HITACHI
Inspire the Next

Biopsy Probe

EUP-B715

INSTRUCTION MANUAL

Notes for operators and responsible maintenance personnel
★ Please read through this Instruction Manual carefully prior to use.
★ Keep this Instruction Manual together with the system with care to make it available anytime.

Hitachi, Ltd.
Tokyo , Japan

Q1E-EP1245-7

CE 0123

Manufacturer:

Hitachi, Ltd.
2-16-1, Higashi-Ueno, Taito-ku, Tokyo,110-0015, Japan
+81-3-6284-3668
http://www.hitachi.com/businesses/healthcare/index.html

European Representative:

Hitachi Medical Systems GmbH
Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany

EU Importer: Hitachi Medical Systems Europe Holding AG
Address: Sumpfstrasse 13 CH-6300 Zug, Switzerland

Local Distributor:

About this manual

This instruction manual shall provide instructions for using, cleaning, disinfecting and/or sterilizing the HITACHI ultrasound probes. It also describes safety considerations, maintenance.

For instructions for operating the main unit, refer to the operation manual for it.

Before using the probe, thoroughly read this manual and keep this book for future reference.

If you have any questions concerning the manual, please contact a service support.

The following conventions are used throughout the manual to denote information of special emphasis.

WARNING: "Warning" indicates the presence of a hazard which may result in severe personal injury, substantial property damage, or death if the warning is ignored.

CAUTION: "Caution" indicates the presence of a hazard which will or can cause minor personal injury or property damage if the caution is ignored.

NOTICE: "Notice" indicates information of installation, operation, or maintenance, which is important, but not hazard related.

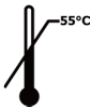
Graphical Symbols for Use in Labeling of Hitachi Ultrasound Probes

Some graphical symbols that are used in labeling of Hitachi Ultrasound Probes are compliant with EN980:2008 standard. Refer to the following table about the meanings of them.

Explanation of Symbol	Symbol	Descriptive Content
Manufacturer Company Name and Address		Hitachi, Ltd. 2-16-1, Higashi-Ueno, Taito-ku, Tokyo,110-0015, Japan +81-3-6284-3668 http://www.hitachi.com/businesses/healthcare/index.html
Authorized Representative in The European Community		Hitachi Medical Systems GmbH Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany
Keep away from Sunlight		Store the probe in a cool place and keep away from high temperature, high humidity, or direct sunlight.

Definition of symbol

The following symbol is also used for HITACHI Ultrasound Probes.

Location	Symbol	Definition
Probe connector	CE 0123	This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector	IPX7	IPX7 mark See section 1.6.
Probe connector		Type BF APPLIED PART
Probe connector		General warning sign
Probe connector		Warning; dangerous voltage
Probe connector		Caution; Biohazard
Probe connector		Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.
Probe connector	Compatible STERRAD	STERRAD sterilization compatibility mark
Probe connector		Upper Limit of Temperature; The probes that are applicable to Ethylene Oxide Gas Sterilization use symbol of "Upper Limit of Temperature: 55 degrees".
Probe connector		Do not waste the instrument as general waste. Comply with a local regulation.
Probe connector	**Rx Only**	By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.
Package of Biopsy Attachment		Do not reuse
Package of Biopsy Attachment		Do not re-sterilize

CONTENTS

1. Introduction

1.1 Features

The probe of Model EUP-B715 has convex array type.

The acoustic output of this probe when connected to ultrasound scanner was measured according to the IEC60601-2-37 standard.

The table of measured acoustic output data is contained in the operation manual of each ultrasound scanner.

This probe is categorized in class IIa according to Directive 93/42/EEC. According to IEC 60601-1 the probe is classified as type BF.

⚠ WARNING

Never use the probe for following applications.

1) Direct contact to the heart.

2) Biopsy to the heart.

1.2 Principles of operation

This probe and the ultrasound diagnostic scanner enable image diagnosis using ultrasonic waves. This system operates under the principles described below.

1) When an electric pulse signal is applied from the transmitter to the transducer of the probe, the transducer converts electric signals into mechanical vibration energy for emitting pulse-shaped ultrasonic waves into the body part, liquid or other medium contacting the transducer.
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 waves and converts mechanical vibrations into electric energy. Electric signals are converted to shades of brightness by brightness modulation to obtain an image.

1.3 Intended Use

The Biopsy Probe EUP-B715 is designed for observation and diagnosis mainly of the following regions by connecting with the HITACHI ultrasound scanner.

- Biopsy (with Biopsy Attachment)
- General abdominal organs

1.4 Components

The probe components of the EUP-B715 are as follows:

1) Biopsy Probe EUP-B715 ····· 1 piece
2) Biopsy attachment for 12G-13G ····· 10 pieces
   for 14G-16G ····· 10 pieces
   for 17G-19G ····· 10 pieces
   for 20G-23G ····· 10 pieces
   for cool-tipTM (17G), LeVeenTM SuperSlim Needle(17G) ····· 10 pieces
3) Instruction Manual ····· 1 copy

⚠ WARNING

1) The biopsy attachment (Needle guide, Needle insert) is disposable. Do not reuse. When the biopsy attachment is reused, it may run the risk of exposing the patient to infectious diseases.

2) When using the needle cannula of the electrosurgical unit while using the biopsy attachment as a guide, be careful not to damage the insulation coating of the needle cannula. [When inserting or removing the needle cannula into or from the biopsy attachment, you may damage the insulation coating of the needle cannula, which may cause a burn to tissue contacting the exposed section of the insulation coating.]

⚠ CAUTION

1) Use appropriate biopsy attachment that is correspondent with the needle that you use.
2) If you use Cool-tip™ 17G or LeVeen™ SuperSlim needle 17G of RFA needle, use the biopsy attachment EZU-PA7B1-C surely.
3) Sterilization has not been made to the probe and biopsy attachment shipped from the factory.
   Prior to use of them, be sure to clean and sterilize them.
4) Do not hold the needle cannula of the electrosurgical unit with metal tweezers, forceps, and the like. [Doing so may damage the insulation section of the needle cannula, and may cause a burn to a non-treated area.]
5) A biopsy should be performed only by a well-trained physician.

1.5 Accessories (Option)

1.5.1 Biopsy Attachment

The biopsy attachment is disposable one.

If more biopsy attachment is needed, you are requested to place an order with us or our authorized agent specifying the model required from the following models.

- EZU-PA7B1-1 for 12G-13G ····· 10 pieces/pack
- EZU-PA7B1-2 for 14G-16G ····· 10 pieces/pack
- EZU-PA7B1-3 for 17G-19G ····· 10 pieces/pack
- EZU-PA7B1-4 for 20G-23G ····· 10 pieces/pack
- EZU-PA7B1-C for Cool-tipTM (17G), LeVeenTM SuperSlim Needle(17G) ····· 10 pieces/pack

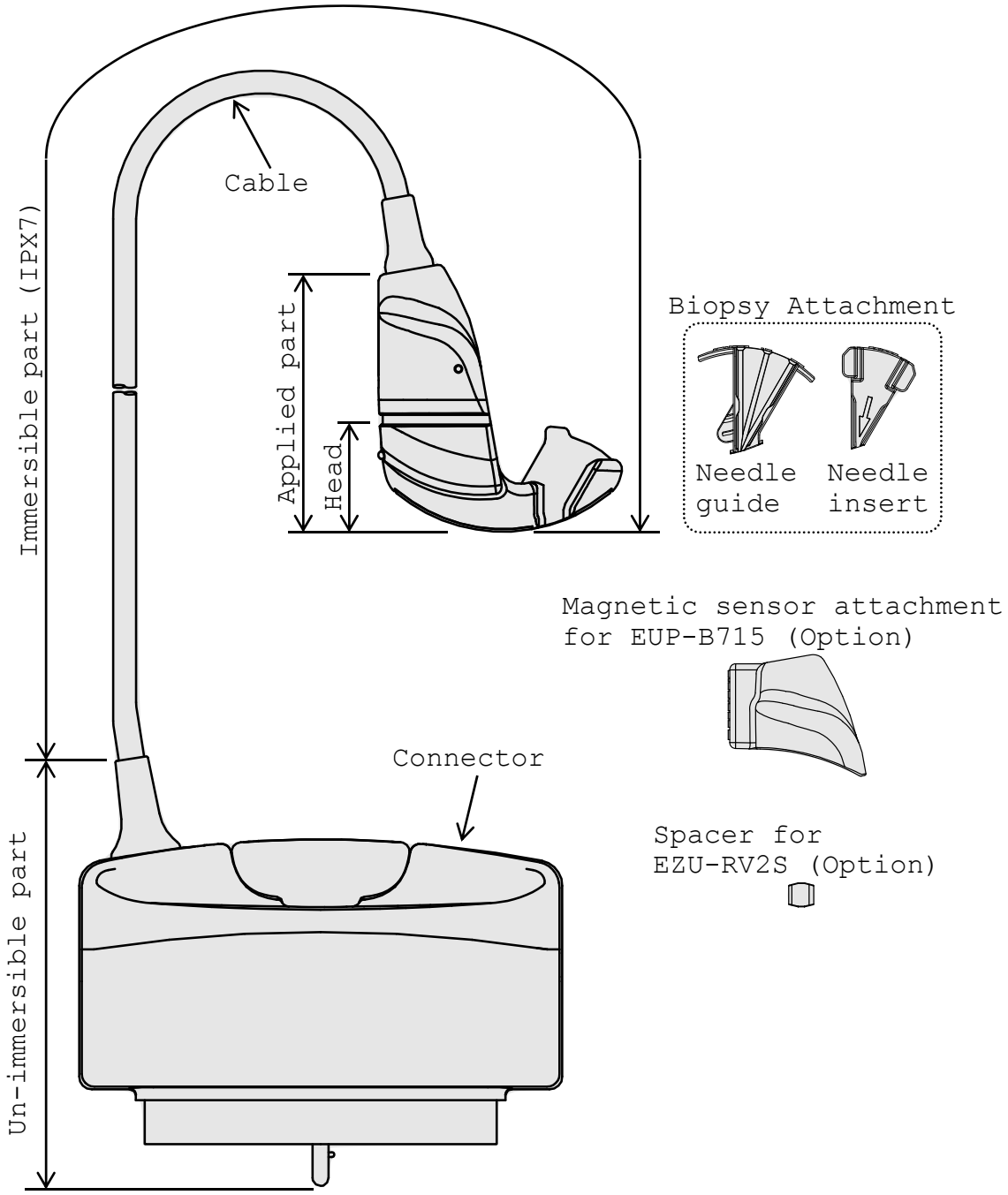
1.5.2 Magnetic Sensor Attachment for EUP-B715 (Option)

1.5.3 Spacer for EZU-RV2S (Option)

⚠ CAUTION

Sterilization has not been made to the Magnetic sensor attachment and the Spacer for EZU-RV2S shipped from the factory. Prior to use of the probe, be sure to clean and sterilize it.

1.6 Construction



Immersible part: This part can be immersed in disinfectant solution and also can be cleaned by water.

Un-immersible part: This part should not be immersed in disinfectant solution and also cannot be cleaned by water.

