FUJIFILM

Diagnostic Ultrasound System

ALOKA ARIETTA 850

Instruction Manual

Instructions for Use

This is the instruction manual for the ALOKA ARIETTA 850 Diagnostic Ultrasound System.

Before using the instrument, please read this manual.

CE 0197

Thank you for purchasing the FUJIFILM Healthcare Corporation ALOKA ARIETTA 850 Diagnostic Ultrasound System; we truly appreciate your business.

IMPORTANT
Before using the instrument, please read this manual and make sure you understand it. Be sure to keep this manual handy for future reference.

Please note that actual screen displays (including icons and design) may differ from the Diagnostic Ultrasound System screens reproduced in this manual.

Some of the messages described in this manual may not be displayed by the Diagnostic Ultrasound System, depending on its configuration (including its options).

For information regarding functions not described in this manual, refer to the separate "Acoustic Output Data", "Basic Operations", "Advanced Operations (1 to 3)" and "Measurements (1 to 3)".

The contents of this manual apply to the ARIETTA 850, the ARIETTA 850SE and the ARIETTA 850CE which are considered to be equivalent models.

Any and all mentions of "ARIETTA 850" in this manual apply to the ARIETTA 850, the ARIETTA 850SE and the ARIETTA 850CE.

Precautions concerning the software incorporated with this instrument

Regarding the software installed in this instrument, the following actions are prohibited.

(1) Reselling, assigning, or transferring the software itself

(2) Reverse engineering, reverse compiling, or reverse assembling

(3) Modification, alteration or translation

(4) Creating copies or duplicates

(5) Leasing to third parties

Symbols Used in this Document

The terms below are used as follows in this manual, to prevent hazards and injuries to operators and patients. The severity of a hazard and injury that can occur when failing to observe the displayed safety information is indicated in 4 levels: DANGER, WARNING, CAUTION, and NOTE.

⚠ DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor injury or property damage.
⚠ NOTE	Indicates a strong request concerning an item that must be observed in order to prevent damage or deterioration of the equipment, and also to ensure that it is used efficiently.

The safety symbols have the meanings shown below.

	This symbol means attention is required.
	This symbol indicates a prohibition.
	This symbol indicates a mandatory action.

About ALOKA ARIETTA 850 Diagnostic Ultrasound System

This device is intended to be used by doctors and other qualified persons to perform tomography and hemodynamic diagnosis of blood flow in the human body.

However, this device cannot be used to perform an eye ultrasound. The acoustic power from this device exceeds the upper ophthalmologic limit according to U.S. FDA standards.

I) Precautions concerning the use and management of this device

- Operations for diagnostic purposes are to be performed by doctors or other quality persons only.
- Perform scans for the minimum length of time and at the lowest output needed for diagnosis.
- Do not disassemble, repair, or modify the device or its optional equipment without the permission of this company. Repair work will be handled by personnel certified by this company. Please notify us when repair work is needed.

  NOTE: Disassembly means the use of tools to remove the casing or other parts of the device.

  NOTE: Modification means the attachment, to this device, of parts or devices other than those specified by this company. Modification includes the replacement of the power cable.
- The device and any optional equipment will be installed (mounted and connected by using tools) by certified partners of this company. Please notify us when the device or optional equipment needs to be installed.
- The device will be transported (moved via vehicle or ship, etc.) will be performed by an authorized representative of this company. Please notify us when the device needs to be transported.
- Periodically clean and inspect the device. For details, see “Instructions for Use”.
- If an abnormality occurs during the use of the device, immediately remove the probe from the patient and stop using the device. If the patient exhibits unusual or abnormal symptoms, immediately provide the appropriate medical treatment. Perform the appropriate measures for the device in accordance with “Instructions for Use”. If the abnormality is not described in “Instructions for Use”, please contact us.

II) Precautions concerning device installation

This device is medical electrical equipment intended for use in hospitals, research institutions, and other similar facilities. Install this device as described below.

- Install the device in accordance with “Instructions for Use”.
- Install the device in an environment that meets the conditions described in “Instructions for Use”.
- Install the device in an environment that can maintain electromagnetic compatibility according to “Instructions for Use”.

  Electromagnetic compatibility (EMC) means that the device can maintain essential performance and safety within the relevant electromagnetic environment, without causing electromagnetic interference that cannot be tolerated by other devices in that environment.

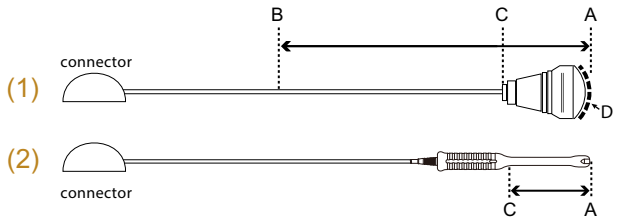
III) External dimensions and weight of the device

External dimensions	Width: 550 mm ±10%, Depth: 900 mm ±10%
	Height: 1220 mm ±10% to 1695 mm ±10%
Weight	145 kg ±10% (main unit only), 163 kg ±10% (main unit and all optional equipment)

Device classification of ALOKA ARIETTA 850 Diagnostic Ultrasound System

- Protection against electric shock: Class I and ME equipment
- Protection against electric shock (applied parts): Type BF applied part
  - Probes and scanner

    Refer to the diagram below (or the probe or scanner diagrams) and table below for applied parts and parts handled as such.



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

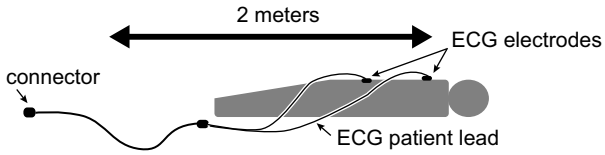
(2) Example of body cavity probes.

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

  - ECG, PCG, Pulse

    Applied parts are regarded as such within a 2 m range from a physiological signal sensor (see drawing below).

    Example: ECG



- Protection against electric shock (Defibrillation-proof applied parts): Not suitable
- Protection against infiltration by water or particulate substances
  - Probe applied part: IPX7 (rated for brief immersion in water)
  - Foot switch

    MP-2819*: IPX7 (rated for brief immersion in water)

    MP-2345B: IPX8 (rated for continuous immersion in water)
  - Other Details: IPX0 (ordinary equipment)

- Suitability for use in an oxygen rich environment: Not suitable
  - Method(s) of sterilization: Not suitable for sterilization/disinfection with medicinal solution, gas or radiation.
- Operation mode: Continuous operation

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1 Precautions

1-1 Safety Precautions

The terms below are used as follows in this manual, to prevent hazards and injuries to operators and patients. The severity of a hazard and injury that can occur when failing to observe the displayed safety information is indicated in 4 levels: DANGER, WARNING, CAUTION, and NOTE.

⚠ DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor injury or property damage.
⚠ NOTE	Indicates a strong request concerning an item that must be observed in order to prevent damage or deterioration of the equipment, and also to ensure that it is used efficiently.

The safety symbols have the meanings shown below.

	This symbol means attention is required.
	This symbol indicates a prohibition.
	This symbol indicates a mandatory action.

1-1-1 Warnings and Safety Information

⚠ DANGER

DO NOT use this instrument in a flammable atmosphere.

Use of this instrument in a flammable atmosphere may cause an explosion.

⚠ WARNING

DO NOT attempt to repair the instrument. Do not disassemble. Do not modify (the power cable must not be replaced). *1, *2

Electric shocks and other accidents could result.

For details regarding instrument repair, please contact our office.

Do not use on patients who may have an allergic reaction to latex products.

Use of a rubber cover when examining such patients could result in an anaphylactic shock. Ask the patient about allergy history beforehand.

Clean, disinfect and sterilize the probes as required.

Wear medical gloves during examination, and wash your hands as standard practice once the examination is complete.

Otherwise, there is a risk of infection to the examiner and patient.

Dispose of probes used for patients with Creutzfeldt-Jakob disease.

Otherwise, there is a risk of infection to the examiner and patient. Our ultrasound probe is not compatible with any disinfection/sterilization method for Creutzfeldt-Jakob disease.

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

*2. Modification means attachment of parts or devices to this instrument other than those specified by the manufacturer. Replacement of a power cable counts as a modification.

⚠ CAUTION

The service life of the instrument is seven years.

This is the service life you can expect when the instrument is used, maintained and inspected under prescribed operating conditions and when components that need regular replacement are replaced as required. For details on recommended maintenance and inspections, refer to "The Need For Regular Maintenance Inspections" in this manual. For details on components that need regular replacement, please contact our office.

Regularly perform maintenance inspection and safety inspection of the instrument and probes.

With prolonged use, some parts of this instrument may deteriorate, causing it to fall below full performance or causing smoke emission and fire.

If anything unusual occurs, immediately stop using it and contact our office.

Do not connect devices and probes other than those specified in this manual to the instrument.

Use with unapproved devices can result in an electric shock, burns, or other injuries to the patient or examiner, and damage to this instrument.

All non-medical devices that are connected to the instrument and to be used must comply with the relevant IEC standards or ISO standards.

Furthermore, the entire configured 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.

⚠ CAUTION

Do not install this instrument or optional equipment without our approval. Do not transport. *1, *2

Electric shocks and other accidents could result.

Contact our office in the event you wish to transport or install this instrument and any optional equipment.

*1. Installation means the use of tools for mounting and connection.

*2. Transportation means the movement of this product on a vehicle, ship, etc.

⚠ CAUTION

Install the instrument in the following locations:

- 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.

Injuries or burns etc. to the patient or the examiner could result.

Adjust the position and orientation of the monitor, keeping a sufficient distance between the instrument and the peripheral equipment, walls and people.

Do not knock the monitor against the touch panel, USB connected medium, cable hook, probe, probe holder, operation panel, or other parts.

Route the probe cables so that they do not become entangled with the monitor, monitor arm and the instrument rear handle.

Contact with the monitor may result in injury or in damage to the surrounding equipment, the walls, the probe, the instrument, the monitor or the touch panel. Warn doctors, patients, and others in the area before adjusting the position and orientation of the monitor.

Should the monitor break and its internal fluid come into contact with the skin, wipe it away and wash the skin in running water for at least 15 minutes. To be on the safe side, consult a doctor. If it gets in someone's eyes, rinse them in running water for at least 15 minutes, and be sure to consult a doctor.

If the monitor is damaged, stop using the instrument immediately and contact our office.

Do not block the ventilation holes.

The temperature inside the instrument will rise, leading to fire or breakdown.

Do not spill water or other liquids on the body of the instrument.

The instrument is not protected against the entry of liquids.

Using the instrument with water on it can cause electric shock and short-circuiting.

Should liquid spill on the instrument, please contact our office.

The instrument must be dry when used.

Avoid rapid temperature changes which can cause condensation.

Using the instrument when condensation or water drops are present could result in malfunction, electric shock or short-circuits.

If you observe anything abnormal in the instrument, probes, peripherals or options, turn the power off immediately, and stop using the instrument.

Such situations can result in injury to the patient or operator, or other unexpected accidents.

Check for messages, temperature, damage and other aspects of instrument status, then contact our office.

If anything unusual occurs in the instrument or the patient when this instrument is used, remove the probe from the patient immediately and stop using the instrument.

If the patient condition is abnormal, take appropriate medical action.

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

⚠ CAUTION

Do not touch the pins that are exposed in the probe connector or DC IN sockets at the same time as you touch the patient.

Do not touch the patient with anything other than an applied part or equivalent applied part.

There is a risk of shorting and of electric shock to the patient.

Do not touch or get close to the pins that are exposed in the probe connector or DC IN sockets.

Touching them could expose them to electrostatic discharge (ESD), which may damage them.

Scan only for the minimum length of time necessary for the diagnosis, and at the lowest possible output. Fetal ultrasound scans must be conducted with 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 can cause electric shock and short-circuiting.

Do not allow sterilized probes to come into contact with the instrument (or the probe holder).

The instrument is not intended to be sterilized.

Before use, coat the probe adequately with ultrasound gel.

Freeze the image as standard practice when the probe is not in use, even during an examination.

Using a probe without a coating of ultrasound gel may cause probe surface temperature to rise, potentially causing burns.

If anything unusual occurs, such as a temperature rise, immediately stop using it and contact our office.

Hold the probe securely during an examination. Store probes in the probe holder when not in use.

Injuries to the patient or the examiner could result.

Do not apply unreasonable force when moving a probe inserted into a body cavity.

That could injure the patient.

Do not freeze an image during a puncture operation (especially not during needle insertion).

Or it will not be possible 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 what will be punctured.

Scan a USB flash drive for viruses before use.

Do not allow the connection of USB flash drives to the instrument as this increases the risk of computer virus infection. If they must be used, make sure to scan them for viruses on a computer before connecting them.

1-1-2 Labels

Labels that indicate the following cautions are attached to the instrument.

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

The following are standard precautions about connection terminals.

⚠ CAUTION

Keep your hands away from the connection terminals.

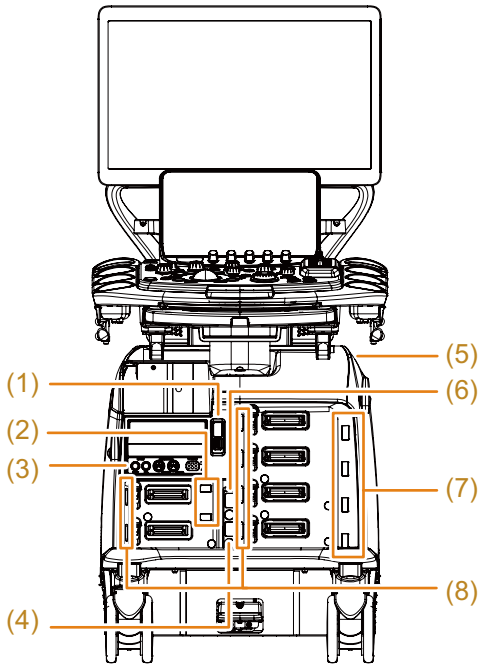
An electrostatic discharge (ESD) could damage or destroy parts that are sensitive to static electricity. For details, refer to section 7-2, "Electrostatic Discharge (ESD) Guidelines".

The label below warns the user not to pinch his hands in openings.

⚠ CAUTION

Take care to avoid pinching your fingers.

There is a risk of electric injury.



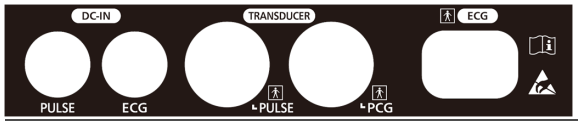
NOTE: For details on Real-time Virtual Sonography, refer to the section "Precautions Concerning Real-time Virtual Sonography" in this volume.

(1)		USB connector (USB 3.0)

(2) 

Dummy connector.

Even if a probe is connected to this socket, no ultrasonic images will be displayed.

(3) 

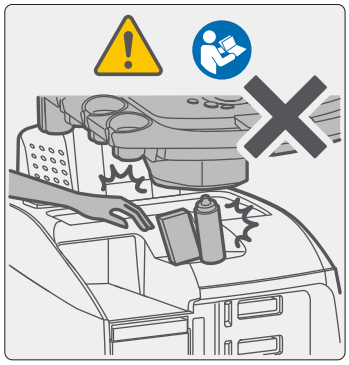
Connection terminals for physiological signals (for connecting physiological cables)

 : This shows a type BF applied part.

DC-IN	: External input terminal.
TRANSDUCER	: Connection terminal for the Physiological Signal Unit cable.

(4) 

Foot switch connector.

(5) 

Do not place objects within the movable area of the panel arm.

Damage could otherwise result.

(6) 

Independent probe connector.

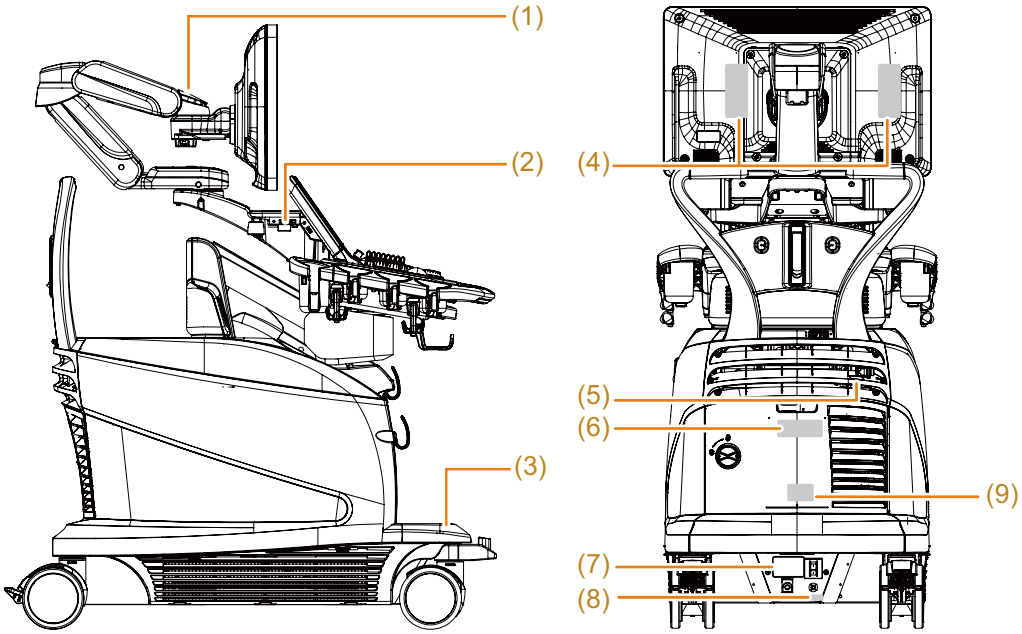
The numbers are connector numbers.

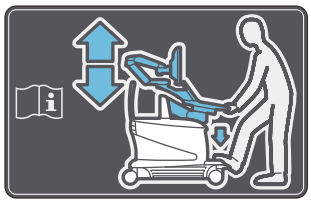
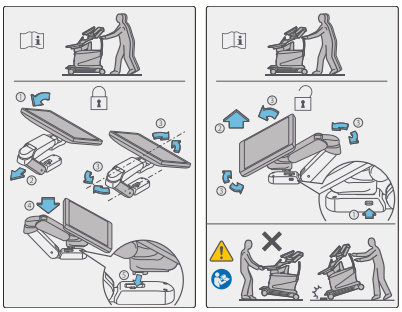
(7) 

A connector for connecting probes.

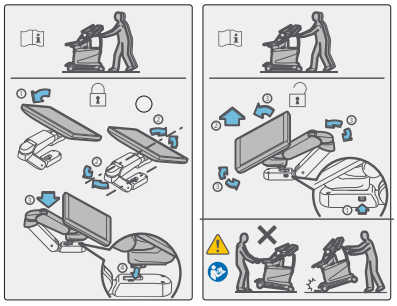
The numbers (1-4) are connector numbers.

(8)		Indicates whether the probe is locked or not. Above: Unlocked Below: Locked



(1)		Take care to avoid pinching your fingers.
(2)		USB connector
(3)		Shows how to adjust operation panel height. Grab the handle on the operation panel and push down on the up-and-down pedal to move the operation panel up or down.
(4)	OLED: 	Follow the instruction manual to lock the monitor in position and to move the instrument. Move the instrument by grasping the handle at the back of the instrument. Do not lift the instrument by grasping the handle of the operation panel. Damage could otherwise result. Take great care when moving the instrument over bumps.

LCD:



(5)

LAN cable connector.

(6)

These symbols indicate safety precautions, etc.

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

Safety and Warning Symbols.

This indicates safety information.

Beware of explosion

⚠ DANGER

DO NOT use this instrument in a flammable atmosphere.

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

Beware of electric shock

⚠ CAUTION

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

Failure to do so may cause short-circuiting and electric shock.

Beware of acoustic power

⚠ CAUTION

Scan only for the minimum length of time necessary for the diagnosis, and at the lowest possible output.

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

Beware of trapping your hands

⚠ CAUTION

Take care to avoid trapping your fingers in unexpected locations.

They could become pinched resulting in an injury.

Follow the supplied documentation

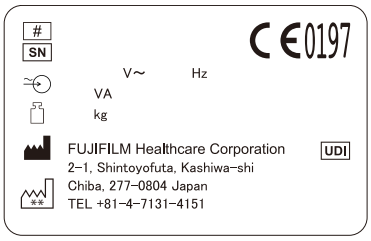
⚠ CAUTION

Operate this instrument as described in the instruction manual.

Failure to observe these instructions could result in injury to the patient or operator and damage to the instrument or its peripheral devices.

 No pushing	⚠ CAUTION **Do not push the side of the device. Do not apply excessive force.** The instrument could tip over, causing injury. The instrument or its peripheral equipment could be damaged.
 No sitting	⚠ CAUTION **Do not sit on the instrument.** The instrument could tip over, causing injury. The instrument or its peripheral equipment could be damaged.
 No disassembly, repair or modification	⚠ WARNING **Do not disassemble, repair or modify the instrument.** It can result in unexpected accidents and electric shocks. For details regarding instrument repair, please contact our office.
 No use of wireless devices	⚠ CAUTION **Do not use wireless devices (e.g. cellular phone, PHS, radio transceiver, etc.) near (nor closer than 30 cm) this device.** The interference from such devices can distort or introduce artifacts in images, disrupt physiological signals and distort the sound from the speakers.

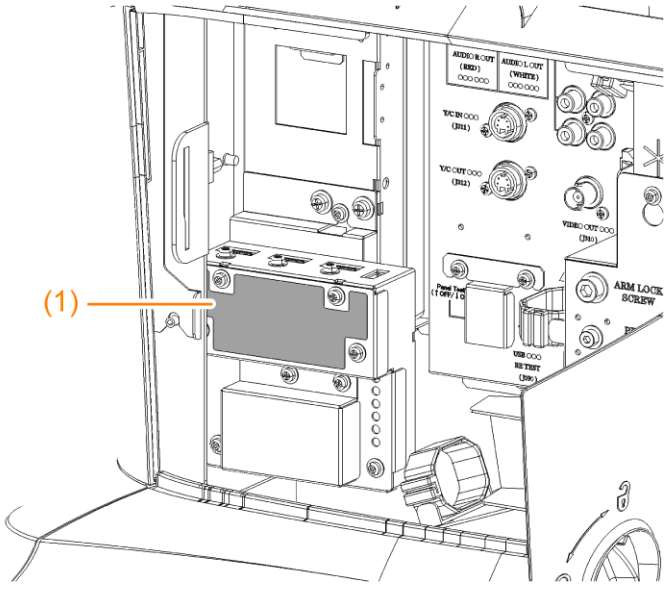
(7)

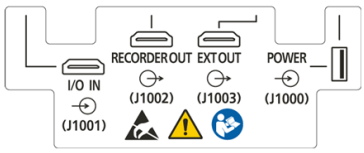


This shows the manufacturer name, model name, and other information.

CE 0197	This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS. This symbol is applied only within EU.
	Manufacturer.
#	Model number.
SN	Serial number.
	Power input of alternating current.
	Weight (approximate maximum value).

		Country of manufacture. The characters, "**" in the symbol are the country of manufacture code defined by the International Organization for Standardization. For example, "JP" means Japan. The numbers adjacent to this symbol indicate the year and the month of manufacture.
		Unique Device Identifier (UDI) The GS1 DataMatrix and plain-text for UDI are printed adjacent to this symbol.
(8)		Equipotential terminal.
(9)		The importer for EEA:European Economic Area region is represented according to European Union Directives 93/42/EEC and 2011/65/EU. This label is applied only within EU and UK.
		Name and address of the Authorized representative in the European Community.
		Importer.



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

1-2 Precautions Concerning Acoustic Power

The human body is composed of soft tissue, water, bone and other tissue, and these properties are different each other. Though ultrasound propagates through the body with losing its energy, the amount of energy loss depends on the tissue. For example, the fetal tissue below amniotic fluid with low attenuation will be exposed to more energy.

Ultrasound produces two types of bioeffects, thermal bioeffects, such as the heating of soft tissue and bone and mechanical bioeffects, such as vibration and cavitation.

Be careful when performing ultrasound examination in the vicinity of tissues, such as bone, which easily convert ultrasound energy into heat. In particular, for the examination of fetus after ossification stage, as almost all of the ultrasound energy passes through the amniotic fluid with much low attenuation, the potential risk due to heating increases.

Even before ossification, fetal cells are sensitive, so growth may be affected, even with a slight rise in temperature.

Thermal bioeffects increase not only with higher energy levels but also with longer exposure time.

On the other hand, the mechanical bioeffects, such as vibration and cavitation, are caused by acoustic pressure and the force occurs to disrupt the cells. These effects occur when the acoustic pressure exceeds the threshold.

Therefore, 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 instrument functions, become familiar with operation methods and understand the parameters that affect acoustic power.

Since thermal bioeffects can be decreased not only by using a lower driving voltage but also by shorter exposure time, we recommend that you always freeze the image as soon as you have obtained the necessary diagnostic information.

Since mechanical bioeffects can be decreased by using a lower driving voltage and higher frequencies, we recommend that you keep the driving voltage as low as you can get enough clinical information and that you try to select an appropriate frequency.

⚠ CAUTION

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

⚠ CAUTION

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 suited to the body tissue that is being analyzed.

Refer to the separate "Basic Operations" volume for details on how to switch between different types of thermal index.

- Soft tissue or fetus in early pregnancy: TIS
- Soft tissue or fetus in mid or late pregnancy with bone at/near the focus: TIB
- With bone at the surface, for example, cranial examination: TIC

Do not use Doppler modes for routine fetal examinations.

Doppler modes in fetal examinations are only to be used where clinically indicated, such as in known or suspected high risk pregnancies.

1-3 Precautions Concerning the Probe

The handling, cleaning, disinfecting, sterilizing and storing of probes varies with the type of probe. For details, refer to the documentation for the probe. The following are common cautions for probes.

1-3-1 Handling Precautions

Probes are precision instruments. 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 probe cables and make sure they do not become entangled with other parts or in the casters.
  - Connect the probe as described in this manual and 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 adequately with ultrasound gel.
  - Do not apply unreasonable force when moving a probe inserted into a body cavity.
  - When a probe is not used in 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.

    Otherwise, there is a risk of infection to the operator or patient. Our ultrasound probe is not compatible with any disinfection/sterilization method for Creutzfeldt-Jakob disease.

Handling Precautions for Probes with Built-in Temperature Sensors

Some probes have built-in temperature sensors in their tips. These sensors monitor the surface temperature of the probe tip to prevent tissue injury from excessive heat. The sensor is influenced by the temperature of patient's deep body regions.

MXS1 Handling Precautions

When the probe tip surface temperature exceeds 37.0°C, the message "TTE T: 37.0°C" displays the current temperature at the top of the screen.

NOTE: The instrument uses a thermistor to maintain temperature within ±0.9°C of the displayed temperature.

The message shown below appears.

Probe tip surface temperature and messages

Surface temperature of probe tip (rough guide)	Message	Status
When 41°C is exceeded	"The temperature is higher than 41.0°C."	An assist message is displayed.
When 43°C is exceeded	"TTE Thermal limit. Auto Cooling Mode in Progress."	A beep sounds. The ultrasonic image freezes and the panel switch lights go out.*1 The following operations are not available: • Panel switches • Touch Panel Menu

*1. When the surface temperature of the probe tip falls below 40.5°C, the message clears, Freeze is turned On, and the examination can be restarted.

Other Messages

Message	Status
"TTE fatal error (5) Discontinue examination and turn the system off."	The temperature sensor may be broken. If the instrument is damaged, stop using it immediately and contact our office.
"Do not remove the probe without freezing the image."	Freeze the image before removing the probe.

Precautions Concerning Mechanical Probes

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

1-3-2 Cautions in Performing a Puncture Operation

NOTE: For details on puncture operations, refer to the documentation for the probe and the puncture adapter.

- Inspection Prior to Use
  - Inspections must be performed according to the documentation provided with the probe and puncture adapter.

    Do not use any probe or puncture adapter that is abnormal.
  - Use a water tank to make sure that needle echo matches the puncture guide line.
  - Make sure that the probe, puncture adapter and puncture needle have been sterilized.
  - Ensure that the puncturing needle is not bent.
- Caution when installing the puncture adapter
  - Install the puncture adapter in the probe as described in the documentation for the probe and the puncture adapter.
- Cautions in performing a puncture operation
  - A puncture operation must only be performed by a skilled doctor.
  - While performing a puncture operation, ensure that the instrument 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 stop probe use.

    If the patient's condition appears abnormal, provide appropriate medical treatment immediately.
- 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, check 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 speed of sound in tissue differs from 1,540m/s, the angles of the puncture guide line and needle echo may not match.
  - Check the safety of any puncture path that is not visible on the display.

    There may be blood vessels or other organs in the puncture path that are not visible on the display.
  - Verify the location of the puncturing needle using the needle echo that is displayed on the display.
  - When puncturing while a 4D probe is connected, close 4D mode and switch to B mode.

    Puncture guidelines cannot be displayed during 4D operation.
  - Do not perform a puncture operation when the assist lines indicated.

    The assist lines do not indicate accurate positional information. Do not use as a puncture guide line.

– When performing a puncture operation when a CC41R probe, a CC41R1 probe, a C41L47RP probe, or a CL4416R probe is connected, check the puncture guideline 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 guideline with the cross-section line, as doing so might cause injury to the patient.

  For details, see the documentation for the probe.

– In Real-time Virtual Sonography, do not puncture while looking only at the virtual image.

  Use the virtual image as a guideline for ultrasonic diagnostics.

1-4 Precautions for Use in Conjunction with Drugs

- Use with ultrasound contrast agent

  When using ultrasound contrast agent, use a 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, always pay constant attention to the patient's condition.

In a perfusion examination using ultrasound contrast agent, the pulse rhythm of the heart may be disturbed even if the mechanical index (MI) is within the standard value.

Handle the ultrasound contrast agent as described in its documentation.

- Use in conjunction with general drugs

  If you perform an ultrasound examination after having the patient ingest a general pharmaceutical, the ultrasound may affect the pharmacological effect of the pharmaceutical. Before using a general pharmaceutical, carefully read the accompanying documentation for using the pharmaceutical and also any cautionary notes.

1-5 Precautions for Use With Other Medical Devices

Thoroughly read through the documentation for the other medical devices to be used with this instrument, and use those devices correctly.

- Connection to the equipotential terminal

  Use the equipotential terminal on the back of the instrument to eliminate potential differences relative to other medical devices, the bed, etc.

- Use in conjunction with devices which use high frequencies

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

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

- Simultaneous use with a defibrillator

  This instrument may not be used in combination with a defibrillator.

  When using a defibrillator, keep probes and the electrodes for physiological signals far enough away from the patient.

  Transesophageal probes shall be removed from the PATIENT prior to application of a defibrillator.

- Use with an external physiological signal monitor

  Use only a physiological monitor that conforms to the international standards for medical electrical equipment with this instrument. Do not use a physiological monitor if the supplied documentation prohibits its use together with the Diagnostic Ultrasound System or similar medical electronic instruments.

- Use with a medical monitor for displaying images (medical monitor) or a robotic surgical unit for surgical procedures

  To use a medical monitor or a robotic surgical unit for surgical procedures together with this system, use the optional HDMI-monitor connection unit.

⚠ CAUTION

Perform safety checks on the other medical devices to be used with this instrument, and do not use them if they are faulty.

Electric shock or instrument breakdown could otherwise result. If the instrument does not operate normally, immediately stop using it.

When using this instrument together with other medical electrical equipment, position the instrument and its cables (probe cables, ECG cables, I/O cables, etc.) as far away as possible from other appliances and their cables.

Note that electromagnetic interference generated by this instrument may prevent the normal operation of other medical electrical equipment that is used together with the instrument. Do not use the instrument together with such equipment.

⚠ CAUTION

If you use a medical monitor or robotic surgical unit for surgical procedures, the monitor or unit must conform to the international standards for medical electrical equipment.

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

Make sure that probes, operator's hands and puncture adapters etc. are not in the path of high-frequency current.

The probe could be damaged, and the patient, examiner or operator could receive burns. High frequencies may impair the ability of this instrument to produce images.

Operate this instrument 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 could be damaged, and the patient, examiner or operator could receive burns.

Use an attachment capable of suitable puncture guidance, and operate it carefully.

Do not use this instrument together with a defibrillator.

Poor instrument performance or malfunction may otherwise result.

1-6 Precautions for Maintaining Electromagnetic Compatibility

Electromagnetic compatibility means that the instrument 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.

Medical electrical equipment, transmitters, radio and TV antennas and similar equipment generate electromagnetic interference and may be affected by such interference. As a 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 it receives such interference, effects can include noise in images, disruption of physiological signals, and abnormal sounds from speakers.

To prevent electromagnetic interference and maintain electromagnetic compatibility, observe all precautions regarding I) the electromagnetic environment, II) use of portable or mobile RF communications equipment and III) use with other medical electrical equipment.

NOTE: A doctor must consider whether artifacts caused by electromagnetic interference could adversely affect images or diagnoses.

I) Electromagnetic environment

This instrument is medical electrical equipment intended for use in hospitals and other health-care facilities.

Install the instrument according to the installation conditions and “Guidelines for Electromagnetic Compatibility”.

- Position this instrument as far away as possible from radio receivers, TV sets, and their cables and antennas. Note that electromagnetic radiation from this instrument may cause electromagnetic interference to radio receivers, TV sets, etc.
- If the instrument is to be used near a motor (elevators, pump rooms, etc.), power transmission line or wireless instrument that generates electromagnetic interference, it is necessary to electromagnetically shield it.

II) Using portable or mobile RF communications equipment

Do not use portable radio communication devices (e.g. cellular phones, PHS, radio transceivers, etc.) near (nor closer than 30 cm) this device. This instrument may be affected by portable or mobile RF communications equipment.

III) Using the instrument with other medical electrical equipment

If this instrument receives electromagnetic interference, effects can include noise in images, disruption of physiological signals, and abnormal sounds from speakers. Position this instrument and its cables (probe cables, ECG cables, I/O cables, etc.) as far away as possible from other equipment used with the instrument and its cables.

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

Use connection cables that satisfy the following conditions.

No.	Cable	Cable Shield	Max. cable length
1	LAN	Yes	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 Guidelines for Electromagnetic Compatibility → p.238

1-7 Precautions Concerning Power Plugs and Power Cables

⚠ CAUTION

Plug the power plug of the instrument directly into a hospital grade power outlet.

Do not connect the instrument to an extension cable, or to a branched circuit. There is a risk of electric shock or fire.

Do not damage, modify or break the power cable. Do not place heavy objects on power cables, twist them, bundle them, pull them, or bend them excessively.

A damaged power cable can cause electric shock and short-circuiting.

Stop using the instrument immediately if the power cable or power plug is damaged. For details regarding instrument 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 instrument.

Continued use can cause poor contact, leading to fire.

For details regarding instrument repair, please contact our office.

Unplug the power plug from the hospital grade outlet periodically and clean it.

If the cable is not properly maintained, it can cause electric shock and short-circuiting.

Wipe away any dust and moisture adhering to the power supply plug with a dry cloth.

If the instrument will not be used for an extended period of time, unplug it from the hospital grade outlet and store the power cable gently coiled.

Note that turning the power switch of the instrument Off does not disconnect the instrument from the power supply.

1-8 Precautions Concerning Real-time Virtual Sonography

Read through the manual before running the Real-time Virtual Sonography software.

Real-time Virtual Sonography should be operated by doctors or those with relevant qualifications who have been educated about it.

⚠ WARNING

Do not attempt to repair the magnetic sensor and the transmitter. Do not disassemble. Do not modify.

Electric shocks and other accidents could result.

Ask us to perform any repairs.

Use the magnetic sensor and its attachments after they have been cleaned, disinfected, and sterilized. After use, they should be cleaned, disinfected, and sterilized again.

Otherwise, there is a risk of infection to the examiner and patient.

For information on cleaning, disinfecting, and sterilizing the probe and its attachments, refer to the documentation supplied with the probe.

E-Field Simulator is to be used by trained professionals who have carefully read the documentation of the medical equipment used in combination with it.

An E-Field image displayed by E-Field Simulator indicates an electric field based on a simulation, and might differ from the actual cauterization range. If you do not use this software correctly, you might not be able to achieve the expected treatment effects.

⚠ CAUTION

Transmitters should not be used near patients with pacemakers or other devices that are adversely affected by magnetism.

Devices such as pacemakers that produce their own magnetic fields could malfunction.

Do not estimate the puncture path by looking only at the virtual image or at the virtual puncture guide lines.

Doing so may result in misalignment when puncturing.

Determine the puncture path while looking at the ultrasound image.

Do not connect objects other than magnetic sensors to the control unit.

The software will not function correctly if something other than a magnetic sensor is connected.

Attach the magnetic sensor and its attachments correctly according to the documentation supplied with the probe.

The software will not function correctly if the magnetic sensor is attached in an incorrect orientation.

Connect the magnetic sensors for the probe, Needle Tracking and Body Motion Tracking to the correct connectors.

The software will not function correctly if the magnetic sensors are incorrectly connected.

Do not expose the magnetic sensor and the transmitter to strong impacts or heavy loads.

Otherwise, you could damage the magnetic sensor or transmitter. If either of these devices are struck with great force, please contact our office.

The value displayed on-screen is to be taken as a reference value.

The distance between the electrode centers of needle markers displayed on a virtual image does not necessarily match the actual length.

⚠ CAUTION

Check that there is no positional shift between the US and the virtual images during the examination.

Rough handling of the probe may result in injury to the patient.

The patient's body movements (breathing, etc.) and environment (metallic component in the bed) may lower the position detection accuracy causing a shift in positional relationship between the US and the virtual image.

Any deviation in the positional relationship between the US image and the virtual image will result in a deviation in the positional relationship between the registered needle mark and the US image. Register a needle mark after checking that the US image matches the virtual image.

Align the positions of the base image and parts images correctly.

Rough handling of the probe may result in injury to the patient.

When using the RVS flexible stand, do not position the transmitter above the patient.

If the upper and lower arm stopper knobs are not properly secured, the arm may fall and injure the patient.

When using the RVS flexible stand, firmly secure the upper and lower arm stopper knobs after adjusting the height of the transmitter.

Otherwise, the arm may slide off. The upper and lower arm stopper knobs prevent the arm from sliding and falling off.

Do not forcefully hit the arms attached to the RVS flexible stand or the RVS Onboard arm. In addition, do not place a heavy load on the arms.

There is a risk that the device could be damaged and cause injury to the patient and the examiner. There is also a risk that the transmitter, the RVS flexible stand, or the RVS Onboard arm could be damaged.

Be sure to fold the arm of the RVS flexible stand when lowering or raising it. At this time, do not move by holding the transmitter or surrounding equipment.

Otherwise, the patient and the operator could be injured.

Pay extra attention when handling the arms on the RVS flexible stand and the RVS Onboard arm.

The patient and the operator could be injured if he/she is hit by the transmitter or the arm.

There is also a risk of pinching your hands or fingers in the openings of the moving parts of the arm (joint).

If the transmitter or the arm comes in contact with a person or an object, the peripheral equipment, the RVS flexible stand, or the RVS Onboard arm might be damaged.

Do not expose the transmitter cable to stress.

The transmitter cable could be damaged causing an open circuit.

When using the RVS flexible stand, handle the transmitter cable with care.

Or the transmitter cable could wrap itself around the RVS flexible stand causing it to fall.

When moving the main unit or the RVS flexible stand, be careful not to bump the transmitter or the arm into other objects.

The operator could be injured if he/she is hit by the transmitter or the arm.

The transmitter, arm and surrounding equipment could be damaged.

Before moving the main unit or the RVS flexible stand, fold and secure the arm.

Otherwise, the arm could accidentally move and injure someone. The arm could accidentally move hitting the transmitter or surrounding equipment in the area and damage them.

Do not lean against the RVS flexible stand, the RVS Onboard arm, or the tray. In addition, do not forcibly push the RVS flexible stand when the casters are locked.

If the RVS flexible stand falls, the patient might be injured and the arm, tray, or other parts of the device might be damaged.

Do not sit on the RVS flexible stand, the RVS Onboard arm, or the tray.

If the RVS flexible stand falls, the patient might be injured and the arm, tray, or other parts of the device might be damaged.

⚠ NOTE

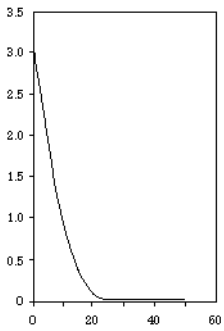
Remove metallic objects (watches, necklaces, etc.) before inspection.
They could cause the virtual image to flicker.

Do not touch the transmitter during the examination.
It could result in noise within the US image.

1-8-1 Precautions for electromagnetic compatibility

- Effect of electromagnetic interference on the magnetic sensor unit
  Magnetic sensor unit performance may be affected if placed near a device generating magnetism or a steel bed or when the transmitter or the magnetic sensor is within 1 m of a large object made with iron or steel.

- Effect of electromagnetic interference from the magnetic sensor unit
  The strength of the magnetic field will weaken the further away from the magnetic sensor unit (and transmitter) you are.



The relationship between distance from the transmitter and strength of the magnetic field
The vertical axis is the strength of the magnetic field (mT), and the horizontal axis is distance from the transmitter (cm)

Devices which could have an effect on the maximum magnetic field strength

Maximum Magnetic Field Strength	Devices which could have an effect
2.0 mT	Motor, camera
1.5 mT	Black and white monitor
1.0 mT	Mechanical clock, credit card, magnetic tape, magnetic disc used in computers
0.5 mT	Pacemaker, CT scanner
0.3 mT	Diagnostic Ultrasound System
0.1 mT	Color monitor, image intensifier, microscope, scintillation camera
0.05 mT	Emission CT

NOTE: It's recommended that you use the magnetic sensor as close to the transmitter as possible to stay within its effective range (20 to 76 cm). If the magnetic sensor is too far away from the transmitter, ripples could appear

in the virtual image.
Its positioning precision will also deteriorate.

NOTE: The receiving frequency (frequency band) of the magnetic sensor is 240 Hz.

NOTE: The transmitter generates a pulsed magnetic field with a frequency of 240 Hz.

2 Product Summary

2-1 Intended Use

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

- Thorax
- Abdomen
- Perineal and pelvic internal organs
- Lower limbs
- Back
- Upper limbs
- Head
- Neck

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

⚠ WARNING

DO NOT use this instrument for performing ultrasound examination of the eyes.
The acoustic power from this instrument exceeds the upper ophthalmologic limit indicated in the U.S. FDA standards.

⚠ CAUTION

Connect the probe in accordance with this manual or the documentation for the probe.
Failure to do so could result in injuries or burns to the patient or operator, and other accidents. Do not use the instrument for purposes other than those specified in this manual.

2-2 Operating principles

A number of transducers of multiple available transducers form a block that almost simultaneously transmit 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, transducers adjacent to the transducers in the first block start sending and receiving ultrasound waves to form the second ultrasound beam. The center of the second ultrasound beam is shifted from the center of the first ultrasound by one transducer. In this manner, different blocks of transducers are used each time to create multiple ultrasound beams with a slightly different center and form a scan plane. Also, the beams can 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 can obtain a beam that is joined in overall focus.

This instrument can also revise the time difference between ultrasonic waves that arrive at different times due to different speeds within the patient or diagnostic region.

The ultrasound beams obtained as explained above are converted to video signals with the digital scanning converter, and are displayed on the viewing monitor.

This instrument can be used for individual or combined display in the image display modes listed below.

- B mode is a display mode in which the tomographic image is formed with plural ultrasound beams by the methods mentioned 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. It indicates these reflected echoes in one direction from the interior of the patient's body's on time-series scale.
- There are two types of D (Doppler) mode: 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.
- Color Doppler mode receives ultrasound from the same direction and detects any changes that occur over time to identify three types of bloodstream information: its direction, its speed, and its inconsistency. In this system, this mode includes Color Flow mode, Power Doppler mode, high-resolution Power Doppler (eFlow) mode, and Detective Flow Imaging (DFI) mode. Switch the modes according to your needs.

The 5 methods of electronic scanning are as follows.

- Linear Scanning Method:
  By this method, 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:
  By this method, the ultrasound beam from the ultrasound probe is emitted radially and draws a tomographic image of the patient.
- Sector Scanning Method:
  By this method, the ultrasound beam from the ultrasound probe is emitted in a fan shape (sector) and draws a tomographic image of the patient.
- Radial Scanning Method:
  By this method, the ultrasound probe emits a 360 degree (radial) ultrasound beam and draws a tomographic image of the test subject.
- Trapezoidal Scanning Method:
  By this method, the ultrasound beam from the ultrasound probe is emitted radially without regard to the form of the probe head and draws a tomographic image of the patient.

2-3 Specifications

Overview	
Electronic scanning method	Linear Scanning Method Convex Scanning Method Sector Scanning Method Radial Scanning Method Trapezoidal Scanning Method
A probe that is suitable for connection	Electronic Probes: 4 units 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 the body cavity Intra-operative (not for direct application to the heart, central circulatory organs, and central nervous system)
Users	Doctors or other qualified persons
External dimensions	Width: 550 mm±10%, Depth: 900 mm±10% High: 1220 mm±10% to 1695 mm±10%
Mass	145 kg ±10% (main unit only), 163 kg ±10% (with all options included)
Service life	7 years

Display mode	
	B Mode
	M Mode
	D Mode
	Color Doppler mode

Viewing monitor	
Organic EL monitor (OLED)*1	22.0 inch, 16:9 aspect ratio
Monitor movement (OLED)	Rotation: Arm joint mechanism makes possible 160° turns. Tilt: Upwards 60°, downwards 10° Up and down movement: 224 mm Longitudinal: 225 mm
Digital LCD monitor*2	23.0 inch, 16:9 aspect ratio
Monitor movement (LCD)	Rotation: Arm joint mechanism makes possible 160° turns. Tilt: Upwards 60°, downwards 20° Up and down movement: 169 mm

*1. Supported for the ARIETTA 850.
*2. Supported for the ARIETTA 850SE and the ARIETTA 850CE.

