FUJIFILM

Diagnostic Ultrasound System
ARIETTA 750

Instruction Manual
Instructions for Use

Requests to operators and maintenance managers:

- Read the document "Instructions for Use" before using the Diagnostic Ultrasound System.
- After reading "Instructions for Use", store it near the system so that it is accessible at all times.

FUJIFILM Healthcare Corporation

MN1-6505 rev.9

CE 0197

Introduction

Introduction

Thank you for purchasing the ARIETTA 750 Diagnostic Ultrasound System by FUJIFILM Healthcare Corporation.
This document is the instruction manual for the ARIETTA 750 Diagnostic Ultrasound System.
This instrument complies with Medical Device Regulation (EU) 2017/745 and Directive 2011/65/EU and (EU) 2015/863 relating to RoHS.

Name and classification of medical equipment

Product name

Diagnostic Ultrasound System ARIETTA 750

Revision history

Revision no.: 9
Revision date: 2022-09-07

Symbols used in this manual

This manual uses the following terms to describe the safety precautions that must be observed to prevent danger or injury to operators and patients. The severity of risks and injuries that might occur if safety precautions are not observed are classified into three levels: DANGER, WARNING, and CAUTION. In addition, NOTICE indicates precautions that operators must observe.

DANGER

Indicates an imminently hazardous situation that, if not avoided, might result in death or serious injury. This symbol also indicates an immediate danger that might result in the total destruction of devices, or in fire.

WARNING

Indicates a potentially hazardous situation that, if not avoided, might result in death or serious injury. This symbol also indicates a potential (latent) danger that might result in the total destruction of devices, or in fire.

CAUTION

Indicates a situation that, if not avoided, might result in light or moderate injury. This symbol also indicates a situation that might result in damage to a device or to part of a device, or in the loss of computer data.

NOTICE

Indicates a precaution that we strongly urge operators to observe to prevent damage to or deterioration of devices during operation, as well as to ensure that the devices are used efficiently. Alternatively, this symbol indicates a recommended procedure, condition, or action that requires careful attention.

Safety precautions are categorized as follows and indicated by the following symbols.

Indicates prohibited conditions or actions. Safety precautions accompanied by this symbol describe conditions or actions that are prohibited.

Indicates required actions that the user must perform.

Non-alphanumeric characters used in this manual

Please note that actual screen displays (including icons and design) might differ from the Diagnostic Ultrasound System screens reproduced in this manual.
Some of the messages described in this manual might not be displayed by the Diagnostic Ultrasound System, depending on its configuration (including options).
For details on functions not described in this manual, see the separate instruction manuals.
In this manual, the term ARIETTA 750 also includes ARIETTA 750LE, ARIETTA 750SE, and ARIETTA 750VE.
The following symbols are used in this manual.

Character	Explanation
α	Alpha
γ	Gamma
π	Pi

About Diagnostic Ultrasound System ARIETTA 750

This system is intended for use by doctors and other qualified persons for the purpose of performing tomography and hemodynamic diagnosis of blood flow in the human body. Note, however, that this system cannot be used to perform ophthalmologic ultrasound examination. The acoustic output power of the system exceeds the upper ophthalmologic limit stipulated in the U.S. FDA standards.

1. Precautions concerning the use and management of the system

    - Only doctors and other qualified persons are allowed to operate the system for diagnostic purposes.
    - Scan for the minimum length of time necessary for making a diagnosis, and at the lowest suitable output.
    - Do not disassemble, repair, or modify the system or its optional equipment without our permission. System repairs must be carried out by our certified personnel. Please notify us when repairs are needed.

NOTE: Disassembly refers to the use of tools to remove the casing or other parts.
NOTE: Modification means the attachment, to this system, of parts or devices other than those specified by our company. Replacement of a power cable is considered a modification.

- Installation of the system and any optional equipment (the mounting and connecting of the system by using tools) is to be performed by our certified partners. Please notify us when the system or any optional equipment needs to be installed.
- Transportation of the system (movement of the product by using a vehicle such as a car or ship) is to be carried out by our certified partners. Please notify us if the system needs to be transported.
- Clean and inspect the system periodically. For details, see "Instructions for Use".
- If any abnormality occurs during the use of the system, remove the probe from the patient immediately, and stop using the system. If the patient exhibits unusual or abnormal symptoms, immediately provide the appropriate medical treatment. Perform the required measures for the system as described in "Instructions for Use". If an abnormality occurs that is not described in "Instructions for Use", please contact our office.

2. Precautions on system installation
   This system is medical electrical equipment intended for use in hospitals, research institutions, and similar facilities. Install the system as described below.
   - Set up the system according to the instructions given in "Setup Before Use" in "Instructions for Use".
   - Install the system in an environment that meets the conditions described in "Ambient conditions" in "Instructions for Use".
   - Install the system in an environment where electromagnetic compatibility can be maintained in accordance with "Precautions for maintaining electromagnetic compatibility" and "Guidelines for electromagnetic compatibility" in "Instructions for Use".
     Electromagnetic compatibility (EMC) means that the system can maintain basic performance and safety within the specified electromagnetic environment, without causing electromagnetic interference that cannot be tolerated by other devices in that environment.
3. External dimensions and weight of the system

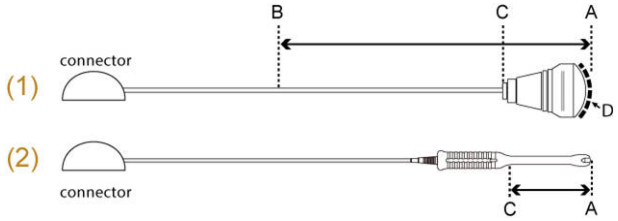
External dimensions	Width: 550 mm ±10% Depth: 900 mm ±10% Height: 1220 mm ±10% to 1695 mm ±10%
Weight	136 kg ±10% (main unit only), 162 kg ±10% (with all options included)

Classification of the ARIETTA 750 Diagnostic Ultrasound System

- Protection against electrical shock: Class I and ME equipment
- Protection against electrical shock (applied parts): Type BF applied parts

◦ Probes and scanner

Refer to the following diagrams (for the probe or scanner) and the following table for details about applied parts and parts that are handled as applied parts.



(1) Example of probes for surface or intraoperative use.

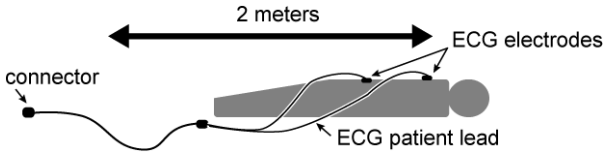
(2) Example of body cavity probes.

Probe Application	Applied part (direct patient contact)	Parts handled as applied parts	Length between B and C
Body surface	Ultrasonic irradiation area (D)	Between A and B	100 cm
Intra-operative	Ultrasonic irradiation area (D)	Between A and B	20 cm
Endocavity	Between A and C	Between A and C	-

◦ ECG, PCG, Pulse

Parts within a 2 m range from a physiological signal sensor are regarded as applied parts. (See the figure below.)

Example: ECG



- Protection against electrical shock (defibrillation-proof applied parts): This system is not suitable for use with defibrillation-proof applied parts.
- Protection against penetration by water or particulate substances
  - Probe applied part: IPX7 (rated for brief immersion in water)
  - Foot switch
    MP-2819*: IPX7 (rated for brief immersion in water)
    MP-2345B: IPX8 (rated for continuous immersion in water)
  - Other Details: IPX0 (ordinary equipment)
- Level of safety for use in air and flammable anesthetic gas, or in oxygen/nitrous oxide and flammable anesthetic gas.
  - This system is not suitable for use in a mixture of air and flammable anesthetic gas, or in a mixture of oxygen or nitrous oxide and flammable anesthetic gas.
- Operation mode: Continuous operation

Recycling or Disposal

CAUTION

Recycle or dispose of this equipment properly according to your organizational rules and your local laws.

Waste Electrical and Electronic Equipment (WEEE) Directive
Do not dispose medical devices together with household waste.
In observance of the European Directive on waste electrical and electronic equipment (WEEE) and its implementation in accordance with national law, medical devices that have reached the end of their product life must be collected separately and returned to an environmentally compatible recycling facility.
Please contact your local distributor of our company for information about qualified recycling facility.

The equipment contains a primary battery (lithium battery). You should recycle or dispose of this equipment properly according to your organizational rules and your local laws. For more detailed information about recycling of this equipment, please contact one of our offices as listed on the back cover, or your household waste disposal service.

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This software is based in part on the work of the Independent JPEG Group.
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OMNITRAX and VIRTUTRAX are trademarks of CIVCO.
Other company names, product names and system names mentioned in the instruction manual of this instrument may be the trademarks or registered trademarks of their respective organizations. This document omits symbols such as ^{TM} and (R).

Precautions concerning the software installed on the system

The following actions are prohibited with respect to the software installed on this system:

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

Contents

1

Precautions

1.1 Safety precautions

This manual uses the following terms to describe the safety precautions that must be observed to prevent danger or injury to operators and patients. The severity of risks and injuries that might occur if safety precautions are not observed are classified into four levels: DANGER, WARNING, CAUTION, and NOTICE.

DANGER

Indicates a hazardous situation that, if not avoided, carries an imminent risk of death or serious injury to the user.

WARNING

Indicates a potentially hazardous situation that, if not avoided, might result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation that, if not avoided, might result in only light to moderate injury or property damage.

NOTICE

Indicates a precaution that we strongly urge operators to observe to prevent damage to or deterioration of devices, as well as to ensure that the devices are used efficiently.

Safety precautions are categorized as follows and indicated by the following symbols.

This symbol indicates a prohibited condition or action.

This symbol indicates a mandatory action.

When the serious accident such as follows occurs with this product, please report it to our company or service representative and the regulator of the member nation where this product install it in immediately.
(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
(c) a serious public health threat;

1.1.1 Warnings and safety information

DANGER

Do not use this system in a flammable atmosphere.
Use of this system in a flammable atmosphere might cause an explosion.

WARNING

Do not attempt to repair the system. Do not disassemble the system. Do not modify the system. (Do not replace the power cable.) [*1] , [*2]
Ignoring these instructions might result in electric shocks or accidents.
For details regarding system repair, please contact our office.

Do not use this system on patients who might be allergic to latex products.
Use of a rubber cover when examining such patients might cause anaphylactic shock. Ask the patient about their allergy history beforehand.

Clean, disinfect and sterilize the probes as required.
During the examination, wear medical gloves. After the examination, wash your hands.
Ignoring this instruction might result in infections in the patient or examiner.

Dispose of probes used on patients with Creutzfeldt-Jakob disease.
Ignoring this instruction might result in infections in the patient or examiner.
Our ultrasound probes are not compatible with any disinfection or sterilization method for Creutzfeldt-Jakob disease.

*1.
Disassembly refers to the use of tools to remove the casing or other parts.

*2.
Modification means the attachment, to this system, of parts or devices other than those specified by our company. Replacement of a power cable is considered a modification.

⚠ CAUTION

The service life of the system is seven years.
This is the service life you can expect when the system is used, maintained, and inspected under the prescribed operating conditions and when components that need regular replacement are replaced as required.
For details on the recommended maintenance and inspections, see "The need for regular maintenance inspections" in this manual. For details on components that need regular replacement, please contact our office.

Regularly perform maintenance inspections and safety inspections of the system and the probes.
With prolonged use, some parts of this system might deteriorate, causing performance to degrade or even resulting in smoke or fire.
If anything unusual occurs, immediately stop using the system and contact our office.

Do not connect any devices and probes other than those specified in this manual to the system.
Using this system with unapproved devices might result in electric shock, burns, or other injuries to the patient or examiner, and damage to this system.

All non-medical devices that are to be connected to this system must comply with the corresponding IEC standards or ISO standards.
In addition, all devices making up the ME system must comply with the international standards for medical electrical equipment.
If there are any applicable ordinances, they should be prioritized. For more details, please contact our office.

Do not install this system or any optional devices without our approval.
Do not transport the system. [*1] , [*2]
Ignoring these instructions might result in electric shocks or accidents.
If you want to transport or install this system or any optional devices, please contact our office.

Install the system in location that meets the following requirements:

- A flat surface of adequate strength not prone to vibration.
- An area where there is no water or other fluid, no large amounts of salt or sulfur, and no direct sunlight.

Ignoring these instructions might result in burns or other injuries to the patient or examiner.

Adjust the position and angle of the monitor, keeping a sufficient distance between the system and the peripheral devices, walls, and people.
Do not knock the monitor against the touch panel, USB-connected storage medium, cable hook, probe, probe holder, operation panel, or other parts.
Route the probe cables so that they do not become entangled with the monitor, monitor arm, or the handle at the back of the system.
Contact with the monitor might cause injury or might damage surrounding equipment, the walls, the probe, the system itself, the monitor, or the touch panel. Warn doctors, patients, and others in the area before adjusting the position or angle of the monitor.
Should the monitor break and its internal fluid come into contact with the skin, wipe the fluid away and wash the skin in running water for at least 15 minutes. To be on the safe side, consult a doctor. If the fluid gets into contact with an eye, rinse the eye in running water for at least 15 minutes, and consult a doctor immediately.
If the monitor is damaged, stop using the system immediately and contact our office.

Do not block the ventilation holes.
The temperature inside the system will rise, leading to fire or malfunction.

Do not spill water or other liquids on the system.
The system is not waterproof.
Using the system when it is wet might result in short circuits or electric shock.
If liquid is spilled on the system, please contact our office.

The system must be dry when used.
Avoid rapid temperature changes, which can cause condensation.
Using the system when condensation or water drops are present could result in malfunction, short circuits, or electric shock.

If you observe anything abnormal in the system, probes, peripherals, or options, turn the power off immediately, and stop using the system.
Ignoring these instructions might result in injury to the patient or operator, or other unexpected accidents.
Check for messages, abnormal temperatures, damage, and other indicators of system status, and then contact our office.

If any abnormalities occur in the system or the patient when this system is used, remove the probe from the patient immediately and stop using the system.
If the patient's condition is abnormal, take appropriate medical action.
When using this system, watch to make sure that it is functioning normally, and that the patient is not abnormally affected.

Do not touch the exposed pins in the probe connector or in the DC IN sockets at the same time as you touch the patient.
Do not touch the patient with anything other than applied parts or other parts that are equivalent to applied parts.
Ignoring these instructions might result in a short circuit or might cause the patient to experience an electrical shock.

Do not touch or get close to the exposed pins in the probe connector or in the DC IN sockets.
Touching these pins could expose them to electrostatic discharge (ESD), which might damage them.

Scan the patient only for the minimum length of time necessary to perform the examination, and at the lowest possible output.
Fetal ultrasound scans must be conducted with particular care.
High output and prolonged exposure to ultrasonic waves can adversely affect the internal tissues of the patient.

Do not damage, modify or break the probe cables. Do not place heavy objects on the probe cables, twist them, bundle them, or bend them excessively.
A damaged probe cable might result in short circuits or electric shock.

Do not allow sterilized probes to come into contact with the system (including the probe holder).
The system is not intended to be sterilized.

Before use, coat the probe with a sufficient amount of ultrasound gel. When a probe is not in use during an examination, freeze the image as standard practice.
Using a probe without a coating of ultrasound gel might cause the surface temperature of the probe to rise, potentially causing burns.
If an abnormality such as a rise in temperature occurs, stop using the probe immediately, and contact our office.

Hold the probe securely during an examination. Store probes in the probe holder when not in use.
Ignoring these instructions might result in injury to the patient or examiner.

Do not apply unreasonable force when moving a probe that is inserted into a body cavity.
Ignoring this instruction might result in injury to the patient.

Do not freeze an image during a puncture operation (especially not while the needle is being inserted).
Freezing the image makes it impossible to correctly determine the puncture position.

The puncture guide line should be used as a guide for the direction of puncture needle insertion.
During a puncture operation, always pay attention to the relative positions of the puncture needle and the body part to be punctured.

Scan USB flash drives for viruses before use.
Connecting removable media such as USB flash drives to the system increases the risk of virus infection. If such media must be used, make sure to scan them for viruses by using a computer or other device before connecting them to the system.

*1.
Installation refers to the use of tools to mount and connect the product.

*2.
Transportation refers to the movement of this product by using a vehicle such as a car or a ship.

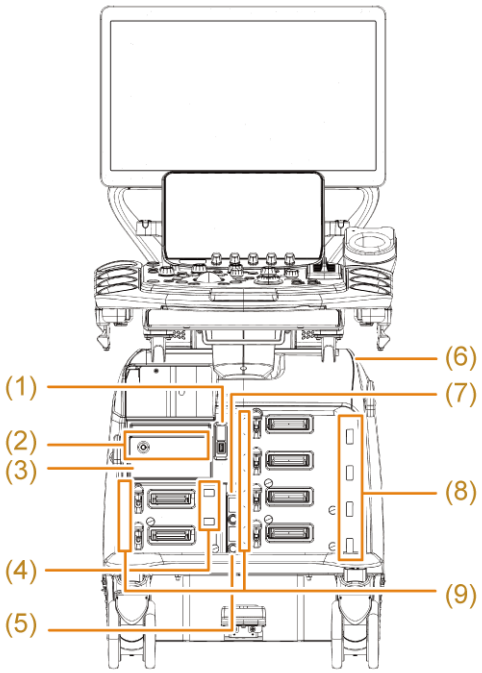
1.1.2 Labels

Labels that indicate the following warnings are attached to the system.
NOTE: Refer to the documentation supplied with the probe for information on probe labels.
The following are precautions are common to all connection terminals.

Keep your hands and fingers away from the connection terminals.
An electrostatic discharge (ESD) could damage or destroy parts that are sensitive to static electricity. For details, see "7-2 Electrostatic discharge (ESD) guidelines".
The following label warns users not to pinch their hands in small openings.

CAUTION

Take care to avoid pinching your fingers.
Ignoring this instruction might result in injury.



NOTE: For details about Real-time Virtual Sonography, see "Precautions concerning Real-time Virtual Sonography" in this manual.

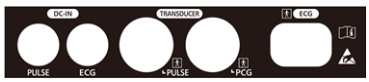
(1)

USB connector (USB 3.0).

(2)

- This label shows how to lock the door.
- Be careful not to get the cable caught in the door. If you ignore this instruction, the cable might become disconnected.
- Do not apply strong physical shocks to, or place a heavy load on, the door. Ignoring this instruction might result in an injury or damage to the door.

(3)



Connection terminals for physiological signals (for connecting physiological signal cables)

: This indicates a type BF applied part.

DC-IN : External input terminal.

TRANSDUCER : Connection terminal for the Physiological Signal Unit cable.

(4) 

Dummy connector.
An ultrasonic image is not displayed, even if a probe is connected to this connector.

(5) 

Foot switch connector.

(6) 

Do not place objects in the movable range of the panel arm.
Ignoring this instruction might result in damage.

(7) 

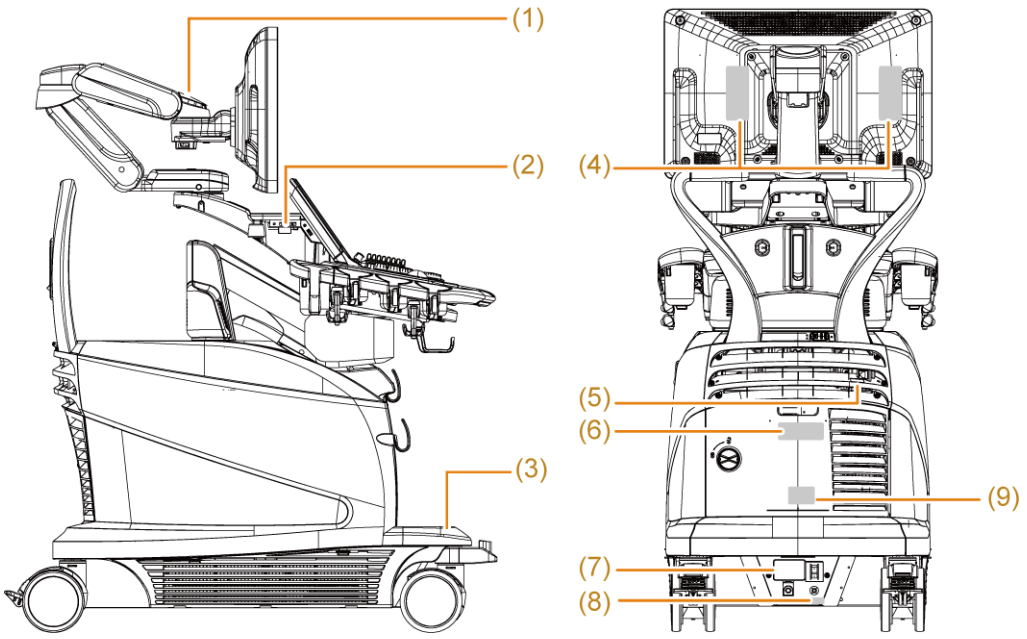
Independent probe connector.
The numbers are connector numbers.

(8) 

Probe connector.
The numbers (1 to 4) are connector numbers.

(9) 

Indicates whether the probe is locked.
Top image: Unlocked
Bottom image: Locked

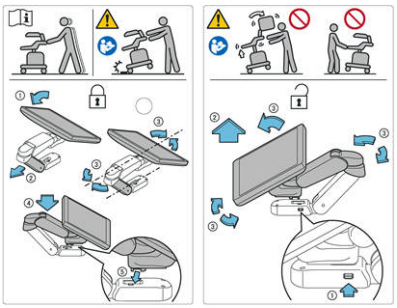


(1)  Take care to avoid pinching your fingers.

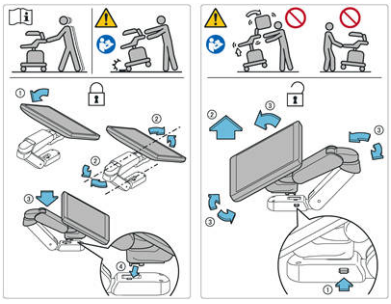
(2)  USB connector.

(3)  This label shows how to adjust the height of the operation panel.
Hold the handle on the operation panel and push the lift pedal to raise or lower the operation panel.

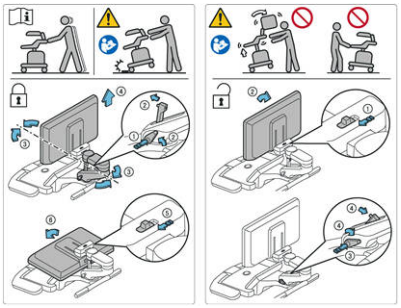
(4) 22-inch monitor (OLED):



23-inch monitor (LCD):



21.5-inch monitor (LCD):



Follow the instructions in the manual to lock the monitor in position and to move the system.
To move the system, use the handle on the back of the system.
Do not lift the system by using the handle on the operation panel.
Ignoring this instruction might result in damage.
Take great care when moving the system over steps and uneven surfaces.

(5)

LAN cable connector.

(6)

These symbols indicate safety precautions.

This product cannot be disposed of as regular garbage. Dispose of it in accordance with your local laws and regulations.

Safety and warning symbols.
These symbols provide safety information.

The following label warns users of the risk of explosion.

DANGER

Do not use this system in a flammable atmosphere.

Use of this system in a flammable atmosphere could cause an explosion.

The following label below warns users of the risk of electric shock.

CAUTION

Plug the provided power cable directly into a hospital-grade outlet.

Ignoring this instruction might result in short circuits or electric shock.

The following label warns users of the risks associated with the acoustic output of the system.

CAUTION

Scan the patient only for the minimum length of time necessary to perform the examination, and at the lowest possible output.

High output and prolonged exposure to ultrasonic waves can adversely affect the tissues of the patient.

The following label warns users of the risk of injury to their hands.

CAUTION

Take care not to pinching your fingers in unexpected locations.

Ignoring this instruction might result in an injury.

The following label cautions users to use the system in accordance with the provided documentation.

CAUTION

Operate this system as described in the instruction manual.

Ignoring these instructions might result in injury to the patient or user, or might damage the system or its peripheral devices.

The following label warns users not to push the system.

CAUTION

Do not push the system from the side. Do not apply excessive force.
Ignoring this instruction might result in the system tipping over and causing injury.
In addition, the system or peripheral devices might be damaged.

The following label warns users not to sit on the system.

CAUTION

Do not sit on the system.
Ignoring this instruction might result in the system tipping over and causing injury.
In addition, the system or peripheral devices might be damaged.

The following label warns users not to disassemble, repair, or modify the system.

WARNING

Do not disassemble, repair, or modify the system.
Ignoring this instruction might result in unexpected accidents or electric shock. For details regarding system repair, please contact our office.

The following label warns users not to use wireless devices.

CAUTION

Do not use wireless devices (such as mobile phones, PHS devices, or radio transceivers) in the vicinity (within 30 cm) of this system.
The interference from such devices can distort or introduce artifacts in images, disrupt physiological signals, and cause unwanted sounds to come from the speakers.

(7)

This shows the manufacturer name, model name, and other information.

CE0197 This instrument complies with Medical Device Regulation (EU) 2017/745.

Manufacturer.

Model number.

SN Serial number.

Power input of alternating current.

Weight (approximate maximum value).

Country of manufacture.
The characters, "**" in the symbol are the country of manufacture code defined by the International Organization for Standardization. For example, "JP" means Japan.
The numbers adjacent to this symbol indicate the year and the month of manufacture.

UDI Unique Device Identifier (UDI)
The GS1 DataMatrix and plain-text for UDI are printed adjacent to this symbol.

MD Medical Device.

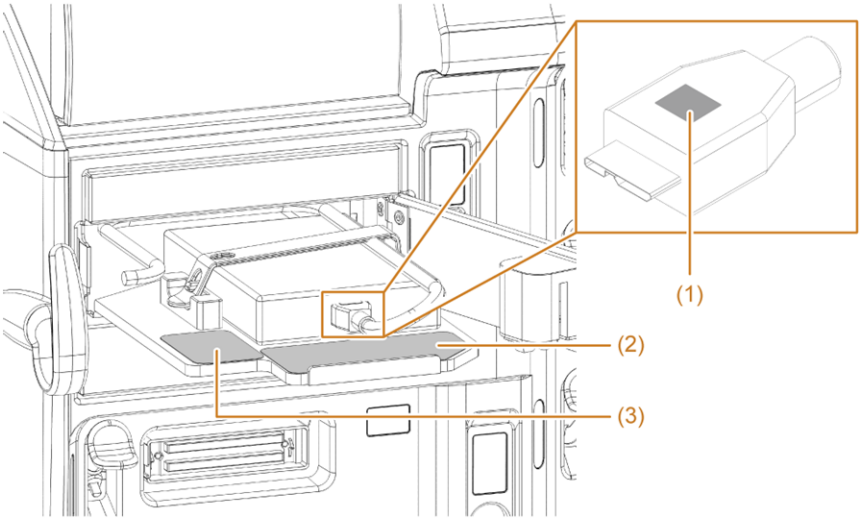
(8)

Equipotential terminal.

(9)

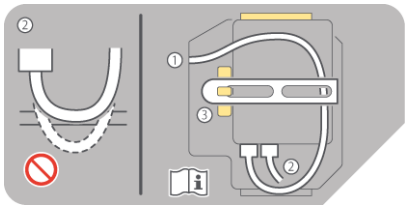
EC REP Name and address of the Authorized representative in the European Community.

Importer.



(1) 

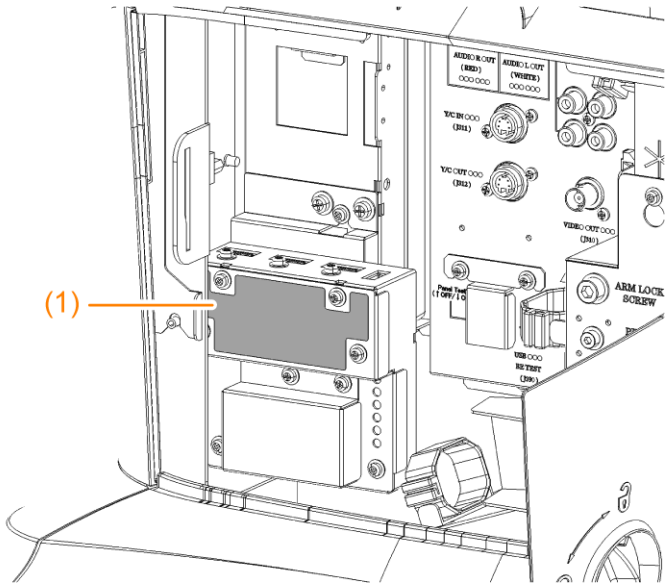
Connection terminal for the USB cable.

(2) 

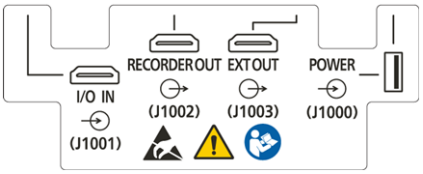
- Do not use the system if the cable extends to outside the drawer tray. Ignoring this instruction might result in a load being applied to the cable and damage to the cable.
- This label shows how to secure the external HDD.

(3) 

- Do not strongly pull on the cable with extensive force. Ignoring this instruction might result in a load being applied to the cable and damage to the cable.
- This label shows how to secure the strap.



(1)



- HDMI, USB connector.
- Ask our service staff if you need to connect to other devices or to switch the images to be output.
  Ignoring this instruction might result in electric shock, burns, or other injuries to the patient or examiner, and damage to this system.
- Only use devices that conform to the international standards for medical electrical equipment.
  Ignoring this instruction might result in electric shock, burns, or other injuries to the patient or examiner, and damage to this system.

1.2 Precautions concerning acoustic output

The human body is composed of soft tissue, water, bone, and other tissue. Ultrasound energy is absorbed, reflected, dispersed, and attenuated as it reaches deep into the body. Tissues behind fluids, which cause less attenuation, will receive relatively large amounts of ultrasound energy.
The biological effects caused by exposure to ultrasound energy involve thermal effects such as heating and mechanical effects such as vibration and cavitation.
It is necessary to be aware of the biological effects of heat in the vicinity of tissues, such as bone, that readily convert ultrasound energy into heat. In particular, in the case of a fetus whose bones are in the process of forming, almost all of the ultrasound energy passes through the amniotic fluid without being attenuated. That raises the danger from heating. Even in a fetus whose bones have not yet formed, the cells are active. This means there is a possibility of growth being affected, even when the rise in temperature is slight.
The biological effects of heat depend on the magnitude of ultrasound energy, and also increases depending on length of irradiation.
On the other hand, mechanical effects, such as vibration and cavitation, that have the potential to damage cells can occur when the acoustic pressure of the ultrasound exceeds a certain threshold.
You can reduce the risk of tissue damage by interrupting the emission of ultrasound energy before it reaches the level at which tissue damage occurs.
To this end, it is necessary to understand system functions, become familiar with operation methods, and understand the parameters that affect acoustic output.
You can reduce the biological effects of heat not only by lowering the transmitter voltage, but also by reducing the irradiation time. Therefore, we recommend that you always freeze the image as soon as you have obtained the necessary diagnostic information. Since the mechanical effects on the body can be reduced by lowering the transmitter voltage or raising the frequency, we recommend that you use the minimum voltage and an appropriate frequency to obtain the necessary diagnostic information.

⚠ CAUTION

Scan the patient only for the minimum length of time necessary to perform the examination, and at the lowest possible output.
Fetal ultrasound scans must be conducted with particular care.
High output and prolonged exposure to ultrasonic waves can adversely affect the internal tissue of the patient.

The display can be switched to show a thermal index suitable for the target region.
The thermal index provides indices for 3 types of body tissue models. It is essential to use a thermal index suitable to the body tissue that is being analyzed.
For details on how to switch between different types of thermal index, see the separate manual "Basic Operations".

- Soft tissue or a fetus in the first trimester of pregnancy: TIS
- Soft tissue with bone behind it, or a fetus in the second or third trimester of pregnancy: TIB
- Tissue with bone near the surface (for example, a cranial examination): TIC

Do not use Doppler modes for routine fetal examinations.
Doppler modes are to be used in fetal examinations only when clinically indicated, such as in known or suspected high-risk pregnancies.

1.3 Precautions concerning the probes

The handling, cleaning, disinfecting, sterilizing, and storing of probes vary depending on the type of probe. For details, see the documentation for the probe. The following precautions are common to all probes.

1.3.1 Handling precautions

Probes are precision devices. Take care not to damage them.

- Caution in handling
  - Store the probe in the probe holder when not in use.
  - Probes are sensitive to shock. Take care not to drop them. Hold the probe firmly, especially when it is coated with ultrasound gel or other lubricants.
  - Do not bend the probe cables. Make sure they do not become entangled with other parts or in the casters.
  - Connect the probe as described in this manual and in the documentation for the probe.

  NOTE: Adjust the probe cable so that it does not catch on the USB flash drive.
- In order to prevent burns or injuries
  - Before use, coat the probe with an appropriate amount of ultrasound gel.

- Do not apply unreasonable force when moving a probe that is inserted into a body cavity.
- When a probe is not in use during an examination, freeze the image as standard practice.

- In order to prevent infection
  - Keep the probes clean and dry.
    Do not let ultrasound gel, water or any other foreign matter adhere to the probes.
  - Clean, disinfect and sterilize the probes as required.
  - The probe holder is not sterilized.
    Do not store sterilized probes.
  - Dispose of probes used for patients with Creutzfeldt-Jakob disease.
    Ignoring this instruction might result in infections in the patient or examiner. Our ultrasound probes are not compatible with any disinfection or sterilization method for Creutzfeldt-Jakob disease.

(1) Precautions concerning a probe with a built-in temperature sensor

Some probes have built-in temperature sensor at their tips. This sensor monitors the surface temperature of the probe tip to avoid damage to tissues from excessive temperature elevation. The sensor is also affected by the core body temperature of the patient.

(a) Precautions when using MXS1

If the surface temperature of the probe tip exceeds 37.0ºC, the current temperature is displayed at the top of the screen as "TTE T: 37.0°C".
NOTE: Based on the temperature detected by the thermistor, control the temperature so that it does not exceed the displayed temperature, taking into account errors of ±0.9 ºC. The following messages are displayed.

Surface temperature of the probe tip and messages

Surface temperature of the probe tip (guide)	Messages	Status
If the temperature exceeds 41ºC	The temperature is higher than 41.0°C.	An assist message is displayed.
If the temperature exceeds 43ºC	TTE Thermal limit. Auto Cooling Mode in Progress.	A beep sounds. The ultrasonic image freezes and the panel switch light turns off. *1 In this case, you cannot operate the following: • Panel switch • Touch panel menus

*1
If the surface temperature of the probe tip falls below 40.5ºC, this message is cleared, and Freeze is turned on. The examination can now be resumed.

Other messages

Messages	Status
TTE fatal error (5) Discontinue examination and turn the system off.	The temperature sensor might be broken. Stop using the system immediately and contact our office.
Do not remove the probe without freezing the image.	Freeze the image before removing the probe.

(2) Precautions Concerning Mechanical Probes

When performing a 4D scan with a high volume rate, the images freeze automatically after a while.

1.3.2 Cautions related to puncture operations

NOTE: For details about puncture operations, see the documentation for the probe and the puncture adapter.

- Inspection prior to use
  - Perform inspections by following the descriptions in the documentation supplied with the probe and the puncture adapter.
    Do not use any probe or puncture adapter for which an abnormality has been detected.
  - Use a water tank to make sure that the needle echo matches the puncture guide line.
  - Make sure that the probe, puncture adapter, and puncture needle have been sterilized.
  - Make sure that the puncturing needle is not bent.
- Cautions when installing the puncture adapter
  - Attach the probe to the puncture adapter by following the descriptions in the documentation supplied with the probe and the puncture adapter.
- Cautions related to puncture operations
  - A puncture operation must be performed only by a skilled doctor.
  - While performing a puncture operation, ensure that the system is functioning normally, and that the patient is not abnormally affected.
  - If anything unusual occurs during a puncture operation, immediately remove the puncture needle from the patient, and cease using the probe.
    If the patient's condition appears abnormal, provide immediate and appropriate medical treatment.
- To avoid puncturing an area that is not intended to be punctured
  - The puncture guide line should be used as a guide for the direction of puncture needle insertion.

- Make sure that the puncture adapter model name on the screen in the puncture guide line display matches the puncture adapter you are currently using.
  When using puncture adapters that have multiple guidelines, confirm that the insertion angle of the puncture adapter is identical to the angle set on the screen.
- Be sure to check the needle echo before using the probe.
  If the acoustic velocity of tissues is not 1,540 m/s, the angles of the puncture guide line and the needle echo might not match.
- Check the safety of any puncture path that is not visible on the display.
  There might be blood vessels or other organs in the puncture path that are not visible on the screen.
- Verify the location of the puncture needle by using the needle echo that is displayed on the screen.
- When performing a puncture operation with a 4D probe connected, turn off 4D mode and switch to B mode.
  During a 4D operation, the puncture guide line is not displayed.
- Do not perform a puncture operation while assist lines are displayed.
  The assist lines do not indicate accurate positional information. Do not use them as puncture guide lines.
- When performing a puncture operation when a CC41R probe, a CL4416R probe, or a C41L47RP probe is connected, check the puncture guide line in the L (longitudinal) image.
  When performing a puncture operation when a CC41R probe is connected, a cross section line is displayed in the L (longitudinal) image and in the T (transverse) image. This line represents the approximate location where the two cross sections intersect.
  Take care not to confuse the puncture guide line with the cross section line, as doing so might cause injury to the patient.
  For details, see the documentation for the probe.
- During Real-time Virtual Sonography, do not perform puncture operations while looking only at the virtual image.
  The virtual image is only to be used as a guide for ultrasonic diagnosis.

1.4 Precautions for use in conjunction with drugs

- Using the system with an ultrasound contrast agent
  When using an ultrasound contrast agent, use an agent that has been approved for the purpose. Refer to the documentation for the ultrasound contrast agent for information about its handling, storage, and disposal.

⚠ CAUTION

When using ultrasound contrast agents during examinations, pay constant attention to the patient's condition.
In a perfusion examination using ultrasound contrast agent, the pulse rhythm of the heart might be disturbed even if the mechanical index (MI) is within the standard value.
Handle the ultrasound contrast agent according to its documentation.

- Use in conjunction with general drugs
  If you perform an ultrasound examination after having the patient ingest a general pharmaceutical, the ultrasound might affect the pharmacological effect of the pharmaceutical. Before using a general pharmaceutical, carefully read the accompanying documentation for using the pharmaceutical, as well as any cautionary notes.

1.5 Precautions for use with other medical devices

Thoroughly read the documentation for any other medical devices that to be used with this system, and use those devices correctly.

- Connection to the equipotential terminal
  Use the equipotential terminal on the back of the system to eliminate differences in potential between the system and other objects, such as other medical devices or the bed.
- Use in conjunction with high-frequency devices
  High-frequency surgical devices might be used to deliberately apply an electromagnetic field or electric current of high frequency to the patient.
  This system is not equipped with any means to protect the patient from burn injury from any of its parts when it is used in conjunction with a high-frequency surgical device.
- Simultaneous use with a defibrillator
  This system might not be used in combination with a defibrillator.
  When using a defibrillator, keep the probes and the electrodes for physiological signals at a safe distance from the patient.
  When using a transesophageal probe, remove the probe from the patient's body cavity before using the defibrillator.
- Use with an external physiological signal monitor
  Only physiological monitors that conform to the international standards for medical electrical equipment can be used with this system. Do not use a physiological monitor if the supplied documentation prohibits its use together with the Diagnostic Ultrasound System or similar medical electronic devices.
- Use with a medical monitor for displaying images (medical monitor) or a robotic surgical unit for surgical procedures
  To use a medical monitor or a robotic surgical unit for surgical procedures together with this system, use the optional HDMI-monitor connection unit.

⚠ CAUTION

Perform safety checks on the other medical devices to be used with this system, and do not use them if they are faulty.
Ignoring this instruction might result in electric shock or damage to the system. If the system does not operate normally, immediately stop using it.

When using this system together with other medical electrical devices, position the system and its cables (probe cables, ECG cables, I/O cables, etc.) as far away as possible from other medical electrical devices and their cables.
Note that electromagnetic interference generated by this system might prevent the normal operation of other medical electrical devices that are used together with the system. If such interference occurs, immediately stop using the devices together.

If you use a medical monitor or robotic surgical unit for surgical procedures, the monitor or unit must conform to the international standards for medical electrical equipment.
Ignoring this instruction might result in electric shock, burns, or other injuries to the patient or examiner, and damage to this system. When connecting a device that does not conform to the international standards for medical electrical equipment, make sure that the system is electrically isolated by using an optical cable.

Make sure that objects such as probes, the operator's hands, and puncture adapters are not in the path of high-frequency current.
Ignoring this instruction might result in damage to the probe or burns to the patient, examiner, or operator. High frequencies might impair the ability of this system to produce images.
Operate this system with caution, paying attention to the positions of the counter electrode plates and the connecting cord relative to the probe.

Do not apply excessive force when inserting electrode needles.
The insulation coating of the electrode needle might be damaged, or the patient, examiner, or operator might receive burns.
Use an attachment capable of suitable puncture guidance, and operate the attachment carefully.

Do not use this system together with a defibrillator.
Ignoring this instruction might result in poor system performance or a malfunction.

1.6 Precautions for maintaining electromagnetic compatibility

Electromagnetic compatibility refers to the ability of the system to maintain the necessary level of performance and safety within the specified electromagnetic environment, without causing electromagnetic interference that cannot be tolerated by other devices in that environment.

Medical electrical devices, transmitters, radio and TV antennas, and similar devices generate electromagnetic interference and might be affected by such interference. Because the Diagnostic Ultrasound System receives radio frequency signals (ultrasonic wave signals on radio frequencies), it can also receive electromagnetic interference emitted by electromagnetic energy sources. If the system receives such interference, effects can include noise in images, disruption of physiological signals, and abnormal sounds from speakers.
To prevent electromagnetic interference and maintain electromagnetic compatibility, observe all precautions regarding I) the electromagnetic environment, II) use of portable or mobile RF communications devices and III) use with other medical electrical devices.
NOTE: A doctor must consider whether artifacts caused by electromagnetic interference could adversely affect images or diagnoses.

1. Electromagnetic environment
   This system is a medical electrical device intended for use in hospitals and other healthcare facilities.
   Install the system according to the installation conditions and "Guidelines for electromagnetic compatibility" in this manual.

   - Position this system as far away as possible from radio receivers, televisions, and their cables and antennas. Note that electromagnetic radiation from this system might cause electromagnetic interference to radio receivers, televisions, etc.
   - If the system is to be used near a motor (such as an elevator or a pump room), a power transmission line, or a wireless system that generates electromagnetic interference, the system must be electromagnetically shielded.

2. Using portable or mobile RF communications devices
   Do not use wireless devices (such as mobile phones, PHS devices, or radio transceivers) in the vicinity (within 30 cm) of this system. This system might be affected by portable or mobile RF communications devices.

3. Using the system with other medical electrical devices
   If this system receives electromagnetic interference, effects can include noise in images, disruption of physiological signals, and abnormal sounds from the speakers. Position this system and its cables (such as probe cables, ECG cables, and I/O cables) as far away as possible from other devices used with the system and the cables attached to those devices.

   - Make sure that electromagnetic interference from the medical electrical devices the system is used with does not affect the system and that electromagnetic interference from the system does not affect the other devices.
   - If the system is used together with high-frequency devices, the electromagnetic interference they generate might distort images displayed on this system.
   - Immediately stop using any medical electrical devices that do not operate normally when exposed to the electromagnetic interference generated by the system. Do not use the system together with such devices.

   Use connection cables that satisfy the following conditions.

No.	Name	Presence of shielding	Max. cable length
1	LAN	Yes	10 m

⚠ WARNING

Do not use portable RF communications devices (including peripheral devices such as antenna cables and external antennas) within a 30-cm radius of any part of the device.
Doing so might worsen device performance.

Avoid using the device near other devices or placing this device on another device.
The device might not operate correctly. If you need to use the device near other devices or to place this device on another device, make sure that this device and the other devices operate normally.

Do not use accessories other than those designated by the manufacturer or accessories, transducers, and cables other than those provided by the manufacturer.
Failure to do so could cause electromagnetic emissions to increase or electromagnetic immunity to decrease, and could result in malfunction of the device.

Reference information

7.1 Guidelines for electromagnetic compatibility on page 206

1.7 Precautions concerning power plugs and power cables

⚠ CAUTION

Plug the system's power cord directly into a hospital-grade power outlet.
Do not connect the system to an extension cable, or to a branched circuit. Ignoring this instruction might result in fire or electric shock.

Do not damage, alter, or break the power cable. Do not place heavy objects on power cables. Do not twist power cords, bundle them, pull them, or bend them excessively.
A damaged power cable might result in short circuits or electric shock. Stop using the system immediately if the power cable or power plug is damaged. For details regarding system repair, please contact our office.

If the power cable or power plug are found to be damaged or deformed, unplug the power plug from the hospital-grade outlet immediately, and stop using the system.
Continued use of a damaged power cable can cause poor contact, leading to fire.
For details regarding system repair, please contact our office.

Unplug the power plug from the hospital-grade outlet periodically and clean it.
Not maintaining the cable properly might result in short circuits or electric shock.
Wipe away any dust and moisture on the power plug with a dry cloth.

If the system will not be used for an extended period of time, unplug the power plug from the hospital-grade outlet, and gently coil the power cable to store it.
Note that turning the system's power switch to Off does not disconnect the system from the power supply.

1.8 Precautions concerning Real-time Virtual Sonography

Read this section before using Real-time Virtual Sonography.
For Real-time Virtual Sonography, operations can only be performed by a doctor or other qualified person with the appropriate education.

⚠ WARNING

Do not attempt to repair the magnetic sensor or transmitter. Do not disassemble the system. Do not modify the system.
Ignoring these instructions might result in electric shocks or accidents.
Ask us to handle any repairs.

Only use cleaned, disinfected, and sterilized attachments and magnetic sensors.
Clean, disinfect, and sterilize attachments and magnetic sensors after use.
Ignoring this instruction might result in infections in the patient or examiner.
For details on cleaning, disinfecting, and sterilizing the probe and its attachments, see the documentation supplied with the probe.

E-Field Simulator can only be operated by a qualified person with the appropriate education who has thoroughly read the documentation included with the medical device to be used.
An E-Field image displayed by E-Field Simulator indicates the electric field based on a simulation and does not necessarily match the actual cauterization range. If you use E-Field images incorrectly, you might be unable to obtain the expected results to support treatment.

⚠ CAUTION

Do not bring transmitters near patients who use devices (such as pacemakers) that can be adversely affected by magnetic fields.
The device emits a magnetic field, which might interfere with the operation of devices such as pacemakers.

Do not estimate a puncture path by looking only at a virtual image or virtual puncture guide line.
If you ignore this instruction, the puncture direction might be inaccurate. Determine the puncture path while looking at the ultrasound image.

Do not connect anything other than a magnetic sensor to the control unit.
The software will not function correctly if anything other than a magnetic sensor is connected.

Attach the magnetic sensor and its attachments correctly according to the documentation supplied with the probe.
The software will not function correctly if the magnetic sensor is attached in an incorrect orientation.

Connect the magnetic sensors for probes, needle tracking, and body motion tracking to the appropriate connectors.
The software will not function correctly if the connectors are not connected properly.

Do not apply a strong physical shock to, or place a heavy load on, the magnetic sensor and the transmitter.
If you ignore this instruction, the magnetic sensor or transmitter might break. If these devices receive a strong physical shock, please contact our office.

Numerical values displayed on the screen are only for reference.
The distance between the electrode centers of the needle markers displayed on the virtual image does not necessarily match the actual length.

During the examination, check to make sure there are no discrepancies in the positions between the ultrasound image and the virtual image.
If you ignore this instruction, the patient might be injured.
Factors such as patient body movements (such as breathing) and the environment (metal in the bed) might reduce the accuracy of detected positions, resulting in inaccuracies in the positional relationships between the ultrasound image and the virtual image.
Inaccuracies in the positional relationships between the ultrasound image and the virtual image lead to inaccuracies in the positional relationships between the registered needle marker and the ultrasound image. Check to make sure that the ultrasound image and the virtual image match, and then register the needle marker.

Correctly match the positions of the base image and the parts image.
If you ignore this instruction, the patient might be injured.

When using an RVS flexible stand, do not place the transmitter on the patient.
If you do not ensure that the upper and lower sliders of the arm stopper are closed, the arm might slip down, injuring the patient.

When using an RVS flexible stand, adjust the transmitter height, and then securely close the upper and lower sliders of the arm stopper.
If you ignore this instruction, the arm might slip down. The upper and lower sliders of the arm stopper are for preventing the arm from slipping down.

Do not apply a strong physical shock to, or place a heavy load on, the RVS flexible stand and the arm part of the RVS Onboard arm.
If you ignore this instruction, damage might occur and the patient or examiner might be injured. The transmitter, the RVS flexible stand, or the RVS Onboard arm might also be damaged.

When moving the RVS flexible stand up or down, make sure that you fold the arm. At this time, do not lift or move the transmitter or its surroundings.
If you ignore this instruction, damage might occur and the patient or examiner might be injured.

Be careful when handling the RVS flexible stand and the arm part of the RVS Onboard arm.
Coming in contact with the transmitter or arm might result in injury.
Your hands or fingers might get caught in the gap in the moving part of the arm.
Contact with the transmitter or the arm might damage the peripheral devices, the RVS flexible stand, or the RVS Onboard arm.

Do not stretch the transmitter cable.
If you ignore this instruction, the transmitter cable might become disconnected.

When using an RVS flexible stand, be careful when routing the transmitter cable.
The transmitter cable might catch on the RVS flexible stand, causing the stand to fall over.

When moving the main unit or the RVS flexible stand, be careful not to let the transmitter or the arm hit any object.
Coming in contact with the transmitter or arm might result in injury.
The transmitter, arm, or peripheral equipment might be damaged.

When moving the main unit or RVS flexible stand, fold and lock the arm.
Ignoring this instruction might result in the arm moving and causing injury.
Also note that the arm might move and come in contact with the transmitter or peripheral equipment, causing damage.

Do not lean against the RVS flexible stand, the RVS Onboard arm, or the tray. Also, do not forcefully push the RVS flexible stand when the casters are locked.
If you ignore this instruction, the RVS flexible stand might fall over, which might cause injuries or damage the arm or tray.

Do not sit on the RVS flexible stand, the RVS Onboard arm, or the tray.
If you ignore this instruction, the RVS flexible stand might fall over, which might cause injuries or damage the arm or tray.

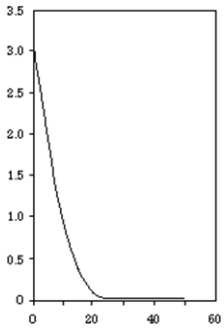
NOTICE

Remove metallic objects (watches, necklaces, etc.) before the examination.
Such objects might cause the virtual image to flicker.

The transmitter must not be touched during the examination.
Doing so might cause noise in the ultrasound image.

1.8.1 Precautions concerning for electromagnetic compatibility

- Influence of electromagnetic waves on the magnetic sensor unit
  The performance of the magnetic sensor unit might be affected by proximity to a device emitting electromagnetic waves or a steel bed, or if a large object made of iron or steel is within a 1-m radius of the transmitter or magnetic sensor of the magnetic sensor unit.
- Influence of electromagnetic waves from the magnetic sensor unit
  The magnetic field grows weaker with increasing distance from (the transmitter of) the magnetic sensor unit.



Relationship between the distance from the transmitter and magnetic field strength
The vertical axis denotes the magnetic field strength (mT), and the horizontal axis denotes the distance from the transmitter (cm).

Potentially affected devices, by maximum magnetic field strength

Maximum Magnetic Field Strength	Potentially Affected Devices
2.0 mT	Motors and cameras
1.5 mT	Monochrome monitors
1.0 mT	Mechanical clocks or watches, credit cards, magnetic tape, and magnetic computer disks
0.5 mT	Pacemakers and CT scanners
0.3 mT	Diagnostic Ultrasound System
0.1 mT	Color monitors, image intensifiers, microscopes, and scintillation cameras
0.05 mT	Emission CT systems

NOTE: Use magnetic sensors as close to the transmitter as possible, within the effective range (20 to 76 cm). Moving the magnetic sensor away from the transmitter might cause distortions in the virtual image. The position might also become less accurate.
NOTE: The receiving frequency (frequency band) of the magnetic sensor is 240 Hz.
NOTE: The transmitter emits a pulsed magnetic field with a frequency of 240 Hz.

2

Product summary

2.1 Indications for Use

This instrument is intended to be used by qualified medical doctors and any qualified persons by national law for performing tomographic and hemodynamics diagnoses in the following parts of the human body:

- Abdominal
- Cardiac
- Obstetrics/Gynecology
- Superficial organs
- Urology
- Intraoperative

Do not use it for any applications other than those stated above. Refer to the documentation accompanying probes or this manual, for information on probe usage applications.

⚠ WARNING

DO NOT use this system to perform ultrasound examinations of the eyes.
The acoustic output power of the system exceeds the upper ophthalmologic limit stipulated in the U.S. FDA standards.

⚠ CAUTION

Connect the probe in accordance with this manual or the documentation for the probe.
Ignoring this instruction might result in injuries or burns to the patient or operator, and other accidents. Do not use the probes for purposes other than those specified in this manual.

2.2 Operating principles

A sequence of multiple transducers from among the total available transducers form a block that almost simultaneously transmits and receive ultrasound waves. The ultrasound waves generated by each transducer combine to form one ultrasound wave with the same effect as a single ultrasound beam emitted from the center of these transducers. When the first beam has been sent and received, the transducers adjacent to the transducers in the first block start sending and receiving ultrasound waves to form a second ultrasound beam. The center of the second ultrasound beam is shifted one transducer away from the center of the first ultrasound beam. In this manner, different blocks of transducers are used each time to create multiple ultrasound beams with slightly different centers, thus forming a scan plane The beams can also be focused together by adding a time difference to the transmission and reception that creates the beams, to join them in an acoustic focus. Continuously setting the focal time difference according to the ultrasonic wave arrival time allows you to obtain a beam for which the focus is joined as a whole.

This system can also correct the time difference between ultrasonic waves that arrive at different times due to differences in acoustic velocity among patients or diagnostic regions. The ultrasound beams obtained in this way are converted to video signals by the digital scanning converter, and are displayed on the viewing monitor.
This system can use the following image display modes either individually or in combination.

- B mode is a display mode in which a tomographic image is formed by using multiple ultrasound beams as explained above. During the process of creating the tomographic image, adaptive filter processing (HI REZ) that modifies the characteristics of each echo filter is used to produce a clear image.
- M mode is a display mode of ultrasound beams received sequentially and repeatedly on the screen from the same direction. This mode displays the changes with time of echoes reflected in one direction from the interior of the patient's body.
- There are two D (Doppler) modes: PW Doppler mode and CW Doppler mode. PW Doppler mode displays bloodstream information consecutively at a sample point that is detected by pulsed Doppler sonography. CW Doppler mode displays bloodstream information continuously in the single-direction ultrasound beam that is detected by the CW Doppler method.
- The Color Doppler mode receives ultrasound waves from the same direction and detects any changes that occur over time to identify three types of bloodstream information: direction, speed, and inconsistencies. Colors are then used to display that information as an overlay on B mode or M mode. With this system, you can use Color Flow Mode, Power Doppler Mode, High-Resolution Power Doppler (eFlow) Mode, or Detective Flow Imaging (DFI) Mode for the color Doppler mode, according to your needs.

The 5 methods of electronic scanning are as follows.

- Linear Scanning Method:
  When this method is used, the ultrasound beam from the ultrasound probe is emitted in a straight line (linearly) and draws a tomographic image of the patient.
- Convex Scanning Method:
  When this method is used, the ultrasound beam from the ultrasound probe is emitted radially and draws a tomographic image of the patient.
- Sector Scanning Method:
  When this method is used, the ultrasound beam from the ultrasound probe is emitted in a fan shape (sector) and draws a tomographic image of the patient.
- Radial Scanning Method:
  When this method is used, the ultrasound beam from the ultrasound probe is emitted in a 360° arc (radially) and draws a tomographic image of the patient.
- Trapezoidal Scanning Method:
  When this method is used, the ultrasound beam from the ultrasound probe is emitted radially without regard to the form of the probe head and draws a tomographic image of the patient.

