HITACHI
Inspire the Next

Biplane Transrectal / Vaginal Probe

EUP-CC531S

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-EP1357-6

CE 0123

Manufacturer: Hitachi, Ltd.

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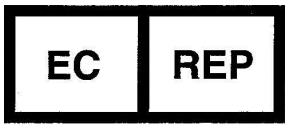
http://www.hitachi.com/businesses/healthcare/index.html

European
Representative: Hitachi Medical Systems GmbH



Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany

EU Importer: Hitachi Medical Systems Europe Holding AG

Address: Sumpfstrasse 13 CH-6300 Zug, Switzerland

Local Distributor:

About this manual

This instruction manual contains safety precautions, the inspection, the operation procedure and the reprocessing procedure of EUP-CC531S. 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.

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

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

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

Graphical Symbols for Use in Labeling of Hitachi Ultrasound Probes

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

Explanation of Symbol	Symbol	Descriptive Content
Manufacturer Company Name and Address		Hitachi, Ltd. 2-16-1, Higashi-Ueno, Taito-ku, Tokyo,110-0015, Japan +81-3-6284-3668 http://www.hitachi.com/businesses/ healthcare/index.html
Authorized Representative in The European Community		Hitachi Medical Systems GmbH Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany
Keep away from Sunlight		Store the probe in a cool place and keep away from high temperature, high humidity, or direct sunlight.
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	CE 0123	This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector	IPX7	IPX7 mark See section 1.6.
Probe connector		Type BF APPLIED PART
Probe connector		General warning sign
Probe connector		Warning; dangerous voltage
Probe connector		Caution; Biohazard
Probe connector		Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.
Probe connector		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

The Biplane transrectal/vaginal probe EUP-CC531S has convex array electronic scanning.
The acoustic output of this probe when connected to Hitachi ultrasound 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 Hitachi 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

The Biplane transrectal/vaginal probe EUP-CC531S is designed for observation and diagnosis of the following regions mainly by connecting with the HITACHI ultrasound diagnostic scanner.

- Transrectal/Vaginal
- Biopsy

⚠ WARNING

Never use the probe for following regions.

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

1.4 Components

Components of EUP-CC531S are as follows:

1) Biplane Transrectal/
   Vaginal Probe EUP-CC531S ..... 1 piece
2) Syringe kit ..... 1 set
   a) Extension Tube ..... 1 piece
   b) Three-way cock ..... 1 piece
   c) Syringe ..... 1 piece
3) 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 Sterile Puncture Adapter EZU-PA5V (Disposable)

Attachment for ultrasound guided transrectal biopsy and aspiration of organs, cyst and tumor. The size of available needle is 16 to 19G. Application requires special care. Sterile Puncture Adapter EZU-PA5V is as follows:

Component	Model	Note
Sterile Puncture Adapter	EZU-PA5V	24 pcs

NOTE: If you need Sterile Puncture Adapters, please contact a service support.

⚠CAUTION

A well-trained physician only should perform a biopsy.

1.5.2 Puncture Guide Fixture EZU-PA3U

Attachment for ultrasound guided transperineal biopsy and aspiration of organs, cyst and tumor. The size of available needle is 14G and 18G. Application requires special care. Puncture Guide Fixture EZU-PA3U is as follows:

Component	Model	Note
Puncture Guide Fixture	EZU-PA3U (14G,18G are compatible)	1 pc

NOTE: If you need Puncture Guide Fixture, please contact a service support.

1.5.3 Mechanical Compression Unit for Elastography EZU-TEMC1 and Balloon Set for Elastography EZU-TEBL1

This mechanical compression unit is used for tissue elasticity imaging, by using the balloon attached to the probe that is connected to a Hitachi's digital ultrasound scanner system and electronic scanning ultrasound tomography system.
Please refer to the instruction manual of option about the method of handling, cleaning and disinfection of EZU-TEMC1 and EZU-TEBL1.

