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DIAGNOSTIC ULTRASOUND SYSTEM

ARIETTA Precision

Instruction Manual

Instructions for Use

This is the instruction manual for the ARIETTA Precision Diagnostic Ultrasound System.

Before using the instrument, please read this manual.

Thank you for purchasing our ARIETTA Precision Diagnostic Ultrasound System.

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.

For information regarding functions not described in this manual, refer to the separate "Acoustic Output Data", "Detailed Operating Instructions" and "Measurements".

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

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 Manual

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 four 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 means the noted action is prohibited.
❗	This symbol means the noted action is required.

ARIETTA Precision Diagnostic Ultrasound System

This instrument is intended to be used by doctors and other qualified persons, who have a basic knowledge of an ultrasound system and have received the required training, for performing tomography and hemodynamics diagnosis of blood flow in the human body.

However, this instrument cannot be used 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.

I) Precautions concerning the use and management of this instrument

- Only doctors and other qualified persons are allowed to perform operations for diagnostic purpose.
- Scan only for the minimum length of time necessary for the diagnosis, and at the lowest possible output.
- Do not disassemble, repair, or modify the instrument or its optional equipment without our permission. Repair of the instrument will be carried out by our certified personnel. Allow us to handle any repair work.

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

  NOTE: Modification means attachment of parts or devices to this instrument other than those specified by the manufacturer. Replacement of a power cable and AC adapter counts as modification.
- Installation of the instrument and any optional equipment (mounting and connecting using tools) will be performed by our certified partners. Allow us to handle any repair work.
- Perform periodical cleaning and inspection of this instrument. For details, refer to “Procedures After Instrument Use”.
- In the event of an instrument malfunction, immediately remove the probe from the patient and stop using the instrument. Provide appropriate medical treatment immediately if the patient's condition is abnormal. Perform the required measures for the instrument as described in “Messages” in this volume. Be sure to contact our office if the abnormality is not described in “Messages” in this volume.

II) Precautions on Instrument Installation

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

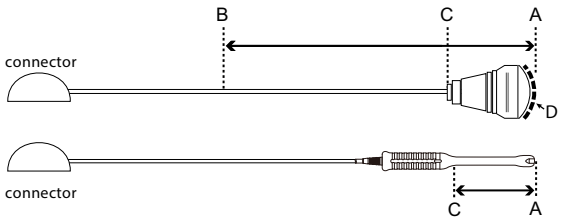
- Install the instrument according to the instructions given in “Setup Before Use” in this volume.
- Install it in an environment that satisfies the conditions described in “Ambient Conditions” in this volume.
- Install the instrument in an environment where electromagnetic compatibility can be maintained in accordance with “Precautions for Maintaining Electromagnetic Compatibility” and “Guidelines for Electromagnetic Compatibility” in this volume.

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

ARIETTA Precision Diagnostic Ultrasound System Classification

- 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.



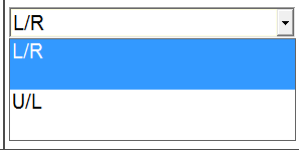
The above is an example of probes for surface or intraoperative use. Below are examples of body cavity probes.

Using a Probe	Applied part	Parts handled as applied parts	Length between B and C
Surface	Ultrasonic irradiation area (D)	Between A and B	100 cm
Intraoperative	Ultrasonic irradiation area (D)	Between A and B	20 cm
Inside the body cavity	Between A and C	Between A and C	–

- Protection against electric shock (Defibrillation-proof applied parts): Not suitable
- Protection against harmful ingress of water or particulate matter
  - Back end unit: IPX2 (drip-proof construction)

    The back end unit is protected from drops of liquid falling within an angle of 15 degrees from vertical. This does not guarantee trouble-free operation when the unit is used in an environment where it is constantly exposed to dripping.
  - Probe applied part: IPX7 (Rated for brief immersion in water)
  - Foot switch: IPX8 (Rated for continuous immersion 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.
- Mode of operation: Continuous operation

Terms Used in This Manual

Example	Operating Procedures	Remarks
Select [Mode > B].	(1) Tap [Mode]. (2) Tap [B].	Screen buttons
Select [Set-Up].	Tap the screen button ([Set-Up] in the example).	• Screen buttons • Screen display items • Thumbnail • Toggle buttons On:  Off:  • Radio buttons On:  Off: 
Select [Probe] from the [Accessories] tab in the function menu.	(1) Swipe the ultrasonic image area upwards from the lower edge. (2) Tap [Accessories] tab. (3) Tab [Probe].	Function menu
Select [Monitor Brightness] from the function menu.	(1) Swipe the ultrasonic image area upwards from the lower edge. (2) Tap Other tab. (3) Tap [Monitor Brightness].	Function menu
Select [Back Space]key.	Tap the specified key on the software keyboard ([Back Space] in the example).	Software keyboard
Insert a checkmark. Remove the checkmark.	Tap the check box on the screen.	Check boxes • Insert:  • Remove: 
Select from the drop-down list.	(1) Tap  . (2) Tap the selection.	Drop-down list 
[Preset Set-Up Menu > Menu-Function]	(1) Swipe the ultrasonic image area upwards from the lower edge. (2) Tap [Accessories] tab. (3) Tap [Preset]. (4) Tap [Set-Up]. (5) Tap the Name list preset. (6) From the Tree View list, tap an item ([Menu-Function] in the example).	Preset screen

Example	Operating Procedures	Remarks
[Common Preset > Common2]	(1) Swipe the ultrasonic image area upwards from the lower edge. (2) Tap [Accessories] tab. (3) Tap [Preset]. (4) Tap [Set-Up]. (5) Tap [Common Preset]. (6) From the Tree View list, tap an item ([Common2] in the example).	Preset screen

NOTE: Provides additional information.

Information is displayed on the screen in the form of “message”.

Table of Contents

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 four 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 means the noted action is prohibited.
	This symbol means the noted action is required.

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 (Replacing a power cable AC adapter is not allowed). *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.

Use probes that are cleaned, disinfected, and sterilized with each examination.

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 AC adapter counts as 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 detailed instructions, refer "Maintenance Inspection" in this volume. For details on components that need regular replacement, please contact our office.

Do not connect equipment, power cables, AC adapters or probes not specified in this manual to the instrument.

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

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.

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.

Do not block the ventilation holes.

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

*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

Do not touch exposed pins in probe connectors, the power supply port, unit cable connectors, etc. when you are also touching a 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 go near exposed pins in probe connectors, the power supply port, unit cable connectors, etc.

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

All non-medical devices connected to the instrument must comply with the relevant IEC or ISO standards (e.g.: IEC 60950-1 for data processing equipment).

Furthermore, the entire configured system must comply with the ME systems standard (refer to clause 16 of IEC 60601-1: Ed.3).

If there are any applicable ordinances, they should be prioritized. For more details, 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.

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 test subject's 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.

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

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

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

Scan only for the minimum length of time necessary for the diagnosis, and at the lowest possible output.
When the subject is a fetus, 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 internal tissues of the patient.

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.

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.

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.

⚠ CAUTION

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

The scanner 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 with condensation or water drops on it can cause electric shock and short-circuiting.

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.

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

The instrument and the cart are not intended to be sterilized.

Scan a USB flash drive for viruses before use.

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

Adjust the position and orientation of the back end unit keeping a sufficient distance between the instrument and surrounding equipment, walls and people.

Do not knock the back end unit, cables or other parts connected to the back end unit against probes, probe holders or other parts.

Make sure probe cables do not become entangled with handles on the back end unit, monitor arm and cart.

Contact with the back end unit may result in injury to people or in damage to surrounding equipment, walls, probes, the instrument or the back end unit. Warn doctors, patients, and others in the area before adjusting the position and orientation of the back end unit.

Should the display 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 display is damaged, stop using it immediately and contact our office.

1-1-2 Labels

Labels that indicate the following cautions are attached to the instrument (some are printed directly on 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 "Electrostatic Discharge (ESD) Guidelines" in this volume.

The following label indicates a safety precaution.

⚠ CAUTION

Safety and Warning Symbols.

This indicates safety information.

This label indicates there is a risk of trapping your hands or fingers in clearances.

⚠ CAUTION

Take care to avoid trapping your fingers in unexpected locations.

They could become pinched resulting in an injury.

This label indicates that prolonged contact may result in low-degree burns.

⚠ CAUTION

Avoid prolonged contact.

Prolonged skin contact with the instrument, for example, by holding it or by placing it on your lap may result in low-degree burns.

Refer to the instruction manual for information on the following label.

⚠ CAUTION

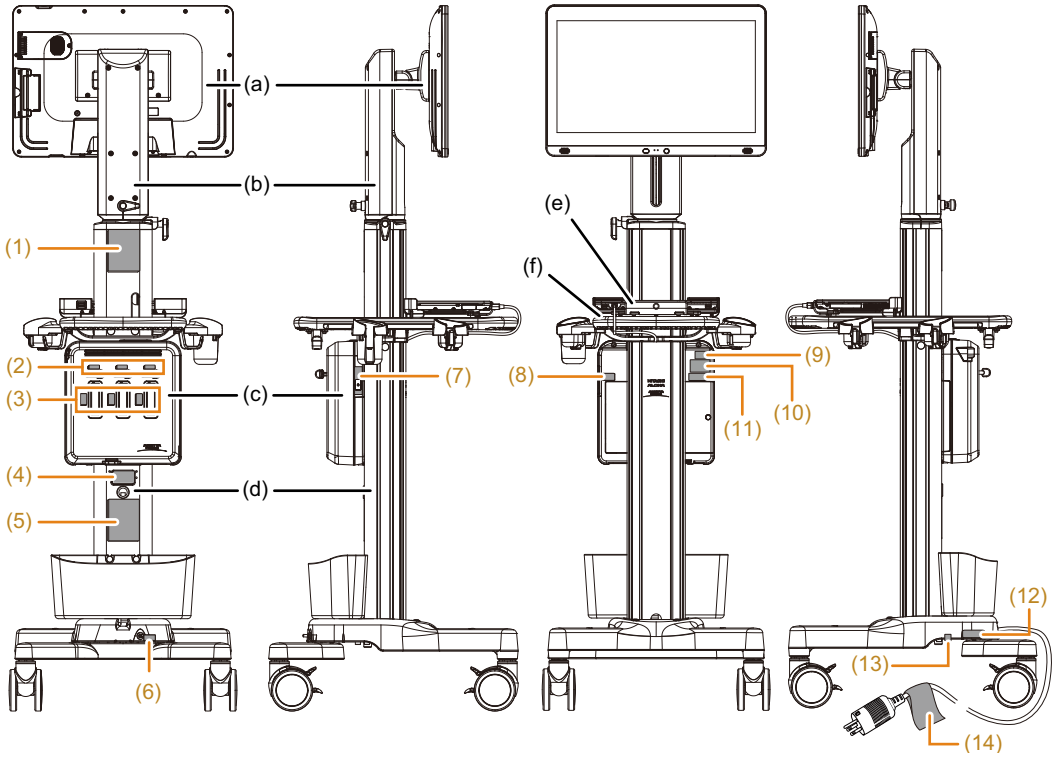
Refer to the instruction manual.

Refer to the instruction manual for details.

Operate this instrument as described in the instruction manual.

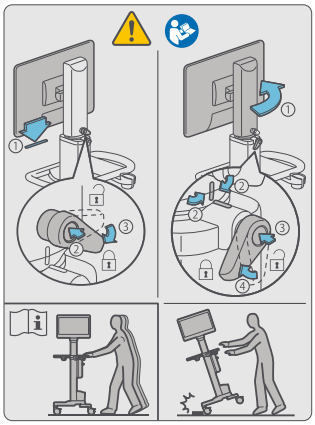
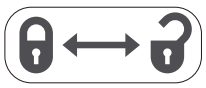
Failure to observe these instructions could result in injury to the patient or operator and damage to the instrument or its peripheral devices.

Labels on Front End Unit/Back End Unit/Cart/Monitor Arm/Remote Controller/Remote Controller Tray

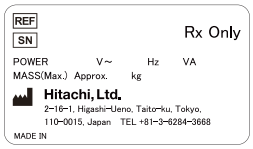


(a) Back end unit (b) Monitor arm (c) Front end unit

(d) Cart (e) Remote Controllerroller (f) Cradle for the remote controller

(1)		Observe the instructions in the instruction manual when securing the back end unit and moving the instrument. Move the instrument by grasping the handle at the back of the cart. Damage could otherwise result. Take great care when moving the instrument over bumps.
(2)		This indicates lock lever status. Left: Locked Right: Unlocked
(3)		A connector for connecting probes. The numbers (1-3) are connector numbers.

(4)



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

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

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

(5)

Move the instrument as described in the instruction manual.
Move the instrument by grasping the handle at the back of the cart.
Damage could otherwise result.
Take great care when moving the instrument over bumps.
These symbols indicate safety precautions, etc.

Safety and Warning Symbols.
This indicates safety information.

Beware of electric shock

⚠ CAUTION

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

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

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 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.

No pushing

⚠ CAUTION

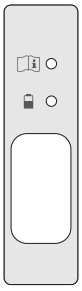
Do not push the side of the instrument. Do not apply excessive force.

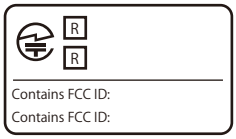
The instrument could tip over, causing injury.

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 this instrument.** The interference from such devices can distort or introduce artifacts in images, disrupt physiological signals and distort the sound from the speakers.
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.
	This product cannot be disposed of as regular garbage. Comply with a local state and Federal regulation.

(6)  Equipotential terminal.

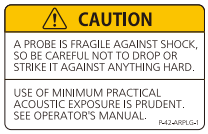
(7)  Probe connector label

(8) 

Radio technical regulations conformity certification label

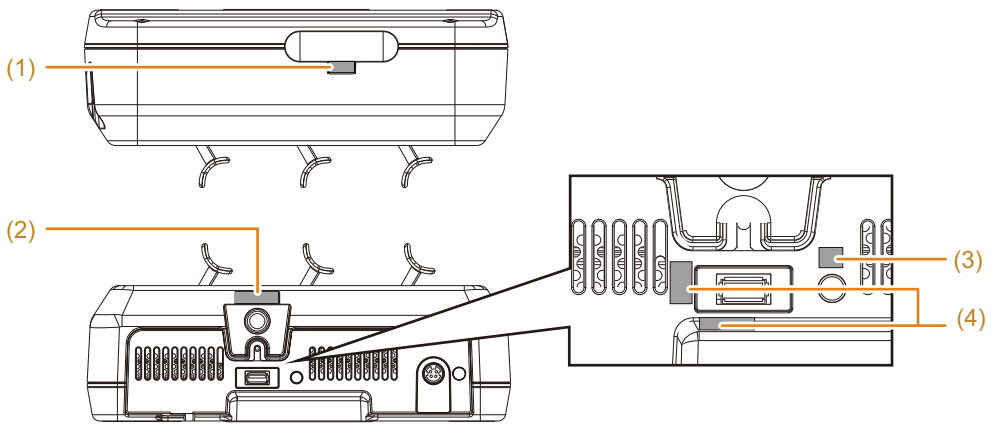
(9) 

(10) 

(11) 

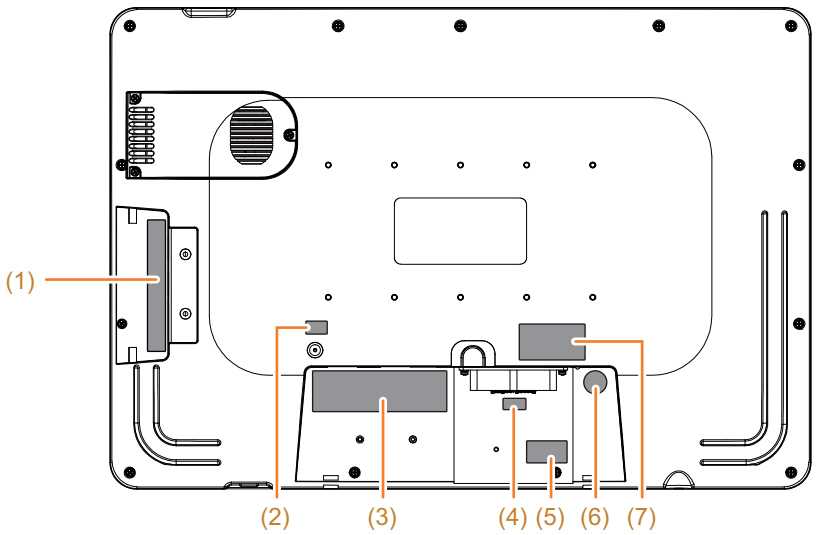
(12)	DISTRIBUTED BY Hitachi Healthcare Americas Corporation 1959 Summit Commerce Park, Twinsburg, Ohio 44087	(13)	TÜVRheinland C US P-52-NRTL-TV	(14)	WARNING GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN THE EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED HOSPITAL ONLY OR HOSPITAL GRADE.

Labels on the Top and Bottom of the Front End Unit



(1)		Unit cable connector
(2)	DC-IN ECG	**DC-IN**: External input terminal. (Connecting a cable from an external physiological signal monitor)
(3)		Battery shutdown switch
(4)		Dedicated foot switch connector.

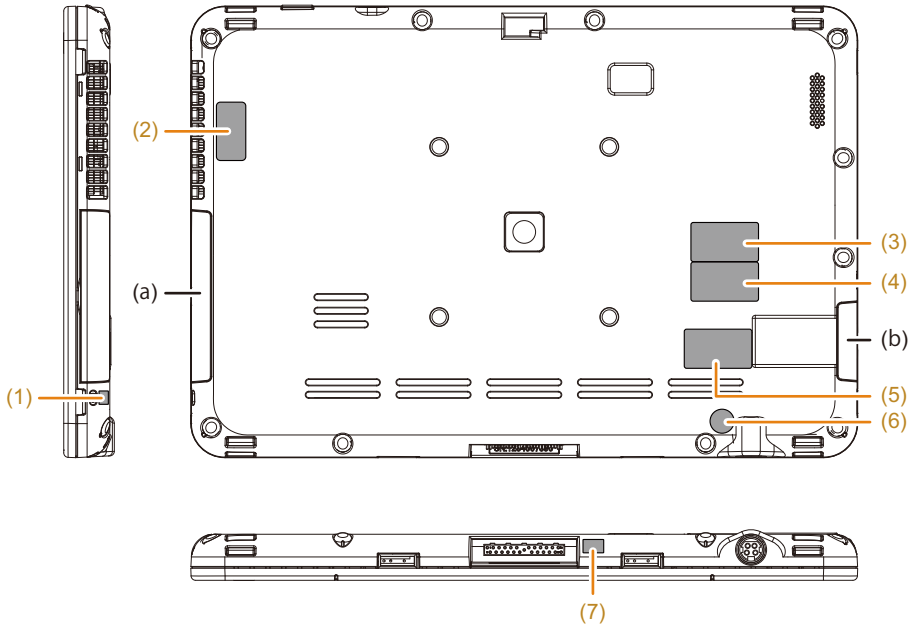
Labels on the Rear Panel of the Back End Unit



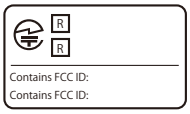
The figure shows the USB and IO covers removed.

(1)	SS	USB connectors
	SD XC	SD card slot
(2)		Battery shutdown switch
(3)	HDMI	HDMI output port
	HDMI	Special HDMI P in P input port
		LAN cable connector
(4)		Unit cable connector
(5)	R R Contains FCC ID: Contains FCC ID:	Radio Technical Regulations Conformity Certification Label
(6)		DC IN connector
(7)	HITACHI REF POWER V ⎓ A Hitachi, Ltd. 2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015, Japan	Distributor, model name, etc.

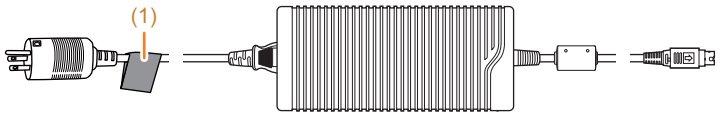
Remote Control Unit Labels

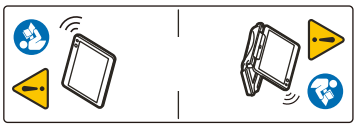


The (a) and (b) connectors cannot be used.

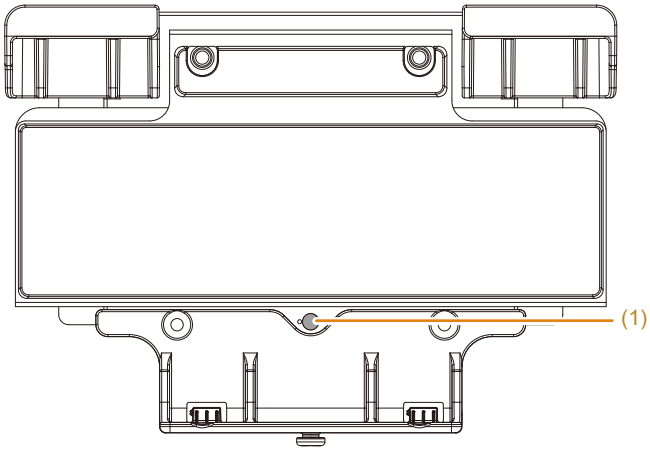
(1)		Battery shutdown switch
(2)		High temperature warning label Follow the supplied documentation.
(3)		Distributor, model name, etc.
(4)		Distributor, model name, etc.
(5)		Radio Technical regulations conformity certification Label
(6)		DC IN connector
(7)		Unit connector

Label on Remote Controller Power Cable



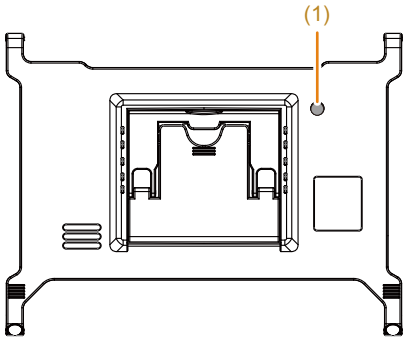
(1)		Remote controller power cable

Label on Remote Controller Tray



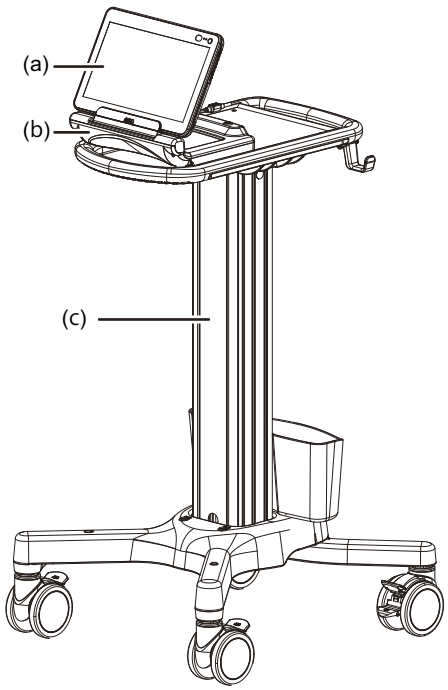
(1)		Follow the supplied documentation.

Label on the Multi-Position Stand



(1)		Follow the supplied documentation.

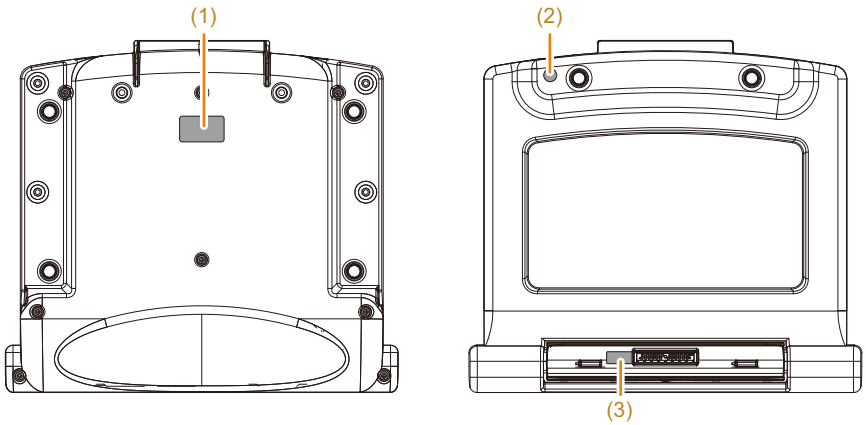
Label on Remote Controller Cradle



(a) Remote controller

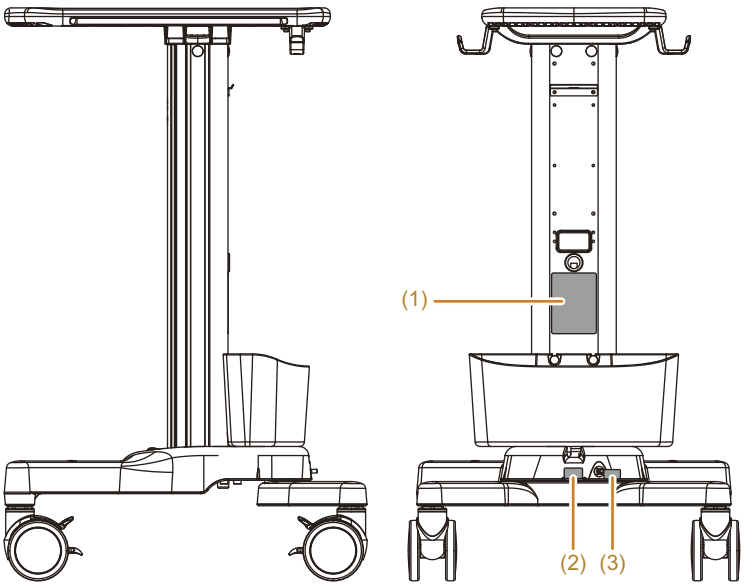
(b) Remote controller cradle

(c) Cart



(1)		Distributor, model name, etc.
(2)		DC IN connector
(3)		Unit connector

Labels on the Cart (Option)



(1)

Move the instrument as described in the instruction manual.

Move the instrument by grasping the handle at the back of the cart.

Damage could otherwise result.

Take great care when moving the instrument over bumps.

These symbols indicate safety precautions, etc.

	Safety and Warning Symbols. This indicates safety information.
Beware of electric shock	**⚠ CAUTION** **Plug the power plug of the instrument into a hospital grade power outlet.** Failure to do so may cause short-circuiting and electric shock.
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 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.
 No pushing	⚠ CAUTION **Do not push the side of the instrument. Do not apply excessive force to the probe holder.** 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 this instrument.** The interference from such devices can distort or introduce artifacts in images, disrupt physiological signals and distort the sound from the speakers.
 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.
	**This product cannot be disposed of as regular garbage. Dispose of it in accordance with laws and regulations.**

(2)		Distributor, model name, etc.
(3)		Equipotential terminal.

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.

When the subject is a fetus, 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 internal tissue of the patient.

The display can be switched to show an acoustic power index suitable for the target region.

There is the possibility of effects on the internal tissue of the patient.

Ultrasound energy is converted into heat in the body while being attenuated. Particularly, there is a greater possibility of heat being generated in bone and the cranium compared to soft tissue.

⚠ CAUTION

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 (option) when not in use.
  - Hold the probe firmly so that it doesn't slip, especially when using ultrasound gel or other lubricants.
  - Do not pull on the probe cables. Do not fold or kink them. Do not allow them to get caught in the casters.
  - Connect the probe as described in this manual and the documentation for the probe.
- In order to prevent burns or injury
  - Before use, coat the probe adequately with ultrasound gel.
  - Do not apply unreasonable force when moving a probe inserted into a body cavity.
  - When the probe is not in use even during an examination, freeze the image as standard practice.
- In order to prevent infection
  - Keep the probes clean and dry.

    Do not allow ultrasound gel, water or any other foreign matter to dry on the probes.
  - Clean, disinfect, and sterilize any probes that have been used.
  - Dispose of probes used for patients with Creutzfeldt-Jakob disease.

    Our ultrasound probe is not compatible with any disinfection/sterilization method for Creutzfeldt-Jakob disease.

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
  - The probe, puncture adapter and puncture needle must be sterilized.
  - Ensure that the puncturing needle is not bent.
  - Use a water tank to make sure that needle echo matches the puncture guide line.
  - It is necessary to perform inspections according to the documentation provided with the probe and puncture adapter.

    Do not use any probe or puncture adapter that is abnormal.
- 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 model name of the currently used puncture adapter is identical to that displayed on the screen.

    When using probes and puncture adapters that have multiple puncture angles check that the insertion angle of the puncture adapter and the angle set on the screen are the same.
  - Be sure to check the needle echo before using the probe.

    When the speed of sound in tissue is not 1,530 m/s, the angles of the puncture guide line and needle echo may not match.
  - Confirm the safety of a puncture path not displayed on the screen.

    There may be blood vessels or other organs in the puncture path that is not visible on the screen.
  - Use the needle echo displayed on the screen to verify the location of the puncturing needle.

1-4 Precautions for use of medications with the Diagnostic Ultrasound System

- Using ultrasound contrast agents with the Diagnostic Ultrasound System

  Only use licensed medications for the ultrasound contrast agent.

  For information on the use, amount, precautions for use, handling, storage, and disposal of ultrasound contrast agents, refer to the separate manual included with the ultrasound contrast agent.

⚠ 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 medium 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 cart 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.

- Use in conjunction with an ECG monitor

  Use only an ECG monitor that conforms to the IEC 60601-1 together with this instrument. Do not use the ECG monitor if its documentation prohibits its use together with Diagnostic Ultrasound System or similar medical electronic instruments.

⚠ 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 it and the probe cables as far away as possible from other appliances and their cables.

Exposure to strong irradiation and electromagnetic interference may cause the instrument to malfunction or distort screen images. Do not place them near the instrument.

Note that when using this instrument with other medical electrical equipment, the electromagnetic wave the instrument generates could affect the operation of such equipment. Stop using together with such an equipment immediately.

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.

⚠ CAUTION

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, communications devices, radio and TV broadcasting antennas and similar devices can both emit electromagnetic energy and receive electromagnetic 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) 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, AC adapters 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 this instrument. This instrument may be affected by portable or mobile RF communications equipment.

III) Use in conjunction 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. Such interference may render wireless transmission impossible. Position this instrument and its cables as far away as possible from other equipment used with the instrument and its cables.

- Make sure that the instrument is not affected by electromagnetic interference generated by equipment it is used with, and that such equipment is not affected by electromagnetic wave generated by the instrument.
- If the instrument is used together with high-frequency devices, the electromagnetic interference they generate may distort images displayed on this instrument.
- If electromagnetic wave from this instrument causes other medical electrical equipment that is used with it to function abnormally, immediately stop using this combination of devices together. Do not use such devices together with this instrument.

Reference Guidelines for Electromagnetic Compatibility → p.9-2

1-7 Precautions Concerning Power Plugs and Power Cables

⚠ CAUTION

Plug the power cable provided into a hospital grade outlet.
There is a risk of electric shock or fire. Do not connect the instrument to an extension cable, or to a branched circuit.

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.
If the power cable or plug is damaged, stop using the instrument immediately. For details regarding instrument repair, please contact our office.

If the power cable and 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 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. Then set the battery shutdown switch to Disconnect mode.
Even if the power switch of the instrument is turned off, it is not completely disconnected from the power supply.

1-8 Precautions for AC adapters

- Since probes are easily affected by electromagnetic waves, the AC adapter should be kept away from probes during use.
- Do not expose the AC adapter to liquids or moisture.
- Do not touch the AC adapter with wet hands.
- Do not drop the AC adapter or expose the AC adapter to strong impact. The AC adapter could be damaged.
- If the AC adapter becomes hot or emits a strange smell, disconnect the power plug from the hospital grade outlet, stop using the instrument and contact our office.
- Do not use or leave the AC adapter in a location exposed to direct sunlight or high temperature.

1-9 Precautions for the Internal Battery

- When the product is shipped, the internal battery is not fully charged. Be sure to charge prior to use.
- The operating environment and the state of the internal battery determine how long the battery can be used. When fully charged, it will operate for about 60 minutes in B mode.
- The internal battery is a consumable part. Battery duration per charge will gradually decrease with repeated charging. When battery duration per charge drops dramatically, the battery is approaching the end of its service life. Please contact our office.
- Be sure to check remaining battery capacity before recording data when the instrument is powered by the battery. Data will not be correctly recorded if power is interrupted during recording.
- If the instrument cannot be connected to a hospital grade outlet, power the instrument from the battery instead of connecting a power plug.
- The screen will display messages as the amount of battery power remaining drops. Follow the instructions in the messages.
- The instrument consumes a small amount of power even when it is turned off. For that reason, the battery will lose some power even when the instrument is turned off and the AC adapter is not connected from the instrument. Under these conditions, a fully charged battery will be completely discharged in about a week in the front end unit and after about 4 days in the back end unit.
- When the instrument will not be used for an extended period of time, charge the battery to about 40 - 60% of its capacity, set the battery shutdown switch to Disconnect mode and store the instrument in a cool location at a temperature of around 68°F.
  Charge the battery to about 40 - 60% of capacity every 6 months.

  Use the battery capacity icon at top right of the screen to check battery capacity.

Icon	Battery capacity
	80% or more
	60% or more but less than 80%
	40% or more but less than 60%
	20% or more but less than 40%
	0% or more but less than 20%

1-10 Precautions for Disconnecting the Power Supply

⚠ CAUTION

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

Such situations can result in injury to the patient or operator, or other unexpected accidents. Stop using the instrument and contact our office.

1-10-1 Disconnecting the Power Supply

1 Press the power switch on the back end unit.

→ Shuts down the back end unit and the front end unit.

2 Disconnect the power cable from the hospital grade outlet.

→ Goes into standby mode.

3 Press the battery shutdown switch.

→ Shuts off the power supply from the battery.

1-11 Precautions Regarding Wireless Communication Function

FCC CAUTION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This equipment should be installed and operated keeping the radiator at least 20cm or more away from person's body.

Caution Exposure to ratio frequency radiation

This device must not be co-located or operating in conjunction with any other antenna or transmitter.

The Radio Act stipulates that the wireless communication function of the instrument cannot be used outdoors. Nor can it be used overseas. Violations are a punishable offense.

Obstacles may reduce sensitivity or prevent wireless transmission.

In the unlikely event of radio interference with another wireless device, immediately perform any of the following steps.

- Switch to an unused wireless channel on other wireless devices.
  For details, refer to the separate "Detailed Operating Instructions".
- Use wired instead of wireless connections.
  For details, refer to the separate "Detailed Operating Instructions".
- Change the location where you use the instrument.
- Shut down the instrument.

2 Product Summary

2-1 Intended Use

This device is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal (Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).), Intra-operative (Spec.) (Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).), Intra-operative (Neuro.), Laparoscopic, Pediatric, Small Organ (Spec.) (Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.), Neonatal Cephalic, Trans-rectal (Includes imaging for guidance of trans-rectal biopsy.), Trans-vaginal (Includes imaging for guidance of trans-vaginal biopsy.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Other (Spec.)-Gynecological, Other (Spec.)-Wound (Includes imaging for Cavernous/Non-Cavernous wounds), Peripheral vessel, clinical applications.

The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), Color Doppler, Power Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), Free Angular M mode and Trapezoid mode.

⚠ WARNING

DO NOT use this instrument for performing ultrasound examination of the eyes.

The acoustic intensity 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.

The ultrasound beams obtained as explained above are converted to video signals with the digital scanning converter, and are displayed on the measurement 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.
- 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.
- The Doppler mode includes the PW Doppler mode. PW Doppler mode displays bloodstream information consecutively at a sample point that is detected by pulsed Doppler sonography.
- 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. The mode then colors that information and displays it as an overlay on B mode or M mode. Color Flow Mode, Power Doppler Mode, High-Resolution Power Doppler (eFlow) Mode can be used with this instrument according to need.

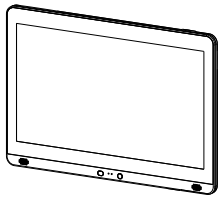
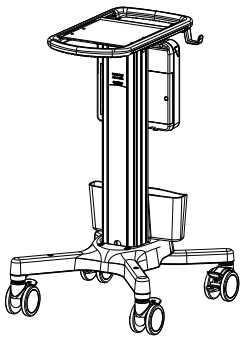
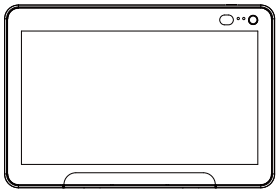
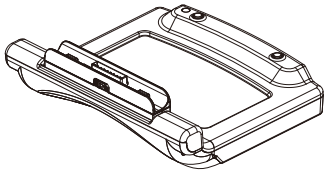
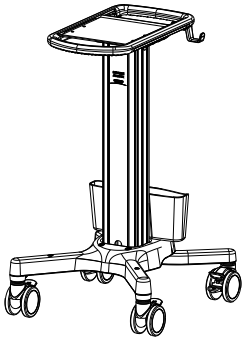
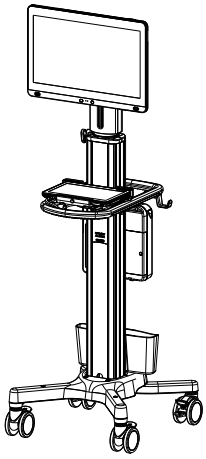
The 5 methods of electronic scanning are as follows.

- 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 test subject.
- Convex Scanning Method:
  By this method, the ultrasound beam from the ultrasound probe is emitted radially and draws a tomographic image of the test subject.

- 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 test subject.
- 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 test subject.