2.3 Specifications

Overview

Electronic scanning method	Linear Scanning Method Convex Scanning Method Sector Scanning Method Radial Scanning Method Trapezoidal Scanning Method
Connectible probes	Electronic probes: 4 Independent probes: 1 (optional)
Diagnostic field	Abdominal digestive organs, obstetrics, gynecology, circulatory organs, urinary organs, superficial organs (mammary glands, thyroid (gland), peripheral blood vessels)
Application to patients	Body surface Inside body cavities Intra-operative (not for direct application to the heart, central circulatory organs, or central nervous system)
Users	Doctors or other qualified persons
External dimensions	Width: 550 mm ±10% Depth: 900 mm ±10% Height: 1220 mm ±10% to 1695 mm ±10%
Weight	136 kg ±10% (main unit only), 162 kg ±10% (with all options included)
Service life	7 years

Display modes

B mode
M mode
D mode
Color Doppler mode

Viewing monitor

Monitor size	
Organic EL monitor (OLED)	22.0 inch, 16:9 aspect ratio 1920 x 1080 Full HD
Liquid crystal display (LCD)	23.0 inch, 16:9 aspect ratio 1920 x 1080 Full HD
Liquid crystal display (LCD)	21.5 inch, 16.9 aspect ratio 1920 x 1080 Full HD

Monitor movement	
Organic EL monitor (OLED) 22.0 inch	Rotation: Depending on the structure of the arm joint, the monitor can rotate a reverse 160°. Tilt: 60° upward and 10° downward Up and down movement: 224 mm Forward and backward movement: 225 mm

Liquid crystal display (LCD) 23.0 inch	Rotation: Depending on the structure of the arm joint, the monitor can rotate a reverse 160°. Tilt: 60° upward and 20° downward Up and down movement: 169 mm
Liquid crystal display (LCD) 21.5 inch	Rotation: Arm joint mechanism makes possible 160° turns. Tilt: 30° upward and 10° downward Up and down movement: 90 mm

Input/output specifications

Video output	DVI-D Y/C Composite Digital video with HDMI connector (when the optional HDMI monitor connection unit is attached)
Video input	DVI-D Y/C
Audio input/output	Audio L/R
Network	LAN
USB	USB 2.0 x 5 USB 3.0 x 1 (when the optional Security box is attached: USB 3.0 x 2)

Recorder

Monochrome printer
Color printer
Video recorder

Basic functions

Gain adjustment	TGC: 8 levels LGC: 8 levels B gain: 80 dB variable M gain: B Gain: ±30 dB variable Doppler gain: 60 dB variable Color Doppler gain: 63.5 dB variable
Focus	Send focus: Up to 16 levels (Up to 4 levels for multi-level focus) Receive focus: Continuous dynamic focus
Probe change frequency	Up to 5 frequencies (depending on the probe) Tissue harmonics: Up to 15 frequencies (depending on the probe)
Ultrasound output power	0% to 100% (Can be set for each mode)
Scanning angle	100% to 25% Maximum scanning angle: 360°
Display depth of field	7.5 mm to 400 mm
Zoom	PAN Zoom (read zoom) HI Zoom (write zoom)

B, M image processing	Dynamic range: 40 dB to 90 dB Smooth/Enhance: 17 levels (including Off) Persistence: 8 levels (including Off) PRF (B): 3 levels AGC: 8 levels (including Off) Graymap: 10 types Speed of sound correction: Available Adaptive imaging: NNR (4 levels, 4 types), the HI REZ function (8 levels) γ curve: 4 types Color map (B, M): 15 types can be assigned
Compound Functions	Available
Trapezoidal Display Functions	Available
B Steer Display Functions	Available

M mode Image Display Functions

Display method	During Real-Time display: Moving Bar Method During Cine Play: Scroll Method
Sweep speed	7 levels (40.0 mm/s to 300.0 mm/s)
Arbitrary Direction M mode Image Display Functions	Available

Pulse Doppler Functions

Analysis method	FFT method
Velocity range	±802.08 cm/s to ±1.26 cm/s
Wall filter	12 levels
Sampler volume width	0.5 mm to 20.0 mm
Sweep speed	7 levels (40.0 mm/s to 300.0 mm/s)
Dual-gate Doppler Functions	Available

Continuous Wave Doppler (CW) Functions

Analysis method	FFT method
Velocity range	±802.08 cm/s to ±25.07 cm/s
Wall filter	12 levels
Sweep speed	7 levels (40.0 mm/s to 300.0 mm/s)
Doppler-γ	8 levels

Tissue Doppler (TDI) Functions

TDI (Flow) Color Display Method	Display direction and time with red and blue coloring
Reference frequency	1 frequency

TD (PW)

Analysis method	FFT method
Velocity range	±802.08 cm/s to ±1.26 cm/s
Sampler volume width	0.5 mm to 20.0 mm
Sweep speed	7 levels (40.0 mm/s to 300.0 mm/s)
Dual-gate Doppler Functions	Available

Color Doppler Functions

Color display method	Velocity / velocity dispersion display Velocity display Power display Directional power Doppler display High-resolution power Doppler display
Color Maps	A maximum of 15 types can be assigned.
Velocity range	±458.33 cm/s to ±0.63 cm/s
Wall filter	6 levels

Presets

Application Functions	Maximum of 25 types per probe (maximum number of types that can be registered by the user: 100)
Preset Group Loading Functions	Maximum of 4 types per application, preset: QSS
Region Data Setting Functions	Maximum of 13 types per diagnostic field (maximum number of types that can be registered by the user: 9)

Cine Memory Functions

Playback Mode	Continuous play (B) Frame-by-frame forward and rewind play (B, M/D) Automatic heartbeat detection play (B)

Measurement Functions

Basic measurement functions	
Applied measurement functions	Abdominal Measurements Urological Measurement Cardiology Measurement Vascular Measurements Obstetric Measurements Gynecological Measurements Superficial Organ Measurements

Measurement accuracy

2D Measurement	Accuracy
Distance in B-mode	±3%
Area by trace in B-mode	±6%
Circumference by trace in B-mode	±6%
Area by ellipses in B-mode	±5%
Volume in B-mode	±7%
Angle	±7%

M-mode Measurement	Accuracy
Excursion in M-mode	±3%
Time in M-mode	±3%
Velocity in M-mode	±10%

Doppler Measurement	Accuracy
Velocity in Doppler mode	±10%
Acceleration in Doppler mode	±11%
Time in Doppler mode	±3%
Heart rate	±1 BPM or 5%

2.3.1 Power supply conditions

Power supply voltage	100 V to 120 V, 200 V to 240 V
Electrical power frequency	50/60 Hz
Power consumption	900 VA or less

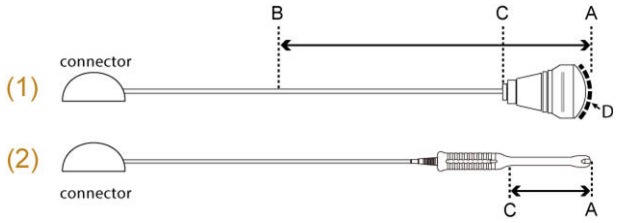
2.3.2 Ambient conditions

Environment	Operating Conditions	Storage conditions or transport conditions (when packed)
Ambient Temperature	+10°C to +40°C When RVS (optional) is used: +10°C to +30°C	-10°C to +50°C
Relative Humidity	30% to 75% (no condensation)	10% to 90% (no condensation or freezing)
Atmospheric pressure	700 hPa to 1,060 hPa	700 hPa to 1,060 hPa
Altitude	No more than 3,000 m	-

2.3.3 Device classifications

- Protection against electrical shock: Class I and ME equipment

- Protection against electrical shock (applied parts): Type BF applied parts
  - Probes and scanner
    Refer to the following diagrams (for the probe or scanner) and the following table for details about applied parts and parts that are handled as applied parts.



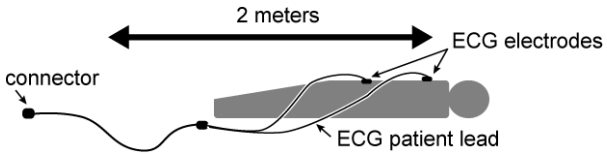
(1) Example of probes for surface or intraoperative use.

(2) Example of body cavity probes.

Probe Application	Applied part (direct patient contact)	Parts handled as applied parts	Length between B and C
Body surface	Ultrasonic irradiation area (D)	Between A and B	100 cm
Intra-operative	Ultrasonic irradiation area (D)	Between A and B	20 cm
Endocavity	Between A and C	Between A and C	-

  - ECG, PCG, Pulse
    Parts within a 2 m range from a physiological signal sensor are regarded as applied parts. (See the figure below.)

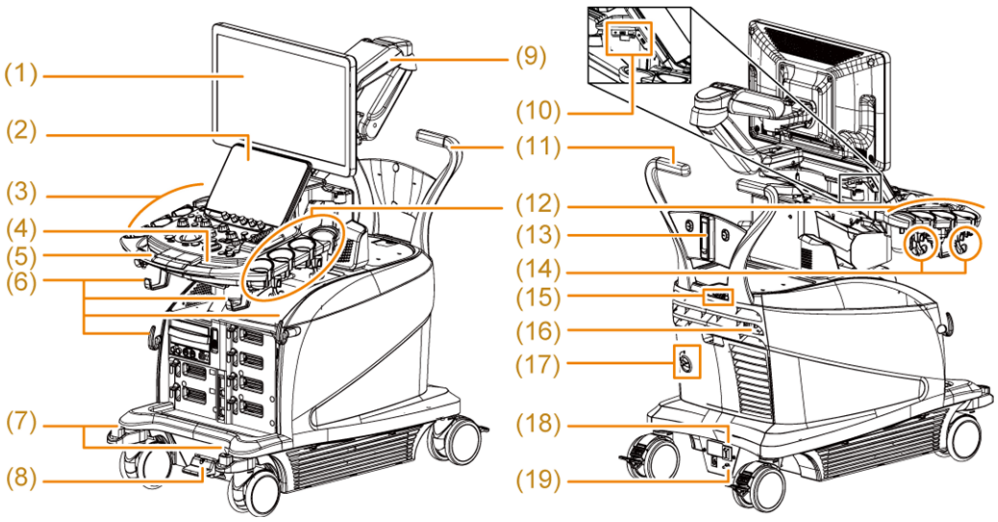
Example: ECG



- Protection against electrical shock (defibrillation-proof applied parts): This system is not suitable for use with defibrillation-proof applied parts.
- Protection against penetration by water or particulate substances
  - Probe applied part: IPX7 (rated for brief immersion in water)
  - Foot switch
    MP-2819*: IPX7 (rated for brief immersion in water)
    MP-2345B: IPX8 (rated for continuous immersion in water)
  - Other Details: IPX0 (ordinary equipment)
- Level of safety for use in air and flammable anesthetic gas, or in oxygen/nitrous oxide and flammable anesthetic gas.
  - This system is not suitable for use in a mixture of air and flammable anesthetic gas, or in a mixture of oxygen or nitrous oxide and flammable anesthetic gas.
- Operation mode: Continuous operation

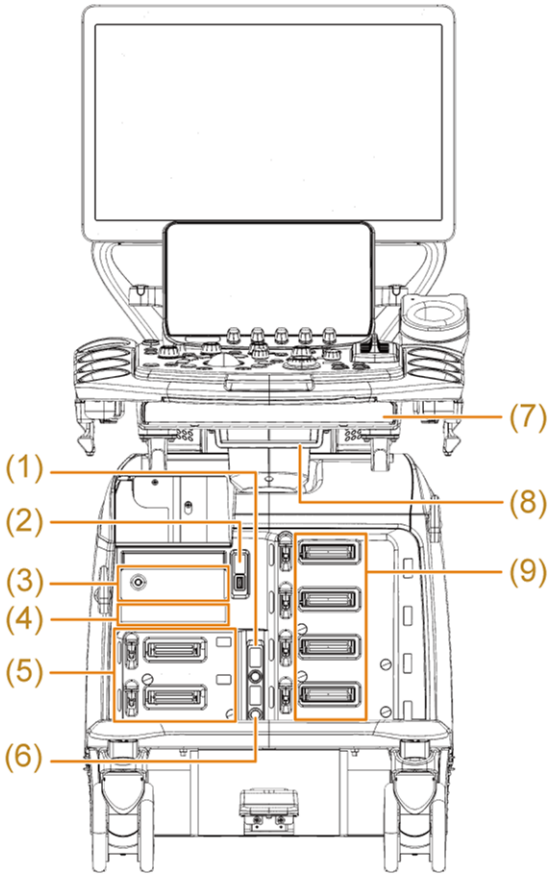
2.4 Part names

1. Device appearance



(1)	Viewing monitor	(9)	Monitor arm
(2)	Touch panel	(10)	USB (2.0) connectors (x 3)
(3)	Operation panel	(11)	Handle
(4)	Handle lever for the operation panel	(12)	Probe holder
(5)	Operation panel handle	(13)	Hook (for the power cable, or for foot switch MP-2819*)
(6)	Cable hook	(14)	Cable hook
(7)	Caster lock	(15)	Cable clip (for the power cable)
(8)	Operation panel height adjustment pedal	(16)	LAN cable connector
		(17)	Lock lever (on the back of the system)
		(18)	Breaker
		(19)	Equipotential terminal

2. Device appearance (Front)



(1) Independent probe connecting unit (optional)

(2) USB (3.0) connector

(3) One of the following: RVS control unit (optional), Security box (optional), or storage drawer

(4) Physiological signal unit (optional)

(5) Dummy connectors*1

(6) Foot switch connector

(7) Alphanumeric keyboard (optional)

(8) ECG clip bar

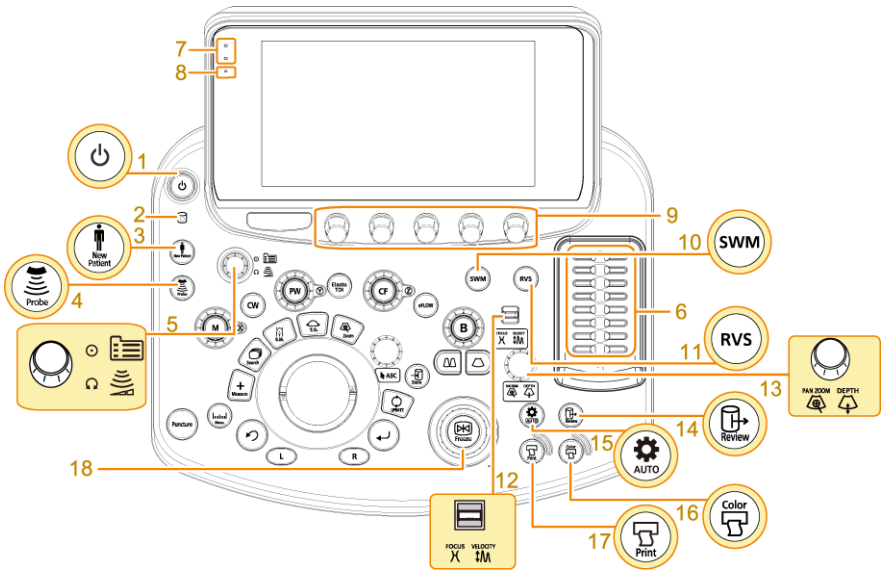
(9) Probe connector
Connectors 1 to 4 (from top to bottom)

*1.

This is a connector for temporarily fastening a probe. No image is displayed, even if a probe is connected to this connector.

3. Operation panel

NOTE: The push button-type integrated rotary encoders have the key name on top and the rotary encoder names on the bottom. Information on how to use the rotary encoders is provided at the end of this section.



Operation panel diagram

(1) [Power] key

(2) Disk access lamp

(3) [New Patient] key

(4) [Probe/Preset] key

(5) [Menu] key
[Acoustic Power] rotary encoder

(6) [TGC] sliders

(7) Optical sensor

(8) Status indication lamp
While the power is on: The lamp blinks white. When a strong force is applied to the operation panel: The lamp blinks orange.

(9) Multi rotary encoders

(10) [SWM] key

(11) [RVS] key

(12) [FOCUS/VELOCITY] paddle switch

(13) [PAN ZOOM] key
[PAN ZOOM/DEPTH] rotary encoder

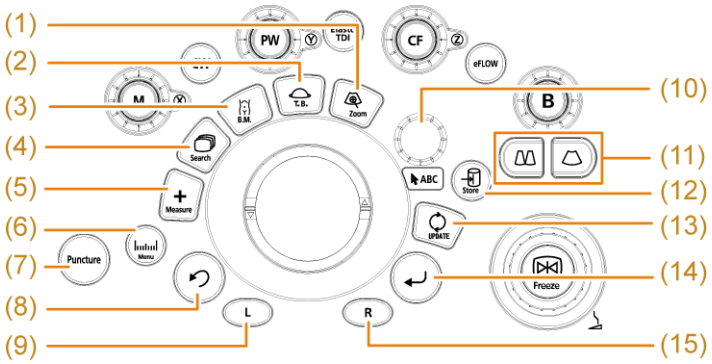
(14) [Review] key

(15) [Auto-optimizer] key

(16) [Color Printer] key

(17) [Print] key

(18) [Freeze] key
[Freeze] rotary encoder



Operation panel (Trackball Area)

(1) [HI Zoom] key

(2) [Trackball Function] key
Referred to as the [T.B.F.] key in this manual.

(3) [Body Mark] key

(4) [Cine Search] key

(5) [Caliper] key

(6) [Measurement] key

(7) [Puncture] key

(8) [UNDO] key

(9) [L] key

(10) [Pointer] key
[Pointer] rotary encoder

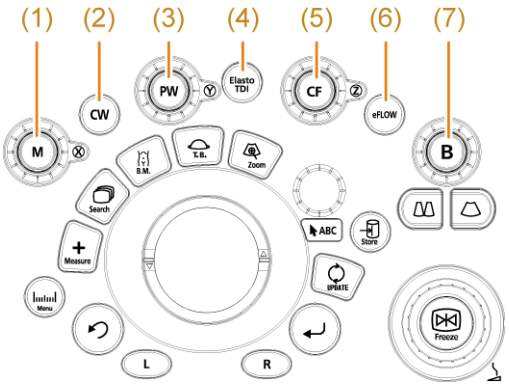
(11) [Single] key, [Dual] key

(12) [Store] key

(13) [Update] key

(14) [Enter] key

(15) [R] key



(1) [M] key
[M] rotary encoder

(2) [CW] key

(3) [PW] key
[PW] rotary encoder

(4) [Elasto/TDI] key

(5) [CF] key
[CF] rotary encoder

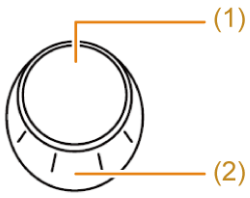
(6) [eFLOW] key

(7) [B] key
[B] rotary encoder

Push button-type integrated rotary encoder

The key name is provided on the top, and the rotary encoder names are provided on the bottom.

Operate the rotary encoders as follows:



(1) Keys
Press to operate.

(2) Rotary encoder
Turn to operate.

3

Setup before use

3.1 Installing and moving the system

3.1.1 Shutdown

This section describes the procedure for shutting down the system and disconnecting the power supply.
You can set procedures for shutting down the system by using presets. Use the preset ([SystemPreset] > [General] > [Common1] > [Shut down] > [Power Button Behavior]). The factory default setting is [Shutdown].
For details, see the separate manual "Basic Operations".

⚠ CAUTION

Do not pull the power plug out of the hospital-grade outlet while the machine is shutting down or restarting.
Ignoring this instruction might result in damage to the system.
Make sure the system has completely shut down before you remove the power plug from the hospital-grade outlet.

Procedure

1. Press the [Power] key to shut down the system.
   When the Auto Image Delete confirmation screen is displayed
   To delete the data, select [Delete].
   To cancel without deleting the data, select [Cancel].
   NOTE: The screen is not displayed if the number of files to be deleted is zero.
   When Power Button Behavior is set to [Selectable]
   "Shutdown Tools." appears on the touch panel. Select a shutdown method from the following options.

Options	Description
Shutdown	Completely shuts down the system and turns the power off.
Hibernation	Puts the system into hibernation and turns the power off. The next time the power is turned on, startup from [Shutdown] will take less time. NOTE: This status is maintained even if you remove the power plug from the hospital-grade outlet. NOTE: When [Hibernation] is selected, if the system is used for over 50 hours (including time in hibernation), [Shutdown] is selected. The next system startup will take the same time as an ordinary startup.
Return	Returns the system to the state it was in before the [Power] key was pressed.

2. If the touch panel displays "Task in progress. System will power off after handle it.", from the options below select a method for turning off the power.
   NOTE: This message appears when the system has not completed all processing.

Options	Description
Return	Returns the system to the state it was in before the [Power] key was pressed.
Yes	Turns off the power after the remaining jobs are complete.

Options	Description
Ignore	Shuts the system down without waiting for remaining jobs to be completed. If you select this option, the following message is displayed: "Task in progress. Power supply off forcibly without handle it. Are you really all right?" Select [Yes] to shut down the system. The system will immediately shut down without deleting images even if you select [Delete] in the Auto Image Delete confirmation screen.

3. If the message "** more seconds until system is power off." is displayed, the system will shut down when the indicated number of seconds elapse.

   - The system shuts down when the number of seconds set in [SystemPreset] > [General] > [Common1] > [Shut down] > [Power Off Waiting Time(s)] elapse.
   - If [Power off immediately] is selected, the system will be shut down immediately without waiting for the set time to elapse.
   - If [Return] is selected, the system will return to step 1 or step 2.

   When the Auto Image Delete is in process screen is displayed
   The message disappears when the data is deleted.
   If you want to interrupt the processing that deletes the data, press the [Enter] key.

3.1.2 Turning the Power Off

CAUTION

If you observe anything abnormal in the system, probes, peripherals, or options, turn the power off immediately, and stop using the system.
Ignoring these instructions might result in injury to the patient or operator, or other unexpected accidents. Stop using the system and contact our office.

Procedure

1. Shut down the system.
2. Disconnect the power plug from the hospital-grade outlet.

Reference information

3.1.1 Shutdown on page 60

3.1.3 Moving the system

CAUTION

Take care not to bump the system or its probes against other equipment, walls, columns or doors in passages when moving it to a different location. Take great care when moving the system a long distance, or on a slope or steps.
Take great care when moving the system over steps or uneven surfaces.
Ignoring this instruction might result in the probe falling from the probe holder and being damaged.
In addition, the system hard disk and data might be damaged. As a result, the system might become unusable.
The system is heavy, and it might not stop once it starts moving.
Ignoring these instructions might result in damage to the surrounding equipment, the walls, or the system, or the system might tip over, which could lead to injury.
In addition, the exterior of the system could be damaged, exposing users to the risk of electric shock.

Before moving the system, remove any USB-connected media[*1].
Ignoring this instruction might result in vibrations when you move the system. Such vibrations might damage the USB-connected media and data.

Do not apply excessive force to the system.
Ignoring this instruction might result in the system tipping over and causing injury or damage.

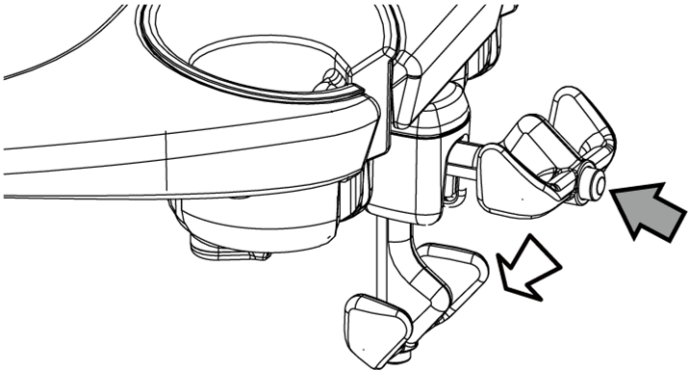
Keep the system away from moisture when moving it.
Ignoring this instruction might result in short circuits or electric shock.

*1.
Exclude the USB-connected media of an external HDD attached to the Security box.

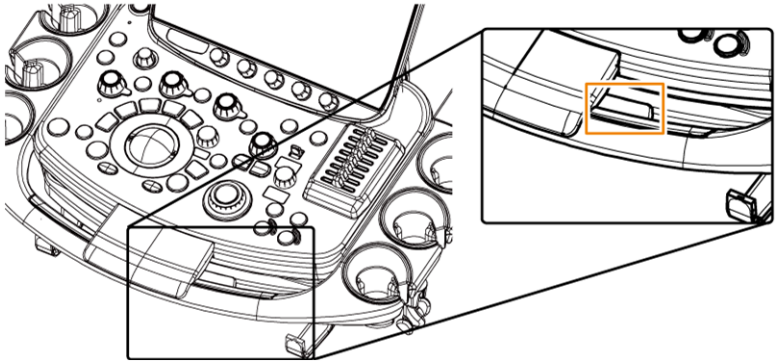
Procedure

1. Shut down the system and prepare it for movement.
   NOTE: When starting the system, first connect the power plug to a hospital grade outlet.
   Power cable
   Unplug the power plug from the hospital-grade outlet, gently coil the power cable, and place the cable on the power cable clip on the back of the system.
   Unsecured objects
   Detach peripherals and other connected equipment from the system. Every peripheral that comes with a case should be returned to its case after use. Peripherals without a case should be wrapped in a soft cloth or similar material.
   Probe
   Place the probe cable on the cable hook, and adjust the length to prevent the cable from being caught between the casters.
   If transvaginal or transrectal probe holders are used, store the probes horizontally. Do not store them vertically.
   Secured peripheral devices
   Remove USB flash drives.
   If you are using an alphanumeric keyboard, push the keyboard until it clicks, and then use the lock lever on the back of the operation panel to secure the keyboard.

2. If the cable hook next to the probe holder is lifted up, lower the cable hook.
   To lower the cable hook, press the button.



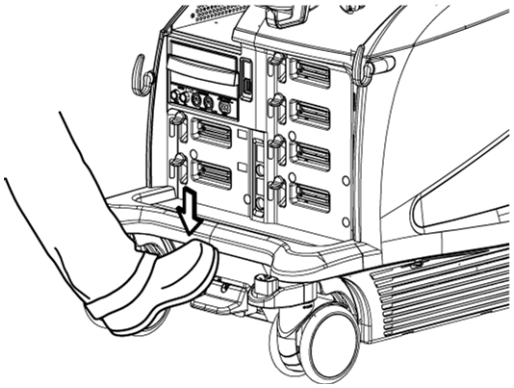
3. Turn the operation panel so it is facing the front.
   Hold the handle lever for the operation panel, and turn the operation panel toward the front.
   If you let go of the lever, the orientation of the operation panel is maintained.



Lever position

NOTE: The operation panel might rotate even if you are not holding the handle lever for the operation panel. This is a design feature, and is not a malfunction. If the operation panel is rotated repeatedly without holding the handle lever for the operation panel, the operation panel's ability to maintain its orientation might change. Make sure that you hold the lever when rotating the operation panel.

4. Move the operation panel to the lowest possible position.
   While holding the operation panel handle and pressing the operation panel height adjustment pedal with your foot, press down on the operation panel.



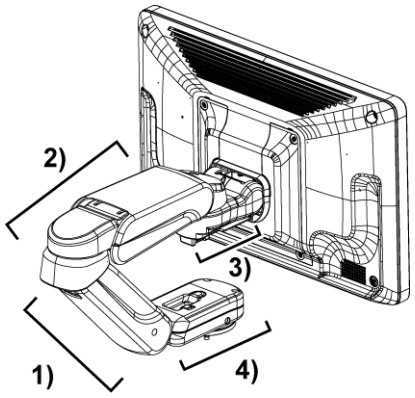
Press the operation panel height adjustment pedal

NOTE: If the probe cable slackens, adjust it to prevent it from being caught between the casters.

5. Fix the monitor in place.
   NOTE: This prevents the monitor from moving while the system is moved.
   <u>For a 22-inch monitor (OLED):</u>

   a. Push Arm #1 to the rear.

   b. Adjust Arm #3 and the base so that they are parallel.

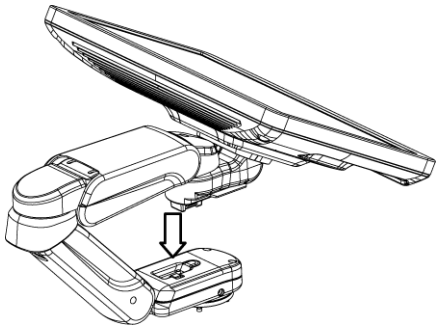


1) Arm #1
2) Arm #2
3) Arm #3
4) Base

   c. Tilt the monitor so that it faces upward.

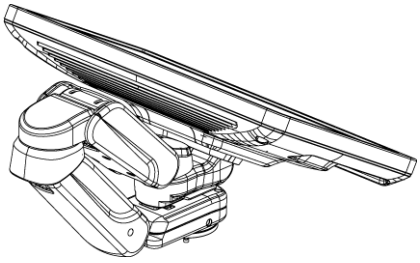
   d. Lower Arm #2, and insert a lock block.

      → Arm #3 locks. When this happens, you will hear a click.



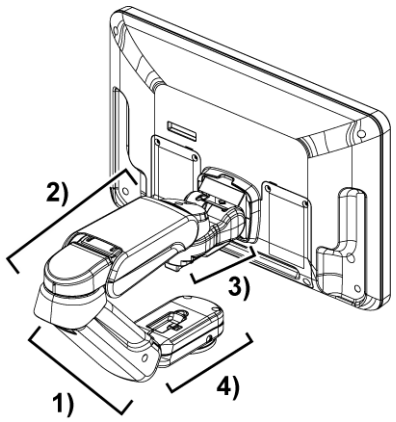
   e. Rotate Arm #1 so that it appears straight when viewed from the front of the system.

      → Arm #1 locks. When this happens, you will hear a click.



   <u>For a 23-inch monitor (LCD):</u>

a. Adjust Arm #3 and the base so that they are parallel.

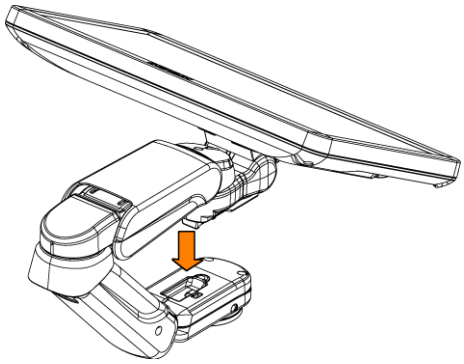


1) Arm #1
2) Arm #2
3) Arm #3
4) Base

b. Tilt the monitor so that it faces upward.

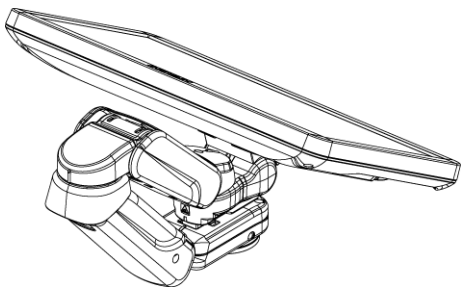
c. Lower Arm #2, and insert a lock block.

→ Arm #3 locks. When this happens, you will hear a click.



d. Rotate Arm #1 so that it appears straight when viewed from the front of the system.

→ Arm #1 locks. When this happens, you will hear a click.

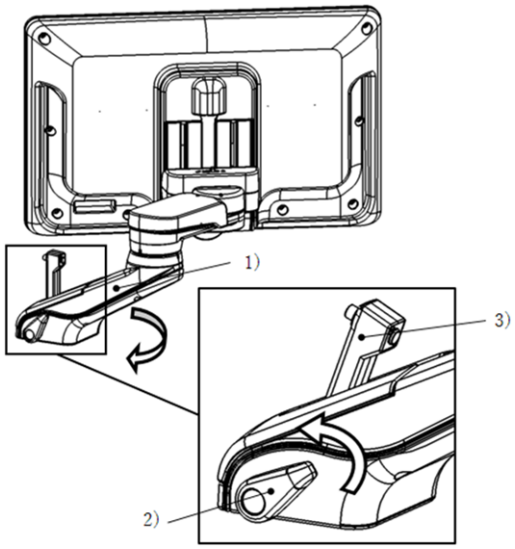


<u>For a 21.5-inch monitor (LCD) :</u>

a. Turn the lock lever while pressing it to lift the lock arm.

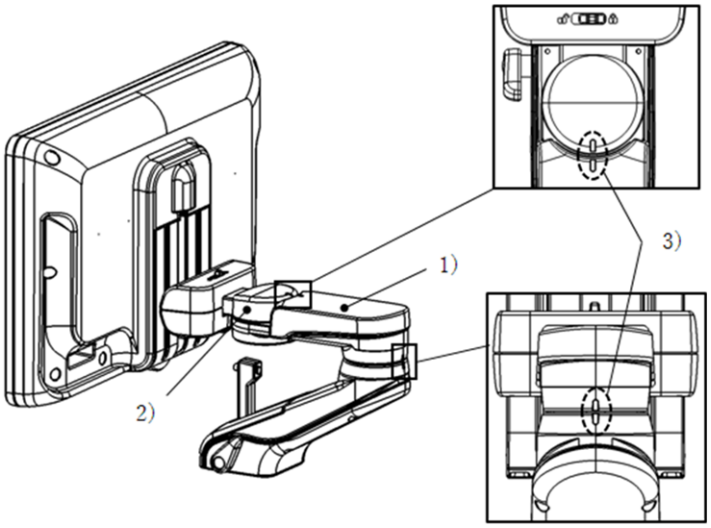
b. Face Arm #1 to the front.

→ Arm #1 is locked.



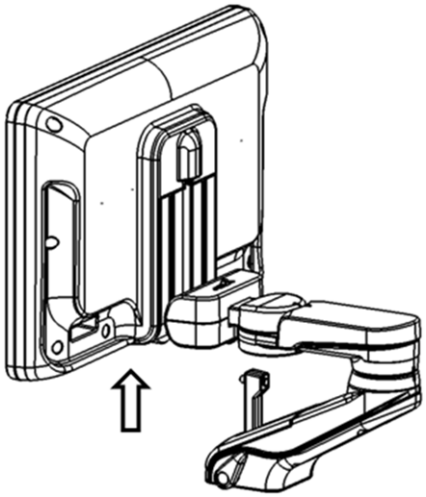
1) Arm #1
2) Lock lever
3) Lock arm

c. Align the position of Arm #2 and Arm #3 to the position of the mark so that they are parallel to Arm #1.

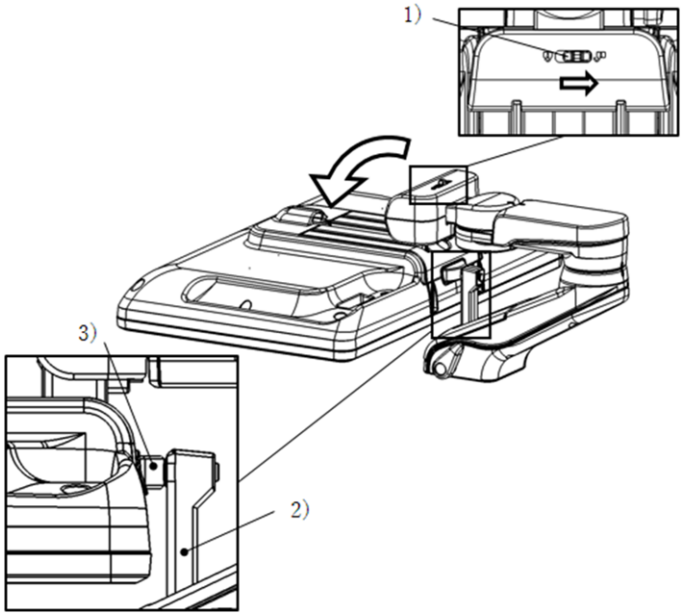


1) Arm #2
2) Arm #3
3) Mark

d. Move the monitor to the highest position.

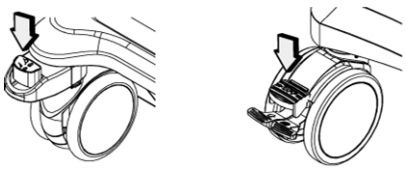


e. Slide the tilt lever to tilt the monitor forward.
If the position of the lock is not aligned with the position of lock receiver:
Adjust the position of the monitor so that the pin on the lock arm is inserted into the lock receiver.



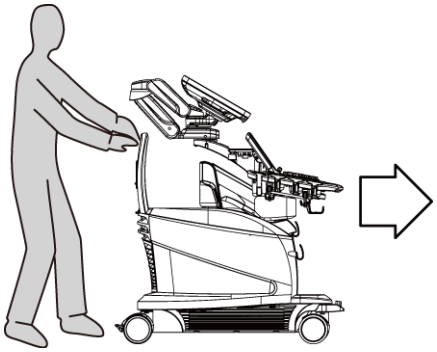
1) Tilt lever
2) Lock arm
3) Lock receiver

6. Unlock the casters.
Depress the caster locks for the front wheels. Depress the lock release pedals for the rear wheels.



Left: Front wheel
Right: Rear wheel
Step in the direction of the arrow to release the casters.

7. To move the system, firmly grasp the handle on the back of the system with both hands.
   NOTE: Grasp the handle on the back of the system, not the operation panel or its handle.
   NOTE: Do not put anything on top of the monitor.



When transporting the system over long distances or up and down slopes:
Depress the swing lock pedals for the rear wheels in the direction of the arrow.

3.1.4 Installing the system

DANGER

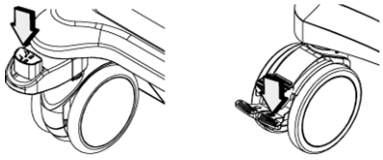
Do not use this system in a flammable atmosphere.
Use of this system in a flammable atmosphere might cause an explosion.

CAUTION

When using this system together with other medical electrical devices, position the system and its cables (probe cables, ECG cables, I/O cables, etc.) as far away as possible from other medical electrical devices and their cables.
Note that electromagnetic interference generated by this system might prevent the normal operation of other medical electrical devices that are used together with the system. If such interference occurs, immediately stop using the devices together.

Procedure

1. At the installation location, make fine adjustments to the position of the system.
2. Once the position and orientation of the system are fixed, lock the casters.
   Depress the caster locks for the front wheels. Depress the lock pedals for the rear wheels.



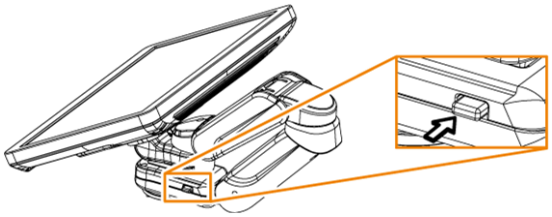
Left: Front wheel (system is locked)
Right: Rear wheel (system is locked in the forward direction)
Step in the direction of the arrow to lock the casters.

NOTE: Place a cloth over the system if it is to be stored for an extended period of time.

3. Connect the power plug directly into a hospital-grade power outlet.

   → The status indication lamp next to the touch panel blinks white twice.

4. Release the monitor lock.



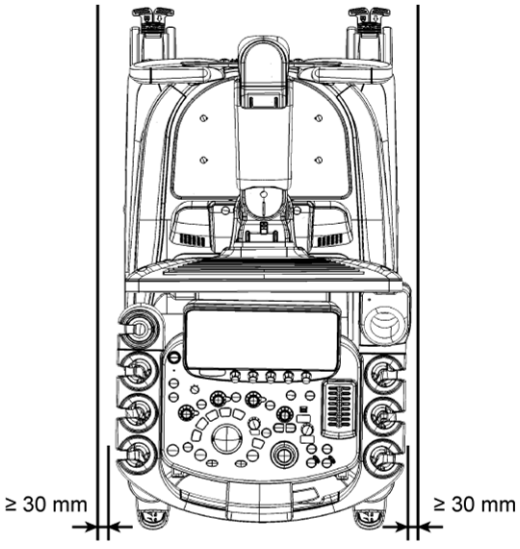
   a. Lift the arm while pressing the monitor unlock button.

   b. Move the monitor to an upright position.

3.1.5 Installation conditions

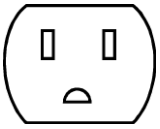
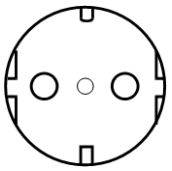
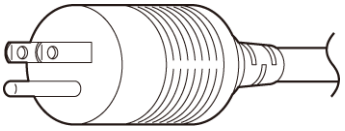
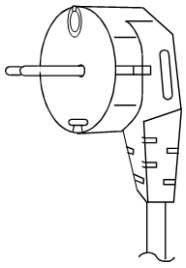
Set up the system in a location that meets the following conditions.

- Open space is required around the system so that heat does not build up inside the system during use.



- Install the system in a location where its power plug can be plugged directly into a hospital-grade outlet, and where it can be moved quickly when the power is disconnected.
  To disconnect the power, remove the power plug from the hospital-grade outlet.

- Install the system in a position where slight movements of the system will not cause the power plug to be pulled out of the outlet.
- Install the system in a location that satisfies the operating conditions described in "Ambient conditions" in this manual.
- The figure shows the type of hospital-grade outlets the power plug can be connected to.

	CP-121 (for 100 V to 120 V)	CP-117 or CP-128 (for 200 V to 240 V)
Power outlet configuration		
Power plug configuration		
Cable length	3.5 meter	3.0 meter

3.2 Connecting a probe

CAUTION

Do not allow sterilized probes to come into contact with the system (including the probe holder).
The system is not intended to be sterilized.

Store transvaginal and transrectal probes in the following probe holders:

- Probe holders with special adapters
- Transvaginal/transrectal probe holders with attached adapters for transvaginal/transrectal probe holders

If a probe other than a transvaginal or transrectal probe is placed in one of these probe holders, the probe might fall out and be damaged.

Do not place a probe with a probe cover horizontally in a transvaginal/ transrectal probe holder.
Ignoring this instruction might result in infection. Remove the cover from a probe before placing it in a probe holder.

NOTICE

Push the probe straight into the probe connector, and make sure that it locks in place.
An incorrectly connected probe will not deliver clear images. Such a connection could also damage the system and the probe.

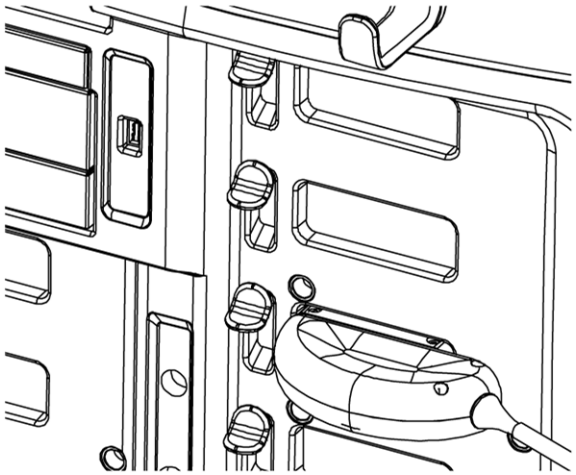
Prior confirmation

For the probe, check the following:

- Make sure the probe is supported by the system.
- Make sure that the probe pins are not bent.

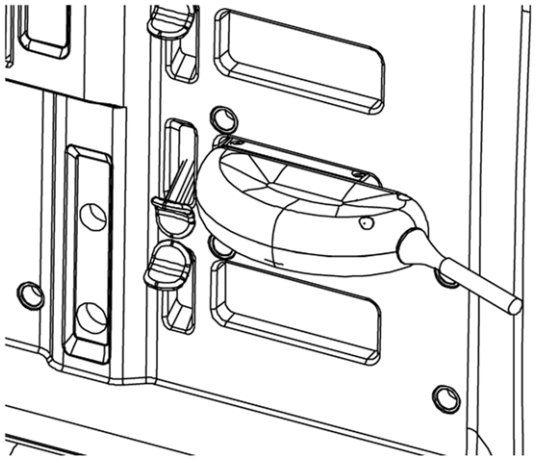
Procedure

1. Shut down or freeze the system.
2. Plug the probe connector into a probe socket.



Example of connecting an electronic probe

3. Hold the probe connector to prevent it from falling while lowering the lock lever on the left side of the socket.



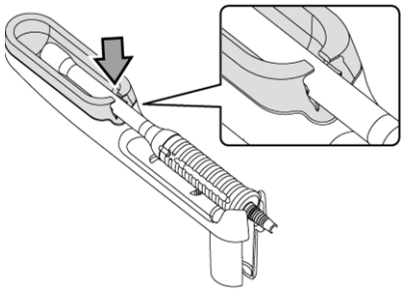
NOTE: Make sure the probe is secured.

4. Store the probe in the probe holder.
NOTE: Place independent probes in probe holders with dedicated adapters attached.

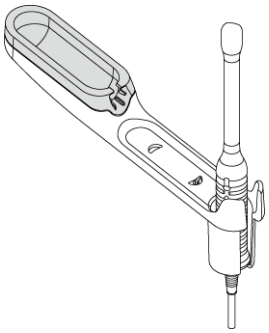
Storing probes in transvaginal and transrectal probe holders (option)

Remove the probe covers from transvaginal/transrectal probes before storing them.

When storing the probe horizontally, press it firmly all the way into the probe adapter.



Example of storing a probe horizontally in a transvaginal/transrectal probe holder
The gray part in the figure represents the transvaginal/transrectal probe holder adapter.



Example of storing a probe vertically in a transvaginal/transrectal probe holder

5. Adjust the probe cable to a convenient length.
   NOTE: Use the cable hook on the cart to adjust the position and length of the probe cable so that it does not touch the floor.
   NOTE: Adjust the probe cable so that it does not catch on the USB flash drive.

3.2.1 Connecting an independent probe

To connect independent probes, the optional part EU-9187 is required.

Procedure

1. Pull the connector locking ring on the probe towards the cable and align the pin with the pin hole in the probe connector on the independent probe.
2. Insert the probe connector in the independent probe connector.

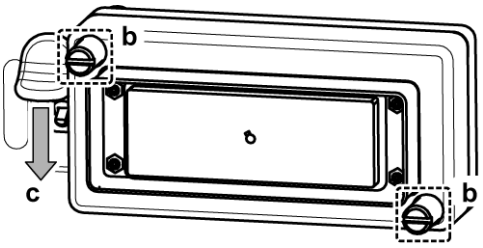
3.2.2 Connecting a probe with a lock lever

To connect a probe with a lock lever to the system, a junction box is required.
For details about target probes, see the probe specifications.

Procedure

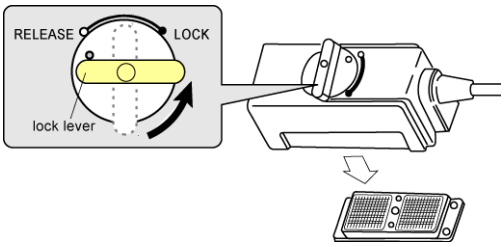
1. Connect a junction box to probe connector 3 or probe connector 4.
   a. Plug the junction box into the probe connector.

b. Secure the junction box and probe connector by securing two knurled screws.

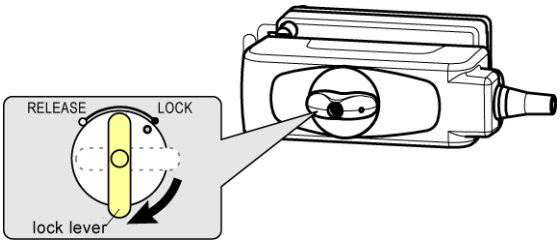


c. Lower the lock lever on the left side of the probe connector.

2. Turn the lock lever of the probe counterclockwise, and align it with the RELEASE position.
3. Plug the probe into the connected junction box.



4. Turn the lock lever of the probe clockwise, and align it with the LOCK position.



If the lock lever does not turn smoothly
Re-insert the probe.

5. Adjust the probe cable to the appropriate length.
Adjust the position and length of the probe cable by using cable hooks so that the cable does not become tangled with the USB flash memory strap or chafe against the floor.
NOTE: When stepping on the operation panel height adjustment lever, be careful not to bump into the junction box or the probe.

3.2.3 Disconnecting a probe

Use the following procedure to remove probes that do not have a lock lever.

Procedure

1. Shut down the system. Alternatively, freeze the image.
2. Hold the probe to prevent it from falling while raising the lock lever on the left side of the socket.
3. Disconnect the probe connector from the probe socket.

(1) Removing a probe with a lock lever

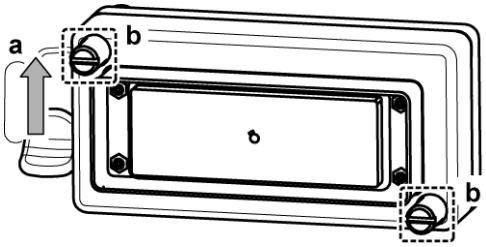
Procedure

1. Shut down the system. Alternatively, freeze the image.
2. Turn the lock lever of the probe counterclockwise, and align it with the RELEASE position.
3. Remove the probe from the junction box.

(2) Removing the junction box

Procedure

1. Remove the junction box from the probe connector.



   a. Raise the lock lever on the left side of the probe connector.
   b. Turn and remove the two knurled screws.
   c. Remove the junction box from the probe connector.

NOTICE

Do not remove the knurled screws themselves from the junction box.
Before moving the system, remove the probes.
Do not remove the junction box while the probes are still connected.

(3) Detaching an independent probe

Procedure

1. Shut down the system. Alternatively, freeze the image.
2. Pull the connector locking ring on the probe towards the cable and disconnect it from the independent probe socket.

3.2.4 Adjusting the positions of the cable hooks

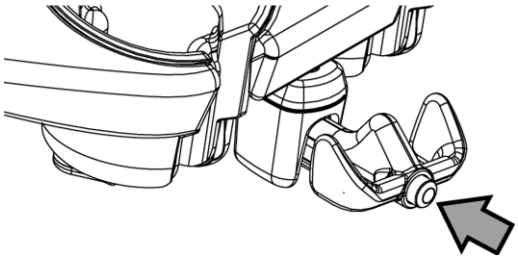
To adjust the position and length of the probe cable, use the cable hooks.
You can adjust the position or angle of each cable hook in accordance with the environment in which the equipment is used.
This section describes the following cable hooks:

- The cable hook next to the probe holder
- The flexible hook (optional)

- The flexible hanger (optional)

(1) The cable hook next to the probe holder

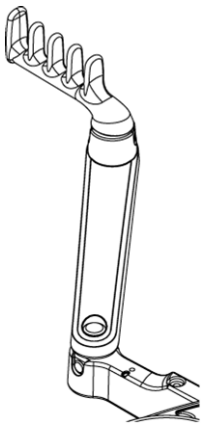
You can change the angle of the cable hook next to the probe holder in accordance with the environment in which the equipment is used.
Press the button, and while pressing it, raise or lower the cable hook.



Position of the button

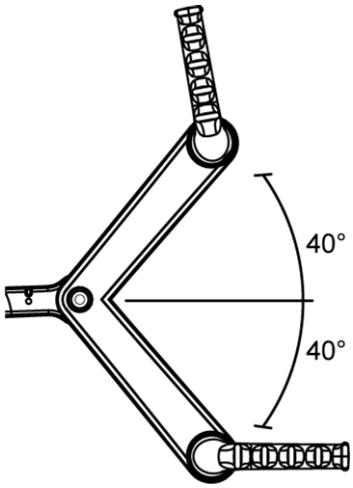
(2) The flexible hook

Adjust the position of the flexible hook (optional) in accordance with the environment in which the equipment is used.



The flexible hook

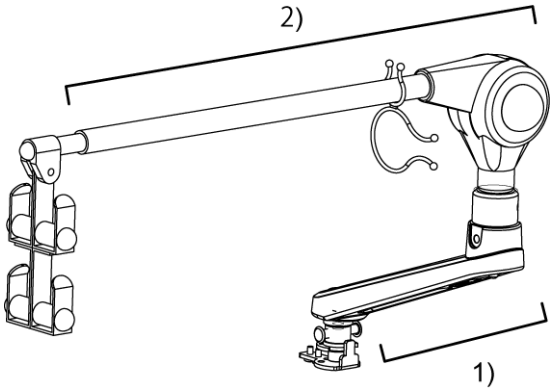
Movable range of the flexible hook



Horizontal: 80°

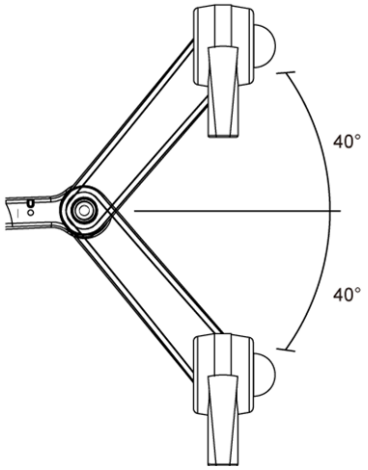
(3) The flexible hanger

Adjust the position and height of the flexible hanger (optional) in accordance with the environment in which the equipment is used.



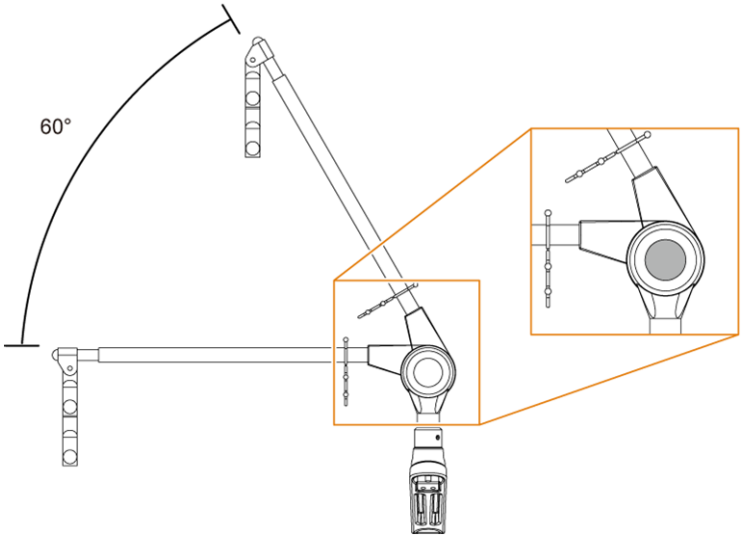
The flexible hanger

Movable range of part 1)

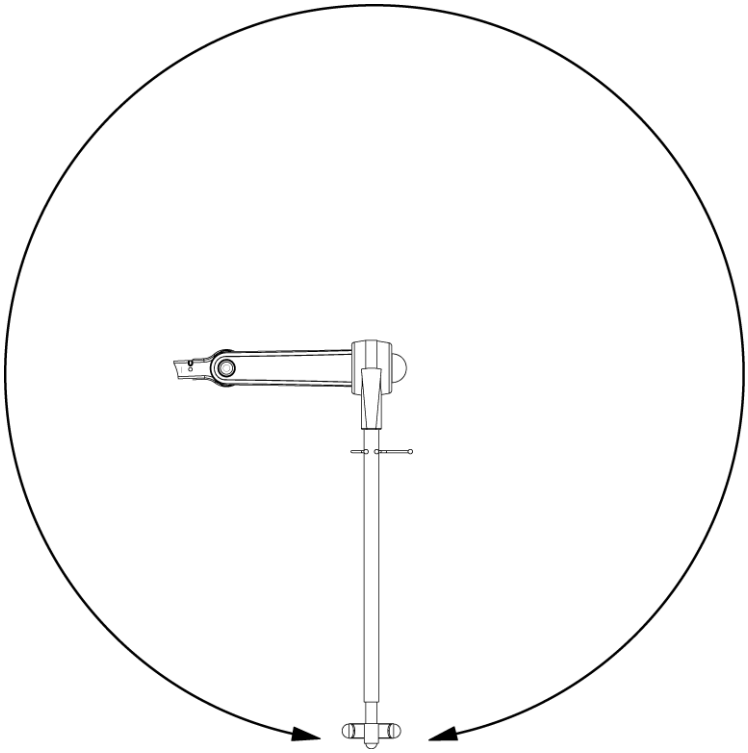


Horizontal: 80°

Movable range of part 2)



Vertical: 60°
Adjust the height while pressing the shaded part.



Rotates horizontally

3.3 Connecting a physiological signal cable

Connect the physiological signal cable to the physiological signal panel.
The optional product PEU-LISENDO880 is necessary to connect the physiological signal cable.
NOTE: ECG prioritizes the display of ECG signals that were set in preset setup. Use ECG Display Select on the General tab in the preset ([Preset Setup] > [Application] > [Edit Data] > [General]) to configure the setting.

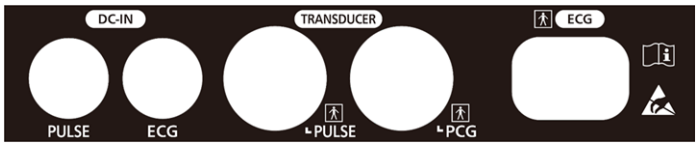
NOTE: If PULSE is connected to DC IN, PULSE will prioritize DC IN.
NOTE: If the external signal is unnecessary, remove the cable from the DC IN connector.

NOTICE

The minimum amplitude required for the ECG input signal is 50 µV.
If a signal is less than that level, the screen might not display the ECG correctly.

Procedure

- Firmly connect the ECG cable to an ECG connector.
  a. Insert the connector of the ECG cable firmly into the ECG socket, with the groove on the connector facing upward.
  b. Attach each of the 3 ECG cables to their respective electrodes.
  c. Attach the electrodes to the patient.
- Insert the plug of the pulse transducer firmly into the PULSE connector.
- Insert the plug of the PCG microphone firmly into the PCG connector.
  NOTE: The PCG microphone is fragile, so do not drop it or strike it against other objects.
- Connect the cable from an external physiological signal monitor.
  NOTE: Before connecting the cable from an external physiological signal monitor to the system, read "Precautions for use with other medical devices" in this manual. Refer also to the documentation provided with the physiological monitor used together with the system.
  - Connect the cable from the ECG output connector of the physiological monitor used together with the system, to the DC IN ECG connector. Set the preset ECG Display Select to [ECG DC IN].
  - Connect the cable from the PULSE output connector of the physiological monitor used together with the system, to the DC IN PULSE connector.

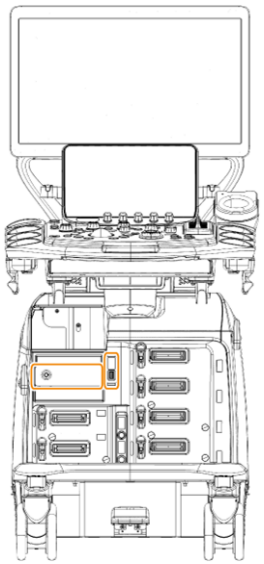


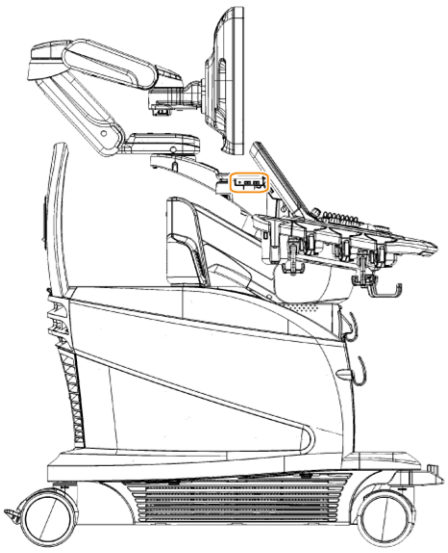
Physiological signal panel

3.4 Connecting to other connectors

3.4.1 Connecting to a USB connector

There are USB connectors at the following locations:





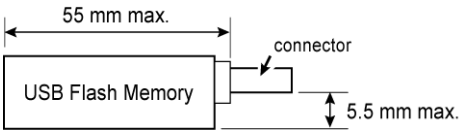
Left:

Front of the system (USB 3.0), when the optional Security box (optional) is attached (USB 3.0 x 2 connectors)

Right:

Side of the operation panel (USB 2.0 x 3 connectors)

- Use a stick-type USB flash drive whose length, excluding the connector, is less than 55 mm and where the distance between the connector and the bottom is less than 5.5 mm. You might be unable to connect some devices because of their physical dimensions. Make sure you can connect your USB flash drive before trying to use it.



- Do not attach a strap to a USB flash drive. A strap might become tangled with the probe cable and hamper system operation.
- Adjust the probe cable so that it does not catch on the USB flash drive.
- When using a USB device that connects by using a bus power source, be sure to use the connection method described in the documentation provided with the USB device. If the bus power is insufficient, the system might not start correctly.
- For details on DVD drives that can be connected, please contact our office.

3.4.2 Connecting to an equipotential terminal

Use this terminal when interconnecting with other devices.
Connect equipotential terminals from other devices to the equipotential terminal on the back of the system.

3.4.3 Connecting a foot switch (option)

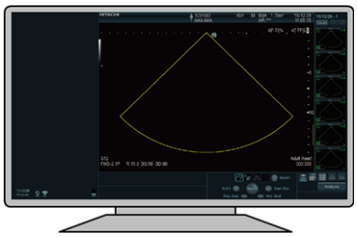
Procedure

1. Align the pin in the foot switch connector with the pin hole in the foot switch connector.
2. Plug in the foot switch connector.
3. Use preset settings to assign functions to the foot switch.

