HITACHI
Inspire the Next

Diagnostic Ultrasound System
ARIETTA 65

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.
- Federal law restricts this device to sale by or on the order of physician.

Hitachi, Ltd.

MN1-6438 rev.5

Preface

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Introduction

Thank you for purchasing the ARIETTA 65 Diagnostic Ultrasound System by Hitachi, Ltd.
This document is the instruction manual for the ARIETTA 65 Diagnostic Ultrasound System.

Name and classification of medical equipment

Product name

ARIETTA 65 Diagnostic Ultrasound System

Revision history

Revision no.: 5
Revision date: 2019-11-12

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).
The following symbols are used in this manual.

Character	Explanation
α	Alpha
γ	Gamma
π	Pi

About the ARIETTA 65 Diagnostic Ultrasound System

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 Hitachi's 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 refers to the acts of attaching, to the system, parts or devices that are not approved by Hitachi. 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.

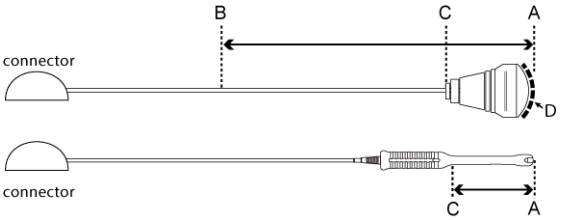
- Clean and inspect the system periodically. For details, see "Instructions for Use".
- If any abnormality occurs during the use of the system, remove the probe from the patient immediately, and stop using the system. If the patient exhibits unusual or abnormal symptoms, immediately provide the appropriate 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 essential 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: 533 mm ±10%
	Depth: 742 mm ±10% (when the monitor arm is folded)
	Height: 1265 mm to 1635 mm
Weight	85 kg ±10% (main unit only), 115 kg ±10% (with all options included)

Classification of the ARIETTA 65 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.

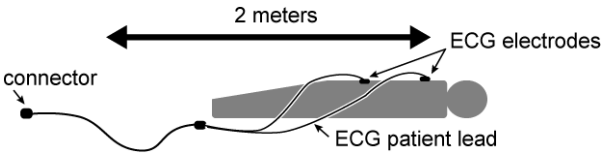


The upper figure is an example of a probe for surface and intra-operative use. The lower figure is an example of a body cavity probe.

Probe application	Applied part	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
Inside body cavities	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-2345*: 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.

This symbol on the equipment or on its packaging indicates that this equipment shall not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic products. By ensuring this equipment is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this equipment. The recycling of materials will help to conserve natural resources.

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 your local city office, your household waste disposal service or the shop where you purchased the product. Perchlorate Material-special handling may apply, See www. dtsc.ca.gov/hazardouswaste/perchlorate.

Trademarks and registered trademarks

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Adobe, Acrobat, and Reader are trademarks or registered trademarks of Adobe Systems Incorporated in the United States or other countries.
The company name, product names, and logo of McAfee, in both English and Japanese, are trademarks or registered trademarks of McAfee, Inc. or its affiliated companies.
Linux is a registered trademark of Linus Torvalds in Japan and other countries.
VS-FlexGrid Pro copyright(C) 1999-2000 Videosoft Corporation.
This software is based in part on the work of the Independent JPEG Group.
Real-time Tissue Elastography, HI REZ, 4Dshading and HdTHI are registered trademarks in Japan of Hitachi, Ltd.
Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.
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 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 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.

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.

For each examination, use probes that have been cleaned, disinfected, and sterilized.
During the examination, wear medical gloves. After the examination, wash your hands.
Ignoring these instructions might result in infections in the operator or patient.

Dispose of probes used on patients with Creutzfeldt-Jakob disease.
Ignoring these instructions might result in infection in the operator or patient.
Our ultrasound probe is 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, refer to *5.2 The need for regular maintenance inspections* on page 135 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 operator, 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 the operator.

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 any other part.
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 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 operator.

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 the image during a puncture operation (especially 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, 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.

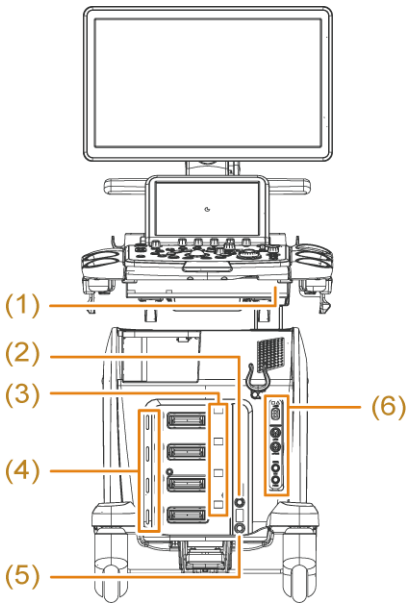
1.1.2 Labels

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* on page 176 in this manual.
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.



(1)

Indicates whether the Keyboard Tray is locked.
Right: Unlocked
Left: Locked

(2)

Independent probe connector.
The numbers are connector numbers.

(3)

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

(4)

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

(5)

Foot switch connector.

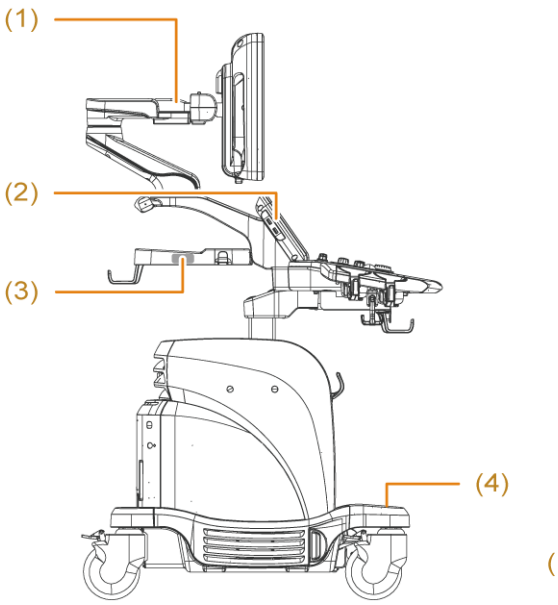
(6)

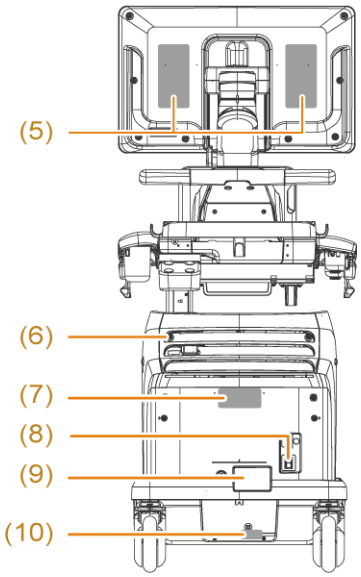
Connection terminals for physiological signals (for connecting physiological signal cables)

 : This indicates a type BF applied part.

TRANSDUCER: Connection terminal for the Physiological Signal Unit cable.

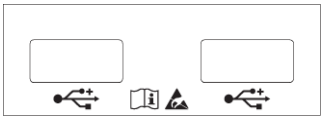
DC-IN: External input terminal.





(1) 

Take care to avoid pinching your fingers.

(2) 

USB connector.

(3) 

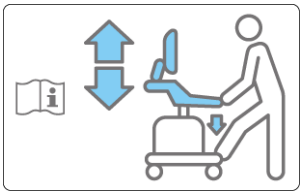
This indicates that a load weight over the specified value is prohibited.

CAUTION

Do not apply a load that is over the specified weight.

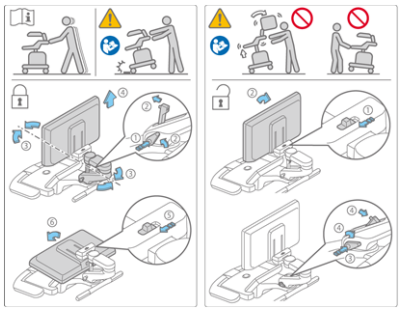
Ignoring this instruction might result in damage to, or deformation of, the system.

In addition, objects might fall and be damaged.

(4) 

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.

(5) 

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.

(6) 

LAN cable connector.

(7) 

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 pinch 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 operator, 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.

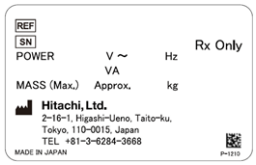
CAUTION

Do not use wireless devices (such as mobile phones, PHS devices, or radio transceivers) 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.

(8) 

Battery power-supply switch

(9) 

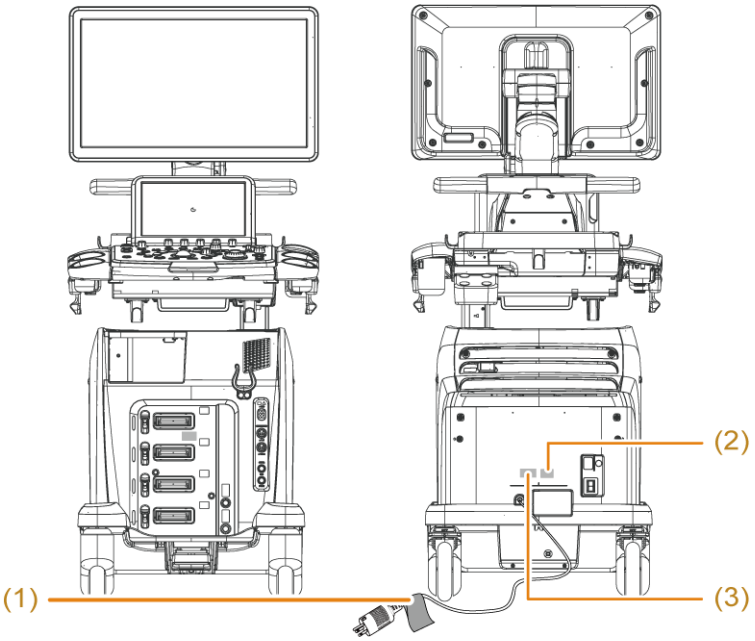
This shows the manufacturer name, model name, and other information.

Rx Only By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.

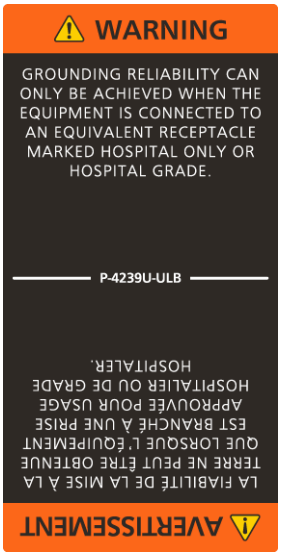
Manufacturer.
Date of manufacture.
The number under the mark indicates the year and month of manufacture.

(10) 

Equipotential terminal.



(1)



(2)

(3)

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 "How to Use".

- 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 operator and the next patient. Our ultrasound probes are not compatible with any disinfection or sterilization method for Creutzfeldt-Jakob disease.

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 qualified person.
  - 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.
  - Do not perform a puncture operation when the 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 CC41R1 probe, a C41L47RP probe, or a CL4416R probe is connected, check the puncture guide line in the L (longitudinal) image.

When performing a puncture operation when a CC41R probe or a CC41R1 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.

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.

- 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.

⚠ 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.

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 or the 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 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 1. the electromagnetic environment, 2. use of portable or mobile RF communications devices and 3. 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 *7.1 Guidelines for electromagnetic compatibility* on page 168 in this manual.
   - Position this system as far away as possible from radio receivers, televisions, and their power 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 a connection cable that meets the following conditions:

No.	Name	Shielded or not shielded	Max. cable length
1	LAN	Shielded	10 m

WARNING

Portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device including cables specified by the manufacturer.
Otherwise, degradation of the performance of this device could result.

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 168

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 power 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, turn the system breaker and the battery power-supply switch to Off, 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 the internal battery

- When the system is shipped from the factory, the internal battery is not sufficiently charged. The battery must be charged before the system is used.
- When fully charged, the internal battery can be used to operate the system for approximately 70 minutes in B mode in an environment where the temperature is 25°C. Note that this might vary, depending on the environment where the system is used or the number of times the internal battery is charged and discharged.
- The internal battery is a consumable part. As the battery is repeatedly charged, the battery life per charge decreases gradually. If a message indicating the battery needs to be replaced is displayed when you start the battery, or if the battery life per charge decreases drastically, you need to replace the internal battery. Please contact our office.
- If you want to record data while the battery is being used to operate the system, take note of the remaining battery charge. If the system loses power while data is being recorded, the data will not be recorded correctly.
- If a hospital-grade outlet is not available, do not connect the power plug to a different outlet. Instead, use the battery to power the system.
- When the battery is being used as the power supply, the optional peripheral equipment and the Gel Warmer cannot be used.
- When the remaining battery charge becomes low, a message appears on the screen. Follow the instructions in the message.
- The system consumes a small amount of power even when the power switch is set to Off. Therefore, when the battery is being used as the power supply, the battery charge will decrease even if the power switch is set to Off and the power plug is not plugged

into a hospital-grade outlet. Under these circumstances, the battery life of a fully-charged battery is approximately two to three days.

- If the system will not be used for an extended period of time, charge the battery to approximately 40-60%, turn the battery power-supply switch to Off, and store the system in a cool place (approximately 20°C). Once every six months, charge the battery to approximately 40-60%. To check the remaining battery charge, check the battery charge status in the on-screen system information.

Battery charging (AC cord connected)	Battery in use	Remaining battery charge
		80% or more
		60% or more, but less than 80%
		40% or more, but less than 60%
		20% or more, but less than 40%
		Less than 20%

2

Product summary

2.1 Indications for Use

This ARIETTA 65 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Spec.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Card.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Other (spec.) - Gynecological, Other (spec.) - Wound, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), Peripheral vessel, clinical applications.
The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Power Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging).

⚠ 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 filters (HI REZ) that modify the characteristics of each echo filter are 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, or High-Resolution Power Doppler (eFlow) Mode for the color Doppler mode, according to your needs.

The 4 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.
- 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
	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	Qualified persons
External dimensions	Width: 533 mm ±10%
	Depth: 742 mm ±10% (when the monitor arm is folded)
	Height: 1265 mm to 1635 mm
Weight	85 kg ±10% (main unit only), 115 kg ±10% (with all options included)
Service life	7 years

Display modes

B mode
M mode
D mode
Color Doppler mode

Viewing monitor

Monitor (LCD)	21.5 inches 1600 × 900
Monitor movement	Rotation: Depending on the structure of the arm joint, the monitor can rotate a reverse 180°.
	Tilt: 30° upward and 10° downward
	Up and down movement: 120 mm

Input/output specifications

Video input/output	DVI-D
	S VIDEO (Y/C)
Audio input/output	Audio L/R
Network	LAN
USB	USB A Receptacle (USB2.0)

Recorder

Black and white digital printer
Color digital printer
HD 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 gain: 63.5 dB variable
	Close distance correction gain: Software TGC supported
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: 195 degrees (depending on the probe)
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
	Enhancement processing (only M): 4 levels (including Off)
	Persistence (only B): 8 levels (including Off)
	PRF (B): 3 levels
	AGC: 8 levels (including Off)
	Graymap: 10 types
	Speed of sound correction: Available
	Adaptive imaging (only B): NNR (4 types, 4 levels), HI REZ (2 types, 8 levels)
	Grayscale enhancement: 4 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	±534.72 cm/s to ±1.26 cm/s
Width of the sample volume	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 Flow 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	±401.08 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 10 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%

Doppler Measurement	Accuracy
Heart rate	±1 BPM or 5%

2.3.1 Power supply conditions

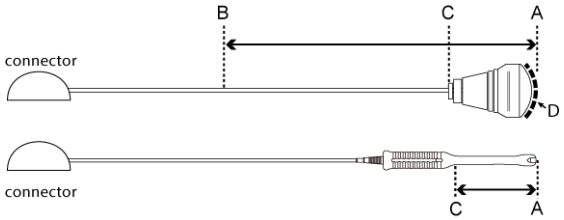
Power supply voltage	100 V to 120 V	
Electrical power frequency	50/60 Hz	
Power consumption	No more than 750 VA	
Internal battery	Lifespan	500 cycles (recommended)

2.3.2 Ambient conditions

Environment	Operating Conditions	Storage conditions or transport conditions (when packed)
Ambient Temperature	50°F to 104°F	14°F to 122°F
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.



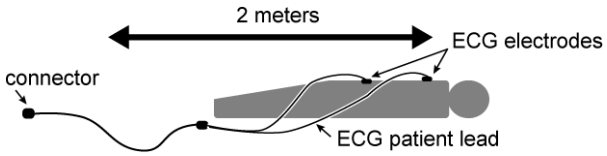
The upper figure is an example of a probe for body surfaces and intra-operative use. The lower figure is an example of a body cavity probe.

Probe application	Applied part	Parts handled as applied parts	Length between B and C
Body surface	Ultrasonic irradiation area (D)	Between A and B	100 cm

Probe application	Applied part	Parts handled as applied parts	Length between B and C
Intra-operative	Ultrasonic irradiation area (D)	Between A and B	20 cm
Inside body cavities	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.)

