HITACHI
Inspire the Next

Transrectum Composite Probe
UST-672-5/7.5
Instruction Manual

MN1-0756 Rev.26

Notes for operators and responsible maintenance personnel

★ *Please read through this Instruction Manual carefully prior to use.*

★ *Keep this Instruction Manual together with the ultrasound diagnostic instrument for any future reference.*

CE 0123

Hitachi, Ltd.

Introduction

This is an instruction for model UST-672-5/7.5, an ultrasound probe.
Read the manual carefully before using the instrument. Take special note of the items in section 1, "Safety Precautions".
Keep this manual securely for future reference.

The CE mark on the probe indicates that this probe is valid when it is connected to equipment bearing the CE mark that is specified as available in section 2 of this document. Therefore, if a probe bearing the CE mark is connected to equipment that is specified as available but does not have a CE mark, part of this instruction manual may not apply.

Symbols used in this document

The terms below are used in the safety information provided to prevent hazards and injuries to the operator or patients. The severity of the hazard and injury that can occur when failing to observe the displayed safety information are 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 to the operator or patient.

⚠ Warning
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury to the operator or patient.

⚠ Caution
Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the operator or patient, or property damage only.

⚠ 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 type of safety information is indicated by the symbols below.

⚠	This symbol means attention is required.
	This symbol means that the described action is prohibited.
	This symbol means the described action is mandatory.

CONTENTS

This Instruction Manual contains the main body of 46pages and 5pages until the CONTENTS.

1. Safety Precautions

1-1. Intended use

This probe is intended for use by a doctor or other qualified operator for inserting into a human rectum and making ultrasonic observations of the prostate and surrounding organs.

⚠ Caution
Do not use this equipment for other than its intended purpose. Use for other purposes can cause burns or other injuries to the patient or operator.

1-2. Usage precautions

The terms below are used in the safety information provided to prevent hazards and injuries to the operator or patients. The severity of the hazard and injury that can occur when failing to observe the displayed safety information are indicated in four levels: "Danger", "Warning", "Caution" and "Note".

⚠ Danger
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⚠ 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 type of safety information is indicated by the symbols below.

⚠ This symbol means attention is required.
This symbol means that the described action is prohibited.
This symbol means the described action is mandatory.

1-2-1. Warnings and safety information

⚠ Warning	
❗	Follow the information in this manual and the documentation supplied with any equipment used together with this probe. Use that is not in accordance with the supplied documentation can result in a serious or moderate injury, equipment breakdown, or physical damage that impairs operation.
❗	Be sure to preparations for use. Use of the equipment while failing to notice an abnormal condition can result in injury to the operator or patient. If any abnormalities are noted on the equipment in the start up inspection, immediately stop using it and contact one of our offices and/or distributor's offices listed on the back cover. See section 3-1 "Start up check" for the start up inspection content and procedure.
⃠	Do not use on the eyes. This equipment is not intended for use on the eyes. The acoustic output can have an adverse effect on the eyes.
⃠	Do not attempt to disassemble, modify, or repair the equipment. Electric shock or other unforeseen accidents could result. Contact one of our offices and/or distributor's offices listed on the back cover to request repair.
❗	Clean, disinfect and sterilize before using the equipment as necessary. Perform properly wash, disinfect and sterilize after use. Otherwise, there is a risk of infection. Note that the probe is not sterilized at the factory. Before using the equipment first, be sure to wash, disinfect and sterilize it as required.
❗	Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
❗	Dispose of the probe used for patients with Creutzfeldt-Jakob disease. Otherwise, there is a risk of infection to the operator or patient. Our ultrasound probe is not compatible with any disinfection/sterilization method for Creutzfeldt-Jakob disease.
❗	When using ultrasound contrast agent, follow the supplied documentation. Unexpected accidents could result. Check the state of the patient and take appropriate precautions to avoid side effects.
⃠	Do not use the equipment fallen on to floor. Otherwise, there is a risk of infection. Stop the operation and perform the procedure in section 8 "Periodic Inspection", section 5 "Washing, Disinfection and Sterilization" and section 3-1 "Start up check".

⚠ Caution	
❗	Constantly check for anything abnormal about the patient's condition and the equipment. Continued use without noticing that an abnormal condition has occurred can result in an electric shock and injury to the operator or patient. If an abnormal condition occurs, immediately move the equipment away from the patient and stop use of the equipment.
❗	The equipment is vulnerable to damage by impact. Therefore, handle it with care. There is a risk of damage to the equipment when the equipment is fallen or hit somewhere.

⃠	Do not use this equipment with other equipment except for those specifically approved in the manual. Use with unapproved equipment can result in an electric shock, burn, or other injury to the patient or operator and damage to this equipment and the other equipment.
❗	Scan for the minimum length of time necessary for the diagnosis and at the lowest suitable output. Overuse can adversely affect the internal tissues of the patient. For details about the acoustic output, please refer to the documentation supplied with the ultrasound diagnostic instrument.
❗	Regularly perform maintenance inspection and safety tests of the equipment. If you use equipment for a long period of time, it can reduce the performance, or cause smoke or fire. If anything unusual occurs, immediately stop using it and contact one of our offices and/or distributor's offices listed on the back cover.
❗	Use, move and transport the equipment under the environmental conditions specified in this manual. Otherwise, it may be damaged. See section 2-5 "Environmental conditions" and section 7-4 "Environmental conditions during transportation".

1-2-2. Option usage precautions

⚠ Warning
Use by covering the balloon over the insertion portion. If the balloon is not used, residual pathogens on the probe could infect the patient.
Use Hitachi-approved balloons only. Use of an item lacking biocompatibility can cause an adverse reaction by the body of the patient.
Check that the balloon is sterilized. Use of an infected item could spread infection to the patient.
Do not reuse the balloon and rubber ring. Use of an infected item could spread infection to the patient.
Do not apply unsterilized acoustic medium to the outer surface of the balloon. Use of an acoustic medium that is contaminated by a pathogen can cause an infection on the patient.
Do not use on patients who may have an allergic reaction to latex products. Use of the balloon for these types of patients could result in anaphylactic shock. Ask the patient about allergy history beforehand.

⚠ Caution
Check the balloon for abnormalities before use. Store the balloons in a cool, dry location not exposed to direct sunlight and do not use balloons that have exceeded their expiration date (for items where the expiration date is not displayed; 2 years from the displayed sterilization date) or severe discoloration, cracks, or other visible defects finds.
Check that the acoustic medium has no air bubbles inside the balloon that is covering the probe. Air bubbles inside the balloon can result in misdiagnosis caused by overlooking or misinterpreting lesions due to poor image quality or improper rendering.

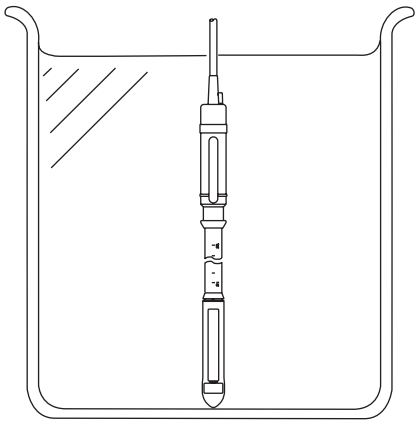
1-2-3. Washing, disinfection and sterilization precautions

⚠ Warning

- Wear protective gloves and other protective gear during washing, disinfection and sterilization. Handling of the probe with your bare hands before disinfection or sterilization can result in an infection.
- After soaking in cleaning agents, thoroughly wash the probe with running water. Residual cleaning agents can cause an adverse reaction on the bodies of the operator or patient.
- After chemical disinfection and sterilization, thoroughly wash the probe with sterilized water. Residual chemicals can cause an adverse reaction on the bodies of the operator or patient.
- Perform aeration completely after gas disinfection and sterilization. Residual gas can cause an adverse reaction on the bodies of the operator or patient.
- Do not wash, disinfect or sterilize using procedures other than those specified in this manual. Infection could result due to incomplete washing disinfection or sterilization. It can also result in damage to the probe or reduced performance. The probe cannot withstand autoclave sterilization or boiling and other types of sterilization at temperatures exceeding 60°C (140°F).
- For details on the usage conditions of chemicals and sterilization procedures, refer to the documentation supplied with the respective chemical or sterilization equipment. Infection could result due to incomplete disinfection or sterilization. This could also cause deterioration of the probe.
- Thoroughly wash, disinfect or sterilize from inlet/drain port to inlet/drain nipple. Infection could result due to incomplete disinfection or sterilization. This could also cause deterioration of the probe.