In/Output specification	
Image output	DVI-D Y/C Composite Digital video with HDMI connector (when the optional HDMI monitor connection unit is attached)
Image input	DVI-D Y/C
Audio in/output	Audio L/R
Network	LAN
USB	USB A receptacle, USB 2.0 × 5, USB 3.0 × 1

Recorder
Monochrome printer
Color printer
Video recorder

Basic Functions	
Gain adjustment	TGC: 8 levels LGC: 8 levels B Gain: 80 dB variable M Gain: B Gain±30 dB variable Doppler gain: 60 dB variable Color Doppler gain: 63.5 dB variable
Focus	Send focus: Up to 16 levels (Up to 4 levels for multi-level focus) Receive focus: Continuous dynamic focus
Probe Change Frequency	Up to 5 frequencies (depending on the probe) Tissue harmonics: A total of 15 frequencies (depending on the probe)
Ultrasonic output power	0% to 100% (can be set for each mode)
Scanning angle	100% to 25% Maximum scanning angle: 360°
Display depth of field	7.5 mm to 400 mm
Zoom	PAN Zoom (read zoom) HI Zoom (write zoom)
B, M image processing	Dynamic range: 40 dB to 90dB Smooth/Enhance: 17 levels (including Off) Persistence: 8 levels (including OFF) PRF (B): 3 levels AGC: 8 levels (including Off) Graymap: 10 types Speed of sound correction: Available Adaptive imaging: HI REZ function (8 levels) γ curve: 4 types Color map (B, M): 15 types can be assigned
Compound Functions	Available

Basic Functions	
Trapezoidal Display Functions	Available
B Steer Display Functions	Available

M mode Image Display Functions	
Display method	During Real-Time: 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 function	
Analysis Method	FFT method
Velocity range	±802.08 cm/s to ±1.26 cm/s
Wall filter	12 levels
Sampler volume width	0.5 mm to 20.0 mm
Sweep speed	7 levels (40.0 mm/s to 300.0 mm/s)
Dual-gate Doppler Functions	Available

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

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

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

Color Doppler function	
Color display method	Velocity / velocity dispersion display Velocity display Power display Directional power Doppler display High-resolution power Doppler display
Color Map	A total of 15 types can be assigned.
Velocity range	±458.33 cm/s to ±0.63 cm/s
Wall filter	3 levels

Presets	
Application Functions	Up to 25 types per probe (number of types that can be user registered: a total of 100 types)
Preset Group Loading Functions	Up to 4 types per application, preset: QSS
Region Data Setting Functions	A total of 12 types per diagnostic field (number of types that can be user registered: a total of 9 types)

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 Measurements Cardiology Measurement Vascular Measurement Obstetrics Measurements Gynecological Measurements Superficial Organ Measurement

Measurement accuracy

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

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

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

2-3-1 Power Supply Conditions

Power supply voltage	100V to 120 V, 200 V to 240 V
Electrical frequency	50/60Hz
Power consumption	1300 VA or less

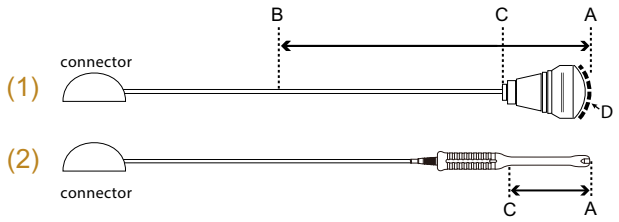
2-3-2 Ambient Conditions

	Operating Conditions	Storage conditions or transporting conditions (when packed)
Ambient Temperature	+10°C to +40°C RVS (option) when used: +10°C to +30°C	-10°C to +50°C
Relative Humidity	30% to 75% (no condensation)	10% to 90% (no condensation or freezing)
Atmospheric pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Altitude	3000 m or less	–

2-3-3 Device classifications

- Protection against electric shock: Class I and ME equipment
- Protection against electric shock (applied parts): Type BF applied part
  - Probes and scanner

    Refer to the diagram below (or the probe or scanner diagrams) and table below for applied parts and parts handled as such.



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

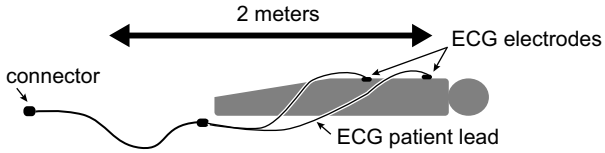
(2) Example of body cavity probes.

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

  - ECG, PCG, Pulse

    Applied parts are regarded as such within a 2 m range from a physiological signal sensor (see drawing below).

    Example: ECG



- Protection against electric shock (Defibrillation-proof applied parts): Not suitable
- Protection against infiltration by water or particulate substances
  - Probe applied part: IPX7 (rated for brief immersion in water)
  - Foot switch

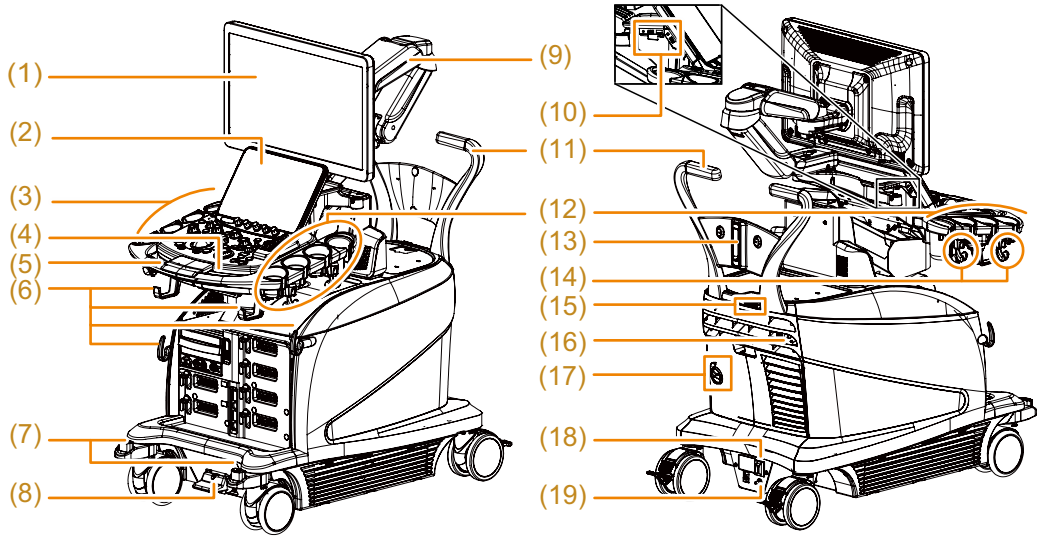
    MP-2819*: IPX7 (rated for brief immersion in water)

    MP-2345B: IPX8 (rated for continuous immersion in water)
  - Other Details: IPX0 (ordinary equipment)
- Suitability for use in an oxygen rich environment: Not suitable
  - Method(s) of sterilization: Not suitable for sterilization/disinfection with medicinal solution, gas or radiation.

- Operation mode: Continuous operation

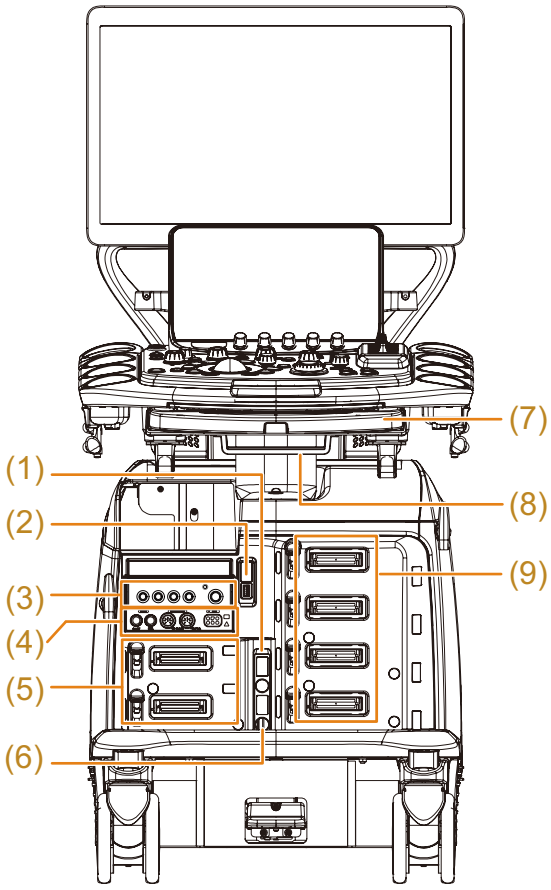
2-4 Part names

I) Instrument appearance



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

II) Instrument exterior (front)



(1) Independent probe connecting unit (option)

(2) USB (3.0) connector

(3) RVS Control unit (optional) or storage drawer

(4) Physiological signal unit (optional)

(5) Dummy Connector*1

(6) Foot switch connector

(7) Alphanumeric keyboard

(8) ECG clip bar

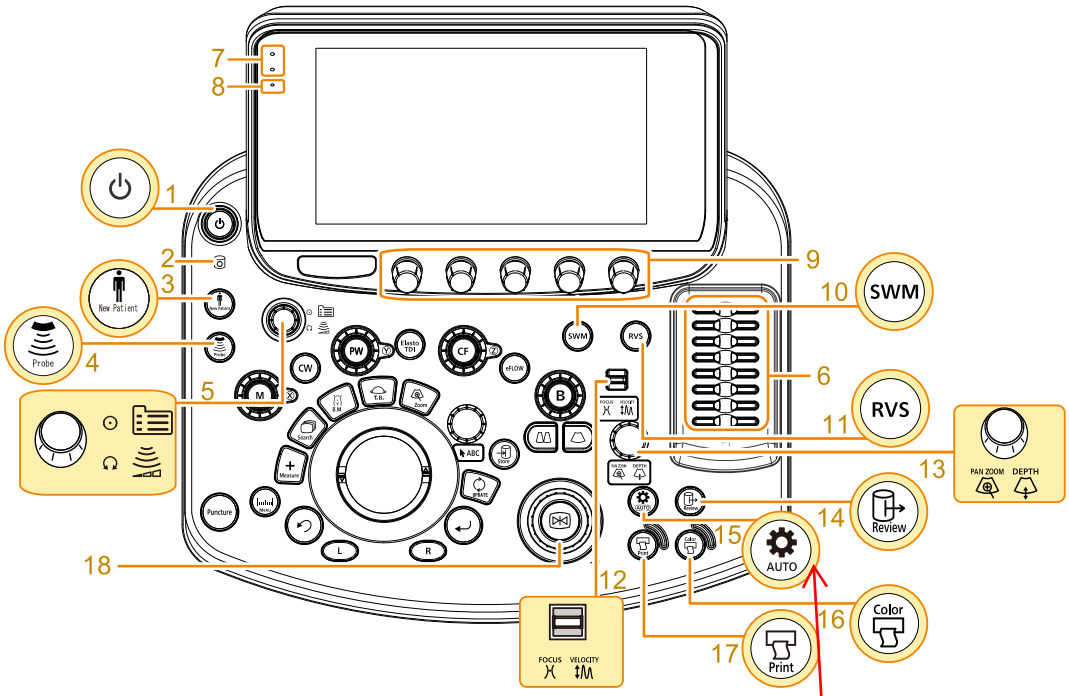
(9) Probe connector

Connector 1 - connector 4 from above

*1. Connector for temporarily fastening a probe. Even if this connector is connected, no images will be displayed.

III) Operation panel

NOTE: The push-button rotary encoders combine keys whose names are provided in the top row with rotary encoders whose names are provided in the bottom row. Information on how to use them is provided at the end of this section.



Operation panel diagram

(1) [Power] key

(2) Disk access lamp

(3) [New Patient] key

(4) [Probe/Preset] key

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

(6) [TGC] knobs

(7) Optical sensor

(8) Status indication lamp
Power on: Blinks white. When the operation panel is exposed to strong shock: Blinks orange.

(9) Multi Rotary encoder

(10) [SWM] key

(11) [RVS] key

(12) [FOCUS/VELOCITY] paddle switch

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

(14) [Review] key

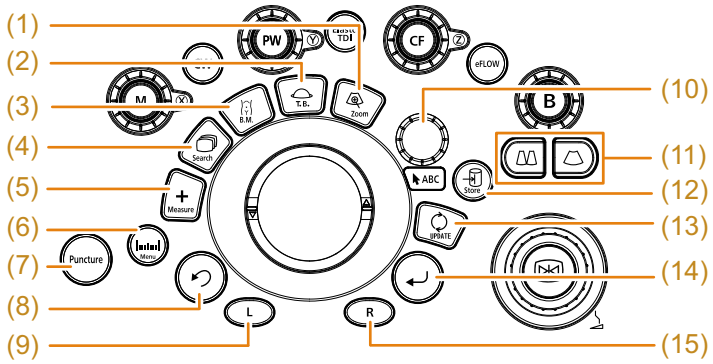
(15) [Auto-optimizer] key

(16) [Color Printer] key

(17) [Print] key

(18) [Freeze] key

[Freeze] rotary encoder



Operation panel (trackball area)

(1) [HI Zoom] key

(2) [Trackball Function] key

This document refers as the [T.B.F.] key.

(3) [Body Mark] key

(4) [Cine Search] key

(5) [Caliper] key

(6) [Measurement] key

(7) [Puncture] key

(8) [UNDO] key

(9) [L] key

[Pointer] key

(10) [Pointer] rotary encoder

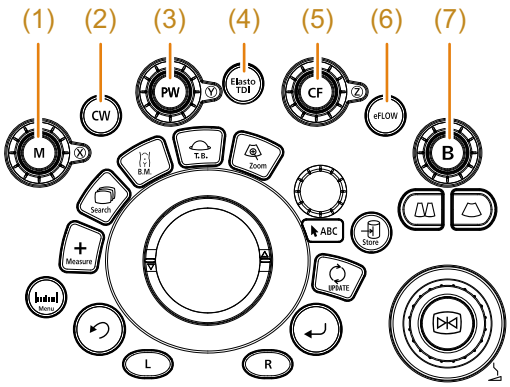
(11) [Single]key, [Dual] key

(12) [Store] key

(13) [Update] key

(14) [Enter] key

(15) [R] key



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

(2) [CW] key

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

(4) [Elasto/TDI] key

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

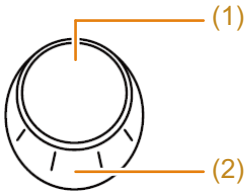
(6) [eFLOW] key

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

Push button type integrated rotary encoder

Key names are in the top row and names for the rotary encoders are in the bottom row.

Use the keys as follows to operate them.



(1) Key
Press to operate.

(2) Rotary encoder
Turn to operate.

3 Setup Before Use

3-1 Installation and Moving

3-1-1 Shutting Down, and Disconnecting the Power Supply

This section describes how to shut down the instrument and disconnect it from the power supply.

You can use the preset to set up a shutdown procedure for the instrument. Use the preset [SystemPreset > General > Common1 > Shut down > Power Button Behavior] to configure this procedure. [Shutdown] is the factory default setting.

For details, refer to the separate “Basic Operations”.

⚠ CAUTION

Do not pull the power plug out of the hospital grade outlet while the machine is shutting down or restarting.
That could cause the instrument to break down.
Make sure the instrument is completely shut down before pulling the power plug out of a hospital grade outlet.

1 Press the [Power] key to shut down.

When the Auto Image Delete confirmation screen is displayed

To delete the data, select [Delete].

To cancel without deleting the data, select [Cancel].

NOTE: The screen is not displayed if the number of files to be deleted is zero.

When Power Button Behavior is [Selectable]

“Shutdown Tools.” appear on the touch panel. Select one of the following shutdown options.

Options	Description
Shutdown	Completely shuts down the system and turns the power off.
Hibernation	Hibernates the system and turns the power off. Provides a quicker startup than [Shutdown] the next time you turn the power on. NOTE: This status is maintained even if you unplug the power plug from a hospital-grade power outlet. NOTE: If usage of the instrument (including hibernation) exceeds 50 hours, [Shutdown] is selected even if you select [Hibernation]. The next time the instrument is started, startup will take the usual amount of time.
Return	Returns the instrument to the state it had before the [Power] key was pressed.

2 When “Task in progress. System will power off after handle it.” is displayed on the touch panel, you can select any of the following options to shut down the instrument.

NOTE: This message appears when the instrument has not completed all tasks.

Options	Description
Return	Returns the instrument to the state it had before the [Power] key was pressed.
Yes	Turns off the power when the remaining jobs are completed.
Ignore	Shuts the system down without waiting for remaining jobs to be completed. If you select this option, the message "Task in progress. Power supply off forcibly without handle it. Are you really all right?" is displayed. 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 window.

3 When the message "** more seconds until system is power off." is displayed on the touch panel, the instrument is shut down when the indicated number of seconds elapse.

I) The instrument is shut down when the number of seconds set in [SystemPreset > General > Common1 > Shut down > Power Off Waiting Time(s)] elapses.

II) If [Power off immediately] is selected, the instrument will shut down immediately without waiting for the set time to elapse.

III) If [Return] is selected, the instrument returns to step 1 or step 2.

When the screen indicating that Auto Image Delete is in progress is displayed

The message disappears when the data is deleted.

To suspend deletion of the data, press the [Enter] key.

4 If required, move the instrument to a location where it is easy to unplug.

5 Make sure that the instrument has been shut down before disconnecting it from a hospital grade outlet.

3-1-2 Moving the Instrument

⚠ CAUTION

Take care not to bump the instrument and its probes against other equipment, walls, columns or doors in passages when moving it to a different location. Take great care when moving the instrument long distances and up slopes and over bumps.

Take great care when moving the instrument over bumps. Otherwise, the probe could fall from the probe holder and be damaged.

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

Otherwise, surrounding equipment, the walls or the instrument could be damaged and the instrument could be overturned, which could lead to injury.

The exterior of the instrument could break open exposing users to electric shock hazards.

Do not apply excessive force to the instrument.

There is a risk of injury or damage should the instrument tip over.

Keep the instrument away from moisture when moving it.

It could cause short circuiting or electric shock.

1 Shut down the instrument and prepare it for movement.

Power cable

Unplug the power cable from the hospital grade outlet, gently coil the cable and place the cable on the power cable hook on the back.

Unsecured objects

Detach peripherals, etc. from the instrument. 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 cable hook adjusting their length so they do not become trapped in the casters.

If transvaginal/transrectal probe holders are used, store the probes horizontally. Do not store them vertically.

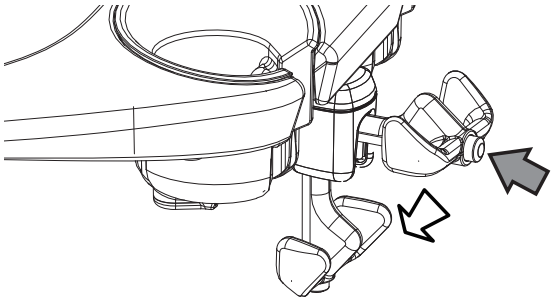
Secured peripheral devices

Remove USB flash drives.

To use an alphanumeric keyboard, push the keyboard in until it clicks into place and secure the keyboard with the lock lever at the back of the operation panel.

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

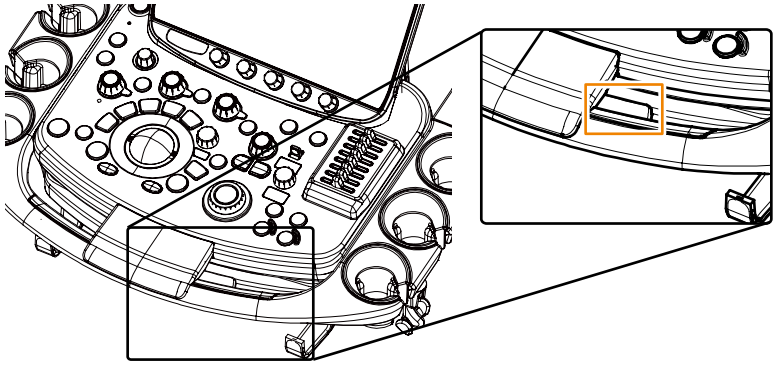
To lower the cable hook, press the button.



3 Face the operation panel to the front.

Holding the handle lever for the operation panel, turn the operation panel towards the front.

Letting go of the lever will hold the orientation of the operation panel in place.



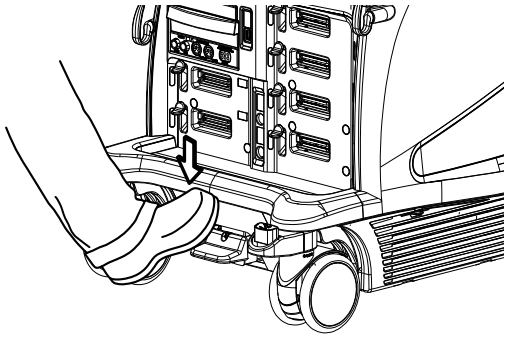
Lever position

NOTE: The operation panel may turn even if you are not holding the handle lever for the operation panel. This is a design feature and not a malfunction.

If the operation panel is repeatedly turned without holding the handle lever for the operation panel, the holding power may change. Be sure to always hold the lever when turning the operation panel.

4 Move the operation panel to the lowest position.

Holding the operation panel handle, press down the operation panel while depressing the operation panel height adjustment pedal with your foot.



Depress the operation panel height adjustment pedal

NOTE: If the probe cables are hanging down, readjust them without getting them caught between the casters.

5 Fix the monitor in place.

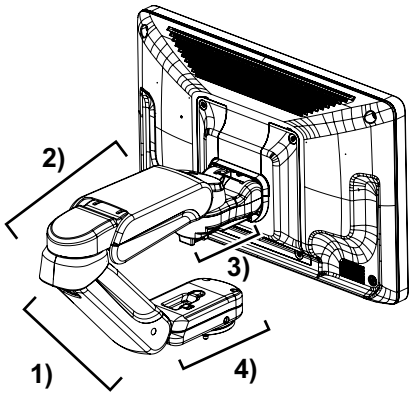
NOTE: This prevents the monitor from moving while the instrument is moved.

For an OLED viewing monitor

1.1.11 Spalvotas monitorius fiksuojamas

a Push the 1st arm to the rear.

b Make the 3rd arm parallel with the base.



1) 1st arm

2) 2nd arm

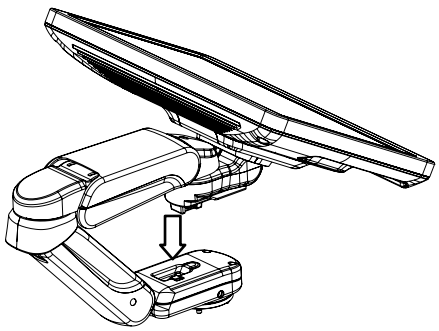
3) 3rd arm

4) Base

c Face the monitor upwards.

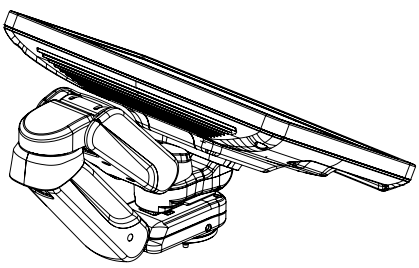
d Lower the 2nd arm and insert a lock block.

→ The 3rd arm is locked when the arm clicks into position.



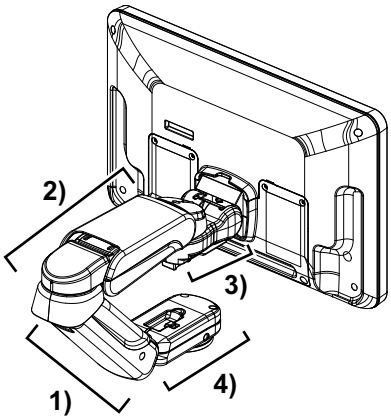
e Turn the 1st arm to a straight position as seen from the front.

→ The 1st arm is locked when the arm clicks into position.



For an LCD viewing monitor

a Make the 3rd arm parallel with the base.



1) 1st arm

2) 2nd arm

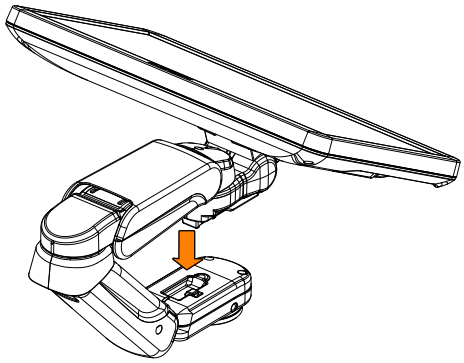
3) 3rd arm

4) Base

b Face the monitor upwards.

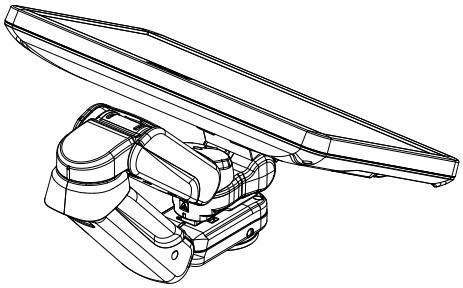
c Lower the 2nd arm and insert a lock block.

→ The 3rd arm is locked when the arm clicks into position.



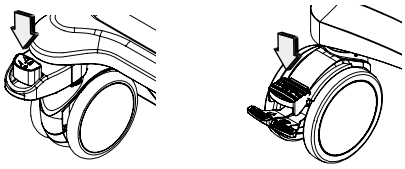
d Turn the 1st arm to a straight position as seen from the front.

→ The 1st arm is locked when the arm clicks into position.



6 Unlock the casters.

Step on the caster locks for the front wheels to push them down. Depress the lock release pedals for the rear wheels.



Left: Front caster

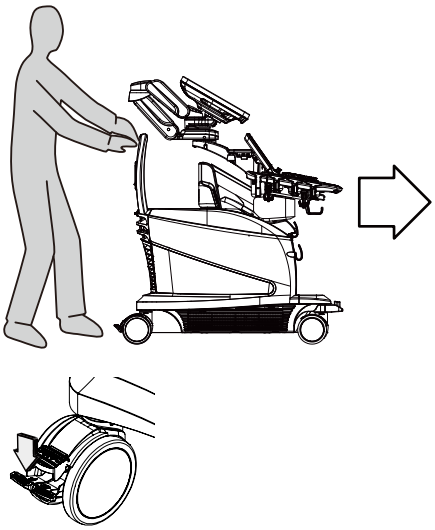
Right: Rear caster

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

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

NOTE: Grasp the handle on the back of the instrument, not the operation panel or its handle.

NOTE: Do not put anything on top of the monitor.



When transporting it over long distances or up and down slopes

Depress the swing lock pedals for the rear wheels in the direction of the arrow.

3-1-3 Installing the Instrument

⚠ DANGER

DO NOT use this instrument in a flammable atmosphere.

Use of this instrument in a flammable atmosphere may cause an explosion.

⚠ CAUTION

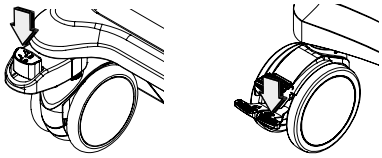
When using this instrument together with other medical electrical equipment, position the instrument and its cables (probe cables, ECG cables, I/O cables, etc.) as far away as possible from other medical electrical equipment and their cables.

Note that electromagnetic interference generated by this instrument may prevent the normal operation of other medical electrical equipment that is used together with the instrument. Stop using together with such equipment immediately.

1 At the installation location, make fine adjustments to the position of the instrument.

2 Once the position and orientation of the instrument are fixed, lock the casters.

Step on the caster locks for the front wheels to push them down. Depress the lock pedals for the rear wheels.



Left: Front caster (the instrument is locked)

Right: Rear caster (the instrument is locked in the forward direction)

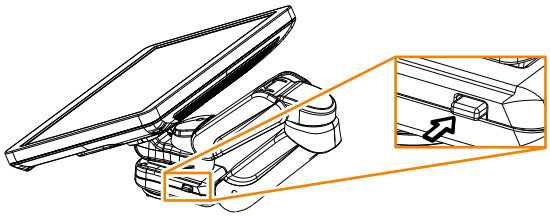
Step in the direction of the arrow to lock the casters.

NOTE: **Place a cloth over the instrument if it is to be in storage for an extended period of time.**

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

→ The status indicator lamp on the side of the touch panel blinks white twice.

4 Release the monitor.



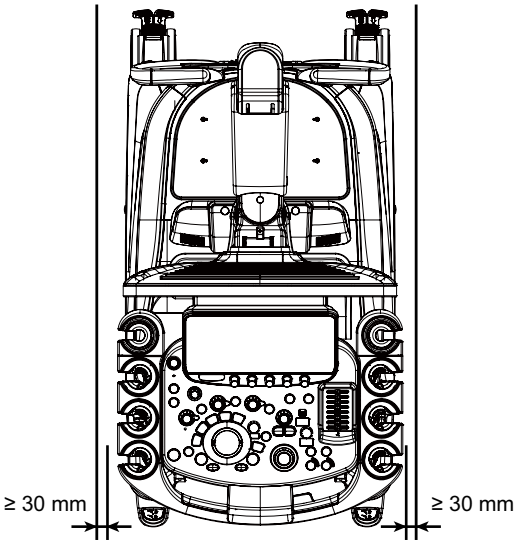
a Hold down the monitor lock release button while raising the arm.

b Raise the monitor.

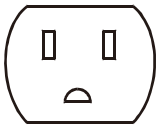
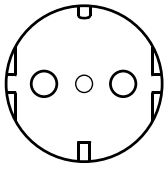
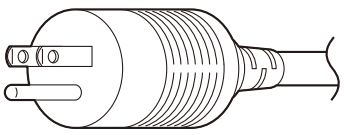
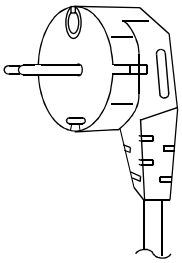
3-1-4 Installation Conditions

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

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



- Install the instrument in a location where its power plug can be plugged directly into a hospital grade outlet, and where it can be moved quickly when the power is disconnected.
  To turn off instrument, disconnect the power plug from the hospital grade outlet.
- Place the instrument in a location where slight instrument movements will not disconnect the power plug.
- Install the instrument in a location that satisfies the operating conditions described in “Ambient Conditions” in this volume.
- The figure shows the type of hospital grade outlets the power plug can be connected to.

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

3-2 Connecting a Probe

⚠ CAUTION

Do not allow sterilized probes to come into contact with the instrument (or the probe holder).

The instrument is not intended to be sterilized.

Store transvaginal/transrectal probes in the following probe holders.

- Probe holders with special adapters
- Transvaginal/transrectal probe holders attached with a transvaginal/transrectal probe holder adapter

If a probe other than a transvaginal/transrectal probe is placed in the above probe holder, the probe may fall out and be damaged.

Do not place a probe with a probe cover horizontally in a transvaginal/transrectal probe holder.

Otherwise, the probe could become a vector of infection. Remove the cover from a probe before placing it in a probe holder.

⚠ NOTE

Push the probe straight into the probe connector making sure it is locked in place.

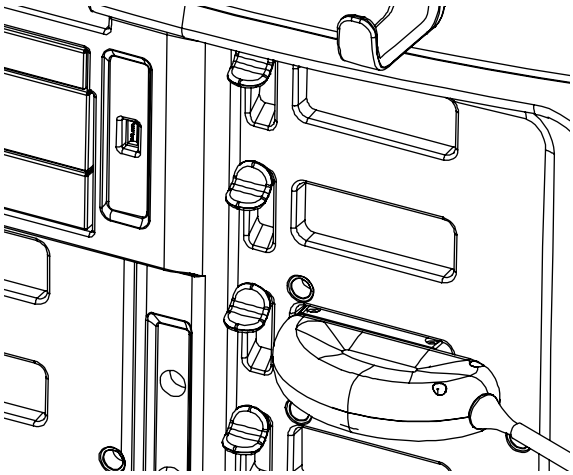
An incorrectly installed probe will not deliver clear images and such a connection could also damage the instrument and the probe.

Prior confirmation Check the following points about the probe.

- The probes must be suitable for connection to the instrument.
- The probe connector pins must not be bent.

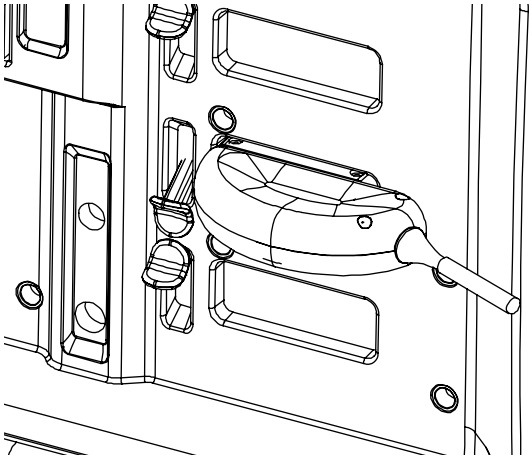
1 The instrument must be shutdown or frozen.

2 Plug the probe connector into a probe socket.



Examples of electronic probe connectors

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.

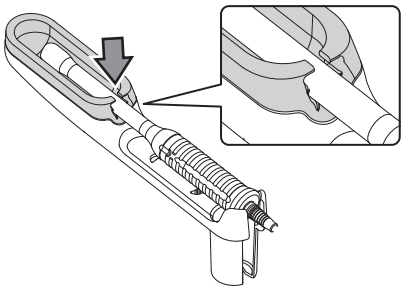
4 Store the probe in the probe holder.

NOTE: Place independent probes in probe holders with dedicated adapters attached.

Storing a probe in a transvaginal and transrectal probe holder (option)

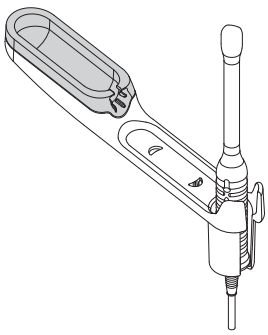
Remove the probe covers from transvaginal/transrectal probes before storing them.

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



Example of horizontal placement in transvaginal/transrectal probe holder

Gray part in the diagram: Transvaginal/Transrectal probe holder adapter



Example of vertical placement in 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

An optional EU-9187 is required to connect independent probes.

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

2. Insert the probe connector in the independent probe connector.

3-2-2 Connecting a Probe with a Lock Lever

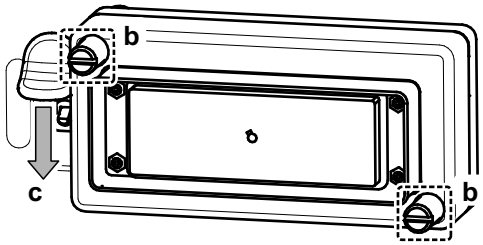
To connect a probe with a lock lever to the instrument, a junction box is required.

For details about target probes, see the probe specifications.

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

a Plug the junction box into the probe connector.

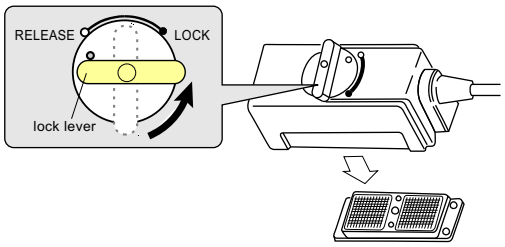
b Secure the junction box and probe connector by using two knurled screws.



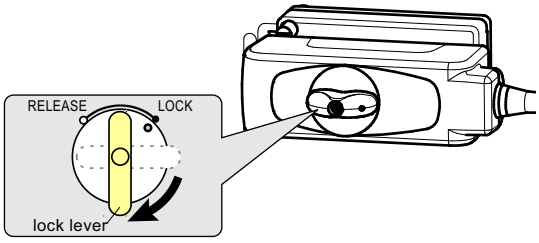
c Lower the lock lever on the left side of the probe connector.

2 Turn the lock lever of the probe counterclockwise, and align it with the RELEASE position.

3 Plug the probe into the connected junction box.



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



If the lock lever does not turn smoothly

Re-insert the probe.

5 Adjust the probe cable to the appropriate length.

Adjust the position and length of the probe cable by using cable hooks so that the cable does not become tangled with the USB flash memory strap or chafe against the floor.

NOTE: When stepping on the operation panel height adjustment lever, be careful not to bump into the junction box or the probe.

3-2-3 Disconnecting a Probe

Use the procedure below to disconnect probes with no lock lever.

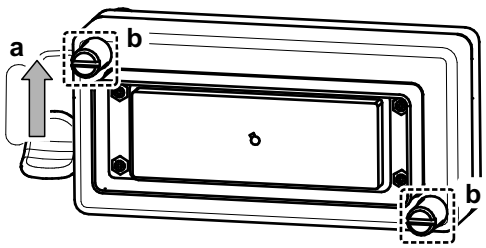
1. Shut down the instrument. Or freeze the probe.
2. Hold the probe to prevent it from falling while raising the lock lever on the left side of the socket.
3. Disconnect the probe connector from the probe socket.

Removing a Probe with a Lock Lever

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

Removing the Junction Box

1. Remove the junction box from the probe connector.



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

⚠ NOTE

Do not remove the knurled screws themselves from the junction box.

Before moving the instrument, remove the probes.

Do not remove the junction box while the probes are still connected.

Detaching an Independent Probe

1 The instrument must be shutdown or frozen.

2 Pull the connector locking ring on the probe towards the cable and disconnect it from the independent probe socket.

3-2-4 Adjusting the positions of the cable hooks

To adjust the position and length of the probe cable, use the cable hooks.

You can adjust the position or angle of each cable hook in accordance with the environment in which the equipment is used.

This section describes the following cable hooks:

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

The cable hook next to the probe holder

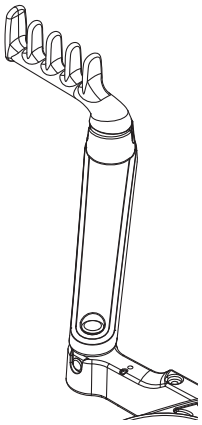
You can change the angle of the cable hook next to the probe holder in accordance with the environment in which the equipment is used.

When you press the button, the cable hook will be raised or lowered.

Position of the button

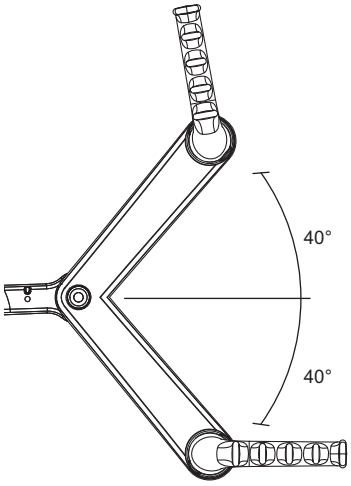
The flexible hook

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



The flexible hook

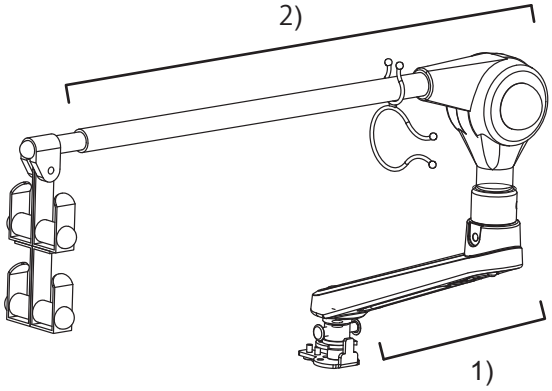
Movable range of the flexible hook



80° to the horizontal

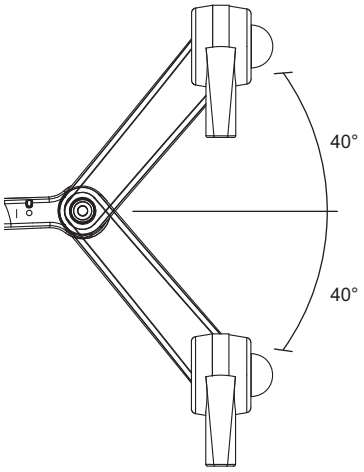
The flexible hanger

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



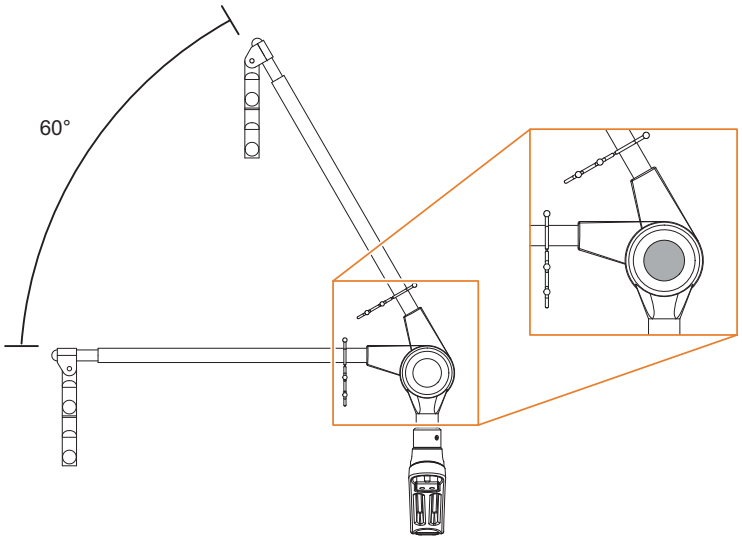
The flexible hanger

Movable range of part 1)



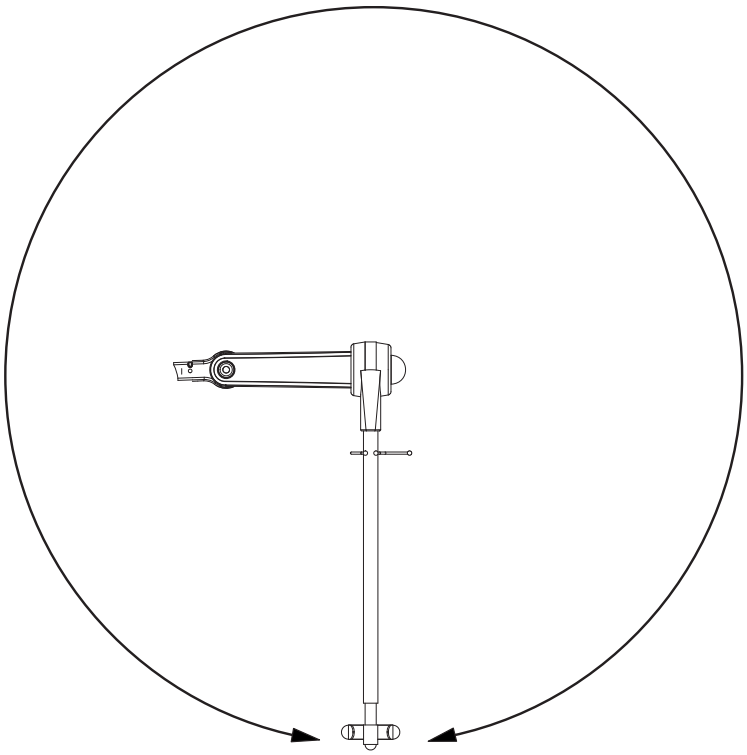
80° to the horizontal

Movable range of part 2)



60° to the vertical

Adjust the height while pressing the shaded part.



Horizontal rotation

3-3 Physiological Signal Cable Connection

Connect the physiological signal cable to the physiological signal panel.

The optional PEU-LISENDO880 is required if you want to connect a physiological signal cable.

NOTE: ECG prioritizes display of ECG signals set in preset setup. Use ECG Display Select in the General tab in the preset ([Preset Setup > Application > Edit Data > General]) to make settings.

NOTE: PULSE will prioritize DC IN if connected.

NOTE: If the external signal is unnecessary, remove the cable from the DC IN connector.

⚠NOTE

The minimum amplitude necessary for the ECG input signal is 50 µV.
A signal which falls short of that level may not be display the ECG correctly.

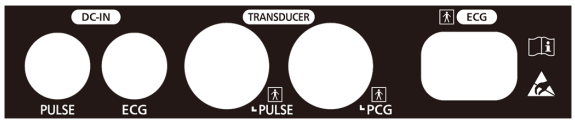
- Be sure to firmly connect the ECG cable to an ECG connector.
  - **a** Insert the connector of the ECG cable firmly into the ECG socket, with the groove on the connector facing upward.
  - **b** Attach each of the 3 ECG cables to their respective electrodes.
  - **c** Attach the electrodes to the patient.
- Insert the plug of the pulse transducer firmly into the PULSE connector.
- Insert the plug of the PCG microphone firmly into the PCG connector.

NOTE: The PCG microphone is fragile, so do not drop it or strike it against other objects.

Connect the cable from an external physiological signal monitor.

NOTE: Before connecting the cable from an external physiological signal monitor to the instrument, read "Precautions for Use With Other Medical Devices" in this volume. Refer also to the documentation provided with the physiological monitor used together with the instrument.

- Connect the cable from the ECG output connector of a physiological monitor used together with the instrument to the DC IN ECG connector. Set the ECG Display Select preset to "ECG DC IN".
- Connect the cable from the PULSE output connector of a physiological monitor used together with the instrument to the DC IN PULSE connector.

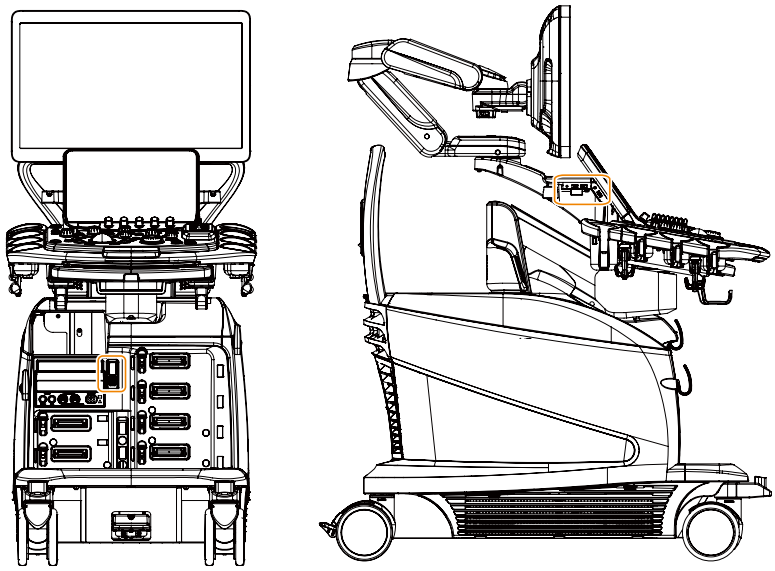


Physiological signal panel

3-4 Connecting to Other Connectors

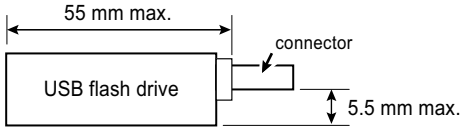
3-4-1 Connecting to a USB Connector

There are USB connectors at the following locations:



Left: Front of the instrument (USB 3.0), Right: Side of operation panel (USB 2.0×3 connectors)

- Use a USB flash drive whose length excluding the connector is less than 55 mm and where the distance between the connector and the side of the drive is less than 5.5 mm.
  The physical dimensions of some devices may prevent their use. Check whether your USB flash drive can be connected before trying to use it.



