

C41RP Probe
Instruction Manual
Specification
MN1-5827 Rev. 6

Notes for operators and responsible maintenance personnel

- ★ *Please read through this Instruction Manual as well as the separate Instruction Manual “Safety (MN1-5990)” and “Cleaning, Disinfection and Sterilization (MN1-6161)” carefully prior to use.*
- ★ *Keep this Instruction Manual together with the ultrasound diagnostic instrument for any future reference.*



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Introduction

This is the instruction manual for C41RP probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be mainly used as a transrectal probe for observation of prostate and surrounding organs respectively. It can also be used for puncture under the condition that the optional puncture adapter is attached to it. 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 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.

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This instruction manual contains 4 pages of front matter and 16 pages of the main content.

1. General Information



General information for the probe is provided below.

1-1. Intended use

This probe is intended to be used by a doctor or other qualified operator for ultrasonic observations of the prostate and surrounding organs. It can also be used for ultrasound-guided puncture.

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 part 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 C41RP probe are as follows.

- C41RP Probe 1 set
- Puncture guide tube MP-2452-G18(for 18G needles) 2
- Washing brush(M) L-ki-266 2
- Storage tray MP-2724 1 set
- Storage case 1 set
- Instruction Manual
 - Specification (MN1-5827) 1 copy
 - Safety (MN1-5990) 1 copy
 - Cleaning, Disinfection and Sterilization (MN1-6161) 1 copy

1-4. Options

The following options are available for C41RP probe.

- Puncture

Please use one of the options listed in Table 1 for performing a puncture. Please refer to the section 4-4 for how to attach Puncture guide tube.

Table 1 Options for puncture

Product Name	Product No.	Remark
Puncture guide tube	MP-2452-G21	Applicable needle size: 21G
Puncture guide tube	MP-2452-G16	Applicable needle size: 16G
Puncture guide tube	MP-2452-G14	Applicable needle size: 14G

- Wash brush

Please use the options listed in Table 2 for performing wash for MP-2452-G14.

Table 2 Options for wash brush

Product Name	Product No.
Wash brush (L)	L-ki-265

- Probe cover

Please use the option listed in Table 3 for probe cover. Please refer to the section 4-2 and 4-3 for hoe to attach/release probe cover.

Table 3 Option for probe cover

Product Name	Product No.
Rubber boot	RB-665P-NS

- 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 box WP-001 as below table 4.

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

Table 4 Accessory for reprocessing by liquid detergent, disinfectant or sterilant

