FUJIFILM

# Biopsy Probe

# EUP-B514

# 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.

FUJIFILM Healthcare Corporation

Q1E-EP0616-15



CE 0197

Manufacturer:

FUJIFILM Healthcare Corporation
2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan
+81-4-7131-4151
https://www.fujifilm.com/fhc/en


FUJIFILM Healthcare Deutschland GmbH
Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany


FUJIFILM Healthcare Logistics and Services Zweigniederlassung
der FUJIFILM Healthcare Europe Holding AG
Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany


FUJIFILM Healthcare UK Ltd.
1 Davy Close, Park Farm Industrial Estate
Wellingborough, Northamptonshire, NN8 6XX, United Kingdom

Local Distributor:

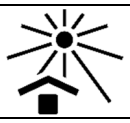
About this manual

This instruction manual shall provide instructions for using, cleaning, disinfecting and/or sterilizing our company's 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 a service support.
The following conventions are used throughout the manual to denote information of special emphasis.

| | |
|---|---|
| WARNING: | "Warning" is used to indicate the presence of a hazard which can cause severe personal injury, death, or substantial property damage if the warnings are ignored. |
| CAUTION: | "Caution" is used to indicate the presence of a hazard which will or can cause minor personal injury or property damage if the caution is ignored. |
| NOTICE: | "Notice" is used to notify people of installation, operation, or maintenance information which is important, but not hazard related. |

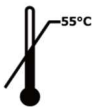
Graphical Symbols for Use in Labeling of Ultrasound Probes

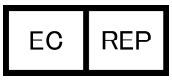
Refer to the following table about the meanings of them.

| Explanation of Symbol | Symbol | Descriptive Content |
|---|---|---|
| Manufacturer Company Name and Address |  | FUJIFILM Healthcare Corporation<br>2-1, Shintoyofuta, Kashiwa-shi, Chiba<br>277-0804 Japan<br>+81-4-7131-4151<br>https://www.fujifilm.com/fhc/en |
| Authorized Representative in The European Community |  | FUJIFILM Healthcare Deutschland GmbH<br>Otto-von-Guericke-Ring 3, D-65205 Wiesbaden<br>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 Ultrasound Probes.

| Location | Symbol | Definition |
|---|---|---|
| Probe connector<br>Storage case | CE 0197 | 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<br>See section 1.7. |
| 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 Sterilization System | STERRAD sterilization compatibility mark |
| Probe connector |  | Upper Limit of Temperature;<br>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 | MD | Medical device |
| Probe connector | Rx Only | By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only. |
| Probe connector<br>Storage case | # | MODEL NUMBER |
| Probe connector<br>Storage case | SN | SERIAL NUMBER |
| Probe connector<br>Storage case | UDI | UNIQUE DEVICE IDENTIFIER |
| Probe connector<br>Storage case |  | MANUFACTURER |

| | | |
|---|---|---|
| Storage case |  | The importer for EEA: European Economic Area region is represented according to European Union Directives 93/42/EEC and 2011/65/EU. |
| Storage case |  | DATE OF MANUFACTURE<br>The number under the mark indicates the year and month of manufacture. (in case of 2021-04)<br><br>COUNTRY OF MANUFACTURE<br>The character in the mark is the country of manufacture code defined by the International Organization for Standardization. (in case of JAPAN) |
| Storage case |  | AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |
| Package of Biopsy Attachment |  | Do not reuse |
| Package of Biopsy Attachment |  | Do not re-sterilize |

Contents

# 1. General

## 1.1. General

The EUP-B514 is a convex array probe.
The acoustic output of the EUP-B514 was measured according to the IEC61157 standard and the measurement was conducted by operating with our company's ultrasound diagnostic scanner.
The measured acoustic output is listed in the instruction manual of our company's ultrasound diagnostic scanner.
The EUP-B514 is categorized in class IIa according to Directive 93/42/EEC and classified as type BF according to IEC60601-1.

**⚠ 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-B514 is designed for observation and diagnosis mainly of the following regions by connecting with our company's ultrasound scanner.

- Biopsy (with Biopsy Attachment)
- General abdominal organs

## 1.4. Composition

The probe components of the EUP-B514 are as follows:

1) Probe EUP-B514 ····· 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

**⚠ CAUTION**

1) Use appropriate biopsy attachment that is correspondent with the needle that you use.
2) If you use Cool-tipTM 17G or LeVeenTM SuperSlim needle 17G of RFA needle, use the biopsy attachment EZU-PA5B4-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.

**⚠ WARNING**

The biopsy attachment is disposable. Do not reuse. When the biopsy attachment is reused, it may run the risk of exposing the patient to infectious diseases.

## 1.5. 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-PA5B4-1 for 12G-13G····· 10 pieces/pack
- EZU-PA5B4-2 for 14G-16G····· 10 pieces/pack
- EZU-PA5B4-3 for 17G-19G····· 10 pieces/pack
- EZU-PA5B4-4 for 20G-23G····· 10 pieces/pack
- EZU-PA5B4-C for Cool-tipTM (17G), LeVeenTM SuperSlim Needle(17G) ····· 10 pieces/pack

### 1.5.2. Puncture Adapter

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

1) Puncture adapter BA-002-G15-A0

There are following types according to the guide distance.

a) BA-002-G15-A0D13: Needle size: 15G, puncture angle: 0° and guide distance: 13mm
b) BA-002-G15-A0D1520: Needle size: 15G, puncture angle: 0° and guide distance: 15mm or 20mm

2) Puncture adapter BA-002-G15-A15

There are following types according to the guide distance.

a) BA-002-G15-A15D13: Needle size: 15G, puncture angle: 15° and guide distance: 13mm
b) BA-002-G15-A15D15: Needle size: 15G, puncture angle: 15° and guide distance: 15mm

### 1.5.3. Waterproof box EZU-WB1 (Option)

1) Waterproof box EZU-WB1····· 1 piece
2) Airtight tester····· 1 piece
3) Instruction manual····· 1 copy

This accessory is necessary for protecting the probe connector against liquid when the probe is disinfected by washer-disinfector. About how to connect this accessory to the probe connector, refer to the instruction manual of Waterproof box EZU-WB1.