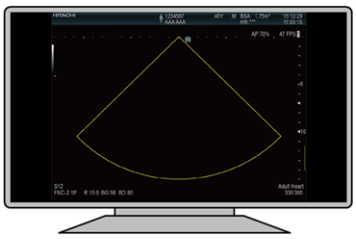
3.4.4 Connecting a medical monitor or a robotic surgical unit for surgical procedures

To connect a medical monitor or a robotic surgical unit for surgical procedures, you need the optional HDMI-monitor connection unit.
By connecting the HDMI-monitor connection unit to the DVI-D signal output terminal, you can also use a video recorder and output images to a medical monitor or to a robotic surgical unit for surgical procedures.
Our service staff can switch the images to be output.
The following resolutions are supported:

- 1920x1080 Full HD
- 1024x768 XGA
- 640x480 VGA



When the HDMI monitor displays the same image as the viewing monitor



When the HDMI monitor displays an enlarged ultrasonic image

NOTE: Images displayed on the viewing monitor cannot be switched.
NOTE: Audio output is not available.
NOTE: To connect to a medical device that requires an analog video signal, use the Y/C output on the connector panel on the interior of the system rear cover.

⚠ CAUTION

Ask our service staff if you need to connect to other devices and switch the images to be output.
Ignoring this instruction might result in electric shock, burns, or other injuries to the patient or examiner, and damage to this system.

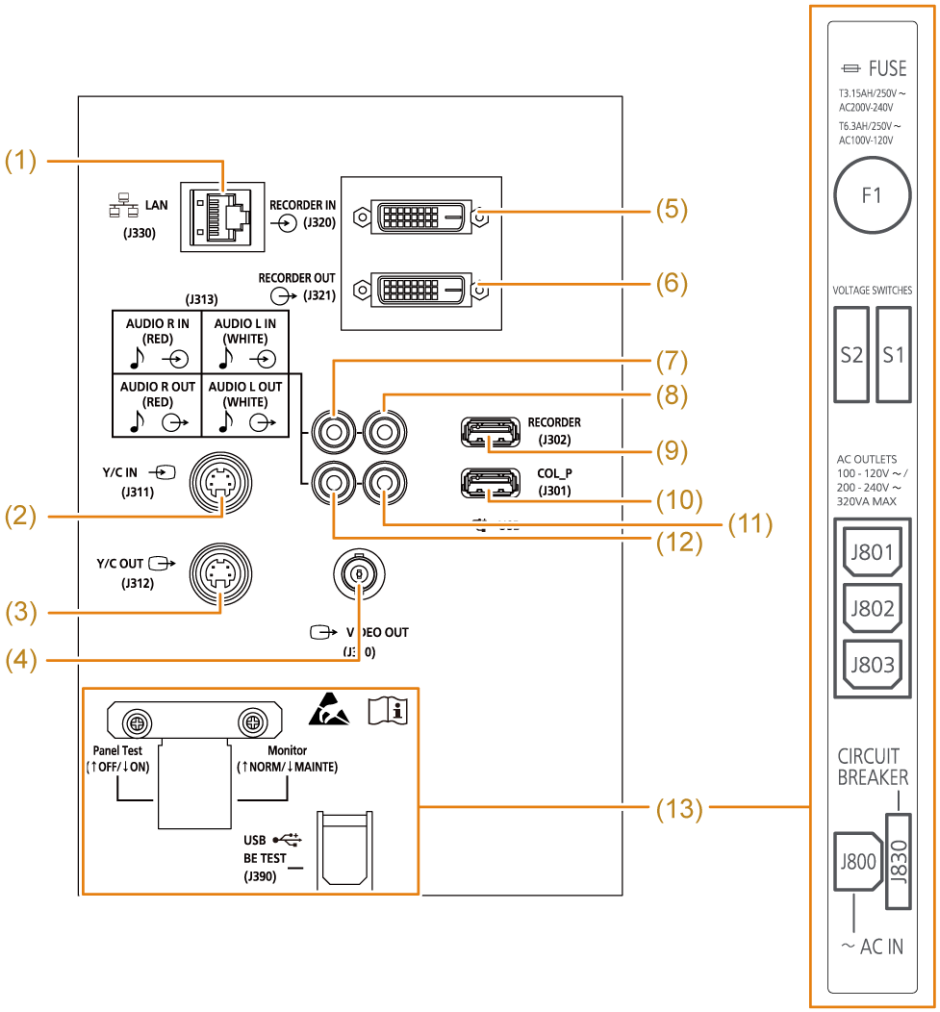
If you use a medical monitor or robotic surgical unit for surgical procedures, the monitor or unit must conform to the international standards for medical electrical equipment.
Ignoring this instruction might result in electric shock, burns, or other injuries to the patient or examiner, and damage to this system.
When connecting a device that does not conform to the international standards for medical electrical equipment, make sure that the system is electrically isolated by using an optical cable.

3.4.5 Connecting peripheral devices

Connect peripheral devices to the connector panel on the interior of the system rear cover. Open the system rear cover by turning the lock lever on the back of the system.
NOTE: Only connect peripheral devices when the system power switch is off. For details on how to connect peripheral devices, please contact our office.

⚠ CAUTION

Do not connect peripheral devices to the secondary power outlet of the system, other than those specified. Also, do not connect additional power strips or extension cords.
An apparent power consumption exceeding 350 VA might blow the system's primary fuse or trip the breaker inside the power supply unit. This might also result in damage.



Left: Connector panel, Right: Secondary power outlet

(1)	Do not use. For use by our service staff only.	
(2)	Y/C IN	S-video signal input terminal.
(3)	Y/C OUT	S-video signal output terminal.
(4)	SYNC OUT	RGB video synchronization signal output terminal.
(5)	RECORDER IN	Input terminal for DVI-D signals from a video output terminal.
(6)	RECORDER OUT	Connect the DVI-D signal output terminal for the video recorder.
(7)	AUDIO R IN	Audio input terminal for the video recorder (right side)
(8)	AUDIO L IN	Audio input terminal for the video recorder (left side)
(9)	RECORDER	Connect the USB (2.0) cable for the video recorder.
(10)	COL_P	Connect the USB (2.0) cable for the color printer.
(11)	AUDIO L OUT	Audio output terminal for the video recorder (left side)
(12)	AUDIO R OUT	Audio output terminal for the video recorder (right side)
(13)	Do not use. For use by our service staff only.	

3.4.6 Safety instructions for connecting network devices

This system complies with the electromagnetic compatibility standards for medical electrical equipment (IEC 60601-1-2: Ed.4).
When connecting non-medical network devices to this system, observe the following precautions to ensure that the entire ME system, including all devices, comply with the requirements of the international standards for medical electrical equipment:
If there are any other ordinances, those should be prioritized. For more details, please contact our office.

1. Network devices
   All non-medical devices (for example, hubs, work stations, personal computers) connected to the system must comply with the IEC 60950-1 standard and must be Class I equipment.

   Network cables that can be connected

Connector	LAN cable connector
LAN cable	Straight (when a hub is used)
Max. cable length	10 m

2. Device installation and network connections
   Non-medical devices (hubs, work stations, personal computers, etc.) must not be installed in the patient environment (a radius of 1.5 m around the patient).
   If you connect the Diagnostic Ultrasound System to a non-medical device located outside the ultrasound examination room, always connect them via a separating device (a network hub).

⚠ CAUTION

Do not use cables other than those specified. Do not use cables longer than the maximum length.
Ignoring this instruction might result in reception of electromagnetic interference.

NOTICE

Connecting the system to an IT network that also includes other devices could expose the patient, operator and third parties to hitherto unidentified risks.
If a problem occurs after a change to the IT network, contact the administrator of the hospital network.
Changes to the IT network might result in new and unacceptable risks, so additional risk management is required. Changes to the IT network include the following:

- Changes to the IT network configuration
- 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

(1) Specifications and configurations when making IT network connections

- Purpose of the PEMS connection to the IT network
  DICOM communications become available.
- Characteristics required by an IT network incorporating the PEMS
  DICOM Conformance Statement
  Refer to "4.3 NETWORK INTERFACES" in the above document.
- Configuration required by an IT network incorporating the PEMS
  DICOM Conformance Statement
  Refer to "4.3 NETWORK INTERFACES" in the above document.
- Technical specifications for networks that connect PEMS (including security specifications)
  The network must comply with DICOM.
- Flow of information intended to be between the PEMS, the IT network and other devices on the IT network; and selection of the intended routing through the IT network
  Refer to the "DICOM Confirmation Statement".

3.5 Checks and inspections prior to powering up

Visually check and inspect the system, peripherals, and probes before powering up.

Procedure

1. Visually check and inspect the system, peripherals, and probes.
   Items to be visually checked and inspected for the system and peripherals
   Make sure that there are no scratches, cracks, dents or discoloration in the following locations:
   - Enclosure and operation panel
   - Power cable and power plug
   - Physiological signal sensor and physiological sensor cable
   - The monitor must be clean (check for ultrasound gel and fingerprints).
   - Status of LAN cables and other connections

   Items to be visually checked and inspected for the probes
   Check and inspect the probes that will be connected to and used with the system, as described in the documentation for each probe.
   - The probes must be cleaned, disinfected and sterilized, as required for intended use.
   - The puncture adapter and needle must be sterilized.
   - The patient applied parts must be free of holes, dents, cracks and deformation
     In particular, you must make sure that the outer surface of the part of the probe to be inserted in the patient is free of any unintended rough surfaces, sharp edges, protrusions, or other potential causes of harm.

- Probe cables and connectors must be free from scratches, cracks and deformation (for example, bent pins).

Checking consumables

- Replace or replenish the ultrasound gel.
- Refer to the printer manual for information on how to replace printer paper.

NOTE: If there is anything wrong with the system or probes, stop using them immediately and contact our office.

3.6 Powering up

NOTE: Make sure that nothing is in contact with the touch panel. If the touch panel is started up while someone is touching the screen or something is in contact with it, the touch panel response might deteriorate.

Procedure

1. Press the [Power] key.
   If a message is displayed
   Not much free space remains on the system hard disk.
   Check the message and press the [Enter] key. After startup, delete unnecessary data.
   → Display the B mode image after setup.
   If the B mode image is not displayed after three minutes, please contact our office.

3.7 Checks and inspections after powering up

After turning on the system, visually check and inspect the system and probes.

Procedure

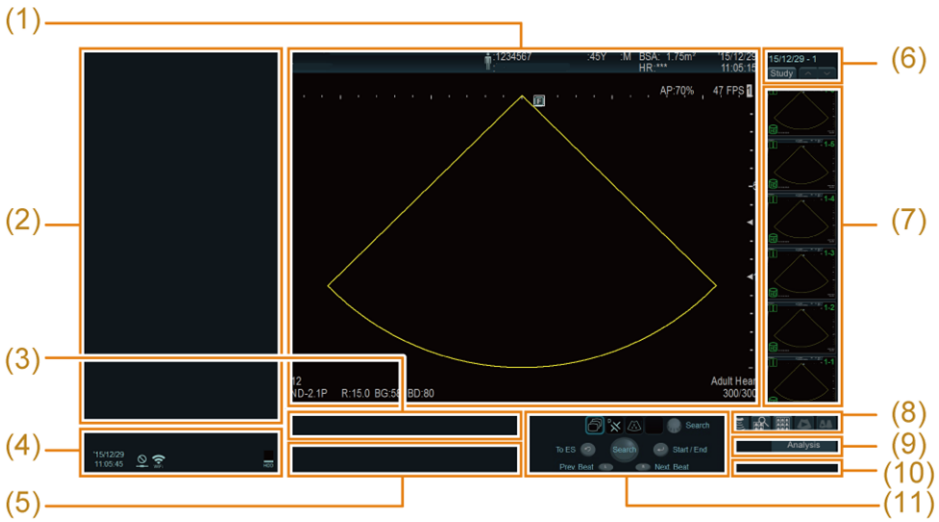
1. Adjust the monitor to an easy-to-see position.
2. Connect the probe to be used.
3. If necessary, turn on any optional and peripheral equipment.
4. Check what is displayed on the screen.
   Main inspection contents
   - The display must show text and images.
   - The current time must be correctly displayed.
     If the current date and time have to be set frequently, the system's internal battery might have run down.
     Stop using the system and contact our office.
   - The connected probe must match the displayed image and probe model name. If no probe is connected, "NO PROBE" must be displayed at the top right of the screen.

If probe information on the screen does not match the connected probe, or if no probe is connected but "NO PROBE" is not displayed at the top right of the screen, a malfunction might have occurred. Stop using the system and contact our office.

- The touch panel must be working.
- The probe transducer surfaces must not be abnormally hot.
- Set a high B gain and color gain; there must be no missing image details or abnormal noise.
- Monitor Contrast and Monitor Brightness must be properly set.

3.7.1 Screen display

The scanning screen has the following layout.



(1) Ultrasonic image
Displays ultrasonic images. Displays patient information, image information and other content.

(2) Assist Information
Displays the stress echo protocol menu and other content.

(3) Seek bar
Displays the cine memory time bar and the acquisition progress bar.

(4) System information
Displays system information.

(5) Messages
An assist message is displayed.

(6) Menu for switching the thumbnail display
Displays a menu that allows you to switch between the thumbnail area, Tile view, and search screen.

(7) Thumbnails
Displays thumbnails of stored images of patients during examination.

(8) Screen transition menu
Touch to go between screens.

(9) [Analysis]
Displays the analysis menu.

(10) Playback operation menu
Displays image playback menus in the full screen and analysis screen.

(11) Trackball function information
Displays the state of the trackball and surrounding keys.

(4) System information

A: Current date and time

B: Various types of status and network connection status

Network connection status (wired)

Connected

Not connected

Error

Network connection status (wireless)

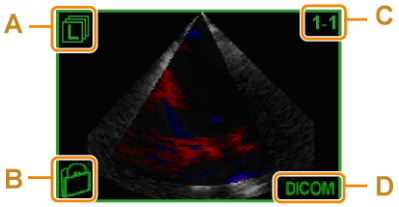
- Reception intensity (Strong) - (Weak)

Connection error

C: Connection/insertion status of the storage medium, and proportion used

(7) Thumbnail

The following information will be displayed in the four corners of the thumbnail.



A: Image type icon
B: Device icon
C: Image number (series number - consecutive number)
D: Stored image format

(11) Trackball function information

(a) Trackball functional state (active state shown inside the frame)

(b) [UNDO] key function

(c) [L] key function

(d) Trackball function

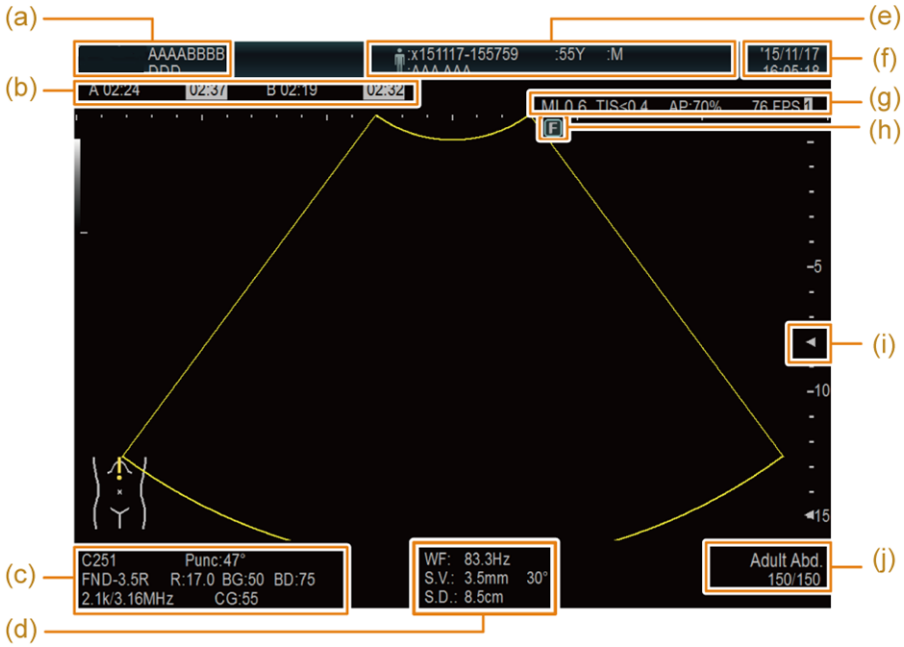
(e) [Pointer] rotary encoder function

(f) [Enter] key function

(g) [R] key function

Function by color		Status
Gray	Start	Inactive status
Blue	Prev. Beat	Standby status
Orange	ES	Active status

(1) Information displayed on the ultrasound Image



(a) Top row: Hospital name
Bottom row: Examiner name

(b) Counter

(c) Top row: Probe name, puncture angle
Middle row: Frequency (B, M), display depth, B gain value, dynamic range (B, M)
Bottom row: PRF/Reference frequency (color Doppler), color Doppler gain

(d) Top row: PW waveform and CW waveform cutoff frequency (displayed in B/D mode)[*1]
Middle row: Width of the sample volume (when PW is used), angle correction value
Bottom row: Depth of the sample volume (when PW is used)

(e) Patient data

(f) Current date and time: When frozen, the time and date when the freeze occurred is displayed.

(g) MI value, TI value, ultrasound output power, frame rate (number of frames per second for an ultrasound image)

(h) Orientation mark

This manual uses the following symbols with the indicated meanings: ●: Active, ○: Inactive

(i) Focus marks

(j) Top row: Application name
Bottom row: Display frame number/total number of frames (displayed when frozen)

*1.

The settings must be specified in the preset (the Display tab that can be displayed by clicking [Preset Setup] > [Region] > [General]).

3.8 Default

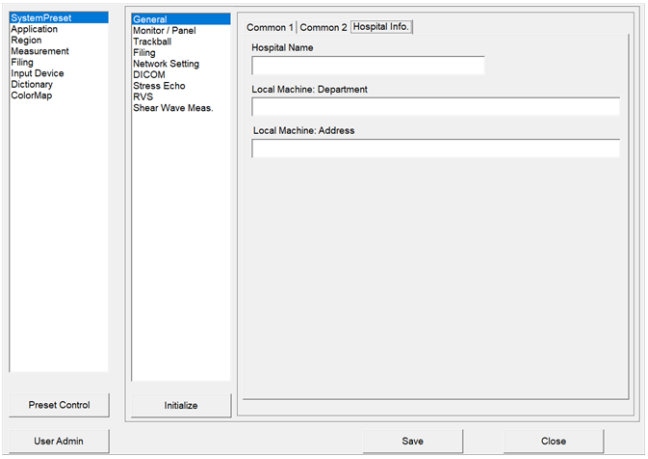
The section explains how to specify the hospital name and network, and how to adjust the date and time.

3.8.1 Setting the hospital name

Set the hospital name to be displayed in the scanning screen.

Procedure

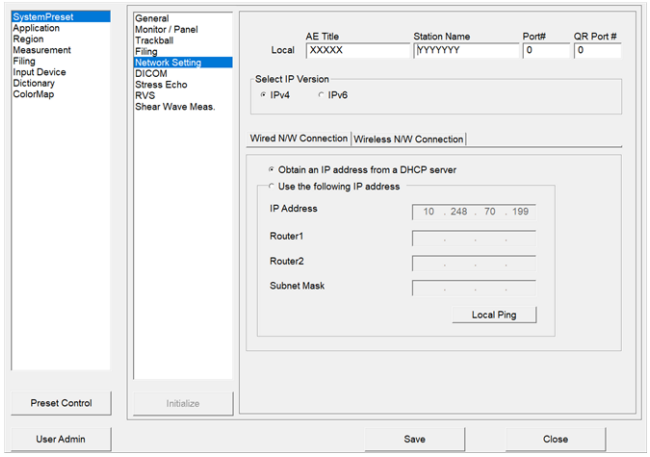
1. Press the [Probe/Preset] key.
2. Select [Preset Setup] on the touch panel.
3. Select [SystemPreset].
4. Select [General].
5. Select the Hospital Info. tab.
6. Enter no more than 40 characters in the Hospital Name field.
7. Select [Save].



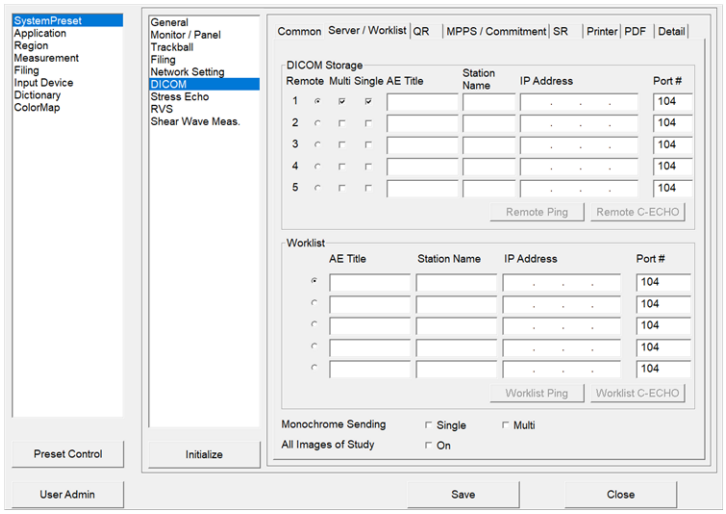
3.8.2 Configuring the DICOM communication settings

Procedure

1. Press the [Probe/Preset] key.
2. Select [Preset Setup] on the touch panel.
3. Select [SystemPreset].
4. Select [Network Setting].
5. Enter the network settings for the system.



6. Select [DICOM].
7. Enter the settings for network servers on the various tabs.



Server/Worklist Tab

- Server/Worklist Tab
  Make server and worklist settings.
- QR Tab
  Set Query/Retrieve server.
- MPPS/Commitment tab
  Specify settings for the MPPS server or Storage Commitment server.
- SR Tab
  Specify settings for the SR Storage server.
- Printer Tab
  Set the DICOM printer.

8. Select [Save].

Reference information

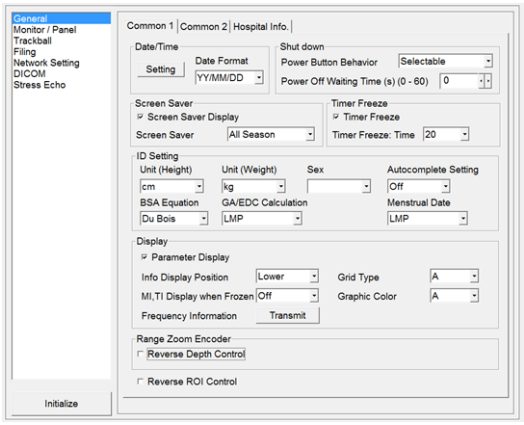
Changes to the IT network might result in new and unacceptable risks, so additional risk management is required.
3.4.6 Safety instructions for connecting network devices on page 83

3.8.3 Adjusting the date and time

Adjust the date and time displayed by the system.

Procedure

1. Press the [Probe/Preset] key.
2. Select [Preset Setup] on the touch panel.
3. Select [SystemPreset].
4. Select [General].
5. Select the Common1 tab.
6. Adjust date and time.



a. Select [Setting] from Date/Time.

   → "The date and time properties" are displayed.

b. Adjust date and time.

To change the date and time display format:
Select a display format in the Date Format field.

7. Select [Save].

3.9 Adjusting the operation panel and monitor

You can adjust the distance to, and the angle of, the user interface so that it suits the examiner. You can adjust the brightness of the monitor and the touch panel to match the environment.

3.9.1 Adjusting the height of the operation panel

Adjust the height of the operation panel by using the panel's up-and-down pedal at the front of the system.

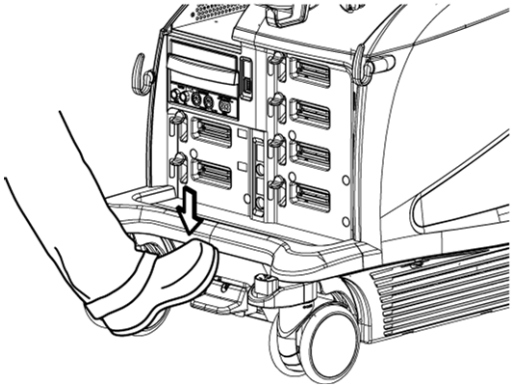
Prior confirmation

Remove any objects placed on any installed options, or on the operation panel.

NOTE: Do not place objects on top of installed options or on the operation panel.

Procedure

1. Depress the caster locks for the front wheels to lock the front wheels in place.
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.
   NOTE: When adjusting the height of the operation panel, grasp the operation panel handle, not the operation panel or probe holder.



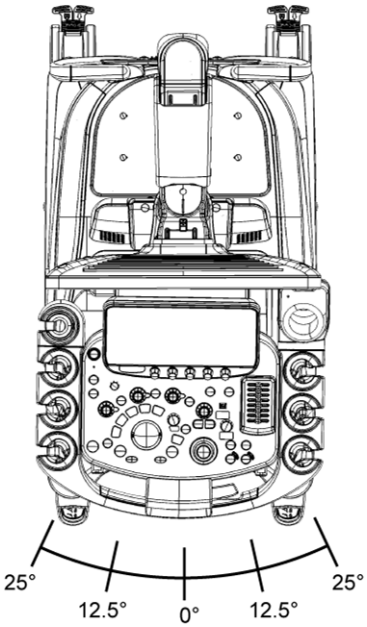
3. Release the up-and-down pedal of the operation panel to lock the height of the operation panel.

3.9.2 Rotating the operation panel

The operation panel can be used in 5 positions. In addition to the front position, the panel can be rotated 12.5 degrees or 25 degrees to the right or left.

Procedure

1. If you are using an optional alphanumeric keyboard, push the keyboard until it clicks.
   NOTE: Be careful not to get your fingers caught between the alphanumeric keyboard and the operation panel handle.
2. While holding the handle lever for the operation panel, rotate the operation panel.
   If you let go of the lever, the orientation of the operation panel is locked.



NOTE: When rotating the operation panel, grasp the operation panel handle, not the operation panel or probe holder.
NOTE: The operation panel might rotate even if you are not holding the handle lever for the operation panel. This is a design feature, and is not a malfunction.
If the operation panel is rotated repeatedly without holding the handle lever for the operation panel, the operation panel's ability to maintain its orientation might change. Make sure that you hold the lever when rotating the operation panel.

3.9.3 Adjusting the monitor height or orientation

⚠ CAUTION

Adjust the position and angle of the monitor, keeping a sufficient distance between the system and the peripheral devices, walls, and people.
Do not knock the monitor against the touch panel, USB-connected storage medium, cable hook, probe, probe holder, operation panel, or other parts.
Route the probe cables so that they do not become entangled with the monitor, monitor arm, or the handle at the back of the system.
Contact with the monitor might cause injury or might damage surrounding equipment, the walls, the probe, the system itself, the monitor, or the touch panel. Warn doctors, patients, and others in the area before adjusting the position or angle of the monitor.
Should the monitor break and its internal fluid come into contact with the skin, wipe the fluid away and wash the skin in running water for at least 15 minutes. To be on the safe side, consult a doctor. If the fluid gets into contact with an eye, rinse the eye in running water for at least 15 minutes, and consult a doctor immediately.
If the monitor is damaged, stop using the system immediately and contact our office.

Be careful not to pinch your hands or fingers in the monitor arm when adjusting the location or orientation of the monitor.
Ignoring this instruction might result in pinch-related injuries of hands and fingers.

Procedure

- Grasp the frame of the monitor in both hands to adjust its height or orientation.
  Grasp the frame of the monitor in both hands and move it in a large swinging movement. Even when the monitor arm axis is vertical, it is easier to move the monitor if you swing it.

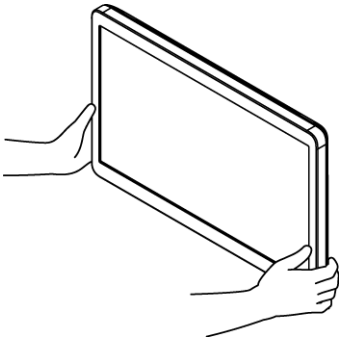
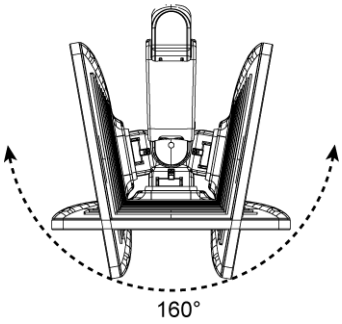
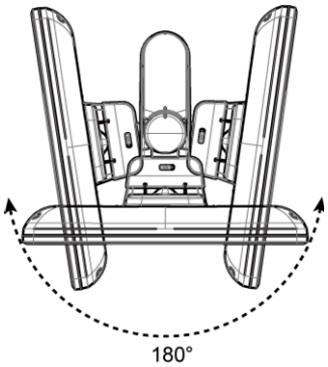
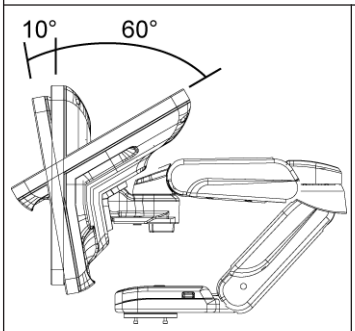
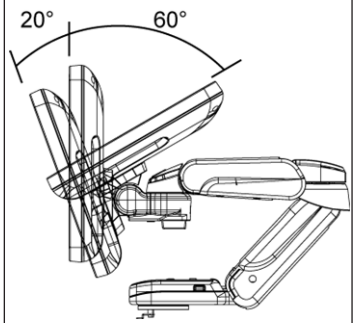


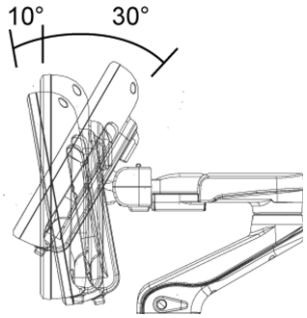
Table 3-1 Movable range of monitor

<table>
<tr><th>22-inch monitor (OLED)</th><th>23-inch monitor (LCD)</th><th>21.5-inch monitor (LCD)</th></tr>
<tr><td colspan="2"> 

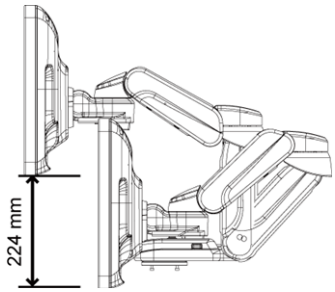
160° left-right</td><td> 

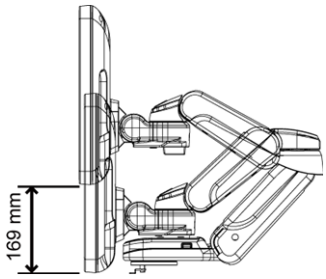
180° left-right</td></tr>
<tr><td> 

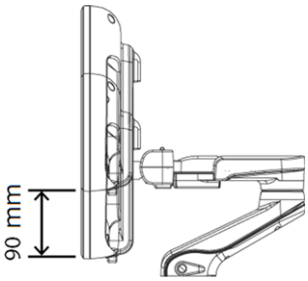
Tilt
10° forward, 60° backward</td><td> 

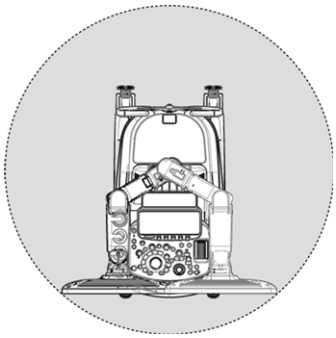
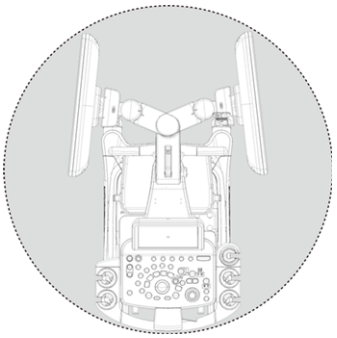
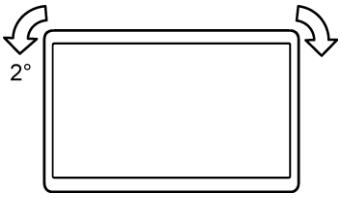
Tilt
20° forward, 60° backward</td><td> 

Tilt
10° forward, 30° backward</td></tr>
</table>

<table>
<tr><th>22-inch monitor (OLED)</th><th>23-inch monitor (LCD)</th><th>21.5-inch monitor (LCD)</th></tr>
<tr><td> 

224 mm up-down</td><td> 

169 mm up-down</td><td> 

90 mm up-down</td></tr>
<tr><td colspan="2"> 
Range of rotation</td><td> 
Range of rotation</td></tr>
<tr><td colspan="3"> 

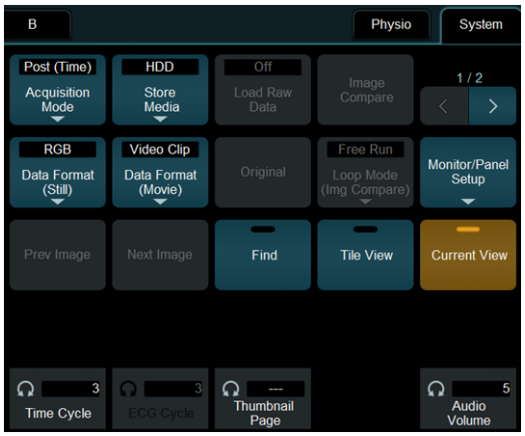
Rotates horizontally</td></tr>
</table>

NOTE: Attempts to move the system beyond its movable range could damage it, or cause it to tip over or fall.

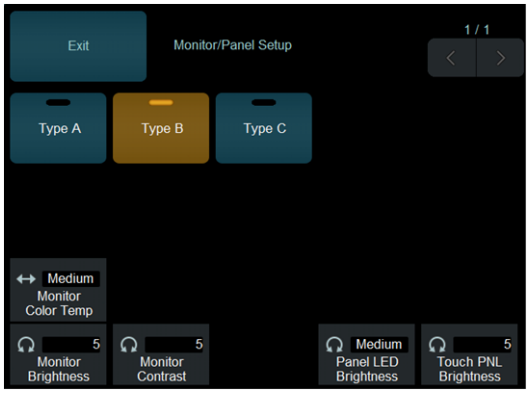
3.9.4 Adjusting the brightness levels of the screen, operation panel, touch panel, and the size of the screen

Procedure

1. Select [Monitor/Panel Setup] on the System tab.



2. Turn the multi rotary encoder according to the menu content, to adjust brightness.



- Operation panel
  Turn the [Panel LED Brightness] multi rotary encoder.
- Touch panel
  Turn the [Touch PNL Brightness] multi rotary encoder.
- Screen (changing settings in a batch)
  On the touch panel, select [Type A], [Type B], or [Type C] according to the brightness of the room.
- Adjusting screen brightness
  Turn the [Monitor Brightness] or [Monitor Contrast] multi rotary encoder.
- Adjusting screen color temperature
  Turn the [Monitor Color Temp] multi rotary encoder in the direction of the arrow.
- Adjusting the monitor backlight
  Turn the [Monitor BackLight] multi rotary encoder.
  NOTE: Items you can set differ depending on the size of the screen.
  NOTE: This item does not appear when a 22-inch monitor is used.
- Adjusting the size of the screen to be displayed on the monitor
  Turn the [Monitor Scaling] multi rotary encoder.
  NOTE: This item appears only when a 23-inch monitor is used.

Supplementary information about adjusting screen brightness

We recommend using Monitor Contrast to adjust screen brightness.
There are two menus that you can use to adjust the screen brightness: Monitor Contrast and Monitor Brightness. In addition, if you display saved images in an environment other than this system, the images might not appear the same as on the screens of the system.

3.10 Gel Warmer

CAUTION

Do not touch the inner tube or interior of the Gel Warmer while it is powered on, or just after it has been switched off.
The interior of the Gel Warmer could be hot, which could result in the operator getting burned.

When the Gel Warmer is used, make sure that the ultrasound gel is not too hot.
Ignoring this instruction might result in burns to the patient. Use our ultrasound gel and ultrasound gel bottle.

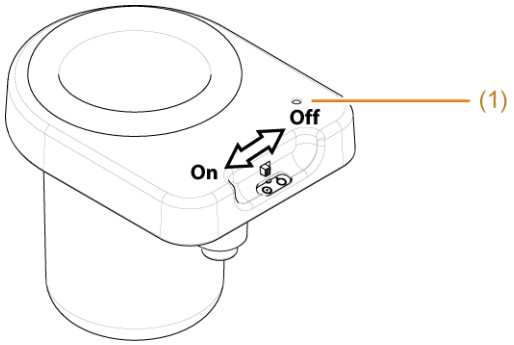
3.10.1 Operating procedures

Procedure

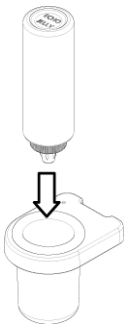
1. Turn on the power switch on the Gel Warmer.

   → The pilot lamp lights orange.
   NOTE: If the main unit is not turned on, press the [Power] key.

(1) Pilot lamp



2. Pour ultrasound gel into the ultrasound gel bottle and close the cap.
3. With the ultrasound gel bottle cap pointing down, insert the bottle into the Gel Warmer.

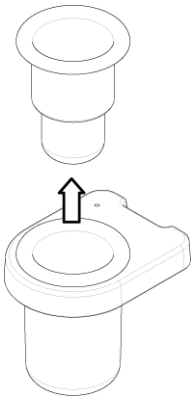


If the Gel Warmer is not used:
Turn the Gel Warmer off.
NOTE: For information on how to use ultrasound gel and the ultrasound gel bottle and the safety precautions that must be observed, see the documentation supplied with the ultrasound gel.
NOTE: Use an ultrasound gel bottle that is not damaged or deformed.

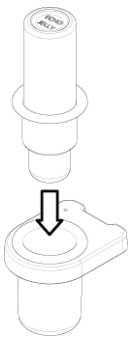
3.10.2 Cleaning

Procedure

1. Remove the silicon rubber packing from the Gel Warmer.



2. Wash it with water. Alternatively, wipe contaminants off.
   When washing in water:
   Rinse off any contaminants with running water. Using a sponge or gauze, rinse off any ultrasound gel or the like clinging to the silicon rubber packing. Next, wipe water off the silicon rubber packing with a clean cloth.
   If the item is very dirty
   Immerse a soft cloth in a weak solution of a neutral detergent, then wring the cloth. Use the cloth to gently wipe away contaminants, then wipe the detergent off.
3. Leave it to dry naturally.
4. Insert the silicon rubber packing in the interior of the Gel Warmer.



   If the silicon rubber packing is difficult to insert
   The silicon rubber packing is easy to insert if placed on the ultrasound gel bottle.

3.10.3 Troubleshooting

If the measures below do not solve the problem, please contact our office.

- If the ultrasound gel does not get warm

Cause	Countermeasures
The power switch is turned off	1. Make sure that the unit is turned on. 2. Check that the Gel Warmer power switch is turned on.

Cause	Countermeasures
The Gel Warmer has just been turned on	1. Allow enough time to let the unit warm up the ultrasound gel. After the Gel Warmer is turned on, it takes about one hour to reach a temperature of approximately 38°C. Wait until it has warmed up.
The Gel Warmer does not contain any ultrasound gel	1. Shake the ultrasound gel bottle so the ultrasound gel collects in the cap. 2. With the ultrasound gel bottle cap pointing down, insert the bottle into the Gel Warmer. NOTE: It will become harder to warm up the ultrasound gel if some of the gel in the bottle is not in proper contact with the Gel Warmer. NOTE: The ultrasound gel will not get warm if the ultrasound gel bottle is inserted cap up in the Gel Warmer.

- If the pilot lamp does not go on

Cause	Countermeasures
The power switch is turned off	1. Make sure that the unit is turned on. 2. Check that the Gel Warmer power switch is turned on.

- If you cannot remove the ultrasound gel bottle from the Gel Warmer, please contact our office.
- If the silicon rubber packing is damaged, please contact our office.

Use our ultrasound gel and ultrasound gel bottle.

3.11 Alphanumeric keyboard

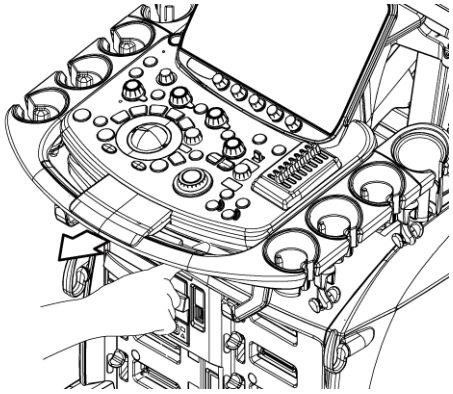
3.11.1 Pulling out the alphanumeric keyboard

The alphanumeric keyboard is an optional part.

(1) If the keyboard has been completely stored

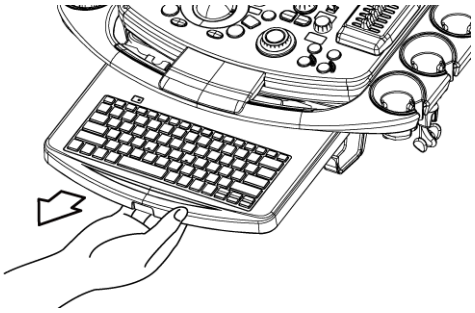
Procedure

1. Gently push the Keyboard Tray with your finger.



→ The alphanumeric keyboard emerges.

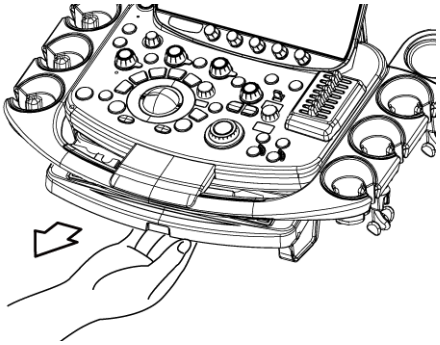
2. Pull the keyboard out to the desired position.



(2) If the keyboard has been temporarily stored

Procedure

1. Pull the keyboard out to the desired position.

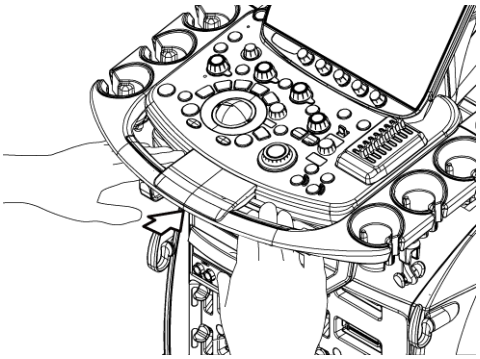


3.11.2 Storing the alphanumeric keyboard

(1) To completely store the keyboard

Procedure

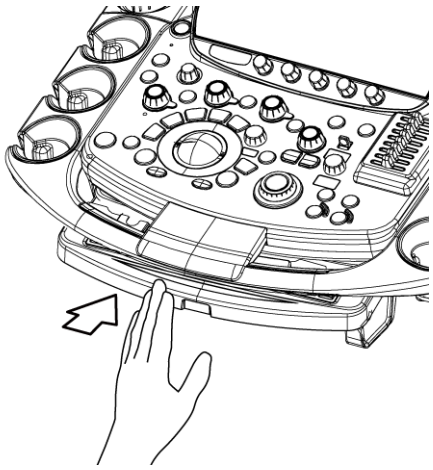
1. Push in the Keyboard Tray until it clicks.



(2) To temporarily store the keyboard

Procedure

1. Gently push in the keyboard tray with your fingers until it approaches the operation panel handle.

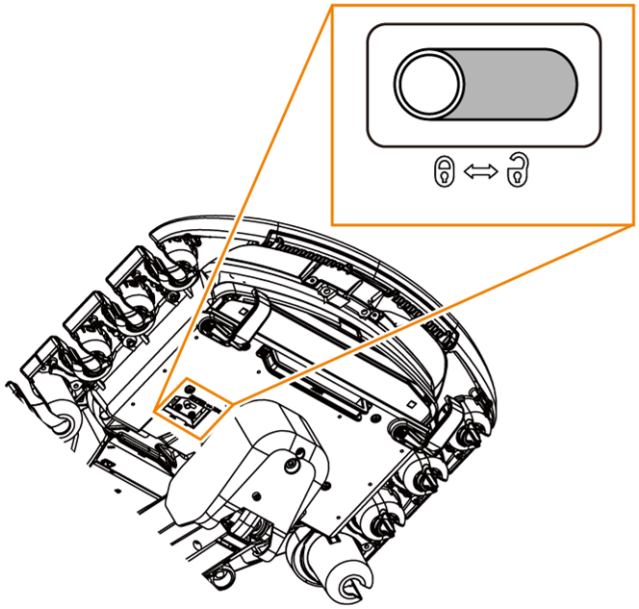


→ The alphanumeric keyboard is now stored.

3.11.3 Securing the alphanumeric keyboard

Procedure

1. Slide the lock lever on the rear of the operation panel in the direction.



The figure shows the keyboard in a locked state.

3.12 Security box

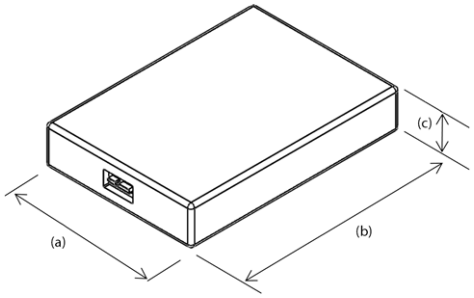
The Security box is an optional part.
You can store an external HDD in the Security box and use the HDD to back up the saved images.
NOTE: Keep the key supplied with the Security box in a safe place. If you lose the key, our service staff can change the key for a fee.

CAUTION

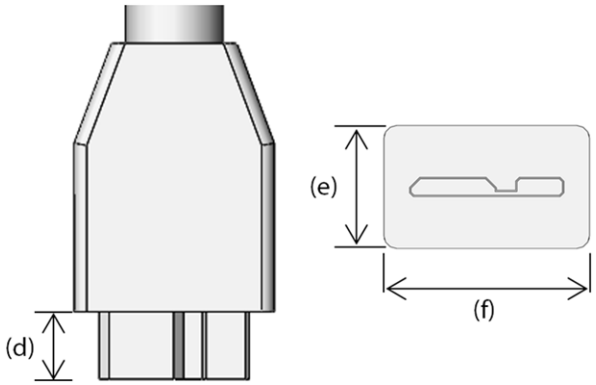
An external HDD must satisfy the following specifications when placing it in the Security box.

- Interface: USB 3.0 bus powered micro-b connector
- External dimensions : width: 84 mm or less, depth: 120 mm or less, height: 9 mm to 22 mm
- A 16 mm wide, 8 mm high, and 5 mm thick connector can be connected. You might not be able to connect your external HDD to the lockable storage depending on the shape of connector. Make sure that your external HDD can connect to the lockable storage.

If you use the Security box, use the system in an environment where the temperature is at least 5°C lower than the maximum temperature at which the manufacturer of the external HDD guarantees operation.
Heat from an external HDD might burn the examiner and damage the external HDD.



(a) 84 mm or less
(b) 120 mm or less
(c) 9 mm to 22 mm



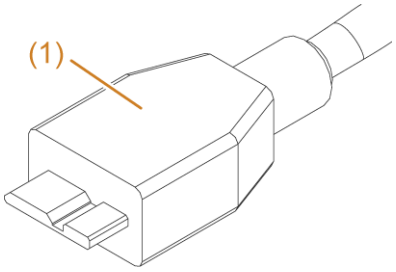
(d) 5 mm or less
(e) 8 mm or less
(f) 16 mm or less

NOTE: To check the free space of the external HDD, select [Disk Remain] in the menu area of the Tile view or the search screen. For details, see the separate manual "Basic Operations".

CAUTION

Do not plug or unplug the USB cable while the system is starting.
The system might not be started or the external HDD might be broken.

When plugging or unplugging the USB cable, always hold the plug part instead of the metal part at the tip.
An electrostatic discharge (ESD) could damage or destroy parts that are sensitive to static electricity. For details see *7.2 Electrostatic discharge (ESD) guidelines* on page 211.



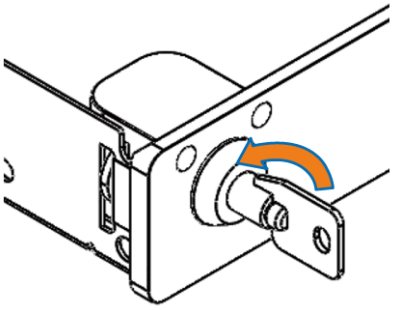
(1) Plug part

3.12.1 Using the Security box

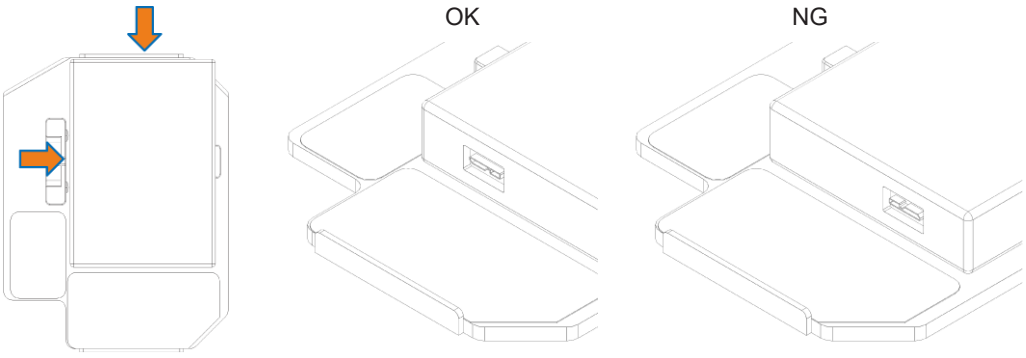
Procedure

1. Insert the key and turn it to the left.

   → The Security box is unlocked.



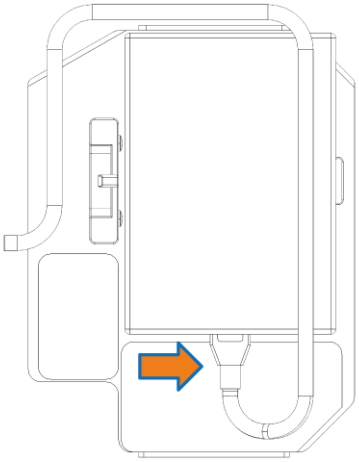
2. Open the cover.
3. Take out the drawer tray, and put in the external HDD.
   NOTE: Align the external HDD to the back and the far left of the drawer tray.
   NOTE: Adjust the position of the external HDD so that the USB cable connector is set in the center or left side of the external HDD.



CAUTION

Adjust the external HDD to the correct position.
Note that when you close the door of the Security box, the USB cable might be damaged if an extra load is applied to the cable.

4. Connect the USB cable to the external HDD.

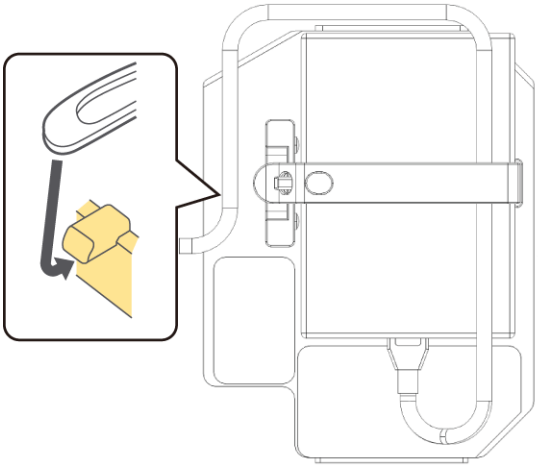


CAUTION

Do not secure the external HDD to the tray if the USB cable extends to outside the tray.
Ignoring this instruction might result in a load being applied to the USB cable and damage to the cable.

Do not strongly pull on the USB cable.
Ignoring this instruction might result in a load being applied to the USB cable and damage to the cable.

5. Secure the external HDD with the attached strap.

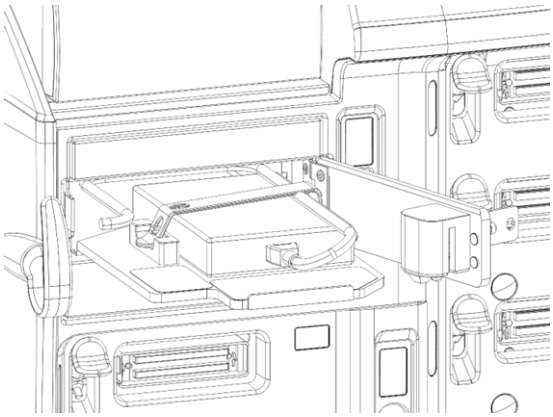


CAUTION

Place the USB cable on the external HDD, and then use the attached strap to secure the external HDD to the tray.
The USB cable might come off the external HDD or the external HDD might be damaged when you move the system.

Put the left hole on the strap on the knob of the drawer tray.
Ignoring this instruction might result in damage to the strap.

6. Place the external HDD in the Security box, and then close the door.

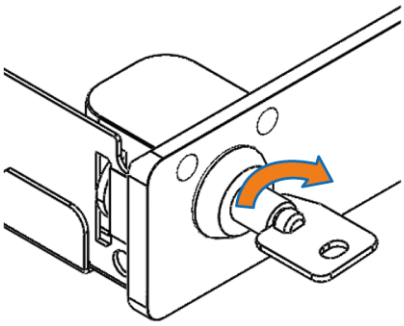


⚠ CAUTION

Be careful not to get the USB cable caught in the door when you close the door of the storage box lockable with a key.
Ignoring this instruction might result in damage to the USB cable.

Do not apply strong physical shocks to, or place a heavy load on, the storage box lockable with a key.
If you ignore this instruction, damage might occur to the door and the patient or examiner might be injured. Also, the door might be damaged.

7. Close the cover and turn the key to the right to lock the cover.
   NOTE: If the cover cannot be closed, place the USB cable inside the cover and then close the cover.



4

Procedure

The following sections provide basic system procedures.
For details, see the related manuals.

4.1 Examination steps

Procedure

1. Set up the system as described in *Chapter 3, Setup before use* on page 59.
   a. Make a visual inspection of the system and the probes.
      Make sure that the exterior the system or the power cable is not scarred, cracked, dented or discolored.
   b. Plug the power cable into a hospital-grade outlet.
   c. Connect a probe.
   d. Press the [Power] key.
   e. Check what is displayed on the screen.
2. Enter the patient data on the ID input screen, and then select [Start].
3. Apply ultrasound gel to the body area of the patient that will be examined and the contact surfaces of the probe.
4. Apply the contact surfaces of the probes to the body areas of the patient that will be scanned to display an image.
5. After you have captured the required image, press the [Freeze] key to produce a still image.
   NOTE: If necessary, press the [Store] key to save the image.
   NOTE: If necessary, press the [Print] key to print the image.
6. Press the [New Patient] key or select [End Exam] to end an examination.
   NOTE: If necessary, assign [End Exam] to a direct or custom switch.
   - Press the [New Patient] key.
     Select this method to switch patients.
   - Select [End Exam].
     Select this method when several examinations have been specified for one patient.
7. When all examinations are complete, press the [Power] key.
8. Clean the system and the area around it.
   Clean, disinfect and sterilize the probes according to the instructions in the supplied documentation.

Reference information

Chapter 3, Setup before use on page 59

4.2 Entering patient data

4.2.1 Screens for entering patient data

Enter patient data in the ID screen before you start an examination. To start examinations efficiently, on the ID screen set the following: the application to start the examination, the probe, the measurement application, and the measurement study.
You must enter the patient ID to save images, make transfers, and create measurement result reports.

The ID screen consists of (A) the search area and (B) the patient data area.
NOTE: For details about the search area, see the document "Basic Operations".

(1) Patient data area

Use this screen to enter basic patient data and set the start time of an examination.
The items displayed change depending on which tab is selected.

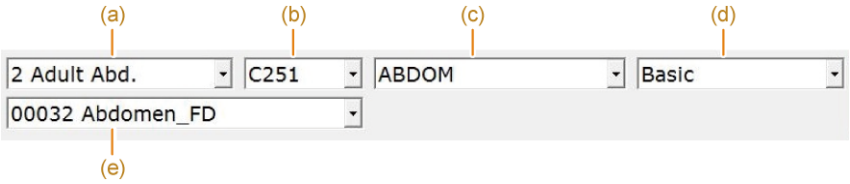
- Worklist tab: Displays patient information obtained from the Hospital Information System (HIS).
- Patient List tab: Displays patient information registered in the system database.
- Paused tab: Displays patient information for exams that were completed that day.

Each area is described below.

(1) List area
This area displays a list of patient data read from the data registered in the database. At the top of the ID screen, select v to show the list area, and select ^ to hide it. When you select patient data from the list view, the input area displays data about the selected patient. You can edit the information in the input area.

(2) Input area
Key in patient data. Depending on the settings in the ID screen, some information is automatically entered.

(3) Set the following: the application to start the examination (a), the probe (b), the measurement application (c), the measurement study (d), and the protocol (e). Setting up the ID screen will enable automatic input.



When When starting examination, store ID Screen of the preset ([Preset Setup] > [SystemPreset] > [Filing] > [Detail] > [Store ID Screen]) is set to On, the Main Setting screen is automatically saved as an image when the ID screen is closed with a patient ID entered.

4.2.2 Entering patient data

Enter patient data in the ID screen before starting an examination.
To enter data, use the alphanumeric keyboard or the virtual keyboard on the touch panel.
You can also load patient data from a magnetic card (patient's registration card) or barcode.

Prior confirmation

- If necessary, assign [ID] to a custom switch.
- To load the data from a magnetic card (patient's registration card) or barcode, use the ID Card tab in the setup screen to select the information to be read using the reader. For details, see the document "Basic Operations".

Procedure

1. Press the [New Patient] key. Alternatively, select the [Patient] tab on the touch panel and then select [New Patient].

   → This will exit the ongoing examination and display the ID screen.
   NOTE: The ID screen is automatically displayed when the system is started up.
   NOTE: The ID screen is displayed if you use a reader to read a magnetic card (patient's registration card) or barcode during an examination.

2. Enter patient data in the input area.
   NOTE: Using the keyboard, move the character cursor.
   [Tab] key or [Enter] key: Moves to next item
   [Shift] and [Tab] keys, or [Shift] and [Enter] keys: Moves to the prior item
   Reading a magnetic card (patient's registration card) or barcode by using a reader
   When a reader is used to read a magnetic card or barcode, the information is entered in the input area.