2-3 Specifications

Electronic scanning method	Linear scanning, convex scanning, sector scanning, radial scanning method and trapezoidal scanning method	
Display mode	B mode M mode D mode Color Doppler mode	
Acoustic power	0% to 100%, continuously variable	
Probes which can be connected simultaneously	Electronic: 3 probe	
Display images	Display orientation	Longitudinal inversion, lateral inversion, 90-degree rotation
	Display depth	2 cm to 40 cm (varies with probe type)
Physiological Signal Display	DC IN	
Measurement functions	Basic measurements	
	Applied measurements	Abdominal measurements, urological measurements, superficial organ measurements, gynecological measurements, obstetrics measurements, cardiological measurements, vascular measurements
Viewing monitor	21.5 inch LCD flat panel display	
In/Output	Video	Special HDMI P in P input port ×1 HDMI output port ×1
	Foot switch	Special connector ×1
	USB	USB 3.0 ×2
	SD card	SD card slot ×1
	Network	LAN
Cine memory	Search, scroll, store, review and loop playback	
Still image data format	Moving image	• Video clip data (DICOM RGB [RLE/Norma], JPEG) • AVI • MP4/MOV • Line
	Still image	• DICOM (Palette, RGB [RLE/Normal], JPEG) • TIFF • BMP • JPEG
External dimensions	When installed on a cart and provided with a monitor arm (both options): Width 520 mm × Height 1743 mm × Depth 600 mm When installed on a cart: Width 520 mm × Height 947 mm × Depth 600 mm Back end unit: 530 mm (W), 364 mm (H), 45 mm (D)	

Mass	Standard Configuration	Back end unit: Approx. 6.5 kg	
		Front end unit + cart: Approx. 28 kg	
	Options	Remote controller: Approx. 1.5 kg	
		Remote controller cradle: Approx. 1.4 kg	
		Cart: Approx. 20 kg	
		With the monitor arm, remote controller and remote controller cradle installed: Approx. 44 kg	
Service life		Main unit 7 years	

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	±1BPM or 5%

B mode	
Gray levels	256 levels
Scan area	100% to 25%, continuously variable
Zoom	Write zoom (real time) up to 6 times Read zoom up to 16 levels
Display range	2 cm to 40 cm (varies with probe type)
Frame rate (line density): 3 levels	
Contrast	23 levels (dynamic range: 36 dB to 96 dB)
TGC	8-level slider
B Gain	10 dB to 90 dB
AGC	16 levels
Relief	4 levels
FTC	On/Off
Frame correlation	16 levels (Auto, Manual)
Smoothing	16 levels
Steered beam	±30° in 5° steps (varies with the probe type)
Gamma Curve	Curve: 5 types, Rejection: 64 levels
Graymap	5 types

M mode	
Sweep speed:	7 levels
Gain	B Gain ±30 dB
Contrast	23 levels (dynamic range: 36 dB to 96 dB)
AGC	16 levels
Relief	4 levels
FTC	On/Off
Free Angular M-mode (FAM): up to 3 lines	

D mode	PW
Display pattern	Frequency spectrum
Maximum velocity range	±6.23 to ±398.44 cm/s
Angle correction	±80 degree auto angle correction enabled
Sample volume	0.5 mm to 20 mm
Doppler gain	0 dB to 50 dB (128 steps)

Color Doppler mode	
Display pattern	Scale display, flow velocity + dispersion display, dispersion display, Power Doppler display, eFlow display, Directional Power Doppler display, Directional eFlow display and TDI display
Scale display	±127 levels
Dispersion display	16 levels
PowerFlow, eFlow display	128 levels (±127 levels in the Directional display)
Flow area	100% to 15%, continuously variable
Frame rate (line density): 9 levels	
Flow gain	0 dB to 31.75 dB (128 steps)
Steered beam	±30° in 5° steps (varies with the probe)
Color coding	Abdomen, Vascular, Cardiology, and others

2-3-1 Power Supply Conditions

Power supply voltage	100V to 120V	
Electrical frequency	50/60Hz	
Power consumption	200 VA or less	
AC adapter	Manufacturer	SINPRO ELECTRONICS CO., LTD.
	Format	HPU180A-107
	Standard	IEC 60601-1, UL/CUL 60601-1
Internal battery	Battery life	500 cycles

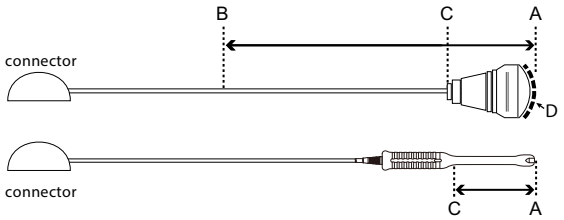
2-3-2 Ambient Conditions

	Operating Conditions	Storage conditions or transporting conditions (when packed)
Ambient Temperature	50 °F to 104 °F (When the remote controller is used independently of the remote controller cradle: 50 °F to 95 °F)	14 °F to 122 °F
Relative Humidity	30% to 75% (no condensation)	10% to 90% (no condensation or freezing)
Atmospheric pressure	700 hPa to 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.



The above is an example of probes for surface or intraoperative use. Below are examples of body cavity probes.

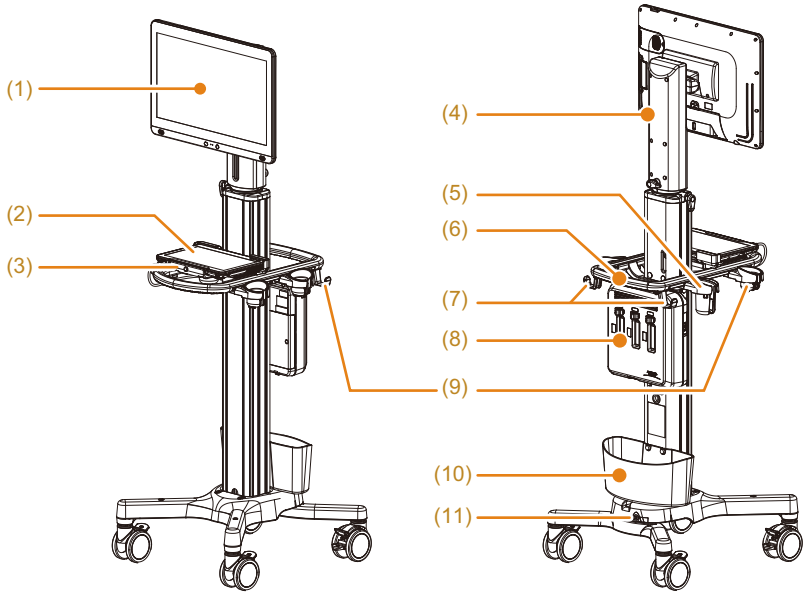
Using a Probe	Applied part	Parts handled as applied parts	Length between B and C
Surface	Ultrasonic irradiation area (D)	Between A and B	100 cm
Intraoperative	Ultrasonic irradiation area (D)	Between A and B	20 cm
Inside the body cavity	Between A and C	Between A and C	–

- Protection against electric shock (Defibrillation-proof applied parts): Not suitable
- Protection against harmful ingress of water or particulate matter
  - Back end unit: IPX2 (drip-proof construction)

    The back end unit is protected from drops of liquid falling within an angle of 15 degrees from vertical. This does not guarantee trouble-free operation when the unit is used in an environment where it is constantly exposed to dripping.
  - Probe applied part: IPX7 (Rated for brief immersion in water)
  - Foot switch: IPX8 (Rated for continuous immersion 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.
- Mode of operation: Continuous operation

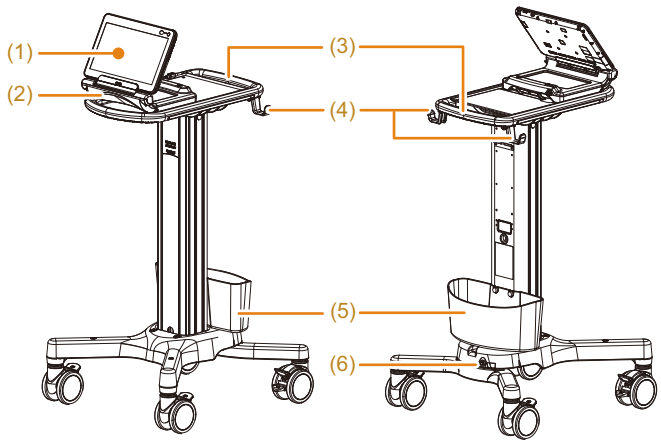
2-4 Part names

I) When a monitor arm, remote controller and a remote controller tray are installed



(1) Back end unit
(2) Remote controller
(3) Remote controller tray
(4) Monitor arm (option)
(5) Gel holder (option)
(6) Handle
(7) Cable hook x 2
(8) Front end unit
(9) Probe holder x 3 (option)
(10) Storage pocket
(11) Equipotential terminal

II) When a cart (option), remote controller and a remote controller cradle are installed



(1) Remote controller

(2) Remote controller cradle

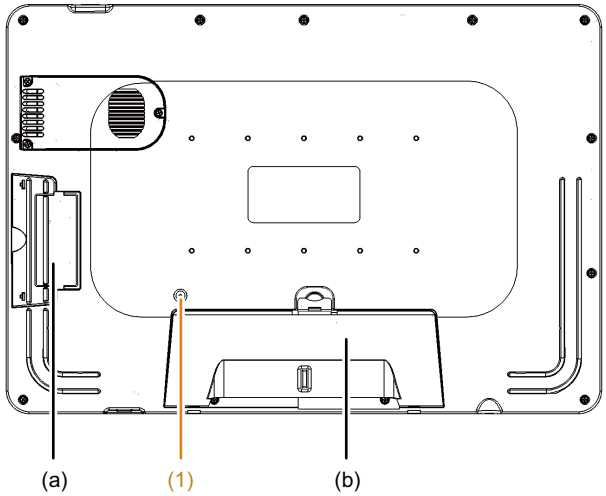
(3) Handle

(4) Cable hook

(5) Storage pocket

(6) Equipotential terminal

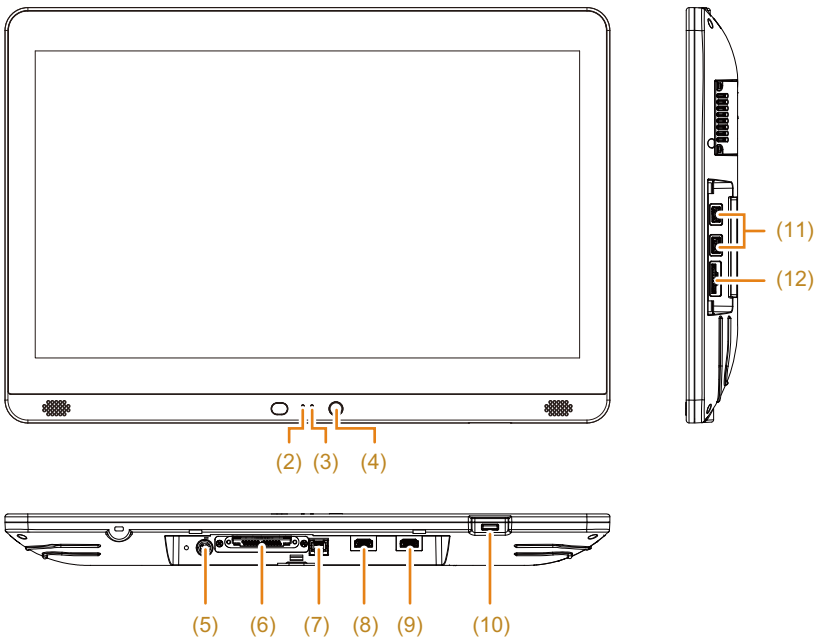
III) Back end unit



(a) USB cover

(b) IO cover

(1) **Battery shutdown switch**



The figure shows the USB and IO covers removed.

(2) **Battery LED**

The LED is lit blue when power is on.

When the instrument is powered by the internal battery, the LED indicates the following conditions.

- When the battery is fully charged: Off
- When remaining battery capacity is 10%: Orange (solid)
- When remaining battery capacity is 5%: Orange (flashing)
- When remaining battery capacity is 0%: Off

(3) **Power switch LED**

The switch is lit orange in standby. The switch is lit white when power is on.

(4) **HOME button**

(5) **Power supply port**

(6) Unit cable connector

(7) LAN Cable Connector

(8) Special HDMI P in P input port

Connect an external monitor to this input to import moving images.

(9) HDMI output port

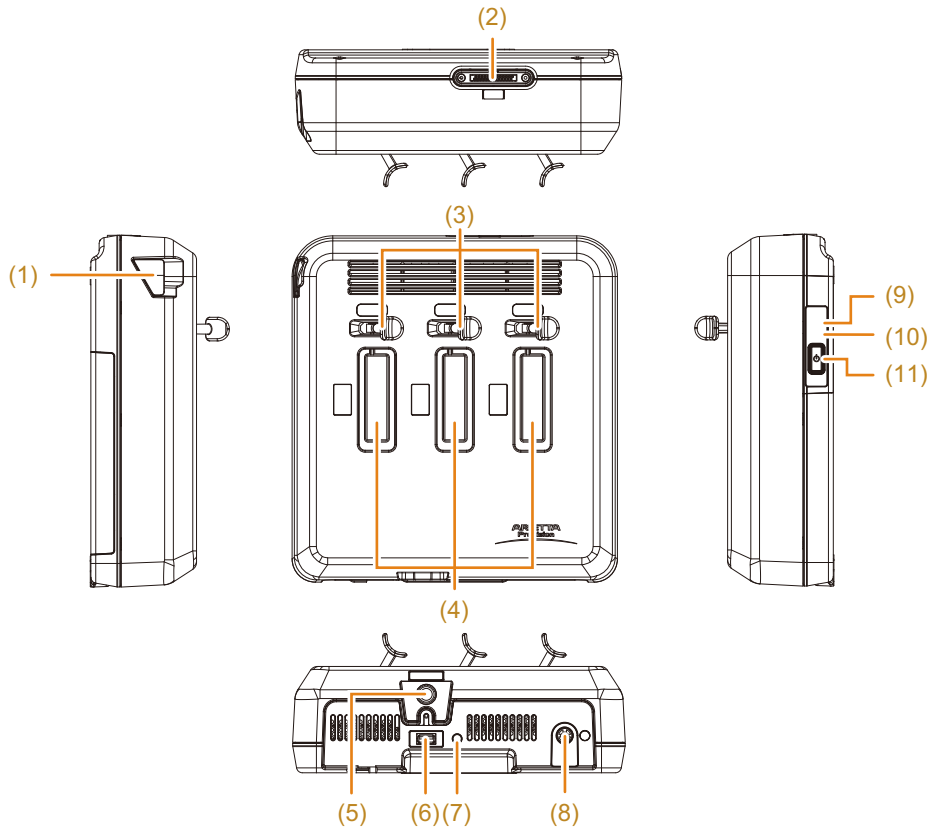
Connect an external monitor to this input to display images.

(10) Power switch→ p.3-29

(11) USB connectors x 2

(12) SD card slot

IV) Front end unit



(1) **Dust filter**

(2) **Unit cable connector**

(3) **Lock lever x 3**

(4) **Probe connector x 3**

(5) **DC IN connector**

(6) **Foot switch connector**

(7) Battery shutdown switch⟶ p.3-40

(8) **Power supply port**

Connect the power cable.

(9) **Maintenance LED**

This LED flashes when the instrument is malfunctioning. Contact us if this LED starts flashing.

(10) **Battery LED**

The LED is lit blue when power is on.

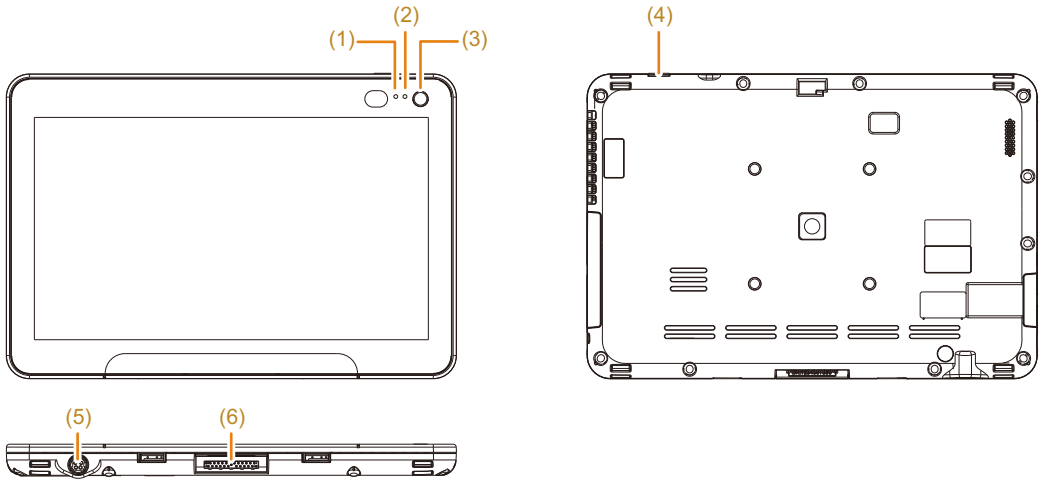
When the instrument is powered by the internal battery, the LED indicates the following conditions.

- When the battery is fully charged: Off
- When remaining battery capacity is 30% : Orange (solid)
- When remaining battery capacity is 15%: Orange (flashing)
- When remaining battery capacity is 0%: Off

(11) **Power switch⟶ p.3-29**

The switch is lit orange in standby. The switch is lit white when power is on.

V) Remote controller (option)



The SD card slot, USB connectors, HDMI connector and the LAN port cannot be used.

(1) **Battery LED**

The blue light is on when power is connected.

When the instrument is powered by the internal battery, it lights or flashes as described below.

- When the battery is fully charged: Off
- When remaining battery capacity is 30%: Orange (solid)
- When remaining battery capacity is 15%: Orange (flashing)
- When remaining battery capacity is 0%: Off

(2) **Power switch LED**

The orange light is on in standby. The white light is on when power is on.

(3) **HOME button**

(4) **Power switch→ p.3-29**

The switch is lit orange in standby. The switch is lit white when power is on.

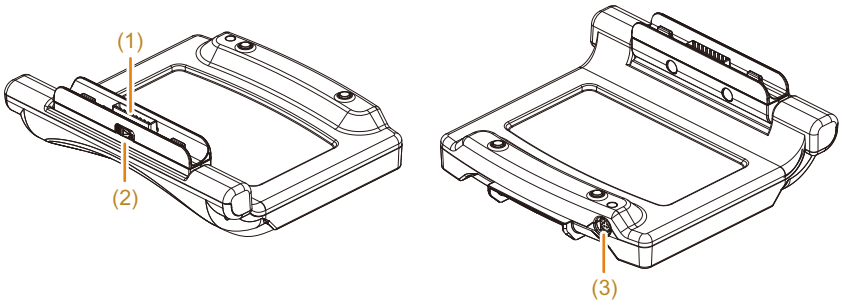
(5) **Remote controller power supply port**

Connect a power cable and AC adapter when the remote controller is removed from the remote controller cradle.

(6) **Unit connector**

Connect the remote controller and the remote controller cradle to these connectors.

VI) Remote controller cradle (option)

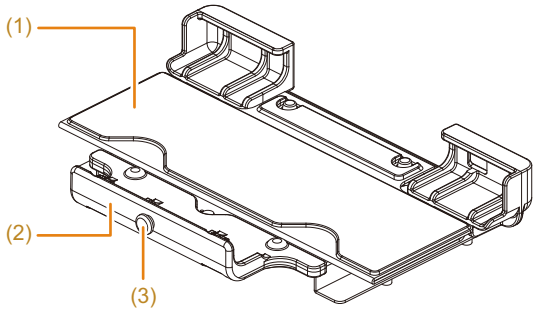


(1) **Unit connector**
Connect the remote controller and the remote controller cradle to these connectors.

(2) **Slider lock**

(3) **Power supply port on remote controller cradle**
Connect the power cable and AC adapter.

VII) Remote controller tray (option)

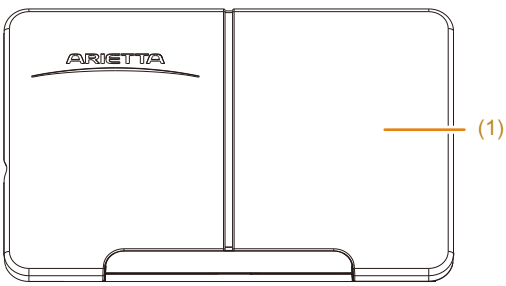


(1) **Remote controller cover**

(2) **Remote controller holder**

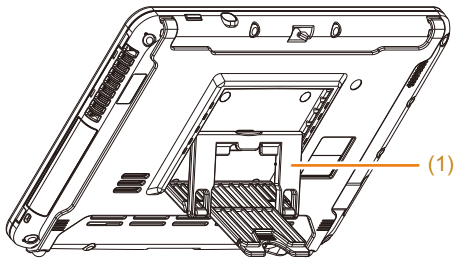
(3) **Knob for securing the remote controller cover**

VIII) Display cover (option)



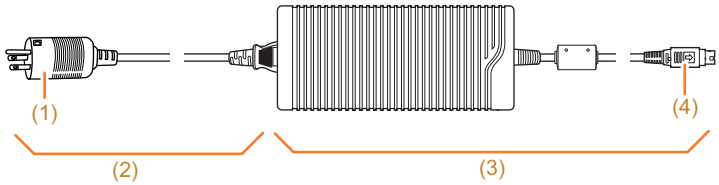
(1) **Display cover**

IX) Multi-Position Stand (option)



(1) Multi-Position Stand

X) Power cable and AC adapter



(1) Power plug

(2) Power cable

(3) AC adapter

(4) AC adapter connector

3 Setup Before Use

3-1 Moving the Instrument

⚠ CAUTION

Take care when moving the instrument in passages and do not let it strike other equipment, walls, columns or doors. Take great care when moving the instrument long distances and up slopes and over bumps.

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

The instrument is heavy and when installed on a cart, it may not easily be stopped once it starts moving.

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

Disconnect the power plug from the hospital grade outlet, gently coil the cable and place it in the storage pocket of the cart.

Probes and Other Peripherals

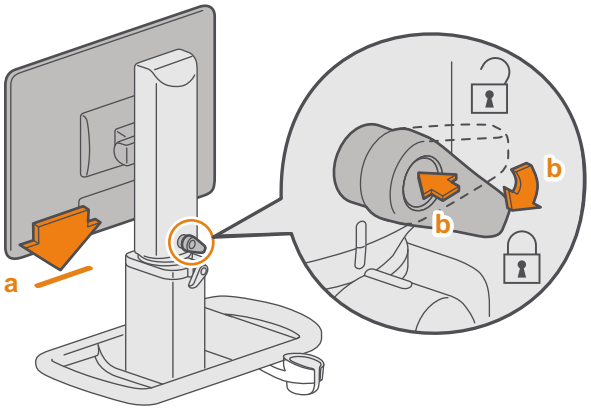
Detach probes, USB flash drives, peripherals etc. from the instrument and put them away in their own cases. Alternatively, wrap them in a soft cloth or similar protective materials.

Monitor Arm (Option)

Secure the monitor arm.

NOTE: Secure the monitor arm before moving the instrument. Otherwise, the monitor could bump into and damage surrounding equipment, the walls or the instrument and the instrument could be overturned, which could lead to injury.

a Hold the display frame by both hands to lower the back end unit to its lowest position.

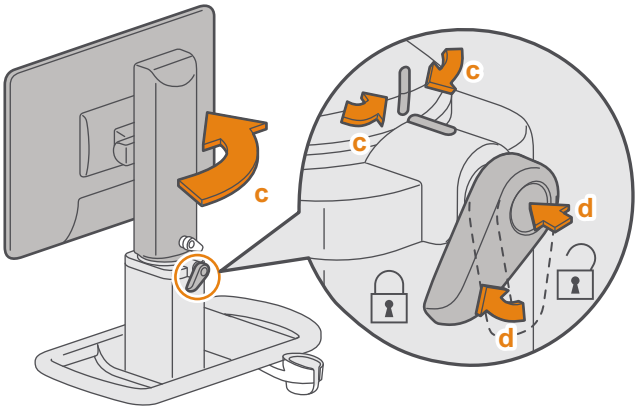


b Hold down the elevating lock lever while turning it to the position shown in the figure .

→ A click will be heard indicating that the monitor arm is locked in place.

c Turn the back end unit to align the bottom rear of the monitor arm with the mark on the cart.

→ The display should face to the left as seen from the rear of the cart.



d Hold down the swing lock lever while turning it to the position shown in the figure .

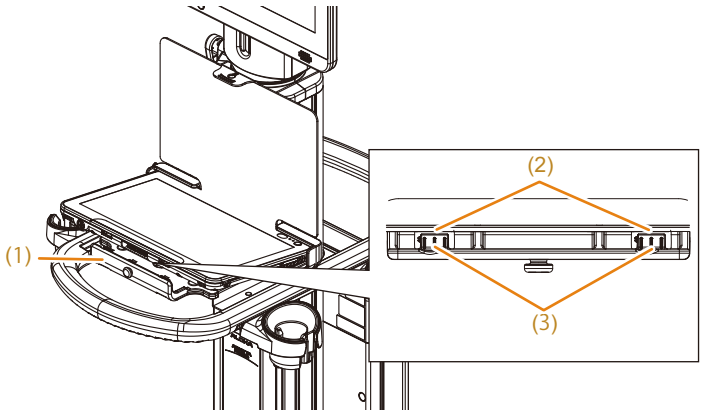
→ The monitor arm is now locked in place.

When the Remote Controller Tray Is Installed

NOTE: Detach the Display cover and the Multi-Position Stand to use the remote controller tray.

a Open up the remote controller cover and install the remote controller in the tray.

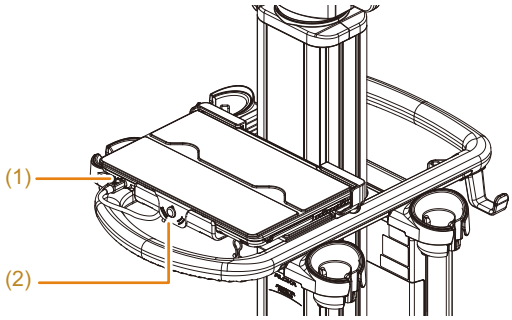
b Fit the protrusions in the remote controller holder into the square holes in the remote controller guide and gently insert the holder.



(1) Remote controller holder
(2) Square holes
(3) Protrusions

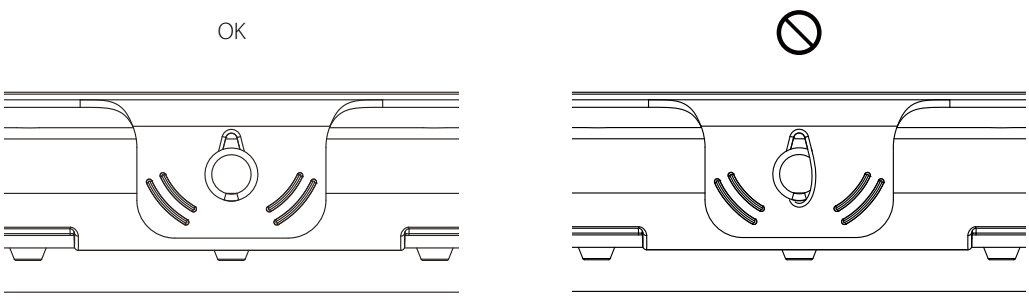
c Latch the remote controller cover to the remote controller cover securing knob on the remote controller holder.

d Connect the DC connector to the remote controller.



(1) AC adapter connector
(2) Knob for securing the remote controller cover

NOTE: The remote controller cover must be latched to the securing knob to secure the remote controller when the instrument will be moved. When latching the remote controller cover to the securing knob, make sure it is completely latched, as shown in the figure below.



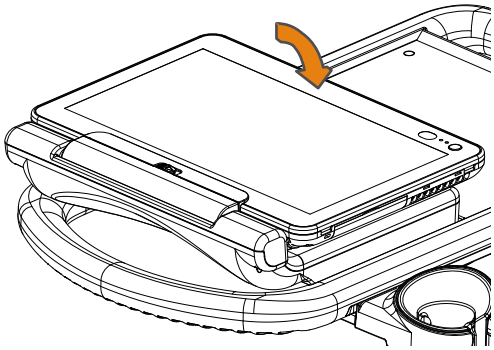
Completely latched

Not completely latched

NOTE: If the remote controller cover is not used or incorrectly oriented, the remote controller could fall.

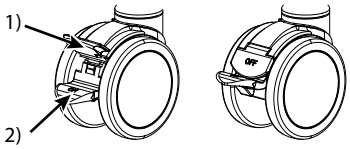
When the Remote Controller Cradle Is Installed

Push the remote controller towards the rear.



2 Press the caster lock release lever to unlock the casters.

Hold the cart handle and push down the lock release lever.

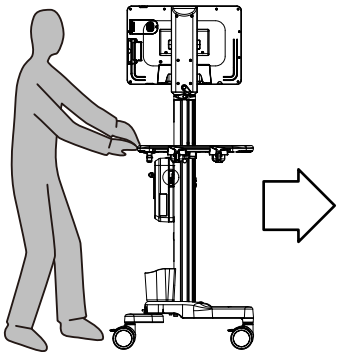


1) Lock release lever
2) Lock lever

3 Move the cart by grasping the handle at the back of the instrument.

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

NOTE: When moving the instrument over a bump, hold the front or rear handle to raise the casters over it. Do not hold instrument by any part other than the handles such as probe holders as it could result in damage to the cart.



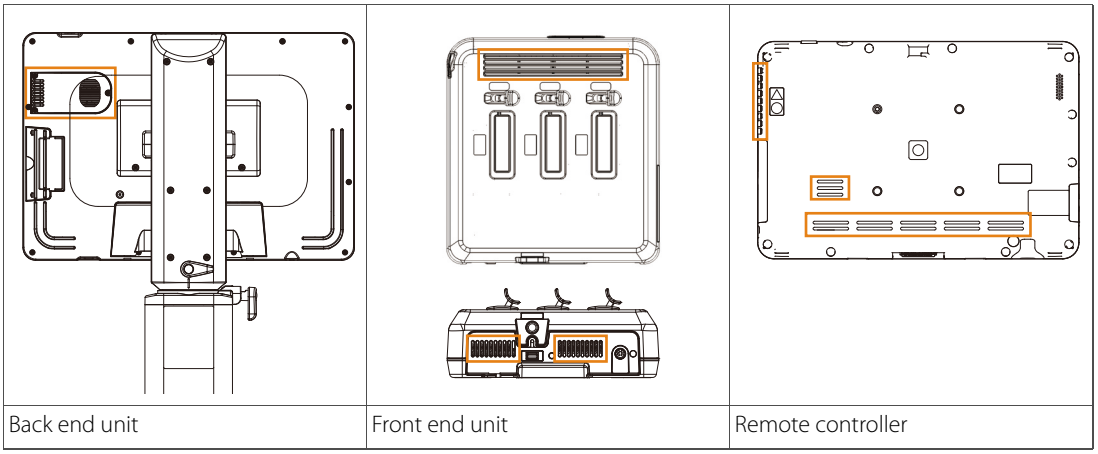
3-2 Installing the Instrument

3-2-1 Installation Conditions

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

- Clearance of 30 mm is required around the instrument to prevent heat from building up inside the instrument.
- Make sure that the air vents are not blocked.

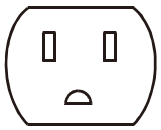
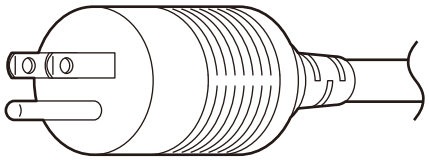
Location of air vents



Back end unit	Front end unit	Remote controller

- Place the instrument on a flat surface and in a location where it will not be exposed to water.
- Install the instrument in a location where its power plug can be plugged into a hospital grade outlet, and where it can be moved quickly when the power is disconnected.
  To turn off the instrument, disconnect the power plug from the hospital grade outlet and set the battery shutdown switch to Disconnect mode.
- 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”.

- The figure shows the type of hospital grade outlets the power plug can be connected to.

Power outlet configuration	
Power plug configuration	

⚠ 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 probe cables as far away as possible from other appliances and their cables.

Exposure to strong irradiation and electromagnetic interference may cause the instrument to malfunction or distort screen images. Do not place them near the instrument.

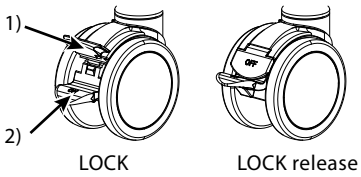
Note that when using this instrument with other medical electrical equipment, the electromagnetic wave the instrument generates could affect the operation of such equipment. Stop using together with such an equipment immediately.

3-2-2 Installing the Instrument

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

2 Once the position and orientation of the instrument have been established, lock the casters.

Hold the cart handle and push down the lock lever.



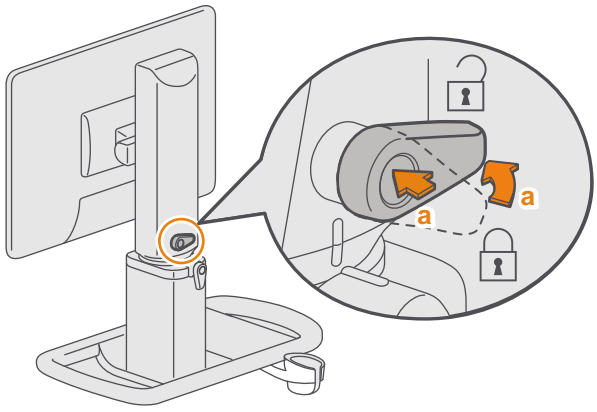
1) Lock release lever
2) Lock lever

NOTE: Place a cloth over the instrument if it is to be in storage for a long period.

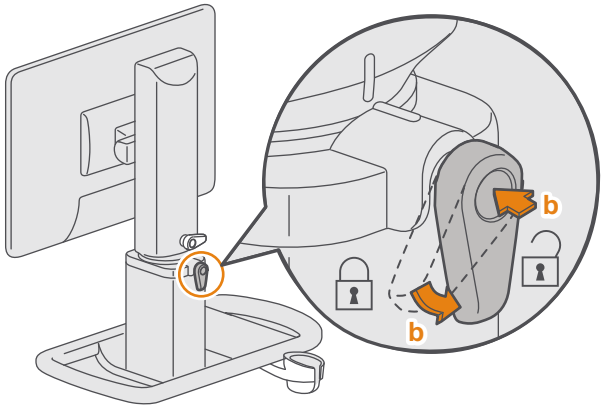
3 Plug the power plug into a hospital grade outlet.

4 If the instrument is equipped with a monitor arm (option), release the back end unit.

a Hold down the elevating lock lever while turning it to the position shown in the figure.



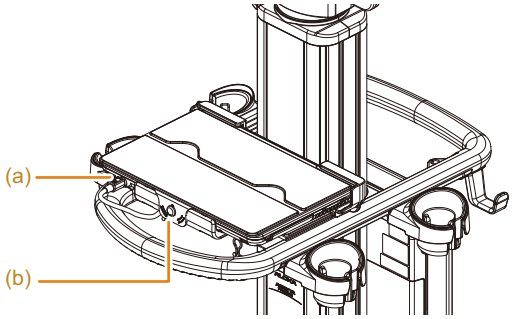
b Hold down the swing lock lever while turning it to the position shown in the figure.



c Adjust the orientation, height and inclination of the back end unit.

Removing the Remote Controller When the Remote Controller Tray Is Installed

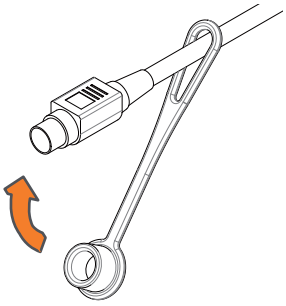
1 Disconnect the AC adapter connector from the remote controller.



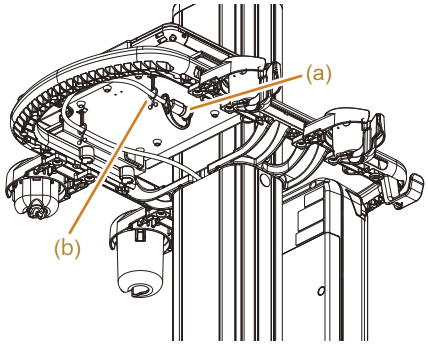
(a) AC adapter connector

(b) Knob for securing the remote controller cover

NOTE: After disconnecting the AC adapter connector, attach the cap and secure it with a clip.



Attach the cap.

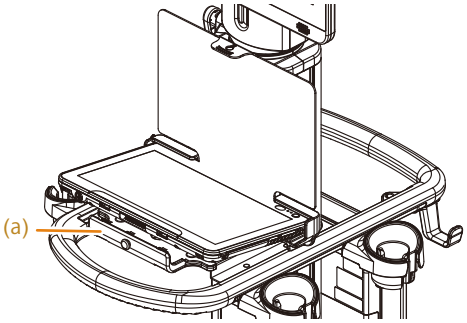


(a) AC adapter connector

(b) Clip

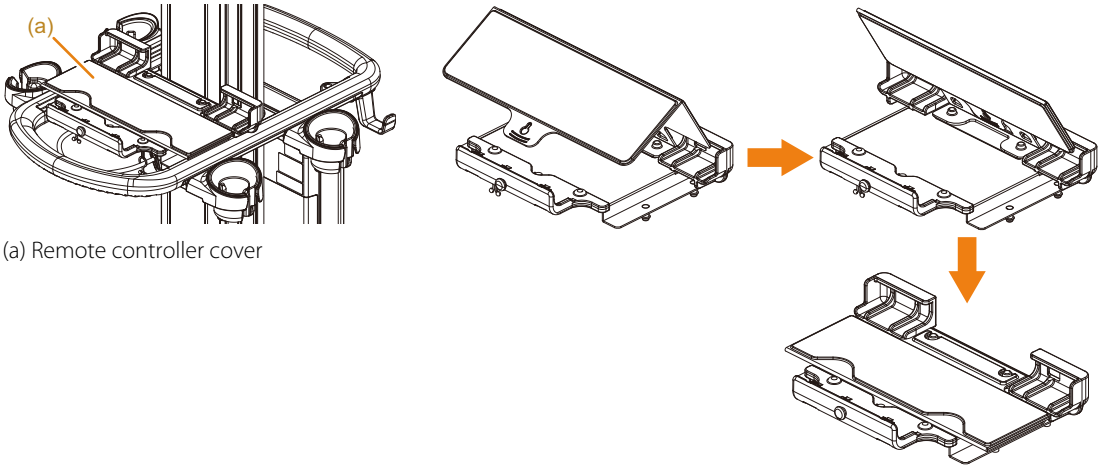
2 Remove the remote controller cover belt from the securing knob.

