Puncture Electronic Convex Probe

UST-9113P-3.5

Instruction Manual

MN1-1014 Rev.15

CE 0123

Hitachi Aloka Medical, Ltd.

Introduction

This is an instruction for model UST-9113P-3.5, 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 severities 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 50pages and 6pages until the CONTENTS.

1. Safety Precautions

1-1. Intended use

This probe is intended for use by a doctor when placed to direct contact with the skin making ultrasonic observations of surrounding organs.
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.
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 severities 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".

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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 the equipment without noticing 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 "Preparations for use".
⃠	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 equipment 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 equipments used for patients with Creutzfeldt-Jakob disease. Otherwise, there is a risk of infection to the operator or patient. Currently, there are no methods for washing, disinfecting and sterilizing equipments which have been used on patients afflicted by Creutzfeldt-Jacob 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 of the probe".

⚠ Caution	
❗	Constantly check for anything abnormal about the patient's condition, 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. Puncturing precautions

⚠ Warning
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 equipment must be washed and sterilized before use. Be sure to always properly wash and sterilize 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 wash and sterilize it as required.
When puncturing, be sure to wear sterilized medical gloves. Puncturing with the bare hands can expose the operator or patient to a risk of infection.
The puncture adapter is used by attaching to the probe and following the instructions in this manual. Attaching improperly to the probe or performing puncture operations without attaching to the probe can result in the puncture adapter coming off during surgery or puncturing an unintended body part. For details on the attachment procedure, see section 4-2 "Attaching of the puncture adapter".
For the acoustic medium, use sterilized physiological saline solution. Using an unsterilized acoustic 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 puncture adapter. Using when the gauge sizes of the puncture needle and puncture adapter do not match can result in puncturing of an unintended body part. Also, even if the gauge size is the same, the diameters may vary between different puncture needle manufacturers and products. For puncture needles diameters can be used for the puncture adapter, see section 2-2-2 "Specifications of the puncture adapter".
Use sterilized puncture needles. Otherwise, an infection can occur.
Do not use needles were bent. Puncturing of an unintended body part causing an injury to the patient.
Be careful when handling the puncture needle. Accidentally puncturing your hand or other body part can result in infection of the operator or 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 an injury to the patient. Display the puncture guide line on the screen referring to the instruction manual supplied with the ultrasound diagnostic instrument, 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.

⚠ Warning
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 deviate from 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 "Washing, Disinfection and Sterilization" section 3-1 "Start up check" and section 3-2 "Checking the needle echo".
When inserting an RFA(Radio Frequency Ablation) needle, do not insert while bending the needle. 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 with the puncture adapter as a guide, 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. If the cannula does not move smoothly or is forced to bend when inserted in or pulled out of the puncture adapter, it may damage the insulation membrane covering the cannula and may cause burns to the tissue exposed to the damaged area of the cannula.

⚠ Caution
Handle the needle carefully to ensure that the probe, the puncture adapter, the needle stopper and the depth gauge are not damaged. Using the probe, the puncture adapter, the needle stopper and the depth gauge 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. When using the puncture needle made of the stainless steel, if the patient has a metal allergy of stainless steel, the puncture needle may be hazardous for patient as an allergic risk.

⚠ Note
Before carrying out 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.

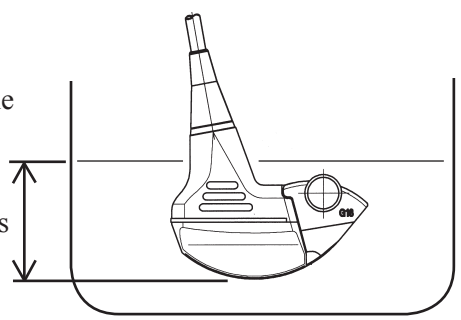
1-2-3. Washing, disinfection and sterilization precautions

⚠ Warning

- Wear protective gloves and other protective gear during washing, disinfection and sterilization. Handling of the equipment with your bare hands before disinfection or 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 chemical disinfection and sterilization, thoroughly wash the equipment 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 equipment or reduced performance. The equipment 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 equipment.

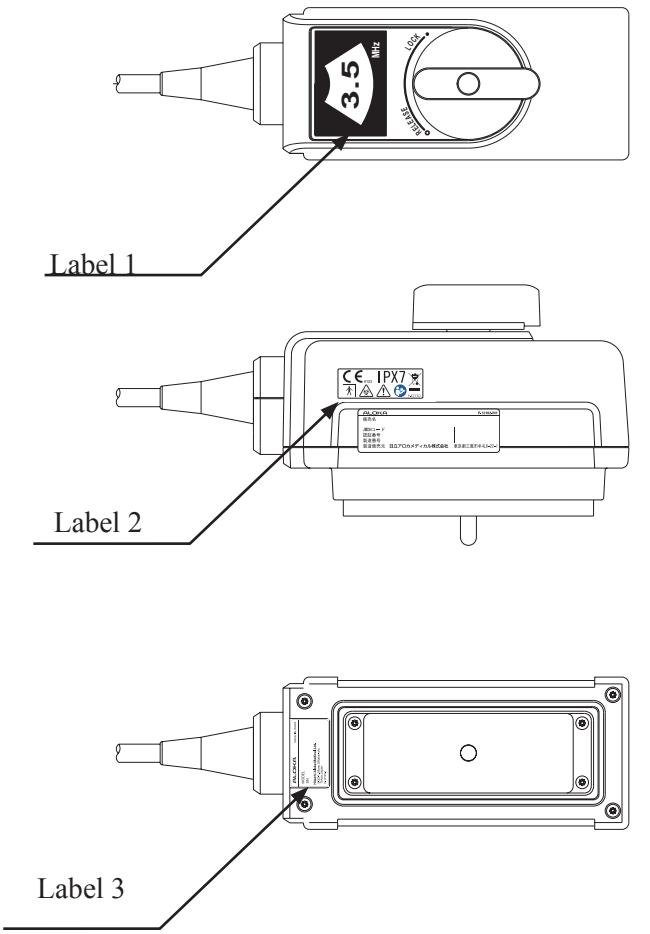
⚠ Caution

- Do not place the probe tip in any liquids beyond the range shown in the figure right. The connector which liquid has intruded can cause the malfunction of the probe and the ultrasound diagnostic instrument. In this case immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.