Product Name	Product No.
Waterproof box	WP-001

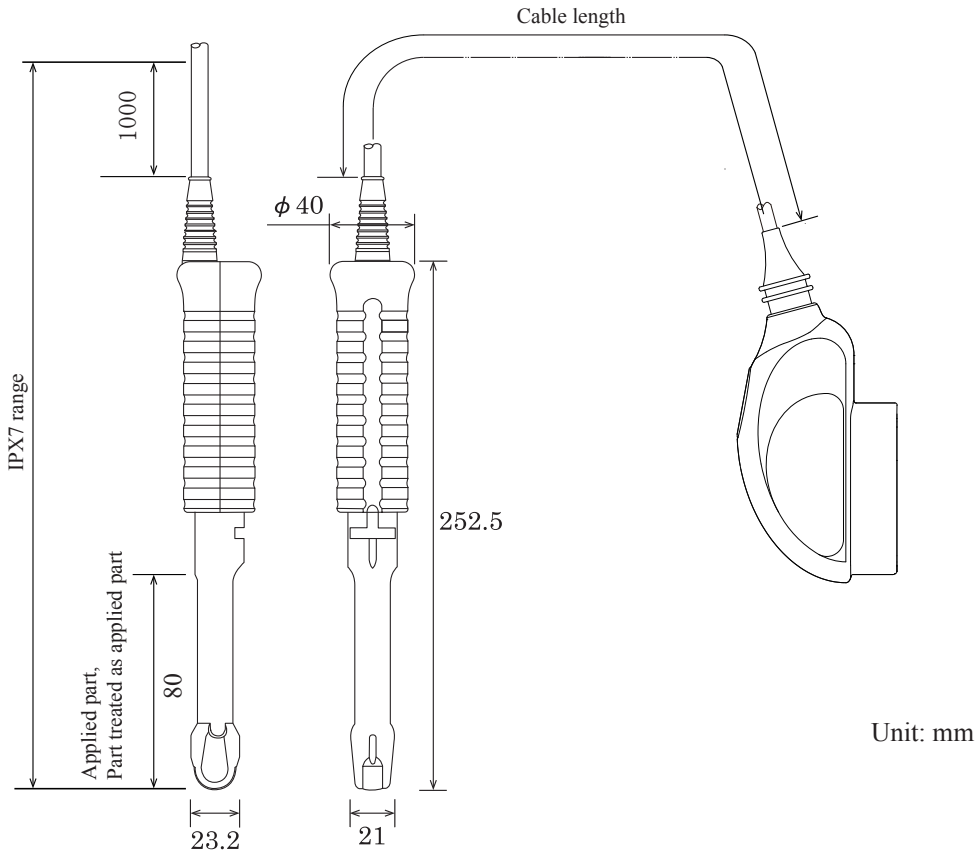
2. Specifications and Parts name

The specifications and the name of each part are provided below.

2-1. Specifications

2-1-1. Specification of the probe

- Application: Urological applications
- Type of patient contact: Transrectum
- Connectable instruments: ARIETTA 70, ARIETTA 60
- 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: 180°
- Frequency: 6.0 MHz
- Cable length: 2.5 m
- Service life: 3 years
- Applied part: See Figure 1
- Part treated as applied part: See Figure 1
- IPX7 range: See Figure 1 (In case that not putting the waterproof box to the ultrasound probe connector)
In case that putting the waterproof box to the ultrasound probe connector, whole the probe from the tip of the ultrasound probe to the connector with Waterproof Box WP-001 is IPX7. range
- Measurement accuracy: Refer to the instruction manual of the ultrasound diagnostic instrument
- External dimensions: See Figure 1

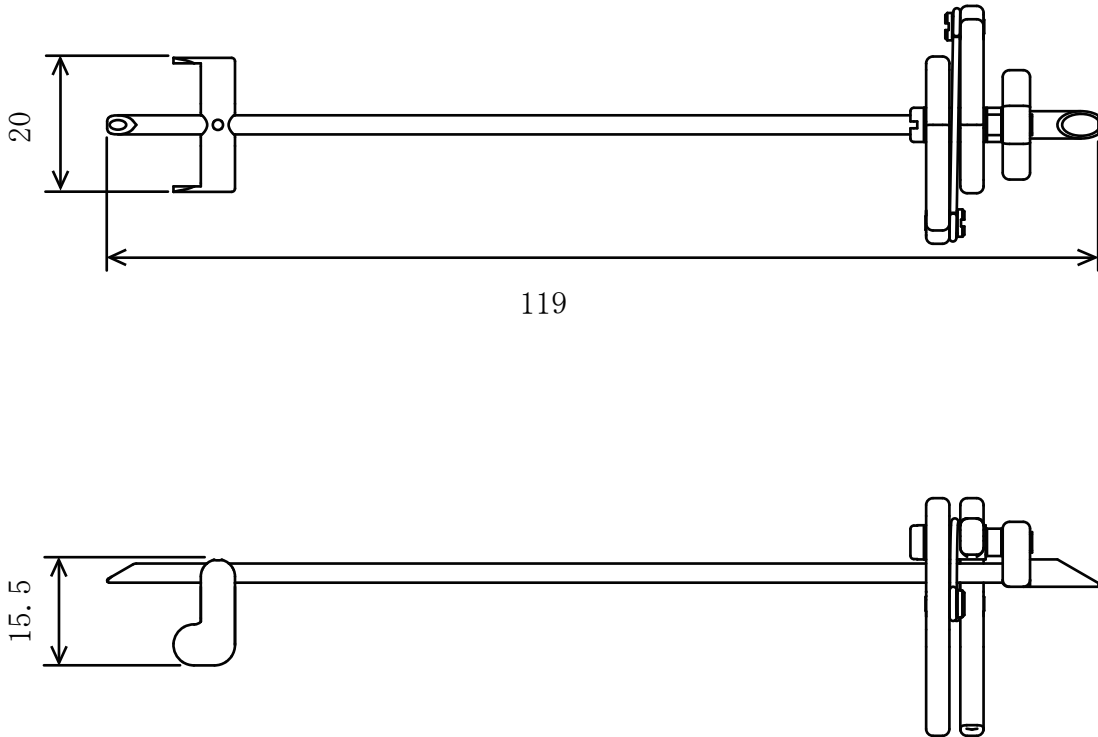


Remark: The tolerance for the dimensions is ±10%.