- Do not attach a strap to a USB flash drive. It may hamper instrument operation by getting tangled with the probe cable.
- Adjust the probe cable so that it does not catch on the USB flash drive.
- When using a USB device that connects by using a bus power, be sure to use the connection method described in the documentation provided with the USB device. If the bus power is insufficient, the system might not start correctly.
- For more information on connectable DVD drives, please contact us.

3-4-2 Making Connections to the 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 instrument.

3-4-3 Connecting a Foot Switch (Option)

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 the preset to assign functions to the foot switch.

3-4-4 Connecting a medical monitor or a robotic surgical unit for surgical procedures

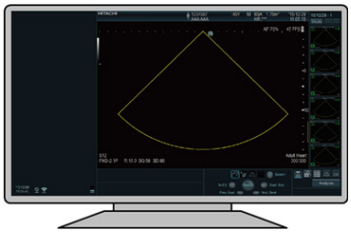
To connect a medical monitor or a robotic surgical unit for surgical procedures, you need the optional HDMI-monitor connection unit.

By connecting the HDMI-monitor connection unit to the DVI-D signal output terminal, you can also use a video recorder and output images to a medical monitor or to a robotic surgical unit for surgical procedures.

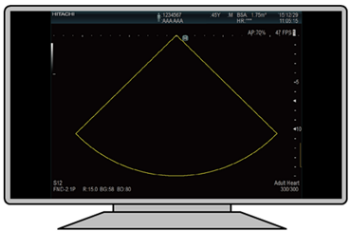
Our service staff can switch the images to be output.

The following resolutions are supported:

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



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



When the HDMI monitor displays an enlarged ultrasonic image

NOTE: Images displayed on the viewing monitor cannot be switched.

NOTE: Audio output is not available.

NOTE: To connect to a medical device that requires an analog video signal, use the Y/C output on the connector panel on the interior of the system rear cover.

⚠ CAUTION

Ask our service staff if you need to connect to other devices and switch the images to be output.

Ignoring this instruction might result in electric shock, burns, or other injuries to the patient or examiner, and damage to this system.

If you use a medical monitor or robotic surgical unit for surgical procedures, the monitor or unit must conform to the international standards for medical electrical equipment.

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

3-4-5 Connecting peripheral equipment

Connect peripheral equipment to the connector panel inside the instrument rear cover.

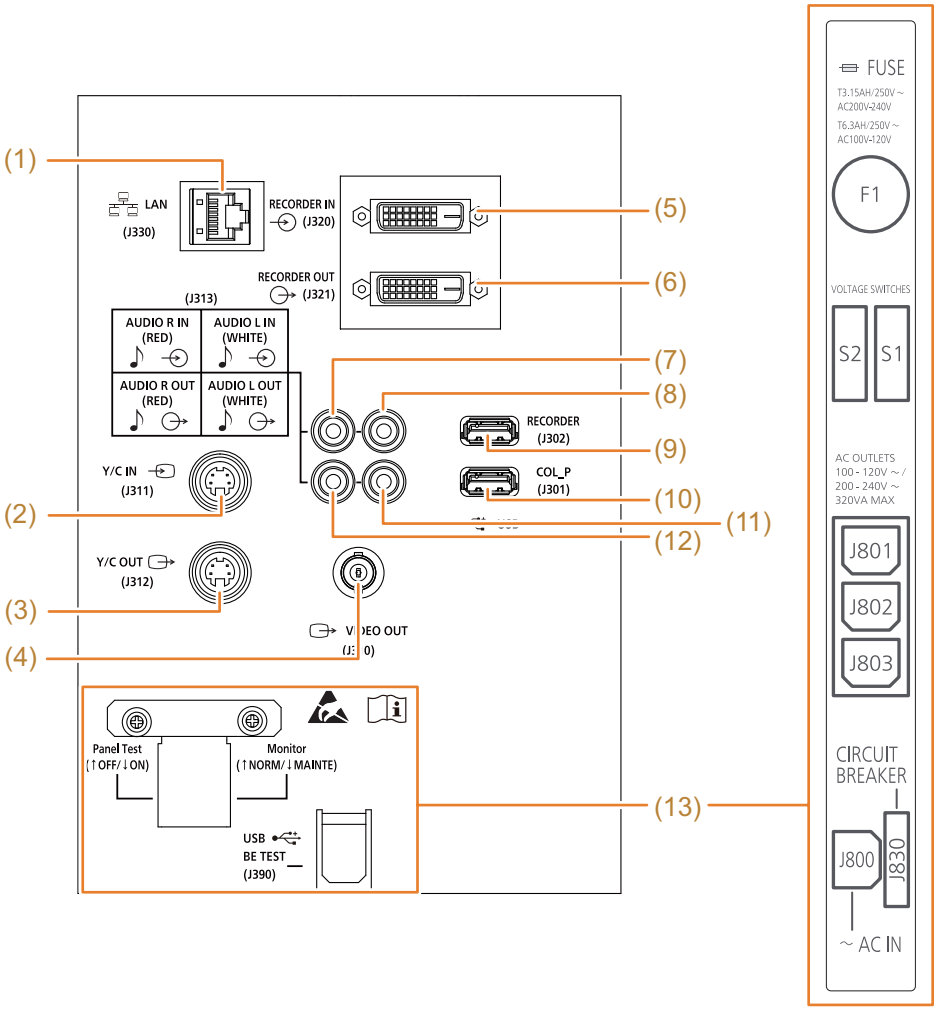
Turn the lock lever on the rear of the instrument to open the instrument rear cover.

NOTE: Turn the power switch off before connecting peripheral equipment to the instrument. For more information on how to connect peripheral equipment, please contact our office.

⚠ CAUTION

Peripherals other than those specified in this manual must not be connected to the secondary power outlet socket on the instrument. Do not connect additional power strips or extension cords.

If the volt-ampere exceeds 350 VA, the primary fuse of the instrument could blow or the breaker in the power supply unit could be triggered. Or an accident could occur.



(left) Connector panel, (right) Secondary power outlet

(1)	Do not use. For use by our service staff only.	
(2)	Y/C IN	S-VIDEO signal input terminal.
(3)	Y/C OUT	S-VIDEO signal output terminal.
(4)	SYNC OUT	RGB video sync signal output terminal.

(5)	RECORDER IN	Input terminal for DVI-D signals from a video output terminal.
(6)	RECORDER OUT	Output terminal for DVI-D signals to a video input terminal.
(7)	AUDIO R IN	Audio input terminal (right side) for connecting a video recorder.
(8)	AUDIO L IN	Audio input terminal (Left side) for connecting a video recorder.
(9)	RECORDER	Connect a USB (2.0) cable from a video recorder to this terminal.
(10)	COL_P	Connect a USB (2.0) cable from a color printer to this terminal.
(11)	AUDIO L OUT	Audio output terminal (left side) for connecting a video recorder.
(12)	AUDIO R OUT	Audio output terminal (Right side) for connecting a video recorder.

(13) Do not use. For use by our service staff only.

3-4-6 Safety Instructions for Connecting Network Devices

This device complies with the electromagnetic compatibility standard for medical electrical equipment IEC 60601-1-2: Ed.3 or IEC 60601-1-2: Ed.4.

Observe the following safety precautions when connecting the device to non-medical network devices to ensure that the entire ME system including all connected network devices satisfies the international standards for medical electrical equipment.

If there are any other ordinances, those should be prioritized. For more details, please contact our office.

I) Network devices

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

Network cables which can be connected

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

II) Equipment installation and network connection

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).

When connecting the Diagnostic Ultrasound System with non-medical devices located outside the ultrasound examination room, always connect through a separation device (network hub).

⚠ CAUTION

⃠ Do not use cables other than those specified, or cables that are longer than the maximum length.
It could pick up electromagnetic interference.

⚠ NOTE

Connecting the instrument to an IT network that also includes other devices could expose the patient, operator and third parties to hitherto unidentified risks.
Contact your network administrator for the hospital network if a problem occurs after changing the IT network.
If the IT network has been changed, it may be open to new and unacceptable risks, so additional risk management is required. Changes in the IT network include the following:

- Changes in 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

Specifications and Configuration for IT Network Connections

- Purpose of the PEMS Connection to IT Network

  DICOM communications become available.

- Characteristics Required by an IT Network Incorporating the PEMS

  DICOM Conformance Statement

  Refer to 4.3, "NETWORK INTERFACES."

- Configuration required by an IT network incorporating the PEMS

  DICOM Conformance Statement

  Refer to 4.3, "NETWORK INTERFACES."

- Technical specifications for networks that connect PEMS (including security specifications)

  The network must comply with DICOM.

- The intended information flow between the PEMS, the IT network and other devices on the IT network, and the intended routing through the IT network

  Refer to the DICOM Confirmation Statement.

3-5 Inspections and Verifications Prior to Powering up

Perform a visual check and inspection of the instrument, peripherals and probes before powering up.

1 Perform a visual check and inspection of the instrument, peripherals and probes.

Visual check and inspection items for the instrument 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
- ☐ The 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

Visual check and verification of probes

Inspect and verify the probes that will be connected to and used with the instrument 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
  Especially, the outer surface of the portions of the probe which is intended to be inserted into a patient should be checked to ensure that there are no unintended rough surfaces, sharp edges or protrusions which may cause harm.
- ☐ Probe cables and connectors must be free from scratches, cracks and deformation (for example, bent pins).

Checking consumables

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

NOTE: If there is anything wrong with the instrument 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, touch panel response may deteriorate.

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.

3-7 Inspections and Verifications After Powering up

Perform a visual check and verification of the instrument and probes after turning on the instrument.

1 Adjust the monitor to a position that is easily visible.

2 Connect the probe to use.

3 If necessary, turn on any optional and peripheral equipment.

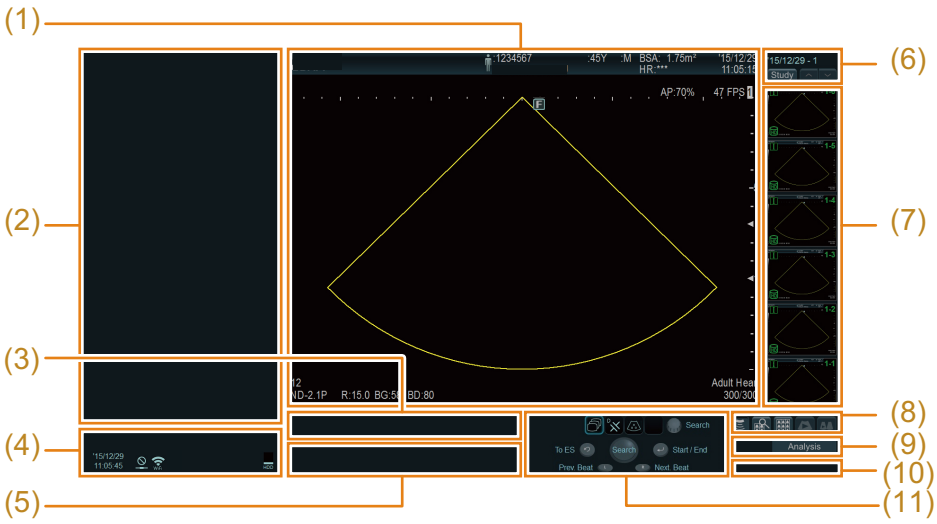
4 Confirm the window that is displayed.

Main inspection content

- ☐ The display must show text and images.
- ☐ The current time must be correctly displayed.
  If it is necessary to frequently set the current date and time, the instrument's internal battery may have run down. Stop using the instrument and contact our office.
- ☐ The connected probe must match the image and the displayed model name of the probe. If no probe is connected, "NO PROBE" must be displayed in the upper right corner of the window.
  If the displayed probe information does not match the connected probe, or if "NO PROBE" is not displayed when no probe is connected, 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.
- ☐ The Monitor Contrast and Monitor Brightness settings must be normal.

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

This displays system information.

(5) Messages

An assist message is displayed.

(6) Thumbnail and other display menus

Displays a menu that allows you to switch between thumbnail area, tile display and search screen.

(7) Thumbnails

Displays thumbnails of stored images of patients during examination.

(8) Screen Transition menu

Touch to go between screens.

(9) [Analysis]

Displays the analysis menu.

(10) Playback operation menu

Displays image playback menus in the full screen and analysis screen.

(11) Trackball function information

Displays the state of the trackball and surrounding keys.

(4) System information

A: Current date and time

B: Various types of status and network connection status

Network connection status (wired)

Connection

Not connected

Error:

Network connection status (wireless)

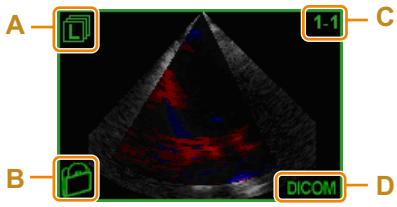
: Reception intensity (Strong) – (Weak)

Connection error

C: Media connection/insertion status 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) Track ball functional state (active state shown inside frame)

(b) [UNDO] key function

(c) [L] key function

(d) Trackball function

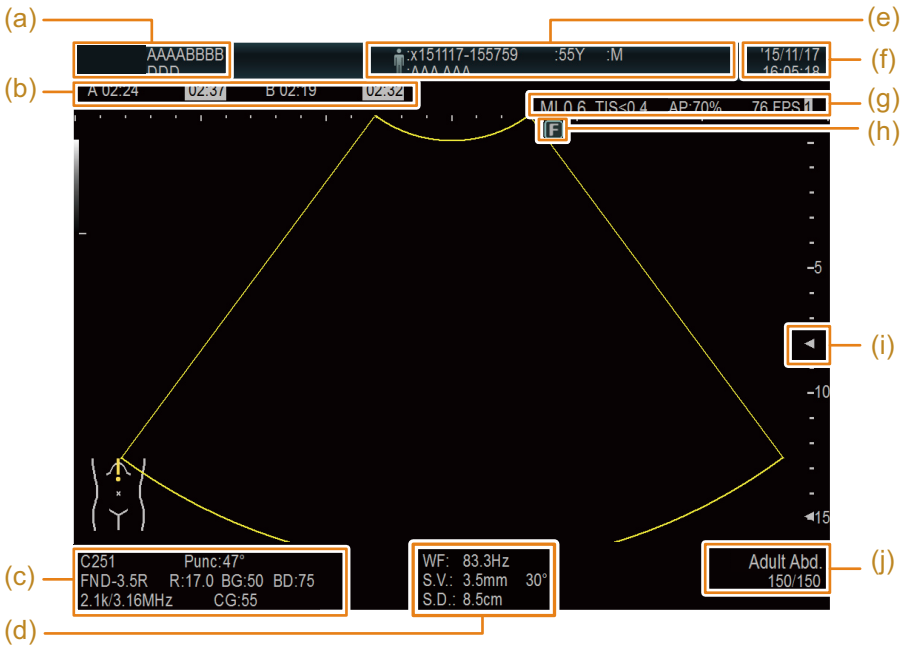
(e) [Pointer] rotary encoder function

(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 (when PW is used), angle correction value
Bottom row: Depth of the sample volume (when PW is used)

(e) Patient data

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

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

(h) Orientation mark
In this manual, the symbols below are used to represent the following; ●: Active, ◯: Inactive

(i) Focus marks

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

*1. Settings must be made in the preset ([Preset Setup > Region > General] Display tab).

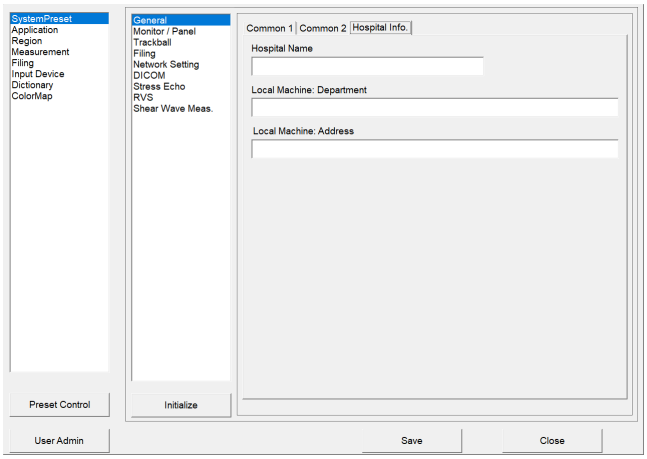
3-8 Default

The section explains the hospital name, network, and date and time adjustment.

3-8-1 Setting the hospital name

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

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. Hospital Name Enter up to 40 characters in the name field.
7. Select [Save].



3-8-2 Configuring the DICOM communication settings

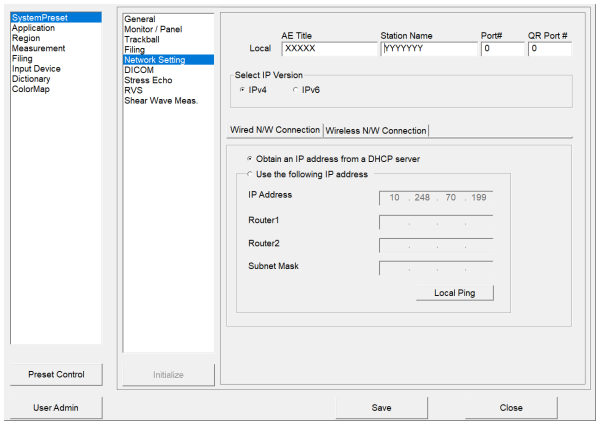
1 Press the [Probe/Preset] key.

2 Select [Preset Setup] on the touch panel.

3 Select “SystemPreset”.

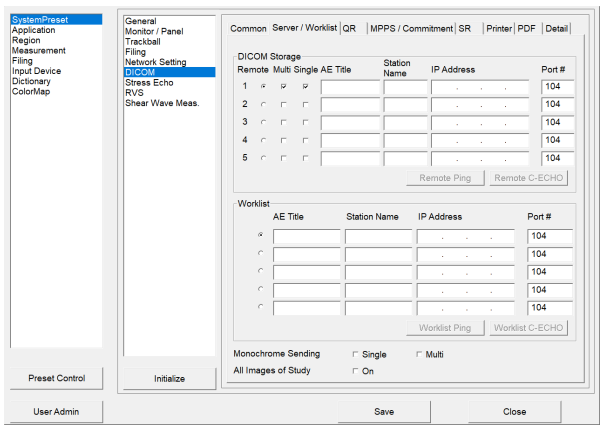
4 Select “Network Setting”.

5 Enter the network settings for the instrument.



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

  Make settings for the MPPS server or Storage Commitment server.

- SR tab

  Make settings for the SR Storage server.

- Printer tab

  Set the DICOM printer.

8 Select [Save].

Reference Information

If the IT network has been changed, it may be open to new and unacceptable risks, so additional risk management is required.

Safety Instructions for Connecting Network Devices → p.91

3-8-3 Date and time adjustment

Adjust the date and time displayed by the instrument.

1 Press the [Probe/Preset] key.

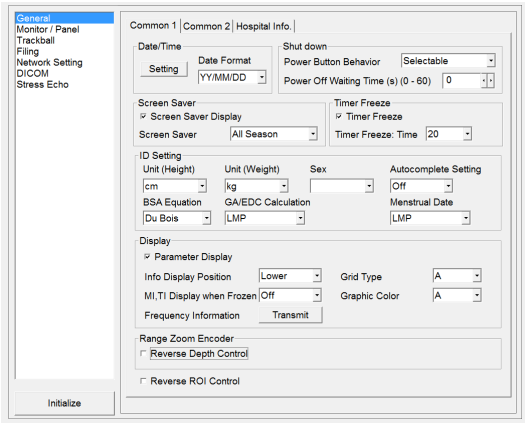
2 Select [Preset Setup] on the touch panel.

3 Select “SystemPreset”.

4 Select “General”.

5 Select the Common1 tab.

6 Adjust date and time.



a Select Date/Time [Setting].

→ “The date and time properties ”are displayed.

b Adjust date and time.

To change the date and time display format

Select a display format in the Date Format field.

7 Select [Save].

3-9 Operation panel and monitor adjustment

The distance from the user interface and the angle of the user interface can be adjusted to set it in the best position for the examiner. The Brightness of the Monitor and the Touch Panel can be adjust for the environment.

3-9-1 Adjust the height of the operation panel

Adjust the height of the operation panel using the up-and-down pedal of the operation panel at the front of the instrument.

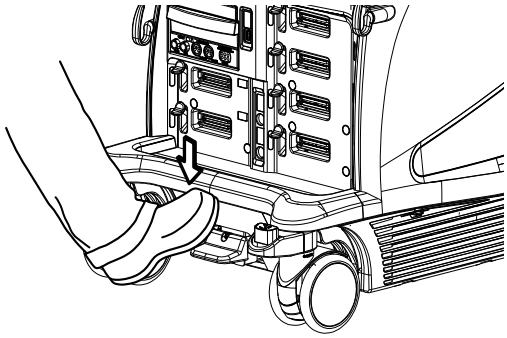
Prior confirmation Remove any objects placed on any installed options, or on the operation panel.

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

1 Step on the caster locks for the front wheels to push them down, locking the front wheels.

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

NOTE: Hold the handle of the operation panel not the operation panel or the probe holder to adjust the height of the operation panel.



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

1.1.7 paspaudus pedalą galima reguliuoti valdymo panelės aukštį

3-9-2 Rotating the operation panel

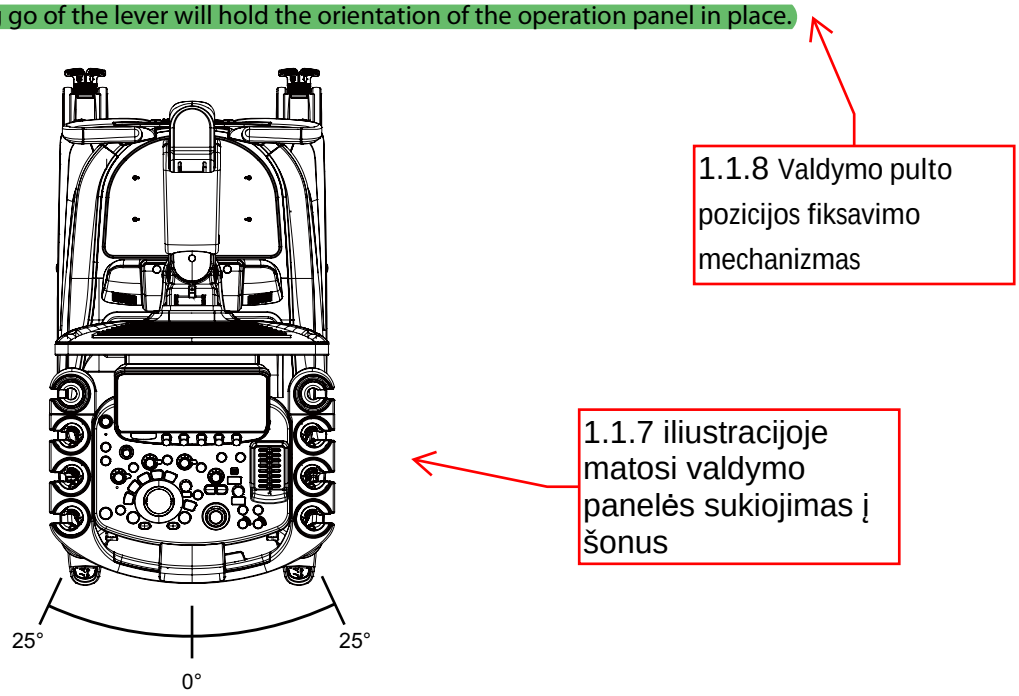
The operation panel can be rotated up to 25 degrees to the right and left.

1 To use the alphanumeric keyboard, push it in until it clicks into place.

NOTE: Take care to avoid trapping your fingers between the alphanumeric keyboard and the operation panel handle.

2 Grasp the handle lever for the operation panel while rotating the operation panel.

Letting go of the lever will hold the orientation of the operation panel in place.



NOTE: Hold the operation panel handle not the operation panel or the probe holder to rotate the operation panel.

NOTE: The operation panel may turn even if you are not holding the handle lever for the operation panel. This is a design feature and not a malfunction.

If the operation panel is repeatedly turned without holding the handle lever for the operation panel, the holding power may change. Be sure to always hold the lever when turning the operation panel.

3-9-3 Adjusting the monitor height or orientation

⚠ CAUTION

Adjust the position and orientation of the monitor, keeping a sufficient distance between the instrument and the peripheral equipment, walls and people.

Do not knock the monitor against the touch panel, USB connected medium, cable hook, probe, probe holder, operation panel, or other parts.

Route the probe cables so that they do not become entangled with the monitor, monitor arm and the instrument rear handle.

Contact with the monitor may result in injury or in damage to the surrounding equipment, the walls, the probe, the instrument, the monitor or the touch panel. Warn doctors, patients, and others in the area before adjusting the position and orientation of the monitor.

Should the monitor break and its internal fluid come into contact with the skin, wipe it away and wash the skin in running water for at least 15 minutes. To be on the safe side, consult a doctor. If it gets in someone's eyes, rinse them in running water for at least 15 minutes, and be sure to consult a doctor.

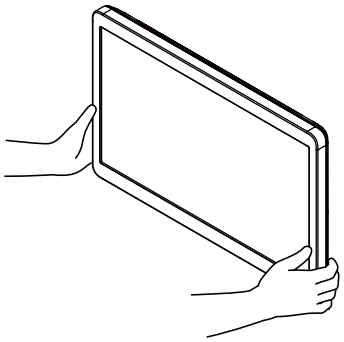
If the monitor is damaged, stop using it, and contact our office.

Be careful not to pinch your hands or fingers in the monitor arm when adjusting the location or orientation of the monitor.

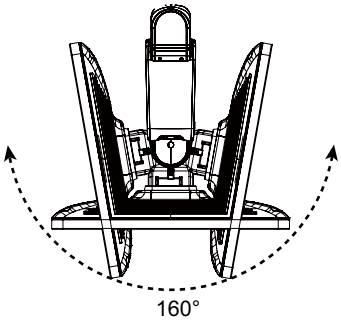
Injury from trapping your hands and fingers may result.

- Grasp the frame of the monitor in both hands to adjust its height or orientation.

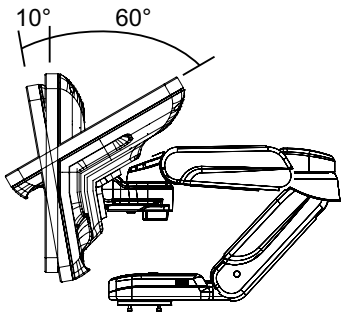
Grasp the frame of the monitor in both hands and move it in a large swinging movement. Even when the monitor arm axis is vertical, it is easier to move the monitor if you swing it.



Monitor moveable range



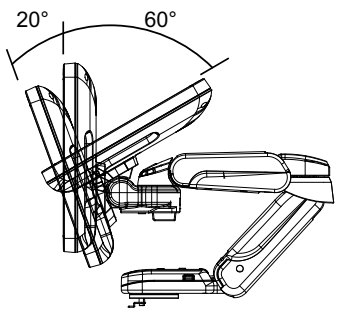
160° in right and left direction



OLED:

Tilt

10° forward, 60° back

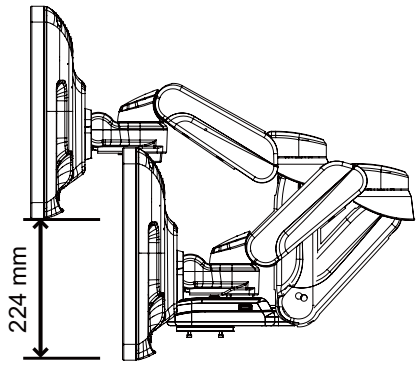


LCD:

Tilt

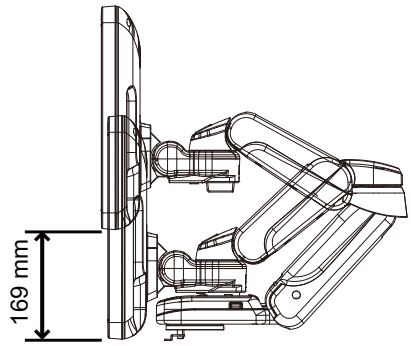
20° forward, 60° back

1.1.11 monitorius nulenkiamas žemyn



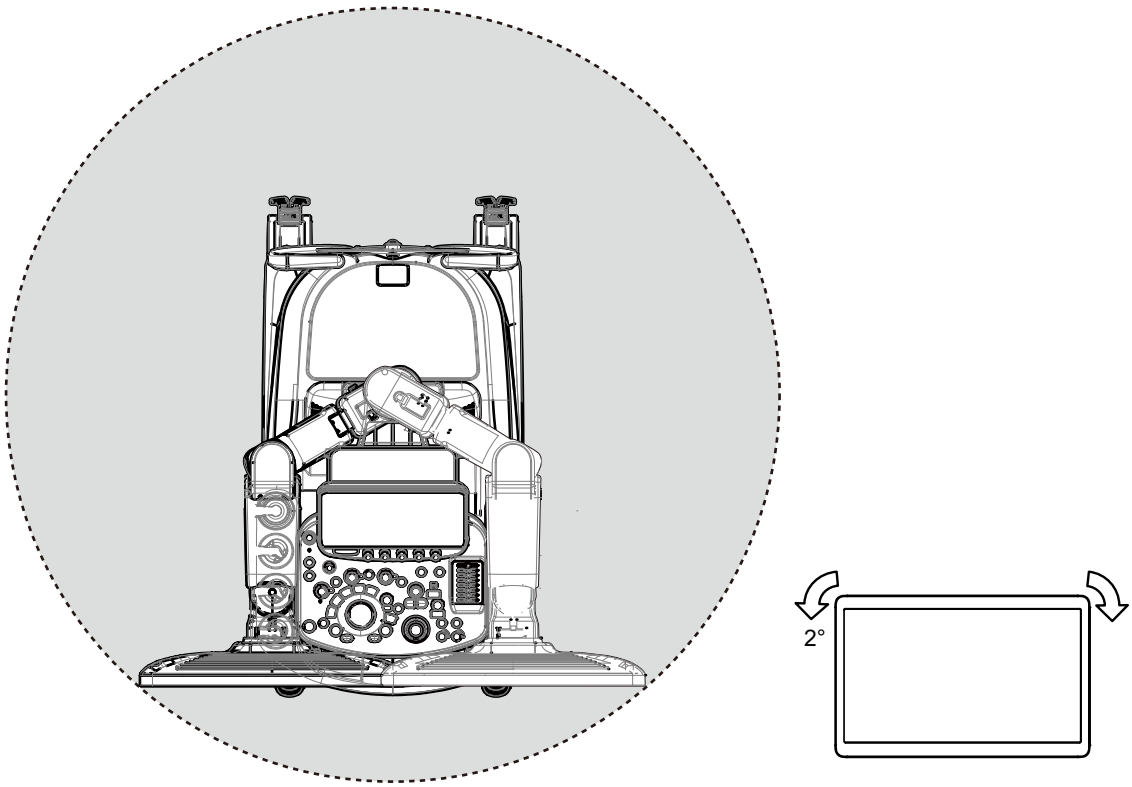
OLED:

224 mm up and down



LCD:

169 mm up and down

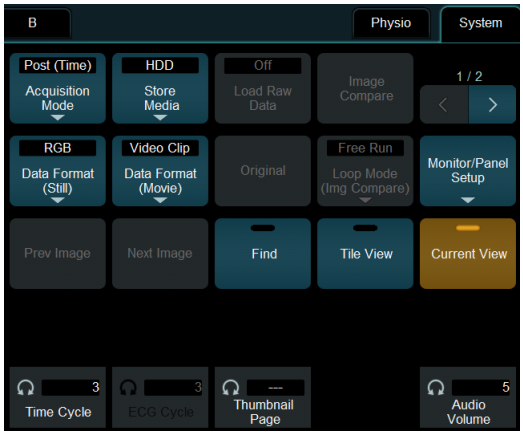


Left: Range of rotation, right: Right: Rotated Horizontally

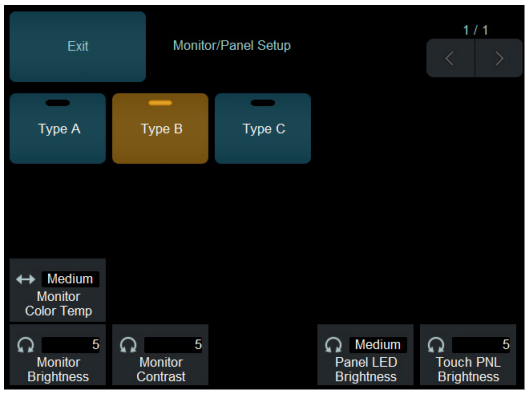
NOTE: Attempts to move the instrument beyond its movable range could damage it, cause it to tip over or fall.

3-9-4 Adjusting the brightness levels of the screen, operation panel, touch panel and the size of the screen

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



2 Turn the menu multi-rotary encoder to adjust brightness.



- Operation panel

  Turn the [Panel LED Brightness] multi rotary encoder.

- Touch panel

  Turn the [Touch PNL Brightness] multi rotary encoder.

- Screen (change settings globally)

  Select [Type A], [Type B] or [Type C] on the touch panel to adjust as required by the brightness of the room.

- Adjusting screen brightness

  Turn the [Monitor Brightness] or [Monitor Contrast] multi rotary encoder.

- Adjusting screen color temperature

  Turn the [Monitor Color Temp] multi rotary encoder in the direction of the arrow.

- Adjusting the monitor backlight

  Turn the multi-rotary encoder for [Monitor BackLight].

  NOTE: This is displayed only if the viewing monitor is an LCD.

- Adjusting the size of the screen to be displayed on the monitor

  Turn the multi-rotary encoder for [Monitor Scaling].

  NOTE: This is displayed only if the viewing monitor is an LCD.

To adjust screen brightness

We recommend using Monitor Contrast to adjust screen brightness.

There are two menus for adjusting screen brightness: Monitor Contrast and Monitor Brightness.

A saved image may look different when displayed in an environment other than the instrument screen.

3-10 Gel warmer

⚠ CAUTION

Do not touch the inner tube or interior of the gel warmer while it is powered, or soon after it is 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.

Burns to the patient could result. Use our ultrasound gel and ultrasound gel bottle.

3-10-1 Operating Procedures

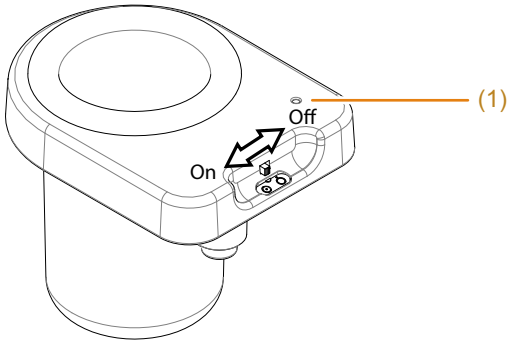
1 Turn On the power switch on the gel warmer.

→ The pilot lamp lights orange.

1.1.30 šildomas gelio laikliklis

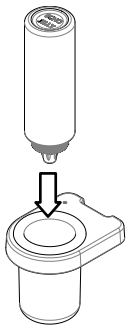
NOTE: If the main unit is not on, press the [Power] key on the main unit.

(1) Pilot lamp



2 Pour ultrasound gel in the ultrasound gel bottle and close the cap.

3 Insert the ultrasound gel bottle cap down in the gel warmer.



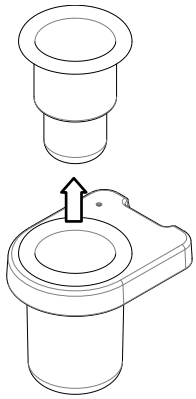
Turn the gel warmer off when it is not used.

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

NOTE: Use an ultrasound gel bottle that is not damaged or deformed.

3-10-2 Cleaning

1 Remove the silicon rubber packing from the gel warmer.



2 Wash it with water. Alternatively, wipe contaminants off.

Washing in water

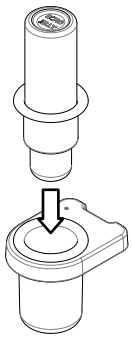
Rinse off any contaminants with running water. Use a sponge or gauze to rinse off any ultrasound gel or the like clinging to the silicon rubber packing. Next, wipe water off the silicon rubber packing with a clean cloth.

When It 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, contact our office.

- If the ultrasound gel does not get warm

Cause	Countermeasure
The power switch is turned off	(1) Make sure that the unit is turned on. (2) Check that the gel warmer power switch is turned on.
The gel warmer has just been turned on	(1) Allow enough time to let the unit warm up the ultrasound gel. The gel warmer will reach a temperature of about 38 degrees when it has been on for about an hour. 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) Insert the ultrasound gel bottle cap down in 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	Countermeasure
The power switch is turned off	(1) Make sure that the unit is turned on. (2) Check that the gel warmer power switch is turned on.

- Please contact our office if you cannot remove the ultrasound gel bottle from the gel warmer.
- Please contact our office, if the silicon rubber packing is damaged.

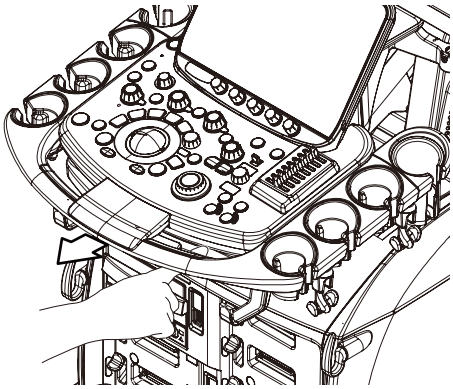
Use our ultrasound gel and ultrasound gel bottle.

3-11 Alphanumeric keyboard

3-11-1 Putting the alphanumeric keyboard out

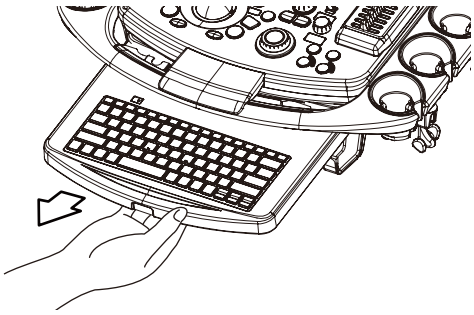
When the keyboard is fully retracted

1 Press gently with your finger.



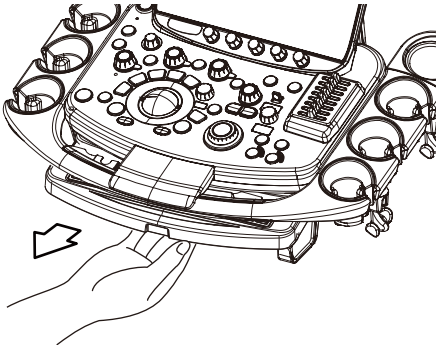
→ Alphanumeric keyboard comes out.

2 Pull out the keyboard to a location that provides access to all keys.



When the keyboard is partially retracted

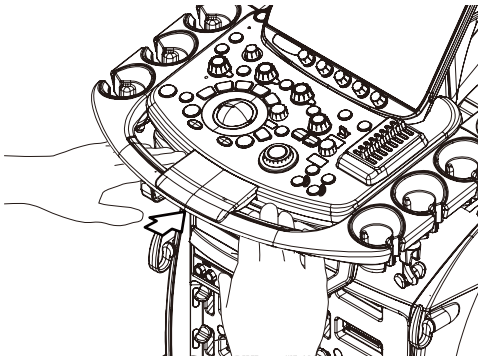
1 Pull out the keyboard to a location that provides access to all keys.



3-11-2 Putting the alphanumeric keyboard away

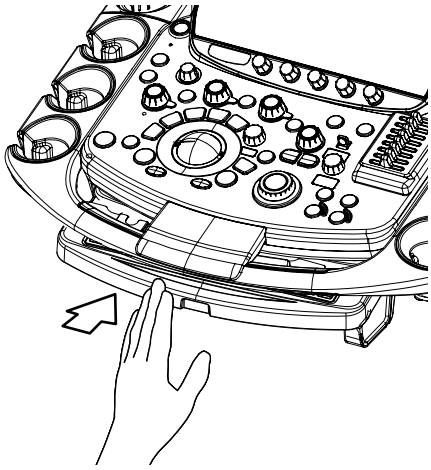
To fully retract the keyboard

1 Push in the keyboard in until it clicks in place.



To partially retract the keyboard

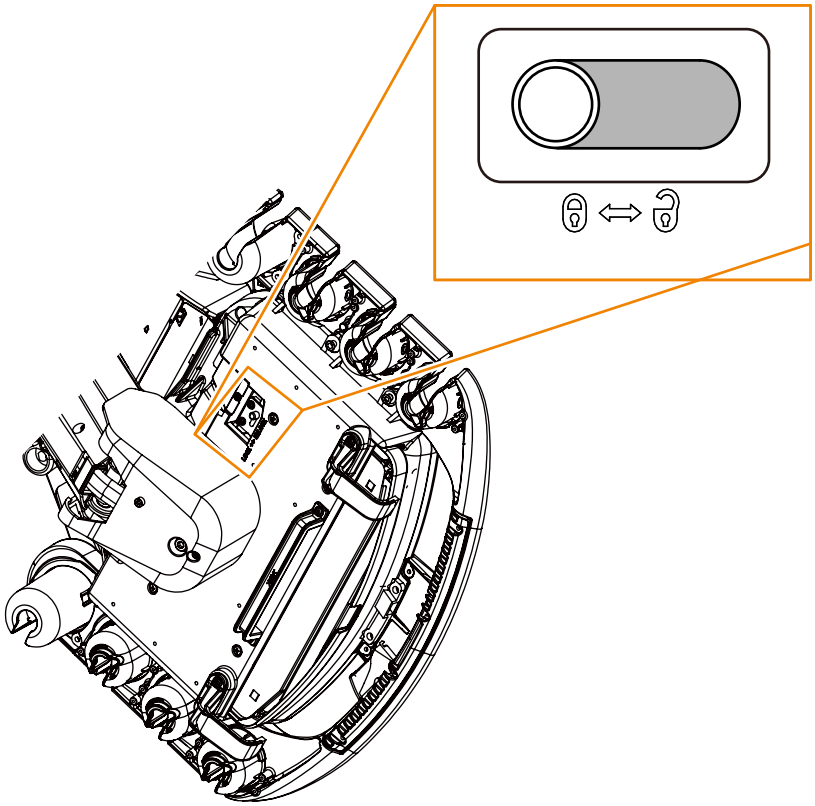
1 Gently push in the keyboard to the location of the operation panel handle.



→ The alphanumeric keyboard will remain in this partially retracted position.

3-11-3 Securing the alphanumeric keyboard

1 Slide the lock lever at the rear of the operation panel to the direction.



The figure shows the keyboard when locked

4 Operating procedures

The following sections provide basic instrument operating procedures.

For detailed instructions, refer to the related attachment.

4-1 Examination Steps

1 Set up the instrument as described in “Setup Before Use”.

a Make a visual inspection of the instrument and the probes.

Make sure that the exterior of the instrument or the power cable is not scarred, cracked, dented or discolored.

b Plug the power cable into a hospital grade outlet.

c Connect a probe.

d Press the [Power] key.

e Confirm what is displayed on the screen.

2 Enter the patient data on the ID input screen, and 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 Press the [Freeze] key when you have captured the required image 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 required, assign [End Exam] to a direct switch 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 have been completed, press the [Power] key.

8 Clean the instrument and the area around it.

Clean, disinfect and sterilize the probes according to the instructions in the supplied documentation.

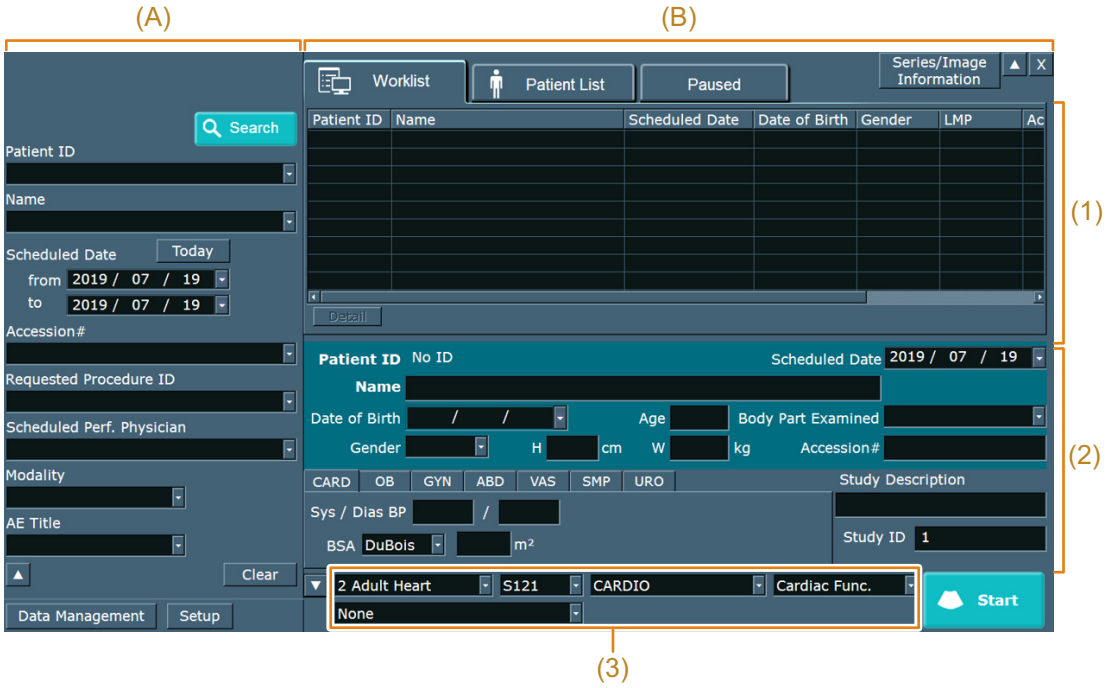
Reference Information Setup Before Use → p.63

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. Use the ID screen to set up the application to start the examination, probes, the measurement application and measurement Study to increase the efficiency of examinations.

You have to enter the patient ID to save images, make transfers and create measurement result reports.



The ID screen consists of the search area (A) and the patient information area (B).

NOTE: For details on the search area, see the document “Basic Operations”.

Patient information area

Use this screen to enter basic patient data and set the start time of an examination.

The items displayed change depending on which tab is selected.

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

The following describes each area.