## 1.6. Option of our company's ultrasound diagnostic scanner

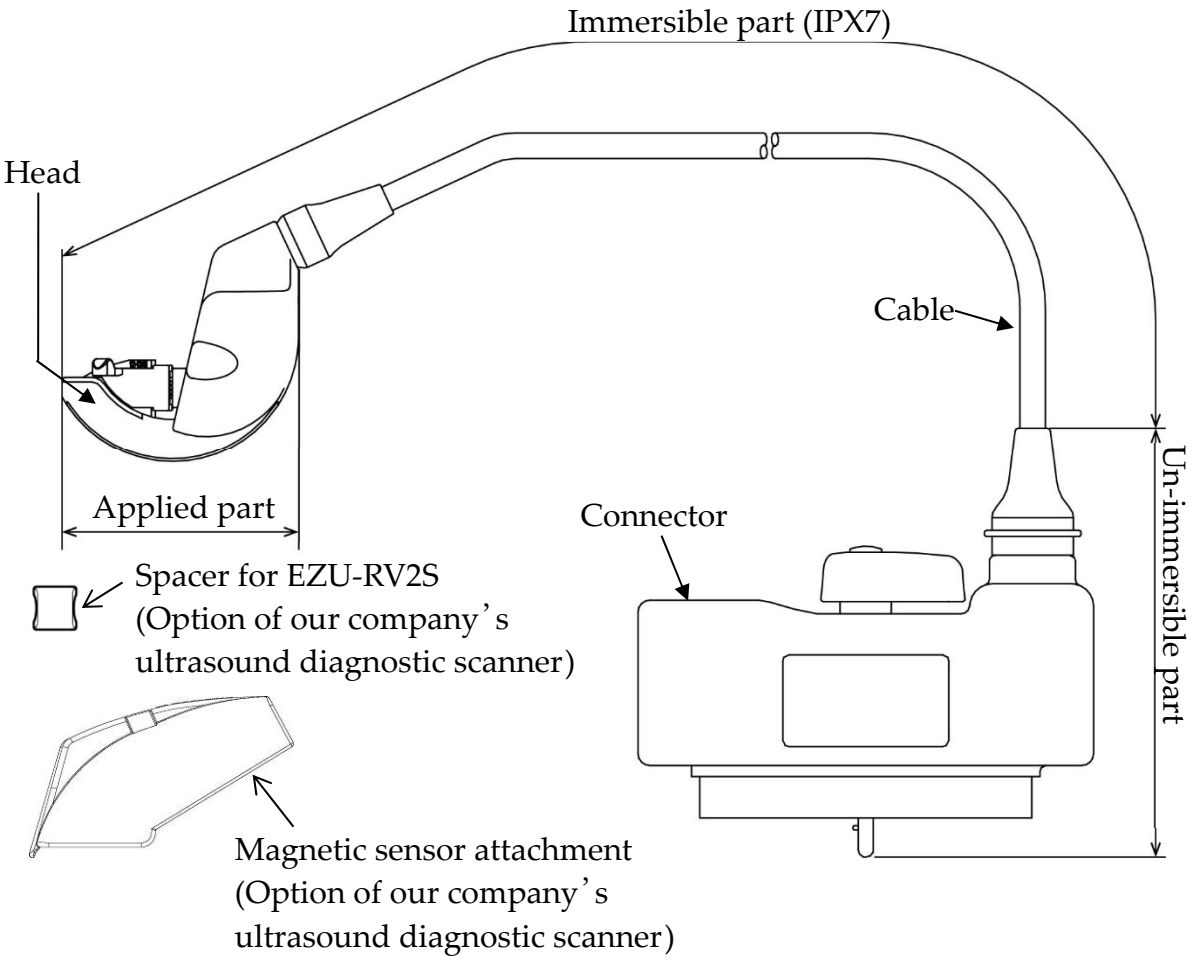
### 1.6.1. Magnetic Sensor Attachment

1) Magnetic sensor attachment
2) Spacer for EZU-RV2S

**⚠ CAUTION**

Sterilization has not been made to the Magnetic sensor attachment and the Elasto coupler, shipped from the factory. Prior to use of it, be sure to clean and sterilize it.

1.7. 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.

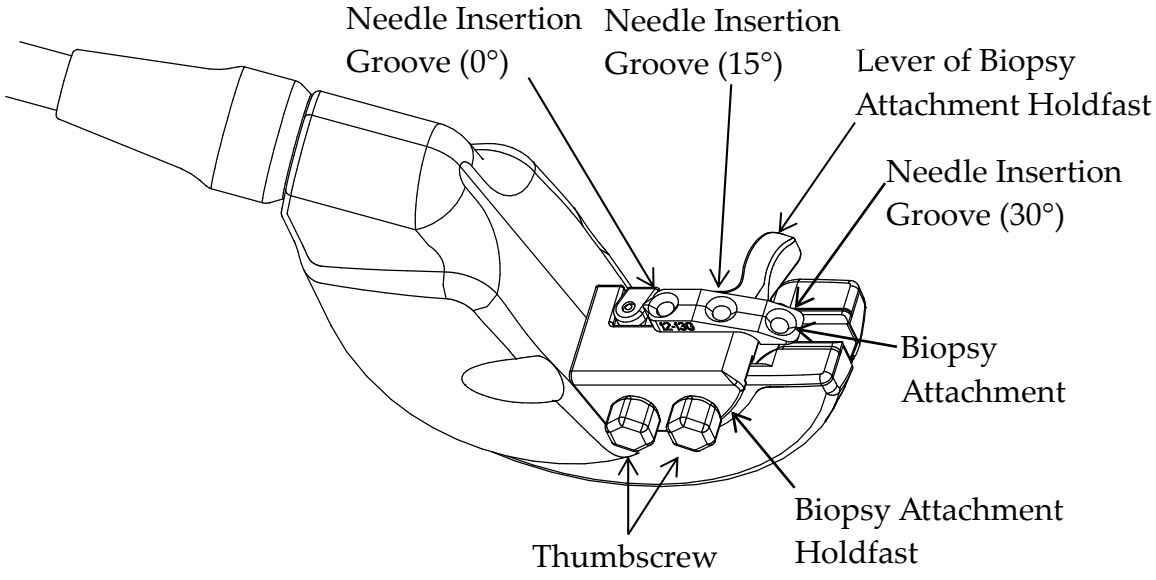



Fig.1 External View

2. Inspection before Use

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

2.1. Inspection for Appropriate Connection

2.1.1. Confirm that the system is correctly operating. Refer to the instruction manual for the ultrasound diagnostic scanner.

2.1.2. 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.2) Relationship between the needle insertion groove and needle guide line angle following "3. Operation Procedure" Fig. 5. Also, Confirm that the needle moves smoothly and there is no blurring between the needle and biopsy attachment.

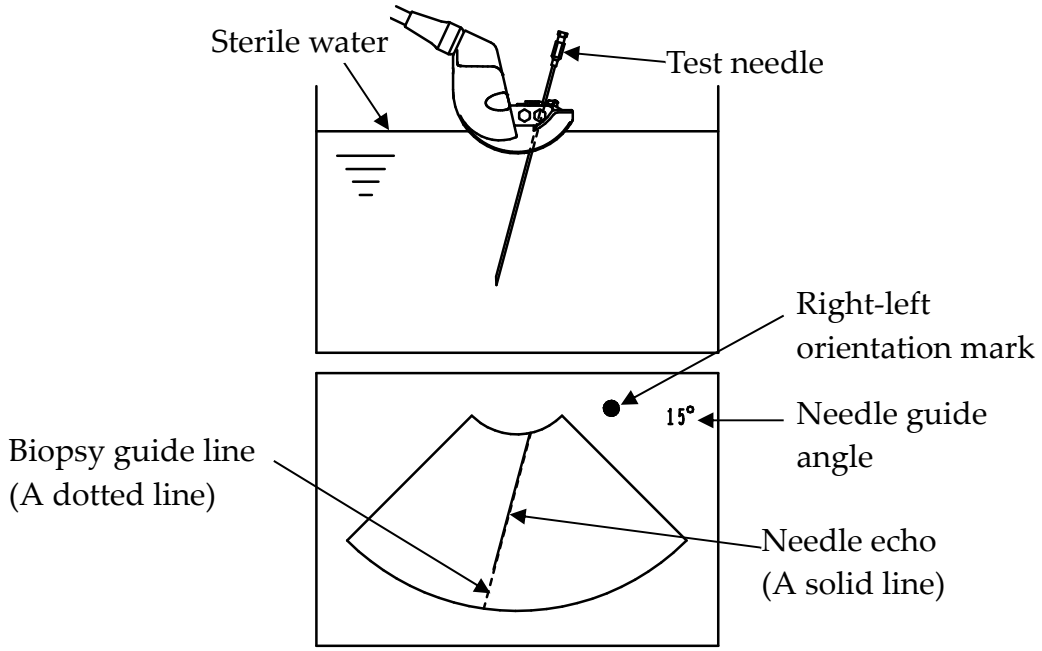



Fig.2 Echo image of test needle

2.1.3. Confirm that the biopsy attachment can be mounted to the biopsy attachment holdfast and detached from it.
2.1.4. Do not attach or connect unauthorized devices or instruments on the probe, such as unauthorized biopsy attachments.

⚠ 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.

2.2. Inspection for Material Surface
2.2.1. Visually inspect the surface of the probe head, housing and cable for any crack, scratch or denaturalization.
2.2.2. Confirm the biopsy attachment for any abnormality. Especially confirm that any foreign article is not in the needle groove and the attachment can be open and closed.
2.2.3. Visually inspect the Magnetic sensor attachment and the Spacer for EZU-RV2S for any crack, deformation or denaturalization.

3. Operation Procedure

1) Confirm that the probe is disinfected or sterilized.
2) Confirm that the biopsy attachment is sterilized.
3) Confirm that the Magnetic sensor attachment and the Spacer for EZU-RV2S are disinfected or sterilized, when use RVS (Real-time Virtual Sonography).
4) Connect the probe to the ultrasound diagnostic scanner, operate the scanner, and adjust the image, all according to the instructions given in the operation manual for the ultrasound diagnostic scanner with which the probe is used as connected.
5) Confirm the direction of the probe. Relationship between the direction of the probe and the image is shown in Fig.3. The Right-left orientation mark on the image indicates the direction of the attachment holdfast side on the probe.