3. Set the following: the application to start the examination, the probe, the measurement application, the measurement study, and the protocol.

4. Exit the ID screen.

   ◦ Select [Start] in the ID screen.

   ◦ On the operation panel, press the [New Patient] key, [Freeze] key, and [B] key.

◦ Press the [ID] key on the alphanumeric keyboard or the custom switch.

→ The ID screen closes and the examination starts using the information displayed in the input area.
NOTE: If you start an examination using a patient ID of an already examined patient, the following message appears: "This order is already performed. Do you want to perform an additional examination?" Select Yes to perform a new examination using the same study ID.
NOTE: Selecting [ID] during an examination displays the ID screen, and the information can be edited. However, the patient ID and study ID cannot be edited.

4.3 Switching probes and applications

Use the steps below to switch probes and applications to be used for an examination.
For details about how to connect probes, see "Connecting a probe" in this manual.
For details about how to register applications to probes, see the separate manual "Basic Operations".
NOTE: Operation procedures vary depending on the [Probe << Preset Link] setting on the touch panel. Check the setting first.
NOTE: To switch to an application that is not displayed on the touch panel, select [All Preset]. All registered applications are displayed.

Procedure

- By selecting an application, you can switch both an application and probe at the same time.

  a. Press the [Probe/Preset] key.

  b. Set [Probe << Preset Link] to On.

  c. Select an application from the application preset switches (c) on the touch panel.

  → The probe will also switch at the same time.

(c) Application preset switch

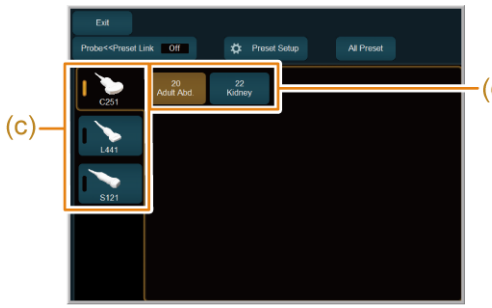
- By selecting a probe, you can switch an application.

  a. Press the [Probe/Preset] key.

  b. Set [Probe << Preset Link] to Off.

  c. Select a probe from the probe switches (c) on the touch panel.

  d. If necessary, select an application from the application preset switches (d).



(c) Probe switch
(d) Application preset switch

4.4 Adjusting the ultrasound output power

Use the steps below to adjust ultrasound output power according to the ALARA principle and operating mode.
Examinations should be conducted according to the ALARA principle of extracting the maximum possible diagnostic information while reducing the acoustic output to the lowest reasonable level. This is the same principle as used with ionizing radiation.
In general, the Diagnostic Ultrasound System is said to be non-invasive. However, since it exposes the human body to ultrasonic waves, it is not completely safe. Therefore, perform examinations using the lowest possible ultrasound output power that the examination requires.

Procedure

- Turn the [Acoustic Power] rotary encoder to adjust the ultrasound output power.

  → The ultrasound output power is displayed on screen as a percentage of actual set transmitter voltage relative to what is regarded as safe maximum possible transmitter voltage under current scanning conditions.
  You can adjust the ultrasound output power in 1% increments.
  Lowering the ultrasound output power lowers the surface temperature at the tip of the probe.

4.4.1 Limiting the ultrasound output power for fetal observation

When the system is used for fetal observation, the ultrasound output power is limited according to our regulations in compliance with the risk management requirements stipulated in IEC 60601-2-37 Ed.2.1 (2015). The MI upper limit and the TI upper limit are both below 1.0.
This limitation on ultrasound output power applies to the following applications: General, Obst. 1st Trim, Obst. 2nd Trim, Obst. 3rd Trim, Obst. TV, Fetal Heart,Obst. 3D, Ob.3D 1st Trim, Ob.3D 2nd Trim, Ob.3D 3rd Trim, STIC, Obst. TV 3D, Ob. *** GP, and other applications that are edited based on the aforementioned applications.

(1) Overriding the limit on the ultrasound output power for fetal observation

Procedure

1. Select [Power Limit Override] from the System tab on the touch panel.

→ The following message is displayed: "Keep the acoustic output level as low as possible. Refer to ALARA recommendations in the Instruction Manual."

2. Select [OK].

→ The ultrasound output power value is highlighted on the screen.
The limit is suspended until the [New Patient] key is pressed. To limit the ultrasound output power again, select [Power Limit Override] again on the touch panel.

4.5 Adjusting audio volume

This function adjusts the volume of the Doppler sound, R-wave beep, and external input audio.

Prior confirmation

Assign [Audio Volume] to the function menu.

Procedure

- Use [Audio Volume] on the touch panel to adjust.
  The sound is muted when the volume is set to 0.

4.6 Mode display

4.6.1 Displaying B mode images

Prior confirmation

For a quad-screen view, use the presets to assign [Quad] to a direct switch.
For details on how to assign menu items, see the separate manual "Basic Operations".

Procedure

- Displaying a B mode image (single-screen view).
  - Press the [B] key.
    It displays a real-time B mode image (single-screen view).
    Pressing the [B] key while in the Freeze state displays the B mode image (single-screen view) in real time.
- Displaying a B mode image (dual-screen view).

  a. Press the [Dual] key.

  → This displays the active screen in real time and the non-active screen as frozen images.
- Displaying a B mode image (quad screen).

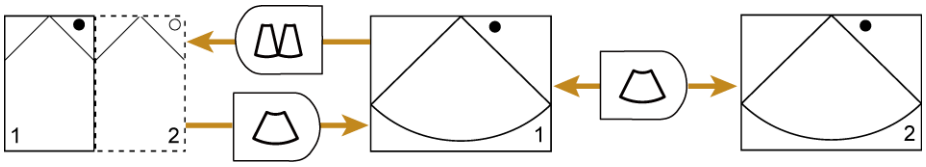
  a. Select [Quad], which you assigned to a direct switch or a custom switch.

  → This displays the active screen in real time and the others as frozen images.

- Switching the active screen.
  - In the dual-screen view, press the [Dual] key.
  - In the quad-screen view, select the direct switch [Quad].
- Changing to the single-screen view after an image is frozen.
  - Press the [Single] key.

→ When the display is switched from the dual-screen view or quad-screen view to the single-screen view, the displayed Cine Memory switches.

For the dual-screen view

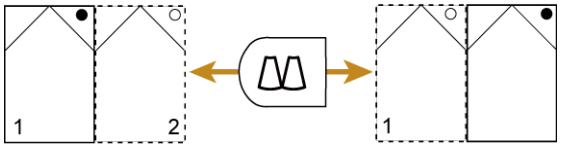


The image inside the solid lines is the active image

- Switching the active image after freezing.

  For the dual-screen view

  Press the [Dual] key.



The image inside the solid lines is the active image

4.6.2 Displaying M mode images

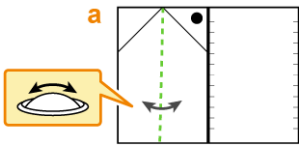
Procedure

1. Press the [M] key.

   → B mode and M mode images are displayed simultaneously in real time. The M cursor is displayed on the B mode image.

2. Move the M cursor.

   a. Use the trackball to move the position of the M cursor.



→ The M mode image at the M cursor position is displayed.

(1) Switching the active screen

Procedure

- Press the [Update] key.

→ Each time you press the [Update] key, the active screen switches.

- Roll the trackball.
  NOTE: This requires that B Active by Cursor Movement is set to On in the Operation tab in the preset ([Preset Setup] > [Region] > [General]).
  → The B mode image becomes active.
  Press the [Update] key to activate M Mode again.

The image inside the solid lines is the active image

(2) Switching screens

NOTE: If necessary, assign [Full M/D] to a direct or custom switch.

Procedure

- Press the [Single] key or select [Full M/D] to switch B/M mode to the single-screen view after an image is frozen.
- Press the [Dual] key or select [Full M/D] to switch M waveform (single-screen view) to B/M mode view after an image is frozen.
- Select [Full M/D] to switch between B/M mode and M waveform (single-screen view) in real time.

4.6.3 Displaying color Doppler mode images

Prior confirmation

Assign [PD] to a direct or custom switch.
If necessary, assign [Directional] to a direct switch, custom switch, or function menu.
For details on how to assign menu items, see the separate manual "Basic Operations".

Procedure

1. Display the B mode image.
2. Switch to color Doppler mode.
   - Press the [CF] key.
     CF mode is engaged.
   - Select [PD].
     PD mode is engaged.
   - Press the [eFlow] key.
     eFlow mode is engaged.
   - Select [DFI].
     DFI mode is engaged.

Displaying the directionality of blood flow in PD mode and eFlow mode

Set [Directional] on the direct switch or function menu to On.

3. Set the flow area.

   a. Use the trackball to move the flow area.

   b. Press the [Enter] key.

   c. Use the trackball to adjust the size of the flow area.

   d. Press the [Enter] key.

   e. Repeat steps a through d to set the flow area.

4.6.4 Displaying the PW waveform

Use the steps below to display Pulse Doppler waveforms.

Prior confirmation

If necessary, assign the following function:

- Assign [Sample Volume] to the function menu.
- Assign [Simultaneous (PW)] to a direct switch or custom switch.

For details on how to assign menu items, see the separate manual "Basic Operations".

Procedure

1. Press the [PW] key.

   ◦ When [Simultaneous (PW)] is On
   Both B mode and D mode images become active.

   ◦ When [Simultaneous (PW)] is Off
   It switches to the B/PW mode and the D cursor is displayed on the B mode image.

2. Configuring the sample volume setting.

   a. Use the trackball to adjust the sample volume to the detection position.

   b. Adjust the size of the sample volume by using the [Sample Volume] multi rotary encoder.

3. Press the [Update] key.

   → The B mode image freezes and the PW waveform is displayed.

(1) Switching the active screen

When D mode is active, B mode images can be activated using the following operations.

Procedure

- Press the [Update] key.
  → Each time you press the [Update] key, it switches which side is active.
- Roll the trackball.

NOTE: This requires that B Active by Cursor Movement is set to On in the Operation tab in the preset ([Preset Setup] > [Region] > [General]).

→ The B mode image becomes active.

Press the [Update] key to activate D Mode again.

The image inside the solid lines is the active image
(The figure shows when in B/PW mode.)

(2) Correcting blood flow direction and the angle of the ultrasound beam

Prior confirmation

If necessary, assign the following function:

- Assign [Angle Correction] to the function menu.
- Assign [Auto Angle Correction] to a direct switch, custom switch, or function menu.

For details on how to assign menu items and on other angle correction menus and presets, see the separate manual "Basic Operations".
Angle correction can be adjusted in real-time and after freezing.

Procedure

- Correct the angle by using the [Angle Correction] multi rotary encoder.
- Use [Auto Angle Correction] on the touch panel or custom switch to automatically adjust the angle.
  NOTE: Only operates in Color Doppler mode.

(3) Switching screens

Prior confirmation

If necessary, assign [Full M/D] to a direct or custom switch.

Procedure

- Press the [Single] key or select [Full M/D] to switch from B/D mode to the single-screen view after an image is frozen.
- Press the [Dual] key or select [Full M/D] to switch D waveform (single-screen view) to B/D mode view after an image is frozen.
- Select [Full M/D] to switch between B/D mode and D waveform (single-screen view) in real time.

4.6.5 Displaying the CW waveform

Use the steps below to display continuous Doppler waveforms.

Prior confirmation

For details about compatible probes, see "Probes" in this manual.

Procedure

1. Press the [CW] key.
   → It switches to the B/CW mode and the D cursor is displayed on the B mode image.
2. Use the trackball to align the D cursor ○ with the detection position.
3. Press the [Update] key.
   → The B mode image freezes and the CW waveform is displayed.

Reference information

4.6.4(1) Switching the active screen on page 116
4.6.4(2) Correcting blood flow direction and the angle of the ultrasound beam on page 117
4.6.4(3) Switching screens on page 117

4.7 Playing back cine memory images

Use the steps below to play back images after they have been frozen.
Moving tomographic image frames back and forward in cine memory image play is called "searching."
In sweep images such as M mode and D mode images, playback in the forward or reverse directions is called "searching".

4.7.1 Using the trackball to search or scroll

Procedure

1. Press the [Freeze] key to freeze the image.
2. Press the [Cine Search] key to turn it On.
   When the trackball function in the freeze mode is set to [Search]
   Go to step 3 without pressing the [Cine Search] key.
   [Search] can be set using Trackball Priority When Frozen (Color On) or Trackball Priority When Frozen (Color Off) in the Operation tab in the presets ([Preset Setup] > [Region] > [General]).
3. Roll the trackball to the right or left.
   → In the dual-screen view, the active screen is used for searching or scrolling.

4.7.2 Using the [Freeze] rotary encoder for searching and scrolling

Prior confirmation

On the Operation tab of the preset ([Preset Setup] > [Region] > [General]), set Freeze Encoder on Frozen to Cine Search.

Procedure

1. Press the [Freeze] key to freeze the image.
2. Turn the [Freeze] rotary encoder.

   → In the dual-screen view, the active screen is used for searching or scrolling.

4.7.3 Using the [Pointer] rotary encoder for searching and scrolling

Procedure

1. Press the [Freeze] key to freeze the image.
2. Press the [Cine Search] key to turn it On.
   When the trackball function in the freeze mode is set to [Search]
   Go to step 3 without pressing the [Cine Search] key.
   [Search] can be set using Trackball Priority When Frozen (Color On) or Trackball Priority When Frozen (Color Off) in the Operation tab in the preset ([Preset Setup] > [Region] > [General]).
3. Turn the [Pointer] rotary encoder.

   → In the dual-screen view, the non-active image is used for searching or scrolling.

4.7.4 Continuously playing back tomographic images

Use the steps below to continuously play back tomographic images stored in cine memory.

Prior confirmation

If necessary, assign [Playback] to a direct switch, custom switch, or function menu.

Procedure

1. Press the [Freeze] key to freeze the image.
2. Press the [Cine Search] key to turn it On.
   When the trackball function in the freeze mode is set to [Search]
   Go to step 3 without pressing the [Cine Search] key.
   [Search] can be set using Trackball Priority When Frozen (Color On) or Trackball Priority When Frozen (Color Off) in the Operation tab in the preset ([Preset Setup] > [Region] > [General]).
3. Start continuous play.

   ◦ Roll the trackball up.

   To change the playback speed:
   Roll the trackball down to decrease and up to increase playback speed during continuous playback.
   To stop playback:
   Roll the trackball left or right.

   ◦ Select [Playback].

To stop playback:
Select [Playback] and turn it Off.

(1) Continuously playing within a chosen interval

Procedure

1. Press the [Freeze] key to freeze the image.
2. Press the [Cine Search] key to turn it On.
3. Set the playback range.
   a. Use the trackball to display the playback start frame or playback end frame.
   b. Press the [Enter] key.
   c. Use the trackball to display the playback start frame or playback end frame.
   d. Press the [Enter] key.

   NOTE: The frame with a low number displayed in step a and c is the beginning frame, and the frame with a high number is the ending frame.
4. Start continuous play.
   ◦ Roll the trackball up.

   To change the playback speed:
   Roll the trackball down to decrease and up to increase playback speed during continuous playback.
   To stop playback:
   Roll the trackball left or right.

   ◦ Select [Playback].

   To stop playback:
   Select [Playback] and turn it Off.

4.8 Entering comments

Use the procedures below to enter text on the screen.

4.8.1 Entering characters from the keyboard

Use the virtual keyboard (touch panel) or alphanumeric keyboard for entering text.

Prior confirmation

Use the preset ([Preset Setup] > [Region] > [Annotation]) to use a user dictionary. For details, see the separate manual "Basic Operations".

Procedure

1. Press the [Pointer] key.

2. Use the trackball to move the pointer to the input location.
3. Enter text.

   Using the virtual keyboard

   A virtual keyboard is displayed when you select the [KB] tab or [Anno.+KB] tab.

[KB] tab

[Anno.+KB] tab

   Changing the size of text

   Select  on the virtual keyboard to switch the text size to one of three sizes. The size is applied to the text entered from the position of the selected text cursor.

4. Press the [Enter] key. Alternatively, select [Enter] on the virtual keyboard.

   Deleting all entered comments after freezing is canceled

   Set Comment Auto Delete in the preset ([Preset Setup] > [Region] > [Annotation]) to [Erase].

   Displaying all entered comments even after freezing is canceled

   Set Comment Auto Delete in the preset ([Preset Setup] > [Region] > [Annotation]) to [Remain].

4.8.2 Entering a pointer

Procedure

1. Press the [Pointer] key.
2. Use the trackball to move the pointer to the input location.

   Changing the direction of the pointer

   Turn the [Pointer] rotary encoder.

3. Press the [Enter] key.

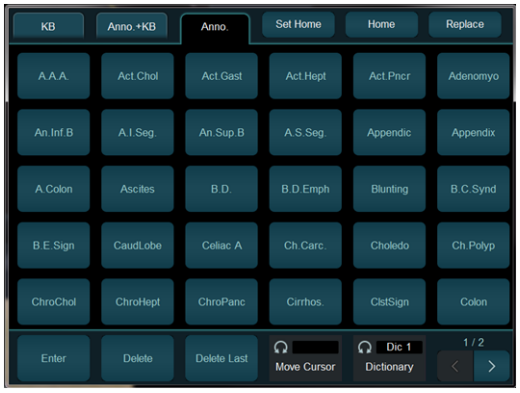
4.8.3 Choosing and entering words

Select a word registered in a user or system dictionary from the Annotation menu to enter it.

Procedure

1. Press the [Pointer] key.
2. Use the trackball to move the pointer to the input location.
3. Select the Anno.+KB tab or the Anno. tab.
   To display words by searching from the first one or two characters
   Use either the virtual keyboard in the Anno.+KB tab or the alphanumeric keyboard to input the first one or two characters of the word you want to display.

Anno.+KB tab



Anno. tab

4. Select the word you want to display from the Annotation menu.
   → The selected word is displayed on the image.

4.8.4 Moving, deleting, replacing, and inserting words

Procedure

- Moving a word.
  a. Place the text cursor in a word (or to the left of the word).
  b. Press the [UNDO] key.
     → The word is highlighted.

     Abd

  c. Use the trackball to move the word. Then press the [UNDO] key.
- Deletes a word.

[Delete] on the touch panel (Anno.+KB tab)

a. Place the text cursor in a word (or to the left of the word).

b. Switch to the Anno. tab or Anno.+KB tab.

c. Select [Delete].

→ The word will be deleted.

- Deleting the last word used.

a. Select [Delete Last] on the touch panel.

- Deleting just one character.

a. Set [Replace] on the touch panel to Off.

b. Place the text cursor to the right of the character you want to delete.

c. Select [BS] on the touch panel.

- Replaces a word.

a. Set [Replace] on the touch panel to On.

b. Move the pointer to the word you want to replace. Alternatively, use the [Move Cursor] multi rotary encoder to select the word you want to replace.

→ The word is highlighted.

c. From the touch panel, select the word to be replaced

→ The word is replaced.

- Replacing a word with a word in the same class.
Replace a word displayed on the screen with a word on the touch panel that is in the same class.
Select [Registration] in the preset ([Preset Setup] > [Dictionary]) and then set the class in the List tab of the User Dictionary screen.

a. Set [Replace] on the touch panel to On.

b. From the touch panel, select a word in the same class as the one to be replaced.

→ The word is replaced.

NOTE: You cannot replace a word with a word of the same class if that word is from another dictionary.

NOTE: The word will not be replaced if multiple words have been entered in the same class.

- Use the keyboard to change the word.
  a. Set [Replace] on the touch panel to On.
  b. Move the pointer to the word you want to replace. Alternatively, use the [Move Cursor] multi rotary encoder to select the word you want to replace.
     → The word is highlighted.
  c. Using the keyboard, enter text.
     → The word is replaced.
- Insert a character or word.
  a. Set [Replace] on the touch panel to Off.
  b. Move the text cursor to inside a word. Alternatively, use the [Move Cursor] multi rotary encoder to select a character or word.
     → The word is underlined.
  c. Using the keyboard, enter text. You can also select words on the touch panel.
     → The characters or word are inserted.

4.9 Displaying body marks

You can display a schema of scanning cross-sections in the scanning screen.

Procedure

- Display the body marks.
  a. Press the [Body Mark] key.

  → The Body Mark Menu appears on the touch panel and the body marks are displayed on the screen.
- Change the body mark.
  a. Press the [Body Mark] key.
  b. Select a body mark from the Body Mark Menu.

  → The selected body mark is displayed.
- Move and rotate probe mark.
  a. Press the [Body Mark] key.
  b. Use the trackball to move the position of the probe.
  c. Turn the [Pointer] rotary encoder to rotate the orientation of the probe mark.
- Attach the left/right mark to the body mark.
  a. Press the [Body Mark] key.
  b. Select [L/R] on the touch panel.

  → If [L/R] is On, then body marks are displayed with L/R marks.

When [L/R] is turned Off, the L/R mark in the body mark is hidden.

- Rotating the fetus mark.
  NOTE: Only single horizontal fetus marks can be rotated.

  a. Press the [Body Mark] key.

  b. Select a fetus body mark from the Body Mark Menu.

  c. Press the [Enter] key.

  d. Turn the [Pointer] rotary encoder to rotate the orientation of the fetus mark.
  Switching probe mark and fetus mark rotation
  Press the [Enter] key to switch the rotation.

- Move the body mark display position.

  a. Press the [Body Mark] key.

  b. Select [Location] on the touch panel, and set it to On.
  → A frame is displayed over the body mark.

  c. Use the trackball to move the frame. Then press the [Enter] key.
  To return it to its prior location
  Press the [UNDO] key.
  → The frame is displayed in the location before the move.

  d. Select [Location] and turn it Off.
  → The frame is cleared and the body mark's location is fixed.

- Hide the body marks.

  a. Select [Body Mark] from the Body Mark Menu.
  → The body marks displayed on the screen are hidden.

4.10 Taking measurements

Measure the distance, time, speed, and other values based on the displayed ultrasonic image.
This section describes procedures for the following basic measurements.

1. B mode
   - Distance Measurement: Dist.
   - Area and Circumference Measurement: Area-T
   - Area and Circumference Measurement: Area-E
2. M mode
   - Velocity Measurement: Velocity
   - Time Measurement: Time
3. D mode
   - Blood Flow Velocity Measurement: D.Vel1

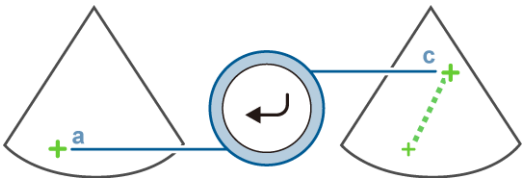
- Blood Flow Velocity Measurement: D.Vel2
- Pulsatility Index Measurement: PI

4.10.1 Distance Measurement: Dist

Use this function to measure the distance between two points.

Procedure

1. Select the measurement menu.
   a. Press the [Measurement] key.
   b. Select [Distance] on the touch panel.
2. Measure length.



   a. Move the plus mark (+) to the start point. Then press the [Enter] key.
   b. Move the plus mark (+) to the end point.
      Each press of the [L] key changes the mark that can be moved.
   c. Press the [Enter] key.

Example of Measurement Results Display

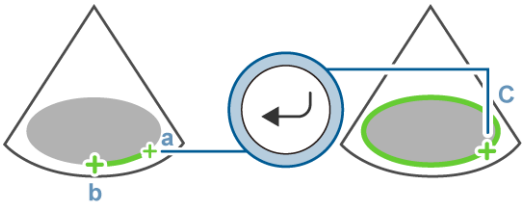
Dist: cm	Selected measurement name and measurement value

4.10.2 Area and Circumference Measurement: Area-T

Use this function to measure the area within a trace line and the area's circumference.

Procedure

1. Select the measurement menu.
   a. Press the [Measurement] key.
   b. Select [Area/Circum] on the touch panel.
   c. Select [Trace] on the touch panel.
2. Measure an area and its circumference.



a. Move the plus mark (+) to the start point. Then press the [Enter] key.

b. Trace the boundary of an area to be measured.
Press the [UNDO] key to return to step a.

c. Press the [Enter] key to close the trace line.

Example of Measurement Results Display

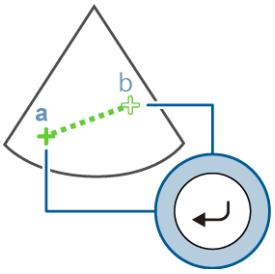
Area-T		Selected measurement name
Area:	cm^2	Area value
Circ:	cm	Circumference

4.10.3 Area and Circumference Measurement: Area-E

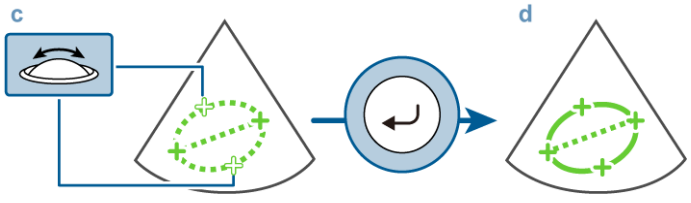
Use this function to measure an area enclosed by an ellipse and its circumference.

Procedure

1. Select the measurement menu.
   a. Press the [Measurement] key.
   b. Select [Area/Circum] on the touch panel.
   c. Select [Ellipse] on the touch panel.
2. Measure an area and its circumference.
   a. Move the plus mark (+) to the start point of the long axis. Then press the [Enter] key.
   b. Move the plus mark (+) to the end point of the long axis. Then press the [Enter] key.



   c. Use the trackball to adjust the length of the other axis.



Each press of the [L] key changes the mark that can be moved.

   d. Press the [Enter] key.

Example of Measurement Results Display

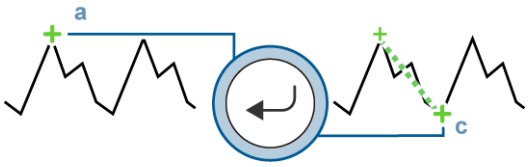
Area-E		Selected measurement name
Area:	cm^2	Area value
Circ:	cm	Circumference of the ellipse
x-ax:	cm	Length of the long axis of the ellipse
y-ax:	cm	Length of the short axis of the ellipse

4.10.4 Velocity Measurement: M.VEL

Use this function to measure the time, amplitude, and velocity based on the slope between two points on an M mode image.

Procedure

1. Select the measurement menu.
   a. Press the [Measurement] key.
   b. Select [M.VEL.] on the touch panel.
2. Measure velocity.



   a. Move the plus mark (+) to the start point. Then press the [Enter] key.
   b. Move the plus mark (+) to the end point.
   Each press of the [L] key changes the mark that can be moved.
   c. Press the [Enter] key.

Example of Measurement Results Display

M.VEL		Selected measurement name
v:	cm/s	Velocity
dD:	cm	Amplitude
dt:	ms	Flash Time

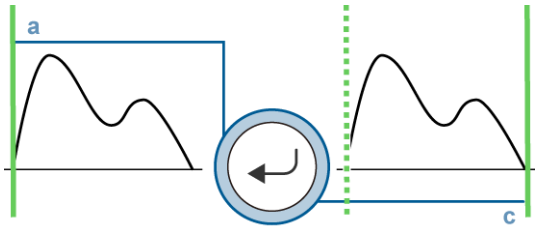
4.10.5 Time Measurement: Time

Use this function to measure the time between two points on an M mode image.

Procedure

1. Select the measurement menu.
   a. Press the [Measurement] key.
   b. Select [Time] on the touch panel.

2. Measure the time.



   a. Move the line cursor to the start point. Then press the [Enter] key.

   b. Move the line cursor to the end point.
   Each press of the [L] key changes the mark that can be moved.

   c. Press the [Enter] key.

Example of Measurement Results Display

dt: ms	Selected measurement name and measurement value

4.10.6 Blood Flow Velocity Measurement: D.VEL1

Use this function to measure the peak blood flow velocity and the peak pressure gradient.

Procedure

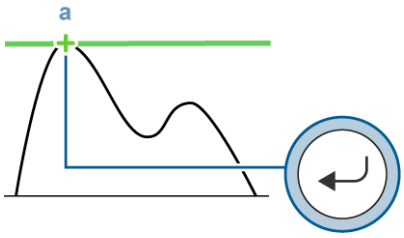
1. Select the measurement menu.

   a. Press the [Measurement] key.

   b. Select [D.VEL1] on the touch panel.

2. Measure the peak blood flow velocity.

   a. Move the plus mark (+) to the peak blood flow velocity. Then press the [Enter] key.



Example of Measurement Results Display

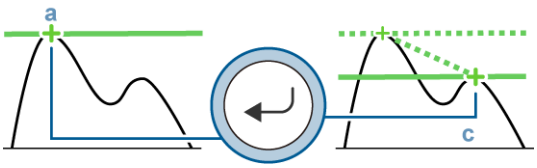
D.VEL1	Selected measurement name
pV: cm/s	Peak blood flow velocity
PG: mmHg	Peak pressure gradient

4.10.7 Blood Flow Velocity Measurement: D.VEL2

Use this function to measure the blood flow velocity and blood flow velocity ratio between two points on a D mode image.

Procedure

1. Select the measurement menu.
   a. Press the [Measurement] key.
   b. Select [D.VEL2] on the touch panel.
2. Measure blood velocity.



   a. Move the plus mark (+) to the first measurement point. Then press the [Enter] key.
   b. Move the plus mark (+) to the 2nd measurement point.
      Each press of the [L] key changes the mark that can be moved.
   c. Press the [Enter] key.

Example of Measurement Results Display

D.VEL2	Selected measurement name
v1: cm/s	Blood flow velocity at the 1st measurement point
v2: cm/s	Blood flow velocity at the 2nd measurement point
dv: cm/s	Blood flow velocity differential
v1/v2:	Blood flow velocity ratio

4.10.8 Pulsatility Index measurement: PI

Use this function to trace the blood flow waveform to measure PI, RI, S/D, and other hemodynamic status data.
NOTE: It has been reported that minimum diastolic blood flow velocity is also used to calculate this index. End-diastolic flow velocity and minimum diastolic blood flow velocity are not necessarily identical. If necessary, set the time phase of EDV to the end diastole or minimum diastolic velocity point.

Procedure

1. Display a blood flow waveform.
2. Select the measurement menu.
   a. Press the [Measurement] key.
   b. Select [PI] on the touch panel.
      → The line cursor is displayed.

(1) Measuring with the Auto (Doppler Trace method)

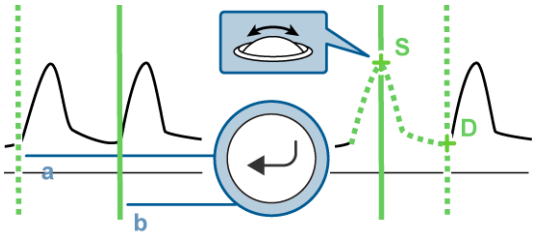
This sets a trace section to measure blood flow information.

Procedure

1. Move the line cursor to the start point. Then press the [Enter] key.
2. Move the line cursor to the end point. Then press the [Enter] key.

   → A trace line, S (Peak Systolic Velocity Point), D (End Diastolic Velocity Point) and the waveform rise position are automatically drawn.

   - Adjusting the trace line
     Use the [Pointer] rotary encoder to adjust the detection level.
   - If the trace line cannot be drawn properly
     Press the [UNDO] key or select [Trace Manual] on the touch panel to switch to Manual.
3. Use the [Enter] key and the trackball to adjust the S, D, and waveform rise positions. Each press of the [L] key changes the adjustment of the S, D, and waveform rise positions.



4. Select a heartbeat from a number of traced heartbeats.

   a. Select [Beat Select] on the touch panel.

   b. Turn the [Pointer] rotary encoder to select a heartbeat.

   c. Use the trackball and the [Enter] key to adjust the blood flow velocity point.

   If several heartbeats are selected:
   Each data item displays the average heart rate detected within the trace section in the measurement results. A line cursor indicating PSV, EDV and waveform rise position for each detected heartbeat appears.

Example of Measurement Results Display

PI	Selected measurement menu
PI:	PI
RI:	RI
PSV: cm/s	Peak systolic blood flow velocity
EDV: cm/s	End diastolic velocity
MnV: cm/s	Mean velocity
FlowT: ms	Flow time
[1Beat avg.]	Detected heart rate

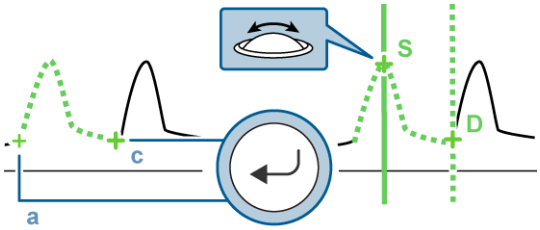
(2) Measuring with the Manual (Doppler Trace Method)

This measures the blood flow information using a manually traced waveform.

Procedure

1. Move the plus mark (+) to the start point. Then press the [Enter] key.
2. Trace a blood flow waveform.
3. Move the plus mark (+) to the end point. Then press the [Enter] key.

   → The end point mark is fixed, and the S, D, and waveform rise positions are drawn.
4. Use the [Enter] key and the trackball to adjust the S, D, and waveform rise positions. Each press of the [L] key changes the adjustment of the S, D, and waveform rise positions.



5. Select a heartbeat from a number of traced heartbeats.

   a. Select [Beat Select] on the touch panel.

   b. Turn the [Pointer] rotary encoder to select a heartbeat.

   c. Use the trackball and the [Enter] key to adjust the blood flow velocity point.

   If several heartbeats are selected:
   Each data item displays the average heart rate detected within the trace section in the measurement results. A line cursor indicating PSV, EDV and waveform rise position for each detected heartbeat appears.

Example of Measurement Results Display

PI	Selected measurement menu
PI:	PI
RI:	RI
PSV: cm/s	Peak systolic blood flow velocity
EDV: cm/s	End diastolic velocity
MnV: cm/s	Mean velocity
FlowT ms	Flow time
[1Beat avg.]	Detected heart rate

4.11 Printing and saving images

4.11.1 Printing images

Perform the following steps to print displayed images on a local printer or DICOM printer.

Prior confirmation

For details about how to select a printer, see the separate manual "Basic Operations".

Procedure

- Follow the steps below to print a frozen image.

  a. Search and scroll to find a high-quality image.

  b. Press the [Print] key.

  → The displayed screen is printed.

- Follow the steps below to print a real-time image.

  a. Display a high quality real-time image.

  b. Press the [Print] key.

  → The image shown when the key was pressed is printed.

4.11.2 Saving still images

Use this function to save an image created during an examination and a displayed screen as a still image. If images on the system hard disk or DICOM images on media are played back and saved in DICOM format, playback images are saved as screen captures.
For details on how to change the storage destination and format, see the separate manual "Basic Operations".

Prior confirmation

Enter the patient ID. You cannot save an image without entering the patient ID.

Procedure

1. Press the [Freeze] key to freeze the image.
2. If necessary, change the storage location and format.
3. Press the [Store] key.

   → Thumbnails of saved images are displayed in the thumbnail area.

4.11.3 Saving video

Use this function to save video during scanning.
You can save a video by using the function menus and Acquisition Mode on the Common1 tab in the preset ([Preset Setup] > [Filing]), or Manual Raw Store.
The following three methods are available for setting in Acquisition Mode.

- [Pre (Time)], [Pre (ECG)]
  Press the [Store] key, and then save the video for a set time interval or set number of heartbeats prior to an event.
- [Post (Time)], [Post (ECG)]

Press the [Store] key, and then save the video for a set time interval or set number of heartbeats.

- [Manual]
  Press the [Store] key to start saving the video and then press the [Store] key again to stop.

NOTE: For details about Manual Raw Store, see "Saving a video in Raw format: Manual Raw Store" in this manual.
NOTE: The saving processing starts if you select [Restart Store] on the touch panel while video images are being saved or being displayed in real time.
You can save a video in Raw format or Video Clip format.
You can save it simultaneously in both Raw format and Video Clip format (Raw&V.C.).
Use the function menu or Data Format (Movie) in the preset ([Preset Setup] > [Filing]) for the video storage format. In B/M, M, B/PW, PW, B/CW, and CW mode, Raw format images cannot be saved to DICOM.
NOTE: In Manual Raw Store, videos are saved in Raw format regardless of the settings in Data Format (Movie).

Storage formats and related properties

Storage format	Raw	Video Clip
Storage Media	System hard disk	System hard disk USB-connected media CD-R Buffer DVD Network
Savable display modes	Tomographic image in the single-screen view (B mode, CF mode) Active screen of a tomographic image (B mode, CF mode) in the dual-screen view Color flow mode image screen in Dual CF DFI image screen in Dual DFI D.S.D mode is not available.	Possible in all modes.

The acquisition progress bar and the cine memory area bar are displayed during the saving of a video in Raw format.
The Acquisition progress bar is displayed during the saving of a video in Video Clip format. However, if the video storage method is set to [Pre Time] or [Post ECG], the Acquisition progress bar and cine memory area bar are not displayed.

Masking patient information

When saving a video to anything other than the system hard disk, patient information can be masked.
When Teaching File (Video Clip) or Teaching File (Net) on the Teaching File tab in the preset ([Preset Setup] > [Filing]) is set to On, the patient ID and name are masked in the saved videos. Turn the applicable items to On to mask the patient's age (Age), gender (Gender) and hospital name (Hosp. & Sonographer Name).

4.11.4 Saving a video for a preset time interval or set number of heartbeats: Post ECG/Post Time

Prior confirmation

Assign [Acquisition Mode] to the function menu and set it to either [Post (Time)] or [Post (ECG)].

- Assign [Time Cycle] to the function menu for [Post (Time)] and select the time to save.
- Assign [ECG Cycle] to the function menu for [Post (ECG)] and select the heart rate to save.

For details on how to assign menu items, see the separate manual "Basic Operations".
NOTE: To check the target range before saving a video, turn On Auto Playback on the Common2 tab in the preset ([Preset Setup] > [Filing]).

Procedure

1. Press the [Store] key to save as a real-time image.
   If Auto Playback is On

   → The target range is played back as a loop.
   A video for the time interval or number of heartbeats set using [Time Cycle] or [ECG Cycle] is saved when the [Store] key is pressed.
   NOTE: The saving processing starts if you press the [R] key while video images are being saved or if you select [Restart Store] on the touch panel.

4.11.5 Saving a video for a set time interval or set number of heartbeats prior to an event: PreECG/PreTime

Prior confirmation

Assign [Acquisition Mode] to the function menu and set [Pre (Time)] or [Pre (ECG)].

- Assign [Time Cycle] to the function menu for [Pre (Time)] and select the time to save.
- Assign [ECG Cycle] to the function menu for [Pre (ECG)] and select the heart rate to save.

For details on how to assign menu items, see the separate manual "Basic Operations".
NOTE: To check the target range before saving a video, turn On Auto Playback on the Common2 tab in the preset ([Preset Setup] > [Filing]).

Procedure

1. Press the [Store] key to save as a real-time image.
   If Auto Playback is On

   → The target range is played back as a loop.
   A video for the time interval or number of heartbeats set using [Time Cycle] or [ECG Cycle] is saved when the [Store] key is pressed.

4.11.6 Storing a video for any period of time: Manual

Press the [Store] key to start saving the video and then press the [Store] key again to stop.

Prior confirmation

Assign [Acquisition Mode] to the function menu and specify [Manual].
For details on how to assign menu items, see the separate manual "Basic Operations".

Procedure

1. Press the [Store] key to save as a real-time image.

   → Saving starts.

2. Press the [Store] key again to stop saving.

   → Saving ends.

(1) Saving Raw data in the same range as a saved video in Video Clip format

Prior confirmation

Make the following settings.

- Assign [Acquisition Mode] to the function menu and set it to [Manual].
- Assign [Data Format (Movie)] to the function menu and set it to [VideoClip].
- Turn Video Clip Auto Stop to On in Video Clip Setting on the Common1 tab in the preset ([Preset Set-Up] > [Filing]).

For details on how to assign menu items, see the separate manual "Basic Operations".

Procedure

1. Press the [Store] key to save as a real-time image.

   → Saving starts.

2. Press the [Store] key to stop saving.

   → Saving ends and the image is frozen.

3. Play the loop.

   a. Turn on the [Cine Search] key.

   b. Roll the trackball upward. Alternatively, turn On [Playback].

4. Press the [Store] key.

   → The loop playback range (same range as a video saved in Video Clip format) is saved in Raw format.
   NOTE: If Video Clip Auto Stop is On, you cannot select [Raw&V.C.] from [Data Format (Movie)].

4.11.7 Saving a video in Raw format: Manual Raw Store

Videos are saved in Raw format regardless of the Data Format (Movie) settings in the preset ([Preset Setup] > [Filing]).
It is also possible to simultaneously save necessary portions of a video in Video Clip format.
NOTE: While saving a video in Video Clip format, select [Manual Raw Store] on the touch screen to begin saving the video in Raw format. In this case, a video in Video Clip format is instantly stopped and saved when [Manual Raw Store] is pressed.
NOTE: Auto Playback is turned Off.
NOTE: If saving of a video in Video Clip format begins while a video in Raw format is being saved, Video Clip Auto Stop is turned Off.

Prior confirmation

- Assign [Manual Raw Store] to a direct switch.
- To save a video both in Video Clip format and in Raw format, set Data Format (Movie) to [Video Clip] in the preset ([Preset Setup] > [Filing]).

Procedure

1. In a real-time image, select [Manual Raw Store] on the touch panel.
   → Saving of a video in Raw format begins.
2. Press the [Store] key to save a video in Video Clip format at the same time as a video in Raw format is being saved.
   → Saving of a video in Video Clip format begins.
   NOTE: Select [Store Media] on the touch panel for the storage location.
3. To end the saving of a video in Video Clip format, press the [Store] key again.
4. To end the saving of a video in Raw format, select [Manual Raw Store] on the touch panel again.

(1) Messages

Messages	Status or cause
Auto Playback is off.	The Auto Playback function turned off.
The Cine Memory is cleared. Video Clip Auto Stop is off.	The Video Clip Auto Stop function turned Off.
Video Clip Auto Stop is off.	The Video Clip Auto Stop function turned Off.

4.11.8 Saving a video at a specified range after a freeze

This function saves tomographic images in the loop playback range as a video during a freeze.
In a tomographic image in the single-screen view (B mode, CF mode, or DFI mode), select the range of the images captured in cine memory and save it as a video in Raw format.
NOTE: For Dual CF mode or Dual DFI mode, you can save a video in Video Clip format.

Procedure

Procedure

1. Press the [Freeze] key to freeze the image.
2. Select the loop sector and save.
   a. Press the [Cine Search] key.
   b. Use the trackball to display the start frame. Then press the [Enter] key.
   c. Display the end frame. Then press the [Enter] key.
      → The selected sectors are saved.
3. Roll the trackball upward. Alternatively, turn On [Playback].
   → Start continuous play.
4. Press the [Store] key.
   → The sectors selected in step 2 are saved.

4.12 Reading the instruction manual

You can read the instruction manual on the supplied CD-ROM or on the system.
Use PDF Reader to read the instruction manual on the system.
PDF Reader is software for displaying PDF format files.
For details on the terms of use of this software, see the License Information stored on the CD-ROM.

4.12.1 Viewing instruction manuals on the system screen

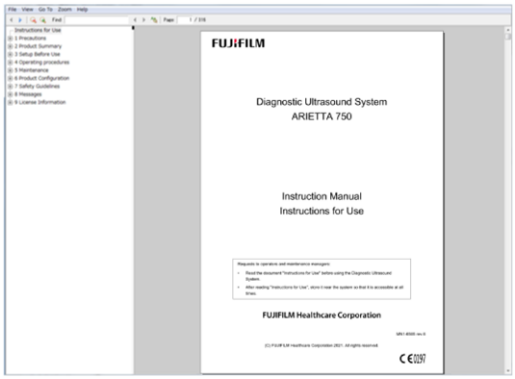
Follow the steps below to read the instruction manual on the system.

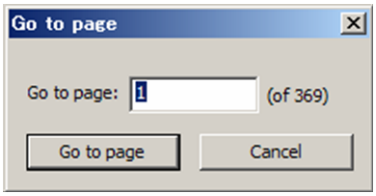
Prior confirmation

Assign [Manual] to a direct switch.

Procedure

1. Select [Manual] on the touch panel.
   → The selection screen is displayed.
2. Use the steps below to open the instruction manual.
   a. Select the instruction manual you want to read in the selection screen.
   b. Select [Open] in the dialog box.
      → The instruction manual opens.



File	Exit	Closes an open file.
	**********	Displays the names of the five most recently opened files.
View	Single page	Displays only single pages.
	Continuous	Scrolls to turn pages.
	Rotate left	Rotates a page 90 degrees to the left.
	Rotate right	Rotates a page 90 degrees to the right.
	Bookmarks	Shows and hides bookmarks.
	Show toolbar	Shows and hides the toolbar.
Go To	Next Page	Displays the next page.
	Previous Page	Displays the previous page.
	First Page	Turns to the first page.
	Last Page	Turns to the last page.
	Page...	Opens a dialog box.  To jump to a page, enter the page number and then press the [Go to page] button.
Zoom	Fit Page	Fits the page to the window.
	Fit Width	Fits the width of the page to the window.
	200% to 25%	Zooms the page to the specified percentage.
Help	About	Displays the version of PDF Reader.

Toolbar

(1) Previous page (2) Next page (3) Zoom out

(4) Zoom in (5) Search text field (6) Previous

(7) Next (8) Case sensitive search (9) Select page

(1) Closing a document

Use the steps below to close an instruction manual.

Procedure

1. Select [Manual] on the touch panel, and set it to Off.
   → All open instruction manuals close and PDF Reader closes.

4.12.2 Viewing instruction manuals stored on the CD-ROM

NOTE: You will need Adobe Reader version 7 or greater to read the instruction manuals stored on the CD-ROM. If Adobe Reader is not installed on the PC, you can download it from the website of Adobe Systems Incorporated.

Procedure

1. Insert the CD-ROM into the DVD/CD-ROM drive of the PC.
2. Display the DVD/CD-ROM drive.
   The instruction manuals include the following documents.

Instructions for Use	Provides information on how to safely operate the system.
Acoustic Output Data	Provides data on acoustic output.
Basic Operations	Describes how to display, adjust, and record ultrasonic images.
Advanced Operations (1 to 3)	Describes optional functions and various types of analyses.
Measurements (1 to 3)	Describes how to measure ultrasonic images.

3. Double click the manual you want to open.
   → The selected instruction manual opens.
   Notes on printing the instruction manuals
   The instruction manuals on the CD-ROM are in A4 page format. Check the printer properties before printing.

4.13 Steps to take after using the system

If you do not carry out these steps after using the system, it could break down or fail to function correctly during the next examination. Follow the procedure and perform the required steps.

⚠ CAUTION

Do not remove the power plug from the hospital-grade outlet while the machine is shutting down.
Ignoring this instruction might result in damage to the system.
Make sure the system has completely shut down before you remove the power plug from the hospital-grade outlet.

Procedure

1. Freeze the image.
2. Make backups of saved images.
   a. Transfer all images saved in the system (system's hard disk, CD-R buffer, and DVD-R buffer) to an external storage medium (USB-connected storage medium, DVD, CD-R, or DVD-R).
   b. Delete unnecessary images from the system.

   NOTE: For details about how to back up data, see the separate manual "Basic Operations".
3. Remove the recording medium from the recording system.
4. Press the [Power] key to shut down the system.
5. Unplug the power plug from the hospital-grade power outlet and gently coil the power cable.
6. Wipe ultrasound gel off the probe surface.
7. Disconnect cables and plugs, etc. as necessary.
   Disconnect any non-fixed probes and clean, disinfect, and sterilize them as described in the supplied probe documentation.
8. Clean.
9. Store it in a suitable environment for storage.

Reference information

3.1.1 Shutdown on page 60
5.1 Cleaning and disinfecting on page 144

4.14 Inspection after using the system

After using the system, confirm that the system, probes, accessories, and peripherals are in the states described below.

State of the system

- The operation panel (including the alphanumeric keyboard) is clean.
- The enclosure (including the probe holder and Gel Warmer) and foot switch are clean.
- The monitor is clean.
- The monitor arm is locked.

- The power plug and the area around the hospital-grade outlet are clean.
- The casters are locked.
- The system is placed in a location that satisfies the conditions for storage environments.
- The system is covered with a cloth to keep dust off.

State of the probes

- Cleaned, disinfected, and sterilized.
- Stored in a probe holder or in their special cases.
- The system is stored in a location that satisfies the conditions for storage environments.

State of the peripherals

- The printer head has been cleaned.

4.15 Storage

Store the system in a suitable environment for storage.

Reference information

2.3.2 Ambient conditions on page 52
3.1.3 Moving the system on page 61

5

Maintenance

5.1 Cleaning and disinfecting

After the examination, switch off the system, and then clean, disinfect, and inspect it.
If you do not clean and disinfect the system, or do not carry out the recommended measures and inspections after using the system, it could break down or fail to function correctly during the next examination.
When cleaning and disinfecting the exterior of the system, use only the chemicals we recommend.
NOTE: For information on the use of disinfectants, see "Using approved disinfectants" in this manual.
NOTE: Shut down the system, and then remove the power plug from the hospital-grade outlet and clean the power plug.
NOTE: Some parts might turn yellow after disinfection.

⚠ DANGER

Do not connect or disconnect the power plug while your hands are wet.
Ignoring this instruction might result in electric shock.

When removing the power cable, hold the power plug. Do not pull on the cable.
Ignoring this instruction might lead to electric shock or short-circuits, which could cause a fire.

Do not use a power plug or power cable that is damaged or hot, or a power plug that cannot be properly seated in a power outlet.
Ignoring this instruction might result in electric shock and short-circuits, which could cause a fire.

Disconnect the power plug and use a dry cloth to regularly remove dust from the power plug. (Unplug the system if it will not be used for a long period of time.)
Ignoring this instruction might result in the absorption of water, which could cause insulation failure and fire.

After cleaning the system, wipe away any remaining moisture. Make sure all surfaces are dry.
Unless the system parts are dry, there is a risk of electric shock and injury.

Do not use when wet.
Ignoring this instruction might result in electric shock and injury.

Do not use benzine or thinner to clean the system.
Ignoring this instruction might result in fire or malfunction.

Use a soft, slightly dampened lint-free cloth or cotton bud to clean or disinfect.
Do not put too much liquid on the lint-free cloth or cotton bud, because excess liquid could enter the system which might result in short circuits or electric shock.
If liquid enters the system, please contact our office.

Do not expose connectors to liquid.
Ignoring this instruction might result in short circuits or electric shock. If water enters a connector, please contact our office.

Avoid direct contact with any chemicals.
Contact with a chemical might lead to inflammation. See the documentation for details about the specific chemical before using the chemical.

Use only chemicals that have been approved for use on the system.
Ignoring this instruction might result in fractures (cracks, etc.).

Take care not to spill liquid onto or into the system.
Ignoring this instruction might result in short circuits or electric shock. If liquid is spilled on the system, please contact our office.

⚠ WARNING

Clean and disinfect the probes after each examination.
Ignoring this instruction might cause infections from the probes. For information about handling, cleaning, disinfecting, sterilizing and inspecting probes, see the supplied documentation.

Be sure to observe the recommendations of the chemical company and local laws and regulations in disposing of chemicals.
Ignoring this instruction might lead to pollution.

Use gloves, masks, goggles and other personal protective equipment (PPE) when handling chemicals.
Handling the system with your bare hands when it is contaminated by body fluids or other liquids could result in an infection.

⚠ CAUTION

Do not clean, disinfect or sterilize the system with chemicals or gases that we do not recommend.
Ignoring this instruction might result in damage to the system.

Before using a chemical, confirm that the usage is permitted in the country or region where the system is used.
This manual does not provide information on chemicals.

Refer to the documentation supplied by the chemical company regarding its effect and suitable clinical use.
Sufficient sterilization and disinfection effects might not be obtained if suitable clinical use are not observed.

Storage and use of a chemical must conform to the instructions in the supplied documentation.
Incorrect storage and use could reduce the effect of a chemical.

Check the expiration date of a chemical.
A chemical that is past its expiration date might no longer be as effective.

Use gloves, masks, goggles and other personal protective equipment (PPE) when handling chemicals.
Ignoring this instruction might result in the eyes, mouth, or skin being exposed to those chemicals.

Dispose of gloves after each cleaning and disinfection job.
Ignoring this instruction might result in contamination.

Lint free cloths or cotton buds used for cleaning or disinfection should be replaced frequently.
Ignoring this instruction might result in contamination.

If sodium hypochlorite is used, make sure none of it remains after disinfection.
Ignoring this instruction might result in fading or discoloring of printed text or images, or rusting in the system.

NOTICE

Wipe gently when cleaning and disinfecting the system.
Do not wipe with too much pressure as it might cause the paint to peel or make labels unreadable.

Clean with organic solvents or disinfectants which are specified in "Using approved disinfectants" on this document.
Using other chemicals which are not specified in "Using approved disinfectants" on this document may cause degradation and/or damage of exterior surfacing.

5.1.1 Using approved disinfectants

We have conducted a survey of new medical disinfectants to find disinfectants that are suitable for disinfecting the system.
Use only the disinfectants in the list below to disinfect the system and the touch panel. Refer to the Usable/not usable field in the table below to determine whether a disinfectant can be used to clean the system and the touch panel.
Storage, use, and disposal of a disinfectant must conform to the instructions that come with the disinfectant.
NOTE: Contact with a disinfectant might lead to inflammation.

Chemicals approved for disinfecting the exterior of the system

Product name and general name	Manufacturer	External housing	Filter	Monitor housing	22-inch monitor OLED surface	23-inch monitor LCD surface	21.5-inch monitor LCD surface	Operation panel	Alphanumeric keyboard	Touch panel	Trackball	Power plug
Cleanisept Wipes	Dr. Schumacher GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cleanisept Wipes forte	Dr. Schumacher GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Meliseptol(R) HBV Tissues	B.Braun Medical AG	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mikrobac(R) Tissues	BODE Chemie GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tristel Duo	Tristel Company	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
WIP'ANIOS EXCEL	Laboratoires ANIOS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mikrozid Universal Wipes	Schuelke & Mayr GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sodium hypochlorite	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ethyl alcohol max. 80% vol.	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Isopropyl alcohol max. 80% vol.	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Product name and general name	Manufacturer	Power cable	Caster	Probe holder	Transvaginal/Transrectal probe holder	Transvaginal/Transrectal probe holder adapter	RVS sensor	ECG cable (ECG cable)	Foot switch	Peripheral devices
Cleanisept Wipes	Dr. Schumacher GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cleanisept Wipes forte	Dr. Schumacher GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Product name and general name	Manufacturer	Power cable	Caster	Probe holder	Transvaginal/Transrectal probe holder	Transvaginal/Transrectal probe holder adapter	RVS sensor	ECG cable (ECG cable)	Foot switch	Peripheral devices
Meliseptol(R) HBV Tissues	B.Braun Medical AG	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mikrobac(R) Tissues	BODE Chemie GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tristel Duo	Tristel Company	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
WIP'ANIOS EXCEL	Laboratoires ANIOS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mikrozid Universal Wipes	Schuelke & Mayr GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sodium hypochlorite	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ethyl alcohol max. 80% vol.	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Isopropyl alcohol max. 80% vol.	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

5.1.2 Frequency of cleaning and disinfecting

- Areas to be cleaned and disinfected at least once a week
  - Power plug, hospital-grade power outlet
    NOTE: The power plug must be disconnected from the hospital-grade power outlet before cleaning.
  - Location where the system is installed
  - Operation panel (including the alphanumeric keyboard)
  - Exterior of the system (including probe holders)
  - Monitor
  - Filter
  - Trackball
- Areas to be cleaned and disinfected as necessary
  - Foot switch
  - Cleaning the printer head

5.1.3 Cleaning and disinfecting the system exterior

Wipe gently using a soft, dry, lint-free cloth.

(1) If the item is very dirty

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

(2) Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps.

Procedure

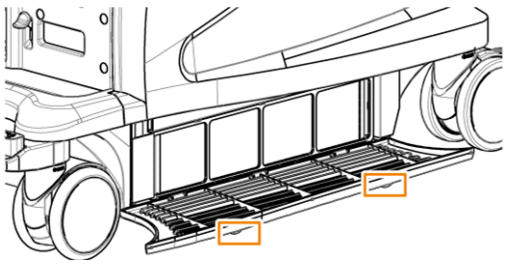
1. Wipe gently with an approved disinfectant.
2. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
3. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.4 Cleaning the filter

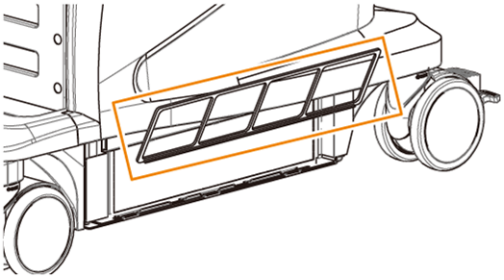
The filters are located on the left and right sides of the system.

Procedure

1. Remove the lid of the filter cover while pressing down the tabs.



2. Pull the filter outward to remove it.



3. Use a vacuum cleaner to remove dust from the filter.
4. Clean the filter under running water.
5. Drain water thoroughly, and then dry the filter in a well-ventilated place out of direct sunlight.
6. Check the front and back of the filter and reattach it in the original location.
   NOTE: Push in the filter completely.
7. Close the filter cover.
   a. Fit the bottom part of the filter cover in the groove in the unit.
   b. Close the filter cover.
      NOTE: Push in the filter cover completely.

5.1.5 Cleaning and disinfecting the viewing monitor cover

Wipe gently using a soft, dry, lint-free cloth.

(1) If the item is very dirty

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

(2) Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps.

Procedure

1. Wipe gently with an approved disinfectant.
2. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.

3. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.6 Cleaning and disinfecting the viewing monitor (OLED surface and LCD surface)

Wipe gently using a soft, dry, lint-free cloth.

CAUTION

Do not wipe the OLED or LCD surfaces of the viewing monitor using an unapproved disinfectant.
The coating of the OLED or LCD surface might peel off.

Gently wipe the OLED surface or LCD surface of the viewing monitor.
Using excessive pressure when wiping the OLED or LCD surface might damage it.

Do not scratch the OLED or LCD surface.
The OLED or LCD surface might be damaged.

(1) If the item is very dirty

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

(2) Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps.

Procedure

1. Wipe gently with an approved disinfectant.
2. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
3. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.7 Cleaning and disinfecting the operation panel and the alphanumeric keyboard

Wipe gently using a soft, dry, lint-free cloth.

