HITACHI
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# Intraoperative Puncture Electronic Sector Probe
# UST-52114P
# Instruction Manual

MN1-5234 Rev.18

*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-52114P, 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 64pages and 6pages until the CONTENTS.

# 1. Safety Precautions

## 1-1. Intended use

This probe is intended for use by  a doctor for making ultrasonic observations of the organs during surgery.
With the exception of Japan, you can use the probe in neurosurgery applications if you attach our recommended transducer cover to the probe.  When using the probe in neurosurgery applications, refer to Section 1-2-3 under "Precautions when using the probe in neurosurgery applications".
It also enables the doctor to guide the puncture needle under the ultrasound guide into the patient's body.

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

## 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 |
|---|
| Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury to the operator or patient. |

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|---|
| 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.<br>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.<br>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 check, 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 of the probe" for the start up check content and procedure. |
| This equipment must not be used in direct contact with the heart.<br>This may cause patient to receive an electric shock. |
| Do not use on the eyes.<br>This equipment is not intended for use on the eyes. The acoustic output can have an adverse effect on the eyes. |
| With the exception of Japan neurosurgery applications are possible if our recommended transducer cover is attached to our probe. |
| Do not attempt to disassemble, modify, or repair the equipment.<br>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 probe.<br>Perform proper cleaning, disinfection and sterilization after use.<br>Otherwise, there is a risk of infection. Note that the probe is not sterilized at the factory.<br>Before using the probe first, be sure to clean, disinfect and sterilize it. |
| Be sure to sterilize the equipment which blood adhered.<br>Otherwise, there is a risk of infection. |
| During surgery, be sure to wear sterilized medical gloves.<br>Conducting examinations with the bare hands can expose the operator to a risk of infection. |
| For the acoustic medium, use sterilized physiological saline.<br>Using an unsterilized ultrasound medium can cause an infection on the patient. |
| Dispose the probe used for patients with Creutzfeldt-Jakob disease.<br>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.<br>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.<br>Ohterwise, there is a risk of infection. Stop the operation and perform the procedure in section 8 "Periodic Inspection", section 5 "Cleaning, disinfection and sterilization" and section 3-1 "Start up check of the probe". |

| ⚠ Caution |
|---|
| Constantly check for anything abnormal about the patient's condition and equipment.<br>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.<br>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.<br>Use with unapproved equipment can result in an electric shock, burn, or other injury to the operator or patient 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.<br>Overuse can adversely affect the internal tissues of the patient.<br>For details about the acoustic output, please refer to the documentation supplied with the ultrasound diagnostic instrument. |
| Do not use it in continuous contact with the human body more than 60 minutes.<br>Overuse can adversely affect the internal tissues of the patient. |
| Regularly perform maintenance inspection and safety tests of the equipment.<br>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.<br>Otherwise, it may be damaged.<br>See section 2-5 "Environmental conditions" and section 7-4 "Environmental conditions during transportation". |

## 1-2-2. Puncturing precautions

| ⚠ Warning |
|---|
| Puncturing must be performed by a skilled doctor.<br>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 ultrasonic guide. |
| The equipment must be cleaned, disinfected and sterilized before use.<br>Be sure to always clean, disinfect and sterilize properly after use.<br>Otherwise, an infection can occur. Note that the equipment is not sterilized when shipped from the factory. Before using the equipment, be sure to clean, disinfect and sterilize it as required. |
| When puncturing, be sure to wear sterilized medical gloves.<br>Puncturing with the bare hands can expose the operator or patient to a risk of infection. |
| This puncture adapter is used by attaching to the probe and following the instructions in this manual.<br>Attaching improperly to the probe or performing puncture operations without attaching to the probe can result in the puncture adapter coming off during puncturing or puncturing an unintended body part. For details on the attachment procedure, see section 4-2 "Attaching of the puncture adapter". |
| For the ultrasound medium, use sterilized physiological saline solution.<br>Using an unsterilized ultrasound medium can cause an infection on the patient. |
| Check that the gauge size of the puncture needle that is used matches the gauge size of the needle guide.<br>Using when the gauge sizes of the puncture needle and needle guide do not match can result in puncturing of an unintended body part. |
| Use sterilized puncture needles.<br>Otherwise, an infection can occur. |
| Do not use needles were bent.<br>Puncturing of an unintended body part causing an injury to the patient. |
| Be careful when handling the puncture needle.<br>Accidentally puncturing your hand or other body part can result in infection of the operator or patient. |
| When inserting an RFA(Radio Frequency Ablation) needle, do not insert while bending the needle.<br>Inserting while bending the needle can break the insulation membrane covering the RFA needle and could cause burns to the patient. |
| Before using a needle cannula as a guide with this equipment, first check that the cannula moves smoothly through the tube without causing any damage on the surface of the cannula, and then operate with caution.<br>If the cannula does not move smoothly or is forced to bend when inserted in or pulled out of this equipment, this could damage the insulation membrane covering the cannula and cause burns to the tissue exposed to the damaged area of the cannula. |

## ⚠ Warning

- 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 an 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.
- Check beforehand any areas not displayed on the ultrasound image that are along the puncturing path.
  If other tissues are in the area not displayed on the ultrasound image, there is a risk of puncturing an unintended body part and causing an injury to the patient.
- Do not puncture the heart region.
  Puncturing the heart region may cause a micro electric shock.
- 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 an injury to the patient. Before puncturing, carefully check the body parts and constantly confirm the needle echo during the operation.
- Constantly check the safety in the needle insertion direction using the needle echo rendered by the ultrasonic wave.
  A bent puncture needle can result in puncturing of an unintended body part and cause an injury to the patient.
- Do not try to forcibly perform operations.
  If excessive force is applied in a direction other than the insertion direction of the puncture needle, the puncture needle can come off the puncture guide line, resulting in puncturing of an unintended body part and causing an injury to the patient.
- For details about the reuse and disposal of puncture needles, follow the instructions in the documentation supplied with the puncture needles.
  Reuse of puncturing needles that are not reusable or improper disposal could result in an infection.
- 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 5 "Cleaning, disinfection and sterilization" section 3-2 "Start up check of the puncture adapter" and section 3-3 "Checking the needle echo".

## ⚠ Caution

- Handle the needle carefully to ensure that the puncture adapter and probe are not damaged.
  Using a puncture adapter or probe that has been damaged by a needle can result in an injury to the operator or patient.
- Check beforehand if the patient has any allergic reactions to metals.
  If the patient has a metal allergy of stainless steel, puncture adapter may be hazardous for patient as an allergic risk.

## ⚠ Note

Before a puncture operation on the patient, check the relative safety not only of the equipment directly related to the puncture operation, but also of peripheral equipment and measuring instruments.

## 1-2-3. Precautions when using the probe in neurosurgery applications

| ⚠ Warning |
|---|
| When using this probe in neurosurgery applications, attach our recommended transducer cover to the probe. Failure to properly use the transducer cover may cause harm to the patient. |
| Use our recommended transducer cover.<br>If you use a transducer cover which is not recommended by our company, it may cause harm to the patient due to tearing or pyrogen. |
| Verify that the transducer cover packaging has not been opened or damaged.<br>If you use a contaminated transducer cover, it may cause patient infection although our recommended transducer cover is sterilized. |
| Verify that there is nothing wrong with the transducer cover.<br>Store the transducer cover according to its instruction. Do not use the transducer cover if the expiration date has passed, if it is discolored, or if there is visible damage, such as a tear. |
| Take precaution in handling the transducer cover so as not to break it as this may then result in direct contact with the edge of bone during a craniotomy.<br>If the transducer cover breaks, it may cause harm to the patient. |
| Verify that there is nothing wrong with the transducer cover and that the puncture adapter is properly attached on the transducer when puncturing.<br>If you attach the puncture adapter incorrectly, it may come off during the procedure, or it may be punctured into a non intended area. Refer to the details on Section 4-9-3 “Puncture”. |
| Properly use the transducer cover and puncture needle according to this instruction.<br>If used incorrectly, it may cause patient or user injury. |
| Verify that the probe is sterilized. Use the sterilized echo jelly attached to our recommended transducer cover as the acoustic medium.<br>If you use contaminated ones, it may cause patient infection. |
| Verify that there are no bubbles of the acoustic medium inside of the transducer cover.<br>If there are bubbles inside the transducer cover, they may cause clinical images changed and erroneous display on the monitor leading to misdiagnosis. |
| When removing the transducer cover, do not pull it forcibly.<br>If you use excessive force, it may cause probe damage or scattering of contaminated material. |
| Do not reuse the transducer cover.<br>If you reuse the transducer cover, it may cause patient infection. |

| ⚠ Caution |
|---|
| When disposing the transducer cover, take appropriate measures for prevention of infection.<br>If you dispose it improperly, it may cause environmental damage. |

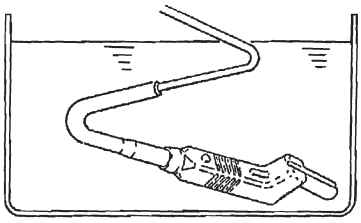
## 1-2-4. Cleaning, disinfection and sterilization precautions

### ⚠ Warning

- Wear protective gloves and other protective gear during cleaning, disinfection and sterilization. Handling of the equipment with your bare hands before sterilization can result in an infection.
- After soaking in cleaning agents, thoroughly wash the equipment with running water. Residual cleaning agents can cause an adverse reaction on the bodies of the operator or patient.
- After soaking in a disinfectant, throughly wash the equipment with deionized water. Leavings of the disinfectant can cause an adverse reaction on the bodies of the operator or patient.
- Perform aeration completely after gas sterilization. Residual gas can cause an adverse reaction on the bodies of the operator or patient.
- Do not clean, disinfect or sterilize using procedures other than those specified in this manual. Infection could result due to incomplete cleaning, disinfection and 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 sterilization. This could also cause deterioration of the equipment.

