

## C41L47RP Probe

# 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-EP1451-6

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## About this manual

This instruction manual contains safety precautions, the inspection, the operation procedure and the reprocessing procedure of C41L47RP Probe.

Please read this manual thoroughly to ensure the safety operation. If you have any questions concerning the operation of the probe, 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 <a href="http://www.hitachi.com/businesses/healthcare/index.html">http://www.hitachi.com/businesses/healthcare/index.html</a>
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.
Contains or presence of natural rubber latex		Contains or presence of natural rubber latex
Do not re-sterilize		Do not re-sterilize
Do not reuse		Do not reuse

**Definition of symbol**

The following symbol is also used for HITACHI Ultrasound Probes.

Location	Symbol	Definition
Probe connector		This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector		IPX7 mark <b>See section 1.6.</b>
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		STERRAD sterilization compatibility mark
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.

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# 1. Introduction

## 1.1 Features

C41L47RP Probe is a transrectal Probe.

The acoustic output of this probe when connected to ultrasound diagnostic scanner was measured according to the IEC60601-2-37 standard. The table of measured acoustic output data is contained in the operational manual of each ultrasound diagnostic scanner. This probe is categorized in class IIa according to Directive 93/42/EEC.

According to IEC60601-1 the probe is classified as type BF.

## 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

C41L47RP Probe is designed for observation and diagnosis of the following regions mainly by connecting with the HITACHI ultrasound diagnostic scanner.

- Transrectal
- Biopsy (with a Puncture Guide Fixture)

 **WARNING**

Never use the probe for following regions.

- 1) The heart (Do not contact directly.)
- 2) The eyeball

1.4 Components

Components of C41L47RP Probe are as follows:

- 1) Probe ..... 1 piece
- 2) Instruction Manual ..... 1 copy

 **CAUTION**

- Sterilization has not been made to the probe shipped from the factory. Prior to use of the probe, be sure to clean, disinfect and sterilize it.

## 1.5 Accessories (Option)

### 1.5.1 Puncture Guide Fixture EZU-PA3U

(Gauge size available:14G and 18G)

If you need a Puncture Guide Fixture EZU-PA3U, please contact a service support.

#### CAUTION

A well-trained physician only should perform a biopsy.

### 1.5.2 Probe cover for Single Use (Disposable)



To protect the probe against contamination, using probe cover is recommended. If using probe cover, lubrication free probe cover which is dry type is recommended.



Lubrication may cause a deterioration of the probe surface. And latex rubber may create allergic reactions, use of non-allergic probe cover is strongly recommended. Take care for the handling of used probe cover.

### 1.5.3 Magnetic sensor attachment

Magnetic sensor attachment is needed for Real-time Virtual Sonography(RVS). It is use to fix the magnetic sensor to the probe.

#### CAUTION

The Magnetic sensor attachment is not sterilized when delivered from the factory. Prior to use, be sure to clean and sterilize it.

1.6 Construction

The external view of C41L47RP Probe is shown in Fig.1.

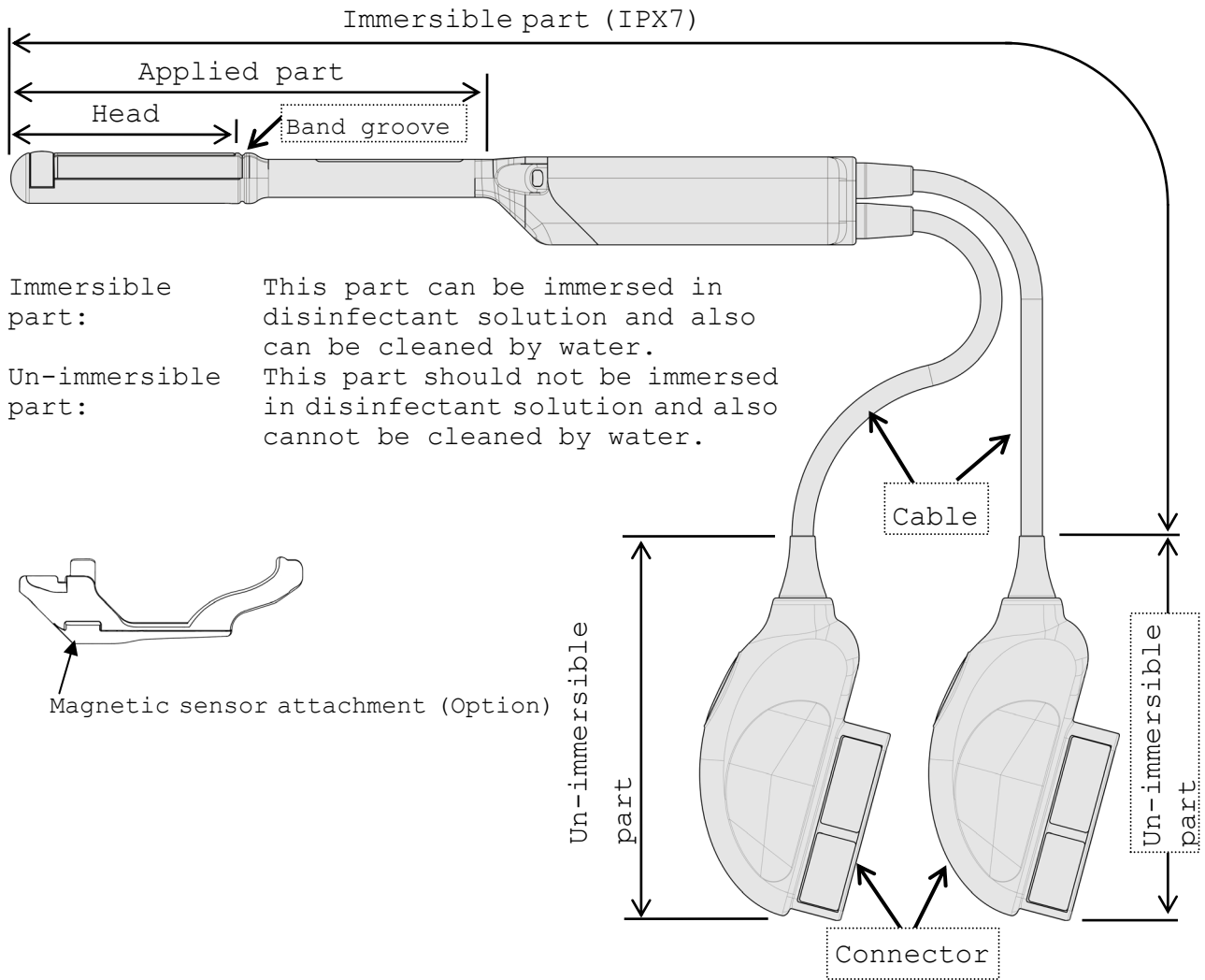


Fig.1 External view

## 2. Inspection before Use

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

### 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 Do not attach or connect unauthorized devices or instruments to the probe, such as unauthorized biopsy attachments.
- 2.1.3 Confirm that the Puncture Guide Fixture and software version and then settings of the scanner are appropriate for the probe. Attach the Puncture Guide Fixture on the probe. Set the ultrasound diagnostic scanner to display the "Needle guide line". (Refer to the operation manual for the ultrasound diagnostic scanner.) Keep the probe head in the water and insert a puncture needle in the Puncture Guide Fixture. Then, confirm that the needle is inserted smoothly and the echo of the needle is displayed on the dot line "Needle guide line" on the monitor.

### 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 Visually inspect that there is no dirt (dust or any liquid) on the connector pins.
- 2.2.3 Visually inspect the Puncture Guide Fixture for damages such as deformation or denaturalization. If you find any damage, do not use the Puncture Guide Fixture.
- 2.2.4 Visually inspect the Magnetic sensor attachment for damages such as deformation or denaturalization. If you find any damage, do not use the Magnetic sensor attachment.

### 3. Operation Procedure

#### 3.1 Connection and Settings

- 1) Confirm that the probe and the Magnetic sensor attachment are disinfected and if necessary sterilized. The Magnetic sensor attachment is need for Real-time Virtual Sonography(RVS). Regarding the option for RVS, please refer to "4.Option of C41L47RP Probe".
- 2) It is recommended to use a disposable probe cover for preventing a patient from infection and the probe cover should be allergy free material to avoid allergic reaction.
- 3) Connect the probe to the ultrasound diagnostic scanner and operate the scanner and adjust the image according to the instructions given in the operation manual for the ultrasound diagnostic scanner.
- 4) The relationship between the direction of the probe and the right-left orientation mark on the image is shown in Fig.2 and Fig.3.