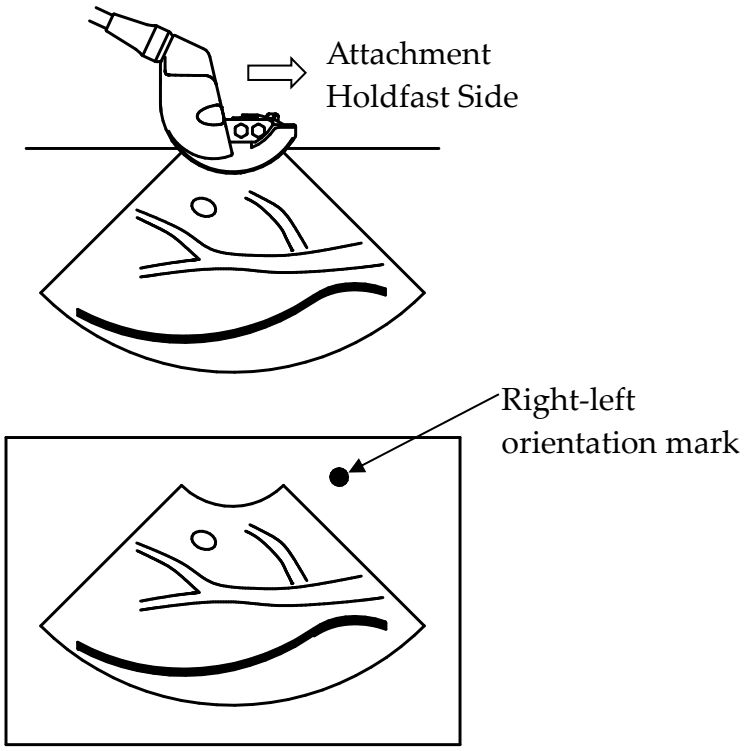



Fig.3 Relationship between the direction of the probe and the Right-left orientation mark

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

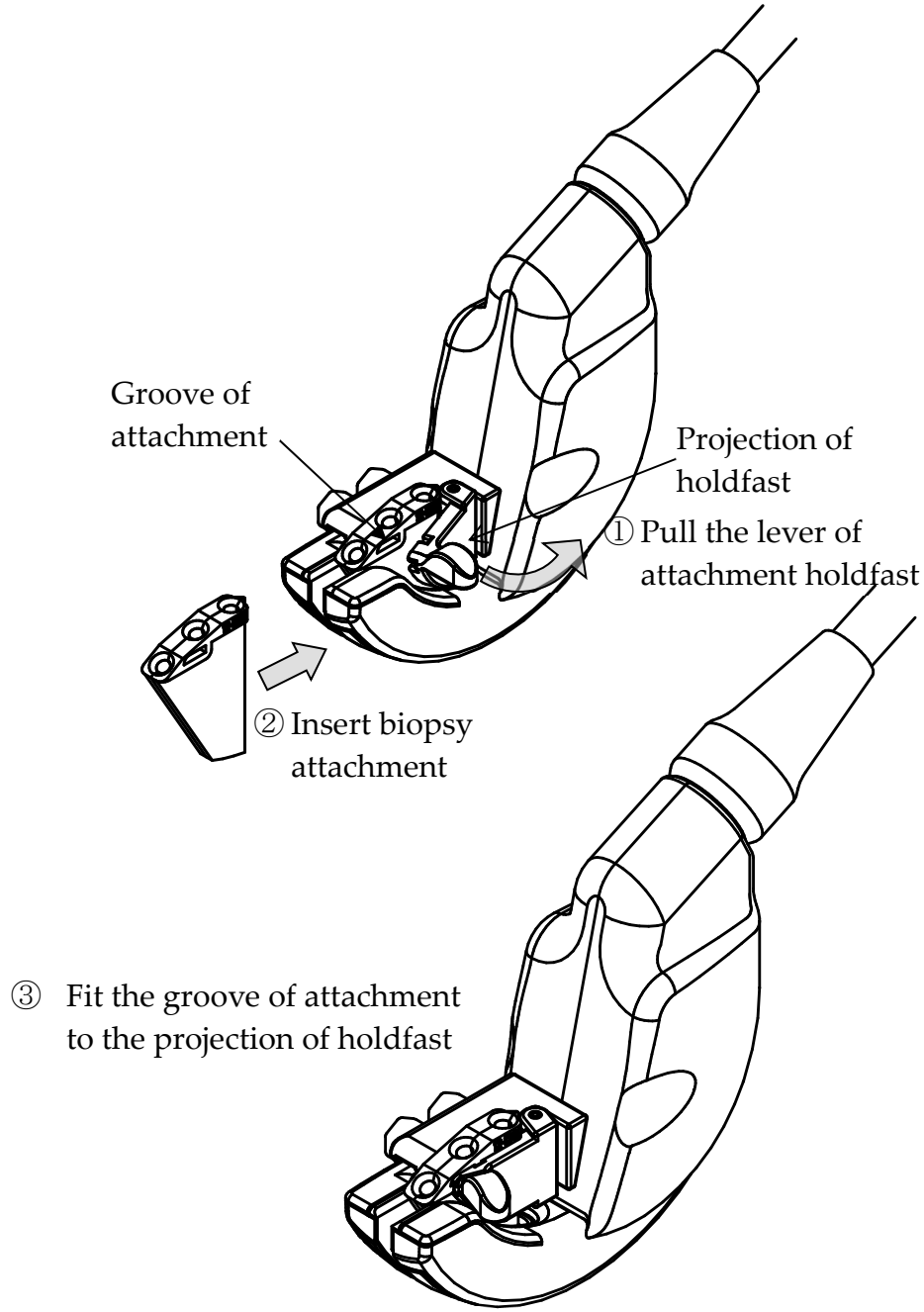



Fig.4 Mounting Biopsy Attachment

⚠ CAUTION

If you operate biopsy procedure, use the biopsy attachment certainly.

7) 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.

8) 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.
9) 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.5.

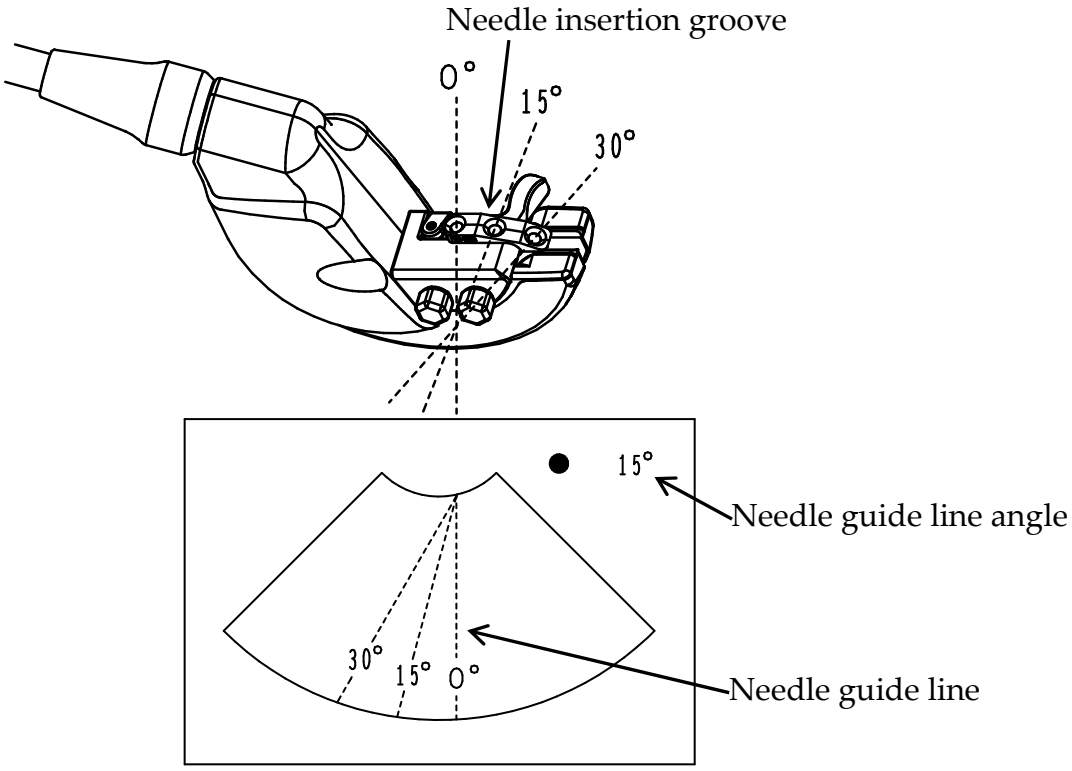



Fig.5 Relationship between the needle insertion groove and biopsy guide line angle

**⚠ WARNING**

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**

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.]

10) 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**

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.

