HITACHI
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C25P Probe
Instruction Manual
Specification

MN1-5821 Rev. 4

Notes for operators and responsible maintenance personnel

★ *Please read through this Instruction Manual as well as the separate Instruction Manual "Safety (MN1-5982)" and "Cleaning, Disinfection and Sterilization (MN1-5998)" carefully prior to use.*

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

CE 0123

Hitachi, Ltd.

Q1E-EP1473-4

Introduction

This is the instruction manual for C25P probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be mainly used for puncture of abdominal organs.
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 patient.

⚠ 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 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 doctors or other qualified operators. The probe is placed on the body for observation of surrounding organs and 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 applied part, the part treated as the 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 C25P probe are as follows.

C25P Probe ····· 1 set
Storage case ····· 1 set
Instruction Manual
- Specification (MN1-5821)····· 1 copy
- Safety (MN1-5982)····· 1 copy
- Cleaning, Disinfection and Sterilization (MN1-5998) ····· 1 copy

1-4. Options

The following options are available for C25P probe.

• Biopsy Attachment

Table 1 provides biopsy attachments needed for performing a puncture. The attachments listed are manufactured by Hitachi Medical Corporation and sold as the options of biopsy probe EUP-B715, but they are fully compatible with C25P probe.

EZU-PA7B1-C is the attachment for Cool-tip™(17G) or LeVeen™SuperSlim.

Since each biopsy attachment is disposable, dispose it after one use.

Table 1 Biopsy Attachment for puncture

Product Name	Gauge Size	Quantity
EZU-PA7B1-1	12 - 13 G	10 pcs/pack
EZU-PA7B1-2	14 - 16 G	10 pcs/pack
EZU-PA7B1-3	17 - 19 G	10 pcs/pack
EZU-PA7B1-4	20 - 23 G	10 pcs/pack
EZU-PA7B1-C	17 G	10 pcs/pack

• Real Time Virtual Sonography (RVS)

Please use the option listed in Table 2 for performing RVS. Regarding how to attach/release the attachment, please refer to the section 4.3.

Table 2 Option for RVS

Product Name	Product No.
Magnetic Position Sensor Attachment	RV-005

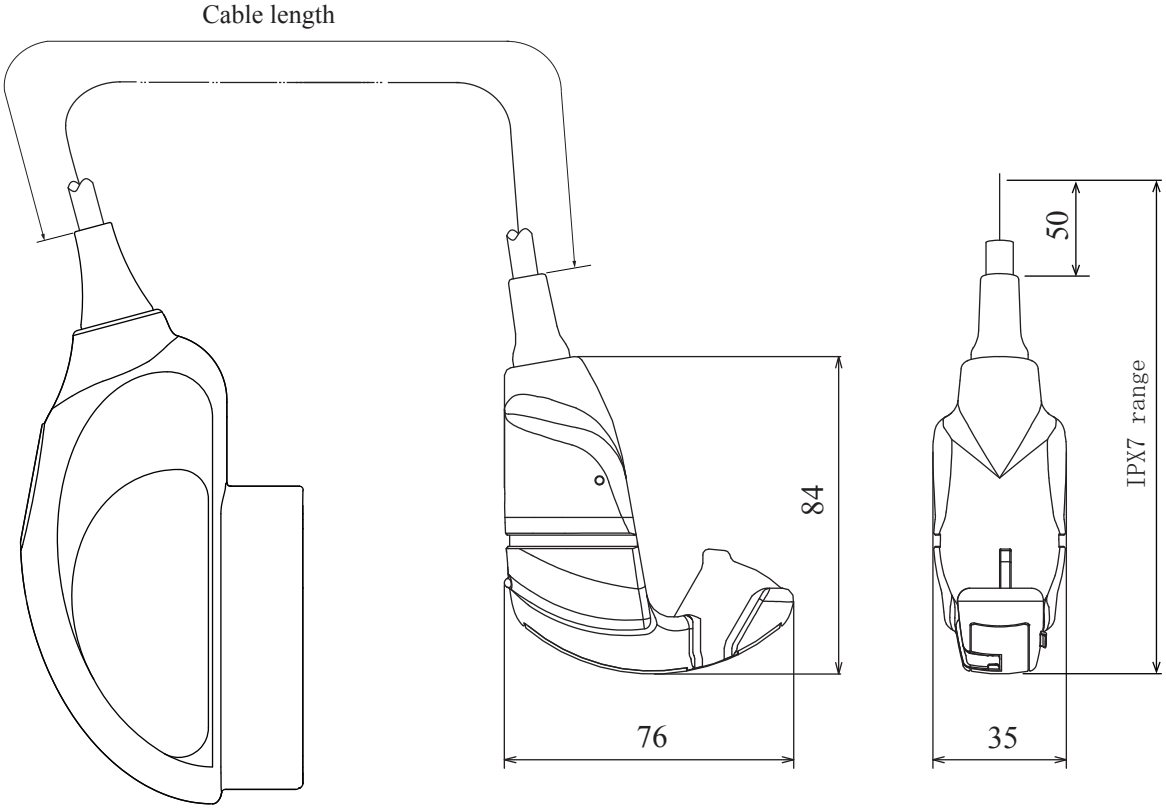
⚠ Warning	
❗	Use a needle which is applicable to the biopsy attachment. Use of the needle which is not applicable to the biopsy attachment can result in puncture at unintended parts and injury to the patient. Use EZU-PA7B1-C if Radio Frequency Ablation (RFA) is performed with either Cool-tip™(17G) or LeVeen™SuperSlim.
❗	Sterilize the biopsy attachment prior to use. The attachments listed in Table 1 are not sterilized, so they must be sterilized prior to use.
⃠	Do not reuse the biopsy attachment. The attachments listed in Table 1 are disposable. Dispose after one use.

