listed on back cover.

  Assemble is installing and connecting the parts or optional accessories in the main equipment using tools.

- Transporting this equipment (via automobile/ship) shall be performed by a third party certified by the manufacturer. Please contact one of our offices listed on back cover.
- Please conduct routine cleaning and inspection of the equipment. Refer to Chapter 5 of the Safety Instruction for details.
- Ensure that the output level of the scan conforms to the required duration of diagnosis.
- If any malfunction or abnormality is discovered during operation of the equipment, remove the probe from the patient immediately and discontinue use. If any abnormality is observed in the patient, provide proper care as quickly as possible. Refer to Chapter 4 of the Safety Instructions for more information on dealing with the equipment appropriately. If the malfunction is not listed in Chapter 4 of the Safety Instructions, contact one of our offices listed on back cover.

2) PRECAUTIONS for the F37 Installation

This equipment is a medical electrical equipment that intended for use in hospitals, research facilities. The equipment should be installed in accordance with the following guidelines.

- Install in accordance with Chapter 3 of the Safety Instructions.
- Install in an environment that conforms to the operating environments indicated in section 2-2-1 of the Safety Instructions.
- Install in an environment that ensures electromagnetic compatibility, in accordance with section 1-2-6 of the Safety Instructions, "Guideline for Electromagnetic Compatibility", and Item 1-3, "Electromagnetic compatibility".

NOTE: The electromagnetic compatibility (EMC) is ability of device to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbance to anything in that environment.

Classification of F37

- Protection against electric shock (ME equipment): class I • ME equipment
- Protection against electric shock (Applied parts): type BF Applied Parts
  - Probe/scanner applied parts and parts treated as applied parts:

    Refer to the following diagram (Probe/Scanner Pattern Diagram) and table.

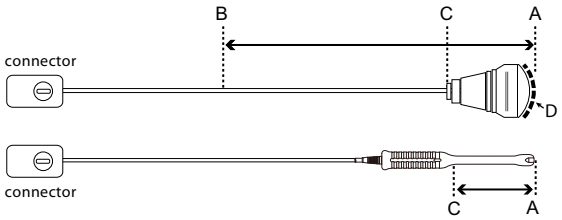


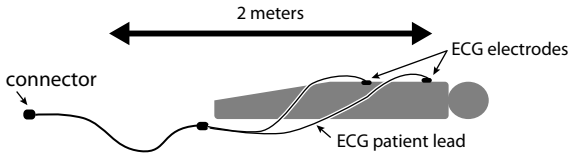
Figure:Probe/Scanner Pattern Diagram

Above illustrates a surface/intraoperative probe. Below shows a coelomic probe.

Applicable part of body	Applied part	Parts treated as applied parts	B - C length
Surface of body	Ultrasonic irradiation area (D)	A to B	100 cm
Intraoperative	Ultrasonic irradiation area (D)	A to B	20 cm
Endocavity	A to C	A to C	N/A

  - ECG

    The 2-meter length of the ECG cable extending from the ECG electrodes is treated as applied part (see diagram below).



- Protection against electric shock (Defibrillation-proof applied parts): Not suitable
- Protection against harmful ingress of water or particulate matter
  - equipment: IPX0 (Ordinary equipment)
  - Probe applied part: IPX7 (Watertight equipment)
- Suitability for use in an oxygen rich environment: Not suitable
- Method (s) of sterilization: Not suitable for sterilization/disinfection with medicinal solution, gas or radiation.
- Mode of operation: Continuous operation

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Terms used in the book

Example	Method	Intended
Press ENTER.	Press the specified switch on the operation panel (ENTER in the example).	Switches on the operation panel (including the Rotary Encoder)
Turn Rotary Encoder.	Rotate a switch such as Rotary Encoder to the left and right. To the left: counterclockwise direction To the right: clockwise direction	• Rotary Encoder • Multi Gain • B Gain • DEPTH/ZOOM
Select Preset key.	Press the specified key (Preset in the example) on the keyboard.	Keyboard
Select Set-Up.	1 Using trackball, move the pointer on the button (Set-Up in the example). 2 Press ENTER.	• Buttons or items on the screen • Thumbnails • Toggle buttons On: On Off: Off • Radio buttons On: Off:
Preset (Set-Up > (Application) > Menu-Function)	Menus in the bracket are shown hierarchy of the Tree View. 1 Press PRESET key. 2 Move the pointer to the Set-Up and press ENTER. 3 Move the pointer to the preset ((Application) in the example) and press ENTER. Repeat until a specified preset is displayed.	

Warning regarding the software used for this instrument

Regarding the software installed in this instrument, the following is prohibited.

1) Reselling, assigning, or transferring the software itself
2) Reverse engineering, reverse compiling, or reverse assembling
3) Modification, alteration or translation
4) Creating copies or duplicates
5) Leasing to third parties

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License Agreement

Microsoft Software License Terms

Notes on Microsoft Software License Terms

This ultrasound diagnostic system uses Windows operating system, a product of Microsoft Corporation in the United States.

Details regarding Windows license terms are described in the following pages. Please read these terms before using the ultrasound diagnostic system.

Terminology that appears in the license terms is defined as follows;

- "This device" refers to the ultrasound diagnostic system.
- "This software" refers to Windows.
- "[OEM]" refers to Hitachi, Ltd..
- "Other software" refers to the ultrasound diagnostic system software and other related software.

For the Microsoft Software License Terms, the following restrictions are given priority to ensure safe and stable operation of the ultrasound diagnostic system. Confirm all of the following;

- Only Windows functions, updates, add-on software, Internet-based services, and support services authorized by Hitachi, Ltd. can be used.
- Internet-related services cannot be used except for Sentinel customer service.
- Terminal services, file services, print services, Internet information services, and Internet connection sharing and telephony services cannot be used.
- The remote boot feature cannot be used.
- Remote access technologies such as Remote Desktop cannot be used.
- Windows Update Agent (Software Update Services) cannot be used.
- Backup copies of Windows cannot be made.

For inquiries to Hitachi, Ltd. regarding these license terms, please contact service support.

MICROSOFT SOFTWARE LICENSE AGREEMENT
WINDOWS EMBEDDED 8 STANDARD

Thank you for choosing a device preinstalled with Windows Embedded 8 Standard. This is a license agreement between you and [OEM]. This agreement describes your rights to use the Windows Embedded 8 Standard software included on this device. The Windows Embedded 8 Standard software also includes any separate media on which you received the software. For your convenience, we've organized this agreement into two parts. The first part includes introductory terms phrased in a question and answer format; the Additional Terms follow and contain greater detail. You should review the entire agreement, including any linked terms, because all of the terms are important and together create this contract that applies to you. You can review linked terms by pasting the forward link into your browser window once the software is running. The Additional Terms contain a binding arbitration clause and class action waiver. If you live in the United States, these affect your rights to resolve a dispute with [OEM], or with Microsoft, and you should read them carefully.

By accepting this agreement or using the software, you agree to all of these terms and consent to the transmission of certain information for Internet-based features of the software. If you do not accept and comply with these terms, you may not use the software or features. Instead, you may contact [OEM] to determine its return policy for a refund or credit under that policy.

How can I use the software? The software is licensed, not sold. Under this agreement, we grant you the right to install and run one copy only on the device with which you acquired the software (the licensed device), for use by one person at a time, but only if you comply with all the terms of this agreement. The software is not licensed to be used as server software or for commercial hosting – so, for example, you may not make the software available for simultaneous use by multiple users over a network. For more information on multiple user scenarios, see the Additional Terms.

May I make a backup copy? Yes, you may make a single copy of the software for backup purposes, and use that backup copy as described below.

Can I transfer the software to another user? You may transfer the software directly to another user, only with the licensed device. The transfer must include the software, proof of purchase, and, if provided with the device, an authentic Windows label such as the certificate of authenticity label, including the product key. You may not keep any copies of the software or any earlier version. Before any permitted transfer, the other party must agree that this agreement applies to the transfer and use of the software.

Does the software collect my personal information? If you connect your licensed device to the Internet, some features of the software may connect to Microsoft or service provider computer systems to send or receive information, including personal information. You may not always receive a separate notice when they connect. If you choose to use any of these features, you agree to send or receive this information when using that feature. Many of these features can be switched off or you can choose not to use them.

How does Microsoft use your information? Microsoft uses the information it collects through the software features to upgrade or fix the software and otherwise improve its products and services. In certain circumstances, Microsoft also shares it with others. For example, Microsoft shares error reports with relevant hardware and software vendors, so that the vendors can use the information to improve how their products run with Microsoft products. You agree that Microsoft may use and disclose the information as described in Microsoft's Privacy Statement at go.microsoft.com/fwlink/?LinkId=190175.

What does this agreement apply to? The Windows Embedded 8 Standard software on this licensed device includes software licensed from Microsoft Corporation or its affiliate. This agreement (including any printed-paper license terms that accompany the software) applies to the software, any separate media on which you received the software, and any Microsoft updates, supplements, and services for the software, unless other terms come with them.

Are there things I'm not allowed to do with the software? Yes. Because the software is licensed, not sold, [OEM] and Microsoft reserve all rights (such as rights under intellectual property laws) not expressly granted in this agreement. In particular, this license does not give you any right to, and you may not: use features of the software separately; publish, copy (other than the permitted backup copy), rent, lease, or lend the software; transfer the software (except as permitted by this agreement); attempt to circumvent technical protection measures in the software; or reverse engineer, decompile, or disassemble the software, except if the laws where you live permit this even when this agreement does not. In that case, you may do only what your law allows. When using Internet-based features , you may not use those features in any way that could interfere with anyone else's use of them, or to try to gain access to any service, data, account, or network in an unauthorized manner.

ADDITIONAL TERMS

1) License Rights and Use Scenarios

a) Device.

In this agreement, "device" means a hardware system with internal storage capable of running the software. The software is licensed to run on up to two processors on the licensed device at any one time.

b) Specific Use.

[OEM] designed the licensed device for a specific use. You may only use the software for that use.

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c) Other Software.

You may use other programs with the software as long as the other programs

– directly support the specific use for the licensed device, or
– provide system utilities, resource management, or anti-virus or similar protection.

Software that provides consumer or business tasks or processes may not run on the licensed device. This includes word processing, spreadsheet, database, scheduling and personal finance software. The licensed device may use terminal services protocols to access such software running on a server.

d) Device connections.

You may not use the software as server software. In other words, more than one device may not access, display, run, share or use the software at the same time. You may allow up to 20 other devices to access the software installed on the licensed device for the purpose of using file services, print services, Internet information services, and Internet connection sharing and telephony services on the licensed device. The 20 connection limit applies to devices that access the software indirectly through "multiplexing" or other software or hardware that pools connections. You may use unlimited inbound connections at any time via TCP/IP.

e) Remote Access Technologies.

The software contains Remote Desktop and Remote Assistance technologies that enable the software or applications installed on the licensed device to be accessed remotely from other devices.

– Remote Desktop.

  The single primary user of the licensed device may access a session from any other device using Remote Desktop or similar technologies. A "session" means the experience of interacting with the software, directly or indirectly, through any combination of input, output and display peripherals. Other users, one at a time, may access the licensed software running on this host device, from any device using Remote Desktop, but only if the remote device is separately licensed to run Windows Embedded 8 Standard.

– Remote Assistance.

  You may use Remote Assistance or similar technologies to share an active session without obtaining any additional licenses for the software. Remote Assistance allows one user to directly connect to another user's device, usually to correct problems.

2) Binding Arbitration and Class Action Waiver

a) Application.

This Section 2 applies to any dispute EXCEPT IT DOES NOT INCLUDE A DISPUTE RELATING TO THE ENFORCEMENT OR VALIDITY OF YOUR, [OEM]'S, OR EITHER OF OUR LICENSORS' INTELLECTUAL PROPERTY RIGHTS. Dispute means any dispute, action, or other controversy between you and [OEM], or you and Microsoft, concerning the software (including its price) or this agreement, whether in contract, warranty, tort, statute, regulation, ordinance, or any other legal or equitable basis. "Dispute" will be given the broadest possible meaning allowable under law.

b) Notice of Dispute.

In the event of a dispute, you or [OEM] must give the other a Notice of Dispute, which is a written statement of the name, address, and contact information of the party giving it, the facts giving rise to the dispute, and the relief requested. Send it by U.S. Mail to [OEM], ATTN: LEGAL DEPARTMENT. [OEM] will send any Notice of Dispute to your U.S. Mail address if available, or otherwise to your e-mail address. You and [OEM] will attempt to resolve any dispute through informal negotiation within 60 days from the date the Notice of Dispute is sent. After 60 days, you or [OEM] may commence arbitration.

c) Small claims court.

You may also litigate any dispute in small claims court in your county of residence or the [OEM]'s principal place of business, if the dispute meets all requirements to be heard in the small claims court. You may litigate in small claims court whether or not you negotiated informally first.

d) Binding arbitration.

If you and [OEM], or Microsoft, do not resolve any dispute by informal negotiation or in small claims court, any other effort to resolve the dispute will be conducted exclusively by binding arbitration. You are giving up the right to litigate (or participate in as a party or class member) all disputes in court before a judge or jury. Instead, all disputes will be resolved before a neutral arbitrator, whose decision will be final except for a limited right of appeal under the Federal Arbitration Act. Any court with jurisdiction over the parties may enforce the arbitrator's award.

e) Class action waiver.

Any proceedings to resolve or litigate any dispute in any forum will be conducted solely on an individual basis. Neither you, [OEM], nor Microsoft, will seek to have any dispute heard as a class action, as a private attorney general action, or in any other proceeding in which any party acts or proposes to act in a representative capacity. No arbitration or proceeding will be combined with another without the prior written consent of all parties to all affected arbitrations or proceedings.

f) Arbitration procedure.

Any arbitration will be conducted by the American Arbitration Association (the "AAA"), under its Commercial Arbitration Rules. If you are an individual and use the software for personal or household use, or if the value of the dispute is $75,000 or less whether or not you are an individual or how you use the software, the AAA Supplementary Procedures for Consumer-Related Disputes will also apply. To commence arbitration, submit a Commercial Arbitration Rules Demand for Arbitration form to the AAA. You may request a telephonic or in-person hearing by following the AAA rules. In a dispute involving $10,000 or less, any hearing will be telephonic unless the arbitrator finds good cause to hold an in-person hearing instead. For more information, see adr.org or call 1-800-778-7879. You agree to commence arbitration only in your county of residence or in the [OEM]'s principal place of business. [OEM] agrees to commence arbitration only in your county of residence. The arbitrator may award the same damages to you individually as a court could. The arbitrator may award declaratory or injunctive relief only to you individually, and only to the extent required to satisfy your individual claim.

g) Arbitration fees and incentives

i) Disputes involving $75,000 or less.

[OEM] will promptly reimburse your filing fees and pay the AAA's and arbitrator's fees and expenses. If you reject the [OEM]'s last written settlement offer made before the arbitrator was appointed ("last written offer"), your dispute goes all the way to an arbitrator's decision (called an "award"), and the arbitrator awards you more than the last written offer, [OEM] will give you three incentives: (1) pay the greater of the award or $1,000; (2) pay twice your reasonable attorney's fees, if any; and (3) reimburse any expenses (including expert witness fees and costs) that your attorney reasonably accrues for investigating, preparing, and pursuing your claim in arbitration. The arbitrator will determine the amounts.

ii) Disputes involving more than $75,000.

The AAA rules will govern payment of filing fees and the AAA's and arbitrator's fees and expenses.

iii) Disputes involving any amount.

In any arbitration you commence, [OEM] will seek its AAA or arbitrator's fees and expenses, or your filing fees it reimbursed, only if the arbitrator finds the arbitration frivolous or brought for an improper purpose. In any arbitration [OEM] commences, it will pay all filing, AAA, and arbitrator's fees and expenses. It will not seek its attorney's fees or expenses from you in any arbitration. Fees and expenses are not counted in determining how much a dispute involves.

h) Claims or disputes must be filed within one year.

To the extent permitted by law, any claim or dispute under this agreement to which Section 2 applies must be filed within one year in small claims court (Section 2.c) or in arbitration (Section 2.d). The one-year period begins when the claim or dispute first could be filed. If such a claim or dispute is not filed within one year, it is permanently barred.

i) Severability.

If the class action waiver in Section 2.e is found to be illegal or unenforceable as to all or some parts of a dispute, then Section 2 will not apply to those parts. Instead, those parts will be severed and proceed in a court of law, with the remaining parts proceeding in arbitration. If any other provision of Section 2 is found to be illegal or unenforceable, that provision will be severed with the remainder of Section 2 remaining in full force and effect

j) Third-Party Beneficiary.

Microsoft Corporation is not a party to this agreement but is a third-party beneficiary of your and the [OEM]'s agreement to resolve disputes through informal negotiation and arbitration. If your dispute is with Microsoft, Microsoft agrees to do everything [OEM] agrees to do in Section 2, and you agree to do everything regarding Microsoft that Section 2 requires you to do regarding [OEM]. Mail a Notice of Dispute with Microsoft to Microsoft Corporation, ATTN: LCA ARBITRATION, One Microsoft Way, Redmond, WA 98052-6399. You may commence an arbitration or small claims court case against Microsoft in your county of residence or King County, Washington.

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3) CHOICE OF LAW

The laws of the state or country where you live govern all claims and disputes under this agreement, including breach of contract claims and claims under state consumer protection laws, unfair competition laws, implied warranty laws, for unjust enrichment, and in tort. If you acquired the software in any other country, the laws of that country apply. This agreement describes certain legal rights. You may have other rights, including consumer rights, under the laws of your state or country. You may also have rights with respect to the party from whom you acquired the software. This agreement does not change those other rights if the laws of your state or country do not permit it to do so.

4) INTERNET-BASED FEATURES; PRIVACY

The following software features use Internet protocols, which send to Microsoft (or its suppliers or service providers) device information, such as your Internet protocol address, the type of operating system, browser and name and version of the software you are using, and the language code of the device where the software is installed. Microsoft uses this information to make the Internet-based features available to you, in accordance with the Windows 8 Privacy Statement, at go.microsoft.com/fwlink/?LinkId=190175. Some Internet-based features may be delivered at a later date via Microsoft's Windows Update service—if, for example, you acquire an application that relies on one of those services. [OEM] may have elected to turn on one or more of the following features in the licensed device.

a) Windows Update.

If you use the Windows Update service in the software, updates or downloads to the Windows Update service will be required for proper functioning of the service, from time to time, and will be downloaded and installed without further notice to you.

b) Windows Digital Rights Management technology.

Some content owners use Windows digital rights management technology (WDRM) to protect their copyrights and other intellectual property, including by disabling the software's ability to play protected content if WDRM fails. You agree that Microsoft may include a revocation list with the licenses.

c) Windows Media Player.

When you use Windows Media Player, it checks with Microsoft for compatible online music services in your region and new versions of the player. You may only use Windows Media Player as described at go.microsoft.com/fwlink/?LinkId=104605.

d) Windows Defender.

If turned on, Windows Defender will search your licensed device for many types of malicious software, including viruses, worms, bots, rootkits, “spyware”, “adware” and other potentially unwanted software. If it finds potentially unwanted software, the software will ask you if you want to ignore, disable (quarantine) or remove it. If you choose the “recommended” security settings when you first start using the software, such malware and other potentially unwanted software rated “high” or “severe” will automatically be removed. This removal may result in other software on your licensed device ceasing to work or your breaching a license to use that software. It is possible that software that is not unwanted may be removed or disabled. If you use Windows Defender and Windows Update, Windows Defender is regularly updated through Windows Update.

e) Malicious software removal.

If you use Windows Update, at least once each month the software will scan for and remove from your licensed device the malware listed at go.microsoft.com/fwlink/?LinkId=241725. After the scan completes, a report will be sent to Microsoft with specific information about malware detected, errors, and other information about your device. This information is used to improve the software and other Microsoft products. You may disable the software’s reporting functionality by following the instructions found at go.microsoft.com/fwlink/?LinkId=241725.

f) SmartScreen Filter.

If enabled, the SmartScreen Filter will check the addresses of webpages and downloads you attempt to view against a frequently updated list of webpages and downloads that have been reported to Microsoft as unsafe or suspicious. SmartScreen will also check downloaded programs that you attempt to run against a list of commonly downloaded or run programs to help you make more informed trust decisions. More information can be found by visiting the Internet Explorer Privacy Statement go.microsoft.com/fwlink/?LinkId=239590. By enabling SmartScreen in either Windows or Internet Explorer, you consent to this feature, and you agree to use the SmartScreen Filter only in conjunction with Windows or Internet Explorer. You may not, either manually or by enabling or authorizing any software or service, copy, display, distribute, collect or store any data provided by the SmartScreen Filter.

g) IPv6 Network Address Translation (NAT) Traversal service (Teredo).

Each time you start your licensed device, Teredo will attempt to locate a public Internet Protocol version 6 (IPv6) service on the Internet. This occurs automatically when your licensed device is connected to a public or private network, but does not occur on managed networks such as enterprise domains. If you use a program that requires Teredo to use IPv6 connectivity, or if you configure your firewall to always enable IPv6 connectivity, then Teredo will periodically contact the Microsoft Teredo service over the Internet. The only information sent to Microsoft is standard computer information and the name of the service requested (for example teredo.ipv6.microsoft.com). The information sent from your licensed device by Teredo is used to determine if your licensed device is connected to the Internet and if it can locate a public IPv6 service. Once the service is located, information is sent to maintain a connection with the IPv6 service.

h) Plug and Play and Plug and Play Extensions.

Your licensed device may not have the drivers needed to communicate with hardware that you connect to your licensed device. If so, the update feature of the software can obtain and install the correct driver on your licensed device. An administrator can disable this update feature.

i) Digital certificates.

The software uses digital certificates to confirm the identity of Internet users sending X.509 standard encrypted information, to digitally sign files and macros, and to verify the integrity and origin of file contents. The software may retrieve and update certificates, certificate revocation lists, and the list of trusted certification authorities, over the Internet.

j) Network awareness.

This feature determines whether a system is connected to a network by either passive monitoring of network traffic or active DNS or HTTP queries. The query transfers only standard TCP/IP or DNS information for routing purposes. You can switch off the active query feature through a registry setting.

k) Accelerators.

When you click on or move your mouse over an Accelerator in Internet Explorer, any of the following may be sent to the applicable service provider (which may not be Microsoft): the title and full web address or URL of the current webpage, standard computer information, and any content you have selected. For more information, see go.microsoft.com/fwlink/?LinkId=239590.

l) Search provider update.

The software will download an update to the data on your device about search providers. This update upgrades your providers with the latest features, such as new icons or search suggestions. This is a one-time update, but the software will try to perform the update several times if it does not successfully download the update. For more information, see go.microsoft.com/fwlink/?LinkId=239590.

m) Cookies.

If you choose to use online features in the software, such as online Help and Support, cookies may be set. To learn how to block, control and delete cookies, please read the cookies section of the privacy statement at go.microsoft.com/fwlink/?linkId=74170.

n) Customer Experience Improvement Program (CEIP).

This software uses CEIP. CEIP automatically sends Microsoft information about your hardware and how you use this software. We do not use this information to identify or contact you. CEIP will also periodically download a small file to your computer. This file helps us collect information about problems that you have while using the software. When available, new help information about the errors might also be automatically downloaded. To learn more about CEIP, see http://go.microsoft.com/fwlink/?LinkID=52097.

o) Automatic Updates.

Software with Click-to-Run technology may check with Microsoft now and then for updates and supplements. If the software finds updates and supplements, it might download and install them on your licensed device.

p) Auto Root Update.

The Auto Root Update feature updates the list of trusted certificate authorities. You can switch off the Auto Root Update feature.

q) Microsoft Error Reporting Service.

This feature helps Microsoft and Windows partners diagnose problems in the software and provide solutions. Not all problems will have a solution but when a solution is available, it will be offered as a step to solve a problem you have reported or as an update to install. As part of setup and installation, the Microsoft Error Reporting Service sends to Microsoft information about setup and installation failures in order to attempt to diagnose the problem. To help prevent problems and make the software more reliable, some solutions are also included in service packs and future versions of the software.

r) Silverlight and Silverlight Software Development Kit.

Silverlight contains an Automatic Update feature that is on by default. You may turn off this feature while Silverlight is running ("opt out"). Unless you expressly opt out of this feature, this feature will

- connect to Microsoft or service provider computer systems over the Internet,
- use Internet protocols to send to the appropriate systems standard computer information, such as
  - your computer's Internet protocol address,
  - the type of operating system, browser and name and version of Silverlight you are using, and
  - the language code of the device where you installed Silverlight, and
- automatically download and install, or prompt you to download and/or install, current updates to Silverlight.

In some cases, you will not receive a separate notice before this feature takes effect. By installing the software, you consent to the transmission of standard computer information and the automatic downloading and installation of updates.

s) Microsoft Digital Rights Management.

If you use Silverlight to access content that has been protected with Microsoft Digital Rights Management (DRM), in order to let you play the content, the software may automatically

- request media usage rights from a rights server on the Internet and
- download and install available DRM Updates.

  For more information about this feature, including instructions for to turning the Automatic Updates off, go to go.microsoft.com/fwlink/?LinkId=147032.

t) Windows Rights Management Services.

The software contains a feature that allows you to create content that cannot be printed, copied or sent to others without your permission. You must connect to Microsoft to use this feature for the first time. Once a year, you must re-connect to Microsoft to update it. You may choose not to use this feature.

u) Windows Time Service.

This service synchronizes with time.windows.com once a week to provide your licensed device with the correct time. You can turn this feature off or choose your preferred time source within the Date and Time Control Panel applet. The connection uses standard NTP protocol.

v) Windows (or Microsoft) Update Feature.

You may connect new hardware to the licensed device. Your licensed device may not have the drivers needed to communicate with that hardware. If so, the update feature of the software can obtain the correct driver from Microsoft and install it on your licensed device. You can switch off this update feature.

5) PROOF OF LICENSE

The elements of a valid license include a genuine product key, successful activation of the software, an authentic Windows label such as a Certificate of Authenticity (COA), and proof of purchase from a supplier of genuine Microsoft software. A valid license may also include a Windows activation file installed on the licensed device by [OEM]. If there is a COA or other Windows label, it must be affixed to the licensed device or appear on the [OEM]'s software packaging or peripherals when purchased. If you receive an authenticity label separate from your licensed device, it does not establish proof of license.

For further information about Microsoft genuine software, see howtotell.com.

6) UPDATES AND UPGRADES

You may only obtain updates or upgrades for the software from Microsoft or authorized sources. You may not be able to obtain certain updates or upgrades from [OEM], or Microsoft, if your copy of the software is improperly licensed. Certain upgrades, support, and other services may be offered only to users of genuine Microsoft software. For more information about Genuine Windows, see go.microsoft.com/fwlink/?LinkId=104612.

To use upgrade software, you must first be licensed for the software that is eligible for the upgrade. Upon upgrade, this agreement takes the place of the agreement for the software you upgraded from. After you upgrade, you may no longer use the software you upgraded from.

7) FONTS, ICONS, IMAGES, AND SOUNDS

a) Font components.

While the software is running, you may use its fonts to display and print content. You may temporarily download the fonts to a printer or other output device to print content, and you may embed fonts in content only as permitted by the embedding restrictions in the fonts.

b) Icons, images, and sounds.

While the software is running, you may access and use its icons, images, sounds, and media only from the licensed device. You may not share the sample images, sounds and media provided with the software or use them for any other purpose.

8) NET FRAMEWORK

The software includes one or more components of the .NET Framework, which you may use only as described at go.microsoft.com/fwlink/?LinkId=66406 if you use the .NET Framework components to conduct internal benchmark testing.

9) VHD BOOT.

Additional copies of the software created using the software's Virtual Hard Disk functionality ("VHD Image") may be pre-installed on the physical hard disk of the licensed device. These VHD Images may only be used for maintaining or updating the software installed on the physical hard disk or drive. If the VHD Image is the only software on your device, it may be used as the primary operating system but all other copies of the VHD Image may only be used for maintenance and updating.

10) NOT FAULT TOLERANT. The software is not fault tolerant. [OEM] installed the software on the licensed device and is responsible for how it operates on the device.

11) RESTRICTED USE.

The Microsoft software was not designed for systems that require fault-tolerant performance. You may not use the Microsoft software in any device or system in which a failure or fault of any kind of the software could reasonably be seen to lead to death or serious injury of any person, or to severe physical or environmental damage.

12) EXPORT RESTRICTIONS.

You must also comply with all domestic and international export laws and regulations that apply to the software, which include restrictions on destinations, end users, and end use. For further information on geographic and export restrictions, visit go.microsoft.com/fwlink/?LinkId=141397 and microsoft.com/exporting.

13) NO WARRANTIES FOR THE SOFTWARE.

The software is provided "as is". You bear all risks of using it. Microsoft gives no express warranties, guarantees or conditions. Any warranties you receive regarding the licensed device or the software do not originate from, and are not binding on, Microsoft or its affiliates. When allowed by your local laws, [OEM] and Microsoft exclude implied warranties of merchantability, fitness for a particular purpose and non-infringement.

14) LIABILITY LIMITATIONS.

You can recover from Microsoft and its affiliates only direct damages up to two hundred fifty U.S. Dollars (U.S. $250.00), or equivalent in local currency. You cannot recover any other damages, including consequential, lost profits, special, indirect or incidental damages.