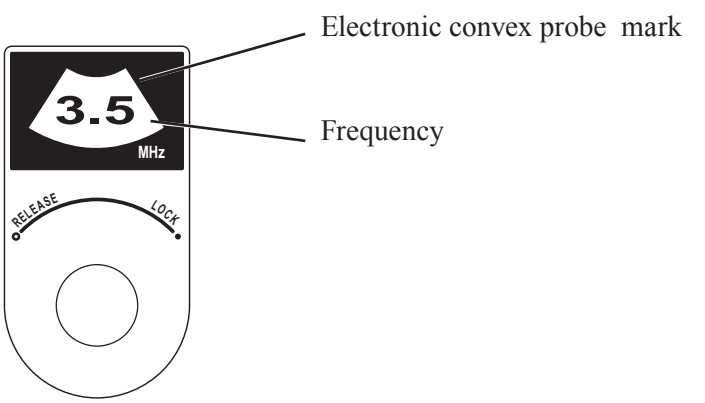


1-2-5. Labels

(1) Probe unit



Label 1



Label 2

This equipment complies with Directive 93/42/EEC relating to Medical Device.

IPX7 mark
See section 2-2, “Specifications”.

Type BF applied part

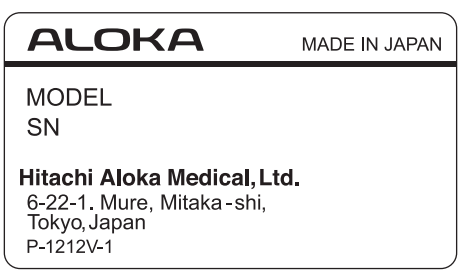
Do not waste the instrument as general waste.
Comply with a local regulation.
See section 10.

Safety warning sign

Biohazard
See section 5.

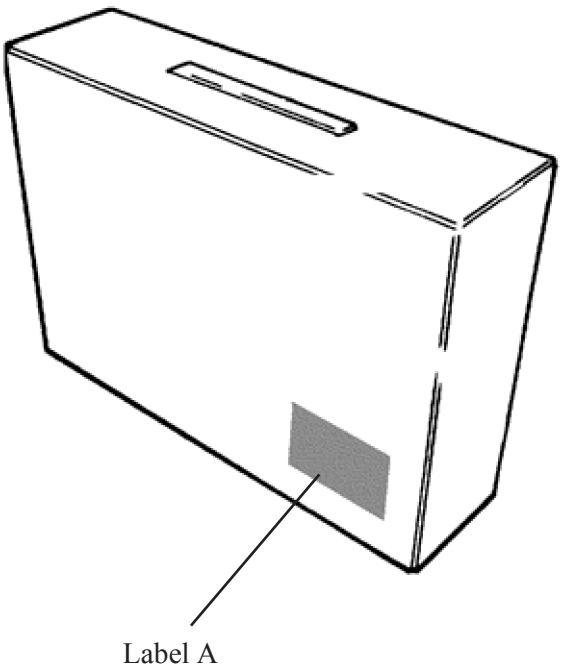
Follow the instruction manual to operate this instrument.
If not avoided, may result in injury, property damage, or the equipment trouble.

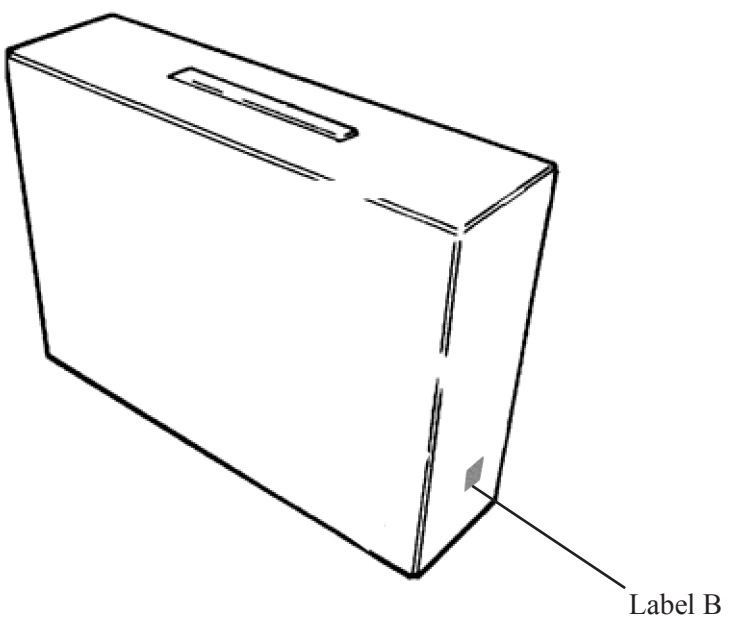
Label 3



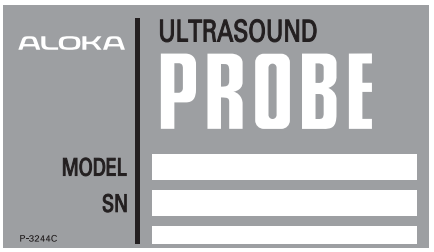
Manufacturer
Model, Serial No.

(2) Storage case





Label A



Model
Serial No.

Label B

This equipment complies with Directive 93/42/EEC relating to Medical Device.

2012

DATE OF MANUFACTURE
(in case of 2012)

MANUFACTURER

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.