(1) If the item is very dirty

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
   NOTE: Remove any dirt by wiping the keys and other parts of the alphanumeric keyboard with a cotton bud dampened with a diluted neutral detergent.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
   NOTE: Wipe the keys and other parts of the alphanumeric keyboard with a cotton bud dampened with water.
5. Use a soft, dry, lint-free cloth or cotton bud to gently wipe away any remaining moisture and leave to dry out.

(2) Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps.

Procedure

1. Wipe gently with an approved disinfectant.
   NOTE: Wipe the keys and other parts of the alphanumeric keyboard with a cotton bud dampened with disinfectant.
2. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
3. If necessary, use a soft, dry, lint-free cloth or cotton bud to gently wipe away any remaining moisture and leave to dry out.

5.1.8 Cleaning and disinfecting the touch panel

Wipe gently using a soft, dry, lint-free cloth.

⚠ CAUTION

Wipe the touch panel gently.
Using excessive pressure when wiping the touch panel might damage it.

Do not scratch the touch panel.
Ignoring this instruction might result in damage to the touch panel.

(1) If the item is very dirty

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

(2) Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps.

Procedure

1. Wipe gently with an approved disinfectant.
2. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
3. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.9 Cleaning and disinfecting the trackball

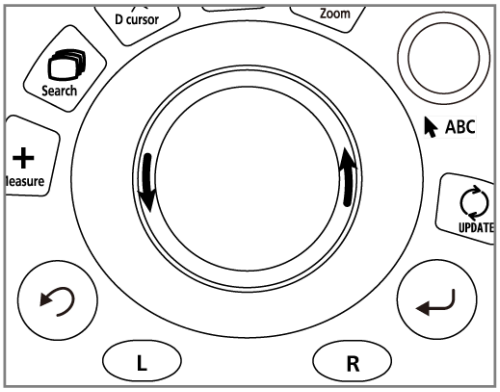
CAUTION

Do not drop the removed trackball or allow objects to strike against it.
Ignoring this instruction might result in damage to the trackball, and it might no longer work normally.

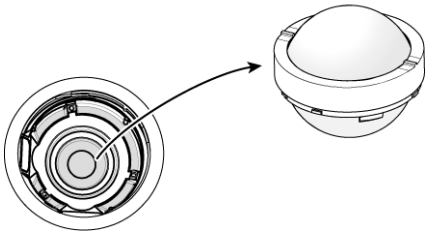
(1) Removing the trackball from the operation panel

Procedure

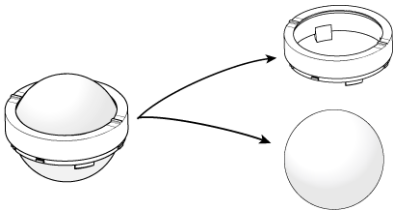
1. Turn the ring counterclockwise.



2. Remove the trackball and the ring from the operation panel.



3. Remove the trackball from the ring and place it on a soft, lint-free cloth.

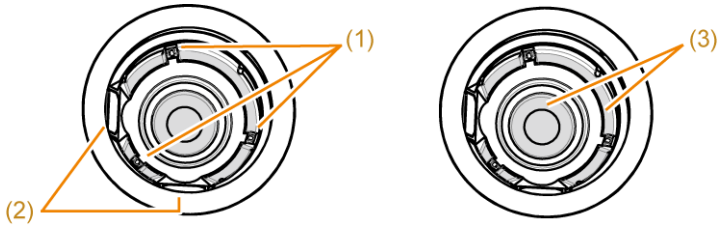


(2) Cleaning and disinfecting

Procedure

- Trackball support balls, sensors, and grooves (on the operation panel side)

  a. Use a dry cotton swab to clean the trackball support balls (3 places) and the grooves. Use a lint-free cloth that will not leave fibers behind to clean the sensors (2 places).
  NOTE: Clean the sensor of any fingerprints, sebum, fibers, or other dirt.
  NOTE: Note that if any sand-like grit or debris remain on the sensor, firmly rubbing the sensor might result in scratches.



(1) Trackball support balls, (2) Sensors, (3) Grooves (the shadowed areas)

If the item is very dirty

Clean as described below. Use a lint-free cloth to wipe the sensors.

a. Dampen a cotton bud with a small amount of neutral detergent diluted with water to clean.

b. Use a cotton bud dampened with water to gently wipe away any remaining detergent.

c. Use a dry cotton bud to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps. Use a lint-free cloth to wipe the sensors.

a. Use a cotton bud dampened with an approved disinfectant for wiping.

b. If necessary, use a cotton bud dampened with water to gently wipe away any remaining disinfectant.

c. If necessary, use a dry cotton bud to gently wipe away any remaining moisture and leave to dry out.

- Trackball and ring

a. Wipe the trackball and ring gently using a soft, dry, lint-free cloth.

If the item is very dirty

Clean as described below.

a. Dampen a lint-free cloth with a small amount of neutral detergent diluted with water to clean.

b. Dampen a soft, lint-free cloth with water and wring it out thoroughly.

c. Use the lint-free cloth in step b to gently wipe away any remaining neutral detergent.

d. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps.

a. Wipe gently with an approved disinfectant.

b. If necessary, dampen a lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.

c. If necessary, use a soft, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

NOTE: Do not strongly rub the surface of the trackball. Ignoring this instruction might result in the trackball losing its lubricity and no longer being able to turn smoothly.

If the trackball no longer turns smoothly

a. Uniformly apply approximately 0.1 g of white Vaseline over the entire trackball.

b. Wipe the trackball with a dry, lint-free cloth until no stickiness can be felt.

(3) Attaching the trackball to the operation panel

NOTE: Be careful not to get Vaseline on the sensors when you attach the trackball.

Procedure

1. Attach the trackball to the ring.
2. Attach the ring and trackball to the operation panel.
3. Turn the ring clockwise.

5.1.10 Cleaning and disinfecting the power plug

CAUTION

Do not expose the electrodes of the power plug to water.
Ignoring this instruction might result in short circuits or electric shock. If water enters a connector, please contact our office.

(1) Power plug prongs

Procedure

1. Wipe gently using a soft, dry, lint-free cloth.

(2) Power plug exterior

Procedure

1. Wipe gently using a soft, dry, lint-free cloth.
   If the item is very dirty
   Clean as described below.
   a. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
   b. Use the lint-free cloth in step a to gently wipe away any dirt.
   c. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
   d. Use the lint-free cloth in step c to gently wipe away any remaining neutral detergent.
   e. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

   Disinfecting
   After performing the above steps, disinfect the relevant part by using the following steps.
   a. Wipe gently with an approved disinfectant.
   b. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.

c. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.11 Cleaning and disinfecting the power cable

Wipe gently using a soft, dry, lint-free cloth.

(1) If the item is very dirty

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

(2) Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps.

Procedure

1. Wipe gently with an approved disinfectant.
2. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
3. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.12 Cleaning and disinfecting the area of the casters that are in contact with the ground

Use the following procedure to clean and disinfect the area of the casters that come into contact with body fluids in operating theaters and other medical facilities.

Procedure

1. Dampen a lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Place the lint-free cloth in step 1 on the floor and move the system so the casters roll over the cloth to clean them.
3. Dampen a lint-free cloth with water and wring it out thoroughly.

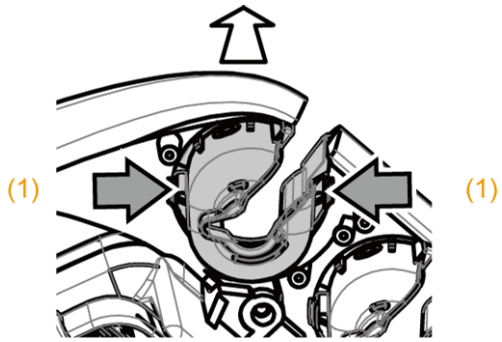
4. Place the lint-free cloth in step 3 on the floor and move the system so the casters roll over the cloth to remove any remaining neutral detergent.
5. Place a dry, lint-free cloth on the floor and move the system so the casters roll over the cloth to remove any remaining moisture and leave to dry out.
6. Dampen a lint-free cloth with an approved disinfectant and wring it out thoroughly.
7. Roll the casters over the lint-free cloth in step 6 to disinfect them.
8. Dampen a lint-free cloth with water and wring it out thoroughly.
9. Place the lint-free cloth in step 8 on the floor and move the system so the casters roll over the cloth to remove any remaining disinfectant.
10. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.13 Cleaning and disinfecting the probe holder

(1) Removing the probe holder from the operation panel

Procedure

1. Press tab (1) in the direction of the arrow and lift the probe holder upwards to remove it.



Rear of the operation panel

(2) Cleaning and disinfecting

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.
   If the item is very dirty
   Clean as described below.

a. Use a sponge or gauze cloth to wash away the dirt under running water.

b. Use a neutral detergent, and a sponge or gauze cloth, for washing.

c. Rinse under running water to make sure no detergent remains.

d. Use a dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

After performing the above steps, disinfect the relevant part by using the following steps.

a. Wipe gently with an approved disinfectant.

b. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.

c. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

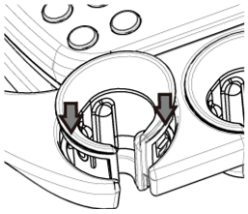
(3) Attaching the probe holder to the operation panel

Procedure

1. Attach the probe holder.

   a. Align the notches and place the probe holder.

   b. Place a finger on each side of the rim above the tabs and press the holder down until the tabs click into place.



5.1.14 Cleaning and disinfecting the transvaginal/transrectal probe holder

Clean and disinfect the optional transvaginal/transrectal probe holder.
The transvaginal/transrectal probe holder is an optional probe holder for storing a transvaginal/transrectal probe. The transvaginal/transrectal probe holder and the holder adapter can be removed separately. Clean and disinfect as necessary.

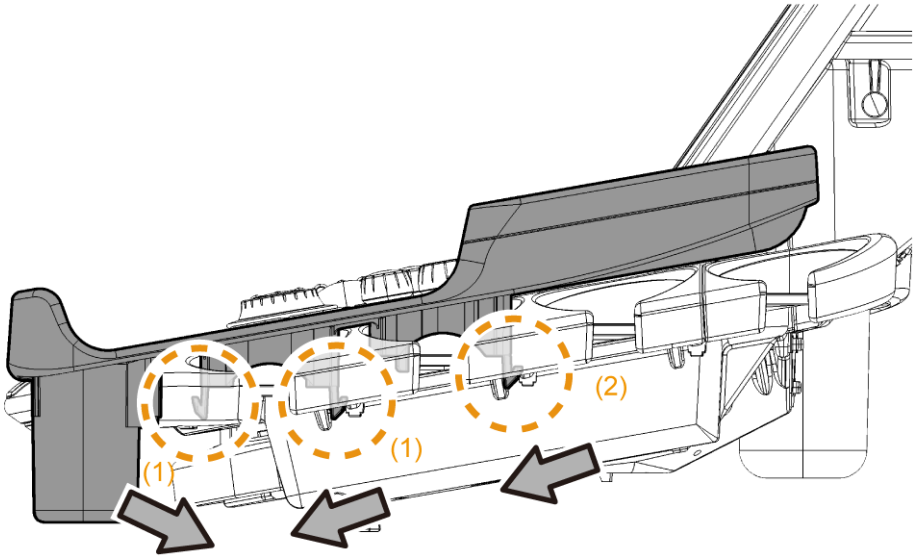
(1) Removing the transvaginal/transrectal probe holder from the operation panel

Procedure

1. Remove the transvaginal/transrectal probe holder.

   a. Press tab (1) in the direction of the arrow and lift to release it.

   b. Press tab (2) in the direction of the arrow and lift to release it.



(2) Cleaning and disinfecting

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

   If the item is very dirty

   Clean as described below.

   a. Use a sponge or gauze cloth to wash away the dirt under running water.
   b. Use a neutral detergent, and a sponge or gauze cloth, for washing.
   c. Rinse under running water to make sure no detergent remains.
   d. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

   Disinfecting

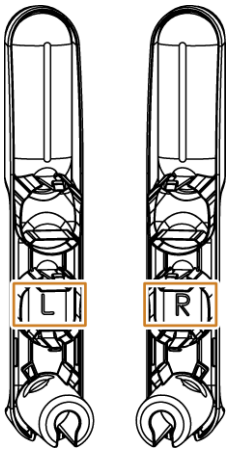
   After performing the above steps, disinfect the relevant part by using the following steps.

   a. Wipe gently with an approved disinfectant.
   b. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
   c. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

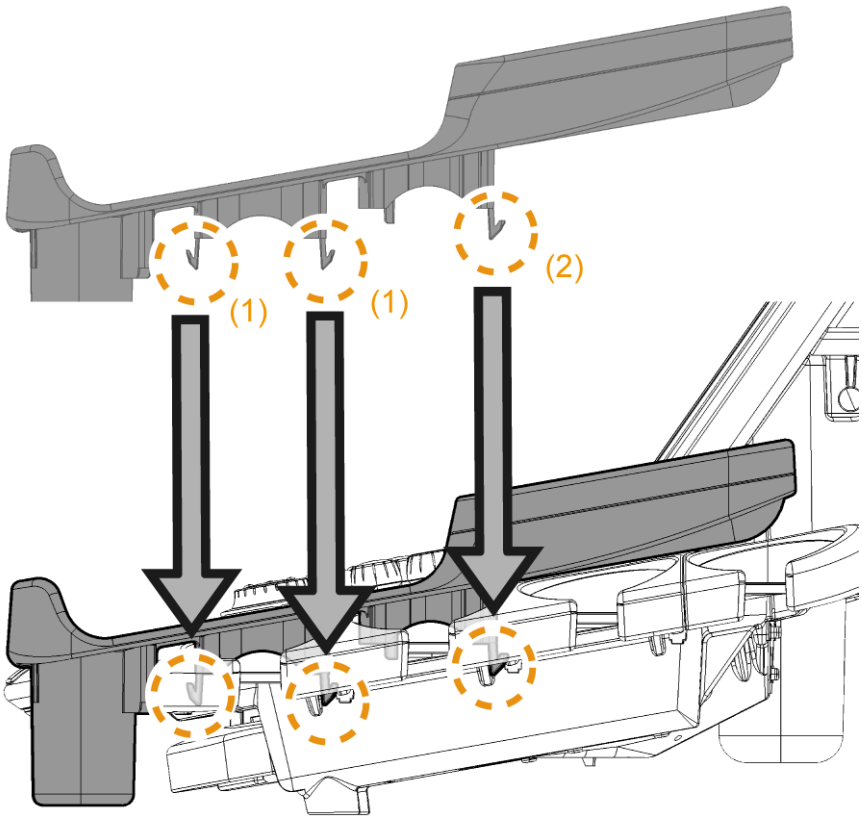
(3) Attaching the transvaginal/transrectal probe holder to the operation panel

Procedure

1. Prepare the probe holder you want to install.
   - To attach a probe holder to the right side (when looking at the front of the system), prepare the R holder.
   - To attach a probe holder to the left side (when looking at the front of the system), prepare the L holder.



2. Attach the transvaginal/transrectal probe holder.
   a. Align tab (1), and press until you hear a click.
   b. Align tab (2), and press until you hear a click.

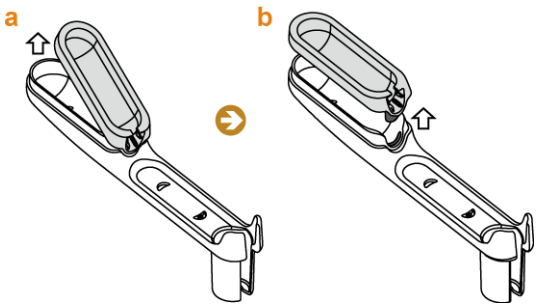


5.1.15 Cleaning and disinfecting the transvaginal/transrectal probe holder adapter

(1) Removing the transvaginal/transrectal probe holder adapter

Procedure

1. Remove the adapter.
   a. Lift up the far end of the adapter to remove it.
   b. Lift up the front part of the adapter to remove it.



(2) Cleaning and disinfecting

Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.
   If the item is very dirty
   Clean as described below.
   a. Use a sponge or gauze cloth to wash away the dirt under running water.
   b. Use a neutral detergent, and a sponge or gauze cloth, for washing.
   c. Rinse under running water to make sure no detergent remains.
   d. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

   Disinfecting
   After performing the above steps, disinfect the relevant part by using the following steps.
   a. Wipe gently with an approved disinfectant.

b. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.

c. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

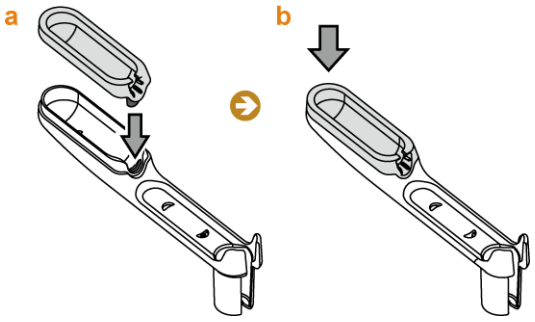
(3) Attaching the transvaginal/transrectal probe holder adapter

Procedure

1. Attach the adapter.

   a. Align the adapter's tab with the slot in the probe holder, and then press it in.

   b. Attach the far end of the adapter to the probe holder.



5.1.16 Cleaning, disinfecting, and sterilizing probes

The method used to clean, disinfect, and sterilize varies with the probe type. See the documentation for each probe.

WARNING

After the examination, clean, disinfect, and sterilize the probes.
Ignoring this instruction might result in probes spreading infections.

5.1.17 Cleaning and disinfecting the RVS sensor

For details on how to clean, disinfect, and sterilize probes, see the separate manual "Advanced Operations 2".

5.1.18 Cleaning and disinfecting an electrocardiogram cable (ECG cable)

Prior confirmation

Disconnect the electrocardiogram cable connector from the ECG cable plug, and then clean and disinfect it.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.
   Disinfecting
   After performing the above steps, disinfect the relevant part by using the following steps.
   a. Wipe gently with an approved disinfectant.
   b. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
   c. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.19 Cleaning and disinfecting the foot switch

Prior confirmation

Disconnect the foot switch connector from the foot switch plug.
Clean as described below.

Procedure

1. Dampen a soft, lint-free cloth with a neutral detergent diluted with water and wring it out thoroughly.
2. Use the lint-free cloth in step 1 to gently wipe away any dirt.
3. Dampen a soft, lint-free cloth with water and wring it out thoroughly.
4. Use the lint-free cloth in step 3 to gently wipe away any remaining neutral detergent.
5. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.
   If the item is very dirty
   Clean as described below.
   a. Use a sponge or gauze cloth to wash away the dirt under running water.
   b. Use a neutral detergent, and a sponge or gauze cloth, for washing.
   c. Rinse under running water to make sure no detergent remains.
   d. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

   Disinfecting
   After performing the above steps, disinfect the relevant part by using the following steps.
   a. Wipe gently with an approved disinfectant.

b. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.

c. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture and leave to dry out.

5.1.20 Cleaning peripheral devices

See the documentation for each option.
For details on how to clean the printer head, see the documentation for the printer.

5.2 The need for regular maintenance inspections

Periodic maintenance inspections are essential to maintain system performance and ensure safe operation.
Maintenance inspection involves three inspections: daily inspections, measurement accuracy inspections, and safety inspections. Safety inspections must be conducted by a technician qualified to perform safety inspections on medical electrical equipment. If you do not have a qualified technician available, our service staff can conduct this inspection for a service charge. To request a service engineer visit, please contact our office.
Observe the precautions related to electrostatic discharges (ESD) when performing maintenance inspections. Ignoring this instruction might result in parts that are sensitive to static electricity being damaged or failing.

Reference information

7.2 Electrostatic discharge (ESD) guidelines on page 211

5.2.1 Daily inspections: For a long service life

Long-term wear of parts and consumables might cause the system to fail to function or break down. In order to prevent accidents from long-term wear, you must conduct periodic inspections as well as inspection before and after use.

1. Daily inspection
   - There must be no buildup of dust on the power plug.
   - The monitor, monitor arm, and other moving parts must be tightly fastened.
   - The monitor arm must not be loose when it is locked.
   - The Monitor Contrast and Monitor Brightness settings must be appropriate.
   - The contrast and brightness settings of the printer must be appropriate.
   - The screws in the mounting base must be tight, and peripheral devices must be fixed securely.

   NOTE: The number of probe inspections that must be performed depends on probe type. Inspect probes as described in their documentation.
2. Items that require periodic inspection at least once a month

- Casters must be properly locked.
- The control panel and handles must be tightly fastened.
- Make sure that there are no cracks, damage, or dents in the enclosure.
- Filters must not be clogged with dust.
- Connectors must not be clogged with dust.

CAUTION

Do not use the system if there are any loose parts, cracks, damage, or dents.
A system that has broken down and can no longer be used must be marked with a sign stating it is out of order. Contact our office as soon as possible.

Do not use the system beyond its specified service life (seven years).
The system might not operate properly if used beyond its service life.

5.2.2 Measurement accuracy inspections

At least once a year, perform a measurement accuracy inspection and calculation accuracy inspection by using an ultrasound phantom to make the following measurements.
The inspection records are stored.

1. Distance measurement accuracy
2. Resolution and sensitivity
3. Doppler measurement accuracy

(1) Preparations for measurement accuracy inspections

Prior confirmation

Provide the following items:

- Ultrasound phantom
  An ultrasound phantom is an object made of a substance that simulates the behavior of body tissues when exposed to ultrasonic waves. It is used for checking the performance of probes and the Diagnostic Ultrasound System, and for adjusting the image settings. The ultrasound phantom has regions with different textures, and targets spaced at preset intervals are embedded in it. Some phantoms contain a mechanism for Doppler measurements.
- The probe used for the inspection, and its documentation
- Measurement Accuracy Inspection Record Table
- The previous measurement accuracy inspection record (if any)

Procedure

1. Copy the Measurement Accuracy Inspection Record Table and enter the required items.

2. Connect the probe to be used for the inspection to the system.
3. Turn on the system.
4. Change the preset to use the settings of the previous inspection. Select the optimum preset for the connected probe.
   If there is no previous inspection record
   Select the optimum preset for the connected probe.
5. Record the presets settings and enter them in the Measurement Accuracy Inspection Record Table. Alternatively, record them as data to a DVD or another type of storage medium, and record the number of the storage medium in the Measurement Accuracy Inspection Record Table.
   Presets screen to record
   - Item B in the Region Data Settings
   - QSS B item
   - QSS M item
   - QSS D item in the PW tab
   - QSS Color item in the Color1 tab

(2) Distance measurement accuracy inspections

Use the ultrasound phantom to determine the orientation direction and distance direction distances.

Procedure

1. Switch to B mode.
2. Line up all of the [TGC] sliders in the middle.
3. Apply ultrasound gel on the contact surface of the probe or ultrasound phantom.
4. Place the probe against the ultrasound phantom.
5. Adjust R (display depth), G (gain), D (dynamic range), and Acoustic Power (ultrasound output power) to match the previous inspection record.
   If there is no previous inspection record
   Adjust the display depth, gain, dynamic range, and ultrasound output power until the best possible image is obtained.
6. Freeze the image.
7. Calculate measurement accuracy in orientation direction.
   a. Measure the distance between targets separated by a known distance in the orientation direction.
   b. Print the image and attach it to the Measurement Accuracy Inspection Record Table.
   c. Calculate measurement accuracy.
      → If the result differs significantly from the previous measurement result, judge the result to be abnormal.

8. Similarly, calculate measurement accuracy in the distance direction.

   → If the result differs significantly from the previous measurement result, judge the result to be abnormal.

(3) Resolution and Sensitivity Inspection

Procedure

1. Switch to B mode.
2. Line up all of the [TGC] sliders in the middle.
3. Apply ultrasound gel on the contact surface of the probe or ultrasound phantom.
4. Place the probe against the ultrasound phantom.
5. Adjust R (display depth), G (gain), D (dynamic range), and Acoustic Power (ultrasound output power) to match the previous inspection record.
   If there is no previous inspection record
   Adjust the display depth, gain, dynamic range, and ultrasound output power until the best possible image is obtained.
6. Freeze the image.
7. Record the presets settings and enter them in the Measurement Accuracy Inspection Record Table. Alternatively, record them as data to a DVD or another type of storage medium, and record the number of the storage medium in the Measurement Accuracy Inspection Record Table.

   → If the result differs significantly from the previous inspection record, judge the result to be abnormal.

(4) Doppler measurement accuracy inspections

Perform an inspection of the accuracy and sensitivity of Doppler measurements.
Two methods are used to inspect Doppler measurement accuracy.

(a) Using the result of an ultrasound phantom sensitivity inspection to substitute for a Doppler measurement accuracy result

The major causes of reduced Doppler measurement sensitivity are probe wear and a damaged transmitter unit.
These causes reduce the directionality and sensitivity of the transceiver beam resulting in flow velocities being underestimated and polarity being reversed.
Normally, an ultrasound Doppler phantom is used to make these inspections. However, if the results of an ultrasound phantom inspection of sensitivity and resolution are normal, they can substitute for a Doppler phantom inspection of measurement accuracy and sensitivity of a probe.

(b) Using an ultrasound Doppler phantom

Use an ultrasound Doppler phantom with a Doppler measurement mechanism to measure flow velocity. Record the results for each measurement.
NOTE: Do not change menu settings during inspection.

Procedure

1. Switch to B/PW mode.
2. Apply ultrasound gel on the contact surface of the Doppler phantom or probe.
3. Place the probe against the Doppler phantom.
4. Set the Doppler phantom flow velocity to the velocity recorded in the previous inspection record, and record it in the Measurement Accuracy Inspection Record Table.
5. Set D gain to the value recorded in the previous inspection record, and record it in the Measurement Accuracy Inspection Record Table.
   If there is no previous inspection record
   Adjust the settings until you obtain the optimum image.
6. Move the sample gate position of the D cursor to a location with blood flow in the tomographic image, and display a Doppler waveform.
7. Freeze the image.
8. Measure the flow velocity.
9. Record the presets settings and enter them in the Measurement Accuracy Inspection Record Table. Alternatively, record them as data to a DVD or another type of storage medium, and record the number of the storage medium in the Measurement Accuracy Inspection Record Table.
   → If the result differs significantly from the previous inspection record, judge the result to be abnormal.

(c) Inspecting sensitivity

Procedure

1. Switch to B+Color mode (Color Flow mode).
2. Apply ultrasound gel on the contact surface of the Doppler phantom or probe.
3. Place the probe against the Doppler phantom.
4. Set the Doppler phantom flow speed to the speed recorded in the previous inspection record, and record it in the Measurement Accuracy Inspection Record Table.
5. Set color Doppler gain to the value recorded in the previous inspection record, and record it in the Measurement Accuracy Inspection Record Table.
   If there is no previous inspection record
   Adjust the settings until you obtain the optimum image.
6. Freeze the image.
7. Record the presets settings and enter them in the Measurement Accuracy Inspection Record Table. Alternatively, record them as data to a DVD or another type of storage medium, and record the number of the storage medium in the Measurement Accuracy Inspection Record Table.
   → If the result differs significantly from the previous inspection record, judge the result to be abnormal.

5.2.3 Measurement accuracy inspection record table

Diagnostic Ultrasound System	Model name	Serial number
Probe	Model name	Serial number
Other peripheral devices	Model name	Serial number

Inspected date:	Inspector affiliation Signature

QSS B item		QSS M item	
Item B in the Region Data Settings		Ultrasound phantom identification (Control No., date of purchase, S/N, etc.)	

Measurement accuracy			
Orientation direction image		Distance direction image	
Known distance between targets (cm): a		Known distance between targets (cm): a	
Measured distance (cm): b		Measured distance (cm): b	
Distance measurement accuracy (%) |b-a| ÷ a × 100 =		Distance measurement accuracy (%) |b-a| ÷ a × 100 =	

Resolution	
Image paste position	

Doppler measurement accuracy (when a Doppler phantom is used)			
Paste position of the QSS D item in the PW tab		Doppler phantom identification (Control No., date of purchase, S/N, etc.)	
Paste position of the QSS Color item in the Color1 tab		Phantom settings Flow velocity (m/s):	
Image paste position in B/PW mode		Image paste position in B+Color mode	
D gain value		CF gain value	

5.2.4 Safety Inspection

The safety inspection must be conducted at least once a year by a technician qualified to perform safety inspections on medical electrical equipment. The inspection record must be stored.
Perform the safety inspection using the procedure below, and confirm that the measured values are no greater than the standard values in the table below.
If the customer does not have a qualified technician available, our service staff can conduct this inspection for a service charge. Please contact our office to request a service engineer visit.

Standard values for periodic safety inspection (extracted from the international standards for medical electrical equipment)

Item		Normal condition	Single fault condition
1.	Earth leakage current	5 mA max	10 mA max
2.	Touch current	0.1 mA max	0.5 mA max
3.	Patient leakage current from patient connection to earth (d.c.)	0.01 mA max	0.05 mA max
	Patient leakage current from patient connection to earth (a.c.)	0.1 mA max	0.5 mA max
	Total patient leakage current with the same types of applied part connected together (d.c.)	0.05 mA max	0.1 mA max
	Total patient leakage current with the same type of applied part connected together (a.c.)	0.5 mA max	1.0 mA max
4.	Patient leakage current caused by an external voltage on the patient connection of an F-type applied part	-	5 mA max
	Total patient leakage current caused by an external voltage on the patient connection of an F-type applied part	-	5 mA max
5.	Patient leakage current caused by an external voltage on a SIP/SOP (d.c.)	0.01 mA max	0.05 mA max
	Patient leakage current caused by an external voltage on a SIP/SOP (a.c.)	0.1 mA max	0.5 mA max
	Total patient leakage current caused by an external voltage on a SIP/SOP (d.c.)	0.05 mA max	0.1 mA max
	Total patient leakage current caused by an external voltage on a SIP/SOP (a.c.)	0.5 mA max	1.0 mA max
6.	Protective earth terminal	0.2 Ω max	-

Standard values for periodic safety inspection (Extracted from IEC 62353)

Item		Normal condition
1.	PROTECTIVE EARTH RESISTANCE For the POWER SUPPLY CORD itself	300 mΩ max
2.	EQUIPMENT LEAKAGE CURRENT - Alternative method (a.c.)	1 mA max

Item		Normal condition
3.	APPLIED PART LEAKAGE CURRENT - Alternative method (a.c.)	5 mA max

NOTICE

Perform facility inspection in the hospital (e.g. measure the protective earth impedance) at least once a year.

(1) Periodic Safety Inspection Procedure

(a) Earth leakage current

Test as described in clause 8.7.4.5 of the international standards for medical electrical equipment.
This instrument does not have an FE (Functional earth terminal).
The PE (Protective earth terminal) of this instrument also functions as a leakage current measurement terminal.
The protective earth terminal is located on the backside of the instrument.

(b) Touch current

Test as described in clause 8.7.4.6 of the international standards for medical electrical equipment.
Signal input and output points of this instrument are protectively earthed except the connectors of the ECG lead. Do not apply a voltage to the signal input or output connectors.
Check the leakage at any part of the enclosure apart from probe connector. To do this, apply two sheets of metal foil of maximum dimensions 20 x 10 cm to arbitrary parts of the enclosure, then measure the leakage current between one metal foil and ground, and also between the two metal foil sheets.

(c) Patient leakage current

Patient leakage current from patient connection to earth

Test as described in clause 8.7.4.7 a) of the international standards for medical electrical equipment.
When using multiple probes at the same time, put the selected probe in a physiological saline solution to measure the leakage current between the ground and the salt solution. Do not put the probes past the "maximum immersion point" indicated in the instruction manual for each probe.
Short-circuit the three plugs of the cardiac induction cables and measure the leakage current between the short-circuited area and ground.

Patient leakage current caused by an external voltage on the patient connection of an F-type applied part

Test as described in clause 8.7.4.7 b) of the international standards for medical electrical equipment.
When using multiple probes at the same time, put the selected probe in a salt solution and measure a leakage current between the outside voltage and the salt solution.

Do not put the probes past the "maximum immersion point" indicated in the instruction manual for each probe.
Short-circuit the three plugs of the cardiac induction cables and measure the leakage current between the short-circuited area and external voltage.

Patient leakage current caused by an external voltage on a SIP/SOP

When conducting the international standards for medical electrical equipment test, as indicated in clause 8.7.4.7 c), "Measurement of patient leakage current due to external voltage on the signal input/output part, causing patient to ground out," contact one of our office.

Total PATIENT LEAKAGE CURRENT

When using ECG cables or multiple probes at the same time, measure the total leakage current.
Test as described in clause 8.7.4.7 h) of the international standards for medical electrical equipment.
The patient-connected parts to be measured shall be a combination of the three electronic probes with the largest measured values in the measurement results described above, a specialized Doppler probe (if available), and ECG cables.

(d) Protective earth terminal

Measure impedance between the protective ground terminal and a touchable metal part with protective grounding, according to clause 8.6.4 a) of the international standards for medical electrical equipment. When the specification of an arbitrary metal part is difficult to identify, it is recommended that the GND side of an unconnected socket is used.

NOTICE

When inspecting the impedance for protective contact to earth, do not bring the probe of the tester into contact with the signal line pins of the connector.
The measuring current may cause damage to the signal line circuit.

(e) Visual Inspection

Perform a visual inspection according to clause 5.2) of IEC 62353.
Covers and housings shall be opened if required in the followings.

- safety related marking, labels and labelling is legible and complete,
- any damage or contamination,
- assess the relevant ACCESSORIES together with the ME EQUIPMENT (e.g. POWER SUPPLY CORDS, patient leads)
- the required documentation is present and reflects the current revision of the ME EQUIPMENT

(f) PROTECTIVE EARTH RESISTANCE

Measure the impedance between the protective earth contact and accessible metal part which is protectively earthed of the instrument according to clause 5.3.2.2 b) of IEC 62353.
NOTE: When using direct current the measurement shall be repeated with opposite polarity. Either value measured shall not exceed the allowable value. The highest value shall be documented.
NOTE: If during the flexing, changes in resistance are observed, it shall be assumed that the protective earth conductor is damaged or the connections are no longer adequate.

(g) EQUIPMENT LEAKAGE CURRENT

Equipment is separated from mains. Perform a leakage current test according to Clause 5.3.3.2.2 of IEC 62353 by using the measurement circuit shown in Figure. 3 of IEC 62353.
NOTE: Switches in the MAINS PART shall be closed during the measurement as in operational condition to cover all insulations of the MAINS PART by the measurement.

(h) APPLIED PART LEAKAGE CURRENT

Perform a leakage current test according to Clause 5.3.3.3.2 of IEC 62353 by using the measurement power supply circuit shown in Figure 6 of IEC 62353.
NOTE: BF-TYPE APPLIED PART shall be measured from all patient connections of the APPLIED PART connected together.
NOTE: Do not immerse the probes past the "maximum immersion point" indicated in the instruction manual for each probe.
NOTE: Short all three of the ECG lead jacks, and measure the leakage current between the shorted part and ground.

5.2.5 Diagnostic Ultrasound System Safety Inspection Data Sheet

(1) In case of IEC 60601-1

Diagnostic Ultrasound System	Model name	Serial number
Probe	Model name	Serial number
Other peripheral instruments	Model name	Serial number

Inspected date:	Inspector affiliation Signature

Earth leakage current		
All possible combinations of switch positions		S5: normal/reverse, S12: close/open
Normal condition Standard: 5 mA	S1 CLOSE	
Single fault condition Standard: 10 mA	S1 OPEN	

Touch current			
All possible combinations of switch positions		S5: normal/reverse, S12: close/open	
Measuring points		Between enclosure and ground	Between two points on the enclosure
Normal condition Standard: 0.1 mA	S1 CLOSE S7 CLOSE		
Single fault condition Standard: 0.5 mA	S1 OPEN S7 CLOSE		
	S1 CLOSE S7 OPEN		

Patient leakage current from patient connection to earth					
All possible combinations of switch positions		S5: normal/reverse, S13: close/open			
Measuring points		Probe	ECG cable		
DC: Normal condition Standard: 0.01 mA Total patient leakage current: 0.05 mA	S1 CLOSE S7 CLOSE				
DC: Single fault condition Standard: 0.05 mA Total patient leakage current: 0.1 mA	S1 OPEN S7 CLOSE				
	S1 CLOSE S7 OPEN				
AC: Normal condition Standard: 0.1 mA Total patient leakage current: 0.5 mA	S1 CLOSE S7 CLOSE				
AC: Single fault condition Standard: 0.5 mA Total patient leakage current: 1.0 mA	S1 OPEN S7 CLOSE				
	S1 CLOSE S7 OPEN				

Patient leakage current caused by an external voltage on the patient connection of an F-type applied part				
All possible combinations of switch positions	S5: normal/reverse, S9: normal/reverse, S13: close/open			
Measuring points	Probe	ECG cable		

Patient leakage current caused by an external voltage on the patient connection of an F-type applied part					
Single fault condition Standard: 5 mA Total patient leakage current: 5 mA	S1 CLOSE				

Patient leakage current caused by an external voltage on a SIP/SOP					
All possible combinations of switch positions		S5: normal/reverse, S9: normal/reverse, S13: close/open			
Measuring points		Probe	ECG cable		
DC: Normal condition Standard: 0.01 mA Total patient leakage current: 0.05 mA	S1 CLOSE S7 CLOSE				
DC: Single fault condition Standard: 0.05 mA Total patient leakage current: 0.1 mA	S1 OPEN S7 CLOSE				
	S1 CLOSE S7 OPEN				
AC: Normal condition Standard: 0.1 mA Total patient leakage current: 0.5 mA	S1 CLOSE S7 CLOSE				
AC: Single fault condition Standard: 0.5 mA Total patient leakage current: 1.0 mA	S1 OPEN S7 CLOSE				
	S1 CLOSE S7 OPEN				

Protective earth terminal	
Standard: 0.2 Ω	

(2) In case of IEC 62353

Diagnostic Ultrasound System	Model name	Serial number
Probe	Model name	Serial number
Other peripheral instruments	Model name	Serial number

Inspected date:	Inspector affiliation Signature

Visual INSPECTION		
	Marking, labels	
	Integrity	
	Damage	
	Accessories	
	Documentation	

PROTECTIVE EARTH RESISTANCE			
For the POWER SUPPLY CORD itself: 300 mΩ	Measuring data	Measuring points	REFERENCE VALUE*1
Configuration*2			

EQUIPMENT LEAKAGE CURRENT			
Total leakage current: 1.0 mA	Measuring data	Measuring points	REFERENCE VALUE*1
APPLIED PART LEAKAGE CURRENT			
Total leakage current: 5.0 mA	Measuring data	Measuring points	REFERENCE VALUE*1
Configuration*2			

*1.

If the measured values are between 90% and 100% of the acceptable limit, previously measured values (REFERENCE VALUE) shall be taken into consideration for the assessment of the ELECTRICAL SAFETY of the ME EQUIPMENT or the ME SYSTEM. If such previous data values are not available, reduced intervals between upcoming RECURRENT TESTS shall be taken into account.

*2.

ME SYSTEMS shall be visually inspected to determine whether the configuration is still the same as at the time of the last INSPECTION, or whether units of the ME SYSTEM have been exchanged, added or removed.

5.3 Troubleshooting

If the measures below do not solve the problem, please contact our office.

- If the system does not respond

Cause	Countermeasures
Software is unresponsive Fluctuating power supply	1. Hold down the [Power] key for 10 seconds or longer. The system shuts down. If the system shutdown does not start after 20 seconds, go to step 2. 2. Disconnect the power plug from the hospital-grade outlet. 3. After a few minutes, insert the power plug into the hospital-grade power outlet. 4. Press the [Power] key to turn the power back on.

- If the current date and time are not displayed correctly

Cause	Countermeasures
Incorrect settings	Revise the date and time in the presets.
The charge in the internal battery is depleted.	Please contact our office.

- If the monitor will not display an image or image quality is poor.
  Check the state of the [Power] key and the monitor, and perform the measures described below.

[Power] key	Display		Cause	Countermeasures
	Graphics	Image		
Unlit	-	-	The power cable is not connected.	Plug the power cable into the hospital-grade outlet.
			The circuit breaker has tripped.	Check the state of the circuit breaker for the connected power outlet.
Orange	-	-	The system is in standby.	Press the [Power] key. If the system does not start properly, please contact our office.
White	Nothing displayed	Nothing displayed	Monitor OSD settings	Check monitor settings. *3.9.4 Adjusting the brightness levels of the screen, operation panel, touch panel, and the size of the screen* on page 95
			[EXT] (external input) was used to display.	Turn [EXT] to [Off].

[Power] key	Display		Cause	Countermeasures
	Graphics	Image		
White	Status displayed	Nothing displayed	The gain is too low.	Adjust the gain by using the [Freeze] rotary encoder, [B] rotary encoder, or [TGC] sliders.
			The probe is not properly connected.	Reconnect the probe.
			The acoustic output is too low.	Adjust the acoustic output by using the [Acoustic Power] rotary encoder.
			Still image display (the orange light on the [Freeze] key is lit)	Press the [Freeze] key to switch to the real-time image.

- If trackball response is sluggish
  Remove the trackball and ring from the operation panel and clean the trackball support ball and the sensor.
- If touch panel response is sluggish
  a. Clean the touch panel.
  b. If there is no improvement, press and hold the [Menu], [L], and [R] keys at the same time for more than three seconds (the status indication lamp blinks orange three times). Make sure that nothing is in contact with the touch panel before rebooting.
  c. If the problem persists, restart the system. Make sure that nothing is in contact with the touch panel before rebooting.
- When the power is disconnected because of an error message, or an error other than the above occurs in the system
  Disconnect the power plug from the hospital-grade outlet.
- If other connected devices do not display images while the HDMI-monitor connection unit is used
  Contact our service staff.

5.4 Repairing, readjusting, and disposing of the product

- Requesting a repair or readjustment
  Turn off the power immediately if a fault occurs in this product.
  Please contact our office and describe the problem, to the best of your knowledge. We will make an on-site inspection and perform the necessary repairs.
  NOTE: Disinfect or sterilize peripheral devices, options, probes, and other parts before requesting their repair. For more details, please contact our office.

- Disposal of the system
  This system and its accessories must be disposed of properly, in compliance with the Waste Management and Public Cleansing Law. For more details, please contact our office.

6

Product configuration

6.1 Standard configuration

Name		Model name	Quantity	Remarks
Diagnostic equipment	Main unit	USI-172LE	1	*1
		USI-172SE	1	*2
		USI-172VE	1	*3
	Viewing monitor	IPF-2201*	1	22-inch monitor (OLED)*1, *2, *4
		IPF-2301*	1	23-inch monitor (LCD)*2, *4
		IPF-2105*	1	21.5-inch monitor (LCD)*2, *3, *4
Accessories	Power cable	CP-121	1	for 100 V to 120 V
	Power cable	CP-128	1	for 200 V to 240 V
	Custom Key Sheet Set	L-KEY-113_KEYSH_SET	1	
	CD Manual Set	MN-CD-ARIETTA750-E	1	
	Instruction Manual (Instructions for Use)	MN1-6505	1	Bound

*1.
Supported for the ARIETTA 750LE.

*2.
Supported for the ARIETTA 750SE.

*3.
Supported for the ARIETTA 750VE.

*4.
Depending on the date of manufacture, the asterisk (*) in the model name might be an alphabetic character.

6.2 Options

Monochrome printer

Name	Model name	Remarks
Hybrid Graphic Printer	UP-X898MD	
Digital BW Printer	P95DW	
Digital BW Printer	P95DE	*1

*1.
EU only

Color printer

Name	Model name	Remarks
Digital Color printer	UP-D25MD	
Digital Color printer	CP30DW	*1

*1.
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.

Video recorder

Name	Model name	Remarks
HD Video Recorder	HVO-500MD /FHD (*)	*1 No optical disc drive
HD Video Recorder	HVO-550MD /FHD (*)	*1 With optical disc drive

*1.
Depending on the date of manufacture, the asterisk (*) in the model name might be an alphabetic character.

Software extension unit

Name	Model name	Availability		Remarks
		EU	outside EU	
Physiological signal display unit	PEU-LISENDO880	Yes	Yes	*1
CW Servo unit	EU-9184	Yes	Yes	
Magnetic sensor unit	EU-9185*	Yes	Yes	*2
Magnetic sensor For Tracking	EU-9197	Yes	Yes	
RVS flexible stand	EZU-RVF1*	Yes	Yes	*2
Magnetic sensor unit connection kit	PM-AR850-H004	Yes	Yes	*3

Name	Model name	Availability		Remarks
		EU	outside EU	
HDMI cable Kit for built-in magnetic sensor	PM-AR850-H006	Yes	Yes	
RVS Onboard arm	MP-FX-AVA-40	Yes	Yes	
Independent Probe connection unit	EU-9187*	Yes	Yes	*2, *4
Performance Acceleration unit	EU-9207*	Yes	Yes	*2
HDMI monitor connection unit	EU-9205*	Yes	Yes	*2
Phonocardiographic transducer	MA-300	-	Yes	
Pulse transducer	TY-307A	-	Yes	
Junction Box for ProSound LN/CV Probes	JB-294*	Yes	Yes	*2
Junction Box for HI VISION Probes	JB-293	Yes	Yes	

*1.

Includes an ECG cable and other accessories.

*2.

Depending on the date of manufacture, the asterisk (*) in the model name might be an alphabetic character.

*3.

EU-9185* is required.

*4.

EU-9184* is required.

Other

Name	Model name	Remarks
Security box	MP-FX-NMH-2	
Mounting Kit of Card Reader	MP-FX-AVA-4	
Jelly Warmer	JW-3000U	
Jelly Warmer right side mounting Kit	MP-FX-AVA-2B-R	
Jelly Warmer left side mounting Kit	MP-FX-AVA-2B-L	
Endo-cavity Probe holder Kit	MP-PH-AVA-11*	*1
Small Probe Holder (RS)	MP-PH-AR70-2U	
Small Probe Holder (LS)	MP-PH-AR70-4U	
Large Probe Holder (LS, RF)	MP-PH-AR70-5U	
Large Probe Holder (RS, LF)	MP-PH-AR70-6U	
Adapter for large probe holder	MP-PH-ADAPTER-5BU	

Name	Model name	Remarks
Adapter for large probe holder (for thin and long probes)	MP-PHAD-AR70-1U	
Flexible hook	MP-HA-AVA-2	
Flexible hanger	MP-HA-AVA-3	
3-point footswitch	MP-2819*	
1-point footswitch	MP-2345B	1 point type
Instruction Manual (Instructions for Use)	MN1-6505	Bound
Instruction Manual (Acoustic Output Data)	MN1-6506	Bound
Instruction Manual (Basic Operations)	MN1-6507	Bound
Instruction Manual (Advanced Operations 1)	MN1-6508	Bound
Instruction Manual (Advanced Operations 2)	MN1-6509	Bound
Instruction Manual (Advanced Operations 3)	MN1-6510	Bound
Instruction Manual (Measurements 1)	MN1-6511	Bound
Instruction Manual (Measurements 2)	MN1-6512	Bound
Instruction Manual (Measurements 3)	MN1-6513	Bound

*1.

Depending on the date of manufacture, the asterisk (*) in the model name might be an alphabetic character.

Software

Name	Model name	Remarks
Real Time 3D software	SOP-ARIETTA750-4	*1
Patient Information Automatic Input software	SOP-ARIETTA750-6	
Flow Profile Measurement software	SOP-ARIETTA750-7	
eTRACKING software	SOP-ARIETTA750-11	*2
TDI Analysis software	SOP-ARIETTA750-13	
Stress Echo software	SOP-ARIETTA750-15	*2
FMD Analysis software	SOP-ARIETTA750-16	*2
DICOM Structured Report software	SOP-ARIETTA750-21	
Wave Intensity software	SOP-ARIETTA750-34	*2
STIC software	SOP-ARIETTA750-41	*1, *3
Automated NT Measurement software	SOP-ARIETTA750-42	
Real-time Tissue Elastography software	SOP-ARIETTA750-43	
Contrast Harmonic Imaging software	SOP-ARIETTA750-44	
Transit Time of Vessel Flow Measurement software	SOP-ARIETTA750-47	*2
2D Tissue Tracking Analysis software	SOP-ARIETTA750-49	
EyeballEF software	SOP-ARIETTA750-58	*2
DICOM Query/Retrieve software	SOP-ARIETTA750-59	

Name	Model name	Remarks
Real-time Tissue Elastography Strain Histogram software	SOP-ARIETTA750-60	*4
Real-time Virtual Sonography software	SOP-ARIETTA750-62	*5
Picture in Picture software	SOP-ARIETTA750-63	
Automated FS Measurement software	SOP-ARIETTA750-71	
Automated FHR Measurement software	SOP-ARIETTA750-72	
Automated Cardiac Measurement software	SOP-ARIETTA750-74	
3D Sim-Navigator software	SOP-ARIETTA750-75	*5, *6
Needle Tracking software	SOP-ARIETTA750-84	*5, *6, *7
Body Motion Tracking software	SOP-ARIETTA750-85	*5, *6, *7
E-field simulator software	SOP-ARIETTA750-96	*5, *6, *8
Volume Data Extension software	SOP-ARIETTA750-97	*5, *6
Detective Flow Imaging software	SOP-ARIETTA750-105	
iEF Software	SOP-ARIETTA750-120	*9, *10
McAfee Embedded Control 3 software	SOP-ARIETTA750-128	
Cardiac 3D B Software	SOP-ARIETTA750-129	*9
Shear Wave Measurement B software	SOP-ARIETTA750-151	

*1.
EU-9184* is required.

*2.
PEU-LISENDO880* is required.

*3.
SOP-ARIETTA750-4 is required.

*4.
SOP-ARIETTA750-43 is required.

*5.
EU-9185*, PM-AR850-H004*, and EZU-RVF1* are required.

*6.
SOP-ARIETTA750-62 is required.

*7.
EU-9197* is required.

*8.
SOP-ARIETTA750-75 is required.

*9.
EU-9207* is required.

*10.
SOP-ARIETTA750-129 and SOP-ARIETTA750-74 are required.

6.3 Probes

This section describes the probes that can be connected and their main specifications.
NOTE: For details about the standard components of and options for each probe, see the documentation for each probe.

Electronic Convex Probe

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
C252	Fetal Abdominal[*a] Pediatric Small Organ (Spec.)[*d]	6 to 1	50R	Body surface
C253	Fetal Abdominal[*a] Pediatric Small Organ (Spec.)[*d]	5 to 1	50R	Body surface
C35	Fetal Abdominal[*a] Pediatric Small Organ (Spec.)[*d]	8 to 2	50R	Body surface
C41	Abdominal Pediatric Small Organ (Spec.)[*c] Musculo-skel. (Convent.) Peripheral vessel	13 to 4	12R	Body surface
C42	Abdominal[*a] Intra-operative (Spec.)[*b] Pediatric Small Organ (Spec.)[*d] Neonatal Cephalic Peripheral vessel	8 to 4	21R	Body surface
C421	Abdominal[*a] Pediatric Small Organ (Spec.)[*d] Neonatal Cephalic Peripheral vessel	12 to 3	21R	Body surface
C22P	Fetal Abdominal[*a]	6 to 1	22R	Body surface
C23	Fetal Abdominal[*a]	6 to 1	25R	Body surface
C23RV[*1]	Fetal Abdominal[*a]	6 to 1	25R	Body surface
C25P	Fetal Abdominal[*a]	5 to 1	50R	Body surface

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
C41V	Fetal Trans-rectal*e Trans-vaginal*f Other (spec.) - Gynecological	8 to 4	10R	Endocavity
C41V1	Fetal Trans-rectal*e Trans-vaginal*f Other (spec.) Gynecological	10 to 2	10R	Endocavity
C41B	Fetal Trans-rectal*e Trans-vaginal*f Other (spec.) Gynecological	10 to 2	10R	Endocavity
C41RP	Trans-rectal*e Trans-vaginal*f	9 to 2	9R	Endocavity
CC41R	Fetal Trans-rectal*e Trans-vaginal*f	T*2: 8 to 4 L*3: 8 to 4	T*2: 10R L*3: 10R	Endocavity
C22I	Intra-operative (Spec.)*b	6 to 1	20R	Intraoperative
C22K	Abdominal*a Intra-operative (Spec.)*b	6 to 1	21R	Intraoperative
C22T	Intra-operative (Spec.)*b	6 to 1	20R	Intraoperative
C42K	Intra-operative (Spec.)*b Small Organ (Spec.)*d Neonatal Cephalic	10 to 4	21R	Intraoperative
C42T	Intra-operative (Spec.)*b Intra-operative	10 to 3	20R	Intraoperative
R41R	Trans-rectal	10 to 5	6R radial	Endocavity
R41RL	Trans-rectal	10 to 5	6R radial	Endocavity

*1.

With built-in magnetic position sensor

*2.

Transverse

*3.

Longitudinal

Electronic Linear Probe

Model name	Intended Purpose	Frequency (MHz)	Visual field width	Application
L34	Abdominal[*a] Pediatric Small Organ (Spec.)[*d] Musculo-skel. (Convent.) Peripheral vessel	7 to 3	38 mm	Body surface
L35	Abdominal[*a] Pediatric Small Organ (Spec.)[*d] Musculo-skel. (Convent.) Peripheral vessel	9 to 2	45 mm	Body surface
L441	Abdominal[*a] Pediatric Small Organ (Spec.)[*d] Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Peripheral vessel	12 to 2	38 mm	Body surface
L442	Abdominal[*a] Pediatric Small Organ (Spec.)[*d] Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Peripheral vessel	12 to 2	38 mm	Body surface
L55	Abdominal[*a] Pediatric Small Organ (Spec.)[*d] Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Other (spec.) - Wound[*h] Peripheral vessel	13 to 5	50 mm	Body surface

Model name	Intended Purpose	Frequency (MHz)	Visual field width	Application
L64	Abdominal[*a] Pediatric Small Organ (Spec.)[*d] Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Other (spec.) - Wound[*h] Peripheral vessel	18 to 5	38 mm	Body surface
L43K	Intra-operative (Spec.)[*b]	12 to 2	26 mm	Intraoperative
L44K	Intra-operative (Spec.)[*b]	14 to 2	42 mm	Intraoperative
L46K1	Intra-operative (Spec.)[*b]	14 to 2	63 mm	Intraoperative
L51K	Intra-operative (Spec.)[*b]	15 to 3	13 mm	Intraoperative
L53K	Intra-operative (Spec.)[*b]	15 to 3	25 mm	Intraoperative
L31KP	Intra-operative (Spec.)[*b]	9 to 2	6 mm	Intraoperative
L44LA	Intra-operative (Spec.) Laparoscopic	13 to 2	36 mm	Intraoperative
L44LA1	Intra-operative (Spec.) Laparoscopic	13 to 2	38 mm	Intraoperative
EUP-L53L[*1]	Abdominal Pediatric Small Organ (Spec.)[*c] Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Peripheral vessel	10 to 5	92 mm	Body surface

*1.

The optional JB-293 is required.

Electronic Sector Probe

Model name	Intended Purpose	Frequency (MHz)	Application
S11	Fetal Abdominal Pediatric Adult Cephalic Cardiac Adult Cardiac Pediatric Peripheral vessel	5 to 1	Body surface
S121	Fetal Abdominal Pediatric Adult Cephalic Cardiac Adult Cardiac Pediatric Peripheral vessel	5 to 1	Body surface
S31	Abdominal Pediatric Neonatal Cephalic Cardiac Adult Cardiac Pediatric	9 to 2	Body surface
S42	Abdominal Pediatric Neonatal Cephalic Cardiac Adult Cardiac Pediatric	14 to 3	Body surface
S3ESEL	Trans-esoph. (non-Card.)*g Trans-esophageal (card.)*g	8 to 2	Endocavity
S3ESL1	Trans-esoph. (non-Card.)*g Trans-esophageal (card.)*g	9 to 2	Endocavity
S3ESCLS	Trans-esoph. (non-Card.)*g Trans-esophageal (card.)*g	8 to 2	Endocavity
S31KP	Intra-operative	8 to 3	Intraoperative

4D Probe

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
VC35	Fetal Abdominal Pediatric Small Organ (Spec.)*c	8 to 2	46R	Body surface
VC41V	Fetal Trans-vaginal Other (spec.) Gynecological	8 to 2	10R	Endocavity

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
MXS1	Fetal Abdominal Pediatric Adult Cephalic Cardiac Adult Cardiac Pediatric Peripheral vessel	5 to 1		Body surface

Other Probe

Model name	Intended Purpose	Frequency (MHz)	Curvature Radius, or Scan Area	Application
C41L47RP	Trans-rectal[*e]	CV[*1]: 8 to 4 LN[*2]: 10 to 5	CV[*1]: 10R LN[*2]: 64 mm	Endocavity
CL4416R	Trans-rectal[*e]	CV[*1]: 10 to 2 LN[*2]: 14 to 2	CV[*1]: 9R LN[*2]: 63 mm	Endocavity
CL4416R1	Trans-rectal[*e]	CV[*1]: 10 to 2 LN[*2]: 14 to 2	CV[*1]: 9R LN[*2]: 63 mm	Endocavity

*1.

Convex Type

*2.

Linear Type

Independent Probes

Model name	Intended Purpose	Frequency (MHz)	Application
UST-2265-2[*1]	Cardiac Adult Cardiac Pediatric Peripheral vessel	2	Body surface

*1.

The optional EU-9187 is necessary.

*a:

Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

*b:

Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

*c:

Includes thyroid, parathyroid, breast, scrotum, penis.

*d:

Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

*e:

Includes imaging for guidance of trans-rectal biopsy.

*f:

Includes imaging for guidance of trans-vaginal biopsy.

*g:

For Adult and Pediatric patients.

*h:

Includes imaging for Cavernous/Non-Cavernous wounds.

