HITACHI
Inspire the Next

S31KP Probe
Instruction Manual
Specification

MN1-5831 Rev.5

Notes for operators and responsible maintenance personnel

★ *Please read through this Instruction Manual as well as the separate Instruction Manual "Safety (MN1-5986)" and "Cleaning, Disinfection and Sterilization (MN1-6000)" 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 the instruction manual for S31KP probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be mainly used for observation of human internal organs during surgery.
Prior to use, read this manual as well as the separate instruction manual "Safety" in which information for safe use is provided.

The probe bears the CE mark but the mark is valid only when the probe is connected to the ultrasound diagnostic instrument bearing the CE mark.

Symbols used in this document

Safety information is classified into Danger ,Warning Caution, and Note according to the level of hazard. Those terms are used in the safety information provided to prevent hazards and injuries to the operator or patients.

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

CONTENTS

This instruction manual contains 5 pages of front matter and 22 pages of the main content.

1. General Information

General information for the probe is provided below.

1-1. Intended use

This probe is intended for use by a doctor when placed in direct contact with human internal organs during surgery for ultrasonic observation.

This probe can also be used for neurosurgery application if our specified transducer cover is mounted on the probe. Please note that this probe is not allowed to be used for neurosurgery application in Japan. Regarding the precautions for neurosurgery applications, please refer to the section 4-7.

Please refer to the ultrasound diagnostic instrument instruction manual used with this probe for the probe intended use information.

Regarding with the connectable instrument, please refer to section 2-1. Specifications of this manual.

⚠ Warning

Do not use this equipment for other than its intended use.
Otherwise it could cause burns or other injuries to the patient or operator.

1-2. Classification of ME equipment

This probe is classified as follows according to IEC60601-1.

Please refer to the section 2-1 for the range of applied part, the parts treated as applied part, and the range of IPX7.

- Classification based on the 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..... Refer to the separate “Instruction Manual Cleaning, Disinfection and Sterilization”

1-3. Standard components

The standard components of S31KP probe are as follows.

Probe	S31KP	1 set
Puncture adapter	MP-2450-MB	1 set
Needle stopper	MP-2477	1 set
Depth gause	MP-2450-DG	1 piece
Storage tray	MP-2698	1 set
Adjustment hexagon screwdriver		1 piece
Storage case		1 set
Instruction manual		
• Specification	MN1-5831	1 copy
• Safety	MN1-5986	1 copy
• Cleaning, Disinfection and Sterilization	MN1-6000	1 copy

1-4. Option

The following options are available for this probe.

- Reprocessing by liquid detergent, disinfectant or sterilant

  Whole the probe is able to immerge into the liquids by putting the connector of the ultrasound probe to the waterproof case WP-001 as below table.

  Precautions about the waterproof case, please refer to the instruction manual.

Accessory for reprocessing by liquid detergent, disinfectant or sterilant

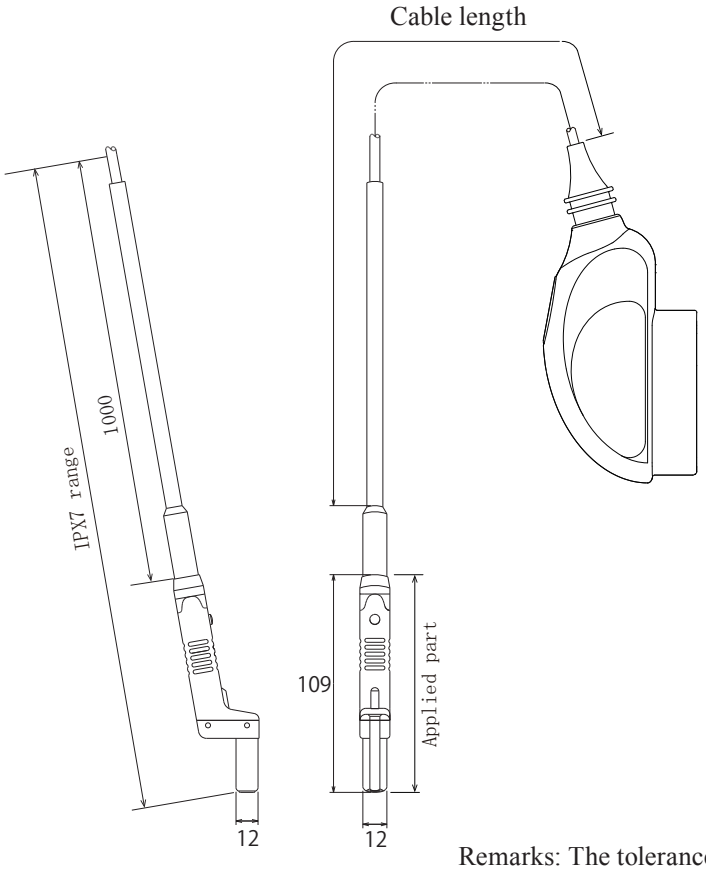
Product Name	Product No.
Waterproof case	WP-001