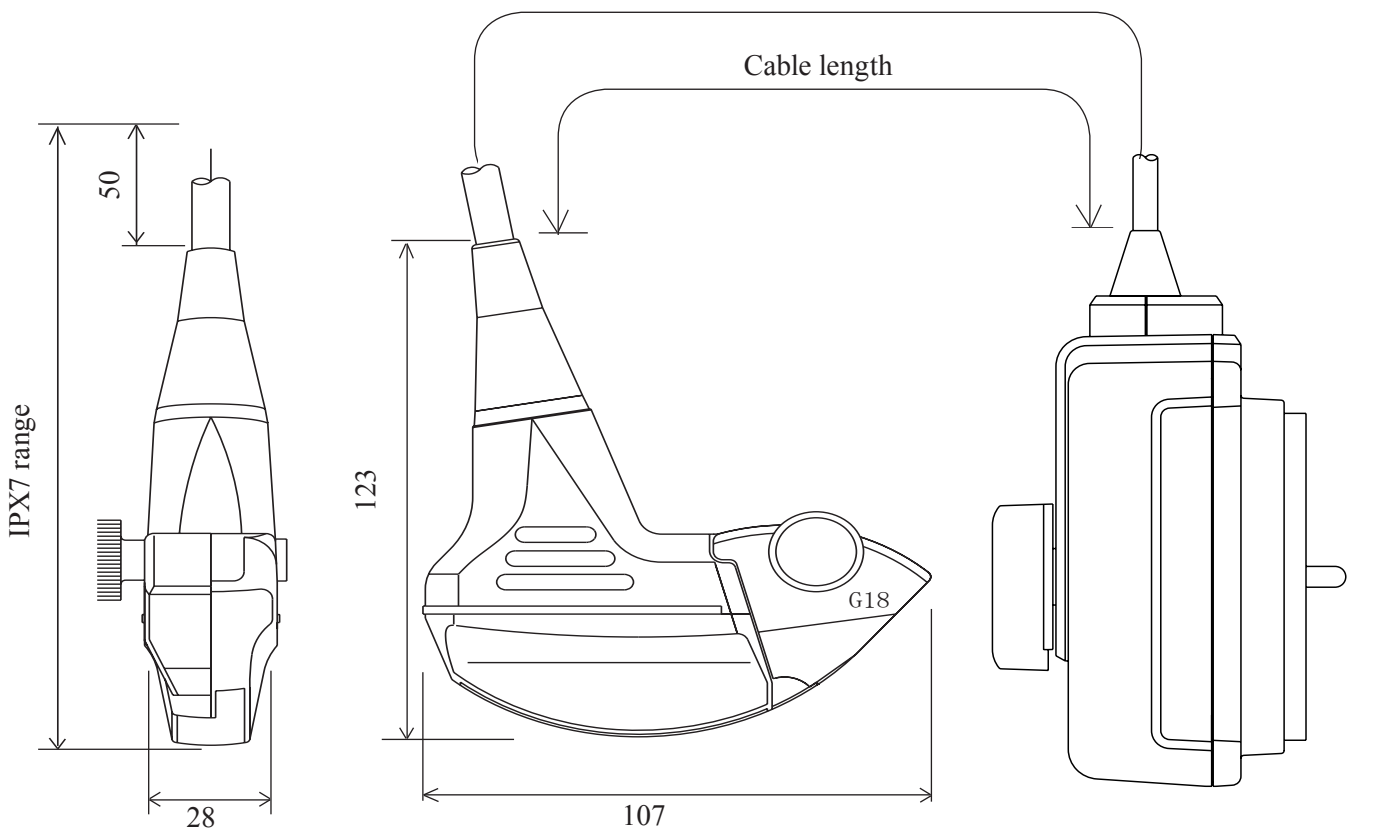
(2) The emitted ultrasonic waves are reflected by boundaries with different acoustic characteristics (acoustic impedance) within the body.

(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:	Surface puncturing, abdomen, general areas
Form of application to patient:	Surface
Connectable instruments:	SSD-900, SSD-1000, SSD-3500, SSD-4000, SSD-α5, Prosound 6
Field of view:	60°
Frequency:	3.5 MHz
Cable length:	2.0 m
Weight:	1060 g
Service life:	Three years
Range of applied part	Ultrasonic irradiation area, see the section 2-4.
Parts treated as applied parts	Probe tip itself and 1 m of the cable near the probe tip.
IPX7 range	As shown in the figure below.
External dimensions:	As shown in the figure below.

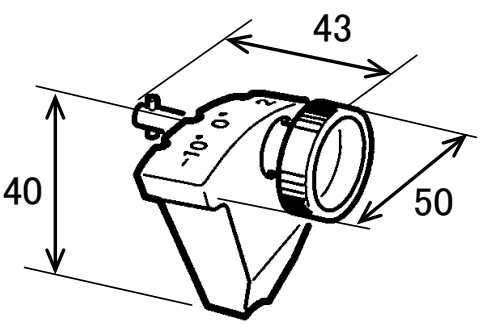


Unit: mm

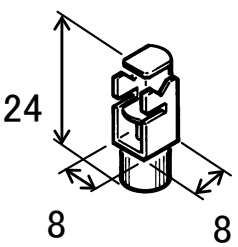
Remarks:
The dimensions and weight are within ±10% of the indicated values.

2-2-2. Specifications of the puncture adapter

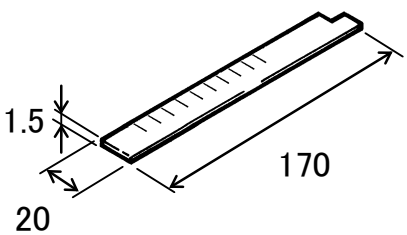
Material		Polyacetal (Puncture adapter (the needle guide))
		Stainless steel
		(Puncture adapter (the knob), needle stopper, depth gauge)
Puncture adapter, usable puncture needle size and diameter		
	Standard	MP-2480-G18 : 18G(1.26±0.02mm)
	Option	MP-2480-G22 : 22G(0.71±0.02mm)
		MP-2480-G21 : 21G(0.81±0.02mm)
		MP-2480-G20 : 20G(0.88±0.02mm)
		MP-2480-G19 : 19G(1.06±0.02mm)
		MP-2480-G17 : 17G(1.48±0.02mm)
		MP-2480-G16 : 16G(1.61±0.02mm)
		MP-2480-G15 : 15G(1.81±0.03mm)
		MP-2480-G14 : 14G(2.11±0.03mm)
		MP-2480-G13 : 13G(2.41±0.03mm)
		MP-2480-G12 : 12G(2.76±0.03mm)
		MP-2480-G11 : 11G(3.06±0.03mm)
Puncture angle		-10°, 0°, 20°, 40°
Service life		Three years
External dimensions		As shown in the figure below.