Fig.1 External view

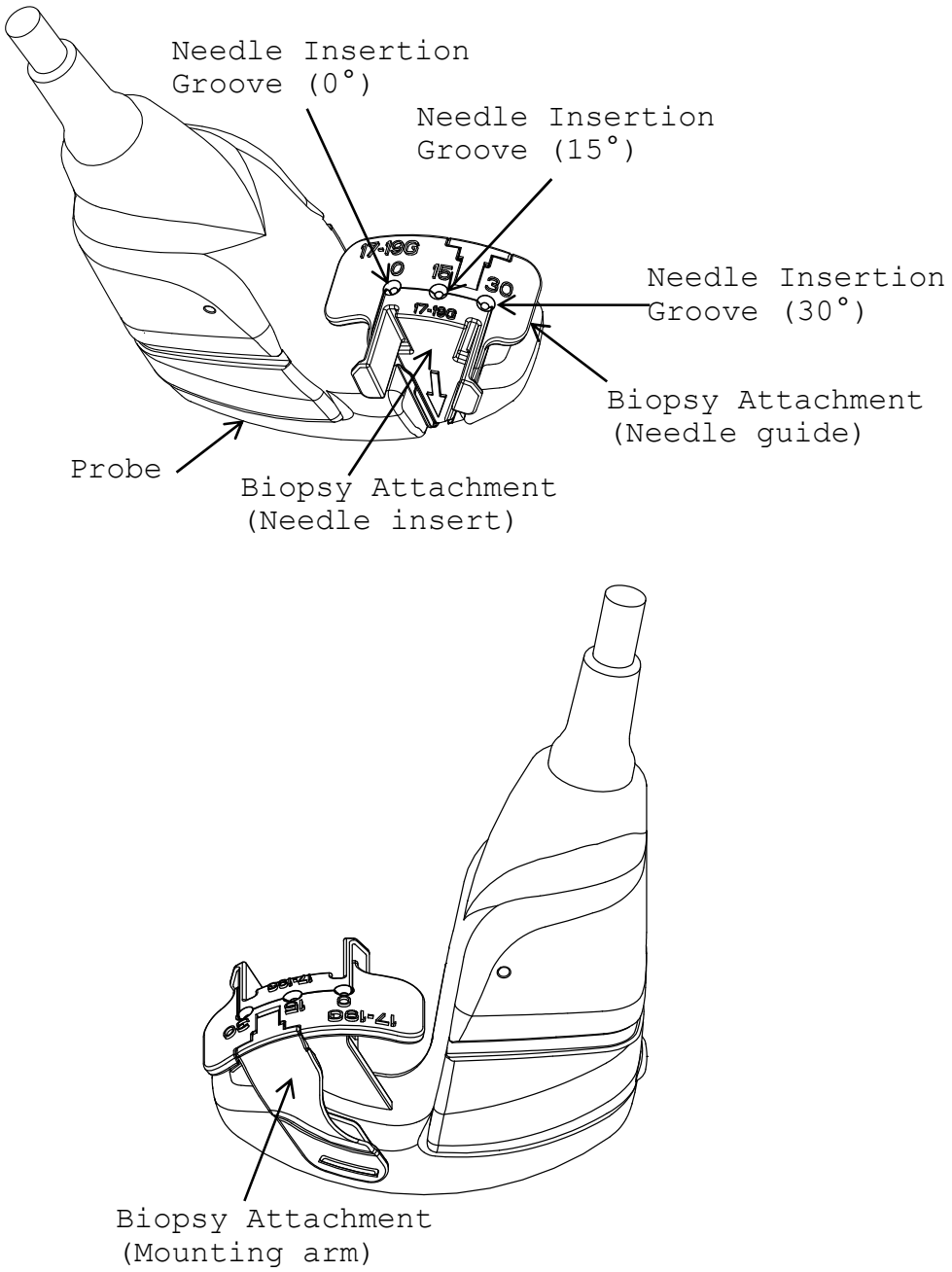


Fig.2 External View of the Biopsy Attachment

2. Inspection before Use

Prior to use, the probe must be carefully inspected that they are appropriate for use. If you find any damage, do not use the probe and immediately contact a service support.

2.1 Inspection for Material Surface

1) Visually inspect the surface of the probe head, housing and cable for any crack, scratch or denaturalization.

2) Visually inspect the surface of the Magnetic sensor attachment and the Spacer for EZU-RV2S for any crack, deformation or denaturalization.

2.2 Inspection of the Biopsy Attachment

1) Check that any foreign article is not in the needle groove. Confirm that the Needle insert can be mounted to the Needle guide.

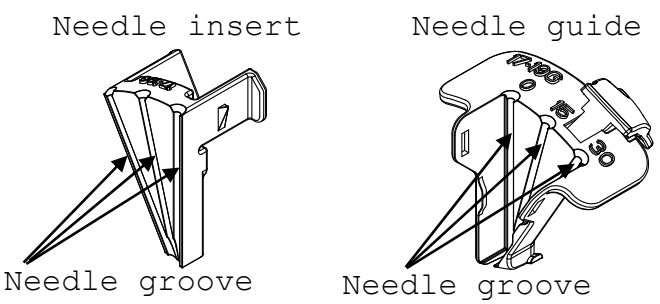


Fig.3 Needle Groove

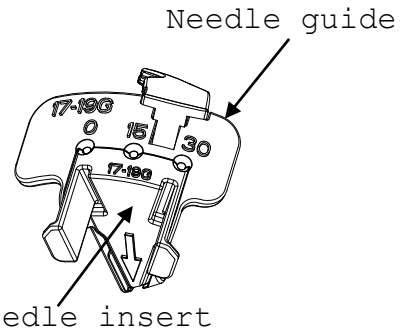


Fig.4 Biopsy Attachment Assembly

2) Confirm that the biopsy attachment can be mounted to the probe and detached from it.

2.3 Inspection for Appropriate Connection

1) Check that the system is correctly operating. Refer to the instruction manual for the Main unit.

2) Fill sterile water into a bucket and confirm that a biopsy guide line and an echo image of test needle are overlapped correctly at all selectable angles. (See Fig.5)

3) Relationship between the needle insertion groove and needle guide line angle following "3. Operation Procedure" Fig.17. Also, Confirm that the needle moves smoothly and there is no blurring between the needle and biopsy attachment.

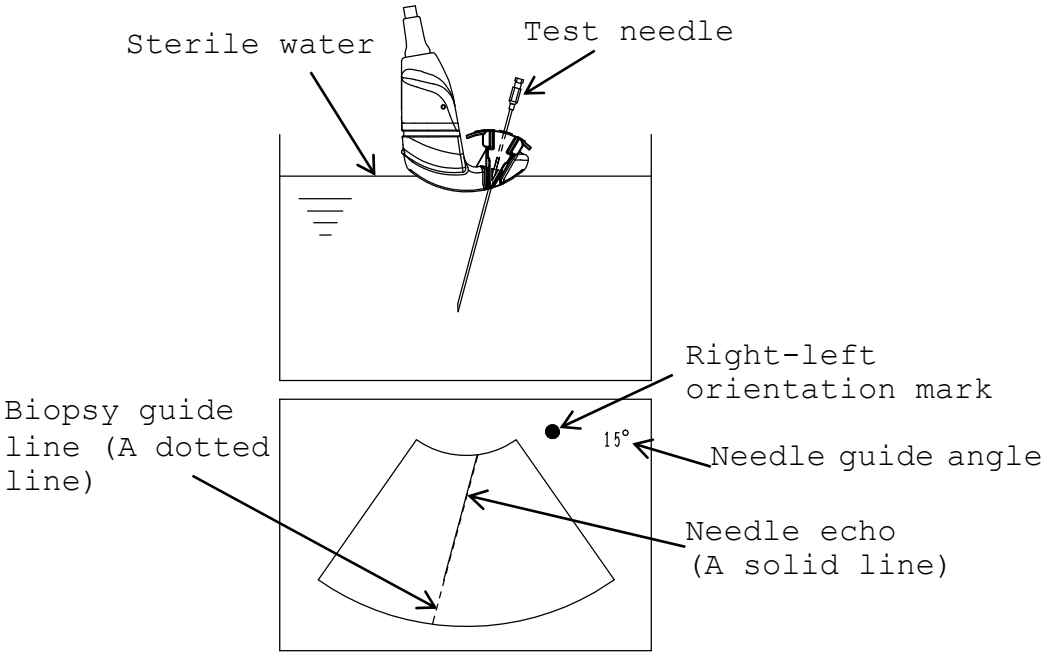


Fig.5 Echo image of test needle

⚠ CAUTION

Before use, make sure there is no damage to the surface to which the needle cannula is attached, and the biopsy attachment works properly.

3. Operation Procedure

1) Connect the probe, operate the Main unit, and adjust the image according to the instructions given in the operation manual for the main unit.

2) Confirm that the probe is disinfected or sterilized.

3) Confirm that the biopsy attachment is sterilized.

4) Confirm that the Magnetic sensor attachment and the Spacer for EZU-RV2S are disinfected or sterilized.

5) Prepare the following probe cover.

- CIV-Flex™ Transducer Cover (610-542) (Option)
  Sterile 14 x 91.5cm telescopically-folded cover

6) To use Real-time Virtual Sonography (RVS), attach the Magnetic sensor to the probe as shown in "4. Attaching the Magnetic Sensor". Place the probe cover to the probe, after attaching of the Magnetic sensor. Do not attach the Magnetic sensor on top of the probe cover.

7) Place an appropriate amount of sterilized gel on the Probe head. (See Fig.6)

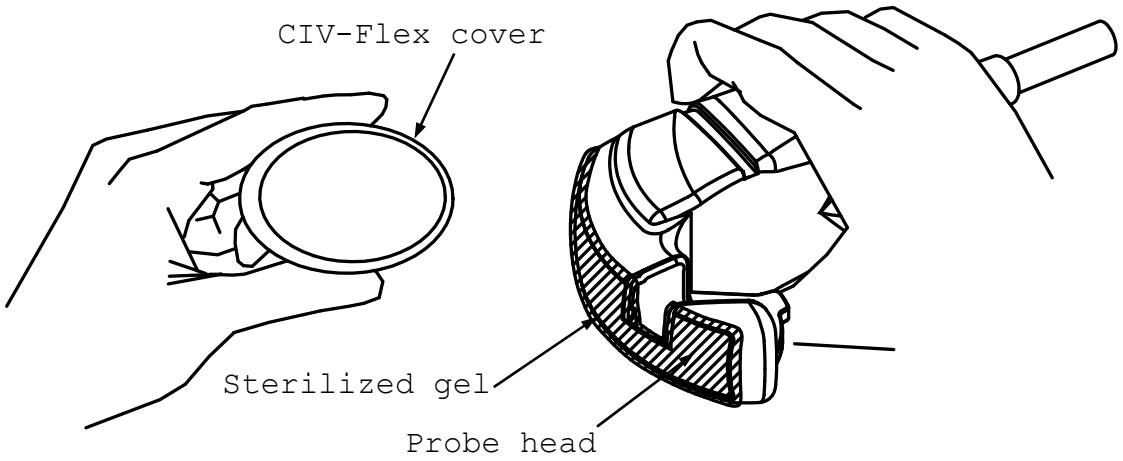


Fig.6 Placing the sterilized gel

8) Pull the cover tightly over the probe face to remove wrinkles and air bubbles, taking care to avoid puncturing the cover.

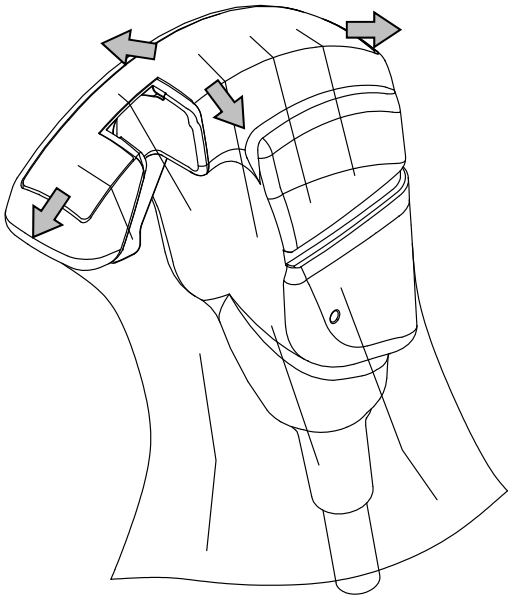


Fig.7 Hold the probe cover to the probe

9) Secure cover to the groove portion of the probe housing with bands.

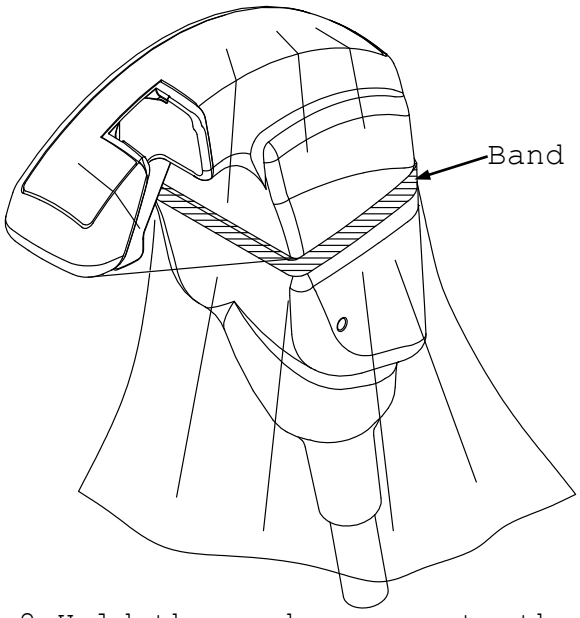


Fig.8 Hold the probe cover to the probe

10) Select a needle insert and needle guide to correspond with the needle size intended to be used in the procedure. Needle size is engraved on the needle insert and the needle guide. Slide the needle insert into the needle guide. Be sure to using combination same needle size. After insert into the needle guide, open outward mounting arm in the direction of fig.10 to easy mount the biopsy attachment.