This limitation applies to:

- anything related to the software, services, content (including code) on third party internet sites, or third party programs, and
- claims for breach of contract, breach of warranty, guarantee or condition, strict liability, negligence, or other tort to the extent permitted by applicable law.

It also applies even if Microsoft should have been aware of the possibility of the damages. The above limitation may not apply to you because your country may not allow the exclusion or limitation of incidental, consequential or other damages.

15) REFUND PROCEDURES

If you are seeking a refund, contact [OEM] to determine its return policy for a refund or credit. You must comply with that policy, which might require you to return the software with the entire licensed device on which the software is installed for a refund.

16) ENTIRE AGREEMENT

This agreement (together with printed-paper license terms or other terms accompanying any software supplements, updates, and services that are provided by [OEM], or Microsoft, and that you use), and the terms contained in web links listed in this agreement, are the entire agreement for the software and any such supplements, updates, and services (unless [OEM], or Microsoft, provides other terms with such supplements, updates, or services).

17) FOR AUSTRALIA ONLY.

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure. Goods presented for repair may be replaced by refurbished goods of the same type rather than being replaced. Refurbished parts may be used to repair the goods.

For further information regarding this warranty and to claim expenses in relation to the warranty (if applicable), please contact the manufacturer or installer; see the contact information provided in the system packaging.

McAfee Embedded Control

The terms of this license agreement constitute the entire agreement between you and Hitachi, Ltd. Please carefully read through the terms of the license agreement listed below. These license terms apply to the software included on this system. They also apply when the software has been installed on other media.

This system includes software provided under a license agreement with McAfee, Inc. and its subsidiaries (hereafter referred to as "McAfee"). These license terms also apply to any McAfee

- Updates
- Supplements
- Support services

for this software, except where these are accompanied by other terms, in which case those terms apply.

By using this software, you agree to accept these terms. If you do not accept these terms, please do not use the software. Instead, contact Hitachi, Ltd. to determine their return policy for a refund or credit.

If you comply with these license terms, you are entitled to the rights listed below

Software License Agreement

Hitachi, Ltd. (hereafter referred to as "we" or "us") grants you permission to use the software (the software program and its related documentation are hereafter collectively referred to as "the software") provided for under this agreement subject to the following terms.

The use of this software is deemed as acceptance of all of the terms of this license agreement. If you do not accept them, please do not use the software.

1) Intellectual Property

   All copyright and other intellectual property rights inherent to the software belongs to the software developer and the software is protected by the copyright laws, and any other applicable rules and regulations, of the country in which it is used. You must therefore handle the software in the same manner as any other copyrighted work.

2) Granted Usage Rights

   a) The user is granted a non-exclusive right to use the software subject to the terms of this agreement.

   b) This software has been designed for a specific purpose. You may use it only for that purpose.

3) Scope of License

This software is licensed, not sold. This agreement only gives you limited rights to use the software. We and the developer of this software reserve all other rights. You must comply with any technical limitations in the software that only allow you to use it in certain ways. Except and only to the extent otherwise permitted by applicable laws, you may not;

a) Work around any technical limitations in the software.

b) Reverse engineer, decompile or disassemble the software.

c) Make copies of the software.

d) Publish the software for others to copy.

e) Rent, lease or lend the software.

4) Limitations

a) Unless expressly permitted by this license agreement, you may not copy or alter the software, in part or in whole.

b) You may not remove copyright notices or notices of other rights from the software or related documentation.

c) This software is not designed for life-sustaining purposes or systems that involve a high level of risk and must therefore not be used in nuclear facilities, aircraft control or air traffic control systems, life supporting systems, weapons or similar systems.

5) Limited Warranty

a) We and the developer of this software (hereafter referred to as "we" or "us") assume no liability whatsoever to any person or entity for damages or losses allegedly caused by the use of the software or the failure to use the software, including business interruptions, data loss, financial loss or loss of anticipated profit, loss of business information, legal expenses, technicians' fees, court expenses or other financial damages that have been incurred as a result of the use of the software, even if we had been directly or indirectly advised of the possibility of such damages beforehand. This software is provided "as is" and we make no claims with regard to its fitness for any purpose. The software may not be free from errors and we do not guarantee uninterrupted operation. By using this software, you acknowledge that you are aware of and accept the fact that file changes potentially caused by a computer virus infection may lead to unforeseen changes in these files as a result of the processes used to remove said viral infection.

b) We provide no warranty with respect to the software except in the cases stated in paragraph c) below.

c) If we produce a bug fix for the software within a period of less than six months after a customer's initial purchase of the software , we will provide said customers with the revised software, or software intended to rectify the bug (such software is hereafter referred to as "revised software") or provide information regarding such revisions. However, the determination of the need for providing revised software or information regarding such revised software, as well as when and how it is provided, is entirely at our discretion. The revised software provided to customers is regarded as part of this software. The above exception is the sole warranty that we provide for the recording media of the software.

6) Liability Limitations

Our and the software developer's (hereafter referred to as "we," "us" or "our") liability and the customer's avenues of recourse are described below.

a) We accept no liability whatsoever for damages incurred by the customer in the use of the software. However, this may not be the case in the event that liability is found to be attributable to us.

b) However, even in the event that we are found to be liable for damages due to the above paragraph a) or applicable laws and/or regulations, our liability to you is limited to no more than half of the price that you paid for this software within the 12 months prior to the action or event giving rise to liability and we accept no liability for damages (normal damages) normally arising from failure, negligence or illegal activities deemed to exceed commonly accepted norms and/or special or indirect damages of any kind arising from data loss, loss of business opportunities and/or loss of revenue, even if we had been advised of the possibility of such damages beforehand.

7) Other Details

a) You must comply with all laws and regulations of the country of export and all applicable international laws and regulations when exporting the software (including related documentation) from the country of export. This software includes software created in the United States and must therefore comply with the Export Administration Regulations (EAR) of the United States.

b) This license agreement is proof of the right to use this software and must therefore be retained by the customer.

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1 Safety Precautions

1-1 Purpose of Use

In the diagnostic ultrasound system, ultrasound images are produced as follows;

Ultrasound wave pulses released from the transducer are reflected from the internal body system. Reflected waves are transmitted back to the transducer, and ultrasound images are produced with the reflected image on the monitor. You can distinguish internal body systems because the acoustic impedances vary among the internal organs.

Ultrasound images are used for various diagnoses of the internal body system.

This F37 is intended to be used by doctors and other qualified persons for performing slice diagnoses and blood circulation diagnoses in the following parts of the human body.

- Thorax
- Abdomen
- Perineum and pelvis
- Lower limbs
- Back
- Upper limbs
- Head
- Neck

Do not use it for any applications other than those stated above.

⚠WARNING

Do not use this equipment for performing ultrasound diagnosis of the eyes.
The acoustic power from this equipment exceeds the upper ophthalmological limits indicated in the U.S. FDA standards.

⚠CAUTION

Do not use it for any application that is not covered in the instruction manual of the probe.
There is a risk of injuries or burns to the patient or oprator. There is a risk of electrical shock, breakdown or other accidents.

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1-2 Precautions for Use

Before using this device, please read this manual. Be especially sure to read "1. Safety Precautions".

Keep this manual securely for future reference.

The following items are important in preventing harm or injury to equipment operator or patient. There are four levels of harm/damage that can be caused by ignoring instructions/displays or using the equipment incorrectly: "Danger," "Warning," "Caution," and "Note."

⚠DANGER	Indicates an imminently hazardous situation that will result in the death of or serious injury to the equipment operator.
⚠WARNING	Indicates a hazardous situation that could result in death or serious injury.
⚠CAUTION	Indicates a hazardous situation that may result in slight or moderate injury, or property damage.
⚠NOTE	Indicates a request concerning an item that must be observed in order to prevent damage or deterioration to the equipment and also to ensure effective use.

Cautions use the following graphics.

	This mark means the corresponding item is "alerted".
	This mark means the corresponding item is "prohibited".
	This mark means the corresponding item is "required".

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1-2-1 Warnings and Safety Notice

⚠DANGER

- Do not use this device in a flammable atmosphere.

This device is not suitable for use in a flammable environment. It could cause an explosion.

⚠WARNING

- Do not disassemble, repair or remodel the equipment or optional features without our consent.

Electric shock or other accidents could result.

Please contact one of our offices listed on back cover.

- Clean, disinfect and sterilze the probes as described in their documentation, before using them.
- Wear medical gloves during inspection, and wash your hands after inspection.
- Destroy the probes used on patients with Creutzfeld-Jacob disease.

  At present, there are no known methods available to properly clean and sterilize probes exposed to Creutzfeld-Jacob disease.

There is a risk of infection of the patient and the examiner.

⚠CAUTION

- If anything unusual occurs when this instrument is used, take the probe away from the patient immediately, and stop using the instrument.

  If the patient's condition is abnormal, provide appropriate medical treatment.

When using this instrument, watch to make sure that it is functioning normally, and that the patient is not abnormally affected.

- DO NOT connect any probes or options to the F37 not specified in this manual.

There is a risk of injuries or burns to the patient or oprator. There is a risk of electrical shock, breakdown or other accidents.

- DO NOT assemble transport the equipment or its options via automobile or ship.

  Electric shock or other accidents could result.

  For assemble or transport the equipment and its options, please contact one of our offices listed on back cover.

Place instrument in the following location.

- Place the instrument on a flat horizontal surface with sufficient stability and minimal vibrations.
- DO NOT place the instrument on a precarious or uneven surface.
- Avoid locations with water or other liquids, avoid places salt-sulfur and avoid exposure to direct sunlight.

These locations may cause injuries such as burns to the patient or examiner.

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⚠ CAUTION
• Scan for the minimum length of time necessary for the diagnosis, and at the lowest suitable output. There is the possibility that the patient's internal tissues could be affected.
• Hold the probe tightly so as no to slip, especially when using ultrasound gel or others. Place the unused probe in the probe holder. Otherwise, the probe may slip out of your hands and hit a patient or a examiner.
• Do not use unreasonable force while inserting a probe into a body cavity. It may cause injuries to the patient.
• Coat the probe with an ultrasound medium before using. • When the probe is not in use even during an examination, freeze the image. Use of an ultrasonic beam into the air without coating the probe with an ultrasound medium, may cause the surface temperature to rise. It could cause burns to the patient or examiner. If you find that a probe is unusually warm, please contact one of our offices listed on back cover.
• DO NOT touch the exposed sockets of the probe's connector, or USB connector sockets. • DO NOT touch the patient with parts other than the applied probe. Doing so may cause electric shock or short circuits.
• Always use the instrument in a dried state. Avoid rapid temperature change which may cause condensation. Using the instrument where condensation occurs or when splashed with, can cause electric shock or short-circuiting. Let the instrument to stand for a while in a newly installed location to allow it become acclimated to the environment before switching it ON. Should you spill liquid on the instrument, contact one of our offices listed on back cover.
• DO NOT cover the vent. If the temperature gets hot, there is a risk of short-circuiting or other accidents.
• Return the monitor at the front, and then fold the monitor. • DO NOT close the monitor by force. DO NOT put anything on the monitor. There is a risk of injury or damage to the monitor. And you may pinch your fingers.
• Perform regular maintenance and inspection as described in this manual. If components of the equipment deteriorate due to years of use, there is a risk for degrading its performance, breaking down, emitting smoke or ignition. If you notice any problems, please contact one of our offices listed on back cover.

Safety precautions about Power Plug and Cable

⚠WARNING
Use the power cable provided, and plug it directly into the wall receptacle (hospital grade). The use of cables, adaptors or extension cords to extend or branch the power connection may cause a short circuit, ground leakage or fire.
• DO NOT damage, modify or sever the power cable and plug. • DO NOT twist, bundle, forcibly bend, pull, or place heavy objects on the cable. Damaging the power cable and plug may cause electric shock or short circuits.
Should you discover deformations or abnormalities in the power cable or plug, stop using the device immediately. Using the device with a damaged cable or plug may cause a loose connection or fire. Please contact one of our offices listed on back cover for servicing.
Routinely disconnect the power cable plug from the outlet for washing. Use a dry cloth to wipe off any dust or moisture that accumulates on the power cable plug. Failure to do so may cause electric shock or short-circuits.
For extended periods of disuse, disconnect the power plug from the outlet. Turning the power switch OFF does not completely shut off power to the equipment.

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1-2-2 Labels

Many marks are used on this equipment.

NOTE: Labels that have a combination  and  (mainly connector sockets) includes following safety caution:

⚠ CAUTION
  DO NOT touch to the connector pins. There is risk of deterioration and failure of parts sensitive to static electricity. For details, See “Electrostatic Discharge (ESD) Guidelines” on page 1-21.

NOTE: Refer to the probe documentation for more information on probe labels.

The following label indicates the risk of being pinched in spaces or openings. Symbols are located in places to indicate the relevant risks at that site.

⚠ CAUTION
 Be careful of catching your fingers. There is a risk of injury of your hands or fingers.

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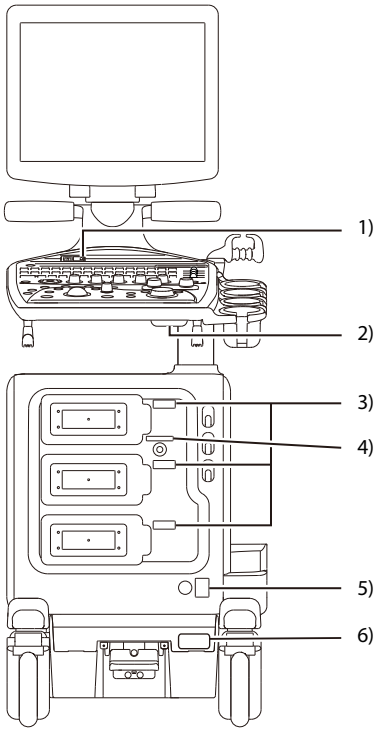
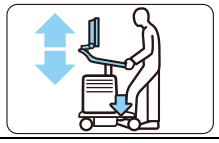
Labels from an anterior view



1)		USB connector
2)		Swinging method and range of the operation panel. Pull this lever slightly and the operation panel can be swing within the range of ±15°. Pull this lever full and the operation panel can be swing within the range of ±45°.
3)		Probe connector. The number is a connector number.
4)		Independent probe connecter (option).
5)		Foot switch connector
6)		Method of adjusting the height of the operation panel. Adjust the height of the operation panel while stepping on this up-and-down pedal of the panel.

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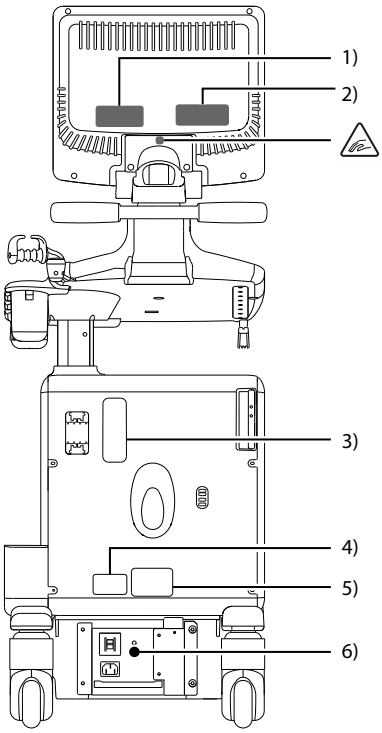
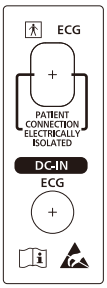
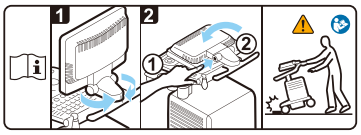
Labels on the Rear of the Instrument



3)



1)		Method of folding the monitor and moving caution. **⚠CAUTION** Before moving, prepare following the instruction manual(→ p.3-11). Move the instrument by grasping the handle at the back of the instrument.
2)		This shows safety precautions, etc.  This product cannot be disposed of as regular garbage. Dispose of it in accordance with laws and regulations.
3)	Kinds of connectors for the physiological signal	 Type BF Applied parts
4)		The importer for EEA: European Economic Area region is represented according to European Union Directives 93/42/EEC and 2011/65/EU. This label is applied to areas inside EU only.

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5)		This shows the manufacturer name, model name, and other information. CE 0123 This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS. This symbol is applied to areas inside EU only. Manufacturer. Date of manufacture. Number under the mark means the manufacturing year.
6)		Equi-potential terminals

Each marks on label 2) means following;

	Safety Warning sign.
 Dangerous Voltage	⚠WARNING Use the power cable provided, and plug it directly into the wall receptacle (hospital grade). There is the risk of short circuiting or ground leakage.
 Explosion	⚠DANGER Do not use this instrument in a flammable atmosphere. It may cause an explosion if used in such an atmosphere.
 CAUTION Acoustic Poser	⚠CAUTION Scan for the minimum length of time necessary for the diagnosis, and at the lowest suitable output. There is the risk of that the patient's internal tissues could be affected.
 CAUTION pinch	⚠CAUTION Be careful of catching your fingers. There is a risk of injury of your hands or fingers.
 No Modification	⚠WARNING Do not disassemble, repair (including replacement of power cord) or remodel this instrument. There is a risk of unexpected accidents or electrical shock. Please contact one of our offices listed on back cover for servicing.

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 DO NOT use cellular phone	⚠CAUTION DO NOT use portable radio communication devices (e.g. cellular phones and radiotransceiver) near this instrument. Effects can include noise in images, disruption of physiological signals, and artifacts on the screen.
 DO NOT pushing	⚠CAUTION Do not push the side of the equipment. Do not exert excessive force on the equipment. Doing so may cause the equipment to fall, which may cause injury or damage to other equipments.
 DO NOT sitting	⚠CAUTION DO NOT sit on the equipment. Doing so may cause the equipment to fall, which may cause injury or damage to other equipments.
 Follow the instruction manual	⚠CAUTION Follow the instruction manual to operate this instrument. If avoided, may result in injury, property damage, or the equipments trouble.

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1-2-3 Precautions concerning acoustic power

The tissues of the human body consist of soft tissues, water, bone, and other tissues. Ultrasound energy is progressively absorbed and attenuated by the body as it penetrates it, hence tissues located behind water, which causes only a small degree of attenuation, receive a relatively large amount of ultrasound energy. Also, it is necessary to be careful of bioeffects due to heat in the vicinity of tissues, such as bone, that readily convert ultrasound energy into heat.

Particularly, a fetus at the bone formation stage is exposed to a high risk of damage due to heating because almost all of the ultrasound energy passes through the amniotic fluid without being attenuated. Even in the case of a fetus prior to bone development, the cells are active, hence there is a possibility of growth being affected, even when the temperature rise is low.

Mechanical bioeffects such as vibration and cavitation occur when the body is exposed to ultrasound energy for a long period. You can reduce the risk of damage to the tissues by interrupting the ultrasound energy before it reaches the level at which tissue damage occurs.

To this end, it is necessary to obtain a grasp of the functions of the instrument, acquire familiarity with the method of operating it, and understand the parameters that affect the acoustic power. Also, get into the habit of always freezing the image as soon as you have obtained the necessary diagnostic information.

⚠CAUTION
Scan for the minimum length of time necessary for the diagnosis, and at the lowest suitable output. There is the possibility that the patient's internal tissues could be affected.
Select the optimum setting for the region to be examined while observing the acoustic power index. There is the possibility that the patient's internal tissues could be affected. Ultrasound energy is converted into heat in the body while being attenuated. Particularly, there is a possibility of heat being generated in bone and the cranium compared to soft tissue.
DO NOT select doppler modes for routine fetal examinations. Doppler modes in fetal examinations are only to be used where clinically indicated, such as in known or suspected high risk pregnancies.

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1-2-4 Precautions for Use in Conjunction with Drugs

- Precautions for use in Conjunction with an ultrasound contrast agent

  If you wish to use an ultrasound contrast agent, be sure to use only a substance that has been approved for use for that purpose. See the specific package insert for the contrast agent being used for details.

⚠CAUTION

Watch to make sure that the patient is not abnormally affected during the exams using the ultrasound contrast agent.

Cardiac rhythm disturbances during perfusion studies using gas ultrasound contrast agents have been observed in the diagnostic range of Mechanical Index (MI) values.

See the specific package insert for the contrast agent being used for details.

- Precautions for use in conjunction with general drugs

  If you perform an ultrasound examination after having the patient ingest a general drug, the ultrasound may affect the pharmacological effect of the drug.

  Before using a general drug, carefully read the instructions provided, and any cautionary notes.

1-2-5 Precautions for Use in Conjunction with Other Medical Devices

- Equalize the potential between this instrument and other instrument

  This equipment has a potential equalization terminal. The potential equalization terminal is on the back panel. For equalizing the potential, connect between the potential equalization terminals.

- Use in conjunction with devices which use high frequencies

  High-frequency surgical instruments may be used to deliberately apply an electromagnetic field or electric current of high frequency to the patient.

  This instrument has not been equipped with any means to protect the patient from burn injury from any of its parts when it is used together with a high-frequency surgical instrument.

- Use in conjunction with a cardiac defibrillator

  Do not use a cardiac defibrillator while a physiological signal is on display.

  Keep probes and physiological electrodes away from a patient body surface when a cardiac defibrillator is used.

⚠CAUTION	
	• When using this instrument together with other electronic medical appliances, position it and its cables (e.g. probe cables, ECG cables, I/O cables, etc.) as far away as possible from other appliances and their cables. Note that electromagnetic radiation from this instrument may cause other electronic medical instruments nearby to function abnormally. If such interference occurs, stop using the other instrument together with this one.
	• Keep probes, body parts and puncture instruments away from the course of high-frequency currents. Failure to observe the following precautions could result in burns to the patient or the examiner. With these radiated high frequencies, the device may be affected with interference when it is drawing monochrome or color images. Operate the device with caution paying attention to the positions of the counter electrode plates and the connecting cord against the probe.
	• Do not apply excessive force for insersion. Damage an insulating membrane and the patient or the examiner could be burned. Use an attachment with the electrode to allow suitable guidance of the puncture.
	• Do not use in conjunction with a cardiac defibrillator. It may cause the instrument break down.

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1-2-6 Guideline for Electromagnetic Compatibility

The electromagnetic compatibility (EMC) is the ability of a device to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbance to anything in that environment.

Medical devices, communications devices, radio and TV broadcasting antennae and similar devices can both emit electromagnetic waves and receive interference from them. A diagnostic ultrasound system can receive electromagnetic disturbance emitted by electromagnetic energy sources. Effects can include noise in images, disruption of physiological signals, and artifacts on the screen.

To prevent electromagnetic disturbances, considerations must be made for the following: 1) Electromagnetic environment, 2) Use of portable and mobile RF communications equipment, 3) Use in Conjunction with Other Medical Devices.

IMPORTANT: The doctor must consider whether electromagnetic disturbance could cause any artifacts which affect images or diagnoses.

1) Electromagnetic environment

For the purposes of preventing electromagnetic interference, this instrument is intended for use in hospitals, research institutions and similar facilities. Install in an environment that conforms to the operating environments and in accordance to section 1-3.

- Position this instrument as far away as possible from a radio receiver, TV set, and it's cables and antenna. The electromagnetic radiation from this instrument may cause the disturbance to a radio receiver, TV set, etc.
- If the instrument is to be used near a motor (elevator, pump room, etc.), power transmission line or wireless instrument, it is necessary to electrostatically shield it.
- When the mains power quality is not satisfied, the instrument can be froze by power supply fluctuation. If the instrument is froze, refer to Chapter 4 (→ p.4-11).

2) Use of portable and mobile RF communications equipment

Do not use portable radio communication devices (e.g. cellular phones or radio transceivers) near this instrument. Use of portable and mobile RF communications equipment such as cellular phones, transceivers, and amateur radio instrument can affect the operation of this device.

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3) Use in Conjunction with Other Medical Devices

When this system receives electromagnetic disturbances, effects can include noise in images, disruption of physiological signals, and artifacts on the screen. Position this instrument and its cables (e.g. probe cables, ECG cables, I/O cables, etc.) as far away as possible from other medical electrical instrument.

- Check that the instrument is not affected by electromagnetic disturbance emitted from any other device and that electromagnetic disturbances emitted by this instrument does not have adverse effects on any other devices.
- Use in conjunction with high-frequency surgical equipment, this instrument may be affected with interference when it is drawing monochrome or color images.
- If electromagnetic radiation from this instrument causes the abnormal operation to other medical electrical instrument nearby, stop using immediately. Do not use this device in conjunction with such effected instrument.

1-3 Electromagnetic compatibility

The electromagnetic compatibility (EMC) of this device is in conformity with IEC 60601-1-2: Ed.3 which is the international standard for EMC of medical instruments. This standard prescribes the testing of the level of electromagnetic energy emanating from equipment (electromagnetic emission) and the tolerance of the equipment for electromagneic disturbance (electromagnetic immunity).

Testing of our ultrasound diagnostic devices has confirmed that they emit no electromagnetic energy.

1-3-1 Guidance and manufacturer's declaration - electromagnetic emissions

The F37 is intended for use in the electromagnetic environment specified below. The customer or the user of the F37 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR11	Group 1	The F37 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The F37 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

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1-3-2 Essential performance

The ultrasound diagnostic devices has been validated to IEC60601-1-2: Ed.3. Testing indicates no electromagnetic wave interference is being transmitted or received. For the description of each essential performance, refer to the specifications or chapter 2.

Essential performance	contents	refer
Scan Area	Scanning range of B mode image	TBF switch (How to Use)
Flow Area	Display in color on the Flow mode image	Screen Display → p.3-20
Marker	Scale marks (distance, time and flow velocity) display	Screen Display → p.3-20
Velocity Range	Display range (scale mark) of flow velocity in the Doppler image display	Vel Range (D) menu (How to Use)
M cursor D cursor	Detect the M mode and the baseline of the Doppler pattern of the B mode image	CURSOR switch (How to Use)
Sample Volume	Volume of the sample gate that extracts the signals from the B mode image in the PW Doppler mode	Sample Volume menu (How to Use)
Image Frequency	Switch the transmitting/receiving frequencies of the probe of the B, D, M, Flow, THE or BbH mode	Image Freq menu (How to Use)
Focus	Number of the focal point and each focal point position	TBF switch (How to Use)
Acoustic Power	Control the acoustic power	8. Acoustic output Safety Information ACOUSTIC POWER key (How to Use)
Frame Rate	Combination of Line Density for black & white and color images, in the Flow or the Power Flow mode.	Frame Rate menu (How to Use)
Image Select	Image quality setting of Doppler spectrum image	Image Select (D) menu, Image Select (Flow) menu, Preset: IP Select (D), IP Select (Flow), IP Select (Power)
Average (Flow)	Number of transmissions used to display blood flow	Average (Flow) menu, Preset: Flow, Power Flow, eFlow, Tissue Flow, Tissue Power Flow (How to Use)
Puncture, Biopsy Select	Display Puncture Guideline	Puncture menu, Biopsy Select menu, Preset: Graphics (How to Use)
Message	Warning messages indicating the correct method of operation, and an alarm tone.	4. Message
Angle Correction	Correct the flow velocity value corresponding to the angle of incidence of the Doppler beam	Angle Correct menu, Preset: Doppler, Tissue Doppler (How to Use)
Heart Rate Display	Compute and display the heart rate from detected R-wave (HR***)	Display of physiological signals, Physio menu, Preset: Physio (How to Use)

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1-3-3 Guidance and manufacturer's declaration - electromagnetic immunity

The F37 is intended for use in the electromagnetic environment specified below.The customer or the user of the F37 should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrorical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line (s) to line (s) ±2 kV line (s) to earth	±1 kV line (s) to line (s) ±2 kV line (s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) 0.5 cycle	< 5% U_T (> 95% dip in U_T) 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the F37 requires continued operation during power mains interruptions, it is recommended that the F37 be powered from an uninterruptible power supply or a battery.
	< 40% U_T (> 60% dip in U_T) for 5 cycles	< 40% U_T (> 60% dip in U_T) for 5 cycles	
	< 70% U_T (> 30% dip in U_T) for 25 cycles	< 70% U_T (> 30% dip in U_T) for 25 cycles	
	< 5% U_T (> 95% dip in U_T) for 5s	< 5% U_T (> 95% dip in U_T) for 5s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

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1-3-4 Guidance and manufacturer's declaration - electromagnetic immunity

The F37is intended for use in the electromagnetic environment specified below. The customer or the user of the F37 should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the F37, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	V_1 = 3V	Recommended separation distance $d = \left(\frac{3.5}{V_1}\right)\sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	E_1 = 3 V/m	$d = \left(\frac{3.5}{E_1}\right)\sqrt{P}$: 80 MHz to 800 MHz $d = \left(\frac{7}{E_1}\right)\sqrt{P}$: 800 MHz to 2.5 GHz
			where P is the maximum output power rating of thetransmitter in watts (W) according to the transmittermanufacturer and d is the recommended separationdistance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipmentmarked with the following symbol: 

NOTE: 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the F37 is used exceeds the applicable RF compliance level above, the F37 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the F37.

b: Over the frequency range 150 kHz to 80 MHz, fields strength should be less than [V_1] V/m.

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1-3-5 Recommended separation distances between portable and mobile RF communications equipment and the F37

The F37 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the F37can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the F37 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left(\frac{3.5}{V_1}\right)\sqrt{P}$	80 MHz to 800 MHz $d = \left(\frac{3.5}{E_1}\right)\sqrt{P}$	800 MHz to 2.5 GHz $d = \left(\frac{7}{E_1}\right)\sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.369	0.369	0.738
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE: 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE: 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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1-4 Electrostatic Discharge (ESD) Guidelines

This guideline includes descriptions to prevent any deterioration and trouble on the part being sensitive to static electricity.