3 Pull the remote controller holder slightly towards you while raising the front end of the remote controller slightly to pull it out.



(a) Remote controller holder

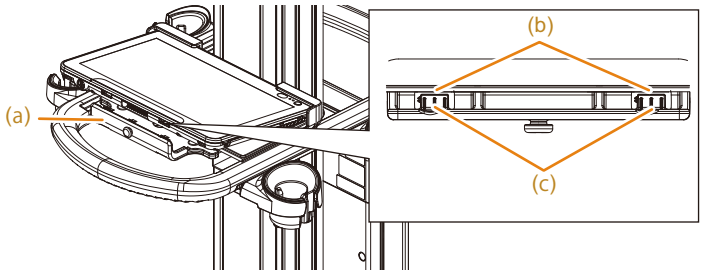
4 After removing the remote controller, fold up the remote controller cover and place it on top of the tray.



(a) Remote controller cover

Installing the Remote Controller When the Remote Controller Tray Is Installed

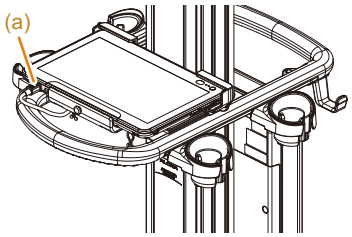
1 Tilt the top of the remote controller to install the tray.



(a) Remote controller holder
(b) Square hole
(c) Protrusion

2 Pull the remote controller holder slightly towards you, fit the protrusions in the remote controller holder into the square guide holes and gently press them in.

3 Connect the AC adapter connector to the remote controller.



(a) AC adapter connector

3-3 Attaching/detaching the Multi-Position Stand

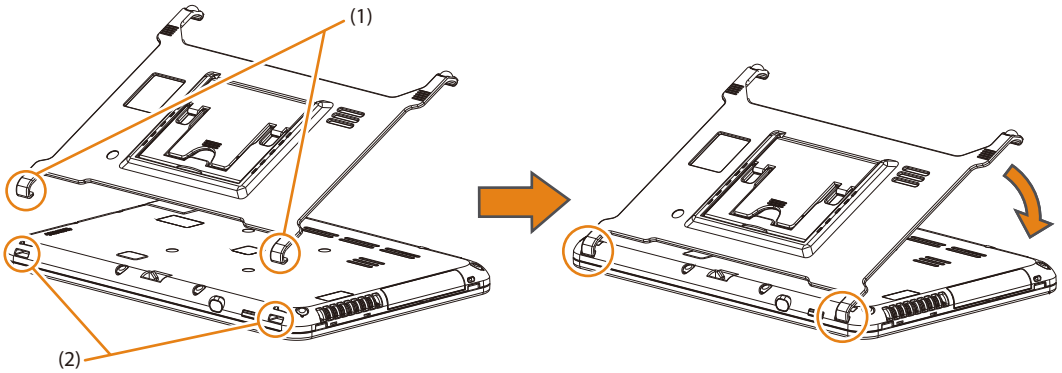
- Detach the Multi-Position Stand to use the remote controller tray.
- Do not open the Multi-Position Stand to a greater angle than necessary. The stand could be damaged.
- Install the Multi-Position Stand in any of the following locations.
  - On a flat surface of adequate strength not prone to vibration.
  - In a location where there is no water or other fluid, no large amounts of salt or sulfur, and no direct sunlight.

  Installing it in other locations may cause injury to the patient or the examiner.
- When moving the remote controller, do not hold it by the Multi-Position Stand. The stand could come loose causing the remote controller to drop leading to remote controller damage or injury to the patient or examiner.
- Do not lean against the remote controller or otherwise expose it to excessive force during use of the Multi-Position Stand. The remote controller and the stand could be damaged or cause injury to the patient or examiner.
- Be sure to properly seat the shaft in the leg of the Multi-Position Stand in a groove before adjusting the angle of the stand. Unless the shaft is properly seated, the remote controller could fall during touch panel operation.

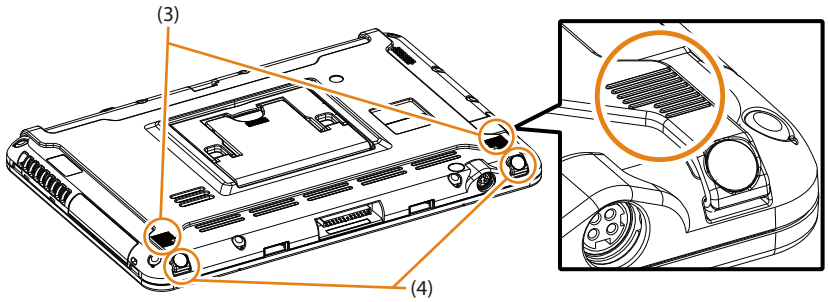
3-3-1 Attaching the Multi-Position Stand

1 Latch the hooks (1) at the top of the Multi-Position Stand to the holes (2) at the top rear of the Back end unit.

NOTE: Take care not to incorrectly orient the Multi-Position Stand.

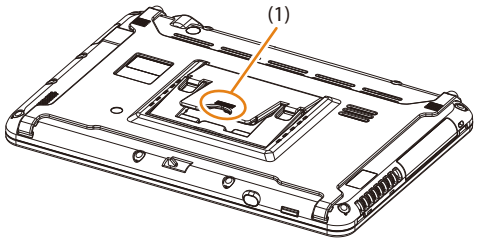


2 Push in the parts (3) in the figure below and latch the hooks at the bottom of the Multi-Position Stand to the holes (4) at the bottom rear of the Back end unit.

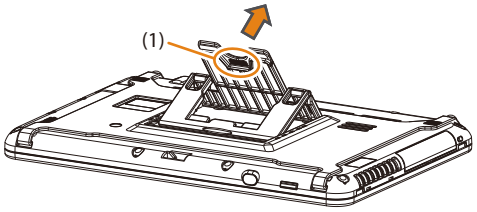


3-3-2 Adjusting the Angle of the Multi-Position Stand

1 Pull out the part (1) at the rear of the Multi-Position Stand.

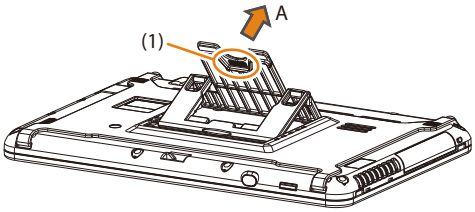


2 Move the part (1) in the direction of the arrow to open the Multi-Position Stand.

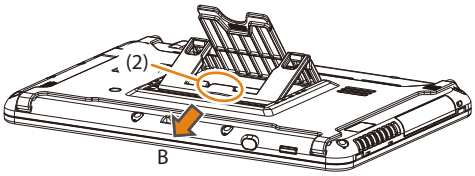


3 Adjust the angle of the Multi-Position Stand.

- Hold and move the part (1) in the direction of arrow A to increase the angle of the Multi-Position Stand.

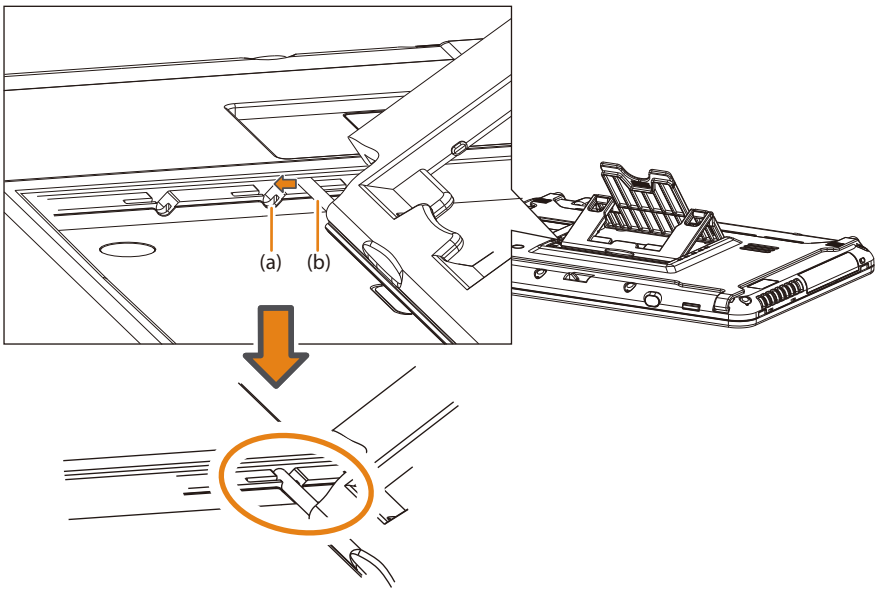


- Hold and move the part (2) in the direction of arrow B to decrease the angle of the Multi-Position Stand.



4 Lock the Multi-Position Stand at the angle you have adjusted it to.

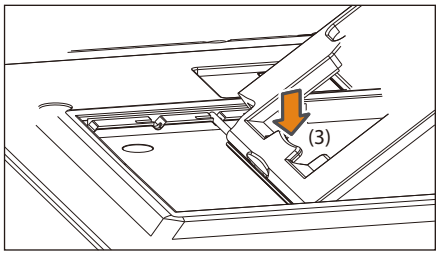
a Make sure the shaft (b) properly engages the groove (a) at the angle you have adjusted it to.



(a) Groove

(b) Shaft

b Gently press in the part (3).



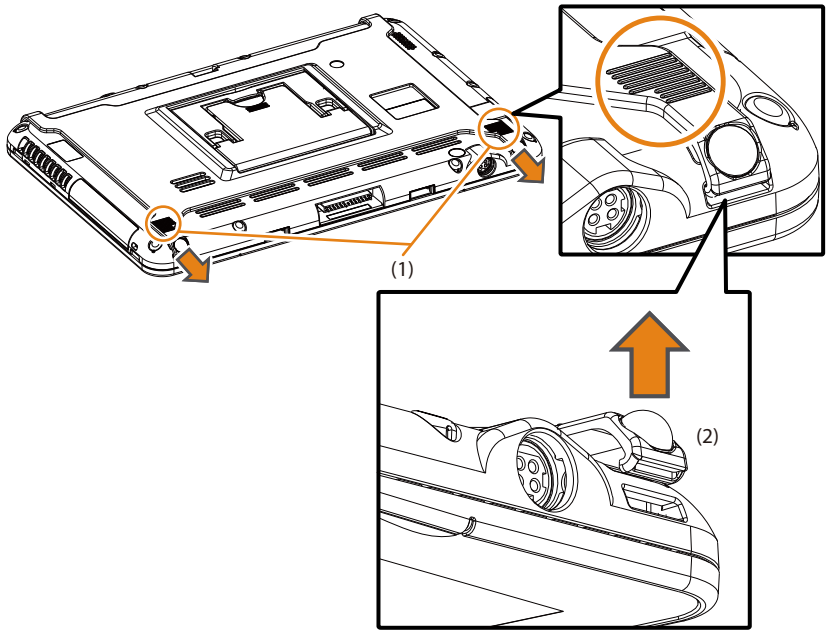
→ The Multi-Position Stand is locked in place.

The Multi-Position Stand can be adjusted to one of three angles: 30°, 45° or 60°.

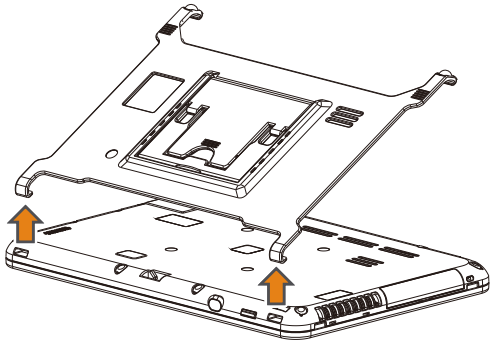
30° 45° 60°

3-3-3 Detaching the Stand

1 Push the parts (2 parts) at the bottom of the Multi-Position Stand (1) in the direction of the arrow while raising the front end (2 hooks) of the hooks (2) to release them.



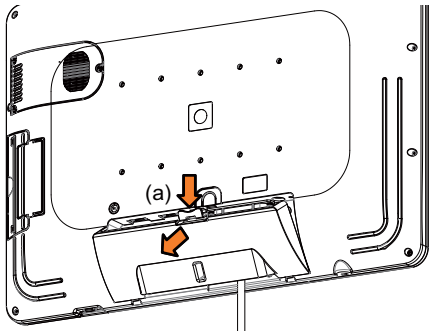
2 Release the hooks at the top of the Multi-Position Stand from the remote controller.



3-4 Removing/Mounting the I/O Cover

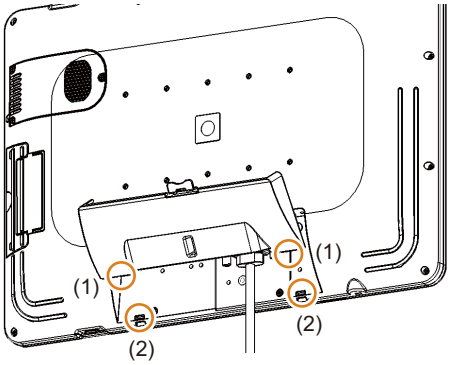
3-4-1 Removing the I/O Cover

- With the tab ((a) in the figure below) of the I/O cover down, pull the cover towards yourself and remove the cover.

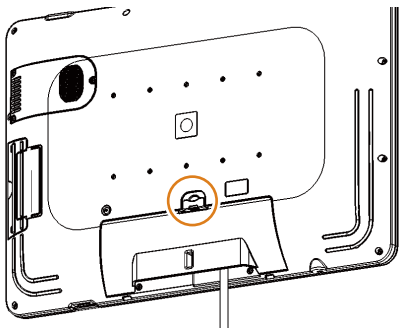


3-4-2 Mounting the I/O Cover

1. Hook the hooks of the I/O cover ((1) in the figure below) in the depressions ((2) in the figure below) in the back of the back end unit.



2. Push the I/O cover into the back of the back end unit and secure it.



3-5 Connecting Unit Cables

Use a unit cable to connect the front end unit and the back end unit of an instrument when the instrument is not equipped with a wireless function.

Also use a unit cable on an instrument when the wireless function cannot provide a reliable connection.

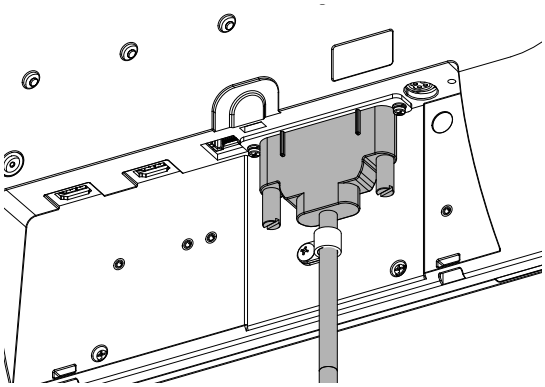
1 Remove the unit cable connector caps from the front end unit.

NOTE: Take care not to lose the removed cap.

2 Confirm connector orientation before firmly inserting the unit cable in the unit cable connector of the instrument.

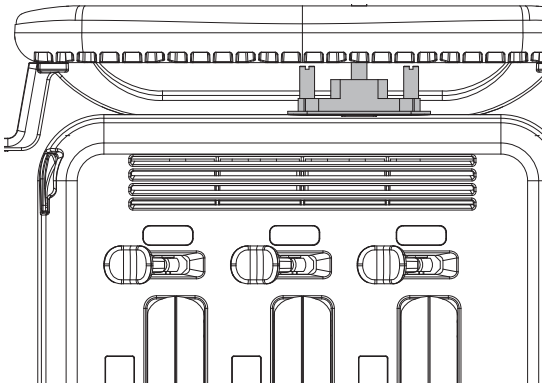
NOTE: Connector orientation can be deduced from the position of the groove.

3 Turn the thumb screws on the right and left side of the cable to secure the unit cable to the instrument.



Unit cable connection

Back end unit side



Unit cable connection

Front end unit side

NOTE: When the unit cable is removed to use the wireless connection, place the caps on the unit cable connectors of the front end unit.

3-6 Connecting the Power Cable and AC Adapter

3-6-1 Precautions when Handling the Power Cable and AC Adapter

⚠ CAUTION

- **Do not connect power cables and AC adapter not specified in this manual to the instrument.**
  Use with unapproved devices can result in an electric shock, burn, or other injury to the patient or examiner, and damage to this instrument.
- **Do not touch any exposed pins in the power supply port while touching a patient.**
  There is a risk of shorting and of electric shock to the patient.
- **Do not use your feet or hands to pull the power cable and AC adapter.**
  The cart could tip over resulting in instrument damage and injury to people. The connector could also be damaged.

NOTE: When the front end unit and back end unit are connected by cable, the power cable and AC adapter need not be connected to the back end unit. The back end unit is supplied with power via the unit cable.

3-7 Connecting a Probe

⚠ CAUTION

Do not allow sterilized probes to come into contact with the instrument, the cart or the probe holder.
The instrument and the cart are not intended to be sterilized.

⚠ 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 Make sure the probe is one that can be connected to the instrument.

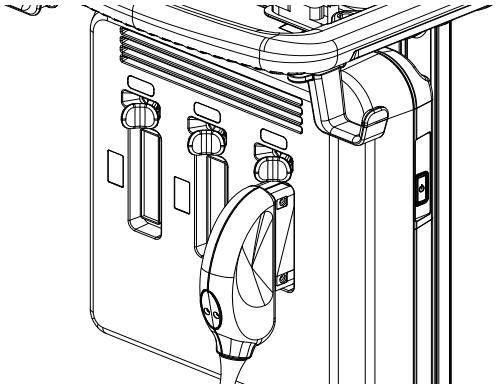
NOTE: You need the JB-298 Junction Box to use the UST-5310 and UST-5311. For information on how to connect the junction box, refer to the documentation supplied with the JB-298.

1 The instrument must be shutdown or frozen.

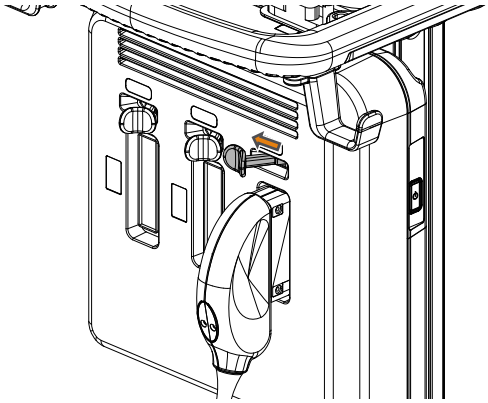
2 Remove the cap from the probe connector you will connect a probe to.

NOTE: Take care not to lose the removed cap.

3 Plug the probe into a probe connector.



4 Hold the probe still while you push the lock lever to the left.



NOTE: Make sure the probe is secured.

5 Place the probe in the probe holder (option).

6 Adjust the probe cable to a convenient length.

Use the probe cable hook on the cart to adjust the position and length of the probe cable so that it does not touch the floor.

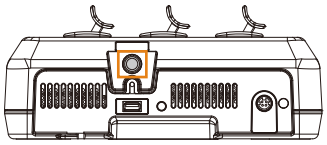
3-7-1 Disconnecting a Probe

1. Shut down the instrument. Or freeze the probe.
2. Hold the probe still while you push the lock lever to the right.
3. Remove the probe from the probe connector.
4. Install a cap in the probe connector.

3-8 Connecting a Cable from an External Physiological Signal Monitor

Connect the output cable from an external physiological signal monitor to the DC IN connector on the front end unit.

- Connect the output cable from an external physiological signal monitor to the DC IN connector.



NOTE: Before connecting the output 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 external physiological monitor used together with the instrument.

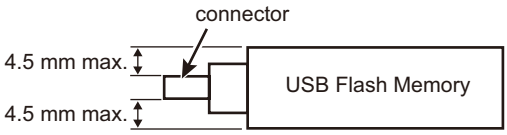
3-9 Connecting to Other Connectors

3-9-1 Connecting to a USB Connector

The USB connectors are found inside the USB cover.

Side panel of the back end unit

NOTE: Use a USB flash memory stick with a height from the bottom to the top of the connector that is less than 4.5 mm.



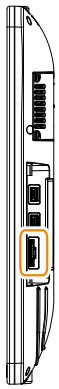
The physical configuration of some USB flash drives may prevent their use. Check whether your USB flash instrument can be connected to the device before trying to use it.

NOTE: Note that opening the terminal cover to allow the connection of a USB flash drive compromises the waterproofing level (IPX2) of the back end unit.

3-9-2 Inserting an SD Card

SD, SDHC and SDXC cards can be connected.

The SD card slot is inside the USB cover at the location shown in the figure.



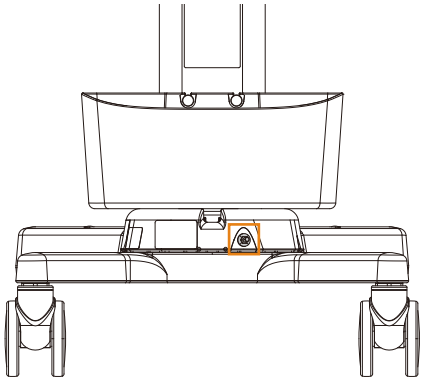
Side panel of the back end unit

NOTE: Make sure the notch of the SD-card is down and insert the metallic terminals in first.

3-9-3 Making Connections to the Equipotential Terminal

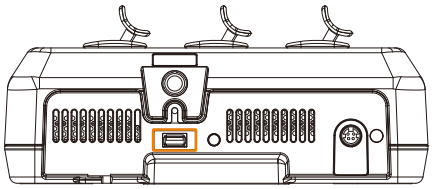
Use this terminal when interconnecting with other devices.

Make a connection to the equipotential terminal on the back of the cart.



3-9-4 Connecting a Foot Switch (Option)

1 Connect the connector on the foot switch to the dedicated foot switch connector on the front end unit.



2 Use the preset to assign functions to the foot switch.

3-9-5 Safety Instructions for Connecting Network Devices

The electromagnetic compatibility (EMC) of this instrument is in conformity with the IEC 60601-1-2: Ed.2 Am.1, which is the international standard for EMC of medical instruments.

The following instructions are applicable, when connecting the diagnostic ultrasound system to non-medical network devices.

The entire configured system must comply with the ME system regulation (clause 16 of IEC 60601-1: Ed.3). If there are any other ordinances, those should be prioritized. For more details, please contact our office.

I) Network devices

All non-medical network devices connected to the diagnostic ultrasound system (non-medical devices such as hubs, work stations and personal computers) 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)
	Cross (when connecting to a PC directly)
Max. cable length	20 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 1.5 m area 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 any cables other than those specified or cables that exceed the maximum length.
It could pick up electromagnetic interference.

⚠ NOTE

Connection of this instrument to the IT network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.
Contact your network administrator for the hospital network if a problem occurs after changing the IT network.
Changes in the IT network may lead to new and unacceptable risks, which require additional risk management.
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.

3-9-6 Safety Instructions for Robotic Surgery Unit

When you connect the ARIETTA Precision to a medical device which requires ANALOG video signal input, HDMI output signal of this device should convert to ANALOG video signal by ANALOG down converter. Also, when you connect it to a medical device which requires DIGITAL video signal input, HDMI output signal of it should convert to DVI output signal by the convert adapter or convert cable. Therefore, External Output must be set to “DVI” . For details, refer to the separate “Detailed Operating Instructions” manual. When converting output signal, use an optical fiber cable or similar to secure the isolation between this ultrasound device and the converter.

3-10 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:

- ☐ Exterior
- ☐ Power cable , power plug and AC adapter
- ☐ External physiological signal cable

Checking consumables

- ☐ Replace or replenish the ultrasound gel.

Visual check and inspection items for 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 connectors must be free of holes, dents, cracks and deformation
- ☐ The cables and connectors must be free of scratches, cracks and deformation

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

2 Adjust the back end unit for ease of viewing.

3 Connect the probe to use.

3-11 Powering up

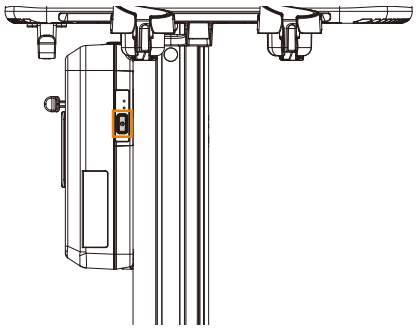
- Hold down the power switch for 1 second or more.

  When connected by cables

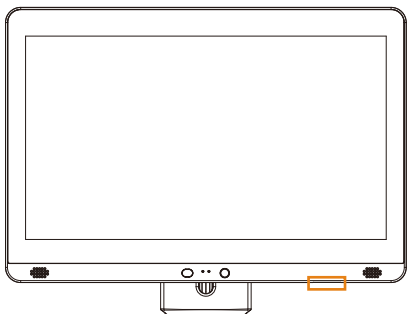
  Press the power switch on the front end unit or the back end unit.

  When connected wirelessly

  Press the power switch on the back end unit.



Front end unit power switch



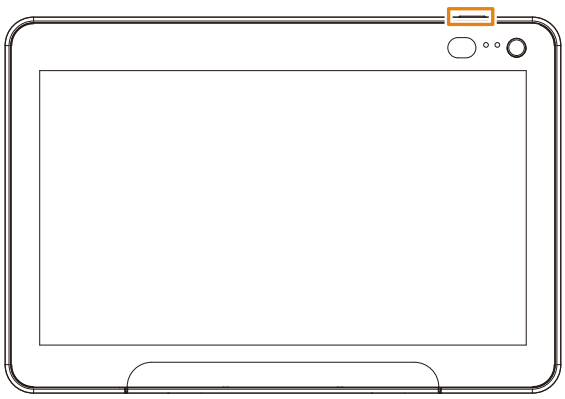
Back end unit power switch

→ The power LED lights up white and the Home Screen appears.

3-11-1 Turning on the Remote Controller (Option)

NOTE: Turn on the remote controller when all instrument units have been turned on.

- Hold down the power switch on the remote controller for 1 second or more.



Remote controller power switch

→ The power LED lights white and the remote controller is powered.

3-11-2 Turning on encrypted equipment

If the hard disk of the equipment is encrypted, decrypt it by using the password or the start-up key.

Prior Confirmation Requires the alphanumeric keyboard.

NOTE: If the recovery key was stored on a USB connection media, the recovery key is saved to the root folder of the media.

NOTE: Connect the USB connection media to a USB connector on the side panel of the back end unit.

Decrypting the hard disk by using a password

1 Push the [Power] key.

→ The password input window appears.

2 Enter the password.

Using a USB connection media on which the recovery key is stored if you forget the password

a Push the [Esc] key on the alphanumeric keyboard.

→ The decryption window appears.

b Connect the USB connection media on which the recovery key is stored to the USB connector.

Using a recovery key recorded as a memo if you forget the password

a Push the [Esc] key on the alphanumeric keyboard.

→ The decryption window appears.

b Push the [Esc] key on the alphanumeric keyboard.

→ The recovery key input window appears.

c Enter the recovery key that you recorded as a memo.

3 Push the [Enter] key on the alphanumeric keyboard.

Decrypting the hard disk by using a start-up key

1 Connect the USB connection media on which the start-up key is stored to a USB connector. You can connect the media either before or after pushing the [Power] key.

Using a USB connection media on which the recovery key is stored if the start-up Key is lost

a Push the [Power] key.

→ The decryption window appears.

b Connect the USB connection media on which the recovery key is stored to a USB connector.

Using a recovery key recorded as a memo if the start-up key is lost

a Push the [Power] key.

→ The decryption window appears.

b Push the [Esc] key on the alphanumeric keyboard.

→ The recovery key input window appears.

c Enter the recovery key that you recorded as a memo.

2 Push the [Enter] key on the alphanumeric keyboard.

3-12 Inspections and Verifications After Powering up

Turn on the instrument and inspect and check what is displayed on the screen.

Confirm the window that is displayed.

Inspection and Check items

- ☐ The screen should correctly display an ultrasonic image and related icons
- ☐ 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 frequency information displayed. If no probe is connected, the frequency information must indicate "NO PROBE".

  If probe information displayed does not match the connected probe, a malfunction may have occurred. When this happens, stop using the instrument and contact our office.

If the "NO PROBE" message appears on the screen

A probe has not been connected. Take the following measures to solve a "NO PROBE" situation.

a Connect a probe.

b Press the HOME button.

→ The Home Screen appears.

c Enter patient information.

d Select a probe.

→ The image for the selected probe image appears.

3-13 Adjusting the Screen

3-13-1 Adjusting Position and Orientation of the Back End Unit

⚠ CAUTION

Adjust the position and orientation of the back end unit keeping a sufficient distance between the instrument and surrounding equipment, walls and people.

Make sure neither the back end unit nor cables and other parts connected to the back end unit come into contact with objects or people in the surroundings.

Make sure probe cables do not become entangled with handles on the back end unit, monitor arm and cart.

Contact with the back end unit may result in injury to people or in damage to surrounding equipment, walls, probes or the back end unit. Warn doctors, patients, and others in the area before adjusting the position and orientation of the back end unit.

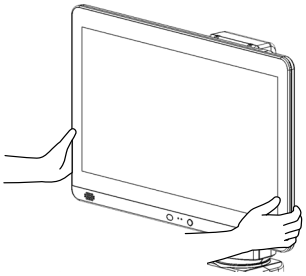
Should the display break and its internal fluid come into contact with the skin, wipe it away and wash the skin in running water for at least 15 minutes. To be on the safe side, consult a doctor. If it gets in someone's eyes, rinse them in running water for at least 15 minutes, and be sure to consult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

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

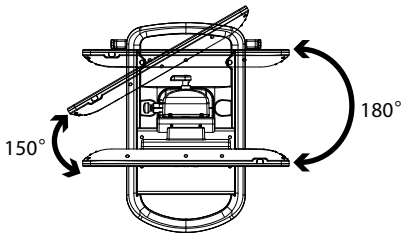
Be careful not to pinch your hands or fingers in the monitor arm when adjusting the location or orientation of the back end unit.

Injury from trapping your hands and fingers may result.

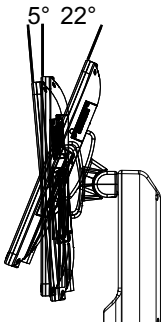
- Hold the back end unit with both hands by its frame when adjusting its position or orientation.



Movable range of the back end unit

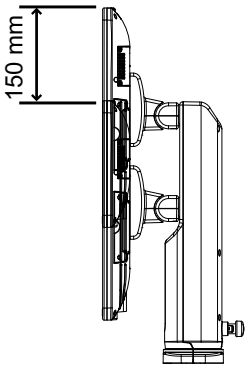


330° in right and left direction



Tilt

5° forward, 22° back



150 mm up and down

3-13-2 Adjusting the Tilt of the Remote Controller Cradle (Option)

⚠ CAUTION

Adjust the inclination of the remote controller keeping a sufficient distance between the instrument and peripheral equipment, walls and people.

Do not knock a USB flash drive or other parts connected to the remote controller against probes, a probe holder or other parts.

Make sure probe cables do not become entangled with the remote controller.

Contact with the remote controller may result in injury to people or in damage to surrounding equipment, walls, probes or the remote controller. Warn doctors, patients, and others in the area before adjusting the inclination of the remote controller.

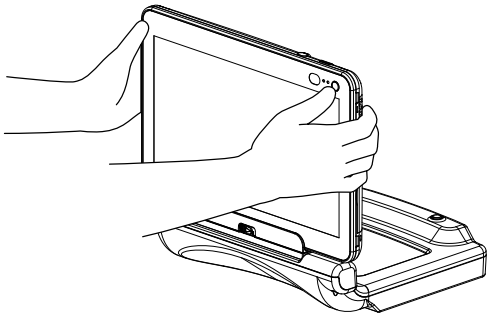
Should the display break and its internal fluid come into contact with the skin, wipe it away and wash the skin in running water for at least 15 minutes. To be on the safe side, consult a doctor. If it gets in someone's eyes, rinse them in running water for at least 15 minutes, and be sure to consult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

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

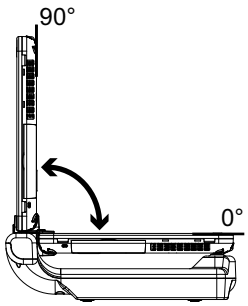
Be careful not to pinch your hands or fingers when adjusting the inclination of the remote controller.

Injury from trapping your hands and fingers may result.

1 Hold the remote controller with both hands by its frame when adjusting its tilt.



NOTE: Do not move the cart by holding the remote controller. The instrument could be damaged or fall.



Movable range of remote controller

Tilt

0° to 90°

3-13-3 Adjusting Brightness of the Display

1 Swipe the ultrasonic image area upwards from the lower edge.

→ This action displays the function menu.

2 Select the [Other] tab.

3 Select or to display "Monitor Brightness" / "Monitor Contrast" / "Monitor BackLight" .

4 Adjust brightness.

Item	Settings	Functions
Monitor Brightness	"0" to "20"	Adjusts brightness of the display.
Monitor Contrast	"0" to "20"	Adjusts contrasts of the display.
Monitor BackLight	"0" to "20"	Adjusts backlight intensity of the display.

3-14 Running the Instrument on the Internal Battery

The instrument has an internal battery. This allows you to move the instrument after startup, perform examinations in locations without power and use the instrument after removing the remote controller (option) from the remote controller cradle.

3-14-1 Charging the Internal Battery

NOTE: Before charging the internal battery, set the battery shutdown switch to Connect mode.

- Plug the power plug into a hospital grade power outlet.

  → Use the icons  on the display to check remaining battery capacity.

  NOTE: Charging the battery in an environment above 86°F will raise the temperature of the internal battery and result in termination of battery charging. The temperature of the internal battery rises during use and charging may not start immediately when it is connected to a power outlet. Put the instrument in standby to lower battery temperature.

Reference Information Information Area → p.4-6

3-14-2 Removing the Remote Controller (Option) from the Remote Controller Cradle (Option)

⚠ CAUTION

Do not knock the remote controller against the monitor arm when installing or removing the controller.
You could pinch your hands and fingers and injure yourself or damage the monitor arm or the back end unit.

When holding the remote controller be sure not to place your hands over any air vents.
Prolonged contact may result in low-degree burns.

Do not drop the remote controller.
The unit could be damaged or it could injure somebody.

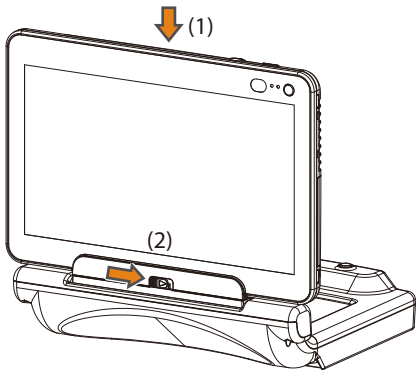
When the unit has not been used for an extended period of time, make sure the connectors are not clogged with dust.
Otherwise, a fire may result.

When the AC adapter is connected to the remote controller, if you plug the power plug into a hospital grade power outlet, you can use the instrument while charging the battery.

NOTE: Before charging the internal battery, set the battery shutdown switch to Disconnect mode.

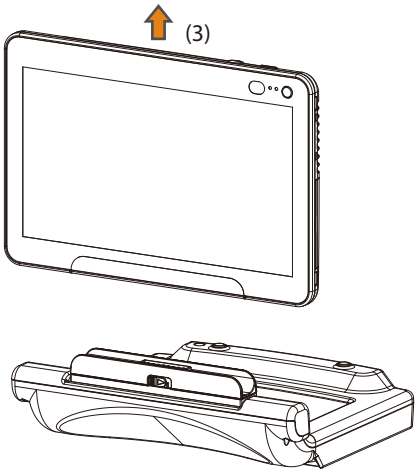
- Use this lever to remove the remote controller from the cradle unit.

  a Gently insert the remote controller (1) from above and slide the slider lock (2) in the direction shown in the figure.



NOTE: Gently pressing down on the remote controller will make it easier to move the slider lock.

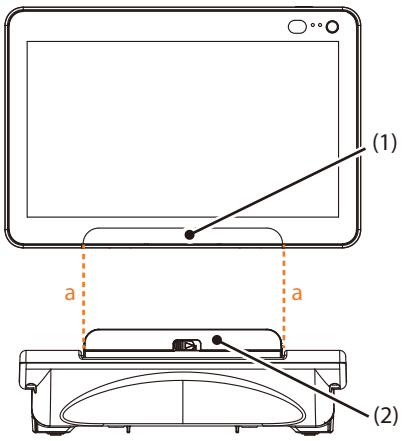
b Pull the remote controller (3) straight up at a right angle to the cradle connectors for the remote controller to remove it.



NOTE: Do not use excessive force when removing. You could damage the connectors.

- After use, attach the remote controller to the cradle unit.

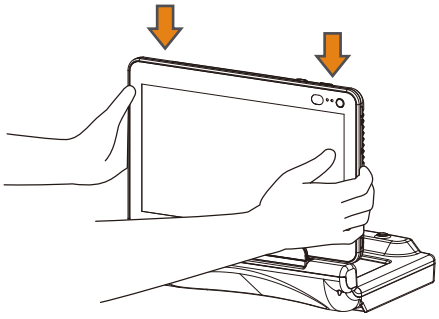
a Align the edge of the protection sheet with the edge of the hinge.



(1) Protection sheet

(2) Hinge

b Hold the remote controller with both hands at a right angle to the connectors for the remote controller to install it.

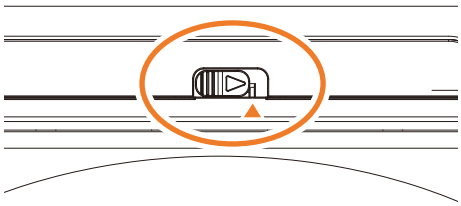


→ The battery LED on the remote controller lights blue indicating that charging has started.