(1) List area

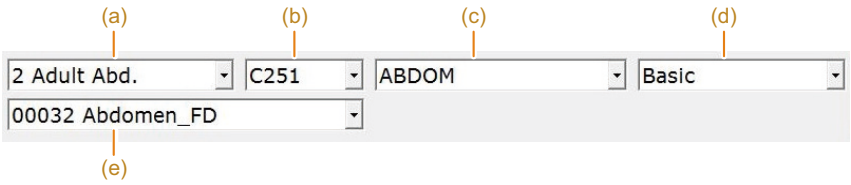
This area reads patient data in the database and displays it in a list. Select ^ at the top of the ID screen to show the list area and select v to hide it.

Select patient data displayed in the list view to display the patient data selected in the input area. The information in the input area can be edited.

(2) Input area

Key in patient data. Depending on the settings in the ID screen some information is automatically entered.

(3) Specify the application (a), probe (b), measurement application (c), measurement study (d), and protocol (e) that you want to use to start the exam. Setting up the ID screen will enable automatic input.



When “When starting examination, store ID Screen“ is enabled in the preset ([Preset Setup > SystemPreset > Filing > Detail > Store ID Screen]), if the patient ID is entered and then the ID screen is closed, the main information screen is automatically saved as an image.

4-2-2 Entering Patient Data

Enter patient data in the ID screen before starting an examination.

Use the alphanumeric keyboard or the virtual keyboard on the touch panel for entering text. You can also load patient data from a magnetic card (patient's registration card) or barcode.

Prior confirmation

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

1 Press the [New Patient] key. You can also select the [Patient] tab and then [New Patient] on the touch panel.

→ This will exit an ongoing examination and display the ID screen.

NOTE: The ID screen is automatically displayed when the instrument is started up.

NOTE: Using a reader to read a magnetic card (patient's registration card) or barcode during an examination will display the ID screen.

2 Enter patient data in the input area.

NOTE: Use the keyboard to move the character cursor.

[Tab] key or [Enter] key: Move to the next item

[Shift] key and [Tab] key or [Shift] key and [Enter] key: Move to the previous item

Using a magnetic card (patient's registration card) or barcode

When a reader is used to read a magnetic card or barcode, the information is entered in the input area.

3 Specify the application, probe, measurement application, measurement study, and protocol that you want to use to start the exam.

4 Exit the ID screen.

- Select [Start] in the ID screen.
- Press the [New Patient] key, [Freeze] key and [B] key on the operation panel.
- Press the [ID] key on the keyboard or the custom switch.

→ The ID screen is exited and a search of the information in the input area starts.

NOTE: If an examination is started using a patient ID of an examined patient, the message “This order is already performed. Do you want to perform an additional examination?” is displayed. Select Yes to make a new examination using the same inspection ID.

NOTE: Selecting [ID] during an examination will display the ID screen making it possible to revise information. However, the patient ID and inspection ID cannot be edited.

4-3 Switching Probes and Applications

Use the steps below to switch probes and applications for use during an examination.

Refer to the section "Connecting Probes" in this volume for information on how to connect probes.

Refer to the separate "Basic Operations" volume for information on how to register applications in probes.

NOTE: Use the [Probe << Preset Link] setting on the touch panel to change operation procedures. Check this setting before making any changes.

NOTE: Select [All Preset] to switch to an application not shown on the touch panel. All registered applications are displayed.

Select an application to switch both applications and probes

a Press the [Probe/Preset] key.

b Turn on [Probe << Preset Link].

c Use the Application preset switch (c) on the touch panel to select an application.

→ A different probe is selected.

(c) Application preset switch

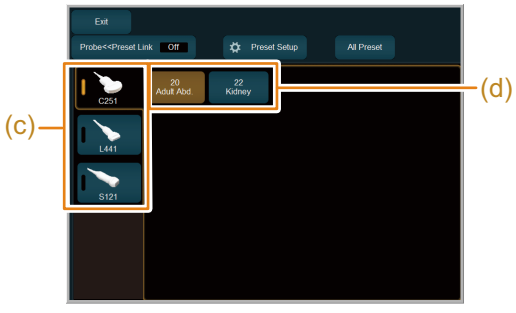
Select a probe before switching applications

a Press the [Probe/Preset] key.

b Turn off [Probe << Preset Link].

c Use the Probe switch (c) on the touch panel to select a probe.

d Select the required application from the application preset switches (d).



(c) Probe switch

(d) Application preset switch

4-4 Adjusting Ultrasonic Output Power

Use the steps below to adjust ultrasound output according to the ALARA principle and operating mode.

Examinations should be conducted using the ALARA principle to extract the maximum possible diagnostic information while reducing the acoustic power level to the lowest reasonable minimum. This is the same principle as used with ionizing radiation.

The output of a 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 make examinations using the lowest possible ultrasonic output power that the examination requires.

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

  → Acoustic 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 ultrasonic output power in 1% increments.

  Lowering ultrasonic output power lowers probe tip temperature.

4-4-1 Ultrasonic Output Power Limit for Fetal Observation

In accordance with the risk management requirements stipulated in IEC 60601-2-37 Ed.2.1 (2015), this instrument limits ultrasonic output power to a value we have determined is appropriate for fetal observation. The MI upper limit and the TI upper limit are both below 1.0.

This ultrasonic output power limit applies to the following applications: General, Obst. 1st Trim, Obst. 2nd Trim, Obst. 3rd Trim, Obst. TV, Fetal Heart, Obst. 3D, Ob.3D 1st Trim, Ob.3D 2nd Trim, Ob.3D 3rd Trim, STIC, Obst. TV 3D, Ob. *** GP, Ob. *** G, and other applications that are edited based on these applications.

Overriding ultrasonic output power restrictions in fetal application

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

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

2. Select [OK].

   → The ultrasonic output power value is highlighted.

   This limit is suspended until the user presses the [New Patient] key. To limit ultrasonic output power, again select [Power Limit Override] on the touch panel.

4-5 Adjusting Audio Volume

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

Prior confirmation Assign [Audio Volume] to the function menu.

- Use [Audio Volume] on the touch panel to adjust.

  Sound is muted when volume is set to 0.

4-6 Mode Display

4-6-1 Displaying B Mode Images

Prior confirmation Use the presets to assign [Quad] to a direct switch for quad-screen viewing.

For details on how to assign menus, refer to the separate “Basic Operations” volume.

Displaying a B mode (single screen) image

- Press the [B] key.

  A real-time B mode image (single screen) is displayed.

  You can also press the [B] key during freezing to display a real-time B mode image (single screen).

Displaying a B mode (dual screen) image

a Press the [Dual] key.

→ The active screen is shown in real time and the non-active screen is shown as a frozen image.

Displaying a B mode (quad screen) image

a Use a direct or custom switch to select [Quad].

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

Switching active screens

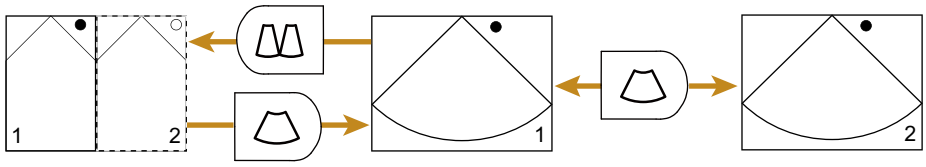
- Press the [Dual] key for dual screen viewing.
- Use a direct switch to select [Quad] for quad-screen viewing.

Changing to single-screen view after freezing

◆ Press the [Single] key.

→ Switching from dual or quad screen view to single-screen view also switches displayed cine memory.

Dual-screen view

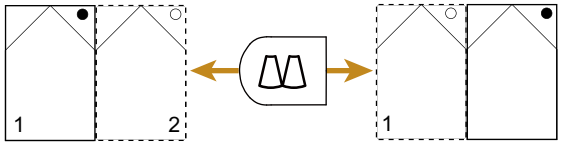


The image inside the dotted lines is the active image.

Switching to activate a frozen image

Dual-screen view

Press the [Dual] key.



The image inside the dotted lines is the active image.

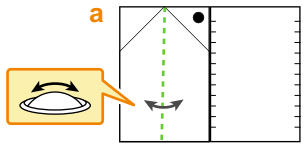
4-6-2 Displaying M Mode Images

1 Press the [M] key.

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

2 Move the M cursor.

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



→ An M mode image is displayed at the M cursor.

Switching active screens

- Press the [Update] key.

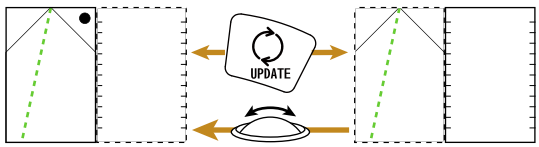
  → Each press of the [Update] key switches the active screen.

- Roll the trackball.

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

  → B mode becomes active.

  To activate the M mode again, press the [Update] key.



The image inside the dotted lines is the active image.

Switching the Screen

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

- To change B/M mode to single screen after freezing, press the [Single] key or select [Full M/D].

- To change an M waveform (single screen) to B/M mode after freezing, press the [Dual] key or select [Full M/D].

- To change B/M mode to M waveform (single screen), select [Full M/D].

4-6-3 Displaying color Doppler images

Prior confirmation Assign [PD] to a direct switch or to a custom switch.

If required, assign [Directional] to a direct switch, custom switch or function menu.

For details on how to assign menus, refer to the separate “Basic Operations”.

1 Display the B mode image.

2 Switch to color Doppler mode.

- Press the [CF] key.

  CF mode is engaged.

- Select [PD].

  PD mode is engaged.

- Press the [eFlow] key.

  eFlow mode is engaged.

- Select [DFI].

  Switches to DFI mode.

When PD mode and eFlow mode display the blood flow direction

Use the direct switch or set [Directional] in the function menu to On.

3 Set a flow area.

a Use the trackball to move the flow area.

b Press the [Enter] key.

c Adjust the size of the flow area using the trackball.

d Press the [Enter] key.

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

4-6-4 Displaying the PW waveform

Use the steps below to display Pulse Doppler waveforms.

Prior confirmation If required, make the following assignment.

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

For details on how to assign menus, refer to the separate “Basic Operations” volume.

1 Press the [PW] key.

◆ When [Simultaneous (PW)] is On

Both B mode and D mode images become active.

◆ When [Simultaneous (PW)] is Off

B/PW will be engaged, and the D cursor will be displayed on the B mode image.

2 Configuring the sample volume setting.

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

b Use the [Sample Volume] multi rotary encoder to adjust sample volume size.

3 Press the [Update] key.

→ The B mode image will freeze, and a PW waveform will appear.

Switching active screens

Use the steps below to activate a B mode image when the D mode is active.

● Press the [Update] key.

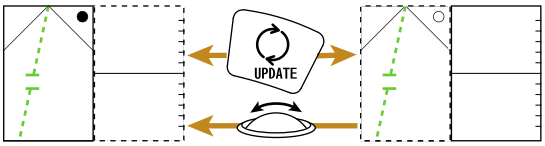
→ Each press of the [Update] key switches the active side.

● Roll the trackball.

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

→ B mode becomes active.

To activate D mode again, press the [Update] key.



The image inside the dotted lines is the active image.

(The figure shows B/PW)

Making both the B mode image and the D waveform active

- Use a direct switch or custom switch to select [Simultaneous (PW)].

Correcting blood flow direction and angle of the ultrasound beam

Prior confirmation If required, assign the following.

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

For more information on assigning tasks to the menu, angle-correction menus and presets, refer to the separate "Basic Operations" volume.

Angle correction can be adjusted in real-time and after freezing.

- Use the [Angle Correction] multi rotary encoder to correct angles.
- Use [Auto Angle Correction] on the touch panel or a custom switch for automatic angle correction.

NOTE: This adjustment can only be performed in color Doppler mode.

Switching screens

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

- To change B/D mode to single screen after freezing, press the [Single] key or select [Full M/D].
- To change a D waveform (single screen) to B/D mode after freezing, press the [Dual] key or select [Full M/D].
- To switch between B/D mode and D waveform (single screen) select [Full M/D] in real time mode.

4-6-5 Displaying the CW Waveform

Use the steps below to display continuous Doppler waveforms.

Prior confirmation For information on supported probes, see the section “Probes” in this volume.

1 Press the [CW] key.

→ B/CW will be engaged, and the D cursor will be displayed on the B mode image.

2 Use the trackball to move the D cursor ○ to the detector position.

3 Press the [Update] key.

→ The B mode image will freeze, and a CW waveform will appear.

Reference Information
Switching active screens → p.125
Correcting blood flow direction and angle of the ultrasound beam → p.129
Switching the Screen → p.125

4-7 Playing back cine memory images

Use the steps below to play back images after they have been frozen.

Moving tomographic image frames back and forward in cine memory image play is called “searching.”

In a sweep image such as an M mode or D mode image, playing the sequence direction in reverse is called “scrolling”.

4-7-1 Using the trackball to search and scroll

1 Press the [Freeze] key to freeze.

2 Press the [Cine Search] key to turn on cine search.

When the trackball function in the freeze mode is set to “Search”

Instead of pressing the [Cine Search] key, go to step 3.

Set the Trackball Priority When Frozen (Color On) or the Trackball Priority When Frozen (Color Off) in the Operation tab of the preset ([Preset Setup > Region > General]) to set “Search”.

3 Roll the trackball to the right or left.

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

4-7-2 Using the [Freeze] rotary encoder to search and scroll

Prior confirmation Set the Freeze Encoder on Frozen in the Operation tab of the preset ([Preset Setup > Region > General]) to Cine Search.

1 Press the [Freeze] key to freeze.

2 Turn the [Freeze] rotary encoder.

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

4-7-3 Using the [Pointer] rotary encoder for searching and scrolling

1 Press the [Freeze] key to freeze.

2 Press the [Cine Search] key to turn On Cine Search.

When the trackball function in the freeze mode is set to “Search”

Go to step 3 instead of pressing the [Cine Search].

“Search” can be set using Trackball Priority When Frozen (Color On) or Trackball Priority When Frozen (Color Off) in the Operation tab in the preset([Preset Setup > Region > General]).

3 Turn the [Pointer] rotary encoder.

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

4-7-4 Continuous playback of tomographic images

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

Prior confirmation If required, assign [Playback] to a direct switch, custom switch or the function menu.

1 Press the [Freeze] key to freeze.

2 Press the [Cine Search] key to turn on cine search.

When the trackball function in the freeze mode is set to “Search”

Instead of pressing the [Cine Search] key, go to step 3.

Set the Trackball Priority When Frozen (Color On) or the Trackball Priority When Frozen (Color Off) in the Operation tab of the preset ([Preset Setup > Region > General]) to set “Search”.

3 Start continuous play.

◆ Roll the trackball up.

To change the playback speed

Roll the trackball down to decrease and up to increase playback speed during continuous playback.

Pausing playback

Roll the trackball left or right.

◆ Select [Playback].

Pausing playback

Select [Playback] and set it to Off.

Continuously playing within a chosen interval

1 Press the [Freeze] key to freeze.

2 Press the [Cine Search] key to turn on cine search.

3 Set the playback range.

a Use the trackball to display the playback start frame or playback end frame.

b Press the [Enter] key.

c Use the trackball to display the playback start frame or playback end frame.

d Press the [Enter] key.

NOTE: In step a and c, the frame with the lowest number is the playback start frame and the frame with the highest number is the playback end frame.

4 Start continuous play.

◆ Roll the trackball up.

To change the playback speed

Roll the trackball down to decrease and up to increase playback speed during continuous playback.

Pausing playback

Roll the trackball left or right.

◆ Select [Playback].

Pausing playback

Select [Playback] and set it to Off.

4-8 Entering Comments

Use the steps below to enter text on the screen.

4-8-1 Entering Text Using the Keyboard

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

Prior confirmation Use the preset [Preset Setup > Region > Annotation] to set use of user dictionary. For details, refer to the separate “Basic Operations”.

1 Press the [Pointer] key.

2 Use the trackball to move the pointer to the insertion point.

Changing pointer direction

Turn the [Pointer] rotary encoder.

3 Making entries from the keyboard.

Using the virtual keyboard

A virtual keyboard will be displayed when you select [KB] tab or [Anno.+KB] tab.

[KB] tab

[Anno.+KB] tab

Changing text size

Select  on the virtual keyboard to switch font size to one of three sizes. The selected text size becomes effective from the text cursor location where text size was selected.

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

Deleting all entered comments after freezing

Use the preset ([Preset Setup > Region > Annotation]) to set Comment Auto Delete to “Erase”.

Displaying all entered comments even after freezing

Use the preset ([Preset Setup > Region > Annotation]) to set Comment Auto Delete to “Remain”.

4-8-2 Entering Pointers

1. Press the [Pointer] key.

2. Use the trackball to move the pointer to the insertion point.

   Changing the direction of the pointer

   Turn the [Pointer] rotary encoder.

3. Press the [Enter] key.

4-8-3 Selecting and Entering Words

Select and enter words registered in the user dictionary and system dictionary from the Annotation menu.

1 Press the [Pointer] key.

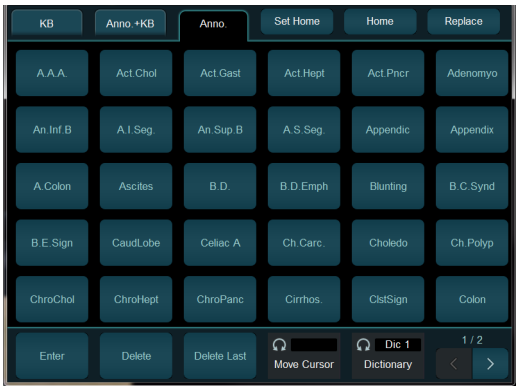
2 Use the trackball to move the pointer to the insertion point.

3 Select the Anno. +KB tab or Anno. tab.

Using the first or the first two characters in a word to search for a word

Use Anno. +KB tab on the virtual keyboard or the alphanumeric keyboard to enter the first or the first two characters in the word you want to display.

Anno. +KB tab



Anno. tab

4 Select the word you want to display from the Annotation menu.

→ The selected word appears on the image.

4-8-4 Moving, Deleting, Replacing and Inserting Words

Moving words

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

b Press the [UNDO] key.

→ The word is highlighted.

c Use the trackball to move the word and press the [UNDO] key.

Deleting words

[Delete] on the Touch Panel (Anno.+KB tab)

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

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

c Select [Delete].

→ The word is deleted.

Deleting the last word used

a Select [Delete Last] on the touch panel.

Deleting a single character

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

b Place the text cursor to the right of the character.

c Select [BS] on the touch panel.

- The word is replaced.

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

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

  → The word will be highlighted.

  c Select the word you want to change from the touch panel.

  → The word will be replaced.

- Replacing a word with a word in the same class.

  Replace a word displayed on the screen with a word on the touch panel that is in the same class.

  Select [Registration] in the class preset ([Preset Setup > Dictionary]) and make a selection from the List tab in the User Dictionary screen that is displayed.

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

  b Select a word in the same class as the word you want to replace using the touch panel.

  → The word will be replaced.

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

  NOTE: If multiple words of the same class as the word you want to replace are entered, you cannot replace the word.

- Use the keyboard to change the word.

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

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

  → The word will be highlighted.

  c Enter text using the keyboard.

  → The word will be replaced.

- The character or word will be replaced.

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

  b Move the character cursor in the word. Alternatively, use the [Move Cursor] rotary encoder to select a character or word.

  → The word will be underlined.

  c Enter text using the keyboard. You can also select words on the touch panel.

  → The word or character is inserted.

4-9 Displaying Body Marks

Use the steps below to display schema of scanning cross-sections in the Scanning Screen.

Display the body marks

a Press the [Body Mark] key.

→ Body Mark Menu appears on the touch panel and the body marks are displayed on the screen.

Changing a body mark

a Press the [Body Mark] key.

b Select a body mark from the Body Mark Menu.

→ The selected body mark is displayed.

Moving and rotating probe marks

a Press the [Body Mark] key.

b Use the trackball to move the position of the probe.

c Turn the [Pointer] rotary encoder to change the direction of the probe mark.

Adding left/right marks to body marks

a Press the [Body Mark] key.

b Select [L/R] on the touch panel.

→ [L/R] is turned On and the L/R mark is displayed on the body mark.

Turn [L/R] Off and the L/R mark is not displayed on the body mark.

Rotating fetus marks

NOTE: It is possible to rotate only single horizontal fetus marks.

a Press the [Body Mark] key.

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

c Press the [Enter] key.

d Turn the [Pointer] rotary encoder to change the direction of the fetus mark.

Switching probe mark and fetal mark rotation

Press the [Enter] to switch.

Moving the displayed body mark position

a Press the [Body Mark] key.

b Select [Location] on the touch panel and turn it On.

→ A frame is displayed over the body mark.

c Use the trackball to move the frame and press the [Enter] key.

Returning the body mark to the location it had before it was moved

Press the [UNDO] key.

→ The frame is displayed in the location it was before the move.

d Select [Location] and set it to Off.

→ The frame is cleared and the body mark's location is confirmed.

Hide body marks

a Select [Body Mark] from the Body Mark Menu.

→ The body marks on the screen are hidden.

4-10 Making Measurements

This function measures the distance, time and velocity based on the displayed ultrasonic image.

The following basic measurements are explained in this section.

I) B Mode

- Distance measurements: Dist.
- Area and circumference measurements: Area-T
- Area and circumference measurements: Area-E

II) M Mode

- Velocity measurements: Velocity
- Time measurements: Time

III) D Mode

- Blood flow velocity measurements: D.Vel1
- Blood velocity measurements: D.Vel2
- Pulsatility index measurements: PI

4-10-1 Distance Measurement: Dist

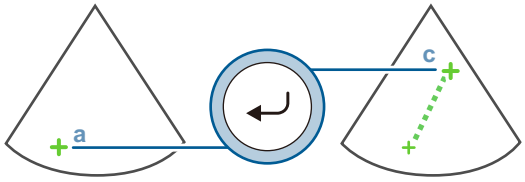
Use this function to measure the distance between two points.

1 Select the measurement menu.

a Press the [Measurement] key.

b Select [Distance] on the touch panel.

2 Measure length.



a Move the + mark to the start point and press the [Enter] key.

b Move the + mark to the end point.

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

c Press the [Enter] key.

Example of measurement results display

Dist: cm	: Selected measurement name and measurement value

4-10-2 Area and Circumference Measurements: Area-T

This function measures an area enclosed by a trace line and the circumference.

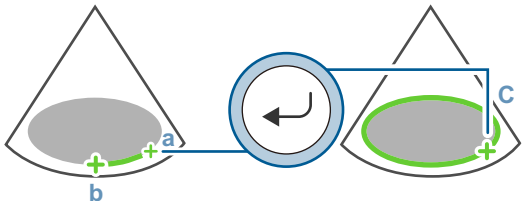
1 Select the measurement menu.

a Press the [Measurement] key.

b Select [Area/Circum] on the touch panel.

c Select [Trace] on the touch panel.

2 Measure an area and its circumference.



a Move the + mark to the start point and press the [Enter] key.

b Trace the boundary of an area to be measured.

Press the [UNDO] key to return to step a.

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

Example of measurement results display

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

4-10-3 Area and Circumference Measurements: Area-E

This function measures an area enclosed by an ellipse and its circumference.

1 Select the measurement menu.

a Press the [Measurement] key.

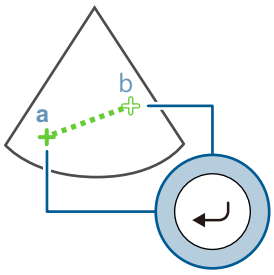
b Select [Area/Circum] on the touch panel.

c Select [Ellipse] on the touch panel.

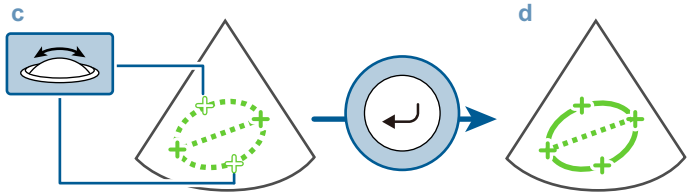
2 Measure an area and its circumference.

a Move the + mark to the long axis start point and press the [Enter] key.

b Move the + mark to the long axis end point and press the [Enter] key.



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



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

d Press the [Enter] key.

Example of measurement results display

Area-E		: Selected measurement name
Area:	cm^2	: Area value
Circ:	cm	: Ellipse circumference
x-ax:	cm	: Long axis of ellipse
y-ax:	cm	: Short axis of ellipse

4-10-4 Velocity Measurement: M.VEL

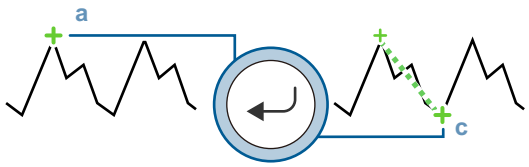
This function measures the time, amplitude and velocity between two inclinations on an M mode image.

1 Select the measurement menu.

a Press the [Measurement] key.

b Select [M.VEL.] on the touch panel.

2 Measure velocity.



a Move the + mark to the start point and press the [Enter] key.

b Move the + mark to the end point.

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

c Press the [Enter] key.

Example of measurement results display

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

4-10-5 Time Measurement: Time

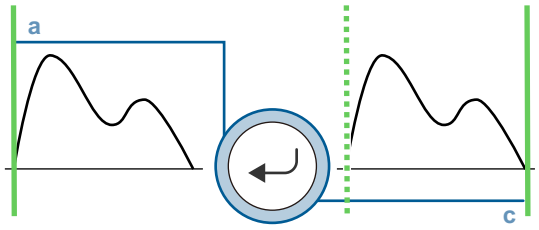
This function measures the time between two points on a M mode image.

1 Select the measurement menu.

a Press the [Measurement] key.

b Select [Time] on the touch panel.

2 Measure the time.



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

b Move the line cursor to the end point.

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

c Press the [Enter] key.

Example of measurement results display

dt: ms	: Selected measurement name and measurement value

4-10-6 Blood flow velocity measurement: D.VEL1

Use the steps below to measure the peak blood flow velocity and the peak pressure gradient.

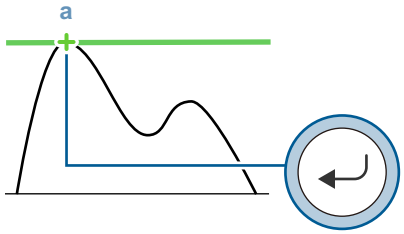
1 Select the measurement menu.

a Press the [Measurement] key.

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

2 Measure the peak blood flow velocity.

a Move the + mark to peak velocity and press the [Enter] key.



Example of measurement results display

D.VEL1		: Selected measurement name
pV:	cm/s	: Peak Blood Velocity
PG:	mmHg	: Peak pressure gradient

4-10-7 Blood flow velocity measurement: D.VEL2

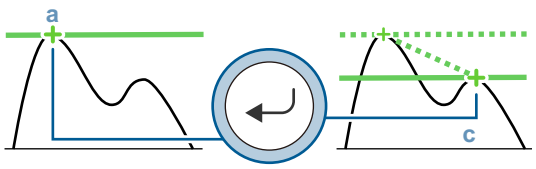
This function measures the blood velocity and blood velocity ratio between two points on a D mode image.

1 Select the measurement menu.

a Press the [Measurement] key.

b Select [D.VEL2] on the touch panel.

2 Measure blood velocity.



a Move the + mark to the first measurement point and press the [Enter] key.

b Move the + mark to the second measurement point.

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

c Press the [Enter] key.

Example of measurement results display

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

4-10-8 Pulsatility Index Measurement: PI

This function traces the blood flow waveform to measure PI, RI, S/D and other hemodynamic status data.

NOTE: It has been reported that minimum diastolic blood flow velocity is also used to calculate this index. End-diastolic flow velocity and minimum diastolic blood flow velocity are not necessarily identical. If required, adjust the EDV phase to the end-diastolic or minimum diastolic blood flow velocity point.

1 Display a blood flow waveform.

2 Select the measurement menu.

a Press the [Measurement] key.

b Select [PI].

→ The line cursor is displayed.

Measuring with the Auto (Doppler Trace method)

Sets a trace section to measure blood flow information.

1 Move the line cursor to the start point and press the [Enter] key.

2 Move the line cursor to the end point and press the [Enter] key.

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

◆ Adjusting the trace line

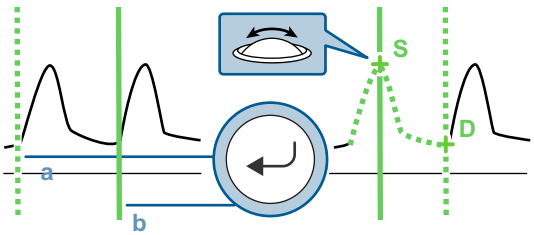
Use the [Pointer] rotary encoder to adjust the detection level.

◆ When the trace line cannot be smoothly drawn

Press the [UNDO] key or select [Trace Manual] on the touch panel to switch to Manual.

3 Use the [Enter] key and the trackball to adjust S, D and waveform rise position.

Each time the [L] key is pressed, the adjustment of S, D and waveform rise position is changed.



4 Select a heartbeat from a number of traced heartbeats.

a Select [Beat Select] on the touch panel.

b Use the [Pointer] rotary encoder to select a heart beat.

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

To select several heart rates

Each data displays the average heart rate detected within the trace section in the measurement results. A line cursor indicating PSV, EDV and waveform rise position for each detected heart rate appears.

Example of measurement results display

PI		: Selected measurement menu
PI:		: PI
RI:		: RI
PSV:	cm/s	: Peak Systolic Velocity
EDV:	cm/s	: End Diastolic Velocity
MnV:	cm/s	: Mean velocity
FlowT	ms	: Flow time
[1Beat avg.]		: Detected Heartbeats

Measuring with the Manual (Doppler Trace Method)

Measures the blood flow information using the manually traced waveform.

1 Move the + mark to the start point and press the [Enter] key.

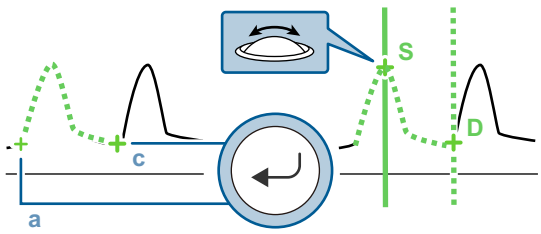
2 Trace a blood flow waveform.

3 Move the + mark to the end point and press the [Enter] key.

→ The end point mark is fixed and S, D and the waveform rise position are drawn.

4 Use the [Enter] key and the trackball to adjust S, D and waveform rise position.

Each time the [L] key is pressed, the adjustment of S, D and waveform rise position is changed.



5 Select a heartbeat from a number of traced heartbeats.

a Select [Beat Select] on the touch panel.

b Use the [Pointer] rotary encoder to select a heart beat.

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

To select several heart rates

Each data displays the average heart rate detected within the trace section in the measurement results. A line cursor indicating PSV, EDV and waveform rise position for each detected heart rate appears.

Example of measurement results display

PI		: Selected measurement menu
PI:		: PI
RI:		: RI
PSV:	cm/s	: Peak Systolic Velocity
EDV:	cm/s	: End Diastolic Velocity
MnV:	cm/s	: Mean velocity
FlowT	ms	: Flow time
[1Beat avg.]		: Detected Heartbeats

4-11 Printing and Saving Images

4-11-1 Printing Images

Use the steps below to print displayed images on a local printer or DICOM printer.

Prior confirmation For information on printer selection, refer to the separate “Basic Operations” volume.

● Follow the steps below to print a frozen image.

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

b Press the [Print] key.

→ The displayed screen is printed.

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

a Display a high quality real-time image.

b Press the [Print] key.

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

4-11-2 Saving a Still Image

Use this function to save an image during scanning or a displayed screen as a still image. Images on the instrument hard disk or DICOM images on media that are played back and saved in the DICOM format are saved as captured playback images.

For details on how to change the storage destination and storage format, refer to the separate “Basic Operations”.

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

1 Press the [Freeze] key to freeze.

2 If required, change storage destination and storage format.

3 Press the [Store] key.

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

4-11-3 Saving Moving Images

Use this function to save an image during scanning.

You can save moving images either by specifying the function menu for Acquisition Mode on the Common1 tab in the preset ([Preset Setup > Filing]), or by using a function called Manual Raw Store.

You can specify one of the following three settings in Acquisition Mode.

- "Pre (Time)", "Pre (ECG)"
  When the [Store] key is pressed, images for the preset time interval or the number of heartbeats prior to pressing the key will be stored in memory.
- "Post (Time)", "Post (ECG)"
  When the [Store] key is pressed, images for the preset time interval or the number of heartbeats will be stored in memory.
- "Manual"
  Press the [Store] key once to start saving moving images and then press the [Store] key again to stop.

NOTE: For details on Manual Raw Store, refer to "Saving Moving Images in Raw Format: Manual Raw Store".

NOTE: The saving processing starts if you select [Restart Store] on the touch panel while video images are being saved or being displayed in real time.

Moving images can be stored in the Raw or Video Clip format.

The Raw format and the Video Clip format can be saved simultaneously (Raw&V.C.). Use the function menu or Data Format (Movie) in the presets ([Preset Setup > Filing]) to set the format for saving moving images. In B/M, M, B/PW, PW, B/CW, and CW mode, Raw format images cannot be saved to DICOM.

NOTE: With Manual Raw Store, moving images are saved in Raw format regardless of the Data Format (Movie) setting specified.

Save Formats and Save-Related Properties

Storage format	Raw	Video Clip
Storage Media	Instrument Hard Disk	Instrument Hard Disk Media connected via USB CD-R Buffer DVD Network
Savable Display Modes	Only single screen tomographic images (B mode, CF mode). Dual screen tomographic images (B mode, CF mode) Active side Color flow mode image in Dual CF DFI image screen in Dual DFI D.S.D. mode is disabled	Can be saved in any mode

During the process of saving moving images in Raw formant, you will see the Acquisition progress bar and the cine memory area bar.

During the process of saving moving images in Video Clip format, you will see the Acquisition progress bar.

However, if “Pre Time” or “Post ECG” is selected as the moving image saving mode, neither the Acquisition progress bar nor the cine memory area bar is displayed.

Masks Patient's Information

Patient data in moving images saved to a media other than the instrument hard disk can be masked.

To save moving images with the patient ID and patient name masked, specify On for either Teaching File (Video Clip) or Teaching File (Net) on the Teaching File tab in the preset ([Preset Setup > Filing]). To mask patient age (Age), gender (Gender) and hospital name (Hosp. & Sonographer Name) turn On the corresponding options.

4-11-4 Saving moving images for a preset time interval or set number of heartbeats: Post ECG/Post Time

Prior confirmation Assign [Acquisition Mode] to the function menu and set “Post (Time)” or “Post (ECG)”.

- Assign [Time Cycle] to the function menu for “Post (Time)” and set the amount of time you want to save.
- Assign [ECG Cycle] to the function menu for “Post (ECG)” and select the heart rate to save.

For details on how to assign menus, refer to the separate “Basic Operations” volume.

NOTE: If you want to check the moving images to be saved before saving them, specify On for Auto Playback on the Common2 tab in the preset ([Preset Setup > Filing]).

---

1 Press the [Store] key in the real-time image.

When Auto Playback is On

→ Playback loops in the target range.

Moving images for the time interval or number of heartbeats set using [Time Cycle] or [ECG Cycle] are saved when the [Store] key is pressed.

NOTE: The saving processing starts if you press the [R] key while video images are being saved or if you select [Restart Store] on the touch panel.

4-11-5 Saving moving images for a set time interval or number of heartbeats prior to an event: PreECG/PreTime

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

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

For details on how to assign menus, refer to the separate “Basic Operations”.

NOTE: If you want to check the moving images to be saved before saving them, specify On for Auto Playback on the Common2 tab in the preset ([Preset Setup > Filing]).

---

1 Press the [Store] key in the real-time image.

When Auto Playback is On

→ Playback loops in the target range.

Moving images for the time interval or number of heartbeats set using [Time Cycle] or [ECG Cycle] are saved when the [Store] key is pressed.

4-11-6 Saving moving images anytime: Manual

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

Prior confirmation Assign [Acquisition Mode] to the function menu and set it to “Manual”.

For details on how to assign menus, refer to the separate “Basic Operations” volume.

1 Press the [Store] key in the real-time image.

→ Saving starts.

2 Press the [Store] key again to stop.

→ Saving ends.

Saving Raw data in the same range as a saved Video Clip

Prior confirmation Make the following settings.

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

For details on how to assign menus, refer to the separate “Basic Operations” volume.

1 Press the [Store] key in the real-time image.

→ Saving starts.

2 Press the [Store] key to stop saving.

→ Saving ends and the image is frozen.

3 Play the loop.

a Set the [Cine Search] key to On.

b Roll the trackball upward. Or turn On [Playback].

4 Press the [Store] key.

→ The loop playback range (the same range as the moving image saved as a Video Clip) will be saved in Raw format.

NOTE: If Video Clip Auto Stop is On, you cannot select “Raw&V.C. ” of [Data Format (Movie)].

4-11-7 Saving Moving Images in Raw Format: Manual Raw Store

You can save moving images in Raw format regardless of the Data Format (Movie) setting specified in the preset ([Preset Setup > Filing]).

At the same time, you can save moving images of the required part in Video Clip format.

NOTE: While saving moving images in Video Clip format, you can start saving moving images in Raw format by selecting [Manual Raw Store] on the touch panel.
In this case, the moment you touch [Manual Raw Store], the moving image in Video Clip format freezes for a second, which is then saved.

NOTE: Auto Playback turns Off.

NOTE: If you start saving moving images in Video Clip format while saving moving images in Raw format, Video Clip Auto Stop turns Off.

Prior confirmation

- Assign [Manual Raw Store] to a direct switch.
- If you are saving moving images in Video Clip format while you are saving moving images in Raw format, set Data Format (Movie) in the preset ([Preset Setup > Filing]) to “Video Clip”.

1 On a real-time image, select [Manual Raw Store] on the touch panel.

→ Saving of moving images in Raw format begins.

2 To store moving images in Video Clip format while you are saving moving images in Raw format, press the [Store] key.

→ Saving of moving images in Video Clip format begins.

NOTE: Use [Store Media] on the touch panel to select the location where files are to be saved.

3 To stop saving moving images in Video Clip format, press the [Store] key again.

4 To stop saving moving images in Raw format, select [Manual Raw Store] on the touch panel again.

Messages

Messages	Status, Cause
“Auto Playback is off.”	The Auto Playback function turned Off.
“The Cine Memory is cleared. Video Clip Auto Stop is off.”	The Video Clip Auto Stop function turned Off.
“Video Clip Auto Stop is off.”	The Video Clip Auto Stop function turned Off.

4-11-8 Saving a Moving Image at a Specified Range after Freezing

This function saves tomographic images in the loop playback range as moving images during freeze.

In a tomographic image in the single-screen view (B mode, CF mode, or DFI mode), specify a range of the images captured in cine memory and save it as a video in Raw format.

NOTE: For Dual CF mode or Dual DFI mode, you can save a video in Video Clip format.

1 Press the [Freeze] key to freeze.

2 Select the loop sector and save.

a Press the [Cine Search] key.

b Use the trackball to display the start frame and press the [Enter] key.

c Display the end frame and press the [Enter] key.

→ Saves the selected section.

3 Roll the trackball upward. Or turn On [Playback].

→ Start continuous play.

4 Press the [Store] key.

→ The sector selected in step 2 will be saved.

4-12 Reading the Instruction Manual

You can read the instruction manual on the supplied CD-ROM or on the instrument.

Use PDF Reader to read the instruction manual on the instrument.

PDF Reader is software for displaying PDF format files.

For details on the usage conditions for the software modules, read the “Free Software License Information” and “Free Software Module User License Agreement” in the software license agreement (in English).

Reference Information

Shutting Down, and Disconnecting the Power Supply → p.64

Free Software Module User License Agreement → p.326

4-12-1 Viewing Instruction Manuals on the Instrument Screen

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

Prior confirmation Assign [Manual] to a direct switch.

1 Select [Manual] on the touch panel.

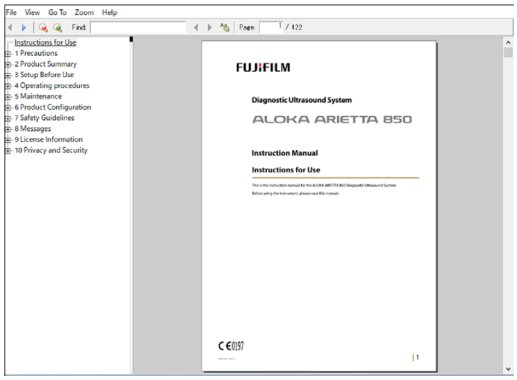
→ The selection screen is displayed.

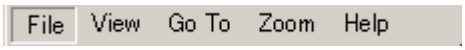
2 Use the steps below to open the instruction manual.

a Select the instruction manual you want to read in the selection screen.

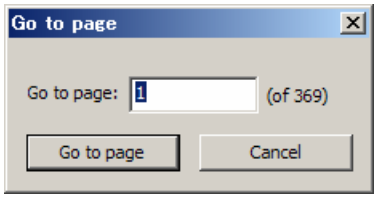
b Select [Open] in the dialog box that appears.

→ 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.  Enter the page number, and press the [Go to page] button to jump to that page.
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

Closing a Document

Use the steps below to close an instruction manual.

1 Set [Manual] on the touch panel to Off.

→ All open instruction manuals close and PDF Reader exits.

4-12-2 Viewing Instruction Manuals Stored on 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.

1 Load the CD-ROM in the DVD/CD-ROM drive of the PC.

2 Mount the DVD/CD-ROM drive.

The instruction manuals include the following documents.

Instructions for Use	Provides information on how to safely operate the instrument.
Acoustic Output Data	Provides information on acoustic power data.
Basic Operations	Describes methods on how to display, adjust and record ultrasonic images.
Advanced Operations (1 to 3)	Describes optional functions and various types of analyses.
Measurements (1 to 3)	Provides procedures on how to make measurements using ultrasonic images.

3 Double click the manual you want to open.

→ The selected instruction manual opens.

Precautions in printing the instruction manuals

The instruction manuals on the CD-ROM are in A4 page format. Check printer properties before printing.

4-13 Procedures After Instrument Use

If you neglect to take these procedures after using the instrument, it could break down or fail to function correctly during the next examination. Perform the required procedures.

⚠ CAUTION

Do not pull the power plug out of the hospital grade outlet while the machine is shutting down.
That could cause the instrument to break down.
Pull the power plug out of the hospital grade outlet once the machine has completely shut down.

1 Freeze the image.

2 Make backups of saved images.

a Transfer all images saved on the system (on the system hard disk and in the CD-R and DVD-R buffers) to external media such as USB-connected media, DVD, CD-R, or DVD-R.

b Delete unnecessary images from the system.

NOTE: For details on how to back up data, refer to the separate “Basic Operations”.

3 Remove the recording medium from the recording instrument.

4 Press the [Power] key to shut down the instrument.

5 Unplug it from the hospital-grade power outlet and gently coil the power cables.

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

Shutting Down, and Disconnecting the Power Supply → p.64
Cleaning and Disinfection → p.168

4-14 Inspection After Instrument Use

After using the instrument, check that the instrument, probes, accessories, and peripherals are in the states described below.

Instrument Condition

- ☐ The Operation Panel (including the alphanumeric keyboard) should be cleaned.
- ☐ 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 instrument is placed in a location that satisfies storage ambient condition.
- ☐ The instrument is covered with a cloth to keep dust off.

Condition of the Probes

- ☐ The probes are clean, disinfected and sterilized.
- ☐ Probes are stored in a probe holder or in their cases.
- ☐ Stored in a location that satisfies storage ambient condition.

Status of Peripherals

- ☐ Head of the printer has been cleaned.

4-15 Storage

When putting away the instrument for a longer period of time, be sure to place it in an environment suitable for storage.

Reference Information

Ambient Conditions → p.53
Moving the Instrument → p.66

5 Maintenance

5-1 Cleaning and Disinfection

Upon completion of the examination, switch off the device, then clean, disinfect and inspect it.

If you neglect to clean and disinfect the device, or to inspect it after use, it could break down or fail to function correctly during the next examination.

Use only the chemicals we recommend for cleaning and disinfecting the exterior of the device.

NOTE: Refer to “Using Approved Disinfectants” for information on the use of disinfectants.

NOTE: Shut down the device, then pull the power plug out of the hospital-grade outlet and clean the power plug.

NOTE: Some parts may turn yellow after disinfection.

⚠ DANGER

Do not connect or disconnect the power plug with wet hands.
There is a risk of electric shock.

Hold the power plug to disconnect the power cable. Do not pull on the cable.
Failure to heed this warning could lead to electric shock or short-circuits that could cause a fire.

Do not use a power plug or power cable that is damaged, hot or a power plug that cannot be properly seated in a power outlet.
Failure to heed this warning could result in electric shock and short-circuits that could cause a fire.

Disconnect the power plug and use a dry cloth to regularly remove dust from the power plug. (Unplug the device when it will not be used for a longer period of time.)
Dust that is allowed to accumulate will absorb moisture which could cause insulation failure and fire.

After cleaning the device, wipe away any remaining water and leave to dry out.
Unless dried, there is a risk of electric shock and injury.

Do not use when wet.
There is a risk of electric shock and injury.

Do not use benzine or thinner to clean the device.
There is a risk of fire or malfunction.

Use a soft, slightly dampened lint free cloth or cotton bud to clean or disinfect.
Do not put too much liquid in a lint free cloth or cotton bud as excess liquid could enter the device which could cause electric shock or short-circuits.
Should liquid enter the device, please contact our office.

Do not expose connectors to liquid.
It could cause short circuiting or electric shock. Should water enter the connectors on the device, please contact our office.

Avoid direct contact with any chemicals.
Contact with a chemical may lead to inflammation. Refer to the documentation for the specific chemical before use.

Use only chemicals that have been approved for use on the device.
Fractures (cracks, etc.) could otherwise occur.

Take care not to spill liquid onto or into the device.
It could cause short circuiting or electric shock. Should liquid spill on the device, please contact our office.

⚠ WARNING

Clean and disinfect the probes after each examination.

There is a risk of infection 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.

Failure to heed such instructions may lead to pollution.

Use gloves, masks, goggles and other personal protective equipment (PPE) when handling chemicals.

Handling the device with your bare hands when it is contaminated by body fluids or other liquids could result in an infection.

⚠ CAUTION

Do not clean, disinfect or sterilize the device with chemicals or gases that we do not recommend.

They could damage the device.

It is necessary to confirm chemical use and application in the country or region where the device 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 sterilizing and disinfecting effect may 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 may no longer be as effective.

Use gloves, masks, goggles and other personal protective equipment (PPE) when handling chemicals.

Otherwise, there is risk that the eyes, mouth and skin may be exposed to those chemicals.

Dispose of gloves after each cleaning and disinfection job.