⚠ Caution

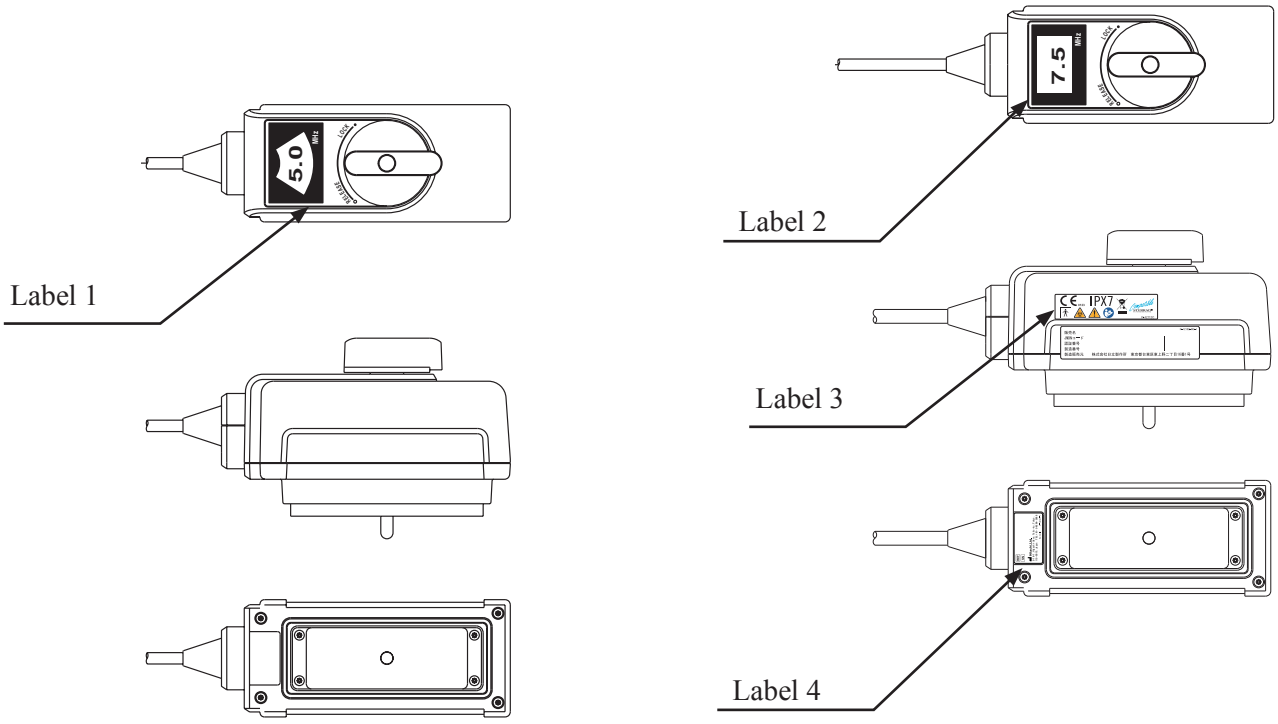
- Do not place the insertion portion and handle in any liquids beyond the range shown in the figure right. Use when liquid has gotten inside the connector can result in a risk of electric shock to the operator or patient. If liquid gets inside the connector, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.



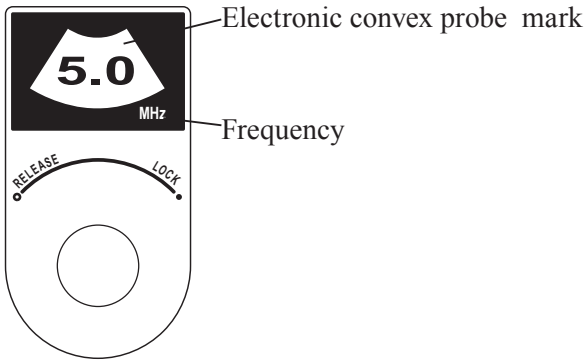
Water or chemical solution

1-2-4. Labels

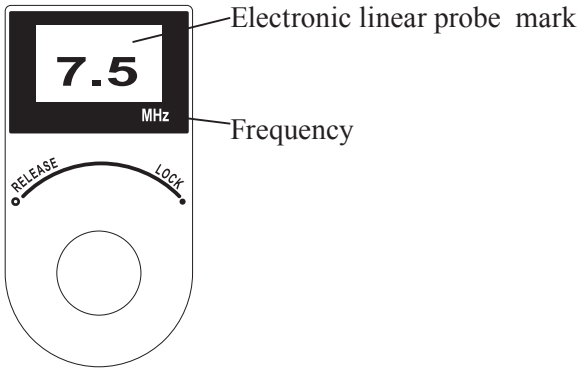
(1) Probe unit



Label 1



Label 2



Label 3

This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS.

IPX7 mark
See section 2-2, "Specifications".

Type BF applied part

Do not waste the instrument as general waste. Comply with a local regulation.
See section 10.

STERRAD sterilization compatibility mark
See section 5.

Safety warning sign

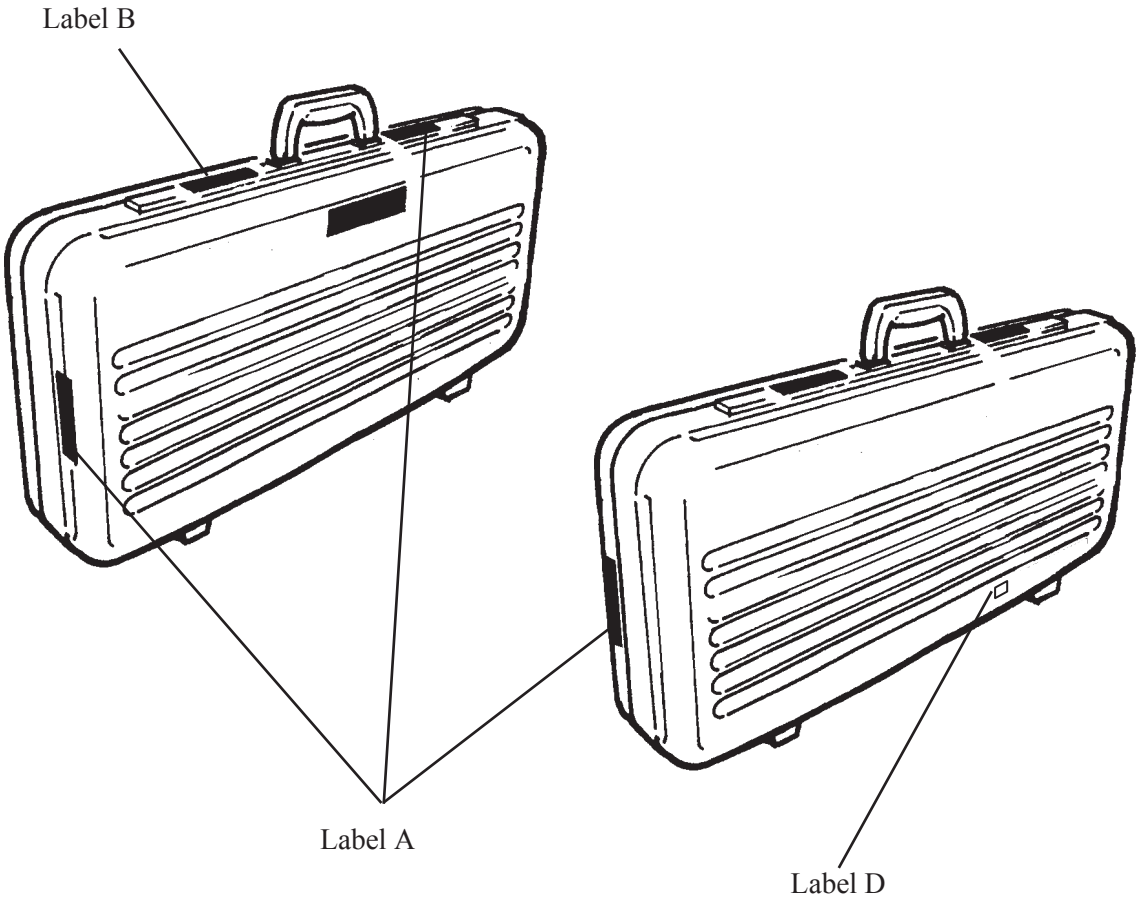
Biohazard
See section 5.