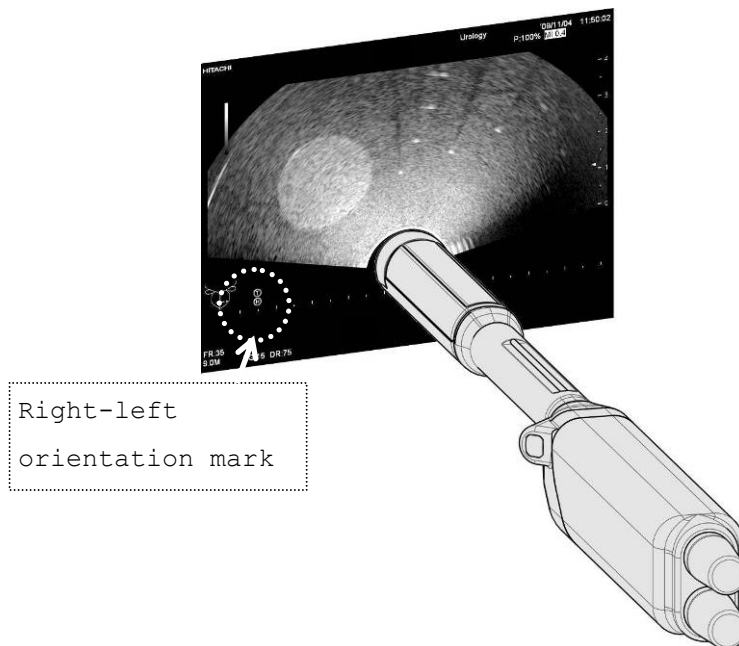


Fig.2 The relationship between the direction of the probe and the Right-left Orientation Mark in Convex US image

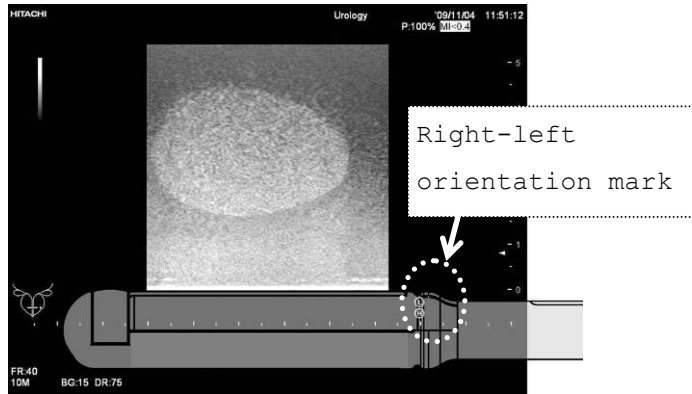


Fig.3 The relationship between the direction of the probe and the Right-left Orientation Mark in Linear US image

**⚠ WARNING**



Be careful with a probe cover made from the latex. The latex may cause such allergic reactions as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, and depression of blood pressure, shock and so on. If you observe any of above-mentioned symptoms in your patient during the operation, stop the use of protective sleeve immediately and take an appropriate treatment to the patient.

- 5) Insert the probe gently and adjust the probe's position for a clear view of the desired image.
- 6) After using the probe, clean and disinfect or sterilize the probe immediately. If RVS is carried out, clean and disinfect or sterilize the Magnetic sensor attachment.
- 7) Store the probe and the Magnetic sensor attachment in the environment indicated in "7 Maintenance and Safety Inspection".

—  CAUTION —

- Do not use the probe if the image and the frequency do not match the probe. An incorrect acoustic output can result in burns or other injuries to the patient.
- Scan for the minimum length of time necessary for the diagnosis and at the lowest possible output. There is the possibility that the patient's tissues could be affected. For details about the acoustic output, please refer to the operation manual of the ultrasound diagnostic instrument.
- 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.]

—  CAUTION —

The needle guideline can be displayed on US image for perineal prostate biopsy. This probe can be used for biopsy with the Puncture Guide Fixture EZU-PA3U.

When the needle guideline is displayed, numeric value is displayed on the upper right of the US image. This numeric value means the distance between the surface of acoustic lens and the needle guideline (see the figure in the next page). Regarding the needle guideline, refer to the instruction manual of the ultrasound scanner that the ultrasound probe is connected to.

The numeric value on the image corresponds to the numeric value engraved on the Puncture Guide Fixture EZU-PA3U. For example, when the Movable Part for guiding the needle is fixed at 10mm position, then the numeric value in the upper right on US image is needed to be adjusted to 10mm. The Movable Part for guiding the needle and the needle guideline can be fixed at from 10 to 50mm in 5mm steps.

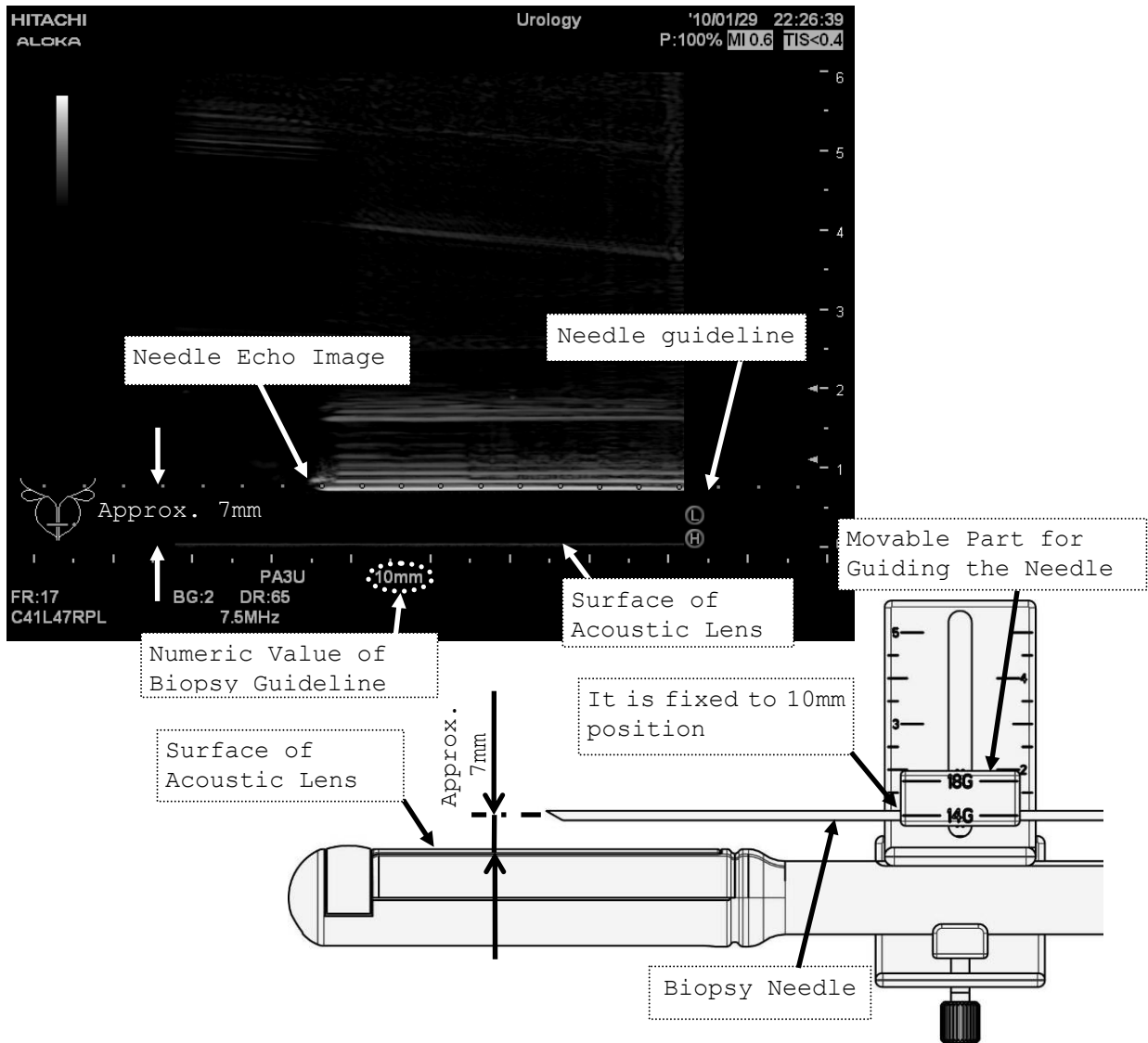
Note that the position of the numeric value on the US image is different in each ultrasound scanner.

Make sure that there is no damage to the Puncture Guide Fixture prior to each use, otherwise the needle or needle cannula might be damaged.

## ⚠ CAUTION

The needle echo image corresponds with the needle guideline, but the actual distance from the surface of acoustic lens to the needle guideline is approximate 3mm shorter than the numeric value in the upper right on US image, so the numeric value is rough indication for biopsy.

Before performing a biopsy, display the needle echo in sterile water, and confirm that the needle echo at each distance overlaps with the correspondent needle guideline. Water temperature depends on the type of the ultrasound diagnostic scanner connected to the probe. If the type of the scanner is EUB series, HI VISION series, or Noblus, set water temperature at room temperature. For the other type of the scanner, set it at 40 degrees Celsius.





### 3.2 Use of Puncture Guide Fixture (EZU-PA3U)

The steps to attach the Puncture Guide Fixture (EZU-PA3U) to the probe is as follows.

- 1) Attaching a sterile probe cover to the probe is recommended.
- 2) Fit the groove of the Puncture Guide Fixture to the projection on the probe. (See Fig.4.)
- 3) Screw the Puncture Guide Fixture to attach to the probe firmly. Visually inspect that there is no hole in the probe cover.