This instrument can be installed in accordance with “The electromagnetism adaptability guideline” mentioned in this book. After installing the instrument, connect the probes or conduct maintenance and inspection of the instrument in accordance with the following.

Electrostatic discharge (ESD) guidelines;

- Do not install the device on a floor covered with a carpet or synthetic materials.

  The floor materials on which the device is installed shall be of wood, concrete or ceramic tile. When installing the device on the floor covered with carpet or synthetic materials, it is requested the floor materials be grounded.
- Keep the humidity of the installed place higher than 30%.
- When connecting probes, foot switch, and cables to the respective connectors of the device, do not touch the connecting pins.

  When servicing or conducting any maintenance on the device, turn the device off but leave the power cord plugged in.

⚠NOTE	Explain the meaning of the ESD warning symbol and provide the training on the protective procedure of ESD mentioned above.

- ESD warning symbol () : Keep your hand away from the connector pins.

  Indicates that the device is subject to deterioration or malfunction due to sensitivity to static electricity by electrostatic discharge.

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2 Specifications and Parts Name

2-1 Principle of Operation

When a block of continuously arranged multiple transducers transmit and receive near-simultaneously, all ultrasonic waves emitted from the individual transducers are combined to provide the same effect as if a single ultrasound beam were released from the center of the multiple transducers. After the first beam is transmitted and received in this fashion, the transducers of the above-mentioned block are shifted by one position, then transmitted and received to provide the second ultrasound beam. This means that the center of the second beam is shifted from the center of the first beam by one transducer. Shifting the transducer block and repeatedly transmitting and receiving in this manner makes it possible to obtain multiple ultrasound beams. Aligning these beams makes planar scanning possible. Furthermore, by creating a time lag in beam transmitting and receiving operations, the beams can be made to converge to an acoustic focal point. Continuously setting focus time lag based on the arrival time of ultrasonic waves enables globally-focused beams.

The ultrasound beam obtained by the above-mentioned method is converted by a digital scan converter into a video signal to display images on a monitoring device.

This product can display a single or combined images in the following image display modes.

- B mode displays a tomographic view obtained by multiple ultrasound beams generated as described above.
- M mode obtains ultrasound beams in the same direction repeatedly and displays them on a screen in sequential and parallel arrangement to display temporal changes in echoes in a single direction in the test subject.
- D (Doppler) mode has two modes: PW Doppler mode and CW Doppler mode.

  PW Doppler mode displays information continuously on blood flow at a sample point detected by the pulse Doppler method.

  In contrast, the CW Doppler mode displays information on blood flow continuously using ultrasound beams in a single direction detected by the CW Doppler method.
- Color Doppler mode detects information on blood flow itself that is, direction and velocity of blood flow as well as their deviations by receiving ultrasonic waves in the same direction and detecting the difference. The information can be displayed in color and superimposed on the B mode or M mode display.

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Three types of electronic scanning are described below.

- Linear scanning system:

  In this system, the probe emits ultrasound beams in a straight line (linear) to obtain and display a tomographic view of a test subject.

- Convex scanning system:

  In this system, the probe emits ultrasound beams radially to obtain and display a tomographic view of a test subject.

- Sector scanning system:

  In this system, the probe emits ultrasound beams in a fan shape (i.e., sector of a circle) to obtain and display a tomographic view of a test subject.

Combined electronic scanning system

- Trapezoidal scan:

  This combines the linear scanning system and the sector scanning systems to obtain and display a tomographic view of the test subject.

2-2 Specifications

Scanning method:	Electronic sector scan, Electronic convex scanning, Electronic linear scanning	
Modes:	B mode M mode D mode (PW and CW modes) Flow mode Power Flow mode, Directional Power Flow mode eFlow mode, Directional eFlow mode TDI mode RT3D (4D) mode (option)	
Acoustic Power:	0% to 100%, continuously changeable	
Preset function:	User settings: 45 kinds (Factory default settings: 33 kinds)	
Number of probe connectors:	For electronic scanning probes: 3 For independent probe: 1 (option)	
Image display:	Direction of slice image display:	Longitudinal inversion, lateral inversion, 90 degrees rotation.
	Image depth: 0.5 cm to 40 cm (38 steps, probe dependent)	
	Accuracy of display: ±5% or less (2.5% or less at a shallower depth point than range 6 cm)	
Physiological signal display:	ECG, DC IN	
Measurement function:	Basic measurement	
	Application measurement:	Cardiac Measurement, Vascular Measurement, Abdominal Measurement, Obstetrical Measurement, Gynecological Measurement, Urological Measurement, Small Parts Measurement
Viewing monitor:	17-inch flat-panel LCD (Tilt and swivel are possible)	

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Input/Output Signals	Data input/output: USB, RS232C	
	• Composite: 1 channel • Y/C input: 1 channel (for DVD recorders) • Y/C output: 1 channel (for DVD recorders)	
	Analog audio input for DVD recorders: 1 channel Analog audio output for DVD recorders: 1 channel	
	DVD control signal: 1 channel	
	DVI-D digital: 1 channel	
Cine memory function:	Search, Scroll, Store, Review, Loop playback	
Image data format:	Moving image:	• VideoClip (DICOM RGB [RLE/Normal], JPEG) • AVI • MP4 • Line
	Still image:	• DICOM (Palette, RGB [RLE/Normal], JPEG) • Tiff • BMP • JPEG
Dimensions:	430 mm (Width), 580 mm (Depth), 1245 mm to 1495 mm (Height)	
Weight:	65 kg ±10% (main unit only), 85 kg ±10% (with all options included)	
Service life:	7 years	

Clinical Measurement Accuracy		
Measurement Feature	General Tolerance	Round-off Tolerance
Distance in B-mode	±3%	±0.01 cm < 10 cm distance ±0.1 cm > 10 cm distance
Area by trace in B-mode	±6%	±0.01 cm^2 < 100 cm^2 area ±0.1 cm^2 > 100 cm^2 area
Circumference by trace in B-mode	±6%	±0.01 cm < 10 cm distance ±0.1 cm > 10 cm distance
Area by ellipses in B-mode	±5%	±0.01 cm^2 < 100 cm^2 area ±0.1 cm^2 > 100 cm^2 area
Volume in B-mode	±7%	±0.01 cm^3 < 100 cm^3 area
Excursion in M-mode	±3%	±0.01 cm < 10 cm distance ±0.1 cm > 10 cm distance
Time in M-mode	±3%	±0.01 ms < 1000 ms time ±0.1s > 10 ms time
Velocity in Doppler mode	±10%	±0.1 cm/sec
Heart rate	±1 BPM or 5%	±1 beat per minites

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B Mode	
Display gray scale:	256 levels
Scanning area:	100% to 25%, continuously variable
Zoom:	Write zoom (real-time): Max. 6 times Read zoom: Max. 16 times
Depth range selections:	0.5 cm to 40 cm (probe dependent)
Frame rate (Line density):	9 selections
Contrast:	23 levels (Dynamic range: 36dB to 96dB)
STC:	8 levels slide-bar
B Gain:	10 dB to 90 dB
AGC:	16 steps
Relief:	4 steps
FTC:	On/Off
Frame correlation:	16 steps (Auto/Manual)
Smoothing:	16 steps
Steered liner scanning:	±30°, 5° steps
Post Process:	Echo enhance curve: 5 kinds, Rejection: 64 steps
View Gamma:	5 kinds

M Mode	
Sweep methods	7 steps
Gain	B Gain ± 30 dB
Contrast	23 levels (Dynamic range: 36dB to 96dB)
AGC	16 steps
Relief	4 steps
FTC	On/Off
Free Angular M-mode (FAM):	Up to 3 M-mode cursors can be set omni-directionally on real-time at any position on a B-mode image.

D Mode	PW	CW
Display patterns:	Power spectrum	Power spectrum
Max. velocity range:	±6.23 cm/s to ±398.44 cm/s	±24.90 cm/s to ±796.88 cm/s
Angle collection:	±80°, Automated angle correction possible	
Sample volume:	0.5 mm to 20 mm	
Doppler gain:	0 dB to 50 dB (128 steps)	

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Flow Mode (Color Doppler)	
Display patterns:	Velocity, Velocity+variance, Variance, Power Flow, eFlow, Directional Power Flow, TDI
Velocity:	±127 levels
Variance:	16 levels
Power Flow, eFlow:	128 levels (Directional: ±127 levels)
Color are size:	100% to 15%, continuously variable
Flow Gain:	0 dB to 31.75 dB (128 steps)
Steered liner scanning:	±30°, 5° steps
Color coding:	Abdomen, Vascular, Cardiology and other

2-2-1 Environmental Conditions

Environmental Conditions	Working environment	Storage environment and moving / transport environment
Ambient temperature	10°C to 40°C	-10°C to 50°C
Relative humidity	30% to 75% (non condensing)	10% to 90% (non condensing)
Atmospheric pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Altitude	< 3000 m	—

2-2-2 Power Requirements

Conditions	
Rated supply voltages or voltage ranges:	100V to 120V, 200V to 240V
Rated frequency or rated frequency range:	50 Hz / 60 Hz
Power input:	900 VA
Power output:	330 VA

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2-2-3 Classification of F37

- Protection against electric shock: class I・ME equipment
- Protection against electric shock (Applied parts): type BF applied parts
  - Probe/scanner applied parts and parts treated as applied parts:
    Refer to the following diagram (Probe/Scanner Pattern Diagram) and table.

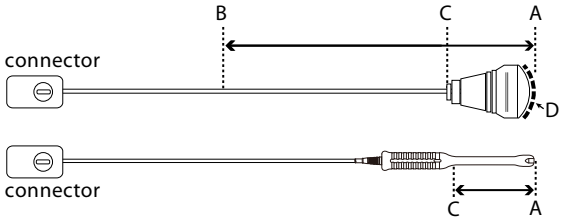
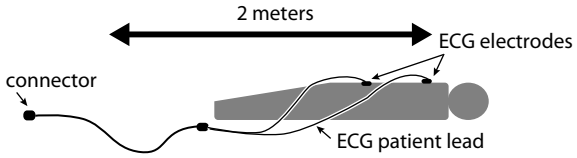


Fig. 1: Probe/Scanner Pattern Diagram

Above illustrates a surface/intraoperative probe. Below shows a coelomic probe.

Applicable part of body	Applied part	Parts treated as applied parts	B - C length
surface of body	Ultrasonic irraditaion area (D)	A to B	100 cm
Intraoperative	Ultrasonic irraditaion area (D)	A to B	20 cm
Endocavity	A to C	A to C	—

  - ECG
    The 2-meter length of the ECG cable extending from the ECG electrodes is treated as applied part (see diagram below).



- Protection against electric shock (Defibrillation-proof applied parts): Not suitable
- Protection against harmful ingress of water or particulate matter
  - equipment: IPX0 (Ordinary equipment)
  - Probe applied part: IPX7 (Watertight equipment)
- Suitability for use in an oxygen rich environment: Not suitable
- Method (s) of sterilization: Not suitable for sterilization/disinfection with medicinal solution, gas or radiation.
- Mode of operation: Continuous operation

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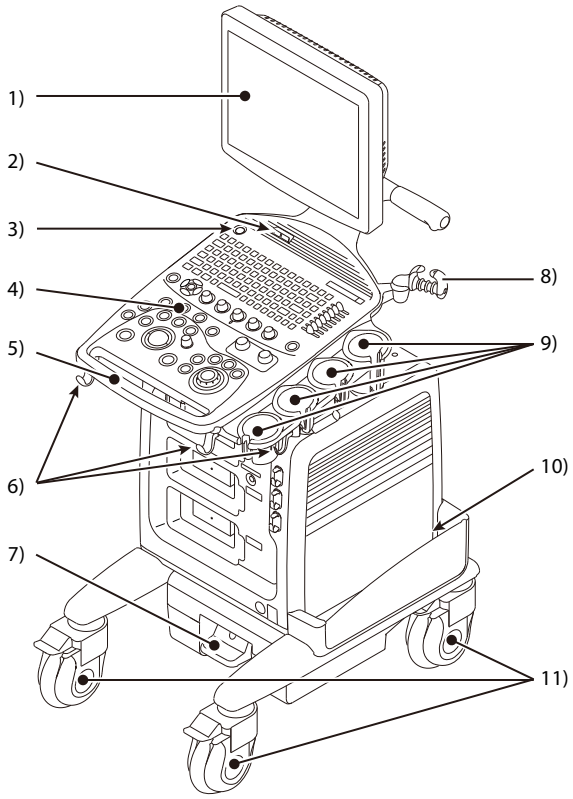
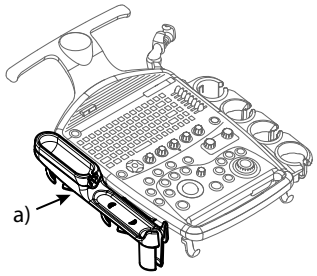
2-3 Parts Names

2-3-1 Exterior





a) Endo-cavity Probe Holder (horizontal storage, option, attached example in the left side of the device)

1) Viewing monitor
2) USB connector (used for connecting to the USB flash memory (stick type only))

   NOTE: In some cases, it may not be possible to connect unusually-shaped USB flash memory products. Check whether your USB flash memory can be connected before trying to use it.

3) POWER switch
4) Operation panel
5) Handle (uses to adjust the position and the height of the operation panel. Or use to lift the equipment to negotiate step)
6) Cable hook (for probe cables)
7) Operation panel up-and-down pedal
8) Cable hanger
9) Probe holder
10) Side pocket

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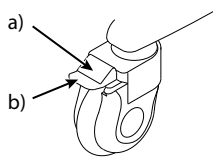
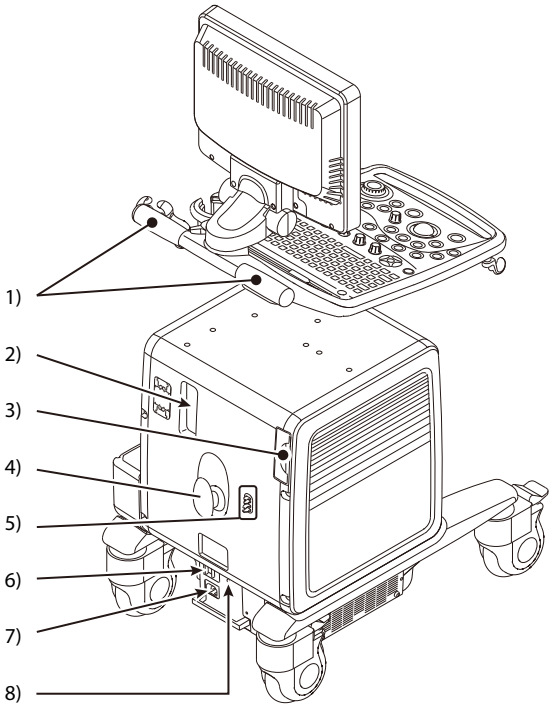
11) Casters



a) Unlock lever

b) Lock lever

Rear



1) Handle (uses to carry the instrument about)
2) Physiological signal Panel
3) Filter
4) Cable hook (for power cable)
5) Cable clip (for power cable)
6) Circuit breaker

   ○ : OFF

   | : ON

7) Power socket (there is the protective earth terminal)
8) Equi-potential terminals

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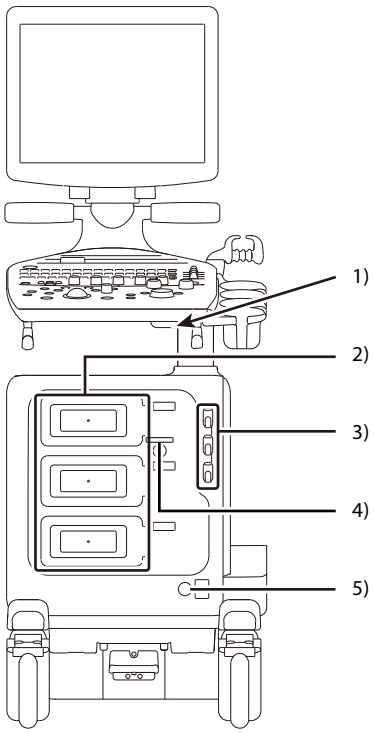
Front



1) Lever for locking the operation panel to the home position

2) Electronic probe connector (in order, from top)

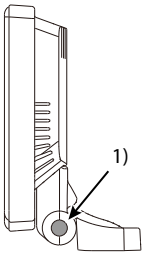
3) Cable hook (for probe cables)

4) Independent probe connecter (option)

5) Foot switch connector

   Used for connecting to the optional foot switch (MP-2345B, MP-2614B).

Monitor



1) Tilting button

   Use for closing the monitor.

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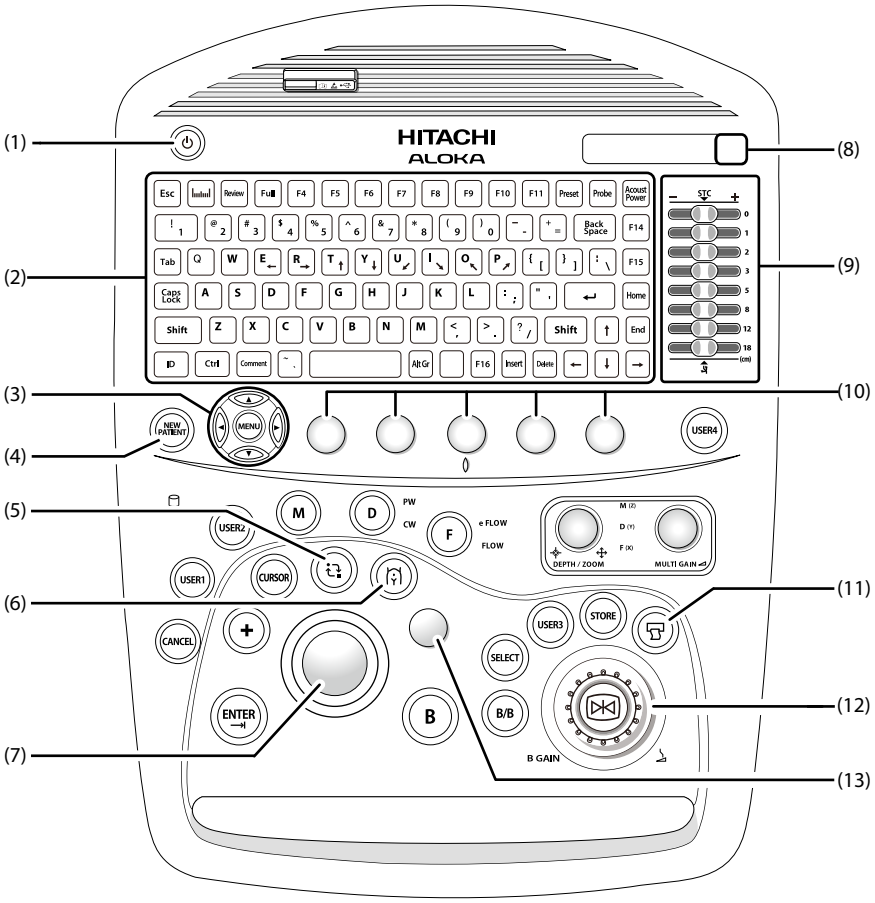
2-3-2 Operation Panel



panel switch names	contents
(1) POWER	The white light indicates that the power is ON. The orange light indicates STAND BY mode.
(2) Keyboard	Keyboard → p.2-14
(3) MENU	Displays the Function menu on the screen. Switching the menu.
(4) NEW PATIENT	Returns to the initial settings. Displays the ID input screen.
(5) Trackball Function (TBF)	Switches between the Focus and Scan Area (Flow Area). Starts the Search function in the freeze mode.
(6) BODY MARK	Displays the Body Mark menu on the Function menu. Switches the Body Mark menu display between show and hide.
(7) Trackball	Move the pointer or cursor.
(8) Illuminance sensor	Photo chromatic sensor of the operation panel switch, keyboard and trackball.

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panel switch names	contents
(9) STC	Adjusts sensitivity at the display depth corresponding to the value.
(10) Rotary Encoder 1 to Rotary Encoder 5	Select the menu or change the set value.
(11) PRINT	Records images to a recording instrument connected to this instrument. You can record images by pressing and holding down this switch.
(12) FREEZE	Press: Switches between the real time display and the still image display. Turn: Works as the B GAIN knob to adjust B Gain.
(13) Rotary Encoder	Used for measuring or linking to the trackball to provide supplementary control.

Switches (factory default)	contents
B	Displays the B mode.
B/B	Displays the B/B mode.
SELECT	Selects the active screen when two or more images (B/B, B/M, etc.) are displayed. If one of the displays was shown in real time such as B/B mode, the real time display can be switched. If both images are displayed in real time, such as in the B/M or the B/D mode, only the M or D mode image can be switched and displayed in real time.
USER1	Activates the function assigned by navigating the preset to Custom SW preset.
USER2	Activates the function assigned by navigating the preset to Custom SW preset.
USER3	Activates the function assigned by navigating the preset to Custom SW preset.
USER4	Activates the function assigned by navigating the preset to Custom SW preset.
STORE	Save a still or moving image on the screen.
ENTER	Sets measurement, preset, comment input, review, Flow Area setup, etc. This switch can be assign to other function as SEND on Custom SW2 preset.
+ (Caliper)	Starts the measurement menu assigned to this switch.
CURSOR	Displays the cursor. Deletes the cursor from the screen.
CANCEL	Cancels the selected operation. Or, goes back to the previous step if measurement was in progress.
M	Displays in the B/M mode.
D	Displays in the B/PW mode. When it is pressed and held down, it displays in the B/CW mode.

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Switches (factory default)	contents
F	Displays a B mode image or an M mode image in FLOW. When it is pressed and held down, it displays in the eFlow mode.
DEPTH/ZOOM	Changes the display depth of the image when the white light is on. Zooms up the B mode image when the orange light is on.
MULTI GAIN	Adjusts sensitivity in the M, D or FLOW modes according to the switching between these modes.

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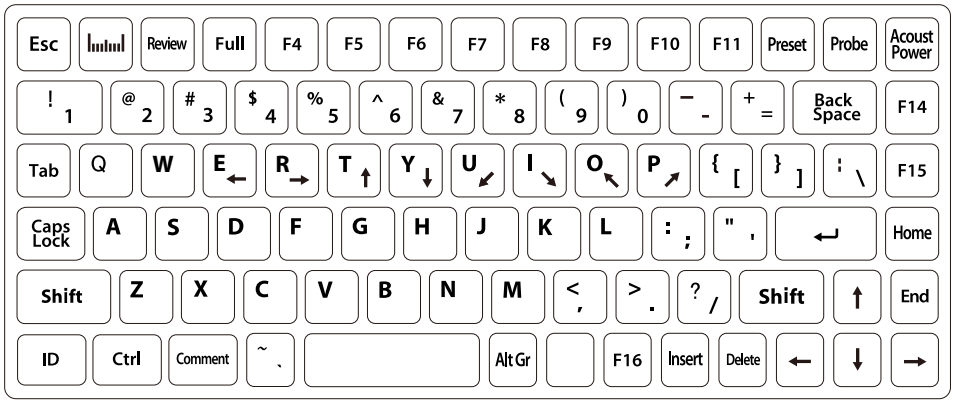
Keyboard



Key	contents
(Measurement)	Displays the measurement menu.
Review	Displays the Review.
Full	Displays the M mode image only during the B/M mode display and the D mode image only during the B/D mode display.
F4 to F7	Function keys.
F8	Function keys. The factory default setting is EXT.
F9 to F11	Function keys.
Preset	Displays the Preset screen.
Probe	Displays the Probe menu.
Acoust Power	Adjusts the Acoustic Power.
F14, F15	Function keys.
ID	Displays the ID input screen without returning to the initial settings.
Comment	Enters comments on the screen or ends comment input.
F16	Function key (SEND key as factory default). It can be assigned as SEND or ENTER.

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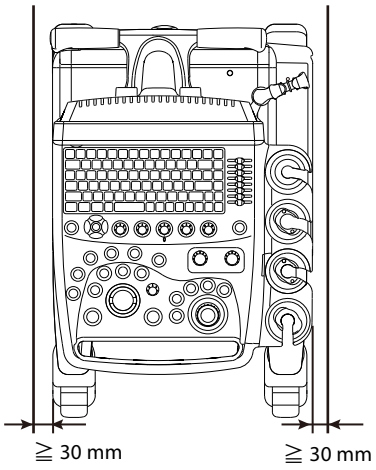
3 Preparation for Use

3-1 Installing the equipment

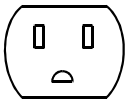
Install the instrument in accordance with the following procedures.

For eliminating heat and isolating from power supply at once, the following amounts of open space are required.

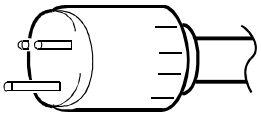


100V to 120V

Power outlet in the wall

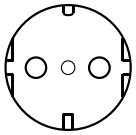


Power plug

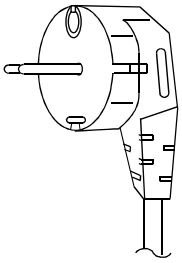


200V to 240V

Power outlet in the wall



Power plug



- Install the instrument according to the “Guidelines for Electromagnetic Compatibility” stated in this manual.
- Insert the power plug into the power outlet (hospital grade) which fits the shape of the power plug.
- Install the instrument no more than 3 meters away from a power outlet in the wall.
- To cut off the power, disconnect the power plug from the power outlet.

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⚠CAUTION
Place instrument according to the following. • Place the instrument on a flat horizontal surface with sufficient stability and minimal vibrations. • DO NOT place the instrument on a precarious or uneven surface. • Avoid locations with water or other liquids, and avoid exposure to direct sunlight. These locations may cause injuries such as burns to the patient or examiner.
• Always use this in dried state. • Avoid rapid temperature change which may cause condensation. Using it with condensation or water droplets on it could cause short circuiting or ground leakage. Leave the instrument to stand for a while in the newly installed location to allow it to become acclimated to the environment before switching it ON.

1. Fix all casters.

   Checking items after moving the instrument

   - Check to ensure that there are no scratches or cracks on the enclosure.
   - If the temperature is different from the new and the previous installation location, leave the instrument to stand for a while in the new installed location to allow it to become acclimated to the environment.

2. Ensure that there are no loose parts, damage, or signs of wear on the instrument.
3. Insert the power plug of the power cable provided into the hospital grade power outlet.
4. Connect the peripheral instrument and probes.

   NOTE: Do not place anything on the top surface.

5. Turn on the POWER switch.

Reference:

Environmental Conditions → p.2-6
Electromagnetic compatibility → p.1-16
Connecting/Removing a Probe → p.3-4
Connecting with Other Instruments → p.3-8
Connect the Physiological Signal Connector → p.3-6
Safety precautions about Power Plug and Cable → p.1-5

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3-2 Connecting Peripheral Instruments

Connect peripheral instruments such as probes and the ECG lead cord in accordance with the following procedures.

When conducting a diagnosis, take care, as described in the electrostatic discharge (ESD) guidelines, to avoid deterioration and failure of parts sensitive to static electricity.

⚠CAUTION
• DO NOT connect any probes or options to the equipment which is not specified in this manual. The patient or the operator may be exposed to burns, electric shock or other injury. There is a risk of the instrument breaking down.
• DO NOT damage, modify or server the probe cable. • DO NOT twist, bundle, forcibly bend, or place heavy objects on the probe cable. There is the risk in electrical shock and other accidents.
• If you find the instrument or a probe to be defective, stop using it immediately. The patient or the operator may be exposed to burns, electric shock or other injury. For repair of the instrument or a probe, please contact one of our offices listed on back cover.
• DO NOT touch to the exposed sockets of probe connectors, physiological signal cable connectors, or USB connector sockets. • DO NOT touch to the patient with parts other than applied parts and parts treated as such. Doing so may cause electric shock or short circuitis.
All non-medical equipment connected to the diagnostic ultrasound system must comply with the respective IEC or ISO standards (e.g. IEC 60950-1 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see clause 16 of the IEC 60601-1: Ed.3, respectively). There is the possibility that local laws and regulatory requirements take priority over the above mentioned requirements. For details, please consult one of our offices listed on back cover.

Reference:

Electrostatic Discharge (ESD) Guidelines → p.1-21

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3-2-1 Connecting/Removing a Probe

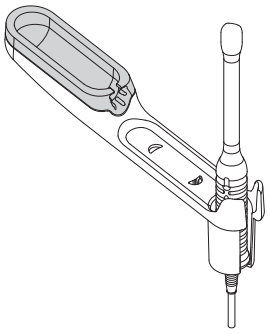
⚠CAUTION
Put UST-2265-2 in probe holder mounted probe adapter (MP-PH-ADAPTER-5). When these probe put in probe holder that is not mounted probe adapter, these probes slip through probe holder and probes could be damaged.
Place the Endo-cavity probe on the special probe holder (horizontal) mounted with the special adapter, Endo-cavity Probe Holder Adapter. If a probe other than an Endo-cavity probe is placed on the special probe holder, the probe may fall out and be damaged.
Before placing the probe horizontally on the special probe holder, remove any attached balloon. There is a risk of infection of the patient and the examiner.

Ensure the probe in accordance with the following items.