2. Specifications and Parts name

2-1. Specifications

2-1-1. Specifications of the probe

Application regions:	Intraoperative diagnosis Neurosurgery application, see 4-7 for precautions
Type of patient contact:	Intraoperative Neurosurgical, see 4-7 for precautions
Connectable instruments:	ARIETTA 70, ARIETTA 60, Noblus, ARIETTA Precision NOTE: At the time of publication of this manual, the connectable diagnostic ultrasound instrument or instrument software version available with this probe is different for each country, please refer to the instrument instruction manual or contact your local Hitachi representative.
Field of view:	90°
Frequency:	5.0 MHz
Cable length:	2.5 m
Service life:	3 years
Applied part:	Probe tip including ultrasonic radiation part, see the section 2-2
Parts treated as applied parts:	Cable up to 0.2 m length from the probe tip
IPX7 range:	See Figure 1 (In case that not putting the waterproof case to the ultrasound probe connector) In case that putting the waterproof case to the ultrasound probe connector, whole the probe from the tip of the ultrasound probe to the connector with Waterproof Case WP-001 is IPX7. range
Tolerance:	Refer to the instruction manual of the ultrasound diagnostic instrument
External dimensions:	See Figure 1

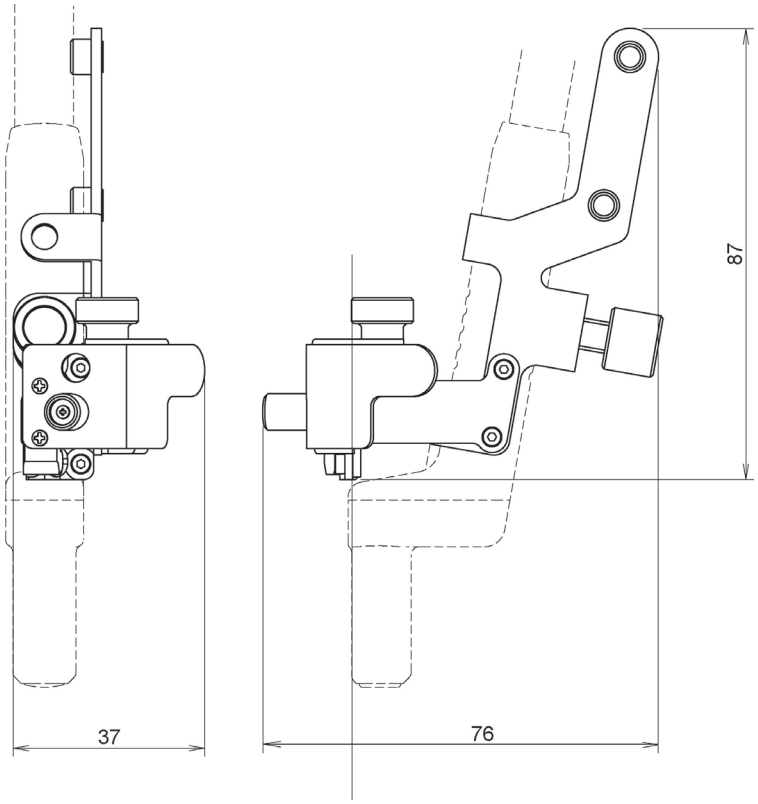


Remarks: The tolerance for the dimensions is ±10%.

Figure 1 External View

2-1-2. 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	3 years
External dimensions	As shown in the figure below.



Remarks

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

Figure 2 External View of the puncture adapter

2-1-3.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 Systems representative.

2-2. Name of each parts

(1) Probe

The name of each parts is shown in Figure 3 and explanation for each parts is listed in Table 1.