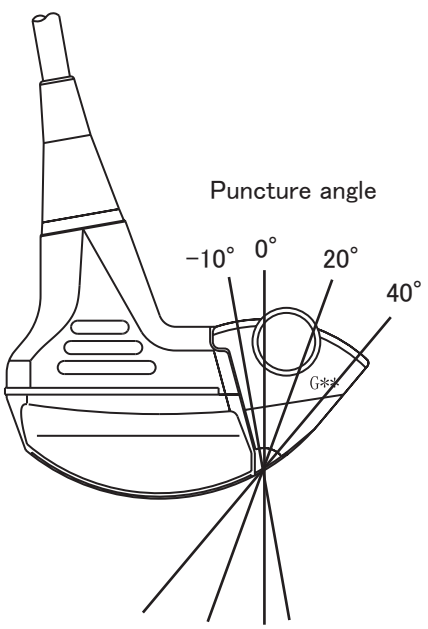
Puncture adapter
MP-2480-G**



Needle stopper
MP-2477



Depth gauge
MP-2480-DG



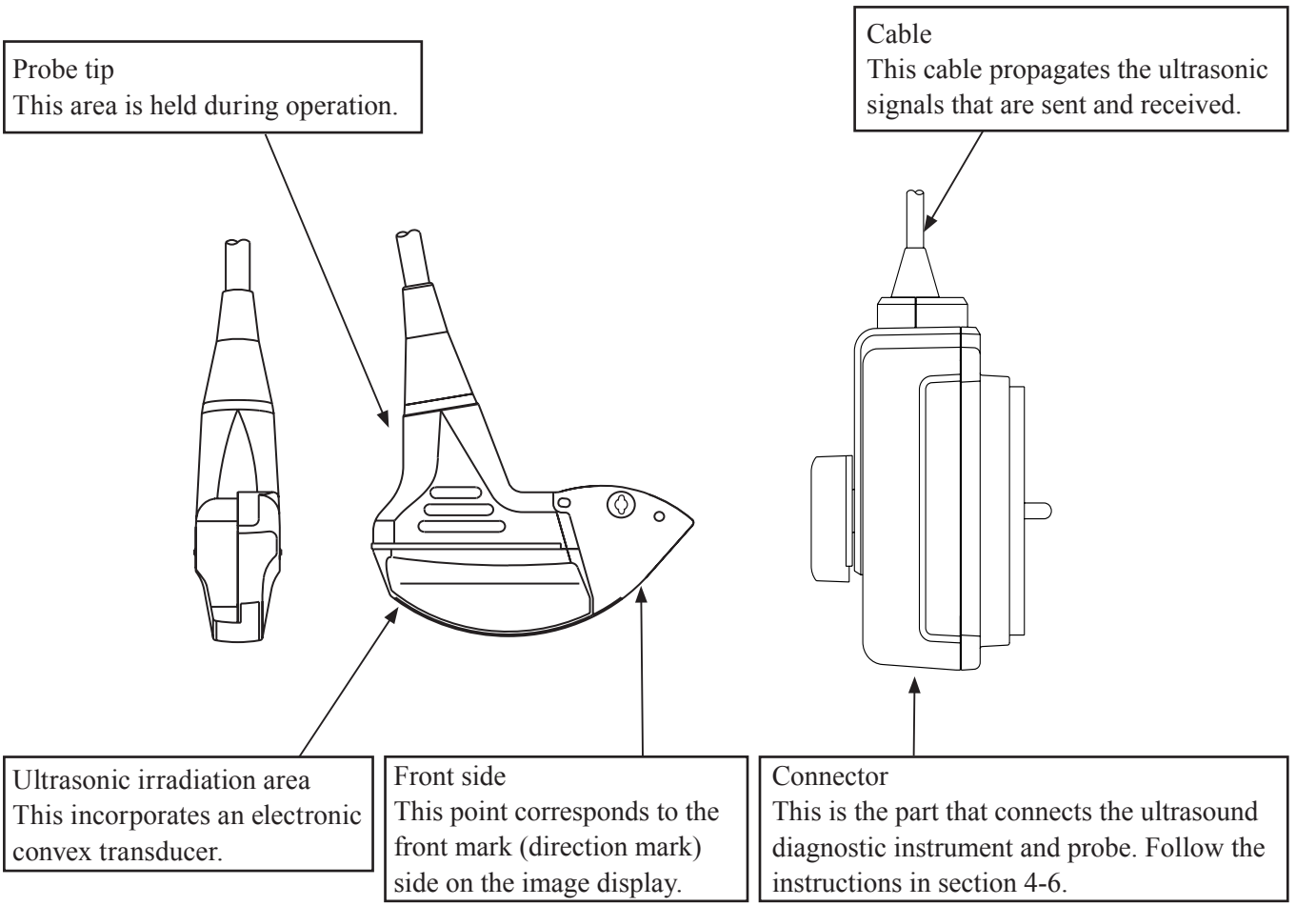
Unit: mm

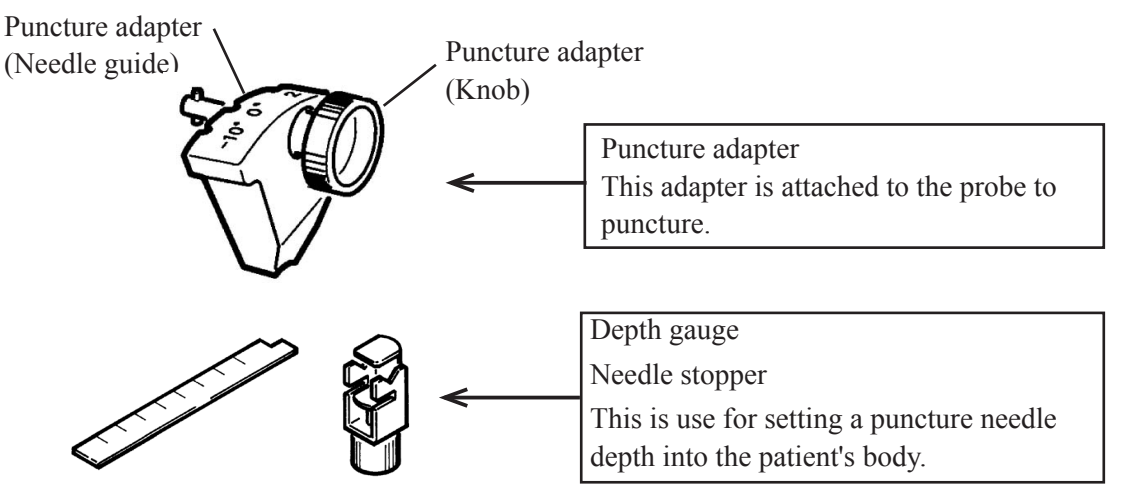
Remarks
The dimensions are within ±10% of the indicated values.

2-3. Performance

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

2-4. Names 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. This could make the probe unusable.

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 “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 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 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 4-6 “Connecting to the ultrasound diagnostic instrument" and check that the selected probe match the convex 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.

⚠ 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 is not in the abnormal conditions listed below.

- Abnormalities seen in visual such as deformation, cracking, abnormal gaps, damage, foreign matter adhering, clogged guide holes, severe discoloration.

3-2-2. Mechanical inspection

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

- The puncture adapter is firmly attached to the probe.

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 preparation

(1) Required items

Tub	(Depth of 20 cm or more)
Warm water	40°C (104°F)
Thermometer	
Probe	
Puncture adapter	MP-2480-G18 (standard configuration) or others (user's selection of the options)
Puncture needle	Size : 18G (standard configuration) or others (depend on user's selection) Length : 150 mm to 200 mm

(2) Setup 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 insert the puncture needle into the puncture adapter.
   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 (104°F) 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.

- Have to selected the guide line of the correct angle.
  The ultrasound diagnostic instrument have four different angled guide lines that is depend on the angle of the puncture adapter.