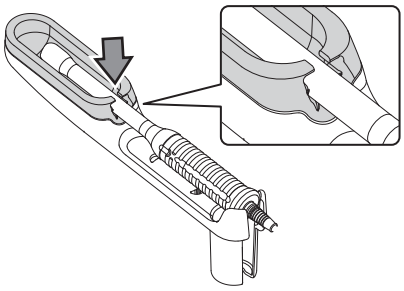
- The probe is possible to connect with the instrument.
- The pins on the probe connector are not bent.

Probes are stored on the probe holder. When storing an endo-cavity probe horizontally, push it firmly all the way into the probe adapter.

Example of vertical storage



Example of horizontal storage



Gray-painted: adapter

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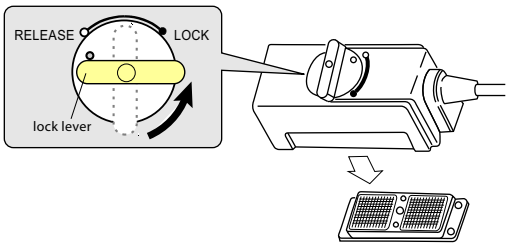
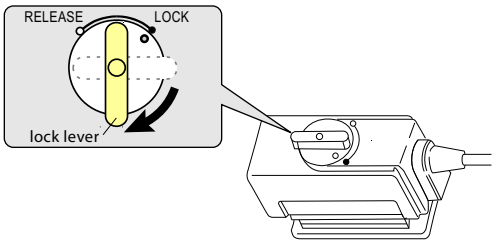
Connecting a Probe to the Instrument

1. Press FREEZE to freeze the image.
2. Turn the lock lever counterclockwise to the RELEASE position.
3. Insert the connector of the electronic type probe into the electronic probe connector on the instrument.



4. Turn the lock lever clockwise to the LOCK position.



If the lock lever is difficult to turn, reinsert the connector.

5. Use the cable hook to adjust the probe cable to a convenient length. Adjust the position and length of the probe cable so that it does not rub or scrape the floor.

Remove the Probe

1. Press FREEZE to freeze the image.
2. Turn the lock lever counterclockwise to the RELEASE position.
3. Remove the probe from the instrument.

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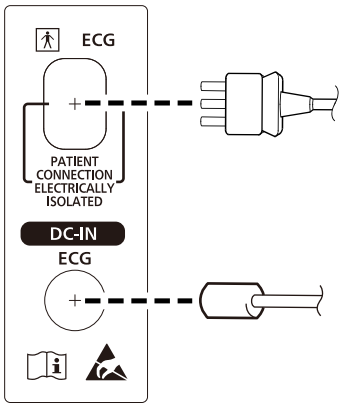
3-2-2 Connect the Physiological Signal Connector

Connection terminals related to physiological signals are found on the rear surface of the main unit.



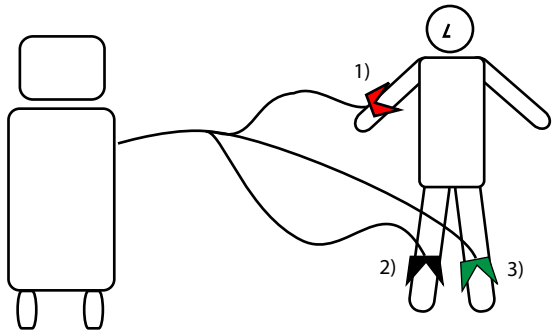
NOTE: When the ECG cord and ECG cord from ECG monitor are connected, external signal from ECG monitor is prior to displayed.

If an external signal is not necessary, release this cable from DC-IN connector.

⚠NOTE	The minimum amplitude of the ECG input necessary for conditioning the ECG signal is ECG 50μV. The signal which is lower than this level may cause inaccurate results.

Connect the ECG Lead Cord

The ECG lead is a second limb lead.



connection points	ECG cable
1) Right arm	Red (R)
2) Right leg	Black (RF)
3) left leg	Green (F)

- Insert the connector of the ECG lead cord firmly into the connector on the panel with the groove on the connector faces upward.
- Before connecting the ECG lead cord to the patient, insert the three jacks of the ECG lead cord into the corresponding ECG electrodes.

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Connect the ECG Monitor Cable

When connecting another ECG monitor to this instrument, the ECG signals obtained by it can be displayed on the images.

⚠CAUTION

- Use only an ECG monitor that conforms to IEC60601-1 together with this instrument.
- For handling and safety inspection on the ECG monitor to be used with this instrument, refer to the instruction manual of the ECG monitor.

Electric shocks and electromagnetic interference could result.

DO NOT use the monitor if the instruction manual states that it must not be used together with diagnostic ultrasound system or similar medical electronic instrument.

Refer to the document of the ECG monitor.

NOTE: Read "Precautions for Use in Conjunction with Other Medical Devices" before connecting the ECG monitor to this instrument.

1. Connect the cable from the ECG output connector of the ECG monitor to the DC IN connector of the ECG.

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3-2-3 Connecting with Other Instruments

⚠ CAUTION

All non-medical equipment connected to the diagnostic ultrasound system must comply with the respective IEC or ISO standards (e.g. IEC 60950-1 for data processing equipment).

Furthermore, all configurations shall comply with the requirements for medical electrical systems (see clause 16 of the IEC 60601-1: Ed.3, respectively).

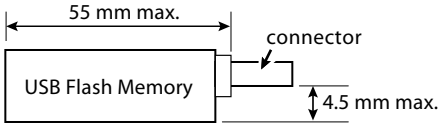
There is the possibility that local laws and regulatory requirements take priority over the above mentioned requirements. For details, please consult one of our offices listed on back cover.

USB Flash Memory

Connecting USB flash memory to the USB connector.

- Use a USB flash memory stick that is shorter than 55 mm excluding the connector, with a height from the bottom to the connector of less than 4.5 mm.

  In some cases, it may not be possible to connect unusually-shaped USB flash memory products. Check whether your USB flash memory can be connected before trying to use it.



NOTE: Abstain from using the strap. It can prevent operation by getting tangled with the cable of the probe.

Equipotential Terminal

The device is equipped with an equipotential terminal on the back panel. Use this terminal as the equipotential conductor when interconnecting or grounding with other equipment.

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Foot Switch

Connect the optional foot switch (MP-2345B, MP-2614B).

1. Insert the power plug into the power outlet. After the instrument is starting, freeze the image.
2. Insert the connector of the foot switch.
3. Set the function for the foot switch using the preset.

Connecting network devices

The EMC of this device is in conformity with the IEC 60601-1-2:Ed.3 which is the international standard for EMC with medical instruments. The following instructions are applicable, when connecting network devices to the diagnostic ultrasound system.

The instructions are provided in order for the entire system with network devices to meet IEC60601-1 Ed.3 Electrical Safety Standard.
All configurations shall comply with the requirements for medical electrical systems (see clause 16 of the IEC 60601-1:Ed.3, respectively). There is the possibility that local laws and regulatory requirements take priority over the above mentioned requirements. For details, please consult one of our offices listed on back cover.

- Connectable network devices

  All non-medical network devices connected to the diagnostic ultrasound system, including hubs, work stations and personal computers, must comply with IEC60950-1 standard and must be Class I devices.

- Connectable network cables
  - Connectors:LAN cable connector
  - LAN cable: Straight (in case of hub-use),
    LAN cable: Cross (when connecting to PC directly)
  - Maximun cable length: 20 m

- Installtion and Network connections
  - Non-medical devices must be kept at least 1.5 meters away from a patient.
  - When connecting the diagnostic ultrasound system with computer devices located out side of the ultrasound examination room, a separation device (network hub) must be used in-between.

⚠CAUTION

DO NOT use any cable which in not specified or longer than the maximum length.
Electromagnetic interference could result.

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⚠NOTE	Contact your network administrator for the hospital network if a problem occurs after changing the IT network. If the IT network has been changed, it may be open to new and unacceptable risks, so additional risk management is required. The IT network may be changed in the following ways: • IT network configuration changes • Connection of additional devices to the IT network • Removal of devices from the IT network • Updates or upgrades to devices connected to the IT network

Specifications and Configuration for IT Network Connections

- Purpose of a connecting PEMS to an IT network

  To enable use of DICOM communications.
- Characteristics required by IT network incorporating the PEMS

  DICOM Conformance Statement

  Refer to “4.3 NETWORK INTERFACES”.
- Configuration required by IT network incorporating the PEMS

  DICOM Conformance Statement

  Refer to “4.3 NETWORK INTERFACES”.
- Technical specifications for networks that connect PEMS (including security specifications)

  The network must comply with DICOM.
- The intended information flow between the PEMS, the IT network and other devices on the IT network, and the intended routing through the IT network

  Refer to the DICOM Conformance Statement.

3-3 Moving the equipment

⚠ CAUTION

DO NOT transport the equipment or its options via automobile or ship.
There is a risk of unexpected accidents or electrical shock.
Transporting this equipment (via automobile/ship) shall be performed by a third party certified by the manufacturer. Please contact one of our offices listed on back cover.

3-3-1 Isolate from the supply main

⚠ CAUTION

DO NOT unplug the power cable from the outlet during shutdown.
The instrument may break down.
After the equipment is shutdown, unplug the power cable from outlet.

1. Press POWER switch to turn off.
2. If necessary, move the equipment to more easily unplug the cable.
3. Unplug the cable from outlet.

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3-3-2 Moving equipment

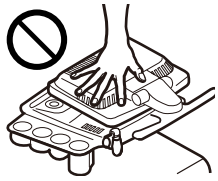
⚠CAUTION

Move the instrument by grasping the handle at the back of the instrument with both hands.

Do not grasp the instrument at a point other than the handle when moving or lifting it, as this may result in damage.

DO NOT close the monitor that is turned to sideways.

DO NOT close by force. DO NOT put anything on.



There is a risk of injury or damage to the monitor. And you may pinch your fingers or cables.

Move the instrument keeping distance that it does not come in contact with people, peripheral equipment, walls, posts, doors and the like.

Move the instrument carefully at a long distance, tilt it, or move it along a passageway that has stairs.

The instrument may fall or topple over and there is a risk injury or damage to peripheral equipment or other devices.

The instrument is heavy and does not stop easily once it starts moving.

DO NOT apply an unreasonably large force to the instrument in the horizontal direction.

The instrument may fall or topple over and there is a risk injury or damage to the instrument.

Avoid places with moisture when moving.

Electric shocks and short circuit could result.

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1. Prepare the moving.

   Power cable

   a Isolate from the supply main → p.3-11

   b Lightly coil the power cable and hang it on the power cable hook at the back of the equipment.

   Peripheral instruments that are not fixed

   Disconnect those that are not fixed, place it in its case or wrap it in a soft cloth or protective material.

   Peripheral instruments that are fixed

   Bunch the cables of the peripheral instrument so that they do not protrude from the instrument or get caught beneath the casters. When you lower the operation panel or close the monitor, adjust the cable lines so that they do not pinch.

   Probes

   Store the probes on the probe holder. For carrying the probe in the Endo-cavity Probe Holder, lay the probe down horizontally. Do not carry the probe in the vertical position. For instruction how to secure the probe horizontally refer to “Connecting/Removing a Probe” on page 3-4.

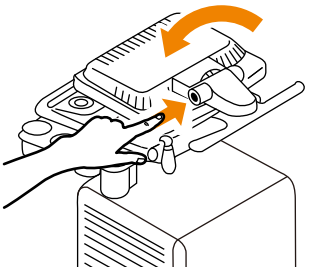
2. Move the operation panel to the lowest position (→ p.3-24).

   If the optional devices are installed, lower the operation panel carefully so that it do not hit on the optional devices.

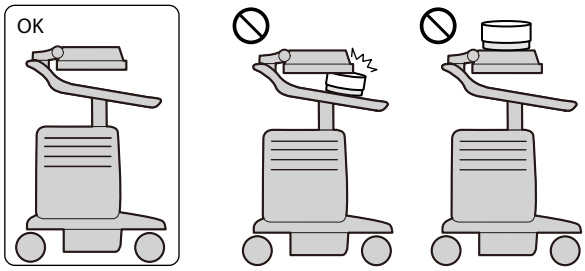
3. Close the monitor.

   a Turn the monitor at the front and correct tilt.

   b Hold the tilt button and close the monitor to stop point.



Do not put anything on the monitor or between the monitor and the operation panel.



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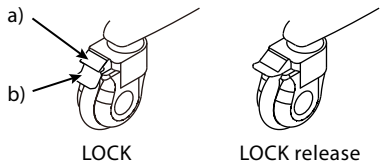
4. Release the lock lever of the caster.

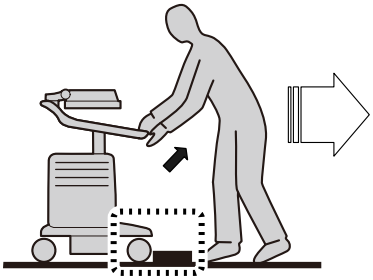


a) Unlock lever
b) Lock lever

5. Grasp the handle on back side firmly when moving the instrument.

Moving across an area with uneven floor levels

Use the handle to lift the instrument over the uneven surface.



6. Fine adjust the position of the instrument at an installed location.
7. Once the position and orientation of the instrument is fixed, lock the casters.

References:

Isolate from the supply main → p.3-11
Connecting/Removing a Probe → p.3-4
Adjusting the Operation Panel → p.3-24

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3-4 Storing the Instrument

When not using the instrument for a long period, store the instrument after carrying out the preparations for storage. If the storage conditions are unsatisfactory, the instrument may break down or fail to function satisfactorily. Store the instrument in accordance with the following procedures.

- Store the instrument under the condition suitable for storing.

---

1. Disconnect and remove all peripheral instrument and probes.

   Peripheral instrument

   Place the peripheral instrument in its case or wrap it in a soft cloth or protective material and store it separately.

   Bunch the cables of the peripheral instrument together when storing them.
2. Depress lock levers and fix the instrument.
3. Cover the instrument with a cloth.

References:
Environmental Conditions → p.2-6
Connect the Physiological Signal Connector → p.3-6
Connecting with Other Instruments → p.3-8

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3-5 Inspection Before Using

Perform the external inspection of the instrument and probes before starting the instrument. After starting the instrument, ensure that the instrument operates normally on the screen.

⚠CAUTION
• If you find the equipment, probes, peripheral instruments or options (recording devices) to be defective, stop using it immediately. There is a risk of injury of the patient. For service, probes, or options, please contact one of our offices listed on back cover.
• Before using a probe, clean, disinfect and sterilize it according to the instruction manual provided for the probe. Use of contaminated probes or puncture adapters carries the risk of infection. For cleaning, disinfecting and safety inspection, refer to the probe documentation.

3-5-1 External Inspection

Perform the following external inspection before using the instrument.

1. Perform the external inspection of the instrument and probe.

   Check items for the external inspection

   Ensure that there are no scratches, cracks, depressions, change of color on the following parts.

   - Enclosure or panel (including vent and air filters)
   - Power cable, plugs
   - ECG lead cord

   External inspection of the probe

   Refer to the instruction manual of the probe, inspect the probe to be used.

   - Ensure that the probes are cleaned, disinfected and sterilized.
   - Ensure that the needle guide adapter and needle are sterilized.
   - Ensure that there are no holes, depressions, cracks, deformation on the applied parts.
   - Ensure that there are no scratches, cracks, change of color on the cable and the connector.
2. Adjust the monitor in a better position to see.
3. Connect the probe.
4. Confirm that there is an adequate supply of consumables.
   - Refill new ultrasound gel.
   - Refer to each instruction manual, replace printing paper.

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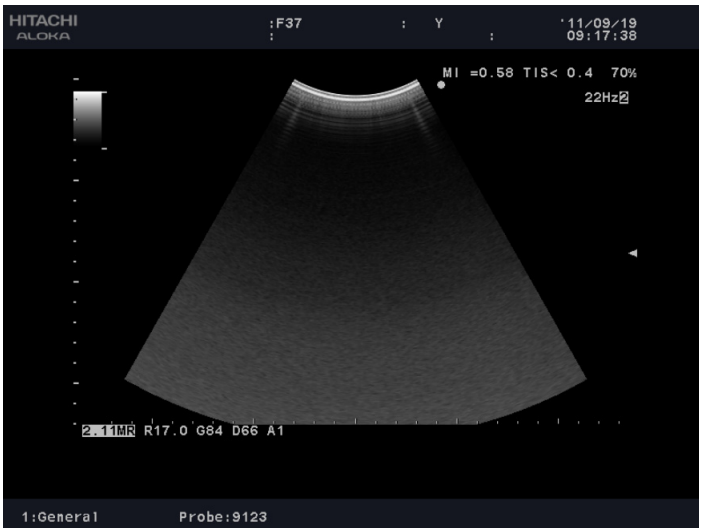
3-5-2 Operation Check

1. Turn ON the power switch on the instrument.

   → The instrument is set up in 90 seconds, then a B mode image appears.



2. Check the screen display.

   check of display

   - Images and characters are displayed on the screen.
   - Ensure that current time and date are displayed.
     If the date and time display is incorrect, a primary battery has run down. Stop using the instrument, then contact one of our offices listed on back cover.
   - Ensure that the connected probe, the image display and the frequency match each other.
     When no probes are connected, ensure that "NO PROBE" is displayed.

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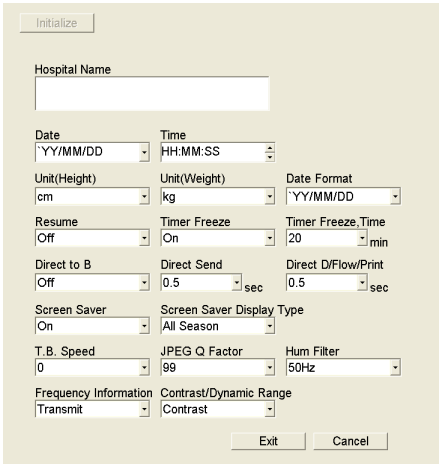
3-5-3 Modifying the Date and Time

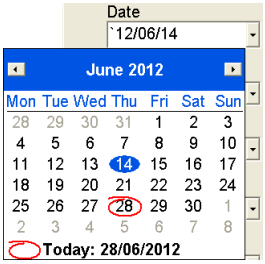
1. Select the Preset key.
2. Select Set-Up.
   → The preset setting selection list is displayed.
3. Select Common Preset.
   → The Common 1 screen is displayed.



4. Enter the date in the Date field from the keyboard. Alternatively, select the date from the pull-down list.

   Selecting the date from the pull-down list

   a Select ▼ to the right of the Date field.
   b Select the date from the displayed calendar.



The highlighted date indicates the selected date.

5. Modify the time in the Time field.
   a Select HH, MM, or SS to modify the time.
   b Enter the time from the keyboard. Alternately, use ▲ / ▼ located at the right end of theTime field to modify the time.
6. Select Exit to close the Common1 screen.
7. Select Exit.

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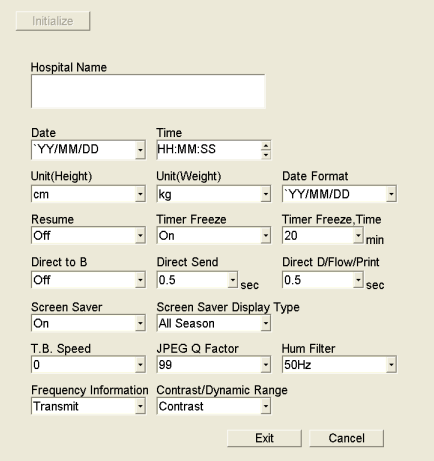
3-5-4 Specifying the Hospital Name

1. Select the Preset key.
2. Select Set-Up.
3. Select Common Preset.

   → The Common 1 screen is displayed.



4. Enter the hospital name using up to two 20-character lines in the Hospital Name field.
5. Select Exit to close the Common1 screen.
6. Select Exit.

   → Input data appears to the left of the patient identification information at the top of the screen.

3-5-5 Volume Control

Sets the audio volume of the Doppler sound, the beep sound of ECG R-waves, and external input volume.

1. Switch to Image Func Other page.
2. Adjust Audio Volume.

   When Audio Volume is set to "0", it is muted.

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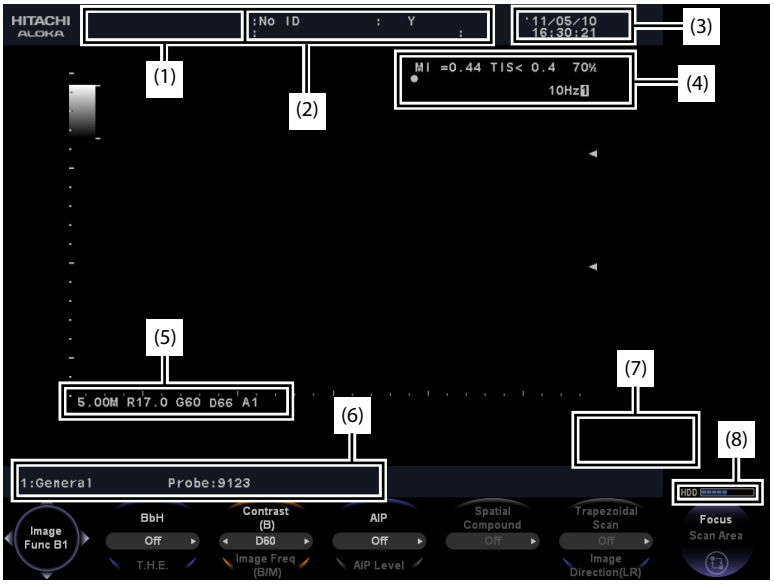
3-6 Screen Display

There are three kinds of displayed information.

- Information that is always displayed.
- Information concerning condition settings for the probe used and ultrasound image.
- Information for patient identification and comments concerning the ultrasound image Display area for ID.

3-6-1 Character Display



(1) Hospital Name

(2) Display area for ID, Name, etc

(3) Current date and time

(4) Automatic display area 1

`MI=0.53`	Mechanical index is displayed in all mode.
`TIS<0.4`	Thermal index (TIS, TIB or TIC) Set the display type from Thermal Index in the menu or preset (Preset Set-Up Menu > Graphics, Information).
`71%`	Acoustic output setting
`31 Hz`	Number of frames per a section.
`1`	Screen number (1 or 2)
`60°`	Corrected value of doppler angle (is displayed when the Angle Correct is ON).

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`300/300`	Indicates the number of images taken into the cine memory or the displayed frame number. (when image is frozen)

(5) Automatic display area 2

`2.11MR`	Frequency of the selected probe.
`R17.0`	Indicates the display depth as a centimeter.
`G70`	Indicates the image gain.
`D66`	Indicates the dynamic range.
`A1`	AGC (Value is not displayed when AGC is Off.)

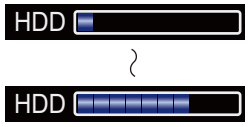
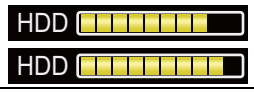
(6) Automatic display area 3 (2 line)

`Sonographer`	Sonographer's name entered on the ID screen (displayed only when it is entered)
`2:Abdomen`	Running preset number and name
`Probe:9123`	Selected probe name
`AIP`	Indicates that AIP is in operation.
`BbH`	Indicates that Broadband Harmonics is in operation.
`SCI`	Indicates that Spatial Compound Imaging is in operation.

(7) Automatic display area 4 (2 line)

`Punc:##°`	Puncture angle at Puncture Guideline (when puncture guideline is displayed)
`S.V.:##.#mm`	Sample volume (when sample volume mark is displayed)
`Depth:##.#cm`	Sample depth (when sample volume mark is displayed)

(8) Status bar — Indicates used memory space on the HDD.

Status bar color and used disk memory space	
	Blue indicates that used memory space ranges from 1% to 70%.
	Yellow indicates that used memory space ranges from 71% to 90%.
	Red indicates that used memory space ranges from 91% to 100%. NOTE: You will be unable to store images if the used memory space reached 100%. Delete unnecessary data from the HDD.

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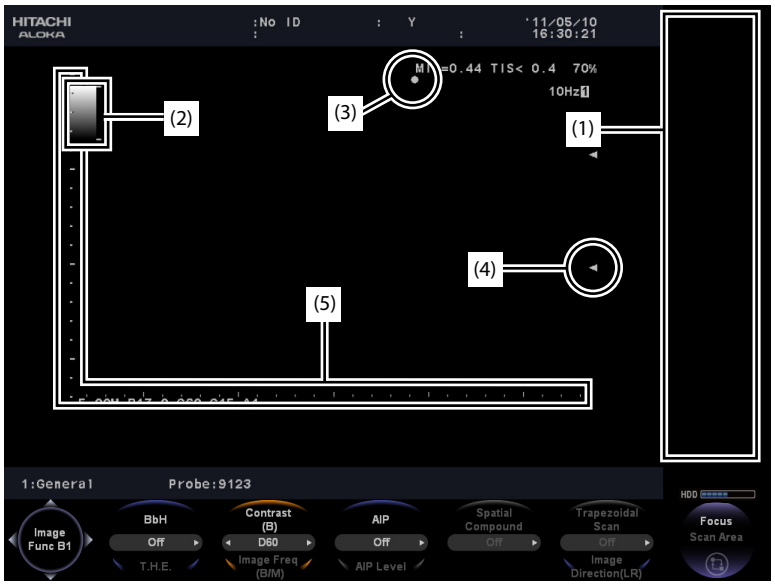
3-6-2 Graphic Display

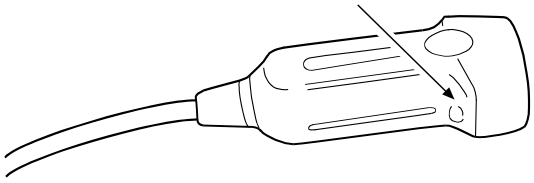


(1) Thumbnail area

Displays the stored images in thumbnail view.

(2) Gray scale bar (gradation of B mode images)

(3) Active mark: An active mark on viewing monitor screen coincides with the front direction mark on the probe.



Active state: Image on which operations can be performed when two or more images are displayed.

Non-active state

(4) Focus mark: Indicates the set focal points.

(5) Scale mark: The scale length changes according to the displayed range.

Displayed range	Scale (small)	Scale (large)
R0.5 to R2.0	0.1 cm	0.5 cm
R2.5 to R6.0	0.5 cm	1.0 cm
R7.0 to R29.0	1.0 cm	5.0 cm
R30, R35, R40	5.0 cm	10.0 cm

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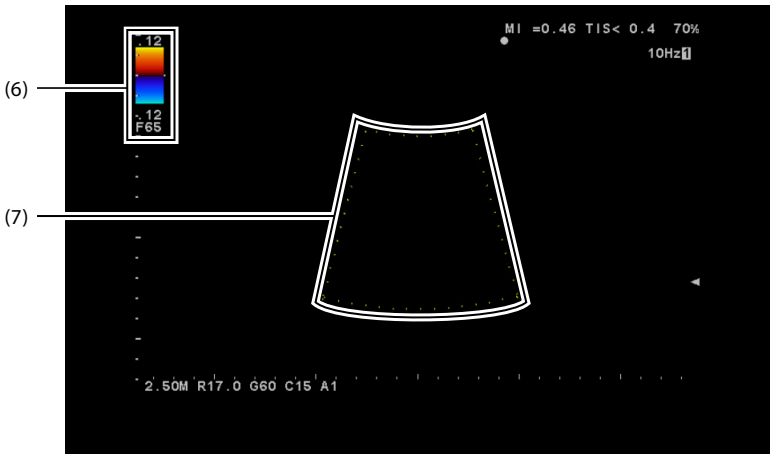

Graphical information displayed in color mode

(6) Color map: This image is a color representation of the set flow velocity and dispersion set by color coding.

Set the display position from Scale Bar Position in the preset (PRESET Set-Up > Graphic Information).

(7) Flow area: Flow or Power Flow display area.

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3-7 Adjusting the Operation Panel

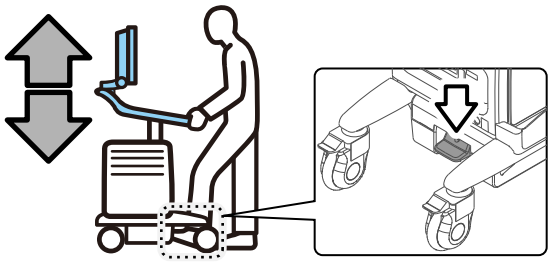
Adjust the height, horizontal and vertical position and orientation of the operation panel.

⚠CAUTION
• DO NOT lift the instrument by the operation panel. Do not apply an excessive force to the instrument. The instrument could break down. Adjust the height of the operation panel by holding the handle.
• Adjust the position and orientation of the monitor and operation panel by keeping a sufficient distance between the instrument and the peripheral equipment, walls and people. There is risk of injury or damage. Warn the doctor or patient before adjusting the position and orientation of the operation panel.

3-7-1 Adjusting the Operation Panel

Adjust the height, horizontal and vertical position and orientation of the operation panel.

1. Lock the front casters.
2. Adjust the height of the operation panel by holding the handle with both hands while stepping on the up-and-down pedal of the panel.