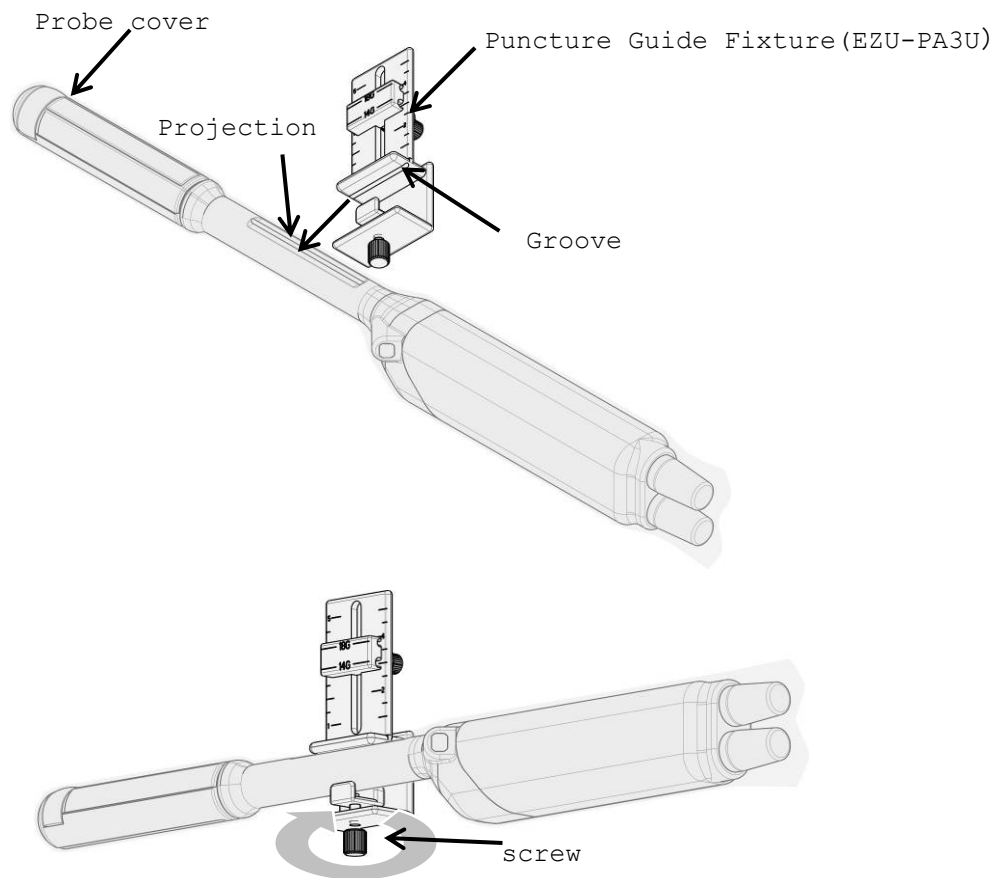


Fig4. How to attach the EZU-PA3U

### 3.3 How to adjust Puncture Guide Fixture (EZU-PA3U)

- 1) Loose thumbscrew on the back side of the puncture guide.
- 2) Slide guide groove in the depth on demand.
- 3) Tighten thumbscrew for fixing guide groove.

The Following figure is an example that guide groove of 14G is combined with the depth of 30mm

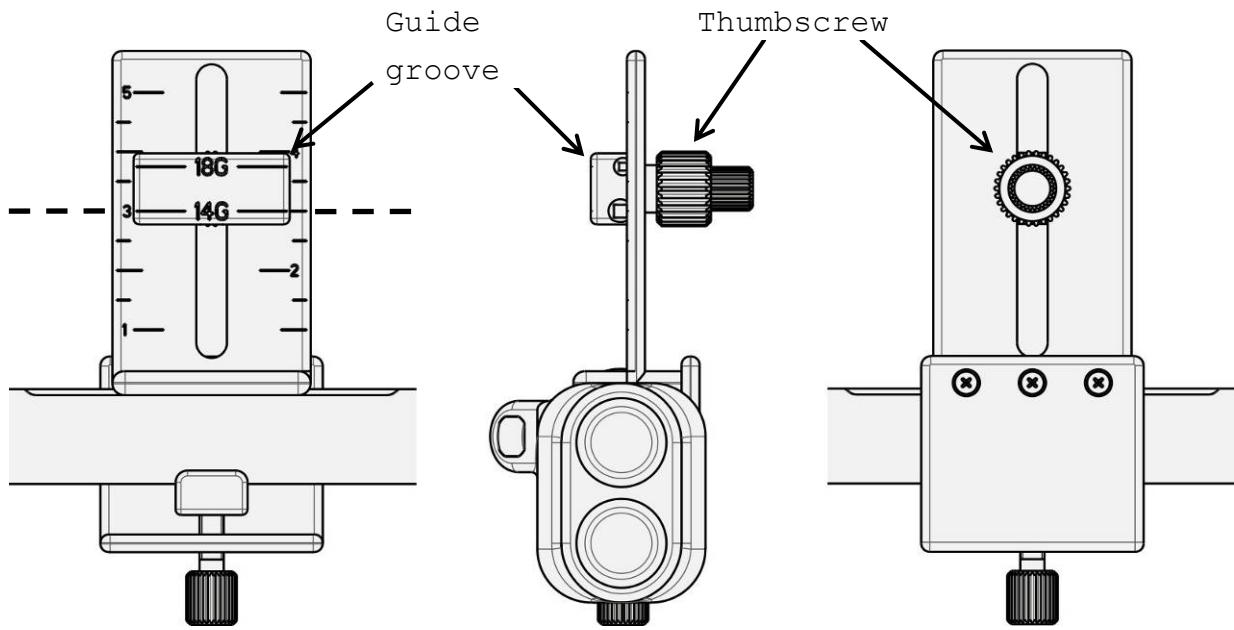


Fig5. How to adjust Puncture Guide Fixture (EZU-PA3U)

 **WARNING**

- 1) Warning in 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, 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.
- 2) The recommended probe covers are disposable and must not be reused.
- 3) Confirm that the needle guide angle corresponds to the angle indicated on the monitor. The needle guide angle is engraved on bracket. Otherwise, the biopsy guide line becomes inconsistent with the inserting position of the biopsy needle.
- 4) When using the needle cannula of the electrosurgical unit while using the Puncture Guide Fixture 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 needle guide, 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.
- 5) Use a needle whose size is compatible with the Puncture Guide Fixture. Use of a puncture needle that is not a compatible size can result in the Puncture Guide Fixture coming off during puncturing or puncturing of an unintended body part, causing injury to the patient.
- 6) During the puncture operation, display a suitable puncture guideline on the screen of the ultrasound diagnostic instrument. Puncturing of an unintended body part can cause injury to the patient. Display the puncture guideline on the screen referring to the documentation supplied with the ultrasound diagnostic instrument, to use it as an aid in determining the puncturing direction.

## 4. Option of C41L47RP Probe

### 4.1 Magnetic sensor

#### 4.1.1 How to attach the Magnetic sensor

The procedure of attaching the magnetic sensor is as follow.

- 1) Confirm that the Magnetic sensor attachment is sterilized or disinfected.
- 2) Insert the Magnetic sensor into the Magnetic sensor attachment in the correct direction as shown in Fig.6.

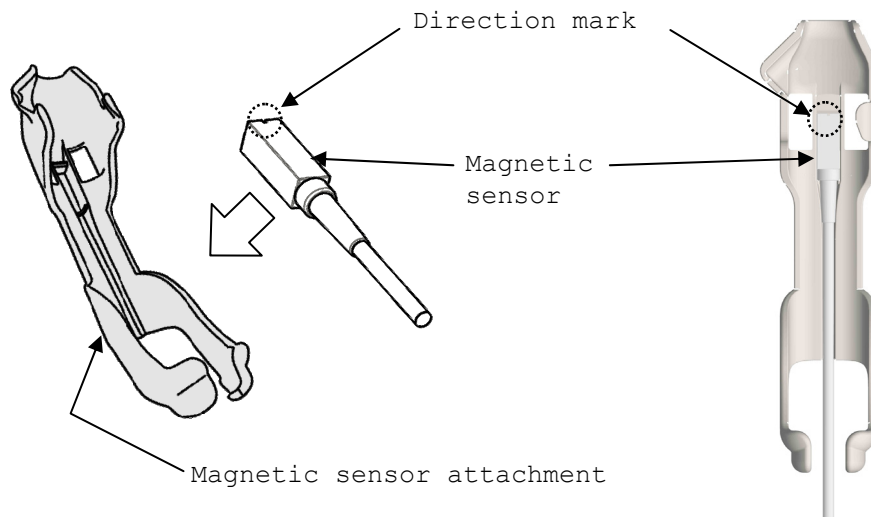


Fig.6 How to attach the Magnetic sensor

### ⚠ CAUTION

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

- 3) Attach the Magnetic sensor attachment to the probe as shown in Fig.7

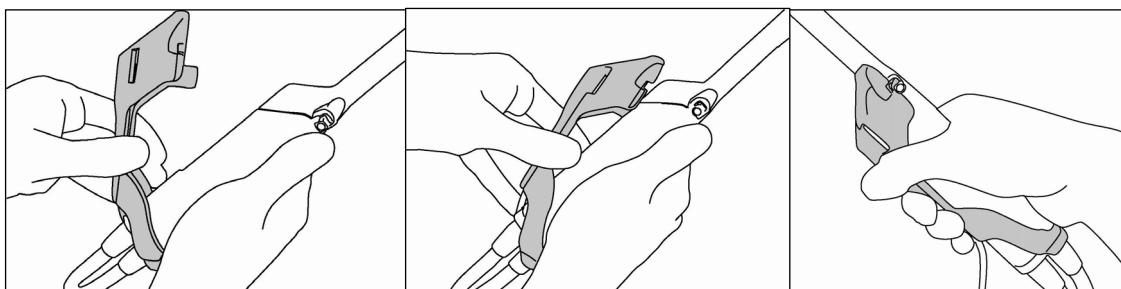


Fig.7 How to attach the Magnetic sensor attachment

### ⚠ CAUTION

Do not put your fingers between the Magnetic sensor attachment and the probe when attaching the Magnetic sensor attachment to the Probe.