1.5.4 Balloon Kit

This is probe cover which is applicable with this probe.
The composition of the "balloon kit" is as follows.

a) Balloon ····· 12 pieces
b) Rubber Band ····· 24 pieces

⚠ CAUTION

1) This balloon kit is not sterilized. If necessary, using sterilized probe cover is recommend.

2) This is disposable one. Do not reuse it.

⚠ WARNING

The balloon kit is made by latex. 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.

1.5.5 Probe cover (Disposable)

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

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.

1.5.6 The Magnetic sensor attachment

The Magnetic sensor attachment is used for Real-time Virtual Sonography (RVS). By using the attachment, the Magnetic sensor is attached to the probe that is connected to a Hitachi digital ultrasound scanner system.

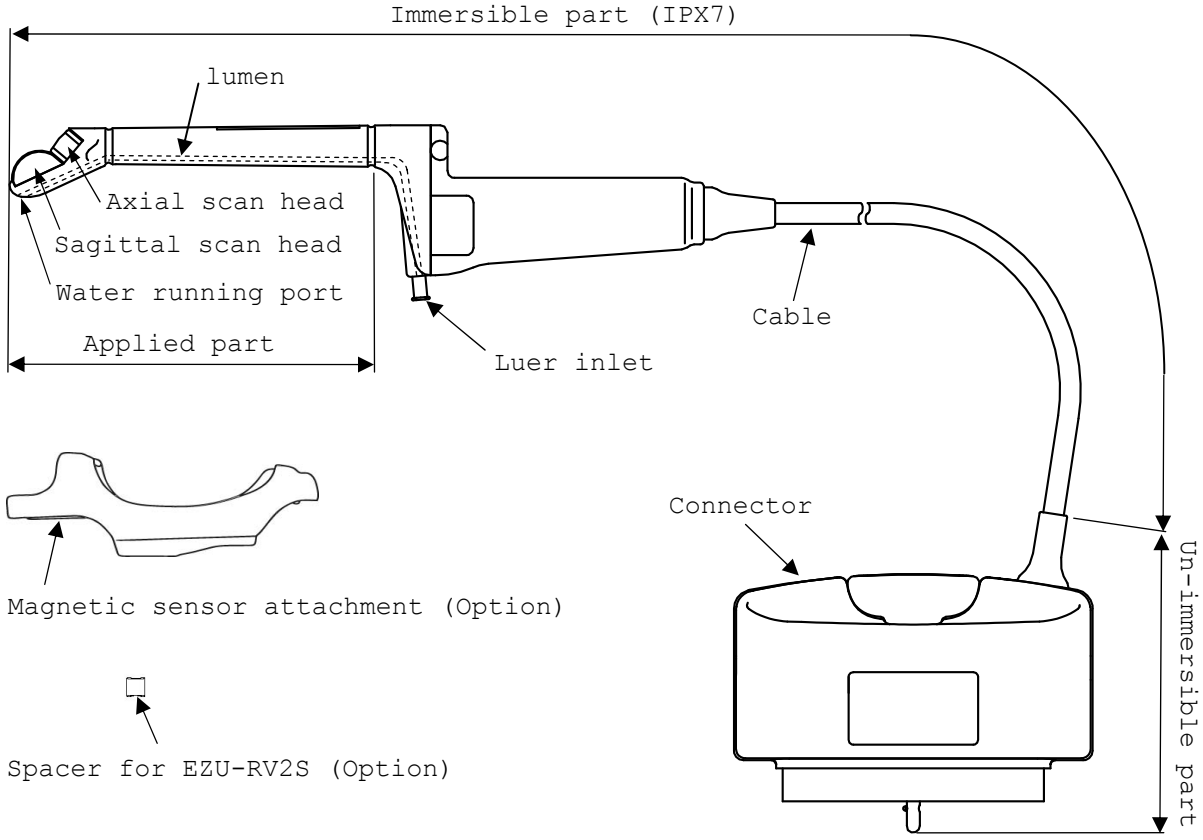
1.5.7 The Spacer for EZU-RV2S

The Spacer for EZU-RV2S is used for Real-time Virtual Sonography (RVS) with EZU-RV2S. By using the Spacer, the Magnetic sensor for EZU-RV2S is attached to the Magnetic sensor attachment.