### ⚠ Caution

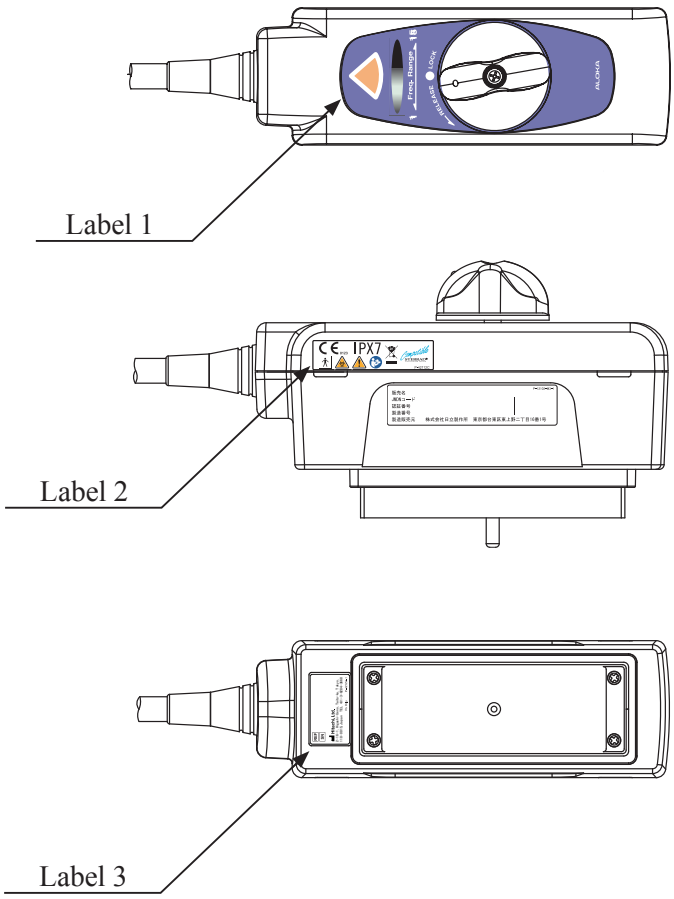
- Do not place the probe tip in any liquids beyond the range shown in the figure right. Use when liquid has gotten inside the connector can result in a risk of electric shock to the operator or patient. If liquid gets inside the connector, immediately stop use and contact one of our offices and/or distributor's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



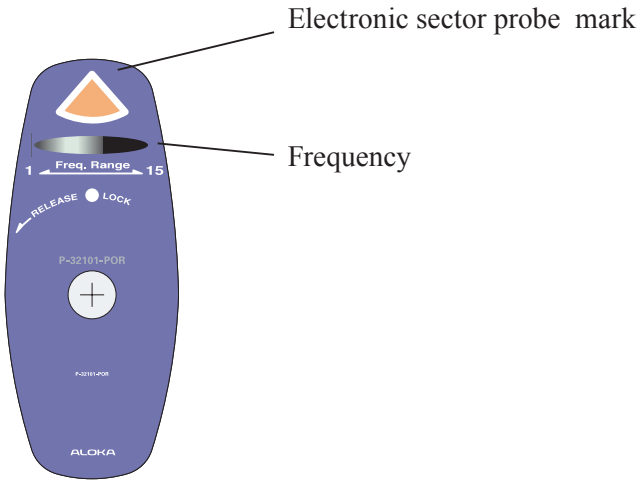
Water or chemical solution

## 1-2-5. Labels

(1) Probe unit




Label 1



Label 2



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

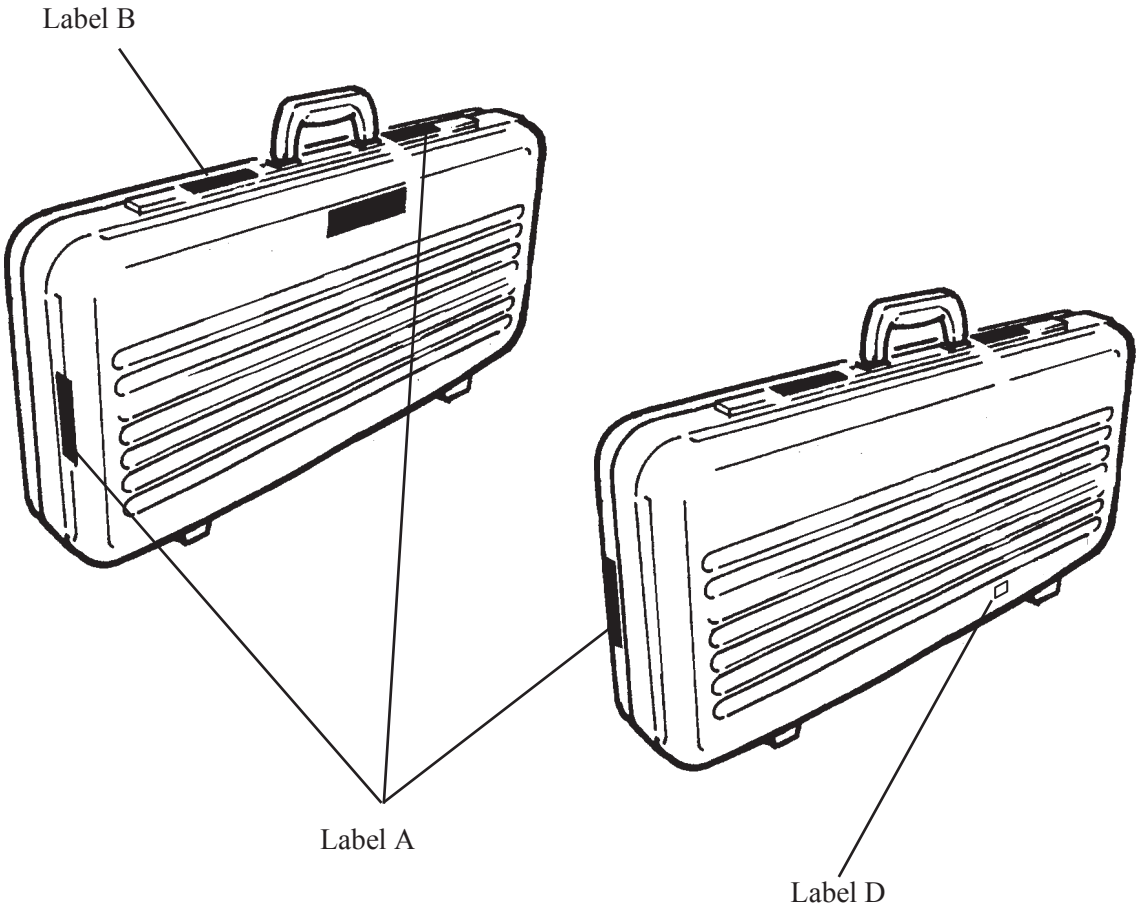
Biohazard
See section 5.

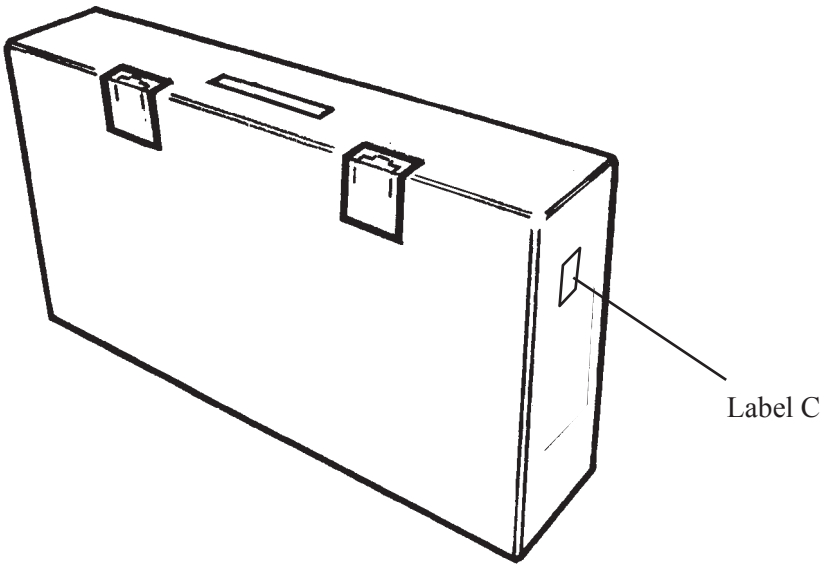
Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.

Label 3

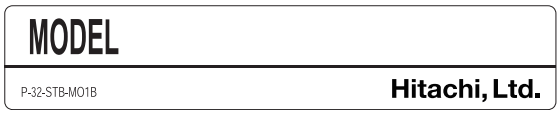

Model
Serial No.
Manufacturer
Address
Rx Only:
By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.

(2) Storage case



Label A

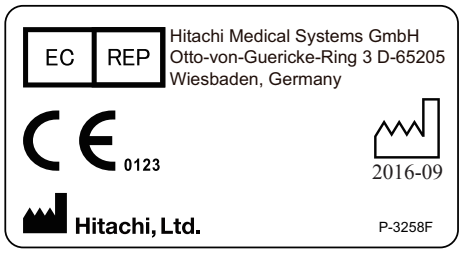



Model

Label B


Serial No.

Label C



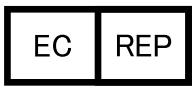


This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS.

2016-09

DATE OF MANUFACTURE
(in case of 2016-09)

MANUFACTURER




AUTHORISED REPRESENTATIVE IN EUROPEAN COMMUNITY

Label D


DATE OF MANUFACTURE
(in case of 2016-09)

# 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.

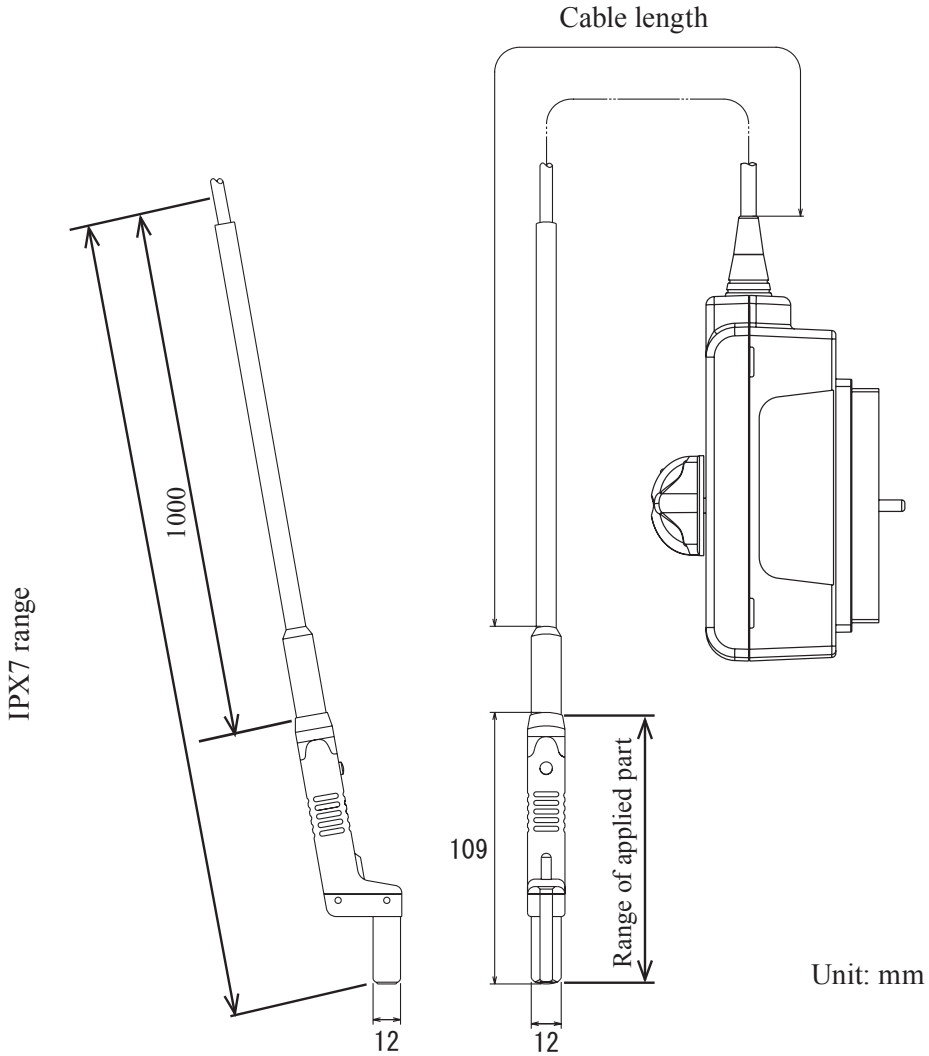
(2) The emitted ultrasonic waves are reflected by boundaries with different acoustic characteristics (acoustic impedance) within the body.