#### 4.1.2 How to release the Magnetic sensor

The procedure of releasing the magnetic sensor is as follow.

- 1) Detach the Magnetic sensor attachment from the probe as shown in Fig.8.

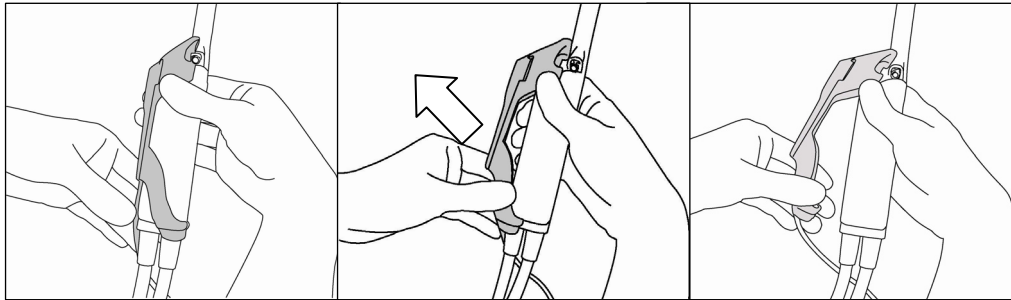


Fig.8 How to release the Magnetic sensor attachment from the probe

- 2) Detach the Magnetic sensor from the Magnetic sensor attachment as shown in Fig.9.

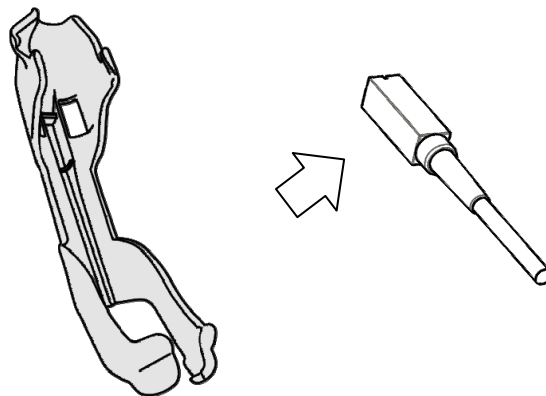


Fig.9 How to release the Magnetic sensor from the Magnetic sensor attachment

#### CAUTION

Clean, disinfect and Sterilize the Magnetic sensor attachment prior to first use as it is not sterilize when delivered.

## 5. Cleaning, Disinfection and Sterilization



The probe and accessory must be reprocessed after each use. Refer to the reprocessing instruction in this chapter.

WARNINGS	<ul style="list-style-type: none"><li>- The probe is delivered unsterile. Prior to the first use, reprocess the probe.</li><li>- Temperature should not exceed 60°C during reprocessing</li><li>- Probe connector is not water resistant.</li></ul>
Limitations on reprocessing	The probe is not completely submersible. The immersible part is shown in Fig.1. The un-immersible part should be disinfected by wipe disinfection.
Transportation before using	The probe should be packed in a sterile pouch or container to transport from Central Sterile Supply Department (CSSD) to an operating room. Be careful not to damage the sterile pouch or container during transportation.

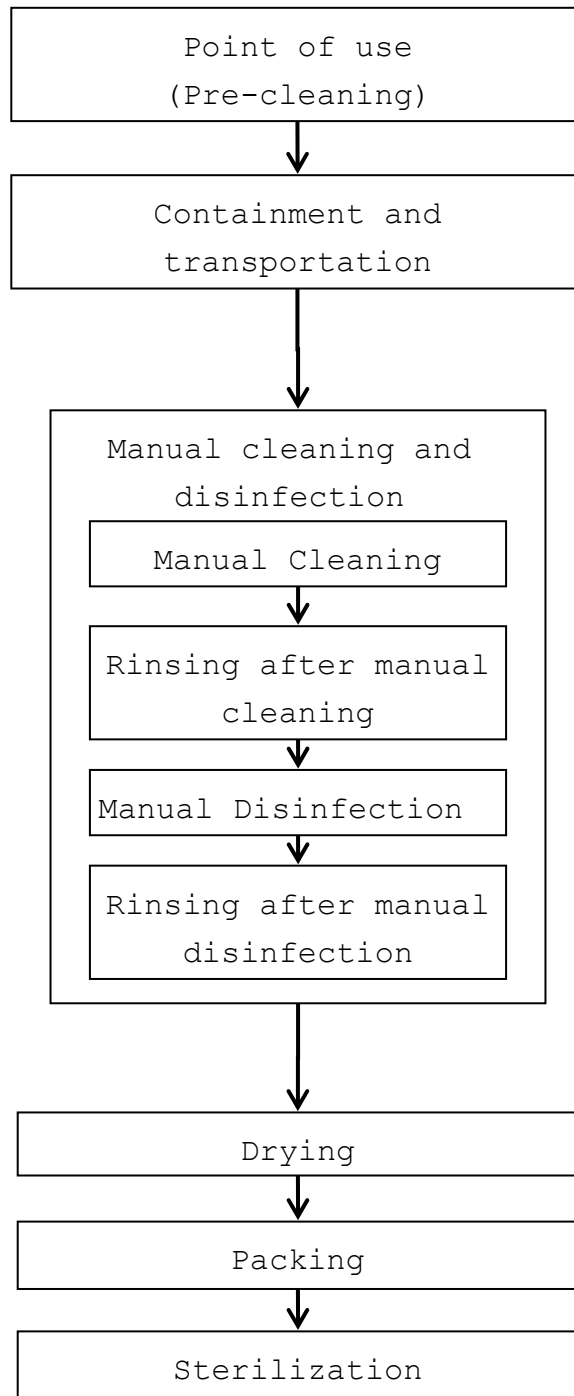
Levels of reprocessing requirements:

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, semi-critical 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

According to the intended use, C41L47RP probe is classified as semicritical.

The flowchart of the reprocessing process of this probe is as follows.





## 5.1 Point of use (Pre-cleaning)

Point of use  
(Pre-cleaning)

Pre-cleaning should be done immediately after each use. The procedure is as follows:

### A) C41L47RP probe

- 1) Remove the protective cover.
- 2) Clean the probe of all patient's blood or fluid with running tap water until the surface of the probe looks visually clean.
- 3) Wipe the whole surface of the probe with gauze pad and remove superficial visible impurities.

### B) Magnetic sensor attachment

- 1) Remove the Magnetic sensor attachment and the magnetic sensor from the probe.
- 2) Immerse the Magnetic sensor attachment in sufficient amount of high quality tap water. Scrub it using soft cloth to remove all visible soil from its surface.

## 5.2 Containment and transportation

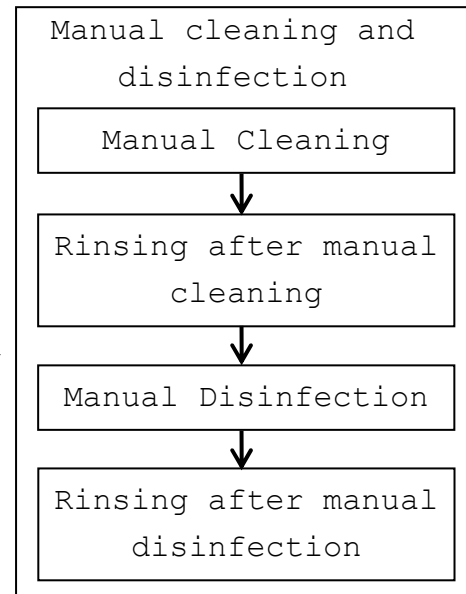
Containment and  
transportation

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.

### 5.3 Manual Cleaning and disinfection

Prepare following items before manual cleaning and disinfection:

- a) Detergent: Cidezyme (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device
- b) Disinfectant: Cidex OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device
- c) Two tanks, one for cleaning and one for disinfection - optional:  
1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the immersible part of the probe at full length)
- d) Soft, fluff free cloth or single use towel
- e) 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:

Prepare the detergent solution in a tank with cold water (please follow the instructions of the detergent manufacturer regarding application, dilution and contact time).

#### A) C41L47RP probe

- 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 differing detergent is used, please also note the approved material compatibility for the medical device.
- 2) Immerse the immersible part of the probe without connector into the diluted detergent solution (see Figure 10). Wipe the immersible part of the probe under the surface of the detergent solution with a soft cloth to remove all visible soil.