6.3.1 Probe functions: Basic functions

Basic Functions		C252	C253	C35	C41	C42	C421	C22P	C23	C23RV	C25P
Compound		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trapezoid											
B steer											
Wide Scanning							Yes		Yes	Yes	
eFocusing		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Acoustic Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane											
OMNI Mode											
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B										
	Color	Yes		Yes					Yes	Yes	
DFI mode		Yes	Yes	Yes			Yes		Yes	Yes	
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TDI mode		Yes	Yes	Yes							
HI Frame	B	Yes	Yes	Yes							
	Color	Yes	Yes	Yes							
Puncture Guide Line		Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes
Needle Emphasis		Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes
Brachy Grid Display											
Assist Line											
CW mode		Yes	Yes	Yes		Yes	Yes				
THI	FmT	Yes	Yes	Yes		Yes	Yes				Yes
	WbT	Yes	Yes	Yes		Yes	Yes				Yes
	HdT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		C41V	C41V1	C41B	C41RP	CC41R	C22I	C22K	C22T	C42K
Compound		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trapezoid										
B steer										
Wide Scanning										
eFocusing			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Acoustic Noise Reduction		Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane						Yes				
OMNI Mode										
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B									
	Color									
DFI mode										
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TDI mode										
HI Frame	B									
	Color									
Puncture Guide Line		Yes	Yes	Yes	Yes	Yes		Yes		Yes
Needle Emphasis		Yes	Yes	Yes	Yes	Yes		Yes		Yes
Brachy Grid Display										
Assist Line										
CW mode										
THI	FmT									
	WbT		Yes	Yes		Yes				
	HdT	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes

Basic Functions	C42T	R41R	R41RL	L34	L35	L441	L442	L55	L64	L43K
Compound	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trapezoid				Yes	Yes	Yes	Yes	Yes	Yes	Yes
B steer				Yes	Yes	Yes	Yes	Yes	Yes	Yes
Wide Scanning										
eFocusing	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Acoustic Noise Reduction	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane										
OMNI Mode										
FAM	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		C42T	R41R	R41RL	L34	L35	L441	L442	L55	L64	L43K
TGC Enhancement	B				Yes	Yes					
	Color					Yes	Yes		Yes	Yes	
DFI mode						Yes	Yes	Yes	Yes	Yes	
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TDI mode									Yes		
HI Frame	B										
	Color						Yes	Yes			
Puncture Guide Line					Yes	Yes	Yes	Yes	Yes	Yes	
Needle Emphasis					Yes	Yes	Yes	Yes	Yes	Yes	
Brachy Grid Display											
Assist Line						Yes		Yes		Yes	
CW mode					Yes	Yes	Yes	Yes		Yes	
THI	FmT										
	WbT		Yes	Yes	Yes	Yes	Yes	Yes		Yes	
	HdT	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		L44K	L46K1	L51K	L53K	L31KP	L44LA	L44LA1	S11	S121	S31
Compound		Yes	Yes	Yes	Yes	Yes	Yes				
Trapezoid		Yes	Yes	Yes	Yes	Yes	Yes				
B steer		Yes	Yes	Yes	Yes		Yes				
Wide Scanning									Yes	Yes	Yes
eFocusing		Yes	Yes	Yes	Yes		Yes		Yes	Yes	
Acoustic Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane											
OMNI Mode											
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B										
	Color										
DFI mode											
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TDI mode									Yes	Yes	Yes
HI Frame	B								Yes	Yes	
	Color								Yes	Yes	Yes
Puncture Guide Line						Yes					
Needle Emphasis											
Brachy Grid Display											

Basic Functions		L44K	L46K1	L51K	L53K	L31KP	L44LA	L44LA1	S11	S121	S31
Assist Line											
CW mode									Yes	Yes	Yes
THI	FmT								Yes	Yes	Yes
	WbT				Yes						
	HdT	Yes	Yes	Yes	Yes		Yes				

Basic Functions		S42	S3ESEL	S3ESL1	S3ESCLS	S31KP	VC35	VC41V	MXS1	C41L47RP (CV)	C41L47RP (LN)
Compound							Yes	Yes		Yes	Yes
Trapezoid											Yes
B steer											Yes
Wide Scanning		Yes	Yes	Yes	Yes						
eFocusing							Yes		Yes	Yes	Yes
Acoustic Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane									Yes		
OMNI Mode								Yes			
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B										
	Color										
DFI mode											
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TDI mode		Yes	Yes	Yes	Yes		Yes		Yes		
HI Frame	B						Yes	Yes	Yes		
	Color	Yes	Yes	Yes	Yes		Yes		Yes		
Puncture Guide Line						Yes					Yes
Needle Emphasis											
Brachy Grid Display										Yes	
Assist Line											
CW mode		Yes	Yes	Yes	Yes				Yes		
THI	FmT	Yes					Yes	Yes	Yes		
	WbT						Yes	Yes		Yes	Yes
	HdT						Yes				

Basic Functions		CL4416R (CV)	CL4416R (LN)	CL4416R1 (CV)	CL4416R1 (LN)	UST-2265-2	EUP-L53L
Compound		Yes	Yes	Yes	Yes		Yes
Trapezoid			Yes		Yes		Yes
B steer			Yes		Yes		Yes
Wide Scanning				Yes			
eFocusing		Yes	Yes	Yes	Yes		Yes
Acoustic Noise Reduction							Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes		Yes
Real-time Biplane							
OMNI Mode							
FAM		Yes	Yes	Yes	Yes		Yes
TGC Enhancement	B						
	Color						
DFI mode							
Dual Gate Doppler		Yes	Yes	Yes	Yes		Yes
TDI mode							
HI Frame	B						
	Color						
Puncture Guide Line			Yes		Yes		
Needle Emphasis							
Brachy Grid Display		Yes		Yes			
Assist Line							
CW mode						Yes	
THI	FmT						
	WbT	Yes	Yes	Yes	Yes		
	HdT						Yes

6.3.2 Probe functions: Optional functions

Optional Functions		C252	C253	C35	C41	C42	C421	C22P	C23	C23RV	C25P	C41V	C41V1
Contrast Harmonic Imaging	Low	Yes	Yes	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Mid	Yes	Yes	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes
	High	Yes	Yes					Yes	Yes	Yes	Yes		
CHI-eFlow		Yes	Yes						Yes	Yes			
Panoramic display		Yes	Yes	Yes		Yes	Yes						
Real-time Tissue Elastography		Yes	Yes	Yes		Yes	Yes					Yes	Yes

Optional Functions	C252	C253	C35	C41	C42	C421	C22P	C23	C23RV	C25P	C41V	C41V1
Shear Wave Measurement	Yes	Yes										
Shear Wave Elastography	Yes											
Real-time Virtual Sonography	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes		Yes
Needle Tracking	Yes	Yes				Yes	Yes	Yes	Yes	Yes		
Attenuation Measurement	Yes	Yes										
Real time 3D												
Cardiac 3D												
STIC												
Stress echo												
Early-stage arteriosclerosis evaluation (eTRACKING)												
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)												
Circulatory dynamics index evaluation (Wave Intensity)												

Optional Functions		C41B	C41RP	CC41R	C22I	C22K	C22T	C42K	C42T	R41R	R41RL	L34	L35
Contrast Harmonic Imaging	Low	Yes		Yes	Yes	Yes	Yes		Yes			Yes	Yes
	Mid	Yes		Yes	Yes	Yes	Yes		Yes			Yes	Yes
	High												
CHI-eFlow													Yes
Panoramic display												Yes	Yes
Real-time Tissue Elastography		Yes		Yes				Yes	Yes	Yes	Yes	Yes	Yes
Shear Wave Measurement													
Shear Wave Elastography													
Real-time Virtual Sonography		Yes		Yes					Yes				Yes
Needle Tracking													Yes

Optional Functions	C41B	C41RP	CC41R	C22I	C22K	C22T	C42K	C42T	R41R	R41RL	L34	L35
Attenuation Measurement												
Real time 3D												
Cardiac 3D												
STIC												
Stress echo												
Early-stage arteriosclerosis evaluation (eTRACKING)												
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)												
Circulatory dynamics index evaluation (Wave Intensity)												

Optional Functions		L441	L442	L55	L64	L43K	L44K	L46K1	L51K	L53K	L31KP	L44LA	L44LA1
Contrast Harmonic Imaging	Low	Yes	Yes	Yes		Yes	Yes	Yes	Yes			Yes	
	Mid	Yes	Yes	Yes		Yes	Yes	Yes	Yes			Yes	
	High												
CHI-eFlow													
Panoramic display		Yes	Yes	Yes	Yes								
Real-time Tissue Elastography		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	
Shear Wave Measurement					Yes								
Shear Wave Elastography					Yes								
Real-time Virtual Sonography				Yes	Yes								
Needle Tracking													
Attenuation Measurement													
Real time 3D													
Cardiac 3D													
STIC													
Stress echo													

Optional Functions	L441	L442	L55	L64	L43K	L44K	L46K1	L51K	L53K	L31KP	L44LA	L44LA1
Early-stage arteriosclerosis evaluation (eTRACKING)	Yes	Yes										
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)	Yes	Yes										
Circulatory dynamics index evaluation (Wave Intensity)	Yes	Yes										

Optional Functions		S11	S121	S31	S42	S3ESEL	S3ESL1	S3ESCLS	S31KP	VC35	VC41V	MXS1	C41L47RP (CV)
Contrast Harmonic Imaging	Low		Yes										
	Mid												
	High												
CHI-eFlow													
Panoramic display													
Real-time Tissue Elastography											Yes		Yes
Shear Wave Measurement													
Shear Wave Elastography													
Real-time Virtual Sonography													Yes
Needle Tracking													
Attenuation Measurement													
Real time 3D										Yes	Yes		
Cardiac 3D												Yes	
STIC										Yes			
Stress echo		Yes	Yes	Yes	Yes							Yes	
Early-stage arteriosclerosis evaluation (eTRACKING)													

Optional Functions	S11	S121	S31	S42	S3ESEL	S3ESL1	S3ESCLS	S31KP	VC35	VC41V	MXS1	C41L47RP (CV)
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)												
Circulatory dynamics index evaluation (Wave Intensity)												

Optional Functions		C41L47RP (LN)	CL4416R (CV)	CL4416R (LN)	CL4416R1 (CV)	CL4416R1 (LN)	UST-2265-2	EUP-L53L
Contrast Harmonic Imaging	Low							
	Mid							
	High							
CHI-eFlow								
Panoramic display		Yes		Yes		Yes		Yes
Real-time Tissue Elastography		Yes	Yes	Yes	Yes	Yes		Yes
Shear Wave Measurement								
Shear Wave Elastography								
Real-time Virtual Sonography		Yes	Yes	Yes	Yes	Yes		
Needle Tracking								
Attenuation Measurement								
Real time 3D								
Cardiac 3D								
STIC								
Stress echo								
Early-stage arteriosclerosis evaluation (eTRACKING)								
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)								
Circulatory dynamics index evaluation (Wave Intensity)								

6.3.3 Measurement scope

This section indicates the maximum range of measurements that the ARIETTA 750 can provide.

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)
C252	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C253	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C35	61.1	999.9	999.9	99.9	9999	29.9	999.9	9.74	6-999
C41	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C42	42.4	999.9	999.9	99.9	9999	19.0	713.0	9.74	6-999
C421	42.4	999.9	999.9	99.9	9999	19.0	713.0	9.74	6-999
C22P	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C23	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C23RV	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C25P	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C41V	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C41V1	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C41B	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C41RP	34.6	999.9	999.9	99.9	9999	17.0	713.0	9.74	6-999
CC41R	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C22I	61.1	999.9	999.9	99.9	9999	29.9	999.9	9.74	6-999
C22K	61.1	999.9	999.9	99.9	9999	29.9	999.9	9.74	6-999
C22T	61.1	999.9	999.9	99.9	9999	29.9	999.9	9.74	6-999
C42K	42.4	999.9	999.9	99.9	9999	19.0	802.1	9.74	6-999
C42T	42.4	999.9	999.9	99.9	9999	19.0	802.1	9.74	6-999
R41R	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
R41RL	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
L34	34.6	999.9	999.9	99.9	9999	17.0	916.7	9.74	6-999
L35	34.6	999.9	999.9	99.9	9999	17.0	916.7	9.74	6-999
L441	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L442	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L55	34.6	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999
L64	28.5	999.9	999.9	99.9	9999	14.0	458.3	9.74	6-999
L43K	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L44K	34.6	999.9	999.9	99.9	9999	17.0	713.0	9.74	6-999
L46K1	34.6	999.9	999.9	99.9	9999	17.0	713.0	9.74	6-999

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)
L51K	28.5	999.9	999.9	99.9	9999	14.0	458.3	9.74	6-999
L53K	28.5	999.9	999.9	99.9	9999	14.0	458.3	9.74	6-999
L31KP	30.5	999.9	999.9	99.9	9999	15.0	802.1	9.74	6-999
L44LA	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L44LA1	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
S11	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
S121	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
S31	48.9	999.9	999.9	99.9	9999	24.0	999.9	9.74	6-999
S42	30.5	999.9	999.9	99.9	9999	15.0	713.0	9.74	6-999
S3ESEL	48.9	999.9	999.9	99.9	9999	24.0	916.7	9.74	6-999
S3ESL1	48.9	999.9	999.9	99.9	9999	24.0	802.1	9.74	6-999
S3ESCLS	48.9	999.9	999.9	99.9	9999	24.0	802.1	9.74	6-999
S31KP	30.5	999.9	999.9	99.9	9999	15.0	802.1	9.74	6-999
VC35	48.9	999.9	999.9	99.9	9999	24.0	999.9	9.74	6-999
VC41V	42.4	999.9	999.9	99.9	9999	19.0	916.7	9.74	6-999
MXS1	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C41L47RP (CV)	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C41L47RP (LN)	34.6	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999
CL4416R (CV)	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
CL4416R (LN)	34.6	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999
CL4416R1 (CV)	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
CL4416R1 (LN)	34.6	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999
UST-2265-2	-	-	-	-	-	-	999.9	9.74	6-999
EUP-L53L	34.6	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999

7

Safety guidelines

7.1 Guidelines for electromagnetic compatibility

This system complies with the electromagnetic compatibility standards for medical electrical equipment (IEC 60601-1-2: Ed.4). This standard specifies electromagnetic energy level (electromagnetic emissions) test requirements and resistance to electromagnetic interference (electromagnetic immunity) test requirements for medical electrical equipment.

7.1.1 Guidelines and directives concerning electromagnetic emissions

The system is intended for use in an electromagnetic environment as specified below. We recommend that customers or users of the system confirm that the system is used in such an environment.

Problems and basic EMC standards	Emission testing level Professional healthcare facility environment	Electromagnetic environment - guidelines
Conducted and emitted RF emissions, CISPR11	Group 1	This system uses RF energy, but only for its internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic devices.
Conducted and emitted RF emissions, CISPR11	Class B	This system is suitable for use in all buildings, including general residential housing and can be directly connected to the commercial low-voltage power supply systems found in such housing.
Harmonic distortion, IEC 61000-3-2	Class A	
Voltage fluctuations and flicker, IEC 61000-3-3	Complied	

7.1.2 Basic performance

The system undergoes electromagnetic interference testing based on electromagnetic compatibility as described in IEC 60601-1-2: Ed.4 and IEC 60601-2-37, to confirm that basic performance (functionality that if removed or reduced might result in unacceptable risk) or safety is not affected.
The system is free of the following potential dangers:

- Waveform artifacts, image distortions, or errors in indicated values that are not caused by bioeffects and that could alter the diagnosis
- Incorrect indicated values that could impact the diagnosis

- Incorrect safety indications

Basic performance	Overview	Reference
Scan Area	Scanning range	[T.B.F.] key (Basic Operations)
Flow Area	Color display range of the color Doppler mode	[T.B.F.] key (Basic Operations)
Velocity Range	Velocity range (scale mark) in the Doppler image display	[FOCUS /VELOCITY] paddle switch (Basic Operations)
M cursor Doppler Cursor	Cursor display which indicates the M or D mode image detection position in B mode	[T.B.F.] key (Basic Operations)
Sample Volume	Doppler detection range settings in the PW Doppler mode	Sample Volume menu (Basic Operations)
Image Frequency Select	Change in frequencies in B and M Mode	Frequency (Basic Operations)
	Change in frequencies in D, Color, and CHI Modes	Reference Frequency (Basic Operations)
Focus	Number of focal points and their positions	[FOCUS /VELOCITY] paddle switch (Basic Operations)
Acoustic Power	Acoustic output	Safety guidelines on the ultrasound output power, [Acoustic Power] rotary encoder (Instructions for Use)
Line Density	Change in scanning line density combinations for black-and-white and color images	Frame Rate menu (Basic Operations)
Packet Size	Number of transmissions used to display blood flow	Menus and Presets: Color Flow, Power Flow, eFlow, TDI, DFI (Basic Operations)
Puncture	Display of puncture guide lines	Puncture menu (Basic Operations)
Message	Display of messages indicating the correct procedure, or warning notifications	Messages (Instructions for Use)
Angle Correction	Display of flow velocity value whose Doppler beam angle has been corrected	Angle Correction menu and Presets: Doppler, Tissue Doppler (Basic Operations)
Heart Rate Display	Computes and displays the heart rate from detected R-wave (HR***)	Displaying Physiological Signals, the Physio menu, and Presets: Physio (Basic Operations)
Display Format Picture	Scale marks (distance, time, and flow velocity) display	

7.1.3 Guidelines and directives concerning electromagnetic immunity

The system is intended for use in an electromagnetic environment as specified below. We recommend that customers or users of the system confirm that the system is used in such an environment.

(1) IEC 60601-1-2 Ed.4 compliant

(a) Enclosure port

Problems and basic EMC standards	Immunity testing level Professional healthcare facility environment	Electromagnetic environment - guidelines
Electrostatic discharge, IEC 61000-4-2	On contact: ±8 kV Atmospheric: ±15 kV	The floor should be made of wood, concrete, or ceramic tile. If the floor is covered with synthetic materials, the relative humidity of these materials should be at least 30%.
Emitted RF electromagnetic field, IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% amplitude modulation (1 kHz)	Recommended separation distance > 30 cm The following symbol is found on devices that generate intentional electromagnetic interference. Interference might occur in the vicinity of devices that bear the following symbol. 
Magnetic fields near RF radio communication equipment, IEC 61000-4-3	Enclosure port for RF radio communication equipment	
Power frequency magnetic fields, IEC 61000-4-8	30 A/m	The power frequency magnetic field should have the same level of characteristics as a standard business or hospital environment.
Remarks	These guidelines might not apply in all circumstances. Electromagnetic propagation is affected by reflection off or absorption by buildings, objects, and people. The field strengths of fixed transmitters (such as a cellular phone base stations, mobile radio, amateur radio, AM/FM radio, and TV broadcast base stations) cannot be theoretically estimated with accuracy. To correctly assess the electromagnetic environment of a fixed RF transmitter, consider conducting an electromagnetic site survey. If the field intensity measured at the location where the system is to be used is higher than the applied RF conformity level mentioned above, monitor the system to verify that the system operates normally. If abnormal behavior is detected, you might need to re-examine where the system should be placed or how it should be installed.	

(b) AC power input port

Problems and basic EMC standards	Immunity testing level Professional healthcare facility environment	Electromagnetic environment - guidelines
Electrical fast transient/ burst, IEC 61000-4-4	±2 kV Repetition frequency: 100 kHz	The system should be supplied with power of the same quality as that provided by a standard business or hospital environment.

Problems and basic EMC standards	Immunity testing level Professional healthcare facility environment	Electromagnetic environment - guidelines
Surge (between lines), IEC 61000-4-5	±1 kV	The system should be supplied with power of the same quality as that provided by a standard business or hospital environment.
Surge (between line and earth), IEC 61000-4-5	±2 kV	
Conducted disturbances induced by RF electromagnetic fields, IEC 61000-4-6	3 V for 0.15 MHz to 80 MHz 6 V for ISM bands from 0.15 MHz to 80 MHz 80% amplitude modulation (1 kHz)	Recommended separation distance > 30 cm
Voltage dips, IEC 61000-4-11	0% Ut 0.5 cycles Phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	The system should be supplied with power of the same quality as that provided by a standard business or hospital environment. If the system user demands continuous operation even during a power outage, it is recommended that the system be supplied with power either from an uninterrupted power supply or a battery.
	0% Ut 1 cycle and 70% Ut 25/30 cycles Single phase, phase angle of 0°	
Short interruptions, IEC 61000-4-11	0% Ut 250/300 cycles	
Remarks	Ut is the AC power supply voltage before the testing level is applied.	

(c) DC Input Power Port

None.

(d) Patient coupling port

Problems and basic EMC standards	Immunity testing level Professional healthcare facility environment	Electromagnetic environment - guidelines
Electrostatic discharge, IEC 61000-4-2	On contact: ±8 kV Atmospheric: ±15 kV	The floor should be made of wood, concrete, or ceramic tile. If the floor is covered with synthetic materials, the relative humidity of these materials should be at least 30%.
Conducted disturbances induced by RF electromagnetic fields, IEC 61000-4-6	3 V for 0.15 MHz to 80 MHz 6 V for ISM bands from 0.15 MHz to 80 MHz 80% amplitude modulation (1 kHz)	Recommended separation distance > 30 cm

(e) Signal I/O unit port

Problems and basic EMC standards	Immunity testing level Professional healthcare facility environment	Electromagnetic environment - guidelines
Electrostatic discharge, IEC 61000-4-2	On contact: ±8 kV Atmospheric: ±15 kV	The floor should be made of wood, concrete, or ceramic tile. If the floor is covered with synthetic materials, the relative humidity of these materials should be at least 30%.
Electrical fast transient/ burst, IEC 61000-4-4	±1 kV Repetition frequency: 100 kHz	The system should be supplied with power of the same quality as that provided by a standard business or hospital environment.
Surge (between line and earth), IEC 61000-4-5	±2 kV	The system should be supplied with power of the same quality as that provided by a standard business or hospital environment.
Conducted disturbances induced by RF electromagnetic fields, IEC 61000-4-6	3 V for 0.15 MHz to 80 MHz 6 V for ISM bands from 0.15 MHz to 80 MHz 80% amplitude modulation (1 kHz)	Recommended separation distance > 30 cm

7.1.4 Recommended separation distance from the system to cellular and mobile RF communication devices

The system is intended for use in an electromagnetic environment where RF interference is controlled. The system customer or system user can help prevent electromagnetic interference by ensuring the minimum distance from the system to any mobile RF communication device (a transmitter), in accordance with the following recommendation, which is based on the maximum output of the transmitter device.

(1) IEC 60601-1-2 Ed.4 compliant

(a) Enclosure port for RF radio communication equipment

Testing frequency and band	Immunity testing level	Electromagnetic environment - guidelines
385 MHz, 380 MHz to 390 MHz	27 V/m, pulse modulation 18 Hz	The system user can help prevent electromagnetic interference by ensuring a minimum distance of at least 30 cm between any portable or mobile RF communication device (transmitter) and the system.
450 MHz, 430 MHz to 470 MHz	28 V/m, frequency modulation by shifting ±5 kHz, 1 kHz sine waves	
710 MHz, 704 MHz to 787 MHz	9 V/m, pulse modulation 217 Hz	
745 MHz, 704 MHz to 787 MHz		
780 MHz, 704 MHz to 787 MHz		
810 MHz, 800 MHz to 960 MHz	28 V/m, pulse modulation 18 Hz	
870 MHz, 800 MHz to 960 MHz		
930 MHz, 800 MHz to 960 MHz		
1720 MHz, 1700 MHz to 1990 MHz	28 V/m, pulse modulation 217 Hz	
1845 MHz, 1700 MHz to 1990 MHz		
1970 MHz, 1700 MHz to 1990 MHz		
2450 MHz, 2400 MHz to 2570 MHz	28 V/m, pulse modulation 217 Hz	
5240 MHz, 5100 MHz to 5800 MHz	9 V/m, pulse modulation 217 Hz	
5500 MHz, 5100 MHz to 5800 MHz		
5785 MHz, 5100 MHz to 5800 MHz		

7.2 Electrostatic discharge (ESD) guidelines

Observe these guidelines to prevent the deterioration or failure of parts that are sensitive to static electricity.
Install the system according to "Guidelines for electromagnetic compatibility" in this manual. Connect the probes and perform maintenance inspections for the system as described below.

- Do not install the system on a carpeted floor or a floor covered with synthetic materials. Install the system on floors made of wood, concrete, or ceramic tile. If you must install the system on a carpeted floor or a floor covered with synthetic materials, place the system on a grounded mat.
- Keep the humidity at the installation location at 30% or higher.

- When connecting probes, the foot switch, cables, etc., to the connectors, keep your hands as far away as possible from the connector pins.
  Before performing any work on the system, turn off the power, but do not disconnect the power plug.

NOTICE

Explain the meaning of the ESD warning symbol to all staff who use the system. Provide training in the ESD preventive procedure described above, to all staff who use the system.

- ESD warning symbol (): Keep your hands and fingers away from the connection terminals.
  Electrostatic discharge (ESD) can destroy parts that are sensitive to static electricity or cause them to malfunction.

7.3 Safety guidelines on the ultrasound output power

7.3.1 Acoustic output index

The Diagnostic Ultrasound System displays output indices that indicate the potential for adverse effects of ultrasonic waves on a living body (bioeffects). The following four types of indices are displayed. Of these types, the mechanical index (MI) indicates mechanical bioeffects and the thermal index (TI) indicates thermal bioeffects. Three indices corresponding to tissue models are available: TIS, TIB, and TIC.

- Mechanical index: MI
  The mechanical index (MI) indicates (on screen) the relative probability of harmful non-thermal bioeffects (mechanical bioeffects), such as cavitation caused by ultrasound. Mechanical bioeffects are caused by tissue movement that occurs when ultrasonic pressure waves pass through or in the vicinity of air bubbles in tissue. Most of the mechanical bioeffects are related to the generation, expansion, oscillation, or collapse of microbubbles within the tissue. This behavior of air bubbles is called cavitation.
  Because thermal bioeffects are minimal in B, B/M, and M modes, MI is important. MI can be displayed in all modes. In other imaging modes, thermal bioeffects are also important.
- Thermal index: TI
  - Soft-tissue thermal index: TIS
    The soft tissue thermal index (TIS) indicates temperature elevation in homogeneous soft tissue (during scans of the heart, the abdomen, fetuses within the first trimester of pregnancy, etc.). TIS can be displayed in all modes.
  - Bone thermal index: TIB
    The bone thermal index (TIB) indicates temperature elevation in bones when an ultrasound beam forms a focus close to a bone after passing through soft tissue (during scans of embryos in the second or third trimesters of pregnancy, etc.). TIB can be displayed in all modes and during probe use. In addition, in B mode and other scan modes, the value of TIB is the same as that of TIS.

- Cranial bone thermal index: TIC
  The cranial bone thermal index (TIC) indicates temperature elevation in bones when an ultrasound beam passes through a bone near the body surface (where the beam enters the body) (during cranial examinations of adults and infants, etc.). TIC can be displayed in all modes.

It is important for operators to be able to distinguish safe levels of bioeffects from dangerous levels of bioeffects. The World Federation for Ultrasound in Medicine and Biology (WFUMB) has issued a number of guidelines. For example, a rise in temperature of more than 4°C over the course of five minutes should be considered potentially dangerous for embryos and embryonic tissue.
On the other hand, the indices indicate conditions under which there is a higher possibility of thermal or mechanical bioeffects affecting a living body compared with other parameters such as acoustic pressure and intensity.
For example, it is better to avoid a TI value exceeding a certain maximum range (more than 1.0) in obstetrics use. This maximum range allows for a reasonable margin of safety, in line with the WFUMB guideline mentioned previously. If clinical results cannot be obtained by using lower values, it might justify increasing the output. However, pay special attention to limiting the exposure time. During fetal examinations where the patient has a fever, be particularly careful to avoid high TI values, so that you do not induce more heat than is necessary.
The following table indicates the importance of maintaining low MI/TI values during clinical use according to IEC 60601-2-37.

Relative importance of keeping acoustic output indices low during various examinations

	Relatively high importance	Low importance
MI	• Heart scans that use an ultrasound contrast agent and for which there is a possibility of pulmonary irradiation • Abdominal scans (enteric gas)	• There are no air bubbles
TI	• Scanning during the first trimester of pregnancy: TIS • Scanning during the second and third trimesters of pregnancy: TIB • Fetal skull and spinal cord • Patients who have a fever • Tissue with almost no perfusion • Irradiation of ribs or bones: TIB	• Tissue with good perfusion (liver, spleen) • Heart scans • Blood vessel scans

CAUTION: It was previously believed that the high frequency range of diagnostic ultrasound systems from several MHz to several tens of MHz would preclude cavitation. However, animal experimentation has shown that lung tissue, stomach tissue, and other tissues where air bubbles exist can be easily damaged (resulting in petechiae, etc.) even at a low acoustic pressure. Furthermore, experiments have shown that fetal pulmonary tissue, which is not used for pulmonary respiration, is not easily affected by ultrasound. Based on these findings, care is required when using an ultrasound contrast agent to intentionally inject air bubbles.

7.3.2 Mutual effects between ultrasound and body tissue

When ultrasound waves pass through body tissue, the tissue might become damaged. Ultrasound images taken during examinations are produced by irradiating tissue with ultrasound energy emitted by a probe and then converting, into an image, the energy that is reflected back from the tissue. However, the tissue absorbs most of the ultrasound energy. Ultrasonic waves generated from the probe are physical pressure waves, whose typical frequency range is from 2 MHz (1 MHz equals 1 million cycles per second) to 10 MHz. In ultrasound irradiation, the energy absorbed by the tissue might cause some reactions in the tissue.

These effects are categorized as mechanical bioeffects and thermal bioeffects.

The first category of bioeffects is that of mechanical bioeffects. Mechanical bioeffects occur because of pressure waves that cause mechanical or physical movement of tissues or tissue components. As a result, the cells, fluids, and other tissue components oscillate. Under certain conditions, this oscillation might affect the structure or function of living tissue. It is currently believed that mechanical bioeffects are temporary and closely related to the peak negative acoustic pressure of an ultrasound wave pulse. An extreme example of the mechanical bioeffects of ultrasound is shock-wave lithotripsy, where focused ultrasound waves are used to break apart kidney stones.

The second category of bioeffects is that of thermal bioeffects. Thermal bioeffects occur when tissue absorbs ultrasound energy. When ultrasound waves pass through the body, the energy of the ultrasound waves attenuates. Attenuation occurs because of two reasons: absorption and dispersion. When absorption occurs, ultrasound energy is converted into heat. When dispersion occurs, the advancing direction of the ultrasound wave is changed. When tissue absorbs ultrasound energy, the temperature of the tissue rises. The mechanism of thermal bioeffects is as follows. Unlike mechanical bioeffects, thermal bioeffects are temporal and closely related to the volume, perfusion ratio, exposure time, and duty factor (ratio of the pulse repetition period to the pulse emission time) of the tissue. The biological effects that occur when tissue heats up impose a high risk of causing problems such as physiological cell abnormalities, lower DNA synthesis rate, or delayed development of the heart, brain, or bones of fetuses.

(1) Expected bioeffects

(a) Mechanical bioeffects

Mechanical bioeffects occur as a result of the oscillation of a pressure wave when an ultrasound wave is transmitted through the body. This pressure wave acts on microscopic gas bubbles and other nucleation sites in tissue. Although nucleation sites are currently not well understood, they are believed to be the starting points from which gas bubbles develop. Because gas is more compressible than fluid, microscopic gas bubbles can expand and contract to a greater degree compared to the immediately surrounding tissue or fluid. The extreme expansion or contraction of gas bubbles can damage the surrounding tissue. Mechanical bioeffects include cavitation (the activation of microbubbles and other nucleation sites in tissue, caused by ultrasound waves), acoustic radiation pressure, and microstreaming. Of these bioeffects, cavitation is the most critical. Cavitation is categorized into non-inertial cavitation (previously referred to as steady cavitation) and inertial cavitation (previously referred to as temporary cavitation).

Non-inertial cavitation occurs when microbubbles repeatedly expand and contract in response to varying pressures in the ultrasound pulse. This oscillation causes a phenomenon called microstreaming. Microstreaming is the oscillation of gas bubbles in tissue, leading to movement of the fluid around the gas bubbles. This phenomenon also has the potential to rupture cell membranes.
Inertial cavitation occurs when pressure changes due to oscillating ultrasound waves cause gas bubbles to expand and contract, and to finally implode violently. Although this phenomenon occurs on a microscopic level, it can produce extremely high temperatures and pressures in the immediate vicinity, sometimes leading to cell death.
The potential for mechanical bioeffects is related to the peak-rarefactional acoustic pressure (peak negative acoustic pressure) and frequency of the ultrasound waves. A higher peak negative acoustic pressure (a higher wave amplitude) increases the potential for mechanical bioeffects. Lower frequencies increase the potential for mechanical bioeffects.
Currently, there is no clear evidence of a causal relationship between the output intensities of the Diagnostic Ultrasound Systems currently in use and cavitation that occurs in body tissue. However, mechanical bioeffects are theoretically possible.

(b) Thermal bioeffects

Thermal bioeffects occur over longer periods of time, where absorption of the ultrasound energy causes tissue to heat up. Excessive heating can lead to the disruption of cell differentiation (especially in developing fetal tissue) and the breakdown of cellular structures. As described above, the energy that reflects off tissue back to the probe (energy from which images are formed) is very limited compared to the total energy that is transmitted to the body. The remaining energy is absorbed by the tissue. As a result of this absorption, two main areas become heated: the surface of the tissue irradiated by the ultrasound beam, and the area around the focal point of the ultrasound beam.
Tissues with different physical properties will absorb ultrasound energy at different rates. Absorption is affected by factors such as the ultrasound output power (amount of energy per unit time), the volume of the irradiated tissue, the perfusion rate of the tissue, and the amount of blood flow through the tissue. Bone tissue has a higher density and lower perfusion rate than soft tissue, and thus absorbs more ultrasound energy. Furthermore, if bone tissue is irradiated by the focal point of the ultrasound beam, even if it is not near the body surface, the tissue will absorb most of the energy. Soft tissue absorbs almost no energy. Because tissue absorbs ultrasound energy at different rates, there is no single model that describes all of the different properties of different tissues. Currently, the following three models are used to describe thermal bioeffects in tissue.

- Soft tissue
- Bone tissue irradiated by the focal point of the ultrasound beam
- Bone tissue near the body surface

The type of ultrasound beam also affects the potential for thermal bioeffects. In non-scanning mode (such as D-mode), because the position and direction of the ultrasound beam converging energy are fixed, high-density ultrasound energy is emitted for a relatively small volume of tissue volume. This tends to increase the thermal bioeffects on the tissue.

On the other hand, in B mode, because the position and direction of ultrasound beam are variable, the ultrasound energy is dispersed within a relatively large volume of tissue. As a result, the perfusion rate increases, mitigating the thermal bioeffects.
Currently, there is no clear evidence that the temperature elevations caused by the Diagnostic Ultrasound System currently in use are harmful to the human body.

7.3.3 Derivation and meaning of MI and TI

In 1992, the American Institute of Ultrasound in Medicine (AIUM) and the National Electrical Manufacturers Association (NEMA) released the voluntary standard "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment". This standard established a method for calculating and displaying indices that indicate the relative potential of mechanical and thermal bioeffects. Currently, the JIS T 0601-2-37 (IEC 60601-2-37) safety standard for the Diagnostic Ultrasound System also uses these same indices, allowing users of most diagnostic ultrasound systems to view and check indices in real-time while regulating the acoustic output.
The mechanical index (MI) and thermal index (TI) are presented as values without units and indicate the potential of harmful bioeffects resulting from ultrasound examinations. The indexes are designed to indicate the possibility of danger if the value exceeds a preset value. As a guideline, if an index exceeds 1, it is recommended that you either perform the examination at a lower acoustic output, or re-evaluate the risks/effectiveness analysis, taking into account relieving factors. Relieving factors include a lack of air bubbles in the target tissue, low susceptibility of morphological damage, and a high perfusion rate. It is also recommended that the examination time be kept as short as possible to avoid unnecessary irradiation. However, there is another risk that must be taken into consideration. That is risk of not obtaining the necessary information, in an effort to avoid performing an ultrasound examination. It is important to acknowledge that the danger of misdiagnosis due to not using the necessary acoustic output during an examination is greater than that of the bioeffects caused by ultrasound waves.

(1) MI: Mechanical index

According to scientific evidence, mechanical (non-thermal) bioeffects such as cavitation will not occur as long as the output does not exceed a certain threshold. However, this threshold varies depending on the tissue. It is believed that the potential of mechanical bioeffects is positively correlated with the peak-rarefactional acoustic pressure (peak negative acoustic pressure), and negatively correlated with the ultrasound wave frequency. Based on this, the formula for MI was defined as follows:

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

C_{MI} = 1 MPa MHz$^{-1/2}$
p_r: Attenuated peak-rarefactional acoustic pressure (MPa)
f_{awf}: Acoustic operating frequency (MHz)

Here, C_{MI} is a standardization coefficient equal defined to be 1 MPa MHz$^{-1/2}$. As a result, the MI value does not have a unit.
The MI is crucial in areas where soft tissue comes in contact with gas. For example, during heart scans, there is a risk of irradiating the surface of a lung. In addition, if you are using an ultrasound contrast agent, it is recommended that you regulate the MI with the utmost caution.

Because ultrasound waves pass through amniotic fluid and the urinary bladder with little to no attenuation, the tissue might be under high acoustic pressure even if the MI value appears to be low.

(2) TI: Thermal index

TI is defined as the result of dividing the attenuated ultrasound output power (P_α [mW]) by the amount of ultrasound output power necessary to raise the temperature of living tissue by 1°C (P_{deg} [mW]).

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

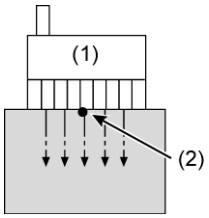
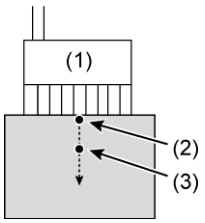
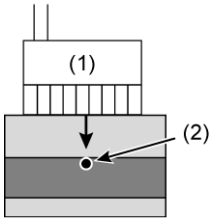
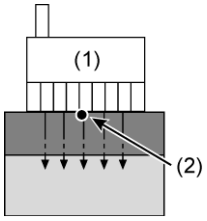
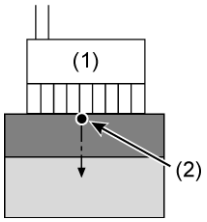
P_α: Attenuated ultrasound output power

Similar to the MI value, the TI value has no unit.
Depending on the combination of soft tissue and bone tissue to be examined, three types of TI can be used: TIS (soft tissue), TIB (bone), and TIC (cranial bone). The TI value informs the user of elevations in temperature that occur under certain conditions, such as those related to the tissue surface and tissue interior or when the focal point of ultrasound waves is in the vicinity of bones. Each type of TI predicts elevations in temperature based on a hypothesis.

- During an ultrasound scans, temperature elevation is believed to be most pronounced at the surface in contact with the probe, regardless of the applicable tissue model.
- In non-linear mode, if there are no bones in the soft tissue, it is possible that most of the heating will occur between the surface in contact with the probe and the region before the focal point.
- In non-scanning mode, if there is a bone in the vicinity of the focal point in the soft tissue being scanned, most of the heating will occur on the surface of the bone. In particular for fetal examinations where nerve tissue (brain, spinal cord, etc.) near bone that will be heated is still in the process of forming, we recommend that you carefully monitor the TIB index value.

If you have difficulty deciding which TI to use, refer to the following chart and decide based on where the bones are located in the region to be irradiated by ultrasound waves.

Thermal index categories and diagrams

	Scanning mode	Non-scanning mode
TIS: Soft-tissue thermal index	 Soft Tissue (1) Probe (2) Tissue Surface	 Soft Tissue (1) Probe (2) Tissue Surface (3) Before a focus
TIB: Bone thermal index		 Soft Tissue Bone (1) Probe (2) Bone Surface
TIC: Cranial bone thermal index	 Soft Tissue Bone (1) Probe (2) Bone Surface	 Soft Tissue Bone (1) Probe (2) Bone Surface

7.3.4 Control settings that affect acoustic output

To use the displayed MI and TI information more effectively, you will need to understand the Diagnostic Ultrasound System's control settings that affect the MI and TI. The formula for calculating the MI uses the peak-rarefactional acoustic pressure. The MI is calculated relative to instantaneous values, whereas the TI is calculated relative to values averaged over a period of time. The following table describes the system's control settings that affect MI and TI. In some cases, the system does not display the pulse repetition frequency on screen. We recommend that you read this manual carefully.

Diagnostic Ultrasound System control settings[*1]		Menu item or function	MI	TI
Common functions	Ultrasound output power	Acoustic Power	Yes	Yes
	Electric focus	Focus	Yes	Yes
	Limit on the ultrasound output power for fetal observation	Power Limit Override	Yes	Yes
B	Pulse repetition frequency	Depth Range	-	Yes
		Vertical Shift	-	Yes
		PAN Zoom	-	Yes
		HI Zoom	-	Yes
		PRF (B/M)	-	Yes
	Transmission frequency	Tx Frequency	Yes	Yes
	Number of scanning lines and line density	Line Density	-	Yes
		ScanArea	Yes	Yes
	Display modes	Fundamental, THI, CHI	Yes	Yes
M	Pulse repetition frequency	Simultaneous	-	Yes
		Echo Tracking	-	Yes
	Transmission frequency	Tx Frequency	Yes	Yes
	Observation mode	Simultaneous	-	Yes
	Display modes	Fundamental, THI	Yes	Yes
PW	Pulse repetition frequency	Velocity Range	Yes	Yes
		Ref. Frequency	Yes	Yes
		High PRF	Yes	Yes
	Reference frequency	Ref. Frequency	Yes	Yes
	Pulse duration (pulse width)	Sample Volume	Yes	Yes
	Observation mode	Simultaneous	Yes	Yes
	Display modes	Tissue Doppler	Yes	Yes
M + Color	Pulse repetition frequency	Velocity Range	Yes	Yes
		Ref. Frequency	Yes	Yes
		Color ROI position (depth)	Yes	Yes
	Reference frequency	Ref. Frequency	Yes	Yes
	Display modes	TDI, WI, FMD	Yes	Yes

Diagnostic Ultrasound System control settings[*1]		Menu item or function	MI	TI
Color	Pulse repetition frequency	Velocity Range	Yes	Yes
		Ref. Frequency	Yes	Yes
		Color ROI position (depth)	Yes	Yes
		Sensitivity Priority	Yes	Yes
	Number of pulse repetitions	Packet Size	-	Yes
	Reference frequency	Ref. Frequency	Yes	Yes
	Number of scanning lines and line density	Line Density	-	Yes
		Flow Area	Yes	Yes
		Color ROI size (width)	-	Yes
	Display modes	CF, eFlow, Power Doppler, TDI, DFI	Yes	Yes

*1.

The only conditions that affect the MI or TI value for continuous-wave Doppler (CWD) are ultrasound output power and focus (Sample Gate).

7.3.5 ALARA: Recommendation of "As Low As Reasonably Achievable"

Examinations should be conducted according to the ALARA principle of extracting the maximum possible diagnostic information while reducing the acoustic output to the lowest reasonable level. This is the same as the principle applied to ionizing radiation.
If you are using the mechanical index (MI) during an actual examination, keep the following points in mind at all times.

- Select an appropriate probe.
- Select an appropriate transmission frequency. (A higher transmission frequency leads to a lower MI value.)
- Select the electronic focus.
- Lower the transmitter voltage.
- Configure the image adjustment settings appropriately. (Increase the gain, etc.)

If you are using a contrast agent, be even more careful.
If you are using the thermal index (TI) during an actual examination, keep the following points in mind at all times.

- Select an appropriate TI.
- Configure the image adjustment settings appropriately. (Increase the gain, etc.)
- Reduce the TI value. (Reduce the transmitter voltage and pulse repetition frequency, and widen the scan width in scanning mode.)
- Reduce the exposure time.

7.3.6 Default settings

To prevent unintentional high acoustic output, the acoustic output is limited by default. (The default is a low value.) This occurs at the following times.

- Power On
- When a preset is selected
- When a probe is changed
- Right after the New Patient switch is pushed (when the ID is entered)

The acoustic output parameters, which include the mechanical index (MI) and the thermal index (TI), are set to their default levels based on the examination type. The default level is AP% = 70%.

7.3.7 Upper limits on acoustic output

For examinations other than fetal observation, the following limitations are applied: $I_{spta,\ \alpha}$ < 720 mW/cm^2, MI < 1.9, and TI < 6.
The mechanical index (MI) and thermal index (TI) are displayed in real time for probes for which there is a possibility of these values exceeding 1.0.
For fetal observation, the upper limits are MI < 1.0 and TI < 1.0.

7.3.8 Statistical examination of uncertainty

(1) Procedure for calculating the uncertainty

The procedure for calculating the measurement uncertainty is based on the methods in NEMA UD-2 (2004).
When reporting the amount of acoustic output, you must clearly indicate the average measured value and a quantitative estimate of the measurement uncertainty. Uncertainty is expressed in terms of the confidence limit or tolerance limit. A 95% confidence limit defines a range of values that will contain the true mean (or some other specified value) 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.
In NEMA UD-2 (2004) supplementary documents, the terms "Type A" and "Type B" are used to differentiate the components of measurement uncertainty. This concept was applied to ISO 1993 and ANSI/NCSL 1997. These new terms replaced the previously used terms "random uncertainty" and "systematic uncertainty". Type A uncertainty and Type B uncertainty differ in the way their numerical values are estimated. Type A uncertainty is evaluated through statistical treatment of repeated measurements, where as Type B uncertainty is evaluated by other means. An important reason for this new classification is to provide an internationally recognized method for mathematically combining individual uncertainty components into the total uncertainty regardless of whether a component was randomly or systematically caused.
This new approach basically estimates uncertainty by expressing each uncertainty component in terms of an estimated standard deviation, referred to as the "standard

uncertainty". Its symbol is u_i and it 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 by using all relevant information. This includes the following.

- Previous measurement data
- Appropriate materials and experience using the system
- The manufacturer's specifications
- Data provided from laboratories following national standards
- Data on uncertainty from handbooks

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

(a) Type A uncertainty evaluation

The Type A standard uncertainty (u_A), of a measured quantity is equal to the standard deviation of the sample mean, which is commonly referred to as the standard error. That is,

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

Here, S_x represents the standard deviation of the sample and n represents the number of repetitions. As shown above in formula (1), Type A uncertainty can be reduced by performing additional measurements. This reduction results from the increase in the value of the denominator. Ideally, measurement should be repeated enough times to yield a reliable estimate of the standard error.

(b) Type B uncertainty evaluation

Type B uncertainty is evaluated 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 having a variance of $a_i^2/3$. Here, a_i is the semi-range limit for the ith uncertainty component. Because the individual distributions are considered independent, the total variance equals the sum of the individual variances. Thus, for n rectangularly distributed uncertainty components, the total variance, σ^2, is calculated by using the following formula.

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

In addition, Type B uncertainty (u_B) is calculated based on the following formula.

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

(c) Combined uncertainty

The combined or total uncertainty of a measured quantity includes both Type A and Type B evaluated components of uncertainty. This value is computed after all errors have been removed from the database, and after all possible systematic corrections have been made. The combined uncertainty (u_C) of a measured quantity is calculated by using the following formula.

$$u_C = \sqrt{u_A{}^2 + u_B{}^2} \quad (4)$$

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 measurement of uncertainty that includes a larger proportion of the distribution of values that could be reasonably attributed to the measured quantity. This is achieved by multiplying the combined standard uncertainty by a coverage factor, *k*, to yield the expanded uncertainty, *U*.

$$U = k \bullet u_C \quad (5)$$

The measurement result is then conveniently expressed as the following.

$$x = \bar{x} \pm U \quad (6)$$

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 from 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, to achieve a 95% level of confidence about the expected value of the measured quantity. Whatever value of *k* is chosen, it must be clearly stated in the final specification of the uncertainty.

(2) Measurement uncertainty results

Here, we will provide the results of evaluating the measurement uncertainty of our products. For this evaluation, we used four ALOKA SSD-4000 systems and six UST-9123 probes. For each of these, we measured the acoustic output four times. Acoustic output was measured in terms of total power, pulse-intensity integral (I_{pi}), peak-rarefactional acoustic pressure (p_r), acoustic working frequency (f_{awf}). We analyzed the results by using a two-way crossed analysis of variance with repeated measurements. Although the product model used for evaluation is different from the model described in this manual, we assume that we can obtain similar results even using different sets of systems and probes.

This analysis assumes that the systems and probes are independent, and that all repeated measurements are independent. The analysis also assumes that all preliminary steps, such as correcting for systematic errors, have been performed.

We performed the evaluating by using six probes (*p* = 6) and four systems (*q* = 4), and by performing four measurements (*r* = 4).

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 1 to p); $S_{.j}$ (columns 1 to q)

ij field average value

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

*i*th probe average value

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

*j*th system average value

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

Total average

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

ij field standard deviation

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

Probe standard deviation

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

System standard deviation

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

Calculate the probe mean, system mean, and overall mean by using formulas (8), (9), and (10), respectively. The standard deviation calculated by using formula (11) is expressed as percentage of the overall mean value.

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

$$S_{\text{meas}} = \sqrt{\frac{1}{pq}\sum_{i=1}^{p}\sum_{j=1}^{q} S_{ij}^{\,2}} \tag{14}$$

The probe variability is quantified by S_{trans}.

$$S_{\text{trans}} = \sqrt{S_{i\bullet} - \frac{1}{rq} S_{\text{meas}}^{\,2}} \tag{15}$$

The system variability is quantified by S_{cons}.

$$S_{\text{cons}} = \sqrt{S_{\bullet j} - \frac{1}{rp} S_{\text{meas}}^{\,2}} \tag{16}$$

The total variability is quantified by S_{total}.

$$S_{\text{total}} = \sqrt{S_{\text{trans}}^{\,2} + S_{\text{cons}}^{\,2} + S_{\text{meas}}^{\,2}} \tag{17}$$

The variance of the measured quantity is calculated by using the following formula.

$$\hat{\sigma}_x^{\,2} = S_{\text{total}}^{\,2} \tag{18}$$

The variance of the average of the measured quantity is calculated by using the following formula.

$$\hat{\sigma}_{\bar{x}}^{\,2} = \frac{S_{\text{trans}}^{\,2}}{p} + \frac{S_{\text{cons}}^{\,2}}{q} + \frac{S_{\text{meas}}^{\,2}}{rpq} \tag{19}$$

The Type A standard uncertainty is the square root of the variance of the average value of the measured quantity. That is,

$$u_{\text{A}}^{\,2} = \sqrt{\hat{\sigma}_{\bar{x}}^{\,2}} \tag{20}$$

The Type B uncertainty is calculated by using the following formula.

$$u_{\text{B}} = \sqrt{\sigma^2} = \sqrt{\frac{a_1^{\,2} + a_2^{\,2} + \ldots + a_n^{\,2}}{3}} \tag{21}$$

Therefore, the combined uncertainty is calculated by using the following formula.

$$u_{\text{C}} = \sqrt{u_{\text{A}}^{\,2} + u_{\text{B}}^{\,2}} \tag{22}$$

For the purposes of ultrasonic exposimetry, the level of confidence for the expanded uncertainty (U) should be set to 95%. In this evaluation, k is set to 2.07, the value of $t_{.975}$ with the degrees of freedom, pq - 1 = 23. (From Table 1 in Appendix A of UD 2-2004)

$$U = k \bullet u_{\text{C}} = t_{.975}(pq - 1) \bullet u_{\text{C}} \tag{23}$$

The ultrasound output power is reported as follows.

$$Power = \overline{m} \pm U \tag{24}$$

An upper 95% tolerance limit is calculated by using the expanded uncertainty, and the coverage factor is an appropriately chosen tolerance coefficient. In addition, the Type A uncertainty for calculating the combined uncertainty uses the standard deviation $\sqrt{\hat{\sigma}_x^2}$ of the measured quantity (not the standard deviation $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ of the average value of the measured quantity, which is used to calculate the expanded uncertainty *U*). Therefore, the upper 95% tolerance limit for 99% of the ultrasound output power values is calculated by using the following formula.

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

k is set to $K_{.99}$ for *pqr* - 1 = 95 degrees of freedom, and the expanded uncertainty becomes the following.

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

In addition, the upper tolerance limit is calculated by using the following formula.

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

(a) Uncertainty evaluation of the ultrasound output power P

The standard deviation of the mean value of six probes calculated by using formula (12)	$S_{i.}$:	6.44%
The standard deviation of the mean value of four systems calculated by using formula (13)	$S_{.j}$:	2.57%
The standard deviation of the measurement variance calculated by using formula (14)	S_{meas}:	1.01%
The standard deviation of the probe variance calculated by using formula (15)	S_{trans}:	6.43%
The standard deviation of the system variance calculated by using formula (16)	S_{cons}:	2.56%
The standard deviation of the total variance calculated by using formula (17)	S_{total}:	7.00%
The Type A uncertainty calculated by using formula (20)	u_A:	2.92%
Uncertainty components for Type B uncertainty evaluation		
The error derived from the scale capacity	a_1:	±2%
The error due to the reference source	a_2:	±4%
The error derived from the alignment of the probe	a_3:	-5%
The error derived from not coupling directly with water	a_4:	-3%
The error derived from insufficient thickness of the absorbing target	a_5:	-5%
The Type B standard uncertainty calculated by using formula (21)	u_B:	5.13%
The total standard uncertainty calculated by using formula (22)	u_C:	5.91%

For the purposes of ultrasonic exposimetry, the level of confidence for the expanded uncertainty (*U*) is set to 95%. In this evaluation, the coverage factor *k* is set to 2.07, the value of $t_{.975}$ with 23 (= *pq* - 1) degrees of freedom. (From Table 1 in Appendix A of UD 2-2004)

The expanded uncertainty calculated by using formula (23)	U:	12.22%

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

An upper 95% tolerance limit is calculated by using the expanded uncertainty, and the coverage factor is an appropriately chosen tolerance coefficient. In addition, the Type A uncertainty for calculating the combined uncertainty uses the standard deviation $\sqrt{\hat{\sigma}_x^2}$ of the measured quantity (not the variance $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ of the average value of the measured quantity, which is used to calculate the expanded uncertainty U).

The upper 95% tolerance limit for 99% of the ultrasound output power values, calculated by using formula (25)	u_C:	8.68%

The $K_{.99}$ value for 95 (= pqr - 1) degrees of freedom is 2.69. Thus, setting the coverage factor k = 2.69:

The upper 95% tolerance limit for 99% of values, calculated by using formula (26)	U:	23.38%

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

(b) Uncertainty evaluation of the pulse-intensity integral I_{pi} or *pii*

The standard deviation of the mean value of six probes calculated by using formula (12)	$S_{i.}$:	3.80%
The standard deviation of the mean value of four systems calculated by using formula (13)	$S_{.j}$:	4.14%
The standard deviation of the measurement variance calculated by using formula (14)	S_{meas}:	1.14%
The standard deviation of the probe variance calculated by using formula (15)	S_{trans}:	3.79%
The standard deviation of the system variance calculated by using formula (16)	S_{cons}:	4.13%
The standard deviation of the total variance calculated by using formula (17)	S_{total}:	5.72%
The Type A uncertainty calculated by using formula (20)	u_A:	2.59%
Uncertainty components for Type B uncertainty evaluation		
The error derived from the voltage measurement of the oscilloscope	a_1:	±3%
The error derived from the time measurement of the oscilloscope	a_2:	±2%
Hydrophone correction error	a_3:	±8.6%
The error derived from the alignment of the probe	a_4:	- 3%
The error derived from the alignment of the hydrophone	a_5:	- 4%
The error derived from the spatial averaging of the hydrophone	a_6:	- 16.6%
The error derived from the non-linear propagation distortion	a_7:	- 6%
The error derived from the directionality of the hydrophone	a_8:	- 4%
The Type B standard uncertainty calculated by using formula (21)	u_B:	12.10%
The total standard uncertainty calculated by using formula (22)	u_C:	12.38%

For the purposes of ultrasonic exposimetry, the level of confidence for the expanded uncertainty (*U*) is set to 95%. In this evaluation, the coverage factor *k* is set to 2.07, the value of $t_{.975}$ with 23 (= *pq* - 1) degrees of freedom. (From Table 1 in Appendix A of UD 2-2004)

The expanded uncertainty calculated by using formula (23)	*U*	25.62%

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

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

An upper 95% tolerance limit is calculated by using the expanded uncertainty, and the coverage factor is an appropriately chosen tolerance coefficient. In addition, the Type A uncertainty for calculating the combined uncertainty uses the standard deviation $\sqrt{\hat{\sigma}_x^2}$ of the measured quantity (not the variance $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ of the average value of the measured quantity, which is used to calculate the expanded uncertainty *U*).

The upper 95% tolerance limit for 99% of the ultrasound output power values, calculated by using formula (25)	u_C:	13.39%

The $K_{.99}$ value for 95 (= *pqr* - 1) degrees of freedom is 2.69. Thus, setting the coverage factor *k* = 2.69:

The upper 95% tolerance limit for 99% of values, calculated by using formula (26)	*U*:	36.03%

$$I_{\mathrm{pi}} \leq \overline{\overline{m}} + 36.03\ \%$$

$$pii \leq \overline{\overline{m}} + 36.03\ \%$$

(c) Uncertainty evaluation of the peak-rarefactional acoustic pressure p_r

The standard deviation of the mean value of six probes calculated by using formula (12)	$S_{i.}$:	1.95%
The standard deviation of the mean value of four systems calculated by using formula (13)	$S_{.j}$:	2.62%
The standard deviation of the measurement variance calculated by using formula (14)	S_{meas}:	1.15%
The standard deviation of the probe variance calculated by using formula (15)	S_{trans}:	1.93%
The standard deviation of the system variance calculated by using formula (16)	S_{cons}:	2.61%
The standard deviation of the total variance calculated by using formula (17)	S_{total}:	3.45%
The Type A uncertainty calculated by using formula (20)	u_A:	1.53%
Uncertainty components for Type B uncertainty evaluation		
The error derived from the voltage measurement of the oscilloscope	a_1:	±1.5%
The error derived from the time measurement of the oscilloscope	a_2:	±2%
Hydrophone correction error	a_3:	±4.3%
The error derived from the alignment of the probe	a_4:	- 3%
The error derived from the alignment of the hydrophone	a_5:	- 2%

The error derived from the spatial averaging of the hydrophone	a_6:	- 8%
The error derived from the non-linear propagation distortion	a_7:	- 3%
The error derived from the directionality of the hydrophone	a_8:	- 2%

The Type B standard uncertainty calculated by using formula (21)	u_B:	6.18%
The total standard uncertainty calculated by using formula (22)	u_C:	6.37%

For the purposes of ultrasonic exposimetry, the level of confidence for the expanded uncertainty (U) is set to 95%. In this evaluation, the coverage factor k is set to 2.07, the value of $t_{.975}$ with 23 (= pq - 1) degrees of freedom. (From Table 1 in Appendix A of UD 2-2004)

The expanded uncertainty calculated by using formula (23)	U	13.19%

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

An upper 95% tolerance limit is calculated by using the expanded uncertainty, and the coverage factor is an appropriately chosen tolerance coefficient. In addition, the Type A uncertainty for calculating the combined uncertainty uses the standard deviation $\sqrt{\hat{\sigma}_x^2}$ of the measured quantity (not the variance $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ of the average value of the measured quantity, which is used to calculate the expanded uncertainty U).