2. Specifications and Parts name

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

2-1. Specifications

Application:	Abdomen
Type of patient contact:	Surface
Connectable instruments:	ARIETTA 70, ARIETTA 60, ARIETTA Precision, ARIETTA Prologue, ALOKA ARIETTA 850 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:	70°
Frequency:	3.0 MHz
Cable length:	2.2 m
Service life:	3 years
Applied part:	Probe tip including ultrasonic radiation part, see the section 2-2
Part treated as Applied part:	Cable up to 1 m length from the probe tip
IPX7 range:	See Figure 1
Measurement accuracy:	Refer to the instruction manual of the ultrasound diagnostic instrument
External dimensions:	See Figure 1



Unit: mm

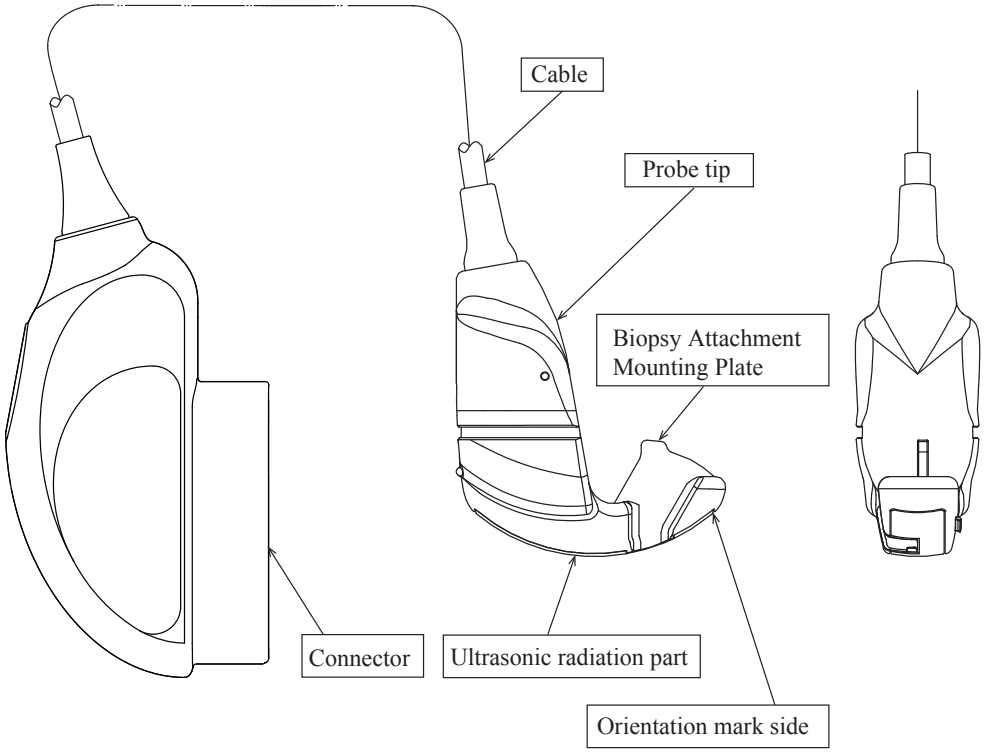
Remark: The tolerance for the dimensions is ±10%.

Figure 1 External View

2-2. Name of each parts

The name of each part is shown in Figure 2 and the explanation for each part is listed in Table 3.