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

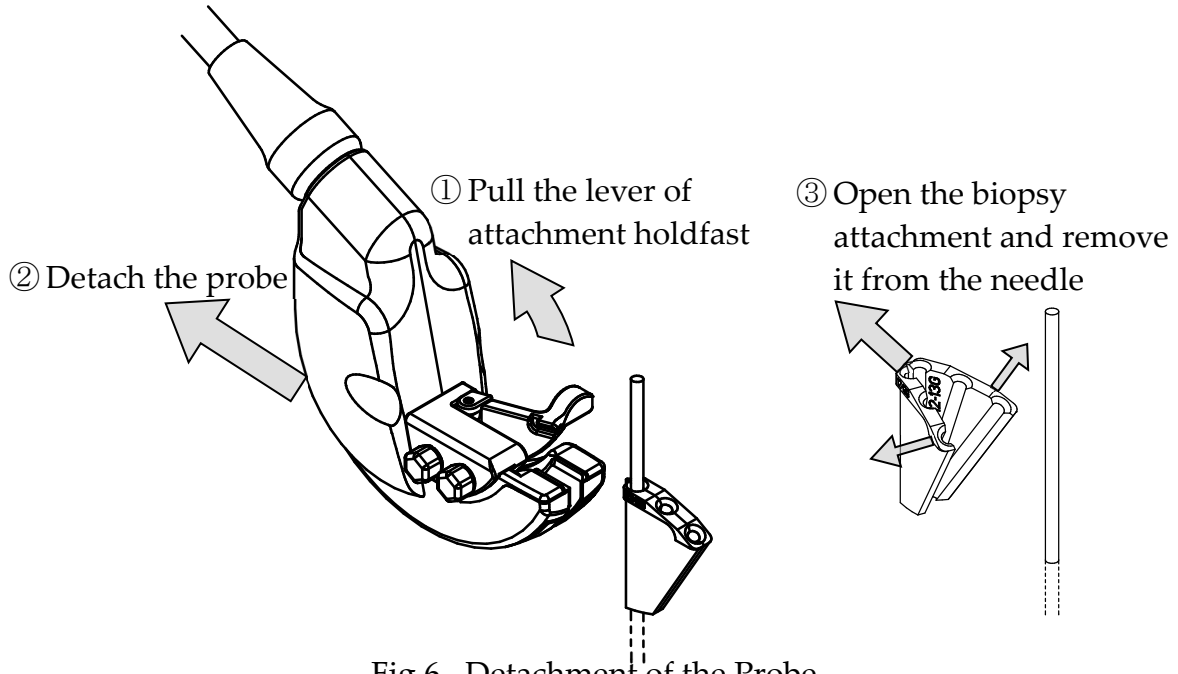



Fig.6 Detachment of the Probe

12) After using the probe, perform the reprocessing procedure in accordance with the procedure stated in "5. Reprocessing procedure of the probe" every time immediately after completing the ultrasound examination.
13) After using the Magnetic sensor attachment and the Spacer for EZU-RV2S, perform the reprocessing procedure in accordance with the procedure stated in "7. Reprocessing procedure of the Magnetic Sensor Attachment and the Spacer for EZU-RV2S" every time immediately after completing the ultrasound examination.

4. Option of our company's ultrasound diagnostic scanner

In case of using RVS (Real-time Virtual Sonography), confirm that type of the Magnetic sensor. There are two types of the Magnetic sensors for the EUP-B514, the EZU-RV2S and the EZU-RV3S. The Magnetic sensor (EZU-RV2S) and the Magnetic sensor (EZU-RV3S) are shown in Fig.7 and Fig.11. The use of the EUP-B514 with either of the Magnetic sensors enables the user to perform RVS (Real-time Virtual Sonography).

4.1. Magnetic sensor (EZU-RV2S)

The Magnetic sensor (EZU-RV2S) as shown in Fig.7 is the Magnetic sensor for the EUP-B514.

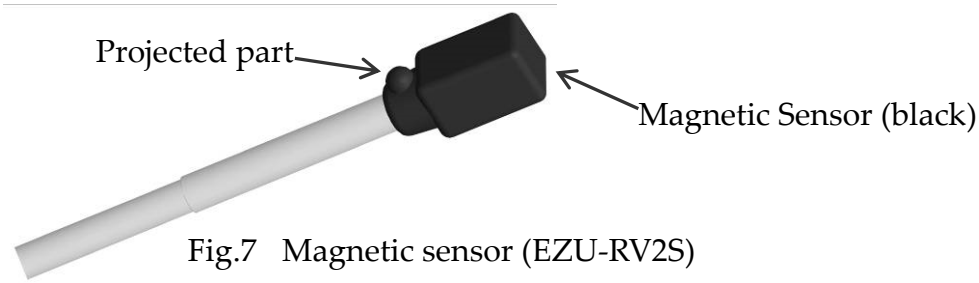



Fig.7 Magnetic sensor (EZU-RV2S)

4.1.1. How to attach the Magnetic sensor

The Procedure of attaching the Magnetic sensor is as follows.

1) Confirm that the probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S are disinfected or sterilized.
2) Connect the probe, operate the ultrasound diagnostic scanner, and adjust the image according to the instructions given in the operation manual for the ultrasound diagnostic scanner.
3) To use Real-time Virtual Sonography (RVS), attach the Magnetic sensor as shown below.
   a) Attach the Spacer for EZU-RV2S to the Magnetic sensor.
   b) Insert the Magnetic sensor (EZU-RV2S) into the Magnetic sensor attachment with the correct direction as shown in Fig.8.
   c) Attach the Magnetic sensor attachment to the probe.

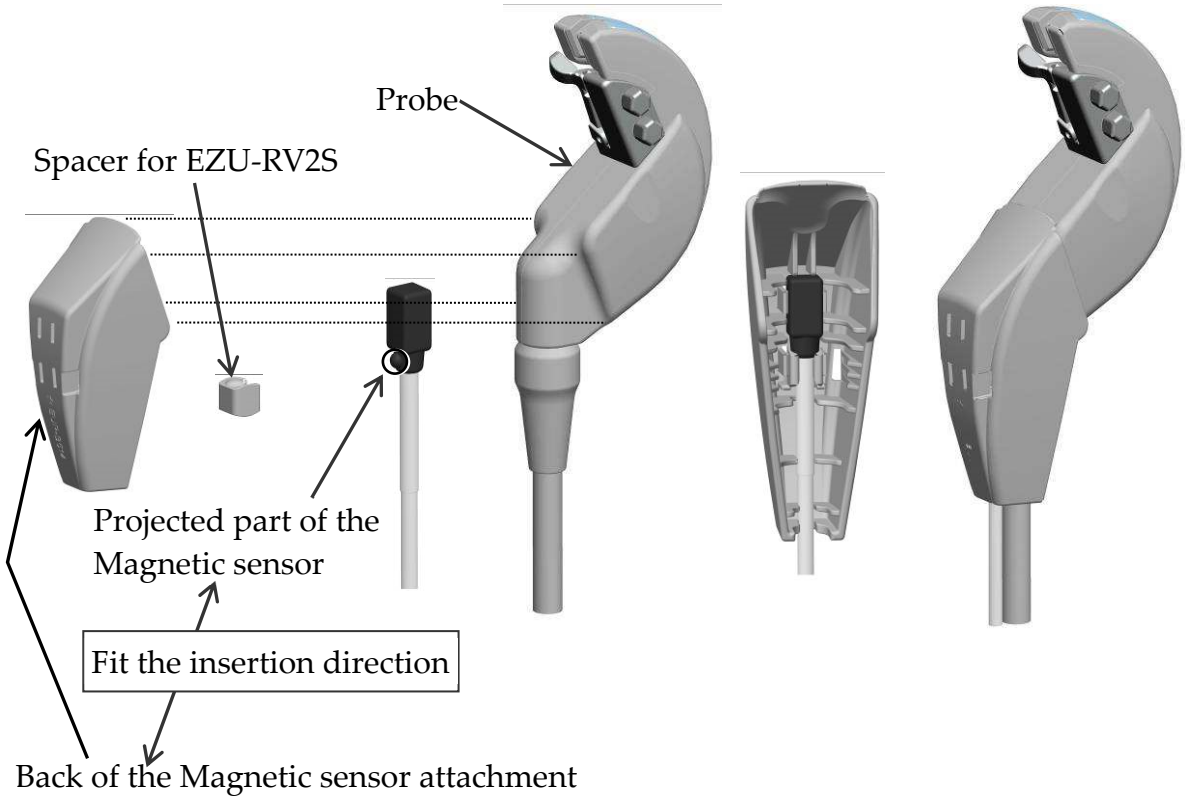



Fig.8 How to attach the Magnetic sensor

⚠ CAUTION

1) Never attach the Magnetic sensor attachment to the probe in the incorrect direction, otherwise it may result 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. How to release the Magnetic sensor

1) The procedure of releasing the Magnetic sensor from the probe is as follow. Release the Magnetic sensor attachment from the probe as shown in Fig.9.