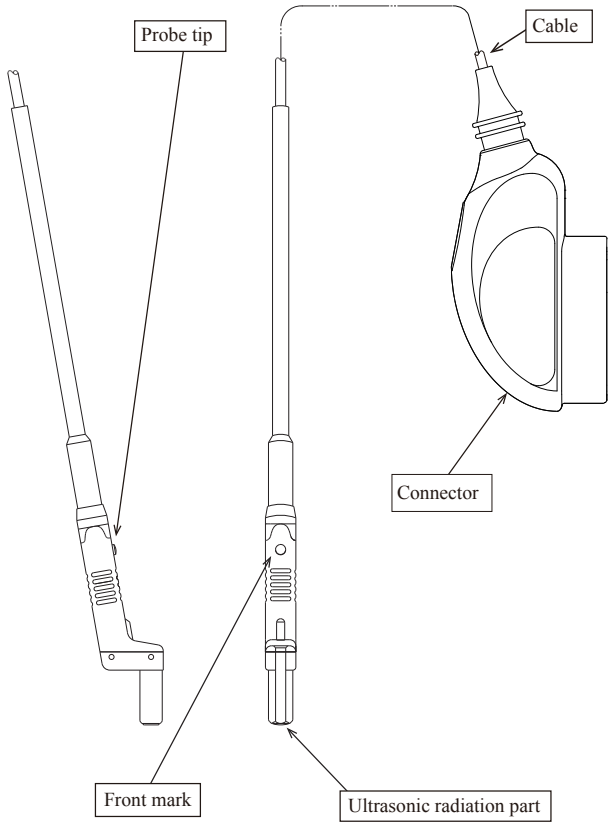


Figure 3 Name of each parts

Table 1 Name of each parts and explanation

Name	Explanation
Ultrasound radiation part	Electronic convex transducer is integrated.
Front mark	A small round protrusion indicates the front direction on the display. This mark also helps attach the puncture adapter.
Probe tip	This is the grip of the probe.
Cable	Ultrasonic signal is transferred through the cable.
Connector	The connector is the part which is connected to the ultrasound diagnostic instrument.

⚠ Caution
Do not pull, bend, twist, or apply excessive force to the cable. The probe may malfunction due to cable disconnection.
Do not subject the ultrasonic radiation part to hard impact. The impact may cause damage to the transducer, and that results in noise or no echo in the image. In most cases, the ultrasonic radiation part itself is not damaged because the part is made of elastic material.

(2) Puncture adapter

The name of each parts is shown in Figure 4 and explanation for each parts is listed in Table 2.

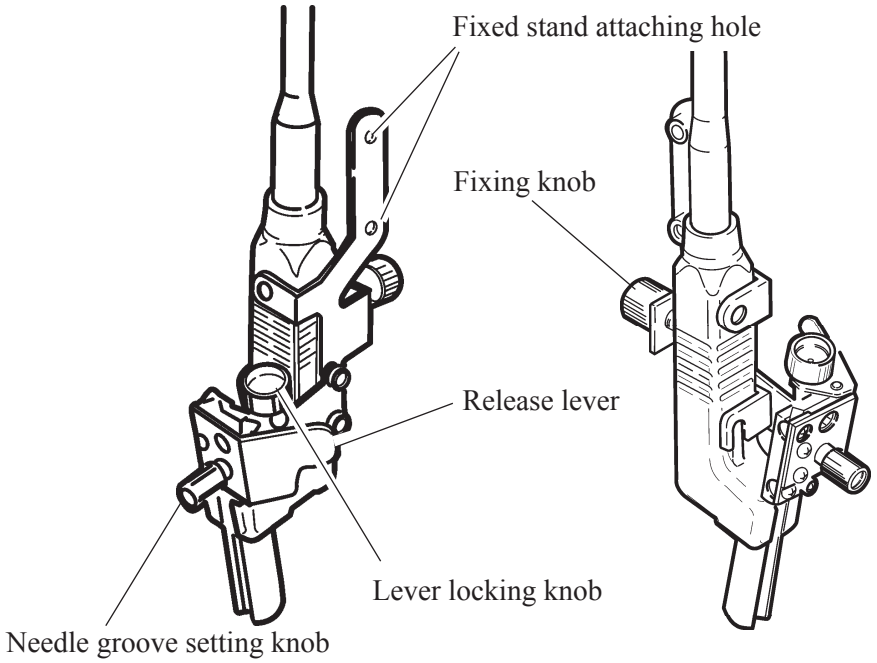


Figure 4 Name of each parts of puncture adapter

Table 2 Name of each parts and explanation of puncture adapter

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

3. Preparations before use

This chapter describes preparations needed to use the probe safely. Please prepare the probe and the puncture adapter prior to each use by following the instructions below.