⚠CAUTION

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

1.6 Construction



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

Fig.1 External view

2 Inspection before Use

Prior to use, the probe and accessories 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 on the probe, such as unauthorized biopsy attachments.

2.1.3 Confirm that the Sterile Puncture Adapter, Puncture Guide Fixture and software version and then settings of the scanner are appropriate for the probe. Attach the Sterile Puncture Adapter or Puncture Guide Fixture on the probe. Set the main unit to display the "Needle guide line". (Refer to the operation manual for the main unit.) Keep the probe head in the water and insert a puncture needle in the Sterile Puncture Adapter or 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 the envelope of the Sterile Puncture Adapter or Puncture Guide Fixture for any break, deformation, crack or denaturalization.

2.2.3 Visually inspect the Magnetic sensor attachment and the Spacer for EZU-RV2S for any crack, deformation or denaturalization.

2.2.4 Confirm whether there is the Spacer for EZU-RV2S nearby when use RVS with EZU-RV2S.

⚠CAUTION

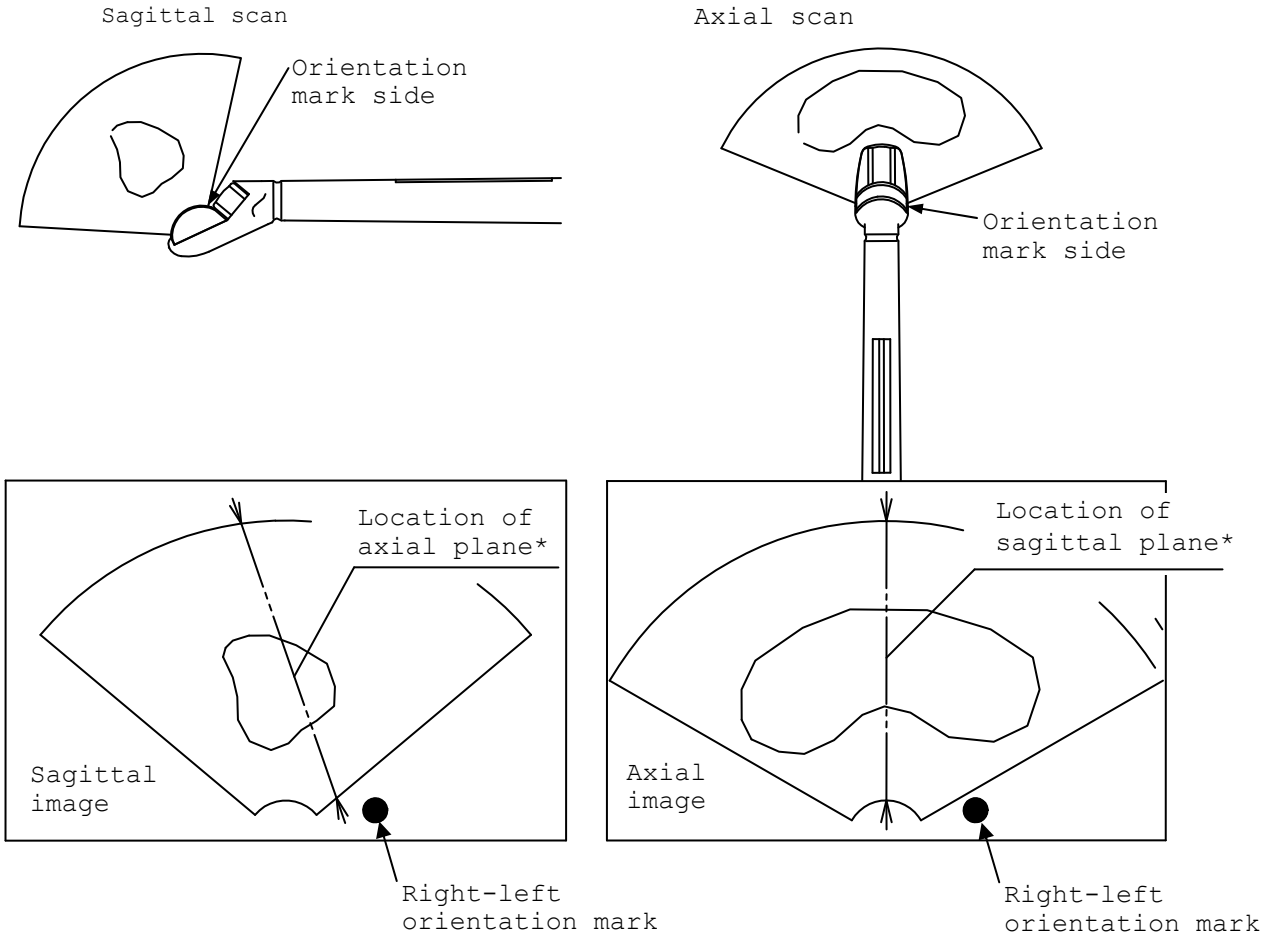
The Spacer for EZU-RV2S is small, please do not lose the Spacer.