(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

### 2-2-1. Specifications of the probe

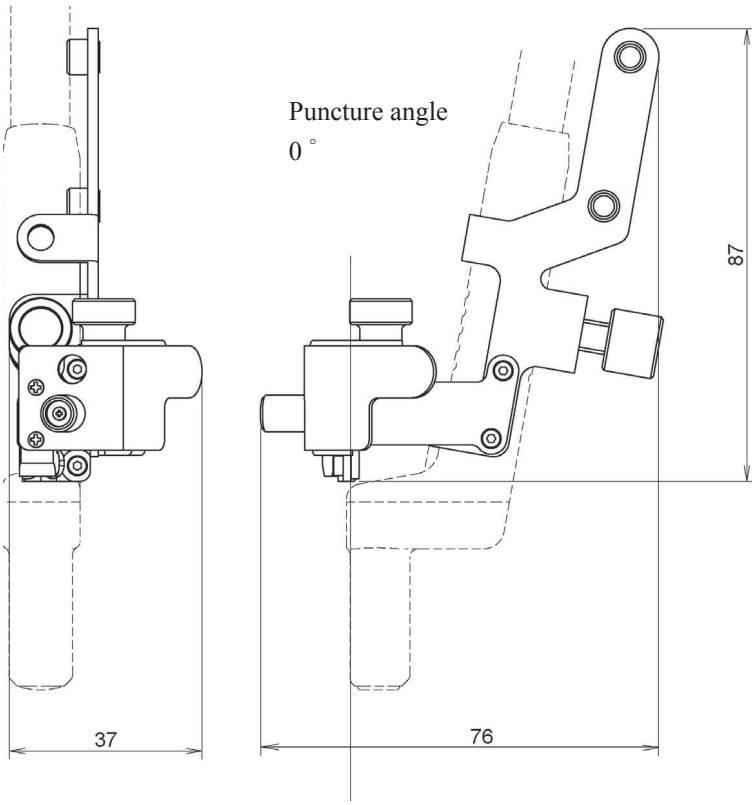
| | |
|---|---|
| Application regions: | Intraoperative diagnosis<br>With the exception of Japan neurosurgery applications are possible if our recommended transducer cover is attached to our probe. |
| Form of application to patient: | Intraoperative<br>With the exception of Japan neurosurgery applications are possible if our recommended transducer cover is attached to our probe. |
| Connectable instruments: | SSD- α10, Prosound α 7, Prosound α 6, ProsoundF75 |
| Field of view: | 90 ° |
| Frequency: | 3 to 7 MHz |
| Cable length: | 2.5 m |
| Weight: | 830 g |
| Service life: | Three years |
| Range of applied part | As shown in the figure below. |
| Parts treated as applied parts | Probe tip itself and 20cm of the cable near the probe tip. |
| IPX7 range | As shown in the figure below. |
| External dimensions: | As shown in the figure below. |




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

## 2-2-2. Specifications of the puncture adapter

| | |
|---|---|
| Material | Stainless steel |
| Usable puncture needle size and diameter | 8G(4.2±0.3mm) to 24G(0.55±0.1mm) |
| Service life | Three years |
| External dimensions | As shown in the figure below. |




Unit: mm

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

## 2-2-3.Transducer cover when using the probe in neurosurgery application

CIVCO Transducer cover 610-956 , 610-956-EU

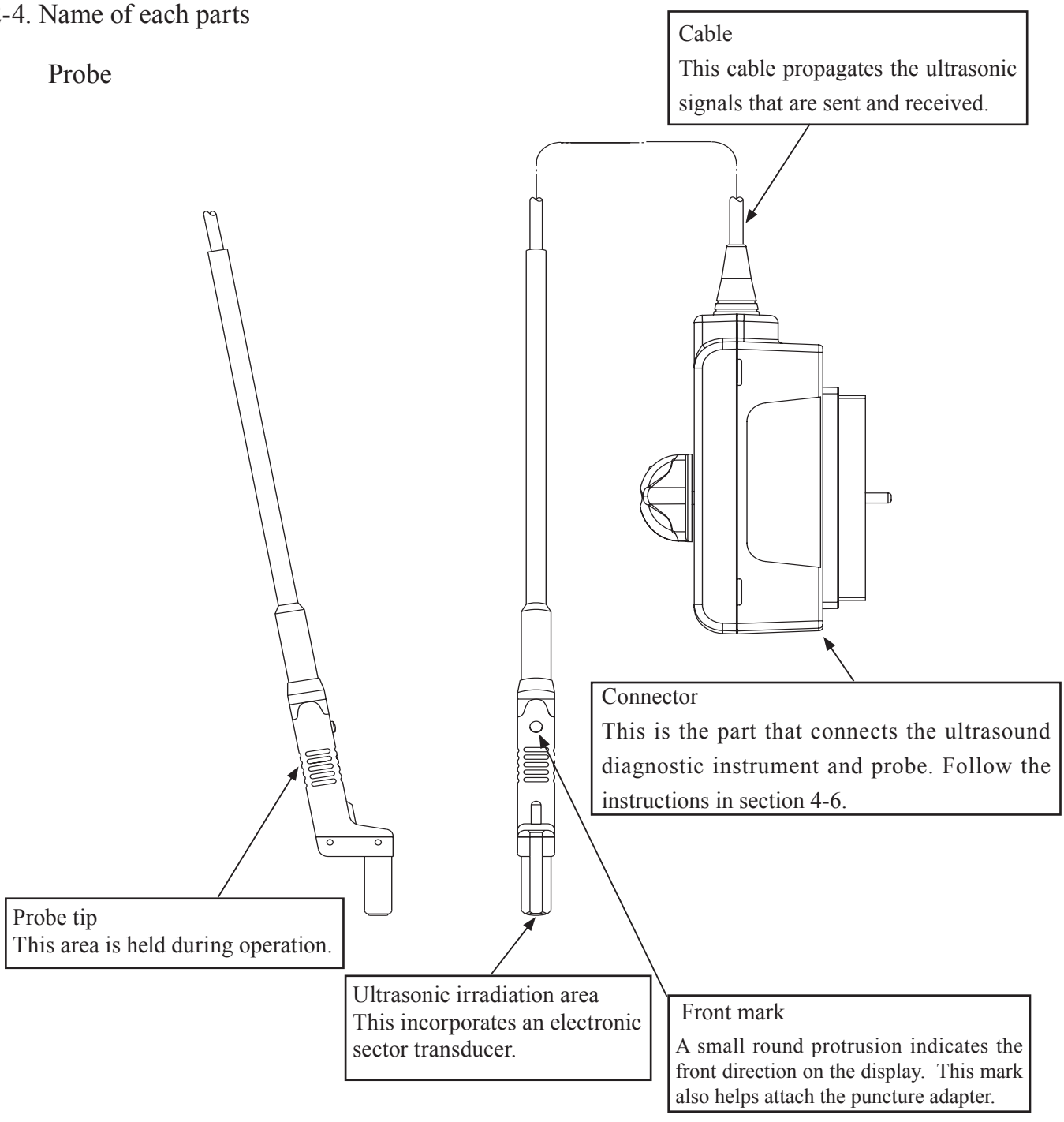
This transducer cover can be used in neurosurgery applications and it is Pyrogen free.
If you are unable to obtain the transducer cover locally, please contact your local Hitachi Medical Systems representative.

## 2-3. Performance

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

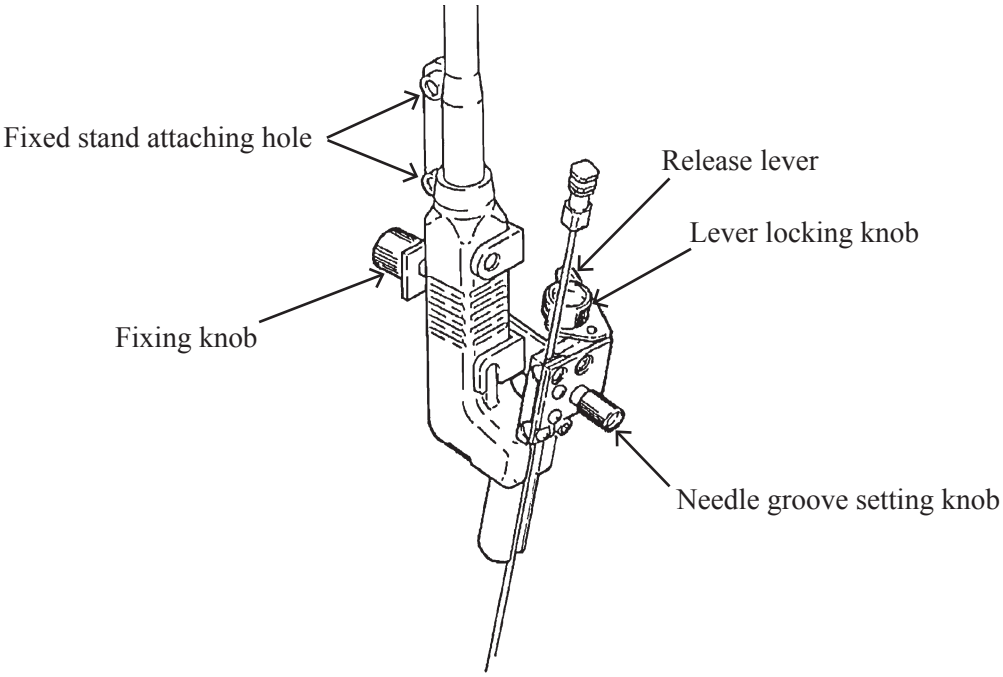
## 2-4. Name of each parts

Probe




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

Puncture adapter




| | |
|---|---|
| (1) Fixing knob | This is used to fix the puncture adapter to the probe.<br>Turning clockwise tightens the screw.<br>Tighten the screw securely referring to 4-2 "Attaching of the puncture adapter″. |
| (2) Needle groove setting knob | Adjust the needle groove width to the diameter of a puncture needle to be used.<br>Turning clockwise widens the needle groove.<br>Refer to the section 4-3 "Setting the needle groove ". |
| (3) Lever locking knob | This is used to prevent unintentional movement of the release lever.<br>Securely tighten this knob by turning clockwise if the puncture needle does not neet to be released. |
| (4) Release lever | By pressing the release lever, the needle groove widens and the puncture needle can remove from the puncture adapter. |
| (5) Fixed stand attaching hole | Used to fix a puncture adapter to a stand used for puncturing. |

## 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 equipment 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 “Cleaning, 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 of the probe

### 3-1-1. Visual check

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

### 3-1-2. Verification of cleaning, disinfection and sterilization

Verify that cleaning, disinfection and sterilization are conducted.