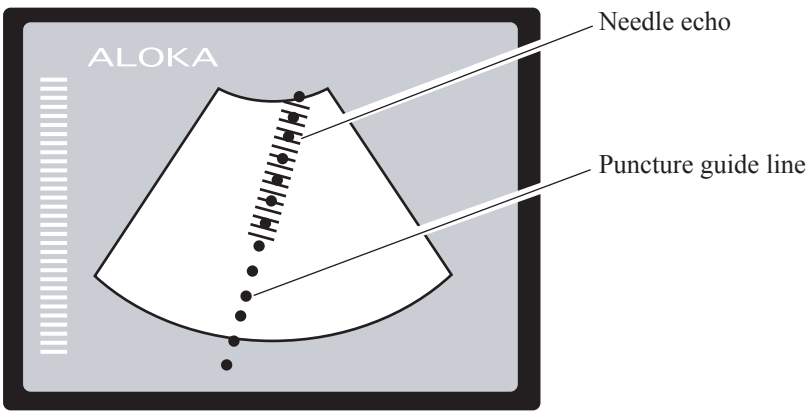
3-3-2. Checking the needle echo

(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



3-4. Performing washing and sterilization

(1) Before use, wash and sterilize the puncture adapter, the needle stopper and the depth gauge.
See section 5 "Washing, Disinfection and Sterilization"

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

⚠ Warning

The equipment must be washed and sterilized before use.
Be sure to always properly wash and sterilize after use.
Failure to do so could result in an infection. Note that the equipment is not sterilized when shipped from the factory. Before using the equipment for the first time, be sure to wash and sterilize it as required.

4. Usage

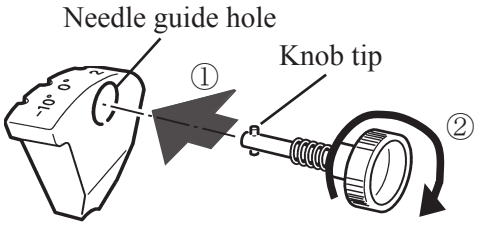
4-1. Operation

Bring the ultrasonic irradiation area of the probe to contact with the skin surface. 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.

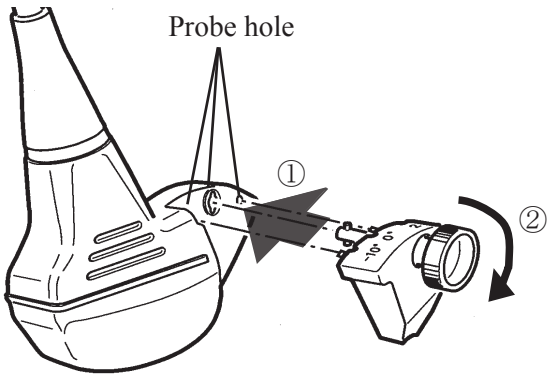
⚠ Caution	
⊘	Do not move the probe with excessive force. Pressing with more force than necessary can cause injury to the patient.
❗	Scan for the minimum length of time necessary for the diagnosis and at the lowest suitable output. There is the possibility that the patient's internal tissues could be 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.

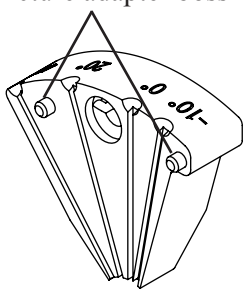
4-2. Attaching of the puncture adapter

(1) The knob tip is passed through the needle guide hole.
Then attach the knob to the needle guide by turning the knob clockwise by six rotations or more.



(2) The puncture adapter boss and the knob tip is inserted in the probe hole.
Then attach the puncture adapter to the probe by turning the knob clockwise until stopping while pushing the knob.





4-3. Usage of 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.

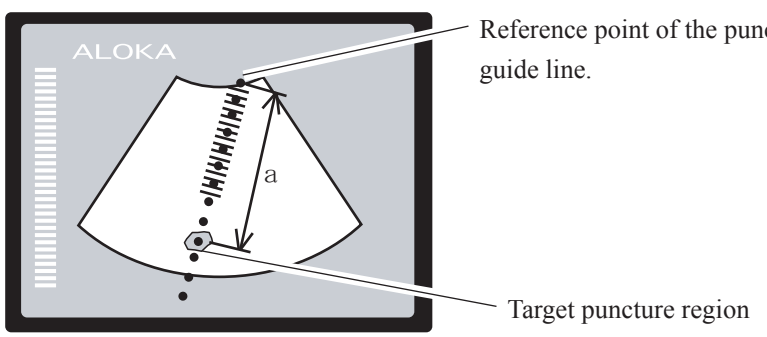
(1) Display the puncture guide line on the monitor screen.

(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.

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.

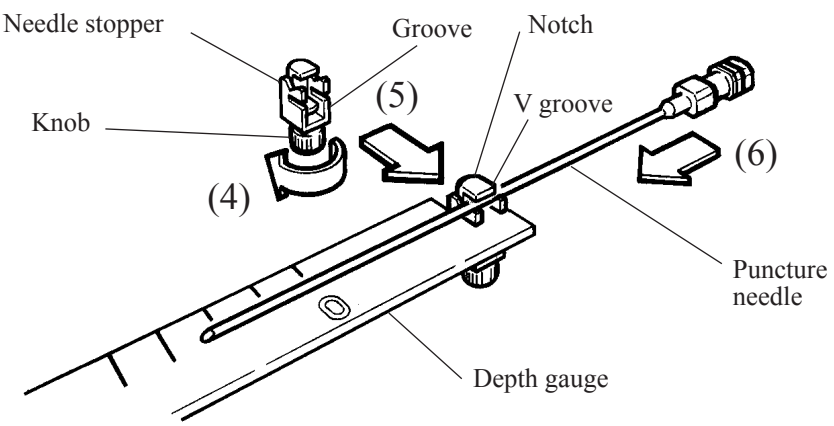
Image on the monitor screen



(4) Loosen the knob of the needle stopper.

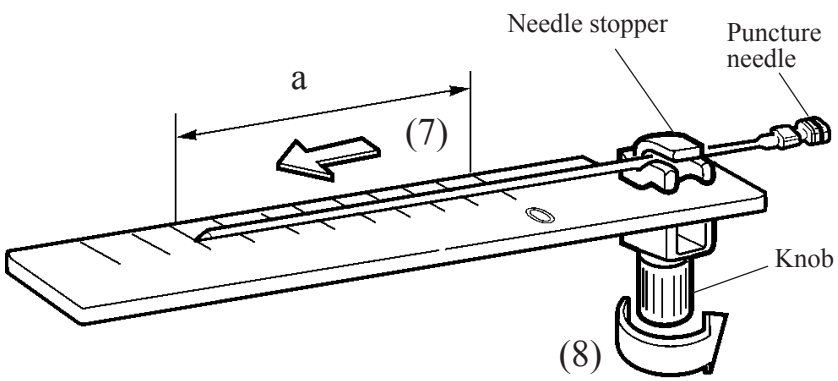
(5) Install the needle stopper on the depth gauge.
The groove of the needle stopper must attach to the notch of the depth gauge.