・Probe



・Biopsy Attachment (Option)

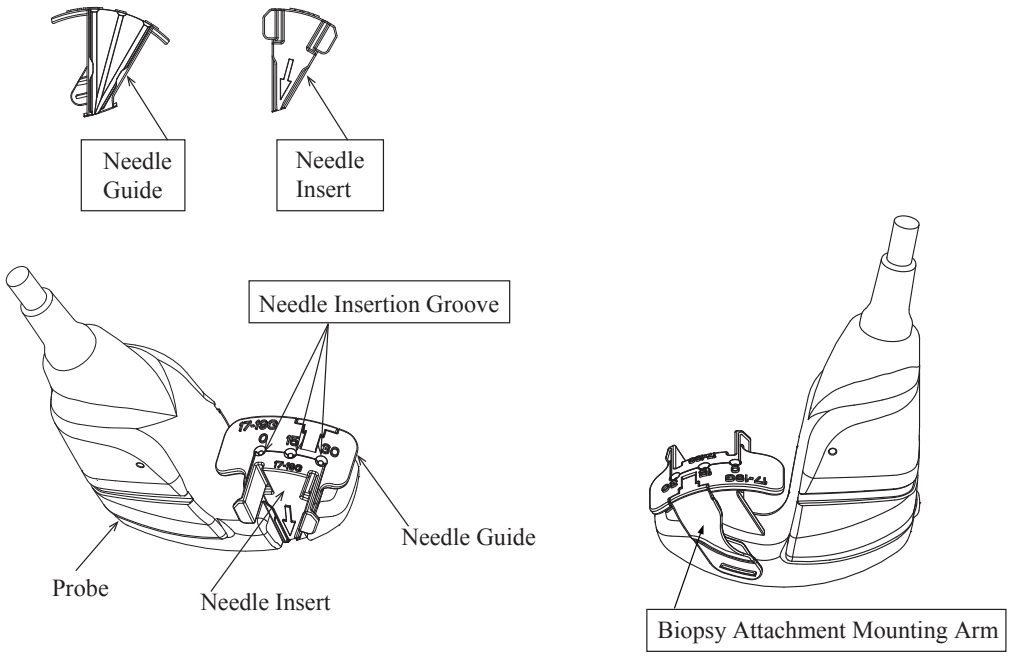


Figure 2 Name of each parts

Table 3 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.
Orientation mark side	The side of the orientation mark corresponds to the side of the orientation mark on the image.
Probe tip	This part is gripped during operation.
Cable	Cable transfers electric input/output signals.
Connector	The connector is the part which is connected to the ultrasound diagnostic instrument.
Needle Guide Needle Insert	The biopsy attachment is needed to be attached to the probe for performing a puncture. The attachment consists of the needle guide and the needle insert. The applicable needle size is marked on each parts. Refer to 4-1 for how to attach the biopsy attachment to the probe.
Needle Insertion Groove	A puncture needle is inserted into this part. The insertion angles are 0°, 15°, and 30°. The angles are marked on the needle guide.
Biopsy Attachment Mounting Arm	This part is used to fix the probe cover to the probe. Please refer to 4-1 for how to fix.
Biopsy Attachment Mounting Plate	This part is used to fix the biopsy attachment to the probe firmly.

⚠ 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 prior to each use by following the instructions below.

3-1. Preparation for 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, 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. Confirm also that options are properly cleaned, disinfected, and sterilized.

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.

3-1-4. Applicable probe cover

Prepare the following applicable probe cover.

Product name: Latex-Free CIV-Flex Covers

Manufacturer: Civco Medical Solutions

Product Number: 610-542

⚠ 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. Preparation for the biopsy attachment

3-2-1. Inspection for the biopsy Attachment

Visually inspect the biopsy attachment for any break, deformation, crack or denaturalization. If you find any damage, do not use them and contact our office written on the back cover.

3-2-2. Confirmation of the needle echo

Conduct the following procedure to confirm the needle echo before puncture. This confirmation should be done before the sterilization of the probe and biopsy attachment.

(1) Fill a tank with water at 40 degrees Celsius, and prepare a test needle for needle echo confirmation.
(2) Connect the probe to the ultrasound diagnostic instrument. Display the puncture guideline on the image. Refer to the documentation supplied with the ultrasound diagnostic instrument for how to display the puncture guideline.
(3) Attach the biopsy attachment to the probe according to 4-1. Insert the test needle into the needle insertion groove. Confirm that the needle can be smoothly inserted.
(4) Put the probe in sterile water so that needle echo is displayed.
(5) Confirm that the needle echo at each angle overlaps with the correspondent puncture guideline. Refer to the Figure 14 for the relationship between the puncture angle and the displayed puncture guideline.