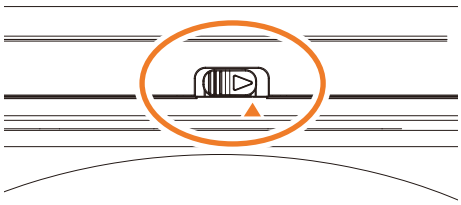
NOTE: Do not use excessive force when installing. You could damage the connectors.

NOTE: The slider lock slides back. Hold the remote controller with both hands to firmly push it down until you see the guide mark as shown in the figure below.

OK



Slider lock position when fully returned (and the guide mark is visible)



The slider lock has not been fully returned (and the guide mark is not visible)

⚠ CAUTION

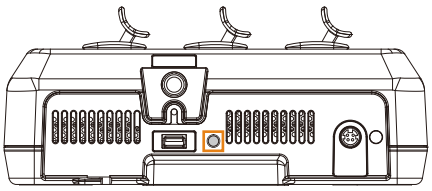
Do not use the instrument if the slider lock has not been fully returned.

If the instrument is used without fully returning the slider, communication errors may occur or the remote controller may come loose.

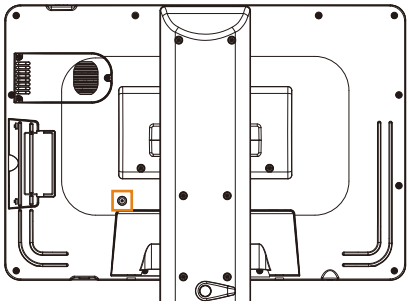
3-14-3 Turning off the Internal Battery

When the instrument will not be used for a longer period of time, be sure to turn off the internal battery.

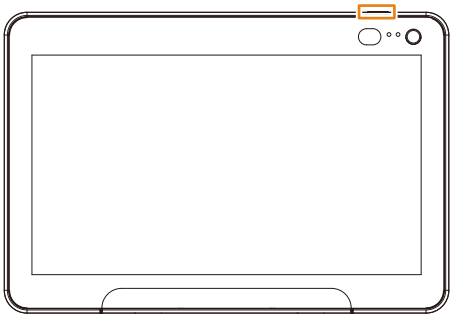
- Set the battery shutdown switch to Disconnect mode.



Front end unit side



Back end unit side



Remote controller side

→ Turns off the power supply from the internal battery to each unit.

Resuming Use of the Internal Battery

- Set the battery shutdown switch to Connect mode.
  - ◆ Front end unit side and back end unit side

    Hold down the battery shutdown switch.
  - ◆ Remote controller side

    Slide the battery shutdown switch upwards.

→ The battery starts supplying the each unit with power.

4 Using the Touch Panel

4-1 How to Use the Touch Panel

The instrument has a touch panel. You can use your fingers or a stylus pen to directly make entries or control objects on the screen. Use the following methods to handle screen control operations.

- Tap

  Lightly touch a button or object on the screen and then quickly remove your finger from the screen.

  This allows you to start an operation, select an item and perform most of the functions the instrument provides.

- Double tap

  Lightly touch a button or object on the screen twice in rapid succession.

  Use this function to select an image in ImageViewer to see it in full screen view.

- Touch and hold

  Touch and hold a button or item on the screen.

  Use to operate functions such as Direct to B.

- Swipe

  Lightly touch the screen and drag your finger in the intended direction.

  Use this function to scroll menus, turn pages and perform other operations.

  It can also be used to display the function menu.

- Pinch out/Pinch in

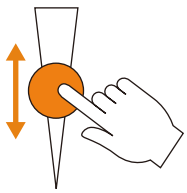
  Place two fingers on the screen, and widen (pinch out) or narrow (pinch in) the distance between them.

  Use this function to enlarge or reduce an image.

- Drag

  Grab something displayed on-screen and move it to the desired position.

  Use this function to adjust gain or zoom, move the cursor and so on.



4-1-1 Touch Panel Precautions

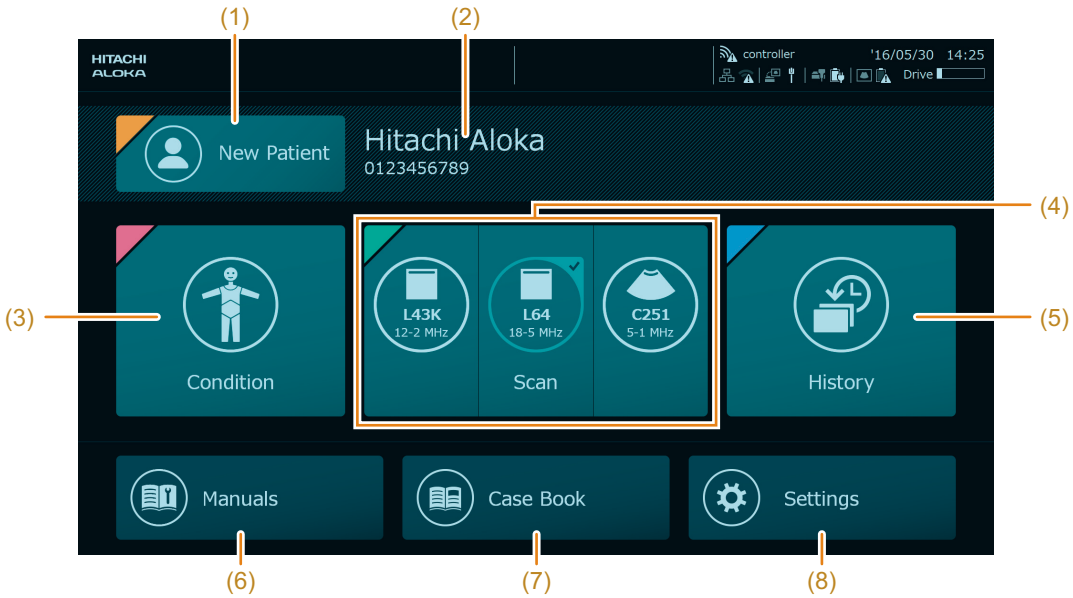
- Handle the touch panel gently. Do not press hard or press it with a pointed object.
- Do not place anything on the top of the touch panel. The touch panel may respond to pressure, which could result in an incorrect entry.
- In the following cases, the touch panel may not register contact.
  - The modes of operation when it is covered with protective film
  - Entries made with your fingernails
  - Entries made with gloved hands
  - Entries made when there are water drops on the screen
  - Entries made with wet fingers

4-1-2 Stylus Pen (commercially available) Precautions

- Use a stylus pen designed for a capacitive touch panel.
- The material in the stylus pen front end may make recognition difficult.
- Handle the touch panel gently. Do not press hard.
- The panel may not register contact if the stylus pen is tilted.
- Make sure your hand or fingers do not touch the screen when using a stylus pen. Otherwise entry errors may occur.
- Please also refer to the instruction manual supplied with the stylus pen.

4-2 Home Screen

Appears after the HOME button is pressed.



(1)	[New Patient]	Tap to enter patient data.
(2)	Patient ID	Displays the patient ID.
(3)	[Condition]	Enter body part examined, patient body shape, probes that will be used and other scanning conditions to start scanning.
(4)	[Scan]	Opens the scanning screen for selecting a probe.
(5)	[History]	Displays the patient history screen.
(6)	[Manuals]	Displays the instruction manual.
(7)	[Case Book]	Opens the case guide.
(8)	[Settings]	Displays the Common Preset menu. Use this menu for making settings.

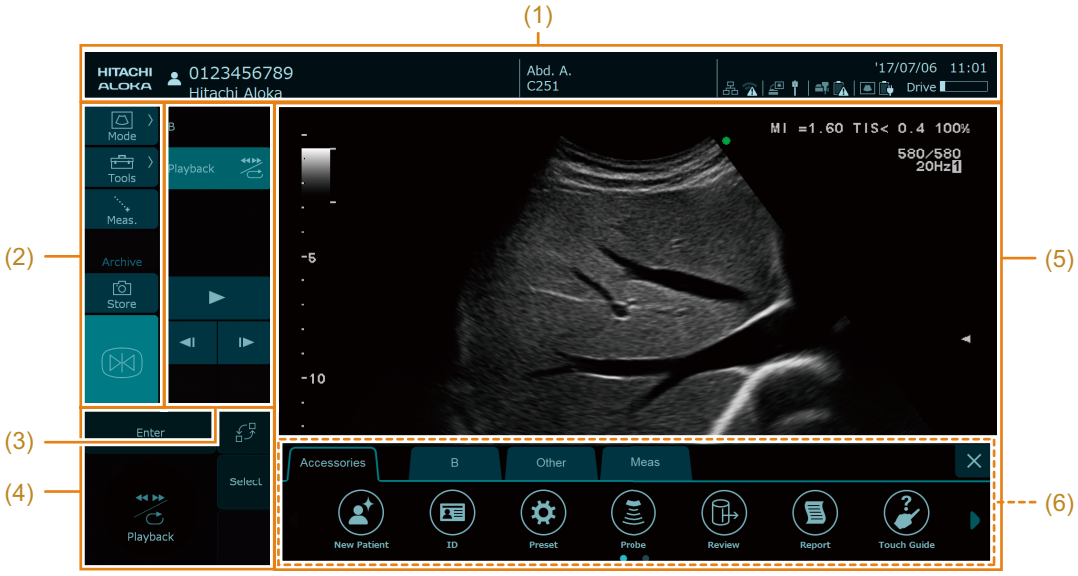
NOTE: The HOME button may not work when messages are displayed or the Review screen is open.

NOTE: Pressing the HOME button will cancel ongoing operations and entries made so far.

4-3 Scanning Screen

4-3-1 Display screen

The scanning screen has the following layout.

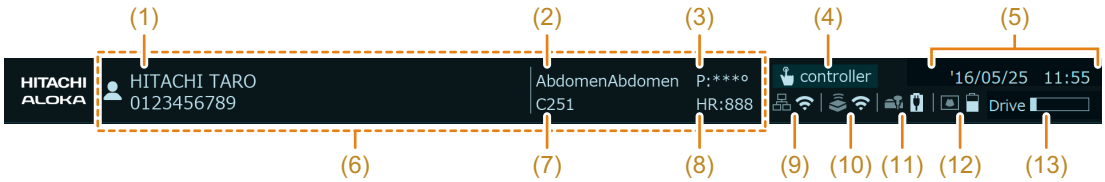


Scanning Screen Configuration

(1)	Information Area	Displays patient data, messages and icons indicating instrument status and other conditions.
(2)	Smart Switch Area	Displays frequently used functions such as Freeze, Change Mode and other buttons.
(3)	Slide Control Area	Displays buttons that extend the functionality of the button selected in the smart switch area.
(4)	Trackpad Area	Use this area for moving the cursor.
(5)	Ultrasonic image Area	Displays ultrasonic images.
(6)	Function Tab Area	Use this area to open the function menu and access any of the functions it provides.

NOTE: You can turn On Mirror Inversion Display in the preset (Common Preset > Common3) to mirror invert the analysis screen configuration after restart, so that areas (2), (3), and (4) on the left side of the screen are switched with the ultrasound image area (5) (as well as the function tab area (6)).

4-3-2 Information Area

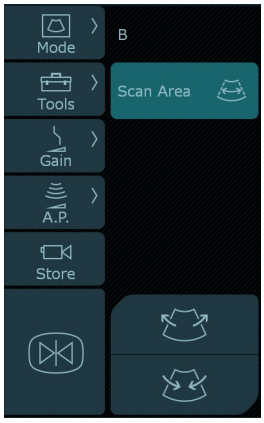


Information Area

(1)	Patient Data	Displays the patient ID and patient name.
(2)	Preset name	
(3)	Puncture Angle	
(4)	Remote controller connection status	: Operates as a remote control : Operated by the remote controller : Connection error
(5)	Date/Time	During real-time image display: Current time In freeze mode: Time when image was frozen In review mode: Time when image was saved
(6)	Assist Message display area	Under some instrument conditions, it may display a message.
(7)	Name of selected probe	
(8)	Heart-rate	
(9)	Indicates the connection status between the back end unit and the Wi-Fi access point or LAN	- : Reception intensity (Strong) - (Weak) : Connection error : LAN connection
(10)	Connection status between the front end unit and back end unit	: Communication enabled (both Wi-Fi and Bluetooth are operational) : Communication disabled (Wi-Fi or Bluetooth is disabled or both are disabled) : Connection error : Connect with a unit cable
(11)	Remaining battery capacity in front end unit	- : Remaining battery capacity (High) - (Low) : Charging : Charging error
(12)	Remaining capacity of battery in the back end unit	- : Remaining battery capacity (High) - (Low) : Charging : Charging error
(13)	Available space on the instrument hard disk	- : Available space on the instument hard disk (small) - Available space on the instument hard disk (large) : Available space on the instrument hard disk error

4-3-3 Smart Switch Area and Slide Control Area

The slide control area displays buttons that extend the functionality of the button selected in the Smart Switch Area.



Smart Switch Area	Slide Control Area	Description
Mode	B	Displays images in B mode.
	Dual	Divides the ultrasonic image area into two areas.
	Color	Displays images in Color Flow mode.
	eFlow	Displays images in eFlow mode.
	Power	Displays images in Power Doppler mode.
	PW	Displays images in B/PW mode.
	M	Displays images in B/M mode.
	Touching and holding [Mode] in a real-time image will display a B mode (Direct to B function) image.	
Tools	Full Image	Displays an enlarged area of the ultrasonic image.
	Depth	Adjusts display depth.
	Focus	Adjusts the location of the focal points and the distance between them.
	TGC	Adjusts TGC.
	Measurement	Starts the basic measurement function.
	Comment	Allows you to enter comments on the screen.
	Zoom	Starts the zoom function.
	Body Mark	Allows you to select a body mark.
	Scan Area	Adjusts the width and location of the Scan Area.
	Meas.Menu	Starts the applied measurement functions.
	PlayBack	Performs search and loop playback of cine memory.
	Cursor	Sets or moves the cursor, sample volume, the baseline of the Doppler pattern and performs other functions.
	Full M/D	Displays M-mode or D-mode images in 1 screen.
	FAM	Starts FAM.
	TDI	Starts TDI mode.
	Quad	Divides the ultrasonic image area into four areas.
	Print	Starts the print function.

Smart Switch Area	Slide Control Area	Description
	Archive	Saves an ultrasonic image to a registered storage device.
	Send	Transfers measurement results to the report.
Gain*1	B	Adjusts the gain in B mode.
	B/Color	Adjusts B mode and color mode gain.
	B/D	Adjusts B mode and D mode (PW) gain.
	B/M	Adjusts B and M mode gain.
	Touching and holding [Gain] will start Auto-optimizer.	
Meas.*2		Displays the basic measurement menu and caliper mark.
A.P.		Adjusts Acoustic Power.
Store		Saves ultrasonic images.  : Waiting to save still image  : Waiting to save moving image  : Saving moving image
FREEZE		Freezes ultrasonic images.  : Freezing image  : Displaying real-time image

*1. Can be selected in real time mode.
*2. Can be selected in freeze mode.

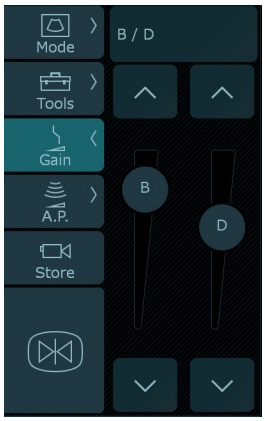
Smart Switch Area and Slide Control Area Operations

Example 1: Adjusting the Gain

1 Select [Gain].

2 Adjusts the gain.

- Drag the slider up or down.
- Select / for the slider.

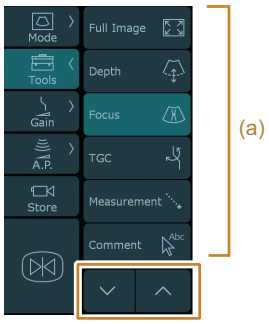


Example 2: Adjusting TGC

1 Select [Tools > TGC].

When selected item is not displayed

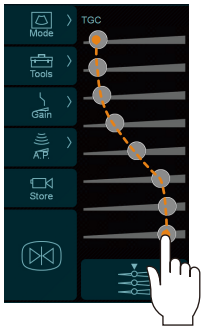
- Select / .
- Swipe (a).



2 Adjust TGC.

- Drag the slider to the left or right.
- Drag the sliders from top to bottom.

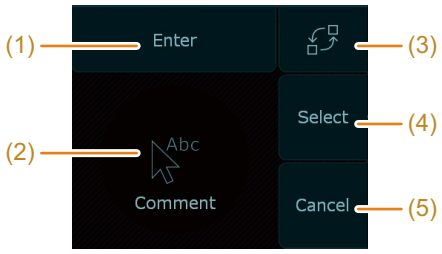
  The sliders will align with your finger as you slide it down.



To return all sliders to center position

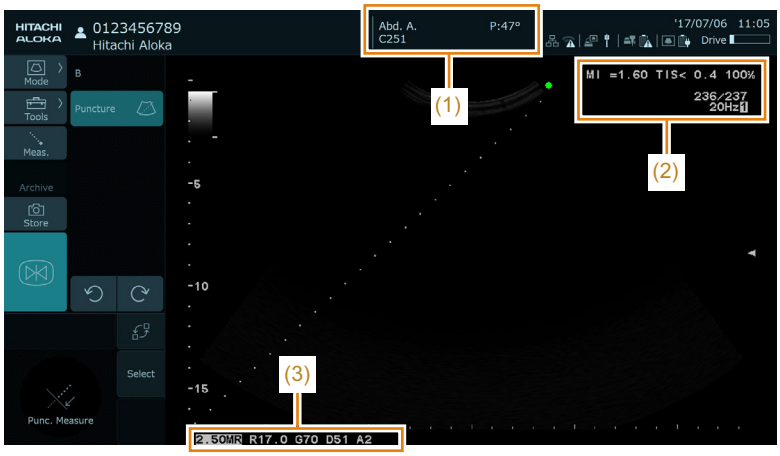
Select .

4-3-4 Trackpad Area



(1)	Enter	Tap to determine cursor position or perform other operations. Alternatively, tap it to change trackpad functions.
(2)	Trackpad	Tap, drag, swipe or touch and hold in this area to move the cursor or change set values.
(3)		Switches trackpad functions. Example: "Focus" and "Scan Area".
(4)	Select	Selects the active screen when two or more screens (B/B, B/M, etc.) are displayed.
(5)	Cancel	Cancels the selected operation.

4-3-5 Ultrasonic image area



B mode images

(1) Automatic display area 1

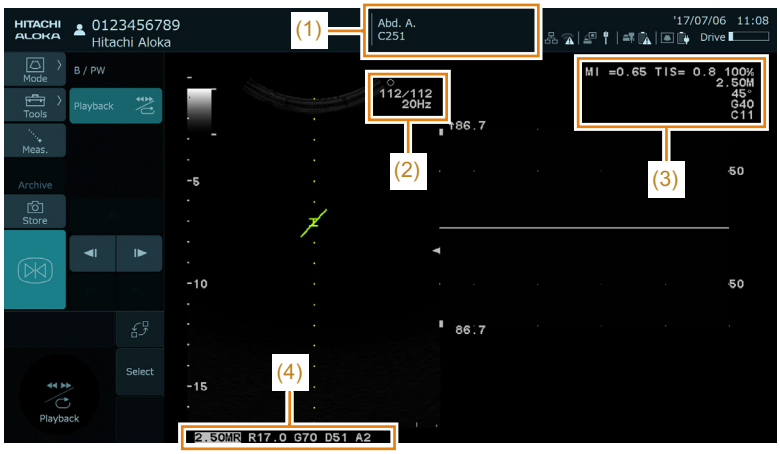
"Abd. A"	Preset name
"C251"	Selected probe
"P: 47°"	Puncture angle of Puncture Guide Line (when Puncture Guide Line is displayed)

(2) Automatic display area 2

"MI=1.60"	Mechanical index
"TIS<0.4"	Thermal index (TIS/TIB/TIC)
"100%"	Acoustic output value
"236/237"	Display frame number/number of images stored in the cine memory
"20 Hz"	Frame rate (number of frames per second for an ultrasonic image)
"1"	Screen number

(3) Automatic display area 3

"2.50 MR"	Transmission frequency
"R17.0"	Diagnosis depth (unit: cm)
"G70"	Gain
"D51"	Dynamic range
"A2"	AGC (hidden when Off)



PW mode images

(1) Automatic display area 1

"Abd. A."	Preset name
"C251"	Selected probe

(2) Automatic display area 2

"112/112"	Display frame number/number of images stored in the cine memory
"20 Hz"	Frame rate (number of frames per second for an ultrasonic image)

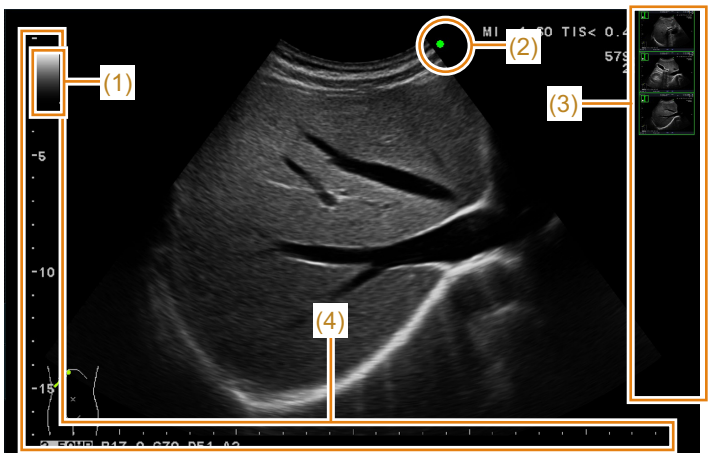
(3) Automatic display area 3

"MI=0.65"	Mechanical index
"TIS<0.8"	Thermal index (TIS/TIB/TIC)
"100%"	Acoustic output value
"2.50M"	Transmission frequency (PW)
"45°"	Correction value for Doppler angle (Angle Correct)
"G40"	Gain (PW)
"C11"	Contrast (PW)

(4) Automatic display area 4

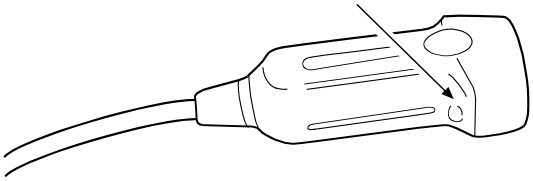
"2.50 MR"	Transmission frequency (B)
"R17.0"	Diagnosis depth (unit: cm)
"G70"	Gain (B)
"D51"	Dynamic range (B)
"A2"	AGC (hidden when Off)

The graphics below indicate the following details.



(1) Grayscale bar (gradation of B mode image)

(2) Active mark: This mark coincides with the front direction mark on the probe.



Active state: An active image is the image on which operations can be performed when two or more images are displayed

Inactive state

(3) Thumbnail area (displayed on the right of the screen)

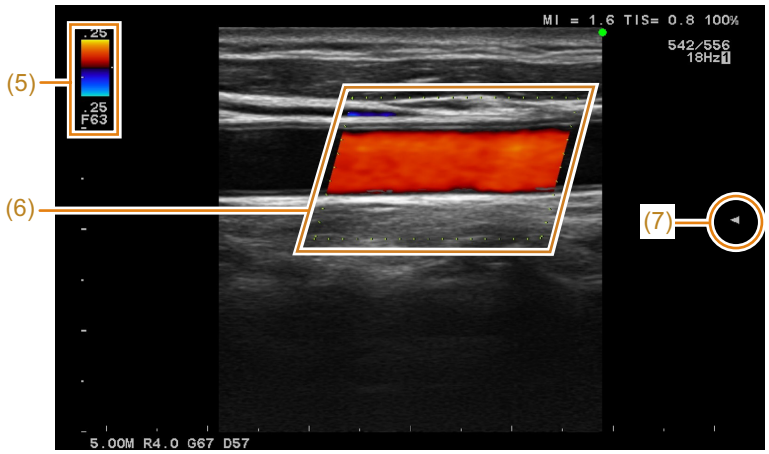
Displays a stored image in thumbnail view.

NOTE: **Not displayed on the Remote Controller screen.**

(4) Scale mark: The scale interval differs with the display range.

When the Depth Value Display in the preset ([Common Preset > Common1]) is set to "On", a value is displayed beside the scale (large).

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



Graphics information in a color display

(5) Color bar: Color coded indication and flow velocity set in the color map
"F63" : Color Gain
"25" : Velocity value

(6) Color map: Color coded flow velocity

(7) Focus mark: Focus location

Displaying the Touch Guide Screen

You can use the ultrasonic image area to pinch in or out or swipe to perform the operations listed below.

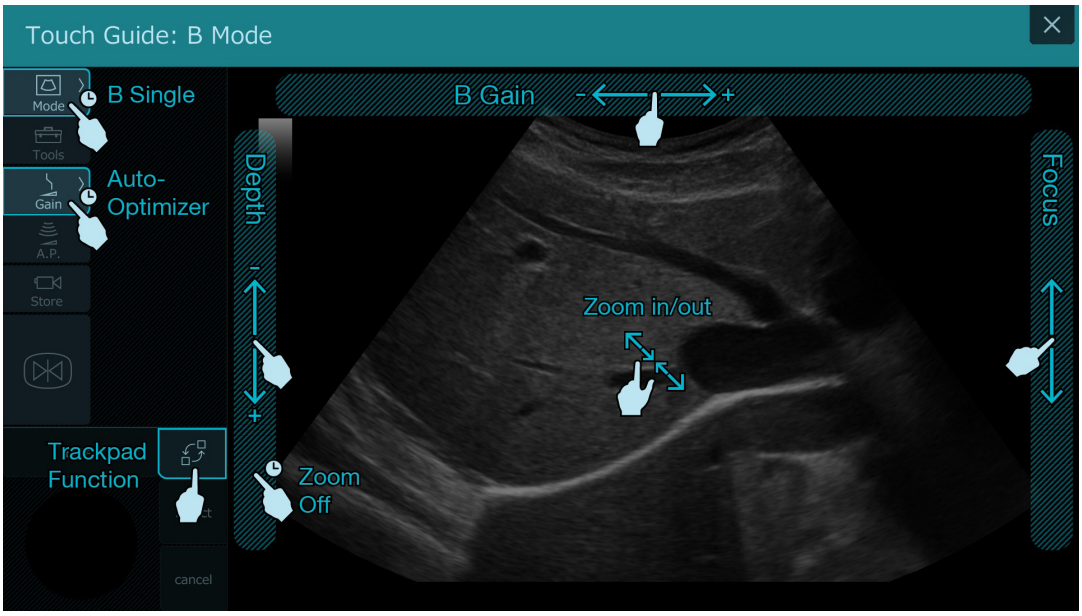
- Select [Touch Guide] from the function menu.

  → The Touch Guide screen appears.

  ◆ The Touch Guide screen provides B mode, Color mode, B/M mode and Doppler mode.

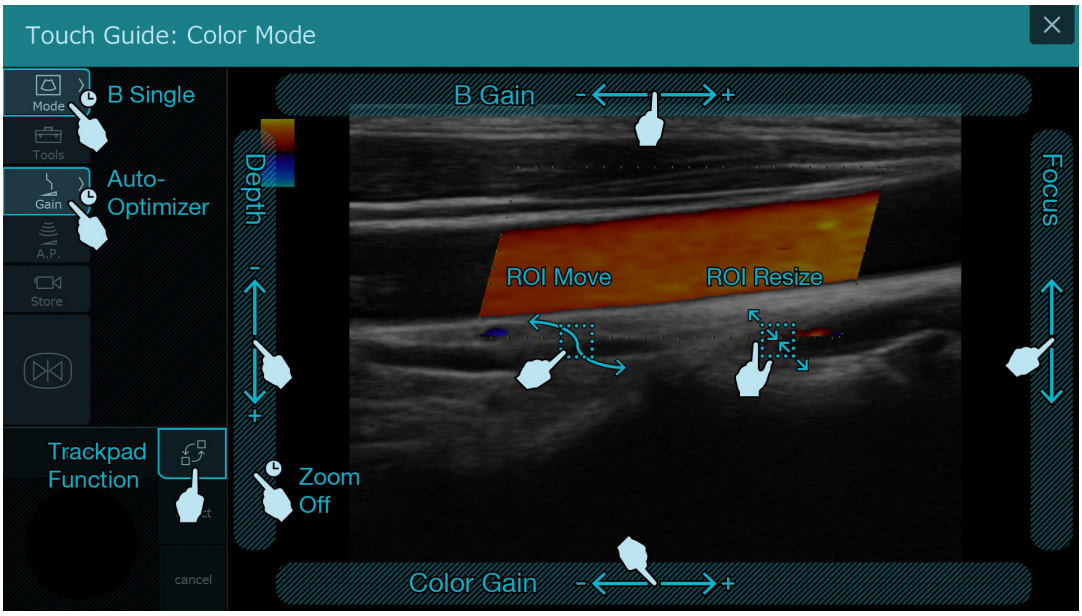
  ◆ Selecting [Touch Guide] in a screen will display a screen tailored to that paticular display mode.

Touch Guide B Mode



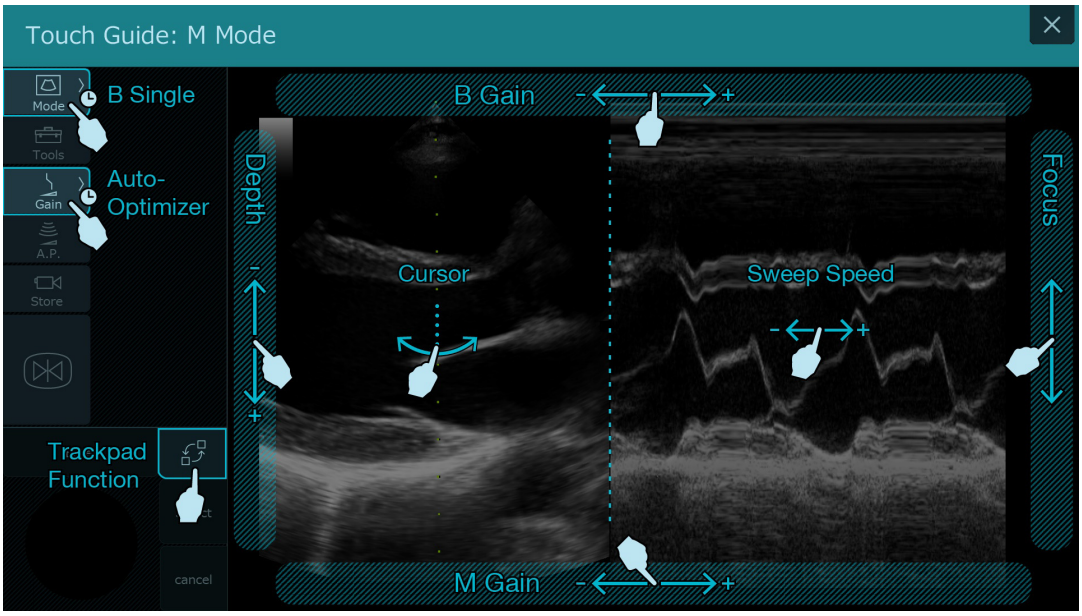
Operation area		Operating procedures	Available function
Smart Switch Area	Mode	Touch and hold	Opens the single B mode screen.
	Gain	Touch and hold	Starts Auto-Optimizer operation.
Image area	Top edge	Swipe	Adjusts B mode gain.
	Left edge	Swipe/Tap	Adjusts display depth.
	Right edge	Swipe	Adjusts focus position.
	Ultrasonic image area	Pinch out/Pinch in	Use Zoom to enlarge or reduce images.
	Left edge	Touch and hold	Turns off the Zoom function.
Trackpad area	Switch function	Tap	Switches trackpad functions.

Touch Guide Color Mode



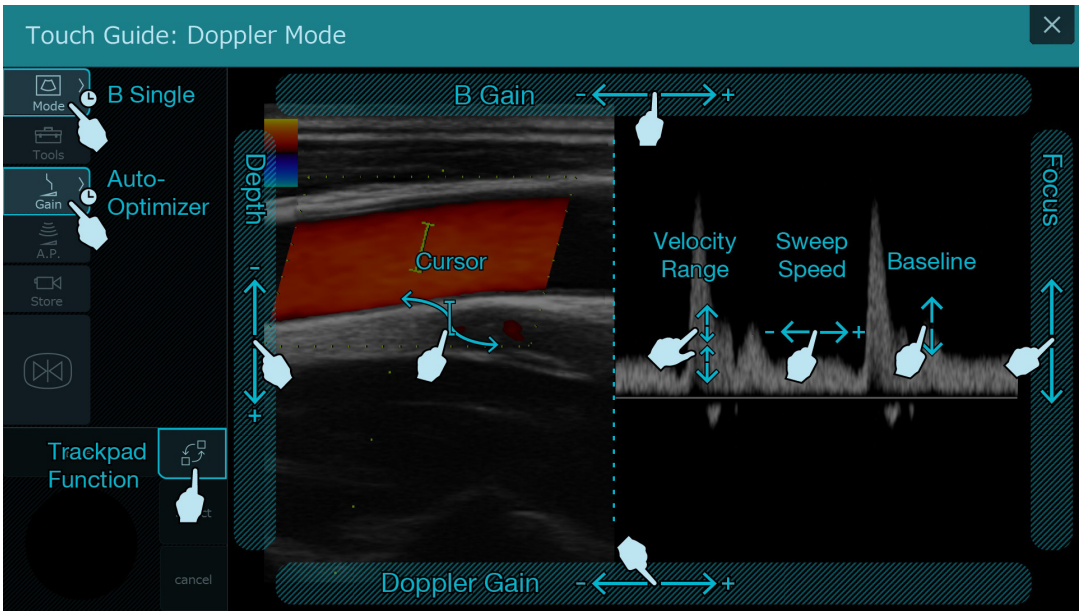
Operation area		Operating procedures	Available function
Smart Switch Area	Mode	Touch and hold	Opens the single B mode screen.
	Gain	Touch and hold	Starts Auto-Optimizer operation.
Image area	Top edge	Swipe	Adjusts B mode gain.
	Left edge	Swipe/Tap	Adjusts display depth
	Right edge	Swipe	Adjusts focus position
	Bottom edge	Swipe	Adjusts color gain
	Ultrasonic image area	Pinch out/Pinch in	Zooms the flow area (ROI).
		Swipe	Moves the flow area (ROI).
	Left edge	Touch and hold	Turns off the Zoom function.
Trackpad area	Switch function	Tap	Switches trackpad functions.

Touch Guide M Mode



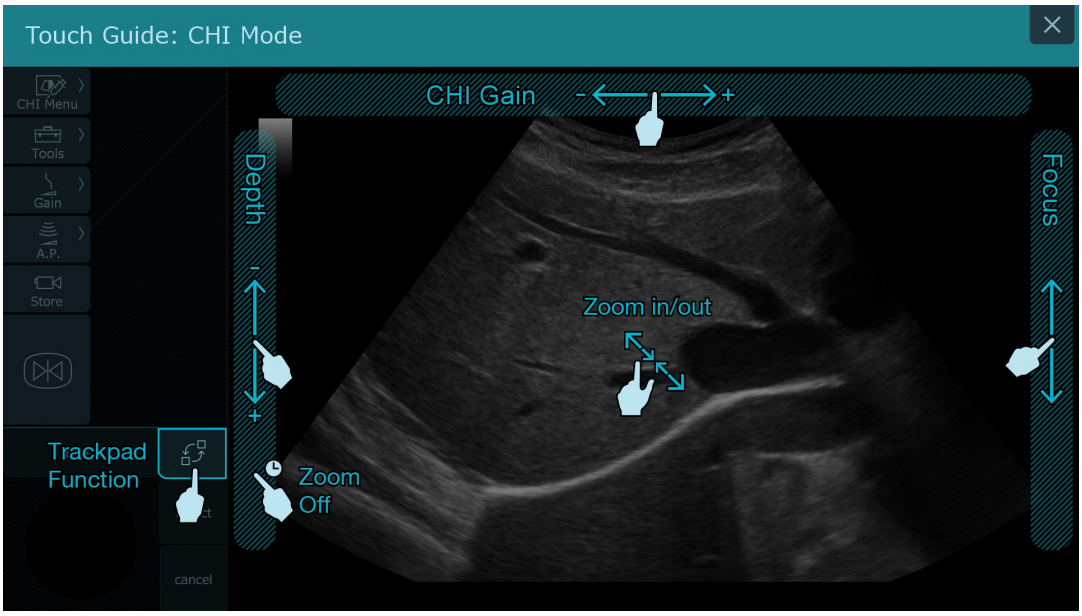
Operation area		Operating procedures	Available function
Smart Switch Area	Mode	Touch and hold	Opens the single B mode screen.
	Gain	Touch and hold	Starts Auto-Optimizer operation.
Image area	Top edge	Swipe	Adjusts B mode gain.
	Left edge	Swipe/Tap	Adjusts display depth.
	Right edge	Swipe	Adjusts focus position.
	Bottom edge	Swipe	Adjusts M mode gain.
	On B mode image	Swipe	Moves the cursor.
	On M mode image	Swipe	Adjusts sweep speed.
Trackpad area	Switch function	Tap	Switches trackpad functions.

Touch Guide Doppler Mode



Operation area		Operating procedures	Available function
Smart Switch Area	Mode	Touch and hold	Opens the single B mode screen.
	Gain	Touch and hold	Starts Auto-Optimizer operation
Image area	Top edge	Swipe	Adjusts B mode gain.
	Left edge	Swipe/Tap	Adjusts display depth.
	Right edge	Swipe	Adjusts focus position.
	Bottom edge	Swipe	Adjusts Doppler gain.
	On B mode image	Swipe	Moves sample volume (Cursor).
	On Doppler image	Right/left swipe	Adjusts sweep speed.
		Up/down swipe	Moves the baseline.
		Pinch out/Pinch in	Adjusts velocity range.
Trackpad area	Switch function	Tap	Switches trackpad functions.