Figure 1 External View

2-1-2. Specification of the puncture guide tube

Material:	Stainless steel
Usable puncture needle size and diameter:	18G (1.26±0.02mm)
Service life:	3 years
External dimensions:	See Figure 2



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

Figure 2 External View of puncture guide tube

2-2. Name of each parts

The name of each part is shown in Figure 3 and the explanation for each part is listed in Table 4.

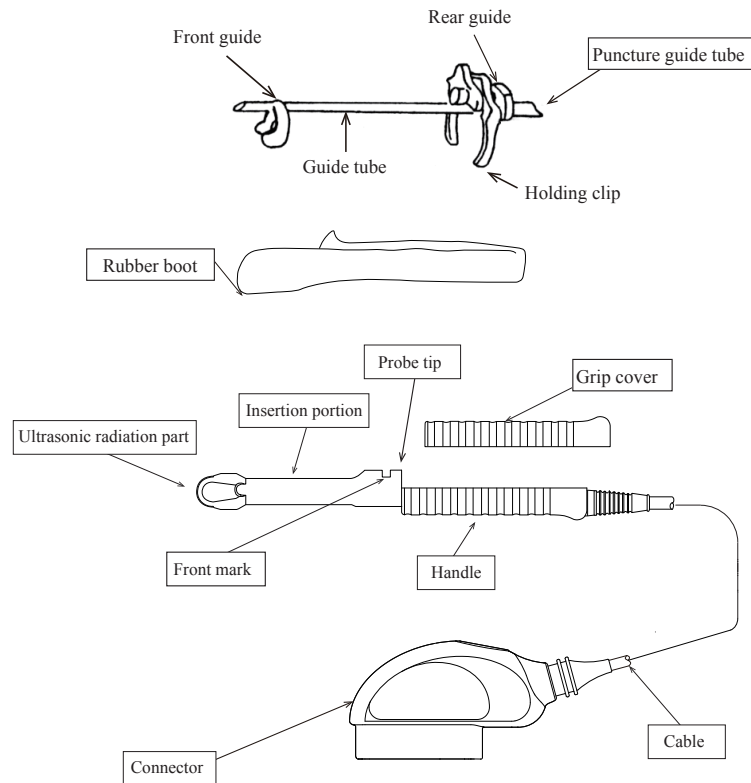


Figure 3 Name of each parts

Table 4 Name of each part and its explanation

Name	Explanation
Ultrasonic radiation part	Ultrasound is radiated from this part. The electronic convex transducer is integrated underneath this part.
Front mark	The dimple corresponds to the side of the orientation mark on the image.
Probe tip	The probe tip is the part includes both the insertion portion and the handle.
Handle	This part is held during operation.
Insertion portion	This part is inserted into the patient.
Grip cover	Please do slide on the cable side and detach it when you do puncturing.
Cable	Cable transfers electric input/output signals.
Connector	The connector is the part which is connected to the ultrasound diagnostic instrument.
Puncture guide tube	This tube is attached to the probe to help insert the probe needle. Attach it as per the instructions in section 4-4.
Rubber boot	Cover the insertion portion with this rubber boot to prevent infection. Follow the instructions in section 4-2.

 **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.

3. Preparations before use

This chapter describes preparations needed to use the probe safely. Please prepare the probe and the puncture guide tube 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 ultrasonic radiation part, insertion portion, handle, cable, and the 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, disinfection, and sterilization



Confirm that the probe is certainly cleaned, disinfected, and sterilized. The degree of reprocessing depends on the intended use. Please refer to the separate instruction manual “Cleaning, Disinfection and Sterilization“ for cleaning, disinfection, 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 guide tube

3-2-1. Visual check

Make sure the puncture guide tube is not in the abnormal condition listed below.

- Abnormalities seen in visual such as deformation, cracking, abnormal gaps, damage, foreign matter adhering, clogged induction tube, severe discoloration.
- The holding clip can not close until the end.
- Loose screws which fix the holding clip.
- A spring of the holding clip is damaged.