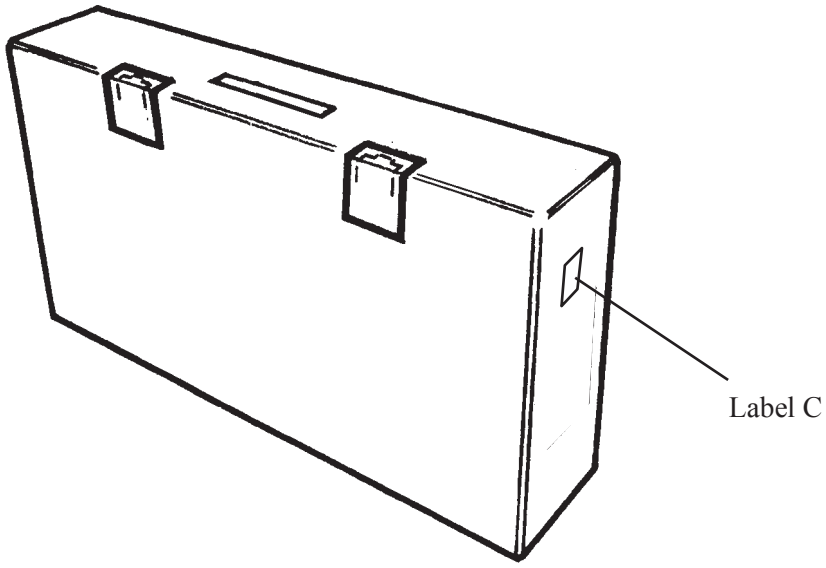
Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.

Label 4

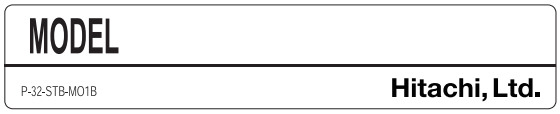
Model
Serial No.
Manufacturer
Address
Rx Only:
By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.

(2) Storage case





Label A

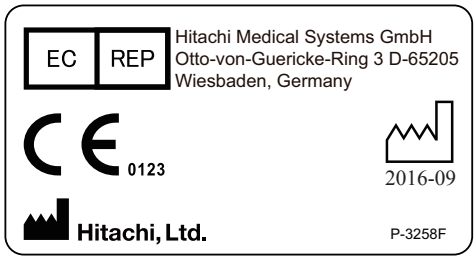


Model

Label B

Serial No.

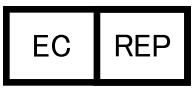
Label C



This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS.

DATE OF MANUFACTURE
(in case of 2016-09)

MANUFACTURER



AUTHORISED REPRESENTATIVE IN EUROPEAN COMMUNITY

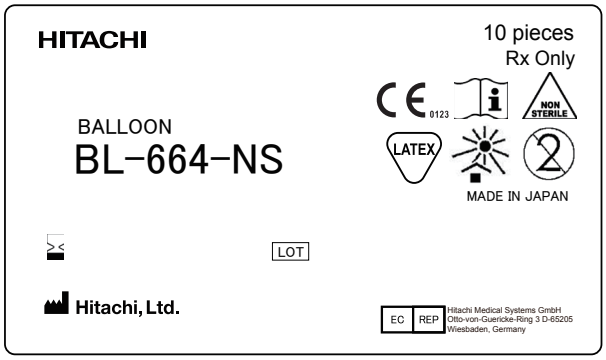
Label D

DATE OF MANUFACTURE
(in case of 2016-09)

(3) balloon

Label for 1 pieces

Label for 10 pieces



Non sterile

Contains or presence natural rubber latex

Use by

Do not reuse

Keep away from sunlight

Lot number

2. Specifications and Parts name

2-1. Principles of operation

This probe and the ultrasound diagnostic instrument enable image diagnosis using ultrasonic waves. These instruments operate under the principles described below.

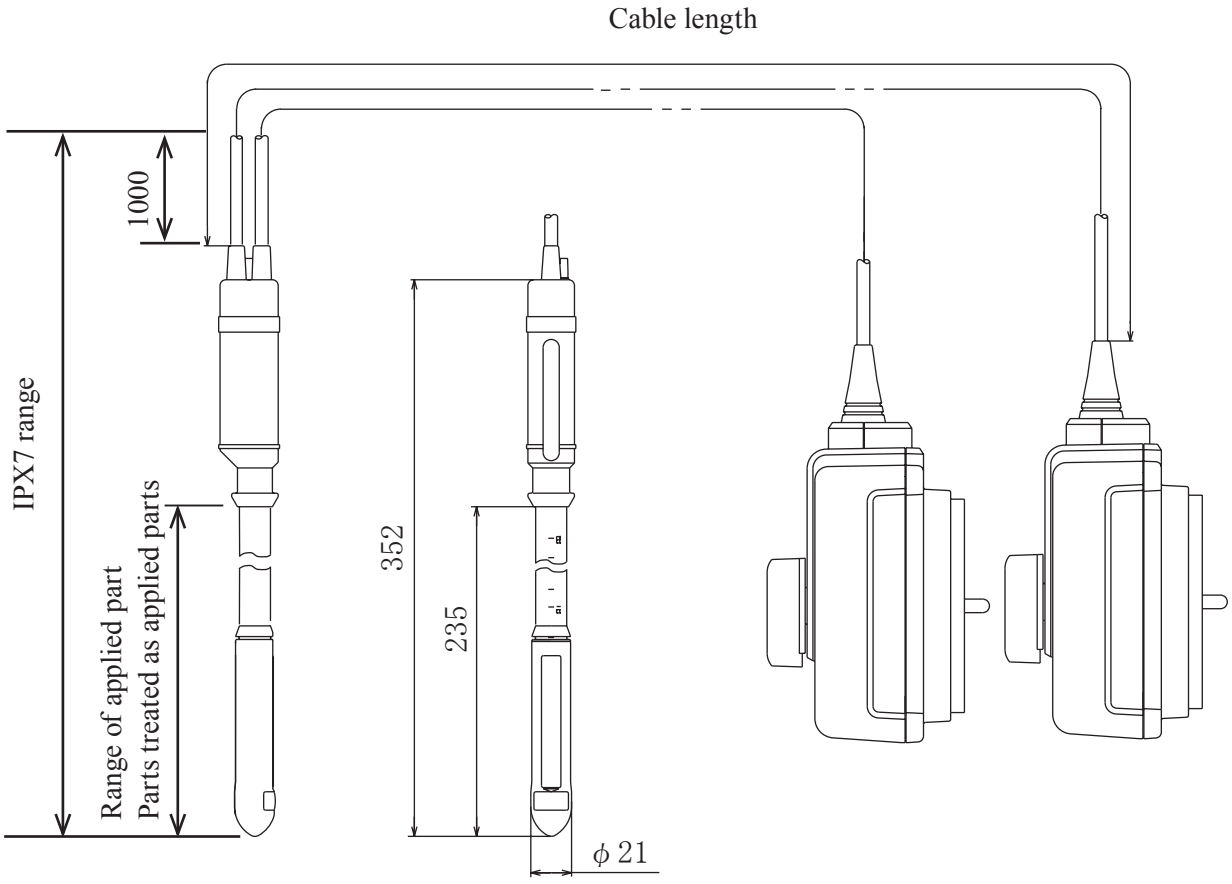
(1) When an electric pulse signal is applied from the transmitter to the transducer of the probe, the transducer operates by converting electrical vibrations to mechanical vibration energy for emitting pulse-shaped ultrasonic waves into the body part contacting the transducer or into liquid or other medium.

(2) The emitted ultrasonic waves are reflected by boundaries with different acoustic characteristics (acoustic impedance) within the body.

(3) The transducer is also used to receive reflected ultrasonic waves. The transducer vibrates mechanically due to the received ultrasonic vibrations and uses an electro-mechanical conversion operation to convert the received mechanical vibrations to electric energy. The received echo is also converted to electric signals and a brightness modulation operation is used to convert the electric pulses to shades of brightness for forming an image.

2-2. Specifications

Application regions:	Urological applications
Form of application to patient:	Transrectum
Connectable instruments:	SSD-900,SSD-1000,SSD-3500,SSD-4000,SSD-α5,Prosound 6, Prosound α6,F37
Field of view:	Vertical to Axis (Convex) : 120°
	Parallel to Axis (Linear) : 60mm
Frequency:	Vertical to Axis (Convex) : 5MHz
	Parallel to Axis (Linear) : 7.5MHz
Cable length:	2.5 m
Weight:	1,800 g
Service life:	Three years
Range of applied part	As shown in the figure below.
Parts treated as applied parts	As shown in the figure below
IPX7 range	As shown in the figure below.
External dimensions:	As shown in the figure below.