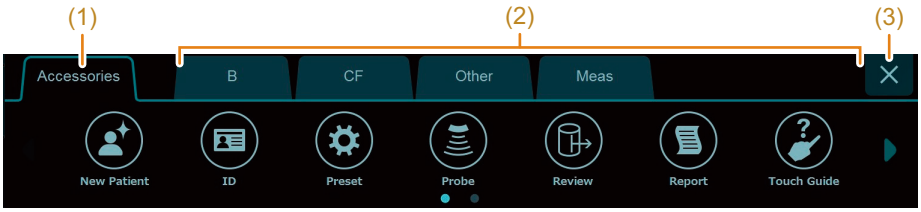
Touch Guide CHI Mode



Operation area		Operating procedures	Available function
Image area	Top edge	Swipe	Adjusts CHI mode gain.
	Left edge	Swipe/Tap	Adjusts display depth.
	Right edge	Swipe	Adjusts focus position.
	Ultrasonic image area	Pinch out/Pinch in	Use Zoom to enlarge or reduce images.
	Left edge	Touch and hold	Turns off the Zoom function.
Trackpad area	Switch function	Tap	Switches trackpad functions.

4-3-6 Function Tab Area

Swipe the ultrasonic image area upwards from the lower edge to open the function menu.



NOTE: The function menu closes after a set time has elapsed.

(1) [Accessories] tab

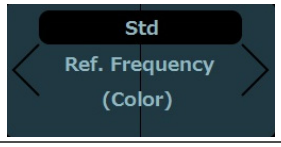
Item	Description
New Patient	Completes the examination and brings up the ID Entry screen (Details). Then it returns to the factory defaults.
ID	Displays the ID Entry screen without returning to the factory defaults.
Preset	Displays the preset screen.
Probe	Displays the probe menu.
Review	Displays the Image Viewer.
Report	Displays reports.
Manuals	Displays the instruction manual.
End Study	Enables you to end an examination and continue with the next one when performing multiple examinations of the same patient.
Thumbnail	Displays a thumbnail image.

(2) Mode specific tab

These tabs provide access to the menus in each mode.

They allow you to assign items used in preset ([Preset Set-Up Menu > Menu-Function]). Some functions have already been assigned when the instrument is shipped.

The following operations are available.

Changing values	Switching between On and Off	When there is no setting
		
Tap / to change a value.	Tapping an item will turn it On or Off.	Tapping an item will start a function.

(3)  Close the function menu.

Function Tab Area Operation

1 Swipe the ultrasonic image area upwards from the lower edge.

→ This action displays the function menu.

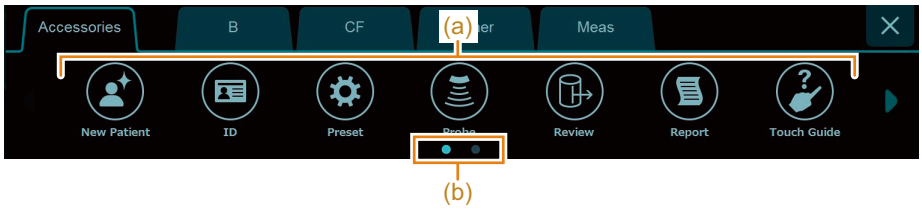
2 Select a tab.

3 Select menu ((a)).

When selected item is not displayed

- Select / .
- Swipe (a) right or left.

(b) will show the page location in the tab.



4 Close the function menu.

- Select .
- Tap another area.
- Swipe the ultrasonic image area upwards from the lower edge, in the same way as you opened it.

Once you close the function menu, thumbnails are hidden.

To turn thumbnails on again, swipe left from the right edge of the screen. Swiping the thumbnail to the right hides it.

4-4 Full Screen View

Switching to full screen view while a B mode (including Color Doppler mode) image is displayed shrinks operation buttons and other indications to make place for an enlarged view of the ultrasonic image.

You cannot switch to full screen view in modes other than B mode or color Doppler mode or from dual/quad screen modes. However, when "Type B" full screen view is set, it is possible to switch from a 2-split screen to full screen view.

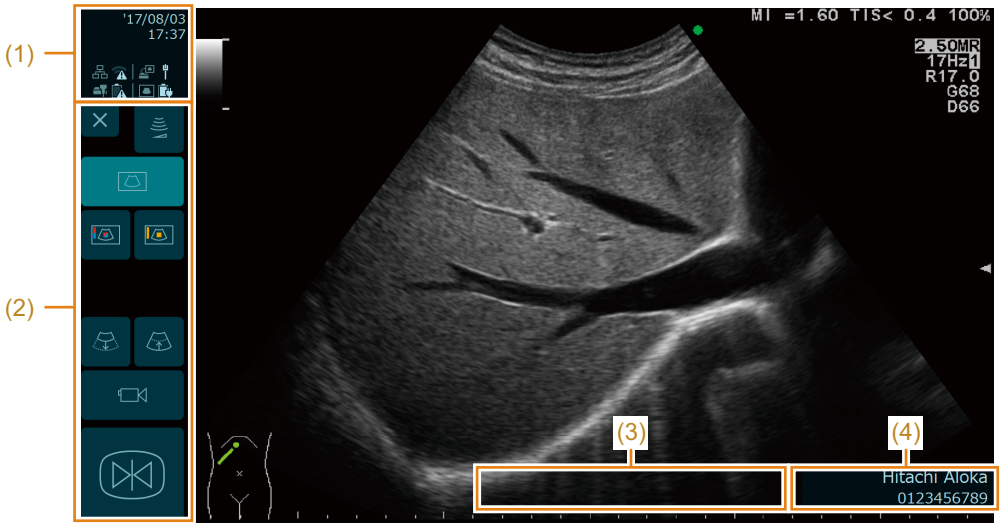
NOTE: In full screen view, the number of available functions is restricted.

4-4-1 Screen Display

Use Layout in the preset ([Preset Set-Up Menu > Display2 > Full Image]) to set a full screen view type. There are the following two full screen view types.

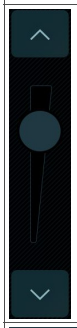
- "Type A" : Opens the regular full screen view type.
- "Type B" : Opens a full screen view with icons for orthopedics.

"Type A" full screen view



(1) Information Area — Displays icons indicating instrument status.

(2) Operation Area

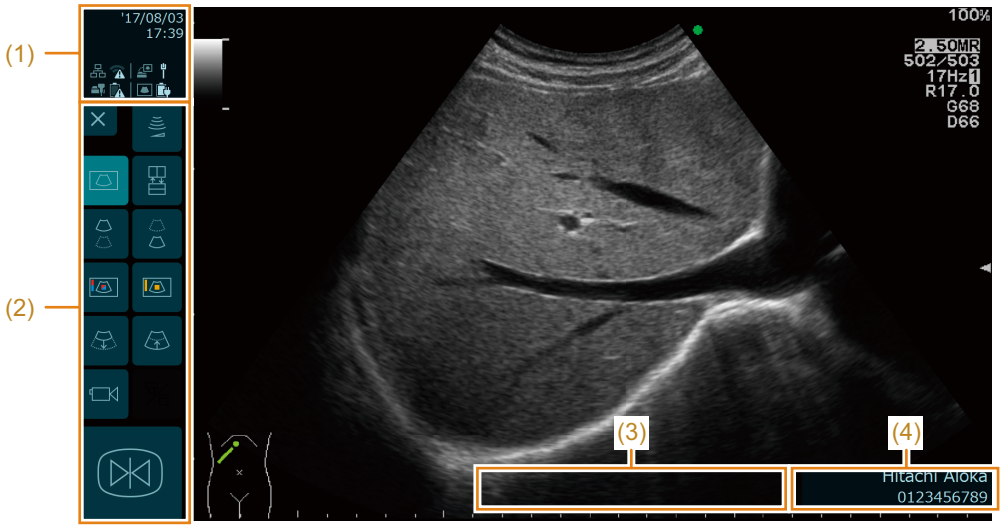
Button	Overview
	Closes the full screen view to display the image at its original size.
	Displays a slider for adjusting Acoustic Power. Can be selected in real time mode.
	Adjusts Acoustic Power. Move the slider upwards or select  to increase Acoustic Power. Move the slider downwards or select to decrease Acoustic Power. NOTE: **Not displayed on the Remote Controller screen.**
	Switches the display to the single B mode screen display.
	Switches to color Doppler mode.
	Switches to eFlow mode. Set Color to "Power Doppler" in the preset ([Preset Set-Up Menu > Display2 > Full Image]) to make changes to Power mode buttons.
	Switches to Power mode. Set Color to "eFlow" in the preset ([Preset Set-Up Menu > Display2 > Full Image]) to make changes to eFlow mode buttons.
	Reduces display depth of an image while enlarging it.
	Increases display depth of an image while reducing it.
	Searches in the forward direction.
	Searches in the reverse direction.
	Saves a still image.
	Saves moving images.
	Saving moving images. Select to stop saving moving images.
	Freezes ultrasonic images.

(3) Assist message display area — Displays messages for some instrument conditions.

NOTE: **Not displayed on the Remote Controller screen.**

(4) Patient data — Displays the patient ID and patient name.

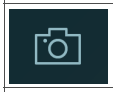
"Type B" full screen view



(1) Information Area — Displays icons indicating instrument status.

(2) Operation Area

Button	Overview
	Closes the full screen view to display the image at its original size.
	Displays a slider for adjusting Acoustic Power. Can be selected in real time mode.
	Adjusts Acoustic Power. Move the slider upwards or select to increase Acoustic Power. Move the slider downwards or select to decrease Acoustic Power. NOTE: **Not displayed on the Remote Controller screen.**
	Switches the display to the single B mode screen display.
	Switches between horizontal dual screen mode or vertical dual screen mode in 2B mode.
	Switches between the following displays. • Switches between active screens in 2B mode. • Displays the screen in 1B mode in the top screen in 2B mode.
	Switches between the following displays. • Switches between active screens in 2B mode. • Displays the screen in 1B mode in the bottom screen in 2B mode.
	Switches between the following displays. • Switches between active screens in 2B mode. • Displays the screen in 1B mode in the left screen in 2B mode.

Button	Overview
	Switches between the following displays. • Switches between active screens in 2B mode. • Displays the screen in 1B mode in the right screen in 2B mode.
	Switches to color Doppler mode.
	Switches to eFlow mode. Set Color to "Power Doppler" in the preset ([Preset Set-Up Menu > Display2 > Full Image]) to make changes to Power mode buttons.
	Switches to Power mode. Set Color to "eFlow" in the preset ([Preset Set-Up Menu > Display2 > Full Image]) to make changes to eFlow mode buttons.
	Reduces display depth of an image while enlarging it.
	Increases display depth of an image while reducing it.
	Searches in the forward direction.
	Searches in the reverse direction.
	Saves a still image.
	Saves moving images.
	Saving moving images. Select to stop saving moving images.
	Starts the function that was assigned with the preset. Use Archive Group1 in the preset ([Common Preset > Print (Freeze)]) or in ([Common Preset > Print (Realtime)]) to set assignment of functions.
	Freezes ultrasonic images.

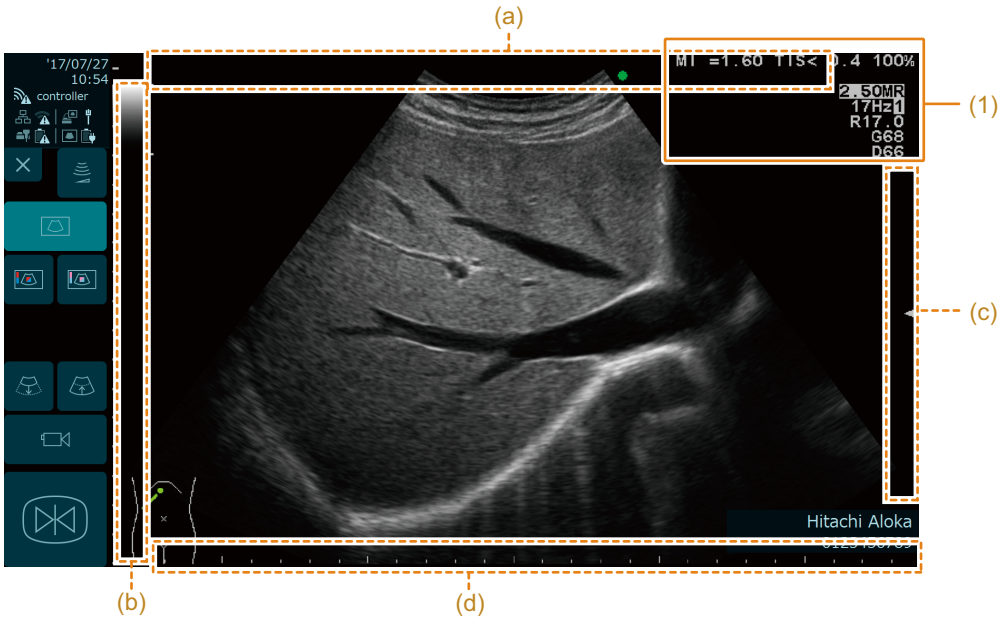
(3) Assist Message display area — Displays messages for some instrument conditions.

NOTE: **Not displayed on the Remote Controller screen.**

(4) Patient data — Displays the patient ID and patient name.

Ultrasonic image area screen

You can use the ultrasonic image area to pinch in or out or swipe the edge of an image to perform the following operations.



Operation	Description
Swipe (a) right or left	Adjusts the gain in B mode.
Swipe (b) up or down	Adjusts display depth.
Tap the top and bottom of area (b).	Adjusts display depth.
When the Zoom function is set to On. Touch and hold (b).	Turns off the Zoom function.
Swipe (c) up or down	Adjusts Focus depth.
Swipe (d) up or down	Adjusts color gain in color Doppler mode.
Pinch an image in or out	Enlarges or reduces the image. Enlarges or reduces the flow area in color Doppler mode.
Swipe up, down, right or left in an image being zoomed	Moves the image display position. Moves the flow area in color Doppler mode.

(1) MI/TI/Acoustic Power/Frequency/Cine memory (number of displayed frame /total number of frames)/FR (frame rate)//Range/Gain/ Dynamicrange/AGC — Displays the value at the top right of the screen.

4-4-2 Switching to Full Screen View

You cannot switch to full screen view in modes other than B mode and color Doppler mode or from 2-split screen or 4-split screen. However, in "Type B" full screen view, it is possible to switch from a 2-split screen to full screen view.

- In a B mode image, select [Tools > Full Image].

  → The full screen view appears.

- Set Initial Screen to "Full Image" in the preset ([Preset Set-Up > Display2 > Full Image]).

  → Opens the full screen view when the preset screen closes.

4-4-3 Deactivating full screen view

- Select the  in the operation area.

  → Full screen view is deactivated.

4-5 Patient History Screen

This screen allows you to display and check past examination results (ultrasonic image) for a patient. You can also use it to perform a new scan with the scanning conditions from a previous examination.

NOTE: Displays only still images. Moving images are not displayed.

4-5-1 Switching to the Patient History Screen

1 Enter the patient ID.

a Select [New Patient] in the Home screen.

b Enter the patient ID in the ID field.

c Move the cursor somewhere other than the ID column.

2 Select [History].

→ Use this operation to display the patient history screen.

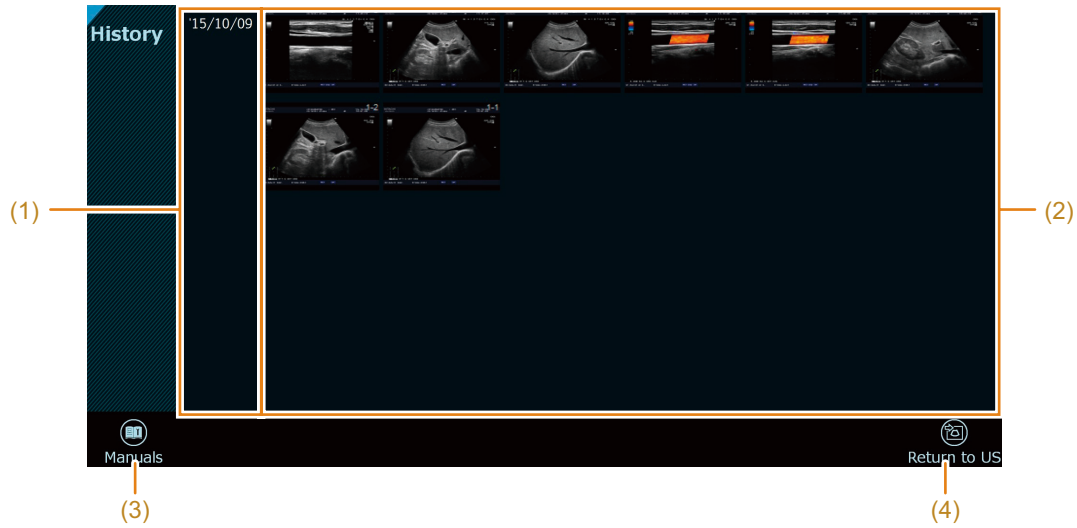


Fig.1: Patient History Screen

(1)	Examination date and time display area	Displays the examination date.

(2) Thumbnail Area — Displays a list of examination results (ultrasonic images) performed on the examination date.

Swipe or tap an image in the thumbnail area to do the following.

Operation	Description
Swipe up or down	Scrolls the thumbnail display.
Double tap a thumbnail image	Displays a review of an image.

(3) Manuals — Displays the instruction manual.

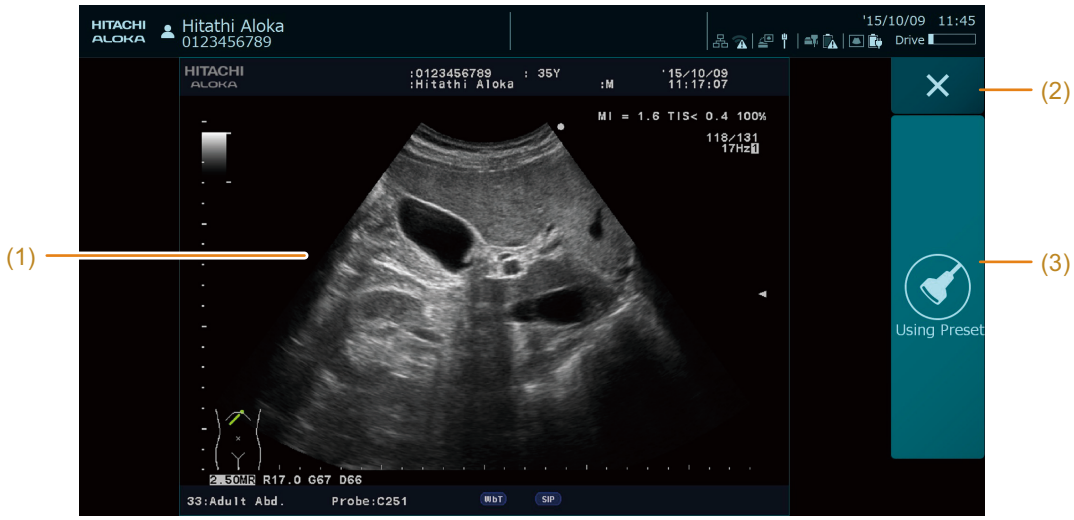
(4) Return to US — The scanning screen reappears.

4-5-2 Switching to the Review Screen

NOTE: The HOME button is not available when the Review screen is displayed.

1 Double tap a thumbnail image in the patient history screen.

→ The review screen is displayed.



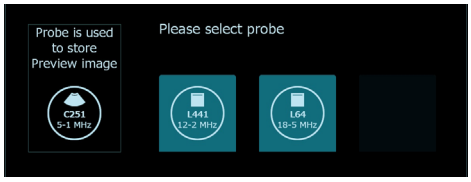
(1) Ultrasonic image area — Displays ultrasonic images.

(2) X — Close the review screen to return to the Patient History screen.

(3) Using Preset — Allows you to scan using the scanning conditions (probe, application, preset) for a previous examination.

NOTE: Previous scanning conditions cannot be replicated when CHI image is displayed.

NOTE: The Select Probe screen shown below appears when a probe is not connected during an examination.



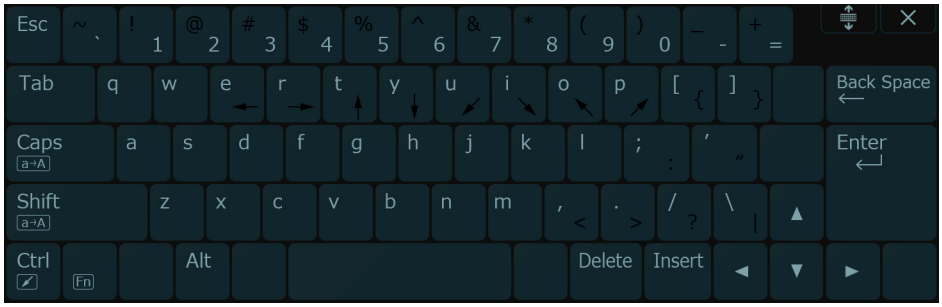
4-6 Software Keyboard

Use the software keyboard to enter text.

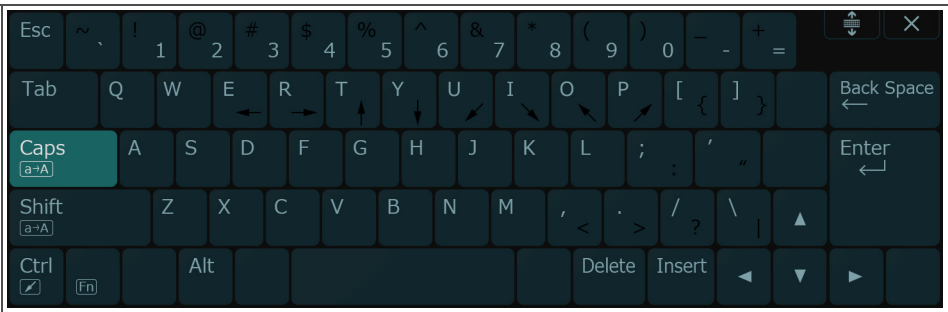
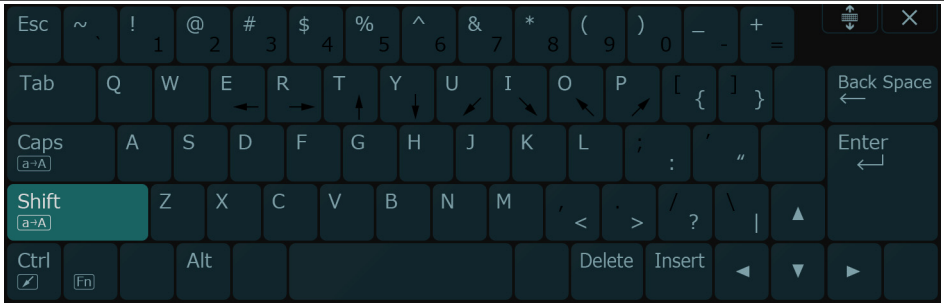
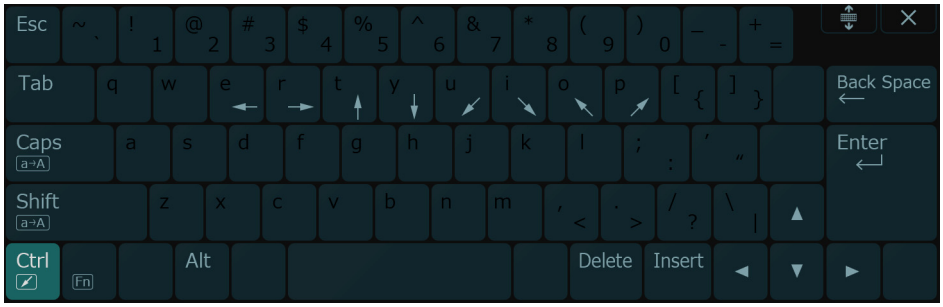
The software keyboard is automatically displayed when the user selects a text entry operation such as entry of comments or fields in the ID Entry screen.

Select  to move the software keyboard up or down.

To hide the software keyboard, select  to hide the software keyboard.



To enter characters other than those above, select the keys below and change the display.

Entering capped text	 Select the [Caps] key.
Entering special characters	 Select the [Shift] key.
Entering arrows	 Select the [Ctrl] key.

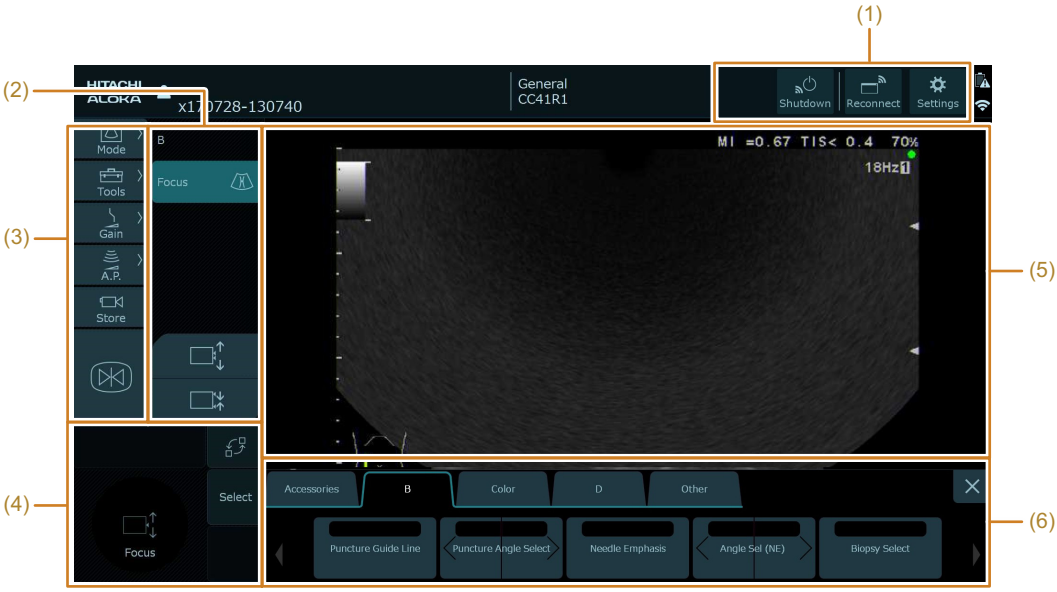
4-7 Remote Controller (Option)

You can use the remote controller to remotely control the instrument. The remote controller also displays ultrasonic images.

NOTE: The ultrasonic image displayed in the remote controller is forwarded from the back end unit and may not be updated in time.

4-7-1 Remote Controller Screen

The remote controller screen is shown below.



(1) Remote controller specific icons

The remote controller specific icons can be displayed/hidden by swiping downward in area (1). If they end up overlapping with other display items, hide the remote controller specific icons.

(2) Slide Control Area

(3) Smart Switch Area

(4) Trackpad area

(5) Ultrasonic image area

(6) Function tab area

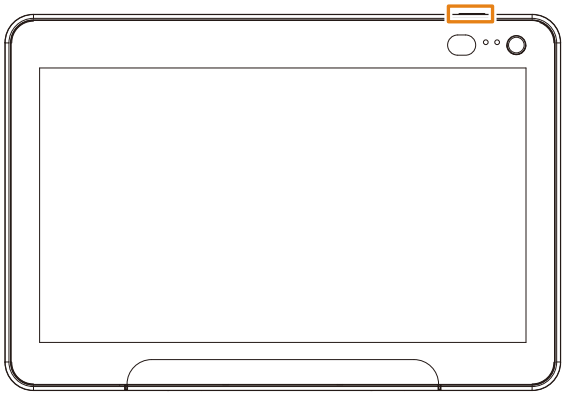
4-7-2 Operating the Remote Controller

Operations on the remote controller are performed in the same way as on the instrument.

Turning On the Remote Controller

NOTE: Turn on the remote controller when the instrument is fully started up.

- Press the power switch on the remote controller

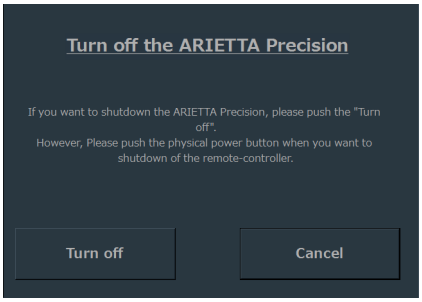


→ The power LED lights white and the remote controller is powered.

Shutting Down the Instrument

1. Select [Shutdown] from a remote controller specific icon.

→ An assist message is displayed on the remote controller.



2. Select [Turn off] from the assist message.

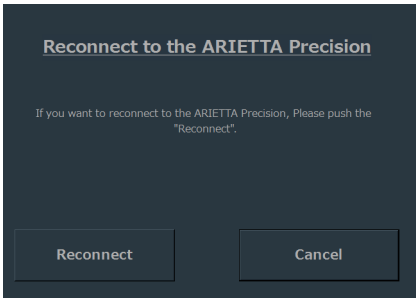
→ The instrument is shut down.

Select [Cancel] and the instrument will not be shut down and the assist message will clear.

Reconnecting the Remote Controller and Instrument

1 Select [Reconnect] from a remote controller specific icon.

→ The following assist message is displayed on the remote controller.



2 Select [Reconnect] from the assist message.

→ The remote controller is reconnected to the instrument.

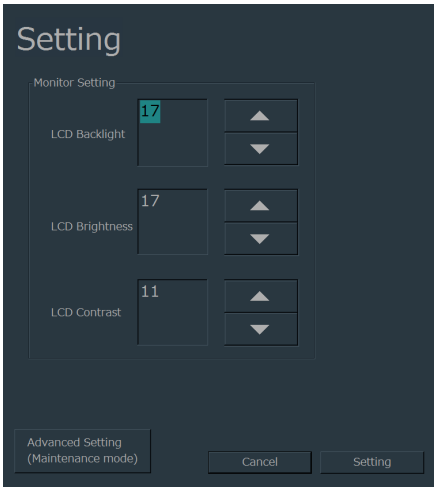
To clear the assist message, select [Cancel].

NOTE: If [Reconnect] is selected when the devices are already connected, they are first disconnected before being reconnected.

Adjusting the Remote Controller Screen

1 Select [Settings] from a remote controller specific icon.

→ An adjusting screen appears on the remote controller.



2 Adjust the screen.

- Backlight: Adjusts backlight brightness to between “0” and “20”.
- Brightness: Adjusts brightness to between “0” and “20”.
- Contrast: Sets the contrast to between “0” and “20”.

3 Select [Setting].

→ Change to the set value and the message clears.

Select [Cancel] to discard the changes and the adjust screen will close.

Shutting Down the Remote Controller

● Press the power switch on the remote controller.

5 Examination Operations

For details, refer to the separate “Detailed Operating Instructions”.

5-1 Examination Steps

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

- **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 plug into a hospital grade outlet.
- **c** Connect a probe.
- **d** Turn on the instrument.
- **e** Confirm the window that is displayed.

2 Enter patient information.

3 Set scanning conditions.

4 Apply ultrasound gel to the body area of the patient that will be examined and the contact surfaces of the probe.

5 Apply the contact surfaces of the probes to the body areas of the patient that will be scanned to display an image.

6 When the required image is acquired, select  and freeze the image.

7 Press the HOME button to end scanning.

Reference Information

Setup Before Use → p.3-1

Making Settings for Starting Scanning → p.5-3

5-2 Making Settings for Starting Scanning

Before starting an examination, enter patient information and set the scanning conditions.

5-2-1 Entering Patient Information

NOTE: To use the Worklist, refer to the separate “Detailed Operating Instructions”.

1 Select [New Patient] in the Home screen.

→ The ID input screen is displayed.

(1) ID field
(2) Name field
(3) BirthDate field
(4) Sex field
(5) Software keyboard
(6) Instruction Manual
(7) Scan filed
(8) History field
(9) Condition field

2 Enter patient information.

a Select the ID field and enter the patient ID.

NOTE: The patient ID is necessary when saving images.

b Select the Name field and enter the name of the patient.

c Select the BirthDate field and enter the birth date of the patient.

You can also select it from the calendar.

d Select the gender of the patient in the Sex field.

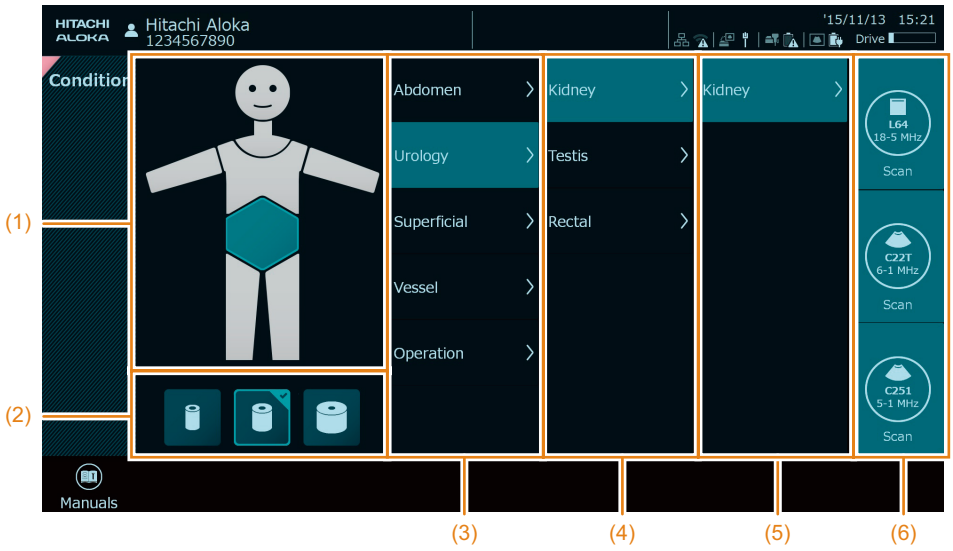
Reference Information

Software Keyboard → p.4-31

5-2-2 Setting Scanning Conditions and Probes

1 Select [Condition] from the ID input screen.

→ The scanning condition input screen opens.



(1) Body chart (2) Build chart (3) Application name
(4) Preset category (5) Preset name (6) Probe

2 Set scanning conditions.

a Select the body part to be examined from the body chart.

b Select the build of the patient from the build chart.

c Select the application name, preset category and preset name.

3 Select the probe to use.

→ The scanning screen appears.

5-2-3 Adjusting Acoustic Power

⚠ CAUTION

Scan only for the minimum length of time necessary for the diagnosis, and at the lowest possible output.When the subject is a fetus, 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 internal tissue of the patient

● Select [A.P.] to adjust acoustic power.

- Drag the slider up or down.
- Select  or  on the slider.

A lower acoustic power setting will reduce the suface temperature of the probe tip.

Ultrasound Output Limit for Fetal Observation

Use the steps below to temporarily cancel the ultrasound output limit for fetal observation.

This instrument limits ultrasound output in accordance with IEC 60601-2-37 Ed.2 (2007) when it is used for fetal observation.

The MI upper limit and the TI upper limit are both below 1.0.

This ultrasound output limit is suitable for General, Obstetrics, Obstetrics TV, Fetal Heart and Fetal Brain applications. This limit can be temporarily suspended using the following steps.

Canceling Ultrasound Output Limits

1 Select [Power Limit Override] from the Other tab in the function menu.

→ The following message "Please keep acoustic output level as low as possible. Exposure to high leveles of Ultrasound waves can be unsafe. Refer to ALARA recommendations in Operator's Manual." is displayed.

2 Select [OK].

→ The acoustic power value is highlighted and the limit is overridden.

If [Cancel] is selected, the message closes without overriding the restrictions.

To limit ultrasound output, select [Power Limit Override] again from the function menu again.

5-2-4 Adjusting Audio Volume

This function adjusts the Doppler volume and the operation sound of each button displayed on the touch pane.

Prior Confirmation Use the preset ([Preset Set-Up Menu > Menu-Function]) to assign [Audio Volume] to the function menu.

- Adjust the volume with the [Audio Volume] on the function menu.

  Sound is muted when volume is set to "0".

5-3 B Mode

5-3-1 Displaying B Mode Images

1 Select [Mode > B].

→ B mode image is displayed.

5-3-2 Displaying Dual Images

Preparations If required, assign [Dual Display Format] to the function menu using the preset ([Preset Set-Up Menu > Menu-Function]).

1 Select [Tools > Dual].

→ Switches to dual screen display.

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

2 If required, switch the dual display format.

Switching to horizontal dual screen mode

Select "L/R" in the [Dual Display Format] in the function menu.

Switching to vertical dual screen mode

Select "U/L" in the [Dual Display Format] in the function menu.

3 Switch the active screen.

- Select [Dual].
- Use the trackpad to select [Select].

4 Display in single screen mode.

- Select [Mode > B].
- Long touch [Mode].

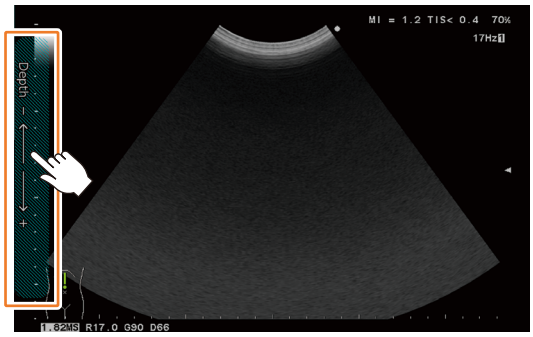
5-3-3 Adjusting Display Depth

1 Select [Tools > Depth].

2 Adjust the display depth.

- Select  or  .
- Swipe the ultrasonic image area up or down from the left edge.
- Tap the upper or lower left corner of the ultrasonic image area.

The adjustable range is displayed when you swipe or tap.



NOTE: The range of adjustments is not displayed on the remote controller screen.