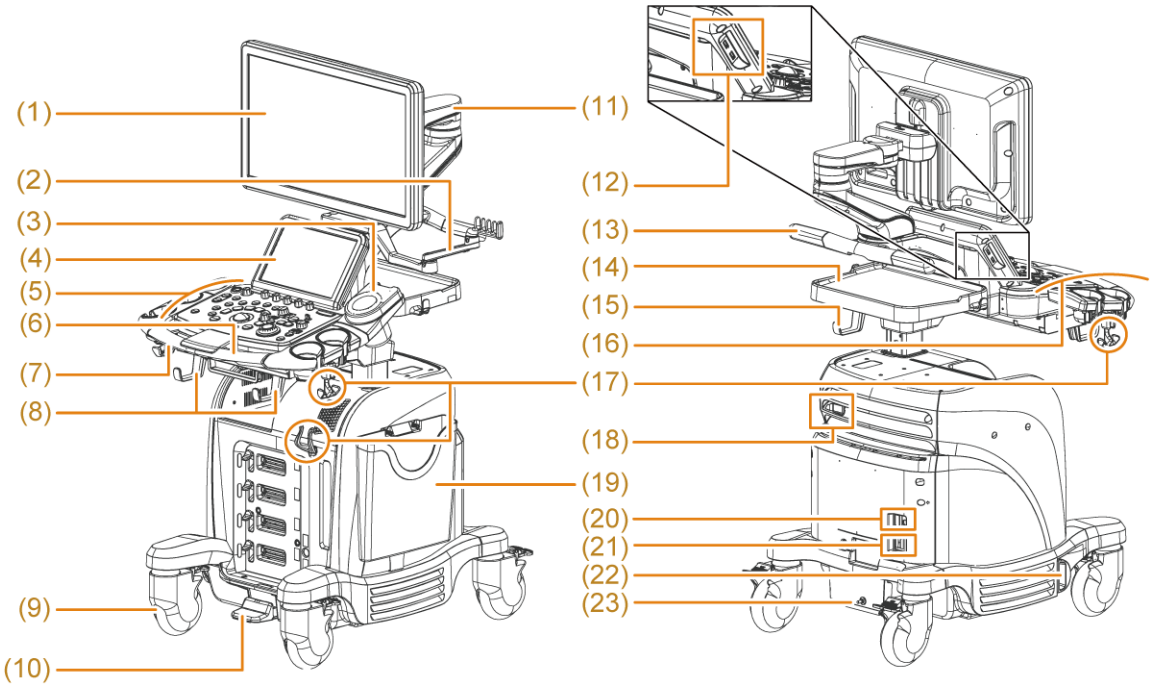
  Example: ECG



- 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-2345*: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

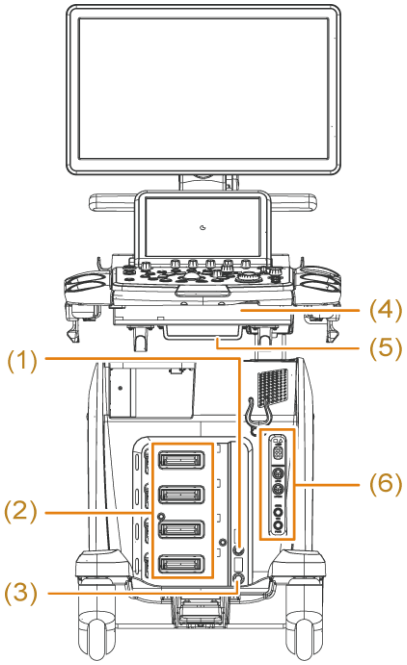
2.4 Part names

I) Device appearance



(1)	Viewing monitor	(11)	Monitor arm
(2)	Flexible hook (optional)	(12)	USB (2.0) connectors (×2)
(3)	Gel Warmer	(13)	Handle
(4)	Touch panel	(14)	Storage Tray
(5)	Operation panel	(15)	Hook (for the power cable, or for foot switch MP-2819*)
(6)	Rotation lever for the operation panel	(16)	Probe holder
(7)	Operation panel handle	(17)	Cable hook
(8)	Cable hook	(18)	LAN cable connector
(9)	Casters	(19)	Side Tray (optional)
(10)	Operation panel height adjustment pedal	(20)	Battery power-supply switch (optional)
		(21)	Breaker
		(22)	Filter
		(23)	Equipotential terminal

II) Device appearance (Front)



(1) Independent probe connecting unit (optional)

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

(3) Foot switch connector

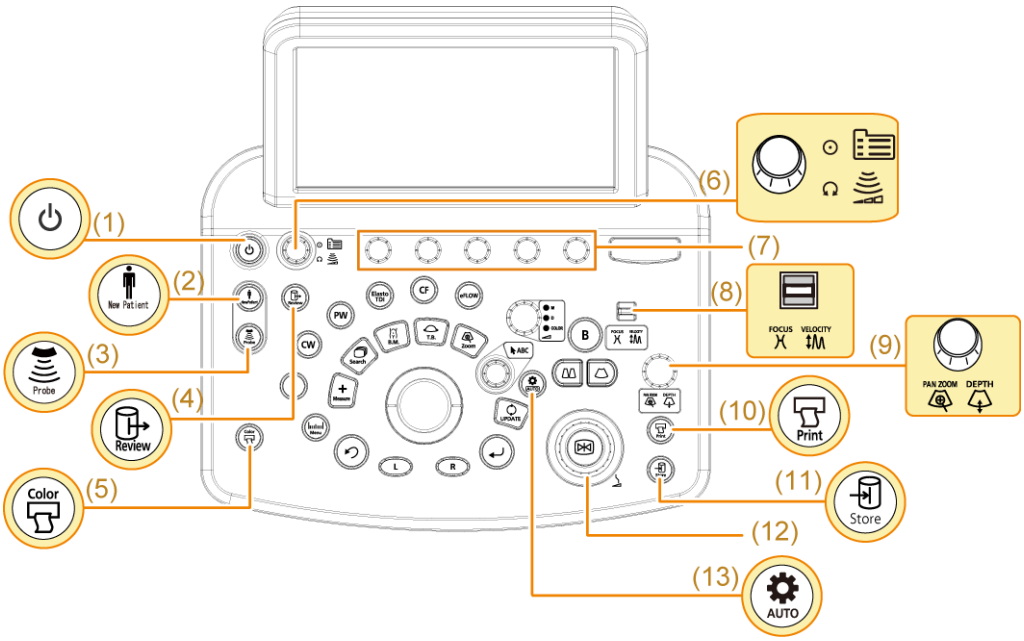
(4) Keyboard Tray (optional)

(5) ECG clip bar

(6) Physiological signal unit (optional)

III) 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) [New Patient] key

(3) [Probe/Preset] key

(4) [Review] key

(5) [Color Printer] key

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

(7) Rotary encoder

(8) [FOCUS/VELOCITY] paddle switch

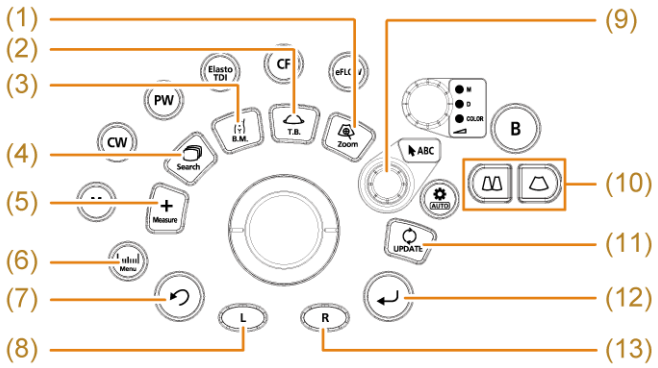
(9) [PAN ZOOM] key
[PAN ZOOM/DEPTH] rotary encoder

(10) [Print] key

(11) [Store] key

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

(13) [Auto-optimizer] key



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) [UNDO] key

(8) [L] key

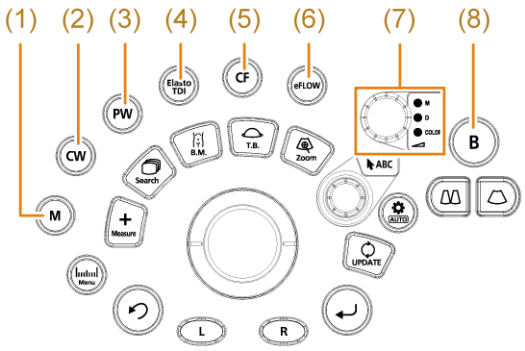
(9) [Pointer] key
[Pointer] rotary encoder

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

(11) [Update] key

(12) [Enter] key

(13) [R] key



(1) [M] key

(2) [CW] key

(3) [PW] key

(4) [Elasto/TDI] key

(5) [CF] key

(6) [eFLOW] key

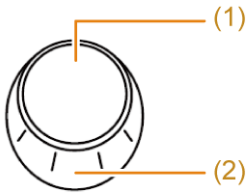
(7) [MULTI GAIN] rotary encoder

(8) [B] key

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

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 pull the power plug out of 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 data items to be deleted is zero or if you are using the system with the internal battery.
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.
Ignore	Shuts the system down without waiting for remaining jobs to be completed. If you select this method, the following message appears: "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 a message is displayed in the Auto Image Delete screen
   The message disappears when the data is deleted.
   If you want to interrupt the processing that deletes the data, press the [Enter] key.
   NOTE: The message is not displayed if you are using the system with the internal battery.

3.1.2 Disconnecting the power

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.
3. Turn the battery power-supply switch to Off if the internal battery (optional) is installed.
   NOTE: If the battery power-supply switch is set to On, power is supplied from the internal battery even if the power plug is removed from the hospital-grade outlet.

Reference information

3.1.1 Shutdown on page 52
3.12.2 Stopping use of the internal battery on page 97

3.1.3 Moving the system

CAUTION

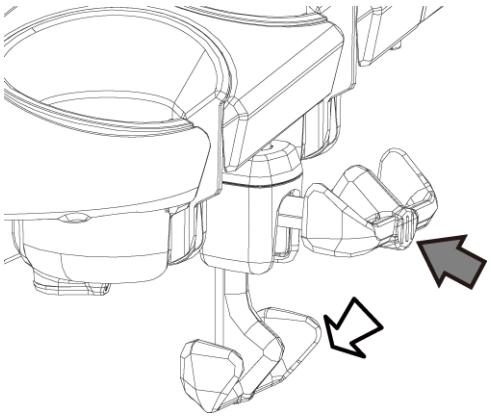
Take care not to bump the system or its probes against other equipment, walls, columns or doors in passages when moving it to a different location. Take great care when moving the system a long distance, or on a slope or steps.
Take great care when moving the system over steps or uneven surfaces.
Ignoring this instruction might result in the probe falling from the probe holder and being damaged.
Also, an object might fall from the tray and be damaged.
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.

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

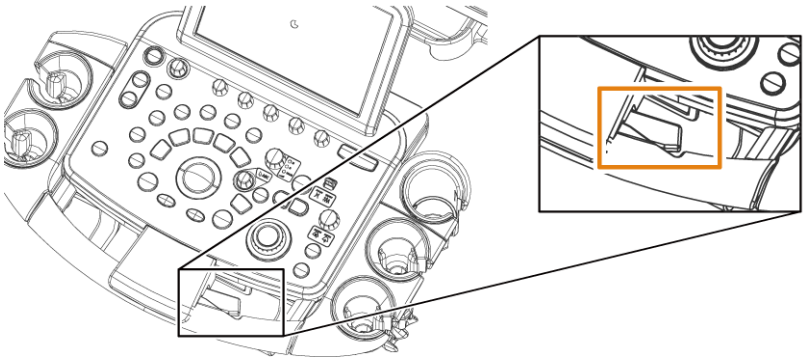
Keep the system away from moisture when moving it.
Ignoring this instruction might result in short circuits or electric shock.

Procedure

1. Shut down the system and prepare it for movement.
   NOTE: If the internal battery (optional) is installed, you can move the system without shutting down the system. Make sure that the battery power-supply switch is turned On and is fully charged.
   NOTE: If the battery power-supply switch is turned On, the system consumes battery power even if you remove the power plug after the system is shut down. If you move the system and then start it by using the internal battery, take note of the remaining battery charge.
   Power cable
   Unplug the power plug from the hospital-grade outlet, gently coil the power cable, and place the cable on the power cable hook 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 probe cables on the hook next to the Storage Tray and adjust their length.
   NOTE: If cables are hanging down around the casters, the cables might become trapped while you are moving the system. The cables might then become disconnected and the system might tip over.
   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 a Keyboard Tray (optional), push the Keyboard Tray until it clicks, and then use the lock lever on the back of the operation panel to secure the Keyboard Tray.
2. Lower the cable hook.
   If the cable hook next to the probe holder is lifted up
   To lower the cable hook, press the button.

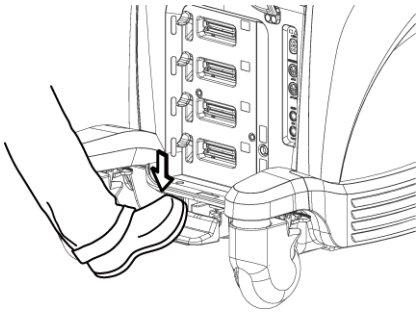


3. Turn the operation panel so it is facing the front.
   Hold the rotation lever for the operation panel, and turn the operation panel toward the front.
   If you turn the operation panel to the front without holding the lever, the direction of the operation panel will be locked.



Lever position

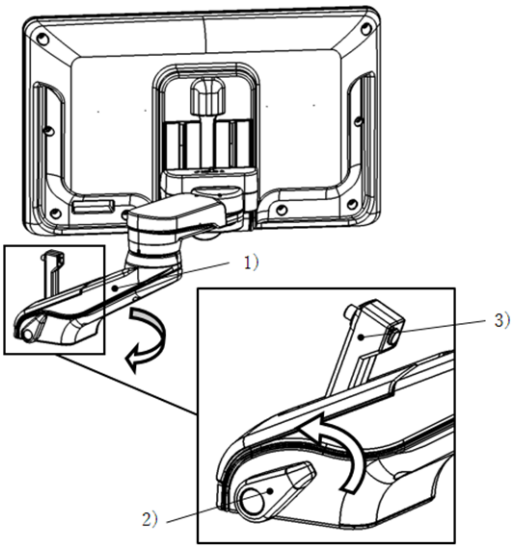
4. Move the operation panel to the lowest possible position.
   While holding the operation panel handle and pressing the operation panel height adjustment pedal with your foot, press down on the operation panel.



Press the operation panel height adjustment pedal

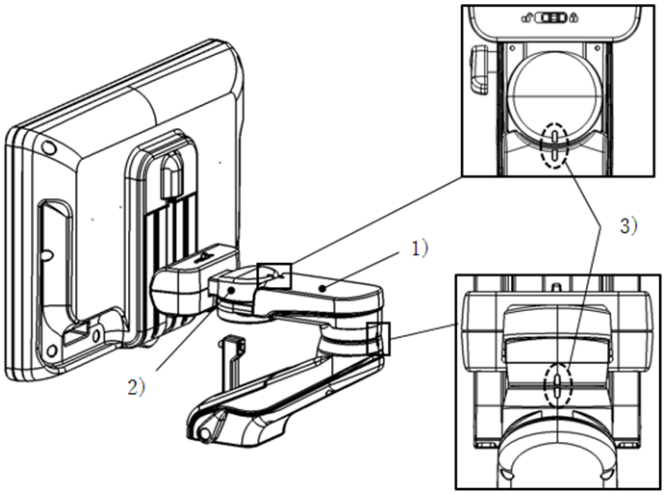
NOTE: If probe cables are hanging down around the casters, place the probe cables on the cable hook next to the Storage Tray and adjust their length.

5. If the flexible hook (optional) is used, rotate the arm part towards the back until it stops, and then fold it.
6. Fix the monitor in place.
   NOTE: This prevents the monitor from moving while the system is moved.
   a. Press and (at the same time) turn the lock lever to raise the lock arm.
   b. Turn the first arm toward front
      The first arm is secured.



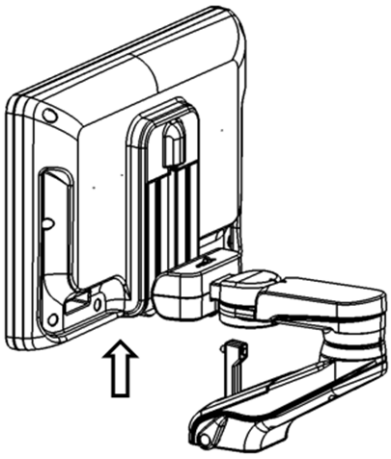
1) Arm #1
2) Lock lever
3) Lock arm

c. Adjust the positions of the marks, so that the second and third arms are parallel to the first arm.

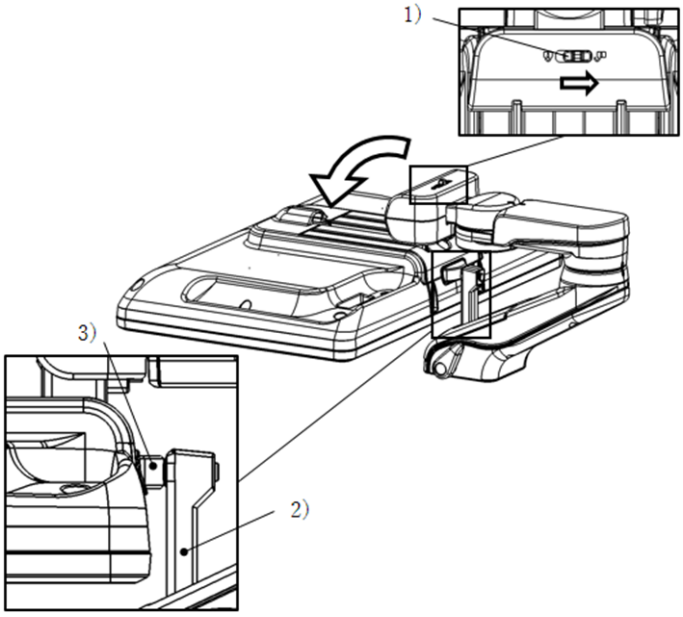


1) Second arm
2) Third arm
3) Marks

d. Set the monitor to the highest position.

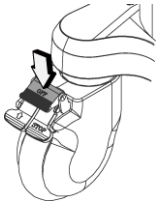


e. Slide the tilt lever, and then tilt the monitor forward.
If the position of the lock is not aligned with the position of lock receiver:
Adjust the position of the monitor so that the pin on the lock arm is inserted into the lock receiver.



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

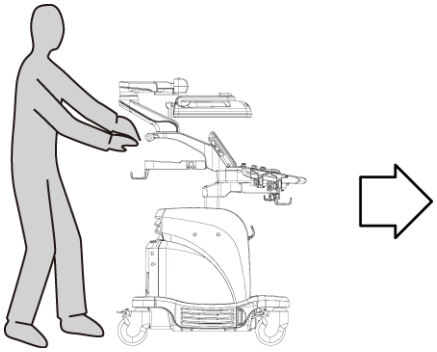
7. Unlock the casters.
Depress the lock release pedals.



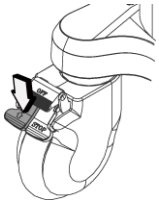
Step in the direction of the arrow to release the casters.

8. 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. Moving the system without using the handle at the back of the system might damage the system.
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

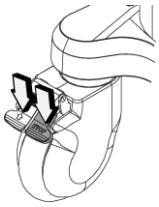
Do not use this system in a flammable atmosphere.
Use of this system in a flammable atmosphere might cause an explosion.

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

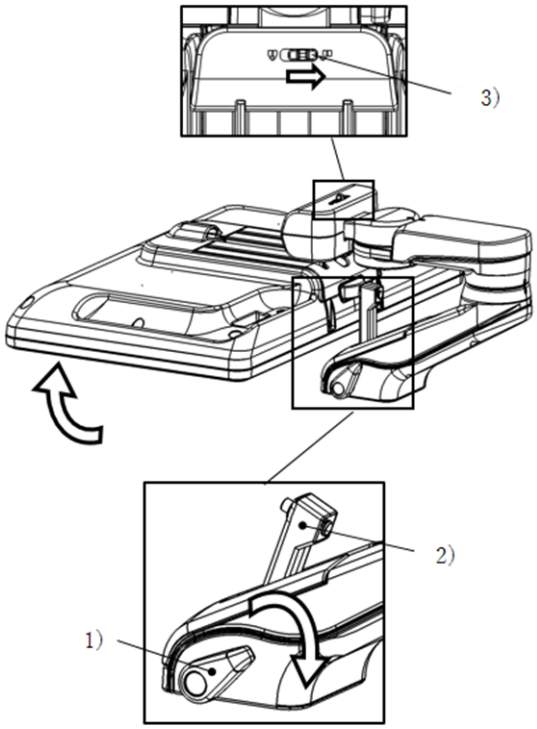
1. At the installation location, make fine adjustments to the position of the system.
2. Once the position and orientation of the system are fixed, lock the casters.
   Depress the lock pedals for the front and rear wheels.



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.
4. Release the monitor lock.



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

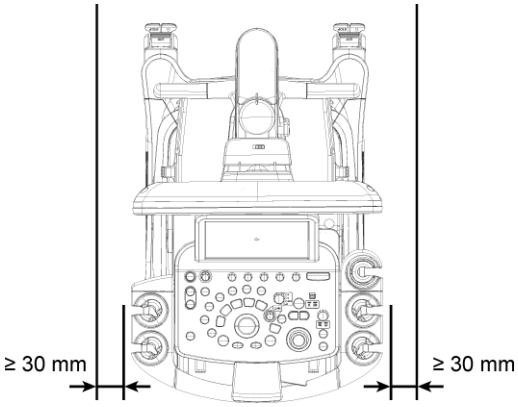
a. Slide the tilt lever, and then straighten up the monitor.

b. Press and (at the same time) turn the lock lever to press down the lock arm.

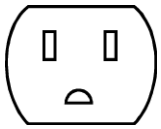
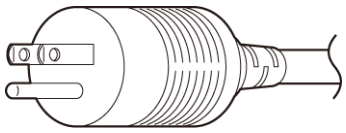
3.1.5 Installation conditions

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 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 and turn the battery power-supply switch (optional) to Off.
- 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 *2.3.2 Ambient conditions* on page 44 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)
Power outlet configuration	
Power plug configuration	
Cable length	3.5 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.