- 3) The immersible part of the probe should be left in the detergent solution according to the specified contact time of the detergent manufacturer.
- 4) Wipe the un-immersible parts of the probe with a soft cloth dipped with the detergent solution.
- 5) Rinse the immersible part of the probe with running tap water for 1 minute. (alternatively: immerse the immersible part of the probe in a tray filled with deionized water/tap water (see Fig.10) for 5 min.)
- 6) Visually check the outer surface of the 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

- 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 differing detergent is used, please also note the approved material compatibility for the medical device.
- 2) Immerse the magnetic sensor attachment into the diluted detergent solution. Wipe it under the surface of the detergent solution with a soft cloth to remove all visible soil.
- 3) The Magnetic sensor attachment should be left in the detergent solution according to the specified contact time of the detergent manufacturer.
- 4) Rinse the Magnetic sensor attachment with running tap water for 1 minute. (alternatively: immerse it in a tray filled with deionized water/tap water (see Fig.10) for 5 min.)
- 5) Visually check the outer surface of the Magnetic sensor attachment for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

Manual disinfection:

A) C41L47RP probe

- 1) Prepare the disinfectant solution in a tank with cold water (please follow the instructions of the disinfectant manufacturer regarding application, concentration, microbiological efficiency, service life and contact time).
- 2) Confirm the concentration of the disinfectant before immersing the probe. Although Cidex® OPA does not need to be diluted, it is recommended to use test strips to verify the concentration. The test strips can indicate whether or not the concentration is 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) Immerse the immersible part of the probe into the disinfectant (see Fig. 10). Set a clock to insure the recommended contact time which is 5 minutes.
- 4) Rinse the immersible part of the probe with deionized water for 1 minute. (alternatively: immerse the immersible part of the probe in a tray filled with deionized water (see Fig.10) for 5 min.)
- 5) Visually check the outer surface of the probe for leavings of the disinfectant. If necessary, repeat the rinsing.

## B) Magnetic sensor attachment

- 1) Prepare the disinfectant solution as stated in the procedure for the probe.
- 2) Immerse the Magnetic sensor attachment into the disinfectant (see Fig. 10). Set a clock to insure the recommended contact time which is 5 minutes.
- 3) Rinse the Magnetic sensor attachment with deionized water for 1 minute. (alternatively: immerse it in a tray filled with deionized water (see Fig.10) for 5 min.)
- 4) Visually check its outer surface for leavings of the disinfectant. If necessary, repeat the rinsing.

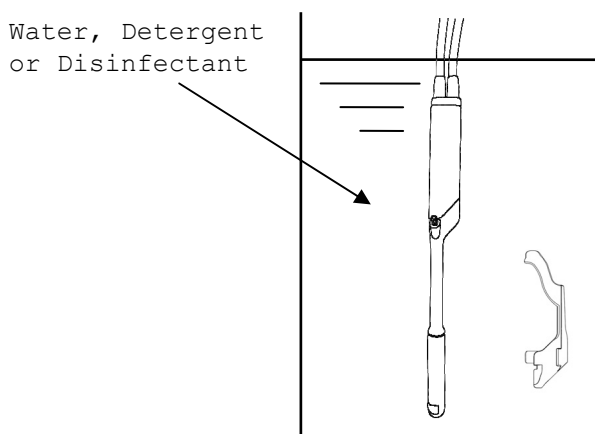


Fig.10 Immersion of the probe and the Magnetic sensor attachment.

## 5.4 Drying

Drying

- 1) Wipe the equipment with a single-use, fluff-free wipe or towel to remove moisture from the surface of the equipment.
- 2) Dry the equipment naturally in an ambient temperature between 15-30°C for a minimum of 4 hours. Alternatively the equipment can be dried using a drying heater at a temperature of less than 60°C.

## 5.5 Inspection

Inspect the equipment for any damage such as crack, scratch or deformation. Do not use it if any damage is found.

## 5.6 Packaging

Packaging
-----------

Pack the equipment in a sterile barrier such as Polypropylene fleece or transparent package made from Polyethylene film and Tyvek®, and then place it into a tray. The tray should be also covered with a sterile barrier.

Additionally the equipment can be placed on plastic mesh wires supplied for plasma sterilization and then packed as mentioned above.

The equipment can be packed in a simple or double packing. Please note that the size of a sterile barrier should be large enough to be able to pack the equipment leaving sufficient space to seal it completely.

A sterile barrier should be sealed by an appropriate sealing machine and it is important to confirm that the package is sealed completely. If the sealing is not complete, pack and reseal again.

The probe and accessory can be sterilized using either ethylen oxide gas (EtO) sterilization or plasma sterilization (see table below).

Follow the manufacturer's instructions of the sterilizer regarding usage, temperature and sterilization-time.

The sterilization method and operating conditions 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	<ul style="list-style-type: none"> <li>➤ Gas Type: 10% EO/ 90% HCFC</li> <li>➤ Temperature: 50-55°C</li> <li>➤ Exposure Time: More than 120 minutes</li> <li>➤ Pressurization: 162-200kPa Depressurization: 13-8kPa</li> <li>➤ Relative humidity: 40-90%</li> <li>➤ Aeration is minimum 12 hours</li> </ul>

\* 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 and the Magnetic sensor attachment.
- 2) Do not sterilize the probe and the Magnetic sensor attachment by Steam Autoclaving. If you autoclave them, they suffers serious damage and will be not functional.

The packaging before sterilization is as follows.

- 1) Put the probe into TYVEK pouch.

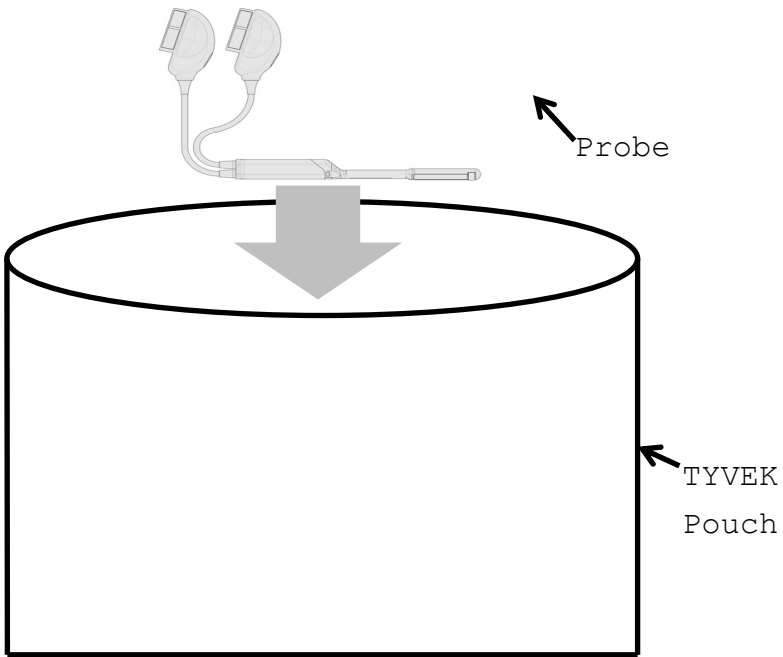


Fig.11 Packaging in the pouch

- 2) Seal the TYVEK Pouch using a heat sealer. Ensure that the seal is complete.

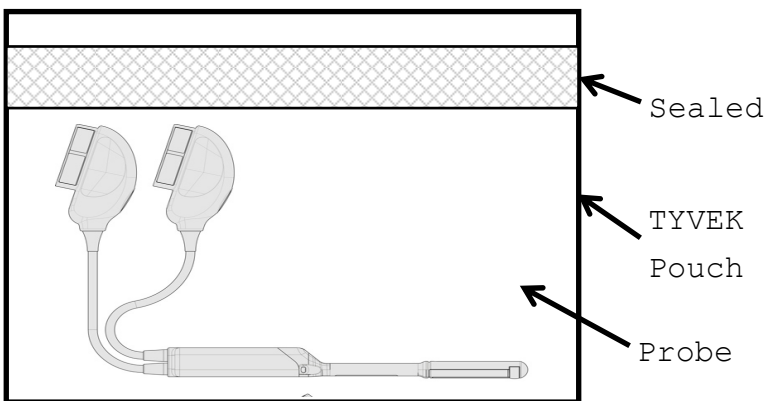


Fig.12 Sealing



3) Put the sealed pouch into a tray or plastic mesh wire for sterilization.

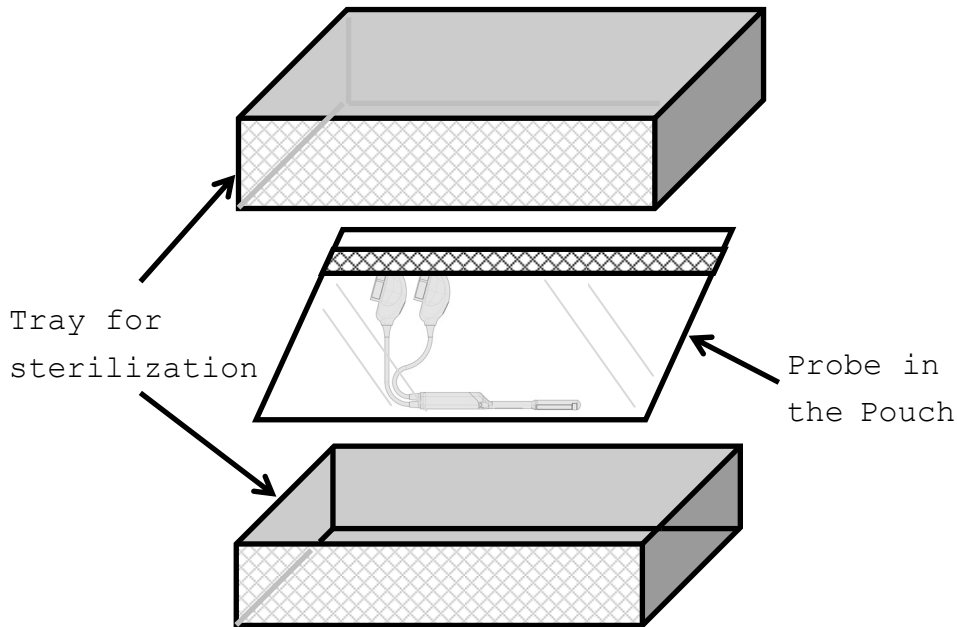


Fig.13 Packaging in a tray

#### 5.8 Storage



Store the equipment in a cool, dustproof and dark space to avoid high temperature, humidity and direct sunlight. Limitations for the time for sterilized equipment belong to package.