3-1.Start up check of the probe

3-1-1. Visual check

Visually check the probe tip, ultrasonic radiation part, cable, and connector.

If any holes, indentations, abrasion, cracks, deformation, looseness, discoloration, or other abnormalities are found, do not use the probe.

Check also the options as necessary.

3-1-2. Confirmation of cleaning and sterilization

Confirm that the probe is certainly cleaned and sterilized. The degree of reprocessing depends on the intended use. Please refer to the separate Instruction Manual “Cleaning, Disinfection and Sterilization“ for cleaning and sterilization procedure.

3-1-3. Operation check

Connect the probe to the ultrasound diagnostic instrument and check that the displayed scan type and frequency correspond to those of the probe. Check also that there is no abnormality in the image.

Remark:Please refer to the documentation supplied with the ultrasound diagnostic instrument for how to connect the probe and information displayed on the monitor.

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

Make preparations prior to each use.
The operator and the patient may be injured if the equipment has any abnormality.
If any abnormality is found in the equipment, stop using it and contact our office written on the back cover.

⚠ Caution

Do not use the probe if the displayed scan type and frequency do not correspond to those of the probe.
Incorrect acoustic output can result in burns or other injuries to the patient. Contact our office written on the back cover.

3-2. Start up check of the puncture adapter

3-2-1. Visual check

Check the punctute 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.

Remark: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 4-2 “Attaching of the puncture adapter” 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 guideline on the monitor screen.

Remarks:For details of the puncture guideline, 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 guideline 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.

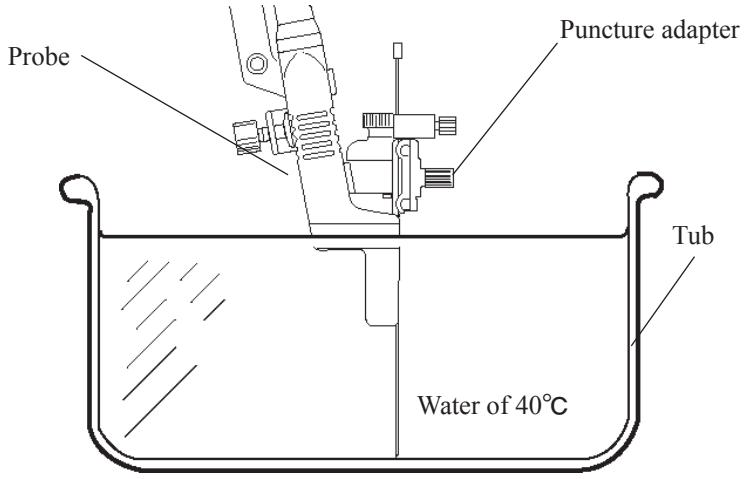


Figure 5 Checking needle echo 1

(2) Check the following points.

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

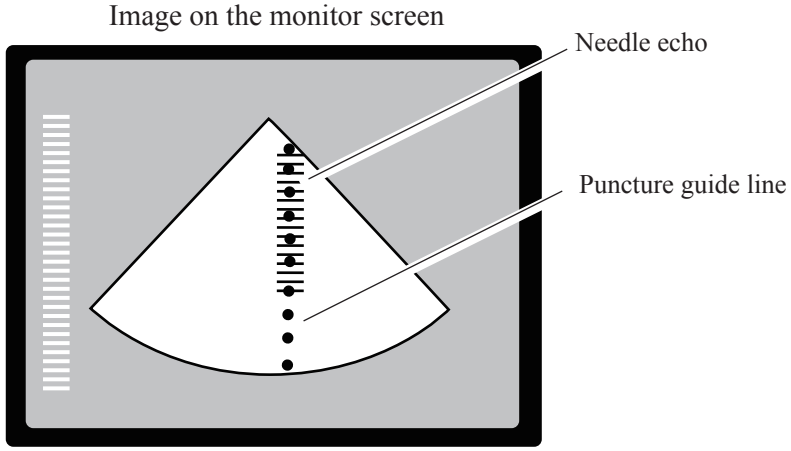


Figure 6 Checking needle echo 2

(3) If the needle echo does not match the puncture guideline 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 guideline.