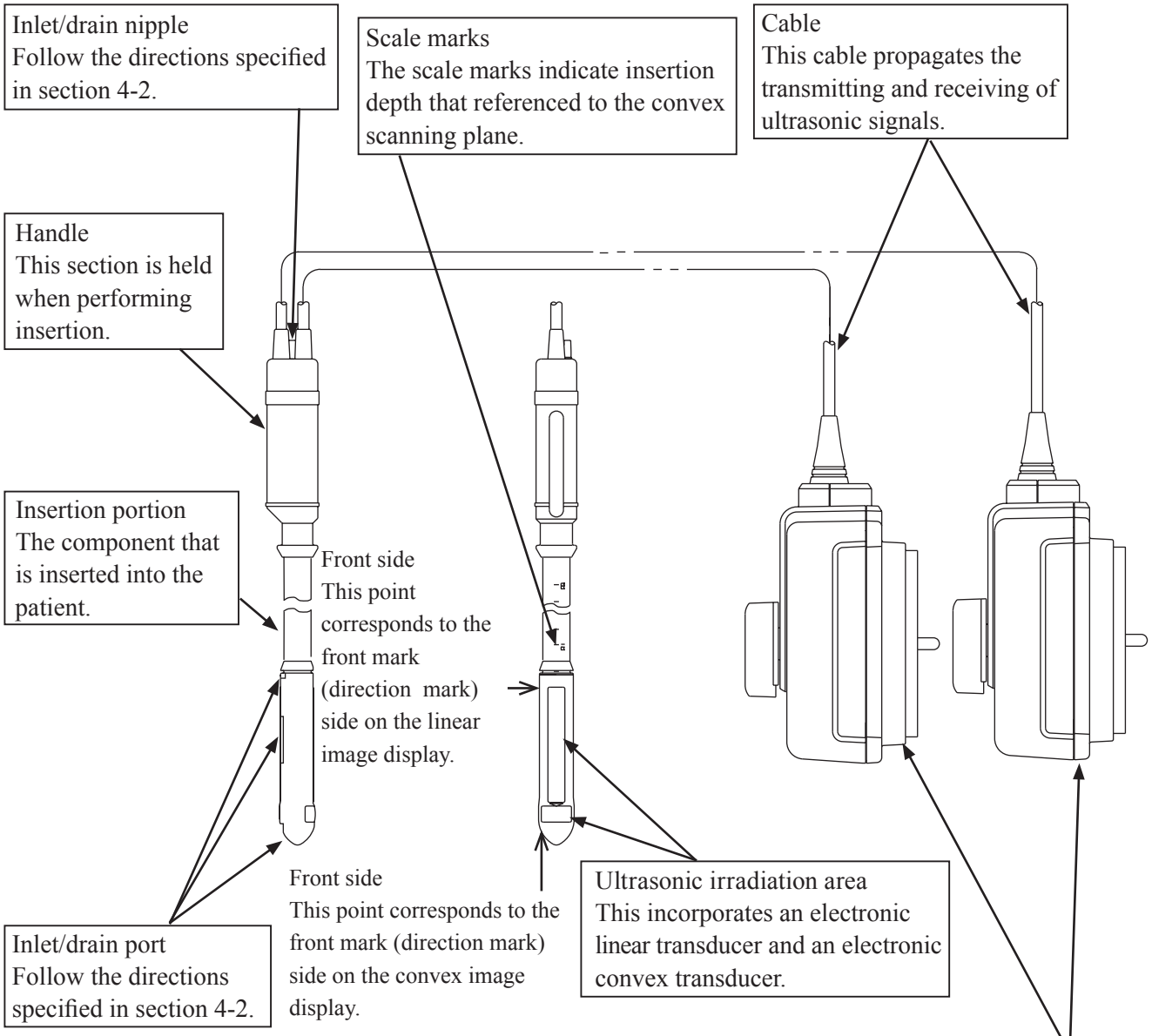
Unit: mm

Remarks
The dimensions and weight are within ±10% of the indicated values.

2-3. Performance

For measurement tolerances, operating tolerances and other data, refer to the instruction manual for the ultrasound diagnostic instrument.

2-4. Name of each parts



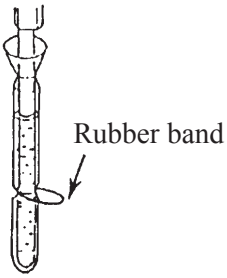
⚠ Caution
⊘ Do not pull, bend, twist, or apply excessive force to the cable. The conductors may break and the cable may become unusable.
⊘ Do not subject the ultrasonic irradiation area to hard impact. The impact may cause damage to the transducer, and that results in noise or no echo in the image. In most cases, the ultrasonic irradiation area itself is not damaged because the part is made of elastic material.

・Balloon

Cover the insertion portion with this balloon to prevent infection. Follow the instructions in section 4-2.

・Rubber band

This is used to keep water in the ballon.

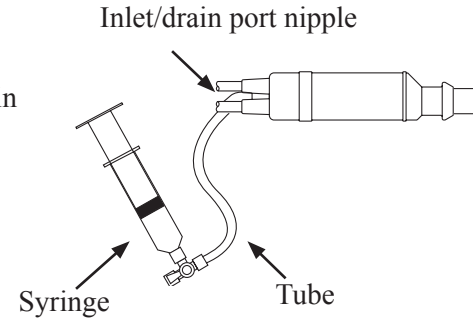


・Syringe

・Three-way cock

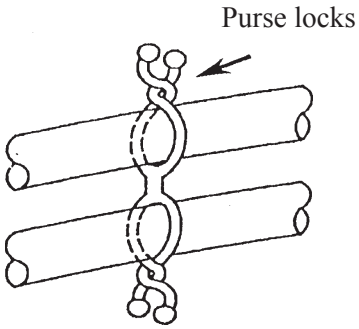
・Extension tube

These are used to inject water to the balloon from the inlet/drain nipple. Follow the instructions in section 4-2.



・Purse locks

This is used to tie two cables together.



・Surgical tape

If the flare of the balloon disturb to use, fasten the flare by this tape.

2-5. Environmental conditions

Use and store the equipment under the following conditions.

2-5-1. Operating environmental conditions

Ambient temperature:	10°C to 40°C
	50°F to 104°F
Relative humidity:	30% to 75%
Atmospheric pressure:	700 hPa to 1060 hPa
Altitude:	3,000 m or less

2-5-2. Storage environmental conditions

Ambient temperature:	–10°C to 50°C
	14°F to 122°F
Relative humidity:	10% to 90%
Atmospheric pressure:	700 hPa to 1060 hPa

⚠ Caution

Avoid operating or storing the equipment in the following locations.

- Locations exposed to water or other liquids
- Locations subject to adverse conditions such as air pressure, temperature, humidity, ventilation, direct sunlight, dust, or air containing salt, sulfur, or other corrosive substances
- Locations where chemical substances are stored or where gases are generated

Storage in these locations can result in a breakdown or reduced performance.

Avoid rapid temperature change which may cause condensation. Avoid using in locations where condensation or water droplets can form.
Condensation can occur when moving the probe from a cool location to a warm one. Use when condensation has occurred can result in a breakdown or reduced performance.

2-6. Classification of ME equipment

- Classification based on degree of protection against electric shock . Type BF applied Part
- Classification for protection against ingress of liquids ..... IPX7 (Watertight equipment)
- Operation mode ..... Continuous operation
- Method of sterilization ..... See section 5 "Washing, Disinfection and Sterilization"

For the range of applied parts, parts treated as applied parts and the range of IPX7, see section 2-2.

3. Preparations for Use

3-1. Start up check

3-1-1. Visual check

Visually check the ultrasonic irradiation area, insertion portion,handle, cable, connector and balloon. If any holes, indentations, abrasion, cracks, deformation, looseness, discoloration, or other abnormalities are found, do not use the equipment.

3-1-2. Verification of washing, disinfection and sterilization

Verify that washing, disinfection and sterilization are conducted according to the intended use.

3-1-3. Verification of operation

Connect to the ultrasound diagnostic instrument by following the instructions in section 4-5, "Connecting to the ultrasound diagnostic instrument" and check that the selected probe match the convex or linear display and the displayed frequency and check the image for errors.

Remarks

For details on the displayed screens, see the documentation supplied with the ultrasound diagnostic instrument.

If the probe is operated in still air, brightness on the top of the image may be non uniform, but this does not affect the performance of the probe.

⚠ Warning

Be sure to preparations for use.
Using the equipment without noticing an abnormal condition can result in injury to the operator or patient. If an inspection finds an abnormal condition in the equipment, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.

⚠ Caution

Do not use the probe if the selected probe and image do not match the frequency.
An incorrect acoustic output can result in burns or other injuries to the patient. Contact one of our offices and/or distributor's offices listed on the back cover.

4. Usage

4-1. Operation

Check that the balloon is mounted and insert into the rectum. An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. Furthermore, this probe enables observation of two sections which cross each other at right angles: a horizontal section and a vertical section. The operator can switch over from one section to the other on the ultrasound diagnostic instrument. For details on displaying and adjusting the screens, see the documentation supplied with the ultrasound diagnostic instrument.

⚠ Caution	
⃠	Do not move the probe with excessive force. Pressing down with more force than necessary can cause injury to the patient.
❗	Scan for the minimum length of time necessary for the diagnosis and at the lowest suitable output. There is the possibility that the patient's internal tissues could be affected. For details about the acoustic output, please refer to the documentation supplied with the ultrasound diagnostic instrument.
⃠	Do not touch the connector terminal pin of the probe. The probe may deteriorate or be damaged due to electrostatic discharge.
⃠	Do not touch the electronic probe connecting socket of the diagnostic instrument and the patient at the same time. It can cause electric shock to the patient.