## 6. Cleaning, Disinfection and Sterilization of EZU-PA3U



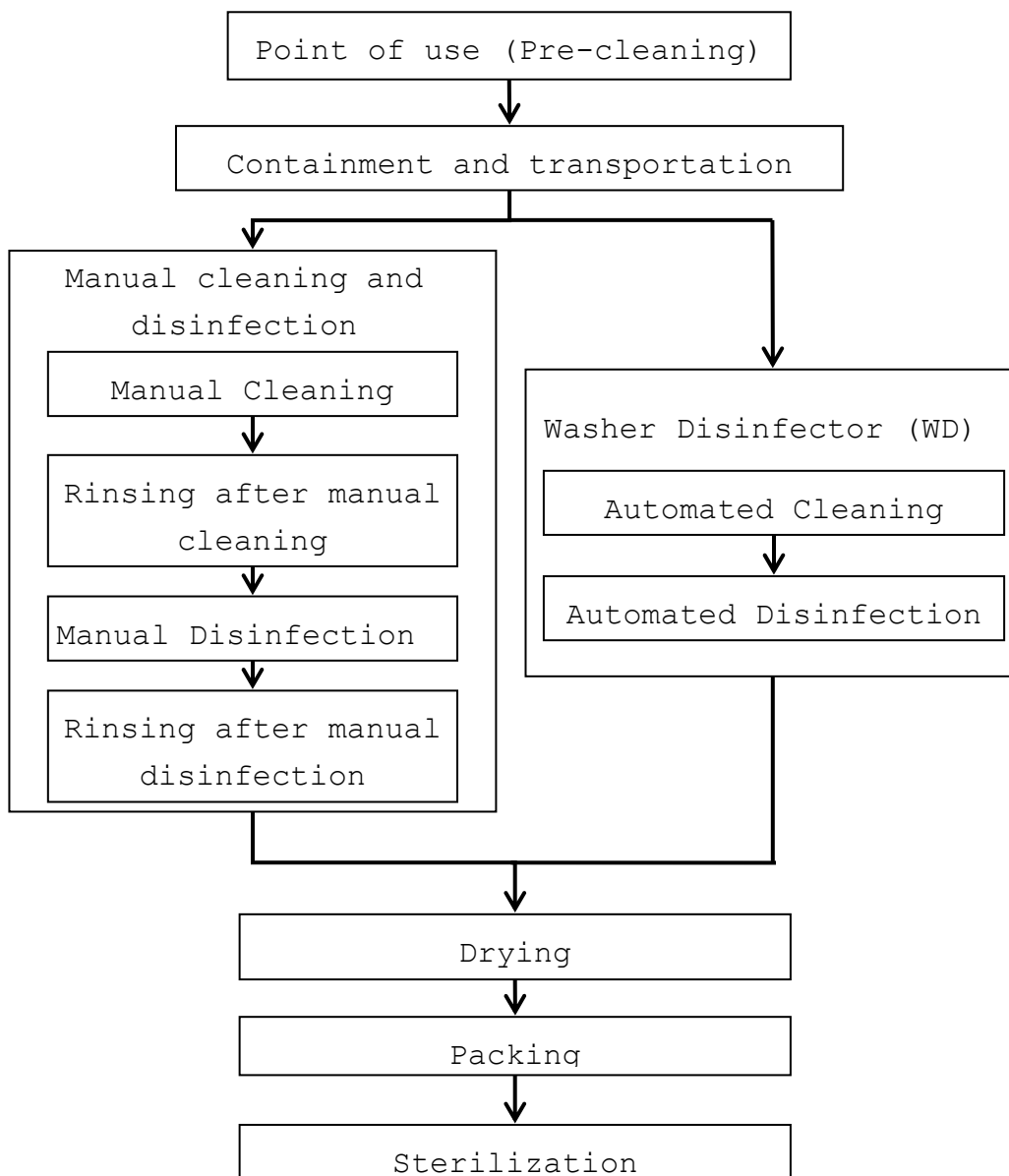
EZU-PA3U must be reprocessed after each use. Refer to the reprocessing instruction in this chapter.

WARNINGS	EZU-PA3U is delivered unsterile. Prior to the first use, reprocess it.
Transportation before using	EZU-PA3U should be packed in a sterile pouch or container to transport from Central Sterile Supply Department (CSSD) to an operating room. Be careful not to damage the sterile pouch or container during transportation.

Levels of reprocessing requirements:

Refer to the chapter 5.

The flowchart of the reprocessing process of EZU-PA3U is as follows.



### 6.1 Point of use (Pre-cleaning)

Point of use  
(Pre-cleaning)

Pre-cleaning should be done immediately after each use. The procedure is as follows:

- 1) Remove the EZU-PA3U from the probe.
- 2) Disassemble the EZU-PA3U (Fig.14) and immerse all parts in sufficient amount of high quality tap water. Scrub them using soft cloth to remove all visible soil and dried protein from their surface.

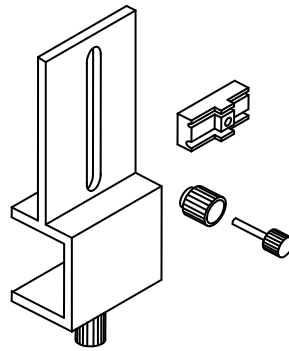


Fig.14 Disassembly of EZU-PA3U

### 6.2 Containment and transportation

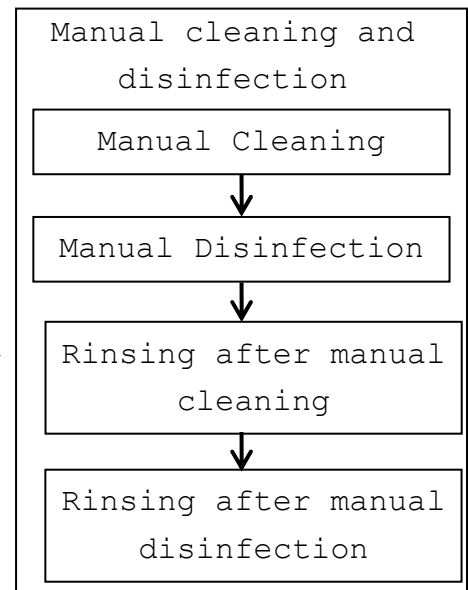
Containment and  
transportation

Refer to 5.2.

### 6.3 Manual Cleaning and disinfection

Prepare following items before manual cleaning and disinfection:

- a) Detergent: Cidezyme (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device
- b) Disinfectant: Cidex OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device
- c) Applicable brush



- d) Two tanks, one for cleaning and one for disinfection - optional:  
1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the puncture guide fixture at full length)
- e) Soft, fluff free cloth or single use towel
- f) 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:

Prepare the detergent solution in a tank with cold water (please follow the instructions of the detergent manufacturer regarding application, dilution and contact time).

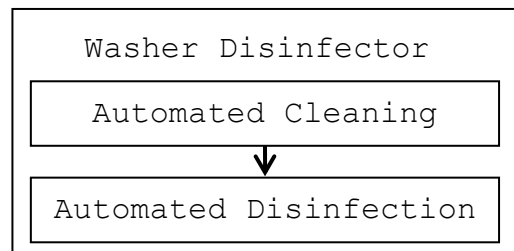
- 1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a differing detergent is used, please also note the approved material compatibility for the medical device.
- 2) Immerse the parts of the EZU-PA3U into the diluted detergent solution. Clean them under the surface of the detergent solution with a brush to remove all visible soil.
- 3) The parts of the EZU-PA3U should be left in the detergent solution according to the specified contact time of the detergent manufacturer.
- 4) Rinse the parts of the EZU-PA3U with running tap water for 1 minute. (alternatively: immerse them in a tray filled with deionized water/tap water (see Fig.10) for 5 min.)
- 5) Visually check the outer surface of the parts of the EZU-PA3U for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

Manual disinfection:

- 1) Prepare the disinfectant solution as stated in the procedure for the probe.
- 2) Immerse the parts of the EZU-PA3U into the disinfectant. Set a clock to insure the recommended contact time which is 5 minutes.
- 3) Rinse the parts of the EZU-PA3U with deionized water for 1 minute. (alternatively: immerse them in a tray filled with deionized water for 5 min.)
- 4) Visually check the outer surface of the parts of the EZU-PA3U for leavings of the disinfectant. If necessary, repeat the rinsing.

6.4 Automated cleaning and disinfection

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 60° C).
- b) Detergent: Korsolex Endo-Cleaner (Bode Chemie; # 972 020) or another cleaning agent with approved material compatibility for this medical device
- c) Disinfectant: Korsolex Endo-Disinfectant (Bode Chemie; # 972 030) or another disinfectant with approved material compatibility for this medical device

1) The parameters of the cleaning and disinfection of the device are as follows:

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

- 2) Place the disassembled parts of EZU-PA3U in the baskets of the washer disinfectant. Smaller parts like the screws must be placed in a strainer basket with lid.
- 3) Close the door of the washer disinfectant and start the chemo-thermal program.
- 4) Open the door after the process is done.
- 5) Take the parts of EZU-PA3U out of the washer disinfectant and check that they are dry. If not, dry them as described in the chapter drying.