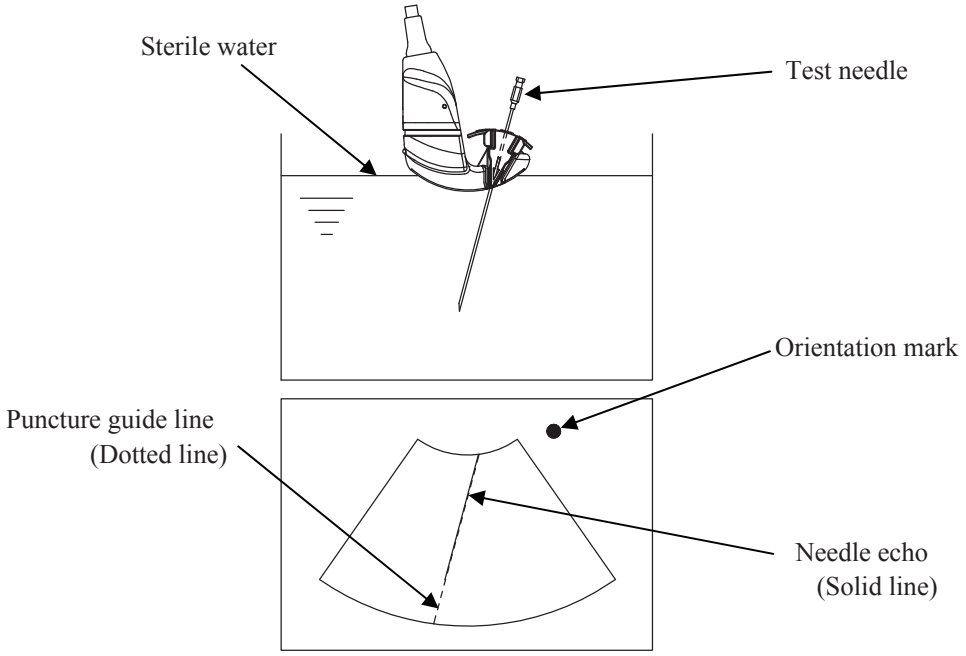


Figure 3 Confirmation of the needle echo

⚠ Caution

When a needle cannula for RFA is used, confirm that the needle cannula can be smoothly inserted to the biopsy attachment without any damage, and operate it carefully.

4. Operation

This chapter describes how to attach a probe cover and the biopsy attachment to the probe, the operation of the probe, and how to attach/release the magnetic position sensor and magnetic position sensor attachment.

4-1. How to attach a probe cover and the biopsy attachment

(1) Apply sterile ultrasound gel to the ultrasonic radiation part (Figure 4).

(2) Mount a probe cover on the probe tip, pull the cover to smooth a wrinkle, and remove air bubbles from the ultrasonic radiation part (Figure 5). Be careful not to break the probe cover during this procedure.

(3) Place a sterile rubber band into the groove of the probe to fix the probe cover to the probe (Figure 6).

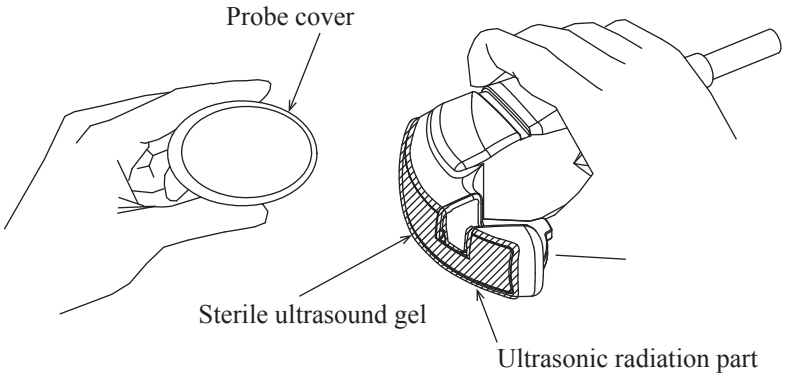


Figure 4 Sterile ultrasound gel applied to the ultrasonic radiation part

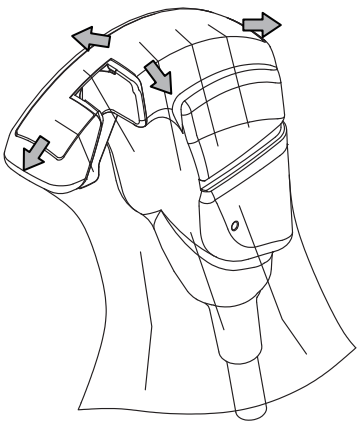


Figure 5 Smoothing of a wrinkle

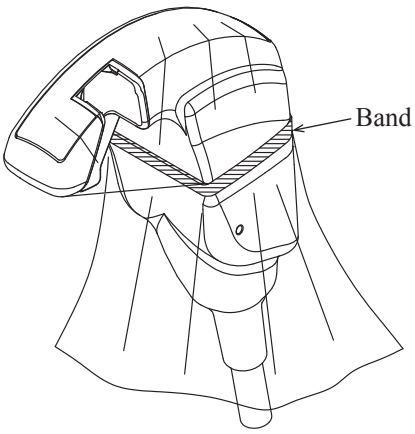


Figure 6 Fixing of the probe cover

(4) Assemble the needle Insert to the needle guide (Figure 7). Be sure that the gauze size engraved on each parts is same. Open the biopsy attachment mounting arm outward to attach the biopsy attachment to the probe (Figure 8).