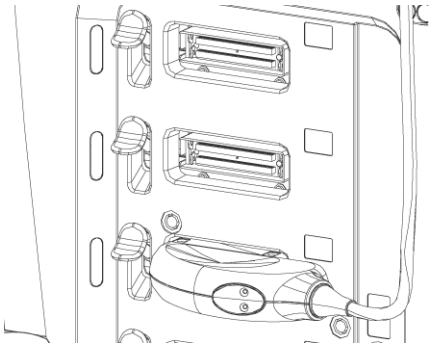
Prior confirmation

For the probe, check the following:

- Make sure the probe is supported by the system.
- Make sure that there is no ultrasound gel or dust on the connector on the probe side.

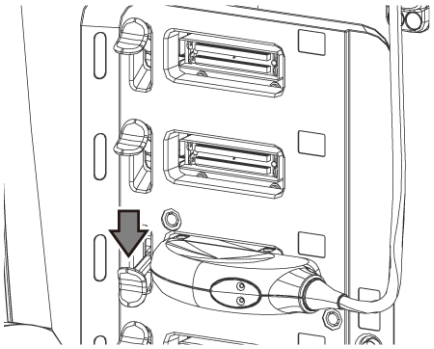
Procedure

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



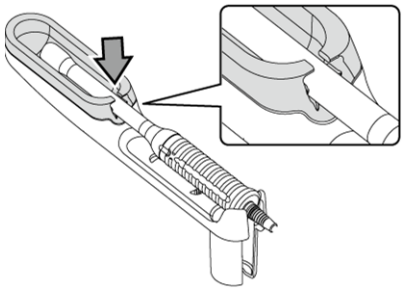
Example of connecting an electronic probe

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

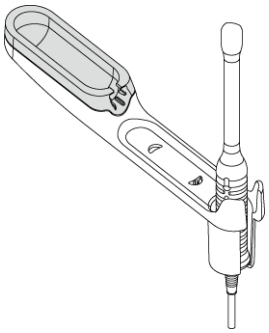


NOTE: Make sure the probe is secured.

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 EU-9187* and EU-9198* are 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 until the probe connector clicks.

3.2.2 Disconnecting a probe

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) 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.

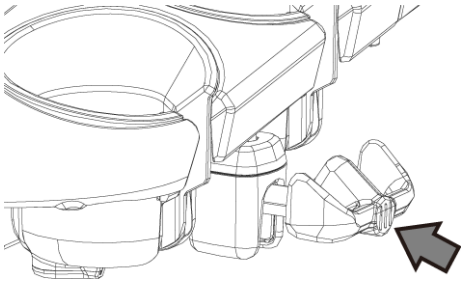
3.2.3 Adjusting the positions of the cable hooks

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 system 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 system is used.
Press the button, and while pressing it, raise or lower the cable hook.

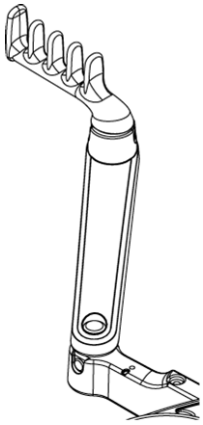


Position of the button

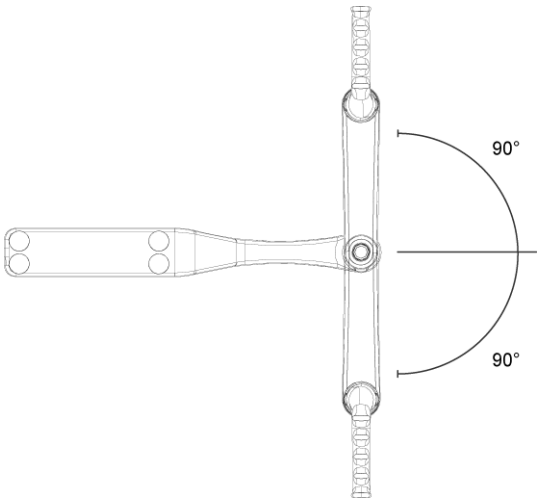
(2) The flexible hook

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

The flexible hook



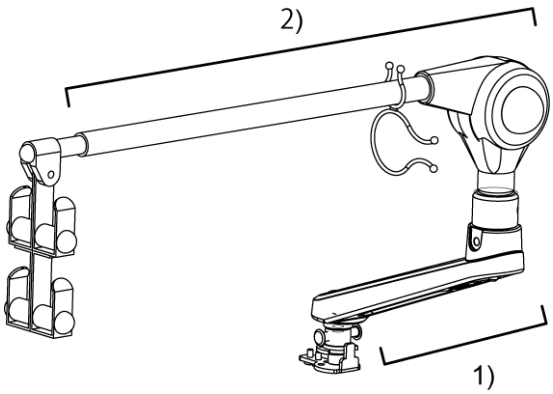
Movable range of the flexible hook



Horizontal: 180°

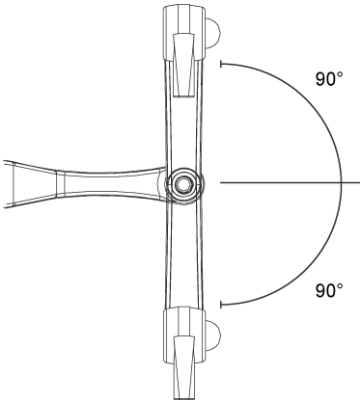
(3) The flexible hanger

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



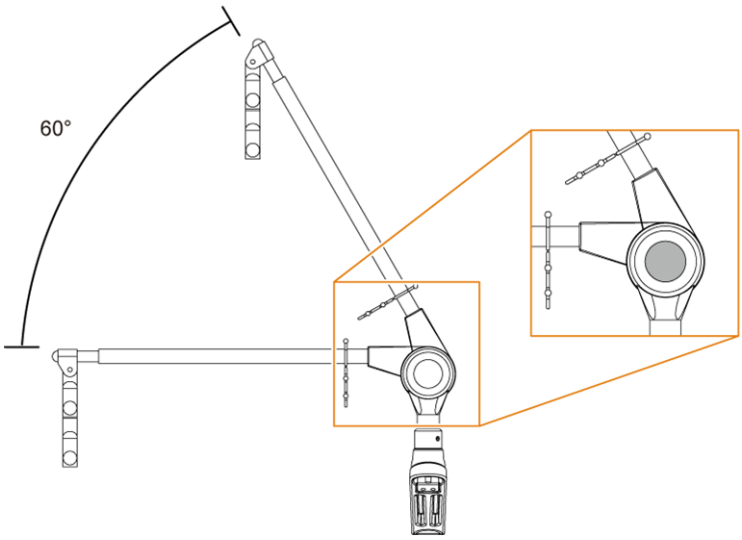
The flexible hanger

Movable range of part 1)



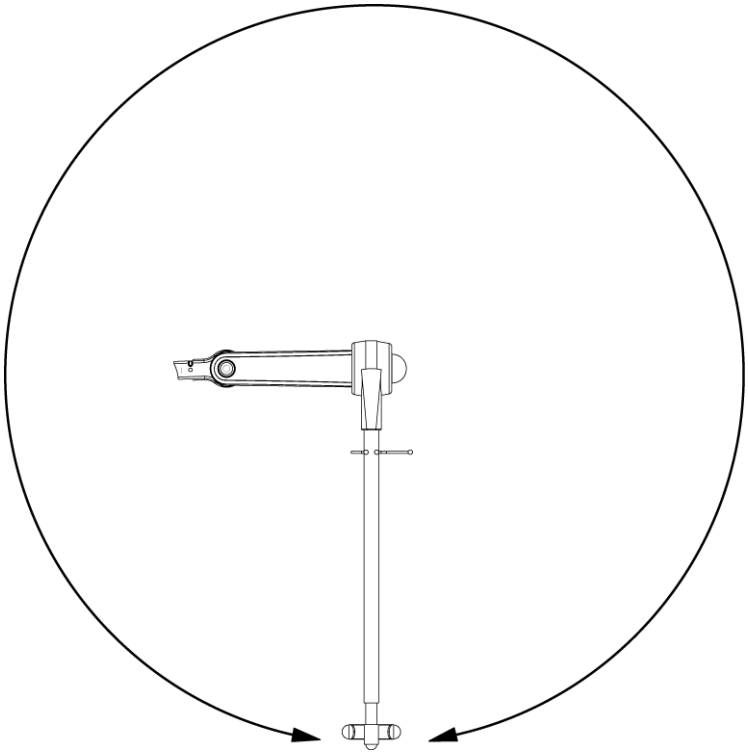
Horizontal: 180°

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-ARIETTA65* 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.

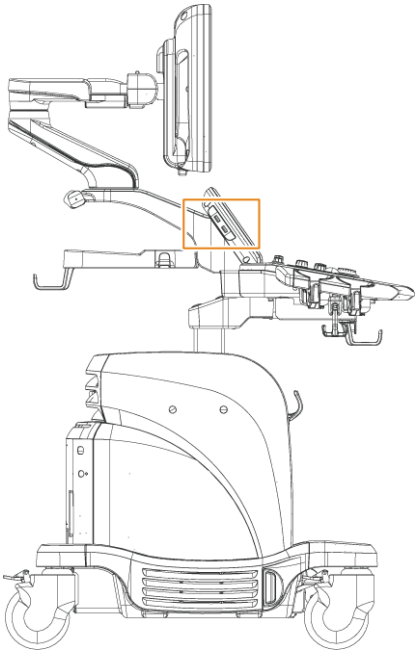
- Insert the plug of the phonocardiographic transducer firmly into the PCG connector.
  NOTE: The phonocardiographic transducer is fragile, so do not drop it or strike it against other objects.
- Connect the cable from an external physiological signal monitor.
  NOTE: Before connecting the cable from an external physiological signal monitor to the system, read *1.5 Precautions for use with other medical devices* on page 30 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

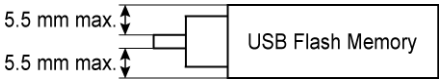
3.4.1 Connecting to a USB connector

There are USB connectors at the following locations:



Side of the operation panel (two USB 2.0 connectors)

- Use a stick-type USB flash drive whose height to the top or the bottom from the connector 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.

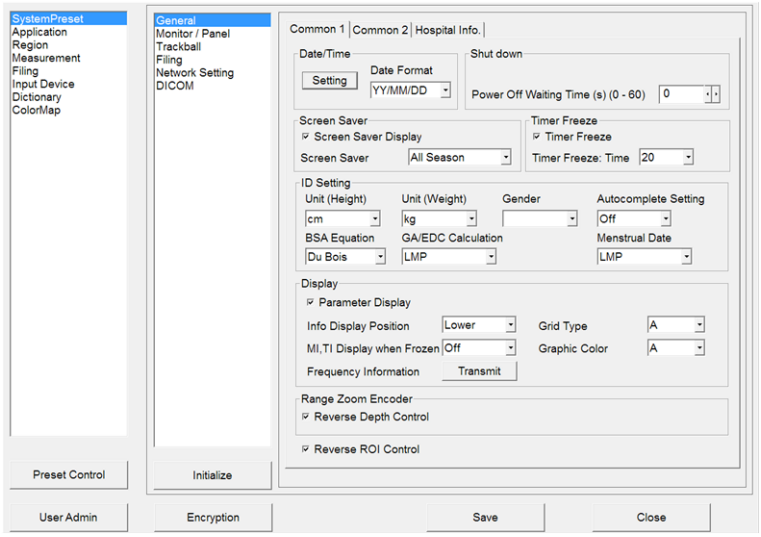
3.4.2 Encrypting USB connection media

Use BitLocker functionality to encrypt USB connection media.
NOTE: When you connect the encrypted USB media to a device such as a computer, a window appears prompting you to enter a password. To access the USB media, enter the password that was set when the USB media was encrypted.
NOTE: If you forget the password that was set when the USB media was encrypted, you will be unable to access the USB media. Take care not to forget this password.

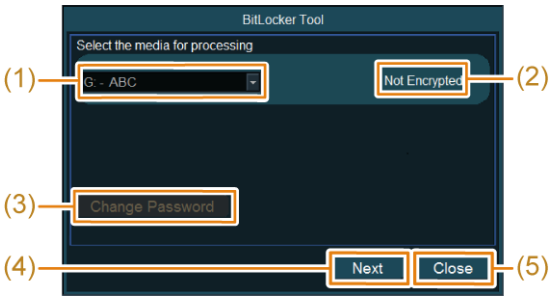
(1) Encrypting USB connection media

Procedure

1. Connect the USB media to a USB connector.
2. Press the [Probe/Preset] key and select [Preset Setup] from the touch panel.



3. Select [Encryption].
   A warning message appears.
4. Select [Next].
   A window for media selection appears.



(1) Dropdown list
Select the USB connection media that you would like to encrypt.

(2) Encryption status
Use BitLocker functionality to encrypt USB connection media.
Not Encrypted: The target USB connection media is not encrypted.
Encrypted: The target USB connection media is encrypted.
Decrypted: The target USB connection media has been decrypted.

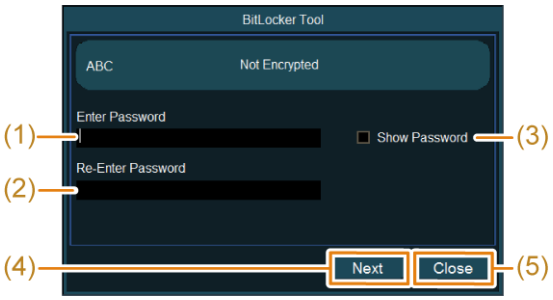
(3) [Change Password]
A window for changing the password appears.

(4) [Next]
The items in the window are displayed according to the status of the USB connection media.
When the encryption status in (2) is Not Encrypted, the password input window appears.
When the encryption status in (2) is Encrypted, the decrypt/disable processing window appears.
When the encryption status in (2) is Decrypted, the disable processing window appears.

(5) [Close]
Closes the BitLocker Tool screen.

5. Select from the dropdown list the USB connection media that you would like to encrypt, and then select [Next].

The password input window appears.



(1) Enter Password
Enter the password.

(2) Re-Enter Password
For verification purposes, re-enter the password that you entered.

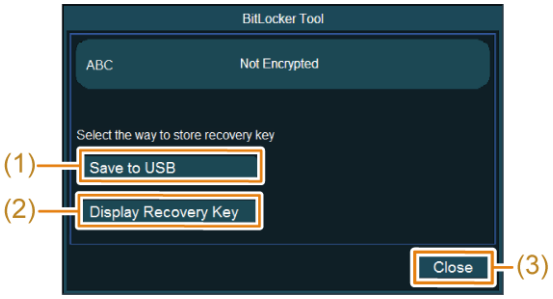
(3) Show Password
Select the check box to show the character strings in the password fields.

(4) [Next]
Move to the window for selecting how to store the recovery key.

(5) [Close]
Closes the BitLocker Tool screen.

6. Enter your password in the Enter Password field.
NOTE: Enter a password consisting of 8 to 30 characters.

7. Re-Enter your password in the Re-Enter Password field, and select [Next].
The window for selecting how to store the recovery key appears.



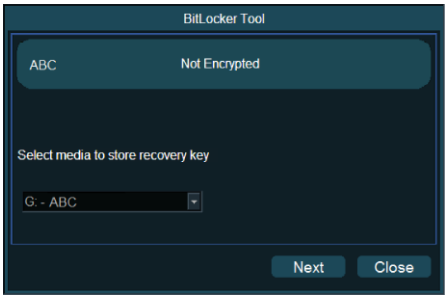
(1) [Save to USB]
Move to the window for selecting the recovery key storage media.

(2) [Display Recovery Key]
Move to the recovery key display window.

(3) [Close]
Closes the BitLocker Tool screen.

8. Select how to store the recovery key.
Storing the recovery key on a USB connection media

a. Select [Save to USB].
The window for selecting a recovery key storage media appears.

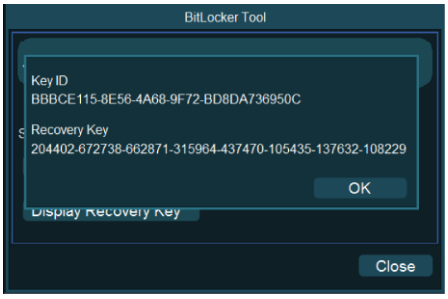


b. Select from the dropdown list the USB connection media on which the recovery key is to be stored.
NOTE: The USB connection media on which the recovery key is to be stored must be provided separately by the user. The recovery key cannot be stored on a USB connection media that uses encryption.
NOTE: If the USB connection media on which the recovery key is to be stored is not authenticated, the media is not displayed in the dropdown list. Authenticate the USB connection media, and then select it from the dropdown list again.

c. Select [Next].
The recovery key is stored, and a window that is ready for processing appears.
NOTE: If the recovery key is stored on a USB connection media, the recovery key will be stored in the root folder of the USB connection media.

Recording the recovery key as a memo

a. Select [Display Recovery Key].
The recovery key window appears.



b. Record the Key ID and the Recovery Key as memos.
NOTE: If you lose the memo on which the recovery key is recorded or forget your password, the encryption of the encrypted USB connection media cannot be decrypted or disabled.

c. Select [OK].
A window that is ready for processing appears.

9. Select [Proceed].
The encryption processing starts and a window appears indicating that the processing is in progress. When the progress bar reaches 100%, encryption processing is complete.
NOTE: Do not remove the USB media while encryption is in process. If you do, the encryption processing might not end normally, and the media might become unstable.
NOTE: Depending on the amount of space on the USB media that is being used, this processing might take time.

10. Select [Close].

(2) Using encrypted USB connection media

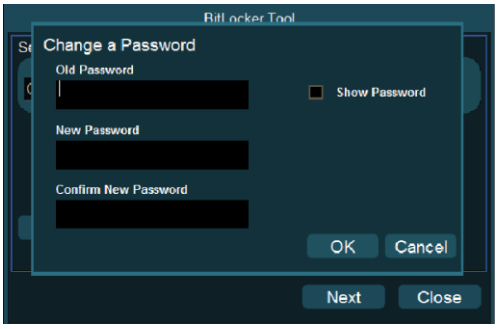
NOTE: This equipment cannot be used to decrypt USB connection media that was encrypted in XTS-AES mode.

Procedure

1. Connect the USB media to a USB connector.
2. Press the [Probe/Preset] key and select [Preset Setup] from the touch panel.
3. Select [Encryption].
   A warning message appears.
4. Select [Next].
   Changing the password

   a. Select from the dropdown list the USB connection media for which you would like to change the password.

   b. Select [Change Password].
   The Change a Password window appears.



   c. Enter the old password in the Old Password field.

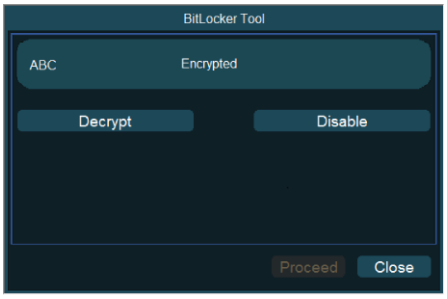
   d. Enter the new password in the New Password field.

   e. Enter the new password in the Confirm New Password field.

   f. Select [OK].
   The new password is applied.

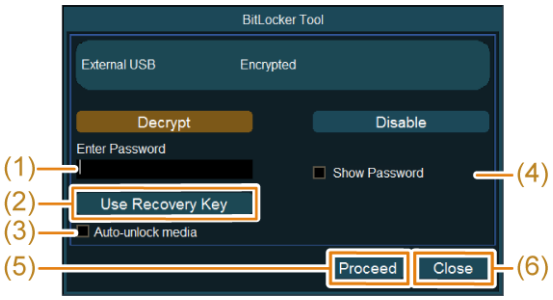
   A window for media selection appears.

5. Select from the dropdown list the USB connection media that you would like to encrypt, and then select [Next].
   The window for processing encryption appears.



6. Select [Decrypt].

The window for decryption processing appears.



(1) Enter Password field
Enter the password necessary for decryption.

(2) [Use Recovery Key]
Move to the recovery key input window.