#### 6.5 Drying

Drying

Refer to 5.4.

#### 6.6 Inspection

Refer to 5.5.

#### 6.7 Packaging

Packaging

Refer to 5.6.

EZU-PA3U can be sterilized using ethylen oxide gas (EtO) sterilization plasma sterilization, or Steam sterilization.

Follow the manufacturer's instructions of the sterilizer regarding usage, temperature and sterilization-time.

The sterilization method and operating conditions 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	<ul style="list-style-type: none"> <li>➤ Gas Type: 10% EO/ 90% HCFC</li> <li>➤ Temperature: 50-55°C</li> <li>➤ Exposure Time: More than 120 minutes</li> <li>➤ Pressurization: 162-200kPa Depressurization: 13-8kPa</li> <li>➤ Relative humidity: 40-90%</li> <li>➤ Aeration is minimum 12 hours</li> </ul>
Steam Autoclaving (that is applicable to only EZU-PA3U)	<ul style="list-style-type: none"> <li>➤ Temperature: min. 132°C</li> <li>➤ Chamber Pressure: 41.7-44.7psia (27-30psig or 3bar)</li> <li>➤ Exposure time: Minimum 10 minutes.</li> </ul>

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

### ⚠ WARNING

Before performing sterilization, check that the operation data of sterilizer are in conjunction with min. and max. data applicable for EZU-PA3U.

## 6.9 Storage

Refer to 5.8.

## 7. Maintenance and Safety Inspection

### 7.1 Daily Inspection

- 7.1.1 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.
- 7.1.2 Visually inspect the Puncture Guide Fixture for deformation or denaturalization. If you find any damage, do not use the Puncture Guide Fixture and contact your local HITACHI distributor immediately.
- 7.1.3 Visually inspect the surface of the Magnetic sensor attachment for any crack, deformation or denaturalization. If you find any damage, do not use it and contact a service support immediately.

### 7.2 Store



After using the probe and accessory, they should be cleaned and disinfected/sterilized according to "5. Cleaning, Disinfection and Sterilization" and "6. Cleaning, Disinfection, and Sterilization of EZU-PA3U" immediately. Then store them in a cool, dustproof and dark place avoid high temperature and humidity direct sunlight.



## 8. Safety Precautions

### WARNING

- 1) Never use the probe if the probe head, shaft or cable are cracked or damaged.
- 2) When use C41L47RP for biopsy purpose, use the Puncture Guide Fixture EZU-PA3U (Option) certainly.
- 3) Never use the Puncture Guide Fixture if the fixture is deformed, cracked or damaged.
- 4) Do not use the latex probe cover for latex sensitive patients. The probe cover, which contains latex, may cause allergic reactions as itching, rubor, urticaria, swelling, fever, anhelation, wheezing and depression of blood pressure, shock and so on.
- 5) The ultrasound gel attached to the ultrasound scanner as one of accessories is not sterile so never use it with C41L47RP.
- 6) Do not attempt to disassemble, modify, or repair the probe. Electric shock or other unforeseen accidents could result.
- 7) Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
- 8) Do not use the probe fallen on to floor. Otherwise, there is a risk of infection. Stop the operation and perform the inspection, cleaning, and disinfection or sterilization according to section 2 "Inspection before Use" and section 4 "Reprocessing Procedure".
- 9) When using ultrasound contrast agent, follow the supplied documentation. Unexpected accidents could result. Check the state of the patient and take appropriate precautions to avoid side effects.
- 10) During a biopsy, use sterilized physiological saline for the acoustic medium. Using an unsterilized ultrasound medium can cause an infection on the patient.
- 11) For details about the reuse and disposal of puncturing needles, follow the instructions in the documentation supplied with the puncturing needles. Reuse of puncturing needles that are not reusable or improper disposal could result in an infection.

 CAUTION

- 1) Keep the acoustic power low and minimize the ultrasound exposure time for the examination of an early pregnancy.
- 2) Do not expose the connector to water or other liquids. The connector is not waterproof.
- 3) Do not hit or drop the probe. The probe is easily damaged by mechanical shock.
- 4) Do not use detergents and disinfectants other than listed in "9.3 Suppliers list".
- 5) Use a sterile probe cover to avoid staining or damaging the acoustic lens.
- 6) Clean, disinfect and sterilize the probe and the Magnetic sensor attachment before the first use as it is not sterilized in the factory.
- 7) Use only the soft cloth or tissue to clean the acoustic lens.
- 8) Only a well-trained physician should perform a biopsy.
- 9) Do not use this probe with other equipment except for those specifically approved in the manual. Use with unapproved equipment can result in an electric shock, burn, or other injury to the patient or operator and damage to the probe and the other equipment.
- 10) Do not wash, disinfect or sterilize using procedures other than those specified in this manual. Infection could result due to incomplete washing disinfection or sterilization. It can also result in damage to the probe or reduced performance.

## 9. Specifications

### 9.1 Probe

Type	: C41L47RP Probe
Acoustic working frequency	
Convex scanning	: 6.5MHz
Linear scanning	: 7.5MHz
Technology	: High density Convex Array and Linear Array Probe
Dimensions	: See Fig.15
Weight	: Approx.1.3kg (Including cable and connector)
Scanning angle (Convex)	: 200 deg
Field of view (Linear)	: 64mm
Probe materials	: Bio-compatible allergy free components
Acoustic output	: According to IEC 60601-2-37 (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 sterilization : Plasma sterilization

#### Operating conditions:

Ambient temperature	: +10 - +40°C
Contact surface temperature (Temperature of examinee)	: max. 42°C
Relative humidity	: 30 - 75%

#### Storage/Transportation conditions:

Temperature	: -10 - +50°C
Relative humidity	: 10 - 90%
	(Subject to no condensation)

## 9.2 Puncture Guide Fixture EZU-PA3U

Type	: EZU-PA3U
External view	: See Fig.16
Acceptable needle gauge	: 14G, 18G
Materials	: Bio-compatible allergy free components
Classification	: MDD classification IIa
Cleaning	: Applicable detergents are listed in the suppliers list
Sterilization	: Steam Sterilization

## 9.3 Suppliers List

The products listed below are seriously tested and approved for use with C41L47RP Probe.

Product name	manufacturer	purpose
Cidezyme®	Johnson & Johnson	Enzymatic detergent
STERANIOS 2%	ANIOS	Disinfectant
ANIOXYDE1000	ANIOS	Disinfectant
CIDEX	Johnson & Johnson	Disinfectant
CIDEX® plus™ 28	Johnson & Johnson	Disinfectant
CIDEX® OPA	Johnson & Johnson	Disinfectant
HYAMINE SOLUTION	RICCA CHEMICAL COMPANY	Disinfectant
STERIHYDE®	Maruishi Pharmaceutical	Disinfectant/sterilant
WAVICIDE-01	Mediacal Chemical Corp	Disinfectant/sterilant

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

## 9.4 Suppliers List for EZU-PA3U

The products listed below are seriously tested and approved for use with EZU-PA3U.

Product name	manufacturer	purpose
Cidezyme®	Johnson & Johnson	Enzymatic detergent
CIDEX® OPA	Johnson & Johnson	Disinfectant
Korsolex® Endo-Cleaner	Bode Chemie	Detergent
Korsolex® Endo-Disinfectant	Bode Chemie	Disinfectant

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

## 10. Disposal of the probe

Recycle or dispose of 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.