### 3-1-3. Verification of operation

Connect to the ultrasound diagnostic instrument by following the instructions in section 4-6, “Connecting to the ultrasound diagnostic instrument" and check that the selected probe match the sector 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.

## 3-2. Start up check of the puncture adapter

### 3-2-1. Visual check

Check the puncture adapter for any of the abnormal conditions below.

- Abnormalities seen in visual such as deformation, cracks, abnormal gaps, damage, foreign matter adhering, severe discoloration.

### 3-2-2. Mechanical inspection of the puncture adapter

Check that the puncture adapter mechanism while attached to the probe.

- The screws (incl. Fixing knob, Needle groove setting knob and Lever locking knob) have no abnormalities such as looseness, backlash and immobility.
- When the release lever is pressed with the lever locking knob loosen, the puncture needle can be removed from the puncture adapter.
- The release lever does not move when the lever locking knob is tightened securely.
- The puncture adapter is firmly attached to the probe.
- A puncturing needle that passes through the needle groove moves smoothly in the puncturing direction.

Remarks

See Section 4-2. "Attaching of the puncture adapter".

### 3-2-3. Verification of operation

When puncturing under the ultrasonic guide, for safety reason, it is also recommended that you have a full understanding of ultrasound diagnostic characteristics and conduct practice beforehand using a tub or similar object.

## 3-3. Checking the needle echo

### 3-3-1. Check setup

(1) Required items

| | |
|---|---|
| Tub | (Depth of 20 cm or more) |
| Warm water | 40°C (104°F) |
| Thermometer | |
| Probe | |
| Puncture adapter | |
| Puncture needle | 18G (length of 150 mm to 200 mm) |

(2) Preparation procedure

1. Put warm water at 40°C (104°F) into the tub.
   Use a thermometer to check the water temperature.

2. Refer to section 4-1 "Operation" and attach the puncture adapter to the probe, and attach the puncture needle into the needle groove.
   Check that the puncture needle has no bending or other defects.

3. Connect the probe to the ultrasound diagnostic instrument.
   Turn on the ultrasound diagnostic instrument to display the puncture guide line on the monitor screen.

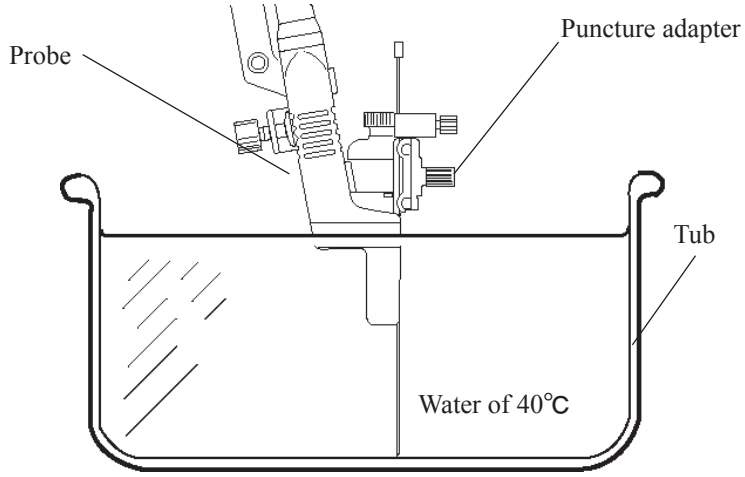
Remarks:
For details of the puncture guide line, refer to the instruction manual of the ultrasound diagnostic instrument.

**⚠ Caution**

Use warm water at 40°C in the check of the needle echo.
In the actual puncture operation, the needle echo and guide line may not match and this could result in puncturing of an unintended body part. It is well-known that the acoustic characteristics of water at 40°C (104°F) are the most similar to those of the human body.

## 3-3-2. Checking the needle echo

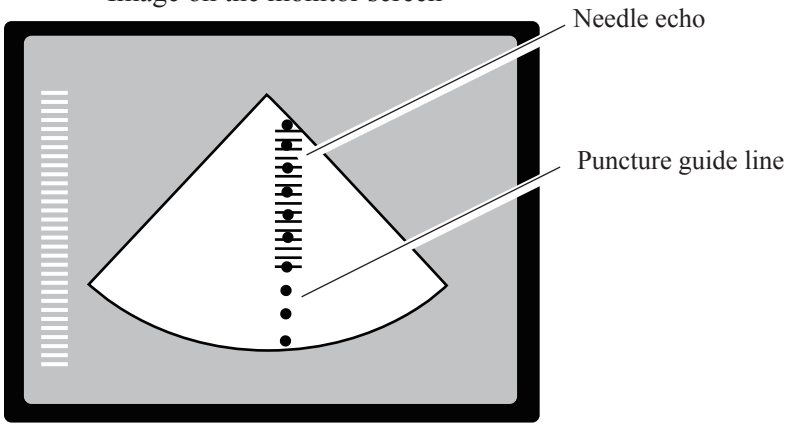
(1) Dip the probe tip into the warm water so that the needle echo is displayed.




(2) Check the following points.

- The needle echo matches with the puncture guide line.
- The echo of the entire needle is displayed fully and clearly.

Image on the monitor screen



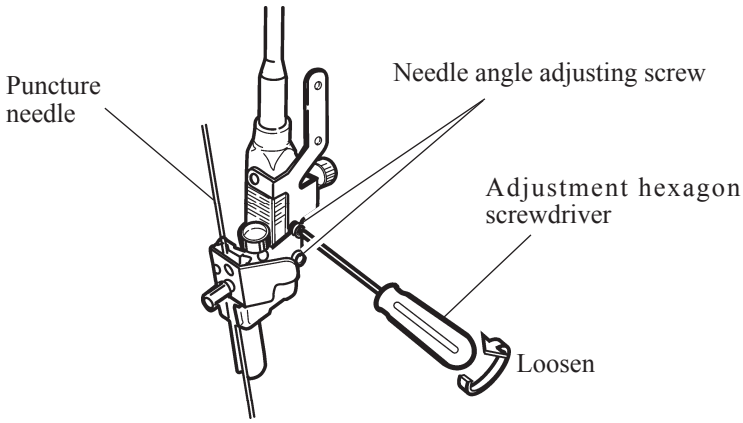

(3) If the needle echo does not match the puncture guide line or is weak, refer to section 3-4 "Adjusting the needle direction", and fine-tune the needle direction so that it is displayed in the optimum state.

## 3-4. Adjusting the needle direction

If the needle echo needs to be adjusted, see section 3-3-1 "Check setup", and perform the adjustment below. After adjustment, tighten the screws securely, and check that they have no backlash.

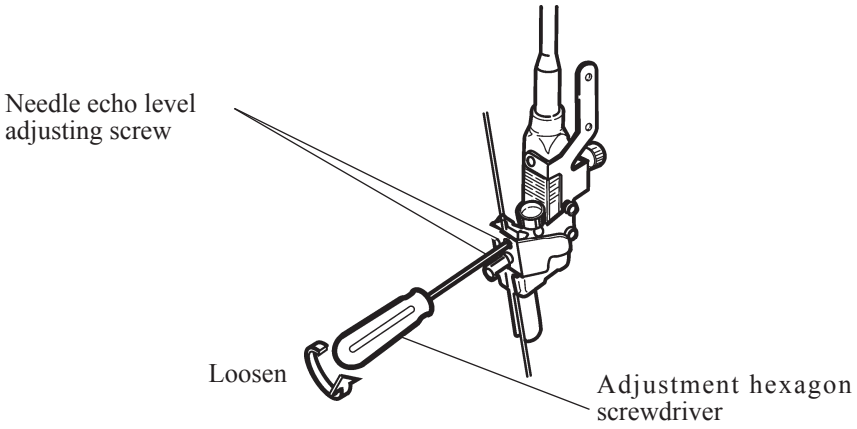
### 3-4-1. When the needle echo does not match the puncture guide line.

As shown below, use the supplied adjustment hexagon screwdriver to loosen the needle angle adjusting screw and align the needle echo with the puncture guide line.




### 3-4-2. When the needle echo is weak

As shown below, use the supplied adjustment hexagon screwdriver to loosen the needle echo level adjusting screw and display the entire needle echo with the strongest signal.



## 3-5. Performing cleaning, disinfection and sterilization

(1) Before use, clean, disinfect and sterilize the puncture adapter, the needle stopper and the depth gauge.
See section 5 "Cleaning, disinfection and sterilization"

(2) Clean, disinfect and sterilize the probe to be used in accordance with its usage purpose.

**⚠ Warning**

The equipment must be cleaned, disinfected and sterilized before use.
Be sure to always clean, disinfect and sterilize properly after use.
Otherwise, an infection can occur. Note that the equipment is not sterilized when shipped from the factory. Before using the equipment be sure to clean, disinfect and sterilize it.

# 4. Usage

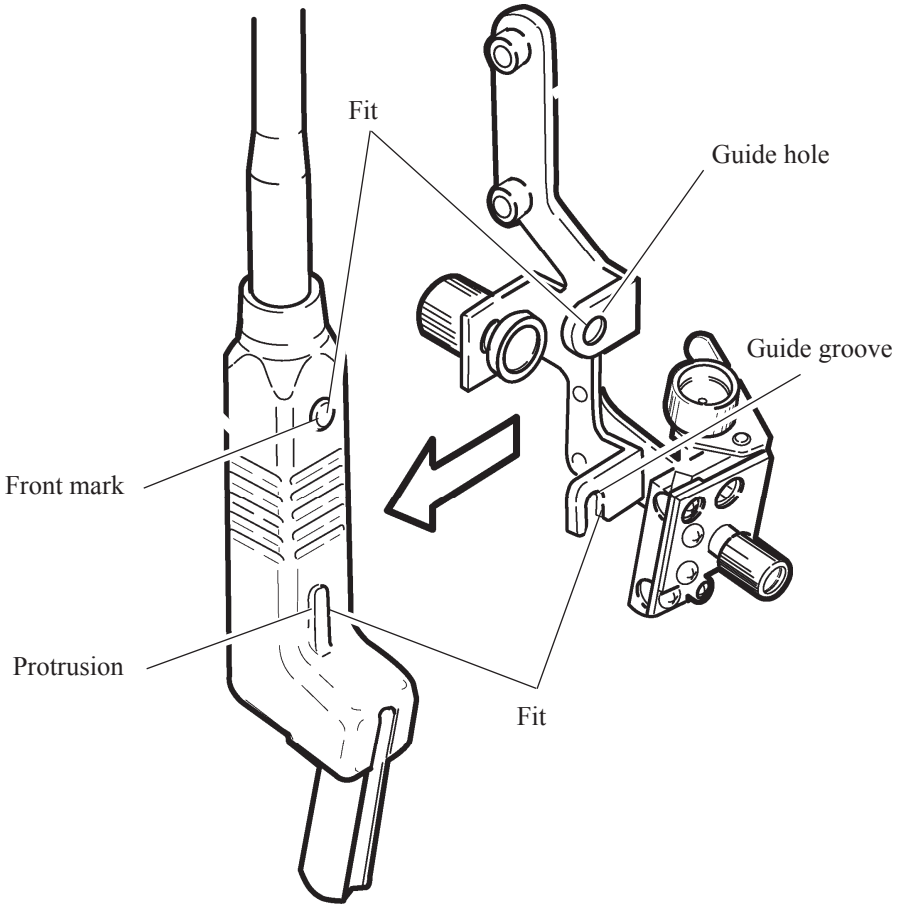
## 4-1. Operation

During surgery, the probe is in direct contact with the inner organs. An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. For details on displaying and adjusting the screens, see the documentation supplied with the ultrasound diagnostic instrument.