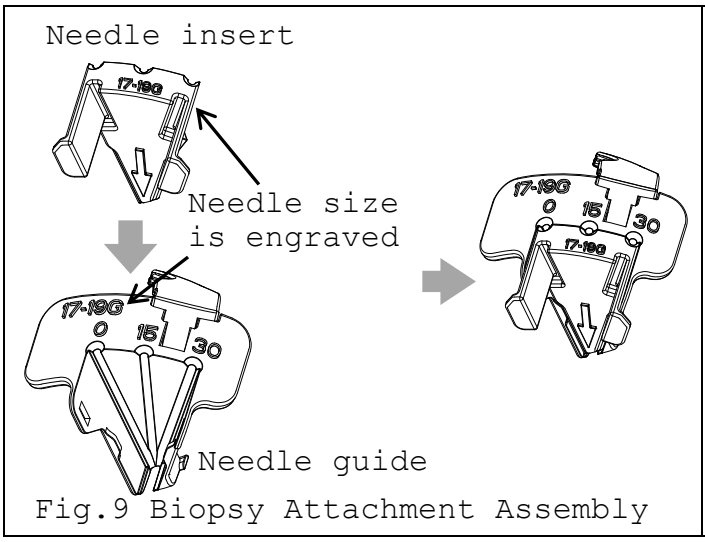


Fig.9 Biopsy Attachment Assembly

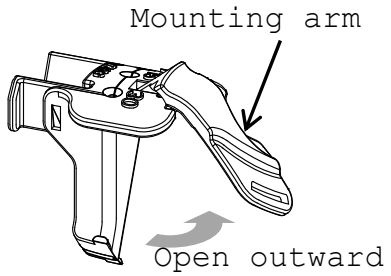


Fig.10 Mounting arm

⚠ CAUTION

When use this probe EUP-B715 for biopsy purpose, use the biopsy attachment (EZU-PA7B1-1,2,3,4,C) certainly.

11) Mount the appropriate biopsy attachment in the probe. Follow the next steps to mount the probe and biopsy attachment.

a) Place the biopsy attachment on the probe as shown in Fig. 11. Insert the projected part of the attachment into the groove of the probe on top of the probe cover.

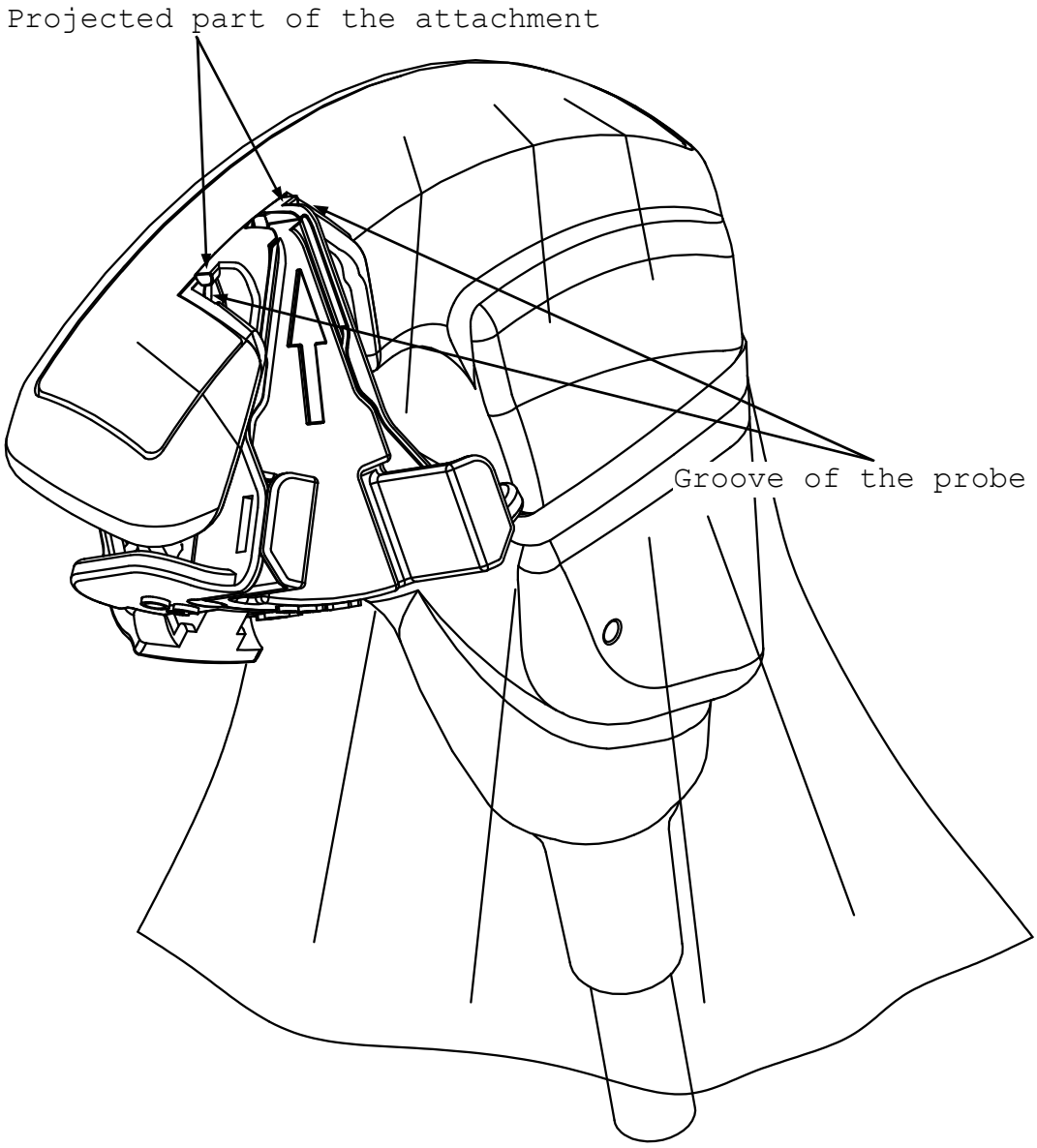


Fig.11 Mounting the biopsy attachment

b) The biopsy attachment tip to the direction of an arrow, secure the biopsy attachment to the biopsy attachment mounting plate.

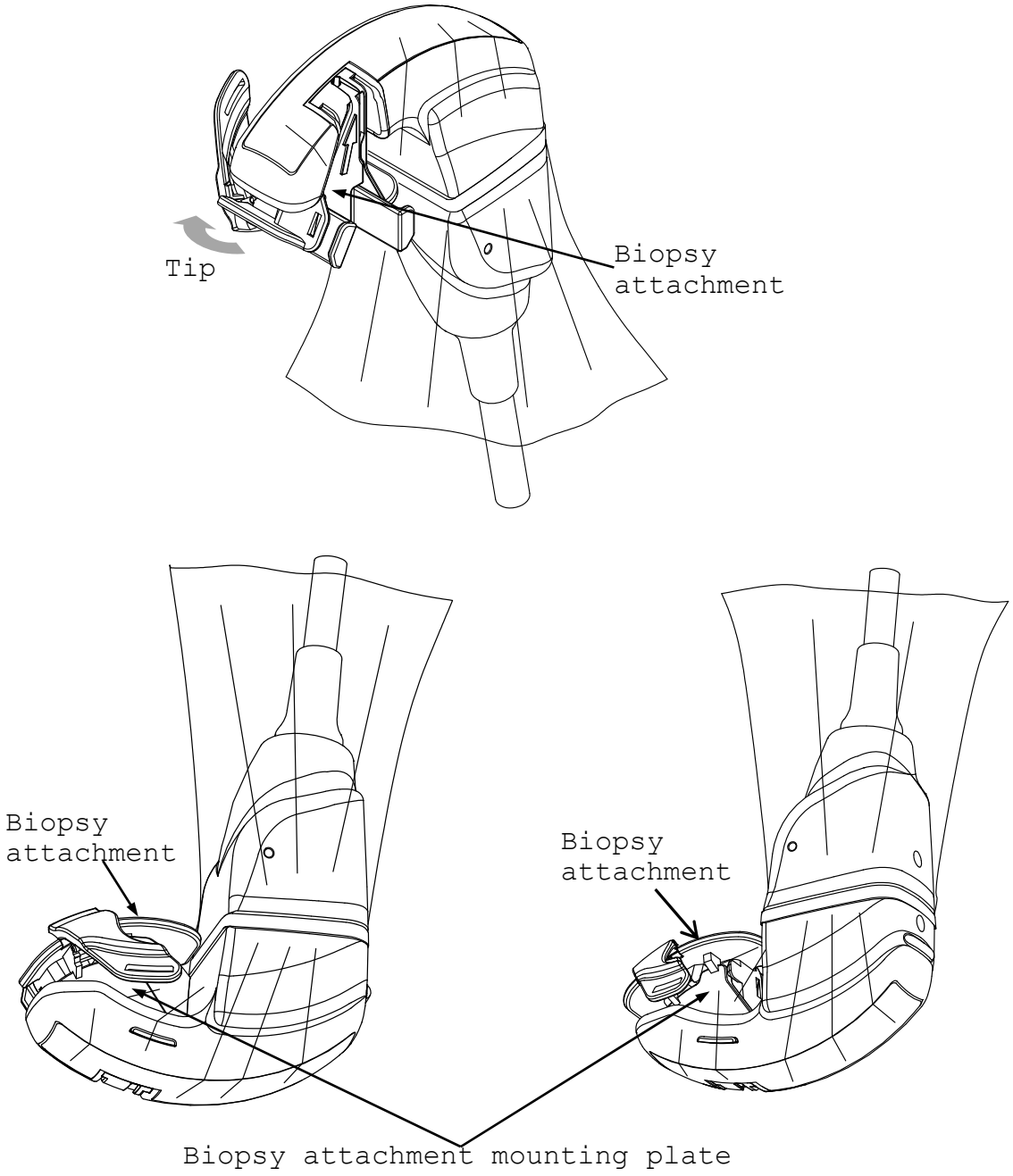


Fig.12 Mounting the biopsy attachment

c) The mounting arm tip to the direction of an arrow pulling the probe cover with thumb. Then the mounting arm lock reduces wrinkling of the probe cover.

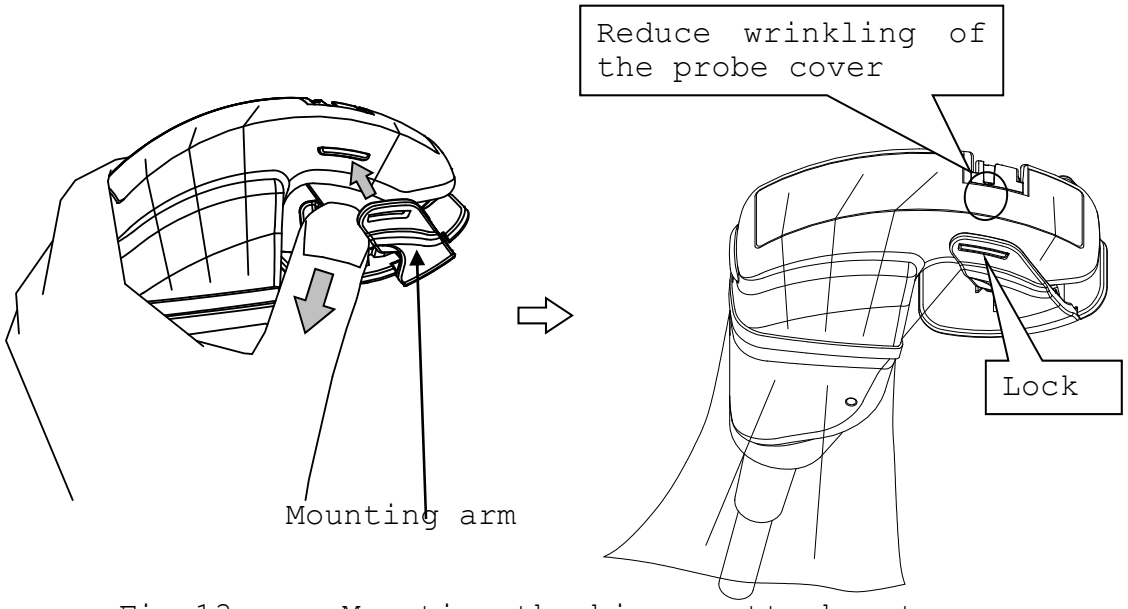


Fig.13 Mounting the biopsy attachment

d) Inspect the probe cover to ensure the needle path is clear of obstructions.