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

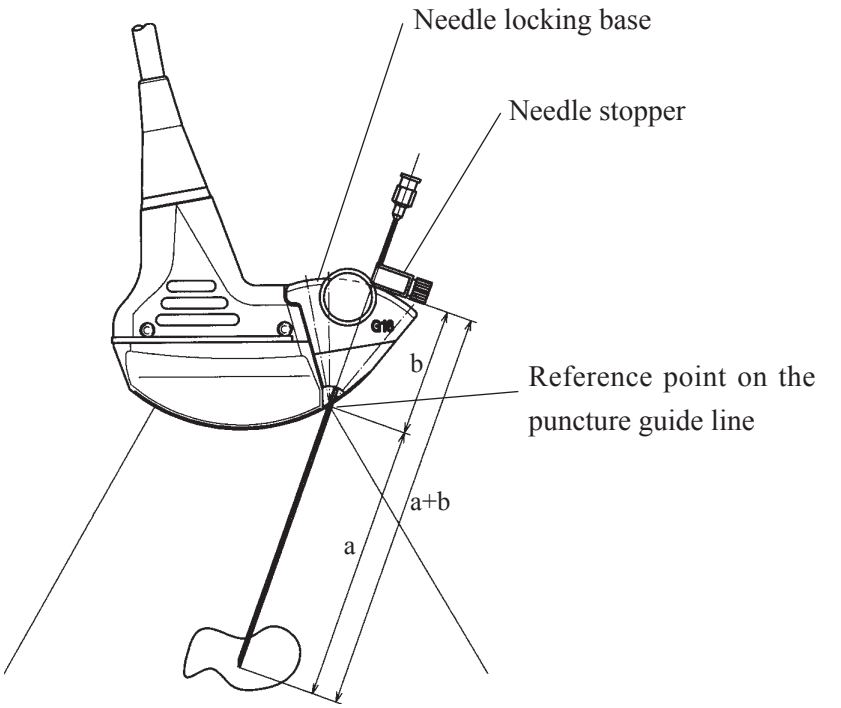


(7) Move the tip of the puncture needle to the scale position corresponding to the distance "*a*" measured in step (3) above.

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



(9) Insert the puncturing needle until the needle stopper contacts the needle locking base.
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*″

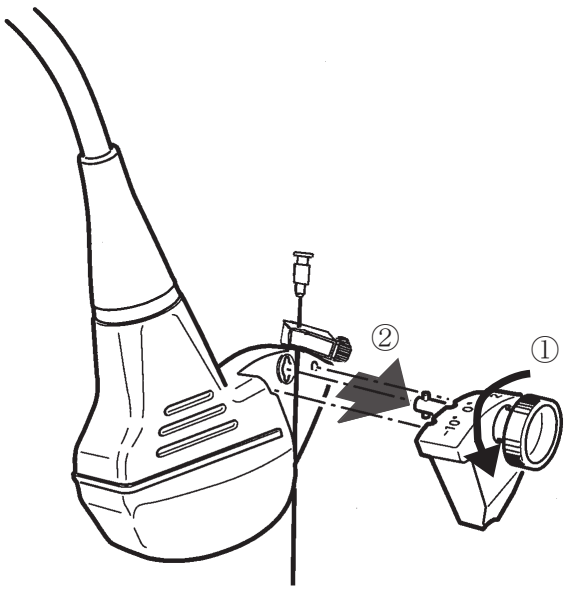
Distance "*a*″ : Distance from the reference point on the puncture guide line to the target puncture region.
* The 0 index line on the depth gauge corresponds to the reference point of the puncture guide line.

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.

4-4. Leaving the needle

The probe and the puncture adapter can be removed from the puncture needle during puncturing.

(1) Turn the knob counter clockwise until stopping, and remove the puncture adapter from the probe.

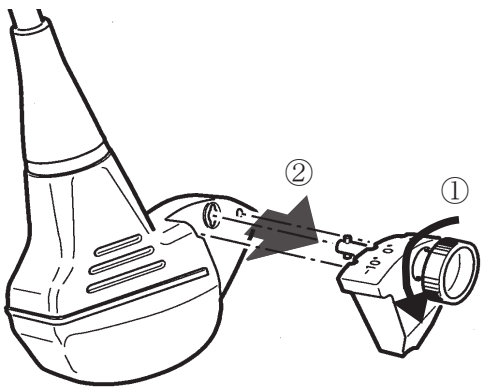


(2) Take the probe off the needle.

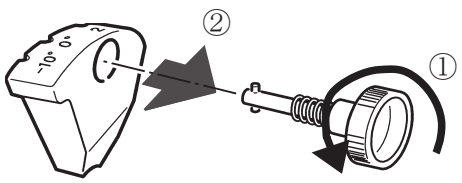
4-5. Removal of the puncture adapter

Remove the puncture adapter using the reverse procedure to that described in section 4-2 "Attaching of the puncture adapter".

(1) Turn the knob counter clockwise until stopping, and remove the puncture adapter from the probe.



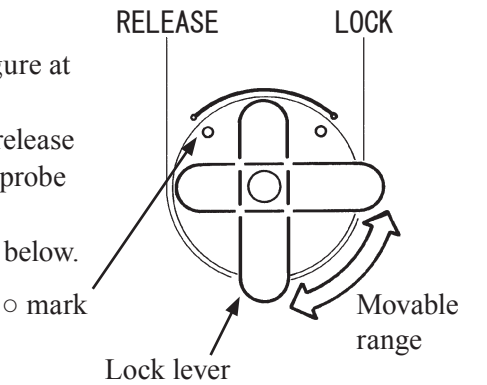
(2) Turn the knob counter clockwise.
Then remove the knob from the needle guide by pulling out the knob tip from the needle guide hole.



(3) Immediately wash and sterilize the puncture adapter (the needle guide and the knob), the needle stopper and the depth gauge after it is removed from the probe.

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.