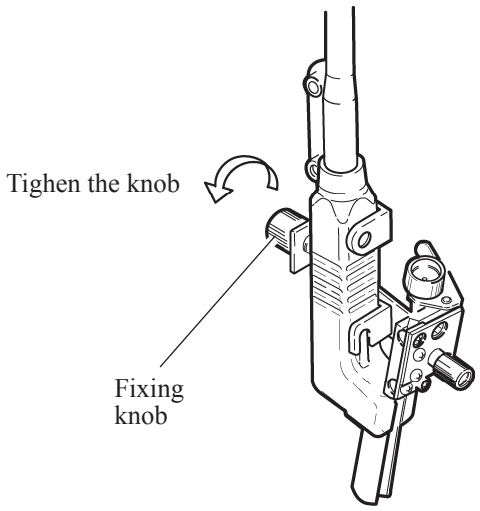
| ⚠ Caution |
|---|
| Do not move the probe with excessive force.<br>Pressing down with more force than necessary can cause injury to the patient. |
| Scan for the minimum length of time necessary for the diagnosis and at the lowest suitable output.<br>There is the possibility that the patient's internal tissues could be affected.<br>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.<br>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.<br>It can cause electric shock to the patient. |

## 4-2. Attaching of the puncture adapter

(1) Align the front mark and the protrusion on the probe with the puncture adapter guide hole and the puncture guide groove, then attach the puncture adapter to the probe.




(2) Check that the front mark and the protrusion on the probe fit the guide hole and guide groove on the adapter respectively. Then, tighten the fixing knob.



## 4-3. Setting the needle groove

(1) Turn the needle groove setting knob fully counter-clockwise to set the needle groove size to the minimum..

(2) Use the release lever to attach the puncture needle to the needle groove.

(3) Face the tip of the puncture needle downward, and adjust the needle groove setting knob so that the size of the needle groove is the minimum size where the puncture needle can move smoothly.

## 4-4. Using the needle stopper and the depth gauge

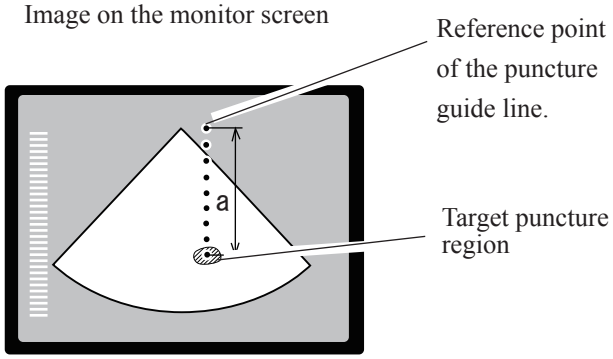
Use of the needle stopper and the depth gauge can prevent the needle tip being inserted beyond the pre-measured depth (target puncture region).
To use the needle stopper and the depth gauge, follow the procedure below.

(1) Display the puncture guide line on the monitor screen.

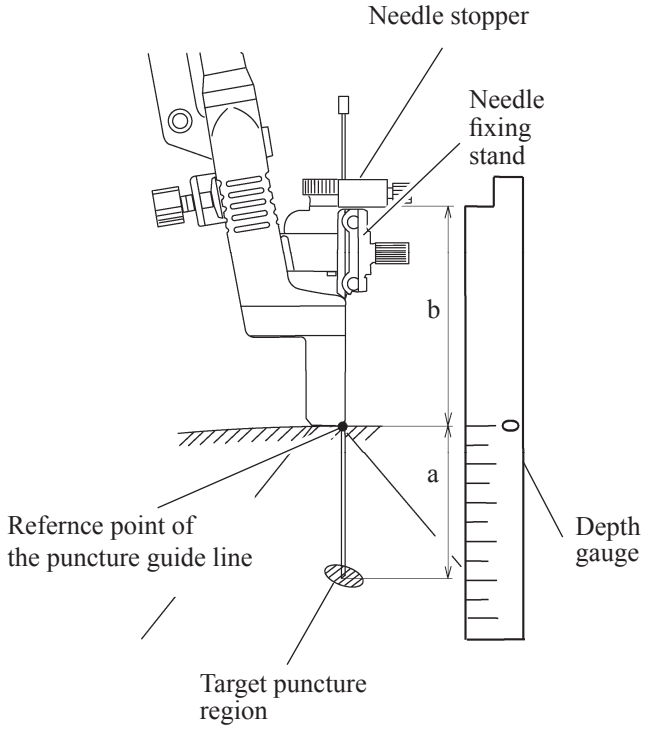
(2) Adjust the position and angle of the probe so that the target puncture region appears over the puncture guide line on the display, and then freeze the image.

(3) Measure the distance "*a*" from the reference point of the puncture guide line on the monitor screen to the target puncture region.
Use the puncture guide distance measurement function of the ultrasound diagnostic instrument.
However the reference point does not appear on the screen.

Remarks:
For details on the method of measuring the distance using the displayed puncture guide line and calipers, see the instruction manual of the ultrasound diagnostic instrument.



(9) Insert the puncturing needle until the needle stopper contacts the needle locking stand.
The tip of the puncturing needle reaches the target puncture region.




—Description—

The distance from the tip of the puncturing needle to the end of the needle stopper is given by length of
Distance "a" + Distance "b"

Distance "*a*" : Distance from the reference point on the puncture guide line to the target puncture region.
* The 0 index line on the depth gauge corresponds to the reference point of the puncture guide line.

Distance "*b*": Distance from the end of the needle locking base on the puncture adapter to the reference point on the puncture guide line.
* On the depth gauge, this corresponds to the distance from the 0 index line to the notch.

## 4-5. Removal of the puncture adapter

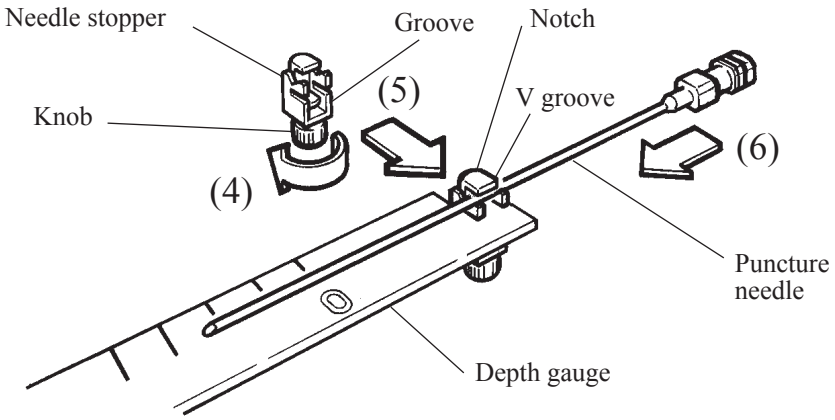
Remove the puncture adapter by performing the procedure in reverse described in section 4-2 "Attaching of the puncture adapter".

Immediately clean, disinfect and sterilize the puncture adapter after it is removed from the probe.

(4) Loosen the knob of the needle stopper.

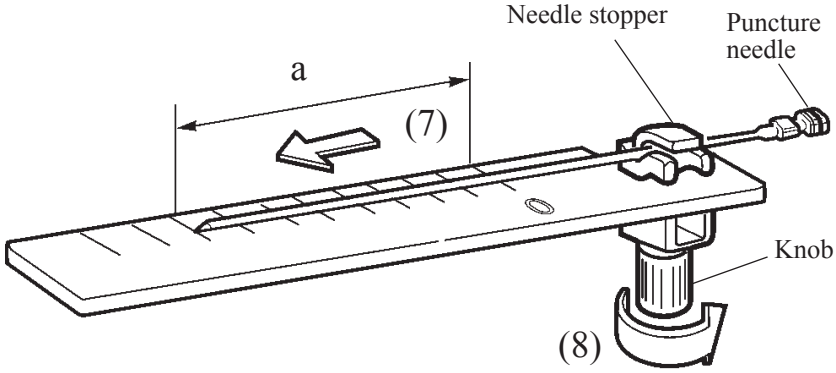
(5) Install the needle stopper on the depth gauge.
The groove of the needle stopper must attach to the notch of the depth gauge.

(6) Insert the puncture needle into the V groove of the needle stopper.



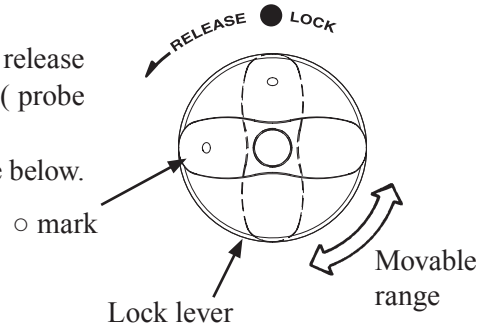

(7) Move the tip of the puncture needle to the scale position corresponding to the distance "*a*" measured in step (3) above.

(8) Tighten the knob of the needle stopper to lock the needle stopper to the puncturing needle.



## 4-6. 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.

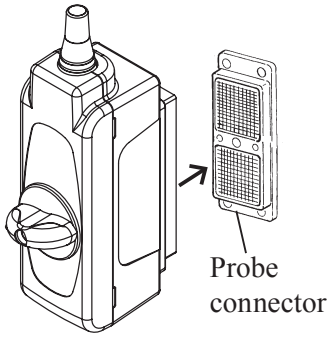



- Connection procedure

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.



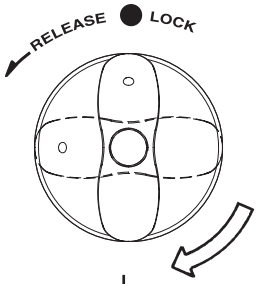

1. Turn the connector lock lever to align the ○ mark on the lever with the RELEASE position.

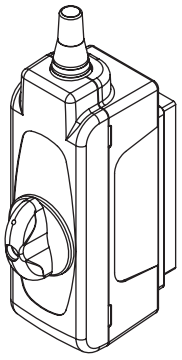
2. Firmly insert the connector into the probe connector.

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.