(3) Auto-unlock media
If you select this check box and decrypt the media, the USB connection media will be decrypted automatically the next time it is connected.
NOTE: Automatic decryption only takes place if a connection is established to a device that is already decrypted.
NOTE: If decryption processing is performed by using the recovery key, the automatic decryption function cannot be used.

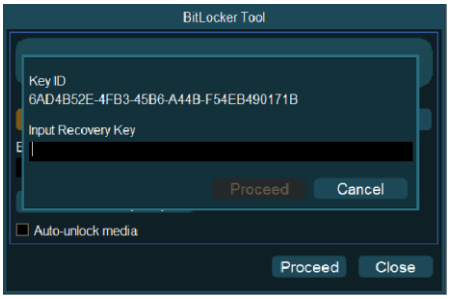
(4) Show Password
Select the check box to show the character strings in the password fields.

(5) [Proceed]
Start processing.

(6) [Close]
Closes the BitLocker Tool screen.

7. Enter your password in the Enter Password field, and then select [Proceed].
<u>If you forget the password</u>
If you forget the password necessary for decryption, use the recovery key to decrypt the USB connection media.

a. Select [Use Recovery Key].
The window for inputting the recovery key appears.



b. Check the Key ID, and then enter the corresponding input Recovery Key in the Input Recovery Key field.

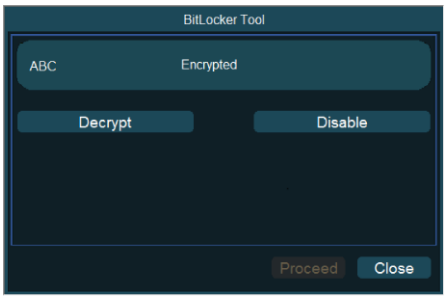
c. Select [Proceed].
Decryption processing starts and the processing window appears. When the progress bar reaches 100%, decryption processing is complete.

8. Select [Close].

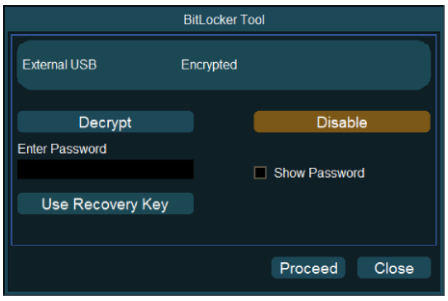
(3) Disabling the encryption of USB connection media

Procedure

1. Connect the USB media to a USB connector.
2. Press the [Probe/Preset] key and select [Preset Setup] from the touch panel.
3. Select [Encryption].
   A warning message appears.
4. Select [Next].
   A window for media selection appears.
5. Select from the dropdown list the USB connection media that you would like to encrypt, and then select [Next].
   The window for processing encryption appears.



6. Select [Disable].
   The window for disabling decryption processing appears.



7. Select [Proceed].
   The processing to disable encryption starts, and the processing window appears. When the progress bar reaches 100%, the processing to disable encryption is complete.
8. Select [Close].

(4) Messages

Messages	Status, Cause	Countermeasure
Removable media is not ready.	The USB connection media is not authenticated.	Authenticate the USB connection media.

Messages	Status, Cause	Countermeasure
Removable media is not connected.	The media displayed in the dropdown list was removed.	Check whether the USB connection media is connected. 1. Connect the media to a USB connector. 2. Select [Next].
Encrypted removable media cannot be used.	An attempt was made to store a recovery key on a USB connection media that is encrypted, or for which an encryption function is activated.	Store the recovery key on a USB connection media that is not encrypted. In addition, provide a USB connection media that is separate from the aforementioned encrypted media. 1. Connect a non-encrypted USB connection media to a USB connector. 2. From the dropdown list, select the connected USB connection media. 3. Select [Next].
Free disk space not available.	There is not enough free space available on the USB connection media.	Check the amount of free space available on the USB connection media. 1. Connect to a USB connector a USB connection media that has enough free space available. 2. Select [Next].
Removable media is not accessible.	An attempt was made to access an external media on which read only or write protection is applied.	Check the write protections applied to the USB connection media. 1. Connect to a USB connector a USB connection media for which write protection was disabled. 2. Select [Next].
Media selected for encryption and removable key storage is same. Please select different media.	An attempt was made to store the recovery key on a USB connection media that is to be encrypted.	Check the USB connection media. 1. Select [OK]. 2. From the dropdown list, select another USB connection media.
Incorrect Recovery Key entered.	The entered recovery key is incorrect.	Check the recovery key. 1. Enter the correct recovery key. 2. Select [Proceed].
Password does not match.	The entered password and confirmation password do not match.	Check the password. 1. Enter the correct password and the confirmation password. 2. Select [OK] or [Next].
Minimum password length is 8 characters.	The entered password contains less than eight characters.	Check the password. 1. Enter a password that contains eight characters or more. 2. Select [OK] or [Next].
Password cannot be empty.	No password was entered.	Check the password. 1. Enter a password that uses eight or more characters. 2. Select [OK] or [Next].

Messages	Status, Cause	Countermeasure
Password changed successfully.	The password is now changed.	The password was changed successfully. 1. Select [OK].
Operation is in progress. Don't remove the media or power off.	An operation is in progress.	Do not remove the USB connection media, or power off the equipment. Wait for the processing to finish. 1. Select [Next].
Encrypting partially encrypted drive. Don't remove the media or power off.	Decryption is performed on a USB connection media and for which encryption operation was ended forcefully.	Encryption is not complete. 1. Retry the operation to encrypt the USB connection media. 2. Retry the operation to decrypt the media.
Disabling partially disabled drive. Don't remove the media or power off.	Decryption is attempted on a USB connection media for which a disable operation was ended forcefully.	Encryption is not disabled. 1. Retry disabling the USB connection media.
Encryption process completed.	Encryption processing is complete.	1. Select [Close].
Disable process completed.	Disable processing is complete.	1. Select [Close].
Decryption process completed.	Decryption processing is complete.	1. Select [Close].
All configurations need to be done again once tool is re-launched. Do you want to reset the setting?	[Close] was selected on the recovery key storage window. (Options--[Yes]: Ends tool, [No]: Closes the dialog box and returns to the previous screen)	The recovery key was not stored. 1. Select [Yes] to end the operation. 2. Select [No] to return to the previous screen.
Failed to retrieve USB device status.	Processing failed, because the USB connection media was removed during processing, or for other reasons.	Processing did not complete. 1. Select [Close]. 2. Retry the encryption operation.
Failed to generate Recovery Key. Please check Removable media and Restart BitLocker tool.	This message was displayed when tool failed to generate Recovery Key.	1. Press the [Close] button to turn off the BitLocker Tool. 2. Please check removable media which you want to encrypt. If you find some problem, please change another media. Or resolve your problem. 3. After confirmation, please re-try again.

3.4.3 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.

3.4.4 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.

3.4.5 Safety instructions for connecting network devices

This system complies with the electromagnetic compatibility standards for medical electrical equipment (IEC 60601-1-2: Ed.3 or 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
  Refer to "4.3 NETWORK INTERFACES" in "DICOM Conformance Statement".
- Configuration required by an IT network incorporating the PEMS
  Refer to "4.3 NETWORK INTERFACES" in "DICOM Conformance Statement".
- 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".

3.4.6 Precautions when connecting to a robotic surgical unit for surgical procedures

To connect to a medical device that requires an analog video signal, use the Y/C output.
Make sure that the robotic surgical unit for surgical procedures is insulated by using optical cables.

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
- 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
   Free space on the hard disk has run low.
   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.

3.6.1 Turning on encrypted equipment

If the storage of the equipment is encrypted, decrypt it by using the password or the Start-Up Key.

NOTE: The recovery key is saved to the root folder of the media.
NOTE: Connect the USB connection media to a USB connector on the side of the operation panel.
NOTE: If you are not sure of the right USB connection media, please contact our office.

(1) Decrypting the storage by using a password

1. Push the [Power] key to powering up the system.
2. Enter the password.
3. Push the [Enter] key on the alphanumeric keyboard.

(2) Decrypting the storage by using a Start-Up Key

1. Connect the USB connection media on which the Start-Up Key is stored to a USB connector.
2. Push the [Power] key to powering up the system.

(3) If the password or Start-Up Key is lost

1. Press the [Power] key to shut down the system.
2. Connect the USB connection media on which the recovery key is stored to a USB connector.
3. Push the [Power] key to powering up the system.

3.7 Checks and inspections after powering up

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

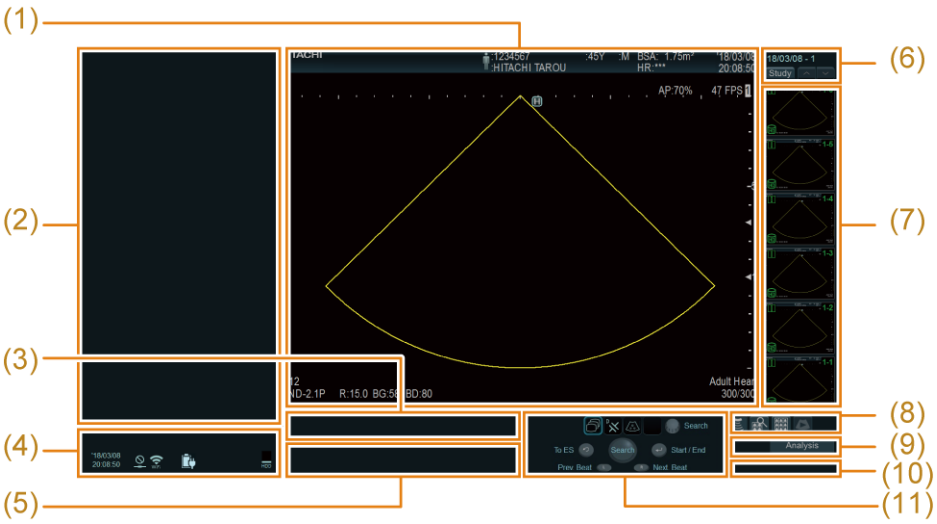
Procedure

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 frequency information. If no probe is connected, the frequency information must indicate "NO PROBE".
     If probe information on the screen does not match the connected probe, or if no probe is connected but the displayed frequency information is not "NO PROBE", 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, the tile display, and the 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

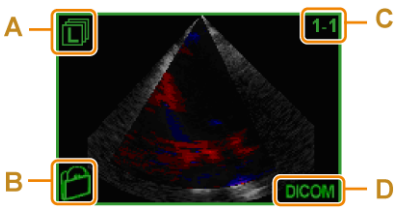
C: Battery charge status (option)

Battery charging (AC cord connected)	Battery in use	Remaining battery charge
		80% or more
		60% or more, but less than 80%
		40% or more, but less than 60%
		20% or more, but less than 40%
		Less than 20%

D: 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

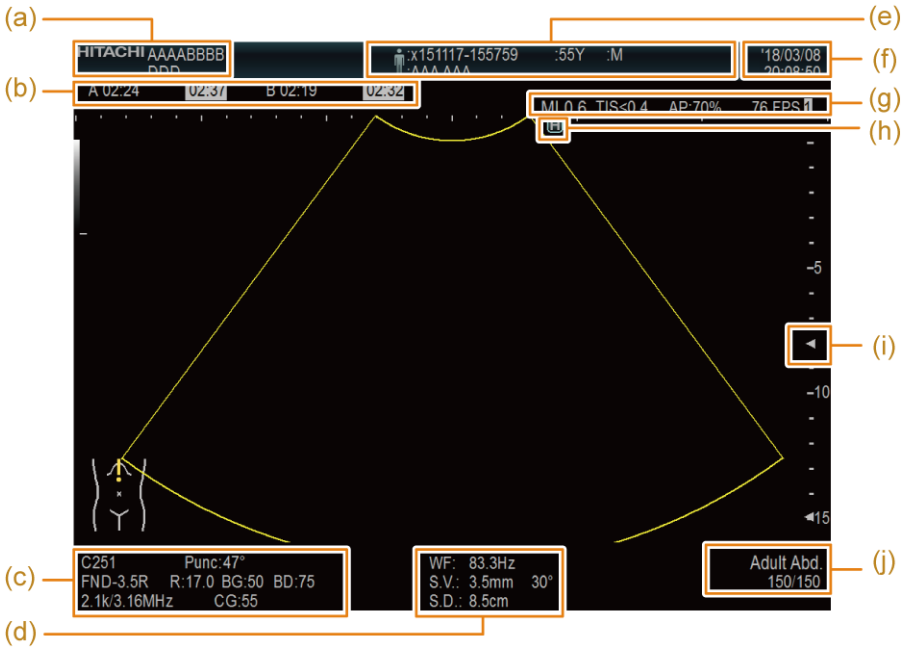
(e) [Pointer] rotary encoder function

(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

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

3.8 Default

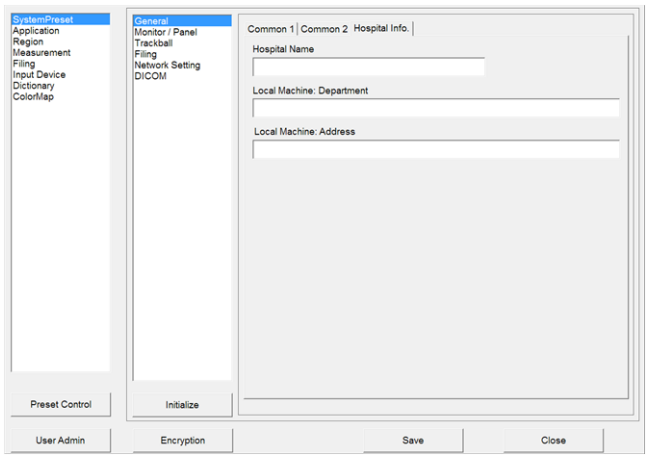
The section explains how to specify the hospital name and network, and how to adjust the date and time.

3.8.1 Setting the hospital name

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

Procedure

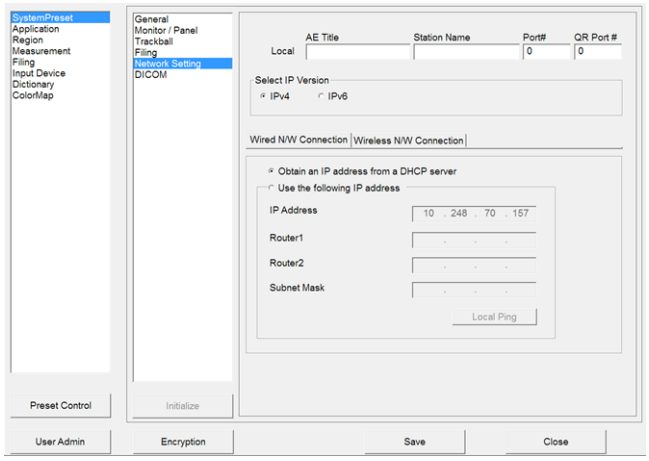
1. Press the [Probe/Preset] key.
2. Select [Preset Setup] on the touch panel.
3. Select [SystemPreset].
4. Select [General].
5. Select the Hospital Info. tab.
6. Enter no more than 40 characters in the Hospital Name field.
7. Select [Save].



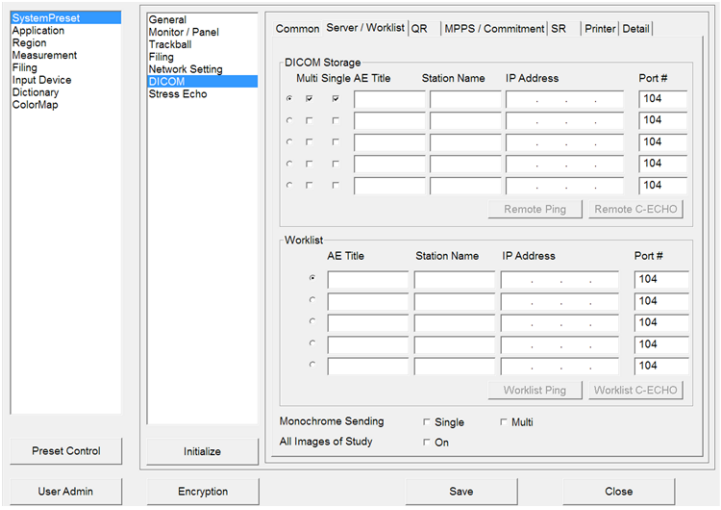
3.8.2 Configuring the DICOM communication settings

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

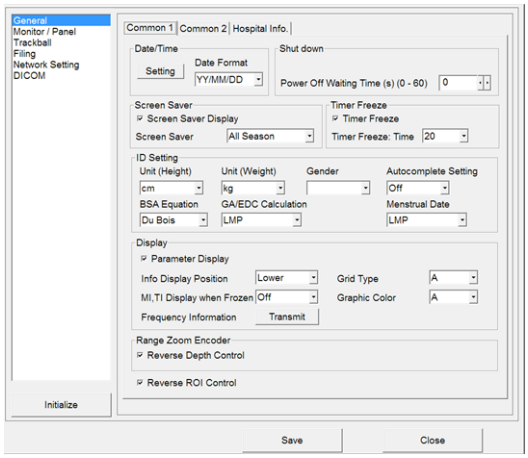
Changes to the IT network might result in new and unacceptable risks, so additional risk management is required.
3.4.5 Safety instructions for connecting network devices on page 77

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] under Date/Time.
"The date and time properties" is 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 you (the operator) You can adjust the brightness of the monitor and the touch panel to match the environment.

CAUTION

When adjusting the position or orientation of the operation panel or monitor, be sure not to pull on the probe cable.
Ignoring this instruction might result in the probe falling from the probe holder and being damaged.

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.

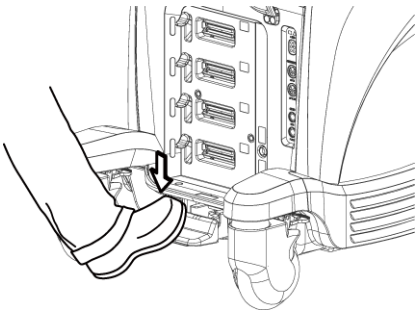
Prior confirmation

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 lock pedal 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.
   Adjusting the height of the operation panel without holding the operation panel handle might damage the system.
   NOTE: If you step on the pedal without holding the handle, the panel might move up or down naturally.



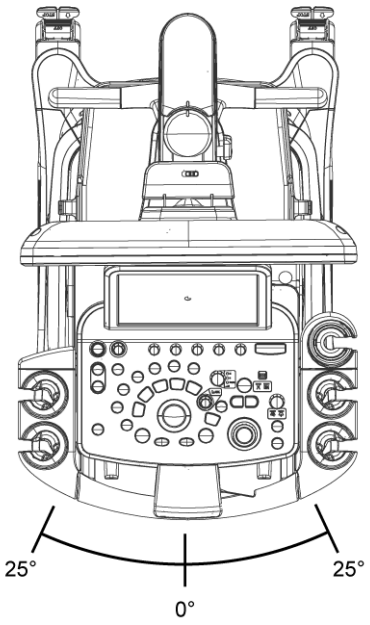
3. Release the up-and-down pedal of the operation panel to lock the height of the operation panel.

3.9.2 Rotating the operation panel

The operation panel can be rotated up to 25 degrees to the right and left.

Procedure

1. If you are using a Keyboard Tray (optional), push in the Keyboard Tray until it clicks.
   NOTE: Be careful not to get your fingers caught between the Keyboard Tray and the operation panel handle.
2. While holding the operation panel handle, pull the rotation lever for the operation panel with your fingertips to rotate the operation panel.
   If you turn the operation panel to the front without holding the rotation lever, the rotation lever returns to its original position and the direction of the operation panel will be locked.



NOTE: Rotating the operation panel without holding the operation panel handle might damage the system.
NOTE: The operation panel might rotate even if you are not holding the rotation lever for the operation panel. This is a design feature, and is not a malfunction.