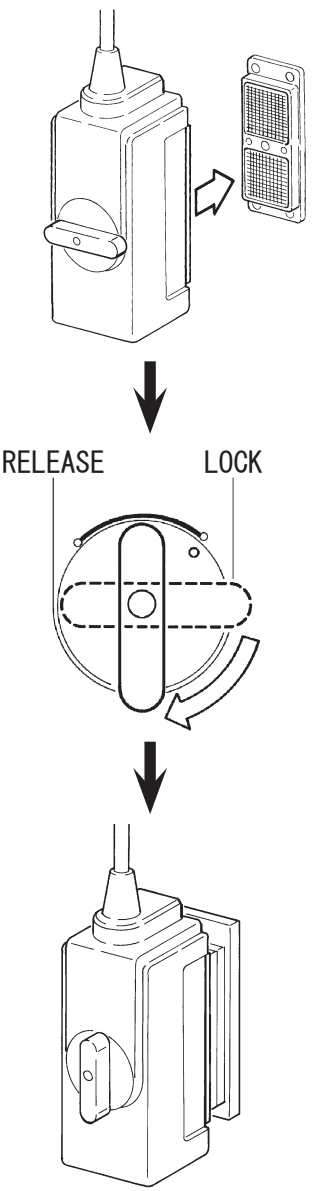
1. Turn the connector lock lever to align the ○ mark on the lever with the RELEASE position.

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.

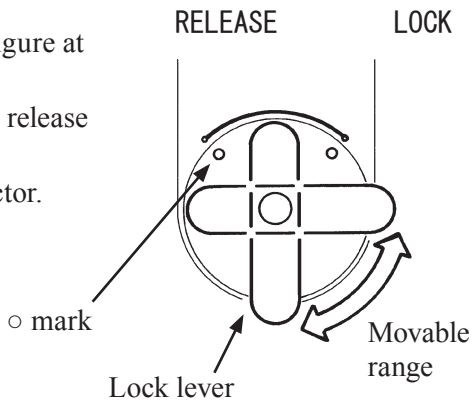


⚠ Caution

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.



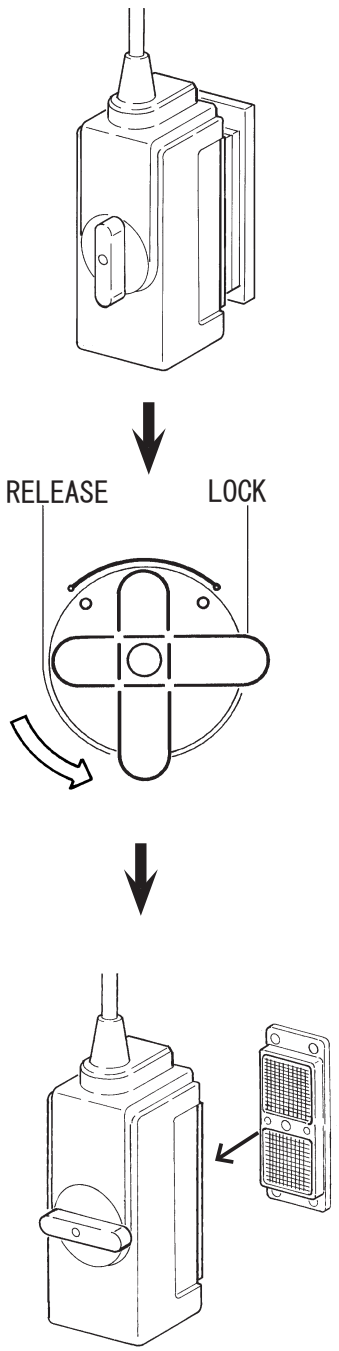
- Removal procedure

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 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".

4-8. Precautions when performing puncture operations

⚠ Warning
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 equipment must be washed and sterilized before use. Be sure to always properly wash and sterilize 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 wash and sterilize it as required.
When puncturing, be sure to wear sterilized medical gloves. Puncturing with the bare hands can expose the operator or patient to a risk of infection.
The puncture adapter is used by attaching to the probe and following the instructions in this manual. Attaching improperly to the probe or performing puncture operations without attaching to the probe can result in the puncture adapter coming off during surgery or puncturing an unintended body part. For details on the attachment procedure, see section 4-2 "Attaching of the puncture adapter".
For the acoustic medium, use sterilized physiological saline solution. Using an unsterilized acoustic 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 puncture adapter. Using when the gauge sizes of the puncture needle and puncture adapter do not match can result in puncturing of an unintended body part. Also, even if the gauge size is the same, the diameters may vary between different puncture needle manufacturers and products. For puncture needles diameters can be used for the puncture adapter, see section 2-2-2 "Specifications of the puncture adapter".
Use sterilized puncture needles. Otherwise, an infection can occur.
Do not use needles were bent. Puncturing of an unintended body part causing an injury to the patient.
Be careful when handling the puncture needle. Accidentally puncturing your hand or other body part can result in infection of the operator or 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 an injury to the patient. Display the puncture guide line on the screen referring to the instruction manual supplied with the ultrasound diagnostic instrument, 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.

⚠ Warning
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 deviate from 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 "Washing, Disinfection and Sterilization" section 3-1 "Start up check" and section 3-2 "Checking the needle echo".
When inserting an RFA(Radio Frequency Ablation) needle, do not insert while bending the needle. 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 with the puncture adapter as a guide, 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. If the cannula does not move smoothly or is forced to bend when inserted in or pulled out of the puncture adapter, it may damage the insulation membrane covering the cannula and may cause burns to the tissue exposed to the damaged area of the cannula.

⚠ Caution
Handle the needle carefully to ensure that the probe, the puncture adapter, the needle stopper and the depth gauge are not damaged. Using the probe, the puncture adapter, the needle stopper and the depth gauge 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. When using the puncture needle made of the stainless steel, if the patient has a metal allergy of stainless steel, the puncture needle may be hazardous for patient as an allergic risk.

⚠ Note
Before carrying out 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. Actions to be taken when an abnormal state is detected

4-9-1. 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.

4-9-2. 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.

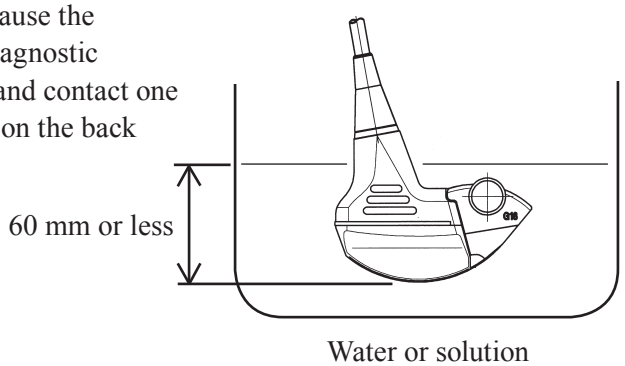
5. Washing, Disinfection and Sterilization

⚠ Warning

- Wear protective gloves and other protective gear during washing, disinfection and sterilization. Handling of the equipment with your bare hands before disinfection or 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 chemical disinfection and sterilization, thoroughly wash the equipment 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 equipment or reduced performance. The equipment 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 equipment.