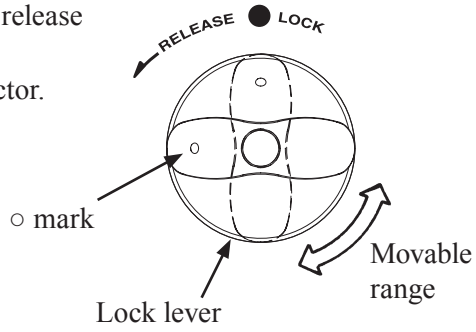



### ⚠ Caution

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.

## 4-7. 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.



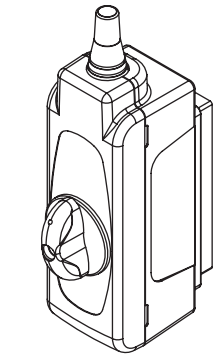

- Removal procedure

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

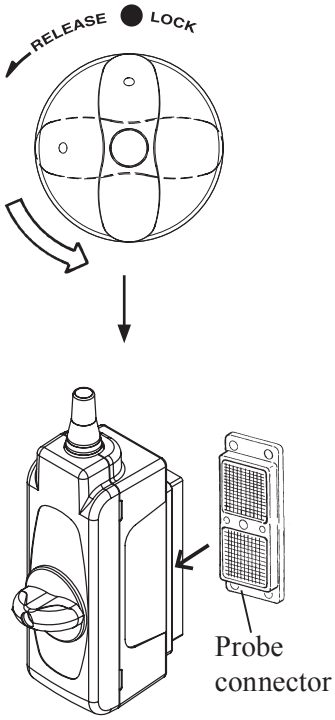
- The power switch is set to OFF.
- The image displayed on the ultrasound diagnostic instrument is frozen.

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 cleaning, disinfection and sterilization of the probe by following the procedure in section 5 “Cleaning, 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".



## 4-8. Puncturing precautions

| ⚠ Warning |
|---|
| Puncturing must be performed by a skilled doctor.<br>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 ultrasonic guide. |
| The equipment must be cleaned, disinfected and sterilized before use.<br>Be sure to always clean, disinfect and sterilize properly after use.<br>Otherwise, an infection can occur. Note that the equipment is not sterilized when shipped from the factory. Before using the equipment be sure to clean, disinfect and sterilize it. |
| When puncturing, be sure to wear sterilized medical gloves.<br>Puncturing with the bare hands can expose the operator or patient to a risk of infection. |
| This puncture adapter is used by attaching to the probe and following the instructions in this manual.<br>Attaching improperly to the probe or performing puncture operations without attaching to the probe can result in the puncture adapter coming off during puncturing or puncturing an unintended body part. For details on the attachment procedure, see section 4-2 "Attaching of the puncture adapter". |
| For the ultrasound medium, use sterilized physiological saline solution.<br>Using an unsterilized ultrasound medium can cause an infection on the patient. |
| Check that the gauge size of the puncture needle that is used matches the gauge size of the needle guide.<br>Using when the gauge sizes of the puncture needle and needle guide do not match can result in puncturing of an unintended body part. |
| Use sterilized puncture needles.<br>Otherwise, an infection can occur. |
| Do not use needles were bent.<br>Puncturing of an unintended body part causing an injury to the patient. |
| Be careful when handling the puncture needle.<br>Accidentally puncturing your hand or other body part can result in infection of the operator or patient. |
| When inserting an RFA(Radio Frequency Ablation) needle, do not insert while bending the needle.<br>Inserting while bending the needle can break the insulation membrane covering the RFA needle and could cause burns to the patient. |
| Before using a needle cannula as a guide with this equipment, first check that the cannula moves smoothly through the tube without causing any damage on the surface of the cannula, and then operate with caution.<br>If the cannula does not move smoothly or is forced to bend when inserted in or pulled out of this equipment, this could damage the insulation membrane covering the cannula and cause burns to the tissue exposed to the damaged area of the cannula. |

| ⚠ Warning |
|---|
| During the puncture operation, display a suitable puncture guide line on the screen of the ultrasound diagnostic instrument.<br>Puncturing of an unintended body part can cause an 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. |
| Check beforehand any areas not displayed on the ultrasound image that are along the puncturing path.<br>If other tissues are in the area not displayed on the ultrasound image, there is a risk of puncturing an unintended body part and causing an injury to the patient. |
| Do not puncture the heart region.<br>Puncturing the heart region may cause a micro electric shock. |
| Check that no other organs lie in the puncture path.<br>If another organ lies in the puncture path, an unintended body part can be punctured and cause an injury to the patient. Before puncturing, carefully check the body parts and constantly confirm the needle echo during the operation. |
| Constantly check the safety in the needle insertion direction using the needle echo rendered by the ultrasonic wave.<br>A bent puncture needle can result in puncturing of an unintended body part and cause an injury to the patient. |
| Do not try to forcibly perform operations.<br>If excessive force is applied in a direction other than the insertion direction of the puncture needle, the puncture needle can come off the puncture guide line, resulting in puncturing of an unintended body part and causing an injury to the patient. |
| For details about the reuse and disposal of puncture needles, follow the instructions in the documentation supplied with the puncture needles.<br>Reuse of puncturing needles that are not reusable or improper disposal could result in an infection. |
| Do not use the equipment fallen on to floor.<br>Otherwise, there is a risk of infection. Stop the operation and perform the procedure in section 5 "Cleaning, disinfection and sterilization" section 3-2 "Start up check of the puncture adapter" and section 3-3 "Checking the needle echo". |

| ⚠ Caution |
|---|
| Handle the needle carefully to ensure that the puncture adapter and probe are not damaged.<br>Using a puncture adapter or probe that has been damaged by a needle can result in an injury to the operator or patient. |
| Check beforehand if the patient has any allergic reactions to metals.<br>If the patient has a metal allergy of stainless steel, puncture adapter may be hazardous for patient as an allergic risk. |

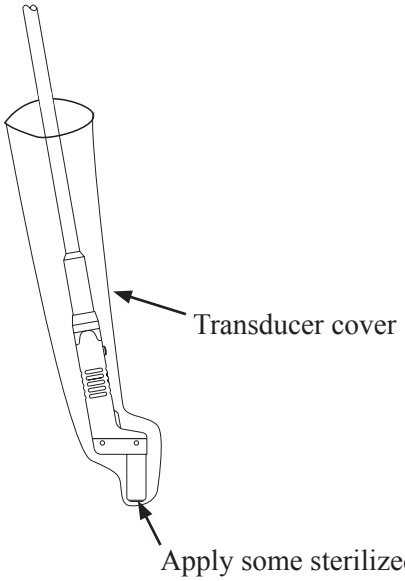
| ⚠ Note |
|---|
| Before a puncture operation on the patient, check the relative safety not only of the equipment directly related to the puncture operation, but also of peripheral equipment and measuring instruments. |

## 4-9. When using the probe for neurosurgery applications

When using the probe in neurosurgery applications, please attach our recommended transducer cover to our sterilized probe.

### 4-9-1. How to attach the transducer cover

Apply some sterilized echo jelly which is attached to our recommended transducer cover to the ultrasound scanning surface of the sterilized probe. Then attach the transducer cover over the probe. Remove any bubbles or wrinkles from the ultrasound scanning surface of the probe.




### 4-9-2. How to remove the transducer cover

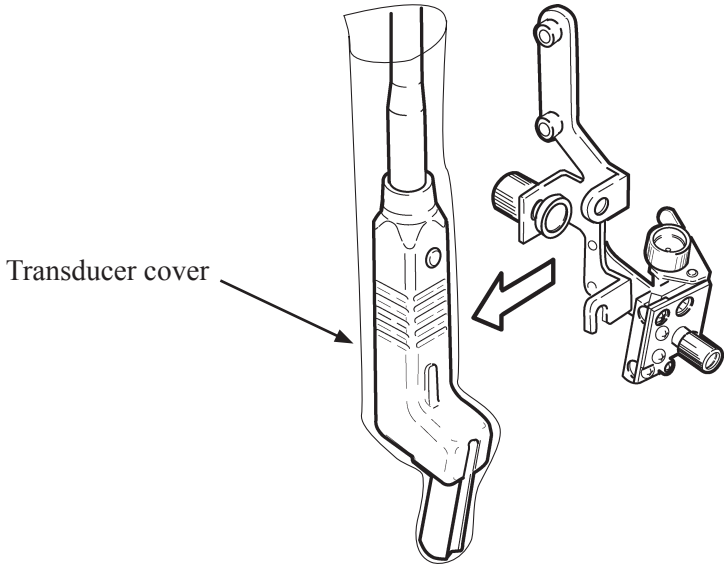
(1) To prevent infection use surgical gloves to remove the used transducer cover from the probe.

(2) Dispose the used surgical gloves and transducer cover in a manner that prevents infection and in accordance with the rules of the medical facility.

### 4-9-3. Puncture

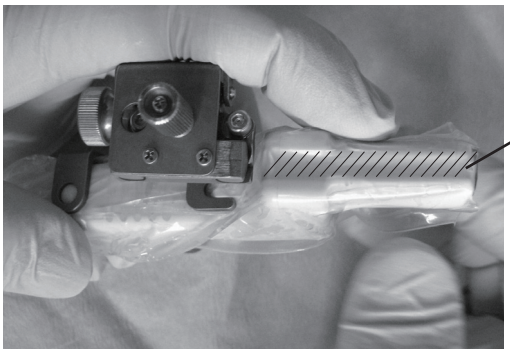
(1) Adjusting the size of the needle groove according to Section 4-3, and attaching the transducer cover according to Section 4-9-1, attach the puncture adapter.

The method of attaching the puncture adapter is the same as described in Section 4-2

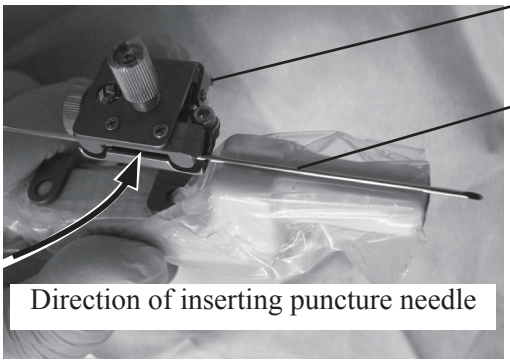


(2)Adhere the transducer cover closely to the probe pushing the transducer cover nearby pathway of puncture needle. Then open the release lever of the puncture adapter and insert the puncture needle into the needle groove.

Puncturing root of puncture needle



Adhere the transducer cover in hatched range closely to the probe to prevent needle stick into swelled transducer cover.




Operate the release lever of the puncture adapter and open the needle groove.

Insert the puncture needle into the needle groove in the direction of the arrow.
(To prevent the contact of the puncture needle tip to the transducer cover.)

(3) Verify that there is nothing wrong with the transducer cover before puncturing.
Do not use the transducer cover if there is visible damage, such as a tear, and throw away the transducer cover.

## 4-9-4. Remove the puncture adapter

In the reverse way of Section 4-2 Attaching of the puncture adapter.
Clean, disinfect and sterilize the puncture adapter immediately after use.