3.9.3 Adjusting the monitor height or orientation

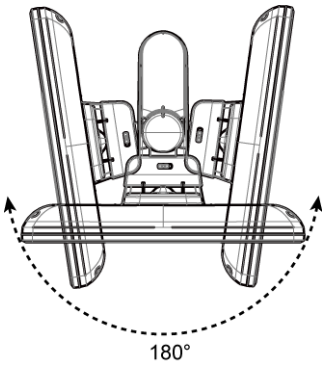
CAUTION

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 any other part.
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.
If you move the monitor, the operation panel might rotate. Be careful of the movement of the operation panel.
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 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.

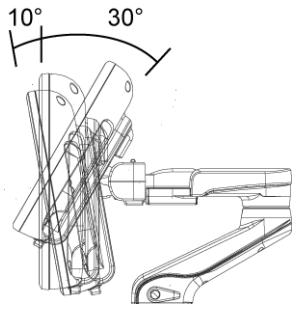
Be careful not to pinch your hands or fingers in the monitor arm when adjusting the location or orientation of the monitor.
Ignoring this instruction might result in pinch-related injuries of hands and fingers.

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.

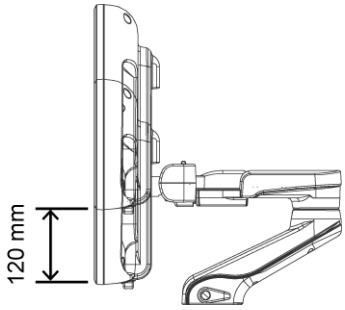


180° left-right

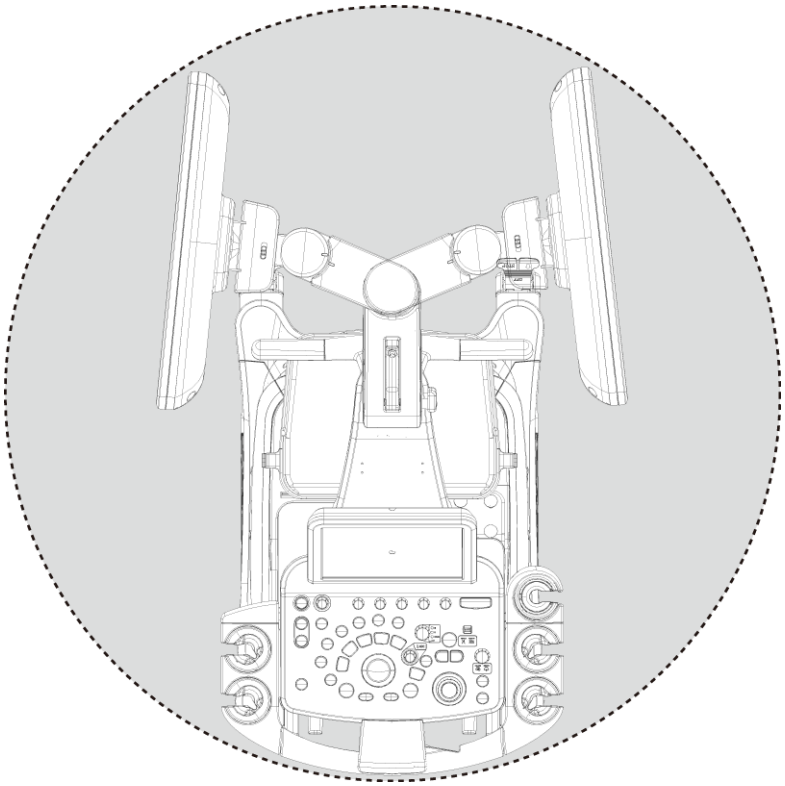


Tilt

10° forward, 30° backward



120 mm up-down



Range of rotation

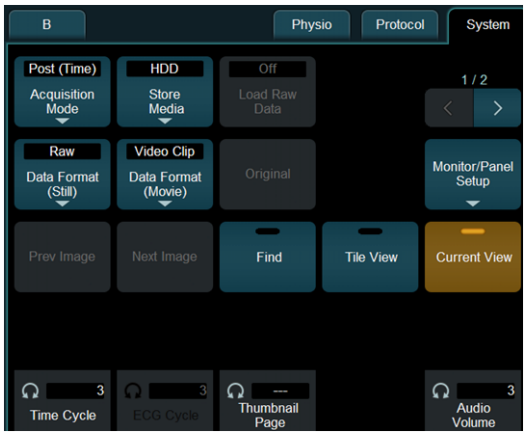
NOTE: Attempts to move the system beyond its movable range could damage it, or cause it to tip over or fall.

NOTE: If you move the monitor, the operation panel might rotate. This is a design feature, and is not a malfunction.

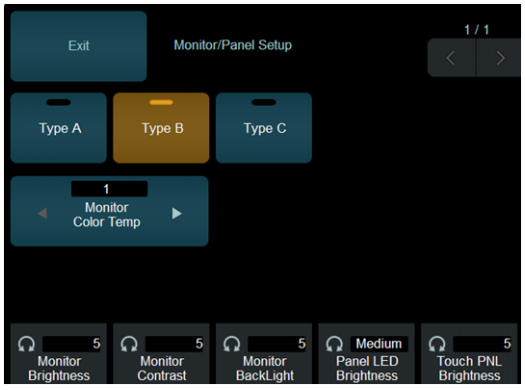
3.9.4 Adjusting the brightness levels of the monitor, operation panel and touch panel.

Procedure

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



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



- Change the brightness levels of the monitor, operation panel, and touch panel at the same time
  Select [Type A], [Type B] or [Type C].
  The settings are changed to reflect the parameters specified for [Type A], [Type B] or [Type C] in the preset ([SystemPreset] > [Monitor/Panel]).
- Adjust the color temperature of the monitor.
  Make adjustments by using [Monitor Color Temp].
  If you use [Monitor Color Temp] to change the color temperature, the brightness is changed. Use [Monitor BackLight] to change the brightness if necessary.
- Adjust the backlight, brightness, and contrast of the monitor.
  Turn the [Monitor BackLight], [Monitor Brightness], or [Monitor Contrast] multi rotary encoder.
  Supplementary information about adjusting monitor brightness
  We recommend using [Monitor BackLight] to adjust the brightness of the monitor.
  There are three menus that you can use to adjust the brightness of the monitor: [Monitor BackLight], [Monitor Contrast] and [Monitor Brightness].
  Making adjustments by using [Monitor Contrast] and [Monitor Brightness] might not result in the best image quality.

Also, if you display saved images in an environment other than this system, the images might not appear the same as on the monitors of the system.

- Adjust the brightness of the operation panel.
  Turn the [Panel LED Brightness] rotary encoder.
- Adjust the brightness of the touch panel.
  Turn the [Touch PNL Brightness] rotary encoder.

3.10 Gel Warmer (optional)

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.

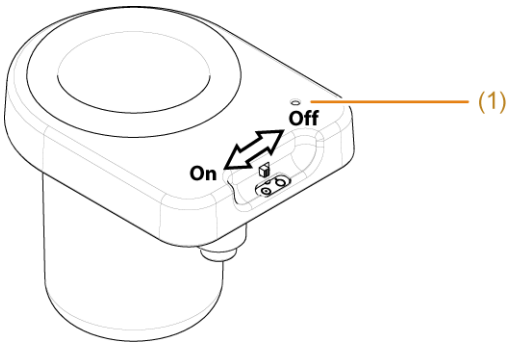
When the Gel Warmer is used, make sure that the ultrasound gel is not too hot.
Ignoring this instruction might result in burns to the patient. Use our ultrasound gel and ultrasound gel bottle.

3.10.1 Operating procedures

To connect the Gel Warmer, the optional EU-6063* is required.

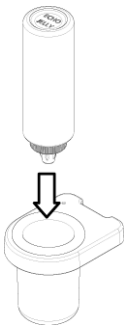
Procedure

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.
   If you are using the system only with the internal battery (optional), you cannot use the Gel Warmer.
   Connect the power plug to a hospital-grade outlet and turn the Gel Warmer power switch On.



(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.

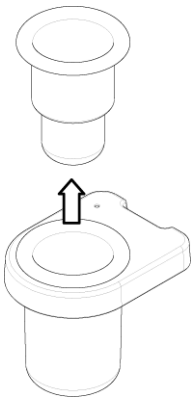
NOTE: For information on how to use ultrasound gel and the ultrasound gel bottle and the safety precautions that must be observed, see the documentation supplied with the ultrasound gel.

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.

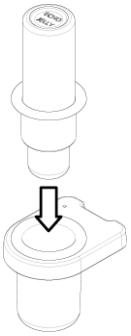
   When washing in water:

   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. Make sure that the Gel Warmer power switch is turned on.
The Gel Warmer has just been turned on.	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 warm up 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. Make sure that the Gel Warmer power switch is turned on. 3. Make sure that the power plug is connected to a hospital-grade outlet. NOTE: If you are using the system only with the internal battery (optional), you cannot use the Gel Warmer.

- 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.

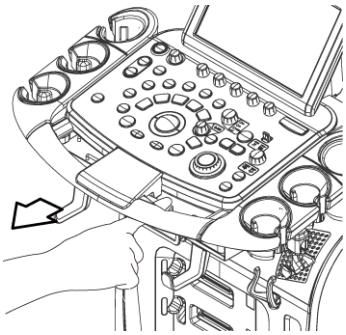
Use our ultrasound gel and ultrasound gel bottle.

3.11 Keyboard Tray (optional)

3.11.1 Pulling out the Keyboard Tray

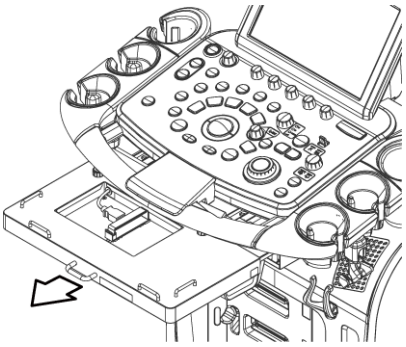
Procedure

1. Gently push the Keyboard Tray with your finger.



The Keyboard Tray extends out.

2. Grab and pull the handle until the Keyboard Tray is in a position suitable for use.

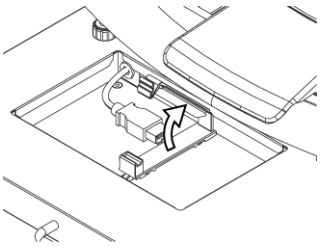


3.11.2 Connecting a Keyboard

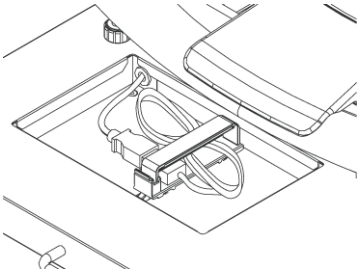
NOTE: Use a keyboard that is no more than 296 mm wide, 141 mm deep, and 19 mm thick.

Procedure

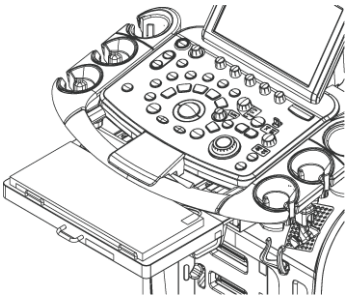
1. Open the clamp.



2. Connect the keyboard to the USB connector on the Keyboard Tray.
3. Roll up the keyboard cable.
4. Fix the rolled up cable in place with the clamp.



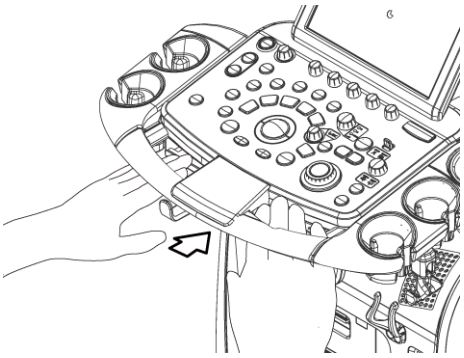
5. Put the keyboard on the Keyboard Tray.



3.11.3 Storing away the Keyboard Tray

Procedure

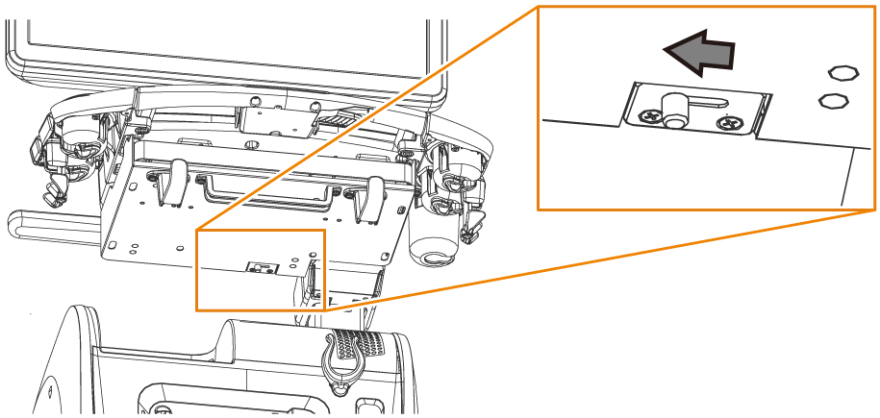
1. Push in the Keyboard Tray until it clicks.



3.11.4 Securing the Keyboard Tray

Procedure

1. Slide the lock lever on the bottom of the Keyboard Tray.



3.12 Using the system with the internal battery

If the internal battery (option) is installed, you can move the system without shutting it down, or perform examinations in locations where no hospital-grade outlet is available.
NOTE: If you use the internal battery (option), do not move the system while images are being saved.
NOTE: If you are using the system only with the internal battery (optional), you cannot use the optional peripheral equipment and the Gel Warmer.

3.12.1 Charging the internal battery

Procedure

1. Turn the battery power-supply switch to On.
2. Connect the power plug to a hospital-grade power outlet.
3. Turn on the breaker.

   You can check the battery charge status with the  icon displayed on the screen when the system starts.
   NOTE: When you use the internal battery, the temperature of the battery might rise, and the battery might not charge right away when you connect it to a power source. Shut down the system, and wait until the battery cools off before charging it.

3.12.2 Stopping use of the internal battery

If the system will not be used for an extended period of time, stop the use of the internal battery.

Procedure

1. Turn the battery power-supply switch to Off.
   NOTE: If the battery power-supply switch is turned On, the system consumes battery power even if you remove the power plug after the system is shut down.

(1) Restarting use of the internal battery

Procedure

1. Turn the battery power-supply switch to On.
   NOTE: Take note of the remaining battery charge.

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 51.
   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. Insert the power plug 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 capture 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

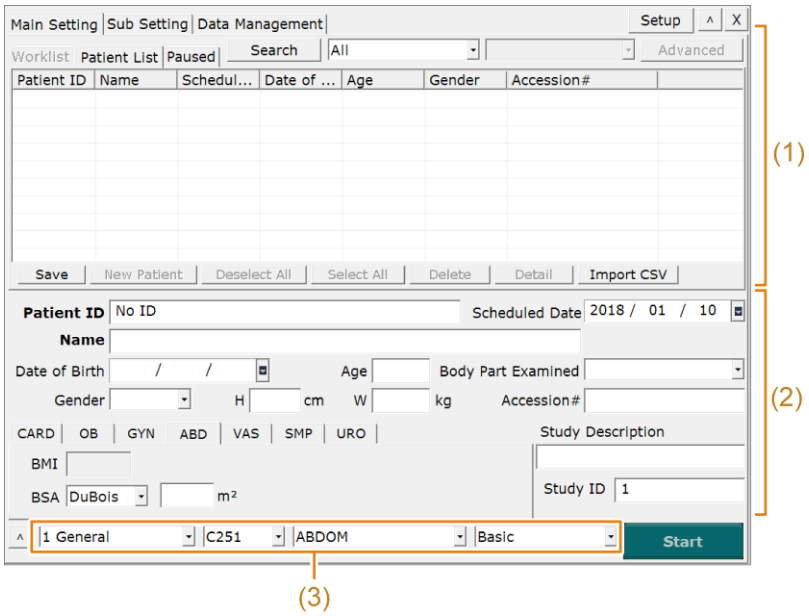
Chapter 3, Setup before use on page 51

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 comprises the Main Setting, Sub Setting, Patient Data Management, and Setup screens.
NOTE: For details about the Sub Setting screen, patient Data Management screen, and the Setup screen, see the separate manual "How to Use".

- Main Setting screen
  Use this screen to enter basic patient data and set the start time of an examination. Select the Main Setting tab to switch to the Main Setting screen. 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), and the measurement study (d). Setting up the ID screen will enable automatic input.

  If "When starting examination" and "store ID Screen" of the preset ([Preset Setup] > [SystemPreset] > [Filing] > [Detail] > [Store ID Screen]) are 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 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 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 separate manual "How to Use".

Procedure

1. Press the [New Patient] key.
   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 the 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, and the measurement study.
4. Exit the ID screen.
   - Select [Start] in the ID screen.
   - Press the [New Patient], [Freeze], or [B] key on the operation panel.
   - Press the [ID] key on the 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 *3.2 Connecting a probe* on page 60 in this manual.

For details about how to register applications to probes, see the separate manual "How to Use".
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 the registered applications are displayed.

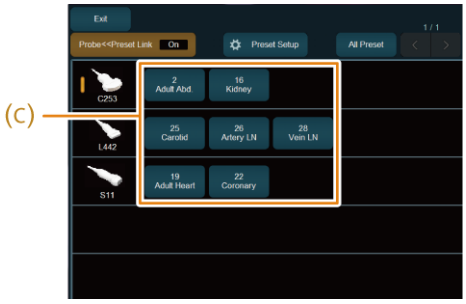
Procedure

- 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.
The output of 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.
  When lowering the ultrasound output power in CW mode, check with the MI/TI display. The transmitter voltage might not change 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

If an application used for fetal observation is selected, the ultrasound output power will be limited accordingly. This limit can be temporarily suspended.
When the system is used for fetal observation, the ultrasound output power is limited according Hitachi's regulations in compliance with the risk management requirements provided in IEC 60601-2-37 Ed.2 (2007). 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, Ob.3D 1st Trim, Ob.3D 2nd Trim, Ob.3D 3rd Trim, Obst.TV 3D, 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 appears: "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.

Preparations

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 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.

4.6.1 Viewing instruction manuals on the system screen

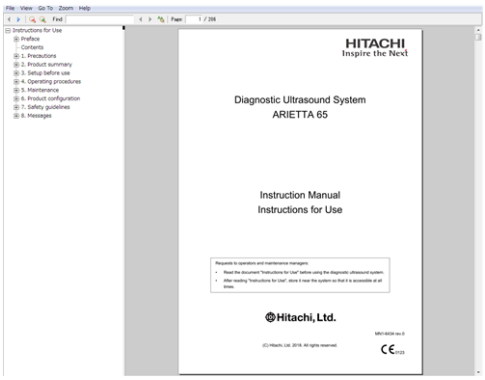
Follow the steps below to read the instruction manual on the system.

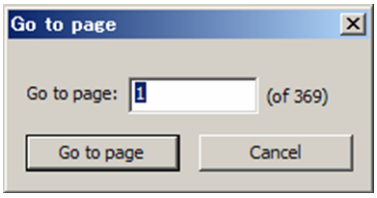
Prior confirmation

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.

4.6.2 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.
How to Use	Describes how to display, adjust, and record ultrasonic images, and describes optional functions and various types of analyses.
Measurements	Describes how to measure ultrasonic images.
License Information	Provides detailed license information. NOTE: License Information is available only on the CD Manual Set.

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.

4.7 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 pull the power plug out of the hospital-grade outlet.

Procedure

1. Freeze the image.
2. Make backups of saved images.
   a. Transfer all images saved on the system's hard disk or in the CD-R buffer to a USB-connected storage medium, DVD, or CD-R.

b. Delete unnecessary images from the system's hard disk or the CD-R buffer.

NOTE: For details about how to back up data, see the separate manual "How to Use".