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

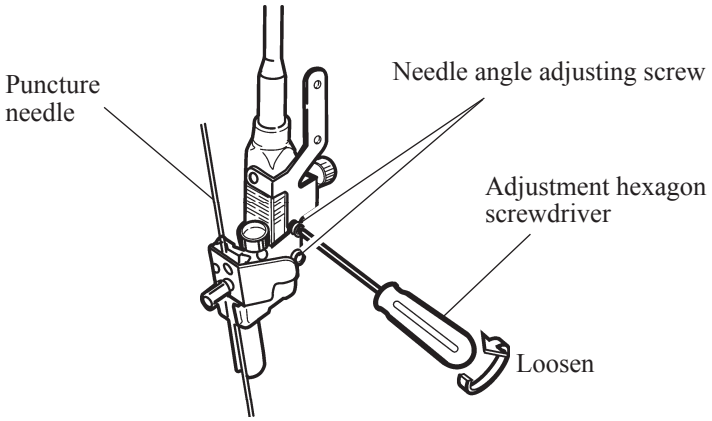


Figure 7 Adjustment of needle angle

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.

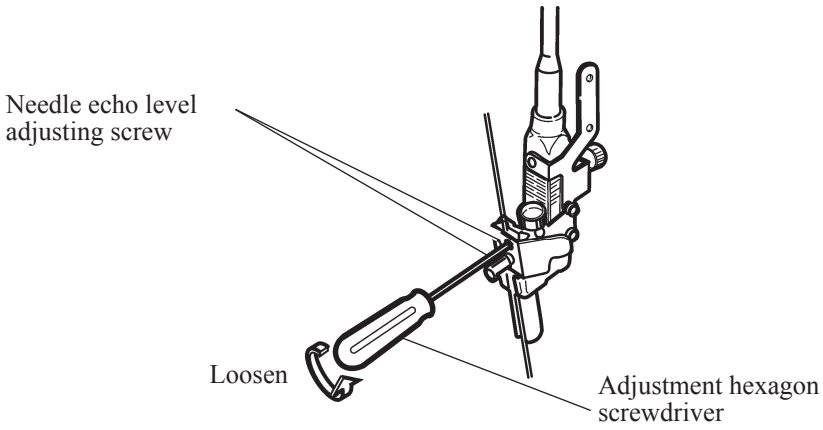


Figure 8 Adjustment of needle echo level

3-5. Performing washing and sterilization

(1) Before use, wash and sterilize the puncture adapter, the needle stopper and the depth gauge.

Please refer to the instruction manual of the puncture adapter.

(2) Wash and 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. Otherwise, an infection can occur. 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.

4. Operation

This chapter describes the operation of the probe, how to attach/release puncture adapter and how to mount/remove the transducer cover for neurosurgery application.

4-1. Operation

Place the ultrasonic radiation part of the probe onto the inner organ surface during surgery. 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 operate the probe with excessive force. Use with excessive force could result in injury to the patient.
Scan for minimum time necessary at the lowest possible acoustic output. Acoustic output may affect the patient's internal tissues. 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. Electrostatic discharge may result in malfunction of the probe.
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) 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.