5-3-4 Adjusting Focus Position

1 Select [Tools > Focus].

2 Adjust the distance between focal points.

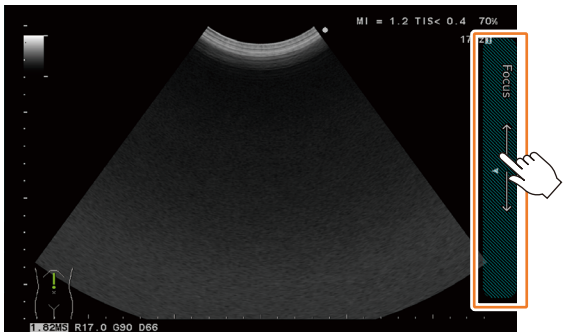
NOTE: You can adjust the distance only when using multiple focal points.

a Select  or  .

3 Adjust the depth of field.

- Drag your finger up or down on the trackpad.
- Swipe the ultrasonic image area up or down from the right edge.

As you swipe, the screen displays the range of the image you can adjust.



NOTE: The range of adjustments is not displayed on the remote controller screen.

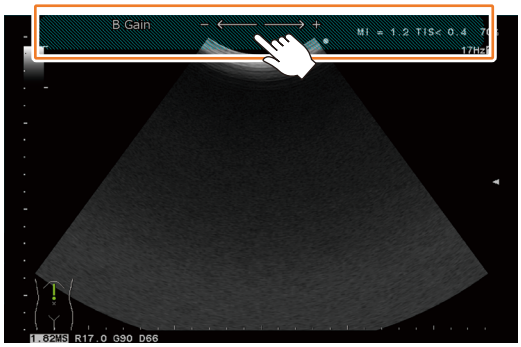
5-3-5 Adjusting B Gain

1 Select [Gain].

2 Adjust B gain.

- Drag the [B] slider up or down.
- Select ^ or v on the [B] slider.
- Swipe the top edge of the ultrasonic image area right or left.

  As you swipe, the screen displays the range of the image you can adjust.



NOTE: The range of adjustments is not displayed on the remote controller screen.

5-3-6 Zooming Images

Use this function to enlarge part of an image.

There are 2 methods for zooming images.

- Center zoom: The image is enlarged from the center.
- Box zoom: Displays a ROI showing an enlarged area and the image inside the ROI is enlarged.

Center Zoom

Prior Confirmation Navigate the preset ([Preset Set-Up Menu > DISP-B, M]) and set Zoom Method to "Center".

1 Start zooming.

- Select [Tools > Zoom].
- Pinch out any item you want to enlarge.

→ The image is enlarged.

2 Zoom and move an image.

Enlarging/reducing images

- Select  or  .
- Pinch out/pinch in an image.

Moving an image

- Drag your finger up, down, right or left on the trackpad.
- Swipe the image up, down, right or left.

Returning an image to its original size

- Select [Tools > Zoom].
- Long touch the left edge of the ultrasonic image are.

Box Zoom

This function displays an enlargement of the ROI.

Prior Confirmation Navigate the preset ([Preset Set-Up Menu > DISP-B, M]) and set Zoom Method to "Box" .

1 Start zooming.

- Select [Tools > Zoom].
- Pinch out any area you want to enlarge.

→ An ROI is displayed.

2 Adjust the ROI.

To move the ROI

- Swipe up, down, right or left on the trackpad.
- Drag the ROI up, down, left or right.

To adjust the ROI size

- Select  or  .
- Pinch the screen in or out.

3 Enlarge the image.

a Select [Enter].

→ The zoomed image is displayed.

Returning an image to its original size

Select [Tools > Zoom].

Tap the left edge of the ultrasonic image.

Switching between Center and Box zooming

● While an images is zoomed, select [Enter].

→ Switches between Center and Box zoom.

Each time you select [Enter], it switches between Center and Box zoom.

5-3-7 Freezing an Image

1 Select  .

→ The image freezes.

2 To unfreeze an image, select  again.

5-3-8 Performing Punctures

Puncture guidelines can be displayed on the screen to determine the direction in which the puncturing needle should be inserted.

NOTE: Refer to “Warnings and Safety Information” and “Cautions in Performing a Puncture Operation” before a puncture operation in this volume.

Prior Confirmation Assign [Puncture Guide Line] and [Puncture Angle Select] to the function menu in the preset ([Preset Set-Up Menu > Menu-Function]).

For details on how to assign menus, refer to the separate “Detailed Operating Instructions”.

1 Turn [Puncture Guide Line] “On” in the function menu.

→ The puncture guide line appears.

2 Select a puncture angle.

NOTE: The puncture angle can be selected only if a probe has multiple puncture angles or a puncture adapter is used.

- Select [Puncture Angle Select] in the function menu to select puncture angle.
- Select  or  .

5-3-9 Displaying the Cursor

1 Select [Tools > Cursor].

→ The cursor is displayed on a B mode image.

2 Move the cursor.

- Swipe on the trackpad.
- Swipe on a B mode image.

3 Switch modes.

- Select [Mode > M] to switch to B/M mode.
- Select [Mode > PW] to switch to PW mode.

5-4 B/M mode

5-4-1 Switching to B/M Mode

- Select [Mode > M].

  → The mode switches to B/M.

5-4-2 Setting the Cursor

- Swipe on the trackpad to move the cursor.

- Swipe on a B mode image to move the cursor.

5-4-3 Adjusting Sweep Speed

Prior confirmation Use the preset ([Preset Set-Up Menu > Menu-Function]) to assign [Sweep Speed (M)] to the function menu.

For details on how to assign menus, refer to the separate “Detailed Operating Instructions”.

- Use [Sweep Speed (M)] in the function menu to adjust the sweep speed.

- Swipe from left or right in an M mode image to adjust sweep speed.

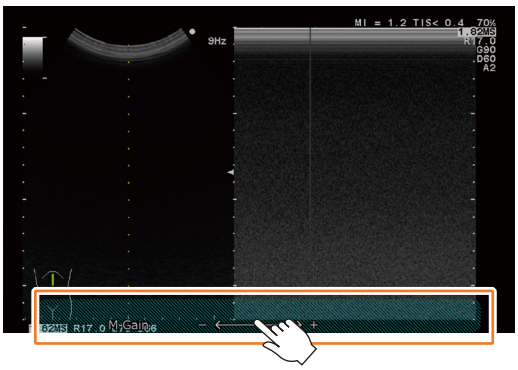
5-4-4 Adjusting M Gain

1 Select [Gain].

2 Adjust M gain.

- Drag the [M] slider up or down.
- Select / on the [M] slider.
- Swipe the bottom edge of the ultrasonic image area right or left.

  As you swipe, the screen displays the range of the image you can adjust.



NOTE: The range of adjustments is not displayed on the remote controller screen.

5-5 Color Mode, eFlow Mode, Power Mode

5-5-1 Switching to Color Mode, eFlow Mode or Power Mode

- Select [Mode > Color], [Mode > eFlow], or [Mode > Power].

  → Switch to Color mode, eFlow mode, or Power mode.

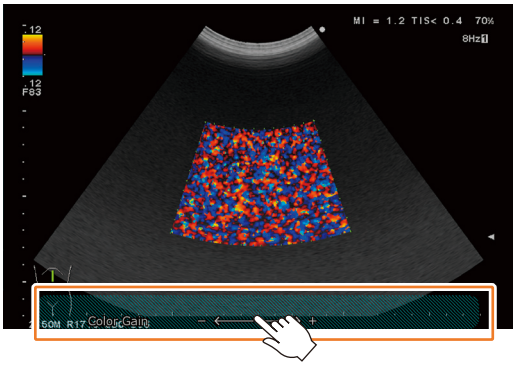
5-5-2 Adjusting the Gain in Color Mode, eFlow Mode, Power Mode

1. Select [Gain].

2. Adjust Color Flow gain, eFlow gain or Power gain.

   - Drag the [Color] slider up or down.
   - Select ^ or v in the [Color] slider.
   - Swipe the bottom edge of the ultrasonic image area right or left.

     As you swipe, the screen displays the range of the image you can adjust.



NOTE: The range of adjustments is not displayed on the remote controller screen.

5-5-3 Adjusting the Flow Area

Prior Confirmation If the “Scan Area” icon is not displayed in the trackpad, select [Tools > Scan Area] to select “Scan Area”.

Moving the Flow Area

1 Use the trackpad or swipe on the ultrasonic image area.

→ Moves the Flow area.

Adjusting Flow Area Size

1 Adjust the size of the Flow area.

To adjust with the trackpad:

a Select [Enter].

→ The Flow area is indicated by a solid line.

b Adjust the size of the Flow area by swiping on the trackpad.

To adjust using the ultrasonic image area:

Pinch in or out directly on the ultrasonic image area and adjust the size of the Flow area.

2 Select [Enter].

5-5-4 Adjusting Velocity Range

Prior Confirmation Use the preset ([Preset Set-Up Menu > Menu-Function]) to assign [Vel. Range (Color)] to the function menu.

For details on how to assign menus, refer to the separate “Detailed Operating Instructions”.

1 Use [Vel. Range (Color)] to select a velocity range in the function menu.

5-6 B/PW Mode

You can obtain bloodstream information for any point on the B mode image.

5-6-1 Switching to B/PW Mode

1. Select [Mode > PW].

   → The B/PW mode is engaged.

5-6-2 Setting Sample Volume

Prior Confirmation Use the preset ([Preset Set-Up Menu > Menu-Function]) to assign [Sample Volume] to the function menu.

For details on how to assign menus, refer to the separate “Detailed Operating Instructions”.

1. Align the sample volume to the detection position.

   To move the sample volume

   - Swipe on the trackpad.
   - Swipe on the B mode image.

   Adjusting sample volume size

   Select [Sample Volume] on the function menu and adjust the sample volume.

5-6-3 Adjusting Velocity Range

Prior Confirmation Use the preset ([Preset Set-Up Menu > Menu-Function]) to assign [Vel. Range(D)] to the function menu.

For details on how to assign menus, refer to the separate “Detailed Operating Instructions”.

1. Select [Vel. Range(D)] in the function menu and adjust the velocity range.

2. Pinch in/pinch out on the PW image and adjust the velocity range.

5-6-4 Adjusting Base Line Position

NOTE: If the "Cursor" icon is not displayed on the trackpad, select [Tools > Cursor] to select "Cursor".

- Select  or  on the slide control area and adjust the baseline position.
- Swipe up or down on a PW image to adjust baseline position.

5-6-5 Adjusting Sweep Speed

Prior confirmation Use the preset ([Preset Set-Up Menu > Menu-Function]) to assign [Sweep Speed (D)] to the function menu.

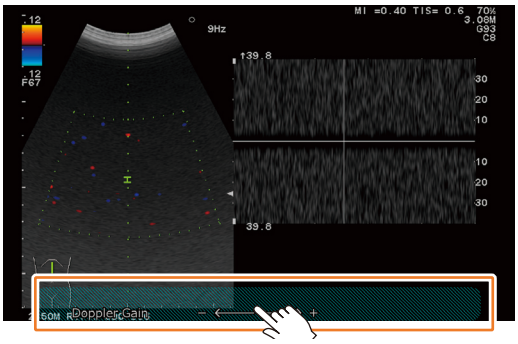
For details on how to assign menus, refer to the separate "Detailed Operating Instructions".

- Use [Sweep Speed (D)] in the function menu to adjust the sweep speed.
- Swipe left or right in a PW image to adjust sweep speed.

5-6-6 Adjusting D Gain

1. Select [Gain].
2. Adjust the D Gain.
   - Drag the [D] slider up or down.
   - Select  or  on the [D] slider.
   - Swipe the bottom edge of the ultrasonic image area right or left.

     As you swipe, the screen displays the range of the image you can adjust.



NOTE: The range of adjustments is not displayed on the remote controller screen.

5-7 Body Mark

Illustrations (body marks) can be used to display the examined body part or body posture during an examination.

Probe positions can be displayed on a body mark.

Select [Tools > Body Mark] to turn the body mark display on or off.

5-7-1 Changing Body Marks

1. Select [Tools > Body Mark].
2. Select [Menu].
   → The Body Mark menu appears and a check mark is displayed at the top right of the currently selected body mark.
3. Select a body mark.
   → The selected body mark replaces the currently selected body mark.

5-7-2 Setting the Probe Mark Position

- Use the trackpad to move to the probe mark.
- Select  or  to rotate the probe mark.

5-8 Entering Comments

Use this function to enter text in the ultrasonic image area.

1 Select [Tools > Comment].

→ The pointer and software keyboard appear on the ultrasonic image area.

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

3 Enter characters from the software keyboard.

4 Select [Enter] or the [Enter] key on the software keyboard.

→ The entry is confirmed.

5-9 Entering a Pointer

1 Select [Tools > Comment].

→ The pointer and software keyboard appear on the ultrasonic image area.

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

Changing the direction of the pointer

Select or .

3 Select [Enter].

5-10 Making Measurements

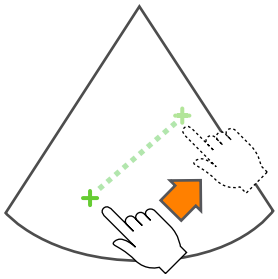
This function measures the distance, time and velocity based on the displayed ultrasonic image.

The procedures for making typical measurements are explained in this section.

NOTE: The HOME button is not available during measurements.

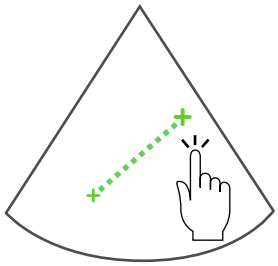
Make the following settings to enable drag and tap operations in the ultrasonic image area during measurements.

- Turn On [Mode Func. (Touch)] in the preset ([Common Preset > Common2]).
- Select the  to select Freeze.
- Set [Trackpad Priority (Freeze On)] in the preset ([Preset Set-Up Menu > Display2]) to “Measurement” .



Drag operation

Moves the caliper mark or pointer.



Tap operation

Confirms the caliper mark position or input/option.

5-10-1 Starting Measurements

1 Open a high-quality image and select .

→ The image freezes.

2 Open the measurement menu.

- Select [Meas.] from the smart switch area.
- Select [Tools > Measurement].

→ A measurement menu for this screen mode is displayed.

3 Select the item you want to measure from the measurement menu.

a Tap the measurement item displayed at the bottom of the screen.

b Use / in the slide control area to move the highlight and select the [Enter] key.

→ The screen will change to display the selected measurement item.

4 Starting Measurements.

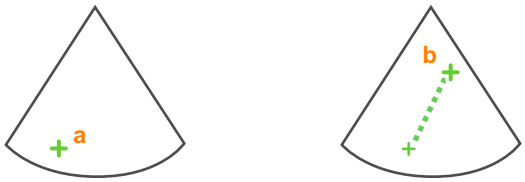
- Directly drag the ultrasonic image area to move the + mark or the line cursor.
- Use the trackpad to move the + mark or the line cursor.

5-10-2 Distance Measurement: Dist.

Use this function to measure the distance between two points.

1 Select [Dist.]from the measurement menu.

2 Measure length.



a Move the + mark to the start point and tap the ultrasonic image area or select [Enter].

b Move the + mark to the end point and tap the ultrasonic image area or select [Enter].

Example of Measurement Results

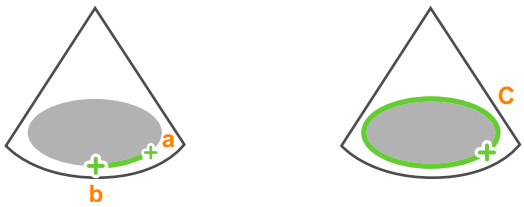
`1Dist:  cm` : selected measurement name and measurement value

5-10-3 Area and Circumference Measurements: Area-T

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

1 Select [Area-T] from the measurement menu.

2 Measure an area and its circumference.



a Move the + mark to the start point and tap the ultrasonic image area or select [Enter].

b Trace the boundary of an area to be measured.

c Tap the ultrasonic image area or select [Enter] to close the trace line.

Example of Measurement Results

1Area-T		: Selected measurement name
Area:	cm^2	: Area value
Circ:	cm	: Circumference

When several regions are enclosed by trace lines, the total area of regions enclosed by the outer trace line is calculated. The circumference is indicated as the total length of the trace line.

5-10-4 Area and Circumference Measurements: Area-E

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

1 Select [Area-E] from the measurement menu.

2 Measure an area and its circumference.

a Move the + mark to the long axis start point and tap the ultrasonic image area or select [Enter].

b Move the + mark to the long axis end point and tap the ultrasonic image area or select [Enter].

c To adjust the length of the other axis, drag up or down in the ultrasonic image area or on the trackpad.

d Tap the ultrasonic image area or select [Enter].

Example of Measurement Results

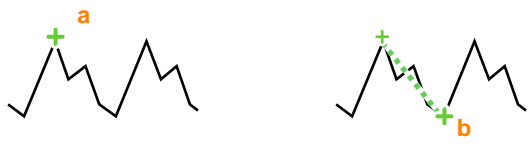
1Area-E		: Selected measurement name
Area:	cm^2	: Area value
Circ:	cm	: Ellipse circumference
x-ax:	cm	: Long axis of ellipse
y-ax:	cm	: Short axis of ellipse

5-10-5 Velocity Measurement: M.VEL.

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

1 Select [M.VEL] from the measurement menu.

2 Measure velocity.



a Move the + mark to the start point and tap the ultrasonic image area or select [Enter].

b Move the + mark to the end point and tap the ultrasonic image area or select [Enter].

Example of Measurement Results

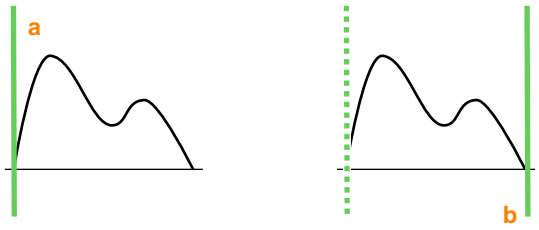
1M.VEL		: Selected measurement name
v:	cm/s	: Velocity
dD:	cm	: Amplitude
dt:	ms	: Time

5-10-6 Time Measurement: Time

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

1 Select [Time] from the measurement menu.

2 Measure the time.



a Move the line cursor to the start point and tap the ultrasonic image area or select [Enter].

b Move the line cursor to the end point and tap the ultrasonic image area or select [Enter].

Example of Measurement Results

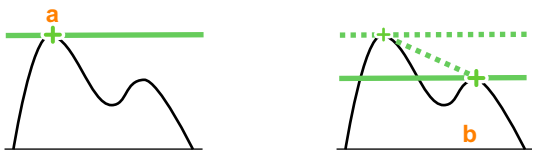
1dt:	ms	: selected measurement name and measurement value

5-10-7 Blood Velocity Measurement: D.Velocity 2

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

1 Select [D.VEL2] from the measurement menu.

2 Measure blood velocity.



a Move the + mark to the first measurement point and tap the ultrasonic image area or select [Enter].

b Move the + mark to the second measurement point and tap the ultrasonic image area or select [Enter].

Example of Measurement Results

1D.VEL2		: Selected measurement name
v1:	cm/s	: First blood velocity
v2:	cm/s	: Second blood velocity
dv:	cm/s	: Blood velocity difference
v1/v2:		: Blood velocity ratio

5-10-8 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.

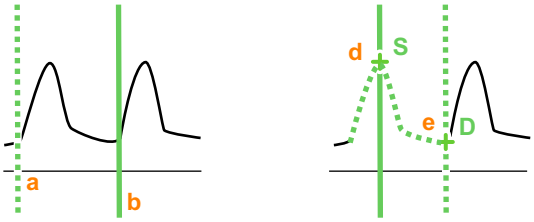
Prior Confirmation Use the measurement preset ([SW Assignment > Touch Panel SW Assignment]) to assign "Beat Select" to the Meas tab.

1 Display a blood flow waveform.

2 Select [PI] from the measurement menu.

3 Measure bloodstream information.

Using the Auto Trace method



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

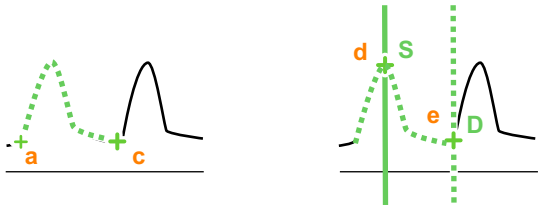
b Move the line cursor to the end point and select [Enter].

c Directly drag the ultrasonic image area or select [<] / [>] to adjust the trace line.

d Adjust S point position and tap the ultrasonic image area or select [Enter].

e Adjust D point position and tap the ultrasonic image area or select [Enter].

Using the Manual Trace method



a Move the + mark to the start point and tap the ultrasonic image area or select [Enter].

b Trace a blood flow waveform.

c Move the + mark to the end point and tap the ultrasonic image area or select [Enter].

d Adjust S point position and tap the ultrasonic image area or select [Enter].

e Adjust D point position and tap the ultrasonic image area or select [Enter].

4 Select a heartbeat from a number of traced heartbeats.

a Select [Beat Select] from the [Meas] tab in the function menu.

b Use < or > to select a heartbeat.

c Use the trackpad and [Enter] to adjust blood velocity.

Example of Measurement Results

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

5-11 Printing and Saving Images

NOTE: The HOME button is not available when printing an image.

5-11-1 Printing Images

Use a DICOM printer to print displayed images.

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

a Display a high quality real-time image.

b Select [Tools > Print].

→ This prints the image displayed when [Print] is selected.

● Follow the steps below to print a frozen image.

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

b Select [Tools > Print].

→ The displayed screen is printed.

5-11-2 Saving a Still Image

Use this function to save an image during scanning or a displayed screen as a still image.

For details on how to change the storage destination and storage format, refer to the “Detailed Operating Instructions”.

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

1 Select  .

→ The image freezes.

2 Search for an image to save.

◆ Drag your finger to the right and left on the trackpad to start a search.

◆ Select  /  to search.

3 Select [Store].

→ When the image is stored in instrument’s hard disk, it will appear as a thumbnail on the right side of the screen.

5-11-3 Saving a Moving Image

Stores the moving image on the internal hard disk of the instrument during an examination.

NOTE: For details on saving moving images, refer to the separate “Detailed Operating Instructions”.

1 Open a real-time image and select [Store].

→ Saving starts.

2 Exit saving.

- Select [Store].

  Saving finishes and real time images are displayed.

- Select [Freeze].

  Saving finishes and still images are displayed.

- The set time elapses.

  When the preset time has elapsed, saving ends.

5-12 Reading the Instruction Manual or the Case Book

You can read the instruction manual on the supplied CD-ROM or on the instrument.

You can read the Case Book[*1] on the instrument.

Use PDF Reader to read the instruction manual or Case Book on the instrument.

PDF Reader is software for displaying PDF format files.

PDF Reader uses software modules licensed under the terms of the GNU GENERAL PUBLIC LICENSE Version 2 established by the Free Software Foundation Inc. in the United States.

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).

*1. Original Source: “Musculoskeletal Ultrasound” (Published by Ohmsha, Ltd. (2014))

Reference Information

Free Software License Information → p.11-18

Free Software Module User License Agreement → p.11-19

5-12-1 Opening the Instruction Manual

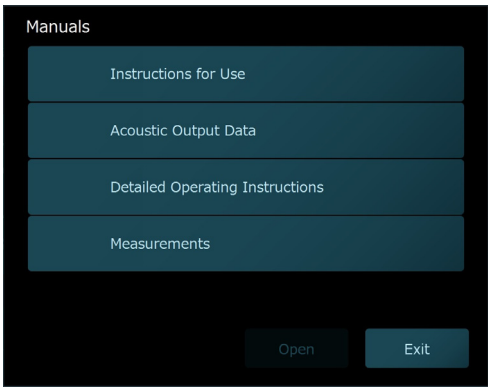
Follow the steps below to read the instruction manual on the instrument.

1 Select [Manuals] from the [Accessories] tab in the function menu.

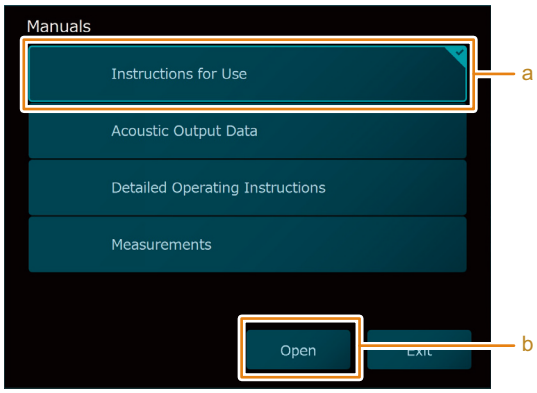
When in the Home screen, Patient History screen, ID input screen or Scanning Condition Input screen

Select [Manuals].

→ A list of instruction manuals appears.



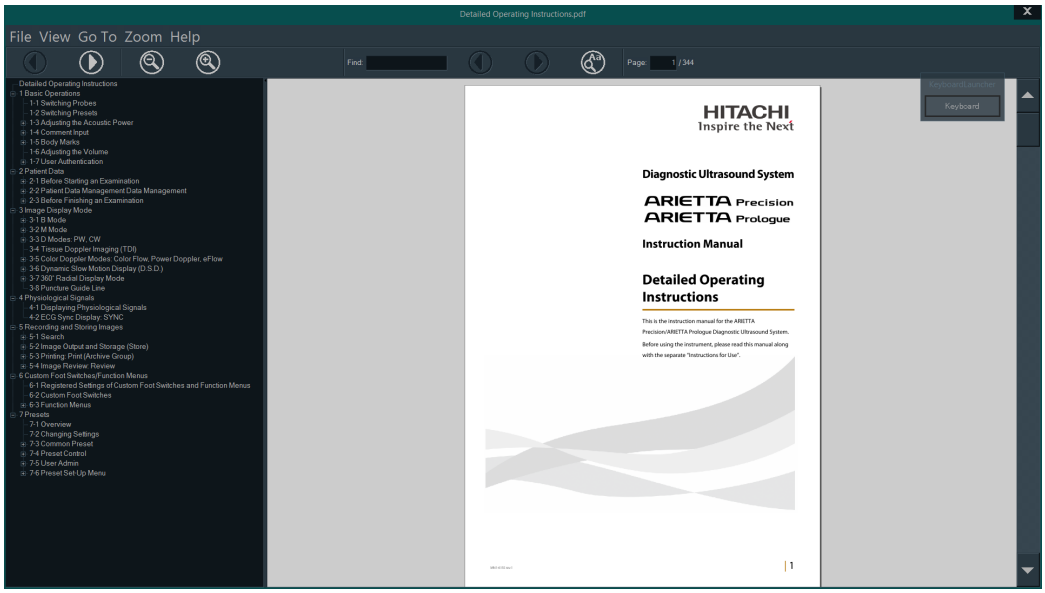
2 Use the steps below to open the instruction manual.



a Select an instruction manual to open.

b Select [Open] in the dialog box that appears.

→ The instruction manual opens.

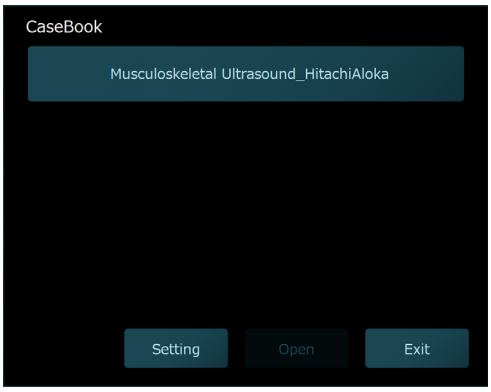


5-12-2 Displaying the Case Book on the Instrument

Follow the steps below to read the Case Book on the instrument.

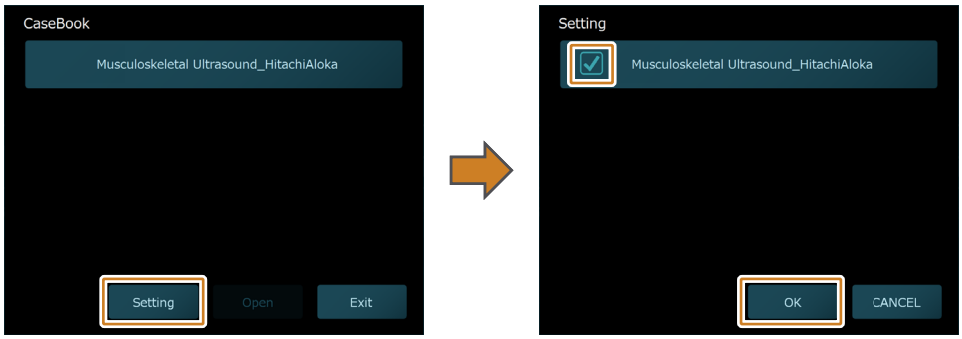
1 Select [Case Book] from the Home Screen.

→ The Case Book list appears.

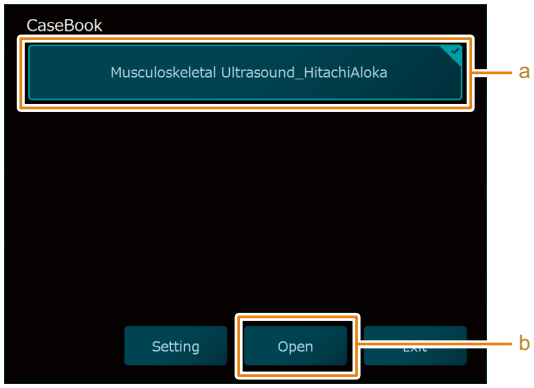


To change the Case Book list

Select [Setting], select the Case Book you want to display and select [OK].



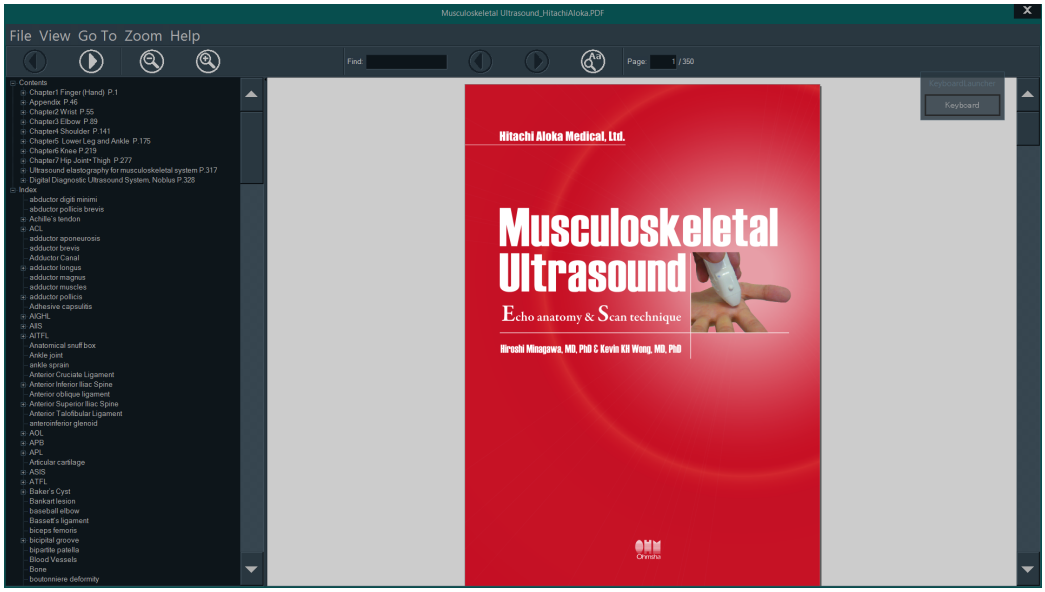
2 Display a Case Book.



a Select the Case Book you want to display.

b Select [Open] in the dialog box.

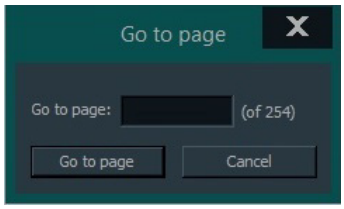
→ The Case Book appears.



5-12-3 Read Operations

File View Go To Zoom Help

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	Turns to the next page.
	Previous Page	Turns to the previous page.
	First Page	Turns to the first page.
	Last Page	Turns to the last page.
	Page...	Opens a dialog box.



Enter a page number, select [Go to page] to display that page.

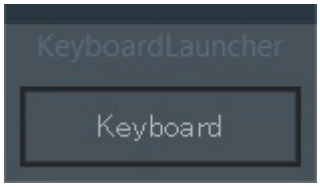
Zoom	Fit Page	Fits the page to the window.
	Fit Width	Fits the width of the page to the window.
	200% to 25%	Zooms the page to the specified percentage.
Help	About	Displays the version of PDF Reader.

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

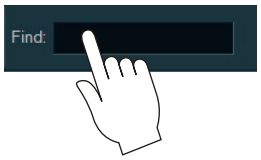
Entering Text & Numbers

1 Select the [KeyboardLauncher] displayed in the top right of the screen.



→ The keyboard is displayed.

2 Touch the field where you wish to enter text or numbers.



3 Enter the text or numbers.

Closing a Document

Use the steps below to close an instruction manual or Case Book.

1 Select [X] in the upper right hand corner of the window.

→ The open instruction manual or Case Book closes and PDF Reader quits.

2 Select [Exit].

→ The previous screen is redisplayed.

5-12-4 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 use the instrument safely and basic operating instructions.
Acoustic Output Data	Provides information on acoustic data.
Detailed Operating Instructions	Provides procedures on how to display, adjust, save and print ultrasonic images.
Measurements	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.

6 Procedures After Instrument Use

6-1 Post Examination Procedures

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.

1. Freeze the image. Alternatively, open the Home Screen.
2. Make backups of saved images.
   - a Transfer all images saved on instrument's hard disk to SD cards or USB flash drives.
   - b Delete unnecessary images from instrument's hard disk.
3. Disconnect a USB flash drive or SD card from the instrument.
4. Shut down the instrument.
5. Wipe ultrasound gel off the probe surface.
6. Disconnect cables and plugs, etc. as necessary.

   NOTE: Remove probes that are not fixed as well. Clean, disinfect and sterilize the probes according to the instructions in the supplied documentation.
7. Clean.
8. Store it in a suitable environment for storage.

Reference Information

Shutdown → p.6-3

Cleaning and Disinfection → p.6-4

6-2 Shutdown

1 Hold down the power switch on the back end unit for about 1 second.

NOTE: When the power switch is held down for 5 seconds or more, the instrument is forcibly shut down. Take care as this differs from a normal shutdown process.

→ The exit screen appears and the instrument is shut down.

After shutting down the power LED changes to orange if the AC adapter is connected and goes off if no AC adapter is connected.

If the instrument generates an error or has been forcibly shut down

This side whose power switch was not pressed sometimes does not shut down. Check the power LED, if the power is still on, hold down the power switch to shut down the instrument.

2 If required, move the instrument to make it easier to remove the power plug, then pull the power plug out of the hospital grade outlet.

NOTE: If the power plug is disconnected from the hospital grade outlet and the battery shutdown switch is in Connect mode, the internal battery will continue to consume power. When using the internal battery for operation, closely monitor battery power consumption.

NOTE: Note that battery power is used even during stanby.

6-3 Cleaning and Disinfection

Upon completion of the examination, switch off the instrument, then clean, disinfect and inspect it.

If you neglect to clean and disinfect the instrument, or to take the proper procedures 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 instrument.

NOTE: Refer to “Using Approved Disinfectants” for information on the use of disinfectants

NOTE: Shut down the instrument, then pull the power plug out of the hospital-grade outlet and clean the power plug.

NOTE: Some chemicals turn yellow.

⚠ DANGER

Do not connect or disconnect the power plug with wet hands.
There is a risk of electric shock.

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 instrument, please contact our office.

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 lead to electric shock or 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 instrument 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 instrument, wipe away any remaining water and leave to dry out.
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 benzene or thinner to clean the instrument.
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 instrument which could cause electric shock or short-circuits.
Should liquid enter the instrument, 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 instrument, 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.

⚠ DANGER

Use only chemicals that have been approved for use on the instrument.

Fractures (cracks, etc.) could otherwise occur.

Take care not to spill liquid onto or into the instrument.

It could cause short circuiting or electric shock. Should liquid spill on the instrument, please contact our office.

⚠ WARNING

Clean, disinfect and sterilize the probes at 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 using chemicals.

Handling the instrument 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 instrument with chemicals or gases that we do not recommend.

They could damage the instrument.

It is necessary to confirm chemical use and application in the country or region where the instrument 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 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 instrument could rust.

Do not wipe the touch panel surface with a disinfectant that has not been approved.

The antireflective coating on the touch panel surface could be damaged.

Wipe the touch panel gently during cleaning.

Do not use excessive force when wiping the touch panel surface as you could damage it.

⚠ CAUTION

Do not scratch the touch panel.

The touch panel could be damaged.

⚠ NOTE

Wipe gently when cleaning or disinfecting the instrument or dust filters.

Do not wipe with too much pressure as doing so may cause tha paint to peel or make labels unreadable.

6-3-1 Using Approved Disinfectants

We have conducted a survey of new medical disinfectants to find disinfectants that are suitable for disinfecting the instrument.

Use only the disinfectants in the list below to disinfect the instrument and the touch panel. Refer to the Usable/not usable field in Table 1 to determine whether a disinfectant can be used for cleaning the instrument or 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 infection.

Chemicals approved for disinfecting the exterior of the instrument

Product name and general name	Manufacturer	Front end unit enclosure	Back end unit enclosure	Touch panel surface	Cart	Monitor arm	Cradle unit	Remote controller enclosure
Sani-Cloth® HB	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sani-Cloth® Plus	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Super Sani-cloth Germicidal	PDI	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SONO ULTRASOUND WIPES	ADVANCED ULTRASOUND SOLUTIONS INC.	Yes	Yes	Yes	Yes	Yes	Yes	Yes
protex wipes	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ethyl alcohol purity 80vol% or less	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Isopropyl alcohol purity 80vol% or less	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sodium Hypochlorite	-	Yes	Yes	-	Yes	Yes	Yes	Yes

6-3-2 Frequency of Cleaning and Disinfection

- Areas to be cleaned and disinfected at least once a week.
  - Power cable, AC adapter, hospital grade outlet

    NOTE: The power plug must be disconnected from the hospital-grade power outlet before cleaning.
  - Installation location of the instrument
  - Exterior of the instrument (including probe holders)
  - Touch panel surface
  - Dust filter
- Areas to be cleaned and disinfected as necessary
  - Foot switch

6-3-3 Cleaning and Disinfecting the Instrument

- Wipe the instrument gently using a soft, dry lint free cloth, and disinfect the instrument.