3. Release the up-and-down pedal of the operation panel to fix the operation panel in place.

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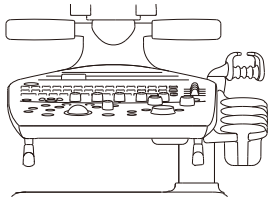
3-7-2 Adjust the Orientation of the Operation Panel

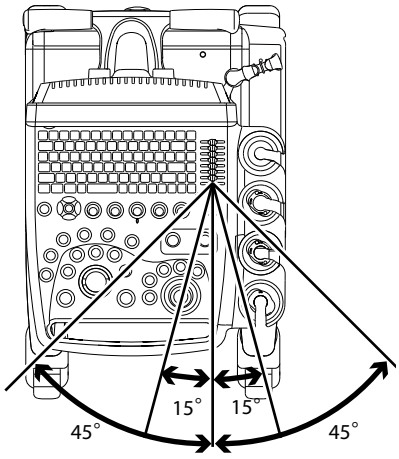
1. Check that there is not anything such as a cable in the swing area of the operation panel.

   If there is something such as a cables in the swing area, it may be pinch.

2. Adjust the position of the operation panel grasping the handle and keeping pull the lever for locking the operation panel to the home position.



Arrow: Lever for locking the operation panel to the home position



Swing area:

Swing area

Pull this lever slightly and the operation panel can be swing within the range of ±15°. Pull this lever full and the operation panel can be swing within the range of ±45°.

3-7-3 Adjusting the Brightness of the Operation Panel Switch

NOTE: At the factory settings, Panel LED Brightness is not in the function menu.To display it on the function menu, assign it in preset to Set-Up > (Application) > Menu-Function.

Adjusting the brightness of the operation panel switch.

1. Display the corresponded function menu.
2. Select Panel LED Brightness from the menu.
3. Select brightness.

   When Low, Med, High or is selected

   Keyboard (except function keys assigned a function) is auto-photo chromatic.

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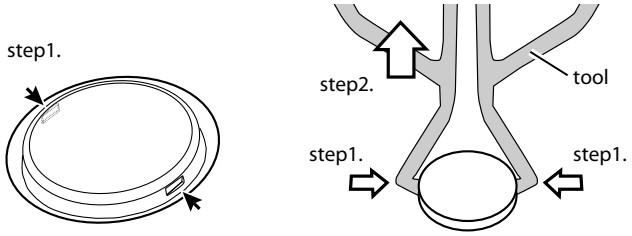
3-7-4 Changing the Labeling of the Operation Panel Switches

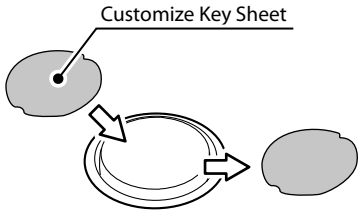
You can change the functions assigned to the operation panel switches using the preset.

You can customize the switch labeling to match the changes in the assigned functions.

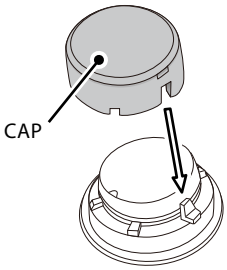
1. Use the supplied tool (for attaching/removing switch cups) to hook the slots of the switch cup.
2. Pull up the tool and remove the switch cup.



3. Change the switch label.
   a Remove the switch label.
   b Place a new switch label aligning its notches with the protrusions on the rubber cap.



4. Attach the switch cup aligning its notches with the protrusions on the rubber cap.



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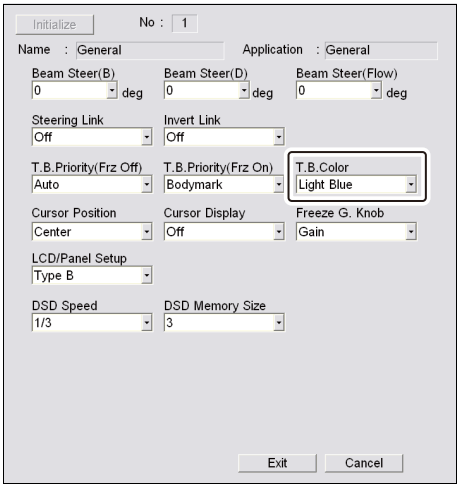
3-7-5 Changing the color of the trackball

You can customize the color of the trackball for each application (preset).

1. Select Preset key.
2. Select Set-Up.
   → The preset setting selection list is displayed.
3. Select Preset from the Name list.
   → Preset Set-Up Menu of the selected preset is displayed.
4. Select Display2.
   → The following screen is displayed.



5. Change the T.B. Color.
6. Select Exit.
   → This finalizes the changed settings and returns to the preset setting selection list.
   Select Cancel to discard the changed settings and return to the preset setting selection list.
7. Select Exit.

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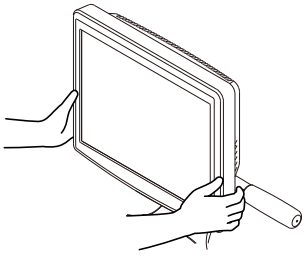
3-8 Adjusting the Monitor

Adjust the height, orientation and brightness.

⚠CAUTION
Take care not o pinch your fingers when adjusting the monitor position or orientation. You may pinch your fingers or hands and cause injury.
• Prevent the monitor from tangling with the probe cable. It may cause damage to the monitor or the area of the monitor that was hit. If the monitor is damaged and the liquid substance inside it touches your skin, wipe it away, wash with running water for 15 minutes or longer, and consult a doctor. If the liquid gets in your eye, wash it with running water for 15 minutes or longer and consult a doctor immediately.

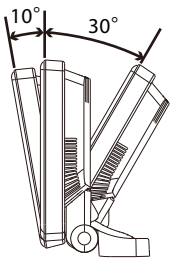
3-8-1 Adjusting the Orientation of the Monitor

To adjust the orientation of the monitor, Grasp the monitor frame with both hands.



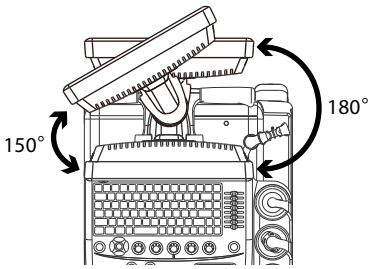
Gradient:

10° to the front,
30° to the back

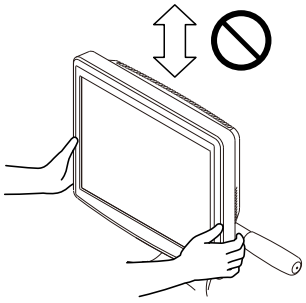


Swing area:

150° to the left, 180° to the right



Height: it cannot be adjusted.



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3-8-2 Adjusting the Brightness of the Monitor

Adjust the Brightness of the Monitor.

Adjusting the Brightness of the Monitor (Menu)

NOTE: At the factory settings, Monitor Contrast, Monitor Brightness, or Monitor Back Light are not in the function menu.To display them on the function menu, assign them in preset to Set-Up > (Application) > Menu-Function.

1. Display the corresponded menu.
2. Adjust Monitor Contrast, Monitor Brightness or Monitor Back Light.

   Monitor setting items on the function menu

   - Monitor Contrast : 0 to 20
   - Monitor Brightness : 0 to 20
   - Monitor Back Light: 0 to 20

Adjusting the Brightness of the Monitor

You can set three types as combinations of Monitor Brightness, Monitor Contrast, Monitor Backlight, Panel LED Brightness. You can select the type for applying to the application.

Setting combinations of Brightness

1. Select PRESET key.
2. Navigate the preset to Set-Up > Common Preset > Common3.
3. Set each items of LCD/Panel Setup.

Set the combination type using the preset

1. Select PRESET key.
2. Navigate the preset to Set-Up > (Application) > Display 2.
3. Select a type from LCD/Panel Setup.

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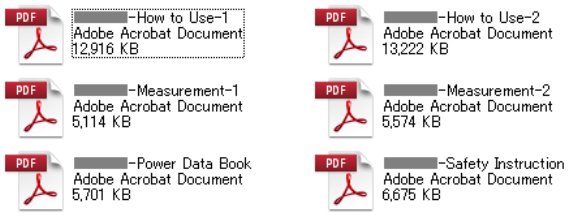
3-9 Viewing the instruction manual on the CD-ROM

NOTE: Adobe Reader version 7.0 or higher is necessary to display the manuals on the CD-ROM. If Adobe Reader is not installed on your computer, please download Adobe Reader from the Home page of Adobe Systems Incorporated.

1. Insert the supplied CD-ROM into the CD-ROM drive.
2. Open the DVD/CD drive.

   The instruction manuals consists four books.

   - Safety Instruction: provides instructions for the safe use of the instrument and how to avoid hazards.
   - How to Use: describes functions for adjusting, displaying and recording images.
   - Measurement: describes measurement methods on an ultrasound image and viewing reports.
   - Power Data Book: provides acoustic output tables of probes.



Example of instruction manuals on the CD-ROM.
(Figure is different from composition of the instruction manuals.)

   Gray area in the above figure shows (parts of) the name of the instrument.

3. Double-click an instruction manual

   → A selected instruction manual is displayed.

   NOTE: Paper size of the instruction manuals on the CD-ROM is Letter. Before printing, check your printer property.

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3-10 The Flow of the preparation to the study

Perform the following procedure of the study.

For inputting a patient information, displaying image, and acquiring images, refer to the How to Use manual.

1. Perform the external inspection of the instrument and probes.
   Ensure that there are no scratches, cracks, depressions, change of color.
2. Insert the power plug into the power outlet (hospital grade).
3. Connect a probe to the probe connector on the instrument.
4. Press POWER to turn on, and then check the screen display.
5. Press NEW PATIENT, and then input a patient information.
6. Coat the ultrasonic irradiation area of the probe and area to be examined of a patient with an ultrasound medium.
7. Apply the probe to the examined area of a patient, and then display an image.
8. When the images are acquired necessary for the diagnosis, and then press FREEZE.

3-10-1 Operating Mode

B mode 	1 Press B or B/B. 2 Adjust an image. • Using DEPTH/ZOOM, adjust size of a tomographic view. • Using B GAIN or STC knob, adjust the sensitivity.
M mode 	1 Press M. 2 Using trackball, move the M cursor on the B mode image. 3 Using MULTI GAIN, control balance of the sensitivity between B mode and M mode.
PW mode 	1 Press D. 2 Using trackball, move the Sample Volume on the B mode image. 3 Adjust an image. • Using Vel Range (D) on the Function menu, adjust the range of the flow velocity. • Using MULTI GAIN, adjust the sensitivity.
CW mode 	1 Press and hold down the D. 2 Using trackball, move the Sample Volume on the B mode image. 3 Adjust an image • Using Vel Range (D) on the Function menu, adjust the range of the flow velocity. • Using MULTI GAIN, adjust the sensitivity.

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Flow mode (Color Doppler) 	1 Press B, B/B, or B/M, and then press F. 2 Adjust an image. • Using Vel Range (D) on the Function Menu, adjust the range of the flow velocity. • Using MULTI GAIN, adjust the sensitivity.

3-10-2 Freezing image/Unfreezing image

- Press FREEZE.

3-10-3 Measuring on a ultrasound image

1. Press Measurement key.
2. Select the measurement item on the measurement menu.
3. Measure according the selected item. (Refer to the Measurement manual.)

3-10-4 Printing images or Storing images

- To Store a still Image
  - a Press FREEZE to stop an image.
  - b To print, press PRINT. To store (save), press STORE.
- To store a moving image
  - a Press FREEZE to unfreeze an image.
  - b Press STORE to start storing a moving image.
  - c To stop storing, press STORE.

  A moving image is acquired for time for heart beats depending the preset setting.

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4 Troubleshooting

4-1 Messages

There area two types of messages that displayed on the screen.

1) Dialog messages

   Dialog messages show the equipment is processing or that an error has occurred. Operation is suspended.

2) Assistance messages

   Assistance messages show additional information to assist in operation. Operation is not interrupted.

4-2 Dialog messages

Message	Causes	Actions
Back up file Reset will destroy any data on this system. Do you still wish to continue?	You select delete the data that is preset or saved.	• Continue Delete the data. • Cancel Return to the previous screen without deleting the data. • If no response in made within 10 seconds, the display returns to the previous screen.
Hard disk Access error. Hard disk requires being diagnosed.	The data cannot be written to the hard disk in the Preset Control.	Please contact one of our offices listed on back cover. • OK Return to the previous screen without writing the data.
This Application is not supported.	When copying preset data from an external media, there are preset data of masked application.	• OK Return to the previous screen without writing the data.
Error: Disk full. Please delete data.	HD free space is insufficient in the Preset Control.	Delete unnecessary data in hard disk, and retry. • OK Return to the previous screen without writing the data.
Disk access error: System parameter has been initialized. Please contact service for assistance.	The data of HD is crashed and has been initialized.	1 Select OK. 2 Stop using the instrument. 3 Please contact one of our offices listed on back cover.
Sending images to storage.	The image is being transmitted to the network from the Review.	The message disappears after transmitting the data.
Storing Data: **%	The image is being saved to the external media from the Review (% shows the progress of saving).	The message disappears after transmitting the data.
Cannot find study information.	The study information cannot be found.	Select Retry, and change the search criteria. • Retry Search the patient data. • Cancel Return to the previous screen without searching.
Cannot find series information.	The series information cannot be found.	
DICOM image file not found.	The DICOM image file cannot be found.	
Searching...Please wait.	During searching the information.	The message disappears after searching, and the search result is displayed.

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Message	Causes	Actions
`Unable to open list file ********`	The image that is searched in the Review cannot be opened (******** shows file name).	Select Retry. If this message is redisplayed for the images, the image file could be breakdown. • Retry Open the file after searching. • Cancel Return to the previous screen.
`Unable to load image information.`	The image that is searched in the Review cannot be displayed.	
`Unable to read image information.`	The information of the image that is searched in the Review cannot be displayed.	• Retry Redisplay the image information after searching. • Cancel Return to the previous screen.
`Unable to build image information.`	The image data that is loaded in the Review cannot be built.	
`In progress. Please wait.`	DICOM file is being converted to BMP or TIFF.	The message disappears after converting, and the completion message appears.
`Process completed.`	Converting DICOM file to BMP or TIFF completed.	The message disappears after 2 seconds.
`Network configuration error.`	The communications in the network have a problem.	1 Check the network configurations (Common Preset > DICOM-Store, Send). 2 If necessary, reset the configurations. • Retry Retransmit the data. • Cancel Return to the previous screen without transmitting the data.
`Printer configuration error.`	The DICOM printer in the network has a problem.	1 Check the network configurations (Common Preset > DICOM-Printer). 2 If necessary, reset the configurations. • Retry Retransmit the data. • Cancel Return to the previous screen without transmitting the data.
`Disk crashed.`	The removable disk is crashed.	Reconnect the removable disk. If redisplayed, change the removable disk. • OK Return to the previous screen.
`Error: Disk write protected.`	The disk is write-protected.	1 Select OK. 2 Replace the writable removable disk. • OK Return to the previous screen without writing the data.

Message	Causes	Actions
Removable disk is not ready.	The instrument contains a write-protected disk.	1 Select OK. 2 Replace the writable disk in the disk drive and select Retry. • OK Return to the previous screen without writing the data.
Error: No disk, or disk unformatted.	There is no disk in the disk drive. The instrument contains an unformatted disk.	Replace the writable disk in the disk drive and select Retry. • Retry Reload the data on the disk. • Cancel Return to the previous screen.
ERROR: Disk Full!!	Space of the removable disk is insufficient.	Replace with the new removable disk and select Continue. Or, adjust data volume to removable disk volume. • Continue Write the data. • Cancel Return to the previous screen without writing the data.
Verification SCP not supported.	The image was transmitted to the SCP that does not have a server function.	Check the network connection and the network configurations of the equipment. • Retry Retransmit the image. • Cancel Return to the previous screen without transmitting the data.
Printer communication error.	A communication error occurs in the printer.	Check the network connection and the network configurations of the equipment. • Retry Retransmit the data. • Cancel Return to the previous screen without transmitting the data.
Network communication error.	A communication error occurs in the network.	Check the network connection and the network configurations of the equipment. • Retry Retransmit the data. • Cancel Return to the previous screen without transmitting the data.

Message	Causes	Actions
There are images not printed in the printer buffer. Do you print them or delete?	Carried out Print Queue or NEW PATIENT, when data exist in the printer buffer.	• Print Print the data in the printer buffer, move to the next operation. • Delete Delete the data in the printer buffer, move to the next operation. • Cancel Return to the previous screen.
The patient of this image is different from the patient during the examination at present. Do you finish an examination, and may I erase an image?	Select the another patient's Line image replay.	Select whether replay a selected image. • OK Erase a display image and replay a selected image. • Cancel A current image is displayed without replay a selected image.
An image is transferred to cinememory. The image preserved in cinememory is erased.	Select the Line image replay.	
Patient data base access error.	An error when it accessed database of a patient in Review.	1 Select OK. 2 Check the network configuration of the equipment and connection of the selected database. • OK Return to the previous screen.
Error: Insufficient disk space. Please insert new disk.	(In the case of Disk on Store Media.) The writing capacity of Disk is insufficient.	Replace with the new removable disk and select Continue. Or, adjust data volume to removable disk volume. The message disappears after five seconds.
Error: Network communication error.	(In the case Net on Store Media.) A communication error occurred with the server.	Check the network connection and the network configurations of the equipment. The message disappears after five seconds.
Error: Disk full;Please delete images.	• Too many images were stored in the case of Cine on Store Media (capacity over of HD). • Space of the Hard disk or CD-R Buffer is insufficient.	Delete unnecessary data in hard disk, and retry. The message disappears after five seconds.

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Message	Causes	Actions
Remote *******. ******* does not support Worklist.	The worklist servers (HIS, RIS) in the hospital cannot transmit the data.	Check the network connection and the network configurations of the equipment. • Retry Retransmit the data. • Cancel Return to the previous screen without transmitting the data.
No worklist records found. Showing old records.	A new worklist cannot be found.	Check the network connection and the network configurations of the equipment. • Retry Retransmit the data. • Cancel Return to the previous screen without transmitting the data.
Please enter 'PATIENT ID'.	The patient ID is not entered when the search starts.	1 Select OK. 2 Input a patient ID on the ID screen. • OK Return to the previous screen.
Loading Patient.	Searching the patient ID in the ID screen.	The message disappears after searching.
Copying Patient.	The patient data is being retrieved from the search list.	The message disappears after retrieving.
Writing Patient.	The patient data is being written to the HD.	The message disappears after writing.
Receiving Patient.	The patient data is being received from the HIS and RIS.	The message disappears after receiving.
Cannot find patient information.	The patient data cannot be found.	Select Retry, and change the search criteria. • Retry Search the patient data. • Cancel Return to the previous screen without searching.
Echo check to *******: ******* started.	C echo check started.	The message disappears after two seconds, or after checking.
Echo check to *******: ******* successful.	C echo check ended.	Select server have its functions corresponding DICOM or is active. • OK Return to the previous screen.

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Message	Causes	Actions
Echo check to *******: ******* failed.	An error occurred at the time of C echo check.	Selected server doesn't have its functions or is not active. Please contact your network administrator. • OK Return to the previous screen.
Ping check to *******: ******* started.	Ping check started.	The message disappears after two seconds, or after checking.
Ping check to *******: ******* successful.	Ping check ended.	TCP/IP is active. • OK Return to the previous screen.
Ping check to *******: ******* failed.	An error occurred at the time of Ping check.	TCP/IP is not active. Please contact your network administrator. • OK Return to the previous screen.
Invalid probe connected.	The connected probe is not suitable for this instrument.	When the probe is removed, the message disappears. NOTE: Connect the probe to the equipment which is specified this manual.
It can't be stored palette image. When Store is done, a color can't be reproduced. Do you change it to RGB?	When storing static images on the DICOM Palette format and in the case that the images on the Palette settings with 3 or more differences in 4B modes are saved.	• OK Change the RGB setting and save. • Cancel Return to the previous screen without saving the setting.
Station name overlaps.	Station names are overlapped.	Check the network configuration. • OK Return to the previous screen.
Invalid data format.	There is an error in the header information of an outside media.	• OK Return to the previous screen.
File access error! A part of the data may not be accessed. Reboot is necessary to access to the relevant data.	USB flash memory was removed during copying to USB flash memory.	Data currently being copied in the instrument can be displayed as a thumbnail, but cannot be opened or copied. Restart the instrument to recopy the data. • OK Return to the previous screen. NOTE: Do not remove the USB flash memory during accessing.
HARDWARE ERROR **********	A malfunction has been detected in instrument hardware.	Note message details and contact one of our offices listed on back cover. • OK Return to the previous screen.

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Message	Causes	Actions
SYSTEM ERROR **********	A malfunction has been detected in software.	Note message details and contact one of our offices listed on back cover. • OK Return to the previous screen.
Data error of this probe was found. shut down and reboot the system. If this message is displayed again, contact our distributor or Aloka Office, please show this message.	A malfunction has been detected in probe parameters. When this message appears, power transmission is shut off immediately.	Restart the instrument. If this message persists, record message information and contact one of our offices listed on back cover.
Disk decreased;Please delete images.	Space of Hard disk is 10% or less after storing images. Or Space of Hard disk is 1% or less after storing images.	Delete unnecessary data from the HDD. • OK Return to the previous screen.

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4-3 Assistance messages

Message	Cause and action
`Invalid Function: This function is inoperable.`	The software for operating the menu or switches is not ready to operate.
`In progress. Please wait.`	The calculation is in progress. The message disappears after calculating, and the completion message appears.
`Process completed.`	The calculation completed. The message disappears after five seconds.
`Press <ENTER> key to rotate Fetus mark.`	When the ENTER key is pressed, the fetus mark rotates.
`Conform press <ENTER> key. Quit<Cancel> key.`	The message appears during the use of Body Mark Location.
`Printer Error: Check printer power.`	The recorder is powered OFF, or when the BUSY signal does not return in the specified time.
`Paper Empty: Check printer paper.`	The EMPTY ERROR is transmitted from the external printer.
	The data exists in the printer buffer, carry out Print Queue or NEW PATIENT.
`Sending images to printer.`	The image is being transmitted to the PC printer.
`STORE Capacity:Free space ***%`	The data is saved in the memory. Free space shows remaining capacity of the store memory as percentage of the remaining capacity of the hard disk. NOTE: Since the status bar indicates how much HDD space is in use, the display may differ from the indication of free space.
`<FREEZE> the image. Then try again.`	The non functional switch or menu for movie was selected.
`Accept this images or cycle : Press STORE sw Retry : Press Cancel sw`	Confirming whether it is saved to hard disk after replaying Loop an object image in saving operation. • CANCEL Cancel saving the image. • STORE Save the image.

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Message	Cause and action
A part of the image couldn't be acquired. Accept this images or cycle : STORE sw, Retry :Cancel sw	In the case that Auto Loop is On, and when the taking-in quantity of the Cine does not reach the settings of heartbeat and the time for taking-in. • CANCEL Cancel taking the image into the cine memory. • STORE Take the image into the cine memory.
A part of the image couldn't be acquired.	In the case that Auto Loop is Off, and when the taking-in quantity of Cine does not reach the settings of heartbeat and the time for taking-in. • CANCEL Cancel taking the image into the cine memory. • STORE Take the image into the cine memory.
It failed in the store of this images!	During or starting the image acquisition, the R wave could not be detected.
Not Connected.	No connection is established at the time of selection by the probe name.
System in AUTO-FREEZE. Press <FREEZE> key to resume.	When it is FREEZE automatically after having left unattended during the time setting subsequent to Timer Freeze by pre-setting on the state of FREEZE OFF.
Backup data file not found.	The backup file cannot be loaded during maintenance.
Network library initialization error.	The network library failed to be initialized.
Detection Error: R-wave of ECG is not detected.	The R wave could not be detected in five sec or more. When the R wave signal is detected, the message disappears.
Range Limit: Selection is not available.	You attempted to set continuous or step real time settings using the trackball or Rotary Encoder and the values are beyond the limits.
Cannot register. If you delete an unnecessary word, you can register newly.	You have attempted to register new words over the limit of the user's dictionary when the learning function is off.
UST-987series: UST-987-7.5/UST-995-7.5/UST-MC11-8731.	Displayed when you select UST-987-7.5, UST-995-7.5, UST-MC11-8731. The name of the probe on the screen is displayed as "UST-987series".

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4-4 Other problems

Case	Cause	Action
The equipment is froze.	Runaway software.	1 Unplug the power cord from the outlet. 2 Let stand for a few minutes. Connect the power plug into the outlet again. 3 Press the POWER switch to turn on.
	Power supply fluctuation.	
The date and time on screen are not correct.	Date and time is not set or has shifted.	Adjust the date and time on Common Preset.
	Internal battery is drained.	Please contact one of our offices listed on back cover.
The equipment is shutdown during start-up. The equipment is started shutdown without warning.	The fan is break down.	Please contact one of our offices listed on back cover.

4-4-1 Image Display and Image Degradation

Check the status of POWER switch and monitor screen.

When there is not improvement in that you performed the procedure based on followings, please contact one of our offices listed on back cover.

check points				
POWER switch	Monitor (graphic)	Monitor (image)	Cause	Action
No	—	—	No connection of the power cable.	Reconnect the power plug into the power outlet.
No	—	—	Circuit breaker is tripped.	Check the condition of the circuit breaker of the connected power outlet.
Yes	No	No	The fan is break down.	Please contact one of our offices listed on back cover.
Yes	No	No	Screen Saver Display Type is Power Saving Monitor.	Press the FREEZE switch to switch the display to real time.
Yes	No	No	EXT (external input) is turned on.	Turn off EXT.
Yes	Yes	No	Gain is lowered.	Adjust the setting with the B Gain knob.
Yes	Yes	No	No connection of the probe.	Reconnect the probe.

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check points				
POWER switch	Monitor (graphic)	Monitor (image)	Cause	Action
Yes	Yes	No	Acoustic power is lowered.	Adjust the setting with the Acoustic Power knob.
Yes	Yes	No	The still image is displayed (The FREEZE switch is ON)	Press the FREEZE switch to switch the display to real time.

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5 Maintenance

5-1 After Using the Instrument

When all today's studies is finished, isolate the instrument from the supply main. If you skip the actions after using the instrument, the instrument is damaged or the performance of the instrument is degraded. Take adequate steps as follows:

⚠CAUTION

DO NOT unplug the power cable from the outlet during shutdown.
The instrument may break down.
After the equipment is shutdown, unplug the power cable from outlet.

1. Freeze the image.
2. Backup the images.
   a Transfer all images in the buffer of the internal memory or CD-R to the USB flash memory, DVD, or CD-R.
   b Delete unnecessary images in the buffer of the internal memory or CD-R.
3. Remove recording medium from recording devices.
4. Isolate from the supply main.
   a Press the POWER for one second or more to light orange the POWER.
   b If necessary, disconnect the power plug from the wall outlet after shutdown in complete.
   c Take care that the power cable which is disconnected does not get entangled.
5. Wipe off ultrasound medium remaining on the probes and the ECG electrodes.
6. Remove cables and plugs as necessary.
   a Take care that the ECG lead cord does not get entangled.
   b Remove the unfixed probes.

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7. Clean the instrument.

   Parts that must be cleaned at least once a week

   - Power Plug (disconnect from the outlet and clean), The area around the device
   - Operation panel, External instrument (include probe holders)
   - Monitor
   - Filter

   Parts that must be cleaned as necessary

   - Foot switch
   - Printer
   - Track ball

8. Store the instrument under conditions suitable for storing.

5-1-1 State of the Instrument and Accessories

1) State of the instrument

   - Check that the operation panel is cleaned.
   - Check that the External instrument (include probe holders) and the foot switch are cleaned.
   - Check that the monitor is cleaned.
   - Check that the instrument is stored under the condition suitable for storing.
   - Check that the power plug is cleaned.
   - Check that the casters are locked.
   - Check that the instrument is covered by a cloth to protect the dust.

2) State of the probe

   - Check that it is cleaned.
   - Check that the probe is placed in the probe holder or its case.
   - Check that the probe is stored under the condition suitable for storing.

3) State of the ECG lead cord

   - Check that those are cleaned.
   - Check that those are bunched to prevent from entangling, or placed in the probe holder or its case.

4) State of peripherals

   - Check that the head of the printer head is cleaned.

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5-2 Cleaning

Upon completion of the operation, clean and inspect the instrument after turning off the power using the following procedure. If you neglect to carry out this procedure, a breakdown may occur or the instrument may fail to function correctly the next time you carry out an examination.

⚠CAUTION
DO NOT sterilize or disinfect the equipment with medicinal solution or gas. Doing so may damage the equipment.
DO NOT spill liquid on the surface or interior of the instrument. Doing so may cause electric shock and/or short circuits. Should you spill liquid on the instrument, contact one of our offices listed on back cover.
Clean, disinfect, and sterilize probes with each examination. Infections may spread via probes. Refer to the probe's documentation for information on handling, cleaning, disinfection, sterilization, and inspection methods.

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5-2-1 Clean the Instrument

Clean the instrument after turning off the power of the instrument and peripherals.

> ⚠NOTE DO NOT clean the instrument with organic solvents such as alcohol or commercial LCD cleaners.

1. Turn off the power of the instrument.
2. Clean the instrument and peripherals.

   Operation panel, enclosure, probe holder, and foot switch

   Clean them with a soft, dry cloth. If they are very dirty, remove the dirt in the following procedure.

   a Immerse a soft cloth in a weak solution of a neutral detergent, and wring water out of it.

   b Wipe the instruments with it softly and clean the dirt.

   c Wipe off the detergent.

   Monitor

   Immerse a soft cloth in water and wring out, wipe the monitor with it softly.