3 Operation Procedure

3.1 Connection and Settings

1) Confirm that the probe is disinfected. In case of using Real-time Virtual Sonography (RVS), confirm that the Magnetic sensor attachment is disinfected and if necessary sterilized. In case of using RVS with EZU-RV2S, confirm that the Spacer for EZU-RV2S is also disinfected and if necessary sterilized.
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 ultrasound diagnostic scanner.

4) Confirm the direction of the probe. The relationship between the direction of the probe and the image is shown in Fig.2. The right-left orientation mark indicates the direction of the index mark of the probe.



(*This line is shown by the two-dot chain line in the Figure, but not displayed on the screen.)

Fig.2 The relationship between the direction of the probe and the right-left orientation mark

3.2 General Instruction

1) In prior to starting the examination, prepare below-mentioned materials.
   - Protective probe cover which is recommended
   - Rubber band
   - Extension tube
   - Three-way cock
   - Syringe
   - Physiological saline
2) Make below-mentioned preparations for the examination.
   (1) Covering the probe with the protective probe cover from the top of probe is recommended.

⚠ WARNING

Be careful with a protective probe cover made from the latex. The latex may cause such allergic reactions as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, 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 probe cover immediately and take an appropriate treatment to the patient.

   (2) Tighten the protective probe cover by the rubber band.
   (3) Connect the extension tube, three-way cock, syringe filled with physiological saline to the water injection port of probe and fill the protection sleeve with physiological saline. In case of remaining the air in the protective probe cover, deflate the air bubble with the syringe.
   (4) Return physiological saline to the syringe.

3) Perform the examination under following procedures.
   (1) Insert the probe into patient's body.
   (2) Pour an adequate volume of physiological saline into the protective probe cover.
   (3) Perform the examination. Regarding adjustments of image and so on, refer to the operating manual of the scanner to which the probe is connected.
   (4) When the examination is finished, return physiological saline in the protective probe cover to the syringe before removing the probe from the body.
   (5) Remove the probe from the body.
4) After using the probe, clean and disinfect and if necessary sterilize the probe immediately and using RVS, also clean and disinfect and if necessary sterilize the Magnetic sensor attachment. In case of using RVS with an EZU-RV2S, also clean and disinfect/sterilize the Spacer for EZU-RV2S.
5) Store the probe and accessory in the environment indicated in "7.Maintenance and Safety Inspection".

3.3 Use of Sterile Puncture Adapter (EZU-PA5V)

The process of attaching the Sterile Puncture Adapter (EZU-PA5V) to the probe is as follows. If the Sterile Puncture Adapter shall be used, take care not to destroy the probe cover.