When It Is Very Dirty

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

NOTE: Be sure to disinfect the instrument after cleaning.

1. Wipe gently with an approved disinfectant.
2. (If necessary,) dampen a soft lint free cloth with water and thoroughly wring it out to gently 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.

When Using Sodium Hypochlorite

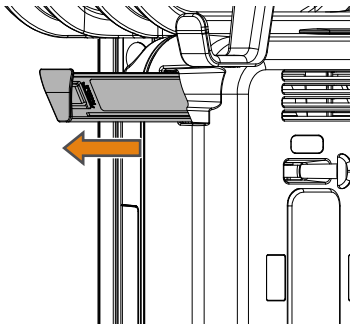
1. Dampen a soft lint free cloth with water and wring it out thoroughly.
2. Use a lint free cloth to gently wipe away any disinfectant.
3. Use a lint free cloth to gently wipe several times to remove any remaining disinfectant.
4. Use a dry, soft lint free cloth to gently wipe away any remaining moisture and leave to dry out.

6-3-4 Cleaning the Dust Filter

The dust filter is located in the front end unit.

NOTE: When the dust filter becomes clogged, instrument temperature will rise and the instrument may stop operating during an examination. It could also damage the instrument.

1 Slide the dust filter to remove it.



2 Use a vacuum cleaner to suck the dust out.

3 Rinse in running water, drain water thoroughly, then dry in a well-ventilated place that is free of direct sunlight.

Disinfecting

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 and leave to dry out.

4 Return the dust filter back to its original position.

NOTE: Push in the dust filter completely.

6-3-5 Cleaning and Disinfecting the Power Cable and AC Adapter

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

When It Is Very Dirty

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

NOTE: Be sure to disinfect the instrument after cleaning.

1. Wipe gently with an approved disinfectant.
2. (If necessary,) dampen a soft lint free cloth with water and thoroughly wring it out to gently 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.

6-3-6 Cleaning and Disinfecting Probes

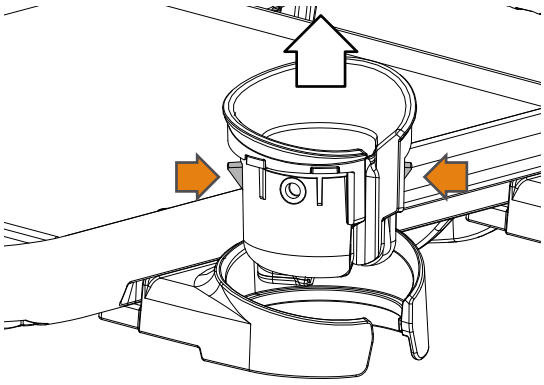
The cleaning, disinfecting, and sterilizing methods vary with probe type. Refer to the documentation for each probe.

6-3-7 Cleaning the Probe Holder

Cleaning the Probe Holder (Option)

1 Detach the probe holder.

a Lift the probe holder while depressing the 2 tabs with your fingers as shown in the figure.



2 Wipe with a soft, dry cloth.

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 d)Use the lint free cloth in step c to gently wipe away any remaining neutral detergent and leave to dry out.

When It Is Very Dirty

a Use a sponge or gauze cloth to wash away the dirt under running water.

b Use a sponge or gauze cloth and a neutral detergent 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

NOTE: Be sure to disinfect the instrument after cleaning.

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.

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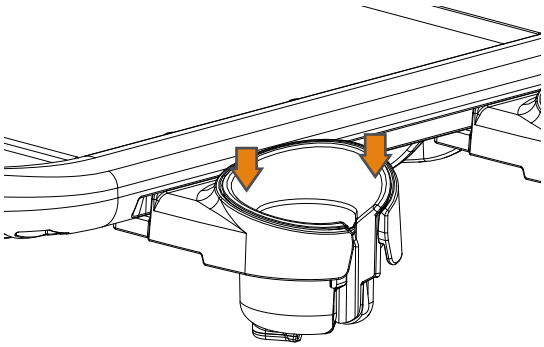
3 Install the probe holder.

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.



6-3-8 Cleaning Unit Connectors

NOTE: Charging may not be possible if the unit connectors are dirty or have accumulated dust.

1 Disconnect the connecting cables or remote controller from the front end unit.

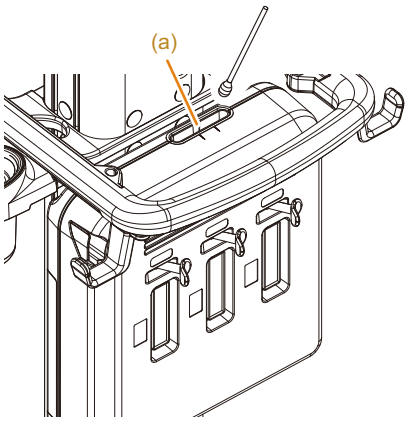
2 Dampen a cotton bud with a suitable amount of ethanol or isopropyl alcohol (80% vol or less).

NOTE: Dampen but do not saturate the cotton bud with ethanol or isopropyl alcohol as excess alcohol could flow into the cradle and damage it.

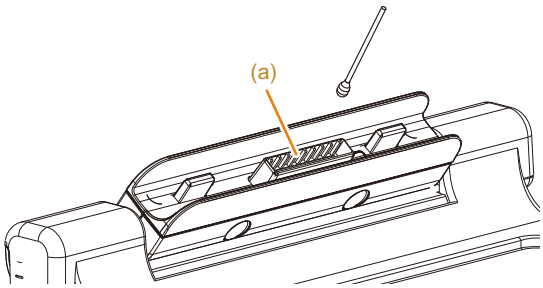
NOTE: Be sure to use ethanol or isopropyl alcohol to clean unit connectors. Use of other agents or detergents for cleaning may lead to poor contact.

3 Use the cotton bud in step 2 to wipe clean the unit connectors of the front end unit or the remote controller cradle.

(a) Unit connector



Front end unit side



Remote controller cradle side

6-3-9 Cleaning the Instrument Area and Connectors

Wipe away dust and moisture.

Using the instrument in a dusty location will reduce ventilation causing the temperature inside the instrument to become abnormally high.

Excessive moisture may cause instrument malfunction or ground leakage.

For details on connectors, refer to the documentation included with each device.

6-3-10 Cleaning Other Peripherals and Options

Refer to the documentation for each option.

6-4 Storage

When putting away the instrument for a longer period of time, be sure to place it in an environment suitable for storage.

NOTE: Be sure to perform an after use inspection before putting away the instrument

Reference Information

Moving the Instrument → p.3-2

Ambient Conditions → p.2-9

Inspections After Use → p.7-3

7 Maintenance Inspection

7-1 The Need for Regular Maintenance Inspections

Periodic maintenance inspections are essential to maintain instrument performance and ensure safe operation.

Maintenance inspection involves 4 inspections: Inspections after use, daily inspection, measurement accuracy inspection and safety inspection. Of these, 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. Please contact our office to request a service engineer visit.

Observe the electrostatic discharge (ESD) precautions when performing the maintenance and safety inspections. Parts that are sensitive to static electricity could be damaged or fail.

Reference Information

Electrostatic Discharge (ESD) Guidelines → p.9-7

7-2 Inspections After Use

After using the instrument, check that the instrument, probes, accessories, and peripherals are in the states described below.

Instrument Condition

- ☐ The exterior (including the probe holder) and foot switch are clean.
- ☐ Display (touch panel) is cleaned.
- ☐ 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.
- ☐ Placed in the probe holder or the dedicated case.
- ☐ Stored in a location that satisfies storage ambient condition.

State of Cable from an External Physiological Signal Monitor

- ☐ Cleaned.
- ☐ Bundled to avoid entanglement or placed in the cases.

7-3 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 arm and other moving parts
- There must be no looseness in the monitor arm when it is locked
- Monitor BackLight, Monitor Contrast and Monitor Brightness must be properly adjusted
- The instrument must be properly secured to the cart
- Check to ensure that peripheral equipment is properly secured
- Dust filters must not be clogged with dust

NOTE: Inspect probes as described in their documentation.

II) Periodic inspection items performed at least once a month

- When using the cart, the caster lock must be in a good state of repair
- The handle of the cart mounting base must not be loose
- Make sure that there are no cracks, damage or dents in the enclosure
- Make sure that no dirt or dust is adhering to the unit connectors.

  Since dirt or small dust particles adhering to the unit connectors of the remote controller cradle (option) may make it impossible to charge the battery, it is recommended to clean the connectors at least once a month.

  NOTE: Refer to “Cleaning Unit Connectors” in this instruction manual for information on how to clean the connectors.

⚠ 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.

Reference Information Cleaning Unit Connectors → p.6-14

7-4 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

7-4-1 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 human 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 and attach them to the measurement accuracy inspection record table.

Presets screen to record

- Image-B, M1
- Image-B, M2
- Doppler1
- Doppler2
- Color Flow

7-4-2 Distance Measurement Accuracy Inspection

Use the ultrasound phantom to determine the orientation direction and distance direction distances.

1 Switch to B mode.

2 Select [Tools > TGC] and then select  to set all sliders to the center position.

3 Apply ultrasound gel on the contact surface of the probe or ultrasound phantom.

4 Let the probe contact the ultrasound phantom.

5 Adjust R (display depth), G (gain), D (dynamic range) and Acoustic Power to match the previous inspection record.

If there is no previous inspection record

Adjust the display depth, gain, dynamic range and acoustic 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 Output the image and leave a 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.

7-4-3 Resolution and Sensitivity Inspection

1. Switch to B mode.
2. Select [Tools > TGC] and then select  to set all sliders to the center position.
3. Apply ultrasound gel on the contact surface of the probe or ultrasound phantom.
4. Let the probe contact the ultrasound phantom.
5. Adjust R (display depth), G (gain), D (dynamic range) and Acoustic Power to match the previous inspection record.

   If there is no previous inspection record

   Adjust the display depth, gain, dynamic range and acoustic power until the best possible image is obtained.
6. Freeze the image.
7. Output the image and leave a measurement accuracy inspection record table.

   → If the result differs significantly from the previous inspection record, the result should be judged as abnormal.

7-4-4 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 phantom sensitivity inspection to substitute for a Doppler measurement sensitivity result

The major causes of reduced Doppler measurement sensitivity are probe wear and a damaged transmitter unit.

These causes reduce the directionality and sensitivity of the transceiver beam resulting in flow velocities being underestimated and polarity being reversed.

Normally, an ultrasound Doppler phantom is used to make these inspections. However, if the results of an ultrasound phantom inspection of sensitivity and resolution are normal, they can substitute for a Doppler phantom inspection of measurement accuracy and sensitivity of a probe.

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. Let 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 Doppler cursor to the area of the image where there is blood flow, and display the Doppler signal.

7 Freeze the image.

8 Measure the flow velocity.

9 Output the image and leave a 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 Color Flow mode.

2 Apply ultrasound gel on the contact surface of the Doppler phantom or probe.

3 Let 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 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 Output the image and leave a measurement accuracy inspection record table.

→ If the result differs significantly from the previous inspection record, the result should be judged as abnormal.

7-4-5 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

Image 1 Preset Screen Pasting Position	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

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

Resolution
Image Pasting Position

Doppler measurement accuracy	
Doppler Preset Screen Pasting Position	Doppler phantom identification (Control No., date of purchase, S/N, etc.)

Doppler measurement accuracy	
Color Flow Preset Screen Pasting Position	Phantom settings Flow velocity (m/s):
B/PW Mode Image Pasting Position	Color Flow Mode Image Pasting Position
D Gain slider	Color Gain slider

7-5 Safety Inspection

The safety inspection must be conducted at least once a year by a technician qualified to perform safety inspections on medical electrical equipment. The inspection record must be stored.

Perform the safety inspection using the procedure below, and confirm that the measured values are no greater than the standard values in the table below.

If the customer does not have a qualified technician available, our service staff can conduct this inspection for a service charge. Please contact our office to request a service engineer visit.

NOTE: Be sure to plug in the power cable and AC adapter before starting a safety inspection.

Table1: Standard values for periodic safety inspection (extracted from IEC 60601-1: Ed.3)

	Item	Normal condition	Single fault condition
1.	Earth Leakage Current	5 mA max	10 mA max
2.	Touch Current	0.1mA 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

Table2: Standard values for periodic safety inspection (Extracted from IEC 62353)

	Item	Normal condition
1.	PROTECTIVE EARTH RESISTANCE For the POWER SUPPLY CORD itself	100 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 a facility inspection in the hospital at least once a year.

7-5-1 Periodic Safety Inspection Procedure

Earth Leakage Current

Test as described in clause 8.7.4.5 of IEC 60601-1: Ed.3.

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 provided as a ground terminal on the power plug.

Touch Current

Test as described in clause 8.7.4.6. of IEC 60601-1: Ed.3.

With the exception of cardiac induction cable connectors, the signal input and output connectors of the instrument have been provided with protective grounding. 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 IEC 60601-1: Ed.3.

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.

Total PATIENT LEAKAGE CURRENT

When using multiple probes at the same time, measure the total leakage current.

Test as described in clause 8.7.4.7 h) of IEC 60601-1: Ed.3.

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.

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 IEC 60601-1: Ed.3.

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.

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.

7-5-2 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
AC adapter	Model name	Serial number
	Model name	Serial number
	Model name	Serial number
Other peripheral instruments	Model name	Serial number
	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 max	S1 CLOSE S7 CLOSE		
Single fault condition Standard: 0.5 mA max	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			Total leakage
DC: Normal condition Standard: 0.01 mA max Total leakage current: 0.05 mA max	S1 CLOSE S7 CLOSE				
DC: Single fault condition Standard: 0.05 mA max	S1 OPEN S7 CLOSE				
Total leakage current: 0.1 mA max	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			Total leakage
AC: Normal condition Standard: 0.1 mA max Total leakage current: 0.5 mA max	S1 CLOSE S7 CLOSE				
AC: Single fault condition Standard: 0.5 mA max	S1 OPEN S7 CLOSE				
Total leakage current: 1.0 mA max	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			Total leakage
Single fault condition Standard: 5 mA Total leakage current: 5 mA	S1 CLOSE				

In case of IEC 62353

Diagnostic ultrasound system	Model name	Serial number
Probe	Model name	Serial number
AC adapter	Model name	Serial number
	Model name	Serial number
	Model name	Serial number
Other peripheral instruments	Model name	Serial number
	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: 100mΩ or less	Measuring data	Measuring points	REFERENCE VALUE*1
Configuration			

EQUIPMENT LEAKAGE CURRENT			
Total leakage current: 1.0 mA max	Measuring data	Measuring points	REFERENCE VALUE*1
APPLIED PART LEAKAGE CURRENT			
Total leakage current: 5.0 mA max	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.

7-6 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 switch on the back end and front end unit for at least 10 seconds. 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) Turn off the battery shutdown switch to Disconnect mode. (4) After several minutes, plug the power plug into a hospital grade power outlet. (5) Turn on the battery shutdown switch to Connect mode. (6) Turn on the instrument again.

- The monitor will not display an image or image quality is poor

  Check the state of the Power LED and the display on the back end and front end unit and perform the steps below.

Power LED	Display		Cause	Countermeasure
	Graphics	Image		
Unlit	–	–	The power cable and AC adapter are not connected.	Plug the power plug into the hospital grade outlet.
Orange	–	–	Instrument is in standby	Press the power switch. If the instrument does not start properly, please contact our office.
White	Nothing displayed	Nothing displayed	When the instrument has not been used for some time	Tap the screen.
White	Status displayed	Nothing displayed	Gain is too low	Select [Gain] or [Tools > TGC] to make adjustments.
			The probe is not properly connected	Reconnect the probe.
			Acoustic power is too low	Select [A.P.] to make adjustments.
			Still image display (is On)	Select to switch to , and switch to the real-time image.

- If the current date and time are not displayed correctly

Cause	Countermeasure
Incorrect settings	Use [Common Preset] to correct the date and time setting.
The internal battery is depleted	Please contact our office.

- When the remote controller cannot be charged

  When the conditions described below occur, follow the instructions in “Cleaning Unit Connectors” in the instruction manual to clean the connectors.

  – An AC adapter connection is disconnected.

    The icon indicating battery capacity in the top right of the remote controller screen changes from “  : Battery charging” to “  to  Remaining battery capacity”.

  Charging may not be possible if the unit connectors are dirty or have accumulated dust.

- If the power has been disconnected according to a displayed message, or an error other than the above occurs in the instrument, unplug the instrument power plug from the hospital grade outlet. Disconnect the power plug from the hospital grade outlet and set the battery shutdown switch to DISCONNECT mode.

Reference Information

Cleaning Unit Connectors → p.6-14

Information Area → p.4-6

7-7 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.

8 Product Configuration

8-1 Standard Configuration

Name	Model name	Quantity	Remarks
Diagnostic Instrument Component			
Diagnostic Instrument Unit (For cable connection)	USI-166	1	Use either one
Diagnostic Instrument Unit (For wireless connection)	USI-166-W	1	
Cart	RMT-AR-PRE	1	For securing the front end unit
Accessories			
AC cord	CP-123	1 or 2	For cable connection: 1, for wireless connection: 2
AC adapter	HPU180A-107B	1 or 2	For cable connection: 1, for wireless connection: 2
Unit Connection Cable	L-CABLE-963		For connecting the front end and back end units
Instruction manual CD set	MN-CD-AR-PRE-A	1	

8-2 Options

Cart-related

Name	Model name	Quantity	Remarks
cart	RMT-AR-PRE	1	
monitor arm	MP-FX-AR-PRE-1	1	For installing the back end unit

Remote controller related items

Name	Model name	Quantity	Remarks
Remote controller	RM-AR-PRE	1	
Remote controller tray	MP-FX-AR-PRE-5	1	
Remote controller cradle	EU-6057	1	

Probe holder

Name	Model name	Remarks
Probe holder right side unit	MP-FX-AR-PRE-2-R	
Probe holder left side unit	MP-FX-AR-PRE-2-L	
Probe Holder (small) RS	MP-PH-AR70-2	
Probe Holder (small) LS	MP-PH-AR70-4	
Probe Holder (large) LSRF	MP-PH-AR70-5	Doubles as a gel holder
Probe Holder (large) RSLF	MP-PH-AR70-6	Doubles as a gel holder

Accessories

Name	Model name	Remarks
Foot switch	MKF 2 1S/1S-MED CDC GP25	2-way foot switch
Display cover	MP-FX-AR-PLG-5	
Multi-Position Stand	MP-FX-AR-PLG-6	

Other

Name	Model name	Remarks
Instruction manual (Instructions for Use)	MN1-6179	Bound
Instruction manual (Acoustic Output Data)	MN1-6180	Bound
Instruction manual (Detailed Operating Instructions)	MN1-6302	Bound
Instruction manual (Measurements)	MN1-6303	Bound

Software

Name	Model name	Remarks
FAM software	SOP-AR-PRE-5	
Patient Information Automatic Input software	SOP-AR-PRE-6	
Flow Profile Measurement software	SOP-AR-PRE-7	
DICOM Network Communication software	SOP-AR-PRE-10	
DICOM Structured Report software	SOP-AR-PRE-21	*1
Automated IMT Measurement software	SOP-AR-PRE-38	
Automated NT Measurement software	SOP-AR-PRE-42	
Contrast Harmonic Imaging software	SOP-AR-PRE-44	
DICOM Query/Retrieve software	SOP-AR-PRE-59	*1
McAfee Embedded Control 2 software	SOP-AR-PRE-69	
Physiological Signal display unit	SOP-AR-PRE-81	
Remote Controler software	SOP-AR-PRE-94	
Scan-Synced Control software	SOP-AR-PRE-104	

*1. Requires SOP-AR-PRE-10.

8-3 Probe

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

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

Electronic Convex Probe

Model name	Intended Purpose	Frequency (MHz)	Curvature	Application
C22I	Intra-operative (Spec.)*b	6 to 1	20R	Intraoperative
C22P	Fetal, Abdominal*a	6 to 1	22R	Body surface
C22T	Intra-operative (Spec.)*b	6 to 1	20R	Intraoperative
C25P	Fetal, Abdominal*a	6 to 1	50R	Body surface
C41V	Fetal, Trans-rectal*e, Trans-vaginal*f, Other (Spec.)-Gynecological	8 to 4	10R	Inside the body cavity
C42K	Intra-operative (Spec.)*b, Small Organ (Spec.)*d, Neonatal Cephalic	10 to 4	21R	Intraoperative
C42T	Intra-operative (Spec.)*b, Intra-operative (Neuro.)	10 to 3	20R	Intraoperative
C251	Fetal, Abdominal*a, Pediatric, Small Organ (Spec.)*d	5 to 1	50R	Body surface
CC41R1	Fetal, Trans-rectal*e, Trans-vaginal*f	10 to 2	9R	Inside the body cavity
R41RL	Trans-rectal	10 to 5	6R Radial	Inside the body cavity

Electronic Linear Probe

Model name	Intended Purpose	Frequency (MHz)	Visual field width	Application
L43K	Intra-operative (Spec.)*b	12 to 2	26 mm	Intraoperative
L44K	Intra-operative (Spec.)*b	14 to 2	42 mm	Intraoperative
L44LA	Intra-operative (Spec.), Laparoscopic	13 to 2	36 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
L64	Abdominal*a, Pediatric, Small Organ (Spec.)*d, Musculo-skel. (Convent.), Musculo-skel. (Superfic), Other (Spec.)-Wound*h, Peripheral vessel	18 to 5	38 mm	Body surface

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
UST-5310*1	Intra-operative (Spec.), Intra-operative (Neuro.)	17 to 4	11 mm	Intraoperative
UST-5311*1	Intra-operative (Spec.), Intra-operative (Neuro.)	17 to 4	11 mm	Intraoperative

*1. The optional JB-298 (Junction Box) is necessary.

Electronic sector probe

Model name	Intended Purpose	Frequency (MHz)	View angle	Application
S31KP	Intra-operative (Neuro.)	8 to 3	90°	Intraoperative

Other probes

Model name	Intended Purpose	Frequency (MHz)	Curvature Radius, or Scan Area	Application
CL4416R (C)	Trans-rectal*e	10 to 2	9R	Inside the body cavity
CL4416R (L)	Trans-rectal*e	14 to 2	63mm	Inside the body cavity

*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.

8-3-1 Probe Functions: Basic Functions

Basic Functions		C22I	C22P	C22T	C25P	C41V	C42K	C42T	C251	CC41R1	R41RL	L43K	L44K
Compound					Yes				Yes			Yes	Yes
Trapezoid												Yes	Yes
B steer												Yes	Yes
Real Time Biplane										Yes			
TDI mode									Yes				
Puncture Guide Line			Yes		Yes	Yes	Yes		Yes	Yes			
THI	Filter method	Yes	Yes	Yes	Yes				Yes				
	Pulse inversion method	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Needle Emphasis													
Brachytherapy													

Basic Functions		L44LA	L44LA1	L46K1	L51K	L53K	L64	L441	S31KP	UST-5310	UST-5311	CL4416R (C)	CL4416R (L)
Compound		Yes		Yes	Yes	Yes	Yes	Yes		Yes	Yes		Yes
Trapezoid		Yes		Yes	Yes	Yes	Yes	Yes		Yes	Yes		Yes
B steer		Yes		Yes	Yes	Yes	Yes	Yes		Yes	Yes		Yes
Real Time Biplane													
TDI mode													
Puncture Guide Line							Yes	Yes	Yes				Yes
THI	Filter method												
	Pulse inversion method	Yes		Yes	Yes	Yes	Yes	Yes				Yes	Yes
Needle Emphasis							Yes	Yes					
Brachytherapy												Yes	

8-3-2 Probe Functions: Optional Functions

Optional Functions		C22I	C22P	C22T	C25P	C41V	C42K	C42T	C251	CC41R1	R41RL	L43K	L44K
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes
Contrast Harmonic Imaging	WbC (P.I.)							Yes	Yes			Yes	Yes
	TrC (A.M.)							Yes	Yes			Yes	Yes
Scan-Synced Control													

Optional Functions		L44LA	L44LA1	L46K1	L51K	L53K	L64	L441	S31KP	UST-5310	UST-5311	CL4416R (C)	CL4416R (L)
FAM		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Contrast Harmonic Imaging	WbC (P.I.)	Yes											
	TrC (A.M.)	Yes											
Scan-Synced Control							Yes						

8-3-3 Measurement Scope

This section indicates the maximum range of measurements that ARIETTA Precision can provide.

Probe	Distance (max, cm)	Area Trace (cm^2)	Area Ellipse (cm^2)	Circumference (Trace, cm)	Volume (cm^3)	Excursion (cm)	Velocity Doppler (cm/s)	Time Interval (s)	Heart Rate (BPM)
C22I	57.3	999.9	999.9	99.9	9999	29.9	579.5	9.71	6-999
C22P	76.4	999.9	999.9	99.9	9999	39.9	637.5	9.71	6-999
C22T	57.3	999.9	999.9	99.9	9999	29.9	579.5	9.71	6-999
C25P	76.4	999.9	999.9	99.9	9999	39.9	637.5	9.71	6-999
C41V	40.1	717.0	999.9	99.9	9999	20.9	398.4	9.71	6-999
C42K	40.1	717.0	999.9	99.9	9999	20.9	318.8	9.71	6-999
C42T	40.1	717.0	999.9	99.9	9999	20.9	318.8	9.71	6-999
C251	76.4	999.9	999.9	99.9	9999	39.9	637.5	9.71	6-999
CC41R1	40.1	717.0	999.9	99.9	9999	20.9	289.8	9.71	6-999
R41RL	40.1	717.0	999.9	99.9	9999	20.9	318.8	9.71	6-999
L43K	26.8	318.7	999.9	73.6	9999	14.0	354.2	9.71	6-999
L44K	32.5	469.9	999.9	89.3	9999	17.0	354.2	9.71	6-999
L44LA	26.8	318.7	999.9	73.6	9999	14.0	354.2	9.71	6-999
L44LA1	26.8	318.7	999.9	73.6	9999	14.0	318.8	9.71	6-999
L46K1	32.5	469.9	999.9	89.3	9999	17.0	354.2	9.71	6-999
L51K	26.8	318.7	999.9	73.6	9999	14.0	265.6	9.71	6-999
L53K	26.8	318.7	999.9	73.6	9999	14.0	265.6	9.71	6-999
L64	26.8	318.7	999.9	73.6	9999	14.0	265.6	9.71	6-999
L441	26.8	318.7	999.9	73.6	9999	14.0	354.2	9.71	6-999
S31KP	28.7	365.8	999.9	78.8	9999	15.0	398.4	9.71	6-999
UST-5310	9.56	40.65	999.9	26.3	635.0	4.99	187.5	9.71	6-999
UST-5311	9.56	40.65	999.9	26.3	635.0	4.99	187.5	9.71	6-999
CL4416R (C)	40.1	717.0	999.9	99.9	9999	20.9	289.8	9.71	6-999
CL4416R (L)	32.5	469.9	999.9	89.3	9999	17.0	354.2	9.71	6-999

9 Safety Guidelines

9-1 Guidelines for Electromagnetic Compatibility

The electromagnetic compatibility (EMC) of this device is in conformity with the IEC 60601-1-2: Ed.2 Am.1, which is the international standard for EMC of medical instruments. This standard specifies electromagnetic energy level (electromagnetic emissions) test requirements and resistance to electromagnetic interference (electromagnetic immunity) test requirements for medical instruments.

Testing has confirmed that our company's Diagnostic Ultrasound System does not emit electromagnetic energy that contravenes the standards.

9-1-1 Guidance and Directive Concerning Electromagnetic Emissions

The ARIETTA Precision is intended for use in an electromagnetic environment as specified in the following. It is desirable for customers or users of the ARIETTA Precision to confirm that the ARIETTA Precision is used in such an environment.

Emission testing	Compliance	Electromagnetic Environment—Guidance
CISPR11 RF Emissions	Group 1	The ARIETTA Precision 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 RF Emissions	Class B	The ARIETTA Precision is suitable for use in all kinds of buildings, including residential buildings and those directly connected to mains for the public supply which are also servicing buildings used for residential purposes.
IEC 61000-3-2 High harmonic emissions	Class A	
IEC 61000-3-3 Power supply variation/flicker emissions	Complies	

9-1-2 Essential Performance

Electromagnetic immunity tests of the ARIETTA Precision Diagnostic Ultrasound System as per IEC 60601-1-2: Ed.2 Am.1 has confirmed that there is no impact on essential performance (performance that would pose an unacceptable risk if absent or degraded).

Essential Performance	Description	Reference
Scan Area	Scanning range	[Tools > Scan Area]
Flow Area	Color display range of color Doppler mode	[Tools > Scan Area]
Marker	Scale marks (distance, time and flow velocity) display	Ultrasonic image area → p.4-12
Velocity Range	Velocity range (scale mark) in the Doppler image display	Vel. Range (D) menu (Detailed Operating Instructions)
M cursor D cursor	Cursor display which indicates the M or D mode image detection position in B mode	[Tools > Cursor] (Detailed Operating Instructions)
Sample Volume	Doppler detection range settings in the PW Doppler mode	Sample Volume menu (Detailed Operating Instructions)
Image Frequency	Switch the transmitting/receiving frequencies of the probe of the B, D, M, Color, FmT or WbT mode	Frequency (B/M) menu, Ref. Frequency (D) menu, Ref. Frequency (Color) menu (Detailed Operating Instructions)
Focus	Number of focal points and their positions	[Tools > Focus] (Detailed Operating Instructions)
Acoustic Power	Acoustic power	Ultrasound Output Safety Information, [A.P.] (Detailed Operating Instructions)
Line Density	Change in scanning line density combinations for black-and-white and color images	Line Density (Color) menu (Detailed Operating Instructions)
Packet Size	Number of transmissions used to display blood flow	Packet Size menu, preset: Packet Size (Color Flow), Packet Size (Power Doppler), Packet Size (eFlow), Packet Size (TDI-Color), Packet Size (TDI-Power) (Detailed Operating Instructions)
Puncture, Biopsy Select	Puncture guide line display	Puncture Guide Line menu, Biopsy Select menu Preset: Graphics (Detailed Operating Instructions)
Message	Warning messages indicating the correct method of operation and alarm tone	Message → p.10-2
Angle Correction Value	Display of flow velocity value whose Doppler beam angle has been corrected	Angle Correction Value menu, preset: Doppler, Tissue Doppler (Detailed Operating Instructions)
Heart Rate Display	Computes and displays the heart rate from detected R-wave (HR***)	Physiological signal display menu, preset: Physiology (Detailed Operating Instructions)

9-1-3 Guidance and Declaration Directive Concerning Electromagnetic Immunity

The ARIETTA Precision is intended for use in an electromagnetic environment as specified in the following. It is desirable for customers or users of the ARIETTA Precision to confirm that the instrument is used in such an environment.

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	It is desirable that the quality of the electric power supply is the same as the standard business or hospital environments.
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	It is desirable that the quality of the electric power supply is the same as the standard business or hospital environments.
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	It is desirable that the quality of the electric power supply is the same as the standard business or hospital environments. When the user of the ARIETTA Precision demands continuous operation even during a power outage, it is recommended that the ARIETTA Precision is 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.			

9-1-4 Table Guidance and Declaration Directive Concerning Electromagnetic Immunity (conducted RF and emitted RF)

The ARIETTA Precision is intended for use in an electromagnetic environment as specified in the following. It is desirable for customers or users of the ARIETTA Precision to confirm that the instrument is used in such an environment.

Immunity Examination	IEC 60601 Testing Level	Conformity level	Electromagnetic Environment—Guidance
			Cellular and Mobile RF communication devices including cables shall not be used close to any parts of the ARIETTA Precision 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 80MHz and 800MHz.

Remark 2 These guidelines may not apply in all circumstances. Electromagnetic propagation is affected by reflection or absorption from buildings, objects and people.

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. If the measured field strength at the location where the ARIETTA Precision is used is higher than the applicable RF compliance level mentioned above, observations must be made to determine whether or not the ARIETTA Precision operates normally. If abnormal operation is observed, an investigation for the location and installation of the ARIETTA Precision may be necessary.

b: For bandwidths outside of 150kHz — 80MHz range, it is desirable that the field intensity is less than 3V/m.

9-1-5 Recommended Separation Distance between Cellular and Mobile RF Communication Instruments and the ARIETTA Precision

The ARIETTA Precision is intended to be used in an electromagnetic environment where RF interference is controlled. Customers or users of the ARIETTA Precision can help prevent electromagnetic interference by maintaining a minimum distance between a mobile RF communication instrument (transmitter) and the ARIETTA Precision according to the following recommendation, based on the maximum output of the transmitter.

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 80MHz and 800MHz. Remark 2: These guidelines may not apply in all circumstances. Electromagnetic propagation is affected by reflection or absorption from buildings, objects and people.			

9-2 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, but leave the power cable connected to the power source.

⚠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.

Reference Guidelines for Electromagnetic Compatibility → p.9-2

9-3 Ultrasound Output Safety Information

9-3-1 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 displayed 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 39.2°F 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 above. 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.

Table1: Relative importance of keeping acoustic power index low at various examinations

	It is more important	It is not important
MI	• When using a 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.

9-3-2 Ultrasound Wave, Interaction between Vital Tissues

When ultrasound waves pass through human tissue, the tissue may be damaged. Ultrasonic images that are taken during examinations are produced as a result of imaged energy reflected 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 and thermal processes, respectively.

Mechanical bioeffects are due to the pressure waves causing mechanical or physical movement of the tissues and tissue components. These components such as cells, fluids, etc., oscillate. If conditions are 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 a 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. Higher frequencies decrease the potential for mechanical bioeffects.

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

9-3-3 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. This can be defined using the following MI formulae.

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

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, it's recommended that you 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 33.8°F.

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

P_{α}: Attenuated output power

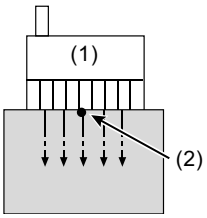
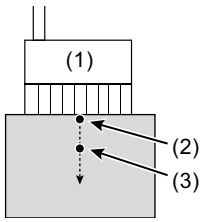
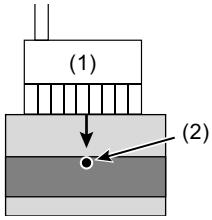
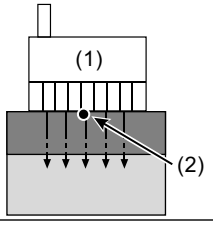
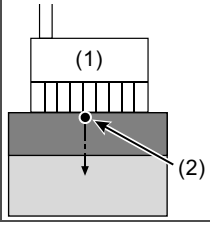
TI, along with the MI, has no unit.

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.

Table2: 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 (3) Bone Surface	 : Soft Tissue : Bone (1) Probe (3) Bone Surface

9-3-4 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 upper screen of the diagnostic instrument. We recommend that you read this manual carefully.

Diagnostic Ultrasound System Control Settings		Menu item or function	MI	TI
Shared Functions	Transmission voltage	A.P.	Yes	Yes
	Electric focus	Focus	Yes	Yes
B	Pulse repetition frequency	Depth, Zoom	—	Yes
		PRF Limit	—	Yes
	Transmission frequency	Frequency (B/M)	Yes	Yes
	Number of scanning lines	Line Density (B)	—	Yes
		Scan Area	—	Yes
	Imaging mode (wave)	WbT, FmT	Yes	Yes
M	Pulse repetition frequency	Depth, Zoom	—	Yes
	Transmission frequency	Frequency (B/M)	Yes	Yes
	Imaging mode (wave)	WbT, FmT	Yes	Yes
PW	Pulse repetition frequency	Vel. Range (D)	—	Yes
		High PRF	—	Yes
		Sample Gate Depth	—	Yes
	Electric focus	Sample Gate Depth	Yes	Yes
	Transmission frequency	Ref. Frequency (D)	Yes	Yes
	Imaging mode (wave)	TDI	Yes	Yes
M+Color	Pulse repetition frequency	Vel. Range (Color)	—	Yes
	Transmission frequency	Ref. Frequency (Color)	Yes	Yes
	Imaging mode (wave)	eFlow, Power, TDI	Yes	Yes
Color	Pulse repetition frequency	Depth, Zoom	—	Yes
		Vel. Range (Color)	—	Yes
	Transmission frequency	Ref. Frequency (Color)	Yes	Yes
	Number of scanning lines	Line Density (Color)	—	Yes
		Scan Area	—	Yes
	Number of transmissions per scanning line	Packet Size	—	Yes
	Imaging mode (wave)	eFlow, Power, TDI	Yes	Yes

9-3-5 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 into consideration the following points.

- Selecting an appropriate probe
- Choice of transmission (higher frequency is lower in MI value)
- Choice of electronic focus
- Lower transmitter voltage
- Increase the gain adjustment

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 appropriate TI
- Appropriate image adjustment settings (raising the gain, etc.)
- Suppress TI value (reducing transmitter voltage, lowering pulse repetition of frequency, or in the case of scan mode, widening the scan width)
- Short exposure time

9-3-6 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
- After selecting a [New Patient] in the Home screen (ID input)
- When preset is selected
- When probes are changed
- After selecting [New Patient] from the [Accessories] tab in the function menu (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 is A.P.% = 70%.

9-3-7 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.

There are cases that the mechanical index (MI) and the thermal index (TI) are more than 1.0 by the type of probe and the mode of image display. At that time, it displays the value in real time.

For fetal observation, the limit will be set at MI< 1.0 and TI < 1.0.

9-3-8 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 ith 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,

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

The result of a measurement is then conveniently expressed as

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

The value of the coverage factor k is chosen based on the level of confidence required for any given application. In general, k will be in the range 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.