There is a risk of contamination.

Lint free cloths or cotton buds used for cleaning or disinfection should be replaced frequently.

There is a risk of contamination.

If sodium hypochlorite is used, make sure none of it remains after disinfection.

Prints could fade, become discolored or the device could rust.

⚠ NOTE

Wipe gently when cleaning and disinfecting the device.

Do not wipe with too much pressure as it could cause the paint to peel or make labels unreadable.

Clean with organic solvents or disinfectants which are specified in "Using Approved Disinfectants" on this document.

Using other chemicals which are not specified in "Using Approved Disinfectants" on this document may cause degradation and/or damage of exterior surfacing.

5-1-1 Using Approved Disinfectants

We have conducted a survey of new medical disinfectants to find disinfectants that are suitable for disinfecting the device.

Use only the disinfectants in the list below to disinfect the device and the touch panel. Refer to the Usable/not usable field in the table below to determine whether a disinfectant can be used for cleaning the device 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 may lead to inflammation.

Chemicals approved for disinfecting the exterior of the device

Product name and general name	Manufacturer	External housing	Filter	Monitor housing	Monitor OLED surface	Monitor LCD surface	Operation panel	Alphanumeric keyboard	Touch panel	Trackball	Power plug
Ethanol purity 80%vol	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Isopropyl alcohol purity 80%vol	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cleanisept Wipes	Dr. Schumacher GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cleanisept Wipes forte	Dr. Schumacher GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Meliseptol®HBV Tissues	B.Braun Medical AG	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mikrobac® Tissues	BODE Chemie GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tristel Duo	Tristel Company	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
WIP'ANIOS EXCEL	Laboratoires ANIOS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mikrozid Universal Wipes	Schuelke & Mayr GmbH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sodium Hypochlorite	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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

5-1-2 Frequency of Cleaning and Disinfection

- 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.
  - Installation location of the device
  - Operation panel (including the alphanumeric keyboard)
  - Exterior of the device (including probe holders)
  - Monitor
  - Filter
  - Trackball
- Areas to be cleaned and disinfected as necessary
  - Foot switch
  - Cleaning the head of the printer

5-1-3 Cleaning and Disinfecting Device Exterior

Wipe gently using a soft, dry lint free cloth.

When It Is Very Dirty

Clean as described below.

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, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

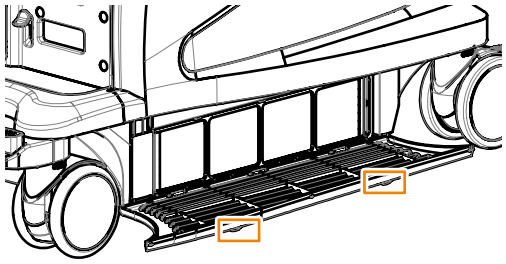
After performing the steps above, disinfect using the following steps.

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

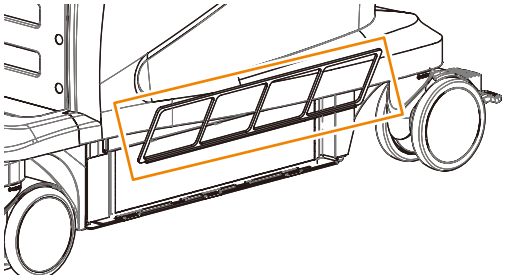
5-1-4 Cleaning the Filters

There are filters on the left and right of the device.

1 Push down the tabs to remove the lid of the filter cover.



2 Remove the filters.



3 Use a vacuum cleaner to remove dust from the filter.

4 Clean the filter under running water.

5 Drain water thoroughly, then dry the filter in a well-ventilated place out of direct sunlight.

6 Check the front and back of the filter and reinstall it to the original location.

NOTE: Push in the filter completely.

7 Close the filter cover.

a Fit the bottom part of the filter in the groove in the device.

b Close the filter cover.

NOTE: Push in the filter cover as far in as it will go.

5-1-5 Cleaning and Disinfecting Viewing Monitor Cover

Wipe gently using a soft, dry lint free cloth.

When It Is Very Dirty

Clean as described below.

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, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

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

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

5-1-6 Cleaning and Disinfecting the Viewing Monitor (the OLED Surface and LCD Surface)

Wipe gently using a soft, dry lint free cloth.

⚠ CAUTION

- Do not wipe the OLED or LCD surface of the viewing monitor with an unapproved chemical agent.
  The coating on the OLED or LCD surface might be damaged.
- Gently wipe the OLED or LCD surface of the viewing monitor.
  Wiping the OLED or LCD surface with excessive force will damage the surface.
- Do not scratch the OLED or LCD surface.
  The OLED or LCD surface might be damaged.

When It Is Very Dirty

Clean as described below.

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, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

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

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

5-1-7 Cleaning and Disinfecting the Operation Panel and Alphanumeric Keyboard

Wipe gently using a soft, dry lint free cloth.

When It Is Very Dirty

Clean as described below.

1. Dampen a soft lint free cloth with a neutral detergent diluted with water and wring it out thoroughly.

2. Use the lint free cloth in step 1 to gently wipe away any dirt.

   NOTE: Use a cotton bud dampened with a neutral detergent diluted with water to clean the key tops and other areas on an alphanumeric keyboard.

3. Dampen a soft lint free cloth with water and wring it out thoroughly.

4. Use the lint free cloth in step 3 to gently wipe away any remaining neutral detergent.

   NOTE: Use a cotton bud dampened with water to clean the key tops and other areas on an alphanumeric keyboard.

5. Use a dry, soft lint free cloth or cotton bud to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

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

1. Wipe gently with an approved disinfectant.

   NOTE: Use a cotton bud dampened in a disinfectant to wipe the key tops and other surfaces on an alphanumeric keyboard.

2. (If necessary,) dampen a soft lint free cloth with water and thoroughly wring it out to wipe off any remaining disinfectant.

3. (If necessary,) use a dry, soft lint free cloth or cotton bud to gently wipe away any remaining moisture and leave to dry out.

5-1-8 Cleaning and Disinfecting the Touch Panel

Wipe gently using a soft, dry lint free cloth.

⚠ CAUTION

Wipe the touch panel gently.
Do not use excessive pressure when wiping the touch panel as you could damage it.

Do not scratch the touch panel.
The touch panel could be damaged.

When It Is Very Dirty

Clean as described below.

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, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

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

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

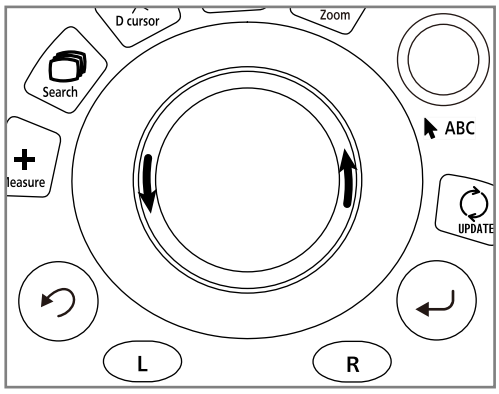
5-1-9 Cleaning and Disinfecting the Trackball

⚠ CAUTION

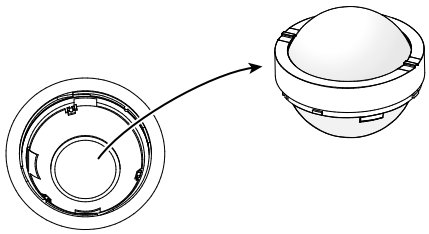
Do not drop the removed trackball or allow objects to strike against it.
The trackball could be damaged and may no longer work normally.

Removing the trackball from the operation panel

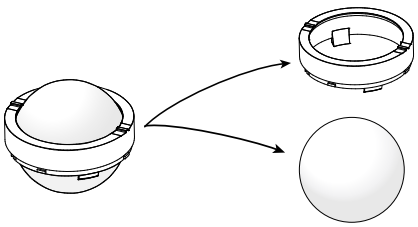
1 Turn the ring counterclockwise.



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



3 Take the trackball out of its ring and place it on a soft lint free cloth.



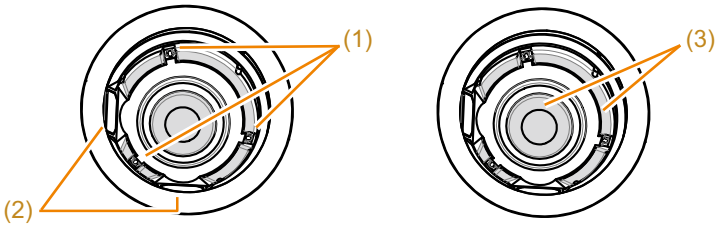
Cleaning and Disinfection

Trackball Support Balls, Sensors and Grooves (on the operation panel side)

a Use a dry cotton bud to clean the trackball support balls (3 pcs.) and the groove. Use a lint-free cloth to prevent fibers from adhering to the sensors (2 pcs.) during cleaning.

NOTE: Wipe away finger prints, oil from hands, fibers and other dirt from the sensors.

NOTE: Do not rub away dust particles from the sensors as they could scratch and damage the sensors.



(1) Support balls, (2) Sensors, (3) Groove (half-tone screening)

When It Is Very Dirty

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

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

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

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

Disinfecting

After performing the steps above, disinfect using the following steps. Use a lint-free cloth to clean the sensors.

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

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

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

Trackball and Ring

a Wipe the trackball and ring gently using a soft, dry lint free cloth.

When It 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 dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

After performing the steps above, 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 to wipe off any remaining disinfectant.

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

NOTE: Do not rub the surface of the trackball. Otherwise, the trackball may lose its lubricity and may no longer turn smoothly.

If the trackball no longer turns smoothly

a Apply about 0.1 g of white Vaseline to the entire surface of the trackball.

b Wipe the trackball with a dry lint free cloth until no stickiness can be felt.

Installing the trackball in the operation panel

NOTE: Make sure that no white Vaseline comes in contact with the sensors when you reassemble the trackball.

1 Place the ring back on the trackball.

2 Place the ring and trackball back on the operation panel.

3 Turn the ring clockwise.

5-1-10 Cleaning and Disinfecting the Power Plug

⚠ CAUTION

Do not expose the electrodes of the power plug to water.

It could cause short circuiting or electric shock. Should water enter the connectors on the device, please contact our office.

Power Plug Prongs

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

Power Plug Exterior

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

When It 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 dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

After performing the steps above, 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 to wipe off any remaining disinfectant.

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

5-1-11 Cleaning and Disinfecting the Power Cable

Wipe gently using a soft, dry lint free cloth.

When It Is Very Dirty

Clean as described below.

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, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

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

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

5-1-12 Cleaning and Disinfecting the Area of the Casters That are in Contact With the Ground

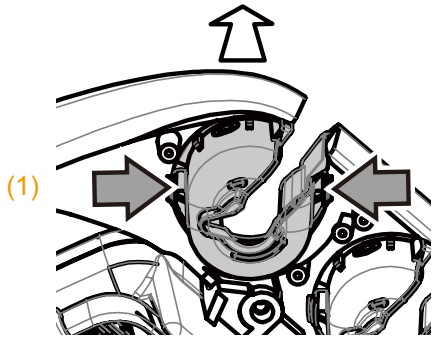
Use the following procedure to clean and disinfect the area of the casters that come into contact with body fluids in operating theaters and other medical facilities.

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 device 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 device 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 device so the casters roll over the cloth to remove any remaining moisture and leave to dry out.
6. Dampen a lint free cloth with an approved disinfectant and wring it out thoroughly.
7. Roll the casters over the lint free cloth in step 6 to disinfect them.
8. Dampen a lint free cloth with water and wring it out thoroughly.
9. Place the lint free cloth in step 8 on the floor and move the device so the casters roll over the cloth to remove any remaining disinfectant.
10. Use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

5-1-13 Cleaning and Disinfecting the Probe Holder

Removing the Probe Holder From the Operation Panel

1 Press the tabs (1) in the direction of the arrow and lift the probe holder upwards to remove it.



Operation panel rear

Cleaning and Disinfection

Clean as described below.

1 Dampen a soft lint free cloth with a neutral detergent diluted with water and wring it out thoroughly.

2 Use the lint free cloth in step 1 to gently wipe away any dirt.

3 Dampen a soft lint free cloth with water and wring it out thoroughly.

4 Use the lint free cloth in step 3 to gently wipe away any remaining neutral detergent.

5 Use a dry lint free cloth to gently wipe away any remaining moisture and leave to dry out.

When It 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, a sponge or gauze cloth for washing.

c Rinse under running water to make sure no detergent remains.

d Use a dry lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

After performing the steps above, 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 to wipe off any remaining disinfectant.

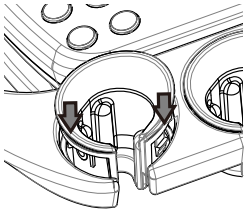
c (If necessary,) use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Installing the Probe Holder in the Operation Panel

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.



5-1-14 Cleaning and Disinfecting the Transvaginal/Transrectal Probe Holder

Clean and disinfect the optional transvaginal/transrectal probe holder.

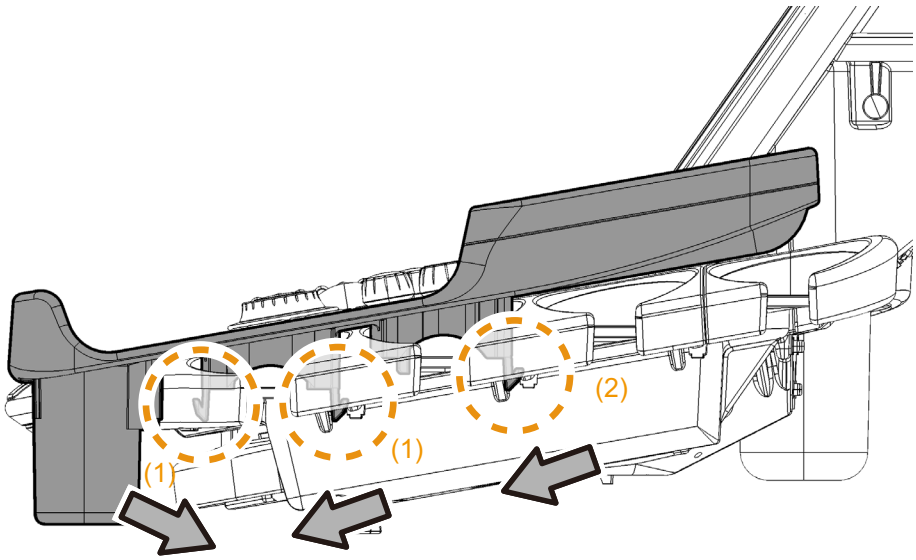
The transvaginal/transrectal probe holder is an optional probe holder for storing a transvaginal/transrectal probe. The transvaginal/transrectal probe holder and the holder adapter can be removed separately. Clean and disinfect as needed.

Removing a transvaginal/transrectal probe holder from the operation panel

1 Remove the transvaginal/transrectal probe holder.

a Press the tab (1) in the direction of the arrow and lift to release it.

b Press the tab (2) in the direction of the arrow and lift to release it.



Cleaning and Disinfection

Clean as described below.

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

When it 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, a sponge or gauze cloth for washing.
c. Rinse under running water to make sure no detergent remains.
d. Use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

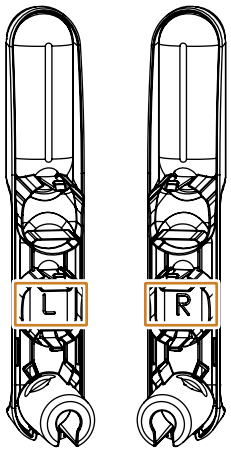
After performing the steps above, disinfect using the following steps.

a. Wipe gently with an approved disinfectant.
b. (If necessary,) dampen a soft lint free cloth with water and thoroughly wring it out to gently wipe off any remaining disinfectant.
c. (If necessary,) use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Attaching a transvaginal/transrectal probe holder on the operation panel

1 Make sure the probe holder you want to install is on hand.

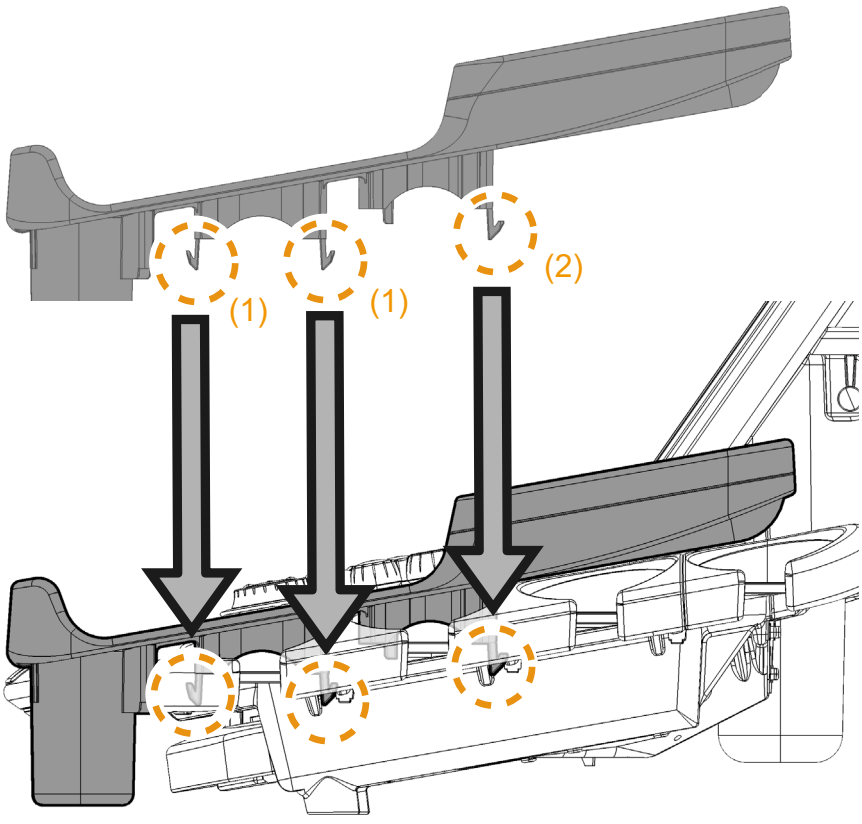
- You need an R adapter to install a probe holder on the right side when facing the device.
- You need an L adapter to install a probe holder on the left side when facing the device.



2 Attach the transvaginal/transrectal probe holder.

a Align the tab (1) and press in until you hear a click.

b Align the tab (2) and press in until you hear a click.



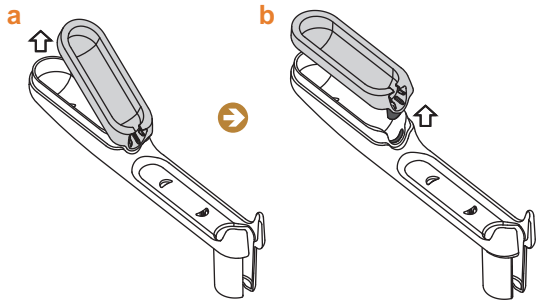
5-1-15 Cleaning and Disinfecting the Transvaginal/Transrectal Probe Holder Adapter

Removing a transvaginal/transrectal probe holder adapter

1 Remove the adapter.

a Lift up the far end of the adapter to remove the adapter.

b Lift up the front part of the adapter to remove the adapter.



Cleaning and Disinfection

Clean as described below.

1 Dampen a soft lint free cloth with a neutral detergent diluted with water and wring it out thoroughly.

2 Use the cloth to gently wipe away any dirt.

3 Dampen a soft lint free cloth with water and wring it out thoroughly.

4 Use the cloth to gently wipe away any remaining detergent.

5 Use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

When it 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, a sponge or gauze cloth for washing.

c Rinse under running water to make sure no detergent remains.

d Use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

After performing the steps above, 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 to gently wipe off any remaining disinfectant.

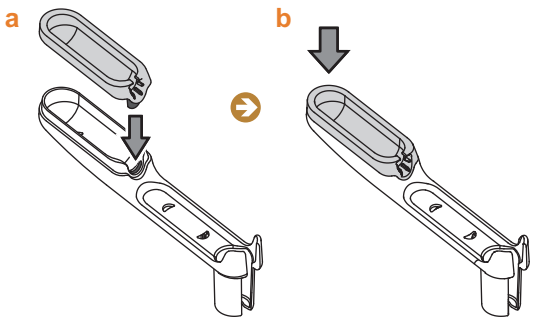
c (If necessary,) use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Attaching a transvaginal/transrectal probe holder adapter

1 Attach the adapter.

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

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



5-1-16 Cleaning, Disinfecting and Sterilizing Probes

The cleaning, disinfecting, and sterilizing methods vary with probe type. Refer to the documentation for each probe.

⚠ WARNING

Clean, disinfect and sterilize probes after an examination.
Probes can otherwise spread infections.

5-1-17 Cleaning and Disinfecting the RVS Sensor

Please refer to "Cleaning, Disinfection and Sterilization Methods" in the separate "Advanced Operations 2" volume.

5-1-18 Cleaning and Disinfecting Electrocardiogram Cable (ECG Cable, etc.)

Prior confirmation Disconnect the electrocardiogram cable (ECG cables, etc.) connector from each cable connector, and clean and disinfect them.

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, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

   Disinfecting

   After performing the steps above, 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 to wipe off any remaining disinfectant.
   c. (If necessary,) use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

5-1-19 Cleaning and Disinfecting the Foot Switch

Prior confirmation Disconnect the foot switch connector from the foot switch plug.

Clean as described below.

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, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

When It 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, a sponge or gauze cloth for washing.
c. Rinse under running water to make sure no detergent remains.
d. Use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

Disinfecting

After performing the steps above, 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 to wipe off any remaining disinfectant.
c. (If necessary,) use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

5-1-20 Cleaning Peripheral Equipment

Refer to the documentation for each option.

Refer to the documentation for each printer for the head cleaning method.

5-2 The Need for Regular Maintenance Inspections

Periodic maintenance inspections are essential to maintain instrument performance and ensure safe operation.

Maintenance inspection involves three inspections: daily inspection, measurement accuracy inspection, and safety inspection. The safety inspection 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 electrostatic discharge (ESD) precautions when performing the maintenance inspections. Parts that are sensitive to static electricity could be damaged or fail.

Reference Information

Electrostatic Discharge (ESD) Guidelines → p.248

5-2-1 Daily inspection: For a Long Service Life

Long-term wear of parts and consumables may cause the instrument 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.

I) Daily inspection

- There must be no buildup of dust on the power plug.
- There must be no looseness in the monitor, monitor arm and other moving parts.
- There must be no looseness in the monitor arm when it is locked.
- Make sure Monitor Contrast and Monitor Brightness are properly set.
- The contrast and brightness settings of the printer should be appropriate.
- There must be no slack in the screws of the mounting base, and peripheral instruments must be fixed securely.

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

II) Items that require periodic inspection at least once a month

- Casters must be properly locked.
- There must be no looseness in the control panel and handles.
- 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 instrument if there are any loose parts, cracks, damage or dents.
An instrument 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 instrument beyond its specified service life (seven years).
The instrument may not operate properly if used beyond its service life.

5-2-2 Measurement Accuracy Inspection

At least once a year, use an ultrasound phantom to make the following measurements in order to perform a measurement accuracy inspection and calculation accuracy inspection.

The inspection record must be stored.

I) Distance measurement accuracy

II) Resolution and sensitivity

III) Doppler measurement accuracy

Preparations for Measurement Accuracy Inspection

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 also 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 measurement.

- The probe to be used for the inspection, and its documentation
- Measurement accuracy inspection record table
- The previous measurement accuracy inspection record (if any)

1 Copy the measurement accuracy inspection record table and enter the necessary items.

2 Connect the probe to be used for the inspection to the instrument.

3 Turn on the instrument.

4 Change the preset to use the settings of the previous inspection. Select the optimum preset for the probe connected to the instrument.

If there is no previous inspection record

Select the optimum preset for the probe connected to the instrument.

5 Record the presets settings and enter them in the measurement accuracy inspection record table. Alternatively, record them as data to a DVD or other 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
- Item B in QSS
- Item M in QSS
- Item D, PW tab, in QSS
- Color item and Color 1 tab in QSS

Distance Measurement Accuracy Inspection

Use the ultrasound phantom to determine the orientation direction and distance direction distances.

1. Switch to B mode.
2. Move all [TGC] knobs to the center position.
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 (ultrasonic output power) to match the previous inspection record.

   If there is no previous inspection record

   Adjust the display depth, gain, dynamic range and ultrasonic 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, the result is judged as abnormal.
8. Similarly, calculate measurement accuracy in distance direction.

   → If the result differs significantly from the previous measurement result, the result is judged as abnormal.

Resolution and Sensitivity Inspection

1. Switch to B mode.
2. Move all [TGC] knobs to the center position.
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 (ultrasonic output power) to match the previous inspection record.

   If there is no previous inspection record

   Adjust the display depth, gain, dynamic range and ultrasonic 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 other 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, the result should be judged as abnormal.

Doppler Measurement Accuracy Inspection

Perform an inspection of the accuracy and sensitivity of Doppler measurements.

There are two methods for inspecting Doppler measurement accuracy.

Using the result of an ultrasound B-mode phantom inspection to substitute for a Doppler measurement sensitivity result

Probe degradation and failure of the transmission unit are the major causes of reduced Doppler measurement accuracy.

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 B-mode phantom inspection of penetration and resolution are normal, they can substitute for a Doppler phantom inspection of measurement accuracy and sensitivity of a probe.

Using 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.

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 the optimum image is obtained.
6. Move the sample gate position of the D cursor to a location with blood flow in the tomographic image to 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 other 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, the result should be judged as abnormal.

Inspecting Sensitivity

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 the optimum 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 other 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, the result should be judged as abnormal.

5-2-3 Measurement Accuracy Inspection Record Table

Diagnostic Ultrasound System	Model name	Serial number
Probe	Model name	Serial number
Other peripheral instruments	Model name	Serial number

Inspected date:	Inspector affiliation Signature

Item B in QSS	Item M in QSS
Item B in the Region Data Settings	Ultrasound phantom identification (Control No., date of purchase, S/N, etc.)

Measurement accuracy			
Orientation Direction Image Pasting Position		Distance Direction Image Pasting Position	
Known distance between targets: a	cm	Known distance between targets: a	cm
Measured distance: b	cm	Measured distance: b	cm
Distance measurement accuracy |b-a|÷a×100=	%	Distance measurement accuracy |b-a|÷a×100=	%

Resolution
Image Pasting Position

Doppler measurement accuracy (when a Doppler phantom is used)	
QSS D Item, PW tab paste position	Doppler phantom identification (Control No., date of purchase, S/N, etc.)
QSS color item, Color 1 tab paste position	Phantom settings Flow velocity (m/s):
B/ PW mode pasting position	B+ Color mode pasting position
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. To request a service engineer visit, please contact our office.

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	0.2Ω 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
3.	APPLIED PART LEAKAGE CURRENT - Alternative method (a.c.)	5 mA max

⚠ NOTE Perform facility inspection in the hospital (e.g. measure the protective earth impedance) at least once a year.

Periodic Safety Inspection Procedure

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.

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.

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.

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.

⚠NOTE 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.

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

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.

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.

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

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	S1 OPEN S7 CLOSE				
Total patient leakage current: 0.1 mA	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	S1 OPEN S7 CLOSE				
Total patient leakage current: 1.0 mA	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		
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	S1 OPEN S7 CLOSE				
Total patient leakage current: 0.1 mA	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	S1 OPEN S7 CLOSE				
Total patient leakage current: 1.0 mA	S1 CLOSE S7 OPEN				

Protective earth terminal	
Standard: 0.2Ω	

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: 300mΩ	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, contact our office.

- If the instrument does not respond

Cause	Countermeasure
Software out of control Fluctuating power supply	(1) Hold down the [Power] key for 10 seconds or longer. The system shuts down. If system shutdown does not start after 20 seconds or more, go on to step (2). (2) Disconnect the power cable 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	Countermeasure
Incorrect settings	Revise the date and time in the presets.
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	Countermeasure
	Graphics	Image		
Unlit	-	-	Power cable is not connected	Plug the power cable into the hospital grade outlet.
			Circuit breaker has tripped	Check the condition of the circuit breaker for the connected power outlet.
Orange	-	-	Instrument is in standby	Press the [Power] key. If the instrument does not start properly, please contact our office.
Blue	Nothing displayed	Nothing displayed	Monitor OSD settings	Check monitor settings. Adjusting the brightness levels of the screen, operation panel, touch panel and the size of the screen → p.106
			Use [EXT] to display (external input).	Turn [EXIT] to "Off".
Blue	Status displayed	Nothing displayed	Gain is too low	Adjust using the [Freeze] rotary encoder, [B] rotary encoder or the [TGC] knobs.
			The probe is not properly connected	Reconnect the probe.
			Acoustic power is too low	Adjust using the [Acoustic Power] rotary encoder.
			Still image display ([Freeze] key lights orange)	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 remove any dust from the trackball support ball and the sensor.

- If touch panel response is sluggish

  i) Clean the touch panel.

  ii) If the problem persists, press and hold the [Menu] key, [L] key and [R] key simultaneously for 3 seconds or more (until the status indicator lamp blinks orange 3 times). Make sure that nothing is in contact with the touch panel before rebooting.

  iii) Reboot the instrument if the problem persists. Make sure that nothing is in contact with the touch panel before rebooting.

- If power has been disconnected due to an error message, or some cause other than those above, disconnect the power plug from the hospital grade outlet.

- If other connected devices do not display images while the HDMI-monitor connection unit is used, contact our service staff.

5-4 Repair, Readjustment and Product Disposal

- Requesting repair or readjustment

  Turn off the power immediately if a fault occurs in this product.

  Inform us of the state of the fault to the best of your knowledge. We will make an on-site inspection and perform the necessary repairs.

  NOTE: Disinfect or sterilize peripherals, options, probes, and other parts before requesting their repair. For more details, please contact our office.

- Disposal of the instrument

  This instrument 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.

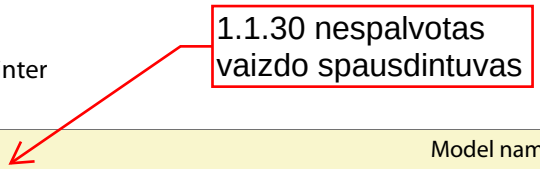
6 Product Configuration

6-1 Standard Configuration

Name	Model name	Quantity	Remarks
Diagnostic equipment			
Main unit	USI-169*	1	*1
Viewing monitor	IPF-2201*	1	*1*2
	IPF-2301*	1	*3*4
Accessories			
Power cable	CP-121	1	for 100 V to 120 V
Power cable	CP-117 or CP-128	1	for 200 V to 240 V
CD Manual Set	MN-CD-ARIETTA850-E	1	
Instruction Manual (Instructions for Use)	MN1-6227	1	Bound
SE label	P-34-SE-1	1	*3
CE label	P-32-CE-1	1	*4
Software extension unit			
Alphanumeric keyboard unit	EU-9186*	1	*1

*1. Depending on the date of manufacture, the asterisk (*) in the model name might be an alphabetic character.
*2. Supported for the ARIETTA 850.
*3. Supported for the ARIETTA 850SE.
*4. Supported for the ARIETTA 850CE

6-2 Options



Monochrome printer

Name	Model name	Remarks
Hybrid Graphic Printer	UP-X898MD	
Digital BW Printer	P95DW	
Digital BW Printer	P95DE	*1

*1. EU only

Color printer

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

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

Video recorder

Name	Model name	Remarks
HD Video Recorder	HVO-500MD /FHD	No optical disc drive
HD Video Recorder	HVO-550MD /FHD	With optical disc drive

Software extension unit

		Availability		
Name	Model name	EU	outside EU	Remarks
Magnetic sensor unit	EU-9185*	Yes	Yes	*1
Magnetic sensor For Tracking	EU-9197*	Yes	Yes	*1
RVS flexible stand	EZU-RVF1*	Yes	Yes	*1
Magnetic sensor unit connection kit	PM-AR850-H004*	Yes	Yes	*1
RVS Onboard arm	MP-FX-AVA-40*	Yes	Yes	*1
Performance Acceleration unit	EU-9207*	Yes	Yes	*1
Independent Probe connection unit	EU-9187*	Yes	Yes	*1
Physiological signal display unit	PEU-LISENDO880*	Yes	Yes	*1*2
Phonocardiographic transducer	MA-300	-	Yes	
Pulse transducer	TY-307A	-	Yes	

Name	Model name	Availability		Remarks
		EU	outside EU	
CW Servo Unit	EU-9184*	Yes	Yes	*1
Junction Box for ProSound LN/CV Probes	JB-294C or later	Yes	Yes	
HDMI monitor connection unit	EU-9205*	Yes	Yes	*1
Junction Box for HI VISION Probes	JB-293	Yes	Yes	

*1. Depending on the date of manufacture, the asterisk (*) in the model name might be an alphabetic character.
*2. Includes an ECG cable and other accessories.

Other

Name	Model name	Remarks
Probe holder for VL54	MP-PH-AR70-7U*	*1
Endo-cavity Probe holder Kit	MP-PH-AVA-11*	*1
Jelly Warmer	JW-3000U*	*1
3-point footswitch	MP-2819*	*1
1-point footswitch	MP-2345B	1 point type
Flexible hook	MP-HA-AVA-2*	*1
Flexible hanger	MP-HA-AVA-3*	*1
Instruction Manual (Instructions for Use)	MN1-6227	Bound
Instruction Manual (Acoustic Output Data)	MN1-6228	Bound
Instruction Manual (Basic Operations)	MN1-6229	Bound
Instruction Manual (Advanced Operations 1)	MN1-6230	Bound
Instruction Manual (Advanced Operations 2)	MN1-6231	Bound
Instruction Manual (Advanced Operations 3)	MN1-6232	Bound
Instruction Manual (Measurements 1)	MN1-6233	Bound
Instruction Manual (Measurements 2)	MN1-6234	Bound
Instruction Manual (Measurements 3)	MN1-6235	Bound

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

Software

Name	Model name	Remarks
Real Time 3D software	SOP-ARIETTA850-4	*1
Patient Information Automatic Input software	SOP-ARIETTA850-6	
Flow Profile Measurement software	SOP-ARIETTA850-7	
eTRACKING software	SOP-ARIETTA850-11	*2
TDI Analysis software	SOP-ARIETTA850-13	
Stress Echo software	SOP-ARIETTA850-15	*2
FMD Analysis software	SOP-ARIETTA850-16	*2
DICOM Structured Report software	SOP-ARIETTA850-21	

Name	Model name	Remarks
Wave Intensity software	SOP-ARIETTA850-34	*2
STIC software	SOP-ARIETTA850-41	*1, *3
Automated NT Measurement software	SOP-ARIETTA850-42	
Real-time Tissue Elastography software	SOP-ARIETTA850-43	
Contrast Harmonic Imaging software	SOP-ARIETTA850-44	
Transit Time of Vessel Flow Measurement software	SOP-ARIETTA850-47	*2
2D Tissue Tracking Analysis software	SOP-ARIETTA850-49	
EyeballEF software	SOP-ARIETTA850-58	*2
DICOM Query/Retrieve software	SOP-ARIETTA850-59	
Real-time Tissue Elastography Strain Histogram software	SOP-ARIETTA850-60	*4
Real-time Virtual Sonography software	SOP-ARIETTA850-62	*5
Picture in Picture software	SOP-ARIETTA850-63	
Automated FS Measurement software	SOP-ARIETTA850-71	
Automated FHR Measurement software	SOP-ARIETTA850-72	*6
Shear Wave Measurement B software	SOP-ARIETTA850-151	
Automated Cardiac Measurement software	SOP-ARIETTA850-74	
3D Sim-Navigator software	SOP-ARIETTA850-75	*5, *6, *7
Needle Tracking software	SOP-ARIETTA850-84	*5, *7, *8
Body Motion Tracking software	SOP-ARIETTA850-85	*5, *7, *8
E-field simulator software	SOP-ARIETTA850-96	*5, *6, *7, *9
Volume Data Extension software	SOP-ARIETTA850-97	*5, *6, *7
Detective Flow Imaging software	SOP-ARIETTA850-105	
iEF software	SOP-ARIETTA850-120	
McAfee Embedded Control 3 software	SOP-ARIETTA850-128	
Cardiac 3D B software	SOP-ARIETTA850-129	*10
4D LV-ANALYSIS software	SOP-ARIETTA850-112	
4D RV-FUNCTION software	SOP-ARIETTA850-113	
4D MV-ASSESSMENT software	SOP-ARIETTA850-114	

*1. Requires the EU-9184
*2. Requires the PEU-LISENDO880
*3. Requires the SOP-ARIETTA850-4
*4. Requires the SOP-ARIETTA850-43
5. Requires the EU-9185, PM-AR850-H004 and EZU-RVF1
*6. Not supported for the ARIETTA 850SE and the ARIETTA850CE.
*7. Requires the SOP-ARIETTA850-62
*8. Requires the EU-9197
*9. Requires the SOP-ARIETTA850-75
*10. Requires the EU-9183

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.

Electronic Convex Probe

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
C22K	Abdominal*a Intra-operative (Spec.)*b	6 to 1	21R	Intraoperative
C22P	Fetal Abdominal*a	6 to 1	22R	Body surface
C23	Fetal Abdominal*a	6 to 1	25R	Body surface
C23RV*1	Fetal Abdominal*a	6 to 1	25R	Body surface
C251	Fetal Abdominal*a Pediatric Small Organ (Spec.)*d	5 to 1	50R	Body surface
C252	Fetal Abdominal*a Pediatric Small Organ (Spec.)*d	6 to 1	50R	Body surface
C253	Fetal Abdominal*a Pediatric Small Organ (Spec.)*d	5 to 1	50R	Body surface
C25P	Fetal Abdominal*a	5 to 1	50R	Body surface
C35	Fetal Abdominal*a Pediatric Small Organ (Spec.)*d	8 to 2	50R	Body surface
C41B	Fetal Trans-rectal*e Trans-vaginal*f Other (spec.) Gynecological	10 to 2	10R	Endocavity
C41RP	Trans-rectal*e Trans-vaginal*f	9 to 2	9R	Endocavity

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
C41V1	Fetal Trans-rectal*e Trans-vaginal*f Other (spec.) Gynecological	10 to 2	10R	Endocavity
C42	Abdominal*a Intra-operative (Spec.)*b Pediatric Small Organ (Spec.)*d Neonatal Cephalic Peripheral vessel	8 to 4	21R	Body surface
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
CC41R	Fetal Trans-rectal*e Trans-vaginal*f	T*2: 8 to 4 L*3: 8 to 4	T*2: 10R L*3: 10R	Endocavity
CC41R1	Fetal Trans-rectal*e Trans-vaginal*f	T*2: 10 to 2 L*3: 10 to 2	T*2: 9R L*3: 9R	Endocavity
R41R	Trans-rectal	10 to 5	6R radial	Endocavity
R41RL	Trans-rectal	10 to 5	6R radial	Endocavity

*1. With built-in magnetic position sensor
*2. Transverse
*3. Longitudinal

Electronic Linear Probe

Model name	Intended Purpose	Frequency (MHz)	Visual field width	Application
L31KP	Intra-operative (Spec.)*b	9 to 2	6 mm	Intraoperative
L34	Abdominal*a Pediatric Small Organ (Spec.)*d Musculo-skel. (Convent.) Peripheral vessel	7 to 3	38 mm	Body surface
L35	Abdominal*a Pediatric Small Organ (Spec.)*d Musculo-skel. (Convent.) Peripheral vessel	9 to 2	45 mm	Body surface
L43K	Intra-operative (Spec.)*b	12 to 2	26 mm	Intraoperative

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
L44K	Intra-operative (Spec.)*b	14 to 2	42 mm	Intraoperative
L44LA1	Intra-operative (Spec.) Laparoscopic	13 to 2	38 mm	Intraoperative
L46K1	Intra-operative (Spec.)*b	14 to 2	63 mm	Intraoperative
L51K	Intra-operative (Spec.)*b	15 to 3	13 mm	Intraoperative
L53K	Intra-operative (Spec.)*b	15 to 3	25 mm	Intraoperative
L44LA	Intra-operative (Spec.) Laparoscopic	13 to 2	36 mm	Intraoperative
L55	Abdominal*a Pediatric Small Organ (Spec.)*d Musculo-skel. (Convent.) Musculo-skel. (Superfic.) 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.) Wound*h Peripheral vessel	18 to 5	38 mm	Body surface
SML44	Abdominal Pediatric Small Organ (Spec.)*c Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Peripheral vessel	22 to 2	38 mm	Body surface

Electronic Sector Probe

Model name	Intended Purpose	Frequency (MHz)	Application
S11	Fetal Abdominal Pediatric Adult Cephalic Cardiac Adult Cardiac Pediatric Peripheral vessel	5 to 1	Body surface
S121	Fetal Abdominal Pediatric Adult Cephalic Cardiac Adult Cardiac Pediatric Peripheral vessel	5 to 1	Body surface
S31	Abdominal Pediatric Neonatal Cephalic Cardiac Adult Cardiac Pediatric	9 to 2	Body surface
S42	Abdominal Pediatric Neonatal Cephalic Cardiac Adult Cardiac Pediatric	14 to 3	Body surface
S3ESL1	Trans-esoph. (non-Card.)*g Trans-esophageal (card.)*g	9 to 2	Endocavity
S3ESEL	Trans-esoph. (non-Card.)*g Trans-esophageal (card.)*g	8 to 2	Endocavity
S3ESCLS	Trans-esoph. (non-Card.)*g Trans-esophageal (card.)*g	8 to 2	Endocavity

4D Probe

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
VC34	Fetal Abdominal Pediatric Small Organ (Spec.)*c	7 to 2	40R	Body surface
VC35	Fetal Abdominal Pediatric Small Organ (Spec.)*c	8 to 2	46R	Body surface

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
VC41V	Fetal Trans-vaginal Other (spec.) Gynecological	8 to 2	10R	Endocavity
MXS1	Fetal Abdominal Pediatric Adult Cephalic Cardiac Adult Cardiac Pediatric Peripheral vessel	5 to 1		Body surface

Other Probe

Model name	Intended Purpose	Frequency (MHz)	Curvanture Radius, or Scan Area	Application
C41L47RP	Trans-rectal*e	CV*1: 8 to 4 LN*2: 10 to 5	CV*1: 10R LN*2: 64 mm	Endocavity
CL4416R	Trans-rectal*e	CV*1: 10 to 2 LN*2: 14 to 2	CV*1: 9R LN*2: 63 mm	Endocavity
CL4416R1	Trans-rectal*e	CV*1: 10 to 2 LN*2: 14 to 2	CV*1: 9R LN*2: 63 mm	Endocavity

*1. Convex Type
*2. Linear Type

Independent Probes

Model name	Intended Purpose	Frequency (MHz)	Application
UST-2265-2*1	Cardiac Adult Cardiac Pediatric Peripheral vessel	2	Body surface
UST-2266-5*1	Cardiac Adult Peripheral vessel	5	Body surface

*1. The optional EU-9187 is necessary.

*a: Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

*b: Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

*c: Includes thyroid, parathyroid, breast, scrotum, penis.

*d: Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

*e: Includes imaging for guidance of trans-rectal biopsy.

*f: Includes imaging for guidance of trans-vaginal biopsy.

*g: For Adult and Pediatric patients.

*h: Includes imaging for Cavernous/Non-Cavernous wounds.