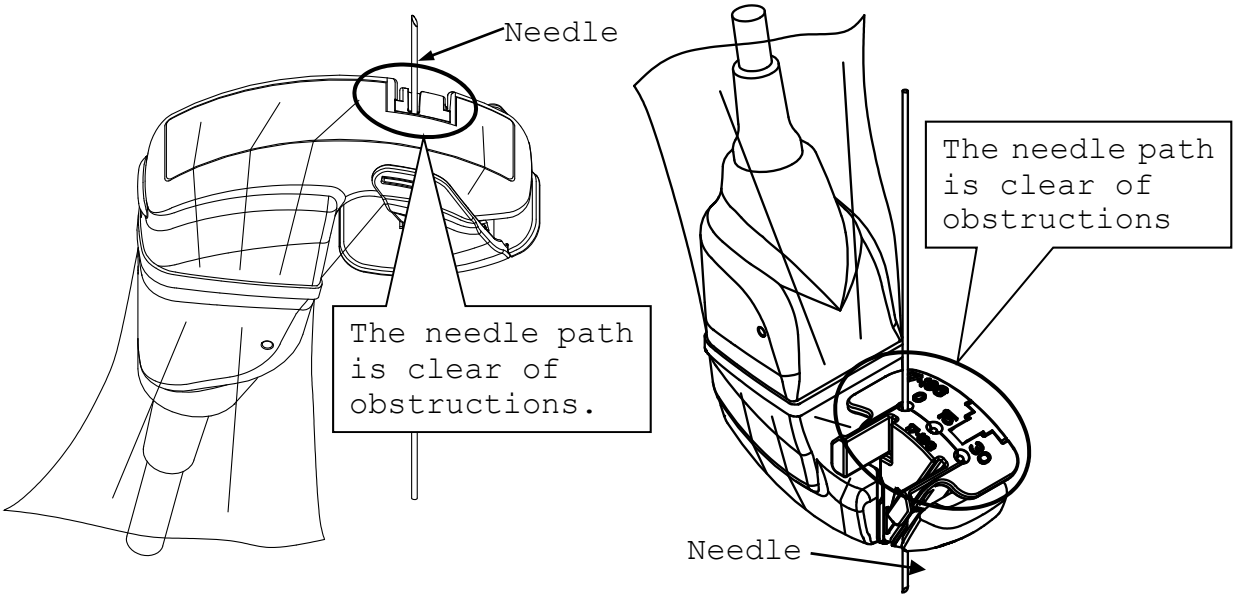


Fig.14 Inspection of the probe cover

e) Confirm that the tip of the biopsy attachment is attached in the correct position.

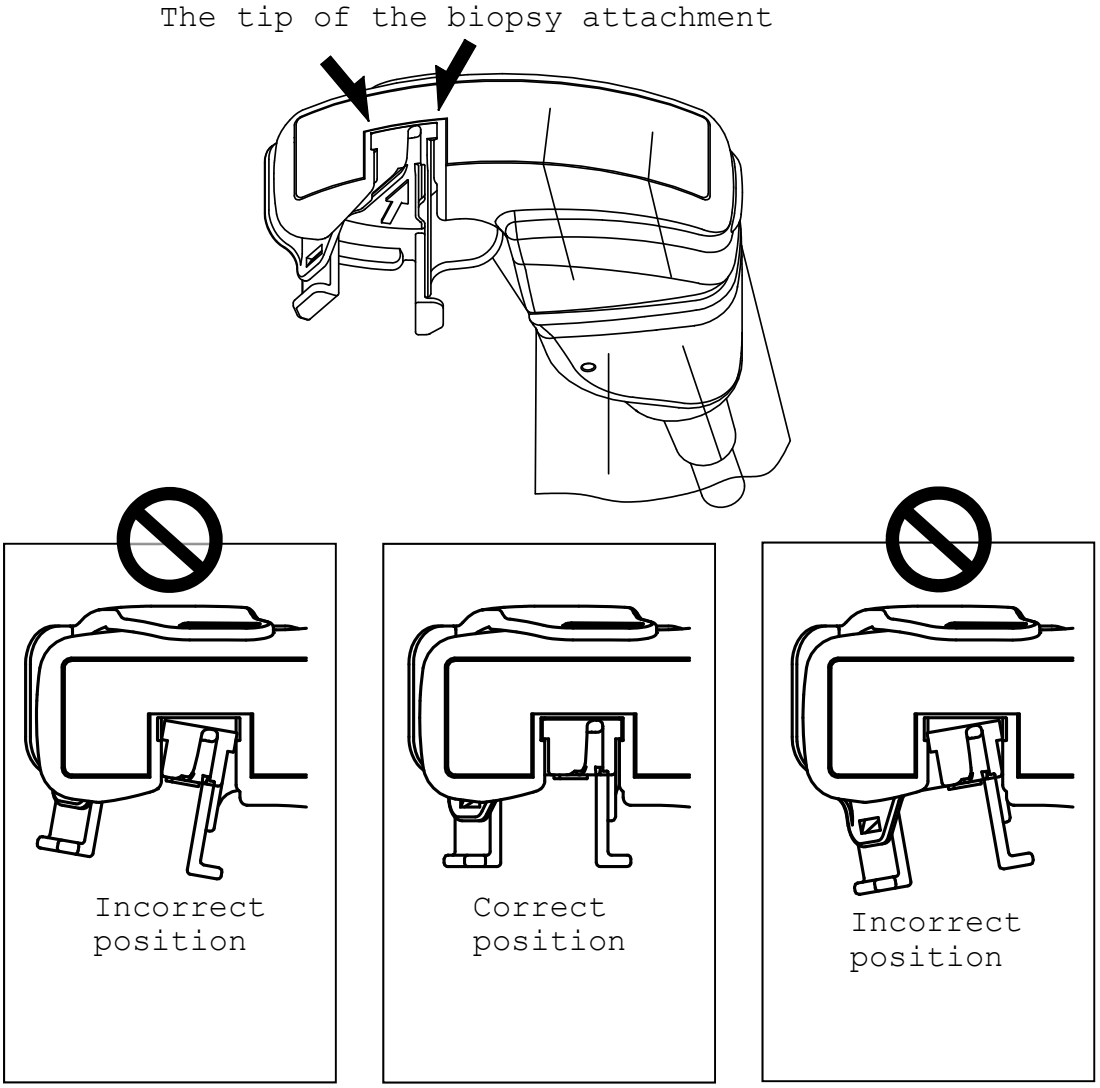


Fig.15 Inspection of the biopsy attachment

12) Visually inspect the cover to ensure that there are no defects or holes. Do not use the cover if it has any holes.

⚠ CAUTION

Cover the probe by the CIV-Flex Cover certainly. If the probe is not covered by the CIV-Flex Cover, It becomes impossible to reuse them because they are contaminated by blood and body fluid.

13) Apply acoustic medium such as physiological saline or sterilized ultrasonic jelly on the probe or examination area.

⚠ CAUTION

The ultrasonic jelly supplied together with the ultrasound scanner has not been sterilized. Never try to use it for biopsy examination.

14) Relationship between direction of the probe and the image is shown in Fig.16. The right-left orientation mark on the image indicates the direction of the biopsy attachment side on the probe.

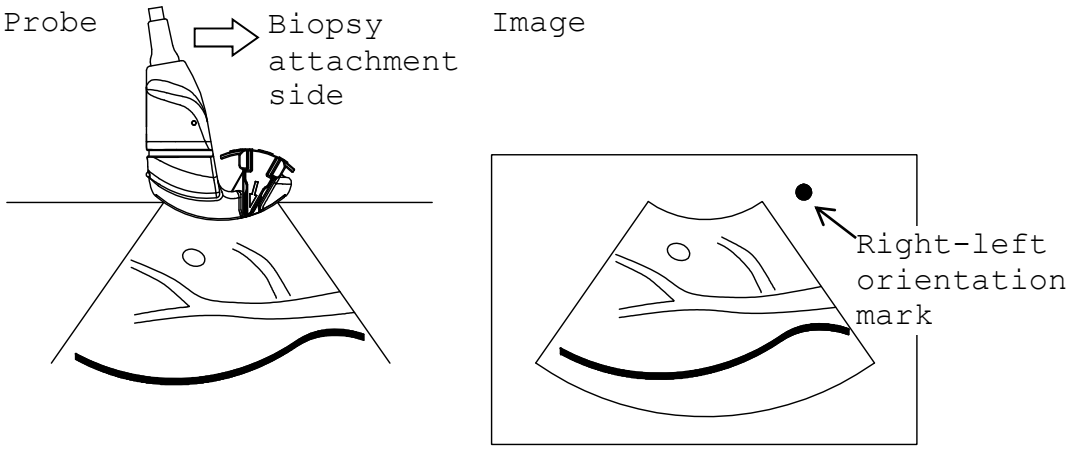


Fig.16 Relationship between direction of the probe and the right-left orientation Mark

15) Placing the probe on the surface of the examination region, depict a sectional image of the target region. Next, referring to the needle guide line, Set the needling direction.

16) Insert a needle into the needle insertion groove of the biopsy attachment set corresponding to the display angle of the needle guide line, fix the probe and perform biopsy. Relationship between the needle insertion groove and needle guide line angle is shown in Fig.17.

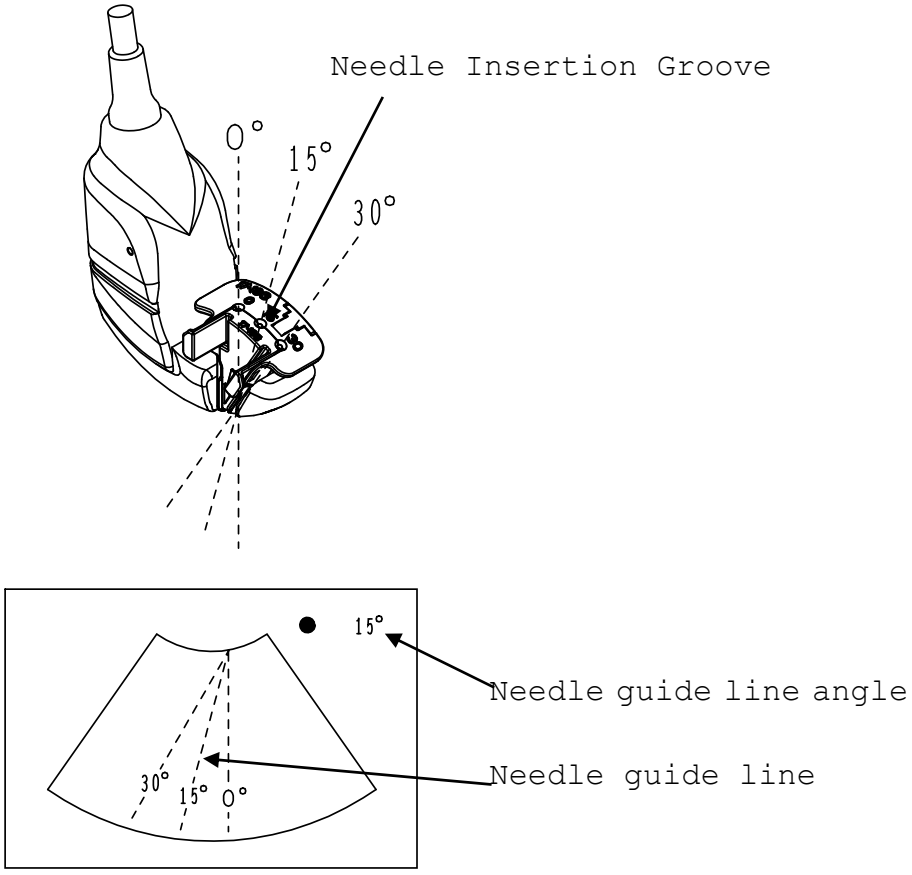


Fig.17 Relationship between the needle insertion groove and biopsy guide line angle

17) As inserting the needle into the body, keep watching the tip of the needle in image not to lose its echo image by manipulating the needle.

⚠ CAUTION

1) In case of bore a hole in the probe cover with a biopsy needle, the probe should be sterilized after use.
2) A thin needle may be inserted as bent in the body. In such case, if the needle is bent in the long-axis direction of the transducer, its image will get out of the guide line. If it is bent in the direction perpendicular to the long-axis, its image will disappear. In this case, pull back the needle slightly, check the needle tip, and then move the probe to follow the needle tip.

18) Follow the next steps to detach the probe and biopsy attachment.