3-2-2. Mechanical inspection

Check that the puncture guide tube mechanism while attached to the probe.

- The screws have no looseness, backlash, immobility, or other abnormalities.
- The puncture guide tube is firmly attached to the probe.
- There are no tears in the rubber boot.

3-2-3. Mounting of rubber boot

Cover the probe insertion portion with the rubber boot to prevent infection and then attach the puncture guide tube over this.

3-2-4. 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	
Puncture guide tube	MP-2452-G18 (standard configuration) or others (user’s selection of the options)
Puncture needle	Size: 18G (standard configuration) or others (depend on a user’s selection) Length: up to 250 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 guide tube to the probe,
and insert the puncture needle into the puncture guide tube.
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 (104°F) 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.

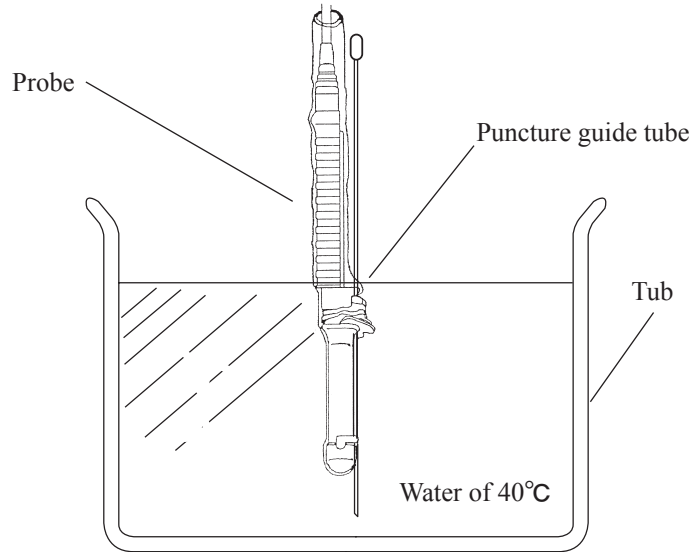


Figure 4 Checking the needle echo 1

- (2) Check the following points.

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

Images on the monitor

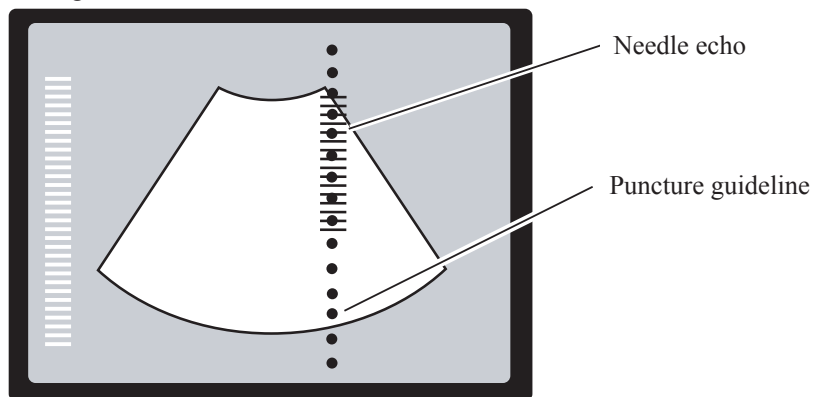


Figure 5 Checking the needle echo 2

3-4. Performing washing and sterilization

- (1) Before use, wash and sterilize the puncture guide tube.

Please refer to the instruction manual of the puncture guide tube.

- (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. Operation

This chapter describes the operation of the probe and how to attach the puncture guide tube.

4-1. Operation

Mount a probe cover on the probe and insert the probe into the rectal. An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. For details on displaying and adjusting the image, refer to 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 probe connector of the ultrasound diagnostic instrument and the patient at the same time. It can cause electric shock to the patient.

4-2. How to mount the rubber boot

Apply a suitable amount of ultrasound gel on the ultrasonic radiation part and then cover it with the rubber boot. Remove air bubbles or wrinkles on the ultrasonic radiation part.