6-3-1 Probe Functions: Basic Functions

Basic Functions		C22K	C22P	C23	C23RV	C251	C252	C253	C25P	C35	C41B	C41RP	C41V1	C42	C42K
Compound		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trapezoid															
Wide Scanning				Yes	Yes										
B steer															
eFocusing		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Acoustic Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane															
OMNI Mode															
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B														
	Color			Yes	Yes		Yes			Yes					
DFI mode				Yes	Yes	Yes	Yes	Yes		Yes					
TDI mode						Yes	Yes	Yes		Yes					
Hi Frame	B					Yes	Yes	Yes		Yes					
	Color					Yes	Yes	Yes		Yes					
Puncture Guide Line		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Needle Emphasis		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Brachy Grid Display															
CW mode						Yes	Yes	Yes		Yes				Yes	
Assist Line															
THI	FmT		Yes			Yes	Yes	Yes	Yes	Yes				Yes	
	WbT	Yes	Yes			Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	
	HdT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		C42T	CC41R	CC41R1	R41R	R41RL	L31KP	L34	L35	L43K	L441	L442	L44K	L46K1
Compound		Yes	Yes	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trapezoid							Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Wide Scanning														
B steer								Yes	Yes	Yes	Yes	Yes	Yes	Yes
eFocusing		Yes	Yes	Yes				Yes	Yes	Yes	Yes	Yes	Yes	Yes
Acoustic Noise Reduction		Yes					Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane			Yes	Yes										
OMNI Mode														
FAM		Yes	Yes	Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B							Yes	Yes					
	Color								Yes		Yes			
DFI mode									Yes		Yes	Yes		
TDI mode														
Hi Frame	B													
	Color										Yes	Yes		
Puncture Guide Line			Yes	Yes			Yes	Yes	Yes		Yes	Yes		
Needle Emphasis			Yes	Yes				Yes	Yes		Yes	Yes		
Brachy Grid Display														
CW mode								Yes	Yes		Yes	Yes		
Assist Line									Yes			Yes		
THI	FmT													
	WbT		Yes	Yes	Yes	Yes		Yes	Yes		Yes	Yes		
	HdT	Yes		Yes				Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		L51K	L53K	L44LA	L44LA1	L55	L64	SML44	S11	S121	S31	S42	S3ESL1	S3ESEL	S3ESCLS
Compound		Yes	Yes	Yes		Yes	Yes	Yes							
Trapezoid		Yes	Yes	Yes		Yes	Yes	Yes							
Wide Scanning									Yes	Yes	Yes	Yes	Yes	Yes	Yes
B steer		Yes	Yes	Yes		Yes	Yes	Yes							
eFocusing		Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes					
Acoustic Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Real-time Biplane															
OMNI Mode															
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TGC Enhancement	B														
	Color					Yes	Yes	Yes							
DFI mode						Yes	Yes	Yes							
TDI mode						Yes			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hi Frame	B								Yes	Yes					
	Color								Yes	Yes	Yes	Yes	Yes	Yes	Yes
Puncture Guide Line						Yes	Yes								
Needle Emphasis						Yes	Yes								
Brachy Grid Display															
CW mode							Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Assist Line							Yes	Yes							
THI	FmT								Yes	Yes	Yes	Yes			
	WbT		Yes				Yes	Yes		Yes					
	HdT	Yes	Yes	Yes		Yes	Yes	Yes							
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes

Basic Functions		VC34	VC35	VC41V	MXS1	C41L47RP(CV)	C41L47RP(LN)	CL4416R (CV)	CL4416R (LN)	CL4416R1(CV)	CL4416R1(LN)	UST-2265-2	UST-2266-5
Compound		Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes		
Trapezoid							Yes		Yes		Yes		
Wide Scanning													
B steer							Yes		Yes		Yes		
eFocusing		Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes		
Acoustic Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes						
Near-field Noise Reduction		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		
Real-time Biplane					Yes								
OMNI Mode				Yes									
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		
TGC Enhancement	B												
	Color												
DFI mode													
TDI mode		Yes	Yes		Yes								
Hi Frame	B	Yes	Yes	Yes	Yes								
	Color	Yes	Yes		Yes								
Puncture Guide Line							Yes		Yes		Yes		
Needle Emphasis													
Brachy Grid Display						Yes		Yes		Yes			
CW mode					Yes							Yes	Yes
Assist Line													
THI	FmT	Yes	Yes	Yes	Yes								
	WbT	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes		
	HdT	Yes	Yes					Yes	Yes				
Dual Gate Doppler		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		

6-3-2 Probe Functions: Optional Functions

Optional Functions		C22K	C22P	C23	C23RV	C251	C252	C253	C25P	C35	C41B	C41RP
Contrast Harmonic Imaging	Low	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
	Mid	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
	High		Yes	Yes	Yes	Yes	Yes	Yes	Yes			
Panoramic display						Yes	Yes	Yes		Yes		
Real-time Tissue Elastography						Yes	Yes	Yes		Yes	Yes	
Shear Wave Measurement						Yes	Yes	Yes				
Shear Wave Elastography							Yes					
Real-time Virtual Sonography			Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Needle Tracking			Yes	Yes	Yes	Yes	Yes	Yes	Yes			
Cardiac 3D												
Real time 3D												
STIC												
Automatic volume measurement (AVM, MFV, TVM)												
Stress echo												
Early-stage arteriosclerosis evaluation (eTRACKING)												
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)												
Circulatory dynamics index evaluation (Wave Intensity)												
CHI-eFlow				Yes	Yes	Yes	Yes	Yes				

Optional Functions		C41V1	C42	C42K	C42T	CC41R	CC41R1	R41R	R41RL	L31KP	L34
Contrast Harmonic Imaging	Low	Yes			Yes	Yes					Yes
	Mid	Yes			Yes	Yes					Yes
	High										
Panoramic display			Yes								Yes
Real-time Tissue Elastography		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes
Shear Wave Measurement											
Shear Wave Elastography											
Real-time Virtual Sonography		Yes	Yes		Yes	Yes	Yes				
Needle Tracking											
Cardiac 3D											
Real time 3D											
STIC											
Automatic volume measurement (AVM, MFV, TVM)											
Stress echo											
Early-stage arteriosclerosis evaluation (eTRACKING)											Yes
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)											Yes
Circulatory dynamics index evaluation (Wave Intensity)											Yes
CHI-eFlow											

Optional Functions		L35	L43K	L441	L442	L44K	L46K1	L51K	L53K	L44LA	L44LA1	L55
Contrast Harmonic Imaging	Low	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes
	Mid	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes
	High											
Panoramic display		Yes		Yes	Yes							Yes
Real-time Tissue Elastography		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes
Shear Wave Measurement												
Shear Wave Elastography												
Real-time Virtual Sonography		Yes										Yes
Needle Tracking		Yes										
Cardiac 3D												
Real time 3D												
STIC												
Automatic volume measurement (AVM, MFV, TVM)												
Stress echo												
Early-stage arteriosclerosis evaluation (eTRACKING)				Yes	Yes							Yes
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)				Yes	Yes							Yes
Circulatory dynamics index evaluation (Wave Intensity)				Yes	Yes							Yes
CHI-eFlow		Yes										

Optional Functions		L64	SML44	S11	S121	S31	S42	S3ESL1	S3ESEL	S3ESCLS	VC34	VC35
Contrast Harmonic Imaging	Low				Yes							
	Mid											
	High											
Panoramic display		Yes	Yes									
Real-time Tissue Elastography		Yes	Yes									
Shear Wave Measurement		Yes										
Shear Wave Elastography												
Real-time Virtual Sonography		Yes	Yes									
Needle Tracking												
Cardiac 3D												
Real time 3D											Yes	Yes
STIC											Yes	Yes
Automatic volume measurement (AVM, MFV, TVM)												
Stress echo				Yes	Yes	Yes	Yes					
Early-stage arteriosclerosis evaluation (eTRACKING)		Yes	Yes									
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)		Yes	Yes									
Circulatory dynamics index evaluation (Wave Intensity)		Yes	Yes									
CHI-eFlow												

Optional Functions		VC41V	MXS1	C41L47RP(CV)	C41L47RP(LN)	CL4416R (CV)	CL4416R (LN)	CL4416R1(CV)	CL4416R1(LN)	UST-2265-2	UST-2266-5
Contrast Harmonic Imaging	Low										
	Mid										
	High										
Panoramic display					Yes		Yes		Yes		
Real-time Tissue Elastography		Yes		Yes	Yes	Yes	Yes	Yes	Yes		
Shear Wave Measurement											
Shear Wave Elastography											
Real-time Virtual Sonography				Yes	Yes	Yes	Yes	Yes	Yes		
Needle Tracking											
Cardiac 3D			Yes								
Real time 3D		Yes									
STIC											
Automatic volume measurement (AVM, MFV, TVM)											
Stress echo			Yes								
Early-stage arteriosclerosis evaluation (eTRACKING)											
Blood flow dependence vasodilatation/vessel dilation response evaluation (Flow Mediated Dilatation)											
Circulatory dynamics index evaluation (Wave Intensity)											
CHI-eFlow											

6-3-3 Measurement Scope

This section will display the maximum scope for each measurement received when using ALOKA ARIETTA 850.

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)
C22K	61.1	999.9	999.9	99.9	9999	29.9	999.9	9.74	6-999
C22P	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C23	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C23RV	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C251	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C252	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C253	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C25P	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
C41B	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C41RP	34.6	999.9	999.9	99.9	9999	17.0	713.0	9.74	6-999
C41V1	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C42	42.4	999.9	999.9	99.9	9999	19.0	802.1	9.74	6-999
C42K	42.4	999.9	999.9	99.9	9999	19.0	802.1	9.74	6-999
C42T	42.4	999.9	999.9	99.9	9999	19.0	802.1	9.74	6-999
CC41R	42.4	999.9	999.9	99.9	9999	19.0	99.9	9.74	6-999
CC41R1	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
R41R	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
R41RL	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
L31KP	30.5	999.9	999.9	99.9	9999	15.0	802.1	9.74	6-999
L34	34.6	999.9	999.9	99.9	9999	17.0	916.7	9.74	6-999
L35	34.6	999.9	999.9	99.9	9999	17.0	916.7	9.74	6-999
L43K	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L441	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L442	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L44K	34.6	999.9	999.9	99.9	9999	17.0	713.0	9.74	6-999
L46K1	34.6	999.9	999.9	99.9	9999	17.0	713.0	9.74	6-999
L51K	28.5	999.9	999.9	99.9	9999	14.0	458.3	9.74	6-999
L53K	28.5	999.9	999.9	99.9	9999	14.0	458.3	9.74	6-999
L44LA	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L44LA1	28.5	999.9	999.9	99.9	9999	14.0	713.0	9.74	6-999
L55	34.6	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999
L64	28.5	999.9	999.9	99.9	9999	14.0	458.3	9.74	6-999
SML44	34.6	999.9	999.9	99.9	9999	17.0	802.1	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)
S11	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
S121	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
S31	48.9	999.9	999.9	99.9	9999	24.0	999.9	9.74	6-999
S42	30.5	999.9	999.9	99.9	9999	15.0	713.0	9.74	6-999
S3ESL1	48.9	999.9	999.9	99.9	9999	24.0	802.1	9.74	6-999
S3ESEL	48.9	999.9	999.9	99.9	9999	24.0	916.7	9.74	6-999
S3ESCLS	48.9	999.9	999.9	99.9	9999	24.0	802.1	9.74	6-999
VC34	48.9	999.9	999.9	99.9	9999	24.0	999.9	9.74	6-999
VC35	48.9	999.9	999.9	99.9	9999	24.0	999.9	9.74	6-999
VC41V	42.4	999.9	999.9	99.9	9999	19.0	916.7	9.74	6-999
MXS1	81.4	999.9	999.9	99.9	9999	39.9	999.9	9.74	6-999
C41L47RP(CV)	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
C41L47RP(LN)	34.6	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999
CL4416R (CV)	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
CL4416R (LN)	34.6	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999
CL4416R1(CV)	42.4	999.9	999.9	99.9	9999	19.0	534.7	9.74	6-999
CL4416R1(LN)	36.4	999.9	999.9	99.9	9999	17.0	534.7	9.74	6-999
UST-2265-2	-	-	-	-	-	-	999.9	9.74	6-999
UST-2266-5	-	-	-	-	-	-	534.7	9.74	6-999

7 Safety Guidelines

7-1 Guidelines for Electromagnetic Compatibility

This device complies with the electromagnetic compatibility standard for medical electrical equipment IEC 60601-1-2: Ed.4. This standard specifies electromagnetic energy level (electromagnetic emissions) test requirements and resistance to electromagnetic interference (electromagnetic immunity) test requirements for medical instruments.

7-1-1 Guidance and Directive Concerning Electromagnetic Emissions

This instrument is intended for use in an electromagnetic environment as specified in the following. We recommend that customers or users of the device confirm that the device is used in such an environment.

Phenomenon, Basic EMC standard	EMISSION TEST LEVELS Professional healthcare facility environment	Electromagnetic Environment—Guidance
CISPR11, Conducted and radiated EMISSIONS	Group 1	The instrument uses RF energy exclusively for its internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic devices.
CISPR11, Conducted and radiated EMISSIONS	Class B	The instrument 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.
IEC 61000-3-2, Harmonic distortion	Class A	
IEC 61000-3-3, Voltage fluctuations and flicker	Complies	

7-1-2 Essential performance

Confirmed that there is no impact on essential performance (the performance of the clinical function(s)) of the device by performing electromagnetic disturbances test as per the electricalmagnetic compatibility of IEC 60601-1-2: Ed.3, IEC 60601-1-2: Ed.4 and IEC 60601-2-37.

Free from the potential risks as follows:

- Noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.
- The display of incorrect numerical values associated with the diagnosis to be performed.
- The display of incorrect safety-related indications.

Essential performance	Overview	Reference
Scan Area	Scanning range	[T.B.F.] key (Basic Operations)
Flow Area	Color display range of color Doppler mode	[T.B.F.] key (Basic Operations)
Velocity Range	Velocity range (scale mark) in the Doppler image display	[FOCUS /VELOCITY] paddle switch (Basic Operations)
M cursor Doppler Cursor	Cursor display which indicates the M or D mode image detection position in B mode	[T.B.F.] key (Basic Operations)
Sample Volume	Doppler detection range settings in the PW Doppler mode	Sample Volume menu (Basic Operations)
Image Frequency Select	Changing Frequencies in B and M Mode	Frequency (Basic Operations)
	Changing Frequencies in D, Color, and CHI Modes	Reference Frequency (Basic Operations)
Focus	Number of focal points and their positions	[FOCUS /VELOCITY] paddle switch (Basic Operations)
Acoustic Power	Acoustic power	Ultrasound Output Safety Information, [Acoustic Power] rotary encoder (Instructions for Use)
Line Density	Change in scanning line density combinations for black-and-white and color images	Frame rate menu (Basic Operations)
Packet Size	Number of transmissions used to display blood flow	Menus and Presets: Color Flow, Power Flow, eFlow, TDI, DFI (Basic Operations)
Puncture	Puncture guide line display	Puncture menu (Basic Operations)
Message	Warning messages indicating the correct method of operation and alarm tone	Message (Instructions for Use)
Angle Correction	Display of flow velocity value whose Doppler beam angle has been corrected	Angle Correction menu, preset: Doppler, Tissue Doppler (Basic Operations)
Heart Rate Display	Computes and displays the heart rate from detected R-wave (HR***)	Displaying Physiological Signals, the Physio Menu, and Presets: Physio (Basic Operations)
Display Format Picture	Scale marks (distance, time and flow velocity) display	

7-1-3 Guidance and Declaration Directive Concerning Electromagnetic Immunity

This instrument is intended for use in an electromagnetic environment as specified in the following. We recommend that customers or users of the device confirm that the device is used in such an environment.

IEC 60601-1-2 Ed.3 compliant

Immunity examination	IEC 60601 Testing Level	Conformity level	Electromagnetic Environment—Guidance
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, it is desirable that the relative humidity of these is 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 instrument 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 instrument 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 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.
	< 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 Power frequency (50/60Hz) magnetic immunity	3 A/m	3 A/m	It is desirable that the power frequency magnetic field has the same level of characteristic as the standard business or hospital environments.
Remarks: U_T is AC power supply voltage before applying a testing level.			

IEC 60601-1-2 Ed.4 compliant

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.	

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.
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.	

DC Input Power Port

None.

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

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 Table Guidance and Declaration Directive Concerning Electromagnetic Immunity (conducted RF and emitted RF)

This instrument is intended for use in an electromagnetic environment as specified in the following. We recommend that customers or users of the device confirm that the device is used in such an environment.

IEC 60601-1-2 Ed.3 compliant

Immunity Examination	IEC 60601 Testing Level	Conformity level	Electromagnetic Environment—Guidance
			Cellular and Mobile RF communication instrument including cables shall not be used close to any parts of the instrument within the recommended separation distances calculated by the equations corresponding to the frequencies of those transmitters.
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz	V_1 = 3V	Recommended separation distance $d = \left(\frac{3.5}{V_1}\right)\sqrt{P}$
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
			Here P stands for the maximum output power rating, expressed in watts (W), of the transmitter according to the transmitter manufacturing company, and d is the recommended separation distance expressed 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 symbol shown below is found on equipment that generates electromagnetic interference intentionally. Interference may occur in the vicinity of equipment with the following symbol. 
Remark 1 Apply high frequency ranges in 80 MHz and 800 MHz. Remark 2 These guidelines may not apply in all circumstances. Electromagnetic propagation is affected by reflection or absorption from buildings, objects and people.			

Immunity Examination	IEC 60601 Testing Level	Conformity level	Electromagnetic Environment—Guidance
a: 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: For bandwidths outside of 150 kHz — 80 MHz range, it is desirable that the field intensity is less than 3 V/m.			

7-1-5 Recommended separation distance between cellular and mobile RF communication instruments and the instrument

The instrument is intended to be used in an electromagnetic environment where RF interference is controlled. Customers or users of the instrument can help prevent electromagnetic interference by maintaining the shortest distance between a mobile RF communication instrument (a transmitter) and the instrument to the following recommendation, based on the maximum output of the transmitter device.

IEC 60601-1-2 Ed.3 compliant

Maximum power output rating of transmitter (W)	Separation distance (m) based on the frequencies of transmitters		
	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 higher rated maximum output power not listed above, the recommended distance d expressed in meters (m) can be estimated using the equation corresponding to the frequency of the transmitter. P in the equation is the rated maximum output power of a transmitter expressed in watts (W) by the transmitter manufacturing supplier.			
Remark 1: Apply high frequency ranges in 80 MHz and 800 MHz. Remark 2: These guidelines may not apply in all circumstances. Electromagnetic propagation is affected by reflection or absorption from buildings, objects and people.			

IEC 60601-1-2 Ed.4 compliant

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 ±5kHz 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

These guidelines provide information on protection for avoiding deterioration and/or failure of parts that are sensitive to static electricity.

This instrument was configured according to the “Guidelines for Electromagnetic Compatibility” in this document. Connect the probes and perform maintenance inspections for this instrument as described below.

- Do not install the instrument on a floor covered with a carpet or synthetic materials.
  The floor materials on which the instrument is installed should be wood, concrete or ceramic tile. If there is no choice but to install the instrument on a floor covered with carpet or synthetic materials, it should be placed on a grounded mat.
- Keep the humidity at the installation location greater than 30%.
- When connecting probes, foot switch, cables etc. to the connectors, keep your hands as far away as possible from the connector pins.
  Before carrying out any work on the instrument, turn off the power without disconnecting the power plug.

⚠NOTE Explain the meaning of the ESD warning symbol to all staff who use this instrument. Provide them with training in the ESD preventive procedure described above.

- ESD Warning Symbol (): Keep hands and fingers away from the connection terminal.
  Electrostatic discharge (ESD) can destroy parts that are sensitive to static electricity or cause them to malfunction.

7-3 Ultrasound Output Safety Information

7-3-1 Acoustic Power Index

Our Diagnostic Ultrasound System displays output indexes that indicate the potential for adverse effects of ultrasonic waves on a living body (bioeffects). The displayed indexes are the following four kinds. Of these, the mechanical index MI indicates mechanical bioeffects and the thermal index TI indicates thermal bioeffects. The three indexes TIS, TIB, and TIC have been prepared according to tissue model.

- Mechanical index: MI

  Mechanical Index (MI) is an index at the top of the screen which displays the relative susceptibility of harmful bioeffects as a result of non-thermal bioeffects (mechanical bioeffects) such as cavitation. Mechanical bioeffects are caused as a result of tissue movement generated when air bubbles are compressed via compressed ultrasound waves passing through the tissue. The majority of the mechanical bioeffects could lead to the generation, expansion, undulation, and deterioration of microbubbles within the tissue. This behavior as a result of air bubbles is called cavitation.

  Because thermal bioeffects are small in B, B/M, and M modes, MI is incredibly important. MI can be displayed on 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) gives information on the elevation of temperature within homogeneous soft tissue (scanning of the heart, fetuses within the first three months of pregnancy, abdomen, etc.). TIS can be displayed on all modes.

  - Bone thermal index: TIB

    Bone thermal index (TIB) shows temperature elevations in bones when ultrasound beams form a focus close to bones after passing through soft tissues (scans for an embryo of the second or third three months of pregnancy, etc.). TIB can be displayed on all modes and at the time of probe use. In addition, with scan modes including B mode, the value of TIB becomes equal to the value of TIS.

  - Cranial-bone thermal index: TIC

    Cranial bone thermal index (TIC) shows temperature elevations when ultrasound beams pass through existing bones in the vicinity of body surface (the part where a beam enters to the body) (head inspection of adults and infants). TIC can be displayed on all modes.

The border between a safe level and a danger level of bioeffects is important for the operators. WFUMB (World Federation for Ultrasound in Medicine and Biology) has issued a number of indicators. For example, “a temperature rise of more than 4°C in five minutes should be considered potentially dangerous for embryos and embryo tissues” and so on.

On the other hand, the index displays conditions that are more susceptible to thermal effects and (or) mechanical effects related to the living body system in comparison to sound pressure, intensity or other parameters.

For example, we suggest that it is better to avoid a TI value exceeding a certain upper limit range (more than 1.0) in obstetrics use. Such a limit gives us a rational safety margin in consideration of the advice of WFUMB mentioned previously. When specific clinical consequences are not provided with lower values, it may justify to increase the output, nevertheless, should pay special attention to limiting exposure time. When examining an embryo whose mother is running with a fever, you should be particularly careful not to use high TI values in order to avoid unnecessary heat load.

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

Relative importance of keeping acoustic power index low at various examinations

	It is more important	It is not important
MI	• When using an ultrasound contrast agent, heart scanning where pulmonary irradiation is possible • Abdominal scanning (enteric gas)	• There are no air bubbles
TI	• Early stage pregnancy scanning: TIS • Scanning after the second trimester: TIB • Fetal skull and spinal cord • Patient who run a fever • Tissue with little perfusion • If ribs or bones are irradiated: TIB	• Tissue with good perfusion (liver, spleen) • Heart scan • Blood vessel scan

CAUTION: It has been thought that the high frequency range of the Diagnostic Ultrasound System from several MHz to several 10s of MHz would preclude cavitation. However, animal experiment have shown that the tissues where air bubbles exist such as lungs and bowels easily receive damage such as petechia even at low sound pressure. Supersonic experiments have shown that fetal pulmonary tissue, which is not used for pulmonary respiration, are not easily affected. These facts indicate care is required when using an ultrasound contrast agent to inject air bubbles intentionally.

7-3-2 Ultrasound Wave, Interaction between Vital Tissues

When ultrasound waves pass through body tissue, the tissue may be damaged. Ultrasonic images that are taken during examinations are produced as a result of turning energy reflected by tissue into images when energy from transmitted ultrasound waves is applied to tissue by a probe. However, the tissue absorb most of the ultrasound wave energy. The typical frequencies for ultrasonic waves generated from the probe as physical pressure waves range from 2 MHz (megahertz is 1 million cycles per second) to 10 MHz. In ultrasound irradiation, the energy absorbed in the tissue may cause some processes within those tissues.

These processes are classed as mechanical bioeffects and thermal processes, respectively.

The first type of bioeffects are mechanical bioeffects. Mechanical bioeffects are due to the pressure waves causing mechanical or physical movement of the tissues and tissue components. These components such as cells, fluids, etc., oscillate. If conditions are favorable, it is possible that these oscillations may affect the structure or function of living tissues. At this time, it can be believed that mechanical bioeffects are only temporary, and they relate closely to peak negative acoustic pressure of the ultrasound wave pulse. An extreme example of the mechanical effects of ultrasound is shock-wave lithotripsy, where focused ultrasound waves are used to break apart kidney stones.

The second type of bioeffects are thermal bioeffects. These bioeffects are caused as a result of tissue absorbing the energy from ultrasound waves. When an acoustic wave transmits through the body system, the energy of a sound wave is attenuated. Deterioration occurs because of one of two reasons, absorption or dispersion. Absorption changes the ultrasound wave energy into heat, and dispersion changes the advancing direction of the ultrasound waves. The temperature of tissue will elevate as a result of acoustic energy being absorbed into it. This is how thermal bioeffects work. Unlike mechanical bioeffects, thermal bioeffects are temporal and relate closely to the volume, perfusion ratio, exposure time, and duty factor (a comparison of the pulse repetition cycle according to its transmission pulse time) of the tissue. Biological effects that occur as a result of tissue heating run a high risk of causing such things as physiological cell abnormalities, drops in DNA synthesis rate, or development delay in the heart, mind, or bones of fetuses.

Expected Bioeffects

Mechanical Bioeffects

Mechanical bioeffects occur as a result of oscillation of a pressure wave when an ultrasound wave is transmitted to the body system. This pressure wave acts on microscopic gas bubbles and other "nucleation sites" in tissue. These nucleation sites, although presently poorly understood, are believed to serve as starting points for the development of gas bubbles. Because gas is much more compressible than fluid, the microscopic gas bubbles can expand and contract greatly in comparison to the immediately surrounding tissues and fluid. Large change in size may damage tissues.

Mechanical bioeffects include cavitation (the phenomenon of microbubbles and other nucleation sites activating within tissue as a result of ultrasound waves), acoustic radiation pressure, micro streaming, of which cavitation is the most crucial. Cavitation is separated into non-inertial cavitation (previously known as steady cavitation) and inertial cavitation (previously known as temporary cavitation).

Non-inertial cavitation is when steady-state effects arise from the repeated expansion and contraction of the micro bubbles in response to the varying pressures in ultrasound pulses. These undulations cause a phenomenon known as "micro streaming". Micro streaming is the oscillation of gas bubbles in tissue that leads to motion in the fluid around the gas bubbles. This phenomenon has shown that micro streaming has the possibility of causing disruption of cell membranes.

In the case of inertial cavitation, transient mechanical effects occur when a pressure change due to the oscillating ultrasound wave causes a gas bubble to expand and then implode violently in a process called "cavitation". Although this phenomenon occurs on the microscopic level, it has been demonstrated to produce extremely high temperatures and pressures in the immediate vicinity, which can lead to cell death.

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

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

Thermal Bioeffects

Thermal bioeffects occur over longer periods of time, where absorption of the ultrasound energy results in heating of tissues. Excessive heating can lead to disruptions in cellular processes and structures, especially in developing fetal tissues. As stated above, the energy which is producing images by receiving reflected energy from the body's internal tissues by the probe is very limited compared to the total energy transmitted to the body system. The rest of the energy must be absorbed by the tissues. As a result of this absorption, two main types of tissues tend to be affected, the area on the surface of the tissue which has been hit by the ultrasound beam, and the area around the focal point of the ultrasound beam.

Because of difference in their physical properties, different tissues absorb ultrasound energy at different rates. Absorption is affected by the ultrasonic power (energy per unit of time), the volume of tissues involved and its perfusion rate, or the amount of blood flow through the target tissues. Bone tissue, with its higher density and lower perfusion than soft tissues, absorbs more ultrasound energy. Bone tissue not at the surface, but at the focus point of the beam, will also absorb a higher portion of energy. Soft tissues absorbs the least. Because tissue absorbs ultrasound energy at different rates, a single model to describe all of the different properties of different tissues is not available. Currently, the following three types of models are used to describe thermal bioeffects within tissue.

- Soft tissue
- Bone tissue that's been hit by the focal point of the ultrasound beam
- Bone tissue on the body's surface

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

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

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

7-3-3 Derivation and Meaning of MI/TI

AIUM (American Institute of Ultrasound in Medicine) and NEMA (National Electrical Manufacturers Association) published their independent standard "TI/MI Real-Time Display Standard (AIUM/NEMA: Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment)" in 1992. This standard has established the method of calculating and displaying indexes relatively susceptible to causing mechanical and thermal bioeffects to a living body system. Currently, the JIS T 0601-2-37 (IEC 60601-2-37) diagnostic ultrasound system safety standard also employs these same indexes, which allows users of most diagnostic ultrasound systems to view and check the indices in real-time while regulating the acoustic power.

These two indexes, the mechanical index MI and thermal index TI, indicate a value without units for the susceptibility of harmful bioeffects that could come as a result of ultrasound wave examinations. The index was designed to indicate the possibility of danger should a value exceed the previously established value. As a guideline, if it exceeds 1, it will be recommended that you consider lowering the acoustic power before conducting the exam, taking into account relieving factors and re-evaluating the risks/effective approach for analysis. Relieving factors include those such as a lack of air bubbles in the target tissue, low susceptibility of morphological damage, and a high level of perfusion. Also, it's recommended that the examination time be kept as short as possible to avoid unnecessary irradiation. However, there is another danger that must be taken into consideration. Which is not obtaining the necessary information as a result of avoiding an ultrasound examination altogether. It's important to acknowledge that the danger of misdiagnosis due to not using the necessary acoustic power during an examination is greater than that of the bioeffects caused by ultrasound waves.

MI: Mechanical index

According to scientific evidence, mechanical (non-thermal) bioeffects such as cavitation are a threshold phenomenon and they won't occur so long as the output does not go above a certain level. However, the threshold level differs depending on the tissue. It can be thought that the susceptibility of mechanical bioeffects rises as the peak-rarefactional acoustic pressure rises, and decreases as the ultrasound wave frequency rises. They defined the following formula for MI.

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

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, and it is 1 [MPa $MHz^{-1/2}$]. Therefore, there is no unit in the MI.

The MI is crucial around the gas/soft tissue border area, for example, there is a risk of irradiation of the lung surface during heart scans. If you use diagnostic ultrasound contrast agent, which includes air bubbles, you are recommended to use the utmost caution while regulating the MI.

Because ultrasound waves pass through amniotic fluid and the urinary bladder with little to no deterioration, there is a high possibility of the tissue receiving acoustic pressure even if the MI value is low.

TI: Thermal index

TI is defined as supersonic wave output P_{α} [mW] which is damped with a living body is divided by supersonic wave output P_{deg} [mW] that it is necessary for raising a life form by 1°C.

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

P_{α}: Attenuated output power

TI, along with the MI, has no unit.

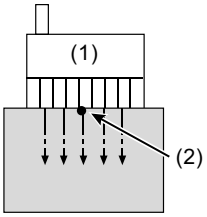
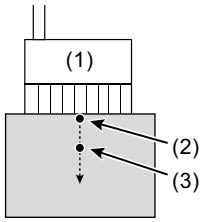
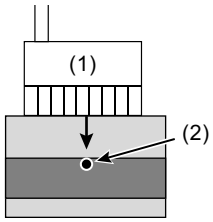
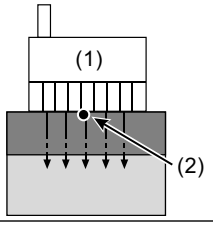
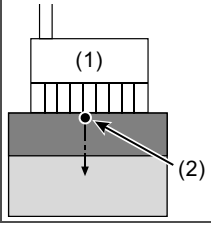
Three types of TI, TIS (soft tissue), TIB (bone), and TIC (cranial bone), are used depending on the combination of soft tissue and bone tissue of the examination subject. The goal of TI is to inform the user when elevations in temperature occur according to conditions where tissue surface, tissue interior, or ultrasound waves focus in the vicinity of the bones. Each type of TI predicts elevations in temperature based on a hypothesis.

- When the ultrasound beam scans, a rise in temperature by supersonic wave is supposed to be highest at the probe osculating plane regardless of the target tissue model.
- When there are no bones within the soft tissue in non-linear mode, there is a possibility that the greatest heat will occur somewhere between the contact surface of the probe and directly in front of the focal point.

- For soft tissues in non-scanning mode, when a bone is in the vicinity of the focus, temperature rises most on the surface of the bone. Especially when nerve tissue (brain and spinal cord, etc.) has formed within the heated bone region in infants, and when diagnosing in non-linear modes such as Doppler mode, it's recommended that you use the TIB and carefully monitor the value.

When you have difficulty deciding which TI to use, it is preferable to refer to the following chart to decide where the bones are located in the region that will be irradiated by supersonic waves.

Classification and Diagram of Thermal Index

	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 Setting Conditions Influencing Device Output

It is necessary to understand the setting condition of the Diagnostic Ultrasound System influencing MI/TI to use the indicated information of MI/TI more effectively. MI is calculated by the peak-rarefactional acoustic pressure like the definitional identity of MI. TI is in proportion to the value that is averaged by time whereas MI is in proportion to instantaneous value. The following table shows diagnosis device control settings to influence MI/TI. Here, there are some cases where the pulse repetition frequency is not displayed in the screen of the diagnostic instrument. We recommend that you read this manual carefully.

Diagnostic Ultrasound System Control Settings[*1]		Menu item or function	MI	TI
Shared Functions	Ultrasonic output power	Acoustic Power	Yes	Yes
	Electric focus	Focus	Yes	Yes
	Ultrasound output limit for fetal use	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 mode	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 mode	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 mode	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 mode	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 mode	CF, eFlow, Power Doppler, TDI, DFI	Yes	Yes

*1. Ultrasonic output power and focus (Sample Gate) are the only operating conditions that influence the continuous Doppler (CWD) MI/TI.

7-3-5 ALARA: As Low As Reasonably Achievable Recommended

Examinations should be conducted using the ALARA principle to extract the maximum possible diagnostic information while reducing the acoustic power level to the lowest reasonable minimum. This is the same principle as used with ionizing radiation.

When using the mechanical index (MI) in practice, perform the examination while constantly taking the following points into consideration.

- Selecting an appropriate probe
- Choice of transmission (higher frequency is lower in MI value)
- Choice of electronic focus
- Lower transmitter voltage
- Appropriate image adjustment settings (raising the gain, etc.)

Be more careful before using a contrast agent.

When using the thermal index (TI), perform the examination while constantly taking into consideration the following points.

- Select an appropriate TI
- Appropriate image adjustment settings (raising the gain, etc.)
- Suppress the TI value (reduce transmitter voltage, lower pulse repetition of frequency or widen the scan width for scan mode)
- Short exposure time

7-3-6 Default Settings

In order to avoid unintentional high acoustic power, the acoustic power is limited by default settings (it becomes a low value). This takes place in the following situations.

- Power On
- When preset is selected
- When probes are changed
- After pressing the New Patient switch (ID input)

The acoustic power parameters, which include mechanical index (MI) and thermal index (TI), are set to default levels based on the type of examination. The default level will either be AP%=70% or MI<1.0/TI<1.0, whichever is lower.

7-3-7 Acoustic Power Upper Limit

For all examinations aside from fetal observation, the acoustic power upper limit is set at $I_{spta,\alpha} < 720$ mW/cm^2, MI < 1.9, TI < 6.

Probes whose mechanical index (MI) or thermal index (TI) may exceed 1.0 displays TI/MI values in real time.

For fetal observation, the limit will be set at MI < 1.0 and TI < 1.0.

7-3-8 Protocol for Calculating the Measurement Uncertainties

Order of Measuring Uncertainties

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

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

In the NEMA UD-2 (2004) accompanying documents, the terms Type A and Type B are used to differentiate the causes of measurement uncertainties. This concept is employed within ISO 1993 and ANSI/NCSL 1997. These new terms replace the previous terms: “random uncertainty” and “systematic uncertainty”. Type A and Type B uncertainties are distinguished on the basis by which their numerical values are estimated. Type A uncertainties are those that are evaluated by statistical treatment of repeated measurements, and Type B are those that are evaluated by other means. An important reason for the new classification is to provide an internationally recognized method for combining each individual cause of uncertainties into one total uncertainty mathematically without regards to whether they were randomly or systematically caused.

Basic to this approach is representing each component of uncertainty by an estimated standard deviation, termed standard uncertainty. That symbol is equivalent to the square root of the estimated variance u_i^2 according to u_i.

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

Type B evaluations are based on scientific judgment using all of the relevant information. These include the following.

- Previous measurement data
- Experience with the relevant materials and instruments
- Manufacturer's specifications
- Data provided from national standards laboratories
- Uncertainty data taken from handbooks

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

Type A Evaluated Uncertainty

A Type A standard uncertainty, u_A, of a measured quantity is equal to the standard deviation of the sample mean, which is commonly called the standard error. In other words

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

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

Type B Evaluated Uncertainty

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

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

Also, Type B uncertainty u_B is calculated based on the following formula.

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

Combined Uncertainty

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

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

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

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

The result of a measurement is then conveniently expressed as

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

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

Measurement Uncertainty Results

Now we would like to offer the results of measurement uncertainties of our products.

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

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

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

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

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

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

$S_{i.}$ (rows) ; $S_{.j}$ (columns)

ij field average value

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

*i*th/nd probe average

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

*j*th/nd instrument average

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

Total average

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

ij field standard deviation

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

Probe standard deviation

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

Instrument standard deviation

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

Using equation (8), (9) and (10), probe mean, console mean and overall mean are calculated respectively. The standard deviation calculated using equation (11) is expressed as percentage of the overall mean value.

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

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

The probe variability is quantified by S_{trans}.

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

The instrument variability is quantified by S_{cons}.

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

The total variability is quantified by S_{total}.

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

The variance of the measured value is displayed using the following formula.

$$\hat{\sigma}_x^{\,2} = S_{\text{total}}^{\,2} \qquad (18)$$

The variance of the average of the measured value is displayed using the following formula.

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

The Type A standard uncertainty is the square root of the variance of the measurand mean. In other words,

$$u_{\text{A}}^{\,2} = \sqrt{\hat{\sigma}_{\bar{x}}^{\,2}} \qquad (20)$$

The Type B uncertainty is displayed using the following formula.

$$u_{\text{B}} = \sqrt{\sigma^2} = \sqrt{\frac{a_1^{\,2} + a_2^{\,2} + \ldots + a_n^{\,2}}{3}} \qquad (21)$$

Therefore, the combined uncertainty is displayed using the following formula.

$$u_{\text{C}} = \sqrt{u_{\text{A}}^{\,2} + u_{\text{B}}^{\,2}} \qquad (22)$$

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

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

The acoustic power is reported as follows.

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

An upper 95% tolerance limit is computed using an expanded uncertainty in which the coverage factor is an appropriately chosen tolerance coefficient. Also, the Type A component of the combined uncertainty equals the standard deviation $\sqrt{\hat{\sigma}_x^2}$ of the measurand value and not the standard deviation $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ of the measurand value median of the expanded uncertainty U. Therefore, the following formula is given for the upper 95% tolerance limit in regards to the 99% acoustic power value.

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

k is set to $K_{.99}$ for pqr - 1 = 95 degrees of freedom, and the expanded uncertainty will become as follows.

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

Also, the upper tolerance limit will appear as follows.

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

Uncertainty Evaluation of Total Power P

The standard deviation obtained from mean value of 6 probes by eq. (12)	S_i:	6.44%
The standard deviation obtained from mean value of 4 consoles by eq. (13)	S_j:	2.57%
The standard deviation obtained from measurement variance by eq. (14)	S_{meas}:	1.01%
The standard deviation obtained from probe variance by eq. (15)	S_{trans}:	6.43%
The standard deviation obtained from instrument variance by eq. (16)	S_{cons}:	2.56%
The standard deviation obtained from total variance by eq. (17)	S_{total}:	7.00%
The type A uncertainty by eq. (20)	u_A:	2.92%
Uncertainty components for type B uncertainty evaluation		
The error derived from scale capacity	a_1:	±2%
The error due to reference source	a_2:	±4%
The error derived from alignment of the probe	a_3:	-5%
The error derived from not coupling directly with water	a_4:	-3%
The error derived from not enough thickness of the absorbing target	a_5:	-5%
The type B standard uncertainty by eq. (21)	u_B:	5.13%
The total standard uncertainty by eq. (22)	u_C:	5.91%

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with pq-1 = 23 degrees of freedom (from Table 1 of UD2-2004, Appendix A).

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

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

An upper 95% tolerance limit is computed using an expanded uncertainty, and the coverage factor is an appropriately chosen tolerance coefficient. Also, the Type A uncertainty for calculation of the combined uncertainty uses the standard deviation $\sqrt{\hat{\sigma}_x^2}$ of the measured quantity, not the diffusion $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ of the average value of the measured quantity, as used for expanded uncertainty U.

The upper 95% tolerance limit for 99% of power values by eq. (25) u_C: 8.68%

The $K_{.99}$ value for pqr -1 = 95 degrees of freedom is 2.69, so taking the coverage factor k = 2.69,

The upper 95% tolerance limit for 99% of values by eq. (26) U: 23.38%

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

Uncertainty evaluation of the pulse-intensity integral I_{pi} or pii

The standard deviation obtained from mean value of 6 probes by eq. (12)	$S_{i.}$:	3.80%
The standard deviation obtained from mean value of 4 consoles by eq. (13)	$S_{.j}$:	4.14%
The standard deviation obtained from measurement variance by eq. (14)	S_{meas}:	1.14%
The standard deviation obtained from probe variance by eq. (15)	S_{trans}:	3.79%
The standard deviation obtained from instrument variance by eq. (16)	S_{cons}:	4.13%
The standard deviation obtained from total variance by eq. (17)	S_{total}:	5.72%
The type A uncertainty by eq. (20)	u_A:	2.59%
Uncertainty components for type B uncertainty evaluation		
The error derived from voltage measurement of the oscilloscope	a_1:	± 3%
The error derived from time measurement of the oscilloscope	a_2:	± 2%
Hydrophone correction error	a_3:	± 8.6%
The error derived from alignment of the probe	a_4:	- 3%
The error derived from alignment of the hydrophone	a_5:	- 4%
The error derived from spatial averaging of the hydrophone	a_6:	- 16.6%
The error derived from non-linear propagation distortion	a_7:	- 6%
The error derived from directionality of the hydrophone	a_8:	- 4%
The type B standard uncertainty by eq. (21)	u_B:	12.10%
The total standard uncertainty by eq. (22)	u_C:	12.38%

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with pq-1 = 23 degrees of freedom (from Table 1 of UD2-2004, Appendix A).

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

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

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

An upper 95% tolerance limit is computed using an expanded uncertainty, and the coverage factor is an appropriately chosen tolerance coefficient. Also, the Type A uncertainty for calculation of the combined uncertainty uses the standard deviation $\sqrt{\hat{\sigma}_x^2}$ of the measured quantity, not the diffusion $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ of the average value of the measured quantity, as used for expanded uncertainty U.

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

The $K_{.99}$ value for pqr -1 = 95 degrees of freedom is 2.69, so taking the coverage factor k = 2.69,

The upper 95% tolerance limit for 99% of values by eq. (26)	U:	36.03%

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

$$pii \leq \overline{\overline{m}} + 36.03\ \%$$

Uncertainty Evaluation of the Peak-Rarefactional Acoustic Pressure p_r

The standard deviation obtained from mean value of 6 probes by eq. (12)	S_i:	1.95%
The standard deviation obtained from mean value of 4 consoles by eq. (13)	S_j:	2.62%
The standard deviation obtained from measurement variance by eq. (14)	S_{meas}:	1.15%
The standard deviation obtained from probe variance by eq. (15)	S_{trans}:	1.93%
The standard deviation obtained from instrument variance by eq. (16)	S_{cons}:	2.61%
The standard deviation obtained from total variance by eq. (17)	S_{total}:	3.45%
The type A uncertainty by eq. (20)	u_A:	1.53%
Uncertainty components for type B uncertainty evaluation		
The error derived from voltage measurement of the oscilloscope	a_1:	± 1.5%
The error derived from time measurement of the oscilloscope	a_2:	± 2%
Hydrophone correction error	a_3:	± 4.3%
The error derived from alignment of the probe	a_4:	- 3%
The error derived from alignment of the hydrophone	a_5:	- 2%
The error derived from spatial averaging of the hydrophone	a_6:	- 8%
The error derived from non-linear propagation distortion	a_7:	- 3%
The error derived from directionality of the hydrophone	a_8:	- 2%
The type B standard uncertainty by eq. (21)	u_B:	6.18%
The total standard uncertainty by eq. (22)	u_C:	6.37%

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with pq-1 = 23 degrees of freedom (from Table 1 of UD2-2004, Appendix A).

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

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

An upper 95% tolerance limit is computed using an expanded uncertainty, and the coverage factor is an appropriately chosen tolerance coefficient. Also, the Type A uncertainty for calculation of the combined uncertainty uses the standard deviation $\sqrt{\hat{\sigma}_x^2}$ of the measured quantity, not the diffusion $\sqrt{\hat{\sigma}_{\bar{x}}^2}$ of the average value of the measured quantity, as used for expanded uncertainty U.

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

The $K_{.99}$ value for pqr -1 = 95 degrees of freedom is 2.69, so taking the coverage factor k = 2.69,

The upper 95% tolerance limit for 99% of values by eq. (26)	U:	19.05%

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

Uncertainty Evaluation of the Acoustic Working Frequency f_{awf}

The standard deviation obtained from mean value of 6 probes by eq. (12)	S_i:	0.085%
The standard deviation obtained from mean value of 4 consoles by eq. (13)	S_j:	0.009%
The standard deviation obtained from measurement variance by eq. (14)	S_{meas}:	0.011%
The standard deviation obtained from probe variance by eq. (15)	S_{trans}:	0.085%
The standard deviation obtained from instrument variance by eq. (16)	S_{cons}:	0.009%
The standard deviation obtained from total variance by eq. (17)	S_{total}:	0.086%
The type A uncertainty by eq. (20)	u_A:	0.035%
Uncertainty components for type B uncertainty evaluation		
The error derived from time measurement of the oscilloscope	a_1:	± 2%
The type B standard uncertainty by eq. (21)	u_B:	1.15%
The total standard uncertainty by eq. (22)	u_C:	1.16%

The expanded uncertainty, U, for the purposes of ultrasonic exposimetry should be set for a level of confidence of 95%. Thus, k should be set equal to 2.07, the value of $t_{.975}$ with pq-1 = 23 degrees of freedom (from Table 1 of UD2-2004, Appendix A).

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

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

7-3-9 References

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8 Messages

8-1 Messages About Image Display

Messages	Status, Cause	Countermeasure
"Range limit: Selection is not available."	You attempted to adjust the display range beyond the upper limit or lower limit of setting values.	Adjust the display range between the upper limit and lower limit of setting values.
"Detection error: Cannot detect ECG R-wave."	This message is displayed when the R-wave cannot be detected for five seconds or more while the ECG waveform is displayed.	The message is cleared when the ECG waveform R-wave is detected for five seconds or more.
"Memorized TGC positions are used. Please set the TGC knobs to the center position."	This message is displayed when the [TGC Curve] is switched to "Custom" after storing a new [TGC] knob position.	The image is displayed with the stored curve once all [TGC] knobs are in the center.
"Overwrite current TGC setting?"	This message is displayed when you change the TGC and switch the active window while the image is frozen in dual or quad-screen view.	• [Yes]: The new TGC settings are applied to the active window. • [No]: The new TGC settings are not applied to the active window.
"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 turned On.	• [ON]: Cancels acoustic output restrictions. • [CANCEL]: Clears the message without canceling the acoustic power restriction.
"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."	• An incompatible probe is connected to the instrument. • A probe subject to correction is connected, but the correction parameters could not be recognized.	• Connect a compatible probe. • The probe may be broken. For details regarding probe inspection, please contact our office.
"Puncture adapter: *******"	This message is displayed when [Puncture Guide Line] is set to On and a probe capable of using multiple puncture adapters is connected.	The displayed model name is the name of the used puncture adapter model. If a different puncture adapter is used, open [Puncture Adapter Select] to select it.
"Press [UNDO] to rotate the fetus mark."	This message is displayed when a rotatable fetus mark is selected for the body mark.	To rotate the fetus mark, (1) Press the [UNDO] key. (2) Turn the [Pointer] rotary encoder.
"Cannot register. Delete any unnecessary entries and start over."	This message is displayed when the user attempts to register the 801 word and the learning function under the annotation preset is Off.	Delete unnecessary words before registering new words.
"System in auto freeze. Press [Freeze] to resume."	This message is displayed when the operation panel or touch panel is left idle for more than a certain period of time.	Press the [Freeze] key.

Messages	Status, Cause	Countermeasure
"Memory data will be deleted."	This message is displayed when the user attempts to delete a registered coordinate position.	• [Yes]: The selected coordinate position is deleted. • [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 switched On.	Select [OK]. NOTE: **Do not use assist lines as puncture guidelines.** [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 a probe parameter error is detected. Transmission stops immediately.	Restart the instrument. If this message persists after restarting, make a note of the message and contact one of our offices.
"The instruction manual does not exist."	This message is displayed when the specified instruction manual does not exist, or is corrupted.	Restart the instrument. If this message persists after restarting, make a note of the message and contact one of our offices.
"Database was broken. Please contact our office near you."	This message is displayed when the display list is corrupted.	Restart the instrument. If this message persists after restarting, make a note of the message and contact one of our offices.
"Invalid name or password."	This message is displayed when an incorrect 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 breaks the password rules.	[OK]: Clears the message. Enter a password consisting of up to 16 alphanumeric characters.
"The passwords did not match. Re-enter your new password."	This message is displayed when the two entries of new the password do not match.	[OK]: Clears the message. Re-enter the correct password.
"Probe temperature is higher than 41.0°C."	This message is displayed when the tip of a probe with a built-in temperature sensor exceeds 41.0°C.	The message is cleared when the temperature of the probe tip returns to below 41.0°C.
"If the temperature rises any further, transmission will be terminated."	This message is displayed when the tip of a probe with a built-in temperature sensor exceeds 42.0°C.	[OK]: Clears the message. This message is cleared when the temperature of the probe tip returns to below 42.0°C. Instead, the message "Probe temperature is higher than 41.0°C" is displayed.
"TEE thermal limit. Auto cooling mode in progress."	This message is displayed when the temperature of the tip of a probe with a built-in temperature sensor exceeds 43.0°C.	The image freezes. The panel switch light goes out. When the surface temperature of the probe tip falls below 40.5°C, the message is cleared, the device is restored to its state immediately before auto-cooling mode was started, and the examination can be restarted.
"TEE fatal error (%d) Discontinue examination and turn the system off."	The temperature sensor is broken in a probe with a built-in temperature sensor.	Stop using the instrument. Make a note of the message before contacting our office.