## 4-10. Precautions when using the probe in neurosurgery applications

| ⚠ Warning |
|---|
| When using this probe in neurosurgery applications, attach our recommended transducer cover to the probe. Failure to properly use the transducer cover may cause harm to the patient. |
| Use our recommended transducer cover.<br>If you use a transducer cover which is not recommended by our company, it may cause harm to the patient due to tearing or pyrogen. |
| Verify that the transducer cover packaging has not been opened or damaged.<br>If you use a contaminated transducer cover, it may cause patient infection although our recommended transducer cover is sterilized. |
| Verify that there is nothing wrong with the transducer cover.<br>Store the transducer cover according to its instruction. Do not use the transducer cover if the expiration date has passed, if it is discolored, or if there is visible damage, such as a tear. |
| Take precaution in handling the transducer cover so as not to break it as this may then result in direct contact with the edge of bone during a craniotomy.<br>If the transducer cover breaks, it may cause harm to the patient. |
| Verify that there is nothing wrong with the transducer cover and that the puncture adapter is properly attached on the transducer when puncturing.<br>If you attach the puncture adapter incorrectly, it may come off during the procedure, or it may be punctured into a non intended area. Refer to the details on Section 4-9-3 “Puncture”. |
| Properly use the transducer cover and puncture needle according to this instruction.<br>If used incorrectly, it may cause patient or user injury. |
| Verify that the probe is sterilized. Use the sterilized echo jelly attached to our recommended transducer cover as the acoustic medium.<br>If you use contaminated ones, it may cause patient infection. |
| Verify that there are no bubbles of the acoustic medium inside of the transducer cover.<br>If there are bubbles inside the transducer cover, they may cause clinical images changed and erroneous display on the monitor leading to misdiagnosis. |
| When removing the transducer cover, do not pull it forcibly.<br>If you use excessive force, it may cause probe damage or scattering of contaminated material. |
| Do not reuse the transducer cover.<br>If you reuse the transducer cover, it may cause patient infection. |

| ⚠ Caution |
|---|
| When disposing the transducer cover, take appropriate measures for prevention of infection.<br>If you dispose it improperly, it may cause environmental damage. |

## 4-11. Actions to be taken when an abnormal state is detected

### 4-11-1. Ensuring safety of patients

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

### 4-11-2. 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 probe where a problem has been found.<br>Using a probe 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. Cleaning, disinfection and sterilization

Applicable cleaning, disinfection and sterilization methods for each product are listed in the Table 1. The detail of each method is described in Chapter 5-2.

Table 1 Applicable cleaning, disinfection and sterilization methods

| Model | Cleaning | | Disinfection | | Sterilization | | | | | Waterproof cover (MP-2790) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Manual | Automated *1 | Manual | Automated *1 | EtO | STERRAD® | Liquid *2 | Autoclave | STERIS® | |
| UST-52114P | X | | X | | X | X | X | | | |

Note: X means “Applicable”

*1: Automated Need waterproof cover

*2: Liquid sterilization USA only

## 5-1. Precautions for cleaning, disinfection and sterilization

The following warnings and cautions must be observed when cleaning, disinfecting and sterilizing the probe and accessories.

| ⚠ Warning |
|---|
| Wear protective gloves and other protective gear during cleaning, disinfection and sterilization. Handling of the probe with your bare hands before sterilization can result in an infection. |
| After finishing soaking the probe in cleaning agents, thoroughly wash it with running water. Residual cleaning agents can cause an adverse reaction to the operator or the patient. |
| After chemical sterilization, thoroughly wash the probe with sterile water. Residual chemicals can cause an adverse reaction to the operator or patient. (USA only) |
| After disinfecting the probe, throughly wash the probe with deionized water. Leavings of the disinfectant can cause an adverse reaction on the bodies of the operator or patient. (EU only) |
| Perform full aeration after gas sterilization. Residual gas can cause an adverse reaction to the operator or patient. |
| Do not clean or sterilize using procedures other than those specified in this manual. Failure to clean and sterilize the equipment can result in an infection. It can also result in damage to the probe or reduced performance. The probe is not compatible with 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 can be resulted due to incomplete sterilization. Wrong sterilization procedure could cause deterioration of the probe. |

| ⚠ Caution |
|---|
| Do not immerse the probe into any liquid beyond the range of IPX7. The range is indicated in the section 2-2 "specification". If any liquid enters the connector, immediately stop using the probe and contact one of our offices and/or distributor's offices listed on the back cover. Liquid in the connector could cause electric shock to the operator or patient. |
| Do not wipe the ultrasonic radiation part with alcohol. Alcohol could damage the part. |
| Do not use organic solvent such as thinner for cleaning to prevent the probe from damage. |
| Do not use hard or sharp objects to remove residue on the probe. Such objects may damage the probe. |

Additional information:
The Instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, material and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

## 5-2. Reprocessing instruction according to ISO 17664

Take care about clean circumstances before using the probe on the next patients. If processors reprocess this equipment, refer to these instructions.

Table 1

| | |
|---|---|
| WARNINGS | • The probe is delivered unsterile. Prior to the first use, reprocess the probe.<br>• Do not exceed 60 °C [140 °F].<br>• Probe connector has no water resistance. |
| Limitations on reprocessing | The probe is not completely submergible (Do not immerse the probe into any liquid beyond the range of IPX7. The range is indicated in the section 2-2 "specification".)<br>Parts which are not submergible can only be disinfected by wipe disinfection. |
| Transportation before using | Sterile pouch or container should be kept between transportation from Central Sterile Supply Department (CSSD) to operating room. Be careful that no damages are applied to sterile pouch or container for transportation. |

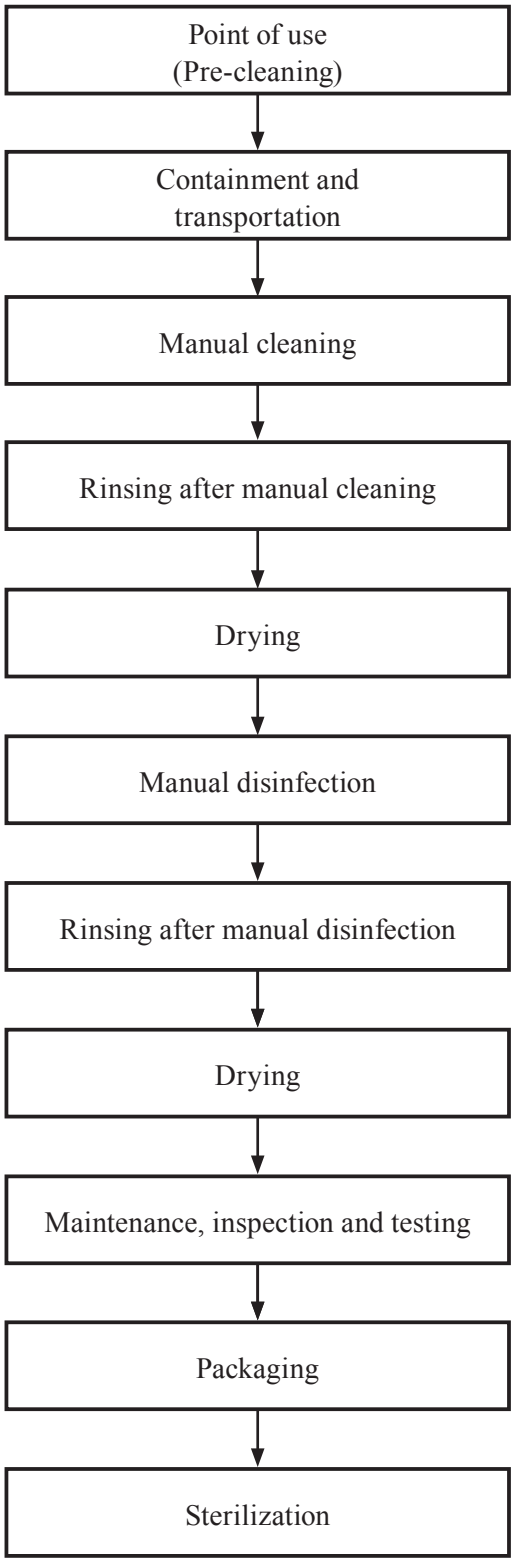
The level of processing required depends on the type of equipment and its use.
The CDC (Centers for Disease Control and Prevention) in the USA and the RKI (Robert Koch Institute) in Germany classify medical devices according to their use. For each classification, they specify the level of disinfection/sterilization processing that is required before use. Table 3 summarizes this information.

Table 2

| **Classification** | **Definition** | **Processing** |
|---|---|---|
| Noncritical | Application part only contacts intact and uninjured skin | Cleaning<br>↓<br>Disinfection<br>[in the USA, low-level disinfection] |
| Semicritical | Application part contacts mucosa (intracavitary application) | Cleaning<br>↓<br>Disinfection (Disinfectant with bactericidal, fungicidal and virucidal effect)<br>[in the USA, high-level disinfection or sterilization] |
| Critical | Application part contacts intracorporeal tissue directly (intraoperative application) | Cleaning<br>↓<br>Disinfection<br>↓<br>Sterilization *1 |

*1. When sterilization is not possible, the FDA in the USA recognize that disinfection (in the USA, high-level disinfection) and the use of a sterile gel and sterile transducer cover, as described in the instructions provided with the transducer cover, is an accepted method of infection control for probe.

Flowchart of reprocessing process of this probe is as follows:



## 5-3. Point of use (Pre-cleaning)

In the operating room after use of the probe

### Probe

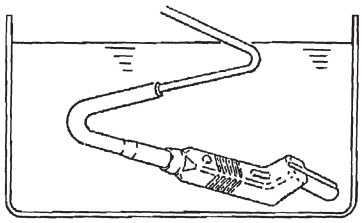
1) Remove any accessories from the probe like biopsy adapters and transducer covers.
2) Flush patient's blood or fluid by tap water directly after use until the surface looks visually clean.
3) Wipe the whole surface of the probe by gauze pad and remove superficial visible impurities until the surface looks visually clean.

## 5-4. Containment and transportation

Putting the contaminated equipment into exclusive shock and damage proof container for transportation is recommended. It is recommended that instruments are reprocessed as soon as possible and not later than 4 hours after usage.

### ⚠ 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

## 5-5. Manual cleaning and disinfection

Prepare following items before manual cleaning and disinfection.