(5) Place the projected parts of the attachment on the grooves of the probe in order to attach the biopsy attachment to the probe. Note that the biopsy attachment is attached over the probe cover (Figure 9).

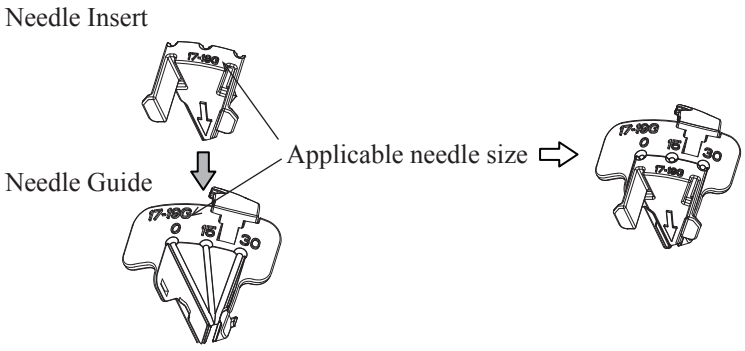


Figure 7 Biopsy Attachment assembly

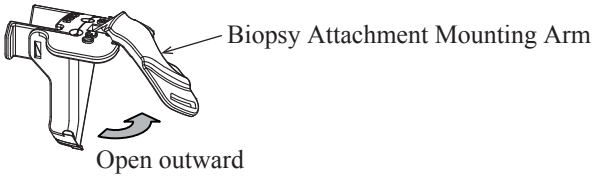


Figure 8 Opening of Biopsy Attachment Mounting Arm

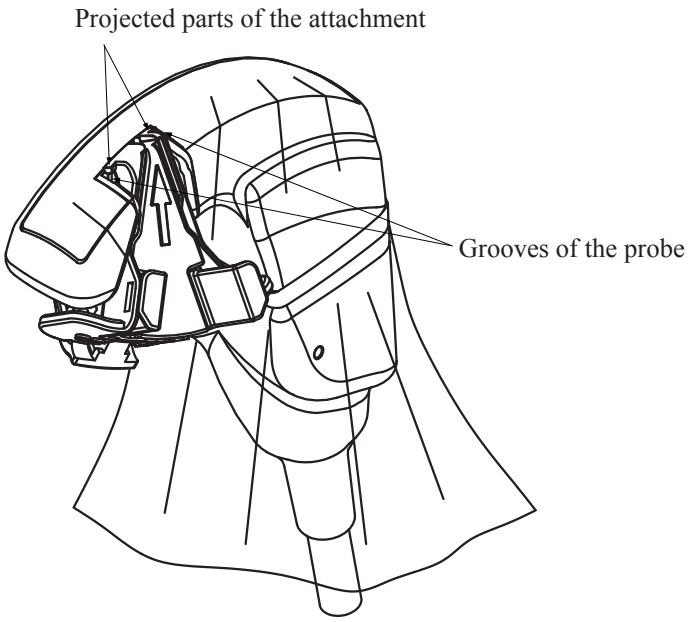


Figure 9 Attachment of Biopsy Attachment

(6) Fix the biopsy attachment to the biopsy attachment mounting plate by pushing it towards the direction shown in Figure 10.

(7) Fix the biopsy attachment mounting arm to the probe while pulling the probe cover as shown in Figure 11. Note that the wrinkle at the part indicated in Figure 11 should be smoothed as possible.