Results of Measurement Uncertainty

The following describes experiment results regarding measurement uncertainties in 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 (PII), peak-rarefactional acoustic pressure (pr), acoustic working frequency (f_c)). 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 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_{p2}	. . .	m_{pq}, s_{pq}	$m_{p.}$
	$m_{.1}$	$m_{.2}$	. . .	$m_{.q}$	$\overline{\overline{m}}$

$S_{i.}$

$S_{.j}$

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

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

Probe standard deviation

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

Instrument standard deviation

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

Using equation (8), (9) and (10), 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.

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

The probe variability is quantified by S_{trans}.

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

The instrument variability is quantified by S_{cons}.

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

The total variability is quantified by S_{total}.

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

The variance of the measured value is displayed using the following formula.

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

The variance of the average of the measured value is displayed using the following formula.

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

The Type A standard uncertainty is the square root of the variance of the measurand mean. In other words,

$$u_{\mathrm{A}}{}^2 = \sqrt{\hat{\sigma}_{\bar{x}}{}^2} \tag{20}$$

The Type B uncertainty is displayed using the following formula.

$$u_{\mathrm{B}} = \sqrt{\sigma^2} = \sqrt{\frac{a_1{}^2 + a_2{}^2 + \ldots + a_n{}^2}{3}} \tag{21}$$

Therefore, the combined uncertainty is displayed using the following formula.

$$u_{\mathrm{C}} = \sqrt{u_{\mathrm{A}}{}^2 + u_{\mathrm{B}}{}^2} \tag{22}$$

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).

$$U = k \bullet u_{\mathrm{C}} = t_{.975}(\, pq - 1) \bullet u_{\mathrm{C}} \tag{23}$$

The acoustic power is reported as follows.

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

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.

$$u_{\mathrm{C}} = \sqrt{u_{\mathrm{A}}{}^2 + u_{\mathrm{B}}{}^2} = \sqrt{\hat{\sigma}_x{}^2 + u_{\mathrm{B}}{}^2} \tag{25}$$

k is set to $K_{.99}$ for pqr - 1 = 95 degrees of freedom, and the expanded uncertainty will become as follows.

$$U = k \bullet u_{\mathrm{C}} = K_{.99}(\, pq - 1) \bullet u_{\mathrm{C}} \tag{26}$$

Also, the upper tolerance limit will appear as follows.

$$Power \leq \overline{m} + U \tag{27}$$

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%

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

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: 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%

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

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 PII 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%

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

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 p_r 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_c

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%

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

9-3-9 Note

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10 Message

10-1 Message

The instrument displays four types of messages.

I) Dialog messages

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

II) Assistance messages

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

III) Messages displayed on the remote controller

These messages indicate malfunctions or other remote controller states during operation.

IV) Other messages

These messages indicate operating conditions or malfunctions other than those described above.

10-2 Dialog Messages

Message	Function/Cause	Countermeasure
"Please Connect Power supply as soon as possible. System will be shutting down within a few minutes because of ** battery charge less than 20%."	Battery capacity in the front end unit (Front-End) or back end unit (Back-End) has dropped to 20% or less.	The system will shut down automatically in a short time. To continue instrument operation, plug the power cable into a hospital grade outlet. • [OK] The previous screen is redisplayed.
"Please Connect Power supply immediately. Or please finish this exam and system shutting down immediately. System will be shutting down automatically within 2 minutes because of ** battery remain capacity too low."	Battery capacity in the front end unit (Front-End) or back end unit (Back-End) has dropped to 15% or less.	The system will shut down automatically in 2 minutes. To continue instrument operation, plug the power cable into a hospital grade outlet. Alternatively, end the examination and shut down the instrument. • [OK] The previous screen is redisplayed.
"Connection Failed. Please try to connect by wire."	Communication cannot be established with the front end unit.	Follow the instructions on the screen to connect the front end unit to the back end unit using a unit cable.
"Please contact your customer support center for recovery of your option information."	An inconsistency occurred in the software option information.	Please contact our office. • [OK] The previous screen is redisplayed.
"Front-end of this system temperature is too high. Please confirm your device cooling duct."	Front end unit temperature is high.	Check the air vents. • [OK] The previous screen is redisplayed.
"Front-end of this system temperature is too high. Ultrasound transmitting will stop within 2 minutes."	Front end unit temperature is high.	The front end unit will shut down automatically in 2 minutes. Wait until the instrument cools down. • [OK] The previous screen is redisplayed.
"Front-end cooling fan has some problem. Please contact customer support center and request to replace Front-end cooling fan."	The front end unit cooling fan is malfunctioning.	Please contact our office. • [OK] The previous screen is redisplayed.
"Reestablish connection between Back-end and Front-end due to link down."	Communication between the front end unit and the back end unit was interrupted and is recovering.	Wait a moment for communication between the front end unit and the back end unit to be established. • [OK] The previous screen is redisplayed.
"The system stopped for safety operation, because of connection unstable. Please shutdown the system by manually. After all power switch turn to orange, please turn on again."	A problem occurred in the connection of the front end unit and back end unit.	Shut down the instrument. After the front end unit power switch and the back end unit power switch LED turn to orange, restart the instrument. • [Shutdown] Shut down the back end unit.

Message	Function/Cause	Countermeasure
"The connection between front-end unit and back-end unit has a problem. Dust might be attaching to the surface of the unit connector. Clean the unit connector according to the user manual. To Continue the examination by wireless communication mode, push OK button."	Because the connection between front-end unit and back-end unit has a problem, communication mode is changed to wireless communication.	[OK] You can continue the examination by wireless communication mode. Dust might be attaching to the surface of the unit connector. Clean the unit connector according to this instruction manual after the examination. NOTE: **Refer to "Cleaning Unit Connectors" in this instruction manual for information on how to clean the connectors.** If the same message is displayed after cleaning the connectors, you can always use by wireless communication mode after turning on Wireless Fixed Mode in the preset ([Common Preset > Wireless Ultrasound Setting]) and restart. NOTE: **For details on how to turn on Wireless Fixed Mode, refer to the separate "Detailed Operating Instructions".** If the above remedies fail to solve the problem, make a note of the message and contact our office.
"Restarting due to startup error."	A problem occurred in the connection of the front end unit and back end unit.	The instrument will be rebooted automatically.
"'System found some error of the Front-end battery. Please connect power supply. And please use battery breaker switch of Front-end to DISCONNECT. And please request to replace with new battery for customer support center."	An error has been detected in the front end unit battery.	Insert the power plug in a hospital grade outlet and set the battery shutdown switch to Disconnect mode to disconnect the battery. You can also contact our office. • [OK] The previous screen is redisplayed.
"Front-End battery temperature is too high. System cannot use this battery for safety reason. System will shut down automatically. If you found this message many time, please request repair battery to customer support center."	Battery temperature in the front end unit is too high.	The instrument will be shut down automatically. Check that instrument air vents are unblocked before plugging the power cable into a hospital grade outlet. If the air vents are unblocked, but the same message keeps appearing, please contact our office.
"Back-End battery temperature is too high. System cannot use this battery for safety reason. System will shut down automatically. If you found this message many time, please request repair battery to customer support center."	Battery temperature in the back end unit is too high.	The instrument will be shut down automatically. Check that instrument air vents are unblocked before plugging the power cable into a hospital grade outlet. If the air vents are unblocked, but the same message keeps appearing, please contact our office.
"System found ultrasound transmit voltage was abnormal. Please shutdown system by manually."	An abnormal transmitter voltage has been detected.	End the examination immediately. • [OK] The previous screen is redisplayed.
"Invalid Local Port number. Please enter another number."	The Local Port setting is overlapping with another one.	Change the Local Port setting.

Message	Function/Cause	Countermeasure
"The surface temperature is getting hot. For your safety, please dock your device to Front End Unit."	The remote controller (option) is used removed from the remote controller cradle (option) or Multi-Position Stand (option), and has reached a temperature exceeding 48°C. Using it when holding it in your hands may result in low-degree burns.	Use the remote controller (option) connected to the remote controller cradle (option) or Multi-Position Stand (option). • [OK] The previous screen is redisplayed.
"System CPU temperature is too high. Please power off this system after saving your exam by manually."	CPU temperature is too high.	Save the diagnostic data and shut down the instrument. • [OK] The previous screen is redisplayed.
"System CPU temperature is too high. System will be shutting down."	CPU temperature is too high.	The instrument will be shut down automatically. Wait until the instrument cools down. • [OK] The previous screen is redisplayed.
"Cooling fan has some problem. Please contact your customer support center and request to replace Back-end cooling fan."	The back end unit cooling fan is malfunctioning.	Please contact our office. • [OK] The previous screen is redisplayed.
"System found some error of the Back-end battery. Please connect power supply. And please use battery breaker switch of Back-end to DISCONNECT. And please request to replace with new battery for customer support center."	An error has been detected in the back end unit battery.	Insert the power plug in a hospital grade outlet and set the battery shutdown switch to Disconnect mode to disconnect the battery. You can also contact our office. • [OK] The previous screen is redisplayed.
"System reports ** battery wear level will reach limitation near the future. Please request spare battery to customer support center."	The battery in the front end unit (Front-End) or back end unit (Back-End) has now been discharged more than 450 times.	The battery must be replaced. Please contact our office. • [OK] Returns to the previous screen.
"System reports ** battery wear level reached limitation. System stopped charging for safety reason. Please turn ** battery switch to DISCONNECT mode. And please request spare battery to customer support center."	The battery in the front end unit (Front-End) or back end unit (Back-End) has now been discharged more than 500 times.	Set the battery shutdown switch to Disconnect mode to stop using it. The battery must be replaced. Please contact our office. • [OK] Returns to the previous screen.
"Back up file Reset will destroy any data on this system. Do you still wish to continue?"	You tried to delete preset or saved data.	• [Continue] Deletes preset or saved data. • [Cancel] Returns to the previous screen without deleting the data. • If no response in made within 10 seconds, the display returns to the previous screen.
"This Application is not supported."	When copying preset data from external media, there is preset data from masked applications.	• [OK] Return to the previous screen without writing the data.

Message	Function/Cause	Countermeasure
"Error: Disk full. Please delete data."	(Preset Control) There is insufficient space on the instrument's hard disk.Not enough free space in Local Storage.	Delete unnecessary images or other data in instrument's hard disk Local Storage, and try again. • [OK] Return to the previous screen without writing the data.
"Disk access error: System parameter has been initialized. Please contact service for assistance."	There is insufficient space on the instrument's hard disk.	(1) Select [OK]. (2) Stop using the instrument. (3) Please contact our office.
"Sending images to storage."	The image is being transmitted to the network from the Review.	The message disappears after transmitting the data.
"Storing Data: **%"	The image is being saved to the external media from the Review (% shows the progress of saving).	The message disappears after transmitting the data.
"Cannot find study information."	The patient information search failed to find the examination information.	Select [Retry], and change the search criteria. • [Retry] The Search screen reappears. • [Cancel] Return to the previous screen without searching.
"Cannot find series information."	Patient information search failed to find series information.	
"DICOM image file not found."	Patient information search failed to find the DICOM file.	
"Searching...Please wait."	During a search for information.	The message disappears when the search ends and the search result is displayed.
"Unable to open list file ********"	An image searched in Review cannot be opened (******** shows file name).	Select [Retry]. If the same message appears after repeated [Retry] attempts, the file may be corrupted. • [Retry] Open the file after searching. • [Cancel] The previous screen is redisplayed.
"Unable to load image information."	An image searched in Review cannot be displayed.	
"Unable to read image information."	Image information searched in Review cannot be displayed.	• [Retry] Redisplay the image information after searching. • [Cancel] The previous screen is redisplayed.
"Unable to build image information."	Image data loaded in Review cannot be built.	
"In progress. Please wait."	DICOM file is being converted to BMP or TIFF.	The message disappears after converting, and the completion message appears.
"Process completed."	Converting DICOM file to BMP or TIFF completed.	The message disappears after 2 seconds.
"Network configuration error."	Network communications are out of order.	(1) Check the network configuration (DICOM Store/Send). (2) If necessary, reset the configurations. • [Retry] Retransmit the data. • [Cancel] The previous screen is redisplayed.

Message	Function/Cause	Countermeasure
"Printer configuration error."	The DICOM printer in the network has a problem.	(1) Check the network configurations (DICOM-Printer). (2) If necessary, reset the configurations. • [Retry] Retransmit the data. • [Cancel] The previous screen is redisplayed.
"Disk crashed."	External media data is corrupted.	Reconnect the removable disk. If redisplayed, change the removable disk. • [OK] The previous screen is redisplayed.
"Error: Disk write protected."	The disk is write-protected.	(1) Select [OK]. (2) Replace the writable removable disk. • [OK] Return to the previous screen without writing the data.
"Removable disk is not ready."	The instrument contains a write-protected disk.	(1) Select [OK]. (2) Replace the writable disk in the disk drive and select Retry. • [OK] Return to the previous screen without writing the data.
"Error: No disk, or disk unformatted."	There is no disk in the disk drive. The instrument contains an unformatted disk.	Replace the writable disk in the disk drive and select [Retry]. • [Retry] Reload the data on the disk. • [Cancel] The previous screen is redisplayed.
"ERROR: Disk Full!!"	Space of the removable disk is insufficient.	Insert a new external disk and select [Continue]. Or, select the amount of data that can be stored on the disk. • [Continue] Write the data. • [Cancel] Return to the previous screen without writing the data.
"Verification SCP not supported."	The image was transmitted to a SCP that does not have a server function.	Check the network connection and the network configurations of the equipment. • [Retry] Retransmit the image. • [Cancel] Return to the previous screen without transmitting the data.
"Printer communication error."	A communication error occurs in the printer.	Check the network connection and the network configurations of the equipment. • [Retry] Retransmit the image. • [Cancel] Return to the previous screen without transmitting the data.

Message	Function/Cause	Countermeasure
"Network communication error."	A communication error occurs in the network.	Check the network connection and the network configurations of the equipment. • [Retry] Retransmit the image. • [Cancel] Return to the previous screen without transmitting the data.
"There are images not printed in the printer buffer. Do you print them or delete?"	If there is data in the print buffer, select [Print Queue]. Or select [New Patient].	• [Print] Print the data in the printer buffer, move to the next operation. • [Delete] Delete the data in the printer buffer, move to the next operation. • [Cancel] The previous screen is redisplayed.
"The patient of this image is different from the patient during the examination at present. Do you finish an examination, and may I erase an image?"	You tried to play back another patient's LINE image.	Select whether or not you want to play back the selected image. • [OK] Erase a display image and replay a selected image. • [Cancel] The selected image is only displayed and not played back.
"An image is transferred to cinememory. The image preserved in cinememory is erased."	Select the Line image replay.	
"Patient data base access error."	An error when it accessed database of a patient in Review.	(1) Select [OK]. (2) Check the network configuration of the equipment and connection of the selected database. • [OK] The previous screen is redisplayed.
"Error: Insufficient disk space. Please insert new disk."	(In the case of Disk on Store Media.) Insufficient disk space.	Insert a new disk and select [Continue]. Or, select the amount of data that can be stored on the disk. The message disappears after 5 seconds.
"Error. Network Communication error."	(In the case Net on Store Media.) A communication error occurred with the server.	Check the network connection and the network configurations of the equipment. The message disappears after 5 seconds.
"Error: Disk full;Please delete images."	When Store Media is on the instrument's hard disk or the CD-R Buffer, there is not enough free space on the instrument's hard disk. Or the selected image is too large.	Delete unnecessary images or other data in instrument's hard disk, and try again. The message disappears after 5 seconds.
"Remote *******. ******* does not support Worklist."	The worklist servers (HIS, RIS) in the hospital cannot transmit data.	Check the network connection and the network configurations of the equipment. • [Retry] Retransmit the image. • [Cancel] Return to the previous screen without transmitting the data.

Message	Function/Cause	Countermeasure
"No worklist records found. Showing old records."	A new worklist cannot be found.	Check the network connection and the network configurations of the equipment. • [Retry] Try sending again. • [Cancel] Return to the previous screen without transmitting the data.
"Please enter 'PATIENT ID'."	The patient ID is not entered when the search starts.	(1) Select [OK]. (2) Enter the patient ID. • [OK] The previous screen is redisplayed.
"Loading Patient."	Searching the patient ID in the ID screen.	The message disappears after searching.
"Copying Patient."	The patient information is being retrieved from the search list.	The message is cleared after copying.
"Writing Patient."	Writing patient information to the instrument's hard disk.	The message is cleared after copying.
"Receiving Patient."	The patient information is being received from the HIS and RIS.	The message is cleared after copying.
"Cannot find patient information."	The patient information cannot be found.	Select [Retry], and change the search criteria. • [Retry] The Search screen reappears. • [Cancel] The search is canceled and the ID input screen is redisplayed.
"Patient information data become a full capacity! Please backup and delete these data immediately, when using data manageme"	Patient information database is full.	Delete unnecessary patient information. NOTE: **For details on how to save and delete patient information, refer to the separate "Detailed Operating Instructions".**
"Echo check to *******: ******* started."	C echo check started.	The message disappears after two seconds, or after checking.
"Echo check to *******: ******* successful."	C echo check ended.	This message indicates the selected server provides DICOM compliant functions that are active. • [OK] The previous screen is redisplayed.
"Echo check to *******: ******* failed."	An error occurred at the time of C echo check.	Selected server doesn't have its functions or is not active. Please contact your network administrator. • [OK] The previous screen is redisplayed.
"Ping check to *******: ******* started."	Ping check started.	The message disappears after two seconds, or after checking.
"Ping check to *******: ******* successful."	Ping check ended.	TCP/IP is active. • [OK] The previous screen is redisplayed.

Message	Function/Cause	Countermeasure
"Ping check to *******: ******* failed."	An error occurred during a Ping check.	TCP/IP is not active. Please contact your network administrator. • [OK] The previous screen is redisplayed.
"Invalid probe connected."	The connected probe is not compatible with this instrument.	Disconnect the probe. Disconnecting the probe clears the message. NOTE: **For information on supported probes, see the "Probe" section in this volume.**
"It can't be stored palette image. When Store is done, a color can't be reproduced. Do you change it to RGB?"	When static images are stored on the DICOM Palette format and 3 or more different Palette settings has been made in 4B mode.	• [OK] Instead, save the file in the RGB format. • [Cancel] Return to the previous screen without saving the setting.
"Station name overlaps."	Station names are overlapped.	Check the network configuration. • [OK] The previous screen is redisplayed.
"Invalid data format."	There is an error in the header information of an outside media.	External media cannot be used. • [OK] The previous screen is redisplayed.
"File access error! A part of the data may not be accessed. Reboot is necessary to access to the relevant data."	USB flash memory was removed during copying to USB flash memory.	Data currently being copied in the instrument can be displayed as a thumbnail, but cannot be opened or copied. Restart the instrument to recopy the data. • [OK] The previous screen is redisplayed. NOTE: **Do not remove the USB flash memory during accessing.**
"HARDWARE ERROR **********"	A malfunction has been detected in instrument hardware.	Restart the instrument. If the same message is displayed after a restart, make sure that the front end unit and the back end unit are correctly connected. Then restart the instrument. If the same message is displayed after cleaning the connectors, make a note of the message and contact our office. • [OK] The previous screen is redisplayed.
"SYSTEM ERROR **********"	A malfunction has been detected in software.	Restart the instrument. If this message persists, record message information and contact one of our offices listed on back cover. • [OK] The previous screen is redisplayed.
"Data error of this probe was found. shut down and reboot the system. If this message is displayed again, contact our distributor or Aloka Office, please show this message."	A malfunction has been detected in probe parameters. When this message appears, transmission ends immediately.	Restart the instrument. If this message persists, record message information and contact one of our offices listed on back cover.

Message	Function/Cause	Countermeasure
"Disk decreased;Please delete images."	After saving the image, there is less than 10% of free space on the instrument's hard disk. Or, there is less than 1% of free space on the instrument's hard disk.	Delete unnecessary images from the instrument's hard disk. • [OK] The previous screen is redisplayed.
"**** has stopped working A problem caused the program to stop working correctly. Please close the program."	Windows (operating system) has detected that an application (**** indicates the name of the application) has stopped working.	Restart the instrument. If this message persists, record message information and contact one of our offices listed on back cover.
"**** has stopped working The program is not responding. To return to Windows and check the status of the program, click Cancel. If you choose to end the program immediately, you will lose any unsaved data. To end the program now, click End Now."	Windows (operating system) has detected that this application (**** indicates the name of the application) has not shut down when the instrument is shut down. Wait until the message clears.	Wait until the message clears. If the message does not clear, select [End Now] to shut down. • [End Now] The shutdown process continues. • [Cancel] Cancels the shutdown operation. Again press the power switch on the back end unit.
"Some packet of wireless is missing. Ultrasound image quality may be getting worse. Please adjust your device position or connect by wire."	An error occurred during ultrasound wave reception and ultrasound wave data is missing.	Change instrument orientation or make a cable connection.
"Machine ID of Back-End and Front-End do not match. Please power off."	The front end unit is connected to the wrong back end unit.	The user owns multiple ARIETTA Precision instruments and connected a back end unit to a front end unit belonging to another instrument. Select [OK] and the instrument will shut down automatically after a short while. Connect a back end unit to a front end unit that belongs to the same instrument. Then restart the instrument. If the above remedies fail to solve the problem and the message appears again, make a note of the message and contact our office.
"Machine ID of Back-End and Front-End do not match. Please reconnect them by the right hardware configuration."	The front end unit was connected to the wrong back end unit.	The user owns multiple ARIETTA Precision instruments and connected a back end unit to a front end unit belonging to another instrument. Connect only units that belong to the same instrument. If the above remedies fail to solve the problem and the message appears again, make a note of the message and contact our office.
"Failed to initialize the system. Please shutdown system by manually."	Instrument hardware was not initialized correctly.	Shut down the instrument. • [OK] Returns to the previous screen.

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10-3 Assistance Messages

Message	Description and Operation
"Please Connect Power supply as soon as possible. Because system ** battery charge is less than 25%."	Battery capacity in the front end unit (Front-End) or back end unit (Back-End) has dropped to 25%. To continue instrument operation, plug the power cable into a hospital grade outlet.
"System CPU temperature is too high. Please confirm your device cooling duct."	CPU temperature is too high. Check the air vents.
"Invalid Function: This function is inoperable."	The selected menu or button has not been assigned to any software.
"In progress. Please wait."	Calculating. The message disappears after calculating, and the completion message appears.
"Process completed."	Calculation completed. The message disappears after five seconds.
"Press <ENTER> key to rotate Fetus mark."	When the [Enter] key is pressed, the fetus mark rotates.
"Conform press <ENTER> key. Quit<Cancel> key."	The message appears during the use of Body Mark Location.
"Sending images to printer."	The image is being transmitted to the PC printer.
"STORE Capacity:Free space ***%"	The data is saved to store memory. Free space indicates the amount of free space on the instrument's hard disk. NOTE: **The information area indicates how much instrument's hard disk is used and is not to be confused with Free space.**
"<FREEZE> the image. Then try again."	The non functional switch or menu for movie was selected.
"Accept this images or cycle : Press STORE sw Retry : Press Cancel sw"	Use a save operation to make a Loop replay of the image to confirm whether or not to save it to instrument's hard disk. • [Cancel] Cancel saving the image. • [Store] Save.
"A part of the image couldn't be acquired. Accept this images or cycle : STORE sw, Retry: Cancel sw"	If Auto Loop is "On" , Cine memory does not have the capacity to import heartbeats and time. • [Cancel] Cancel loading the image. • [Store] Take the image into the cine memory.

Message	Description and Operation
"A part of the image couldn't be acquired."	If Auto Loop is "Off" , Cine memory does not have the capacity to import heartbeats and time. • [Cancel] Cancel loading the image. • [Store] Take the image into the cine memory.
"It failed in the store of this images!"	During or starting the image acquisition, the R wave could not be detected.
"System in AUTO-FREEZE. Press <FREEZE> key to resume."	The instrument was left unattended longer than the time setting in preset [Timer Freeze] and the instrument automatically entered freeze mode.
"Backup data file not found."	The backup file cannot be loaded during maintenance.
"Network library initialization error."	The network library failed to be initialized.
"Detection Error: R-wave of ECG is not detected."	R wave of ECG cannot be detected 5 sec or more. The message is cleared as soon as an ECG R-wave is detected.
"Range Limit: Selection is not available."	You tried to configure a mark outside of the possible range.
"Cannot register. If you delete an unnecessary word, you can register newly."	You have attempted to register new words exceeding the user dictionary limit when the learning function is off.
"SERVER Answer Time out W:**** R: ****"	The front end unit and the back end unit are not correctly connected. Check the connection and restart the device. NOTE: **If the problem does not improve, please contact our office.**
"Cannot access home screen. Printing is in progress."	You pressed the HOME button during printing. Wait for printing to end before pressing the HOME button again.
"Cannot access home screen. Please exit measurement function."	You pressed the HOME button during measurements. Wait for measurements to end before pressing the HOME button again.
"Cannot access home screen. Please stop cine loop."	You pressed the HOME button during loop playback. Wait for loop playback to end before pressing the HOME button again.
"Cannot access home screen. Please close Preset window."	You pressed the HOME button in the Preset screen. Close the preset screen before pressing the HOME button again.
"Cannot access home screen. Please close Review window"	You pressed the HOME button in the Review screen. Close the Review screen before pressing the HOME button again.
"Cannot access home screen. Please close report window."	You pressed the HOME button in the Report screen. Close the Report screen before pressing the HOME button again.

Message	Description and Operation
"Cannot access home screen. Please close user authentication window."	You pressed the HOME button in the User authentication screen. Close the User authentication screen before pressing the HOME button again.
"Cannot access home screen. Please close ID window."	You pressed the HOME button in the ID input screen. Close the ID input screen before pressing the HOME button again.
"Cannot access home screen. Please exit needle emphasis function."	You pressed the HOME button during Needle Emphasis operation. Turn off the Needle Emphasis function before pressing the HOME button again.
"Cannot access home screen. Please erase Puncture Guideline."	You pressed the HOME button in the Puncture Guideline display. Turn off Puncture Guideline before pressing the HOME button again.
"Cannot access home screen. Image Optimizer is in progress"	You pressed the HOME button during Auto-optimizer operation. Wait for Auto-optimizer operation to end before pressing the HOME button again.
"Cannot access home screen. Please select Brachy Mode: Off."	The HOME button was pressed during use of the Brachytherapy function. Turn Off the brachytherapy function and press the HOME button again.
"Content does not exist."	The instruction manual or Case Book does not appear. NOTE: **Contact our office to request a service engineer visit. Please contact our office to request a service engineer visit.**

10-4 Messages displayed on the remote controller

Message	Function/Cause	Countermeasure
"Stop the screen update because it is in VideoClip store. Please wait until the store end."	Image update stopped while saving a Video Clip on the instrument.	Ultrasonic images on the remote controller screen are not updated when a Video Clip is being saved. Wait until saving completes.
"System reports a battery wear level will reach limitation near the future. Please request spare battery to customer support center."	The battery in the remote controller has been recharged more than 450 times.	The battery must be replaced. Please contact our office. • [OK] The previous screen is redisplayed.
"System reports a battery wear level reached limitation. System stopped charging for safety reason. Please turn Remote controller battery switch to DISCONNECT mode. And please request spare battery to customer support center."	The battery in the remote controller has been recharged more than 500 times.	Set the battery shutdown switch on the remote controller to DISCONNECT mode to stop using it. The battery must be replaced. Please contact our office. • [OK] The previous screen is redisplayed.
"If you want to shutdown the ARIETTA Precision, please push the "Turn off". However, Please push the physical power button when you want to shutdown of the remote-controller."	Select [Shutdown] from a remote controller specific icon.	• [Turn off] The instrument shuts down. • [Cancel] You return to the previous screen without shutting down the instrument.
"If you want to reconnect the ARIETTA Precision, Please push the "Reconnect"."	You selected [Reconnect] from a remote controller specific icon.	• [Reconnect] Reconnect the remote controller to the instrument. • [Cancel] You return to the previous screen without reconnecting.
"If you want to retry the connection, please push the reconnect button."	The connection between the main unit and the remote controller has failed.	Select [Recconect] to reconnect them. • [OK] The previous screen is redisplayed. NOTE: **If the main unit and the remote controller do not reconnect when [Reconnect] is selected, restart the main unit.**
"For your safety, please been suspended the use of the remote-controller."	An abnormality occurred with the temperature of the surface of the remote controller.	Stop using the remote controller and return it to the remote controller cradle. • [OK] The previous screen is redisplayed.

10-5 Other Messages

Message	Function/Cause	Countermeasure
"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 [Shut down] button or press and hold the power switch on the back end unit for four 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.
"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 switch on the back end unit for four seconds or more to turn the instrument off. Restart the instrument (If the instrument is off, press the power switch again). If this message is displayed repeatedly, a hard disk failure may have occurred. Please contact our office.
"Reboot and Select proper Boot device or Insert Boot Media in selected Boot device and press a key"	The operating system failed to start up.	Press and hold the power switch on the back end unit for four 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.

11 License Information

11-1 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

11-2 Microsoft Software License Terms

11-2-1 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 Hitachi, Ltd.
- "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 Hitachi, Ltd. can be used.

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

11-2-2 WINDOWS EMBEDDED 8.1 INDUSTRY PRO

This is a license agreement between you and [OEM] that describes your rights to use Windows Embedded 8.1 Industry Pro ("Windows Embedded Industry").

The software on this device includes software licensed from Microsoft Corporation or its affiliate.

For your convenience, we've organized this agreement into two parts. The first part includes introductory terms phrased in a question and answer format and the Additional Terms follow and contain greater detail. You should review the entire agreement, including any linked terms, because all of the terms are important and together create this contract that applies to you. You can review linked terms by pasting the forward link into your browser window once the software is running. **The Additional Terms contain a binding arbitration clause and class action waiver. If you live in the United States, these affect your rights to resolve a dispute with [OEM], or with Microsoft, so you should read them carefully.**

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

How can I use the software? We do not sell our software or your copy of it – we only license it. The software may require a key to install or access it. If it does, you are responsible for the use of keys assigned to you. You should not share the keys with third parties.

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

What about updating the software? If the software covered by this agreement is an update to your existing operating system software, the update replaces the original software. You do not retain any rights to the original software after it has been updated and you may not continue to use it or transfer it in any way. This agreement governs your rights to use the update software and replaces the agreement for the software from which it was updated. After the update is complete, some apps may not migrate or may be incompatible with Windows Embedded 8.1 Industry Pro and additional software may be required to play back or record certain types of media, including DVDs.

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

How does Internet activation work? The first time you or [OEM] 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. This process is called "activation." Because activation is meant to identify unauthorized changes to the licensing or activation functions of the software, and to otherwise prevent unlicensed use of the software, **you or [OEM] may not bypass or circumvent activation.**

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

How does Microsoft use your information? Microsoft uses the information it collects through the software features to upgrade or fix the software and otherwise improve our products and services. In certain circumstances, Microsoft also share it with others. For example, Microsoft share error reports with relevant hardware and software vendors, so that they can use the information to improve how their products run with Microsoft products. You agree that Microsoft may collect, use and disclose the information as described in the Privacy Statements at go.microsoft.com/fwlink/?LinkID=301572.

What does this agreement apply to? This agreement applies to the software, the media on which you received the software, if received on media, and any Microsoft updates, supplements, and services for the software, unless other terms come with them. If you obtain updates or supplements directly from Microsoft, then Microsoft, and not [OEM], licenses those to you.

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

ADDITIONAL TERMS

1. License Rights

   The software license is permanently assigned to the device (physical hardware system) with which you acquired the software. You may only use the software on that device.

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

   b. Storage/Network Use. You may also store or install one (1) copy of the software on a storage device, such as network server, used only to install or run the software on your other industry systems over an internal network; however, you must acquire and dedicate an additional license for each separate industry system on or from which the software is installed, used, accessed, displayed or run. Except as otherwise permitted by Remote Assistance features described below, a license for the software may not be shared or used concurrently on different industry systems.

   c. Multiple or Pooled Connections. Hardware or software you use to multiplex or pool connections, or reduce the number of devices 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 copy of the software you are using.

   d. Device Connections. You may permit a maximum of twenty (20) computers or other electronic devices (each a "Device") to connect via Server Message Bloc (SMB) to the industry system to utilize one or more of the following services of the software: file services, print services, Internet information services, Internet connection sharing and telephony services. The twenty connection maximum includes any indirect connections made through "multiplexing" or other software or hardware which pools or aggregates connections. Unlimited inbound connections are allowed via TCP/IP (Transmission Control Protocol ("TCP") and the Internet Protocol ("IP").

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

      - Remote Desktop. The single primary user of the licensed device may access a session from any other device using Remote Desktop or similar technologies. A "session" means the experience of interacting with the software, directly or indirectly, through any combination of input, output and display peripherals. Other users, one at a time, may access the licensed software running on this host device, from any device using Remote Desktop, but only if the remote device is separately licensed to run Windows Embedded 8.1 Industry Pro.
      - Remote Assistance. You may use Remote Assistance or similar technologies to share an active session without obtaining any additional licenses for the software. Remote Assistance allows one user to directly connect to another user's device, usually to correct problems.

f. Device. In this agreement, "device" means a hardware system with an internal storage device capable of running the software. A hardware partition or blade is considered to be a device. The software is licensed to run on up to two processors on the licensed device.

g. Multiple versions. The software includes multiple versions (such as 32-bit and 64-bit versions), and you or [OEM] may install only one of those versions at a time. Installing the 32-bit version of Windows Embedded 8.1 Industry Pro on this system requires a change to the BIOS settings to legacy BIOS mode. If you switch to the 64-bit version of Windows Embedded 8.1 Industry Pro from the 32-bit version of Windows Embedded 8.1 Industry Pro, then you should revert back to the original BIOS settings. If you do not revert back to these BIOS settings when switching back to the 64-bit version, the following Windows Embedded 8.1 Industry Pro functionalities will not work as they rely on UEFI mode boot:

- Secure Boot,
- Seamless Boot experience,
- Network unlock for Bitlocker for computer with a Trusted Platform Module (TPM) and
- eDrive support.

Reverting back to UEFI mode will require a hard drive reformat. All data and personal settings will be lost. It is highly recommended that you back up your data before you revert back to UEFI mode.

2. Binding Arbitration and Class Action Waiver

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

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

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

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

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

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

g. Arbitration fees and incentives

   i. Disputes involving $75,000 or less. [OEM] will promptly reimburse your filing fees and pay the AAA's and arbitrator's fees and expenses. If you reject the [OEM]'s last written settlement offer made before the arbitrator was appointed ("last written offer"), your dispute goes all the way to an arbitrator's decision (called an "award"), and the arbitrator awards you more than the last written offer, [OEM] will give you three incentives: (1) pay the greater of the award or $1,000; (2) pay twice your reasonable attorney's fees, if any; and (3) reimburse any expenses (including expert witness fees and costs) that your attorney reasonably accrues for investigating, preparing, and pursuing your claim in arbitration. The arbitrator will determine the amounts.

   ii. Disputes involving more than $75,000. The AAA rules will govern payment of filing fees and the AAA's and arbitrator's fees and expenses.

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

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

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

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

3. Choice of Law

The laws of the state or country where you live govern all claims and disputes concerning the software 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, except that the FAA governs all provisions relating to arbitration. If you acquired the software in any other country, the laws of that country apply. This agreement describes certain legal rights. You may have other rights, including consumer rights, under the laws of your state or country. You may also have rights with respect to the party from whom you acquired the software. This agreement does not change those other rights if the laws of your state or country do not permit it to do so.

4. Activation

a. More on how activation works. The software will notify you or [OEM], if [OEM] activates the software, whether the installed copy of the software is properly licensed. During activation, the software will send information about the software and your device to Microsoft. This information includes the version, language, and product key of the software, the Internet protocol address of the device, and information derived from the hardware configuration of the device. For more information about activation, see go.microsoft.com/fwlink/?linkid=280262. If the licensed device is connected to the Internet, the software will automatically connect to Microsoft for activation. You can also activate the software manually by Internet or telephone. In either case, Internet and telephone service charges may apply.

b. Re-activation. Some changes to your device components or the software may require re-activation of the software.

c. Activation failure. During online activation, if the licensing or activation functions of the software are found to be counterfeit, improperly licensed, or include unauthorized changes, activation will fail and the software will attempt to repair itself by replacing any tampered Microsoft software with genuine Microsoft software. The software will notify you or [OEM] if the installed copy of the software is improperly licensed or includes unauthorized changes. In addition, you or [OEM] may receive reminders to obtain a properly licensed copy of the software. You may not be able to obtain certain updates or upgrades from Microsoft if your copy of the software is found to be improperly licensed.

5. Internet-Based Features; Privacy

Some software features use Internet protocols, which send to Microsoft (or its suppliers or service providers) device information, such as your Internet protocol address, the type of operating system, browser and name and version of the software you are using, the language code of the device where you installed the software, and other information described below, in the Windows Privacy Statement at go.microsoft.com/fwlink/?linkid=280262, or in the Windows Embedded user interface. Microsoft uses this information to make the Internet-based features available to you, in accordance with the Windows Privacy Statement at go.microsoft.com/fwlink/?linkid=301572 and information that may be presented to you in the Windows Embedded user interface. Some Internet-based features may be delivered and updated at a later date if, for example, you acquire an application that relies on one of those services, or to help make the software safer or more reliable. Internet features include, but are not limited to the features described below, in the Windows 8.1Privacy Statement at go.microsoft.com/fwlink/?linkid=301572 and the Windows Embedded user interface. [OEM] may have elected to turn on one or more of the following features in the licensed device.

a. Accelerators. When you click on or move your mouse over an Accelerator in Internet Explorer, any of the following may be sent to the applicable service provider (which may not be Microsoft): the title and full web address or URL of the current webpage, standard device information, and any content you have selected. For more information, see go.microsoft.com/fwlink/?linkid=280122.

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

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

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