3. Remove the recording medium from the recording system.
4. Press the [Power] key to shut down the system.
   If the internal battery (option) is used
   Turn the battery power-supply switch to Off.
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 52
5.1 Cleaning and disinfecting on page 112

4.8 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 Keyboard Tray) 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 stored 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.

4.9 Storage

When putting away the system for a longer period of time, store it in a location that satisfies the conditions for storage environments.

Reference information

2.3.2 Ambient conditions on page 44
3.1.3 Moving the system on page 53

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 *5.1.1 Using approved disinfectants* on page 114 in this manual.
NOTE: Shut down the system, and then pull the power plug out of the hospital-grade outlet and clean the power plug. Turn the battery power-supply switch to Off if the internal battery (optional) is used.
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.

Use gloves when touching the caster tires.
The caster tires contain natural rubber. Natural rubber might infrequently cause allergy symptoms such as itching, redness, hives, swelling, fever, dyspnea, asthmatic responses, decrease in blood pressure, and shock. If you experience any of these symptoms, immediately stop using the system and consult a doctor.

⚠ 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.

Do not use organic solvents such as alcohol, or commercially available LCD cleaners.
Ignoring this instruction might result in deterioration of, or damage to, the enclosure.

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	Monitor LCD surface	Operation panel	Keyboard Tray	Touch panel	Trackball	Power plug
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
Sani-Cloth(R) HB	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sani-Cloth(R) Plus	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Super Sani-Cloth(R)	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SONO ULTRASOUND WIPES	ADVANCED ULTRASOUND SOLUTIONS inc.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ProteX wipe	Parker Laboratories, inc.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Accel PREVention Wipes	AHP	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Accel PREVention RTU	AHP	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sodium hypochlorite	-	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	ECG cable (ECG cable)	Foot switch	Peripheral devices
Ethyl alcohol max. 80% vol.	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Isopropyl alcohol max. 80% vol.	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sani-Cloth(R) HB	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sani-Cloth(R) Plus	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Super Sani-Cloth(R)	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SONO ULTRASOUND WIPES	ADVANCED ULTRASOUND SOLUTIONS inc.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ProteX wipe	Parker Laboratories, inc.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Accel PREVention Wipes	AHP	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Accel PREVention RTU	AHP	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	ECG cable (ECG cable)	Foot switch	Peripheral devices
Sodium hypochlorite	-	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. Turn the battery power-supply switch to Off if the internal battery (optional) is used.
  - Location where the system is installed
  - Operation panel (including the Keyboard Tray)
  - 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. Make sure all surfaces are dry.

(2) Disinfecting

After performing the above steps, disinfect using the following steps.

Procedure

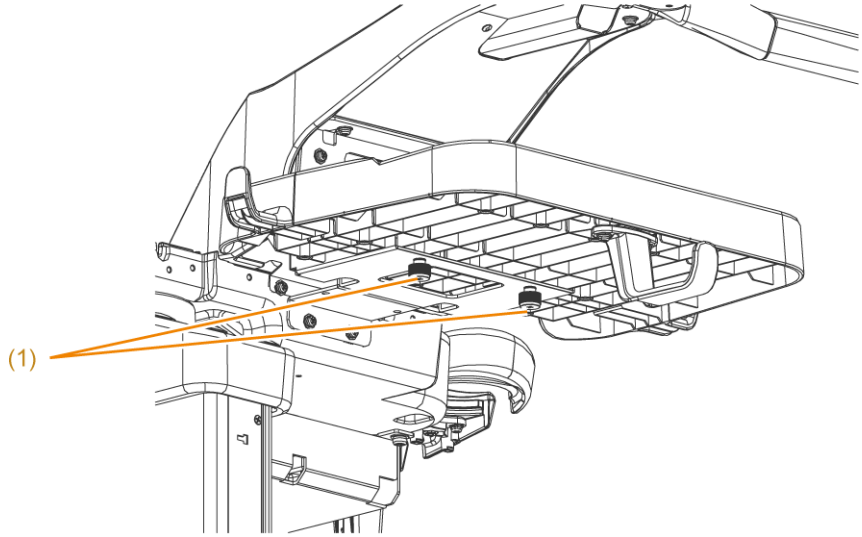
1. Wipe gently with an approved disinfectant.
2. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
3. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture. Make sure all surfaces are dry.

5.1.4 Cleaning the Storage Tray

(1) Removing the Storage Tray from the operation panel

Procedure

1. Rotate knob (1), and lift the Storage Tray upward 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 soft, dry, lint-free cloth to gently wipe away any remaining moisture. Make sure all surfaces are dry.
   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. Make sure all surfaces are dry.

   Disinfecting:
   After performing the above steps, disinfect 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. Make sure all surfaces are dry.

(3) Attaching the Storage Tray

Procedure

1. Attach the Storage Tray.

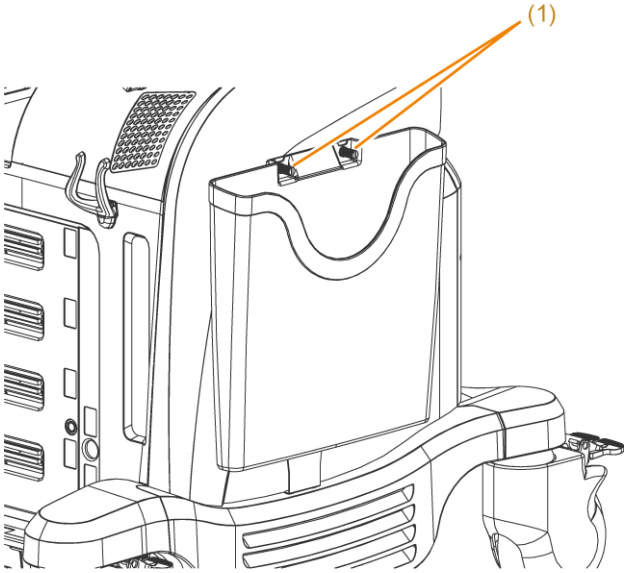
   a. Align the groove on the back of the Storage Tray with the rail.
   b. Incline the Storage Tray, and hook the edge on the tab to level the Storage Tray.
   c. Alternately rotate the knobs, and firmly fasten them until they stop.

5.1.5 Cleaning the Side Tray

(1) Removing the Side Tray from the operation panel

Procedure

1. Rotate knob (1), and lift the Side Tray upward 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. Make sure all surfaces are dry.

   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. Make sure all surfaces are dry.

   Disinfecting:

   After performing the above steps, disinfect 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. Make sure all surfaces are dry.

(3) Attaching the Side Tray

Procedure

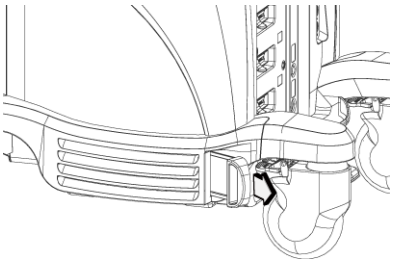
1. Attach the Side Tray.
   a. Hook the tab of the Side Tray.
   b. Alternately rotate the knobs, and firmly fasten them until they stop.

5.1.6 Cleaning the filter

The filter is located on the left side of the system.

Procedure

1. Pull out the filter.



2. Use a vacuum cleaner to remove dust from the filter.
3. Clean the filter under running water.
4. Drain water thoroughly, and then dry the filter in a well-ventilated place out of direct sunlight.
5. Check the front and back of the filter and reinstall it to the original location.
   NOTE: Push in the filter completely.

5.1.7 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. Make sure all surfaces are dry.

(2) Disinfecting

After performing the above steps, disinfect 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. Make sure all surfaces are dry.

5.1.8 Cleaning and disinfecting the viewing monitor

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. Make sure all surfaces are dry.

(2) Disinfecting

After performing the above steps, disinfect 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. Make sure all surfaces are dry.

5.1.9 Cleaning and disinfecting the operation panel and Keyboard Tray

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 or cotton bud to gently wipe away any remaining moisture. Make sure all surfaces are dry.

(2) Disinfecting

After performing the above steps, disinfect 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 or cotton bud to gently wipe away any remaining moisture. Make sure all surfaces are dry.

5.1.10 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. Make sure all surfaces are dry.

(2) Disinfecting

After performing the above steps, disinfect 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. Make sure all surfaces are dry.

5.1.11 Cleaning and disinfecting the trackball

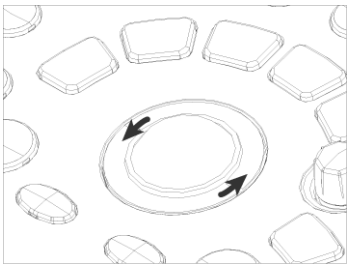
CAUTION

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.

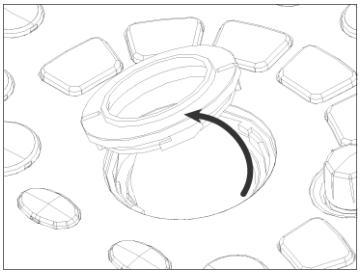
(1) Removing the trackball from the operation panel

Procedure

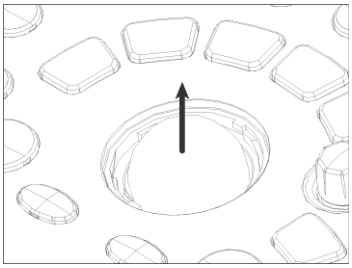
1. Turn the ring counterclockwise.



2. Remove the ring from the operation panel.



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

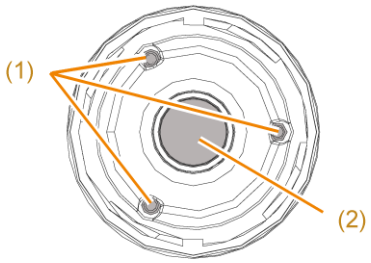


(2) Cleaning and disinfecting

Procedure

- Trackball support balls and the underside of the cup

  a. Use a dry cotton swab to clean the trackball support balls (3 places.). Use a lint-free cloth that will not leave fibers behind to clean the underside of the cup.



(1) Trackball support balls (2) Underside of the cup (the shadowed areas)

If the item is very dirty:
Clean as described below.

  a. Use an air duster to blow off dust. Alternatively, apply water or Isopropyl alcohol to a lint-free cloth, and then gently wipe away dust.

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

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

  d. Use a dry cotton bud to gently wipe away any remaining moisture. Make sure all surfaces are dry.

Disinfecting:
After performing the above steps, disinfect using the following steps. Use a lint-free cloth to wipe the underside of the cup.

  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. Make sure all surfaces are dry.

- 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. Make sure all surfaces are dry.

Disinfecting:
After performing the above steps, disinfect 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. Make sure all surfaces are dry.
   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.
   NOTE: Do not remove the sponge part of the ring. Ignoring this instruction might result in the trackball no longer being able to turn smoothly.

If the trackball no longer turns smoothly

a. Uniformly apply white Vaseline over the entire trackball.
b. Wipe the trackball with a dry, lint-free cloth until no stickiness can be felt.

(3) Installing the trackball in the operation panel

NOTE: Be careful not to get Vaseline on the underside of the cup when you install the trackball.

Procedure

1. Install the trackball in the operation panel.
2. Install the ring in the operation panel.
3. Turn the ring clockwise.

5.1.12 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. Make sure all surfaces are dry.

   Disinfecting:
   After performing the above steps, disinfect 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. Make sure all surfaces are dry.

5.1.13 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. Make sure all surfaces are dry.

(2) Disinfecting

After performing the above steps, disinfect 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. Make sure all surfaces are dry.

5.1.14 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.

⚠ WARNING

Use gloves when touching the caster tires.
The caster tires contain natural rubber. Natural rubber might infrequently cause allergy symptoms such as itching, redness, hives, swelling, fever, dyspnea, asthmatic responses, decrease in blood pressure, and shock. If you experience any of these symptoms, immediately stop using the system and consult a doctor.

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. Make sure all surfaces are dry.
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.

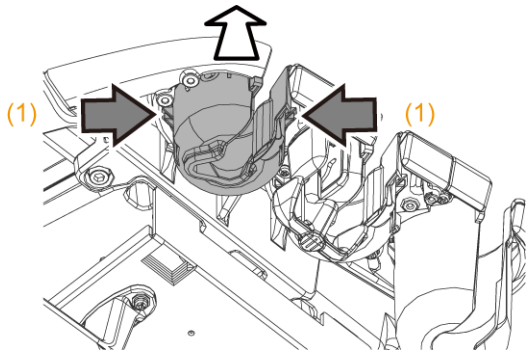
8. Dampen a lint-free cloth with water and wring it out thoroughly.
9. Place the lint-free cloth in step 8 on the floor and move the system so the casters roll over the cloth to remove any remaining disinfectant.
10. Use a soft, dry, lint-free cloth to gently wipe away any remaining moisture. Make sure all surfaces are dry.

5.1.15 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. Make sure all surfaces are dry.
   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. Make sure all surfaces are dry.

Disinfecting:
After performing the above steps, disinfect 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. Make sure all surfaces are dry.

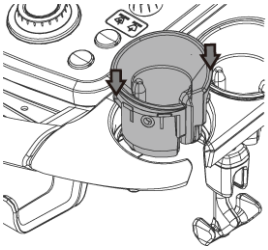
(3) Installing the probe holder in the operation panel

Procedure

1. Install 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.



5.1.16 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.

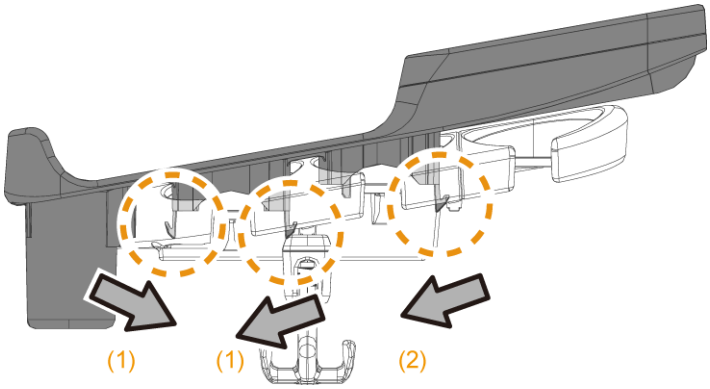
(1) Removing the transvaginal/transrectal probe holder from the operation panel

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. Make sure all surfaces are dry.
   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. Make sure all surfaces are dry.

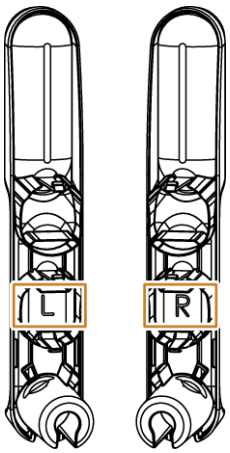
   Disinfecting:
   After performing the above steps, disinfect using the following steps.
   a. Wipe gently with an approved disinfectant.
   b. If necessary, dampen a soft, lint-free cloth with water and thoroughly wring it out. Then wipe off any remaining disinfectant.
   c. If necessary, use a soft, dry, lint-free cloth to gently wipe away any remaining moisture. Make sure all surfaces are dry.

(3) Installing the transvaginal/transrectal probe holder in the operation panel

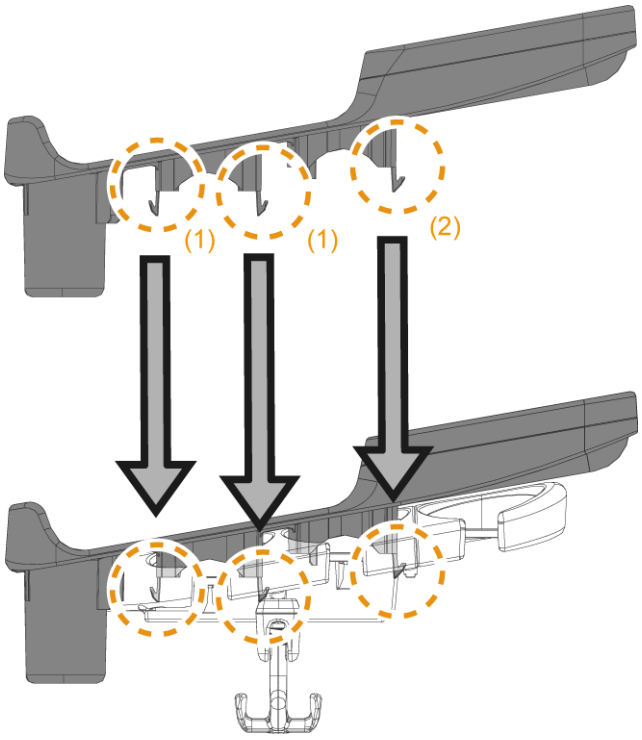
Procedure

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.

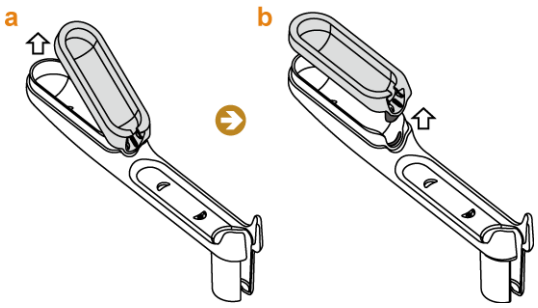


5.1.17 Cleaning and disinfecting the transvaginal/transrectal probe holder adapter

(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. Make sure all surfaces are dry.
   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. Make sure all surfaces are dry.

   Disinfecting:
   After performing the above steps, disinfect 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. Make sure all surfaces are dry.

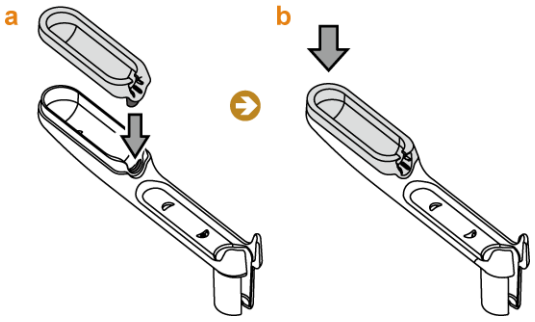
(3) Installing the transvaginal/transrectal probe holder adapter

Procedure

1. Attach the adapter.

   a. Align the adapter's tab with the slot in the probe holder, and then press it in.

   b. Install the far end of the adapter into the probe holder.



5.1.18 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.

5.1.19 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. Make sure all surfaces are dry.
   Disinfecting:
   After performing the above steps, disinfect 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. Make sure all surfaces are dry.

5.1.20 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. Make sure all surfaces are dry.
   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. Make sure all surfaces are dry.

   Disinfecting:
   After performing the above steps, disinfect 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. Make sure all surfaces are dry.

5.1.21 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 the customer does 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 176

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.

- 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.
  - Make sure that the monitor contrast and monitor brightness are properly set.
  - 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.
  - The knobs of the Storage Tray and the Side Tray must not be loose.
  - If stickers are attached to the back of the touch panel, the stickers must not be peeling away.

  NOTE: The number of probe inspections that must be performed depends on probe type. Inspect probes as described in their documentation.
- 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.

- Distance measurement accuracy
- Resolution and sensitivity
- 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
   - OSS 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 into 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 into 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	

Doppler measurement accuracy (when a Doppler phantom is used)			
QSS D item in the PW tab		Doppler phantom identification (Control No., date of purchase, S/N, etc.)	
QSS Color item in the Color1 tab		Phantom settings Flow velocity (m/s):	
B/PW mode image		B+Color mode image	
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 × 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 system automatically repeats the startup and shutdown twice

Cause	Countermeasures
The charge in the internal battery is depleted.	Please contact our office.

- 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. See *3.9.4 Adjusting the brightness levels of the monitor, operation panel and touch panel.* on page 91.
			[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.	Use the [Freeze] rotary encoder or the [TGC] slider to adjust the gain.
			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 then remove any dust attached to the trackball support balls and the underside of the cup.
- If touch panel response is sluggish

  a. Clean the touch panel.

  b. Reboot 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
  Remove the power plug from the hospital-grade outlet and turn the battery power-supply switch to Off.
- If a sticker attached to the back of the touch panel peels away
  Please contact our office.
  Do not touch the screw that was covered by the sticker that peeled away.