Messages	Status, Cause	Countermeasure
"Probe temperature is higher than 41.0°C."	This message is displayed when the temperature of the tip of a probe with a built-in temperature sensor exceeds 41.0 °C.	The message is cleared when the temperature of the probe tip returns to below 41.0°C.
"TTE thermal limit. Auto cooling mode in progress."	This message is displayed when the temperature of the tip of a probe with a built-in temperature sensor exceeds 43.0°C.	The image freezes. The panel switch light goes out. When the surface temperature of the probe tip falls to below 40.5°C, the message is cleared, Freeze is turned On, and the examination can be restarted.
"TTE fatal error (%d) Discontinue examination and turn the system off."	The temperature sensor is broken in a probe with a built-in temperature sensor.	Stop using the instrument. Make a note of the message before contacting our office.

8-2 Messages about patient data entry

These messages are displayed on the Patient Information Entry screen.

Messages	Status, Cause	Countermeasure
"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) Enter the date with reference to the message display example. [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.	(1) Select the [OK] button. (2) Enter the date with reference to the message display example. [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.	(1) Select the [OK] button. (2) Enter the date with reference to the message display example. [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) Enter the date with reference to the message display example. [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) Enter the date with reference to the message display example. [OK]: Clears the message.
"A person's name cannot contain any of the following characters: \="	Personal names (Patient Name, Referring Phys, Sonographer) cannot contain back slashes or equal signs.	(1) Select the [OK] button. (2) Delete back slashes and equal signs. [OK]: Clears the message.
"Enter the patient name using up to 64 characters."	This message is displayed when the total number of characters in the Family, Given and Name fields exceeds 64 characters.	(1) Select the [OK] button. (2) Enter the patient name in up to 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 or when a decimal point and decimal places are entered.	(1) Select the [OK] button. (2) Enter in the range 0 - 999. Alternatively, enter a birth date. [OK]: Clears the message.

Messages	Status, Cause	Countermeasure
"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 in the range of 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 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 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 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 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) Enter the number of gestation weeks, with reference to the message display example. [OK]: Clears the message.
"Now making worklist... Do not turn off the system."	Acquiring the Worklist.	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 none was connected.	Connect a device to the USB connector.
"This order is already performed. Do you want to perform an additional examination?"	This message is displayed when the entered SPS already exists. Or if the patient ID for a completed scan is entered.	• [Yes]: Examination with the same examination ID. • [No]: Clear the message without updating the examination information.

Messages	Status, Cause	Countermeasure
"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 when data received from an ID card reader appears in the ID screen and the relevant patient ID exists on the instrument hard disk.	• [ID Card]: Reflect data received from the ID card reader in the patient information. • [Local]: Use the patient information that is on the instrument hard disk. • [Cancel]: Clear the message without updating patient information.
"Now searching... Please wait."	Searching for patient information.	The message is cleared when searching for patient information is complete.
"Now reading... Do not turn off the system."	Loading patient information.	The message is cleared when loading patient information is complete.
"Now writing... Do not turn off the system."	Writing patient information to the instrument hard disk.	The message is cleared when writing patient information is complete.
"Now making worklist... Do not turn off the system."	The patient information is being received from the HIS and RIS.	The message is cleared when reception of patient information is complete.
"Blood Pressure Error."	The Blood Pressure value entered for the ID setting screen is not valid.	Enter a valid Blood Pressure value in the ID setting screen. NOTE: **Enter the value in up to 301 characters. Enter the maximum blood pressure value on the left and the minimum blood pressure value on the right.**
"The specified patient ID has been registered with different patient data. Do you want to overwrite it with new patient data?"	This message is displayed if you try to change 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"."	The patient ID has not been entered.	Enter the patient ID.
"Patient information is not saved. Do you want to abort the input?"	This message is displayed when the user attempts to close the ID input screen without saving patient information.	• [OK]: Closes the ID input screen without saving patient information. • [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 user information.

Messages	Status, Cause	Countermeasure
"A problem occurred at the MWM Server. Unable to connect to the MWM Server."	An attempt was made to search for patient information in the worklist, but the worklist failed to respond.	(1) Select [OK]. (2) Retry after solving the worklist server connection problem.
"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 an attempt was made to import patient information from external device that already exists on the instrument hard disk.	• [Yes]: Imports the patient information indicated in the message and overwrites the corresponding information on the instrument hard disk. • [All Yes]: Imports all patient information from the external device and overwrites the patient information on the instrument hard disk. • [Cancel]: Does not import all patient information from the external device. • [No]: Does not import the indicated patient information.
"Patient information is not saved. Do you want to save it?"	This message is displayed when the user selects [New Patient] before saving entered patient information.	• [Yes]: Cancels New Patient selection and saves entered patient information. • [No]: Accepts New Patient selection and clears entered patient information.
"Are you sure you want to delete this item?"	This message is displayed when the user attempts to delete an item in the Body Part Examined Items setup dialog box in the ID screen.	• [OK]: Deletes the specified item. • [Cancel]: Clears the message without deleting the specified item.
"Caution! The numbers of patient information data are close to the limit. Please make back-up and delete data from Data Management screen."	This message is displayed when the number of saved images exceeds 145,000 or the number of examinations exceeds 32,000.	(1) Select the [OK] button. (2) Back up the image data on the search screen. (3) Back up the patient information on the Data Management screen. (4) Delete the patient information that was backed up on the Data Management screen.
"Warning! The numbers of patient information data have reached to the limit. Please make back-up and delete data from Data Management screen."	This message is displayed when the number of saved images or the number of examinations reaches the upper limit and the next examination cannot be performed.	(1) Select the [OK] button. (2) Select the [X] button at the top right of the ID screen. (3) Back up the image data on the search screen. (4) Back up the patient information on the Data Management screen. (5) Delete the patient information that was backed up on the Data Management screen.
"There are too many results to display. Please refine the search conditions and search again."	This message is displayed when the number of patient information search results to be displayed in the list view exceeds the upper limit.	(1) Select the [OK] button. (2) Enter patient data in the search information input field. (3) Select [Search].

Messages (Data Management)	Status, cause	Countermeasure
"Multiple patient IDs have been selected. Select only one patient."	This message is displayed when the user pressed the [Edit] button and multiple patients were 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 user pressed the [OK] button in patient information correction under Data Management.	• [OK]: Updates patient information. • [Cancel]: Clears the message without updating patient information.
"The entered patient ID already exists. Enter another patient ID."	When the patient ID is in use elsewhere during patient information correction under Data Management.	(1) Select the [OK] button. (2) Re-enter the patient ID. [OK]: Clears the message.
"Warning! In case you import a database file from a different system, you may get an incorrect merge if the database file contains the same patient records. In that case, press [Cancel] and delete all stored images and waveform data in the system. Do you still want to continue?"	This message is displayed when the [Import From Media] button is selected for the import of patient information under Data Management.	• To import database files saved in the same system, select the [OK] button. • If the database file to be imported and the database file in the import destination do not contain the same patient information, click the [OK] button. • If the patient information to be imported also exists in the system to which that information is to be imported, select the [Cancel] button, and then delete the duplicate patient information in the system by using the Data Management screen. NOTE: **For details on how to delete patient information, see the document "Basic Operations".**
"Are you sure you want to delete the selected data?"	This message is displayed when deletion of patient information is selected in Data Management.	• [OK]: Deletes patient information. • [Cancel]: Clears the message without deleting patient information.
"Selected data includes locked data. Are you sure you want to delete all data?"	This message is displayed when all patient information on the instrument is selected for deletion in Data Management.	• [Yes, delete all]: Deletes all selected patient data. • [No, delete open data only]: Deletes all unlocked patient data. • [Cancel]: Clears the message without deleting 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 instrument hard disk is selected for deletion in Data Management.	• [OK]: Deletes patient information. • [Cancel]: Clears the message without deleting 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 selected in Data Management that includes patient information on the instrument hard disk.	The message is cleared when deletion is complete. [Cancel]: Clears the message without deleting patient information.

Messages (Data Management)	Status, cause	Countermeasure
"Deleting stored images... Please wait. Do not turn off the system."	This message is displayed during deletion of images in Data Management that includes patient information on the instrument hard disk.	The message is cleared when deletion is complete.
"Found follow filename in USB."	This message appears when a filename already used on the USB device is selected in the Write to USB storage dialog box in Data Management.	• [REPLACE]: Deletes the file on the USB and creates a new file storing the hard disk data on the USB device. • [Add]: Adds the data to the USB file. • [Cancel]: Does not save the data and clears the message.
"Now optimizing..."	This message is displayed when the user selects the [Update] button in the Data Management screen.	The message is cleared when the database is updated.
"You are about to write all study data. Writing once started cannot be interrupted. Do you still want to write the data?"	This message is displayed when the user selects to write all patient information to an external device in the Management screen.	• [OK]: Writes the selected patient information to an external device. • [Cancel]: Returns you to the state you were at before selecting [Write to Media].
"Are you sure you want to delete this data?"	This message is displayed when the user attempts to delete patient information in the Data Management screen.	• [OK]: Deletes the selected patient information. • [Cancel]: Returns you to the Data Management screen without deleting the selected patient information.
"Now writing... Do not turn off the system."	This message is displayed when you select [Write to Media], and data is being written to the external media.	• The message is cleared when processing is complete. • [Cancel]: Forcibly terminates the processing.
"Error occurred. Writing function will now terminate. Data returns back to before [Write to Media]."	This message is displayed when an attempt to write to the external media fails.	(1) Check the status of the storage medium. If a problem is found on the storage medium, use a different storage medium to perform the processing again. (2) If the same message is displayed even after you perform step (1), make a note of this message and contact our office.
"Now importing... Do not turn off the system."	This message is displayed when you select [Import from Media], and data is being read from the external media.	• The message is cleared when processing is complete. • [Cancel]: Forcibly terminates the processing.
"A Fatal error occurred. Import function will now terminate. Data returns back to before [Import from Media]."	This message is displayed when an attempt to read from the external media fails.	(1) Check the status of the storage media. If a failure is found on the storage media, store the database you want to restore on different storage media, and then perform the processing again. (2) If the same message is displayed even after you perform step (1), make a note of this message and contact our office.
"Some of data could not be imported. Try this function again."	This message is displayed when a database access error occurs during the [Import from Media] processing.	If the same message is displayed even after you retry the operation, make a note of this message and contact our office.
"Now reconstructing... Do not turn off the system."	This message is displayed during the [Reconstruction from Store Image] processing.	• The message is cleared when processing is complete. • [Cancel]: Forcibly terminates the processing.
"A Fatal error occurred. Reconst function will now terminate. Data returns back to before [Reconstruction from Store Image]."	This message is displayed when an error occurs during the [Reconstruction from Store Image] processing.	If the same message is displayed even after you retry the operation, make a note of this message and contact our office.

Messages (Data Management)	Status, cause	Countermeasure
"Some of data could not be reconstructed. Try this function again."	This message is displayed when a database access error occurs during the [Reconstruction from Store Image] processing.	If the same message is displayed even after you retry the operation, make a note of this message and contact our office.
"There are too many results to display. Please refine the search conditions and search again."	This message is displayed when the display limit of the search results list area is exceeded.	(1) Select the [OK] button. (2) Enter patient data in the search information input field. (3) Select [Search].

Messages (image import)	Status, cause	Countermeasure
"Importing selected images..."	This message is displayed when images are selected in the Import screen and the [Import] button is selected.	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 instrument hard disk is less than 2GB after an import.	Delete unnecessary images.
"Error: Disk full. Delete unnecessary data."	This message is displayed when there is insufficient free space on the instrument hard disk and the import cannot continue.	Delete unnecessary images.

Messages (Japanese Calendar)	Status, cause	Countermeasure
"Are you sure you want to delete this item?"	This message is displayed when the [Delete] button is selected in the Japanese Calendar settings dialog box.	• [OK]: Deletes the selected item. • [Cancel]: Clears the message without deleting the item.
"The registration limit (2) has been reached. Delete the older item."	This message is displayed when the user attempts to register a third item.	(1) Select the [OK] button. (2) Delete an item registered in the past. (3) Register the Western calendar year and the first letter of the traditional Japanese era name.
"The starting year is invalid. Enter a value 2019 - %d."	This message is displayed when the value for "Starting year" is invalid.	(1) Select the [OK] button. (2) For "Starting year", enter a Western year in the range between 2019 and the year following the year in which you perform the registration operation. For example, if you are performing the registration operation in 2020, you can enter 2019, 2020, or 2021.
"Already exists."	This message is displayed when the user attempts to register a character for "First letter" that 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, Cause	Countermeasure
"Enter Patient ID."	This message is displayed when the user presses the [Store] key without entering a patient ID or patient name.	Enter patient information.
"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 images that are being played back.	• Press the [Store] key to save images that are being played back. • Use the [Pointer] rotary encoder to shift the time phase from images being played back to new or old images. • Press the [UNDO] key to shoot 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 On and the amount of captured cine data does not cover the set heart rate or set time.	• Press the [Store] key to save images that are being played back. • Press the [UNDO] key shoot new images.
"Part of the image could not be acquired."	This message is displayed when [Auto Playback] is 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 images that are being played back. • Press the [UNDO] key shoot 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 moving image. • Turn the [Freeze] key On and save the image again.
"Store capacity: Free space ***%"	This message is displayed when the user presses the [Store] key.	The message is cleared after 5s.
"Error: Disk full. Delete unnecessary images."	This message is displayed when the user attempts to save data that exceeds the free space on the instrument hard disk.	• Delete unnecessary images from the instrument hard disk. • Save only data that does not exceed the free space on the instrument 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 the [Data Format (Still)] is [Raw] and B mode (including Color Flow mode) Dual or Quad screens were saved as still images.	Save the images in the [RGB] format. The message is cleared after 5s.
"The image could not be acquired."	• This message is displayed when the [Store] key is pressed before detecting the R-wave in [Pre (ECG)] mode. • This message is displayed when the [R-wave] cannot be detected for a certain period of time after pressing 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.

Messages	Status, Cause	Countermeasure
"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 instrument hard disk (including the CD-R buffer), and the number of captured frames exceeds a certain number.	• [Continue]: Save. • [Local HDD]: Change the storage destination to the instrument hard disk, then save the data.
"The Cine Memory is cleared. Video Clip Auto Stop is off."	This message is displayed when [Video Clip Auto Stop] is used after manually saving a moving image to change the display range and clear cine images.	Re-save the moving image if necessary. The message is cleared after 5s.
"Not enough capacity on selected disk."	The connected device has insufficient space.	Connect a device with sufficient free space. • [Retry]: Retransmit the image. • [Cancel]: Close the message without sending it.
"Error: Disk full. Delete unnecessary images."	There is insufficient space on the instrument hard disk.	Delete unnecessary images to increase free space on the instrument hard disk. • [Retry]: Retransmit the image. • [Cancel]: Close the message without sending it.
"Hard disk access error: Hard disk must be diagnosed."	Images cannot be saved to the instrument hard disk.	Please contact our office. • [Retry]: Retransmit the image. • [Cancel]: Close the message without sending it.
"Media not found. The file is stored on the local hard disk instead."	No device is connected.	Connect a device. • [Retry]: Retransmit the image. • [Cancel]: Close the message without sending it.
"Error: No disk or disk is not formatted."	This message is displayed when no external storage medium to which data is to be saved is inserted or the medium is not formatted.	Connect a formatted external storage medium to the system. • [OK]: Clears the message.
"Error: Disk write protected."	The disk is write-protected.	Undo write protection on the connected disk. Connect another disk. • [OK]: Clears the message.
"Error: Removable disk is not ready."	This message is displayed when the preparation for connecting an external storage medium is not complete.	After the preparation for connecting the external storage medium is complete, save the data. • [OK]: Clears the message.
"The DICOMDIR is full. Change to another media."	The DICOM DIR cannot be updated.	Replace the storage medium. • [OK]: Clears the message.
"Destination servers are not set. The file was stored on the local hard disk instead. Store capacity: Free space ***%"	This message is displayed when still images are saved to the hard disk because they are sent by using Send to Net(Preset) on the Archive tab of the preset ([Preset Setup > SystemPreset > Filing]) without the destination server to which they are to be sent specified.	Use the following procedure to send the images saved on the hard disk to the destination server. (1) Set the destination server on the Server/Worklist tab of the preset ([Preset Setup > SystemPreset > DICOM]). (2) Select the images saved on the hard disk in the Tile view or on the search screen. (3) Select [>>Network (Preset)] from the menu. (4) Select [OK].

Messages	Status, Cause	Countermeasure
"The file was stored on the local hard disk instead of network as RGB data, not raw data. Store capacity: Free space ***%"	This message is displayed when still images are saved to the hard disk in RGB format because they are sent by using Send to Net(Preset) on the Archive tab of the preset ([Preset Setup > SystemPreset > Filing]) under the condition that they cannot be saved in Raw format without the specification of the destination server to which they are to be sent.	To send the images (RGB format) saved on the hard disk to the destination server, perform the following procedure: (1) Set the destination server on the Server/Worklist tab of the preset ([Preset Setup > SystemPreset > DICOM]). (2) Select the images saved on the hard disk in the Tile view or on the search screen. (3) Select [>>Network (Preset)] from the menu. (4) Select [OK].
"Media not found. The file is stored on the local hard disk instead."	No device is connected.	Images are saved to the instrument 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 instrument starts.	• [Print]: Print the data in the Print Queue folder. • [Cancel]: Close the message without printing or deleting. • [Delete]: Clear 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. Contact the administrator for the hospital network if communication is not restored.
"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, Cause	Countermeasure
"The image cannot be compared."	• The selected images do not include images from the same patient, or B mode 1-screen images. • You selected an image that cannot be comparison displayed, and attempted to comparison display it.	To use comparison display, select B mode 1-screen images for the same patient.
"Loading data: ***%"	Transferring raw data to cine memory.	The message is cleared when forwarding is complete.
"Copying..." "Saving..." "Sending..." "Deleting..." "Printing..." "DICOM Printing..."	Processing	The message is cleared when processing is complete. [Cancel]: Terminates processing.
"Preparing to copy..." "Preparing to save..." "Preparing to send..." "Preparing to delete..." "Preparing to print..."	Preparing to process	The message is cleared when preparation is complete. [Cancel]: Terminates processing.
"Loading stress data..."	Loading Stress Echo data.	The message is cleared when forwarding is complete. [Cancel]: Terminates processing.
"Are you sure you want to delete this image?"	This message is displayed when you select to delete the selected image (1).	• [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 to delete the selected image (1).	• [OK]: Deletes the image. • [Cancel]: Clears the message without deleting the image.
"Are you sure you want to delete the *** stored images?"	This message is displayed when you select to delete the selected images.	The number of selected images is displayed in the message. • [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 to delete the selected images.	The number of selected images is displayed in the message. • [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 to delete the selected images.	The number of selected images is displayed in the message. • [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 to delete the selected images.	The number of selected images is displayed in the message. • [OK]: Deletes the images. • [Cancel]: Clears the message without deleting the images.

Messages	Status, Cause	Countermeasure
"Are you sure you want to copy this image?"	This message is displayed when you select to copy the selected image (1).	• [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 to copy the selected image (1).	• [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 to copy the selected images.	The number of selected images is displayed in the message. • [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 to copy the selected images.	The number of selected images is displayed in the message. • [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 to copy the selected images.	The number of selected images is displayed in the message. • [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 to copy the selected images.	The number of selected images is displayed in the message. • [OK]: Copies the images. • [Cancel]: Clears the message without copying the images.
"Some of the selected data cannot be copied. Do you want to continue?"	This message is displayed when the selected images include data that cannot be copied.	• [OK]: Copies the images. • [Cancel]: Clears the message without copying the images.
"Are you sure you want to save this image?"	This message is displayed when you select to save the selected image (1).	• [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 saving of the selected image (1) is selected.	• [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 to save the selected images.	The number of selected images is displayed in the message. • [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 to save the selected images.	The number of selected images is displayed in the message. • [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 saving of the selected images is selected.	The number of selected images is displayed in the message. • [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 saving of the selected images is selected.	The number of selected images is displayed in the message. • [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 to send the selected image (1).	• [OK]: Sends the image. • [Cancel]: Clears the message without sending the image.
"Are you sure you want to send the stored image?"	This message is displayed when you select to send the selected image (1).	• [OK]: Sends the image. • [Cancel]: Clears the message without sending the image.

Messages	Status, Cause	Countermeasure
"Are you sure you want to send the *** stored images?"	This message is displayed when you select to send the selected images.	The number of selected images is displayed in the message. • [OK]: Sends the images. • [Cancel]: Clears the message without sending the images.
"Images from multiple devices are selected (*** stored images). Do you want to send them?"	This message is displayed when you select to send the selected images.	The number of selected images is displayed in the message. • [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 to transfer the selected images.	The number of selected images is displayed in the message. • [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 to transfer the selected images.	The number of selected images is displayed in the message. • [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 to print the selected image (1).	• [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 to print the selected image (1).	• [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 to print the selected images.	The number of selected images is displayed in the message. • [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 to print the selected images.	The number of selected images is displayed in the message. • [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 to print the selected images.	The number of selected images is displayed in the message. • [OK]: Prints the images. • [Cancel]: Clears the message without printing the images.
"Images from multiple patients are selected (*** stored images). Do you want to print them?"	This message is displayed when you select to print the selected images.	The number of selected images is displayed in the message. • [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 read-only device, etc.)	[OK]: Closes the message.

Messages	Status, Cause	Countermeasure
"Delete failed. The system is busy."	This message is displayed when an image was deleted during the save process from the Analysis screen.	[OK]: Closes the message.
"There is no file to be deleted."	This message is displayed when none of the selected image can be deleted.	[OK]: Closes the message.
"Delete succeeded."	This message is displayed when deletion of selected images is completed.	[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 disk is write-protected.	Release write protection on the disk, or connect a writable disk. • [Retry]: Copy again. • [Cancel]: Clears the message without copying the image.
"Not enough capacity on selected disk."	This message is displayed when the disk has no free space.	Connect a new disk and select [Retry]. • [Retry]: Copy again. • [Cancel]: Clears the message without copying the image.
"Media is not ready."	This message is displayed when no disk is connected.	Connect a new disk and select [Retry]. • [Retry]: Copy again. • [Cancel]: Clears the message without copying the image.
"Some of the files could not be copied."	This message is displayed when there is a file that could not be copied after data was copied.	[OK]: Closes the message.
"Copy failed."	This message is displayed when data could not be copied. (Data on a read-only device, etc.)	[OK]: Closes the message.
"Copy failed. The system is busy."	This message is displayed when an image was copied during the save process from 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 copying of selected images is completed.	[OK]: Closes the message.
"There is no file to be saved"	This message is displayed when none of the selected files could be saved.	[OK]: Closes the message.
"Some of the files could not be saved."	This message is displayed when some of the files could not be saved.	[OK]: Closes the message.
"Save failed."	This message is displayed when data could not be saved. (Data on read-only device, etc.)	[OK]: Closes the message.
"Save failed. The system is busy."	This message is displayed when an image was saved during the save process from the Analysis screen.	[OK]: Closes the message.

Messages	Status, Cause	Countermeasure
"Save cancelled."	This message is displayed when [Cancel] is selected during saving.	[OK]: Closes the message.
"Save succeeded."	This message is displayed when the selected image has been saved.	[OK]: Closes the message.
"Network configuration error."	Network initialization error. Improper content in the printer setup file, etc.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Network communication error. DICOM association failure."	The transfer syntax and SOP class defined by the instrument are not supported on the server side.	Contact the administrator for the hospital network. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Unable to build image information."	This message is displayed when the DICOM file is corrupted.	• [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Network communication error. DICOM data error."	This message is displayed when a network error caused a failure in transmission to the DICOM network. This message is displayed when an error was returned by the DICOM printer.	Contact the administrator for 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 unsent files when the instrument starts. (Transmission was canceled during transmission to DICOM Storage the last time the instrument was used)	• [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 something other than "Success".	Contact the administrator for the hospital network. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Storage Commitment invalid."	An invalid preset storage commitment is set.	Make a note of the message before contacting 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 commitment completion within the preset "transaction limit."	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Storage Commitment Network communication error."	This message is displayed when Storage Commitment returned an unclear error.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Storage Commitment Processing failure."	This message is displayed when Storage Commitment returned a "0110H - Processing failure" code.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Storage Commitment Resource limitation."	This message is displayed when Storage Commitment returned a "0213H - Resource limitation" code.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.

Messages	Status, Cause	Countermeasure
"Storage Commitment Duplicate transaction UID."	This message is displayed when Storage Commitment returned a "0131H - Duplicate transaction UID" code.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Storage Commitment No such object instance."	This message is displayed when Storage Commitment returns a "0112H - No such object instance" code.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Storage Commitment Referenced SOP Class not supported."	This message is displayed when Storage Commitment returns a "0122H - Referenced SOP Class not supported" code.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Storage Commitment Class/Instance conflict."	This message is displayed when Storage Commitment returns a "0119H - Class/Instance conflict" code.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"MPPS invalid."	The preset MPPS is an invalid setting.	Make a note of the message before contacting 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 MPP server returns an "0110H - Processing failure, Error ID = A710" code.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"MPPS retry file read error."	This message is displayed when the MPPS resend file was corrupted and reading it failed.	Make a note of the message before contacting our office. • [Retry]: Resends communications. • [Cancel]: Cancels all communications.
"Send cancelled."	This message is displayed when [Cancel] is selected during sending.	[OK]: Closes the message.
"There is no file to be sent."	This message is displayed when none of the selected images could be sent.	[OK]: Closes the message.
"Send succeeded."	This message is displayed when selected images have been 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 cannot be printed.	[OK]: Closes the message.
"Print failed. Select the correct printer."	This message is displayed when the printer setting did not match the actual situation.	[OK]: Closes the message.
"Are you sure you want to clear the CD-R buffer?"	This message is displayed when clearing the CD-R Buffer was selected.	• [OK]: Clears the CD-R Buffer. • [Cancel]: Closes the message without clearing the CD-R Buffer.
"Are you sure you want to clear the DVD-R Buffer?"	This message is displayed when you select an operation that will clear the DVD-R Buffer.	• [OK]: Clears the DVD-R Buffer. • [Cancel]: Closes the message without clearing the DVD-R Buffer.

Messages	Status, Cause	Countermeasure
"Failed clearing the CD-R buffer."	This message is displayed when the CD-R buffer clearing has failed.	[OK]: Closes the message.
"Failed deleting DVD-R Buffer."	This message is displayed when the DVD-R Buffer cannot be cleared.	[OK]: Closes the message.
"Write to CD-R?"	This message is displayed when writing to CD-R was selected.	• [OK]: Writes to CD-R. • [Cancel]: Closes the message without writing to CD-R.
"Other operations become impossible during writing. Are you sure you want to start DVD-R writing?"	This message is displayed when you select an operation that will write to DVD-R.	• [OK]: Writes to DVD-R. • [Cancel]: Closes the message without writing to DVD-R.
"CD-R writing is completed."	This message is displayed when CD-R writing is completed.	[OK]: Closes the message.
"DVD-R writing is completed."	This message is displayed when writing to DVD-R is complete.	[OK]: Closes the message.
"Operation is canceled."	This message is displayed when [Cancel] is selected while writing to CD-R or DVD-R.	[OK]: Closes the message.
"No image in CD-R buffer."	This message is displayed when writing to CD-R was selected and there was no data in the CD-R Buffer.	[OK]: Closes the message.
"No image in DVD-R Buffer."	This message is displayed when you select an operation that writes to DVD-R when there is no data in the DVD-R Buffer.	[OK]: Closes the message.
"Failed deleting CD-R buffer."	This message is displayed when CD-R buffer data couldn't be deleted after writing to a CD-R.	[OK]: Closes the message.
"Failed deleting DVD-R Buffer."	This message is displayed if deletion of the data in the DVD-R Buffer fails after writing to a DVD-R.	[OK]: Closes the message.
"Please set blank media to drive."	This message is displayed when a used disc is inserted in the drive.	Insert a new disc. [OK]: Closes the message.
"Failed to open library."	This message is displayed when an attempt to open a CD library or DVD library fails.	[OK]: Closes the message.
"CD-R drive is not connected."	This message is displayed when the CD drive is not connected.	[OK]: Closes the message.
"DVD-R drive is not connected."	This message is displayed when the DVD drive is not connected.	[OK]: Closes the message.
"The recorder is not supported."	This message is displayed when the recorder does not support writing to CD or DVD.	[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 in the CD-R drive. [OK]: Closes the message.
"No disc in DVD-R drive."	This message is displayed when there is no disc in the DVD-R drive.	Insert a new disc into the DVD-R drive. [OK]: Closes the message.

Messages	Status, Cause	Countermeasure
"CD-R type is not known."	This message is displayed when an unsupported disc type is inserted.	Insert a writable disc in the CD-R drive. [OK]: Closes the message.
"DVD-R type is not known."	This message is displayed when an unwritable disc is inserted into the DVD-R drive.	Insert a writable disc into the DVD-R drive. [OK]: Closes the message.
"No more space available on CD-R."	This message is displayed when the free space on the disc is smaller than the quantity of data in the CD-R Buffer.	Insert a disc with more free space, or use a new disc. [OK]: Closes the message.
"No more space available on DVD-R."	This message is displayed when the free space on the disc is smaller than the quantity of data in the DVD-R Buffer.	Insert a disc with more free space, or use a new disc. [OK]: Closes the message.
"Invalid characters/symbols in CD name."	This message is displayed when invalid characters are used in the CD name.	Use single-byte alphanumeric characters in the CD name. Or insert a different disc. [OK]: Closes the message.
"Invalid characters/symbols in DVD name."	This message is displayed when the DVD name uses invalid characters.	Use alphanumeric characters for the DVD name. Alternatively, insert a new disc. [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 try again. [OK]: Closes the message.
"CD-R write error occurred."	This message is displayed when a CD-R write error occurs.	(1) Select [OK] and restart the system. (2) Replace the storage media with a new one, and the retry the operation.
"DVD-R write error occurred."	This message is displayed when a DVD-R write error occurs.	(1) Select [OK] and restart the system. (2) Replace the storage media with a new one, and the retry the operation.
"Unknown error"	This message is displayed when an error relating to writing to CD-R or DVD-R 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 completed.	[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 image was saved during the save process from 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 it is not possible to reproduce all volume data as 3D images.	• [OK]: Reconstruct the 3D image. • [Cancel]: Closes the message without reconstructing the 3D image.

Messages	Status, Cause	Countermeasure
"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 raw data or other data in cine memory is selected for sending.	• [OK]: Clear data from cine memory and play images. • [Cancel]: Closes the message without playing back the image.
"Acquiring analysis data..."	Sending analysis data to cine memory.	[Cancel]: Closes the message without playing back the image.
"Converting video clip data..."	Converting video clip data.	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 200MB.	Select [OK] and insert a new disc. [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 tried 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 a stress status file before starting stress echo. [OK]: Closes the message.
"Send was finished."	This message is displayed when DICOM SR has been sent.	The message is cleared.
"Unsupported data. Failed to Restore."	When the trimming function is run for a DICOM moving image file that does not support it.	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.	Retry after solving the MPPS server connection problem. • [Retry]: Try connecting to the MPPS server again. • [Cancel]: Terminates the connection to the MPPS server and clears the message. • [Suspend]: Temporarily terminates 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 an WMV file or MP4 file. NOTE: **The patient information in an WMV file or MP4 file cannot be masked.**	• [Exit]: Saves the selected image without masking patient information. • [Cancel]: You are returned to the original screen without saving the selected image.
"Formatting will erase all data on this DVD-RAM. Are you sure you want to proceed?"	This message is displayed when the user attempts to start DVD-RAM formatting while [Quick format] was 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] was Off.	• [Yes]: Starts DVD-RAM formatting. • [No]: Clears the message without starting formatting.
"There are too many results to display. Please refine the search conditions and search again."	This message is displayed when the display limit of the patient ID list is exceeded.	(1) Select the [OK] button. (2) Enter patient data in the search information input field. (3) Select [Search].

8-5 Messages about the recorder

Messages	Status, Cause	Countermeasure
"Do you want to finalize your DVD-R before ejecting?"	This message is displayed when the user attempts to eject an unfinalized disc.	• [Yes.]: Finalizes the DVD-R and then ejects it. • [Cancel.]: Close the message without ejecting the DVD-R. • [No.]: Ejects the DVD-R without finalizing it.
"No storage media. Insert a storage device."	No storage device has been inserted.	Insert a storage device.
"Cannot record data because of insufficient space on storage device. Press [EXT] for details."	There is no free space on the storage device.	Insert a new storage device.
"Storage device cannot be recognized. Press [EXT] for details."	Unsupported storage device was inserted or attached.	Insert supported storage device.
"Recorder error detected. Press [EXT] for details."	This message is displayed when an error occurred in the recorder.	Check the recorder. For details, refer to 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.	Turn [EXT] Off and check remaining capacity of the recorder.
"Not enough space on recorder hard disk. Press [EXT] for details."	This message is displayed when there is no free space on the internal hard disk of the recorder.	Turn [EXT] Off and check remaining capacity of the recorder.

8-6 Messages about the presets

Messages	Status, Cause	Countermeasure
"Enter a QSS preset name."	This message is displayed when the [Preset Copy] button was selected in QSS preset copy.	(1) Enter up to 64 characters in the name field. (2) Select [OK]. • [OK]: Copy QSS presets. • [Cancel]: Clear 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 not unassigned options 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 is selected in the preset screen.	• [OK]: Close the preset screen after saving parameters. • [Cancel]: Close 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 is selected in application preset.	• [OK]: Delete the selected application preset, then close the dialog box. • [Cancel]: Close the dialog box without deleting the selected application preset.
"*** already exists. Specify a different name."	This message is displayed when the user changes a name in a preset and the new name is already in the list.	Enter a name that is not in the list. [Close]: Close the dialog box.
"Are you sure you want to return the application preset settings to their factory settings?"	This message is displayed when the [Factory Data] button is selected in application preset.	• [OK]: Change the selected application preset to the default settings, then close the dialog box. • [Cancel]: Close the dialog box without deleting the selected application preset.
"Are you sure you want to replace the current application?"	This message is displayed when the [Paste] button is selected in application preset.	• [OK]: Replace the application preset with the copied data, then close the dialog box. • [Cancel]: Closes the dialog box without replacing the selected application with the copied data.
"Are you sure you want to replace the current settings?"	This message is displayed when the [Paste] button is selected in a preset screen other than the application preset.	• [OK]: Replace the preset other than the selected application preset with the copied data, then close the dialog box. • [Cancel]: Closes the dialog box without replacing the preset other than 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 [Factory Data] button is selected in a preset screen other than the application preset.	• [OK]: Closes the dialog box after changing the preset other than the selected application to the factory settings. • [Cancel]: Closes the dialog box without changing the preset other than the selected application to the factory settings.

Messages	Status, Cause	Countermeasure
"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 is changed using the Common tab for DICOM items and the [Save] button is selected.	• [Yes]: Close the Presets menu and restart the instrument. • [No]: Closes the preset menu. The instrument is not restarted.
"The specified device cannot be recognized. "	The device cannot be recognized for reading or writing presets.	Check device status. • [Retry]: Retry saving to the device or reading from it. • [Cancel]: Clear the message without saving to the device or reading from it.
"The preset which cannot be identified is included. This preset cannot be imported. "	The file cannot be read because some of the presets are in a version that cannot be identified.	[OK]: Returns to the previous screen. Check the version of the preset file.
"Data has not been stored to selected media. Do you want to store?"	This message is displayed when you change devices during data export.	• [Yes]: Save the data to the selected device. • [No]: Closes the menu 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]: Save the data to the selected device. • [No]: Closes the menu 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]: Overwrite the data. • [No]: Saves by adding a serial number starting with 00 to the file name. • [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]: Use data on the selected device to restore data on the instrument. 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 data is overwritten when [OK] or [Cancel] is selected in the Select data screen.
"Unsupported data."	This message is displayed when the target data for batch import is not compatible.	[OK]: Close 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 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]: Save the data to the selected device. • [No]: Cancels 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 batch backup.	• [Yes]: Also copy the network settings. • [No]: Restores without copying the network settings.
"Please increase space capacity of disk."	The connected disk has insufficient space.	Connect a disk with sufficient free space.
"The specified device is write-protected"	The disk is write-protected.	[OK]: Closes the message. Undo write protection on the connected disk. Or connect another disk.

Messages	Status, Cause	Countermeasure
"The specified path is invalid."	The entered file path exceeds 128 characters.	[OK]: Closes the message. Set the file hierarchy so that it is not too deep. Or use short folder names.
"Failed to Import."	This message is displayed when data could not be imported.	If the same message is displayed when you retry, contact our office.
"Failed to Export."	This message is displayed when data could not be exported.	If the same message is displayed when you retry, contact our office.
"Failed to Backup."	This message is displayed when data could not be backed up.	If the same message is displayed when you retry, contact our office.
"Failed to Restore."	This message is displayed when data could not be restored.	If the same message is displayed when you retry, contact our office.
"An SR file could not be created due to an illegal study instance UID (0020,000D)."	The instance UID (0020,0000) is incorrect during "DICOM SR" output in [Output] from the measurement report.	Contact our office if the same message is displayed even after the SR file is recreated.
"SR storage: "	This message is displayed when "DICOM SR" and [OK] are selected in [Output] from the measurement report.	The message is cleared when SR file send is complete.
"This will delete preset settings and data saved on this system. Do you still want to continue?"	When the operator attempted to delete a preset or saved data.	• [Yes]: Deletes preset or saved data. • [Cancel]: Close the message without deleting the data. If 10s elapses without a selection, the system goes back to full screen display without deleting data.
"Cannot set the same value in Port # and QR Port #."	This message is displayed when the same value is entered for the Port # and the QR Port # on the Common tab for DICOM items and the [Save] button is selected.	[OK]: Closes the message. Enter different values for Port # and QR Port #.
"You have not selected any multi image servers. Multi images will not be sent. Are you sure?"	This message is displayed when all of the Multi check boxes are cleared under DICOM Storage of the preset ([Preset Setup > SystemPreset > DICOM > Server/Worklist]).	• [OK]: Leaves the destination server unselected, and closes the message. • [Cancel]: Returns to the state where the destination server is selected, and closes the message.
"You have not selected any single image servers. Single images will not be sent. Are you sure?"	This message is displayed when all of the Single check boxes are cleared under DICOM Storage of the preset ([Preset Setup > SystemPreset > DICOM > Server/Worklist]).	• [OK]: Leaves the destination server unselected, and closes the message. • [Cancel]: Returns to the state where the destination server is selected, and closes the message.

Messages (User Management)	Status, Cause	Countermeasure
"Invalid name or password."	This message is displayed when an incorrect user name or password was entered on 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 password the user tried to newly register or change to violates restrictions.	[OK]: Clears the message. Enter a password consisting of up to 16 alphanumeric characters.

Messages (User Management)	Status, Cause	Countermeasure
"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 the 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 turned off or on.	[OK]: Clears the message. The changed settings are enabled when the instrument 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. Delete unnecessary users, if necessary.
"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 up to 16 single-byte alphanumeric characters.
"Are you sure you want delete the selected user name?"	This message is displayed when deletion is selected for the user selected on the User Management screen.	• [Yes]: Delete the selected user name. • [No]: Close the message without deleting the selected user name.
"Your password will expire in ** day(s). Do you want to change the password?"	This message is displayed when the difference between the password expiration date and the current date is fewer than the number of days set for Password Expiration notice.	• [Yes]: Clears the message and displays the PasswordSetting screen. • [No]: Clears the message.
"Your password has expired. Please change the password."	This message is displayed when the password-setting date is after the password-expiration date. The date of the last password update is set to a future date because of a change in the system settings.	[OK]: Clears the message and displays the PasswordSetting screen.
"New password is same as Current password. Please set New password different from Current password."	This message is displayed when the passwords in [Current password] and [New password] are the same.	[OK]: Clears the message. For the new password, enter a password that is different from the current password.

8-7 Messages About Importing CSV Files

Messages	Status, Cause	Countermeasure
"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 saving the CSV file.
"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 appears when there are no CSV files on the USB flash drive or the data has been corrupted.	[OK]: Closes the dialog box. Check CSV file data and try again.
"The CSV files are unsupported format."	This message appears when CSV file character encoding is not supported or because of some other problem.	[OK]: Closes the dialog box. Change the character code and try again.
"CSV Import is finished. (Succeed: %d, Partly Failed %d, All Failed %d)"	Import processing completed. (Success: %d instances, partial success %d instances, fail %d instances)	Check the content. [OK]: Closes the dialog box.
"Processing... Please wait."	Loading CSV Files.	The message is cleared when CSV file has been loaded.
"USB Memory cannot be connected."	This message is displayed when a CSV file could not be imported because a USB flash drive has not been connected.	(1) Select [OK]. (2) Connect an external device.
"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 importing a CSV file.	If the same message is displayed when you retry, contact our office.
"No search file or directory. Please review search condition."	This message is displayed when there is no CSV file that matches the search conditions and a CSV file cannot be imported.	(1) Select [OK]. (2) Check 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)"	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 importing a CSV file.	If the same message is displayed when you retry, contact our office.

Messages	Status, Cause	Countermeasure
"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 an external device could not be deleted. (When Delete CSV File after Importing is checked in a CSV Import setting.) (Success: %d instances, partial success %d instances, fail %d instances)	Check the content. [OK]: Close the dialog box.
"Column position error. Please review an input file or setting."	The number of patient information columns set in the instrument is larger than the number of items in the CSV file to be imported.	(1) Select [OK]. (2) Set Column Position correctly in the CSV Import setting screen.

8-8 Other Messages

These messages are displayed in the event of a system error or similar situation.

Messages	Status, Cause	Countermeasure
"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 is displayed when the instrument started with less than 10GB of capacity on the instrument hard disk.	(1) Press the [Enter] key to start the instrument. (2) Delete unnecessary data from the instrument 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 is displayed when the instrument started with less than 100MB of capacity on the instrument hard disk.	Press the (1) [Enter] key to start the instrument. (2) Delete unnecessary data from the instrument hard disk.
"Shutdown Tools. Hibernation: The contents of the internal memory are stored to the HDD when the ultrasound equipment is shut down. Start-up time is shortened in next start-up operation by expanding in the memory from HDD."	This message id displayed when the user presses the [Power] key. (If the power supply button behavior settings are configured to be "Selectable" in the basic system presets settings.)	Choose how to turn the power off. [Shutdown]: Completely shuts down the system and turns the power off. [Hibernation]: Hibernates the system and turns the power off. [Return]: The system returns to its status before the [Power] key was pressed.
"Task in progress. System will Power Off after handle it."	This message is displayed when the operator pressed the [Power] key to turn the power off when there was a remaining job.	[Yes]: Turn the power off after the remaining job is finished. [Ignore]: Force quit the system without processing remaining jobs, and turn the power off. [Return]: The system returns to its status before the [Power] key was pressed. Processing of remaining jobs continues.
"Please wait until process is completed."	When [Yes] is selected in the above message.	[Ignore]: Force quit the system without processing remaining jobs, and turn the power off.
"Task in progress. Power supply off forcibly without handle it. Are you really all right?"	• When the operator selected [Ignore] while selecting how to process remaining jobs. • When the operator selected [Ignore] while remaining jobs are being processed.	[Yes]: Force quit the system without processing remaining jobs, and turn the power off. [No]: A dialog box is displayed asking how to process the remaining job and turn the power off.

Messages	Status, Cause	Countermeasure
"** more seconds until system is power off."	This message id displayed when the user presses the [Power] key. (When the basic setting in System Presets sets the waiting period for power cutoff operation at more than 1s and there are no remaining jobs.)	When the countdown reaches 0s, the power is turned off by the selected or set method. [Power off immediately]: Turn the power off by the selected or set method, without waiting for the countdown. [Return]: The system returns to its status 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 is the set date for a maintenance reminder.	Press the [Enter] key to continue startup. Perform a periodical maintenance inspection and safety inspection. Alternatively, ask us to perform an inspection.
"Some duplicated data was not restored."	Some examination data could not 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?"	When a work database is corrupted during startup.	(1) Select the [Yes] button. [OK]: Substitutes an empty database and closes the message. [No]: Clears the message.
"Database Access Error. Please reboot equipment."	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?"	When a master database is corrupted during startup.	(1) Select the [Yes] button. (2) Please contact our office. [Yes]: Substitutes an empty database and closes 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?"	When an empty database is substituted for one that was corrupted during startup.	(1) Select the [Yes] button. (2) Please contact our office. [Yes]: Clears the message and restores the master database. [No]: Clears the message.
"Restoration success."	The database was successfully restored.	(1) Select the [OK] button. [OK]: Clears the message.
"Restoration cancelled."	Database restoration was canceled.	(1) Select the [OK] button. [OK]: Clears the message.
"Restoration failed."	Database restoration failed.	(1) Select the [OK] button. (2) Please contact our office. [OK]: Clears the message.