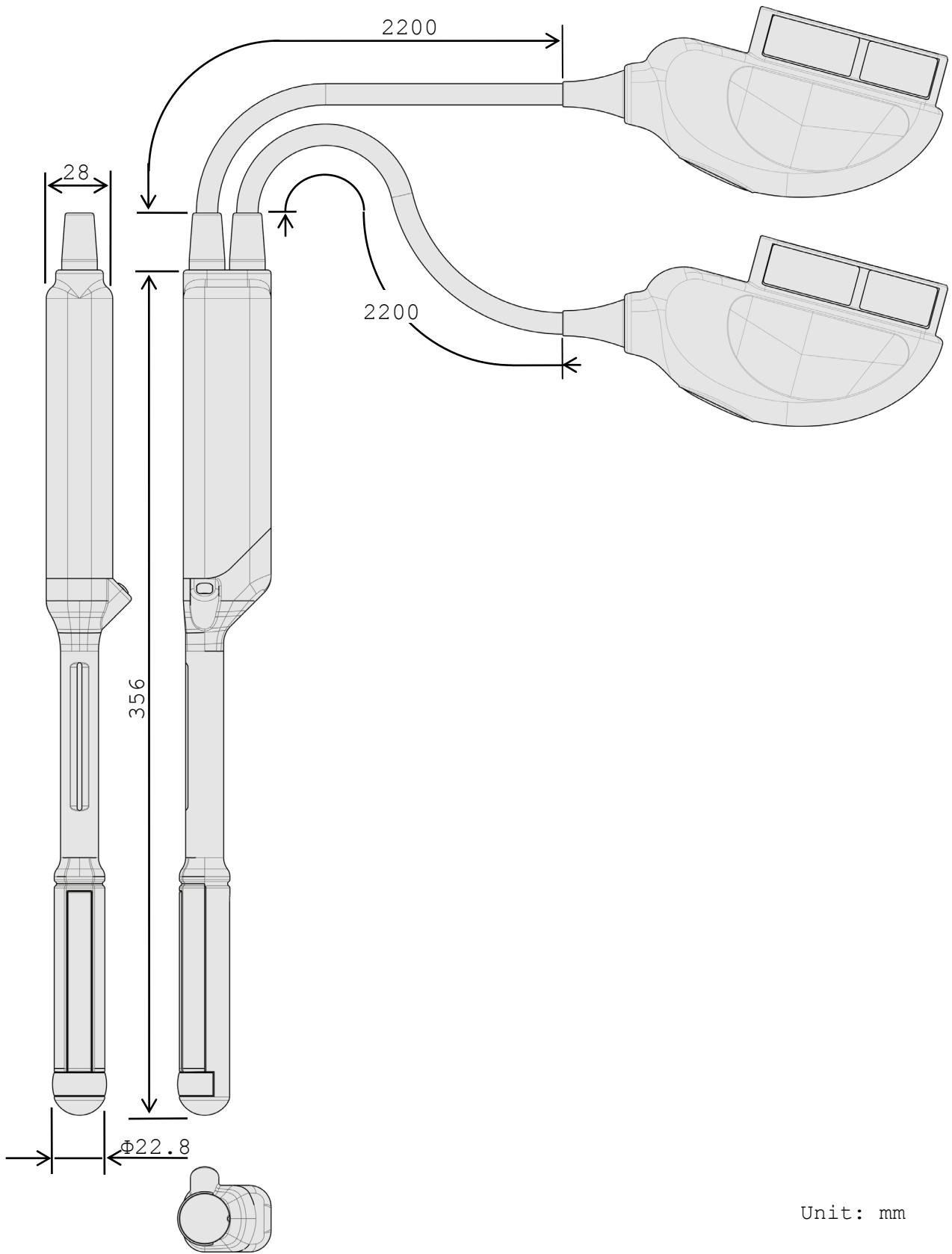
Disposal of the equipment without taking the proper preventative measures can lead to infection.

### 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.





Unit: mm

Fig.15 External view of C41L47RP Probe

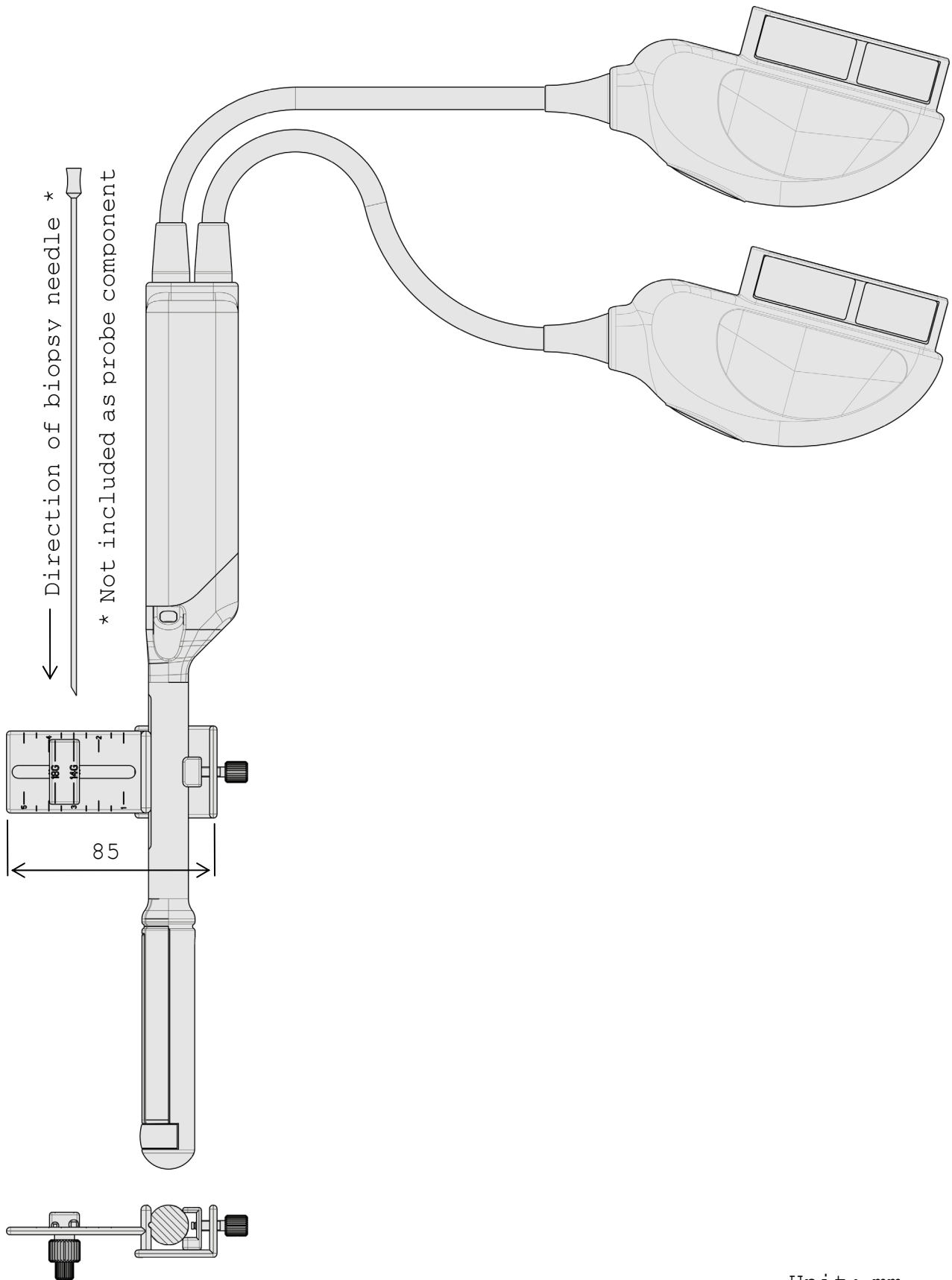
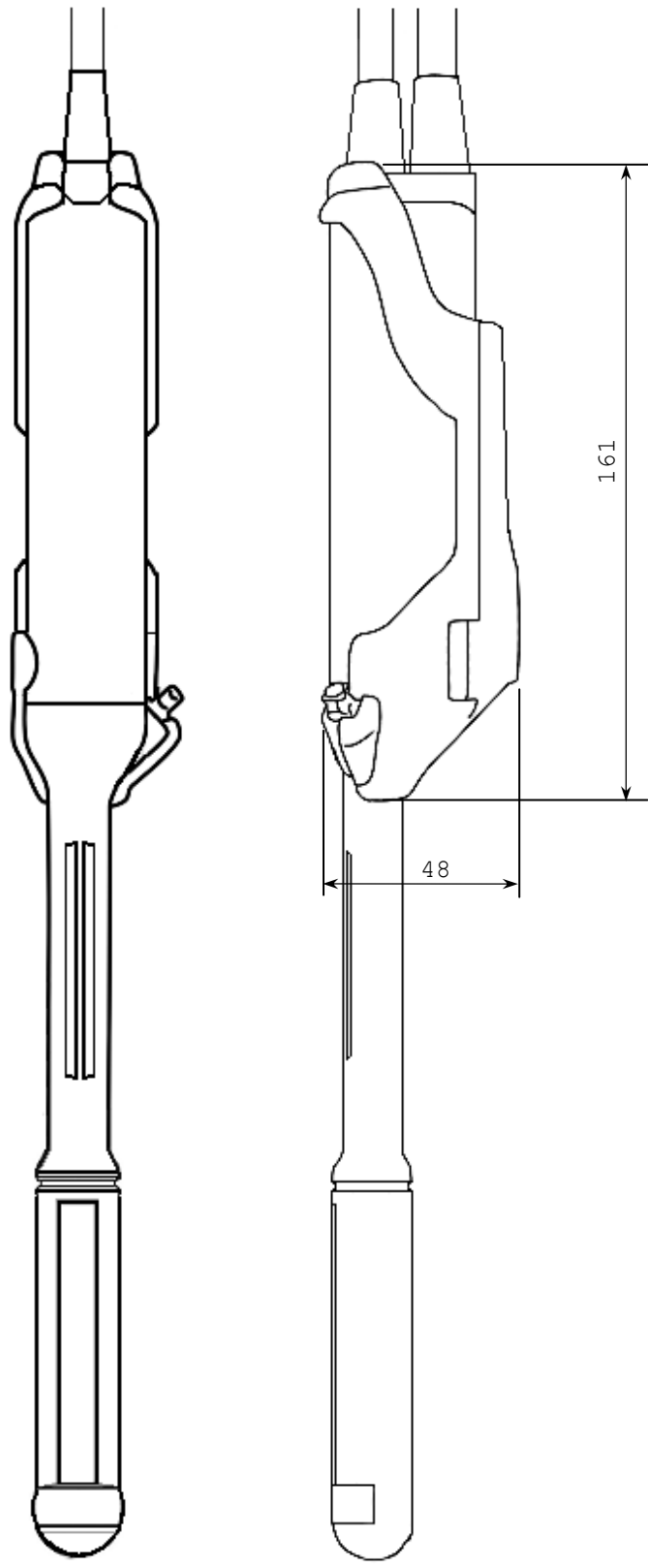


Fig.16 Dimension Diagram with the Puncture Guide Fixture (EZU-PA3U)



Unit: mm

Fig.17 Dimension Diagram with the Magnetic sensor attachment