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-170	1	
	Viewing monitor	IPF-2104*	1	*1
Accessories	Power cable	CP-121	1	for 100 V to 120 V
	CD Manual Set	MN-CD-ARIETTA65-A	1	
	Instruction Manual (Instructions for Use)	MN1-6438	1	Bound

*1.
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	

Color printer

Name	Model name	Remarks
Digital Color printer	UP-D25MD	*1
Digital Color printer	CP30DW	*1 *2

*1.
EU-6060* is required.

*2.
It can be connected to a supply mains having voltage 120 V.

Video recorder

Name	Model name	Remarks
HD Video Recorder	HVO-500MD /FHD	*1 *2
HD Video Recorder	HVO-550MD /FHD	*1 *3

*1.
EU-6060* is required.

*2.

No optical disc drive.

*3.

With optical disc drive.

Software extension unit

Name	Model name	Remarks
Physiological signal display unit	PEU-ARIETTA65*	*1 *3
CW Servo unit	EU-9198*	*3
Independent Probe connection unit	EU-9187*	*2 *3
Battery unit	EU-9199*	*3
Battery	L-BT-12*	*3
Outlet unit	EU-6060*	*3
Gel Warmer	JW-3000*U	*3 *4
AC Adaptor for Gel Warmer	EU-6063*	*3
Gel Warmer left side mounting Kit	MP-FX-AVA-2*-L	*3
Gel Warmer right side mounting Kit	MP-FX-AVA-2*-R	*3

*1.

Includes an ECG cable and other accessories.

*2.

EU-9198* is required.

*3.

Depending on the date of manufacture, the asterisk (*) in the model name might be an alphabetic character.

*4.

EU-6063*, MP-FX-AVA-2*-L, or MP-FX-AVA-2*-R is required.

Other

Name	Model name	Remarks
3-point footswitch	MP-2819*	*1
1-point footswitch	MP-2345*	*1, 1 point type
Endo-cavity Probe holder Kit	MP-PH-AVA-11*	*1
Side Tray	MP-FX-ALB-22*	*1
Flexible hook	MP-HA-ALB-2*	*1
Flexible hanger	MP-HA-ALB-3*	*1
Keyboard Tray	MP-FX-ALB-6*	*1
Instruction Manual (Instructions for Use)	MN1-6438	Bound
Instruction Manual (Acoustic Output Data)	MN1-6439	Bound
Instruction Manual (How to Use)	MN1-6440	Bound

Name	Model name	Remarks
Instruction Manual (Measurements)	MN1-6441	Bound

*1.

Depending on the date of manufacture, the asterisk (*) in the model name might be an alphabetic character.

Software

Name	Model name	Remarks
Dynamic Slow-motion Display software	SOP-ARIETTA65-57	
Panoramic View software	SOP-ARIETTA65-1	
Real Time 3D software	SOP-ARIETTA65-4	*1
FAM software	SOP-ARIETTA65-5	
Patient Information Automatic Input software	SOP-ARIETTA65-6	
DICOM Network Communication software	SOP-ARIETTA65-10	
DICOM Structured Report software	SOP-ARIETTA65-21	*2
DICOM Query/Retrieve software	SOP-ARIETTA65-59	*2
Stress Echo software	SOP-ARIETTA65-15	*3
Real-time Tissue Elastography software	SOP-ARIETTA65-43	
Real-time Tissue Elastography Strain Histogram software	SOP-ARIETTA65-60	
2D Tissue Tracking Analysis software	SOP-ARIETTA65-49	
TDI Analysis software	SOP-ARIETTA65-13	
Flow Profile Measurement software	SOP-ARIETTA65-7	
Automated IMT Measurement software	SOP-ARIETTA65-38	
Contrast Harmonic Imaging software	SOP-ARIETTA65-44	
Transit Time of Vessel Flow Measurement software	SOP-ARIETTA65-47	*3
McAfee Embedded Control 3 software	SOP-ARIETTA65-128	
Automated Cardiac Measurement software	SOP-ARIETTA65-74	
Protocol Assistant software	SOP-ARIETTA65-79	

*1.

EU-9198* is required.

*2.

Requires the SOP-ARIETTA65-10

*3.

PEU-ARIETTA65* is required.

6.3 Probes

This section lists the probes that can be connected and their specifications.

NOTE: For information about the standard component parts and options of a probe, refer to the documentation provided with the probe.
NOTE: Do not use for neurosurgery with C42T.

Electronic Convex Probe

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
C251	Fetal Abdominal[*a] Pediatric Small Organ (Spec.)[*d]	5 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
C22P	Fetal Abdominal[*a]	6 to 1	22R	Body surface
C25P	Fetal Abdominal[*a]	5 to 1	50R	Body surface
C41V	Fetal Trans-rectal[*e] Trans-vaginal[*f] Other (spec.) - Gynecological	8 to 4	10R	Endocavity

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
C41V1	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
C41B	Fetal Trans-rectal*e Trans-vaginal*f Other (spec.) - Gynecological	10 to 2	10R	Endocavity
CC41R	Fetal Trans-rectal*e Trans-vaginal*f	T: 8 to 4 L: 8 to 4	T: 10R L: 10R	Endocavity
CC41R1	Fetal Trans-rectal*e Trans-vaginal*f	CV*1: 10 to 2 CV*1: 10 to 2	CV: 9R CV: 9R	Endocavity
C22K	Abdominal*a Intra-operative (Spec.)*b	6 to 1	21R	Intraoperative
C42K	Intra-operative (Spec.)*b Small Organ (Spec.)*d Neonatal Cephalic	10 to 4	21R	Intraoperative
C42T	Intra-operative (Spec.)*b	10 to 3	20R	Intraoperative
R41R	Trans-rectal	10 to 5	6R radial	Endocavity

*1.
Convex Type

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

Model name	Intended Purpose	Frequency (MHz)	Visual field width	Application
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
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

Model name	Intended Purpose	Frequency (MHz)	Visual field width	Application
L51K	Intra-operative (Spec.)*b	15 to 3	13 mm	Intraoperative
L53K	Intra-operative (Spec.)*b	15 to 3	25 mm	Intraoperative

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
S211	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
S3ESEL	Trans-esoph. (non-Card.)*g Trans-esophageal (card.)*g	8 to 2	Endocavity

4D Probe

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
VC35*1	Fetal Abdominal Pediatric Small Organ (Spec.)*c	8 to 2	46R	Body surface
VC41V*1	Fetal Trans-vaginal Other (spec.) - Gynecological	8 to 2	10R	Endocavity

*1.

EU-9198* is required.

Other Probe

Model name	Intended Purpose	Frequency (MHz)	Curvanture Radius, or Scan Area	Application
C41L47RP	Trans-rectal*e	CV*1: 8 to 4 LN*2: 10 to 5	CV: 10R LN: 64 mm	Endocavity
CL4416R	Trans-rectal*e	CV*1: 10 to 2 LN*2: 14 to 2	CV: 9R LN: 63 mm	Endocavity

*1.

Convex Type

*2.

Linear Type

Independent Probe

Model name	Intended Purpose	Frequency (MHz)	Application
UST-2265-2*1	Cardiac Adult Cardiac Pediatric Peripheral vessel	2	Body surface

*1.

Requires the EU-9187* and EU-9198*

*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		C251	C253	C35	C41	C42	C22P	C25P	C41V
Compound		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trapezoid									
B steer									
Acoustic Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane									
OMNI Mode									
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B								
	Color								
TDI mode		Yes	Yes	Yes					
Puncture Guide Line		Yes	Yes	Yes		Yes	Yes	Yes	Yes
Needle Emphasis									
Brachy Grid Display									
Assist Line									
Tissue Harmonic Imaging	FmT	Yes	Yes	Yes		Yes	Yes	Yes	
	WbT	Yes	Yes	Yes		Yes	Yes	Yes	
	HdT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		C41V1	C41RP	C41B	CC41R	CC41R1	C22K	C42K	C42T
Compound		Yes	Yes	Yes			Yes	Yes	Yes
Trapezoid									
B steer									
Acoustic Noise Reduction		Yes	Yes	Yes			Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane					Yes	Yes			
OMNI Mode									
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B								
	Color								
TDI mode									
Puncture Guide Line		Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Needle Emphasis									
Brachy Grid Display									
Assist Line									

Basic Functions		C41V1	C41RP	C41B	CC41R	CC41R1	C22K	C42K	C42T
Tissue Harmonic Imaging	FmT								
	WbT								
	HdT	Yes	Yes	Yes			Yes	Yes	Yes
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic functions		R41R	L34	L441	L442	L55	L64	L43K	L44K
Compound			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trapezoid			Yes	Yes	Yes	Yes	Yes	Yes	Yes
B steer			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Acoustic Noise Reduction			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane									
OMNI Mode									
FAM			Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B								
	Color								
TDI mode						Yes			
Puncture Guide Line			Yes	Yes	Yes	Yes	Yes		
Needle Emphasis			Yes	Yes	Yes	Yes	Yes		
Brachy Grid Display									
Assist Line					Yes		Yes		
Tissue Harmonic Imaging	FmT								
	WbT		Yes	Yes	Yes	Yes	Yes		
	HdT		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		L46K1	L51K	L53K	S11	S211	S31	S3ESEL
Compound		Yes	Yes	Yes				
Trapezoid		Yes	Yes	Yes				
B steer		Yes	Yes	Yes				
Acoustic Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane								
OMNI Mode								
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B							
	Color							

Basic Functions		L46K1	L51K	L53K	S11	S211	S31	S3ESEL
TDI mode					Yes	Yes	Yes	Yes
Puncture Guide Line								
Needle Emphasis								
Brachy Grid Display								
Assist Line								
Tissue Harmonic Imaging	FmT				Yes	Yes	Yes	
	WbT							
	HdT	Yes	Yes	Yes				
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		VC35	VC41V	C41L47RP (CV)	C41L47RP (LN)	CL4416R (CV)	CL4416R (LN)	UST-2265-2
Compound		Yes	Yes			Yes	Yes	
Trapezoid					Yes		Yes	
B steer					Yes		Yes	
Acoustic Noise Reduction		Yes	Yes	Yes	Yes			
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	
Real-time Biplane								
OMNI Mode			Yes					
FAM		Yes	Yes	Yes	Yes	Yes	Yes	
TGC Enhancement	B							
	Color							
TDI mode		Yes						
Puncture Guide Line					Yes		Yes	
Needle Emphasis								
Brachy Grid Display				Yes		Yes		
Assist Line								
Tissue Harmonic Imaging	FmT	Yes	Yes					
	WbT	Yes	Yes					
	HdT	Yes						
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	

6.3.2 Probe functions: Optional functions

Optional Functions	C251	C253	C35	C41	C42	C22P	C25P	C41V
CW mode	Yes	Yes	Yes		Yes			

Optional Functions	C251	C253	C35	C41	C42	C22P	C25P	C41V
Contrast Harmonic Imaging		Yes						
Panoramic display	Yes	Yes	Yes		Yes			
Real-time Tissue Elastography	Yes	Yes	Yes		Yes			Yes
Real time 3D								
Stress echo								

Optional Functions	C41V1	C41RP	C41B	CC41R	CC41R1	C22K	C42K	C42T
CW mode								
Contrast Harmonic Imaging								
Panoramic display								
Real-time Tissue Elastography	Yes		Yes	Yes	Yes		Yes	Yes
Real time 3D								
Stress echo								

Optional Functions	R41R	L34	L441	L442	L55	L64	L43K	L44K
CW mode		Yes	Yes	Yes		Yes		
Contrast Harmonic Imaging								
Panoramic display		Yes	Yes	Yes	Yes	Yes		
Real-time Tissue Elastography	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real time 3D								
Stress echo								

Optional Functions	L46K1	L51K	L53K	S11	S211	S31	S3ESEL
CW mode				Yes	Yes	Yes	Yes
Contrast Harmonic Imaging							
Panoramic display							
Real-time Tissue Elastography	Yes	Yes	Yes				
Real time 3D							
Stress echo				Yes	Yes	Yes	

Optional Functions	VC35	VC41V	C41L47RP (CV)	C41L47RP (LN)	CL4416R (CV)	CL4416R (LN)	UST-2265-2
CW mode							Yes

Optional Functions	VC35	VC41V	C41L47RP (CV)	C41L47RP (LN)	CL4416R (CV)	CL4416R (LN)	UST-2265-2
Contrast Harmonic Imaging							
Panoramic display				Yes		Yes	
Real-time Tissue Elastography		Yes	Yes	Yes	Yes	Yes	
Real time 3D	Yes	Yes					
Stress echo							

6.3.3 Measurement scope

This section indicates the maximum range of measurements that the ARIETTA 65 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)
C251	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	916.7	9.74	6-999
C41	38.7	639.4	999.9	99.9	9999	19.0	534.7	9.74	6-999
C42	38.7	639.4	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
C25P	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C41V	38.7	639.4	999.9	99.9	9999	19.0	802.1	9.74	6-999
C41V1	38.7	639.4	999.9	99.9	9999	19.0	802.1	9.74	6-999
C41RP	34.6	511.9	999.9	94.3	9999	17.0	802.1	9.74	6-999
C41B	38.7	639.4	999.9	99.9	9999	19.0	802.1	9.74	6-999
CC41R	38.7	639.4	999.9	99.9	9999	19.0	534.7	9.74	6-999
CC41R1	38.7	639.4	999.9	99.9	9999	19.0	534.7	9.74	6-999
C22K	61.1	999.9	999.9	99.9	9999	29.9	999.9	9.74	6-999
C42K	38.7	639.4	999.9	99.9	9999	19.0	713.0	9.74	6-999
C42T	38.7	639.4	999.9	99.9	9999	19.0	713.0	9.74	6-999
R41R	38.7	639.4	999.9	99.9	9999	19	534.7	9.74	6-999
L34	34.6	511.9	999.9	94.3	9999	17.0	916.7	9.74	6-999
L441	28.5	347.2	999.9	77.6	9999	14.0	713.0	9.74	6-999
L442	28.5	347.2	999.9	77.6	9999	14.0	713.0	9.74	6-999
L55	34.6	511.9	999.9	94.3	9999	17.0	534.7	9.74	6-999
L64	28.5	347.2	999.9	77.6	9999	14.0	493.6	9.74	6-999
L43K	28.5	347.2	999.9	77.6	9999	14.0	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)
L44K	34.6	511.9	999.9	94.3	9999	17.0	713.0	9.74	6-999
L46K1	34.6	511.9	999.9	94.3	9999	17.0	713.0	9.74	6-999
L51K	28.5	347.2	999.9	77.6	9999	14.0	493.6	9.74	6-999
L53K	28.5	347.2	999.9	77.6	9999	14.0	493.6	9.74	6-999
S11	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
S211	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
S31	48.9	318.7	999.9	73.6	9999	24.0	999.9	9.74	6-999
S3ESEL	48.9	999.9	999.9	99.9	9999	24.0	916.7	9.74	6-999
VC35	48.9	318.7	999.9	73.6	9999	24	999.9	9.74	6-999
VC41V	38.7	639.4	999.9	99.9	9999	19	916.7	9.74	6-999
C41L47RP (CV)	38.7	639.4	999.9	99.9	9999	19.0	534.7	9.74	6-999
C41L47RP (LN)	34.6	511.9	999.9	94.3	9999	17.0	534.7	9.74	6-999
CL4416R (CV)	38.7	639.4	999.9	99.9	9999	19.0	534.7	9.74	6-999
CL4416R (LN)	34.6	511.9	999.9	94.3	9999	17.0	534.7	9.74	6-999
UST-2265-2	-	-	-	-	-	-	999.9	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.3 or 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.

Problem and basic EMC standards	Emission testing level Specialized medical 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 interfere with 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 Essential performance

Electromagnetic interference tests based on the electromagnetic compatibilities stipulated in IEC 60601-1-2: Ed.3, IEC 60601-1-2: Ed.4, or IEC 60601-2-37 have confirmed that there is no impact on essential performance (functions that might pose an unacceptable risk if absent or degraded) or safety of the system.
The following potential risks are not present:

- Artifacts on waveforms, image distortions, or incorrectly displayed numerical values which are not caused by bioeffects which and might affect diagnoses
- Incorrectly displayed numerical values that affect diagnoses
- Incorrectly displayed safety information

Essential performance	Overview	Reference
Scan Area	Scanning range	[T.B.F.] key (How to Use)
Flow Area	Color display range of the color Doppler mode	[T.B.F.] key (How to Use)
Velocity Range	Velocity range (scale mark) in the Doppler image display	[FOCUS /VELOCITY] paddle switch (How to Use)
M cursor Doppler Cursor	Cursor display which indicates the M or D mode image detection position in B mode	[T.B.F.] key (How to Use)
Sample Volume	Doppler detection range settings in the PW Doppler mode	Sample Volume menu (How to Use)
Image Frequency Select	Change in frequencies in B and M Mode	Frequency (How to Use)
	Change in frequencies in D, Color, and CHI Modes	Reference Frequency (How to Use)
Focus	Number of focal points and their positions	[FOCUS /VELOCITY] paddle switch (How to Use)
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 (How to Use)
Packet Size	Number of transmissions used to display blood flow	Menus and Presets: Color Flow, Power Flow, eFlow, TDI (How to Use)
Puncture	Puncture guideline display	Puncture menu (How to Use)
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 (How to Use)
Heart Rate Display	Computes and displays the heart rate from detected R-wave (HR***)	Displaying Physiological Signals, the Physio Menu, and Presets: Physio (How to Use)
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.3 compliant

Immunity examination	IEC 60601 testing level	Conformity level	Electromagnetic environment - guidelines
IEC 61000-4-2 Electrostatic Discharge (ESD)	±6 kV Contact ±8 kV Air gap	±6 kV Contact ±8 kV Air gap	The floor material should be made of wood, concrete, or ceramic tile. If the floor is covered with synthetic materials, the relative humidity of these should be at least 30%.
IEC 61000-4-4 Electrical fast transient/burst	±2 kV for the power supply line ±1 kV for the input line	±2 kV for the power supply line ±1 kV for the input line	The system should be supplied with power of the same quality as that provided by a standard business or hospital environment.
IEC 61000-4-5 Surge	±1kV Line to line intervals ±2kV Line to earth intervals	±1kV Line to line intervals ±2kV Line to earth intervals	The system should be supplied with power of the same quality as that provided by a standard business or hospital environment.
IEC 61000-4-11 Voltage dips, short-time outages, and voltage fluctuations on the power supply input line	< 5% U_T (> 95% U_T deterioration) 0.5 cycle intervals	< 5% U_T (> 95% U_T deterioration) 0.5 cycle intervals	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.
	< 40% U_T (> 60% U_T deterioration) 5 cycle intervals	< 40% U_T (> 60% U_T deterioration) 5 cycle intervals	
	< 70% U_T (> 30% U_T deterioration) 25 cycle intervals	< 70% U_T (> 30% U_T deterioration) 25 cycle intervals	
	< 5% U_T (> 95% U_T deterioration) 5 second intervals	< 5% U_T (> 95% U_T deterioration) 5 second intervals	
IEC 61000-4-8 Electrical power frequency (50/60 Hz) magnetic immunity	3 A/m	3 A/m	The power frequency magnetic field should have the same level of characteristics as a standard business or hospital environment.
Remark: U_T is the AC power supply voltage before the testing level is applied.			