Messages	Status, Cause	Countermeasure
"No Backup DB."	Database restoration failed.	(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."	When the software generates an error.	After creating an error log, messages are automatically deleted.
"Creating error log was completed. Please push [Shutdown] button and call service person."	When an error log has been created.	Select the [Shutdown] button to turn off the instrument. NOTE: **Please contact our office.**
"HARDWARE ERROR **********"	An instrument hardware malfunction has been detected.	Note message details and contact our office. [OK]: Returns you to the previous screen.
"SYSTEM ERROR **********"	A software malfunction has been detected.	Note message details and contact our office. [OK]: Returns you 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."	Pressing the on screen [Shutdown] button will not shut down the instrument when images are being transferred or there are other jobs in progress.	The instrument will shut down automatically when all jobs have been completed. Or, the instrument is terminated in 30 seconds. NOTE: **Should this happen, image and other data may be corrupted.**
"Power for ultrasound transmission was shut down as the system detected an abnormal drive voltage. Reboot the system. [HV SW ERROR]"	Instrument hardware detected an error in the temperature sensor in the probe and shut down the instrument.	Restart the instrument. If the same message is displayed after restarting, contact our office.
"The setting of the monitor is failed."	This message is displayed when the setting of the monitor has failed.	Note message details and contact our office. [OK]: Clears the message.
"The system clock may have been reset. Please check the clock in the status area after boot up. For clock adjustment, please refer to the operation manual. Press [Enter] to continue."	This message is displayed when the clock displayed on the device is reset.	If you press the [Enter] key, the startup process continues. Adjust the date and time displayed on the device. Note message details and contact one of our offices.
"Automatic Repair Automatic Repair couldn't repair your PC [**********]"	The automatic repair function of the operating system attempted an automatic repair. The automatic repair function alone could not perform a complete recovery and will now attempt a cold boot.	Select the [Shutdown] button or press and hold the [Power] key for ten seconds or more to turn the instrument off. Turn the power back on to start up the instrument. If this message is displayed repeatedly, a hard disk failure may have occurred. Please contact our office.

Messages	Status, Cause	Countermeasure
"Automatic Repair Your PC did not start correctly [**********]"	The automatic repair function of the operating system attempted an automatic repair. The automatic repair function managed to solve the problem and will now restart the PC.	Select the [Restart] button or press and hold the [Power] key for ten seconds or more to turn the instrument off. Restart the instrument (If the instrument is off, press the [Power] key again). If this message is displayed repeatedly, a hard disk failure may have occurred. Please contact our office.
"Windows cannot access the specified device, path, or file. You may not have the appropriate permissions to access the item."	This message is displayed when an invalid attempt to execute a program is blocked. Please note down the message details and contact our office.	[OK]: Returns to the previous screen.
"Auto Image Delete All the data stored before the following date will be deleted. yyyy/mm/dd Estimated time hh:mm:ss (xxx files)"	This message is displayed if the system is shut down with the Auto Image Delete preset set to "Time".	This is a conformation screen displayed in relation to the Auto Image Delete function. Select the [Delete] or [Cancel] button. [Delete]: Deletes data and shuts down the system. [Cancel]: Shuts down the system without deleting data.
"Auto Image Delete All the data stored on Storage Commitment will be deleted. Estimated time hh:mm:ss (xxx files)"	This message is displayed if the system is shut down with the Auto Image Delete preset set to "Storage Commitment".	This is a conformation screen displayed in relation to the Auto Image Delete function. Select the [Delete] or [Cancel] button. [Delete]: Deletes data and shuts down the system. [Cancel]: Shuts down the system without deleting data.
"[Auto Image Delete] function is working. Now deleting stored data... **% Please do not turn off the system. Please wait. By pressing [ENTER], the system will stop deleting, and will shutdown."	Auto Image Delete is running.	This message is displayed while the Auto Image Delete function is running. When deletion is complete, the message disappears and the system shuts down. If you press the [Enter] switch, the deletion process is interrupted and the system shuts down.

9 License Information

9-1 Warning regarding the software used for this instrument

Regarding the software installed in this instrument, the following actions are prohibited.

- Reselling, assigning, or transferring the software itself
- Reverse engineering, reverse compiling, or reverse assembling
- Modification, alteration or translation
- Creating copies or duplicates
- Leasing to third parties

9-2 Microsoft Software License Terms

9-2-1 Notes on Microsoft Software License Terms

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

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

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

- "This device" refers to the diagnostic ultrasound system.
- "This software" refers to Windows.
- "[OEM]" refers to FUJIFILM Healthcare Corporation.
- "Other software" refers to the diagnostic ultrasound system software and other related software.

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

- Only the Windows functions, program updates, add-on software, Internet-based services, and support services authorized by FUJIFILM Healthcare Corporation can be used.

For inquiries to FUJIFILM Healthcare Corporation regarding these license terms, please contact service support.

9-2-2 WINDOWS 10 IOT ENTERPRISE & MOBILE (ALL EDITIONS)

IF YOU LIVE IN (OR IF YOUR PRINCIPAL PLACE OF BUSINESS IS IN) THE UNITED STATES, PLEASE READ THE BINDING ARBITRATION CLAUSE AND CLASS ACTION WAIVER IN SECTION 8. IT AFFECTS HOW DISPUTES ARE RESOLVED.

Thank you for choosing Microsoft!

Depending on how you obtained the Windows software, this is a license agreement between (i) you and the device manufacturer or software installer that distributes the software with your device; or (ii) you and Microsoft Corporation (or, based on where you live or if a business where your principal place of business is located, one of its affiliates) if you acquired the software from a retailer. Microsoft is the device manufacturer for devices produced by Microsoft or one of its affiliates, and Microsoft is the retailer if you acquired the software directly from Microsoft.

This agreement describes your rights and the conditions upon which you may use the Windows software. You should review the entire agreement, including any supplemental license terms that accompany the software and any linked terms, because all of the terms are important and together create this agreement that applies to you. You can review linked terms by pasting the (aka.ms/) link into a browser window.

By accepting this agreement or using the software, you agree to all of these terms, and consent to the transmission of certain information during activation and during your use of the software as per the privacy statement described in Section 3. If you do not accept and comply with these terms, you may not use the software or its features. You may contact the device manufacturer or installer, or your retailer if you purchased the software directly, to determine its return policy and return the software or device for a refund or credit under that policy. You must comply with that policy, which might require you to return the software with the entire device on which the software is installed for a refund or credit, if any.

1. Overview.
   a. Applicability. This agreement applies to the Windows software that is preinstalled on your device, or acquired from a retailer and installed by you, the media on which you received the software (if any), any fonts, icons, images or sound files included with the software, and also any Microsoft updates, upgrades, supplements or services for the software, unless other terms come with them. It also applies to Windows apps developed by Microsoft that provide functionality such as mail, calendar, contacts, music and news that are included with and are a part of Windows. If this agreement contains terms regarding a feature or service not available on your device, then those terms do not apply.
   b. Additional terms. Depending on your device's capabilities, how it is configured, and how you use it, additional Microsoft and third party terms may apply to your use of certain features, services and apps.
      (i) Some Windows apps provide an access point to, or rely on, online services, and the use of those services is sometimes governed by separate terms and privacy policies, such as the Microsoft Services Agreement at (aka.ms/msa). You can view these terms and policies by looking at the service terms of use or the app's settings, as applicable; please read them. The services may not be available in all regions.
      (ii) The manufacturer or installer may also preinstall apps, which will be subject to separate license terms.

(iii) The software may include third party software such as Adobe Flash Player that is licensed under its own terms. You agree that your use of Adobe Flash Player is governed by the license terms for Adobe Systems Incorporated at (aka.ms/adobeflash). Adobe and Flash are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries.

(iv) The software may include third party programs that are licensed to you under this agreement, or under their own terms. License terms, notices and acknowledgements, if any, for the third party program can be view at (aka.ms/thirdpartynotices).

2. Installation and Use Rights.

a. **License.** The software license is permanently assigned to the device with which you acquired the software. You many only use the software on that device.

b. **Device.** In this agreement, "device" means a physical hardware system) with an internal storage device capable of running the software. A hardware partition or blade is considered to be a device.

c. **Restrictions.** The manufacturer or installer and Microsoft reserve all rights (such as rights under intellectual property laws) not expressly granted in this agreement. For example, this license does not give you any right to, and you may not:

(i) use or virtualize features of the software separately;

(ii) publish, copy (other than the permitted backup copy), rent, lease, or lend the software;

(iii) transfer the software;

(iv) work around any technical restrictions or limitations in the software;

(v) use the software as server software, for commercial hosting, make the software available for simultaneous use by multiple users over a network, install the software on a server and allow users to access it remotely, or install the software on a device for use only by remote users;

(vi) reverse engineer, decompile, or disassemble the software, or attempt to do so, except and only to the extent that the foregoing restriction is (a) permitted by applicable law; (b) permitted by licensing terms governing the use of open source components that may be included with the software; or (c) required to debug changes to any libraries licensed under the GNU Lesser General Public License which are included with and linked to by the software; and

(vii) when using Internet-based features you may not use those features in any way that could interfere with anyone else's use of them, or to try to gain access to or use any service, data, account, or network, in an unauthorized manner.

d. Multi use scenarios.

(i) **Multiple versions.** If when acquiring the software, you were provided with multiple versions (such as 32-bit and 64-bit versions), you may install and activate only one of those versions at a time.

(ii) **Multiple or pooled connections.** Hardware or software you use to multiplex or pool connections, or reduce the number of devices or users that access or use the software, does not reduce the number of licenses you need. You may only use such hardware or software if you have a license for each instance of the software you are using.

(iii) **Device connections.** You may allow up to 20 other devices to access the software installed on the licensed device for the purpose of using the following software features: file services, print services, Internet information services, and Internet connection sharing and telephony services on the licensed device. The 20 connection limit applies to devices that access the software indirectly through "multiplexing" or other software or hardware that pools connections. You may allow any number of devices to access the software on the licensed device to synchronize data between devices. This section does not mean, however, that you have the right to install the software, or use the primary function of the software (other than the features listed in this section), on any of these other devices.

(iv) **Remote access.** Users may access the licensed device from another device using remote access technologies, but only on devices separately licensed to run the same or higher edition of this software.

(v) **Remote assistance.** You may use remote assistance technologies to share an active session without obtaining any additional licenses for the software. Remote assistance allows one user to connect directly to another user's computer, usually to correct problems.

(vi) **POS application.** If the software is installed on a retail point of service device, you may use the software with a point of service application ("POS Application"). A POS Application is a software application which provides only the following functions: (i) process sales and service transactions, scan and track inventory, record and/or transmit customer information, and perform related management functions, and/or (ii) provide information directly and indirectly to customers about available products and services. You may use other programs with the software as long as the other programs: (i) directly support the manufacturer's specific use for the device, or (ii) provide system utilities, resource management, or anti-virus or similar protection. For clarification purposes, an automated teller machine ("ATM") is not a retail point of service device.

(vii) **Cloud Computing Devices.** If your device uses Internet browsing functionality to connect to and access cloud hosted applications: (i) no desktop functions may run locally on the device, and (ii) any files that result from the use of the desktop functions may not be permanently stored on the system. "Desktop functions," as used in this agreement, means a consumer or business task or process performed by a computer or computing device. This includes but is not limited to email, word processing, spreadsheets, database, scheduling, network or internet browsing and personal finance.

(viii) **Desktop Functions.** If your system performs desktop functions, then you must ensure that they: (i) are only used to support the application, and (ii) operate only when used with the application.

e. **Windows 10 IoT Enterprise Features for Development and Testing Only.**

(1) Device Health Attestation. You may only implement Device Health Attestation in a commercial use if you execute a Microsoft Windows IoT Core Services Agreement at: https://azure.microsoft.com/en-us/services/windows-10-iot-core/.

f. **Specific Use.** The manufacturer designed the licensed device for a specific use. You may only use the software for that use.

3. **Privacy; Consent to Use of Data.** Your privacy is important to us. Some of the software features send or receive information when using those features. Many of these features can be switched off in the user interface, or you can choose not to use them. By accepting this agreement and using the software you agree that Microsoft may collect, use, and disclose the information as described in the Microsoft Privacy Statement available at (aka.ms/privacy), and as may be described in the user interface associated with the software features.
4. **Authorized Software and Activation.** You are authorized to use this software only if you are properly licensed and the software has been properly activated with a genuine product key or by other authorized method. When you connect to the Internet while using the software, the software will automatically contact Microsoft or its affiliate to confirm the software is genuine and the license is associated with the licensed device. You can also activate the software manually by Internet or telephone. In either case, transmission of certain information will occur, and Internet, telephone and SMS service charges may apply. During activation (or reactivation that may be triggered by changes to your device's components), the software may determine that the installed instance of the software is counterfeit, improperly licensed or includes unauthorized changes. If activation fails the software will attempt to repair itself by replacing any tampered Microsoft software with genuine Microsoft software. You may also receive reminders to obtain a proper license for the software. Successful activation does not confirm that the software is genuine or properly licensed. You may not bypass or circumvent activation. To help determine if your software is genuine and whether you are properly licensed, see (aka.ms/genuine). Certain updates, support, and other services might only be offered to users of genuine Microsoft software.
5. **Updates.** You may obtain updates only from Microsoft or authorized sources, and Microsoft may need to update your system to provide you with those updates. The software periodically checks for system and app updates, and may download and install them for you. To the extent automatic updates are enabled on your device, by accepting this agreement, you agree to receive these types of automatic updates without any additional notice.

6. **Geographic and Export Restrictions.** If your software is restricted for use in a particular geographic region, then you may activate the software only in that region. You must also comply with all domestic and international export laws and regulations that apply to the software, which include restrictions on destinations, end users, and end use. For further information on geographic and export restrictions, visit (aka.ms/exporting).
7. **Support and Refund Procedures.** For the software generally, contact the device manufacturer or installer for support options. Refer to the support number provided with the software. For updates and supplements obtained directly from Microsoft, Microsoft may provide limited support services for properly licensed software as described at (aka.ms/mssupport). If you are seeking a refund, contact the manufacturer or installer to determine its refund policies. You must comply with those policies, which might require you to return the software with the entire device on which the software is installed for a refund.
8. **Binding Arbitration and Class Action Waiver if You Live in (or if a Business Your Principal Place of Business is in) the United States.**

   We hope we never have a dispute, but if we do, you and we agree to try for 60 days to resolve it informally. If we can't, you and we agree to **binding individual arbitration before the American Arbitration Association ("AAA") under the Federal Arbitration Act ("FAA"), and not to sue in court in front of a judge or jury.** Instead, a neutral arbitrator will decide and the arbitrator's decision will be final except for a limited right of appeal under the FAA. **Class action lawsuits, class-wide arbitrations, private attorney-general actions, and any other proceeding where someone acts in a representative capacity aren't allowed. Nor is combining individual proceedings without the consent of all parties.** "We," "our," and "us" includes Microsoft, the device manufacturer, and software installer.

   a. **Disputes covered-everything except IP.** The term "dispute" is as broad as it can be. It includes any claim or controversy between you and the manufacturer or installer, or you and Microsoft, concerning the software, its price, or this agreement, under any legal theory including contract, warranty, tort, statute, or regulation, **except disputes relating to the enforcement or validity of your, your licensors', our, or our licensors' intellectual property rights.**

   b. **Mail a Notice of Dispute first.** If you have a dispute and our customer service representatives can't resolve it, send a Notice of Dispute by U.S. Mail to the manufacturer or installer, ATTN: LEGAL DEPARTMENT. If your dispute is with Microsoft, mail it to Microsoft Corporation, ATTN: LCA ARBITRATION, One Microsoft Way, Redmond, WA 98052-6399. Tell us your name, address, how to contact you, what the problem is, and what you want. A form is available at (aka.ms/disputeform). We'll do the same if we have a dispute with you. After 60 days, you or we may start an arbitration if the dispute is unresolved.

   c. **Small claims court option.** Instead of mailing a Notice of Dispute, and if you meet the court's requirements, you may sue us in small claims court in your county of residence (or if a business your principal place of business) or our principal place of business-King County, Washington USA if your dispute is with Microsoft. We hope you'll mail a Notice of Dispute and give us 60 days to try to work it out, but you don't have to before going to small claims court.

   d. **Arbitration procedure.** The AAA will conduct any arbitration under its Commercial Arbitration Rules (or if you are an individual and use the software for personal or household use, or if the value of the dispute is $75,000 USD or less whether or not you are an individual or how you use the software, its Consumer Arbitration Rules). For more information, see (aka.ms/adr) or call 1-800-778-7879. To start an arbitration, submit the form available at (aka.ms/arbitration) to the AAA; mail a copy to the manufacturer or installer (or to Microsoft if your dispute is with Microsoft). In a dispute involving $25,000 USD or less, any hearing will be telephonic unless the arbitrator finds good cause to hold an in-person hearing instead. Any in-person hearing will take place in your county of residence (of if a business your principal place of business) or our principal place of business-King County, Washington if your dispute is with Microsoft. You choose. The arbitrator may award the same damages to you individually as a court could. The arbitrator may award declaratory or injunctive relief only to you individually to satisfy your individual claim.

e. Arbitration fees and payments.

(i) **Disputes involving $75,000 USD or less.** The manufacturer or installer (or Microsoft if your dispute is with Microsoft) will promptly reimburse your filing fees and pay the AAA's and arbitrator's fees and expenses. If you reject our last written settlement offer made before the arbitrator was appointed, your dispute goes all the way to an arbitrator's decision (called an "award"), and the arbitrator awards you more than this last written offer, the manufacturer or installer (or Microsoft if your dispute is with Microsoft) will: (1) pay the greater of the award or $1,000 USD; (2) pay your reasonable attorney's fees, if any; and (3) reimburse any expenses (including expert witness fees and costs) that your attorney reasonably accrues for investigating, preparing, and pursuing your claim in arbitration. The arbitrator will determine the amounts unless you and we agree on them.

(ii) **Disputes involving more than $75,000 USD.** The AAA rules will govern payment of filing fees and the AAA's and arbitrator's fees and expenses.

(iii) **Disputes involving any amount.** If you start an arbitration we won't seek our AAA or arbitrator's fees and expenses, or your filing fees we reimbursed, unless the arbitrator finds the arbitration frivolous or brought for an improper purpose. If we start an arbitration we will pay all filing, AAA, and arbitrator's fees and expenses. We won't seek our attorney's fees or expenses from you in any arbitration. Fees and expenses are not counted in determining how much a dispute involves.

f. **Must file within one year.** You and we must file in small claims court or arbitration any claim or dispute (except intellectual property disputes - see Section 9.a.) within one year from when it first could be filed. Otherwise, it's permanently barred.

g. **Severability.** If the class action waiver is found to be illegal or unenforceable as to all or some parts of a dispute, those parts won't be arbitrated but will proceed in court, with the rest proceeding in arbitration. If any other provision of Section 9 is found to be illegal or unenforceable, that provision will be severed but the rest of Section 9 still applies.

h. **Conflict with AAA rules.** This agreement governs if it conflicts with the AAA's Commercial Arbitration Rules or Consumer Arbitration Rules.

i. **Microsoft as party or third-party beneficiary.** If Microsoft is the device manufacturer or if you acquired the software from a retailer, Microsoft is a party to this agreement. Otherwise, Microsoft is not a party but is a third-party beneficiary of your agreement with the manufacturer or installer to resolve disputes through informal negotiation and arbitration.

9. **Governing Law.** The laws of the state or country where you live (or if a business where your principal place of business is located) govern all claims and disputes concerning the software, its price, or this agreement, including breach of contract claims and claims under state consumer protection laws, unfair competition laws, implied warranty laws, for unjust enrichment, and in tort, regardless of conflict of law principles. In the United States, the FAA governs all provisions relating to arbitration.

10. **Consumer Rights, Regional Variations.** This agreement describes certain legal rights. You may have other rights, including consumer rights, under the laws of your state or country. You may also have rights with respect to the party from which you acquired the software. This agreement does not change those other rights if the laws of your state or country do not permit it to do so. For example, if you acquired the software in one of the below regions, or mandatory country law applies, then the following provisions apply to you:

a. **Australia.** References to "Limited Warranty" are references to the express warranty provided by Microsoft or the manufacturer or installer. This warranty is given in addition to other rights and remedies you may have under law, including your rights and remedies in accordance with the statutory guarantees under the Australian Consumer Law.

In this section, "goods" refers to the software for which Microsoft or the manufacturer or installer provides the express warranty. Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

b. **Canada.** You may stop receiving updates on your device by turning off Internet access. If and when you re-connect to the Internet, the software will resume checking for and installing updates.

c. Germany and Austria.

(i) **Warranty.** The properly licensed software will perform substantially as described in any Microsoft materials that accompany the software. However, the manufacturer or installer, and Microsoft, give no contractual guarantee in relation to the licensed software.

(ii) **Limitation of Liability.** In case of intentional conduct, gross negligence, claims based on the Product Liability Act, as well as, in case of death or personal or physical injury, the manufacturer or installer, or Microsoft is liable according to the statutory law.

Subject to the preceding sentence, the manufacturer or installer, or Microsoft will only be liable for slight negligence if the manufacturer or installer or Microsoft is in breach of such material contractual obligations, the fulfillment of which facilitate the due performance of this agreement, the breach of which would endanger the purpose of this agreement and the compliance with which a party may constantly trust in (so-called "cardinal obligations"). In other cases of slight negligence, the manufacturer or installer or Microsoft will not be liable for slight negligence.

d. **Other regions.** See (aka.ms/variations) for a current list of regional variations

11. Additional Notices.

a. **Networks, data and Internet usage.** Some features of the software and services accessed through the software may require your device to access the Internet. Your access and usage (including charges) may be subject to the terms of your cellular or internet provider agreement. Certain features of the software may help you access the Internet more efficiently, but the software's usage calculations may be different from your service provider's measurements. You are always responsible for (i) understanding and complying with the terms of your own plans and agreements, and (ii) any issues arising from using or accessing networks, including public/open networks. You may use the software to connect to networks, and to share access information about those networks, only if you have permission to do so.

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c44	cjb2	csepdjvu
djvmcvt	djvuextract	djvumake
djvused	libpoppler-19	libintl-8
PDFViewer	bash	busybox
Incron	Linux kernel	lv
numactl	pciutils	PDF Reader
procps	spu-tools	base-files
adduser	alsa-base	atftpd
aufs-tools	base-passwd	busybox-initramfs
busybox-syslogd	dash	e2fslibs
e2fsprogs	freeglut3	ifupdown
initramfs-tools	initramfs-tools-bin	insserv
iproute2	keyboard-configuration	libacl1
libapt-pkg4.12	libattr1	libblkid1
libbz2-1.0	libc-bin	libcomerr2
libdbus-1-3	libelf1	libgcrypt11
libgdbm3	libglew1.10	libklibc
libkmod2	liblocale-gettext-perl	libnih-dbus1
libnih1	libpci3	libpopt0
libprocps3	libsamplerate0	libsemanage1
libsepol1	libslang2	libustr-1.0-1
libuuid1	libxcb-dri2-0	libxcb-present0
libxcb-sync1	libxcb-util0	linux-image-4.4.0-42-lowlatency-m
linux-sound-base	login	mawk
module-init-tools	mount	passwd
pciutils	plymouth	procps
sed	sensible-utils	ubuntu-keyring
udev	update-inetd	util-linux
vim-common	vim-tiny	xserver-xorg-input-synaptics
xserver-xorg-input-wacom	libxcb-glx0	alsa-utils
apt	xserver-xorg	bsdutils
busybox	x11-common	debianutils
dpkg	usbutils	fsprotect
hugepages	upstart	initscripts

inotify-tools	sysvinit-utils	klibc-utils
kmod	sysv-rc	libaudit-common
libaudit1	powermgmt-base	libc6
libcgmanager0	pm-utils	libfile-copy-recursive-perl
libfreetype6	net-tools	libglu1-mesa
libinotifytools0	mountall	liblzma5
libmount1	makedev	libplymouth2
libpng12-0	lsb-base	libselinux1
libsemanage-common	linux-headers-4.4.0-42-lowlatency-m	libss2
libudev1	libxcb1	libxcb-dri3-0

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At-spi	at-spi2	FFTReal 2.11
JavaScriptCore	WebCore	XHTML Renderer
gzip	libasound2	libasound2-data
libgl1-mesa-glx	libglapi-mesa	libgpg-error0
libusb-0.1-4	libusb-1.0-0	locales
libfribidi0	libgl1-mesa-dri	libhugetlbfs0
libnewt0.52	multiarch-support	whiptail

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bash	coreutils	cpio
gcc-4.8-base	gcc-4.9-base	gnupg
hostname	libgcc1	libreadline6
perl-base	perl-modules	readline-common
diffutils	findutils	gpgv
grep	libstdc++6	perl
tar	libsndfile	

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avalon-framework-api-4.3.1	avalon-framework-impl-4.3.1	batik-anim-1.7
batik-awt-util-1.7	batik-bridge-1.7	batik-codec-1.7
batik-css-1.7	batik-dom-1.7	batik-ext-1.7
batik-gvt-1.7	batik-js-1.7	batik-parser-1.7
batik-script-1.7	batik-svg-dom-1.7	batik-svggen-1.7
batik-transcoder-1.7	batik-util-1.7	batik-xml-1.7
cglib-2.2.2	Clucene Core Library	commons-beanutils-1.8.3
commons-codec-1.6	commons-io-2.4	commons-lang-2.6

core-renderer-v20120624134849	fop-0.94	javax.inject 1
jetty-annotations-9.1.5.v20140505	jetty-http-9.1.5.v20140505	jetty-io-9.1.5.v20140505
jetty-jndi-9.1.5.v20140505	jetty-plus-9.1.5.v20140505	jetty-security-9.1.5.v20140505
jetty-server-9.1.5.v20140505	jetty-servlet-9.1.5.v20140505	jetty-util-9.1.5.v20140505
jetty-webapp-9.1.5.v20140505	jetty-xml-9.1.5.v20140505	joda-time 2.3
shiro-core-1.1.0	shiro-web-1.1.0	spring-aop-3.2.3.RELEASE
spring-beans-3.2.3.RELEASE	spring-context-3.2.3.RELEASE	spring-core-3.2.3.RELEASE
spring-expression-3.2.3.RELEASE	spring-tx-3.2.3.RELEASE	spring-web-3.2.3.RELEASE
spring-webmvc-3.2.3.RELEASE	Wicket 6.6.0	wicket-auth-roles-6.6.0
wicket-core-6.6.0	wicket-devutils-6.6.0	wicket-extensions-6.6.0
wicket-ioc-6.6.0	wicket-request-6.6.0	wicket-spring-6.6.0
wicket-util-6.6.0	wicketstuff-shiro-1.5.8	xercesImpl-2.9.1
xml-apis 2.0.2	xml-apis-ext-1.3.04	xmlgraphics-commons-1.2

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asm-3.3.1	asm-4.1	asm-commons-4.1
asm-tree-4.1	DCMTK 3.6.2	jing-20091111
debconf	libncurses5	libssl1.0.0
dropbear	libncursesw5	libtinfo5
libcap2	libpam-modules	libwrap0
libdb5.3	libpam-modules-bin	libxfont1
libdebconfclient0	libpam-runtime	ncurses-base
libedit2	libpam0g	ncurses-bin
libllvm3.5	libpcre3	sudo
QuickTest	dcmrt	dcmsr

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stax-utils-20070216	cielabutil

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LIBXML2-2	LIBXSLT-1	slf4j-api-1.7.5
slf4j-merlin	Pixman 0.17.11	libdrm-intel1
libx11-data	libxshmfence1	libdrm-nouveau2
libx11-xcb1	libxt6	libdrm-radeon1
libxau6	libxv1	libdrm2
libxaw7	libxvmc1	libexpat1
libxdamage1	libxxf86vm1	libffi6
libxdmcp6	x11-xkb-utils	libfontenc1
libxext6	xkb-data	libice6
libxfixes3	xserver-common	libjson-c2

libxi6	xserver-xorg-core	libjson0
libxinerama1	xserver-xorg-input-all	libmtdev1
libxkbfile1	xserver-xorg-input-evdev	libpciaccess0
libxmu6	xserver-xorg-input-mouse	libpixman-1-0
libxpm4	xserver-xorg-input-vmmouse	libsm6
libxrandr2	xserver-xorg-video-intel	libx11-6
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OpenSSL1.1.0g	OpenSSL1.0.2r

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Version 2.1, February 1999

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Finally, software patents pose a constant threat to the existence of any free program.

We wish to make sure that a company cannot effectively restrict the users of a free program by obtaining a restrictive license from a patent holder. Therefore, we insist that any patent license obtained for a version of the library must be consistent with the full freedom of use specified in this license.

Most GNU software, including some libraries, is covered by the ordinary GNU General Public License. This license, the GNU Lesser General Public License, applies to certain designated libraries, and is quite different from the ordinary General Public License. We use this license for certain libraries in order to permit linking those libraries into non-free programs.

When a program is linked with a library, whether statically or using a shared library, the combination of the two is legally speaking a combined work, a derivative of the original library. The ordinary General Public License therefore permits such linking only if the entire combination fits its criteria of freedom. The Lesser General Public License permits more lax criteria for linking other code with the library.

We call this license the "Lesser" General Public License because it does Less to protect the user's freedom than the ordinary General Public License. It also provides other free software developers Less of an advantage over competing non-free programs. These disadvantages are the reason we use the ordinary General Public License for many libraries. However, the Lesser license provides advantages in certain special circumstances.

For example, on rare occasions, there may be a special need to encourage the widest possible use of a certain library, so that it becomes a de-facto standard. To achieve this, non-free programs must be allowed to use the library. A more frequent case is that a free library does the same job as widely used non-free libraries. In this case, there is little to gain by limiting the free library to free software only, so we use the Lesser General Public License.

In other cases, permission to use a particular library in non-free programs enables a greater number of people to use a large body of free software. For example, permission to use the GNU C Library in non-free programs enables many more people to use the whole GNU operating system, as well as its variant, the GNU/Linux operating system.

Although the Lesser General Public License is Less protective of the users' freedom, it does ensure that the user of a program that is linked with the Library has the freedom and the wherewithal to run that program using a modified version of the Library.

The precise terms and conditions for copying, distribution and modification follow. Pay close attention to the difference between a "work based on the library" and a "work that uses the library". The former contains code derived from the library, whereas the latter must be combined with the library in order to run.

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A "library" means a collection of software functions and/or data prepared so as to be conveniently linked with application programs (which use some of those functions and data) to form executables.

The "Library", below, refers to any such software library or work which has been distributed under these terms. A "work based on the Library" means either the Library or any derivative work under copyright law: that is to say, a work containing the Library or a portion of it, either verbatim or with modifications and/or translated straightforwardly into another language. (Hereinafter, translation is included without limitation in the term "modification".)

"Source code" for a work means the preferred form of the work for making modifications to it. For a library, complete source code means all the source code for all modules it contains, plus any associated interface definition files, plus the scripts used to control compilation and installation of the library.

Activities other than copying, distribution and modification are not covered by this License; they are outside its scope. The act of running a program using the Library is not restricted, and output from such a program is covered only if its contents constitute a work based on the Library (independent of the use of the Library in a tool for writing it). Whether that is true depends on what the Library does and what the program that uses the Library does.

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You may charge a fee for the physical act of transferring a copy, and you may at your option offer warranty protection in exchange for a fee.

2. You may modify your copy or copies of the Library or any portion of it, thus forming a work based on the Library, and copy and distribute such modifications or work under the terms of Section 1 above, provided that you also meet all of these conditions:

a) The modified work must itself be a software library.

b) You must cause the files modified to carry prominent notices stating that you changed the files and the date of any change.

c) You must cause the whole of the work to be licensed at no charge to all third parties under the terms of this License.

d) If a facility in the modified Library refers to a function or a table of data to be supplied by an application program that uses the facility, other than as an argument passed when the facility is invoked, then you must make a good faith effort to ensure that, in the event an application does not supply such function or table, the facility still operates, and performs whatever part of its purpose remains meaningful.

(For example, a function in a library to compute square roots has a purpose that is entirely well-defined independent of the application. Therefore, Subsection 2d requires that any application-supplied function or table used by this function must be optional: if the application does not supply it, the square root function must still compute square roots.)

These requirements apply to the modified work as a whole. If identifiable sections of that work are not derived from the Library, and can be reasonably considered independent and separate works in themselves, then this License, and its terms, do not apply to those sections when you distribute them as separate works. But when you distribute the same sections as part of a whole which is a work based on the Library, the distribution of the whole must be on the terms of this License, whose permissions for other licensees extend to the entire whole, and thus to each and every part regardless of who wrote it.

Thus, it is not the intent of this section to claim rights or contest your rights to work written entirely by you; rather, the intent is to exercise the right to control the distribution of derivative or collective works based on the Library.

In addition, mere aggregation of another work not based on the Library with the Library (or with a work based on the Library) on a volume of a storage or distribution medium does not bring the other work under the scope of this License.

3. You may opt to apply the terms of the ordinary GNU General Public License instead of this License to a given copy of the Library. To do this, you must alter all the notices that refer to this License, so that they refer to the ordinary GNU General Public License, version 2, instead of to this License. (If a newer version than version 2 of the ordinary GNU General Public License has appeared, then you can specify that version instead if you wish.) Do not make any other change in these notices.

Once this change is made in a given copy, it is irreversible for that copy, so the ordinary GNU General Public License applies to all subsequent copies and derivative works made from that copy.

This option is useful when you wish to copy part of the code of the Library into a program that is not a library.

4. You may copy and distribute the Library (or a portion or derivative of it, under Section 2) in object code or executable form under the terms of Sections 1 and 2 above provided that you accompany it with the complete corresponding machine-readable source code, which must be distributed under the terms of Sections 1 and 2 above on a medium customarily used for software interchange.

If distribution of object code is made by offering access to copy from a designated place, then offering equivalent access to copy the source code from the same place satisfies the requirement to distribute the source code, even though third parties are not compelled to copy the source along with the object code.

5. A program that contains no derivative of any portion of the Library, but is designed to work with the Library by being compiled or linked with it, is called a "work that uses the Library". Such a work, in isolation, is not a derivative work of the Library, and therefore falls outside the scope of this License.

However, linking a "work that uses the Library" with the Library creates an executable that is a derivative of the Library (because it contains portions of the Library), rather than a "work that uses the library". The executable is therefore covered by this License. Section 6 states terms for distribution of such executables.

When a "work that uses the Library" uses material from a header file that is part of the Library, the object code for the work may be a derivative work of the Library even though the source code is not. Whether this is true is especially significant if the work can be linked without the Library, or if the work is itself a library. The threshold for this to be true is not precisely defined by law.

If such an object file uses only numerical parameters, data structure layouts and accessors, and small macros and small inline functions (ten lines or less in length), then the use of the object file is unrestricted, regardless of whether it is legally a derivative work. (Executables containing this object code plus portions of the Library will still fall under Section 6.)

Otherwise, if the work is a derivative of the Library, you may distribute the object code for the work under the terms of Section 6. Any executables containing that work also fall under Section 6, whether or not they are linked directly with the Library itself.

6. As an exception to the Sections above, you may also combine or link a "work that uses the Library" with the Library to produce a work containing portions of the Library, and distribute that work under terms of your choice, provided that the terms permit modification of the work for the customer's own use and reverse engineering for debugging such modifications.

You must give prominent notice with each copy of the work that the Library is used in it and that the Library and its use are covered by this License. You must supply a copy of this License. If the work during execution displays copyright notices, you must include the copyright notice for the Library among them, as well as a reference directing the user to the copy of this License. Also, you must do one of these things:

a) Accompany the work with the complete corresponding machine-readable source code for the Library including whatever changes were used in the work (which must be distributed under Sections 1 and 2 above); and, if the work is an executable linked with the Library, with the complete machine-readable "work that uses the Library", as object code and/or source code, so that the user can modify the Library and then relink to produce a modified executable containing the modified Library. (It is understood that the user who changes the contents of definitions files in the Library will not necessarily be able to recompile the application to use the modified definitions.)

b) Use a suitable shared library mechanism for linking with the Library. A suitable mechanism is one that (1) uses at run time a copy of the library already present on the user's computer system, rather than copying library functions into the executable, and (2) will operate properly with a modified version of the library, if the user installs one, as long as the modified version is interface-compatible with the version that the work was made with.

c) Accompany the work with a written offer, valid for at least three years, to give the same user the materials specified in Subsection 6a, above, for a charge no more than the cost of performing this distribution.

d) If distribution of the work is made by offering access to copy from a designated place, offer equivalent access to copy the above specified materials from the same place.

e) Verify that the user has already received a copy of these materials or that you have already sent this user a copy.

For an executable, the required form of the "work that uses the Library" must include any data and utility programs needed for reproducing the executable from it. However, as a special exception, the materials to be distributed need not include anything that is normally distributed (in either source or binary form) with the major components (compiler, kernel, and so on) of the operating system on which the executable runs, unless that component itself accompanies the executable.

It may happen that this requirement contradicts the license restrictions of other proprietary libraries that do not normally accompany the operating system. Such a contradiction means you cannot use both them and the Library together in an executable that you distribute.

7. You may place library facilities that are a work based on the Library side-by-side in a single library together with other library facilities not covered by this License, and distribute such a combined library, provided that the separate distribution of the work based on the Library and of the other library facilities is otherwise permitted, and provided that you do these two things:

a) Accompany the combined library with a copy of the same work based on the Library, uncombined with any other library facilities. This must be distributed under the terms of the Sections above.

b) Give prominent notice with the combined library of the fact that part of it is a work based on the Library, and explaining where to find the accompanying uncombined form of the same work.

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Some devices are designed to deny users access to install or run modified versions of the software inside them, although the manufacturer can do so. This is fundamentally incompatible with the aim of protecting users' freedom to change the software. The systematic pattern of such abuse occurs in the area of products for individuals to use, which is precisely where it is most unacceptable. Therefore, we have designed this version of the GPL to prohibit the practice for those products. If such problems arise substantially in other domains, we stand ready to extend this provision to those domains in future versions of the GPL, as needed to protect the freedom of users.

Finally, every program is threatened constantly by software patents. States should not allow patents to restrict development and use of software on general-purpose computers, but in those that do, we wish to avoid the special danger that patents applied to a free program could make it effectively proprietary. To prevent this, the GPL assures that patents cannot be used to render the program non-free.

The precise terms and conditions for copying, distribution and modification follow.

TERMS AND CONDITIONS

0. Definitions.

"This License" refers to version 3 of the GNU General Public License.

"Copyright" also means copyright-like laws that apply to other kinds of works, such as semiconductor masks.

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To "modify" a work means to copy from or adapt all or part of the work in a fashion requiring copyright permission, other than the making of an exact copy. The resulting work is called a "modified version" of the earlier work or a work "based on" the earlier work.

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To "propagate" a work means to do anything with it that, without permission, would make you directly or secondarily liable for infringement under applicable copyright law, except executing it on a computer

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1. Source Code.

The "source code" for a work means the preferred form of the work for making modifications to it. "Object code" means any non-source form of a work.

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a) Convey the object code in, or embodied in, a physical product (including a physical distribution medium), accompanied by the Corresponding Source fixed on a durable physical medium customarily used for software interchange.

b) Convey the object code in, or embodied in, a physical product (including a physical distribution medium), accompanied by a written offer, valid for at least three years and valid for as long as you offer spare parts or customer support for that product model, to give anyone who possesses the object code either (1) a copy of the Corresponding Source for all the software in the product that is covered by this License, on a durable physical medium customarily used for software interchange, for a price no more than your reasonable cost of physically performing this conveying of source, or (2) access to copy the Corresponding Source from a network server at no charge.

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10 Privacy and Security

The following sections describe the matters related to privacy and security that need to be considered.

10-1 Principles

This manual assumes that customers understand the concept of privacy and security.

For medical devices, you need to maintain balance among safety, privacy, and security. This chapter provides explanations so that the user who manages the system can implement risk management by themselves for these three risk areas.

Note that there is a policy in which only our service staff are allowed to make important changes to the system such as performing virus scans and updating product software. For details, see “Updating of the Product and Handling of Security Incidents” in this manual.

NOTE: For details on how to specifically use the security functionality, see the separate manual “Basic Operations”.

10-2 Privacy and Security Environments

We have designed the system assuming the following environments:

- The environment is physically protected from unintended access through implementation of measures such as entrance and exit control, prevention of theft, peeping, etc., and prevention of devices, the system, information media, etc. from being stolen or lost.
- All passwords are strictly managed to avoid being known by persons who do not need to know them.
- The environment is connected as needed to a segmented and safe network (LAN or VLAN, WAN) for which settings are specified. In addition, the environment uses the network configuration recommended by the network device to be adopted.
- Images, patient data, etc. are appropriately exported, and data that is no longer used is periodically deleted. In addition, data is backed up every day after it is used.
- Regarding the monitor of the system, visibility is restricted so that only persons who have legitimate purposes (medical staff, patients, etc. as well as operators) can view the monitor.
- The media and storage to be connected are scanned in advance by using an anti-malware product.

10-3 Main Security Specifications

This section focuses on and describes the internal capabilities of the system's privacy and security capabilities. For details on how to specifically use the security functionality, see the separate manual “Basic Operations”.

10-3-1 Access Control

Managing Users

You can add or delete users, specify user levels, and specify behavior settings for each user.

Authentication

You can use password authentication when users use the system.

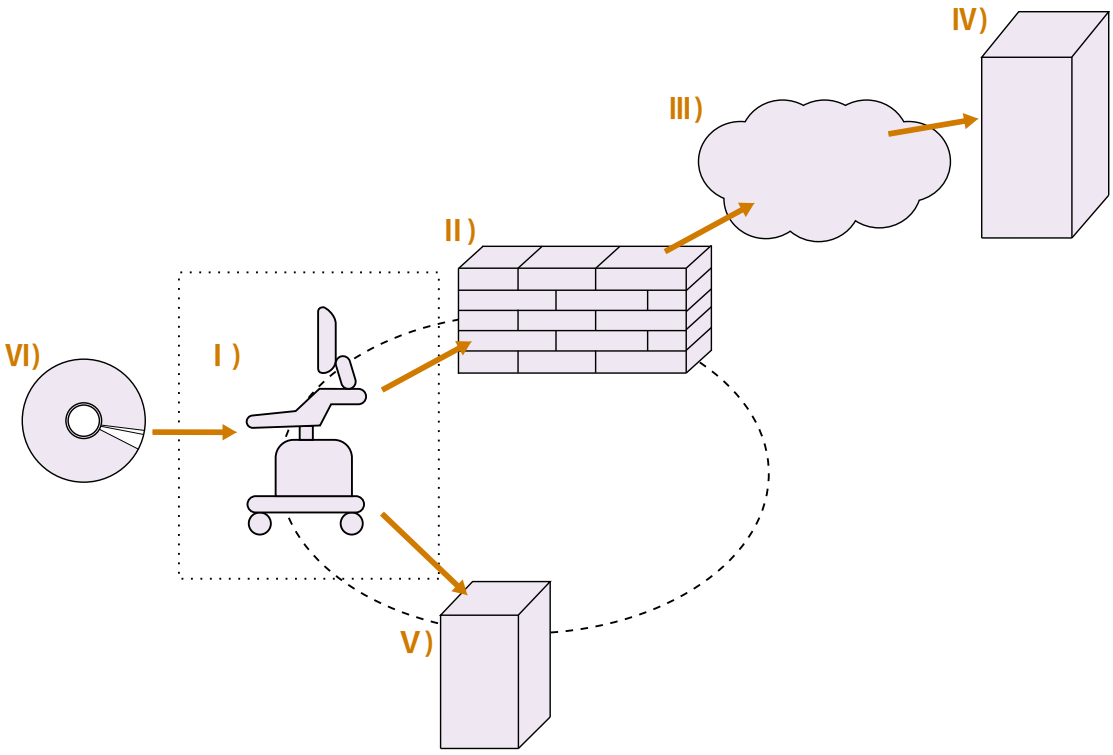
Password Policy

You can define the password policy for passwords that are used by users to be authenticated when using the system.

Screen Lock

You can start a screen saver after a period of inactivity to protect privacy and security.

10-3-2 System Connection



Main connections of the system

I) Authorization boundary of the system

For Ethernet connections, a cable (RJ45) can be used. Alternatively, a wireless connection that can be separately set up can be used. In addition, IPv4 or IPv6 of static or dynamic addressing can be used.

II) Firewall of the Customer

When you connect to the Internet, we recommend that you use it within the firewall.

III) Internet

IV) Server outside the hospital

V) PACS, DICOM printers, and other information systems within the hospital

VI) CD, DVD, USB Drives

Network Requirements

For some system configurations, a network connection is necessary.

- When the system connects to the PACS server, etc.
- When you have a contract of the remote service provided by our company.

NOTE: The remote service is a charged service and might be unavailable depending on the region of use.

DICOM

For details on DICOM-related security requirements, see 7. SECURITY in the DICOM Conformance Statement.

Network Security

The system is equipped with the application firewall and configured so that communications are blocked for ports other than those used.

Wireless Security

We do not provide any wireless modules.

The customer can use the wireless module only if the customer separately purchases a USB Wi-Fi Adapter recommended by us and our service staff sets up it.

At this time, the security encryption that can be used conforms to the USB Wi-Fi Adapter in use.

10-3-3 Audit Log Output

The system supports outputting of audit logs.

Customers need to strictly implement management for preventing unauthorized access to and manipulation of the output logs.

NOTE: For details on how to specify Audit Log settings, see the separate manual “Basic Operations”.

10-3-4 Anti-malware Measures

For the system, you can introduce McAfee Embedded Control of WhiteList Technology as paid optional software.

McAfee Embedded Control allows only programs registered in the dynamic whitelist to be executed. Other programs (exe, dll, script) are considered as unapproved. Attempts to execute them are blocked, which is recorded in a log. This can prevent worms, viruses, spyware, and other malware from being executed.

If you want to introduce optional products, please contact our office.

10-4 Updating of the Product and Handling of Security Incidents

We continuously monitor vulnerability of the components installed in the product. If some vulnerability is found, we evaluate the impact on the product, and then quickly respond by updating software if necessary, etc.

10-4-1 When WhiteList Technology Detects an Abnormality

If a dialog box stating "Windows cannot access the specified device, path, or file. You may have the appropriate permissions to access the item." is displayed, WhiteList Technology might have blocked the execution of suspicious software.

If the system is connected to a network, immediately disconnect the network connection by removing the LAN cable connected to the system, etc.

Please contact our office and describe the problem, to the best of your knowledge.

10-4-2 When a Security Incident Occurs in the Environment in Use

If a security incident occurs in the environment in which the product is used, regardless of whether the system is affected, disconnect from the network. After the incident is resolved and you make sure that the network has no problem, connect the system to the network.

Note that if our product operates abnormally, please contact our office and describe the problem, to the best of your knowledge.

Recycling or Disposal

⚠ CAUTION

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

Waste Electrical and Electronic Equipment (WEEE) Directive

Do not dispose medical devices together with household waste.

In observance of the European Directive on waste electrical and electronic equipment (WEEE) and its implementation in accordance with national law, medical devices that have reached the end of their product life must be collected separately and returned to an environmentally compatible recycling facility.

Please contact your local distributor of our company for information about qualified recycling facility.

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

■ Manufacturer

FUJIFILM Healthcare Corporation

2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan

■ Contact

+81-4-7131-4151

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