   Installation location and Power plug

   Clean and remove moisture.

   If you use the instrument in a dusty location, the ventilation may deteriorate which can cause malfunction of the instrument.

   Probes

   Cleaning, disinfection, and sterilization methods vary according to the probe.

   Refer to probe documentation.

   Cleaning recording devices

   Refer to the peripheral device's documentation.

   Refer to printer documentation for information on printer head cleaning.

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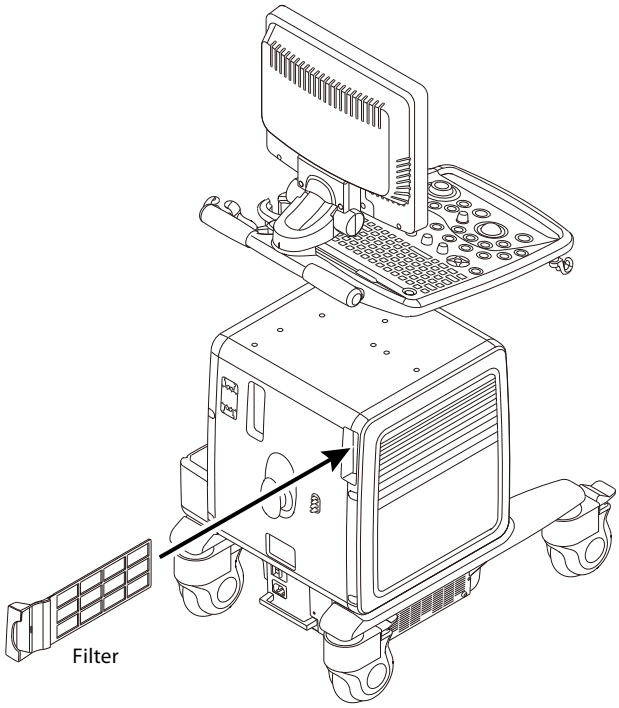
5-2-2 Cleaning the Air Filter

1. Take out each filter as shown in the figure below.

   Location of the filters



2. Vacuum-clean the filter.
3. Wash it with running water.
4. Swish water off, dry the filter completely in a shaded area.
5. Check the front and back of the filter and reinstall it to the original location.

   NOTE: Push the filter in completely.

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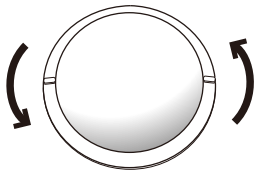
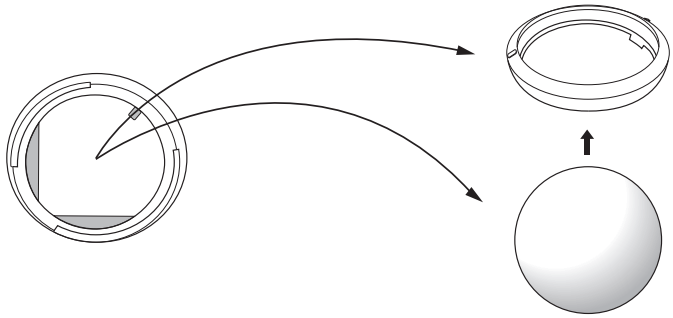
5-2-3 Cleaning the Trackball

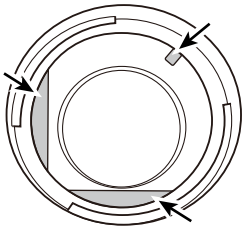
1. Turn the ring to the left.



2. Remove the trackball and put in on a soft cloth.



3. Clean the ring and the trackball with a soft cloth.
4. Clean three places (arrows on the figure below) with a cotton bud.



If the ruby balls are very dirty:

Remove the dirt with a cotton bud that has been immersed in a weak solution of a neutral detergent.

5. Replace the trackball and replace the ring.

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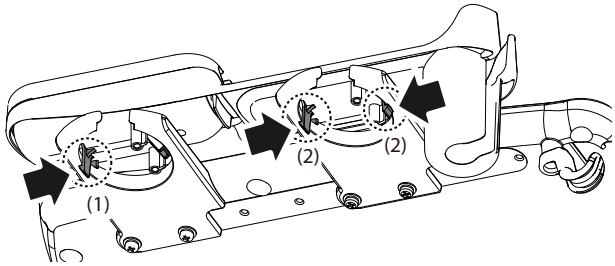
5-2-4 Cleaning Endo-cavity Probe Holder(Horizontal)

This is a optional probe holder that is put the endo-cavity probes. The probe holder and the adaptor can respectively be removed from the instrument. If necessary, clean it.

Cleaning Endo-cavity Probe Holder(Horizontal)

1. Remove the Endo-cavity Probe Holder.



a Pull (1) tab in the direction of arrow and draw it upward to remove the tab.

b Pull (2) tab in the direction of arrow and draw it upward to remove the tab.

2. Clean it with a soft, dry cloth.

If dirt is heavy

a Immerse a soft cloth in a weak solution of a neutral detergent, and wring water out of it.

b Wipe the instruments with it softly and clean the dirt.

c Wipe off the detergent.

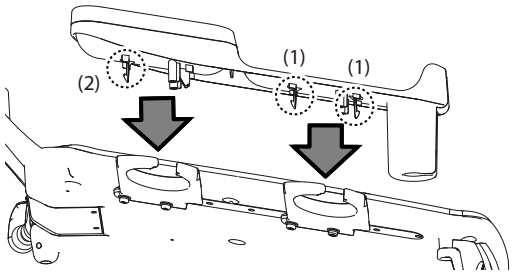
If washing in water

a Rinse the probe holder in running water.

b Wash off ultrasound medium and other substances adhering to the probe holder using a sponge or gauze.

c Wipe off moisture.

3. Set the probe holder.



a Match (1) tab position. Push the probe holder until you hear with a click.

b Match (2) tab position. Push the probe holder until you hear with a click.

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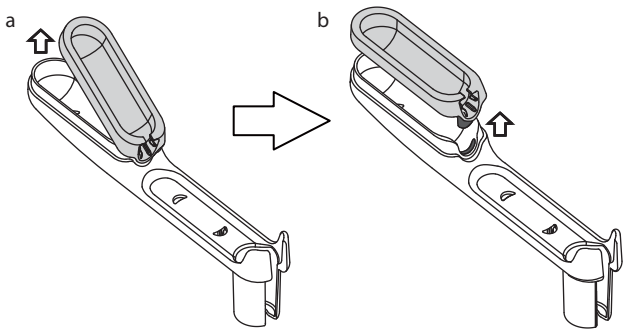
Cleaning Endo-cavity Probe Holder Adapter

1. Remove the adapter.
   - a Remove the adapter from the back of the probe holder.
   - b Remove the adapter from near side of the probe holder.

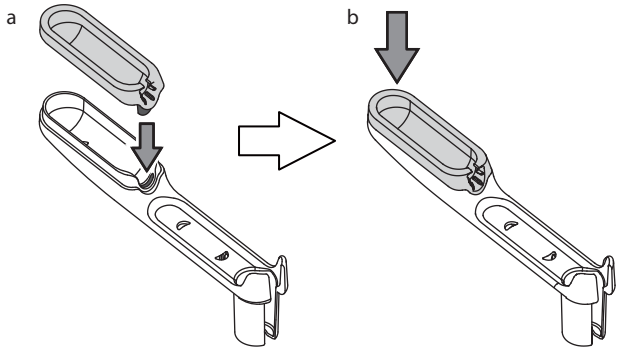


2. Clean it with a soft, dry cloth.

   IF dirt is heavy
   - a Immerse a soft cloth in a weak solution of a neutral detergent, and wring water out of it.
   - b Wipe the instruments with it softly and clean the dirt.
   - c Wipe off the detergent.

   If washing in water
   - a Rinse the probe holder in running water.
   - b Wash off ultrasound medium and other substances adhering to the adapter using a sponge or gauze.
   - c Wipe off moisture.

3. Set the adapter.



   - a Insert the tumour of the adapter into the hole of the probe holder.
   - b Set the back of the adapter to the probe holder.

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5-3 Maintenance

Perform regular inspections to ensure the safe use of the instrument and maintain performance.

There are three kinds of inspections: daily inspections (pre-use inspections/post-use inspections), measurement accuracy inspections, and safety inspections. Safety inspections are performed by a technician qualified to conduct safety inspections on electric medical equipment. If a technician is unavailable, one of our service representatives may be requested for a fee. For more information on service representatives, contact one of our offices listed on back cover.

When conducting an inspections, in accordance with the attention points related to the following electrostatic discharges (ESD), be careful not to invite any deterioration and trouble on the part being sensitive to static electricity. See “Electrostatic Discharge (ESD) Guidelines” on page 1-21.

⚠CAUTION

If you find the instrument or a probe to be defective, stop using it immediately.

If you continue to use an instrument or probe that is defective, you risk causing injury to the patient. For repair of the instrument or a probe, please contact one of our offices listed on back cover.

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5-3-1 Daily check: For Using the Instrument for a Long Period

The equipment may fail to function correctly or may become damaged as a result of deterioration of parts and consumables. In order to prevent this, you must maintain and inspect the instrument before or after use, and do periodically.

NOTE: Inspect the probes in accordance with the instruction manual for the probe.

Daily check points

- Check to ensure that there is no dust on the power plug.
- Check to ensure that neither the monitor nor the monitor arm is loose.
- Check to ensure that the Brightness and Contrast settings on the monitor are correct.
- Check to ensure that the Brightness and Contrast settings on the printer are correct.
- Check to ensure that the mounting base is not loose and also that the peripheral instrument is fixed securely.

Monthly Inspection

- Check to ensure that the casters are locked securely.
- Check to ensure that none of the screws fixing the operation panel and handles are loose.
- Check to ensure that there are no cracks, dents or other enclosure signs of damage on the instrument.

⚠CAUTION
If you find any loose parts, cracks, dents or other signs of damage on the instrument, make a suitable indication on the instrument, such as attaching a “BROKEN” tag to it, then contact one of our offices listed on back cover.
Operate the instrument within its service life (seven years). A system used over the service life may not provide sufficient perfomence.

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5-3-2 Checking the Measurement Accuracy

At least once a year, carry out the following measurements using an ultrasound phantom in order to check the measurement accuracy and calculation accuracy, and keep a record of the results.

1) Distance measurement accuracy (horizontal and vertical directions)
2) Resolution and sensitivity (horizontal direction and vertical direction)
3) Doppler measurement accuracy

Preparation for Checking the Measurement Accuracy

- Prepare the following items to inspect.

  a) Ultrasound phantom

  An ultrasound phantom is made of a substance which resemble those of human body tissues. It is used for checking the performance of probes and the diagnostic ultrasound system, and also for adjusting the image settings. It contains parts of different densities and targets separated by known distances. Some phantoms contain a mechanism for performing Doppler measurement.

  b) Probe connected to the instrument and the accompanying document

  c) Measurement accuracy inspection data sheet

  d) A record of the previous inspection (If you have it)

---

1. Copy the measurement accuracy inspection data sheet and write the necessary items.
2. Connect the probe to be used for inspecting the instrument.
3. Press the POWER switch to turn on the power of the instrument.
4. Change the settings of the preset so that they are the same as those used for the previous inspection. Select the optimum preset for the probe connected to the instrument.

   If there is no record of the previous inspection:

   Select the optimum preset for the probe connected to the instrument.
5. Record the preset and paste it to the data sheet, or record the preset to a DVD, indicate details identifying the DVD at the place on the data sheet where the record is to be pasted.

   Record the following preset screens.

   - Image-B, M1
   - Doppler1
   - Doppler2
   - Flow

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Checking the Distance Measurement Accuracy

Using the ultrasound phantom, determine the horizontal direction and vertical direction distances.

1. Activate the B mode.
2. Set all of the STC knobs to the center position.
3. Refer to the instruction manual of the probe and adjust the DEPTH/ZOOM switch so as to obtain the optimum display depth for the inspection.
4. Apply the probe to an ultrasound phantom.
5. Adjust the various switches so that the values conform to R (display depth), G (gain), C (contrast) and DVA (acoustic power) of the previous record.

   If there is no record of the previous inspection:

   Adjust the GAIN, CONTRAST, and ACOUSTIC POWER switches so as to obtain the optimum image.
6. Freeze the image.
7. Calculate the distance measurement accuracy in the horizontal direction.

   a Measure the distance between targets separated by a known distance in the horizontal direction.

   b Print the record of the preset screen and paste it to the data sheet. If you recorded the preset screen to a DVD, indicate details identifying the DVD at the place on the data sheet where the record is to be pasted.

   c Calculate the distance measurement accuracy.

   → Compare it with the record of the previous inspection to judge that it is abnormal if there is any obvious difference in measurement values.
8. In the same way, calculate the distance measurement accuracy in the vertical direction.

   → Compare it with the record of the previous inspection to judge that it is abnormal if there is any obvious difference in measurement values.

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Inspection of the Resolution and Sensitivity

1. Activate the B mode.
2. Set all of the STC knobs to the center position.
3. Refer to the instruction manual of the probe and adjust the DEPTH/ZOOM switch so as to obtain the optimum display depth for the inspection.
4. Apply the probe to an ultrasound phantom.
5. Adjust the various switches so that the values conform to R (display depth), G (gain), C (contrast) and DVA (acoustic power) of the previous record.

   If there is no record of the previous inspection:

   Adjust the GAIN, CONTRAST, and ACOUSTIC POWER switches so as to obtain the optimum image.
6. Freeze the image.
7. Print the record of the preset screen and paste it to the data sheet. If you recorded the preset screen to a DVD, indicate details identifying the DVD at the place on the data sheet where the record is to be pasted.

Inspection of the Doppler Measurement Accuracy

Perform an inspection of the flow velocity measurement accuracy. Next, using an ultrasound phantom that has a Doppler measurement mechanism (Hereafter called Doppler phantom), determine the flow velocity by Doppler measurement. Record the measurement results for each measurement.

Preset settings:

- Select Setup > Flow of the preset setup, set Color for Display Priority.
- Do not change the setting during inspecting.

Inspect the flow velocity measurement accuracy

1. Display a B/D mode image.
2. Place the probe against the Doppler phantom.
3. Set the velocity of the flow of the Doppler phantom to the recorded velocity of the previous inspection.
4. Adjust the D gain to the recorded value of the previous inspection.

   If you do not have a record of the previous inspection;

   Set the D gain so that you obtain the optimal image.
5. Move the Doppler cursor to the area where the blood flows, and display the Doppler signal.
6. Freeze the image.
7. Measure the velocity of the flow.
8. Print the record of the preset screen and paste it to the data sheet. If you recorded the preset screen to a DVD, indicate details identifying the DVD at the place on the data sheet where the record is to be pasted.

   → Compare it with the record of the previous inspection to judge that it is abnormal if there is any obvious difference in measurement values.

Inspect the Doppler sensitivity

1. Display a B/flow mode image.
2. Place the probe against the Doppler phantom.
3. Set the velocity of the flow of the Doppler phantom to the recorded velocity of the previous inspection.
4. Set the flow gain to the recorded value of the previous inspection, and record the result on the data sheet.

   If you do not have a record of the previous inspection;

   Set the D gain so that you obtain the optimal image.
5. Freeze the image.
6. Print the record of the preset screen and paste it to the data sheet. If you recorded the preset screen to a DVD, indicate details identifying the DVD at the place on the data sheet where the record is to be pasted.

   → Compare it with the record of the previous inspection to judge that it is abnormal if there is any obvious difference in measurement values.

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Measurement Accuracy Inspection Data Sheet

Diagnostic ultrasound system	Model No.		Manufacturing No.	
Probes	Model No.		Manufacturing No.	
Other peripheral instruments	Model No.		Manufacturing No.	

Inspection date		Inspector Dep./Signature	

Image 1 Control preset screen Pasting position	Particulars of ultrasound phantom (control No.,date of purchase, S/N, etc.)

Distance measurement accuracy			
Horizontal direction Image pasting position		Vertical direction Image pasting position	
Known distance between targets: a	cm	Known distance between targets: a	cm

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Distance measurement accuracy			
Measured distance: b	cm	Measured distance: b	cm
Distance measurement accuracy |b-a|÷a×100 ＝	%	Distance measurement accuracy |b-a|÷a×100 ＝	%

Resolution
Image pasting position

Doppler measurement accuracy	
Position for pasting Doppler control preset image	Details identifying the Doppler phantom (control No.,date of purchase, S/N, etc.)

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Doppler measurement accuracy	
Position for pasting Flow Control preset image	Velocity of flow of phantom Velocity of flow (m/s):
Position for pasting B/D mode image	Position for pasting B+ flow mode image
D gain knob	FLOW gain knob

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5-3-3 Safety Inspection

A safety inspection is performed by a person who is licensed to carry out safety inspections on electrical medical instrument at least once a year. And the record of inspection results must be stored.

If there is no qualified person at the customer's place, our serviceman will carry out this inspection for a service charge. If you require a serviceman, contact one of our offices listed on back cover.

Perform the following inspection, and confirm that the measured values are no greater than the values in the table.

Standard values for periodic safety inspection (Extracted from IEC 60601-1)

Item		Normal condition	Single fault condition
1)	Earth leakage current	0.5 mA max	10 mA max
2)	Enclosure leakage current	0.1 mA max	0.5 mA max
3)	Patient leakage current from the patient connection (d.c.)	0.01 mA max	0.05 mA max
	Patient leakage current from the patient connection (a.c.)	0.1 mA max	0.5 mA max
	Total patient leakage current from the patient connection (d.c.)	0.05 mA max	0.1 mA max
	Total patient leakage current from the patient connection (a.c.)	0.5 mA max	1.0 mA max
4)	Patient leakage current on the patient connection(s)	N/A	5 mA max
	Total patient leakage current on the patient connection(s)	N/A	5 mA max
5)	Impedance for protective contact to earth	0.1Ω max	-

⚠NOTE	Check the power circuits (including power outlets) in the hospital (e.g. measure the protective earth impedance) at least once a year.

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Safety Inspection procedure

1) Earth leakage current

Perform a leakage current test according to Fig.13 of IEC 60601-1: Ed.3 by using the measurement power supply circuit shown in Fig.F.1 of IEC 60601-1: Ed.3.

This instrument does not have FE (Functional earth terminal). PE (Protective earth terminal) of this instrument corresponds to leakage current measurement terminal.

Protective earth terminal is located on the rear panel.

2) Touch current

Perform a leakage current test according to Fig.14 of IEC 60601-1: Ed.3 by using the measuring supply circuit shown in Fig.F.1 of IEC 60601-1: Ed.3.

Signal input and output points of this instrument are protectively earthed except connectors of ECG lead. Do not apply a voltage to these signal input or output points.

Check the leakage at any part of the enclosure apart from connectors. To do this, apply two sheets of metal foil of maximum dimensions 20 × 10 cm to arbitrary parts of the enclosure, then measure the leakage current between one metal foil and earth, and also between the two metal foils.

3) Patient leakage current from the patient connection to earth

Perform a leakage current test according to Fig. 15 of IEC 60601-1: Ed.3 by using the measurement power supply circuit shown in Fig. F.1 of IEC 60601-1: Ed.3.

When using multiple probes at the same time, put the probe on selection into a salt solution and measure a leakage current between the ground and the salt solution.

Do not immerse the probes past the “maximum immersion point” indicated in the instruction manual for each probe.

Short all three of the ECG lead jacks, and measure the leakage current between the shorted part and ground.

4) Patient leakage current via the patient connection(s) of an F-type applied part to earth caused by an external voltage on patient connection(s)

Perform a leakage current test according to Fig. 16 of IEC 60601-1: Ed.3 by using the measurement power supply circuit shown in Fig. F.1 of IEC 60601-1: Ed.3.

When using multiple probes at the same time, put the probe on selection into a salt solution and measure a leakage current between the outside voltage and the salt solution.

Do not immerse the probes past the “maximum immersion point” indicated in the instruction manual for each probe.

Short all three of the ECG lead jacks, and measure the leakage current between the shorted part and ground.

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When using an ECG lead cable or multiple probes, measure total leakage current. As a result of the above measurements, the patient contact for measurement is a combination of three electronic probes with high measurement values, a Doppler probe (if available), and an ECG cable.

5) Impedance for protective contact to earth

Measure the impedance between the protective earth contact and accessible metal part which is protectively earthed of the instrument according to clause 8.6.4 a) of IEC 60601-1: Ed.3.

When the specification of arbitrary metal part is difficult, GND side of unconnected connector is recommended.

NOTE: When measuring the impedance for, do not bring the probe of the tester into contact with the signal line pins of the connector. This is because the measuring current may cause damage to the signal line circuit.

6) In addition to measurings

When conducting an IEC 60601-1 Ed.3 test, as indicated in Figure 17, "Measurement of patient leakage current due to external voltage on the signal input/output part, causing patient to ground out," contact one of our offices listed on back cover.

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DIAGNOSTIC ULTRASOUND SYSTEM Safety Inspection Data Sheet

Diagnostic ultrasound system	Model:		S/N:			
Probe	Model:		S/N:			
Other peripheral Instruments	Model:		S/N:			
Inspected date		Position and name of inspector				
Earth leakage current	All possible combinations of positions of switches		S5: normal/reverse S12: close/open			
	Normal condition Allowable: 0.5 mA	S1 CLOSE				
	Single fault condition Allowable: 10 mA	S1 OPEN				
Touch current	All possible combinations of positions of switches		S5: normal/reverse S12: close/open			
	Measuring points		Between enclosure and earth		Between two points of enclosure	
	Normal condition Allowable: 0.1 mA	S1 CLOSE S7 CLOSE				
	Single fault condition Allowable: 0.5 mA	S1 OPEN S7 CLOSE				
		S1 CLOSE S7 OPEN				
Patient leakage current from the patient connection to earth	All possible combinations of positions of switches		S5: normal/reverse S13: close/open			
	Measuring points		Probe	ECG lead cord		Total patient leakage current
	DC: Normal condition Allowable value: 0.01 mA max Total leakage current: 0.05 mA	S1 CLOSE S7 CLOSE				
	DC: Single fault condition Allowable value: 0.05 mA Total patient leakage current : 0.1 mA	S1 OPEN S7 CLOSE				
		S1 CLOSE S7 OPEN				
	AC: Normal condition Allowable value: 0.1 mA Total patient leakage current : 0.5 mA	S1 CLOSE S7 CLOSE				
	AC: Single fault condition Allowable value: 0.5 mA Total patient leakage current : 1.0 mA	S1 OPEN S7 CLOSE				
		S1 CLOSE S7 OPEN				

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Diagnostic ultrasound system	Model:		S/N:			
Probe	Model:		S/N:			
Other peripheral Instruments	Model:		S/N:			
Inspected date		Position and name of inspector				
Patient leakage current via the patient connection(s) of an F-type applied part to earth caused by an external voltage on the patient connection(s)	All possible combinations of positions of switches		S5: normal/reverse S9: normal/reverse S13: close/open			
	Measuring points		Probe	ECG lead cord		Total patient leakage current
	Single fault condition Allowable value: 0.5 mA Total patient leakage current : 5.0 mA	S1 CLOSE				
Impedance for protective contact to earth	Allowable value: 0.1 Ω					
the patient leakage current from patient connection(s) to earth caused by an external voltage on a signal input/output part	All possible combinations of positions of switches		S5: normal/reverse S9: normal/reverse S13: close/open			
	Measuring points		Probe	ECG lead cord		Total patient leakage current
	DC: Normal condition Allowable value: 0.01 mA max Total leakage current: 0.05 mA	S1 CLOSE S7 CLOSE				
	DC: Single fault condition Allowable value: 0.05 mA Total patient leakage current : 0.1 mA	S1 OPEN S7 CLOSE				
		S1 CLOSE S7 OPEN				
	AC: Normal condition Allowable value: 0.1 mA Total patient leakage current : 0.5 mA	S1 CLOSE S7 CLOSE				
	AC: Single fault condition Allowable value: 0.5 mA Total patient leakage current : 1.0 mA	S1 OPEN S7 CLOSE				
		S1 CLOSE S7 OPEN				

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6 Accessories and Options

6-1 Instrument and Accessories

Parts name	Parts No.	value
Main Unit	USI-162B	1
Power Code	100V to 120V: CP-121	1
	200V to 240V: CP-117	
Viewing monitor	IPF-1707	1
Printer		
Power Cable (B/W printer)	L-CABLE-405-12	1
Power Cable (Color printer)	L-CABLE-807-10C0	1
USB Cable (B/W printer and Color printer)	L-CABLE-889-10C0	2
Overlay sheet	MP-SH-F37-1	1
Instruction Manual (with CD-ROM)	MN-CD-F37-E	1

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6-2 Options

⚠ CAUTION
• DO NOT assemble the instrument or its options without our authorization. Electric shocks and unexpected accidents could result. A person recognized by our company assemble the instrument and option when it is delivered to the user's premises.
• Connect only options specified by this instruction manual to this equipment. Failure to observe the following precautions could result in injuries or burns to the patient or the examiner, or electric shocks and other accidents could result.

6-2-1 Viewing monitor and Recording Devices

Model Name		Code Number	Remarks
Viewing monitor			
	Viewing monitor	IPF-1507 *1	
DVD Recorder			
	DVD Recorder	DVO-1000MD	
	DVO-1000MD connection kit	PM-F37-H005	
	Mounting rack of DVO-1000MD	MP-FX-F37-5	
Printer			
	Digital Graphic Printer	UP-D897	
	Mounting rack of B/W printer	MP-FX-F37-1	
	Hybrid Graphic Printer	UP-X898MD	
	Mounting rack of B/W printer	MP-FX-F37-1B	
	Digital B/W printer	P95DW	
	Digital Color printer	UP-D25MD	
	Mounting rack of Color printer	MP-FX-F37-2	for UP-D25MD
	Digital Color printer	CP30DW	*2
	Mounting rack of Color printer	MP-FX-F37-3	for CP30DW
Color printer, DVD recorder simultaneous connection rack			
	(Standard type)	MP-FX-F37-6	for UP-D25MD
	(Wide type)	MP-FX-F37-7	for CP30DW

*1. Depending on the date of manufacture, the model name could be proceeded by a letter of the alphabet.

*2. It can be connected to a supply mains having voltage 120V. Or it can be connected to a supply mains having voltage between 220V and 240V.

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6-2-2 Functional Expansion Units

Model Name	Code Number	Remarks
Independent Probe connection unit	EU-9145	Includes an adapter for probe holder
Function Addition unit	EU-9151B	
Physiological signal display unit	PEU-F37	

6-2-3 Other Accessories

Model Name	Code Number	Remarks
1-point foot switch	MP-2345 *1	
3-point foot switch	MP-2614*1	
Endo-Cavity Probe Holder	MP-PH8	Necessary for installation metal fittings
Instruction Manuals	MN-P-F37-E	Bound volumes
Overlay sheet	MP-SH-F37-1	

*1. Depending on the date of manufacture, the model name could be proceeded by a letter of the alphabet.

For probe holder, please consult one of our offices listed on back cover.

6-2-4 Softwares

Model Name	Code Number	Remarks
Extend Field of View software	SOP-F37-1	
Real Time Dop Auto Trace software	SOP-F37-3	
Real Time 3D software	SOP-F37-4	EU-9151B is necessary.
Free Angular M Mode software	SOP-F37-5	
Flow Profile Measurement software	SOP-F37-7	
DICOM Network Communication software	SOP-F37-10	
3D Volume Measurement software	SOP-F37-20	EU-9151B and SOP-F37-4 are necessary.
DICOM Structure Report software	SOP-F37-21	SOP-F37-10 is necessary.
Spatial Compound Imaging software	SOP-F37-22	
AIP software	SOP-F37-24	
Flow 3D software	SOP-F37-35	EU-9151B and SOP-F37-4 are necessary.
Freehand 3D software	SOP-F37-37	
Auto IMT Measurement software	SOP-F37-38	
Auto NT Measurement software	SOP-F37-42	
McAfee Embedded Control2 software	SOP-F37-69	McAfee For install this software, please contact one of our offices listed on back cover.
4Dshading software	SOP-F37-51	

Reference:

Probe specifications → p.7-5

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7 Probes

7-1 Caution in the Handling of Probes

The handling of probes differs by the type of probe. For details, refer to the instruction manual for the probe. The following are common cautions for probes.

7-1-1 Caution about Handling of Probes

These probes are precision instruments. Handle them carefully not to damage probes.

- Caution in handling
  - Store the probe in the probe holder when not in use.
  - Hold the probe tightly so that it doesn't slip especially when using ultrasound gel or other lubricants.
  - Avoid stretching or bending the cable.

    Avoid getting the cable pinched under the casters.
  - Connect the probe in accordance with this manual and the instruction manual for the probe.
- In order to prevent burns or injury
  - Hold the probe tightly so that it doesn't slip especially when using ultrasound gel or other lubricants.
  - Before using, coat probe adequately with ultrasound gel.
  - Do not use unreasonable force while inserting a probe into a body cavity.
  - As standard practice, freeze the image when the probe is not in use, even during an examination.

  For ultrasound gel, please contact one of our offices listed on the back cover.
- In order to prevent infection
  - Keep the probes clean and dry.

    Do not allow ultrasound gel, water or any other foreign matter to dry on the probes.
  - Clean, disinfect and sterilize the probe after using.
  - Probes used on patients with Creutzfeld-Jacob disease must be destroyed in order to prevent inadvertent transmission of this disease.