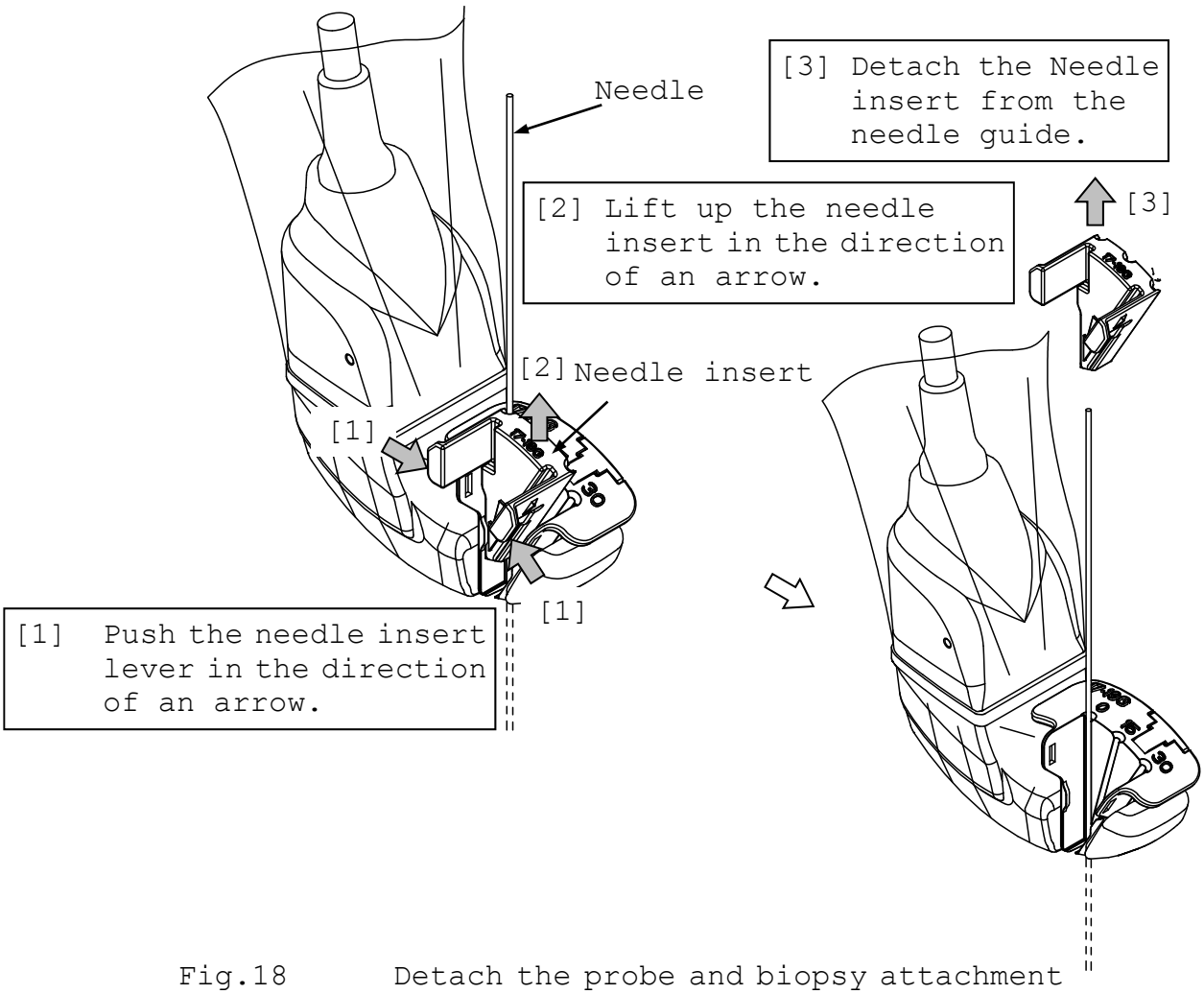


Fig.18 Detach the probe and biopsy attachment

19) After using the probe, perform the reprocessing procedure in accordance with the procedure stated in "5. Cleaning, Disinfection and Sterilization of the Probe, Biopsy Attachment and Magnetic sensor attachment" every time immediately after completing the ultrasound examination.

20) After using the Magnetic sensor attachment and the Spacer for EZU-RV2S, perform the reprocessing procedure in accordance with the procedure stated in "5. Cleaning, Disinfection and Sterilization of the Probe, Biopsy Attachment and Magnetic sensor attachment" every time immediately after using Real-time Virtual Sonography (RVS).

21) Store the probe, the Magnetic sensor attachment and the Spacer in the environment indicated in "6. Maintenance and Safety Inspection".

4. Attaching the Magnetic Sensor

To use Real-time Virtual Sonography (RVS), attach the Magnetic sensor to the probe. There are two types of Magnetic sensors, for EZU-RV2S and EZU-RV3S. The Magnetic Sensor (EZU-RV2S) and the Magnetic Sensor (EZU-RV3S) are shown in Fig.19 and Fig.20.
To attach the Magnetic sensor as shown in "4.1 Magnetic Sensor (EZU-RV2S)" or "4.2 Magnetic Sensor (EZU-RV3S)" depend on your Magnetic sensor.

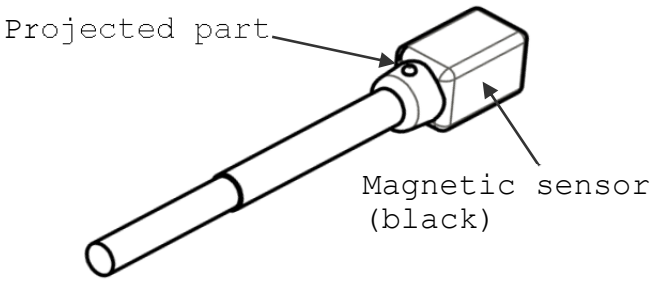


Fig.19 Magnetic Sensor (EZU-RV2S)

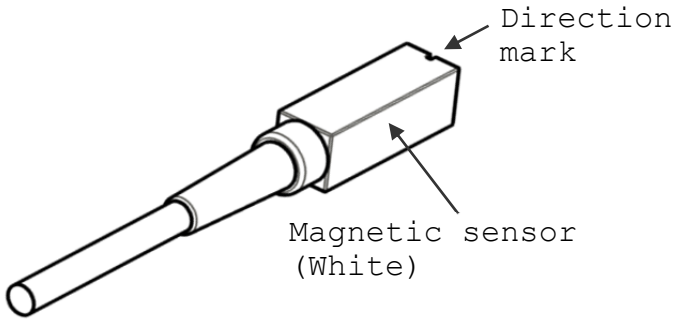


Fig.20 Magnetic Sensor (EZU-RV3S)

4.1 Magnetic Sensor (EZU-RV2S)

4.1.1 Attaching the Magnetic Sensor

To use Real-time Virtual Sonography (RVS), attach the Magnetic sensor as shown below.

1) Insert the Spacer for EZU-RV2S in the Magnetic sensor [1] and into the Magnetic sensor attachment with correct direction [2] as shown in Fig.21. Place the projected part upward as shown in Fig.21.

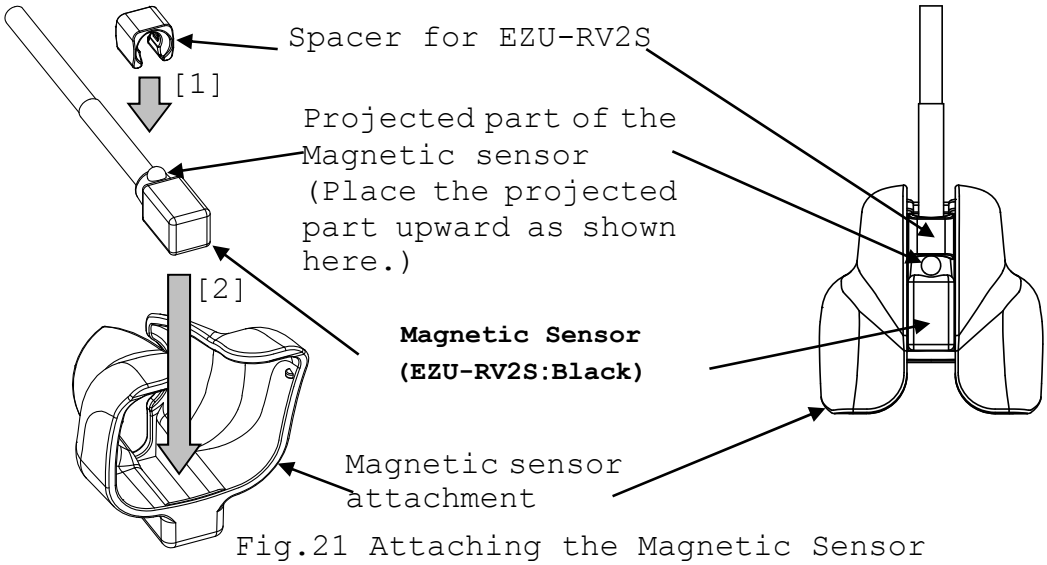


Fig.21 Attaching the Magnetic Sensor

2) Place the Magnetic sensor attachment on the probe as shown in Fig.22. Insert the projected part of the attachment into the groove of the probe.

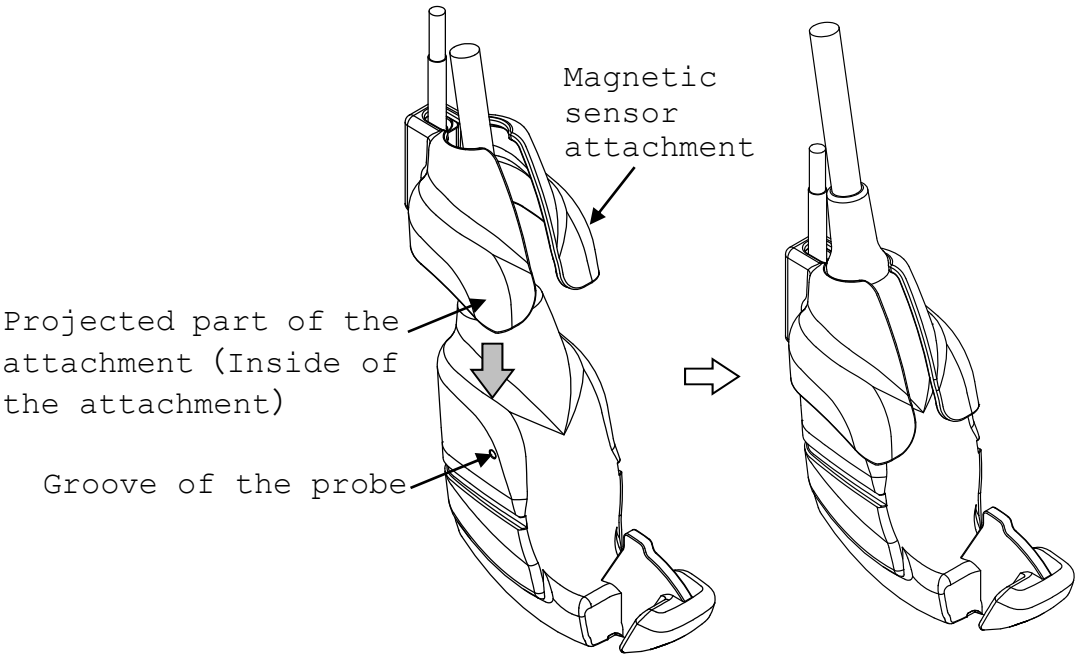


Fig.22 Attaching the Magnetic sensor attachment

⚠ CAUTION

1) Never attach the Magnetic sensor attachment to the probe in the incorrect direction, otherwise it may result in false diagnosis.
2) Never forget to attach the Spacer for EZU-RV2S to the Magnetic sensor, otherwise it may result in false diagnosis.

4.1.2 Removing the Magnetic Sensor

Procedure of removing the Magnetic sensor is reverse procedure to attaching the Magnetic sensor.

4.2 Magnetic Sensor (EZU-RV3S)

4.2.1 Attaching the Magnetic Sensor

To use Real-time Virtual Sonography (RVS), attach the Magnetic sensor as shown below.

1) Insert the Magnetic sensor into the Magnetic sensor attachment with correct direction as shown in Fig.23. Place the direction mark upward as shown in Fig.23.