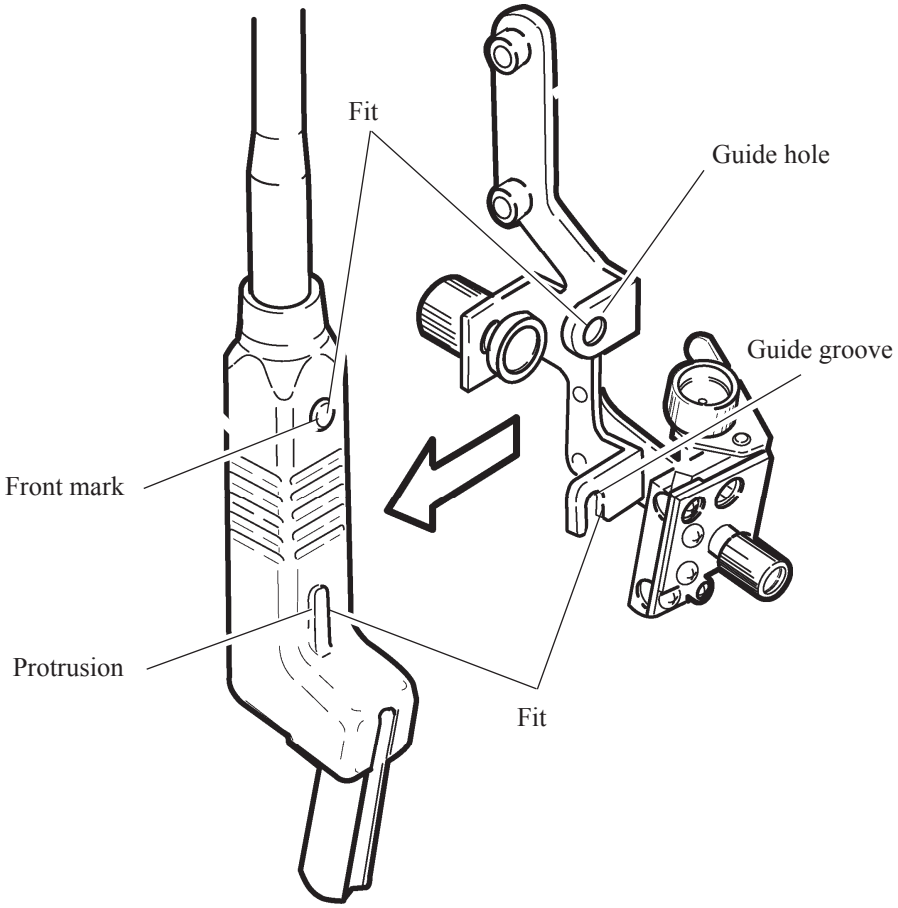


Figure 9 Attachment and fixture of puncture adapter 1

(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.

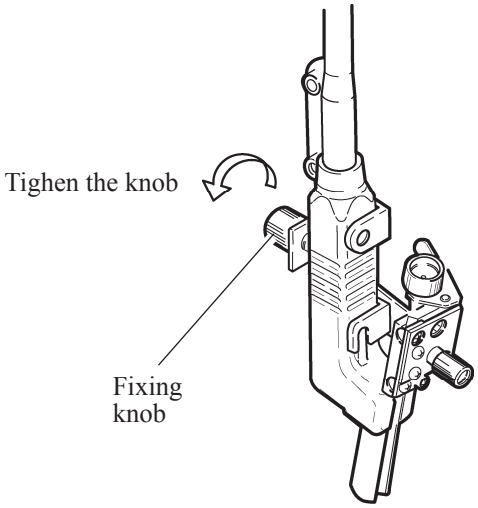


Figure 10 Attachment and fixture of puncture adapter 2

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 guideline on the monitor screen.

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

(3) Measure the distance "*a*" from the reference point of the puncture guideline 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 guideline and calipers, see the instruction manual of the ultrasound diagnostic instrument.

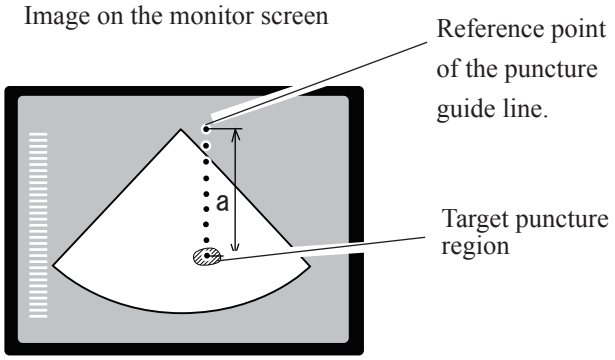


Figure 11 Measurement of insertion distance

(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.