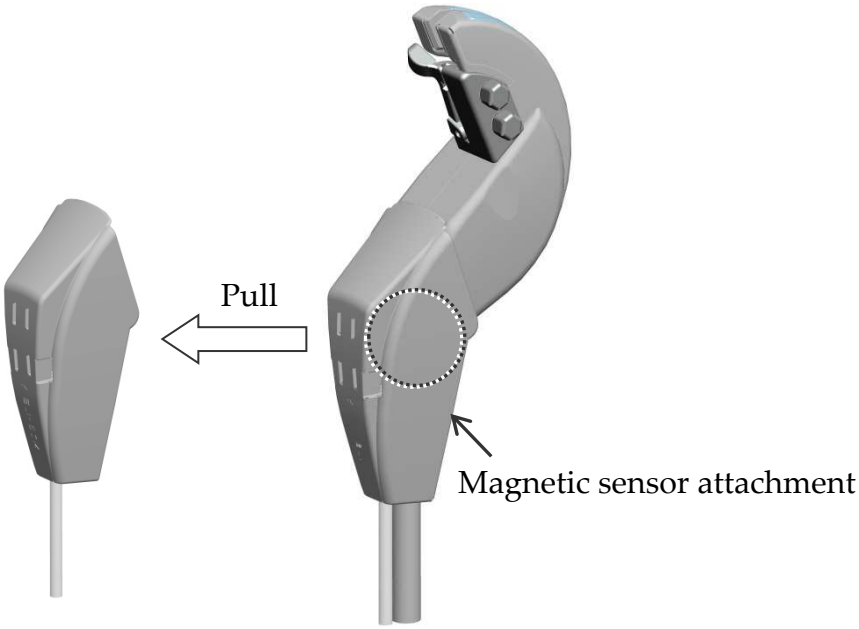



Fig.9 How to release the Magnetic sensor attachment

2) Release the Magnetic sensor from the Magnetic sensor attachment as shown in Fig.10 and release the Spacer for EZU-RV2S from the Magnetic sensor.

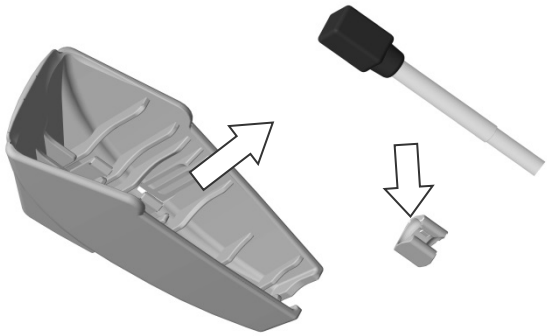


Fig.10 How to release the Magnetic sensor

⚠ CAUTION

Do not lose the spacer for EZU-RV2S because it is very small.

4.2. Magnetic sensor (EZU-RV3S)

The Magnetic sensor (EZU-RV3S) as shown in Fig.11 is also the Magnetic sensor for the EUP-B514.

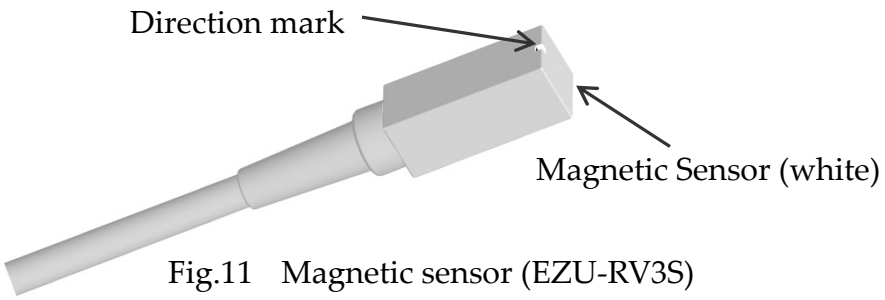



Fig.11 Magnetic sensor (EZU-RV3S)

4.2.1. How to attach the Magnetic Sensor

The procedure of attaching the Magnetic sensor is as follows.

1) Confirm that the probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S are disinfected or sterilized.
2) Connect the probe, operate the ultrasound diagnostic scanner, and adjust the image according to the instructions given in the operation manual for the ultrasound diagnostic scanner.
3) To use Real-time Virtual Sonography (RVS), attach the magnetic sensor as shown below.
   a) Attach the Magnetic sensor into the probe with the correct direction as shown in Fig.12.
   b) Place the Magnetic sensor attachment on the probe as shown in Fig.12.

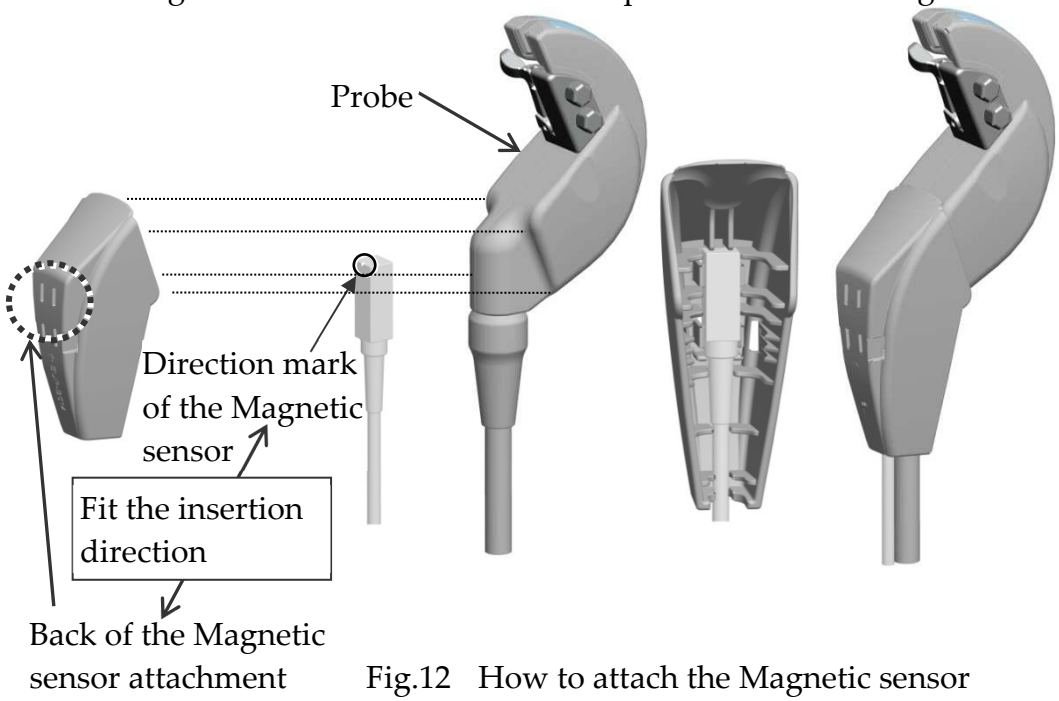



Fig.12 How to attach the Magnetic sensor

⚠ CAUTION

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

4.2.2. How to release the Magnetic Sensor

The procedure of releasing the Magnetic sensor from the probe is as follow.

1) Release the Magnetic sensor attachment from the probe as shown in Fig.13.

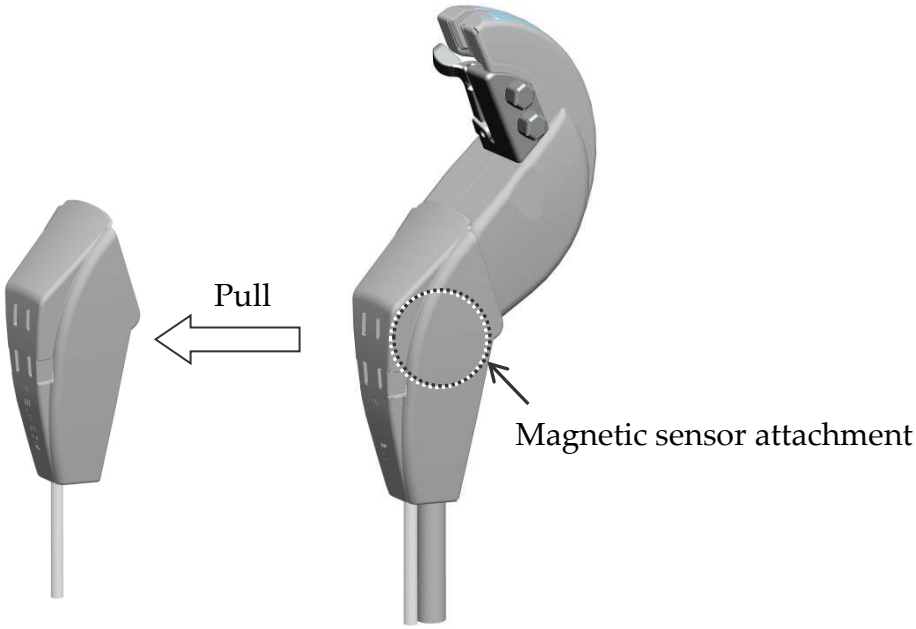



Fig.13 How to release the Magnetic sensor attachment

2) Release the Magnetic sensor from the Magnetic sensor attachment as shown in Fig.14.