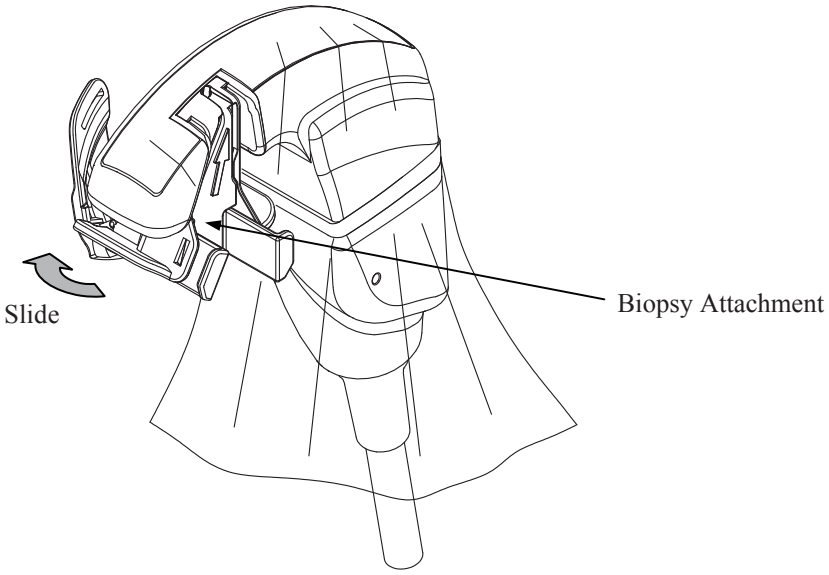


Figure 10 Fixing Biopsy Attachment

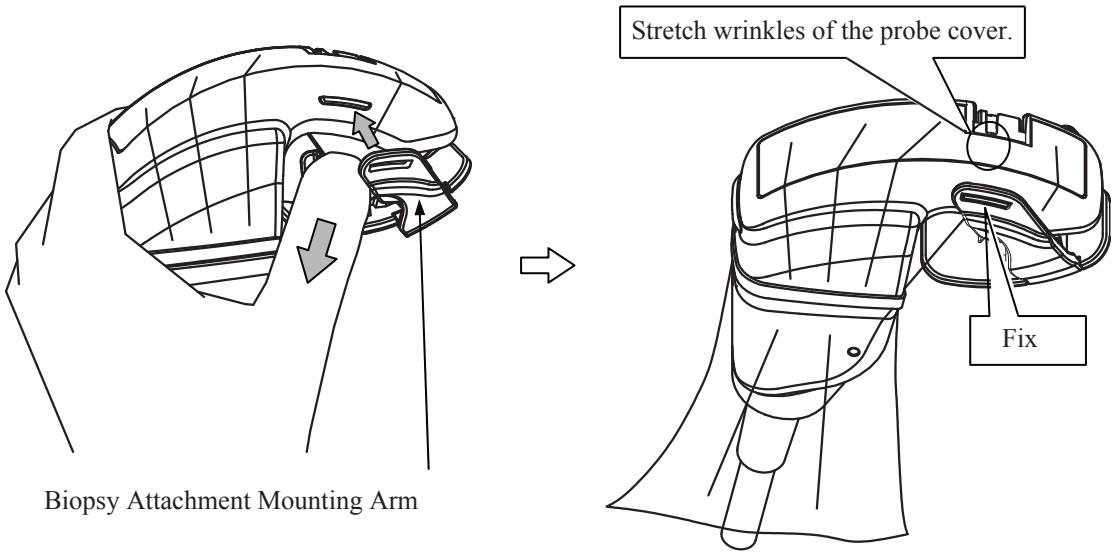


Figure 11 Fixing Biopsy Attachment Mounting Arm

(8) Confirm that the probe cover does not interfere with the needle path by inserting a needle in each needle insertion groove (Figure 12).

(9) Confirm that the biopsy attachment is properly attached to the probe (Figure 13). Visually inspect that there is no hole or tear in the probe cover. Set a new probe cover if a hole or tear is found.