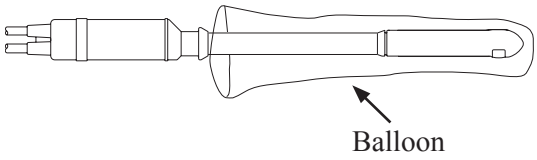
4-2. Mounting of balloon

⚠ Warning	
❗	Use by covering the balloon over the insertion portion. If the balloon is not used, residual pathogens on the probe could infect the patient.
❗	Use Hitachi-approved balloons only. Use of an item lacking biocompatibility can cause an adverse reaction by the body of the patient.
❗	Check that the balloon is sterilized. Use of an infected item could spread infection to the patient.
⃠	Do not reuse the balloon and rubber ring. Use of an infected item could spread infection to the patient.
⃠	Do not apply unsterilized acoustic medium to the outer surface of the balloon. Use of an acoustic medium that is contaminated by a pathogen can cause an infection on the patient.
⃠	Do not use on patients who may have an allergic reaction to latex products. Use of the balloon for these types of patients could result in anaphylactic shock. Ask the patient about allergy history beforehand.

⚠ Caution	
❗	Check the balloon for abnormalities before use. Store the balloons in a cool, dry location not exposed to direct sunlight and do not use balloons that have exceeded their expiration date (for items where the expiration date is not displayed; 2 years from the displayed sterilization date) or severe discoloration, cracks, or other visible defects finds.
❗	Check that the acoustic medium has no air bubbles inside the balloon that is covering the probe. Air bubbles inside the balloon can result in misdiagnosis caused by overlooking or misinterpreting lesions due to poor image quality or improper rendering.

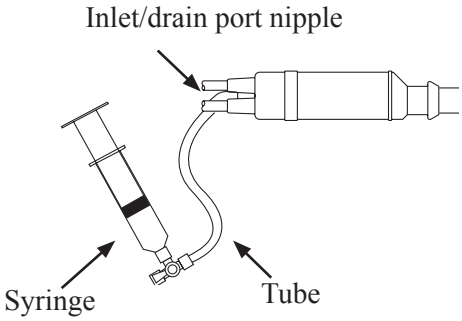
① Connect one end of the extension tube to the inlet/drain nipple of the probe, and connect the other end of the tube to the three-way cocks. Either of the three-way cocks may be connected.

② Insert the probe into the balloon.



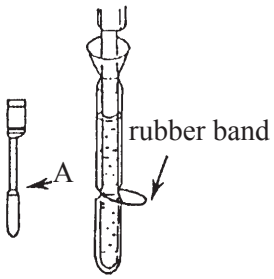
③ Put the proper amount of deaerated water in the syringe, then connect the syringe to the extension tube.

④ To evacuate air from inside of the probe, inject the proper amount of deaerated water from the syringe to the balloon.

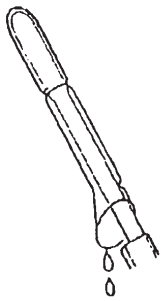


⑤ Remove bubbles in the tip of the balloon.

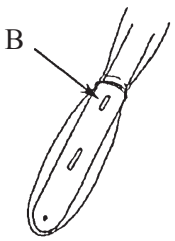
⑥ Attach a rubber band supplied as an accessory, on the groove of the probe (Part A of the figure).



⑦ Remove excessive water from the top of the balloon.



⑧ If bubbles still remain in the balloon, inject water from the syringe into the balloon. Using the same method as that used for draining water from the inlet/drain port of the probe (Part B of the figure), remove bubbles from the balloon.



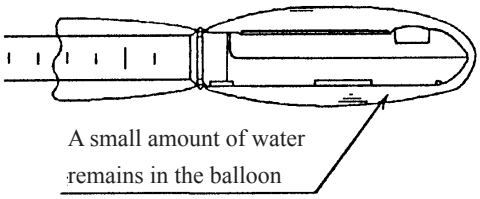
[Remarks]

Surgical tape is included in the accessory pack. When the flare of the balloon disturb to use, fasten the flare by this tape.

4-3. Insertion of the probe

① Return deaerated water to the syringe untill the balloon becomes deflated, with only a small amount of water remaining in it. Then, insert the probe into the rectum.

② After inserting the probe in the rectum, inject deaerated water into the balloon in order to inflate it.



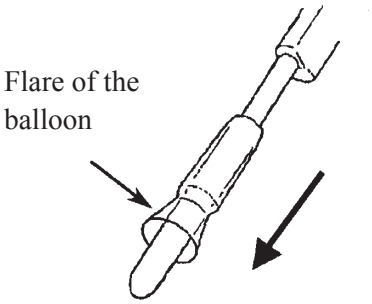
Condition of the probe
inserted into the body cavity

③ The balloon is used to provide the distance needed between the probe and the region to be observed to produce sharp and clear images. Adjust the amount of deaerated water in the balloon to obtain the best level of inflation.

④ Before pulling the probe out of the body,drain the water from the balloon.

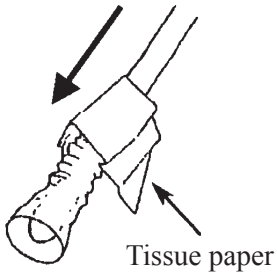
4-4. Removal of balloon

① Turn the flare of the balloon inside out, as illustrated right.



② Rubber boots wrapped in tissue paper and removed from the probe.

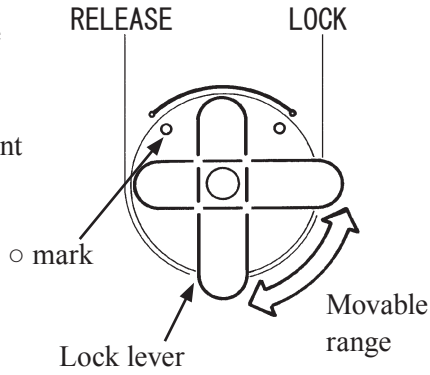
③ Dispose of used tissue paper, rubber boots and a rubber band using infection prevention procedures based on the rules of your facility.



⚠ Caution
Before disposing of the equipment, disinfect or take other infection-prevention measures. Disposal of the equipment without taking the proper preventative measures can lead to infection.

4-5. Connecting to the ultrasound diagnostic instrument

The lock lever of the connector moves over the range shown in the figure at right.
Align the ○ mark with the LOCK or RELEASE position and lock or release the electronic probe connecting socket of the diagnostic instrument (probe connector).
Connect the probe to the probe connector by following the procedure below.



- Connection procedure

The probe is connected when in one of the following states.

- The power switch is set to OFF.
- The image displayed on the ultrasound diagnostic instrument is frozen.

Before inserting the probe into the probe connector, check that the connector pins are not bent.

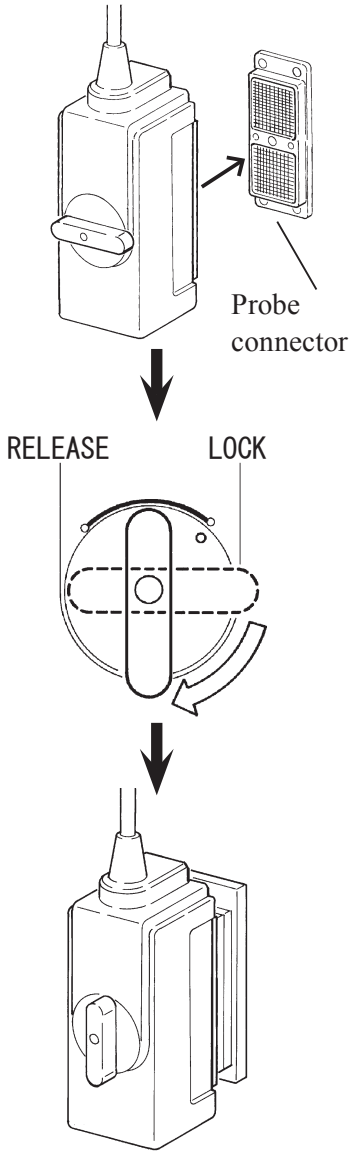
1. Turn the connector lock lever to align the ○ mark on the lever with the RELEASE position.

2. Firmly insert the connector into the probe connector.

3. Turn the lock lever clockwise by 1/4 turn until the ○ mark is aligned with the LOCK position.

4. Check that the connector is firmly inserted into the probe connector.

   This completes connection of the probe.