⚠ Caution

- Do not place the probe tip in any liquids beyond the range shown in the figure right. The connector which liquid has intruded can cause the malfunction of the probe and the ultrasound diagnostic instrument. In this case immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.



5-1. Washing

Wash the probe tip, the puncture adapter, the needle stopper and the depth gauge immediately after use with water or soak in a cleaning agent.
Washing before disinfection and sterilization is very important.

○: Compatible methods

	Probe	Puncture adapter (Needle guide)	Puncture adapter (Knob)	Needle stopper	Depth gauge
Enzyme cleaning agent	○	○	○	○	○

5-1-1. Probe tip and accessories

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

Water rinsing - - - - - - - - - - - Rinse the probe tip, the puncture adapter, the needle stopper and the depth gauge with running water.
Wash off blood, mucus and other substances adhering to the equipment using a sponge or gauze.

or

Soaking in cleaning agent - - - - - - - - - - - Minimize the soaking time.

↓

Water rinsing - - - - - - - - - - - Sufficiently rinse the equipment using running water to remove all traces of chemicals.

⚠ Warning

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.

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

Perform following disinfection as necessary.

○: Compatible methods

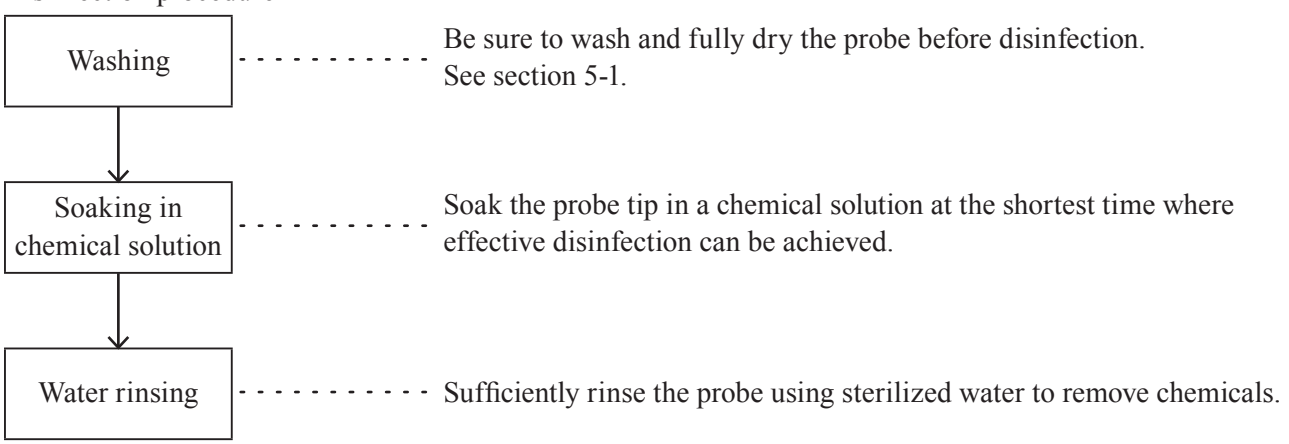
	Probe	Puncture adapter (Needle guide)	Puncture adapter (Knob)	Needle stopper	Depth gauge
Liquid disinfection	○	Perform sterilization the puncture adapter or other equipment.			
Gas disinfection	○				

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 probe tip in CIDEX OPA™ solution 0.55% may result in discoloration of the silicone, but this does not affect performance or safety.

⚠ Warning

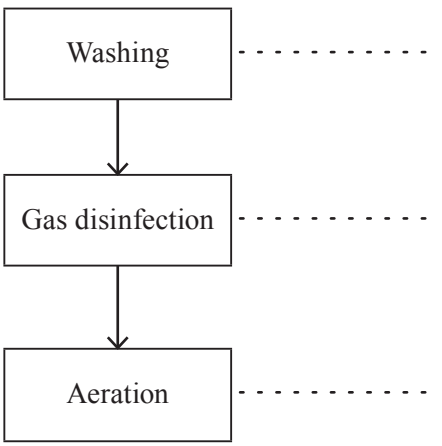
After chemical disinfection, thoroughly wash the probe with sterilized water.
Residual chemicals can cause an adverse reaction on the bodies of the operator or patient.

5-2-2. Gas disinfection

Applicable gases

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

Disinfection procedure



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

Disinfection the following conditions:

Temperature:	Room temperature
Humidity:	Normal humidity
Atmospheric pressure:	Normal pressure

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

5-3. Sterilization

Perform following sterilization as necessary.

○: Compatible methods

	Probe	Puncture adapter (Needle guide)	Puncture adapter (Knob)	Needle stopper	Depth gauge
EOG sterilization	○	○	○	○	○
Liquid sterilization	○	○	Not compatible	Not compatible	Not compatible

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

Washing

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

↓

EOG sterilization

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

↓

Aeration

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. 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 equipment before sterilization. See section 5-1.
↓	
Soaking in chemical solution	Soak the equipment in a chemical solution at the shortest time where effective sterilization can be achieved.
↓	
Washing with water	Sufficiently rinse the equipment using sterilized water to remove chemicals.

⚠ Warning

After chemical sterilization, thoroughly wash the equipment 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

When the probe 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.
Wash and sterilize the puncture adapter, the needle stopper and the depth gauge 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 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. 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, Aloka trained service personnel can conduct a test at the user's expense. Contact one of our offices and/or distributor's offices listed 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 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 judgment

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.
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-9113P-3.5	1 set
Puncture adapter	MP-2480-G18	1 set
Needle stopper	MP-2477	1 piece
Depth gauge	MP-2480-DG	1 piece
Storage case	CB-UST-1-P2	1 set
Instruction manual	MN1-1014	1 copy

9-2. Option

Puncture adapter

The following puncture adapter is available to match the various-sized needle.

11G (MP-2480-G11)
12G (MP-2480-G12)
13G (MP-2480-G13)
14G (MP-2480-G14)
15G (MP-2480-G15)
16G (MP-2480-G16)
17G (MP-2480-G17)
19G (MP-2480-G19)
20G (MP-2480-G20)
21G (MP-2480-G21)
22G (MP-2480-G22)

10. Disposal of the Device

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

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

Waste Electrical and Electronic Equipment (WEEE) Directive

This products is a duty of the display of WEEE marking is imposed, into the European Union (EU).
In case you dispose this product in the EU member nation, please contact any of the offices or agencies, should follow the law of each country or your local legislation.

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