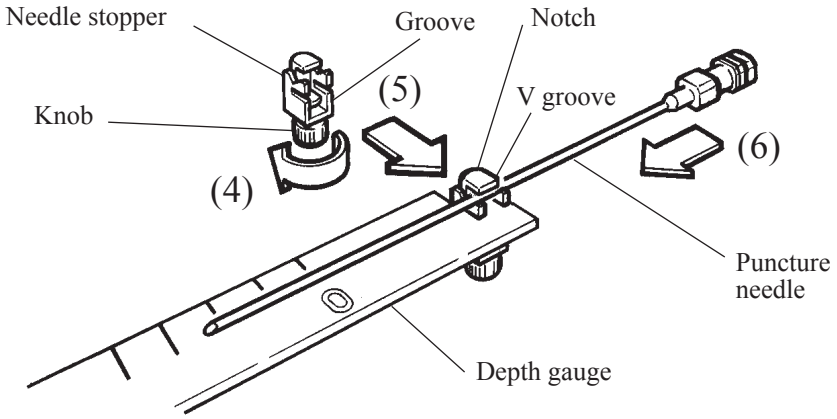


Figure 12 Attaching the needle stopper and puncturing needle

(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.

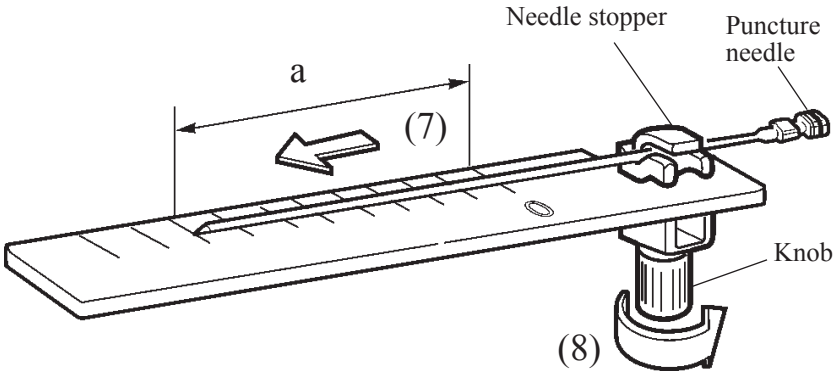


Figure 13 Locking the needle stopper

(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.

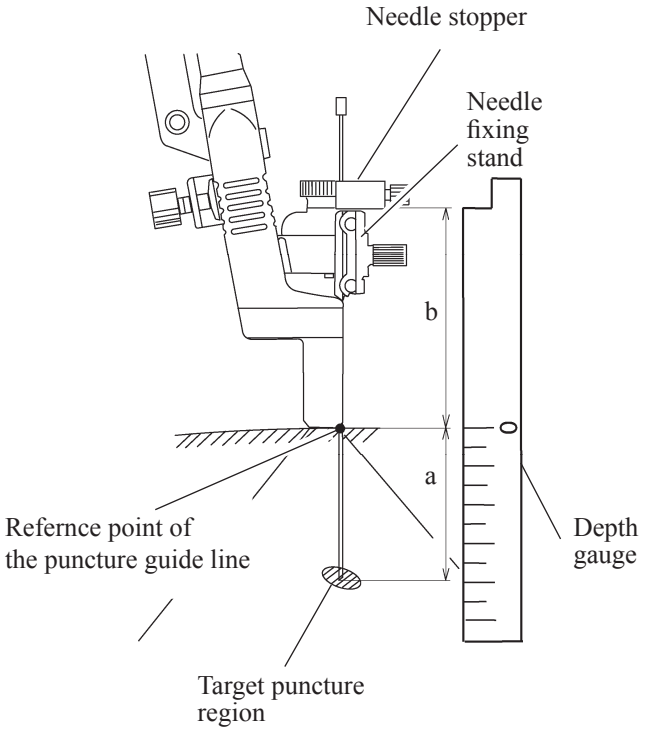


Figure 14 Inserted condition

—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 guideline to the target puncture region.

* The 0 index line on the depth gauge corresponds to the reference point of the puncture guideline.

Distance "*b*": Distance from the end of the needle locking base on the puncture adapter to the reference point on the puncture guideline.

* 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 wash and sterilize the puncture adapter after it is removed from the probe.

4-6. When using the probe for neurosurgery applications

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

4-6-1. 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.