The upper 95% tolerance limit for 99% of the ultrasound output power values, calculated by using formula (25)	u_C:	7.08%

The $K_{.99}$ value for 95 (= pqr - 1) degrees of freedom is 2.69. Thus, setting the coverage factor k = 2.69:

The upper 95% tolerance limit for 99% of values, calculated by using formula (26)	U:	19.05%

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

(d) Uncertainty evaluation of the acoustic working frequency f_{awf}

The standard deviation of the mean value of six probes calculated by using formula (12)	$S_{i.}$:	0.085%
The standard deviation of the mean value of four systems calculated by using formula (13)	$S_{.j}$:	0.009%
The standard deviation of the measurement variance calculated by using formula (14)	S_{meas}:	0.011%
The standard deviation of the probe variance calculated by using formula (15)	S_{trans}:	0.085%
The standard deviation of the system variance calculated by using formula (16)	S_{cons}:	0.009%
The standard deviation of the total variance calculated by using formula (17)	S_{total}:	0.086%
The Type A uncertainty calculated by using formula (20)	u_A:	0.035%

Uncertainty components for Type B uncertainty evaluation

The error derived from the time measurement of the oscilloscope	a_1:	±2%

The Type B standard uncertainty calculated by using formula (21)	u_B:	1.15%
The total standard uncertainty calculated by using formula (22)	u_C:	1.16%

For the purposes of ultrasonic exposimetry, the level of confidence for the expanded uncertainty (U) is set to 95%. In this evaluation, the coverage factor k is set to 2.07, the value of $t_{.975}$ with 23 (= pq - 1) degrees of freedom. (From Table 1 in Appendix A of UD 2-2004)

The expanded uncertainty calculated by using formula (23)	U	2.39%

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

7.3.9 References

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8

Messages

8.1 Messages about image display

Messages	Status or cause	Countermeasures
Range limit: Selection is not available.	This message is displayed when the user attempts to adjust the display range beyond the upper limit or lower limit of values that can be set.	Adjust the display range between the upper limit and lower limit of setting values.
Detection error: Cannot detect ECG R-wave.	This message is displayed when the R-wave cannot be detected for five or more seconds while the ECG waveform is displayed.	The message is cleared when the ECG waveform R-wave is detected for five or more seconds.
Memorized TGC positions are used. Please set the TGC knobs to the center position.	This message is displayed after a new [TGC] knob position is stored and [TGC Curve] is switched to [Custom].	The image is displayed with the stored curve when all [TGC] sliders are in the center positions.
Overwrite current TGC setting?	This message is displayed if the image is frozen in the dual-screen view or quad-screen view and then TGC is changed and the active screens are switched.	• [Yes]: Applies the new TGC settings to the active screen. • [No]: Does not apply the new TGC settings to the active screen.
Keep the acoustic output level as low as possible. Refer to ALARA recommendations in the Instruction Manual.	This message is displayed when [Power Limit Override] is set to On.	• [ON]: Cancels the acoustic output restrictions. • [CANCEL]: Clears the message without canceling the acoustic output restrictions.
Sound Speed cannot be optimized.	This message is displayed when [Auto Optimizer] is set to On, but optimization is not possible.	Display the image immediately before [Auto Optimizer] was set to On.
Invalid probe.	• A probe not suitable for the system is connected. • A probe subject to correction is connected, but the correction parameters could not be recognized.	• Connect a probe that is suitable for connection. • The probe might be broken. For details on probe inspections, please contact our office.
Puncture adapter: *******	This message is displayed when [Puncture Guide Line] is set to On while a probe capable of using multiple puncture adapters is connected.	The displayed model name is that of the puncture adapter model in use. If a different puncture adapter is used, open [Puncture Adapter Select] to select it.
Press [UNDO] to rotate the fetus mark.	This message is displayed when a rotatable fetus mark is selected for the body mark.	To rotate the fetus mark, 1. Press the [UNDO] key. 2. Turn the [Pointer] rotary encoder.
Cannot register. Delete any unnecessary entries and start over.	This message is displayed when the user attempts to register the 801st word while the learning function under the annotation preset is set to Off.	Delete unnecessary words before registering new words.

Messages	Status or cause	Countermeasures
System in auto freeze. Press [Freeze] to resume.	This message is displayed when there is no operation of the operation panel or touch panel within a set period.	Press the [Freeze] key.
Memory data will be deleted.	This message is displayed when the user attempts to delete a registered coordinate position.	• [Yes]: Deletes the selected coordinate position. • [Cancel]: Clears the message without deleting the selected coordinate position.
Memory full	This message is displayed when the user attempts to register the 31st coordinate position.	Delete unnecessary coordinate positions before registering new coordinates.
An assist line will appear. Use it as assistance in marking. DO NOT use it as a puncture guide line.	This message is displayed when [Assist Line] is set to On.	Select the [OK] button. NOTE: Do not use assist lines as puncture guide lines. [OK]: Clears the message.
A data error in this probe was found. Shut down and reboot the system. If this message is displayed again, contact our office.	This message is displayed when an error is detected in probe parameters. Transmission is stopped immediately.	Restart the system. If this message persists after restarting, make a note of the message and contact our office.
The instruction manual does not exist.	This message is displayed when the specified instruction manual does not exist, or is corrupted.	Restart the system. If this message persists after restarting, make a note of the message and contact our office.
Database was broken. Please contact our office near you.	This message is displayed when the patient database is corrupted.	Restart the system. If this message persists after restarting, make a note of the message and contact our office.
Invalid name or password.	This message is displayed when an invalid user name or password is entered in the login screen.	[OK]: Clears the message. Enter the correct user name and password.
Invalid password. Enter another password.	This message is displayed when the new password does not follow the password rules.	[OK]: Clears the message. Enter a password consisting of no more than 16 alphanumeric characters.
The passwords did not match. Re-enter your new password.	This message is displayed when the two entries of the password do not match when the user changes the password.	[OK]: Clears the message. Re-enter the correct password.
Probe temperature is higher than 41.0°C.	This message is displayed when you are using a probe with a built-in temperature sensor, and the temperature of the probe tip exceeds 41.0 °C.	When the temperature of the probe tip falls below 41.0 °C, this message is cleared.

Messages	Status or cause	Countermeasures
If the temperature rises any further, transmission will be terminated.	This message is displayed when you are using a probe with a built-in temperature sensor, and the temperature of the probe tip exceeds 42.0°C.	[OK]: Clears the message. When the temperature of the probe tip falls below 42.0 °C, this message is cleared, and the message "Probe temperature is higher than 41.0°C" is displayed.
TEE thermal limit. Auto cooling mode in progress.	This message is displayed when you are using a probe with a built-in temperature sensor, and the temperature of the probe tip exceeds 43.0 °C.	The image freezes. The panel switch lights turn off. If the surface temperature of the probe tip falls below 40.5 °C, this message is cleared, and the system returns to its status immediately before the automatic freeze mode began. The examination can now be resumed.
TEE fatal error (%d) Discontinue examination and turn the system off.	This message is displayed when the temperature sensor in the probe is broken.	Stop using the system. Please note down the message details and contact our office.
Probe temperature is higher than 41.0°C.	This message is displayed when you are using a probe with a built-in temperature sensor, and the temperature of the probe tip exceeds 41.0 °C.	When the temperature of the probe tip falls below 41.0 °C, this message is cleared.
TTE thermal limit. Auto cooling mode in progress.	This message is displayed when you are using a probe with a built-in temperature sensor, and the temperature of the probe tip exceeds 43.0 °C.	The image freezes. The panel switch lights turn off. If the surface temperature of the probe tip falls below 40.5 °C, this message is cleared, and Freeze is turned on. The examination can now be resumed.
TTE fatal error (%d) Discontinue examination and turn the system off.	This message is displayed when the temperature sensor in the probe is broken.	Stop using the system. Please note down the message details and contact our office.

8.2 Messages about patient data entry

These messages are displayed on the Patient Information Entry screen.

Messages	Status or cause	Countermeasures
Birth Date Error: ex. 2010/09/17	This message is displayed when you enter a value that does not conform to the input format.	1. Select the [OK] button. 2. Refer to the example displayed in the message, and then enter the date. [OK]: Clears the message.
OB Date Error: ex. 2010/09/17	This message is displayed when you enter a value that does not conform to the input format in the date field on the OB tab.	1. Select the [OK] button. 2. Refer to the example displayed in the message, and then enter the date. [OK]: Clears the message.

Messages	Status or cause	Countermeasures
GYN Date Error: ex. 2010/09/17	This message is displayed when you enter a value that does not conform to the input format in the date field on the GYN tab.	1. Select the [OK] button. 2. Refer to the example displayed in the message, and then enter the date. [OK]: Clears the message.
From Date Error: ex. 2010/09/17	This message is displayed when you enter a value that does not conform to the input format.	1. Select the [OK] button. 2. Refer to the example displayed in the message, and then enter the date. [OK]: Clears the message.
Until Date Error: ex. 2010/09/17	This message is displayed when you enter a value that does not conform to the input format.	1. Select the [OK] button. 2. Refer to the example displayed in the message, and then enter the date. [OK]: Clears the message.
A person's name cannot contain any of the following characters: \=	This message is displayed when a personal name (Patient Name, Referring Phys, Sonographer) contains a backslash or an equal sign.	1. Select the [OK] button. 2. Delete any back slashes and equal signs. [OK]: Clears the message.
Enter the patient name using up to 64 characters.	This message is displayed when the patient name entry field is divided into three parts and the total number of characters in Family, Given, and Name is 64 or more.	1. Select the [OK] button. 2. Enter the patient name using no more than 64 characters. [OK]: Clears the message.
Age Error: Age = 0-999[y][m][w][d]	This message is displayed when text other than numerals is entered. It is also displayed when a decimal point and decimal places are entered.	1. Select the [OK] button. 2. Enter a value in the range 0 - 999. Alternatively, enter a birth date. [OK]: Clears the message.
Height Error	This message is displayed when text other than numerals is entered. It is also displayed when a value less than 0 or greater than 1,000 is entered.	1. Select the [OK] button. 2. Enter a value in the range 0 - 999. [OK]: Clears the message.
Weight Error	This message is displayed when text other than numerals is entered. It is also displayed when a value less than 0 or greater than 1,000 is entered.	1. Select the [OK] button. 2. Enter a value in the range 0 - 999. [OK]: Clears the message.
Study ID Error	This message is displayed when the field is left blank.	1. Select the [OK] button. 2. Enter a value in the range 0 - 999. [OK]: Clears the message.
BSA Error: BSA = 0-9.99	This message is displayed when text other than numerals is entered. It is also displayed when a value less than 0 or greater than 10.00 is entered.	1. Select the [OK] button. 2. Enter a value in the range 0 - 9.99. [OK]: Clears the message.

Messages	Status or cause	Countermeasures
PSA Error: PSA = 0-999.9	This message is displayed when text other than numerals is entered. It is also displayed when a value less than 0 or greater than 1,000 is entered.	1. Select the [OK] button. 2. Enter a value in the range 0 - 999.9. [OK]: Clears the message.
OB Week Error: Week Format = **w*d (ex. 24w3d)	This message is displayed when you enter a value that does not conform to the input format.	1. Select the [OK] button. 2. Refer to the example displayed in the message, and then enter the number of gestation weeks. [OK]: Clears the message.
Now making worklist... Do not turn off the system.	This message is displayed while the worklist is being acquired.	The message is cleared when worklist acquisition is complete.
USB drive not ready.	This message is displayed when USB was selected as the Target Medium, but no USB device was connected.	Connect a storage medium to the USB connector.
This order is already performed. Do you want to perform an additional examination?	This message is displayed when there is an SPS that is the same as the entered test. It is also displayed if the patient ID for a completed scan is entered.	• [Yes]: Performs an examination with the same examination ID. • [No]: Clears the message without updating the examination information.
Found the following ID in HDD. Patient ID: Patient Name: Overwrite this data? ID Card Patient ID: Patient Name: Birth Date: Sex: Local HDD Patient ID: Patient Name: Birth Date: Sex:	This message is displayed if the applicable patient ID is on the system hard disk when data received from the ID card reader is reflected in the ID screen.	• [ID Card]: Applies the data received from the ID card reader to the patient information. • [Local]: Uses the patient information that is on the system hard disk. • [Cancel]: Clears the message without updating the patient information.
Now searching... Please wait.	This message is displayed while patient information is being searched.	The message is cleared when the search of patient information is complete.
Now reading... Do not turn off the system.	This message is displayed while patient information is being loaded.	The message is cleared when the loading of patient information is complete.
Now writing... Do not turn off the system.	This message is displayed while patient information is being written to the system hard disk.	The message is cleared when the writing of patient information is complete.
Now making worklist... Do not turn off the system.	This message is displayed while the patient information is being received from the HIS and RIS.	The message is cleared when reception of patient information is complete.

Messages	Status or cause	Countermeasures
"Blood Pressure Error."	This message is displayed when the value entered for Blood Pressure in the ID setting screen is not valid.	Enter a valid value for Blood Pressure in the ID setting screen. NOTE: Enter a value using no more than 301 characters. Enter the maximum blood pressure value on the left and the minimum blood pressure value on the right.
The specified patient ID has been registered with different patient data. Do you want to overwrite it with new patient data?	This message is displayed when the user attempts to update the patient data registered in the database and start a scan.	• [Yes]: Updates the database and starts a scan. • [Cancel]: Returns you to the ID input screen.
Patient ID not registered. Please enter "Patient ID".	This message is displayed when the Patient ID has not been entered.	Enter the patient ID.
Patient information is not saved. Do you want to abort the input?	This message is displayed when the user attempts to close the ID input screen without saving patient information.	• [OK]: Closes the ID input screen without saving the patient information being entered. • [Cancel]: Returns you to the ID input screen.
No Patient Information can be found.	This message is displayed when there is no patient Information that matches the search conditions.	[OK]: Clears the message and returns you to the ID input screen.
The select %d data will be deleted. Do you want to continue?	This message is displayed when the user attempts to use the Patient List tab to delete patient information.	• [Yes]: Deletes the selected patient information. • [No]: Returns you to the ID input screen without deleting the selected patient information.
A problem occurred at the MWM Server. Unable to connect to the MWM Server.	This message is displayed when the user attempts to search for patient information in the worklist, but there is no response from the worklist.	1. Select [OK]. 2. Resolve the problem in the connection with the worklist server, and then retry the operation.
Found the following ID in %s Patient ID: %s Study ID: %s Overwrite this data? ********** Patient Name: %s Examined date: %s Local HDD Patient Name: %s Examined date: %s	This message is displayed when the user attempts to import patient information from an external storage medium, but the same information already exists on the system hard disk.	• [Yes]: Imports the patient information indicated in the message and overwrites the corresponding information on the system hard disk. • [All Yes]: Imports all patient information from the external storage medium and overwrites the patient information on the system hard disk. • [Cancel]: Does not import all patient information from the external storage medium. • [No]: Does not import the indicated patient information.

Messages	Status or cause	Countermeasures
Patient information is not saved. Do you want to save it?	This message is displayed when the user selects [New Patient] before saving the entered patient information.	• [Yes]: Saves the entered patient information, and clears the information currently being entered • [No]: Does not save the entered information, and clears the information currently being entered.
Are you sure you want to delete this item?	This message is displayed when the user attempts to delete an item in the Body Part Examined Items setup dialog box in the ID screen.	• [OK]: Deletes the specified item. • [Cancel]: Clears the message without deleting the specified item.
Caution! The numbers of patient information data are close to the limit. Please make back-up and delete data from Data Management screen.	This message is displayed when the number of saved images exceeds 145,000 or the number of examinations exceeds 32,000.	1. Select the [OK] button. 2. Back up the image data on the search screen. 3. Back up the patient information on the Data Management screen. 4. Delete the patient information that was backed up on the Data Management screen.
Warning! The numbers of patient information data have reached to the limit. Please make back-up and delete data from Data Management screen.	This message is displayed when the number of saved images or the number of examinations reaches the upper limit and the next examination cannot be performed.	1. Select the [OK] button. 2. Select the [X] button at the top right of the ID screen. 3. Back up the image data on the search screen. 4. Back up the patient information on the Data Management screen. 5. Delete the patient information that was backed up on the Data Management screen.
There are too many results to display. Please refine the search conditions and search again.	This message is displayed when the number of patient information search results to be displayed in the list view exceeds the upper limit.	1. Select the [OK] button. 2. Enter patient data in the search information input field. 3. Select [Search].

Messages (Data Management)	Status or cause	Countermeasures
Multiple patient IDs have been selected. Select only one patient.	This message is displayed if the [Edit] button is selected while multiple patients are selected in Data Management.	1. Select the [OK] button. 2. Select one patient (multiple examinations can be selected). [OK]: Clears the message.
The patient data and image data information will be changed.	This message is displayed when the [OK] button is selected for correction of patient information under Data Management.	• [OK]: Updates the patient information. • [Cancel]: Clears the message without updating the patient information.

Messages (Data Management)	Status or cause	Countermeasures
The entered patient ID already exists. Enter another patient ID.	This message is displayed if the patient ID is in use elsewhere during correction of patient information under Data Management.	1. Select the [OK] button. 2. Re-enter the patient ID. [OK]: Clears the message.
Warning! In case you import a database file from a different system, you may get an incorrect merge if the database file contains the same patient records. In that case, press [Cancel] and delete all stored images and waveform data in the system. Do you still want to continue?	This message is displayed when the [Import From Media] button is selected for the import of patient information under Data Management.	• To import database files saved in the same system, select the [OK] button. • If the database file to be imported and the database file in the import destination do not contain the same patient information, click the [OK] button. • If the patient information to be imported also exists in the system to which that information is to be imported, select the [Cancel] button, and then delete the duplicate patient information in the system by using the Data Management screen. NOTE: For details on how to delete patient information, see the separate manual "Basic Operations".
Are you sure you want to delete the selected data?	This message is displayed when you select an operation that will delete patient information in Data Management.	• [OK]: Deletes the patient information. • [Cancel]: Clears the message without deleting the patient information.
Selected data includes locked data. Are you sure you want to delete all data?	This message is displayed when all patient information on the system is selected for deletion under Data Management.	• [Yes, delete all]: Deletes all of the selected patient information. • [No, delete open data only]: Deletes all unlocked patient information. • [Cancel]: Clears the message without deleting the patient information.
You are about to delete all study data. Deletion once started cannot be interrupted. Do you still want to delete the data?	This message is displayed when all patient information on the system hard disk is selected for deletion in Data Management.	• [OK]: Deletes the patient information. • [Cancel]: Clears the message without deleting the patient information.
Deleting... Please wait.	This message is displayed when [OK] is selected in response to the above message.	The message is cleared when deletion is complete.
Now deleting... Do not turn off the system. Patient ID: Patient Name: Examined Date: Study ID:	This message is displayed during deletion of patient information if patient information on the system hard disk is subject to deletion under Data Management.	The message is cleared when deletion is complete. [Cancel]: Clears the message without deleting the patient information.

Messages (Data Management)	Status or cause	Countermeasures
Deleting stored images... Please wait. Do not turn off the system.	This message is displayed during deletion of images if patient information on the system hard disk is subject to deletion under Data Management.	The message is cleared when deletion is complete.
Found follow filename in USB.	This message is displayed when a file name already used on the USB device is selected as the storage destination in the Write to USB storage dialog box in Data Management.	• [REPLACE]: Deletes the file on the USB device, and creates a file storing the hard disk data. • [Add]: Adds the data to the file on the USB device. • [Cancel]: Clears the message without saving the data.
Now optimizing...	This message is displayed if the user selected [Update] in the Data Management screen.	The message is cleared when the optimization of the database is complete.
You are about to write all study data. Writing once started cannot be interrupted. Do you still want to write the data?	This message is displayed when the user attempts to select all the patient information displayed in the Data Management screen and write it to an external storage medium.	• [OK]: Writes the selected patient information to an external storage medium. • [Cancel]: Returns you to the state you were at before you selected [Write to Media].
Are you sure you want to delete this data?	This message is displayed when the user attempts to delete patient information in the Data Management screen.	• [OK]: Deletes the selected patient information. • [Cancel]: Returns you to the Data Management screen without deleting the selected patient information.
Now writing... Do not turn off the system.	This message is displayed when you select [Write to Media], and data is being written to the external media.	• The message is cleared when processing is complete. • [Cancel]: Forcibly terminates the processing.
Error occurred. Writing function will now terminate. Data returns back to before [Write to Media].	This message is displayed when an attempt to write to the external media fails.	1. Check the status of the storage medium. If a problem is found on the storage medium, use a different storage medium to perform the processing again. 2. If the same message is displayed even after you perform step 1, make a note of this message and contact our office.
Now importing... Do not turn off the system.	This message is displayed when you select [Import from Media], and data is being read from the external media.	• The message is cleared when processing is complete. • [Cancel]: Forcibly terminates the processing.

Messages (Data Management)	Status or cause	Countermeasures
A Fatal error occurred. Import function will now terminate. Data returns back to before [Import from Media].	This message is displayed when an attempt to read from the external media fails.	1. Check the status of the storage medium. If a failure is found on the storage media, store the database you want to restore on different storage media, and then perform the processing again. 2. If the same message is displayed even after you perform step 1, make a note of this message and contact our office.
Some of data could not be imported. Try this function again.	This message is displayed when a database access error occurs during the [Import from Media] processing.	If the same message is displayed even after you retry the operation, make a note of this message and contact our office.
Now reconstructing... Do not turn off the system.	This message is displayed during the [Reconstruction from Store Image] processing.	• The message is cleared when processing is complete. • [Cancel]: Forcibly terminates the processing.
A Fatal error occurred. Reconst function will now terminate. Data returns back to before [Reconstruction from Store Image].	This message is displayed when an error occurs during the [Reconstruction from Store Image] processing.	If the same message is displayed even after you retry the operation, make a note of this message and contact our office.
Some of data could not be reconstructed. Try this function again.	This message is displayed when a database access error occurs during the [Reconstruction from Store Image] processing.	If the same message is displayed even after you retry the operation, make a note of this message and contact our office.
There are too many results to display. Please refine the search conditions and search again.	This message is displayed when the display limit of the search results list area is exceeded.	1. Select the [OK] button. 2. Enter patient data in the search information input field. 3. Select [Search].

Messages (image import)	Status or cause	Countermeasures
Importing selected images...	This message is displayed if the user selects images in the Import screen and then selects the [Import] button.	The message is cleared when image import ends. [Cancel]: Cancels the import. Images that were copied when they were selected are left as they were.
Little free space left on the hard disk. Free up disk space.	This message is displayed when the free space on the system hard disk is less than 2 GB after an import.	Delete unnecessary images.
Error: Disk full. Delete unnecessary data.	This message is displayed when there is insufficient free space on the system hard disk and the import cannot continue.	Delete unnecessary images.

Messages (Japanese Calender)	Status or cause	Countermeasures
Are you sure you want to delete this item?	This message is displayed when the user selects [Delete] in the Japanese Calender setup dialog box.	• [OK]: Deletes the selected item. • [Cancel]: Clears the message without deleting the item.
The registration limit (2) has been reached. Delete the older item.	This message is displayed when the user attempts to register a third item.	1. Select the [OK] button. 2. Delete an item registered in the past. 3. Register the Western calendar year and the first letter of the traditional Japanese era name.
The starting year is invalid. Enter a value 2019 - %d.	This message is displayed when the value for Starting year is invalid.	1. Select the [OK] button. 2. For Starting year, enter a Western year, from 2019 to the next year of the registration. For example, if registering in 2020, you can enter 2019, 2020, or 2021.
Already exists.	This message is displayed when the user attempts to register a First letter but that character has already been registered.	1. Select the [OK] button. 2. Enter an alphabetic character that has not been registered for First letter.

8.3 Messages about saving display images

These messages are displayed when the user presses the [Store] key to save a displayed image.

Messages	Status or cause	Countermeasures
Enter Patient ID.	This message is displayed when the user presses the [Store] key without entering a patient ID or patient name.	Enter patient data.
Part of the image could not be acquired. Press the [Store] key to store the images or cycles. To retry without storing, press the [UNDO] key.	This message is displayed when the user attempts to use [Pre(Time)] or [Pre(ECG)] to save video that is being played back.	• Press the [Store] key to save the images that are being played back. • Use the [Pointer] rotary encoder to shift the time phase from images being played back to new and old images. • Press the [UNDO] key to take new images.
Part of the image could not be acquired. Press [Store] to store, press [UNDO] to retry without storing.	This message is displayed when [Auto Playback] is set to On and the amount of captured cine data does not cover the set heart rate or set time.	• Press the [Store] key to save the images that are being played back. • Press the [UNDO] key to take new images.
Part of the image could not be acquired.	This message is displayed when [Auto Playback] is set to Off and the amount of captured cine memory data does not cover the set heart rate or set time.	• Press the [Store] key to save the images that are being played back. • Press the [UNDO] key to take new images.

Messages	Status or cause	Countermeasures
The image could not be acquired.	This message is displayed when the R-wave cannot be detected.	• The image is frozen, so specify the range and save the video. • Turn the [Freeze] key On, and save the image again.
Store capacity: Free space ***%	This message is displayed when the [Store] key is pressed.	The message is cleared after 5 seconds.
Error: Disk full. Delete unnecessary images.	This message is displayed when the user attempts to save data that exceeds the free space on the system hard disk.	• Delete unnecessary images from the system hard disk. • Save only data that does not exceed the free space on the system hard disk.
This image was stored as RGB data, because 2B or 4B images cannot be stored as raw data. Store capacity: Free space ***%.	This message is displayed when [Data Format (Still)] is [Raw] and B mode (including Color Flow mode) Dual or Quad screens were saved as still images.	The images are saved in [RGB] format. The message is cleared after 5 seconds.
The image could not be acquired.	• This message is displayed when the user presses the [Store] key before the R-wave is detected in [Pre(ECG)] mode. • This message is displayed when the R-wave cannot be detected for a certain period of time after the user presses the [Store] key in [Post(ECG)] mode.	• The image is saved when the R-wave is detected. • Change [Acquisition Mode] to [Pre(Time)], [Post(Time)], or [Manual] before saving the image.
It may take time to store this video clip on media or network server. Do you want to continue, or store the clip temporarily on a Local HD?	This message is displayed when the storage destination is not the system hard disk (including the CD-R buffer), and the number of captured frames exceeds a certain number.	• [Continue]: Saves the data. • [Local HDD]: Changes the storage destination to the system hard disk, and saves the data.
The Cine Memory is cleared. Video Clip Auto Stop is off.	This message is displayed after a video is manually saved and the user uses [Video Clip Auto Stop] to change the display range, etc., and to clear cine memory.	If necessary, re-save the video. The message is cleared after 5 seconds.
Not enough capacity on selected disk.	The connected storage medium has insufficient space.	Connect a storage medium with sufficient free space. • [Retry]: Retransmits the image. • [Cancel]: Closes the message without sending the image.
Error: Disk full. Delete unnecessary images.	This message is displayed when there is insufficient space on the system hard disk.	Delete unnecessary images to increase free space on the system hard disk. • [Retry]: Retransmits the image. • [Cancel]: Closes the message without sending the image.

Messages	Status or cause	Countermeasures
Hard disk access error: Hard disk must be diagnosed.	This message is displayed when images cannot be saved to the system hard disk.	Please contact our office. • [Retry]: Retransmits the image. • [Cancel]: Closes the message without sending the image.
Media not found. The file is stored on the local hard disk instead.	This message is displayed when no storage medium is connected.	Connect a storage medium. • [Retry]: Retransmits the image. • [Cancel]: Closes the message without sending the image.
Error: No disk or disk is not formatted.	This message is displayed when no external storage medium to which data is to be saved is inserted or the medium is not formatted.	Connect a formatted external storage medium to the system. • [OK]: Clears the message.
Error: Disk write protected.	This message is displayed when the storage medium is write-protected.	Undo write protection on the connected storage medium. Connect another storage medium. • [OK]: Clears the message.
Error: Removable disk is not ready.	This message is displayed when the preparation for connecting an external storage medium is not complete.	After the preparation for connecting the external storage medium is complete, save the data. • [OK]: Clears the message.
The DICOMDIR is full. Change to another media.	This message is displayed when the DICOM DIR cannot be updated.	Replace the storage medium. • [OK]: Clears the message.
Destination servers are not set. The file was stored on the local hard disk instead. Store capacity: Free space ***%	This message is displayed when still images are saved to the hard disk because they are sent by using Send to Net(Preset) on the Archive tab of the preset ([Preset Setup] > [SystemPreset] > [Filing]) without the destination server to which they are to be sent specified.	Use the following procedure to send the images saved on the hard disk to the destination server. 1. Set the destination server on the Server/Worklist tab of the preset ([Preset Setup] > [SystemPreset] > [DICOM]). 2. Select the images saved on the hard disk in the Tile view or on the search screen. 3. Select [>>Network (Preset)] from the menu. 4. Select [OK].

Messages	Status or cause	Countermeasures
The file was stored on the local hard disk instead of network as RGB data, not raw data. Store capacity: Free space ***%	This message is displayed when still images are saved to the hard disk in RGB format because they are sent by using Send to Net(Preset) on the Archive tab of the preset ([Preset Setup] > [SystemPreset] > [Filing]) under the condition that they cannot be saved in Raw format without the specification of the destination server to which they are to be sent.	To send the images (RGB format) saved on the hard disk to the destination server, perform the following procedure: 1. Set the destination server on the Server/Worklist tab of the preset ([Preset Setup] > [SystemPreset] > [DICOM]). 2. Select the images saved on the hard disk in the Tile view or on the search screen. 3. Select [>>Network (Preset)] from the menu. 4. Select [OK].
Media not found. The file is stored on the local hard disk instead.	No storage medium is connected.	Images are saved to the system hard disk.
There are unprinted images in the printer buffer. Do you want to print them or delete them? DICOM Print ***d/***d PC Print ***d/***d	This message is displayed when there is data in the Print Queue folder when the system starts.	• [Print]: Prints the data in the Print Queue folder. • [Cancel]: Closes the message without printing or deleting the data. • [Delete]: Clears the data in the Print Queue folder.
Printer: Network communication error.	This message is displayed when it was not possible to communicate with the DICOM printer.	Check the connection with the DICOM printer. If you cannot restore communication, contact the administrator of the hospital network.
Sending images to printer...	This message is displayed when data is being output to the printer.	It is cleared once data output to the printer is complete.

8.4 Messages about searching for, playing, and transferring saved images

These messages are displayed with the search screen, Tile view, full-screen display, and comparison display.

Messages	Status or cause	Countermeasures
The image cannot be compared.	• This message is displayed when the selected images do not include images from the same patient, or B mode 1-screen images. • It is also displayed when the user selects an image for which a comparison display is not possible, and then attempts a comparison display.	To use the comparison display, select B mode 1-screen images for the same patient.
Loading data: ***%	This message is displayed while raw data is being transferred to cine memory.	The message is cleared when forwarding is complete.
Copying... Saving... Sending... Deleting... Printing... DICOM Printing...	This message is displayed during processing.	The message is cleared when processing is complete. [Cancel]: Forcibly terminates the processing.
Preparing to copy... Preparing to save... Preparing to send... Preparing to delete... Preparing to print...	This message is displayed during processing preparation	The message is cleared when preparation is complete. [Cancel]: Forcibly terminates the processing.
Loading stress data...	This message is displayed while Stress Echo data is being loaded.	The message is cleared when forwarding is complete. [Cancel]: Forcibly terminates the processing.
Are you sure you want to delete this image?	This message is displayed when you select an operation that will delete the selected image (one).	• [OK]: Deletes the image. • [Cancel]: Clears the message without deleting the image.
Are you sure you want to delete the stored image?	This message is displayed when you select an operation that will delete the selected image (one).	• [OK]: Deletes the image. • [Cancel]: Clears the message without deleting the image.
Are you sure you want to delete the *** stored images?	This message is displayed when you select an operation that will delete the selected images.	The message displays the number of selected images. • [OK]: Deletes the images. • [Cancel]: Clears the message without deleting the images.
Images from multiple devices are selected (*** stored images). Do you want to delete them?	This message is displayed when you select an operation that will delete the selected images.	The message displays the number of selected images. • [OK]: Deletes the images. • [Cancel]: Clears the message without deleting the images.

Messages	Status or cause	Countermeasures
Images from multiple studies are selected (*** stored images). Do you want to delete them?	This message is displayed when you select an operation that will delete the selected images.	The message displays the number of selected images. • [OK]: Deletes the images. • [Cancel]: Clears the message without deleting the images.
Images from multiple patients are selected (*** stored images). Do you want to delete them?	This message is displayed when you select an operation that will delete the selected images.	The message displays the number of selected images. • [OK]: Deletes the images. • [Cancel]: Clears the message without deleting the images.
Are you sure you want to copy this image?	This message is displayed when you select an operation that will copy the selected image (one).	• [OK]: Copies the image. • [Cancel]: Clears the message without copying the image.
Are you sure you want to copy the stored image?	This message is displayed when you select an operation that will copy the selected image (one).	• [OK]: Copies the image. • [Cancel]: Clears the message without copying the image.
Are you sure you want to copy the *** stored images?	This message is displayed when you select an operation that will copy the selected images.	The message displays the number of selected images. • [OK]: Copies the images. • [Cancel]: Clears the message without copying the images.
Images from multiple devices are selected (*** stored images). Do you want to copy them?	This message is displayed when you select an operation that will copy the selected images.	The message displays the number of selected images. • [OK]: Copies the images. • [Cancel]: Clears the message without copying the images.
Images from multiple studies are selected (*** stored images). Do you want to copy them?	This message is displayed when you select an operation that will copy the selected images.	The message displays the number of selected images. • [OK]: Copies the images. • [Cancel]: Clears the message without copying the images.
Images from multiple patients are selected (*** stored images). Do you want to copy them?	This message is displayed when you select an operation that will copy the selected images.	The message displays the number of selected images. • [OK]: Copies the images. • [Cancel]: Clears the message without copying the images.
Some of the selected data cannot be copied. Do you want to continue?	This message is displayed when the selected images include data that cannot be copied.	• [OK]: Copies the images. • [Cancel]: Clears the message without copying the images.
Are you sure you want to save this image?	This message is displayed when you select an operation that will save the selected image (one).	• [OK]: Saves the image. • [Cancel]: Clears the message without saving the image.
Are you sure you want to save the stored image?	This message is displayed when you select an operation that will save the selected image (one).	• [OK]: Saves the image. • [Cancel]: Clears the message without saving the image.

Messages	Status or cause	Countermeasures
Are you sure you want to save the *** stored images?	This message is displayed when you select an operation that will save the selected images.	The message displays the number of selected images. • [OK]: Saves the images. • [Cancel]: Clears the message without saving the images.
Images from multiple devices are selected (*** stored images). Do you want to save them?	This message is displayed when you select an operation that will save the selected images.	The message displays the number of selected images. • [OK]: Saves the images. • [Cancel]: Clears the message without saving the images.
Images from multiple studies are selected (*** stored images). Do you want to save them?	This message is displayed when you select an operation that will save the selected images.	The message displays the number of selected images. • [OK]: Saves the images. • [Cancel]: Clears the message without saving the images.
Images from multiple patients are selected (*** stored images). Do you want to save them?	This message is displayed when you select an operation that will save the selected images.	The message displays the number of selected images. • [OK]: Saves the images. • [Cancel]: Clears the message without saving the images.
Some of the selected data cannot be saved. Do you want to continue?	This message is displayed when the selected images include data that cannot be saved.	• [OK]: Saves the images. • [Cancel]: Clears the message without saving the images.
Are you sure you want to send this image?	This message is displayed when you select an operation that will transfer the selected image (one).	• [OK]: Transfers the image. • [Cancel]: Clears the message without transferring the image.
Are you sure you want to send the stored image?	This message is displayed when you select an operation that will transfer the selected image (one).	• [OK]: Transfers the image. • [Cancel]: Clears the message without transferring the image.
Are you sure you want to send the *** stored images?	This message is displayed when you select an operation that will transfer the selected images.	The message displays the number of selected images. • [OK]: Transfers the images. • [Cancel]: Clears the message without transferring the images.
Images from multiple devices are selected (*** stored images). Do you want to send them?	This message is displayed when you select an operation that will transfer the selected images.	The message displays the number of selected images. • [OK]: Transfers the images. • [Cancel]: Clears the message without transferring the images.
Images from multiple studies are selected (*** stored images). Do you want to send them?	This message is displayed when you select an operation that will transfer the selected images.	The message displays the number of selected images. • [OK]: Transfers the images. • [Cancel]: Clears the message without transferring the images.

Messages	Status or cause	Countermeasures
Images from multiple patients are selected (*** stored images). Do you want to send them?	This message is displayed when you select an operation that will transfer the selected images.	The message displays the number of selected images. • [OK]: Transfers the images. • [Cancel]: Clears the message without transferring the images.
Some of the selected data cannot be sent. Do you want to continue?	This message is displayed when the selected images include data that cannot be transferred.	• [OK]: Transfers the images. • [Cancel]: Clears the message without transferring the images.
Are you sure you want to print this image?	This message is displayed when you select an operation that will print the selected image (one).	• [OK]: Prints the image. • [Cancel]: Clears the message without printing the image.
Are you sure you want to print the stored image?	This message is displayed when you select an operation that will print the selected image (one).	• [OK]: Prints the image. • [Cancel]: Clears the message without printing the image.
Are you sure you want to print the *** stored images?	This message is displayed when you select an operation that will print the selected images.	The message displays the number of selected images. • [OK]: Prints the images. • [Cancel]: Clears the message without printing the images.
Images from multiple devices are selected (*** stored images). Do you want to print them?	This message is displayed when you select an operation that will print the selected images.	The message displays the number of selected images. • [OK]: Prints the images. • [Cancel]: Clears the message without printing the images.
Images from multiple studies are selected (*** stored images). Do you want to print them?	This message is displayed when you select an operation that will print the selected images.	The message displays the number of selected images. • [OK]: Prints the images. • [Cancel]: Clears the message without printing the images.
Images from multiple patients are selected (*** stored images). Do you want to print them?	This message is displayed when you select an operation that will print the selected images.	The message displays the number of selected images. • [OK]: Prints the images. • [Cancel]: Clears the message without printing the images.
Some of the selected data cannot be printed. Do you want to continue?	This message is displayed when the selected images include data that cannot be printed.	• [OK]: Prints the images. • [Cancel]: Clears the message without printing the images.
Some of the files could not be deleted.	This message is displayed when there is a file that could not be deleted after data was deleted.	[OK]: Closes the message.
Delete failed.	This message is displayed when data could not be deleted. (Data on a read-only storage medium, etc.)	[OK]: Closes the message.

Messages	Status or cause	Countermeasures
Delete failed. The system is busy.	This message is displayed when an image was deleted during the save processing in the Analysis screen.	[OK]: Closes the message.
"There is no file to be deleted."	This message is displayed when none of the selected images can be deleted.	[OK]: Closes the message.
Delete succeeded.	This message is displayed when the selected images were deleted.	[OK]: Closes the message.
Delete cancelled.	This message is displayed when [Cancel] is selected during deletion.	[OK]: Closes the message.
The disk is write protected.	This message is displayed when the storage medium is write-protected.	Undo write protection on the storage medium, or connect a writable disk. • [Retry]: Copies the images again. • [Cancel]: Clears the message without copying the images.
Not enough capacity on selected disk.	This message is displayed when the storage medium has no free space.	Connect a new storage medium and select [Retry]. • [Retry]: Copies the images again. • [Cancel]: Clears the message without copying the images.
Media is not ready.	This message is displayed when no storage medium is connected.	Connect a new storage medium and select [Retry]. • [Retry]: Copies the images again. • [Cancel]: Clears the message without copying the images.
Some of the files could not be copied.	This message is displayed after data is copied, if one or more files could not be copied.	[OK]: Closes the message.
Copy failed.	This message is displayed when data could not be copied. (Data on a read-only storage medium, etc.)	[OK]: Closes the message.
Copy failed. The system is busy.	This message is displayed when an image was copied during the save processing in the Analysis screen.	[OK]: Closes the message.
Copy cancelled.	This message is displayed when [Cancel] is selected during copying.	[OK]: Closes the message.
There is no file to be copied.	This message is displayed when none of the selected images can be copied.	[OK]: Closes the message.

Messages	Status or cause	Countermeasures
Copy succeeded.	This message is displayed when the selected images were copied.	[OK]: Closes the message.
There is no file to be saved.	This message is displayed when none of the selected images can be saved.	[OK]: Closes the message.
Some of the files could not be saved.	This message is displayed when there is a file that could not be saved after data was saved.	[OK]: Closes the message.
Save failed.	This message is displayed when data could not be saved. (Data on a read-only storage medium, etc.)	[OK]: Closes the message.
Save failed. The system is busy.	This message is displayed when an attempt was made to save one or more images during the save processing on the Analysis screen.	[OK]: Closes the message.
Save cancelled.	This message is displayed when [Cancel] is selected during saving.	[OK]: Closes the message.
Save succeeded.	This message is displayed when the selected images were saved.	[OK]: Closes the message.
Network configuration error.	This message is displayed when a network initialization error occurred. For example, when the contents of the printer setup file are invalid.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Network communication error. DICOM association failure.	This message is displayed when the transfer syntax and SOP class defined by the system are not supported on the server side.	Contact the administrator of the hospital network. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Unable to build image information.	This message is displayed when the DICOM file is corrupted.	• [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Network communication error. DICOM data error.	This message is displayed when transmission to the DICOM network fails due to a network error. This message is displayed when an error was returned by the DICOM printer.	Contact the administrator of the hospital network. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.

Messages	Status or cause	Countermeasures
Some DICOM data remains to be sent. Do you want to send it?	This message is displayed when there are files that have not been transmitted when the system starts. (The last time the system was used, transmission was canceled during transmission to DICOM Storage.)	• [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Network communication error. DICOM Response Status (0000,0900) is not Success.	This message is displayed when the response status from the server was not "Success".	Contact the administrator of the hospital network. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Storage Commitment invalid.	This message is displayed when the preset Storage Commitment is invalid.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Storage Commitment Transaction UID expired.	This message is displayed when the server does not return a commit completion within the preset "transaction limit"	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Storage Commitment Network communication error.	This message is displayed when an unknown error is returned from Storage Commitment.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Storage Commitment Processing failure.	This message is displayed when the code "0110H - Processing failure" is returned from Storage Commitment.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Storage Commitment Resource limitation.	This message is displayed when the code "0213H - Resource limitation" is returned from Storage Commitment.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Storage Commitment Duplicate transaction UID.	This message is displayed when the code "0131H - Duplicate transaction UID" is returned from Storage Commitment.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Storage Commitment No such object instance.	This message is displayed when the code "0112H - No such object instance" is returned from Storage Commitment.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Storage Commitment Referenced SOP Class not supported.	This message is displayed when the code "0122H - Referenced SOP Class not supported" is returned from Storage Commitment.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.

Messages	Status or cause	Countermeasures
Storage Commitment Class/Instance conflict.	This message is displayed when the code "0119H - Class/ Instance conflict" is returned from Storage Commitment.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
MPPS invalid.	This message is displayed when the preset MPPS settings are invalid.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Network communication error. Performed Procedure Step Object may no longer be updated.	This message is displayed when the code "0110H - Processing failure, Error ID = A710" is returned from the MPPS server.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
MPPS retry file read error.	This message is displayed when the MPPS retransmission file is corrupted and cannot be read.	Please note down the message details and contact our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
Send cancelled.	This message is displayed when [Cancel] is selected during transmission.	[OK]: Closes the message.
There is no file to be sent.	This message is displayed when none of the selected images can be sent.	[OK]: Closes the message.
Send succeeded.	This message is displayed when the selected images were sent.	[OK]: Closes the message.
Print cancelled.	This message is displayed when [Cancel] is selected during printing.	[OK]: Closes the message.
There is no file to be printed.	This message is displayed when none of the selected images can be printed.	[OK]: Closes the message.
Print failed.	This message is displayed when data could not be printed.	[OK]: Closes the message.
Print failed. Select the correct printer.	This message is displayed when the printer setting did not match the actual situation.	[OK]: Closes the message.
Are you sure you want to clear the CD-R buffer?	This message is displayed when you select an operation that will clear the CD-R buffer.	• [OK]: Clears the CD-R buffer. • [Cancel]: Closes the message without clearing the CD-R buffer.
Are you sure you want to clear the DVD-R Buffer?	This message is displayed when you select an operation that will clear the DVD-R Buffer.	• [OK]: Clears the DVD-R Buffer. • [Cancel]: Closes the message without clearing the DVD-R Buffer.
Failed clearing the CD-R buffer.	This message is displayed when the CD-R buffer cannot be cleared.	[OK]: Closes the message.

Messages	Status or cause	Countermeasures
Failed deleting DVD-R Buffer.	This message is displayed when the DVD-R Buffer cannot be cleared.	[OK]: Closes the message.
Write to CD-R?	This message is displayed when you select an operation that will write to CD-R.	• [OK]: Writes to CD-R. • [Cancel]: Closes the message without writing to CD-R.
Other operations become impossible during writing. Are you sure you want to start DVD-R writing?	This message is displayed when you select an operation that will write to DVD-R.	• [OK]: Writes to DVD-R. • [Cancel]: Closes the message without writing to DVD-R.
CD-R writing is completed.	This message is displayed when writing to CD-R is complete.	[OK]: Closes the message.
DVD-R writing is completed.	This message is displayed when writing to DVD-R is complete.	[OK]: Closes the message.
Operation is canceled.	This message is displayed when [Cancel] is selected during writing to CD-R or DVD-R.	[OK]: Closes the message.
No image in CD-R buffer.	This message is displayed when you select an operation to write to CD-R, but no data exists in the CD-R buffer.	[OK]: Closes the message.
No image in DVD-R Buffer.	This message is displayed when you select an operation to write to DVD-R, but no data exists in the DVD-R Buffer.	[OK]: Closes the message.
Failed deleting CD-R buffer.	This message is displayed after data was written to a CD-R, when deletion of the CD-R buffer data fails.	[OK]: Closes the message.
Failed deleting DVD-R Buffer.	This message is displayed after data was written to DVD-R, when deletion of the DVD-R Buffer data fails.	[OK]: Closes the message.
Please set blank media to drive.	This message is displayed when a used storage medium is inserted in the drive.	Insert a new storage medium. [OK]: Closes the message.
Failed to open library.	This message is displayed when the CD library or the DVD library fails to open.	[OK]: Closes the message.
CD-R drive is not connected.	This message is displayed when the CD drive is not connected.	[OK]: Closes the message.
DVD-R drive is not connected.	This message is displayed when the DVD drive is not connected.	[OK]: Closes the message.
The recorder is not supported.	This message is displayed when the recorder does not support CD or DVD writing.	[OK]: Closes the message.

Messages	Status or cause	Countermeasures
No disk in CD-R drive.	This message is displayed when there is no disk in the CD-R drive.	Insert a new disk into the CD-R drive. [OK]: Closes the message.
No disk in DVD-R drive.	This message is displayed when there is no disk in the DVD-R drive.	Insert a new disk into the DVD-R drive. [OK]: Closes the message.
CD-R type is not known.	This message is displayed when an unwritable disk is inserted into the CD-R drive.	Insert a writable disk into the CD-R drive. [OK]: Closes the message.
DVD-R type is not known.	This message is displayed when an unwritable disk is inserted into the DVD-R drive.	Insert a writable disk into the DVD-R drive. [OK]: Closes the message.
No more space available on CD-R.	This message is displayed when the free space on the disk is smaller than the quantity of data in the CD-R Buffer.	Insert a disk with more free space, or a new storage medium. [OK]: Closes the message.
No more space available on DVD-R.	This message is displayed when the free space on the disk is smaller than the quantity of data in the DVD-R Buffer.	Insert a disk with more free space, or a new storage medium. [OK]: Closes the message.
Invalid characters/symbols in CD name.	This message is displayed when the CD name uses invalid characters.	Use alphanumeric characters for the CD name. Alternatively, insert a new storage medium. [OK]: Closes the message.
Invalid characters/symbols in DVD name.	This message is displayed when DVD name uses invalid characters.	Use alphanumeric characters for the DVD name. Alternatively, insert a new storage medium. [OK]: Closes the message.
Error occurred while generating the image file.	This message is displayed when creation of an image file failed.	Select [OK], and then retry the operation. [OK]: Closes the message.
CD-R write error occurred.	This message is displayed when a CD-R write error occurs.	1. Select [OK] and restart the system. 2. Replace the storage media with a new one, and then retry the operation.
DVD-R write error occurred.	This message is displayed when a DVD-R write error occurs.	1. Select [OK] and restart the system. 2. Replace the storage media with a new one, and then retry the operation.
Unknown error	This message is displayed when a CD-R or DVD-R write error occurs.	[OK]: Closes the message.
These files cannot be analyzed.	This message is displayed when the selected image is in a file format that cannot be analyzed.	[OK]: Closes the message.
More than 256 files selected. Only up to 256 files can be analyzed.	This message is displayed when 256 or more files are selected for analysis.	[OK]: Closes the message.

Messages	Status or cause	Countermeasures
Store completed.	This message is displayed when output from the Analysis screen is complete.	[OK]: Closes the message.
Store failed.	This message is displayed when output from the Analysis screen failed.	[OK]: Closes the message.
Store failed. The system is busy.	This message is displayed when an attempt was made to save one or more images during the save processing on the Analysis screen.	[OK]: Closes the message.
None of the 3D volume data can be reproduced. Do you want to continue? Do not show this message again.	This message is displayed when none of the volume data can be saved as 3D images.	• [OK]: Reconstructs the 3D image. • [Cancel]: Closes the message without reconstructing the 3D image.
Playing back this image will delete cine memory data. Do you want to continue? Do not show this message again.	This message is displayed when you select an image, such as raw data, that will transfer data to cine memory.	• [OK]: Clears data from cine memory and plays the image. • [Cancel]: Closes the message without playing the image.
Acquiring analysis data...	This message is displayed while analysis data is being transferred to cine memory.	[Cancel]: Closes the message without playing the image.
Converting video clip data...	This message is displayed while video clip data is being converted.	The message is cleared when conversion is complete.
The DICOMDIR is full. The data cannot be added. Change to another media.	This message is displayed when DICOMDIR exceeds 200 MB.	Select [OK] and insert a new storage medium. [OK]: Closes the message.
The stress echo data file is selected. The related image data files will also be processed.	This message is displayed when the user attempts to copy or delete a stress status file.	[OK]: Closes the message.
The stress echo data file is not selected.	This message is displayed when the user started stress echo without selecting a stress status file.	Select [OK], and then select a stress status file before starting stress echo. [OK]: Closes the message.
Send was finished.	This message is displayed when DICOM SR was sent.	The message is cleared.
Unsupported data. Failed to Restore.	This message is displayed when the trimming function is executed during playback of a DICOM video file that is not supported by the trimming function.	Use files that can be trimmed. [OK]: Closes the message.

Messages	Status or cause	Countermeasures
MPPS: Network communication error. DICOM association failure.	This message is displayed when it is not possible to connect to the MPPS server.	Resolve the problem in the connection with the MPPS server, and then retry the operation. • [Retry]: Attempts to connect to the MPPS server again. • [Cancel]: Terminates the connection to the MPPS server and clears the message. • [Suspend]: Temporarily suspends the connection to the MPPS server and clears the message.
WMV or MP4 files have not been masked.	This message is displayed when the user attempts to mask the patient information in a WMV file or MP4 file. NOTE: The patient information in a WMV file or MP4 file cannot be masked.	• [Exit]: Saves the selected image without masking patient information. • [Cancel]: Returns you to the original screen without saving the selected image.
Formatting will erase all data on this DVD-RAM. Are you sure you want to proceed?	This message is displayed when the user attempts to start DVD-RAM formatting while [Quick format] is set to On.	• [Yes]: Starts DVD-RAM formatting. • [No]: Clears the message without starting formatting.
Formatting will erase all data on this DVD-RAM. This will take about 35-55 minutes. Are you sure you want to proceed?	This message is displayed when the user attempts to start DVD-RAM formatting while [Quick format] is set to Off.	• [Yes]: Starts DVD-RAM formatting. • [No]: Clears the message without starting formatting.
There are too many results to display. Please refine the search conditions and search again.	This message is displayed when the display limit of the patient ID list is exceeded.	1. Select the [OK] button. 2. Enter patient data in the search information input field. 3. Select [Search].

8.5 Messages about the recorder

Messages	Status or cause	Countermeasures
Do you want to finalize your DVD-R before ejecting?	This message is displayed when the user attempts to eject an unfinalized storage medium.	• [Yes.]: Finalizes the DVD-R and then ejects it. • [Cancel.]: Closes the message without ejecting the DVD-R. • [No.]: Ejects the DVD-R without finalizing it.
No storage media. Insert a storage device.	This message is displayed when no storage medium has been inserted.	Insert a storage medium.
Cannot record data because of insufficient space on storage device. Press [EXT] for details.	This message is displayed when there is no free space on the storage medium.	Insert a new storage medium.

Messages	Status or cause	Countermeasures
Storage device cannot be recognized. Press [EXT] for details.	This message is displayed when an unsupported storage medium is inserted or attached.	Insert a supported storage medium.
Recorder error detected. Press [EXT] for details.	This message is displayed when an error occurred in the recorder.	Check the recorder. For details, see the documentation for the recorder.
Not enough space on recorder hard disk. Press [EXT] for details.	This message is displayed when free space on the internal hard disk of the recorder drops to 20% or less.	Set [EXT] to Off, and then check the remaining capacity on the recorder.
Not enough space on recorder hard disk. Press [EXT] for details.	This message is displayed when there is no free space on the internal hard disk of the recorder.	Set [EXT] to Off, and then check the remaining capacity on the recorder.

8.6 Messages about presets

Messages	Status or cause	Countermeasures
Enter a QSS preset name.	This message is displayed when the [Preset Copy] button was selected in QSS preset copy.	1. Enter no more than 64 characters in the name field. 2. Select [OK]. • [OK]: Copies QSS presets. • [Cancel]: Clears the message without copying the QSS presets.
Color Map setting is not assigned continuously. Please reassign again.	This message is displayed when the user tried to save presets while there were unassigned options within the preset color map.	Set the color map so that there are no unassigned options interposed between set options.
No color map has been assigned. Assign a color map.	This message is displayed when the user tried to save presets while all options were unassigned in the preset color map.	Set one or more options in the color map. When doing so, make sure there are no unassigned options interposed between set options in the color map.
Save changes to preset data?	This message is displayed when the [Close] button was selected in the preset screen.	• [OK]: Saves the parameters, and then closes the preset screen. • [Cancel]: Closes the preset screen without saving parameters.
Are you sure you want to delete this application preset settings?	This message is displayed when the [Delete] button was selected in application presets.	• [OK]: Deletes the selected application preset, and then closes the dialog box. • [Cancel]: Closes the dialog box without deleting the selected application preset.
*** already exists. Specify a different name.	This message is displayed when a name was changed in a preset, but the input name was already in the list.	Enter a name that is not in the list. [Close]: Closes the dialog box.

Messages	Status or cause	Countermeasures
Are you sure you want to return the application preset settings to their factory settings?	This message is displayed when the [Factory Data] button was selected in application presets.	• [OK]: Changes the selected application preset to the default settings, and then closes the dialog box. • [Cancel]: Closes the dialog box without changing the selected application preset.
Are you sure you want to replace the current application?	This message is displayed when the [Paste] button was selected in application presets.	• [OK]: Replaces the selected application preset with the copied data, and then closes the dialog box. • [Cancel]: Closes the dialog box without replacing the selected application preset with the copied data.
Are you sure you want to replace the current settings?	This message is displayed when the [Paste] button was selected in a preset screen other than application presets.	• [OK]: Replaces the selected preset other than application presets with the copied data, and then closes the dialog box. • [Cancel]: Closes the dialog box without replacing the selected preset other than application presets with the copied data.
Are you sure you want to return to the factory settings?	This message is displayed when the [Factory Data] button was selected in a preset screen other than application presets.	• [OK]: Changes the selected preset other than application presets to the default settings, and then closes the dialog box. • [Cancel]: Closes the dialog box without changing the selected preset other than application presets to the default settings, and then closes the dialog box.
You must restart the system for the changes to take effect. Restart now?	This message is displayed when the Station Name, Port#, or IP setting method was changed on the Common tab for DICOM items, and the [Save] button was selected.	• [Yes]: Closes the Presets menu and restarts the system. • [No]: Closes the Presets menu. The system is not restarted.
The specified device cannot be recognized.	This message is displayed when the storage medium cannot be recognized for reading or writing presets.	Check the status of the storage medium. • [Retry]: Retries saving to the storage medium or reading from it. • [Cancel]: Clears the message without saving to the storage medium or reading from it.
The preset which cannot be identified is included. This preset cannot be imported.	This message is displayed when the file cannot be read because at least one of the presets has a version that cannot be identified.	[OK]: Returns to the previous screen. Check the version of the preset file.

Messages	Status or cause	Countermeasures
Data has not been stored to selected media. Do you want to store?	This message is displayed when the storage medium selection is changed during data export.	• [Yes]: Saves the data to the selected storage medium. • [No]: Clears the message without saving the data.
Data has not been stored to selected media. Do you want to store?	This message is displayed when the [Close] button is selected while exported data remains in temporary storage.	• [Yes]: Saves the data to the selected storage medium. • [No]: Clears the message without saving the data.
Overwrite the existing application? Application to be overwritten: **********	This message is displayed when there is an application preset in the storage destination that has the same name and same source application.	• [Yes]: Overwrites the data. • [No]: Appends a serial number, starting from 00, to the file name at the end of the data, and saves the data. • [Cancel]: Closes the message without saving the data.
Setup will be overwritten. Do you still want to continue?	This message is displayed in a batch backup when [Restore] is selected and [OK] is selected in the Select data screen.	• [OK]: Restores data on the selected storage medium to the system. All preset data will be overwritten. • [Cancel]: Clears the message without restoring the data.
Please select database.	This message is displayed in a batch backup when [Restore] is selected.	The message is cleared when [OK] or [Cancel] is selected in the Select data screen.
Unsupported data.	This message is displayed when the target data for the batch import is not compatible.	[OK]: Closes the dialog box without importing data.
Unsupported data is included. Only supported data will be restored.	This message is displayed when the target data for a batch restore is not compatible.	[OK]: Only compatible data will be restored.
Preset setting updated. System will reboot to reflect the setting changes.	This message is displayed in a batch backup when [Restore] is selected and [OK] is selected in the Select data screen.	• [Yes]: Saves the data to the selected storage medium. • [No]: Cancels the restore.
Do you want to restore the network setting from backuped data? Current data will be Overwrite.	This message is displayed when [OK] is selected in response to the above message during a batch backup.	• [Yes]: Also copies the network settings. • [No]: Restores without copying the network settings.
Please increase space capacity of disk.	This message is displayed when there is insufficient space on the connected storage medium.	Connect a storage medium with sufficient free space.
The specified device is write-protected.	This message is displayed when the storage medium is write-protected.	[OK]: Closes the message. Undo write protection on the connected storage medium. Alternatively, connect another storage medium.