⚠ Caution

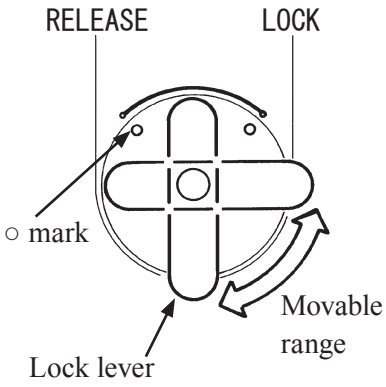
If there is resistance when trying to turn the lock lever when connecting the connector, do not forcibly try to connect it. Instead, correctly perform the steps for connecting the connector and firmly insert it into the probe connector.
Forcibly turning the lever may damage the connector and the probe connector on the instrument.

⚠ Note

Connect both connectors on the linear side and the conve side to the ultrasound diagnostic instrument.

4-6. Removing from the ultrasound diagnostic instrument

The lock lever of the connector moves over the range shown in the figure at right.
Align the ○ mark with the LOCK or RELEASE position and lock or release the probe connector.
Use the procedure below to remove the probe from the probe connector.



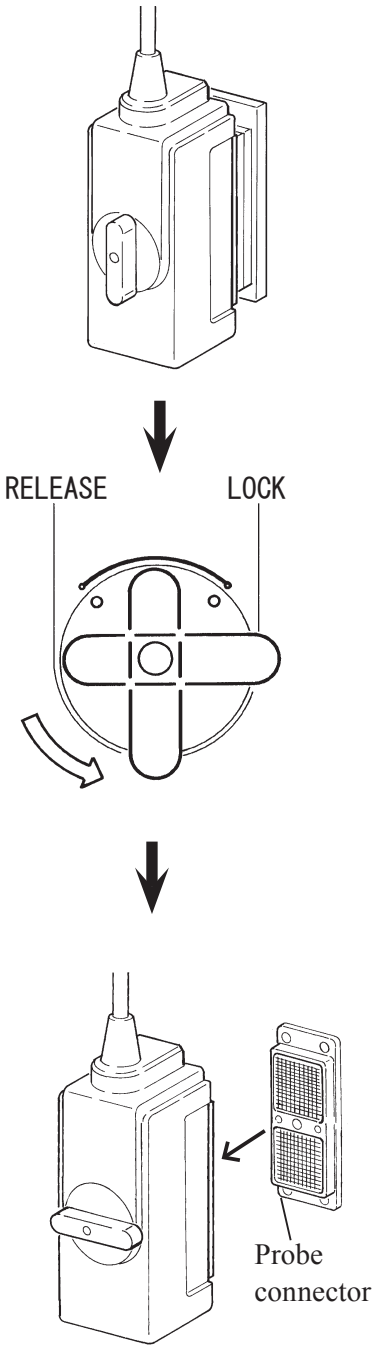
- Removal procedure

The probe is removed when in one of the following states.

- The power switch is set to OFF.
- The image displayed on the ultrasound diagnostic instrument is frozen.

1. Turn the connector lock lever to align the ○ mark on the lever with the RELEASE position.

2. Firmly grasp the connector unit and pull it out from the probe connector.



This completes the removal of the probe.
After use, perform washing, disinfection and sterilization of the probe by following the procedure in section 5 "Washing, Disinfection and Sterilization".
If the probe will not be used for an extended period of time, store it by following the instructions in section 6 "Storage".

4-7. Precautions when performing puncture operations

⚠ Warning
Carefully read the usage precautions in the documentation supplied with the puncture adapter. Be sure that the preparations for use are completed before using.
Puncturing must be performed by a skilled doctor. Improper puncturing can injure the patient. Puncturing operations must be performed by a doctor who fully understands the characteristics of ultrasound diagnostics and who is skilled and has a thorough knowledge of puncture operations under an ultrasound guide.
The puncture adapter must be properly mounted on the probe during use. Puncturing with the puncture adapter improperly mounted or the puncture adapter uninstalled can result in the puncture adapter coming off during puncturing or puncturing of an unintended body part, causing injury to the patient. For details about the puncture adapter mounting procedure, see the documentation supplied with the puncture adapter.
Be sure that the puncture adapter and the needle are sterilized before use. Use of unsterilized items can cause an infection. For details concerning the puncture adapter sterilization procedure, see the documentation supplied with the puncture adapter.
For the acoustic medium, use sterilized physiological saline. Using an unsterilized ultrasound medium can cause an infection on the patient.
Use a compatible puncture needle size. Use of a puncture needle that is not a compatible size can result in the puncture adapter. coming off during puncturing or puncturing of an unintended body part, causing injury to the patient. For the compatible puncture needle sizes, see the documentation supplied with the puncture adapter.
Always use a straight needle. Puncturing of an unintended body part can cause injury to the patient.
During the puncture operation, display a suitable puncture guide line on the screen of the ultrasound diagnostic instrument. Puncturing of an unintended body part can cause injury to the patient. Display the puncture guide line on the screen referring to the documentation supplied with the ultrasound diagnostic instrument, to use it as an aid in determining the puncturing direction.
Constantly check the safety in the needle insertion direction using the needle echo rendered by the ultrasonic wave. A bent puncturing needle can result in puncturing of an unintended body part and cause injury to the patient.
Check that no other organs lie in the puncture path. If another organ lies in the puncture path, an unintended body part can be punctured and cause injury to the patient. Before puncturing, carefully check the body parts and constantly confirm the needle echo during the operation.
Do not try to forcibly perform operations. If excessive force is applied in a direction other than the insertion direction of the puncturing needle, the puncturing needle can come off the guide line, resulting in puncturing of an unintended body part, causing injury to the patient.

⚠ Caution
Handle the needle carefully to ensure that the probe or puncture adapter is not damaged. Using a probe or puncture adapter that has been damaged by a needle can result in an injury to the operator or patient.

4-8. Actions to be taken when an abnormal state is detected

4-8-1. Ensuring safety of patients

Immediately move the equipment away from the patient and quit operation.
Keep the patient in safe condition and administer the required medical treatment.

4-8-2. Handling the instrument

Turn off the ultrasound diagnostic instrument, remove its plug from the AC socket and sterilize if it is contaminated. For details, refer to the instruction manual for the ultrasound diagnostic instrument.

⚠ Caution
Do not use a equipment where a problem has been found. Using a equipment in an abnormal state can cause injury to the patient. Contact one of our offices and/or distributor's offices listed on the back cover.

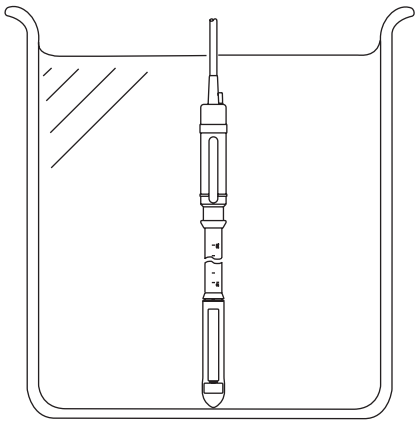
5. Washing, Disinfection and Sterilization

⚠ Warning

- Wear protective gloves and other protective gear during washing, disinfection and sterilization.
  Handling of the probe with your bare hands before disinfection or sterilization can result in an infection.
- After soaking in cleaning agents, thoroughly wash the probe with running water.
  Residual cleaning agents can cause an adverse reaction on the bodies of the operator or patient.
- After chemical disinfection and sterilization, thoroughly wash the probe with sterilized water.
  Residual chemicals can cause an adverse reaction on the bodies of the operator or patient.
- Perform aeration completely after gas disinfection and sterilization.
  Residual gas can cause an adverse reaction on the bodies of the operator or patient.
- Do not wash, disinfect or sterilize using procedures other than those specified in this manual.
  Infection could result due to incomplete washing disinfection or sterilization. It can also result in damage to the probe or reduced performance. The probe cannot withstand autoclave sterilization or boiling and other types of sterilization at temperatures exceeding 60°C (140°F).
- For details on the usage conditions of chemicals and sterilization procedures, refer to the documentation supplied with the respective chemical or sterilization equipment.
  Infection could result due to incomplete disinfection or sterilization. This could also cause deterioration of the probe.
- Thoroughly wash, disinfect or sterilize from inlet/drain port to inlet/drain nipple.
  Infection could result due to incomplete disinfection or sterilization. This could also cause deterioration of the probe.

⚠ Caution

- Do not place the insertion portion and handle in any liquids beyond the range shown in the figure right.
  Use when liquid has gotten inside the connector can result in a risk of electric shock to the operator or patient. If liquid gets inside the connector, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.