### Probe

1) Detergent: ENZOL®/Cidezyme® (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device.
2) Disinfectant: Cidex® OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device.
3) 2 tanks, 1 for cleaning and 1 for disinfection - optional: 1 additional tank for rinsing with deionized/ tap water. (sufficient size for immersion of the submergible part of the probe at full length)
4) Soft, fluff free cloth or single use towel
5) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses see also instructions of the manufacturer for the detergent and the disinfectant)

## 5-5-1. Manual cleaning

### Probe

1) The temperature of the detergent solution should be between 15-30 °C [59-86 °F], concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a differing detergent is used, please also consider the approved material compatibility for this probe.
2) Immerge the submergible part of the probe (see figure) without connector into the detergent.
3) Wipe the submergible part of the probe under the surface of the detergent solution with a single-use, fluff free soft cloth to remove all visible soil. Be sure that all grooves of the probe are implemented during the cleaning process. If necessary use an appropriate cleaning brush for this purpose.
4) Wipe the non-submergible parts of the probe with a soft cloth dipped with a detergent.
5) Rinse the submergible part of the probe with running tap water for 1 minute.
6) Alternatively to step 5 suspend the submergible part of the probe in a tray filled with deionized water/tap water for 5 min.
7) Visually check the outer surface of the probe for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

## 5-5-2. Manual disinfection

### Probe

1) Before immersing the equipment, it is recommended to test the concentration of disinfectant solution before each usage. The solution Cidex® OPA is ready for use and does not need to be diluted. Test strips to verify that the appropriate concentration of Cidex® OPA is correct are available by manufacturer. Test strips will indicate a concentration above the Minimum Effective Concentration (MEC). Temperature of disinfectant solution should be minimum 20 °C[68 °F]. The minimum contact time is 5 minutes. If a differing disinfectant is used follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.
2) Wipe the non-submergible parts of the probe with a soft and fluff free cloth with disinfectant.
3) Immerge the submergible part of the probe (see figure) into the disinfectant. Set a clock to insure the recommended contact time is observed.
4) Rinse the submergible part of the probe with running deionized water for 1 minute.
5) Alternatively to step 4 suspend the submergible part of the probe in a tray filled with deionized water for 5 min.
6) Visually check the outer surface of the probe for that there are no leavings of the disinfectant. If necessary, repeat the rinsing.

**⚠ Caution**

Do not wipe the ultrasonic radiation part with alcohol.
Alcohol could damage the part.

**⚠ Warning**

After finishing soaking the probe in the cleaning agent or disinfectant, thoroughly rinse it with running water (after cleaning) and deionized water (after disinfection). Residual agent can cause an adverse reaction to the operator or patient.

## 5-5-3. Cable and connector

Wipe the cable in 20 cm intervals with gauze dipped in ethyl alcohol or water, and dry it after wiping.
Clean the connector with gauze dipped in ethyl alcohol, and dry it after cleaning.
Clean the other parts of the probe which must not be soaked in liquid in the same manner as the connector.

**⚠ Note**

If the entire length of the cable is wiped at once, a part of the cable may be wrinkled.
If this occurs, pull the wrinkled part in the opposite direction to smooth it.

## 5-6. Automated cleaning and disinfecting

Probe

| ⚠ Warning |
| --- |
| ⃠ The probe cannot withstand Automated cleaning and disinfecting. |

## 5-7. Applicable cleaners and disinfectants / Suppliers List

The applicable chemical solutions are listed below.

| General name | Trade name | Manufacturer |
|---|---|---|
| Enzyme cleaning agent | ENZOL®/Cidezyme® Practical liquid 0.8V/V% | ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc. |
| Alkylpolyalkylenglykole-ther | Korsolex® Endo-Cleaner | BODE Chemie GmbH |

| 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 | Cidex plus® | |
| Glutaral | STERIHYDE® * Practical liquid 2W/V% | Maruishi Pharmaceutical Co., Ltd. |
| Benzethonium chloride | Hyamine® * Practical liquid 0.1W/V% | DAIICHI SANKYO Co., Ltd. |
| Didecyl dimethylammonium chloride | Cleanisept® Wipes * Solution 7.5% | Dr. Schumacher GmbH |
| Hydrogen peroxide | ANIOXYDE 1000 * Solution 0.15% | Laboratories ANIOS |
| Dimethyl-dioctyl-ammonium-chloride | Gigasept® AF forte * Solution 2.0% | Schülke & Mayr |
| Glutaral | Korsolex extra * | BODE Chemie GmbH |
| Glutaral | Korsolex Endo-Disinfectant | BODE Chemie GmbH |

Note: * indicates that the marked disinfectant is not applicable in Canada.

High-level disinfection

| General name | Trade name | Manufacturer |
|---|---|---|
| Hydrogen peroxide | PERASAFE™ * Practical liquid 1.62W/V% | ANTEC INTERNATIONAL |
| Peracetic acid | Acecide® * Solution 6% | Saraya Co., Ltd. |
| Glutaraldehyde | WAVICIDE®-01 * Solution 2.65% | Medical Chemical Corporation |
| Glutaraldehyde | STERANIOS * Solution 2.0% | Laboratoires ANIOS |
| Glutaral | Cidex plus® Solution 3.4% | ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc. |

Note: * indicates that the marked disinfectant is not applicable in Canada.

⚠ Warning

After disinfection, thoroughly rinse the probe with deionized water.
Residual disinfectant can cause an adverse reaction to the operator or patient.

## 5-8. Drying

### Probe

1) Wipe the probe with single use, fluff free wipe or towel for removing moisture on the surface of the equipment.
2) If using drying heater for medical equipment, the temperature limit is a maximum of 60 °C [140 °F]. Dry until no visible moisture is left.
3) If using natural drying, temperature range should be between 15-30°C[59-86°F] for a minimum time of 4 hours.

## 5-9. Maintenance, inspection and testing

Confirm following items

1) the function of mechanical moving parts
2) the image performance when the probe is connected to the scanner
3) there are no abnormal exterior damages such as cracks on the surface of the equipment
4) Safety tests (See section 8-1)

## 5-10. Packaging

Store the disinfected probe in a dustproof environment until next application. Before sterilization it is necessary to pack all parts in a pouch suitable for sterilization, or in a tray with wrap according to ISO 11607-1 and ISO 11607-2 “Packaging for terminally sterilized devices” and ISO/TS 16775 “Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2” or the local hospital procedure. Follow the pouch manufacturer’s specifications or the local regulations for how to pack and seal the pouches. Check the sealing seam after heat sealing for any defects. In case of processing mistakes or defects the package has to be opened again and the device has to be packed and sealed again.

## 5-11. Sterilization

See “Table 1. Applicable cleaning, disinfection and sterilization methods” for available sterilization methods Follow the instructions of the sterilizer manufacturer regarding usage, temperature and sterilization-time etc. Handling and maximum input to chamber of sterilizer should be according to operation manual of the sterilizer.

### 5-11-1. Ethylene oxide (EtO) gas sterilization

Sterile conditions of applicable sterilization methods are as follows.

Regarding the operation of the sterilizer, refer to the documentation supplied with the sterilizer.

| Perform sterilization in the following conditions: | |
|---|---|
| Gas Type: | 10% EO/ 90% HCFC |
| Temperature: | 50 - 60°C |
| | 122 - 140°F |
| Exposure Time: | More than 120 minutes |
| Pressurization: | 162 - 200kPa |
| Depressurization: | 13 - 8kPa |
| Relative humidity: | 40 - 90% |
| Aeration is minimum | 12 hours |

**⚠ Warning**

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

## 5-11-2. STERRAD® sterilization

Sterile conditions of applicable sterilization methods are as follows.
The applicable gas is listed below.

| General name | Trade name | Manufacturer |
|---|---|---|
| Hydrogen peroxide (58% density) | STERRAD® Sterilization system (STERRAD® 50, 100S, 200, NX or 100NX ) | ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc. |

Regarding the operation of the sterilizer, refer to the documentation supplied with the sterilizer.

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

**⚠ Caution**

Do not sterilize the probe using the STERRAD system if the probe is not compatible with the STERRAD system. STERRAD compatibility is shown by the STERRAD label on the connector.
Perform STERRAD sterilization only for STERRAD compatible probes, otherwise it can cause damage or deterioration to the probe.


* STERRAD label

Do not put the probe directly into the sterilization pouch*.
Otherwise the pouch sticks to the cable and results in damage to the cable. Completely wrap the entire probe (including the probe tip, cable and connector) with sterilization wraps* before putting it into the sterilization pouch*.
*: A Johnson & Johnson company Division of Ethicon, Inc. product

## 5-11-3. Liquid sterilization (USA only)

• Applicable chemical solution for sterilization
The applicable sterilants are listed below.

| General name | Trade name | Manufacturer |
|---|---|---|
| Hydrogen peroxide | PERASAFE® *<br>Practical liquid 1.62W/V% | ANTEC INTERNATIONAL |
| Peracetic acid | Acecide® *<br>Solution 6% | Saraya Co., Ltd. |
| Glutaraldehyde | WAVICIDE®-01 *<br>Solution 2.65% | Medical Chemical Corporation |
| Glutaraldehyde | STERANIOS *<br>Solution 2.0% | Laboratoires ANIOS |
| Glutaral | Cidex plus®<br>Solution 3.4% | ADVANCED STERILIZATION PRODUCTS®<br>A Johnson & Johnson company<br>Division of Ethicon, Inc. |

Note: * indicates that the marked sterilant is not applicable in Canada.

**⚠ Warning**

After chemical sterilization, thoroughly rinse the probe with sterile water.
Residual sterilant can cause an adverse reaction to the operator or patient.

## 5-12. Storage

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

# 6. Storage

## 6-1. Actions before storing the probe

When the probe will not be used for an extended period of time, perform the procedures described in section 5 “Cleaning, disinfection and sterilization" and then store it in its storage case.
Wash and sterilize the puncture adapter and store in sterile.

## 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 equipment for repairs".

## 7-2. Preparing the probe and accessories for moving

Store in the storage case and the storage tray after performing the procedure in section 5 “Cleaning, disinfection and sterilization".

## 7-3. Packing for transportation

Store in the storage case and the storage tray after performing the procedure in section 5 “Cleaning, disinfection and sterilization" and then put the storage case in a cardboard box for additional protection.

## 7-4. Environmental 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 probe. |

# 8. Periodic Inspection

## 8-1. Safety tests of the probe

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 probe tip 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 probe tip 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<br>DC<br>AC | <br><br>10 µA or less<br>100 µA or less | <br><br>50 µA or less<br>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.

## 8-3. Safety tests of the puncture adapter

Conduct a periodic safety tests at least once a year by referring to section 3-2 "Start up check of the puncture adapter" and section 3-3 "Checking the needle echo". Also conduct the safety tests for the probe that is used.

| ⚠ Warning |
| --- |
| Be sure a safety tests at least once a year.<br>Failure to notice an abnormal condition while using the equipment can result in an injury to the operator or patient. If a problem is found in the inspection, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover. |

# 9. Configuration

## 9-1. Standard configuration

| | | |
|---|---|---|
| Probe | UST-52114P | 1 set |
| Puncture adapter | MP-2450-MB | 1 set |
| Needle stopper | MP-2477 | 1 set |
| Depth gauge | MP-2450-DG | 1 piece |
| Storage tray | MP-2698 | 1 set |
| Adjustment hexagon screwdriver | | 1 piece |
| Storage case | STB-45-PA1 | 1 set |
| Instruction manual | MN1-5234 | 1 copy |

## 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.<br>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:

EC REP

Hitachi Medical Systems GmbH

Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany

EU Importer: Hitachi Medical Systems Europe Holding AG

Address: Sumpfstrasse 13 CH-6300 Zug, Switzerland

Distributor