(2) IEC 60601-1-2 Ed.4 compliant

(a) ENCLOSURE PORT

Phenomenon, Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment	Electromagnetic Environment - Guidance
ELECTROSTATIC DISCHARGE, IEC 61000-4-2	±8 kV contact ±15 kV air	The floor material should be made of wood, concrete or ceramic tile. If the floor is covered with synthetic materials, it is desirable that the relative humidity of these is at least 30%.
Radiated RF EM fields, IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	Recommended separation distance > 30 cm The symbol shown below is found on equipment that generates electromagnetic interference intentionally. Interference may occur in the vicinity of equipment with the following symbol. 
Proximity fields from RF wireless communications equipment, IEC 61000-4-3	ENCLOSURE PORT IMMUNITY to RF wireless communications equipment	
RATED power frequency magnetic fields, IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	It is desirable that the power frequency magnetic field has the same level of characteristic as the standard business or hospital environments.
Remarks:	These guidelines may not apply in all circumstances. Electromagnetic propagation is affected by reflection or absorption from buildings, objects and people. For example, field strengths from fixed transmitters, such as cellular phone base stations, mobile radio, amateur radio, AM/FM radio and TV broadcast base stations cannot be theoretically estimated with accuracy. Consider an electromagnetic site survey to correctly assess the electromagnetic environment of a fixed RF transmitter. When the field intensity measured at the place where the instrument is used is higher than the applied RF conformity level mentioned above, inspections shall be conducted to determine whether it operates normally. When abnormal movement was confirmed, an investigation for the placement or installment of the instrument may be necessary.	

(b) Input a.c. power PORT

Phenomenon, Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment	Electromagnetic Environment - Guidance
Electrical fast transients / bursts, IEC 61000-4-4	±2 kV, 100 kHz repetition frequency	The instrument should be supplied with power of the same quality as that provided by a standard business or hospital environment.

Phenomenon, Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment	Electromagnetic Environment - Guidance
Surges (Line to Line), IEC 61000-4-5	±1 kV	The instrument should be supplied with power of the same quality as that provided by a standard business or hospital environment.
Surges (Line to ground), IEC 61000-4-5	±2 kV	
Conducted disturbances induced by RF fields, IEC 61000-4-6	3V, 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Recommended separation distance > 30 cm
Voltage dips, IEC 61000-4-11	0% Ut; 0.5cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270 and 315°	The instrument should be supplied with power of the same quality as that provided by a standard business or hospital environment. When the user of the instrument demands continuous operation even during a power outage, it is recommended that the instrument 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: at 0°	
Voltage interruptions, IEC 61000-4-11	0% Ut; 250/300 cycle	
Remarks:	Ut is AC power supply voltage before applying a testing level.	

(c) DC Input Power Port

None.

(d) PATIENT coupling PORT

Phenomenon, Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment	Electromagnetic Environment - Guidance
IEC 61000-4-2, ELECTROSTATIC DISCHARGE	±8 kV contact ±15 kV air	The floor material should be made of wood, concrete or ceramic tile. If the floor is covered with synthetic materials, it is desirable that the relative humidity of these is at least 30%.
Conducted disturbances induced by RF fields, IEC 61000-4-6	3 V, 0.15MHz - 80MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Recommended separation distance > 30 cm

(e) Signal input/output parts PORT

Phenomenon, Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment	Electromagnetic Environment - Guidance
IEC 61000-4-2, ELECTROSTATIC DISCHARGE	±8 kV contact ±15 kV air	The floor material should be made of wood, concrete or ceramic tile. If the floor is covered with synthetic materials, it is desirable that the relative humidity of these is at least 30%.
Electrical fast transients / bursts, IEC 61000-4-4	±1 kV, 100 kHz repetition frequency	The instrument should be supplied with power of the same quality as that provided by a standard business or hospital environment.
Surges (Line to ground), IEC 61000-4-5	±2 kV	The instrument should be supplied with power of the same quality as that provided by a standard business or hospital environment.
Conducted disturbances induced by RF fields, IEC 61000-4-6	3V, 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Recommended separation distance > 30 cm

7.1.4 Guidelines and directives concerning electromagnetic immunity (conducted RF and emitted RF)

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.3 compliant

Immunity examination	IEC 60601 testing level	Conformity level	Electromagnetic environment - guidelines
			Cellular and mobile RF communication devices (including cables) must not be used near any part of the system. Such a device must be used outside of the recommended separation distance calculated by using the formula corresponding to the frequency of the transmitter.
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz	V_1 = 3 V	Recommended separation distance $d = \left(\frac{3.5}{V_1}\right)\sqrt{P}$

Immunity examination	IEC 60601 testing level	Conformity level	Electromagnetic environment - guidelines
IEC 61000-4-3 Emitted RF	3 V/m 80 MHz to 2.5 GHz	E_1 = 3 V/m	$d = \left(\frac{3.5}{E_1}\right)\sqrt{P}$: 80 MHz to 800 MHz $d = \left(\frac{7}{E_1}\right)\sqrt{P}$: 800 MHz to 2.5 GHz
			In the above formulas, *P* represents the transmitter's maximum output power rating in watts (W) (according to the transmitter manufacturing company), and *d* represents the recommended separation distance in meters (m). The electric field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency bandwidth[b]. 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. 
Remark 1: For 80 MHz and 800 MHz, apply a high frequency range. Remark 2: These guidelines might not apply in all circumstances. Electromagnetic propagation is affected by reflection off or absorption by buildings, objects, and people.			
a: 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: For bandwidths outside of the 150 kHz - 80 MHz range, the field intensity should be less than 3 V/m.			

7.1.5 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.3 compliant

Maximum output power rating of the transmitter (W)	Separation distance (m) based on the frequency of the transmitter		
	150 kHz to 80 MHz $d = \left(\frac{3.5}{V_1}\right)\sqrt{P}$	80 MHz to 800 MHz $d = \left(\frac{3.5}{E_1}\right)\sqrt{P}$	: 800 MHz to 2.5 GHz $d = \left(\frac{7}{E_1}\right)\sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.369	0.369	0.738
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3
For a transmitter with a maximum output power rating that is not listed above, the recommended distance *d* in meters (m) can be estimated using the formula corresponding to the frequency of the transmitter. In the formula, *P* represents the transmitter's maximum output power rating in watts (W), according to the manufacturer of the transmitter.			
Remark 1: Apply high frequency ranges for 80 MHz and 800 MHz. Remark 2: These guidelines might not apply in all circumstances. Electromagnetic propagation is affected by reflection off or absorption by buildings, objects, and people.			

(2) IEC 60601-1-2 Ed.4 compliant

(a) ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency,Band	IMMUNITY TEST LEVELS	Electromagnetic Environmen - Guidance
385 MHz, 380 MHz - 390 MHz	27 V/m, Pulse modulation 18 Hz	Customers or users of the instrument can help prevent electromagnetic interference by maintaining 30 cm and more distance between a mobile RF communication instrument (a transmitter) and the instrument.
450 MHz, 430 MHz - 470 MHz	28 V/m, FM ±5 kHz deviation 1 kHz sine	
710 MHz, 704 MHz - 787 MHz	9 V/m, Pulse modulation 217 Hz	
745 MHz, 704 MHz - 787 MHz		
780 MHz, 704 MHz - 787 MHz		
810 MHz, 800 MHz - 960 MHz	28 V/m, Pulse modulation 18 Hz	
870 MHz, 800 MHz - 960 MHz		
930 MHz, 800 MHz - 960 MHz		
1720 MHz, 1700 MHz - 1990 MHz	28 V/m, Pulse modulation 217 Hz	
1845 MHz, 1700 MHz - 1990 MHz		
1970 MHz, 1700 MHz - 1990 MHz		
2450 MHz, 2400 MHz - 2570 MHz	28 V/m, Pulse modulation 217 Hz	
5240 MHz, 5100 MHz - 5800 MHz	9 V/m, Pulse modulation 217 Hz	
5500 MHz, 5100 MHz - 5800 MHz		
5785 MHz, 5100 MHz - 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 *7.1 Guidelines for electromagnetic compatibility* on page 168 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 in 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 megahertz 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]).

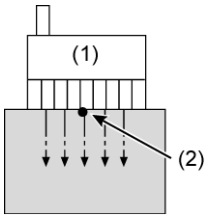
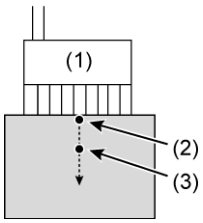
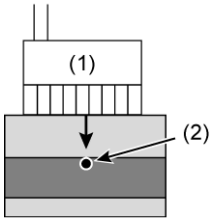
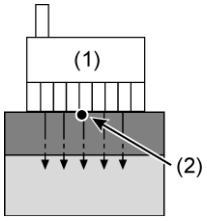
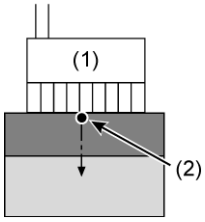
$$TI = \frac{P_\alpha}{P_{deg}}$$

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	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%. However, when AP%=70% and MI>1.0 and TI>1.0, the default level adjusts automatically to ensure that MI≤1.0 and TI≤1.0.

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, whereas 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.

$$u_C = \sqrt{u_A{}^2 + u_B{}^2} \qquad (4)$$

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*. That is,

$$U = k \bullet u_C \qquad (5)$$

The measurement result is then conveniently expressed as the following.

$$x = \bar{x} \pm U \qquad (6)$$

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 (P), pulse-intensity integral (PII), peak-rarefactional acoustic pressure (p_r), acoustic working frequency (f_c)). 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 $\begin{cases} p : \text{transducers} \\ q : \text{consoles} \\ r : \text{repetetions} \end{cases}$

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}	$m_{p.}$
	$m_{.1}$	$m_{.2}$	. . .	$m_{.q}$	$\overline{\overline{m}}$

$S_{i.}$ (braces the $m_{1.}$ … $m_{p.}$ column)

$S_{.j}$ (braces the $m_{.1}$ … $m_{.q}$ row)

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 23 (= pq - 1) degrees of freedom. (From Table 1 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.

$$Power = \bar{m} \pm U \tag{24}$$

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 95 (= pqr - 1) 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.

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

(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, k is set to 2.07, the value of $t_{.975}$ with 23 (= pq - 1) degrees of freedom. (From Table 1 Appendix A of UD 2-2004)

The expanded uncertainty calculated by using formula (23)	U:	12.22%

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

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 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, *k* is set to 2.07, the value of $t_{.975}$ with 23 (= *pq* - 1) degrees of freedom. (From Table 1 Appendix A of UD 2-2004)

The expanded uncertainty calculated by using formula (23)	*U*:	25.62%

$$\mathrm{PII} = \overline{\overline{m}} \pm 25.62\ \%(95\%\ \mathrm{C.I.})$$

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%

$$\mathrm{PII} \leq \overline{\overline{m}} + 36.03\ \%$$

(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, *k* is set to 2.07, the value of $t_{.975}$ with 23 (= *pq* - 1) degrees of freedom. (From Table 1 Appendix A of UD 2-2004)

The expanded uncertainty calculated by using formula (23)	U:	13.19%

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

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_c

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, k is set to 2.07, the value of $t_{.975}$ with 23 (= pq - 1) degrees of freedom. (From Table 1 Appendix A of UD 2-2004)

The expanded uncertainty calculated by using formula (23)	U:	2.39%

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

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. Detection error:	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] slider 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.
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.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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.

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.
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 backslash or equal sign is entered in personal names (Patient Name, Reffering Phys, Sonographer).	1. Select the [OK] button. 2. Delete any back slashes and equal signs. [OK]: Clears the message.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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's 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's 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's 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 patient information is being received from the HIS and RIS.	The message is cleared when reception of patient information is complete.
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.

Messages	Status or cause	Countermeasures
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 no patient ID is 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's hard disk.	• [Yes]: Imports the patient information indicated in the message and overwrites the corresponding information on the system's hard disk. • [All Yes]: Imports all patient information from the external storage medium and overwrites the patient information on the system's 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 setup dialog box in the ID screen.	• [OK]: Deletes the specified item. • [Cancel]: Clears the message without deleting the specified item.
Warning! The disk capacity is insufficient to save all patient information data. 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 exceeds 32,000.	Back up the image data on the Search screen. Alternatively, back up the patient information on the Data Management screen, and then delete the data.

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.
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.
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.

Messages (Data Management)	Status or cause	Countermeasures
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's 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's 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.
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's 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. Write 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].

Messages (Data Management)	Status or cause	Countermeasures
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.
The entered patient ID already exists. Enter another patient ID.	This message is displayed when the user enters a registered patient ID to modify patient information on the Data Management screen.	• [OK]: Clears the message.

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's 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's 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 if the user entered an invalid value for starting year.	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.

Messages (Japanese Calender)	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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's hard disk.	• Delete unnecessary images from the system's hard disk. • Save only data that does not exceed the free space on the system's 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's 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's 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.	This message is displayed when there is insufficient space on the connected storage medium.	Connect a storage medium with sufficient free space. • [Retry]: Retransmits the image. • [Cancel]: Closes the message without sending the image.

Messages	Status or cause	Countermeasures
Error: Disk full. Delete unnecessary images.	This message is displayed when there is insufficient space on the system's hard disk.	Delete unnecessary images to increase free space on the system's hard disk. • [Retry]: Retransmits the image. • [Cancel]: Closes the message without sending the image.
Hard disk access error: Hard disk must be diagnosed.	This message is displayed when images cannot be saved to the system's 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: 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. • [Retry]: Retransmits the image. • [Cancel]: Closes the message without sending the image.
The DICOMDIR is full. Change to another media.	This message is displayed when the DICOM DIR cannot be updated.	Re-save the image. • [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.	Images are saved to the system's 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 display, 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...	This message is displayed during processing.	The message is cleared when processing is complete. [Cancel]: Forcibly terminates the processing.
Saving...		
Sending...		
Deleting...		
Printing...		
DICOM Printing...		
Preparing to copy...	This message is displayed during processing preparation	The message is cleared when preparation is complete. [Cancel]: Forcibly terminates the processing.
Preparing to save...		
Preparing to send...		
Preparing to delete...		
Preparing to print...		
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.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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. NOTE: If you are using encrypted communications, the certificate may have expired. Please contact our office.
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.
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.

Messages	Status or cause	Countermeasures
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 MPP 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.

Messages	Status or cause	Countermeasures
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.
Failed clearing the CD-R buffer.	This message is displayed when the CD-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.
CD-R writing is completed.	This message is displayed when writing to CD-R is complete.	[OK]: Closes the message.
Operation is canceled.	This message is displayed when [Cancel] is selected during writing to CD-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.
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.
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 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.
The recorder is not supported.	This message is displayed when the recorder does not support CD writing.	[OK]: Closes the message.
No disk in CD-R drive.	This message is displayed when there is no disc in the CD-R drive.	Insert a new disc into the CD-R drive. [OK]: Closes the message.
CD-R type is not known.	This message is displayed when an unwritable disc is inserted into the CD-R drive.	Insert a writable disc into the CD-R drive. [OK]: Closes the message.

Messages	Status or cause	Countermeasures
No more space available on CD-R.	This message is displayed when the free space on the disc is smaller than the quantity of data in the CD-R Buffer.	Insert a disc 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.
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.	[OK]: Closes the message.
Unknown error	This message is displayed when a CD-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.
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.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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.
Launch failed. The system is busy.	This message is displayed when the user attempts to start an analysis application while an image is being copied, saved, transferred, printed, or deleted.	Start the analysis application after the image is copied, saved, transferred, printed, or deleted. [OK]: Closes the message.

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.
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.

Messages	Status or cause	Countermeasures
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 [Initialize] 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 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 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 return to the factory settings?	This message is displayed when the [Initialize] button was selected in a preset screen other than application presets.	• [OK]: Replaces the selected data with the copied data, and then closes the dialog box. • [Cancel]: Closes the dialog box without replacing the selected data with the copied data.
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.

Messages	Status or cause	Countermeasures
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.
The specified path is invalid.	This message is displayed when the entered file path is longer than 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.

Messages	Status or cause	Countermeasures
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 #.

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.
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.

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 finishes. (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

Messages	Status or cause	Countermeasures
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.
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 Messages about the battery

Messages	Status or cause	Countermeasures
Please connect the power supply as soon as possible. Because the battery charge is less than 25%.	This message is displayed when the remaining battery level drops to 25% or less.	To keep the system operating, insert the power plug into a hospital grade outlet.

Messages	Status or cause	Countermeasures
Battery Low! Please connect the power supply as soon as possible. The system will be shutting down within a few minutes because of the battery charge less than 20%.	This message is displayed when the remaining battery level drops to 20% or less.	The system will automatically shut down after a while. To keep the system operating, insert the power plug into a hospital grade outlet. [OK]: Returns to the previous screen.
Battery Low! Please connect the power supply immediately. The system will be shutting down automatically within 2 minutes because of the battery charge less than 15%. This may cause damage to system file or data.	This message is displayed when the remaining battery level drops to 15% or less.	The system will automatically shut down after two minutes. Insert the power plug into a hospital grade outlet in order to continue using the system, because the system files and data might be corrupted. If you no longer need to use the system, finish the examination, and then shut down the system.
Because it changed to battery drive, the power supply of the peripheral devices was cut off. If you use the peripheral devices, please connect the power supply.	This message is displayed when you remove the power plug and the system switches to battery power.	When battery power is used, power of the peripherals is shut down because of the power capacity. To keep the peripherals operating, insert the power plug into a hospital grade outlet. [OK]: Returns to the previous screen.
The battery temperature is too high. Because it cannot be used the battery anymore for safety reasons, the system will be shutting off automatically. If you found this message many time, please request a new battery to the customer support center.	This message is displayed when the battery temperature is too high.	The system will automatically shut down. Before using the system, check the air vent and insert the power plug into a hospital grade outlet. If the same message appears even though the air vent is normal, contact our office. [OK]: The system shuts down automatically.
The system found some error of the battery. Please connect the power supply and turn the battery switch to the DISCONNECT mode. And please request a new battery to the customer support center.	This message is displayed when a battery abnormality is detected.	Insert the power plug into a hospital grade outlet, and then set the battery switch to the DISCONNECT mode to disconnect the battery. Then, contact our office. [OK]: Returns to the previous screen.
Please agree to shut down the system. It may not boot up because of the battery remain capacity too low.	This message is displayed when an attempt was made to start the system on battery power when the remaining battery level is less than 15%.	Because the remaining battery level is low, the system could shut down during startup. • [Shutdown]: The system shuts down automatically. • [Start up] The system starts by using the remaining battery power.

Messages	Status or cause	Countermeasures
Please connect the power supply immediately.	This message is displayed when [Start up] is selected while the following message is displayed: "Please agree to shut down the system. It may not boot up because of the battery remain capacity too low."	Because the remaining battery level is low, the system could shut down during startup. Insert the power plug into a hospital-grade outlet.
This battery may drain fast. If you need the new one, please request it to the customer support center.	The battery cycle count has exceeded 500.	The battery life has decreased. The battery needs to be replaced. Please contact our office.

8.9 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 system's hard disk is less than 10 GB.	1. Press the [Enter] key to start the system. 2. Delete unnecessary data from the system's hard disk.
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 system's hard disk is less than 100 MB.	1. Press the [Enter] key to start the system. 2. Delete unnecessary data from the system's hard disk.
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.

Messages	Status or cause	Countermeasures
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 us to perform an inspection.
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.

Messages	Status or cause	Countermeasures
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.
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.

Messages	Status or cause	Countermeasures
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.
Please shutdown system.	This message is displayed when a hardware error occurs at startup. If the operation panel was not initialized normally	Shut down the system. 1. Press the [Shutdown] key. 2. The system shuts down automatically. If the same message is displayed after restarting, make a note of the message and contact our office.
Auto Image Delete All the data stored before the following date will be deleted. yyyy/mm/dd Estimated time hh:mm:ss (*** files)	This message is displayed if the system is shut down when the preset [Auto Image Delete] is set to [Time].	[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 (*** files)	This message is displayed if the system is shut down when the preset [Auto Image Delete] is set to [Storage Commitment].	[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... **% Do not turn off the system. Do not unplug the AC power cable while deleting. Please wait. By pressing [ENTER], the system will stop deleting, and will shutdown.	This message is displayed while Auto Image Delete is running.	The message disappears when deletion is complete. Press the [Enter] key to interrupt the deletion and shut down the system.

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