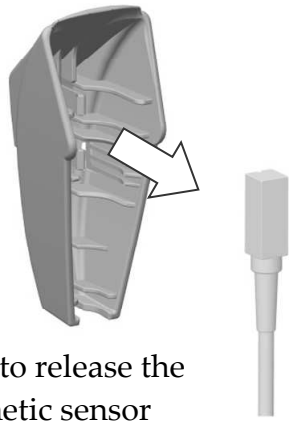


Fig.14 How to release the Magnetic sensor

5. Cleaning, Disinfection and Sterilization of the Probe, Biopsy Attachment Holdfast 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-PA5B4 and biopsy attachment holdfast shipped from the factory. Prior to the first use, be sure to sterilize them. Before sterilization process, clean the biopsy attachment holdfast as described here. The biopsy attachment EZU-PA5B4 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, Biopsy Attachment Holdfast, 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-PA5B4, 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.

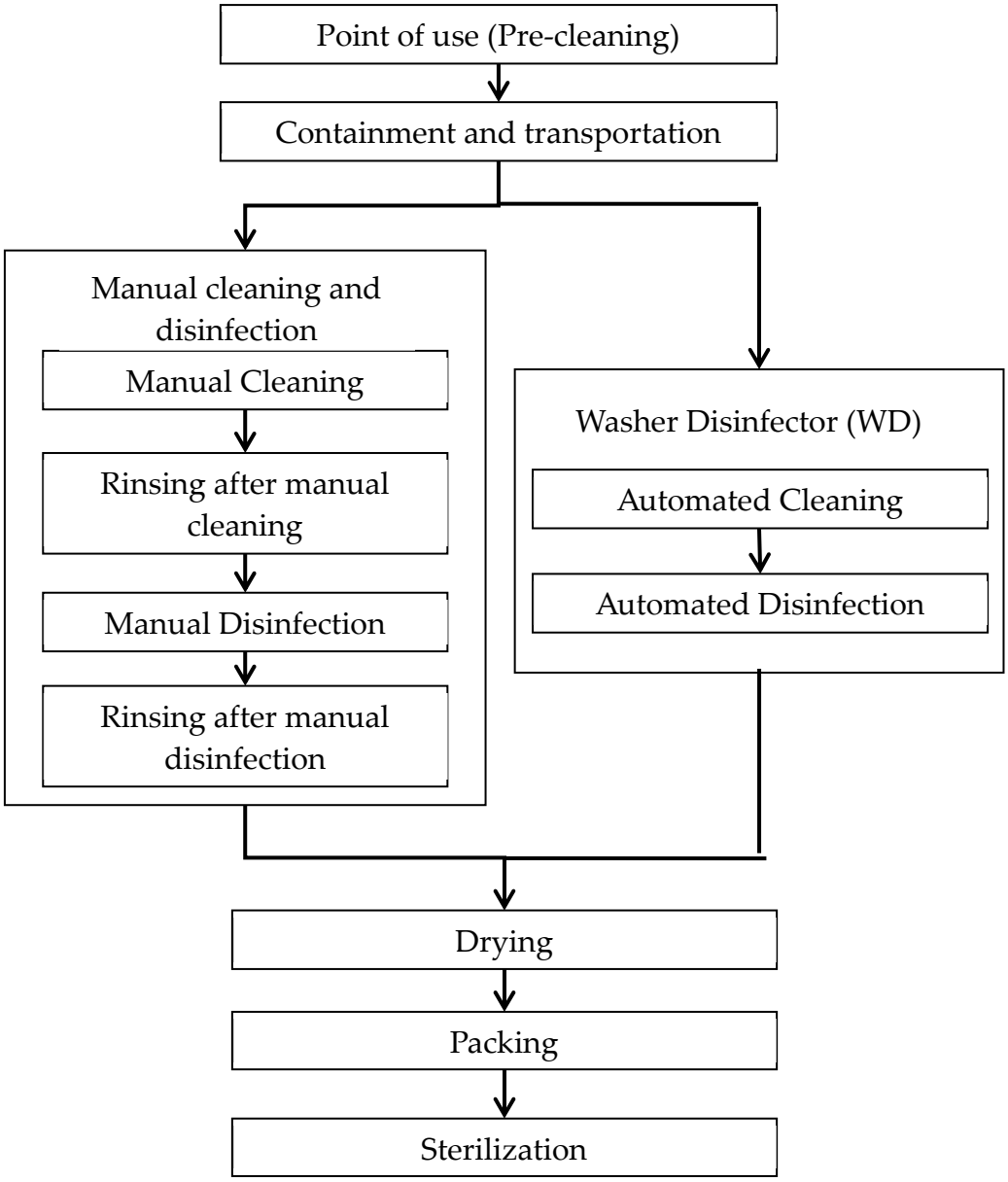
| | |
|---|---|
| WARNINGS | - The probe and the biopsy attachment holdfast are delivered unsterile. Prior to the first use sterilize the probe and the biopsy attachment holdfast.<br>- The cavity and the spiral spring of the biopsy attachment holdfast require particular attentions during all processes. The biopsy attachment holdfast must be manually pre-cleaned using ultrasound prior to manual reprocessing as well as automated reprocessing.<br>- Do not exceed 55°C (131°F).<br>- Probe connector has no water resistance. If washer-disinfector is used, connect the waterproof box to the probe connector certainly. |
| 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.<br>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<br><br>Disinfection |
| semicritical | Application part contacts mucosa (intracavitary application) | Cleaning<br><br>Disinfection (Disinfectant with virucidal effect) |
| critical | Application part contacts intracorporeal tissue directly (operative application) | Cleaning<br><br>Disinfection (Disinfectant with virucidal effect - minimum)<br><br>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-B514

In the operating room after use of the probe.

1) Remove the biopsy attachment and biopsy attachment holdfast from the biopsy probe (see figure 6 and 15).
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.

B) Biopsy Attachment Holdfast

Flush the biopsy attachment holdfast directly after use. Then proceed as described below.

Manual pre-cleaning of the biopsy attachment holdfast using ultrasound:

1) Prepare following items before manual pre-cleaning of the biopsy attachment holdfast using ultrasound:
   a) Ultrasound bath: i.e. Euronda, Eurosonic 4D
   b) Detergent: Cidezyme®/ENZOL® (Johnson & Johnson)
   c) 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)
2) Fill the ultrasound bath with the detergent. The temperature of the detergent solution should be between 15-30°C (59-86°F), concentration is 1.6%. If a different detergent is used, follow the manufacturer's instructions. Please also consider the material compatibility.
3) Immerge the biopsy attachment holdfast into the diluted detergent in the ultrasound bath and switch on the ultrasound bath for a time of 20 min. at 25°C (77°F).
4) Remove the biopsy attachment holdfast and continue with the manual or automated reprocessing.

C) Magnetic sensor attachment and spacer for EZU-RV2S

1) Remove the Magnetic sensor attachment and the Spacer for EZU-RV2S from the scanner.
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.

D) Biopsy attachment EZU-PA5B4

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)
b) Disinfectant: Cidex® OPA (Johnson & Johnson)
c) Cleaning brushes if applicable, i.e. REF 09098 (Interlock) and REF 09326 (Interlock, for cleaning the entire probe and the biopsy attachment holdfast).
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-B514

1) The temperature of the detergent solution should be between 15-30°C (59-86°F), 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 16). 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.

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.

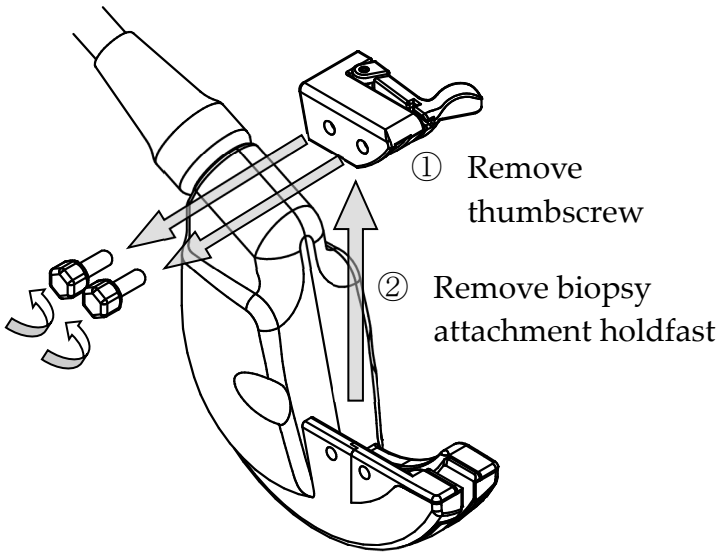



Fig.15 Detachment of the Biopsy Attachment Holdfast

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.