Water or chemical solution

5-1. Washing

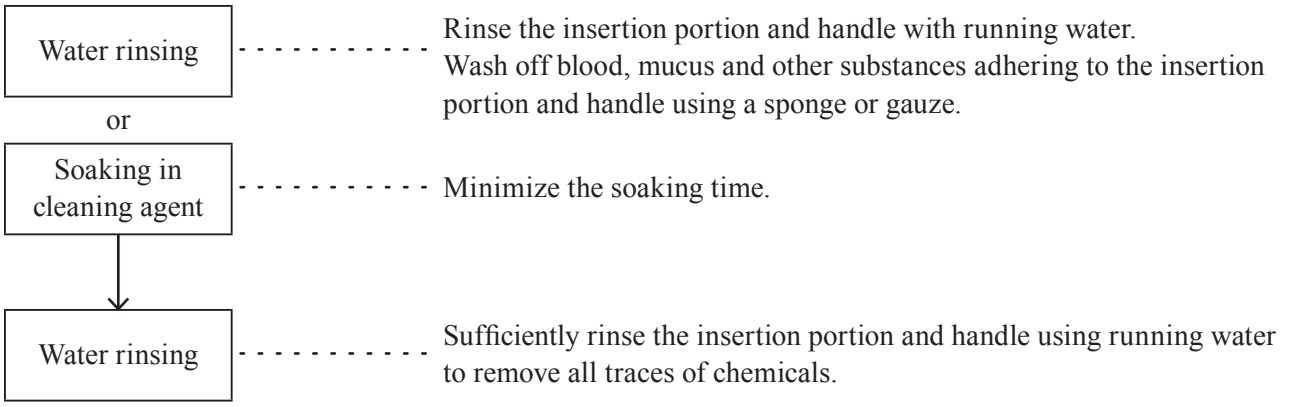
Wash the insertion portion and handle immediately after use with water or soak in a cleaning agent.
Washing before disinfection and sterilization is very important.

5-1-1. Insertion portion and handle

Applicable cleaning agents

General name	Trade name	Manufacturer
Enzyme cleaning agent	ENZOL™ Practical liquid 0.8V/V%	ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc.

Washing procedure



⚠ Warning

- After soaking in cleaning agents, thoroughly wash the probe with running water.
  Residual cleaning agents can cause an adverse reaction on the bodies of the operator or patient.
- Thoroughly wash, disinfect or sterilize from inlet/drain port to inlet/drain nipple.
  Infection could result due to incomplete disinfection or sterilization. This could also cause deterioration of the probe.

⚠ Caution

- Do not wipe the ultrasonic irradiation area with alcohol.
  Alcohol could damage the part. If it is necessary to wipe with alcohol, wipe it as lightly as possible.

5-1-2. Cable and connector

Gently wipe the cable with gauze dipped in ethyl alcohol or water each divided into approximately 20 cm and dry.
Gently clean the connector and other parts of the probe that must not be soaked in liquid with gauze dipped in ethyl alcohol and dry.

⚠ Note

Wiping the entire length of the cable at once can result in wrinkled surface.
If this occurs, pull the wrinkled part in the opposite direction to undo it.

5-2. Disinfection

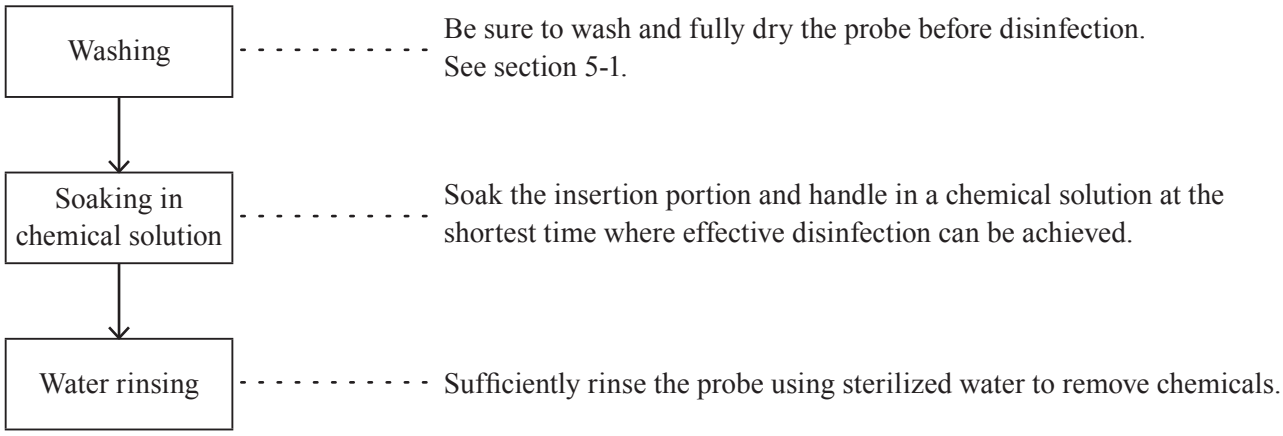
Either chemical disinfection or gas disinfection is performed as necessary.

5-2-1. Chemical disinfection

Applicable chemicals

General name	Trade name	Manufacturer
Glutaral	CIDEX™ Solution 2.4%	ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc.
Ortho-phthalaldehyde	CIDEX OPA™ Solution 0.55%	
Glutaral	STERIHYDE™ Practical liquid 2W/V%	Maruishi Pharmaceutical Co., Ltd.
Benzalkonium chloride	DETERGICIDE™ Practical liquid 0.2W/V%	Yufu Itonaga Co., Ltd.
Benzethonium chloride	HYAMINE™ Practical liquid 0.1W/V%	DAIICHI SANKYO Co., Ltd.

Disinfection procedure



Remarks

Soaking the insertion portion and handle in CIDEX OPA™ solution 0.55% may result in discoloration of the silicone, but this does not affect performance or safety.

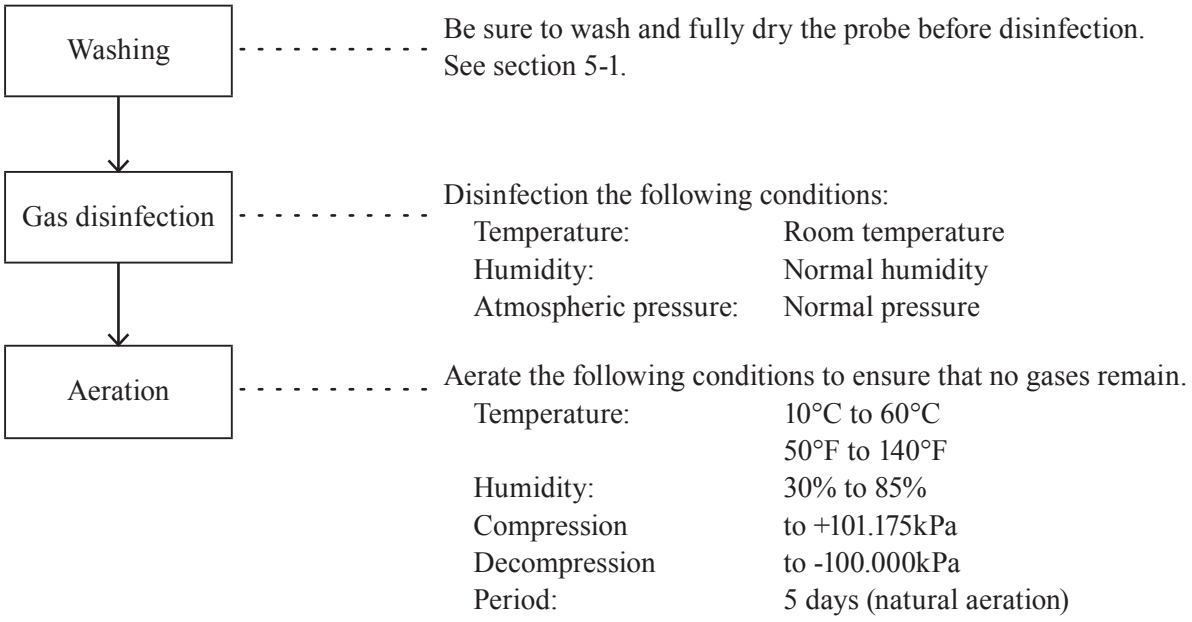
⚠ Warning
After chemical disinfection, thoroughly wash the probe with sterilized water. Residual chemicals can cause an adverse reaction on the bodies of the operator or patient.

5-2-2. Gas disinfection

Applicable gases

General name	Trade name	Manufacturer
Formalin gas	F. gen (14% formaldehyde)	Aso Pharmaceutical Co., Ltd.

Disinfection procedure



⚠ Warning

Perform full aeration after gas disinfection.
Residual gas can cause an adverse reaction on the bodies of the operator or patient.

5-3. Sterilization

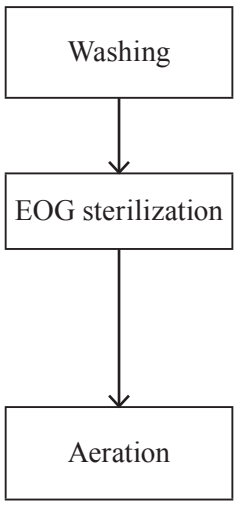
Perform Ethylene oxide gas (EOG) sterilization, STERRAD sterilization or Liquid sterilization as necessary.