Messages	Status or cause	Countermeasures
The specified path is invalid.	This message is displayed when the entered file path exceeds 128 characters.	[OK]: Closes the message. Set the file hierarchy so that it is not too deep. Alternatively, specify settings so that the folder name is not too long.
Failed to Import.	This message is displayed when data could not be imported.	Retry the operation. If the same message is displayed, please contact our office
Failed to Export.	This message is displayed when data could not be exported.	Retry the operation. If the same message is displayed, please contact our office
Failed to Backup.	This message is displayed when data could not be backed up.	Retry the operation. If the same message is displayed, please contact our office
Failed to Restore.	This message is displayed when data could not be restored.	Retry the operation. If the same message is displayed, please contact our office
An SR file could not be created due to an illegal study instance UID (0020,000D).	This message is displayed if the instance UID (0020,000D) is incorrect when [DICOM SR] is output by clicking [Output] for the measurement report.	If the same message is displayed even after the SR file is recreated, please contact our office.
SR storage:	This message is displayed when [DICOM SR] and [OK] are selected in [Output] from the measurement report.	The message is cleared when sending of the SR file is complete.
This will delete preset settings and data saved on this system. Do you still want to continue?	This message is displayed when the operator attempted to delete a preset or saved data.	• [Yes]: Deletes preset or saved data. • [Cancel]: Closes the message without deleting the data. If 10 seconds elapses without a selection, the system goes back to full screen display without deleting data.
Cannot set the same value in Port # and QR Port #.	This message is displayed when the same value is entered for the Port # and the QR Port # on the Common tab for DICOM items and the [Save] button is selected.	[OK]: Closes the message. Enter different values for Port # and QR Port #.
You have not selected any multi image servers. Multi images will not be sent. Are you sure?	This message is displayed when all of the Multi check boxes are cleared under DICOM Storage of the preset ([Preset Setup] > [SystemPreset] > [DICOM] > [Server/Worklist]).	• [OK]: Leaves the destination server unselected, and closes the message. • [Cancel]: Returns to the state where the destination server is selected, and closes the message.
You have not selected any single image servers. Single images will not be sent. Are you sure?	This message is displayed when all of the Single check boxes are cleared under DICOM Storage of the preset ([Preset Setup] > [SystemPreset] > [DICOM] > [Server/Worklist]).	• [OK]: Leaves the destination server unselected, and closes the message. • [Cancel]: Returns to the state where the destination server is selected, and closes the message.

Messages (User Management)	Status or cause	Countermeasures
Invalid name or password.	This message is displayed when an invalid user name or password is entered in the login screen.	[OK]: Clears the message. Enter the correct user name and password.

Messages (User Management)	Status or cause	Countermeasures
Invalid password. Enter another password.	This message is displayed when the user tried to register a new password or tried to modify a password, and the new password does not follow the password rules.	[OK]: Clears the message. Enter a password consisting of no more than 16 alphanumeric characters.
The passwords did not match. Re-enter your new password.	This message is displayed when the two entries of the password do not match when the user registers a password.	[OK]: Clears the message. Re-enter the correct password.
Changes will not be effective until the system is rebooted.	This message is displayed when the preset User Authentication is switched to Off or On.	[OK]: Clears the message. The changed settings are enabled when the system is restarted.
The maximum number of user accounts has been reached.	This message is displayed when the 100th user is registered.	[OK]: Clears the message. If necessary, delete unnecessary users.
The name you entered is already in use.	This message is displayed in user registration when the same user name already exists.	[OK]: Clears the message. Re-enter a different user name.
Invalid user name. Enter another name.	This message is displayed when the user name has not been entered, or when the entered user name violates restrictions.	[OK]: Clears the message. Enter a user name of no more than 16 single-byte alphanumeric characters.
Are you sure you want delete the selected user name?	This message is displayed when you select an operation that will delete the user selected on the User Management screen.	• [Yes]: Deletes the selected user name. • [No]: Closes the message without deleting the selected user name.
Your password will expire in ** day(s). Do you want to change the password?	This message is displayed when the difference between the password expiration date and the current date is fewer than the number of days set for Password Expiration notice.	• [Yes]: Clears the message and displays the PasswordSetting screen. • [No]: Clears the message.
Your password has expired. Please change the password.	This message is displayed when the date on which the password is set is after the password expiration date. This message is also displayed when the last update date of the password is changed to a future date as the result of changes to the system settings.	[OK]: Clears the message and displays the PasswordSetting screen.
New password is same as Current password. Please set New password different from Current password.	This message is displayed when [Current password] and [New password] are the same.	[OK]: Clears the message. For the new password, enter a password different from the current password.

8.7 Messages about importing CSV files

Messages	Status or cause	Countermeasures
Are you sure you want to import CSV files?	This message is displayed for confirmation before importing CSV files	• [OK]: Closes the dialog box. • [Cancel]: Closes the dialog box without importing CSV files.
USB Memory cannot be connected.	This error message is displayed when a USB flash drive is not connected.	[OK]: Closes the dialog box. Connect a USB flash drive and try again.
Failed to read CSV files. Please confirm whether the file exists and it is correct.	This message is displayed when there are no CSV files on the USB flash drive or the data has been corrupted.	[OK]: Closes the dialog box. Check the CSV file data and try again.
The CSV files are unsupported format.	This message is displayed when CSV file character encoding is not supported or because of some other problem.	[OK]: Closes the dialog box. Change the character encoding and try again.
CSV Import is finished. (Succeed: %d, Partly Failed %d, All Failed %d)	This message is displayed when the import processing is complete. (Success: %d instances, partial success: %d instances, fail: %d instances)	Check the details. [OK]: Closes the dialog box.
Processing... Please wait.	This message is displayed while CSV files are being loaded.	The message is cleared when loading of the CSV files is complete.
USB Memory cannot be connected.	This message is displayed when a CSV file could not be imported because no external USB storage medium is connected.	1. Select [OK]. 2. Connect an external USB storage medium.
Please review an input item. (Search File Name, Delimiter, Column Position)	This message is displayed when the user attempts to close the setting screen and there is an error in the Retrieval Name, Character, or Column Position of the Import CSV settings.	1. Select [OK]. 2. Reset Retrieval Name, Character, or Column Position .
Database registration failed.	This message is displayed when an internal error occurs while a CSV file is being imported.	Retry the operation. If the same message is displayed, please contact our office
No search file or directory. Please review search condition.	This message is displayed when there is no CSV file that matches the search conditions and a CSV file cannot be imported.	1. Select [OK]. 2. Change the search conditions and CSV file names and try again.

Messages	Status or cause	Countermeasures
Import number was beyond the upper limit. (Succeed: %d, Partly Failed %d, All Failed %d)	This message is displayed when the number of CSV files you are trying to import exceeds the upper limit. (Success: %d instances, partial success: %d instances, fail: %d instances) NOTE: The upper limit is 999 instances.	1. Select [OK]. 2. Decrease the number of files you import at a time and try again.
An exception occurred.	This message is displayed when an internal error occurs while a CSV file is being imported.	Retry the operation. If the same message is displayed, please contact our office
CSV Import is finished. (Succeed: %d, Partly Failed %d, All Failed %d) CSV file delete failed.	This message is displayed when a CSV file on the external storage medium could not be deleted. (When Delete CSV File after Importing is selected in a CSV Import setting.) (Success: %d instances, partial success: %d instances, fail: %d instances)	Check the details. [OK]: Closes the dialog box.
Column position error. Please review an input file or setting.	This message is displayed when the number of patient information columns set in the system is larger than the number of items in the CSV file to be imported.	1. Select [OK]. 2. Set Column Position correctly in the CSV Import setting screen.

8.8 Other messages

These messages are displayed if a system error or similar situation occurs.

Messages	Status or cause	Countermeasures
Warning Please delete some stored images after boot up. Free space on [Local HDD] is now below 10GB. System will not be able to start with storage capacity below 100MB. Press [Enter] to continue.	This message is displayed when an attempt was made to start the system while the free space on the hard disk of the system is less than 10 GB.	1. Press the [Enter] key to start the system. 2. Delete unnecessary data from the system hard disk.

Messages	Status or cause	Countermeasures
Warning Please delete some stored images after boot up. Free space on [Local HDD] is now below 100MB. System will not be able to start with this storage capacity. Press [Enter] to continue.	This message is displayed when an attempt was made to start the system while the free space on the hard disk of the system is less than 100 MB.	1. Press the [Enter] key to start the system. 2. Delete unnecessary data from the system hard disk.
Shutdown Tools. Hibernation: The contents of the internal memory are stored to the HDD when the ultrasound equipment is shut down. Start-up time is shortened in next start-up operation by expanding in the memory from HDD.	This message is displayed when the [Power] key is pressed. (If the power supply button behavior settings are configured to be [Selectable] in the basic settings in System Presets)	Choose how to turn the power off. [Shutdown]: Completely shuts down the system and turns the power off. [Hibernation]: Puts the system into hibernation and turns the power off. [Return]: Returns the system to the state it was in before the [Power] key was pressed.
Task in progress. System will Power Off after handle it.	This message is displayed when the operator presses the [Power] key to turn the power off while there are remaining jobs.	[Yes]: Turns off the power after the remaining jobs are complete. [Ignore]: Forces the system to quit without processing the remaining jobs, and turns the power off. [Return]: Returns the system to the state it was in before the [Power] key was pressed. Processing of the remaining jobs continues.
Please wait until process is completed.	This message is displayed when [Yes] is selected in response to the above message.	[Ignore]: Forces the system to quit without processing the remaining jobs, and turns the power off.
Task in progress. Power supply off forcibly without handle it. Are you really all right?	• This message is displayed when the operator selected [Ignore] as the processing method for the remaining jobs. • It is also displayed when the operator selected [Ignore] while remaining jobs were being processed.	[Yes]: Forces the system to quit without processing the remaining jobs, and turns the power off. [No]: A dialog box is displayed asking how to process the remaining jobs and how to turn the power off.
** more seconds until system is power off.	This message is displayed when the [Power] key is pressed. (When the basic setting in System Presets sets the waiting period for power cutoff operation to 1 second or more, and there are no remaining jobs.)	When the countdown reaches 0 seconds, the power is turned off by the selected or set method. [Power off immediately]: Turns the power off by the selected or set method, without waiting for the countdown. [Return]: Returns the system to the state it was in before the [Power] key was pressed.
Please contact technical support for regular maintenance in order to keep the system fully functional. Press [ENTER] to continue.	This message is displayed on the date set for a maintenance reminder.	Press the [Enter] key to continue startup. Perform a periodical maintenance inspection and safety inspection. Alternatively, contact our office to request an inspection.

Messages	Status or cause	Countermeasures
Some duplicated data was not restored.	This message is displayed when some examination data cannot be restored.	1. Select the [OK] button. 2. Please contact our office. [OK]: Clears the message.
Invalid Patient Diagnosis Information File May I delete study information after the last New Patient?	This message is displayed when a work database is corrupted during startup.	1. Select the [Yes] button. [OK]: Substitutes an empty database and clears the message. [No]: Clears the message.
Database Access Error. Please reboot equipment.	This message is displayed when a database is corrupted during startup.	1. Select the [OK] button. 2. Please contact our office. [OK]: Clears the message.
Master Database Access Error. May I replace the new Database?	This message is displayed when the master database is corrupted during startup.	1. Select the [Yes] button. 2. Please contact our office. [Yes]: Substitutes an empty database and clears the message. [No]: Clears the message.
Database was broken. Please contact our office near you. It was exchanged to the new Database. Restore the past data?	This message is displayed when an empty database is substituted for one that was corrupted during startup.	1. Select the [Yes] button. 2. Please contact our office. [Yes]: Clears the message and restores the master database. [No]: Clears the message.
Restoration success.	This message is displayed when the database was successfully restored.	1. Select the [OK] button. [OK]: Clears the message.
Restoration cancelled.	This message is displayed when the database restoration was canceled.	1. Select the [OK] button. [OK]: Clears the message.
Restoration failed.	This message is displayed when recovery of the database fails.	1. Select the [OK] button. 2. Please contact our office. [OK]: Clears the message.
No Backup DB.	This message is displayed when recovery of the database fails.	1. Select the [OK] button. 2. Please contact our office. [OK]: Clears the message.
Software Error! Now creating error log. (about 20 seconds) Please do not shut off the power supply. Please wait.	This message is displayed when the software generates an error.	After an error log is created, messages are automatically deleted.
Creating error log was completed. Please push [Shutdown] button and call service person.	This message is displayed when an error log has been created.	Select the [Shutdown] button to turn off the system. NOTE: Please contact our office.
HARDWARE ERROR **********	This message is displayed when a malfunction is detected in the system hardware.	Please note down the message details and contact our office. [OK]: Returns to the previous screen.
SYSTEM ERROR **********	This message is displayed when a malfunction is detected in the software.	Please note down the message details and contact our office. [OK]: Returns to the previous screen.

Messages	Status or cause	Countermeasures
Shutdown can't start by the reasons why the images are transferring and so on. When the condition of the shutdown is met or 30 seconds, the shutdown starts. Please wait for a while until the shutdown ends.	This message is displayed when pressing the on-screen [Shutdown] button will not shut down the system, because images are being transferred or because other jobs are in progress.	The system will shut down automatically when all jobs finish. Alternatively, the system will be forced to shut down after 30 seconds. NOTE: If this happens, image and other data might be corrupted.
Power for ultrasound transmission was shut down as the system detected an abnormal drive voltage. Reboot the system. [HV SW ERROR]	This message is displayed when the system hardware detects an error in the temperature sensor in the probe and shuts down the system.	Restart the system. If the same message is displayed after restarting, please contact our office.
The setting of the monitor is failed.	This message is displayed when an attempt to configure the monitor fails.	Please note down the message details and contact our office. [OK]: Clears the message.
The system clock may have been reset. Please check the clock in the status area after boot up. For clock adjustment, please refer to the operation manual. Press [Enter] to continue.	This message is displayed when the clock displayed on the system is reset.	Press the [Enter] key to continue startup. Adjust the date and time displayed on the system. Please note down the message details and contact our office.
Automatic Repair Automatic Repair couldn't repair your PC [**********]	This message is displayed when an automatic repair was attempted by using the automatic repair function of the operating system. The system is attempting a cold boot because the automatic repair function alone did not result in a complete recovery.	Turn off the system by clicking the [Shutdown] button, or by pressing and holding the [Power] key for 10 seconds or more. Press the [Power] key again to start the system. If this message is displayed multiple times, the system hard disk might be broken. Please contact our office.
Automatic Repair Your PC did not start correctly [**********]	This message is displayed when an automatic repair was attempted by using the automatic repair function of the operating system. The system is attempting to restart because the automatic repair function resolved the problem.	Turn off the system by clicking the [Restart] button, or by pressing and holding the [Power] key for 10 seconds or more. The system will now restart (if the power is turned off, press the [Power] key again). If this message is displayed multiple times, the system hard disk might be broken. Please contact our office.
Windows cannot access the specified device, path, or file. You may not have the appropriate permissions to access the item.	This message is displayed when execution of an unauthorized program is blocked.	Please note down the message details and contact our office. [OK]: Returns to the previous screen.

Messages	Status or cause	Countermeasures
Auto Image Delete All the data stored before the following date will be deleted. yyyy/mm/dd Estimated time hh:mm:ss (xxx files)	This message is displayed if you perform a shutdown while the preset Auto Image Delete is set to [Time].	This is a confirmation screen for performing Auto Image Delete. Select the [Delete] button or the [Cancel] button. • [Delete]: Deletes data and shuts down the system. • [Cancel]: Shuts down the system without deleting data.
Auto Image Delete All the data stored on Storage Commitment will be deleted. Estimated time hh:mm:ss (xxx files)	This message is displayed if you perform a shutdown while the preset Auto Image Delete is set to [Storage Commitment].	This is a confirmation screen for performing Auto Image Delete. Select the [Delete] button or the [Cancel] button. • [Delete]: Deletes data and shuts down the system. • [Cancel]: Shuts down the system without deleting data.
[Auto Image Delete] function is working. Now deleting stored data... **% Please do not turn off the system. Please wait. By pressing [ENTER], the system will stop deleting, and will shutdown.	This message is displayed while Auto Image Delete is running.	This screen is displayed while Auto Image Delete is in progress. When deletion is complete, this message is cleared and the system is shut down. If you press the [Enter] switch, the deletion is interrupted, and the system is shut down.
The monitor connection error has occurred. Please reboot the system to set the monitor.	This message is displayed when a monitor connection error occurs.	Restart the system.

9

License information

9.1 Precautions related to system software

The following actions are prohibited with respect to the software installed on this system:

- Reselling, assigning, or transferring the software itself
- Reverse engineering, reverse compiling, or reverse assembling
- Modification, alteration or translation
- Creating copies or duplicates
- Leasing to third parties

9.2 Microsoft Software License Terms

9.2.1 About the Microsoft Software License Terms

This system uses Windows, marketed by the US company Microsoft Corporation, as an operating system (OS).
The details of the license terms for Windows are described on the next page and subsequent pages. Be sure to read them before using the Diagnostic Ultrasound System.
The terms used in the license terms and their definitions are described below.

- "This device" and "your device" refer to the Diagnostic Ultrasound System.
- "This software" refers to Windows.
- "Device manufacturer" refers to FUJIFILM Healthcare Corporation.
- "Other software" refers to the Diagnostic Ultrasound System software and related software.

For safe and stable use of the Diagnostic Ultrasound System, the following restrictions are more highly regarded in the contents described in the Microsoft Software License Terms. Read this carefully before using this device.

- With respect to all of the following, you can use only functions permitted by FUJIFILM Healthcare Corporation: Windows functions, update programs, additional software, web-based services, and support services.

For details about the terms of this license, contact a service representative of FUJIFILM Healthcare Corporation.

9.2.2 WINDOWS 10 IOT ENTERPRISE & MOBILE (ALL EDITIONS)

IF YOU LIVE IN (OR IF YOUR PRINCIPAL PLACE OF BUSINESS IS IN) THE UNITED STATES, PLEASE READ THE BINDING ARBITRATION CLAUSE AND CLASS ACTION WAIVER IN SECTION 8. IT AFFECTS HOW DISPUTES ARE RESOLVED.
Thank you for choosing Microsoft!
Depending on how you obtained the Windows software, this is a license agreement between (i) you and the device manufacturer or software installer that distributes the software with your device; or (ii) you and Microsoft Corporation (or, based on where you live or if a

business where your principal place of business is located, one of its affiliates) if you acquired the software from a retailer. Microsoft is the device manufacturer for devices produced by Microsoft or one of its affiliates, and Microsoft is the retailer if you acquired the software directly from Microsoft.

This agreement describes your rights and the conditions upon which you may use the Windows software. You should review the entire agreement, including any supplemental license terms that accompany the software and any linked terms, because all of the terms are important and together create this agreement that applies to you. You can review linked terms by pasting the (aka.ms/) link into a browser window.

By accepting this agreement or using the software, you agree to all of these terms, and consent to the transmission of certain information during activation and during your use of the software as per the privacy statement described in Section 3. If you do not accept and comply with these terms, you may not use the software or its features.

You may contact the device manufacturer or installer, or your retailer if you purchased the software directly, to determine its return policy and return the software or device for a refund or credit under that policy. You must comply with that policy, which might require you to return the software with the entire device on which the software is installed for a refund or credit, if any.

1. **Overview.**
    a. **Applicability.** This agreement applies to the Windows software that is preinstalled on your device, or acquired from a retailer and installed by you, the media on which you received the software (if any), any fonts, icons, images or sound files included with the software, and also any Microsoft updates, upgrades, supplements or services for the software, unless other terms come with them. It also applies to Windows apps developed by Microsoft that provide functionality such as mail, calendar, contacts, music and news that are included with and are a part of Windows. If this agreement contains terms regarding a feature or service not available on your device, then those terms do not apply.
    b. **Additional terms.** Depending on your device's capabilities, how it is configured, and how you use it, additional Microsoft and third party terms may apply to your use of certain features, services and apps.
        (i) Some Windows apps provide an access point to, or rely on, online services, and the use of those services is sometimes governed by separate terms and privacy policies, such as the Microsoft Services Agreement at (aka.ms/msa). You can view these terms and policies by looking at the service terms of use or the app's settings, as applicable; please read them. The services may not be available in all regions.
        (ii) The manufacturer or installer may also preinstall apps, which will be subject to separate license terms.
        (iii) The software may include third party software such as Adobe Flash Player that is licensed under its own terms. You agree that your use of Adobe Flash Player is governed by the license terms for Adobe Systems Incorporated at (aka.ms/adobeflash). Adobe and Flash are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries.
        (iv) The software may include third party programs that are licensed to you under this agreement, or under their own terms. License terms, notices and acknowledgements, if any, for the third party program can be view at (aka.ms/thirdpartynotices).
2. **Installation and Use Rights.**

a. **License.** The software license is permanently assigned to the device with which you acquired the software. You many only use the software on that device.

b. **Device.** In this agreement, "device" means a physical hardware system) with an internal storage device capable of running the software. A hardware partition or blade is considered to be a device.

c. **Restrictions.** The manufacturer or installer and Microsoft reserve all rights (such as rights under intellectual property laws) not expressly granted in this agreement. For example, this license does not give you any right to, and you may not:

   (i) use or virtualize features of the software separately;

   (ii) publish, copy (other than the permitted backup copy), rent, lease, or lend the software;

   (iii) transfer the software;

   (iv) work around any technical restrictions or limitations in the software;

   (v) use the software as server software, for commercial hosting, make the software available for simultaneous use by multiple users over a network, install the software on a server and allow users to access it remotely, or install the software on a device for use only by remote users;

   (vi) reverse engineer, decompile, or disassemble the software, or attempt to do so, except and only to the extent that the foregoing restriction is (a) permitted by applicable law; (b) permitted by licensing terms governing the use of open source components that may be included with the software; or (c) required to debug changes to any libraries licensed under the GNU Lesser General Public License which are included with and linked to by the software; and

   (vii) 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 or use any service, data, account, or network, in an unauthorized manner.

d. **Multi use scenarios.**

   (i) **Multiple versions.** If when acquiring the software, you were provided with multiple versions (such as 32-bit and 64-bit versions), you may install and activate only one of those versions at a time.

   (ii) **Multiple or pooled connections.** Hardware or software you use to multiplex or pool connections, or reduce the number of devices or users that access or use the software, does not reduce the number of licenses you need. You may only use such hardware or software if you have a license for each instance of the software you are using.

   (iii) **Device connections.** You may allow up to 20 other devices to access the software installed on the licensed device for the purpose of using the following software features: 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 allow any number of devices to access the software on the licensed device to synchronize data between devices. This section does not mean, however, that you have the right to install the software, or use the primary function of the software (other than the features listed in this section), on any of these other devices.

(iv) **Remote access.** Users may access the licensed device from another device using remote access technologies, but only on devices separately licensed to run the same or higher edition of this software.

(v) **Remote assistance.** You may use remote assistance technologies to share an active session without obtaining any additional licenses for the software. Remote assistance allows one user to connect directly to another user's computer, usually to correct problems.

(vi) **POS application.** If the software is installed on a retail point of service device, you may use the software with a point of service application ("POS Application"). A POS Application is a software application which provides only the following functions: (i) process sales and service transactions, scan and track inventory, record and/or transmit customer information, and perform related management functions, and/or (ii) provide information directly and indirectly to customers about available products and services. You may use other programs with the software as long as the other programs: (i) directly support the manufacturer's specific use for the device, or (ii) provide system utilities, resource management, or anti-virus or similar protection. For clarification purposes, an automated teller machine ("ATM") is not a retail point of service device.

(vii) **Cloud Computing Devices.** If your device uses Internet browsing functionality to connect to and access cloud hosted applications: (i) no desktop functions may run locally on the device, and (ii) any files that result from the use of the desktop functions may not be permanently stored on the system. "Desktop functions," as used in this agreement, means a consumer or business task or process performed by a computer or computing device. This includes but is not limited to email, word processing, spreadsheets, database, scheduling, network or internet browsing and personal finance.

(viii) **Desktop Functions.** If your system performs desktop functions, then you must ensure that they: (i) are only used to support the application, and (ii) operate only when used with the application.

e. Windows 10 IoT Enterprise Features for Development and Testing Only.

(1) Device Health Attestation. You may only implement Device Health Attestation in a commercial use if you execute a Microsoft Windows IoT Core Services Agreement at: https://azure.microsoft.com/en-us/services/windows-10-iot-core/.

f. Specific Use. The manufacturer designed the licensed device for a specific use. You may only use the software for that use.

3. Privacy; Consent to Use of Data. Your privacy is important to us. Some of the software features send or receive information when using those features. Many of these features can be switched off in the user interface, or you can choose not to use them. By accepting this agreement and using the software you agree that Microsoft may collect, use, and disclose the information as described in the Microsoft Privacy Statement available at (aka.ms/privacy), and as may be described in the user interface associated with the software features.

4. **Authorized Software and Activation.** You are authorized to use this software only if you are properly licensed and the software has been properly activated with a genuine product key or by other authorized method. When you connect to the Internet while using the software, the software will automatically contact Microsoft or its affiliate to confirm the software is genuine and the license is associated with the licensed device. You can also activate the software manually by Internet or telephone. In either case, transmission of certain information will occur, and Internet, telephone and SMS service charges may apply. During activation (or reactivation that may be triggered by changes to your device's components), the software may determine that the installed instance of the software is counterfeit, improperly licensed or includes unauthorized changes. If activation fails the software will attempt to repair itself by replacing any tampered Microsoft software with genuine Microsoft software. You may also receive reminders to obtain a proper license for the software. Successful activation does not confirm that the software is genuine or properly licensed. You may not bypass or circumvent activation. To help determine if your software is genuine and whether you are properly licensed, see (aka.ms/genuine). Certain updates, support, and other services might only be offered to users of genuine Microsoft software.
5. **Updates.** You may obtain updates only from Microsoft or authorized sources, and Microsoft may need to update your system to provide you with those updates. The software periodically checks for system and app updates, and may download and install them for you. To the extent automatic updates are enabled on your device, by accepting this agreement, you agree to receive these types of automatic updates without any additional notice.
6. **Geographic and Export Restrictions.** If your software is restricted for use in a particular geographic region, then you may activate the software only in that region. 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 (aka.ms/exporting).
7. **Support and Refund Procedures.** For the software generally, contact the device manufacturer or installer for support options. Refer to the support number provided with the software. For updates and supplements obtained directly from Microsoft, Microsoft may provide limited support services for properly licensed software as described at (aka.ms/mssupport). If you are seeking a refund, contact the manufacturer or installer to determine its refund policies. You must comply with those policies, which might require you to return the software with the entire device on which the software is installed for a refund.
8. **Binding Arbitration and Class Action Waiver if You Live in (or if a Business Your Principal Place of Business is in) the United States.**
   We hope we never have a dispute, but if we do, you and we agree to try for 60 days to resolve it informally. If we can't, you and we agree to **binding individual arbitration before the American Arbitration Association ("AAA") under the Federal Arbitration Act ("FAA"), and not to sue in court in front of a judge or jury.** Instead, a neutral arbitrator will decide and the arbitrator's decision will be final except for a limited right of appeal under the FAA. **Class action lawsuits, class-wide arbitrations, private attorney-general actions, and any other proceeding where someone acts in a representative capacity aren't allowed. Nor is combining individual proceedings without the consent of all parties.** "We," "our," and "us" includes Microsoft, the device manufacturer, and software installer.
   a. **Disputes covered - everything except IP.** The term "dispute" is as broad as it can be. It includes any claim or controversy between you and the manufacturer or installer, or you and Microsoft, concerning the software, its price, or this agreement, under any legal theory including contract, warranty, tort, statute, or regulation, **except disputes relating to the enforcement or validity of your, your licensors', our, or our licensors' intellectual property rights.**

b. **Mail a Notice of Dispute first.** If you have a dispute and our customer service representatives can't resolve it, send a Notice of Dispute by U.S. Mail to the manufacturer or installer, ATTN: LEGAL DEPARTMENT. If your dispute is with Microsoft, mail it to Microsoft Corporation, ATTN: LCA ARBITRATION, One Microsoft Way, Redmond, WA 98052-6399. Tell us your name, address, how to contact you, what the problem is, and what you want. A form is available at (aka.ms/disputeform). We'll do the same if we have a dispute with you. After 60 days, you or we may start an arbitration if the dispute is unresolved.

c. **Small claims court option.** Instead of mailing a Notice of Dispute, and if you meet the court's requirements, you may sue us in small claims court in your county of residence (or if a business your principal place of business) or our principal place of business-King County, Washington USA if your dispute is with Microsoft. We hope you'll mail a Notice of Dispute and give us 60 days to try to work it out, but you don't have to before going to small claims court.

d. **Arbitration procedure.** The AAA will conduct any arbitration under its Commercial Arbitration Rules (or if you are an individual and use the software for personal or household use, or if the value of the dispute is $75,000 USD or less whether or not you are an individual or how you use the software, its Consumer Arbitration Rules). For more information, see (aka.ms/adr) or call 1-800-778-7879. To start an arbitration, submit the form available at (aka.ms/arbitration) to the AAA; mail a copy to the manufacturer or installer (or to Microsoft if your dispute is with Microsoft). In a dispute involving $25,000 USD or less, any hearing will be telephonic unless the arbitrator finds good cause to hold an in-person hearing instead. Any in-person hearing will take place in your county of residence (of if a business your principal place of business) or our principal place of business - King County, Washington if your dispute is with Microsoft. You choose. 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 to satisfy your individual claim.

e. **Arbitration fees and payments.**

   (i) **Disputes involving $75,000 USD or less.** The manufacturer or installer (or Microsoft if your dispute is with Microsoft) will promptly reimburse your filing fees and pay the AAA's and arbitrator's fees and expenses. If you reject our last written settlement offer made before the arbitrator was appointed, your dispute goes all the way to an arbitrator's decision (called an "award"), and the arbitrator awards you more than this last written offer, the manufacturer or installer (or Microsoft if your dispute is with Microsoft) will: (1) pay the greater of the award or $1,000 USD; (2) pay 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 unless you and we agree on them.

   (ii) **Disputes involving more than $75,000 USD.** The AAA rules will govern payment of filing fees and the AAA's and arbitrator's fees and expenses.

   (iii) **Disputes involving any amount.** If you start an arbitration we won't seek our AAA or arbitrator's fees and expenses, or your filing fees we reimbursed, unless the arbitrator finds the arbitration frivolous or brought for an improper purpose. If we start an arbitration we will pay all filing, AAA, and arbitrator's fees and expenses. We won't seek our attorney's fees or expenses from you in any arbitration. Fees and expenses are not counted in determining how much a dispute involves.

f. **Must file within one year.** You and we must file in small claims court or arbitration any claim or dispute (except intellectual property disputes - see Section 9.a.) within one year from when it first could be filed. Otherwise, it's permanently barred.

g. **Severability.** If the class action waiver is found to be illegal or unenforceable as to all or some parts of a dispute, those parts won't be arbitrated but will proceed in court, with the rest proceeding in arbitration. If any other provision of Section 9 is found to be illegal or unenforceable, that provision will be severed but the rest of Section 9 still applies.

h. **Conflict with AAA rules.** This agreement governs if it conflicts with the AAA's Commercial Arbitration Rules or Consumer Arbitration Rules.

i. **Microsoft as party or third-party beneficiary.** If Microsoft is the device manufacturer or if you acquired the software from a retailer, Microsoft is a party to this agreement. Otherwise, Microsoft is not a party but is a third-party beneficiary of your agreement with the manufacturer or installer to resolve disputes through informal negotiation and arbitration.

9. **Governing Law.** The laws of the state or country where you live (or if a business where your principal place of business is located) govern all claims and disputes concerning the software, its price, or 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, regardless of conflict of law principles. In the United States, the FAA governs all provisions relating to arbitration.

10. **Consumer Rights, Regional Variations.** 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 which 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. For example, if you acquired the software in one of the below regions, or mandatory country law applies, then the following provisions apply to you:

a. **Australia.** References to "Limited Warranty" are references to the express warranty provided by Microsoft or the manufacturer or installer. This warranty is given in addition to other rights and remedies you may have under law, including your rights and remedies in accordance with the statutory guarantees under the Australian Consumer Law.
In this section, "goods" refers to the software for which Microsoft or the manufacturer or installer provides the express warranty. 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.

b. **Canada.** You may stop receiving updates on your device by turning off Internet access. If and when you re-connect to the Internet, the software will resume checking for and installing updates.

c. **Germany and Austria.**

(i) **Warranty.** The properly licensed software will perform substantially as described in any Microsoft materials that accompany the software. However, the manufacturer or installer, and Microsoft, give no contractual guarantee in relation to the licensed software.

(ii) **Limitation of Liability.** In case of intentional conduct, gross negligence, claims based on the Product Liability Act, as well as, in case of death or personal or physical injury, the manufacturer or installer, or Microsoft is liable according to the statutory law.

Subject to the preceding sentence, the manufacturer or installer, or Microsoft will only be liable for slight negligence if the manufacturer or installer or Microsoft is in breach of such material contractual obligations, the fulfillment of which facilitate the due performance of this agreement, the breach of which would endanger the purpose of this agreement and the compliance with which a party may constantly trust in (so-called "cardinal obligations"). In other cases of slight negligence, the manufacturer or installer or Microsoft will not be liable for slight negligence.

d. Other regions. See (aka.ms/variations) for a current list of regional variations

11. Additional Notices.

a. Networks, data and Internet usage. Some features of the software and services accessed through the software may require your device to access the Internet. Your access and usage (including charges) may be subject to the terms of your cellular or internet provider agreement. Certain features of the software may help you access the Internet more efficiently, but the software's usage calculations may be different from your service provider's measurements. You are always responsible for (i) understanding and complying with the terms of your own plans and agreements, and (ii) any issues arising from using or accessing networks, including public/open networks. You may use the software to connect to networks, and to share access information about those networks, only if you have permission to do so.

b. H.264/AVC and MPEG-4 visual standards and VC-1 video standards. The software may include H.264/MPEG-4 AVC and/or VC-1 decoding technology. MPEG LA, L.L.C. requires this notice:
THIS PRODUCT IS LICENSED UNDER THE AVC, THE VC-1, AND THE MPEG-4 PART 2 VISUAL PATENT PORTFOLIO LICENSES FOR THE PERSONAL AND NON-COMMERCIAL USE OF A CONSUMER TO (i) ENCODE VIDEO IN COMPLIANCE WITH THE ABOVE STANDARDS ("VIDEO STANDARDS") AND/OR (ii) DECODE AVC, VC-1, AND MPEG-4 PART 2 VIDEO THAT WAS ENCODED BY A CONSUMER ENGAGED IN A PERSONAL AND NON-COMMERCIAL ACTIVITY AND/OR WAS OBTAINED FROM A VIDEO PROVIDER LICENSED TO PROVIDE SUCH VIDEO. NO LICENSE IS GRANTED OR SHALL BE IMPLIED FOR ANY OTHER USE. ADDITIONAL INFORMATION MAY BE OBTAINED FROM MPEG LA, L.L.C. SEE WWW.MPEGLA.COM

c. Malware protection. Microsoft cares about protecting your device from malware. The software will turn on malware protection if other protection is not installed or has expired. To do so, other antimalware software will be disabled or may have to be removed.

12. **Entire Agreement.** This agreement (together with the printed paper license terms or other terms accompanying any software supplements, updates, and services that are provided by the manufacturer or installer, 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 the manufacturer or installer, or Microsoft, provides other terms with such supplements, updates, or services). You can review this agreement after your software is running by going to (aka.ms/useterms) or going to Settings - System - About within the software. You can also review the terms at any of the links in this agreement by typing the URLs into a browser address bar, and you agree to do so. You agree that you will read the terms before using the software or services, including any linked terms. You understand that by using the software and services, you ratify this agreement and the linked terms. There are also informational links in this agreement. The links containing notices and binding terms are:
    - Windows 10 Privacy Statement (aka.ms/privacy)
    - Microsoft Services Agreement (aka.ms/msa)
    - Adobe Flash Player License Terms (aka.ms/adobeflash)

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NO WARRANTY

THE SOFTWARE ON YOUR DEVICE (INCLUDING THE APPS) IS LICENSED "AS IS." TO THE MAXIMUM EXTENT PERMITTED BY YOUR LOCAL LAWS, YOU BEAR THE ENTIRE RISK AS TO THE SOFTWARE'S QUALITY AND PERFORMANCE. SHOULD IT PROVE DEFECTIVE, YOU ASSUME THE ENTIRE COST OF ALL SERVICING OR REPAIR. NEITHER THE DEVICE MANUFACTURER NOR MICROSOFT GIVES ANY EXPRESS WARRANTIES, GUARANTEES, OR CONDITIONS FOR THE SOFTWARE. TO THE EXTENT PERMITTED UNDER YOUR LOCAL LAWS, THE MANUFACTURER AND MICROSOFT EXCLUDE ALL IMPLIED WARRANTIES AND CONDITIONS, INCLUDING THOSE OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT. YOU MAY HAVE ADDITIONAL CONSUMER RIGHTS OR STATUTORY GUARANTEES UNDER LOCAL LAWS THAT THESE TERMS CANNOT CHANGE.

IF YOUR LOCAL LAWS IMPOSE A WARRANTY, GUARANTEE, OR CONDITION EVEN THOUGH THIS AGREEMENT DOES NOT, ITS TERM IS LIMITED TO 90 DAYS FROM WHEN THE FIRST USER ACQUIRES THE SOFTWARE. IF THE MANUFACTURER OR MICROSOFT BREACHES SUCH A WARRANTY, GUARANTEE, OR CONDITION, YOUR SOLE REMEDY, AT THE MANUFACTURER'S OR MICROSOFT'S ELECTION, IS (I) REPAIR OR REPLACEMENT OF THE SOFTWARE AT NO CHARGE, OR (II) RETURN OF THE SOFTWARE (OR AT ITS ELECTION THE DEVICE ON WHICH THE SOFTWARE WAS INSTALLED) FOR A REFUND OF THE AMOUNT PAID, IF ANY. THESE ARE YOUR ONLY REMEDIES FOR BREACH OF A WARRANTY, GUARANTEE, OR CONDITION YOUR LOCAL LAWS IMPOSE.

TO THE EXTENT NOT PROHIBITED BY YOUR LOCAL LAWS, IF YOU HAVE ANY BASIS FOR RECOVERING DAMAGES, YOU CAN RECOVER FROM THE MANUFACTURER OR MICROSOFT ONLY DIRECT DAMAGES UP TO THE AMOUNT YOU PAID FOR THE SOFTWARE (OR UP TO $50 USD IF YOU ACQUIRED THE SOFTWARE FOR NO CHARGE). YOU WILL NOT, AND WAIVE ANY RIGHT TO, SEEK TO RECOVER ANY OTHER DAMAGES OR REMEDY, INCLUDING LOST PROFITS AND DIRECT, CONSEQUENTIAL, SPECIAL, INDIRECT, OR INCIDENTAL DAMAGES, UNDER ANY PART OF THIS AGREEMENT OR UNDER ANY THEORY. THIS LIMITATION APPLIES TO (I) ANYTHING RELATED TO THIS AGREEMENT, THE SOFTWARE (INCLUDING THE APPS), THE DEVICE, SERVICES, CORRUPTION OR LOSS OF DATA, FAILURE TO TRANSMIT OR RECEIVE DATA, CONTENT (INCLUDING CODE) ON THIRD PARTY INTERNET SITES OR THIRD PARTY PROGRAMS, AND (II) CLAIMS FOR BREACH OF CONTRACT, WARRANTY, GUARANTEE, OR CONDITION; STRICT LIABILITY, NEGLIGENCE, OR OTHER TORT; VIOLATION OF A STATUTE OR REGULATION; UNJUST ENRICHMENT; OR UNDER ANY OTHER THEORY.

THE DAMAGE EXCLUSIONS AND REMEDY LIMITATIONS IN THIS AGREEMENT APPLY EVEN IF YOU HAVE NO REMEDY (THE SOFTWARE IS LICENSED "AS IS"), IF REPAIR, REPLACEMENT, OR A REFUND (IF REQUIRED BY YOUR LOCAL LAW) DOES NOT FULLY COMPENSATE YOU FOR ANY LOSSES, IF THE MANUFACTURER OR MICROSOFT KNEW OR SHOULD HAVE KNOWN ABOUT THE POSSIBILITY OF THE DAMAGES, OR IF THE REMEDY FAILS OF ITS ESSENTIAL PURPOSE.

Check with your device manufacturer to determine if your device is covered by a warranty.

9.3 McAfee Embedded Control

This license forms a contract between the customer and FUJIFILM Healthcare Corporation. Please read these license terms carefully. These license terms apply to this software included in this device. This software also includes other media containing this software. The software of this device includes the software licensed by McAfee, Inc. and its affiliates (hereinafter referred to as "McAfee"). These license terms also apply to the following McAfee products related to this software:

- Software updates
- Additional software
- Support services

If these products include their own license terms, such license terms apply.
By using this software, you agree to be bound by these license terms. If you do not agree with these license terms, you cannot use this software. In this case, please contact FUJIFILM Healthcare Corporation to ask about our policy on refunds.
On the condition that you comply with these license terms, you are allowed to:

9.3.1 Software License Agreement

FUJIFILM Healthcare Corporation (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.
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*1.
DICOM SR

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pdf2djvu	libdjvulibre-21	bzz
c44	cjb2	csepdjvu
djvmcvt	djvuextract	djvumake
djvused	libpoppler-19	libintl-8
PDFViewer	bash	busybox
Incron	Linux kernel	lv
numactl	pciutils	PDF Reader
procps	spu-tools	base-files
adduser	alsa-base	atftpd
aufs-tools	base-passwd	busybox-initramfs
busybox-syslogd	dash	e2fslibs
e2fsprogs	freeglut3	ifupdown
initramfs-tools	initramfs-tools-bin	insserv
iproute2	keyboard-configuration	libacl1
libapt-pkg4.12	libattr1	libblkid1
libbz2-1.0	libc-bin	libcomerr2
libdbus-1-3	libelf1	libgcrypt11
libgdbm3	libglew1.10	libklibc
libkmod2	liblocale-gettext-perl	libnih-dbus1
libnih1	libpci3	libpopt0
libprocps3	libsamplerate0	libsemanage1
libsepol1	libslang2	libustr-1.0-1
libuuid1	libxcb-dri2-0	libxcb-present0
libxcb-sync1	libxcb-util0	linux-image-4.4.0-42-lowlaten cy-m
linux-sound-base	login	mawk
module-init-tools	mount	passwd
pciutils	plymouth	procps
sed	sensible-utils	ubuntu-keyring
udev	update-inetd	util-linux
vim-common	vim-tiny	xserver-xorg-input-synaptics
xserver-xorg-input-wacom	libxcb-glx0	alsa-utils
apt	xserver-xorg	bsdutils
busybox	x11-common	debianutils
dpkg	usbutils	fsprotect
hugepages	upstart	initscripts
inotify-tools	sysvinit-utils	klibc-utils

kmod	sysv-rc	libaudit-common
libaudit1	powermgmt-base	libc6
libcgmanager0	pm-utils	libfile-copy-recursive-perl
libfreetype6	net-tools	libglu1-mesa
libinotifytools0	mountall	liblzma5
libmount1	makedev	libplymouth2
libpng12-0	lsb-base	libselinux1
libsemanage-common	linux-headers-4.4.0-42-lowlate ncy-m	libss2
libudev1	libxcb1	libxcb-dri3-0

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libiconv		

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At-spi	at-spi2	FFTReal 2.11
JavaScriptCore	WebCore	XHTML Renderer
gzip	libasound2	libasound2-data
libgl1-mesa-glx	libglapi-mesa	libgpg-error0
libusb-0.1-4	libusb-1.0-0	locales
libfribidi0	libgl1-mesa-dri	libhugetlbfs0
libnewt0.52	multiarch-support	whiptail

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bash	coreutils	cpio
gcc-4.8-base	gcc-4.9-base	gnupg
hostname	libgcc1	libreadline6
perl-base	perl-modules	readline-common
diffutils	findutils	gpgv
grep	libstdc++6	perl
tar	libsndfile	

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avalon-framework-api-4.3.1	avalon-framework-impl-4.3.1	batik-anim-1.7
batik-awt-util-1.7	batik-bridge-1.7	batik-codec-1.7
batik-css-1.7	batik-dom-1.7	batik-ext-1.7
batik-gvt-1.7	batik-js-1.7	batik-parser-1.7
batik-script-1.7	batik-svg-dom-1.7	batik-svggen-1.7
batik-transcoder-1.7	batik-util-1.7	batik-xml-1.7
cglib-2.2.2	Clucene Core Library	commons-beanutils-1.8.3
commons-codec-1.6	commons-io-2.4	commons-lang-2.6

core-renderer-v20120624134849	fop-0.94	javax.inject 1
jetty-annotations-9.1.5.v20140505	jetty-http-9.1.5.v20140505	jetty-io-9.1.5.v20140505
jetty-jndi-9.1.5.v20140505	jetty-plus-9.1.5.v20140505	jetty-security-9.1.5.v20140505
jetty-server-9.1.5.v20140505	jetty-servlet-9.1.5.v20140505	jetty-util-9.1.5.v20140505
jetty-webapp-9.1.5.v20140505	jetty-xml-9.1.5.v20140505	joda-time 2.3
shiro-core-1.1.0	shiro-web-1.1.0	spring-aop-3.2.3.RELEASE
spring-beans-3.2.3.RELEASE	spring-context-3.2.3.RELEASE	spring-core-3.2.3.RELEASE
spring-expression-3.2.3.RELEASE	spring-tx-3.2.3.RELEASE	spring-web-3.2.3.RELEASE
spring-webmvc-3.2.3.RELEASE	Wicket 6.6.0	wicket-auth-roles-6.6.0
wicket-core-6.6.0	wicket-devutils-6.6.0	wicket-extensions-6.6.0
wicket-ioc-6.6.0	wicket-request-6.6.0	wicket-spring-6.6.0
wicket-util-6.6.0	wicketstuff-shiro-1.5.8	xercesImpl-2.9.1
xml-apis 2.0.2	xml-apis-ext-1.3.04	xmlgraphics-commons-1.2

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asm-3.3.1	asm-4.1	asm-commons-4.1
asm-tree-4.1	DCMTK 3.6.2	jing-20091111
debconf	libncurses5	libssl1.0.0
dropbear	libncursesw5	libtinfo5
libcap2	libpam-modules	libwrap0
libdb5.3	libpam-modules-bin	libxfont1
libdebconfclient0	libpam-runtime	ncurses-base
libedit2	libpam0g	ncurses-bin
libllvm3.5	libpcre3	sudo
QuickTest	dcmrt	dcmsr

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stax-utils-20070216	cielabutil	

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HarfBuzz	isorelax-20030108	jcl-over-slf4j-1.7.5
LIBXML2-2	LIBXSLT-1	slf4j-api-1.7.5
slf4j-merlin	Pixman 0.17.11	libdrm-intel1
libx11-data	libxshmfence1	libdrm-nouveau2
libx11-xcb1	libxt6	libdrm-radeon1
libxau6	libxv1	libdrm2
libxaw7	libxvmc1	libexpat1
libxdamage1	libxxf86vm1	libffi6

libxdmcp6	x11-xkb-utils	libfontenc1
libxext6	xkb-data	libice6
libxfixes3	xserver-common	libjson-c2
libxi6	xserver-xorg-core	libjson0
libxinerama1	xserver-xorg-input-all	libmtdev1
libxkbfile1	xserver-xorg-input-evdev	libpciaccess0
libxmu6	xserver-xorg-input-mouse	libpixman-1-0
libxpm4	xserver-xorg-input-vmmouse	libsm6
libxrandr2	xserver-xorg-video-intel	libx11-6
libxrender1	cJSONr53	Lua5.1.2
Lua RS 232 1.0.3-3	Lua socket2.0.1	joyent-http-parser2.4

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itext-2.1.7		

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javax.servlet-api 3.1.0	Javax.annotation-api-1.2	

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libfreetype-6		

Libtiff Software License

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libgcc	libstdc++	elfutils

OpenSSL License / SSLeay License

OpenSSL1.1.0g	OpenSSL1.0.2r	

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Version 2, June 1991
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[This is the first released version of the library GPL. It is
numbered 2 because it goes with version 2 of the ordinary GPL.]

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Finally, any free program is threatened constantly by software patents. We wish to avoid the danger that companies distributing free software will individually obtain patent licenses, thus in effect transforming the program into proprietary software. To prevent this, we have made it clear that any patent must be licensed for everyone's free use or not licensed at all.

Most GNU software, including some libraries, is covered by the ordinary GNU General Public License, which was designed for utility programs. This license, the GNU Library General Public License, applies to certain designated libraries. This license is quite different from the ordinary one; be sure to read it in full, and don't assume that anything in it is the same as in the ordinary license.

The reason we have a separate public license for some libraries is that they blur the distinction we usually make between modifying or adding to a program and simply using it. Linking a program with a library, without changing the library, is in some sense simply using the library, and is analogous to running a utility program or application program. However, in a textual and legal sense, the linked executable is a combined work, a derivative of the original library, and the ordinary General Public License treats it as such.

Because of this blurred distinction, using the ordinary General Public License for libraries did not effectively promote software sharing, because most developers did not use the libraries. We concluded that weaker conditions might promote sharing better.

However, unrestricted linking of non-free programs would deprive the users of those programs of all benefit from the free status of the libraries themselves. This Library General Public License is intended to permit developers of non-free programs to use free libraries, while preserving your freedom as a user of such programs to change the free libraries that are incorporated in them. (We have not seen how to achieve this as regards changes in header files, but we have achieved it as regards changes in the actual functions of the Library.) The hope is that this will lead to faster development of free libraries.

The precise terms and conditions for copying, distribution and modification follow. Pay close attention to the difference between a "work based on the library" and a "work that uses the library". The former contains code derived from the library, while the latter only works together with the library.

Note that it is possible for a library to be covered by the ordinary General Public License rather than by this special one.

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A "library" means a collection of software functions and/or data prepared so as to be conveniently linked with application programs (which use some of those functions and data) to form executables.

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"Source code" for a work means the preferred form of the work for making modifications to it. For a library, complete source code means all the source code for all modules it contains, plus any associated interface definition files, plus the scripts used to control compilation and installation of the library.

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(For example, a function in a library to compute square roots has a purpose that is entirely well-defined independent of the application. Therefore, Subsection 2d requires that any application-supplied function or table used by this function must be optional: if the application does not supply it, the square root function must still compute square roots.)

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This option is useful when you wish to copy part of the code of the Library into a program that is not a library.

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If such an object file uses only numerical parameters, data structure layouts and accessors, and small macros and small inline functions (ten lines or less in length), then the use of the object file is unrestricted, regardless of whether it is legally a derivative work. (Executables containing this object code plus portions of the Library will still fall under Section 6.)

Otherwise, if the work is a derivative of the Library, you may distribute the object code for the work under the terms of Section 6. Any executables containing that work also fall under Section 6, whether or not they are linked directly with the Library itself.

6. As an exception to the Sections above, you may also compile or link a "work that uses the Library" with the Library to produce a work containing portions of the Library, and distribute that work under terms of your choice, provided that the terms permit modification of the work for the customer's own use and reverse engineering for debugging such modifications.

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b) Accompany the work with a written offer, valid for at least three years, to give the same user the materials specified in Subsection 6a, above, for a charge no more than the cost of performing this distribution.
c) If distribution of the work is made by offering access to copy from a designated place, offer equivalent access to copy the above specified materials from the same place.
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In other cases, permission to use a particular library in non-free programs enables a greater number of people to use a large body of free software. For example, permission to use the GNU C Library in non-free programs enables many more people to use the whole GNU operating system, as well as its variant, the GNU/Linux operating system.
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//
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Module: Log4CPLUS
File: appender.h
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10

Privacy and security

The following sections describe the matters related to privacy and security that need to be considered.

10.1 Principles

This manual assumes that customers understand the concept of privacy and security.
For medical devices, you need to maintain balance among safety, privacy, and security. This chapter provides explanations so that the user who manages the system can implement risk management by themselves for these three risk areas.
Note that there is a policy in which only our service staff are allowed to make important changes to the system such as performing virus scans and updating product software. For details, see "Updating of the product and handling of security incidents" in this manual.
NOTE: For details on how to specifically use the security functionality, see the separate manual "Basic Operations".

10.2 Privacy and security environments

We have designed the system assuming the following environments:

- The environment is physically protected from unintended access through implementation of measures such as entrance and exit control, prevention of theft, peeping, etc., and prevention of devices, the system, information media, etc. from being stolen or lost.
- All passwords are strictly managed to avoid being known by persons who do not need to know them.
- The environment is connected as needed to a segmented and safe network (LAN or VLAN, WAN) for which settings are specified. In addition, the environment uses the network configuration recommended by the network device to be adopted.
- Images, patient data, etc. are appropriately exported, and data that is no longer used is periodically deleted. In addition, data is backed up every day after it is used.
- Regarding the monitor of the system, visibility is restricted so that only persons who have legitimate purposes (medical staff, patients, etc. as well as operators) can view the monitor.
- The media and storage to be connected are scanned in advance by using an anti-malware product.

10.3 Main security specifications

This section focuses on and describes the internal capabilities of the system's privacy and security capabilities. For details on how to specifically use the security functionality, see the separate manual "Basic Operations".

10.3.1 Access control

(1) Managing users

You can add or delete users, specify user levels, and specify behavior settings for each user.

(2) Authentication

You can use password authentication when users use the system.

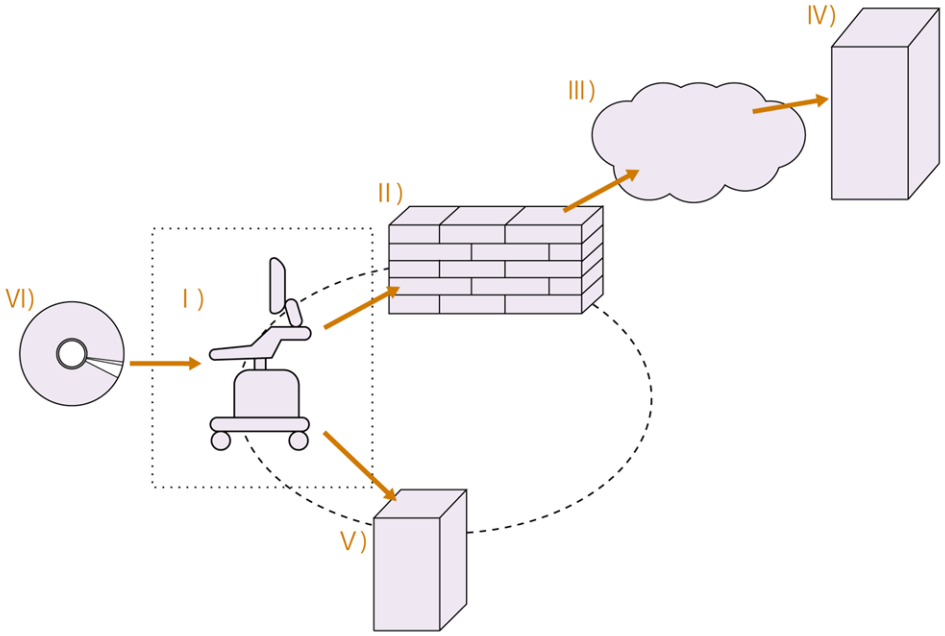
(3) Password policy

You can define the password policy for passwords that are used by users to be authenticated when using the system.

(4) Screen lock

You can start a screen saver after a period of inactivity to protect privacy and security.

10.3.2 System connections



Main connections of the system

I)	Authorization boundary of the system For Ethernet connections, a cable (RJ45) can be used. Alternatively, a wireless connection that can be separately set up can be used. In addition, IPv4 or IPv6 of static or dynamic addressing can be used.
II)	Firewall of the customer When you connect to the Internet, we recommend that you use it within the firewall.
III)	Internet
IV)	Server outside the hospital
V)	PACS, DICOM printers, and other information systems within the hospital
VI)	CD, DVD, USB drives

(1) Network requirements

For some system configurations, a network connection is necessary.

- When the system connects to the PACS server, etc.

- If you have a contract for remote services provided by our company

NOTE: The remote service is provided for a fee and might not be supported in some regions.

(2) DICOM

For details on DICOM-related security requirements, see 7. SECURITY in the DICOM Conformance Statement.

(3) Network security

The system is equipped with the application firewall and configured so that communications are blocked for ports other than those used.

(4) Wireless security

We do not provide any wireless modules.
The customer can use the wireless module only if they separately purchase a USB Wi-Fi Adapter recommended by our company and our service staff sets it up.
At this time, the security encryption that can be used conforms to the USB Wi-Fi Adapter in use.

10.3.3 Outputting of audit logs

The system supports outputting of audit logs.
Customers need to strictly implement management for preventing unauthorized access to and manipulation of the output logs.
NOTE: For details on how to specify Audit Log settings, see the separate manual "Basic Operations".

10.3.4 Countermeasures against malware

For the system, you can introduce McAfee Embedded Control of WhiteList Technology as paid optional software.
McAfee Embedded Control allows only programs registered in the dynamic whitelist to be executed. Other programs (exe, dll, script) are considered as unapproved. Attempts to execute them are blocked, which is recorded in a log. This can prevent worms, viruses, spyware, and other malware from being executed.
If you want to introduce optional products, please contact our office.

10.4 Updating of the product and handling of security incidents

We continuously monitor for vulnerabilities in the components installed in the product. If some vulnerability is found, we evaluate the impact on the product, and then quickly respond by updating software if necessary, etc.

10.4.1 When WhiteList Technology detects an abnormality

If a dialog box stating "Windows cannot access the specified device, path, or file. You may have the appropriate permissions to access the item." is displayed, WhiteList Technology might have blocked the execution of suspicious software.
If the system is connected to a network, immediately disconnect the network connection by removing the LAN cable connected to the system, etc.
Please contact our office and describe the problem, to the best of your knowledge.

10.4.2 When a security incident occurs in the environment in use

If a security incident occurs in the environment in which the product is used, regardless of whether the system is affected, disconnect from the network. After the incident is resolved and you make sure that the network has no problem, connect the system to the network.
Note that if our product operates abnormally, please contact our office and describe the problem, to the best of your knowledge.

Manufacturer

FUJIFILM Healthcare Corporation
2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan

Contact

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