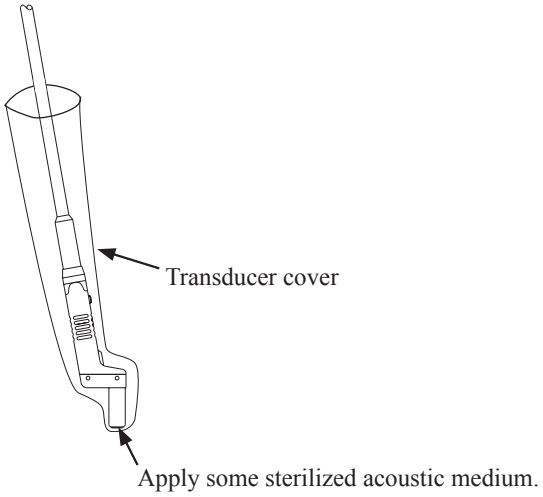


Figure 15 How to attach the transducer cover

4-6-2. How to remove the transducer cover

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

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

4-6-3. Puncture

(1) Adjusting the size of the needle groove according to Section 4-3, and attaching the transducer cover according to Section 4-6-1, attach the puncture adapter.

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

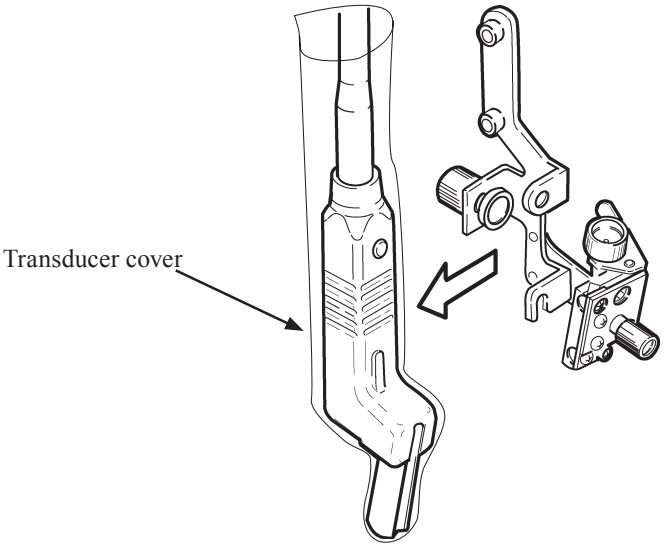
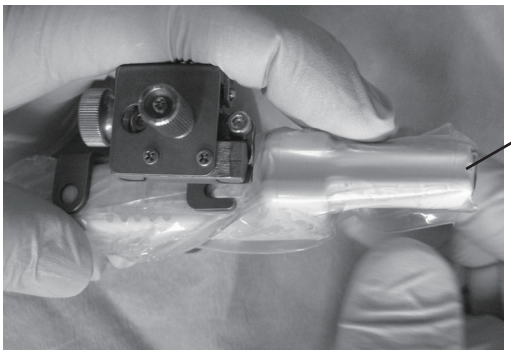


Figure 16 Attach the puncture adapter 1

(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.



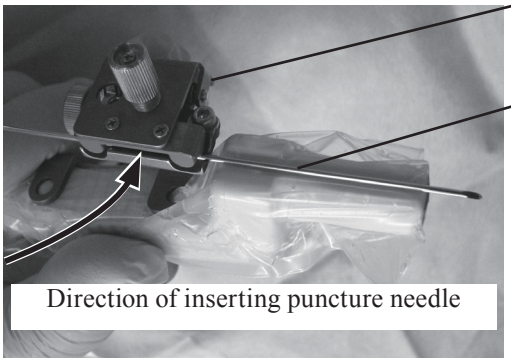


Figure 17 Attach the puncture adapter 2

(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.

4-6-4. Remove the puncture adapter

In the reverse way of Section 4-2 Attaching of the puncture adapter.

Wash the puncture adapter immediately and disinfect it properly.

4-7. Precautions when using the probe in neurosurgery applications

⚠ Warning	
❗	When using this probe in neurosurgery applications, attach a transducer cover over the top of the probe properly. You can use the probe in neurosurgery applications if you 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. 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. 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. 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. 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. 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 4-6-3 “Puncture”.
❗	Properly use the transducer cover and puncture needle according to this instruction. 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. 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. 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. If you use excessive force, it may cause probe damage or scattering of contaminated material.
⃠	Do not reuse the transducer cover. If you reuse the transducer cover, it may cause patient infection.

⚠ Caution	
❗	When disposing of the transducer cover, take appropriate measures for prevention of infection. If you dispose of it improperly, it may cause environment damage.

■Manufacturer

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

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