5-3-1. Ethylene oxide gas (EOG) sterilization

Applicable gases

General name	Trade name	Manufacturer
Ethylene oxide gas	AMPROLENE™ 84% density	Central Uni Co., LTD.

Sterilization procedure



Be sure to wash and fully dry the probe before sterilization.
See section 5-1.

Sterilize the following conditions:

Temperature:	10℃ to 60℃
	50°F to 140°F
Humidity:	30% to 85%
Compression	to +101.175kPa
Decompression	to -100.000kPa

Aerate the following conditions to ensure that no gases remain.

Temperature:	10°C to 60°C
	50°F to 140°F
Humidity:	30% to 85%
Compression	to +101.175kPa
Decompression	to -100.000kPa
Period:	5 days (natural aeration)

⚠ Warning

Perform full aeration after gas sterilization.
Residual gas can cause an adverse reaction on the bodies of the operator or patient.

5-3-2. STERRAD® sterilization

Applicable gases

General name	Trade name	Manufacturer
Hydrogen peroxide (58% density)	STERRAD Sterilization system	ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc.

Sterilization procedure

Washing - - - - - - - - - - - - Be sure to wash and fully dry the probe before sterilization. See section 5-1.

↓

STERRAD sterilization

Remarks
Some discoloration of the probe may occur, but this does not affect performance or safety.

⚠ Caution

⃠ Do not sterilize a probe without a STERRAD label* using the STERRAD system.
It can cause damage or deterioration to the probe shell. Use the STERRAD system only to sterilize a probe with a STERRAD label.

* STERRAD label

⃠ Do not put the probe directly into the sterilization pouch*.
This can cause the film of the sterilization pouch to stick to the cable covering, resulting in damage to the cable. Completely wrap the entire probe (including the transducer, cable and connector) with sterilization wraps* before putting it into the sterilization pouch*.
*: A Johnson & Johnson company Division of Ethicon, Inc product

5-3-3. Liquid sterilization

Applicable chemicals

＊ Except Canada

General name	Trade name	Manufacturer
Hydrogen peroxide	PERASAFE™ ＊ Practical liquid 1.62W/V%	ANTEC INTERNATIONAL

Sterilization procedure

Washing	Be sure to wash and fully dry the probe before sterilization. See section 5-1.
↓	
Soaking in chemical solution	Soak the insertion portion and handle in a chemical solution at the shortest time where effective sterilization can be achieved.
↓	
Washing with water	Sufficiently rinse the probe using sterilized water to remove chemicals.

⚠ Warning

After chemical sterilization, thoroughly wash the probe with sterilized water.
Residual chemicals can cause an adverse reaction on the bodies of the operator or patient.

6. Storage

6-1. Actions before storing the probe

When the equipment will not be used for an extended period of time, perform the procedures described in section 5 "Washing, Disinfection and Sterilization" and then store it in its storage case.

6-2. Environmental conditions for storage

For details about the storage environmental conditions, see section 2-5-2 "Storage environmental conditions".

7. Moving and Transporting

7-1. Moving and transporting

In this section, *moving* refers to "carrying of the equipment within a facility" and *transporting* refers to "transferring using a vehicle or sending the probe for repairs".

7-2. Preparing the probe and accessories for moving

Store in the storage case after performing the procedure in section 5 "Washing, Disinfection and Sterilization".

7-3. Packing for transportation

Store in the storage case after performing the procedure in section 5 "Washing, Disinfection and Sterilization" and then put the storage case in a cardboard box for additional protection.

7-4. Eenvironmental conditions during transportation

Ambient temperature:	–10°C to 50°C
	14°F to 122°F
Relative humidity:	10% to 90%
Atmospheric pressure:	700 hPa to 1060 hPa

⚠ Note
This equipment is a precision equipment and is vulnerable to physical impact. Protect it by packing it properly for transportation.
Contact one of our offices and/or distributor's offices listed on the back cover when transporting the equipment.

8. Periodic Inspection

8-1. Safety tests

The safety tests should be conducted at least once a year by a qualified technician. The test record should be stored for future reference.

Remarks 1
Qualified technician: personnel for conducting safety tests of medical electrical equipment.
If the user requires an appropriate qualified technician, service personnel trained by us can conduct a test at the user's expense. Contact one of our office written on the back cover.

Remarks 2
Make a copy of the Safety Inspection Data Sheet provided in the instruction manual of the ultrasound diagnostic instrument. Use the sheet as a test record.

Procedure for periodic safety tests and judgment

(1) Test of patient leakage current from the patient connection to earth
Using the measuring instruments which usable to the requirement of IEC 60601-1 :2005, conduct the test as shown in Fig. 15 of IEC 60601-1 :2005.
Soak the insertion portion and handle in saline solution and measure the leakage current between the applied part and earth.
Do not soak probes in saline solution beyond the "IPX7 range" provided in section 2-2.

(2) Test of patient leakage current caused by an external voltage on the patient connection of an F-type applied part.
Using the measuring instruments which usable to the requirement of IEC 60601-1 :2005, conduct the test as shown in Fig. 16 of IEC 60601-1 :2005.
Soak the insertion portion and handle in saline solution and measure the leakage current between the applied part and earth.
Do not soak probes in saline solution beyond the "IPX7 range" provided in section 2-2.

Item	Normal condition	Single fault condition
(1) Patient leakage current from the patient connection to earth DC AC	 10 µA or less 100 µA or less	 50 µA or less 500 µA or less
(2) Patient leakage current caused by an external voltage on the patient connection of an F-type applied part		5000 µA or less

Table. Standard Values for Periodic Safety tests
(Extract from IEC 60601-1 :2005)

⚠ Warning

Perform a safety tests at least once a year and keep a record of the inspection results.
Failure to notice an abnormal condition while using the probe can result in injury to the operator or patient. If an inspection finds an abnormal condition in the probe, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.

8-2. Testing of measurement tolerances

Perform the measurements specified below using an ultrasonic phantom* at least once per year. The test record should be stored for future reference.

- Sensitivity
- Resolution

Remarks
Make a copy of the Measurement accuracy inspection data sheet provided in the instruction manual for the ultrasound diagnostic instrument. Use the sheet as a test record.

* The ultrasonic phantom is made of a substance which is similar to human tissue in terms of its response to ultrasonic waves.
Regions with different textures and targets spaced at preset intervals are embedded in the phantom. Some phantoms contain a mechanism for Doppler measurement. The phantom is used to check the performance of the probe and ultrasonic diagnostic instrument, as well as to adjust the image settings.

8-2-1. Conducting tests

Some types of ultrasonic phantoms have targets with narrow gaps between them for confirming the resolution.
This enables you to check the level of detail that images can be viewed on the display. For phantoms with no targets, the resolution determines the fineness of the displayed textures. The sensitivity can be determined by examining the luminance of ultrasonic images. Other factors that affect the resolution include the type of connected probe, gain, focus and recording instrument. The specific testing conditions must be recorded in detail to enable proper comparison at the next inspection.

8-2-2. Result judgement

Compare the currently-obtained value with the value recorded at the last test. If there is a significant difference between the two values, the current value is considered to be abnormal.
It is important to note that the resolution varies depending on the type of ultrasonic phantom and phantoms generally deteriorate over time.

⚠ Caution

Do not use a probe or ultrasound diagnostic instrument where a problem has been found.
This can result in an incorrect diagnosis. Contact one of our offices and/or distributor's offices listed on the back cover.

9. Configuration

9-1. Standard configuration

Probe	UST-672-5/7.5	1 set
Rubber band	FS 5/16"	50 pieces
Syringe	SS-50L	1 piece
Three-way cock	TS-TL2K	1 piece
Extension tube	SF-ET3825L	1 piece
Surgical tape	#1525 1/2"	3 rolls
Purse locks	58 (Black)	10 pieces
Storage case	STB-45-PA2	1 set
Instruction manual	MN1-0756	1 copy

9-2. Options

Puncture adapter	MP-2451 The optional puncture adapter is connected to the probe and enables puncturing.
Balloon	BL-664-NS non-sterilized
Grip holder	MP-2447 When a grip holder is attached to the handle, you can hold the probe more easily when puncturing a subject.

10. Disposal of the Device

Recycle or dispose this equipment properly in compliance with the Waste Management and Public Cleansing Law.

⚠ Caution
Before disposing the equipment, disinfect or take other infection-prevention measures. Disposal of the equipment without taking the proper preventative measures can lead to infection.

Waste Electrical and Electronic Equipment (WEEE) Directive

The illustration on the right is required by the EU WEEE Directive to appear on all electrical and electronic equipment.
For proper disposal of this product in an EU nation, contact an EU office or agency and observe appropriate local and national regulations and laws.

■Manufacturer

Hitachi, Ltd.

2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015, Japan

■Contact

+81-3-6284-3668

http://www.hitachi.com/businesses/healthcare/index.html

Overseas Offices:

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Distributor