    At present, there are no known methods available to properly clean and sterilize probes exposed to Creutzfeld-jacob disease.

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References:
Connecting/Removing a Probe → p.3-4

Cautions in Performing a Puncture Operation

By installing a puncture adapter, you can carry out a puncture operation. For details, refer to the instruction manuals for the probe and the puncture adapter.

- External inspection
  - Ensure that the probe are sterilized.
  - Ensure that the needle is not bent.
  - Be sure to check the needle echo using a water tank.
- Caution when installing the puncture adapter
  - Be sure that the puncture adapter and the needle have been sterilized before using them.
  - Installing the puncture adapter to the probe in accordance with the instruction manuals for the probe and the puncture adapter.
- Precautions for performing a puncture operation
  - A puncture operation must only be performed by a skilled physician.
  - While performing a puncture operation, ensure that it is functioning normally, and that the patient is not abnormally affected.
  - If anything unusual occurs when a puncture operation is performed, take the probe away from the patient immediately, and stop using the instrument.

    If the patient's condition is abnormal, provide appropriate medical treatment.
- To avoid puncturing an area that is not intended to be punctured
  - The puncture guideline indicates the direction of puncture needle insertion.
  - Use the puncture guideline displayed on screen only as a guide for puncture needle insertions.

    When a puncture adapter has puncture angles, be sure to check a puncture angle on the screen that is corresponded with current puncture angle.
  - Be sure to check the needle echo before using the probe.

    If sound velocity of the tissue is not 1,530 m/s, displayed puncture guideline could be shifted from needle echo.
  - Be sure to check the part of the puncture path that is not visible on the screen, and ensure that it is safe to proceed.

    There may be a blood vessel or other organ in the puncture path that is not visible on the screen.
  - Verify the bending and direction of the puncture needle with the puncture needle echo that is displayed on the monitor.

Caution about handling the Transesophageal Echo cardiogram probes

The transesophageal echocardiogram probe is used for observing the cardiac ultrasonic wave by touching the tip of the probe to the esophagus paries, after inserting the probe through the esophagus by a doctor or other qualified personnel.

- Connect the probe in accordance with this manual and the instruction manual for the probe.
- Use, clean, disinfect or store in accordance with the instruction manual for the probe.

7-1-2 Cautions about Cleaning and Storage

The safety inspection, cleaning, disinfection and sterilization for each probe differs depending upon the type of probe. The following are the basic outline of them. For details, refer to the instruction manual for the probe.

Cleaning, Disinfection and Sterilization

NOTE: DO NOT immerse the probes past the maximum immersion point. For details, refer to the instruction manual for the probe.

● Clean the probe

a Turn off the power to the instrument.

b Wipe off any ultrasound gel or cream on the probe.

c Clean the probe's surface in accordance with the instruction manual for the probe.

● Disinfect and sterilize the probe

Method of disinfection and sterilization

They differ depending upon the type of probe. For details, refer to the instruction manual for the probe.

Probe cover

Refer to the Transducer User's Manual for sterilization information and the fitting of disposable sterile probe covers.

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Safety Inspection

After using the probe, inspect the outside of it. If any abnormalities are noted on the probe, immediately stop using it and contact one of our offices listed on back cover.

- There must be no scratches, holes, cracks or dents on the ultrasonic radiation surface.
- There must be no scratches, holes, cracks or dents on the top of the probe.
- There must be no scratches, cracks or dents on the probe cables.
- There connector must be free of holes, dents, cracks and deformation.

Storage

Store the probe under the following storage environment.

- Ambient temperature: -10 ℃ to 50 ℃ (if 3D scanners, 0 ℃ to 50 ℃)
  Condensation may occur when storing the instrument in a place, such as a warehouse, where the temperature and/or humidity varies markedly. Avoid using where condensation occurs.
- Relative humidity: 10% to 90%
- Atmospheric pressure: 700 hPa to 1060hPa

7-2 Probe specifications

⚠ CAUTION

Use probes only for their intended purpose.

Failure to observe the precautions could result in injuries or burns to the patient or the examiner. Do not use them incorrectly.

In the probe of intraoperative applications, there is one that can be used for neurosurgery. For details, refer to the instruction manual for the probe.

Connect probes to this instrument which are specified in this section.

There is a possibility that you are emitting an acoustic beam of an output that is incorrect for the particular application, or electric shocks and other accidents could result. Do not connect an unspecified probe.

Only place probe UST-2265-2 on the probe holder attached the adapter (MP-PH-ADAPTER-5).

When the probe except UST-2265-2 is not attached on the probe holder for UST-2265-2, the probe could be damaged. On the probe holder for UST-2265-2, only install the probe UST-2265-2.

Table 7-1: Probe List (Applied to areas outside EU.)

Convex Sector Probes		Linear Probes		Phased Array Sector Probes
UST-676P	UST-984-5	UST-536	UST-568	UST-5293-5
UST-987-7.5	UST-995-7.5	UST-579T-7.5	UST-5045P-3.5	UST-5298
UST-9102U-3.5	UST-9115-5	UST-5413	UST-5417	UST-5299
UST-9118	UST-9123	UST-5550	UST-5712	
UST-9124	UST-9130			
UST-9133	UST-9135P			
UST-9136U	UST-MC11-8731			

Biplane Probe	3DScanners	Independent Probe
UST-672-5/7.5	ASU-1010	UST-2265-2
	ASU-1012	
	ASU-1014	

NOTE: Please refer to the document supplied with the probe for information on the probe's standard configuration and options.

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Table 7-2: Probe List (Applied to areas inside EU only.)

Convex Sector Probes		Linear Probes		Phased Array Sector Probes
UST-676P	UST-984-5	UST-536	UST-568	UST-5298
UST-987-7.5	UST-995-7.5	UST-579T-7.5	UST-5045P-3.5	UST-5299
UST-9102U-3.5	UST-9115-5	UST-5413	UST-5417	
UST-9118	UST-9123	UST-5550	UST-5712	
UST-9124	UST-9130			
UST-9133	UST-9135P			
UST-9136U	UST-MC11-8731			

Biplane Probe	3DScanners	Independent Probe
UST-672-5/7.5	ASU-1010	UST-2265-2
	ASU-1012	
	ASU-1014	

NOTE: Please refer to the document supplied with the probe for information on the probe's standard configuration and options.

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7-2-1 Convex Sector Probes

Model	UST-676P	UST-984-5	UST-987-7.5	UST-995-7.5
Intended Uses	Transrectal	Transvaginal Gynecological	Intraoperative	Intraoperative
	Transvaginal	Fetal	Neonatal Cephalic	Small Parts, Peripheral Vascular
Applicable part of body	Endocavity	Endocavity	Intraoperative	Intraoperative
Surface max. temp.	< 43 ℃	< 43 ℃	< 43 ℃	< 43 ℃
Scan Angle or Width	178°	118°	65°	65°
Curvature Radius	9 mm	14 mm	20 mm	20 mm
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD
Image Frequency	6.1 MHz	4.8 MHz	7.5 MHz	7.5 MHz
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃
Remarks				
T.H.E	Yes	–	–	–
BbH	Yes	–	–	–
eFlow	Yes	–	Yes	Yes
CW doppler	–	–	–	–
Trapezoid	–	–	–	–
Spatial Compound	–	–	–	–
TDI	–	–	–	–
EFV	–	–	–	–
Freehand 3D	–	–	–	–
4Dshading	–	–	–	–
Needle Emphasis	–	–	–	–

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Model	UST-9102U-3.5	UST-9115-5	UST-9118	UST-9123
Intended Uses	Abdominal	Abdominal	Transvaginal	Abdominal
	Pediatric	Gynecological, Fetal	Fetal	Gynecological, Fetal
Applicable part of body	Surface of Body	Surface of Body	Endocavity	Surface of body
Surface max. temp.	< 43 ℃	< 43 ℃	< 43 ℃	< 43 ℃
Scan Angle or Width	90°	60°	178°	59°
Curvature Radius	20 mm	60 mm	9 mm	60 mm
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD
Image Frequency	3.4 MHz	5.2 MHz	6.1 MHz	3.5 MHz
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃
Remarks				
T.H.E	–	–	–	–
BbH	–	Yes	Yes	Yes
eFlow	–	Yes	Yes	Yes
CW doppler	–	–	–	–
Trapezoid	–	–	–	–
Spatial Compound	–	Yes	–	Yes
TDI	–	–	–	–
EFV	–	Yes	–	Yes
Freehand 3D	–	Yes	–	Yes
4Dshading	–	–	–	–
Needle Emphasis	–	–	–	–

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Model	UST-9124	UST-9130	UST-9133	UST-9135P
Intended Uses	Transvaginal Gynecological	Abdominal	Intraoperative	Abdominal
	Fetal	Gynecological, Fetal	Neonatal Cephalic	Gynecological, Fetal
Applicable part of body	Endocavity	Surface of Body	Intraoperative	Surface of Body
Surface max. temp.	< 43 ℃	< 43 ℃	< 43 ℃	< 43 ℃
Scan Angle or Width	178°	60°	82°	60°
Curvature Radius	9 mm	60 mm	20 mm	60 mm
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD
Image Frequency	6.1 MHz	3.5 MHz	3.4 MHz	3.5 MHz
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃
Remarks				
T.H.E	Yes	–	–	–
BbH	Yes	Yes	Yes	Yes
eFlow	Yes	Yes	Yes	Yes
CW doppler	–	–	–	–
Trapezoid	–	–	–	–
Spatial Compound	–	Yes	–	Yes
TDI	–	–	–	–
EFV	–	Yes	–	Yes
Freehand 3D	–	Yes	–	–
4Dshading	–	–	–	–
Needle Emphasis	–	–	–	–

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Model	UST-9136U	UST-MC11-8731		
Intended Uses	Abdominal	Intraoperative		
	Cardicac	Small Parts, Peripheral Vascular		
Applicable part of body	Surface of Body	Intraoperative		
Surface max. temp.	< 43 ℃	< 43 ℃		
Scan Angle or Width	100°	65°		
Curvature Radius	11 mm	20 mm		
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD		
Image Frequency	6.1 MHz	7.2 MHz		
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃		
Remarks				
T.H.E	Yes	–		
BbH	Yes	–		
eFlow	Yes	Yes		
CW doppler	–	–		
Trapezoid	–	–		
Spatial Compound	–	–		
TDI	–	–		
EFV	–	–		
Freehand 3D	–	–		
4Dshading	–	–		
Needle Emphasis	–	–		

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7-2-2 Linear Probes

Model	UST-536	UST-568	UST-579T-7.5	UST-5045P-3.5
Intended Uses	Intraoperative	Peripheral Vascular	Intraoperative	Abdominal
	Vascular, Small Parts, Breast & Pediatrics	Small Parts, Muscle-skeletal	Small Parts, Peripheral Vascular	Gynecological
Applicable part of body	Intraoperative	Surface of Body	Intraoperative	Surface of Body
Surface max. temp.	< 43 ℃	< 43 ℃	< 43 ℃	< 43 ℃
Scan Angle or Width	19.2 mm	50 mm	60 mm	80 mm
Curvature Radius	N/A	N/A	N/A	N/A
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD
Image Frequency	8.2 MHz	6.9 MHz	6.9 MHz	4.0 MHz
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃
Remarks				
T.H.E	–	–	–	–
BbH	–	Yes	–	–
eFlow	Yes	Yes	–	–
CW doppler	–	–	–	–
Trapezoid	–	Yes	–	–
Spatial Compound	–	Yes	–	–
TDI	–	–	–	–
EFV	–	Yes	–	–
Freehand 3D	–	Yes	–	–
4Dshading	–	–	–	–
Needle Emphasis	–	–	–	–

Model	UST-5413	UST-5417	UST-5550	UST-5712
Intended Uses	Peripheral Vascular	Peripheral Vascular	Laparoscopic Intraoperative	Peripheral Vascular
	Small Parts	Small parts, Muscle-skeletal		Small parts, Muscle-skeletal
Applicable part of body	Surface of Body	Surface of Body	Intraoperative	Surface of Body
Surface max. temp.	< 43 ℃	< 43 ℃	< 43 ℃	< 43 ℃
Scan Angle or Width	38 mm	38 mm	33 mm	60 mm
Curvature Radius	N/A	N/A	N/A	N/A
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD
Image Frequency	7.2 MHz	9.2 MHz	7.5 MHz	7.2 MHz
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃
Remarks				
T.H.E	–	–	–	–
BbH	Yes	Yes	–	Yes
eFlow	Yes	Yes	Yes	Yes
CW doppler	–	–	–	–
Trapezoid	Yes	Yes	Yes	Yes
Spatial Compound	Yes	Yes	–	Yes
TDI	–	–	–	–
EFV	Yes	Yes	–	Yes
Freehand 3D	Yes	Yes	–	–
4Dshading	–	–	–	–
Needle Emphasis	Yes	Yes	–	–

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7-2-3 Phased Array Sector Probes

Model	UST-5293-5	UST-5298	UST-5299	
Intended Uses	Cardiac, TEE	Cardiac, Pediatric	Cardiac	
Applicable part of body	Endocavity	Surface of Body	Surface of body	
Surface max. temp.	< 41 ℃	< 43 ℃	< 43 ℃	
Scan Angle or Width	90°	90°	90°	
Curvature Radius	N/A	N/A	N/A	
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD, CWD, B/CWD, B/CD/CWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD, CWD, B/CWD, B/CD/CWD	B, M, B/M, B/PWD, PWD, M/CD, B/CD/PWD, CWD, B/CWD, B/CD/CWD	
Image Frequency	5.2 MHz	4.1 MHz	2.9 MHz	
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃	
Remarks	*1			
T.H.E	–	Yes	Yes	
BbH	–	–	Yes	
eFlow	–	Yes	Yes	
CW doppler	Yes	Yes	Yes	
Trapezoid	–	–	–	
Spatial Compound	–	–	–	
TDI	Yes	Yes	Yes	
EFV	–	–	–	
Freehand 3D	–	–	–	
4Dshading	–	–	–	
Needle Emphasis	–	–	–	

*1. Optional function addition unit (EU-9151B) is necessary.

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7-2-4 Biplane Probes

Model	UST-672-5/7.5			
	(Convex)	(Linear)		
Intended Uses	Transrectal	Transrectal		
	Intraoperative	Intraoperative		
Applicable part of body	Endocavity	Endocavity		
Surface max. temp.	< 43 ℃	< 43 ℃		
Scan Angle or Width	120°	60mm		
Curvature Radius	9 mm	N/A		
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, B/CD/PWD		
Image Frequency	4.8 MHz	7.6 MHz		
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃		
Remarks				
T.H.E	–	–		
BbH	–	–		
eFlow	–	–		
CW doppler	–	–		
Trapezoid	–	–		
Spatial Compound	–	–		
TDI	–	–		
EFV	–	–		
Freehand 3D	–	–		
4Dshading	–	–		
Needle Emphasis	–	–		

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7-2-5 3D Scanners

Model	ASU-1010	ASU-1012	ASU-1014	
Intended Uses	Gynecological, Fetal	Transvaginal Gynecological	Fetal	
	Abdominal	Fetal	Abdominal	
Applicable part of body	Surface of Body	Endocavity	Surface of Body	
Surface max. temp.	< 43 ℃	< 43 ℃	< 43 ℃	
Scan Angle or Width	60°	140°	67°	
Curvature Radius	40 mm	10 mm	40 mm	
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	B, M, B/M, B/PWD, PWD, M/CD, CD, B/CD/PWD	
Image Frequency	3.5 MHz	5.6 MHz	5 MHz	
Operating Temp.	10 ℃ to 40 ℃	10 ℃ to 40 ℃	10 ℃ to 40 ℃	
Remarks	*1	*1	*1	
T.H.E	Yes	Yes	Yes	
BbH	–	–	Yes	
eFlow	Yes	Yes	Yes	
CW doppler	–	–	–	
Trapezoid	–	–	–	
Spatial Compound	Yes	–	–	
TDI	–	–	–	
EFV	–	–	–	
Freehand 3D	–	–	–	
4Dshading	Yes	Yes	Yes	
Needle Emphasis	–	–	–	

*1. Optional Function Addition unit (EU-9151B) is necessary.

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7-2-6 Independent Probe

Model	UST-2265-2			
Intended Uses	Cardiac			
Applicable part of body	Surface of body			
Surface max. temp.	< 43 ℃			
Scan Angle or Width	N/A			
Curvature Radius	N/A			
Operating Mode (PWD: PW Doppler CWD: CW Doppler CD: Flow Mode)	CWD			
Image Frequency	2.0 MHz			
Operating Temp.	10 ℃ to 40 ℃			
Remarks	*1 , *2			
T.H.E	–			
BbH	–			
eFlow	–			
CW doppler	Yes			
Trapezoid	–			
Spatial Compound	–			
TDI	–			
EFV	–			
Freehand 3D	–			
4Dshading	–			
Needle Emphasis	–			

*1. Optional Adapter MP-PH-ADAPTER-5 is necessary for probe holder.
*2. Optional Independent Probe connection unit (EU-9145) is necessary.

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7-3 Clinical Measurement Range

The following is the maximum measurement range per each measurement feature which can be expected with the this equipment.

PROBE	Distance (max, cm)	Area (Trace, cm^2)	Area (Ellipse, cm^2)	Circumference (Trace, cm)	Volume (cm^3)	Excursion (cm)	Velocity Doppler (cm/s)	Time Interval (s)	Heart Rate (BPM)
ASU-1010	57.3	999.9	999.9	99.9	999.9	29.9	99.5	9.73	12 - 998
ASU-1012	32.5	469.9	999.9	89.3	999.9	17.0	99.5	9.73	12 - 998
ASU-1014	57.3	999.9	999.9	99.9	999.9	29.9	99.5	9.73	12 - 998
UST-536	9.6	40.7	999.9	26.3	999.9	5.0	99.5	9.73	12 - 998
UST-568	22.9	234.1	999.9	63.1	999.9	12.0	99.5	9.73	12 - 998
UST-579T-7.5	22.9	234.1	999.9	63.1	999.9	12.0	99.5	9.73	12 - 998
UST-672-5/7.5 (Convex)	28.7	365.8	999.9	78.8	999.9	15.0	455.4	9.73	12 - 998
UST-672-5/7.5 (Linear)	28.7	365.8	999.9	78.8	999.9	15.0	318.8	9.73	12 - 998
UST-676P	32.5	469.9	999.9	89.3	999.9	17.0	398.4	9.73	12 - 998
UST-984-5	32.5	469.9	999.9	89.3	999.9	17.0	99.5	9.73	12 - 998
UST-987-7.5	22.9	234.1	999.9	63.1	999.9	12.0	289.9	9.73	12 - 998
UST-995-7.5	22.9	234.1	999.9	63.1	999.9	12.0	289.9	9.73	12 - 998
UST-2265-2	-	-	-	-	-	-	1593.8	9.73	12 - 998
UST-5045P-3.5	36.3	587.0	999.9	99.9	999.9	19.0	455.4	9.73	12 - 998
UST-5293-5	45.9	936.5	999.9	99.0	999.9	23.9	796.8	9.73	12 - 998
UST-5298	45.9	936.5	999.9	99.9	999.9	23.9	99.5	9.73	12 - 998
UST-5299	57.3	999.9	999.9	99.9	999.9	29.9	637.6	9.73	12 - 998
UST-5413	22.9	234.1	999.9	63.1	999.9	12.0	318.8	9.73	12 - 998
UST-5417	22.9	234.1	999.9	63.1	999.9	12.0	99.5	9.73	12 - 998
UST-5550	22.9	234.1	999.9	63.1	999.9	12.0	99.5	9.73	12 - 998
UST-5712	22.9	234.1	999.9	63.1	999.9	12.0	99.5	9.73	12 - 998
UST-9102U-3.5	36.39	587.0	999.9	99.9	999.9	19.0	99.5	9.73	12 - 998
UST-9115-5	45.9	936.5	999.9	99.9	999.9	23.9	99.5	9.73	12 - 998
UST-9118	32.5	469.9	999.9	89.6	999.9	17.0	398.4	9.73	12 - 998
UST-9123	57.3	999.9	999.9	99.9	999.9	29.9	637.6	9.73	12 - 998
UST-9124	32.5	469.9	999.9	89.3	999.9	17.0	398.4	9.73	12 - 998
UST-9130	76.4	999.9	999.9	99.9	999.9	39.9	99.5	9.73	12 - 998

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PROBE	Distance (max, cm)	Area (Trace, cm^2)	Area (Ellipse, cm^2)	Circumference (Trace, cm)	Volume (cm^3)	Excursion (cm)	Velocity Doppler (cm/s)	Time Interval (s)	Heart Rate (BPM)
UST-9133	57.3	999.9	999.9	99.9	999.9	29.9	99.5	9.73	12 - 998
UST-9135P	57.3	999.9	999.9	99.9	999.9	29.9	99.5	9.73	12 - 998
UST-9136U	22.9	234.1	999.9	63.1	999.9	12.0	99.5	9.73	12 - 998
UST-MC11-8731	22.9	234.1	999.9	63.1	999.9	12.0	289.9	9.73	12 - 998

8 Acoustic Output Safety Information

8-1 Acoustic output index

With this device, output indices about the potential for ultrasound induced biological effect to the tissue are displayed. The displayed indices are the four forms. Of these, mechanical index, MI shows the mechanical bioeffect in tissue, and thermal indices, TIs show the thermal bioeffect in tissue provided three forms according to tissue models.

- Mechanical index: MI

  Mechanical index (MI) provides an on-screen indication of the relative potential for ultrasound to induce an adverse bioeffect by a non-thermal mechanism such as cavitation.

  The mechanical bioeffect is caused by the motion of tissue induced when ultrasound pressure waves pass through or near a gaseous body. The majority of the mechanical interactions relate to the generation, growth, vibration and possible collapse of microbubbles within the tissue. This behavior is referred to as cavitation.

  Because the thermal bioeffect is not so significant in the mode of B, B/M, and M respectively, the mechanical index becomes important.

  The mechanical index is displayed on all modes.

  In other imaging modes, the thermal bioeffect is also important.

- Thermal index: TI

  – Soft tissue Thermal Index : TIS

    The soft tissue thermal index provides information on temperature increase within soft homogeneous tissue (heart, first trimester fetal and abdominal scans). TIS can be displayed on all modes.

  – Bone Thermal index: TIB

    The bone thermal index (TIB) provides information on temperature increase of bone at or near the focus when the beam passes through soft tissue (second and third trimester fetal and neonatal cephalic through the fontanels scans).

    TIB can be displayed on all modes and at the time of transducer use. In addition, with scan modes including B mode imaging, the value of TIB becomes equal to the value of TIS.

  – Cranial Bone Thermal index : TIC

    The cranial bone thermal index (TIC) provides information on temperature increase of bone at or near the surface, such as may occur during pediatric and adult cranial scan, in which the ultrasound beam passes through bone near the beam entrance into the body.

    TIC can be displayed on all modes.

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The demarcation between safe levels and levels that the potential for biological effects exist is important for the operators. The WFUMB (World Federation for Ultrasound in Medicine and Biology) gives some guidelines.

For example, "Embryonic and fetal in situ temperature above 41 ℃ (4 ℃ above normal temperature) for 5 min or more should be considered potentially hazardous.", etc.

On the other hand, the indices provide us an indication of the conditions which are more likely than others to produce thermal and/or mechanical bioeffect in comparison with other physical quantities such as the peak rarefactional acoustic pressure or its intensity.

For example, TI values above a certain upper level of the range (more than 1.0) might be better to avoid in obstetric applications. Such a restriction allows a reasonable safety margin considering the WFUMB recommendation that a temperature increase of 4 ℃ for 5 min or more should be considered as potentially hazardous to embryonic and fetal tissue.

However if particular clinical results cannot be obtained with lower values, increased output may be warranted, but particular attention to limit the exposure time should be made. Any extra thermal load to the fetus when the mother has a fever is also unwise, and again note should be made to avoid high TI values.

The following list shows an indication of importance of maintaining low values of MI/TI in clinical use by IEC 60601-2-37.

Table 8-1: Relative importance of maintaining low exposure indices in various scanning situations

	Of greater importance	Of less importance
MI	• With contrast agents • Cardiac scanning (lung exposure) • Abdominal scanning (bowel gas)	• In the absence of gas bodies: i.e. in most tissue imaging
TI	• First trimester scanning • Fetal skull and spine • Patient with fever • In any poorly perfused tissue • If ribs or bones are exposed: TIB	• In well-perfused tissue: For example, Liver and spleen • In Cardiac scanning • In vascular scanning

CAUTION: It has been thought that cavitation is hard to occur with the diagnostic ultrasound because it contains as high as several MHz to several dozen MHz frequencies.

However, according to the animal experiments, it is reported that the tissues where originally air bubbles exist such as lung and bowel are easy to receive the damage of petechia in low acoustic pressure.

Also according to the animal experiments, ultrasonically induced lung damage in the fluid-filled lungs of fetuses is not to be expected.

From these facts, it is requested to be careful for using contrast agent to inject air bubbles intentionally.

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8-2 Interaction between ultrasound and tissue

When ultrasound propagates through human tissue, there is a potential for tissue damage. During an exam, though ultrasound images are produced with "receiving" a part of the energy of the transmitted ultrasound wave by the transducer, which energy is reflected from the irradiated tissue, much of the ultrasound energy is absorbed by body tissue. Ultrasound generated by the transducer is a physical pressure wave with typical frequencies range from 2 MHz (megahertz, or millions of cycles per second) to 10 MHz. In ultrasound irradiation, the energy absorbed in the tissue may cause some biological effects.

These mechanisms are classified as mechanical action and thermal action, respectively.

Mechanical bioeffects are due to the pressure waves causing mechanical or physical movement of the tissues and tissue components. These components such as cells, fluids, etc., oscillate. If conditions are met, it is possible that these oscillations may affect the structure or function of living tissues. At present, mechanical effects are thought to be instantaneous in nature, and closely relate to the peak-rarefactional (peak-negative) acoustic pressure of the ultrasound pulse.

An extreme example of the mechanical effects of ultrasound is shock - wave lithotripsy, where focused ultrasound waves are used to break apart kidney stones.

The second type of bioeffect, the thermal bioeffect, is due to the tissues absorbing the energy of the ultrasound beam. When an acoustic wave transmits through the body tissue, the energy of a sound wave is attenuated. There are two main causes for attenuation: Absorption and scattering. Absorption is the conversion of ultrasonic energy into heat; whereas, scattering is the redirection of the ultrasound away from the direction it was originally traveling. Absorption of acoustic energy by tissue results in the generation of heat in the tissue. This is what is referred to as the thermal mechanism. Unlike mechanical bioeffect, thermal bioeffect is thought to be temporal in nature, and relate to a tissue volume, perfusion rate, exposure time, and duty factor (ratio of the duration of transmitting pulse to the pulse repetition period).

Among the physiological effects known to occur due to tissue heating are abnormalities in cell physiology or the low rate of DNA synthesis and increased possibility for the retardation of growth of systems such as the heart, brain and skeleton of the fetus.

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8-2-1 Possible Biological Effects

Mechanical bioeffect

Mechanical bioeffect is occurred by the oscillation of a pressure wave when ultrasound wave is transmitted to the body system. This pressure wave acts on microscopic gas bubbles and other "nucleation sites" in tissue.

These nucleation sites, although presently poorly understood, are believed to serve as starting points for the development of gas bubbles. Because gas is much more compressible than fluid, the microscopic gas bubbles can expand and contract greatly in comparison to the immediately surrounding tissues and fluid. The large change in size may damage tissues.

Though mechanical bioeffect contain cavitation (ultrasonically activated behavior of micro bubbles and other "nucleation sites" in tissue), acoustic radiation force and microstreaming, etc, cavitation is thought to be most important.

There are two categories of cavitation: Non-inertial (once termed Steady-state) cavitation and Inertial (once termed Transient) cavitation.

Non-inertial cavitation arises from the repeated expansion and contraction of the micro bubbles in response to the varying pressures in ultrasound pulses. This oscillation can lead to a phenomenon known as "micro streaming", where the oscillation of gas bubbles in tissue leads to motion in the fluid around the gas bubbles. This phenomenon has shown that micro streaming has the possibility of causing disruption of cell membranes.

During inertial cavitation, pre-existing bubbles or cavitation nuclei expand from the pressure of the ultrasonic field and then collapse in a violent implosion. Although this phenomenon occurs on the microscopic level, it has been demonstrated to produce extremely high temperatures and pressures in the immediate vicinity, which can lead to cell death.

The potential for mechanical bioeffects is related to the peak negative (rarefactional) pressure of the ultrasound wave and its frequency. Higher values of negative pressure (if amplitude wave becomes large) increase the potential for mechanical bioeffect. Higher frequencies decrease the potential for mechanical bioeffect.

At this time, there is no solid evidence that cavitation occurs in human tissue with the output intensities available on current ultrasound diagnostic systems. However, mechanical effects are theoretically possible.

Thermal bioeffect

Thermal bioeffect occurs over longer periods of time, where absorption of the ultrasound energy results is heating of tissues. Excessive heating can lead to disruptions in cellular processes and structures, especially in developing fetal tissues. As stated above, the energy which is producing image by receiving reflected energy from the body's internal tissues by the transducer is very limited out of the total energy transmitted to the body system. The residual energy must be absorbed by the tissues. With this absorption, heat is developed mainly in two areas such as at the surface of the body where ultrasound beam enters and in the vicinity of the focus of the beam.