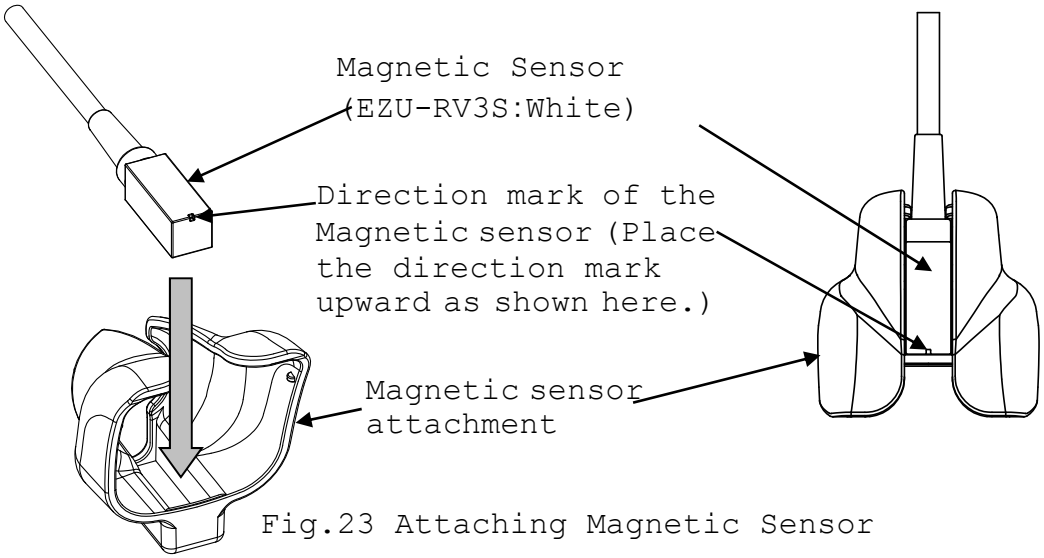


Fig.23 Attaching Magnetic Sensor

2) Place the Magnetic sensor attachment on the probe as shown in Fig.24. Insert the projected part of the attachment into the groove of the probe.

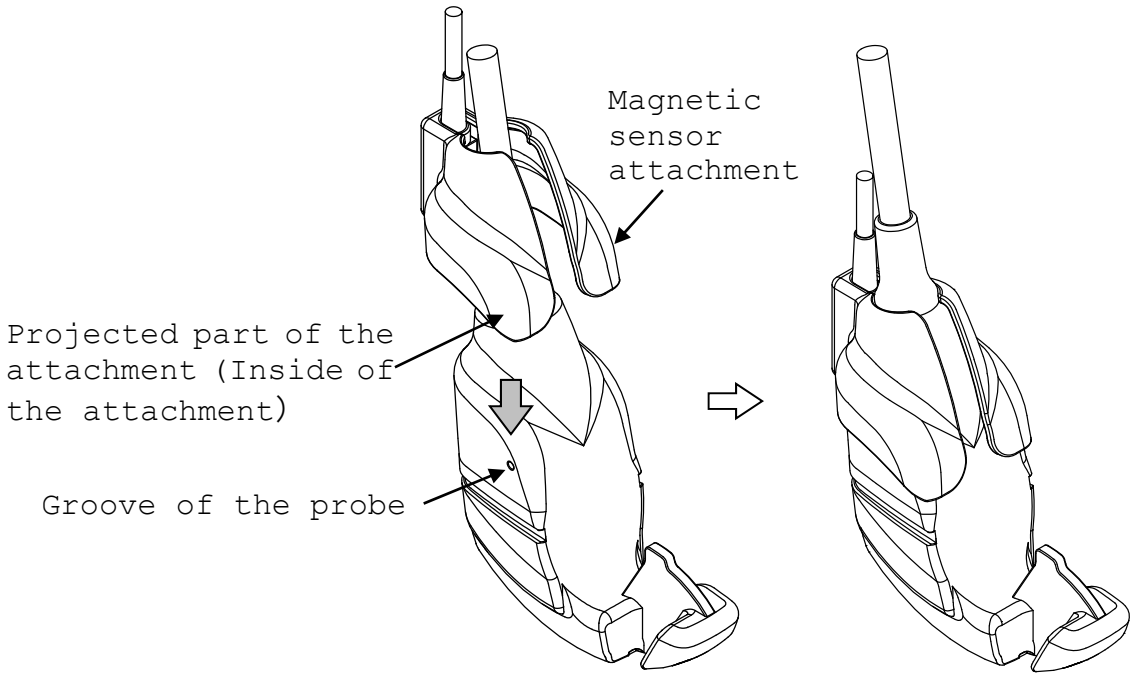


Fig.24 Attaching the Magnetic sensor attachment

⚠ CAUTION

Never attach the Magnetic sensor attachment to the probe in the incorrect direction, otherwise it may result in false diagnosis.

4.2.2 Removing the Magnetic Sensor

Procedure of removing the Magnetic sensor is reverse procedure to attaching the Magnetic sensor.

5. Cleaning, Disinfection and Sterilization of the Probe, Biopsy Attachment and Magnetic sensor attachment

- Take care about clean circumstances before using the probe on the next patients. If processors reprocess this equipment, refer to these instructions.
- Sterilization has not been made to the biopsy attachment EZU-PA7B1 shipped from the factory. Prior to the first use, be sure to sterilize them. The biopsy attachment EZU-PA7B1 is disposable. Do not reuse.
- Take care about clean circumstances before using the Magnetic sensor attachment and the Spacer for EZU-RV2S on the next patients. Before disinfection or sterilization process, clean the Magnetic sensor attachment and the Spacer for EZU-RV2S.

⚠ CAUTION

- After using the probe, Magnetic sensor attachment and Spacer for EZU-RV2S, clean, disinfect or sterilize them immediately according to the following reprocessing procedure. If they are left for long time after use, residue on them becomes hard to remove.
- Do not sterilize the probe, Biopsy attachment EZU-PA7B1, Magnetic sensor attachment and Spacer for EZU-RV2S by autoclave, they may suffer serious damage.

Additional information:

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

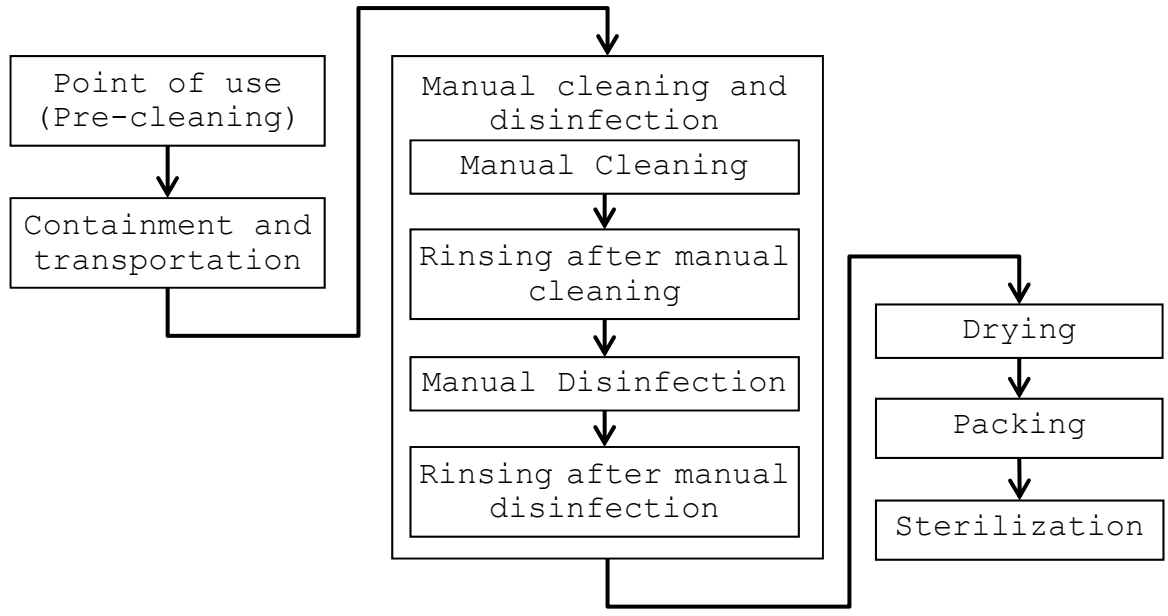
WARNINGS	- The probe is delivered unsterile. Prior to the first use sterilize the probe. - Do not exceed 60°C. - Probe connector has no water resistance.
Limitations on reprocessing	The probe is not completely submergible. Parts which are not submergible can only be disinfected by wipe disinfection.
Transportation before using	Sterile pouch or container should be kept between transportation from Central Sterile Supply Department (CSSD) to operating room. Be careful that no damages are applied to sterile pouch or container for transportation.

Levels of Reprocessing requirements:

Depending on the application of the product and with regard to risk evaluation the user has to classify the medical device according to the current Medical Device Directive for processing of medical devices as uncritical, semicritical or critical. Supporting information concerning this topic is listed in the table below. The user is responsible for correct classification of the medical device.

Classification	Definition	Processing
uncritical	Application part only contacts intact and uninjured skin	Cleaning Disinfection
semicritical	Application part contacts mucosa (intracavitary application)	Cleaning Disinfection (Disinfectant with virucidal effect)
critical	Application part contacts intracorporeal tissue directly (operative application)	Cleaning Disinfection (Disinfectant with virucidal effect - minimum) Sterilization

Flowchart of reprocessing process of this probe and accessories is as follows.



INSTRUCTIONS

5.1 Point of use (Pre-cleaning):

A) Biopsy probe EUP-B715

In the operating room after use of the probe.

1) Remove the biopsy attachment from the biopsy probe.
2) Flush the probe directly after use.
3) Flush patient's blood or fluid by tap water until the surface looks visually clean.
4) Wipe the surfaces of the probe with patient contact by gauze pad and remove superficial visible impurities.

B) Magnetic sensor attachment and spacer for EZU-RV2S

1) Remove the Magnetic sensor attachment and the Spacer for EZU-RV2S from the probe.
2) Immerse the Magnetic sensor attachment and the Spacer for EZU-RV2S in sufficient amount of high quality tap water. Scrub them using soft cloth or sponge to remove all visible soil and dried protein from the surface of them.

C) Biopsy attachment EZU-PA7B1

After first use, do not reprocess the biopsy attachment. The biopsy attachment is disposable. Do not reuse.

Containment and transportation:

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

5.2 Manual Cleaning and Disinfecting:

Prepare following items before manual cleaning and disinfection.

a) Detergent: Cidezyme®/ENZOL® (Johnson & Johnson) or another cleaning agent with approved material compatibility for this medical device.

b) Disinfectant: Cidex® OPA (Johnson & Johnson) or another disinfectant with approved material compatibility for this medical device.

c) Cleaning brushes if applicable, i.e. REF 09098 (Interlock) and REF 09326 (Interlock, for cleaning the entire probe).

d) Two tanks, one for cleaning and one for disinfection - optional: 1 additional tank for rinsing with deionized or tap water (sufficient size for immersion of the submergible part of the probe at full length)

e) 50 ml syringe

f) Soft, fluff free cloth or single use towel

g) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)

Manual Cleaning:

A) Biopsy probe EUP-B715

1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a different detergent is used, follow the manufacturer's instructions. If a different detergent is used, please also consider the approved material compatibility for the medical device.

2) Immerge the submergible part of the probe without connector into the diluted detergent (see figure 25). Using a 50 ml syringe flush the cavity of the probe 5 times under the liquid surface with 50 ml diluted detergent. Brush the whole length of the cavity of the probe 5 or more times by using an applicable brush. In addition the probe is brushed until visually clean.

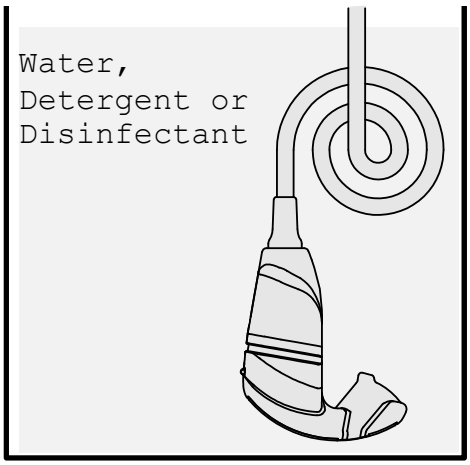


Fig.25 Immersion of the Probe

3) Wipe the submergible part of the probe under the surface of the detergent solution with a single-use fluff free soft cloth to remove all visible soil.

4) Wipe the non-submergible parts of the probe with a soft cloth dipped with a detergent.

5) Rinse the submergible part of the probe with running tap water for 1 minute.

6) Alternatively to step 5 suspend the submergible part of the probe in a tray filled with deionized water/tap water for 5 min.

7) Visually check the cavity and the outer surface of the biopsy probe for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

B) Magnetic sensor attachment and spacer for EZU-RVS2

1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a different detergent is used, follow the manufacturer's instructions. If a different detergent is used, please also consider the approved material compatibility for the medical device.

2) Immerge the Magnetic sensor attachment and the Spacer for EZU-RV2S into the diluted detergent (see figure 26). Wipe the magnetic sensor attachment under the surface of the detergent solution with a single-use fluff free soft cloth to remove all visible soil.