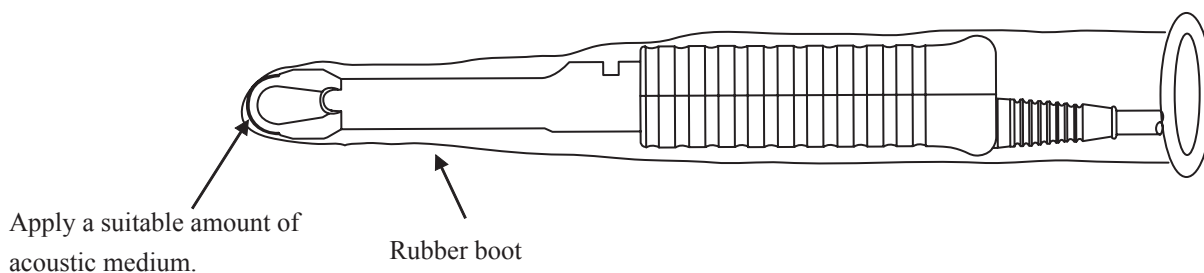


Figure 6 How to mount the rubber boot

⚠ Warning	
	Use by covering the rubber boot over the insertion portion.
!	If the rubber boot is not used, residual pathogens on the scanner could infect the patient. Also, the puncture guide tube could become loose during puncturing, resulting in puncturing of an unintended body part.
!	Use Hitachi-approved rubber boots only. Use of an item lacking biocompatibility can cause an adverse reaction by the body of the patient.
!	Check that the rubber boot is sterilized. Use of an infected item could spread infection to the patient.
⊘	Do not reuse the rubber boot. Use of an infected item could spread infection to the patient.
⊘	Do not apply unsterilized acoustic medium to the outer surface of the rubber boot. Use of an acoustic medium that is contaminated by a pathogen can cause an infection on the patient.
⊘	Do not use on patients who may have an allergic reaction to latex products. Use of the rubber boot for these types of patients could result in anaphylactic shock. Ask the patient about allergy history beforehand.

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

4-3. How to remove the rubber boot

- (1) Wrap the rubber boots in tissue paper and remove the rubber boots from the probe.
- (2) Dispose tissue paper and the rubber boots according to the infection prevention procedures of your facility.

<p>⚠ Caution</p> <p>! Before disposing of the equipment, disinfect or take other infection-prevention measures. Disposal of the equipment without taking the proper preventative measures can lead to infection.</p>
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4-4. Attaching of the puncture guide tube

4-4-1. Selecting the guide tube

Select a puncture guide tube that matches the size of the puncture needle that is used.

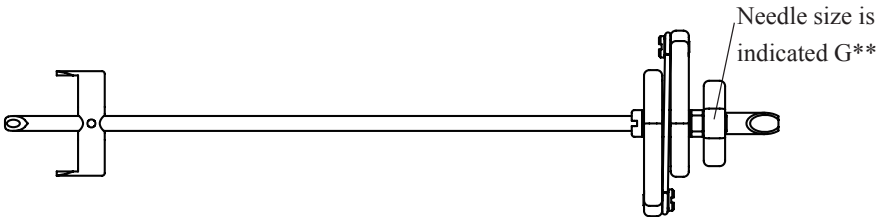


Figure 7 Selecting the guide tube

4-4-2. Attaching of the puncture guide tube

After covering the probe insertion portion with the rubber boot, use the procedure below to attach the puncture guide tube onto the probe.

- (1) When grips on the top of the puncture guide tube holding clip are squeezed from both sides, the holding clip opens.

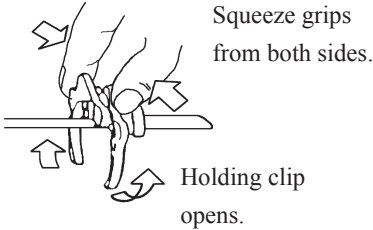


Figure 8 Attaching of the puncture guide tube 1

- (2) Open the holding clip, and insert the hooks of the front guide into the grooves on both sides of the probe tip as shown in figure below.