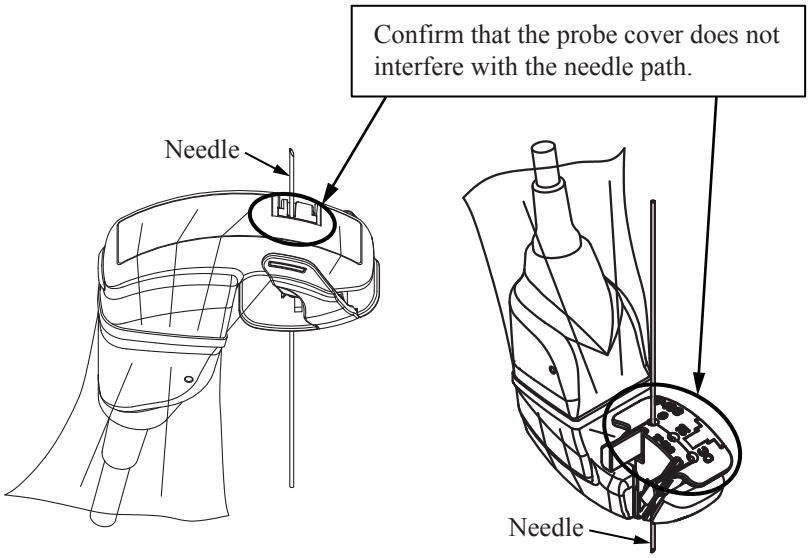


Figure 12 Confirmation of the needle path

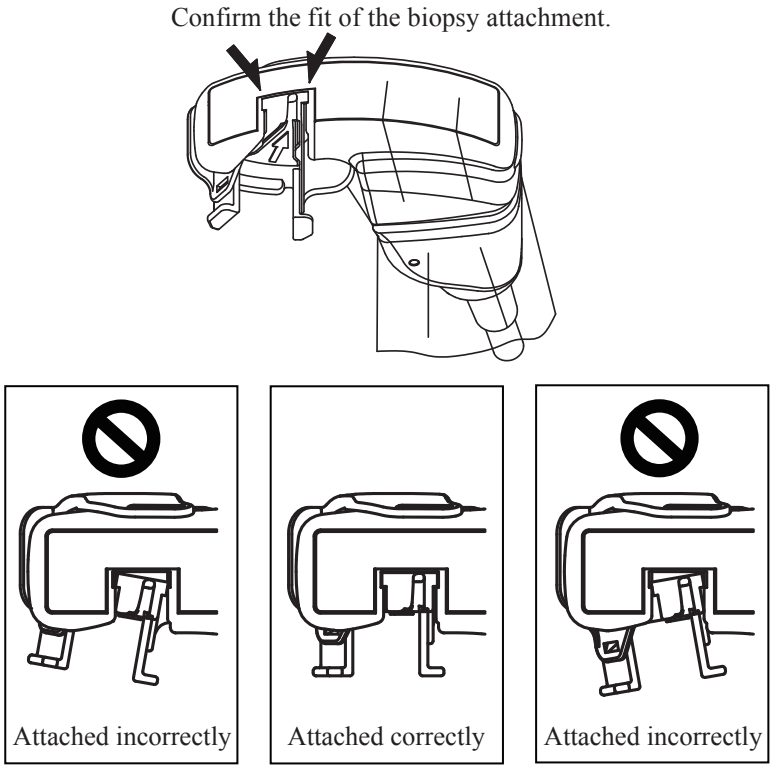


Figure 13 Confirmation of the attachment

4-2. Operation

Mount a probe cover according to 4-1, apply sterile ultrasound gel to either the ultrasonic radiation part or the body of the patient, and place the ultrasonic radiation part of the probe onto 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 image, refer to the documentation supplied with the ultrasound diagnostic instrument.

Fix the probe firmly and perform a puncture by inserting a needle to the needle insertion groove. Confirm that the puncture guideline which corresponds to the insertion angle is displayed. Figure 14 indicates the relationship between the insertion angle and the guideline. If the probe is needed to be released from the biopsy attachment during puncture, release the needle insert as indicated in Figure 15 and then release the probe.