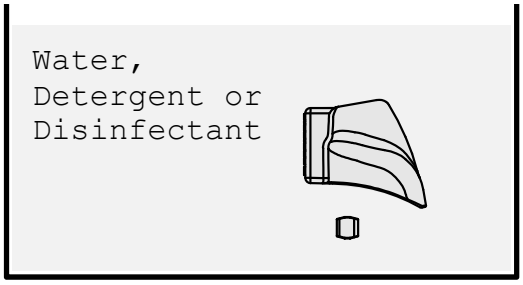


Fig.26 Immersion of the Magnetic sensor attachment and the Spacer for EZU-RV2S

3) Rinse the Magnetic sensor attachment and the Spacer for EZU-RV2S thoroughly with high-quality tap water to remove all debris and residue of the detergent solution.

4) Alternatively to step 3 suspend the Magnetic sensor attachment and the spacer for EZU-RV2S in a tray filled with deionized water/tap water for 5 min.

5) Visually check the outer surface of the Magnetic sensor attachment and the Spacer for EZU-RV2S for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

C) Biopsy Attachment EZU-PA7B1

Sterilization has not been made to the biopsy attachment shipped from the factory. Prior to the first use, be sure to clean, disinfect and sterilize it.

1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a different detergent is used, follow the manufacturer's instructions. If a different detergent is used, please also consider the approved material compatibility for the medical device.

2) Immerge the biopsy attachment into the diluted detergent for the recommended contact time of the detergent. (see figure 27).

3) Rinse the biopsy attachment thoroughly with high-quality tap water to remove all debris and residue of the detergent solution.

4) Alternatively to step 3 suspend the biopsy attachment in a tray filled with deionized water/tap water for 5 min.

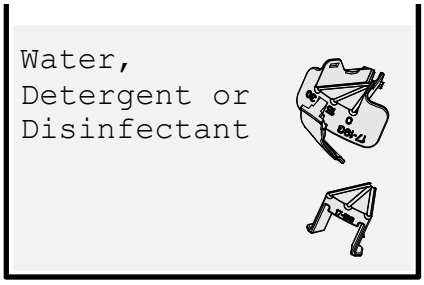


Fig.27 Immersion of the biopsy attachment EZU-PA7B1

Manual Disinfection:

A) Biopsy probe EUP-B715

1) Wipe the non-submergible parts of the probe with a soft and fluff free cloth with disinfectant.

2) Before immersing the device, it is recommended to test the concentration of disinfectant solution before each usage. The solution Cidex® OPA is ready for use and does not need to be diluted. Test strips to verify that the appropriate concentration of Cidex® OPA is correct are available by manufacturer. Test strips will indicate a concentration above the Minimum Effective Concentration (MEC). Please also note the expiration date of the test stripes. Temperature of disinfectant solution should be minimum 20 °C. The minimum contact time is 5 minutes. If a different disinfectant is used, follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.

3) Immerge the submergible part of the probe into the disinfectant. (see figure 25). Rinse the cavity of the biopsy probe with 50 ml disinfectant solution. Repeat this 4 times. Set a clock to insure the recommended contact time is 5 minutes.

4) Rinse the submergible part of the probe with running deionized water for approximately 1 minute.

5) Alternatively to step 4 suspend the submergible part of the probe in a tray filled with deionized water for 5 min.

6) Visually check the cavity of the biopsy probe and the outer surface of the probe for leavings of the disinfectant. If necessary, repeat the rinsing.

B) Magnetic sensor attachment and spacer for EZU-RVS2

1) Before immersing the device, it is recommended to test the concentration of disinfectant solution before each usage. The solution Cidex® OPA is ready for use and does not need to be diluted. Test strips to verify that the appropriate concentration of Cidex® OPA is correct are available by manufacturer. Test strips will indicate a concentration above the Minimum Effective Concentration (MEC). Please also note the expiration date of the test stripes. Temperature of disinfectant solution should be minimum 20°C. The minimum contact time is 5 minutes. If a different disinfectant is used, follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.
2) Immerge the Magnetic sensor attachment and spacer for EZU-RVS2 into the disinfectant. (see figure 26). Set a clock to insure the recommended contact time is 5 minutes.
3) Rinse the Magnetic sensor attachment and spacer for EZU-RVS2 with running deionized water for approximately 1 minute.
4) Alternatively to step 3 suspend the Magnetic sensor attachment and spacer for EZU-RVS2 in a tray filled with deionized water for 5 min.
5) Visually check the Magnetic sensor attachment and spacer for EZU-RVS2 for leavings of the disinfectant. If necessary, repeat the rinsing.

C) Biopsy attachment EZU-PA7B1

1) Before immersing the device, it is recommended to test the concentration of disinfectant solution before each usage. The solution Cidex® OPA is ready for use and does not need to be diluted. Test strips to verify that the appropriate concentration of Cidex® OPA is correct are available by manufacturer. Test strips will indicate a concentration above the Minimum Effective Concentration (MEC). Please also note the expiration date of the test stripes. Temperature of disinfectant solution should be minimum 20°C. The minimum contact time is 5 minutes. If a different disinfectant is used, follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.
2) Immerge the biopsy attachment into the disinfectant. (see figure 27). Set a clock to insure the recommended contact time is 5 minutes.
3) Rinse the biopsy attachment with running deionized water for 1 minute.
4) Alternatively to step 3 suspend the biopsy attachment in a tray filled with deionized water for 5 min.
5) Visually check the biopsy attachment for leavings of the disinfectant. If necessary, repeat the rinsing.

5.3 Drying:

1) Wipe the device with single use, fluff free wipe or towel for removing moisture on the surface of the equipment.
2) Dry the cavities by an air gun with compressed air. The compressed air should be filtered with a sterile filter that removes air particles of less than 0.2 µm. Dry until no visible moisture is left.
3) If using drying heater for medical device, the temperature limit is a maximum of 60°C. Dry until no visible moisture is left.
4) If using natural drying, temperature range should be between 15-30°C for a minimum time of 4 hours.

5.4 Packaging:

Store the disinfected probe in a dustproof environment until next application. If sterilization is necessary pack the cleaned and disinfected probe in a sterile barrier system for plasma sterilization (for example Polypropylene fleece or transparent package out of Polyethylene film and Tyvek®).

Additionally the probe can be placed on plastic mesh wires sufficient for plasma sterilization supplied by the manufacturer and packed in the material mentioned above afterwards.

The probe can be packed in a simple or double packing. The probe should be packed either in Polypropylene fleece or transparent package. The package has to be large enough to avoid tension to the sealing seam. Check the sealing seam after hot sealing for any defects.

The sealing machine should be designed for sealing transparent package out of Polypropylene film or Tyvek®.

In case of processing mistakes or defects the package has to be opened again and the device has to be packed and sealed again.

5.5 Sterilization: Sterilization

Sterilization methods of ethylene oxide gas, Sterrad 50, Sterrad 100S and Sterrad 200, STERRAD NX and STERRAD 100NX are available to this probe and accessories.

Follow the instructions of the sterilizer manufacturer regarding usage, temperature and sterilization-time etc. Handling and maximum input to chamber of sterilizer should be according to operation manual of the sterilizer.

Put a biopsy attachment EZU-PA7B1 and the magnetic sensor attachment and the spacer for EZU-RVS2 in an appropriate bag for sterilization (see figure 28).

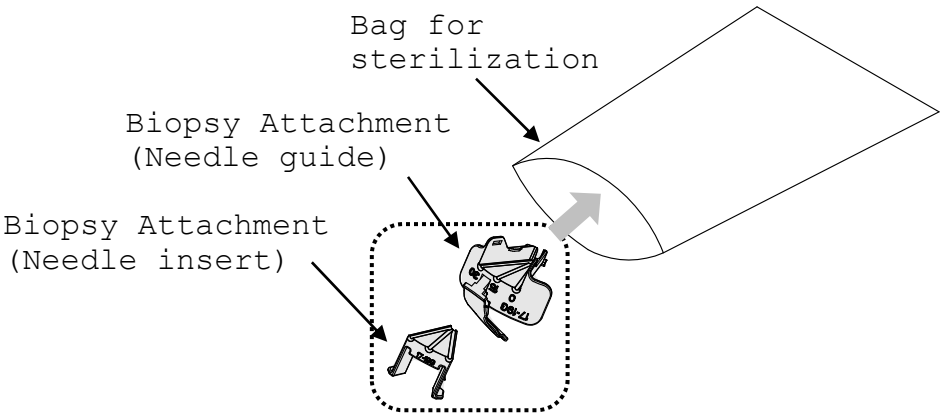


Fig.28 Sterilization of Biopsy Attachment

Sterile conditions of each method are as follows.

Sterilization Method	Condition
Plasma Sterilization: STERRAD® 50, 100S or 200 (*)	Short Cycle
Plasma Sterilization: Sterrad® NX or 100NX (*)	Standard cycle
ETO Sterilization	➢ Gas Type: 10% EO/ 90% HCFC ➢ Temperature: 50-55°C ➢ Exposure Time: More than 120 minutes ➢ Pressurization: 162-200kPa Depressurization: 13-8kPa ➢ Relative humidity: 40-90% ➢ Aeration is minimum 12 hours

* STERRAD® systems are manufactured by "Johnson & Johnson"

⚠ WARNING

1) Before performing sterilization, check that the operation data of sterilizer are in conjunction with min. and max. data applicable for the probe, biopsy attachment EZU-PA5B4, the Magnetic sensor attachment and the Spacer for EZU-RV2S.

2) Do not sterilize the probe and Biopsy attachment EZU-PA5B4, Magnetic Sensor Attachment and its spacer by Steam Autoclaving. If you autoclave them, they suffers serious damage and will be not functional.

3) Do not resterilize the biopsy attachment EZU-PA5B4. The biopsy attachment EZU-PA5B4 would be damaged by resterilization and cannot be used normally after resterilization.

6. Maintenance and Safety Inspection

1) After using the probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S, it should be cleaned and disinfected and Sterilization following "5. Cleaning, High Level Disinfection and Sterilization of the Probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S", then store it in a cool and dark place avoid high temperature and humidity, direct sunlight.

2) Visually inspect the surface of the probe head, housing, cable and connector for any crack, scratch or denaturalization. If you find any damage, do not use the probe and contact a service support immediately.

3) Visually inspect the surface of the Magnetic sensor attachment and the Spacer for EZU-RV2S for any crack, deformation or denaturalization. If you find any damage, do not use them and contact a service support immediately.

7. Safety Precautions

⚠ WARNING

1) Never use the probe if the probe head, housing or cable are cracked or damaged.

2) Warning is case of using probe covers which latex is contained to. The latex may cause such allergic reactions as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, and depression of blood pressure, shock and so on. For the patients suspected of latex allergy, do not use the latex-containing medical devices. If you observe any of above mentioned symptoms in your patient during the operation, stop the use of the latex-containing medical devices immediately and take an appropriate treatment to the patient.

3) In case of using sterile probe covers, probe covers are packaged sterile and are single-use only. Do not use if integrity of packaging is violated or if expiration date has passed.

⚠ CAUTION

1) The probe connector is not waterproof. Do not allow liquid to contact the connector.

2) Do not drop, hit or bent the probe.

3) Use only water, detergents and disinfectants in the suppliers list. Between uses store the probe holder of scanner.

4) Under sterile condition use appropriate protection for probe and cable. Some Latex material may create allergic reactions.

5) The probe and the biopsy attachment are not delivered disinfected or sterilized.

8. Specifications

8.1 Probe

Type:	EUP-B715 Biopsy probe
Acoustic working frequency:	3.5MHz
Technology:	Convex Array Probe
Dimensions:	See Fig.29 to 31
Weight:	Approx. 0.78kg (incl. cable and connector)
Scanning angle:	74 deg.
Biopsy needle angle:	0, 15 and 30degree
Biopsy attachment:	12-23G, Cool-tip™ (17G) and LeVeen™ Super Slim Needle (17G) (Usable needle size)
Probe materials:	Bio-compatible allergy free components
Acoustic output:	According to IEC60601-2-37 (ee Main Unit manual.)
Applicable system:	Depending on production and upgrade status. For detailed information contact a service support.
Classification:	MDD classification IIa
Cleaning:	Applicable detergents are listed in the suppliers list
Disinfection:	Applicable disinfectants are listed in the suppliers list
Sterilization:	ETO gas sterilization and Plasma sterilization
Operating conditions:	
Ambient temperature:	+10 – +35°C
Contact surface temperature (Temperature of examinee):	Max. 42°C
Relative humidity:	30 – 85%
Storage conditions:	
Temperature:	–10 – +55°C
Relative humidity:	10 – 95% (Subject to no condensation)

8.2 Suppliers List

The products listed below are seriously tested and approved for use with the biopsy probe EUP-B715.