Because of difference in their physical properties, different tissues absorb ultrasound energy at different rates. Absorption coefficient is affected by the ultrasonic power (energy per unit of time), the volume of tissues involved and its perfusion rate, or the amount of blood flow through the target tissues. Bone tissue, with its higher density and lower perfusion rate than those of soft tissues, absorbs more ultrasound energy.

Bone tissue at the surface will absorb the largest portion, and has the highest susceptibility to heating from ultrasound exposure. Bone tissue not at the surface, but at the focus point of the beam, will also absorb a higher portion of energy. Soft tissues absorb the least. Because tissue absorbs ultrasound energy at different rates, a single model to describe all of the different properties of different tissues is not available. Currently, there are three different models to describe thermal bioeffects in tissue. The three models are

- Soft tissues
- Bone at focus and
- Bone at the surface

The type of ultrasound beam also influences the potential for thermal bioeffect. In non-scanning mode (example: D-mode), as the position and direction of an ultrasound beam converging energy are fixed, the ultrasound energy of high-density occurs for a comparatively small tissue volume. This tends to increase the thermal bioeffects in the tissue.

In addition, in B mode, as the position and direction of ultrasound beam are variable, the energy of ultrasound is scattered in a comparatively large volume of tissues so that the perfusion rate becomes high and the process of heat becomes not so significant.

At this time, there is no solid evidence that the temperature elevation with currently available ultrasound diagnostic systems is harmful to the human body.

8-3 Derivation and Meaning of MI/TI

In 1992, AIUM (The American Institute of Ultrasound in Medicine) and NEMA (National Electrical Manufacturers Association) published the voluntary standard "TI/MI output display standard" (AIUM/NEMA: Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment). This standard has established the method calculating and displaying indices relatively indicating the possibility of mechanical and thermal bioeffect. IEC 60601-2-37 "Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment" employs the same indices. Therefore the user can control the acoustic output while confirming the indices are real-time displayed on the majority of modern diagnostic ultrasound equipment.

These indices, the thermal index (TI) and the mechanical index (MI), provide unitless numbers giving information on the likelihood of an adverse biological effect resulting from the current ultrasound examination. The indices were designed so that if either index exceeded a predefined value, there was a potential for harm. When the value of index exceeds 1.0, the user should assess if the examination could be performed with a lower acoustic output, or consider mitigating factors in reevaluating the risk-benefit analysis. Mitigating factors include the absence of gas-containing structures, anatomical sites that would be particularly invulnerable to damage and the perfusion rate in the region being examined. Also, the duration of the examination should be kept to a minimum to avoid any unnecessary exposure. However there is another risk that must be considered: the risk of not doing the ultrasound exam and either not having the enough information necessary to diagnose. It is also important to recognize that the potential harm from misdiagnosis can have greater consequences than that of ultrasound-induced bioeffect.

8-3-1 Mechanical Index (MI)

Scientific evidence suggests that mechanical or nonthermal bioeffect, like cavitation, are a threshold phenomenon, occurring only when a certain level of output is exceeded. However the threshold level varies depending on the tissue. The potential for mechanical effects is thought to increase as peak-rarefactional acoustic pressure increases, but to decrease as the ultrasound frequency increases.

Therefore the mechanical index MI is defined as:

$$MI = \frac{p_{r,\alpha} f_{awf}^{-1/2}}{C_{MI}}$$

C_{MI} = 1 MPa $MHz^{-1/2}$

p_r : attenuated peak-rarefactional acoustic pressure (MPa)

f_{awf}: acoustic working frequency (MHz)

C_{MI} is a standardization coefficient, and it is 1 [MPa $MHz^{-1/2}$]. Therefore, MI is unitless.

The MI becomes important at a gas/soft tissue interface, for example in cardiac scanning where the lung surface may be exposed. Most critically, however, is with the use of contrast materials containing gas bubbles when most attention should be paid to limit MI.

As the ultrasound goes through the fluid such as amniotic fluid or bladder with very little decrease, the sound pressure received by the tissues might be high even if the value of MI is low.

8-3-2 Thermal Index (TI)

TI is defined that the ratio of attenuated acoustic power at a specified point, P_α [mW] to the attenuated acoustic power required to raise the temperature at that point in a specific tissue model by 1 ℃ , P_{deg} [mW].

$$TI = \frac{P_\alpha}{P_{deg}}$$

P_α : attenuated output power

TI is unitless as well as MI.

There are three thermal indices are used for different combinations of soft tissue and bone in the area to be examined, namely, TIS (soft tissue), TIB (bone) and TIC (cranial bone). The purpose of the thermal indices is to keep users aware of conditions that may lead to a temperature rise whether at the surface, within the tissues, or at the point where the ultrasound is focusing on bone. Each thermal index estimates temperature rise under certain assumptions.

- For scanning mode, the position of the maximum heating is assumed to be at the surface of the probe for all tissue models.
- For non-scanning mode, if bone is not present, the maximum heating is likely to occur between the surface of the probe and the focus of the ultrasonic beam.

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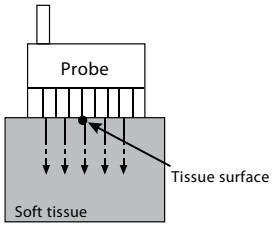
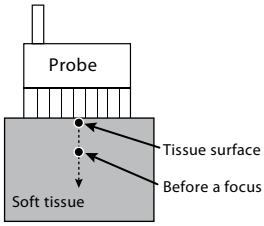
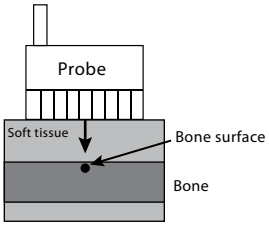
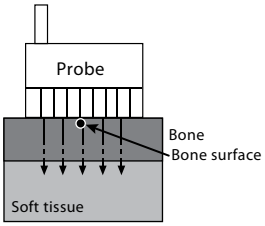
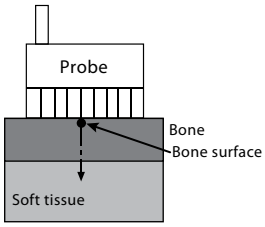
- For non-scanning mode, if bone is present and located near the focus of the ultrasonic beam, the maximum heating is likely to occur at the surface of the bone. When doing diagnoses of the fetus that are developing neural tissues, such as the brain and spinal cord, that may be in a region of heated bone, it is recommended to display TIB and pay attention to its value.

When you are undecided which TI should be displayed, it is preferable to refer the following chart to decide where the bones are located in the region at which is irradiated by ultrasound.

Table 8-2: Thermal Index categories and models

	Scanning mode	Non-scanning mode
TIS: Soft tissue thermal index		
TIB: Bone thermal index		
TIC: Cranial-bone thermal index		

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8-4 Setting condition influencing device output

It is necessary to understand the setting condition of the ultrasonic diagnostic equipment influencing MI/TI to use the indicated information of MI/TI more effectively. MI is calculated using the peak rarefactional (negative) acoustic pressure. TI is proportional to the time averaged value whereas MI is proportional to instantaneous value. The following table shows diagnosis device control settings to influence MI/TI.

Some parameters such as the pulse repetition frequency are not displayed on a screen of the device. Therefore it is recommended to read carefully the instruction manual (Safety Instruction) in use.

Table 8-3: Ultrasound Diagnostic System setting condition to influence MI/TI

∗1 Settings condition to influence MI/TI in continuous wave doppler (CWD) are only drive voltage and electric focus.

System Control Settings*1		Switch or function	MI	TI
COMMON	Transmission Voltage	Acoustic Power	Yes	Yes
	Electric focus	Focus	Yes	Yes
B	Pulse repetition frequency	Depth/Zoom	—	Yes
		Residual Echo Reject	Yes	Yes
	Transmission frequency	Image Freq	—	Yes
	Number of scanning lines	Frame Rate	—	Yes
		Scan Area	Yes	Yes
M	Pulse repetition frequency	Depth/Range	—	Yes
	Transmission frequency	Image Freq	Yes	Yes
	Imaging mode (wave)	BbH, T.H.E.	Yes	Yes
PW	Pulse repetition frequency	Velocity Range	—	Yes
		High PRF	—	Yes
	Transmission frequency	Image Freq	Yes	Yes
	Pulse duration	Image Freq	—	Yes
	Imaging mode (wave)	TDI	Yes	Yes
Mflow	Pulse repetition frequency	Velocity Range	—	Yes
		High PRF	—	Yes
	Transmission frequency	Image Freq	Yes	Yes
	Pulse duration	Image Freq	—	Yes
	Imaging mode (wave)	TDI	Yes	Yes

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System Control Settings*1		Switch or function	MI	TI
Flow	Pulse repetition frequency	Depth/Zoom	—	Yes
		Velocity Range	—	Yes
	Transmission frequency	Image Freq	Yes	Yes
	Number of scanning lines	Frame Rate	—	Yes
		Flow Area	—	Yes
		Average (Flow)	—	Yes
	Pulse duration	Image Freq	—	Yes
	Imaging mode (wave)	eFlow, Power, TDI	Yes	Yes

8-5 Recommendation on ALARA principle

ALARA stands for "As Low As Reasonably Achievable". Following the ALARA principle means that total acoustic output is kept as low as reasonably achievable, while diagnostic information being optimized. This guiding philosophy is the same as in the use of X-ray equipment.

For example, when the mechanical index (MI) is considered,

- Selection of appropriate probe
- Selection of transmission frequency (higher frequency is lower in MI value)
- Selection of electronic focus
- Lower transmission voltage
- Adjust Gain (Higher Gain)

Keep in mind these points during examination. In addition, be more careful before using a contrast agent.

When Thermal Index(TI) is considered,

- Selection of appropriate TI
- Appropriate image adjustment (raise the gain, etc.)
- Reduction of TI value (reduce transmission voltage, lowering pulse repetition frequency, widen the scan width in the case of scan mode)
- Shorten exposure time

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8-6 Default Setting

In order to avoid unintentional high acoustic output, the acoustic output is limited by default setting in the following cases (it becomes a low value):

- Power On
- Select the type of examination (Application) with the preset feature
- Switching the probe
- NEW PATIENT Function Operation (ID input)

Default setting (Low value) limits the acoustic output less than DVA% = 70%, $I_{spta,\,\alpha}$ < 94 mW/cm^2, MI<1.0, or TI<3.0 whichever less.

8-7 Acoustic output Limits

The values of spatial peak temporal average intensity ($I_{spta,\,\alpha}$), mechanical index (MI) and thermal indices (TIs) do not exceed 720 mW/cm^2, 1.9 and 6 respectively for other than fetal examination.

There are cases that the mechanical index (MI) and the thermal index (TI) are more than 1 by the type of probe and the mode of image display. At that time, it displays the value in real time.

For fetal examination, the mechanical index (MI) and thermal indices (TIs) do not exceed 1.0 and 3.0 respectively.

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8-8 Measurement uncertainties

8-8-1 Protocol for calculating the measurement uncertainties

The protocol for calculating the measurement uncertainties follows the methods used in NEMA UD 2-2004.

The reporting of an acoustic output quantity requires the specification of the measurement mean and a quantitative estimate of the uncertainty associated with the measurement. Uncertainty is expressed in terms of confidence limits or tolerance limits. A 95% confidence limit defines a range of values that will contain the true mean (or some other specified quantity) 95% of the time. A 95% tolerance limit defines a range of values that will contain a specified percentage of all values 95% of the time.

An important feature of this approach is the incorporation of the Type A and Type B terminology in classifying the components of measurement uncertainty, as recommended by the International Organization for Standardization (ISO, 1993), and adopted by the American National Standards Institute (ANSI/NCSL, 1997). These new terms replace the previous terms: "random uncertainty" and "systematic uncertainty". Type A and Type B uncertainties are distinguished on the basis by which their numerical values are estimated.

Type A uncertainties are those that are evaluated by statistical treatment of repeated measurements, and Type B are those that are evaluated by other means. An important reason for the new classification is to provide an internationally accepted procedure for mathematically combining individual components of uncertainty into a single total uncertainty regardless of whether arising from random or systematic effects.

Basic to this approach is representing each component of uncertainty by an estimated standard deviation, termed standard uncertainty. Its symbol is u_i and is equal to the positive square root of the estimated variance u_i^2 .

For a Type A uncertainty component, u_i equals the statistically estimated standard deviation. Statistical methods involve the analysis of multiple replications to estimate population parameters, such as the mean and the standard deviation.

Type B evaluations are based on scientific judgment using all of the relevant information, which may include:

- previous measurement data,
- experience with the relevant materials and instruments,
- manufacturer's specifications,
- data provided national standards laboratories,
- uncertainty data taken from handbooks.

It should be noted that Type A evaluations of uncertainty based on limited data are not necessarily more reliable than soundly based Type B evaluations (Taylor and Kuyatt, 1994).

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Type A Evaluated Uncertainty

A Type A standard uncertainty, u_A, of a measured quantity is equal to the standard deviation of the sample mean, which is commonly called the standard error. It is given by,

$$u_A = \frac{S_x}{\sqrt{n}} \quad (1)$$

where S_x is the sample standard deviation and n is the number of repetitions. As indicated in equation(1), a Type A uncertainty is reduced by performing additional measurements. This results from the increase in the size of the denominator. Ideally, the measurements should be repeated a sufficient number of times to yield a reliable estimate of the standard error.

Type B Evaluated Uncertainty

A Type B evaluation of uncertainty is performed after all adjustments for correctable systematic errors have been made. The statistical distributions of all remaining systematic errors are combined to produce an overall statistical distribution. Unless there is information to the contrary, the individual probability distributions are considered independent rectangular distributions, each possessing a variance equal to $a_i^2/3$, where a_i is the semi-range limit for the i^{th} uncertainty component. Because of the independence of the individual distributions, the total variance equals the sum of the individual variances. Thus, for n rectangularly distributed uncertainty components, the total variance, σ^2, is given by

$$\sigma^2 = \sigma_1^2 + \sigma_2^2 + \ldots + \sigma_n^2 \quad (2)$$

and the Type B standard uncertainty, u_B, is then

$$u_B = \sqrt{\sigma^2} = \sqrt{\frac{a_1^2 + a_2^2 + \ldots + a_n^2}{3}} \quad (3)$$

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Combined Uncertainty

The combined or total uncertainty of a measured quantity includes both Type A and Type B evaluated components of uncertainty. It is computed after all blunders have been removed from the data base, and after all possible systematic corrections have been made. The combined uncertainty, u_C, of a measured quantity is given by

$$u_C = \sqrt{u_A^2 + u_B^2} \tag{4}$$

The ISO (1993) advocates using the combined standard uncertainty as the parameter for expressing quantitatively the uncertainty of the result of a measurement and in giving the results for all international comparisons of measurements. Although u_C can be universally used to express the uncertainty of a measurement result, in many commercial, industrial, and regulatory applications, and when health and safety are concerned, it is often desirable to provide a measure of uncertainty that includes a larger proportion of the distribution of values that could be reasonable attributed to the measurand. This is provided by multiplying the combined standard uncertainty by a coverage factor k to yield the expanded uncertainty U. That is,

$$U = k \bullet u_C \tag{5}$$

The result of a measurement is then conveniently expressed as

$$x = \bar{x} \pm U \tag{6}$$

The value of the coverage factor k is chosen based on the level of confidence required for any given application. In general, k will be in the range of 2 to 3. NIST has adopted a policy of setting $k = 2$, unless stated otherwise (Taylor and Kuyatt, 1994). In ultrasonic exposimetry, k is usually set to the value of $t_{.975}$, at the appropriate number of degrees of freedom, in order to provide a 95% level of confidence about the expected value of the measurand. Whatever the value of k chosen, it must be clearly stated in the final specification of the uncertainty.

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8-8-2 Results of measurement uncertainties

Now we would like to offer the results of measurement uncertainties of our products. 4 units of ALOKA SSD-4000 and 6 units of UST-9123 for 4 times repeated acoustic output measurements (e.g. total power (P), pulse-intensity integral (I_{pi}), peak-rarefactional acoustic pressure (p_r), acoustic working frequency (f_{awf})). Though this product model may be different from the model specified in this manual, we believe we can obtain the similar results from different set of console and probes. The results were analyzed using a two-way crossed analysis of variance with repeated measurements.

In this analysis it is assumed that the consoles and transducers are independent and that all repeated measurements are independent. It is also assumed that all preliminary steps, such as correcting for systematic errors, have been performed.

There are six transducers ($p = 6$), four consoles ($q = 4$) and four times ($r = 4$) repeated measurements.

COMPUTATIONAL SET UP FOR { p : transducers; q : consoles; r : repetetions }

consoles (j =1, 2,..., q)

transducers (i =1, 2,..., p)	1	2	. . .	q	
1	m_{11}, s_{11}	m_{12}, s_{12}	. . .	m_{1q}, s_{1q}	$m_{1.}$
2	m_{21}, s_{21}	m_{22}, s_{22}	. . .	m_{2q}, s_{2q}	$m_{2.}$
⋮	⋮	⋮		⋮	⋮
p	m_{p1}, s_{p1}	m_{p2}, s_{p2}	. . .	m_{pq}, s_{pq}	$m_{p.}$
	$m_{.1}$	$m_{.2}$	. . .	$m_{.q}$	$\overline{\overline{m}}$

$S_{i.}$ (rows)

$S_{.j}$ (columns)

ij^{th} cell mean

$$m_{ij} = \frac{1}{r}\sum_{k=1}^{r} x_{ijk} \tag{7}$$

i^{th} transducer mean

$$m_{i\bullet} = \frac{1}{q}\sum_{j=1}^{q} m_{ij} \tag{8}$$

j^{th} console mean

$$m_{\bullet j} = \frac{1}{p}\sum_{i=1}^{p} m_{ij} \tag{9}$$

overall mean

$$m = \frac{1}{pq}\sum_{i=1}^{p}\sum_{j=1}^{q} m_{ij} \tag{10}$$

standard deviation of ij^{th} cell

$$S_{ij} = \sqrt{\sum_{k=1}^{r}(x_{ijk} - m_{ij})^2/(r - 1)} \tag{11}$$

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standard deviation of transducer

$$S_{i\bullet} = \sqrt{\sum_{i=1}^{p}(m_{i\bullet} - \overline{\overline{m}})^2/(p - 1)} \quad (12)$$

standard deviation of console

$$S_{\bullet j} = \sqrt{\sum_{ij=1}^{q}(m_{\bullet j} - \overline{\overline{m}})^2/(q - 1)} \quad (13)$$

Using equation (8), (9) and (10), transducer mean, console mean and overall mean are calculated respectively. The standard deviation calculated using equation (11) is expressed in percentage to overall mean value.

The variability inherent in the measurement technique is quantified by S_{meas}, the square root of the variance attributed solely to the measurement technique. That is,

$$S_{meas} = \sqrt{\frac{1}{pq}\sum_{i=1}^{p}\sum_{j=1}^{q}S_{ij}^2} \quad (14)$$

The transducer variability is quantified by S_{trans}, which is given by

$$S_{trans} = \sqrt{S_{i\bullet} - \frac{1}{rq}S_{meas}^2} \quad (15)$$

And the console variability is quantified by S_{cons}, which is given by

$$S_{cons} = \sqrt{S_{\bullet j} - \frac{1}{rp}S_{meas}^2} \quad (16)$$

The total variability is quantified by S_{total}, which is given by

$$S_{total} = \sqrt{S_{trans}^2 + S_{cons}^2 + S_{meas}^2} \quad (17)$$

The variance of the measurand is given by

$$\hat{\sigma}_x^2 = S_{total}^2 \quad (18)$$

And the variance of the measurand mean is given by

$$\hat{\sigma}_{\bar{x}}^2 = \frac{S_{trans}^2}{p} + \frac{S_{cons}^2}{q} + \frac{S_{meas}^2}{rpq} \quad (19)$$

The Type A standard uncertainty is the square root of the variance of the measurand mean. That is,

$$u_A^2 = \sqrt{\hat{\sigma}_{\bar{x}}^2} \quad (20)$$

The type B uncertainty is given by

$$u_B = \sqrt{\sigma^2} = \sqrt{\frac{a_1^2 + a_2^2 + \ldots + a_n^2}{3}} \quad (21)$$

Then the combined uncertainty will be

$$u_C = \sqrt{u_A^2 + u_B^2} \quad (22)$$

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with $pq - 1 = 23$ degrees of freedom (from Table 1 of UD 2-2004 Appendix A). Then,

$$U = k \bullet u_C = t_{.975}(pq - 1) \bullet u_C \quad (23)$$

And the ultrasound power should be reported as

$$Power = \overline{\overline{m}} \pm U \quad (24)$$

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An upper 95% tolerance limit is computed using an expanded uncertainty in which the coverage factor is an appropriately chosen tolerance coefficient and the Type A component of the combined uncertainty equals $\sqrt{\hat{\sigma}_x^2}$, instead of $\sqrt{\hat{\sigma}_{\bar{x}}^2}$.

Thus, for an upper 95% tolerance limit for 99% of power values is given by,

$$u_C = \sqrt{u_A^2 + u_B^2} = \sqrt{\hat{\sigma}_x^2 + u_B^2} \quad (25)$$

k should be set to the value of $K_{.99}$ for pqr - 1 = 95 degrees of freedom.Then the expanded uncertainty is

$$U = k \bullet u_C = K_{.99}(\, pq - 1) \bullet u_C \quad (26)$$

And the upper tolerance limit is expressed as

$$Power \leq \bar{m} + U \quad (27)$$

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Uncertainty evaluation of total power : P

The standard deviation obtained from mean value of 6 transducers by eq. (12),	$S_{i.}$:	6.44%
The standard deviation obtained from mean value of 4 consoles by eq. (13),	$S_{.j}$:	2.57%
The standard deviation derived from measurement technique by eq.(14),	S_{meas}:	1.01%
The standard deviation due to the transducer variability by eq. (15),	S_{trans}:	6.43%
The standard deviation due to the console variability by eq. (16),	S_{cons}:	2.56%
The total standard deviation calculated by eq. (17)	S_{total}:	7.00%
The type A uncertainty by eq. (20),	u_A:	2.92%
Uncertainty components for type B uncertainty evaluation		
The error due to reading the balance scale,	a_1:	±2%
The error due to the reference source,	a_2:	±4%
The error derived from alignment of the transducer,	a_3:	- 5%
The error derived from not coupling directly between the transducer and water,	a_4:	- 3%
The error derived from not enough thickness of the absorbing target,	a_5:	- 5%
The type B uncertainty by eq. (21),	u_B:	5.13%
The combined uncertainty by eq. (22),	u_C:	5.91%

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with pq-1 = 23 degrees of freedom (from Table 1 of UD 2-2004, Appendix A).

The expanded uncertainty by eq. (23), U 12.22%

$$P = \overline{\overline{m}} \pm 12.22\ \%\ \text{(95\% C.I.)}$$

An upper 95% tolerance limit is computed using an expanded uncertainty in which the coverage factor is an appropriately chosen tolerance coefficient and the Type A component of the combined uncertainty equals $\sqrt{\hat{\sigma}_x^2}$ and not $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ as before.

The upper 95% tolerance limit for 99% of power values, u_C: 8.68%

The coverage factor, k should be set to the value of $K_{.99}$ for pqr - 1=95 degrees of freedom. Since a value for $K_{.99}$ for 95 degrees of freedom is 2.69, then the coverage factor k = 2.69

The expanded uncertainty for the upper 95% tolerance limit by eq. (26), U 23.38%

$$P \leq \overline{\overline{m}} + 23.38\ \%$$

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Uncertainty evaluation of pulse-intensity integral: I_{pi}

The standard deviation obtained from mean value of 6 transducers by eq. (12),	S_i:	3.80%
The standard deviation obtained from mean value of 4 consoles by eq. (13),	S_j:	4.14%
The standard deviation derived from measurement technique by eq.(14),	S_{meas}:	1.14%
The standard deviation due to the transducer variability by eq. (15),	S_{trans}:	3.79%
The standard deviation due to the console variability by eq. (16),	S_{cons}:	4.13%
The total standard deviation calculated by eq. (17)	S_{total}:	5.72%
The type A uncertainty by eq. (20),	u_A:	2.59%
Uncertainty components for type B uncertainty evaluation		
The error derived from voltage measurement of the oscilloscope,	a_1:	± 3%
The error derived from time measurement of the oscilloscope,	a_2:	± 2%
The error derived from calibration of the hydrophone,	a_3:	± 8.6%
The error derived from alignment of the transducer,	a_4:	- 3%
The error derived from alignment of the hydrophone,	a_5:	- 4%
The error derived from the effect of spatial averaging over the aperture of the hydrophone,	a_6:	- 16.6%
The error derived from the effect of non-linear distortion,	a_7:	- 6%
The error derived from the directivity of the hydrophone	a_8:	- 4%
The type B uncertainty by eq. (21),	u_B:	12.10%
The combined uncertainty by eq. (22),	u_C:	12.38%

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with pq-1 = 23 degrees of freedom (from Table 1 of UD 2-2004, Appendix A).

The expanded uncertainty by eq. (23), U 25.62%

$$I_{pi} = \overline{\overline{m}} \pm 25.62\ \%\ \text{(95\% C.I.)}$$

An upper 95% tolerance limit is computed using an expanded uncertainty in which the coverage factor is an appropriately chosen tolerance coefficient and the Type A component of the combined uncertainty equals $\sqrt{\hat{\sigma}_x^2}$ and not $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ as before.

The upper 95% tolerance limit for 99% of I_{pi} values by eq.(25), u_C: 13.39%

The coverage factor, k should be set to the value of $K_{.99}$ for pqr - 1=95 degrees of freedom. Since a value for $K_{.99}$ for 95 degrees of freedom is 2.69, then the coverage factor k = 2.69.

The expanded uncertainty for the upper 95% tolerance limit by eq. (26), U 36.03%

$$I_{pi} \le \overline{\overline{m}} + 36.03\ \%$$

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Uncertainty evaluation of peak-rarefactional acoustic pressure: p_r

The standard deviation obtained from mean value of 6 transducers by eq. (12),	S_i:	1.95%
The standard deviation obtained from mean value of 4 consoles by eq. (13),	S_j:	2.62%
The standard deviation derived from measurement technique by eq.(14),	S_{meas}:	1.15%
The standard deviation due to the transducer variability by eq. (15),	S_{trans}:	1.93%
The standard deviation due to the console variability by eq. (16),	S_{cons}:	2.61%
The total standard deviation calculated by eq. (17)	S_{total}:	3.45%
The type A uncertainty by eq. (20),	u_A:	1.53%

Uncertainty components for type B uncertainty evaluation

The error derived from voltage measurement of the oscilloscope,	a_1:	± 1.5%
The error derived from time measurement of the oscilloscope,	a_2:	± 2%
The error derived from calibration of the hydrophone,	a_3:	± 4.3%
The error derived from alignment of the transducer,	a_4:	- 3%
The error derived from alignment of the hydrophone,	a_5:	- 2%
The error derived from the effect of spatial averaging over the aperture of the hydrophone,	a_6:	- 8%
The error derived from the effect of non-linear distortion,	a_7:	- 3%
The error derived from the directivity of the hydrophone	a_8:	- 2%
The type B uncertainty by eq. (21),	u_B:	6.18%
The combined uncertainty by eq. (22),	u_C:	6.37%

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with pq-1 = 23 degrees of freedom (from Table 1 of UD 2-2004, Appendix A).

The expanded uncertainty by eq. (23), U 13.19%

$$p_r = \overline{\overline{m}} \pm 13.19\ \%\ \text{(95\% C.I.)}$$

An upper 95% tolerance limit is computed using an expanded uncertainty in which the coverage factor is an appropriately chosen tolerance coefficient and the Type A component of the combined uncertainty equals $\sqrt{\hat{\sigma}_x^2}$ and not $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ as before.

The upper 95% tolerance limit for 99% of p_r values by eq.(25), u_C: 7.08%

The coverage factor, k should be set to the value of $K_{.99}$ for pqr - 1=95 degrees of freedom. Since a value for $K_{.99}$ for 95 degrees of freedom is 2.69, then the coverage factor k = 2.69.

The expanded uncertainty for the upper 95% tolerance limit by eq.(26), U 19.05%

$$p_r \le \overline{\overline{m}} + 19.05\ \%$$

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Uncertainty evaluation of acoustic working frequency: f_{awf}

The standard deviation obtained from mean value of 6 transducers by eq. (12),	$S_{i.}$:	0.085%
The standard deviation obtained from mean value of 4 consoles by eq. (13),	$S_{.j}$:	0.009%
The standard deviation derived from measurement technique by eq.(14),	S_{meas}:	0.011%
The standard deviation due to the transducer variability by eq. (15),	S_{trans}:	0.085%
The standard deviation due to the console variability by eq. (16),	S_{cons}:	0.009%
The total standard deviation calculated by eq. (17)	S_{total}:	0.086%
The type A uncertainty by eq. (20),	u_A:	0.035%
Uncertainty components for type B uncertainty evaluation		
The error derived from time measurement of the oscilloscope,	a_1:	± 2%
The type B uncertainty by eq. (21),	u_B:	1.15%
The combined uncertainty by eq. (22),	u_C:	1.16%

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with pq-1 = 23 degrees of freedom (from Table 1 of UD 2-2004, Appendix A).

The expanded uncertainty by eq. (23),	U	2.39%

$$f_{awf} = \overline{\overline{m}} \pm 2.39\ \%\ \text{(95\% C.I.)}$$

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8-9 References

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