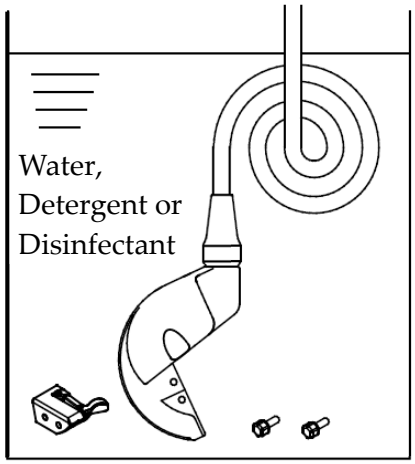



Figure 16 Immersing the biopsy probe and biopsy attachment holdfast

B) Biopsy Attachment Holdfast

1) The temperature of the detergent solution should be between 15-30°C (59-86°F), 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) Remove the 2 screws from the biopsy attachment holdfast (see figure 15) and immerge them into the diluted detergent. Immerge the biopsy attachment holdfast into the diluted detergent (see figure 16). Using a 50 ml syringe flush the cavity and the spiral spring of the biopsy attachment holdfast 5 times under the liquid surface with 50 ml diluted detergent. Brush the whole length of the cavity and the spiral spring of the biopsy attachment holdfast 5 or more times by using an applicable brush. In addition the biopsy attachment holdfast is brushed until visually clean.
3) Wipe the parts of the biopsy attachment holdfast under the surface of the detergent solution with a single-use fluff free soft cloth to remove all visible soil.
4) Rinse the biopsy attachment holdfast with running tap water for 1 minute.
5) Alternatively to step 5 suspend the equipment in a tray filled with deionized water/tap water for 5 min and rinse the cavity of the biopsy attachment holdfast with 50 ml deionized water/tap water 5 times.
6) Visually check the cavity and the outer surface of the biopsy attachment holdfast for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

C) Magnetic sensor attachment and spacer for EZU-RVS2

1) The temperature of the detergent solution should be between 15-30°C (59-86°F), 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 17). 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.
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 5 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.

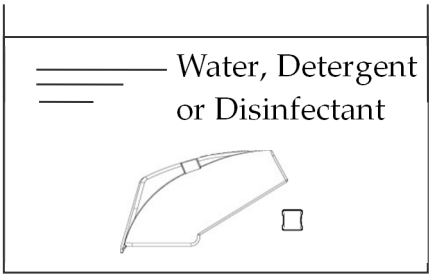



Fig.17 Immersion of the Magnetic sensor attachment and the Spacer for EZU-RV2S

D) Biopsy Attachment EZU-PA5B4

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 (59-86°F), 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 18).
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 5 suspend the biopsy attachment in a tray filled with deionized water/tap water for 5 min.

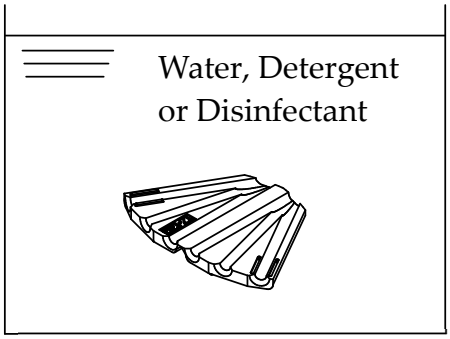



Fig.18 Immersion of the biopsy attachment EZU-PA5B4

Manual Disinfection:

A) Biopsy probe EUP-B514

1) Wipe the non-submergible parts of the probe with a soft and fluff free cloth with disinfectant.
2) Before immersing the equipment, 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 (68°F). 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 16). 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) Biopsy attachment holdfast

1) Before immersing the equipment, 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 (68°F). 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 dismantled biopsy attachment holdfast into the disinfectant. (see figure 16). Rinse the cavity of the dismantled biopsy attachment holdfast with 50 ml disinfectant solution. Repeat this 4 times. Set a clock to insure the recommended contact time is 5 minutes.
3) Rinse equipment with running deionized water for approximately 1 minute.

4) Alternatively to step 4 suspend the parts in a tray filled with deionized water for 5 min. and rinse the cavity of the biopsy attachment holdfast with 50 ml deionized water or tap water five times.

5) Visually check the cavity of the biopsy attachment holdfast for leavings of the disinfectant. If necessary, repeat the rinsing.

C) Magnetic sensor attachment and spacer for EZU-RVS2

1) Before immersing the equipment, 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 (68°F). 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 17). 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 4 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.

D) Biopsy attachment EZU-PA5B4

1) Before immersing the equipment, 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 (68°F). 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 18). 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 4 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. Automated Cleaning and Disinfecting:

The following items must be provided prior to automated cleaning and disinfection:

a) Washer disinfector: according to DIN EN ISO 15883 with chemo-thermal program (temperature: max 55°C (131°F))

b) Waterproof box for probe connector EZU-WB1

c) Detergent: Korsolex ® Endo-Cleaner (Bode Chemie)

d) Disinfectant: Korsolex® Endo Disinfectant (Bode Chemie)

1) Washer disinfector accessories: basket for holding the biopsy probe and the dismantled parts of the biopsy attachment holdfast. The parameters of the cleaning and disinfection of the device are as follows:

| **Program step** | **Water (40l)** | **Dosage (ml/l)** | **Temp. (°C)/(°F)** | **Time (min)** |
|---|---|---|---|---|
| Pre-Rinse | Cold water | | | 5 |
| Cleaning | Deionized water | 5 (0.5%) | 50/122 | 10 |
| Rinse | Deionized water | | | 1 |
| Disinfection | Deionized water | 10 (1%) | 55/131 | 5 |
| Rinse | Deionized water | | | 1 |
| Rinse | Deionized water | | 55/131 | 1 |
| Drying | | | 55/131 | 15 |

2) Remove the biopsy attachment holdfast from the probe head of the biopsy probe.

3) Connect the waterproof box EZU-WB1 to the probe connector and confirm there is no leak by tester. About detail information, refer to the instruction manual of the waterproof box EZU-WB1.

4) Perform the wipe disinfection of the instrument ports to be connected to the washer disinfector.

5) Decomposed accessories are placed directly into baskets. Small parts must be placed in a strainer basket with lid.

6) After closing the door, start the chemo-thermal program.

7) After the end of the program, open the door.

8) Remove the probe and the accessories and check whether they are dry. If not, proceed as described under drying.

5.4. Drying:

1) Wipe the equipment 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 equipment, the temperature limit is a maximum of 55°C (131°F). Dry until no visible moisture is left.

4) If using natural drying, temperature range should be between 15-30°C (59-86°F) for a minimum time of 4 hours.

5.5. 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.

5.6. Sterilization:

Sterilization methods of ethylene oxide gas, Sterrad 50, Sterrad 100S and Sterrad 200 are available to this probe and accessories (see table below). Steam sterilization is only available to biopsy attachment holdfast.

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-PA5B4 and the magnetic sensor attachment and the spacer for EZU-RVS2 in an appropriate bag for sterilization (see figure 19).

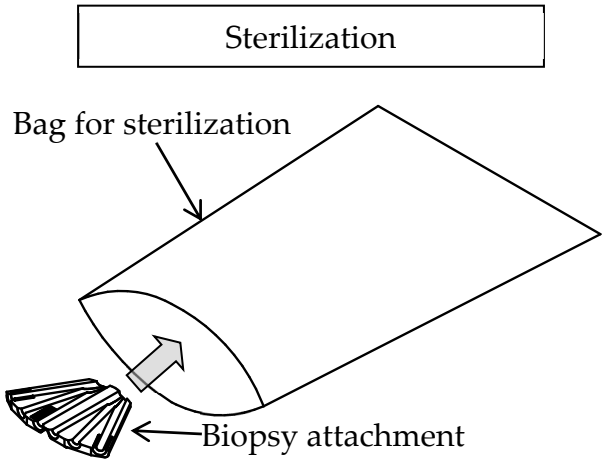



Fig.19 Sterilization of Biopsy Attachment EZU-PA5B4

Applicable sterilization methods for each component are as follows.

| Sterilization Method | Probe, Biopsy attachment EZU-PA5B4, Magnetic Sensor Attachment and its spacer | Biopsy attachment holdfast |
|---|---|---|
| Plasma Sterilization: STERRAD® 50, 100S or 200 (*) | Applicable | Applicable |
| ETO Sterilization | Applicable | Applicable |
| Steam Autoclaving | Not Applicable | Applicable |

Sterile conditions of each method are as follows.