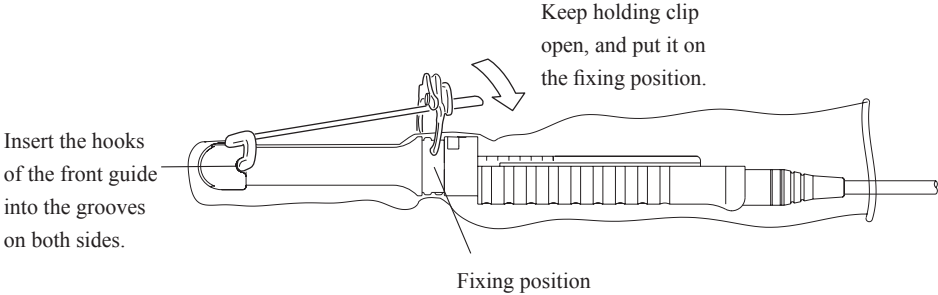


Figure 9 Attaching of the puncture guide tube 2

- (3) Put the holding clip on the fixing position.
- (4) When part marked “G**” is pushed, holding clip closes and fixes on the probe.

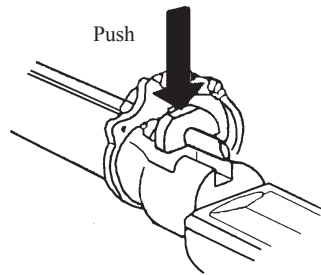


Figure 10 Attaching of the puncture guide tube 3

⚠ Caution

Carefully attach the puncture guide tube.



There is a risk of infection if the rubber boot is damaged. If the position of the puncture guide tube is misaligned, check the position of the puncture guide tube again without forcibly trying to attach it.

⚠ Note

Remove any air bubbles or wrinkles. Any air bubbles on the ultrasonic irradiation area of the probe or wrinkles in the rubber boot can result in reduced quality of the ultrasound image.

- 5) Move the rear guide and check that puncture guide tube is attached firmly on probe. Before inserting into the patient, check for air bubbles on the acoustic irradiation area again.

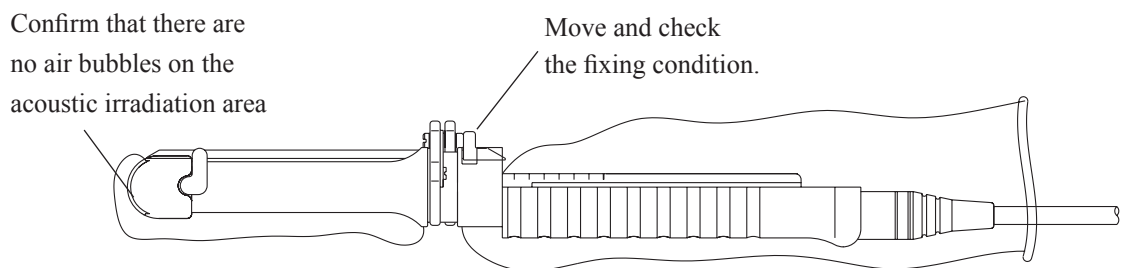


Figure 11 Attaching of the puncture guide tube 4

4-5. Removal of the puncture guide tube

- (1) When grips on the top of the puncture guide tube holding clip are squeezed from both sides, the holding clip opens.

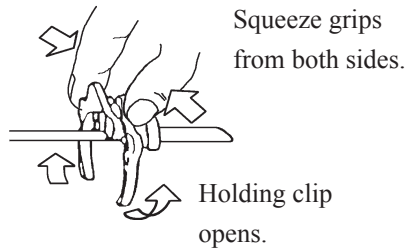


Figure 12 Removal of the puncture guide tube 1

- (2) Open holding clip and pull up the puncture guide tube as shown in figure below.

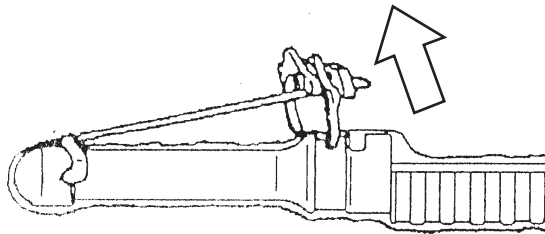


Figure 13 Removal of the puncture guide tube 2

- (3) Immediately wash and sterilize the puncture guide tube after it is removed from the probe.

⚠ Note

After use of the probe and puncture guide tube, immediately care of them.
 If the probe and puncture guide tube are left uncleaned for a long period of time after use, the adhered muci-
 lage and blood coagulate make difficult to care for them.

■ Manufacturer



Hitachi, Ltd.

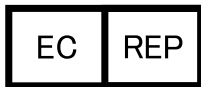
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