Suppliers List

Product name	Manufacturer	Purpose
CIV-Flex™ Transducer Cover Sterile 14 X 91.5cm cover Telescopically-folded (610-542)	CIVCO MEDICAL INSTRUMENTS	Cover
Cidezyme™	Johnson & Johnson	Enzymatic detergent
Cidex Opa™	Johnson &Johnson	Disinfectant
Cidex Plus™ 28 day solution	Johnson & Johnson	Disinfectant
Cidex™	Johnson & Johnson	Disinfectant

Please contact your local distributor for a current version of the "Disinfectant/Sterilization Method Compatibility for Ultrasound Probe and Accessory List

9. Disposal of the probe

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

⚠ CAUTION

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.

Waste Electrical and Electronic Equipment (WEEE) Directive

The illustration on the right is required by the EU WEEE Directive to appear on all electrical and electronic equipment.
For proper disposal of this product in an EU nation, contact an EU office or agency and observe appropriate local and national regulations and laws.

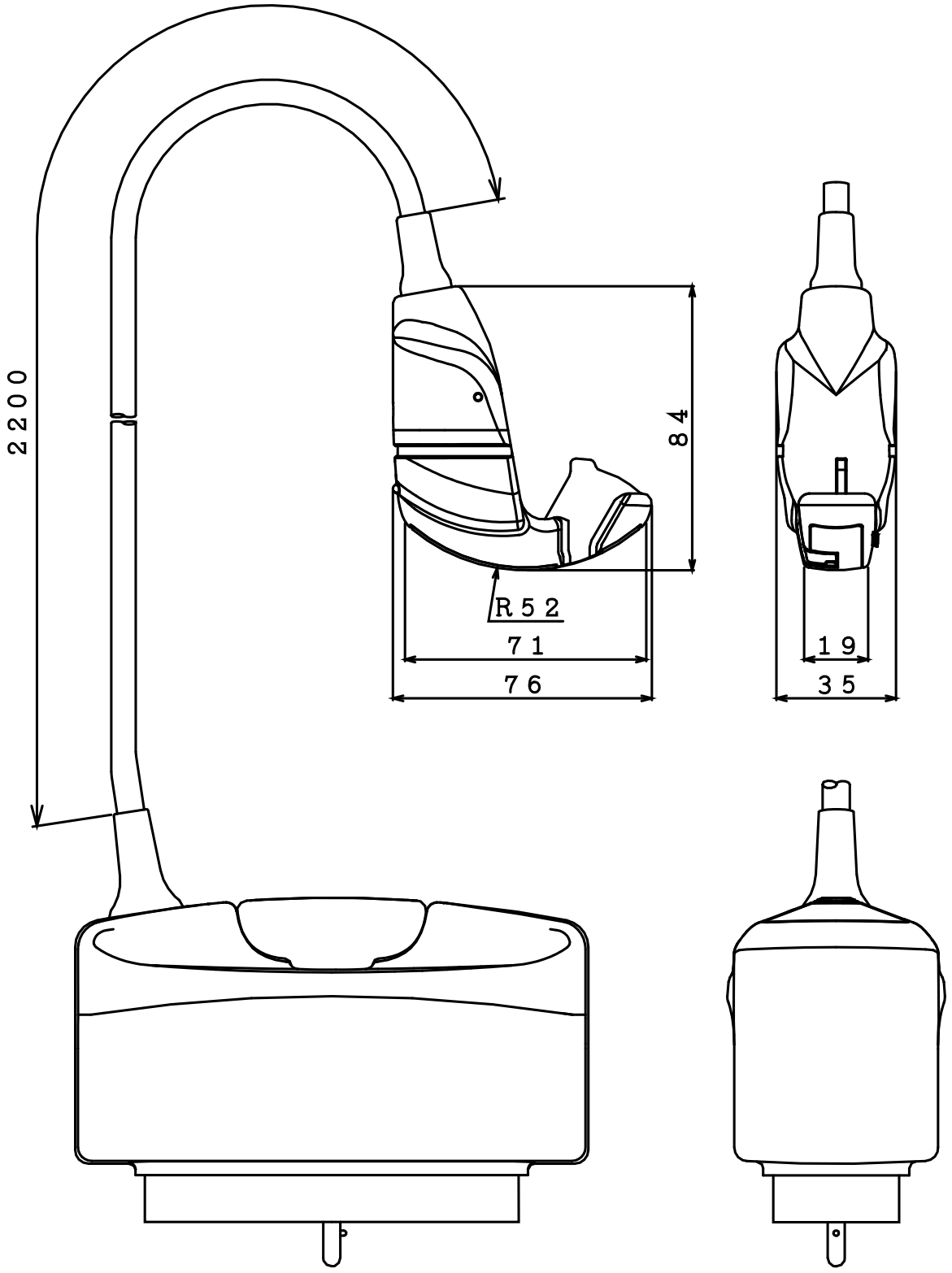


Fig.29 Dimension

Unit: mm

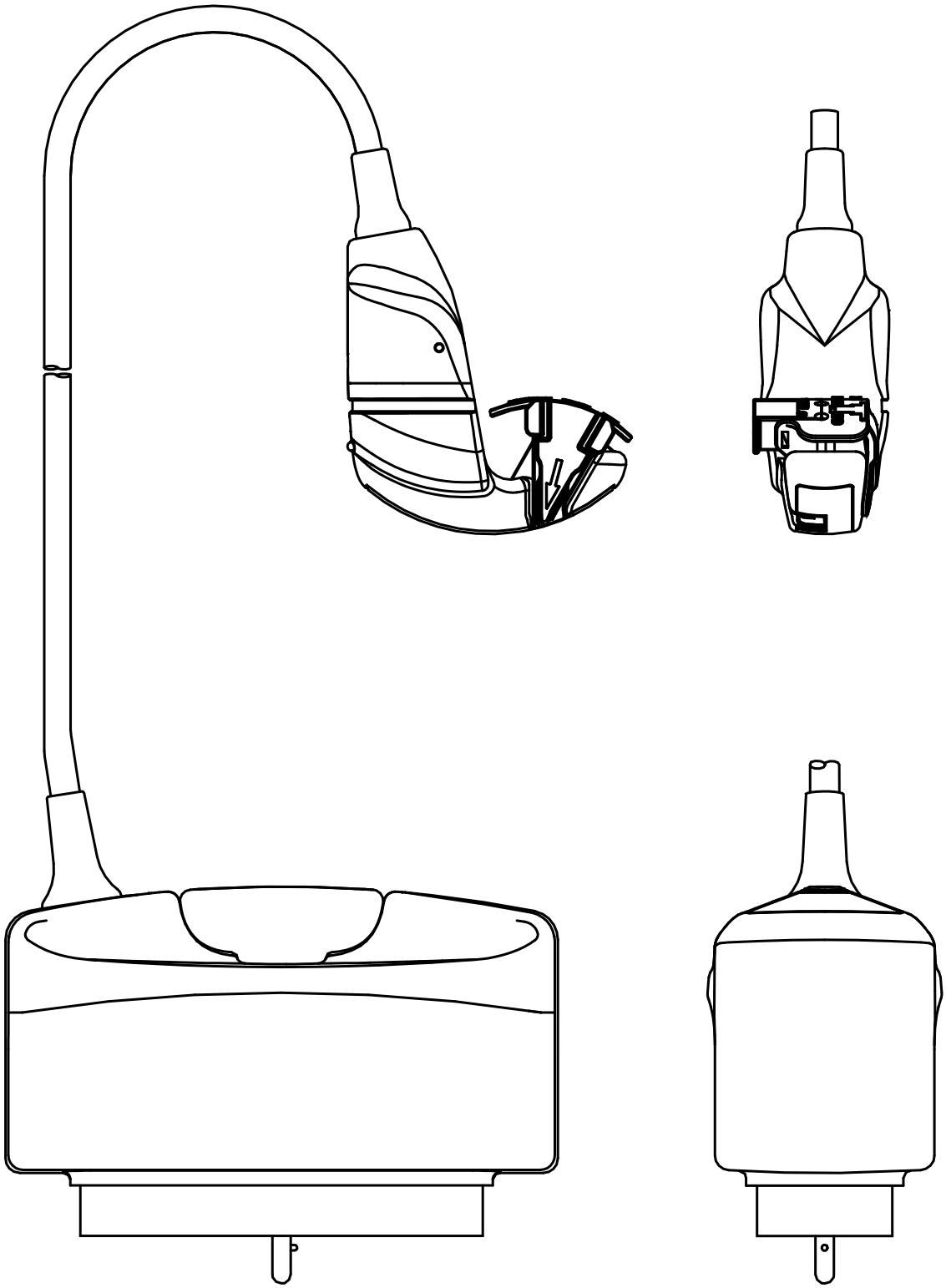


Fig.30 External view (with biopsy attachment)

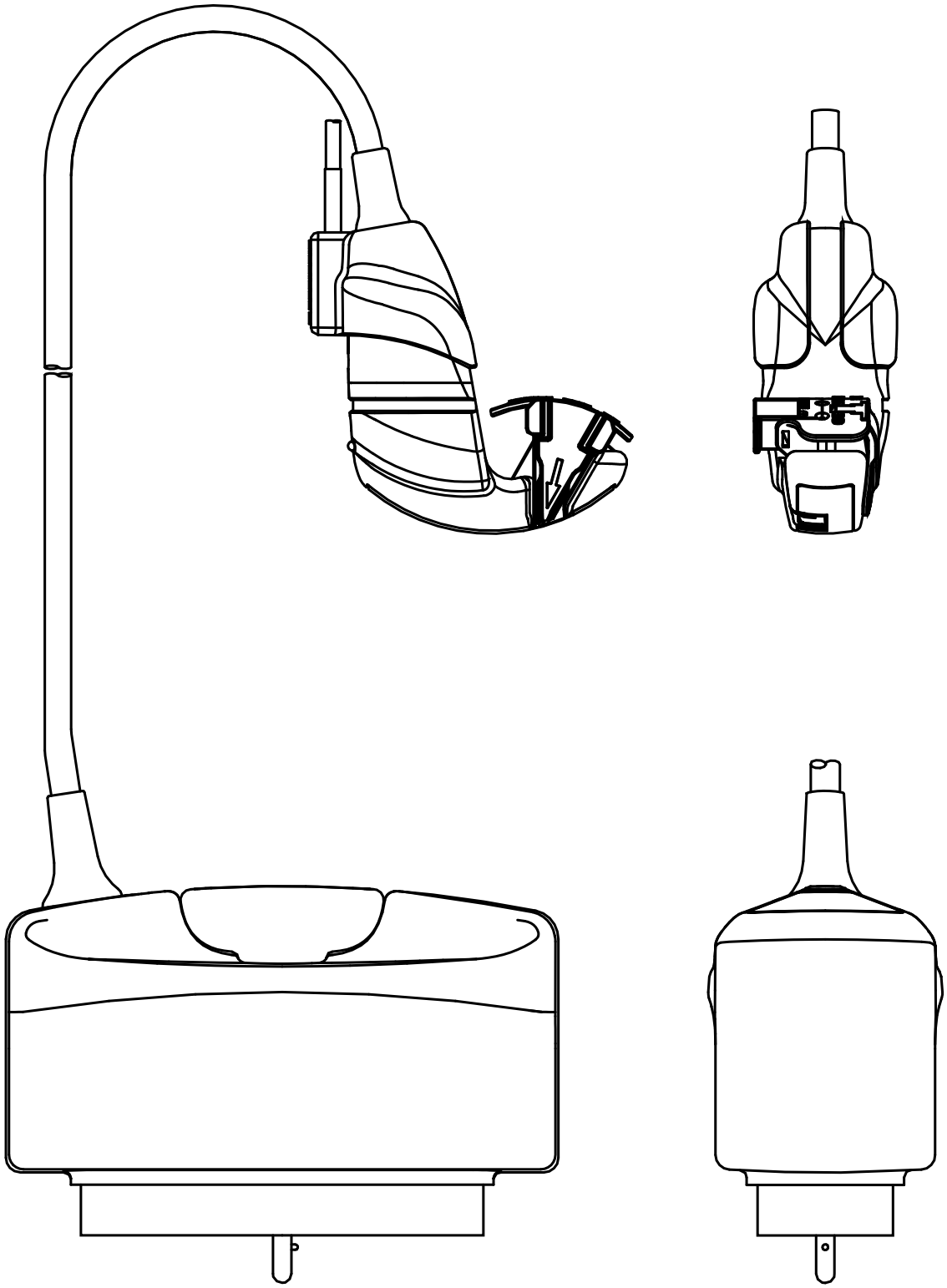


Fig.31 External view (with the Magnetic sensor attachment)