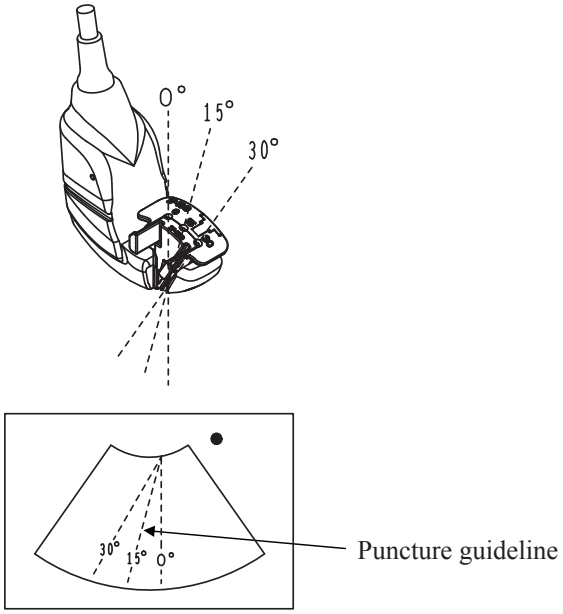


Figure 14 Relationship between the insertion angle and the puncture guideline

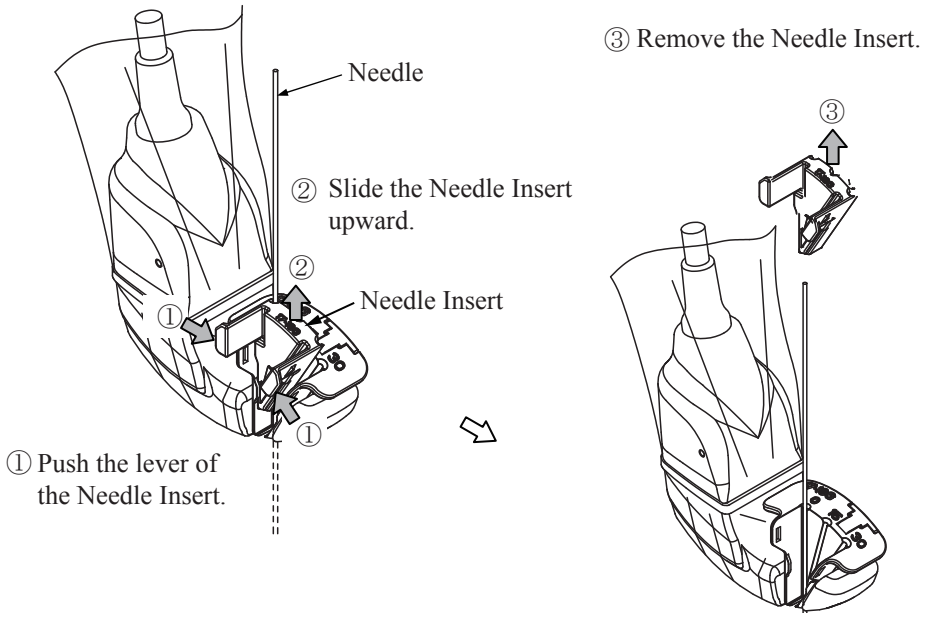


Figure 15 Release of the probe from the biopsy attachment during puncture

⚠ Warning	
⊘	Use only sterile ultrasound gel. The use of non-sterile ultrasound gel could result in infection to the patient.
❗	Use only the biopsy attachment specified in this manual. A puncture with the other attachment can result in puncture at unintended parts.
⊘	Sterilize the probe after use, if the probe cover was broken during use. Sterilize the probe according to the separate instruction manual “Cleaning, Disinfection and Sterilization“, otherwise there is a risk of infection to the patient.
⊘	Do not reuse the probe cover that was used. Reuse of the probe cover can result in infection to the patient.

⚠ 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.

4-3. How to attach/release the magnetic position sensor and the magnetic position sensor attachment

This section provides the procedure to attach the magnetic position sensor and the magnetic position sensor attachment to the probe. Note that a probe cover is mounted after attaching these devices to the probe.
After use, reverse the procedure to remove these devices from the probe.

(1) Place the magnetic position sensor into the magnetic position sensor attachment. The direction mark of the sensor is upward as shown in Figure 16.

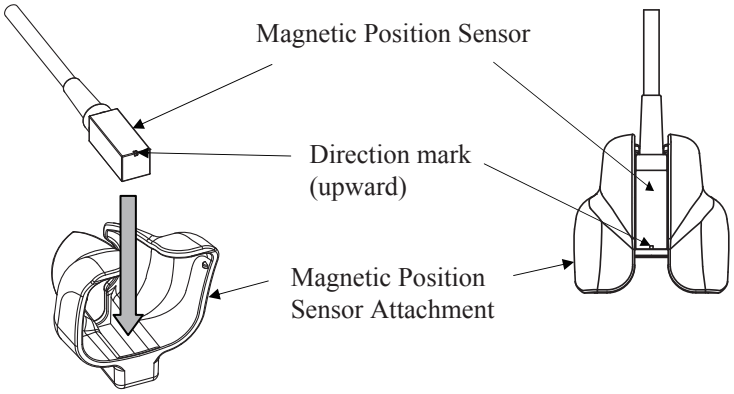


Figure 16 How to attach Magnetic Position Sensor

(2) Attach the magnetic position sensor attachment to the probe as shown in Figure 17.

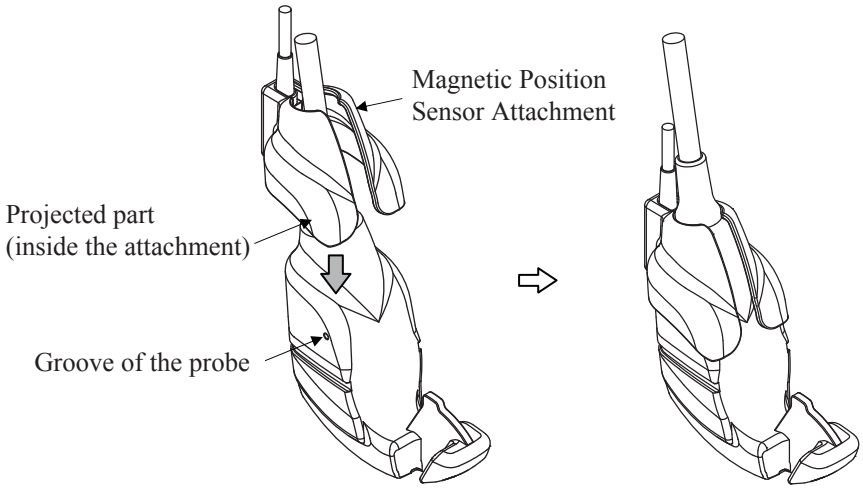


Figure 17 How to attach Magnetic Position Sensor Attachment

⚠ Caution
Attach the magnetic position sensor to the magnetic position sensor attachment correctly. A false diagnosis may be caused if the sensor is attached in the wrong direction.

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