| Sterilization Method | Condition |
|---|---|
| Plasma Sterilization: STERRAD® 50, 100S or 200 (*) | Short Cycle |
| ETO Sterilization | ➢ Gas Type: 10% EO/ 90% HCFC<br>➢ Temperature: 50-55°C<br>122-131°F<br>➢ Exposure Time: More than 120 minutes<br>➢ Pressurization: 162-200kPa<br>Depressurization: 13-8kPa<br>➢ Relative humidity: 40-90%<br>➢ Aeration temperature: 53°C<br>127.4°F<br>➢ Aeration is minimum 12 hours |
| Steam Autoclaving (that is applicable to only "Biopsy attachment holdfast") | ➢ temperature: min. 132°C<br>269.6°F<br>➢ Chamber Pressure: 41.7-44.7 psia (27-30 psig or 3 bar)<br>➢ exposure Time: Minimum 10 minutes |

* 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. Storage, Maintenance and Safety Inspection

1) The Biopsy Attachment store it in a cool and dark place avoid high temperature and humidity, direct sunlight.
2) After using the probe, the probe should be cleaned and disinfected or sterilized according to "5. Reprocessing Procedure of the probe", store the probe in a cool and dark space to avoid high temperature, humidity and direct sunlight.
3) Visually inspect the surface of the probe head, the housing, the cable and the connector for any crack, scratch or denaturalization. If you find any damage, do not use the probe, and contact a service support immediately.
4) After using the Magnetic sensor attachment and the Spacer for EZU-RV2S, it should be cleaned and disinfected or sterilized according to "5. Reprocessing Procedure of the Magnetic Sensor Attachment", store it in a cool and dark space to avoid high temperature, humidity and direct sunlight.
5) 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**

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

**⚠ CAUTION**

- Keep the acoustic power low and minimize the ultrasound exposure time for the examination of an early pregnancy.
- Do not expose the connector to water or other liquids. The connector is not waterproof.
- Do not hit or drop the probe. The probe is easily damaged by mechanical shock.
- Do not use detergents and disinfectants other than listed in “8.2 Suppliers list”.
- Clean and sterilize the probe and the Magnetic sensor attachment and the Spacer for EZU-RV2S, before the first use as it is not sterilized in the factory.
- Use only the soft cloth or tissue to clean the acoustic lens.
- A biopsy should be performed only by a well-trained physician.
- Do not attach unapproved devices to the probe.

# 8. Specifications

## 8.1. Probe

| | |
|---|---|
| Type: | EUP-B514 Biopsy Probe |
| Center frequency: | 3.5MHz |
| Technology: | Convex Array Probe |
| Dimensions: | See Fig. 20. |
| Weight: | Approx. 0.85kg (incl. cable and connector) |
| Scanning angle: | 90 degrees |
| Biopsy needle angle: | 0, 15 and 30 degrees |
| Biopsy attachment: | 12 – 23G, Cool-tip™(17G), LeVeen™ SuperSlim Needle(17G) (Usable needle size) |
| Probe materials: | Bio-compatible allergy free components |
| Acoustic output: | According to IEC60601-2-37 (See 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 or Plasma sterilization is available. |

Operating conditions:

| | |
|---|---|
| Ambient temperature; | +25 – +35°C |
| | +77 – +95°F |
| Relative humidity; | 30 – 85% |

Storage conditions:

| | |
|---|---|
| Temperature; | –10 – +55°C |
| | +14 – +131°F |
| Relative humidity (subject to no condensation); | 10 – 95% |

8.2. Suppliers List

The products listed below are seriously tested and approved for use with the Biopsy Probe EUP-B514.

| Product name | manufacturer | purpose |
|---|---|---|
| Cidezyme™ | Johnson & Johnson | Enzymatic detergent |
| Cidex OPA™ | Johnson & Johnson | Disinfectant |
| Cidex Plus™ 28 day solution | Johnson & Johnson | Disinfectant |
| Cidex™ | Johnson & Johnson | Disinfectant |
| ALKAZYME | ALKAPHARM | Detergent |
| Waterproof box for probe connector EZU-WB1 | FUJIFILM Healthcare Corporation | Waterproof box for probe connector |
| CIDEX OPA test strips | Johnson & Johnson | Test strip for verifying concentration of Cidex OPA |
| Korsolex Endo-Cleaner | Bode Chemie | Detergent for Washer-disinfector |
| Korsolex Endo-Disinfectant | Bode Chemie | Disinfectant for Washer-disinfector |
| Anioxyde 1000 | Anios Laboratoires | Disinfectant |
| Steranios 2% | Anios Laboratoires | Disinfectant |
| Tristel 1 Day | Tristel Company | Disinfectant |
| Tristel Multi-Shot | Tristel Company | Disinfectant |

For manual pre-cleaning also the following products are tested according to material compatibility:

- Bacillol® 25 (BODE Chemie)
- Meliseptol HBV Tissues (B. Braun Medical)

Please note that the application of these tissues doesn't replace a complete reprocessing for this medical devices.

9. Disposal of the probe

Recycle or dispose of this equipment properly in compliance with your organizational rules and your local laws.

**⚠ 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.

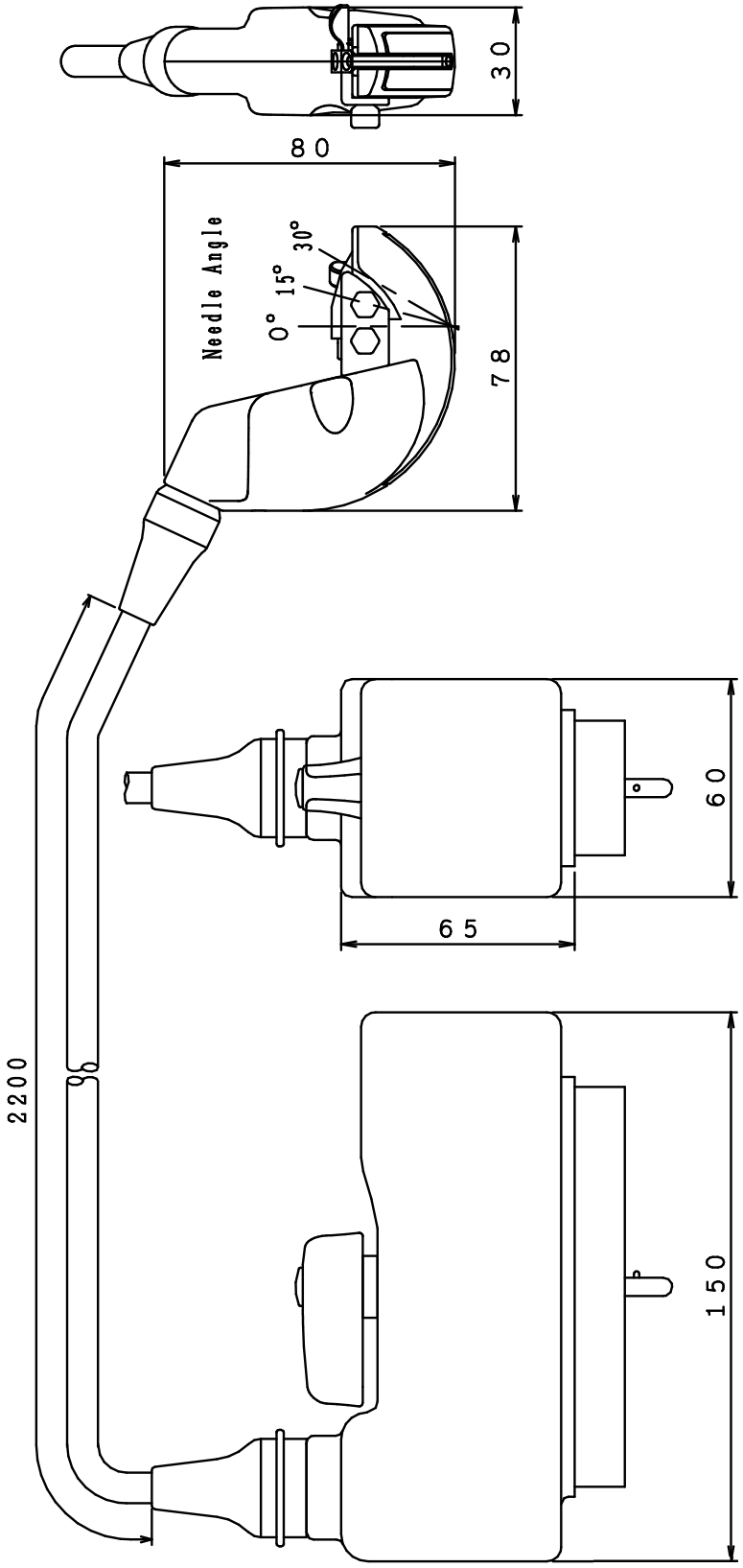



Fig.20 Dimensions Unit: mm