1) Attach a protective probe cover to the probe. (See "3.2 General Instruction")
2) Put the picks of the Sterile Puncture Adapter to the grooves on the tip of the probe. (See Fig.3)
3) Push the other end of the Sterile Puncture Adapter until fix the dents of the Sterile Puncture Adapter to the projection on the probe. (See Fig.4)

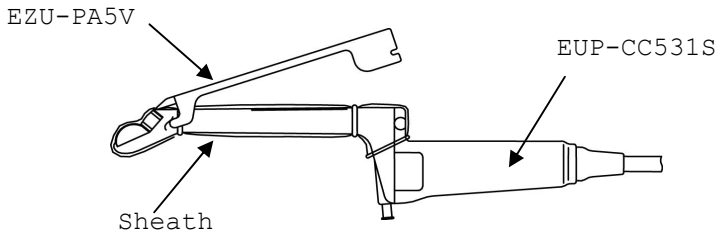


Fig. 3

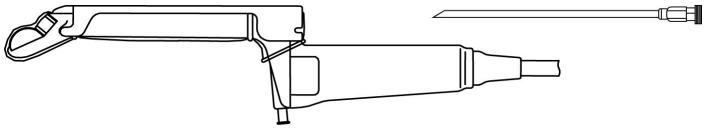


Fig. 4

3.4 Use of Puncture Guide Fixture (EZU-PA3U)

The process of attaching the Puncture Guide Fixture (EZU-PA3U) to EUP-CC531S is as follows;

1) Attaching the protective probe cover to the probe is recommended. (See "3.2 General Instruction")
2) Set the Puncture Guide Fixture on the probe as shown in Fig.5, and fix it by tightening the screw 1.
3) By loosing the screw 2, the needle holder in which the guide recess is formed can be moved vertically. The scale on the Puncture Guide Fixture is of 0.5cm/division.

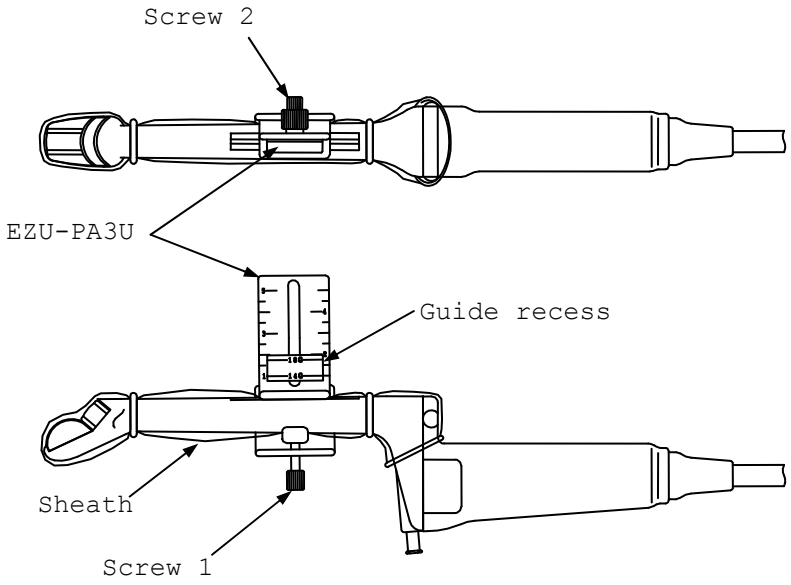


Fig. 5

3.5 Display of Needle Guide Line

When puncture is to be conducted, the needle guideline can be displayed by dot marks. Operation procedure for displaying the needle guideline on the main unit must be referred to the part of "Needle Guide Line" in the manual of the connected ultrasound scanner.

NOTE: The needle guideline will be displayed to provide a visual guide to the direction of the puncture needle pathway. Be sure to check the actual location of the needle on the ultrasound image when performing the puncture operation.

1) When using the sterile puncture adapter EZU-PA5V, make it sure that the mark "FIX" shows up on the upper right corner of the screen in place of the above two digits.(See Fig.6)
2) When using the puncture guide fixture EZU-PA3U, the positional information on the puncture fitting will be shown in two digits on the upper right corner of the screen showing the sagittal image.(See Fig.6)

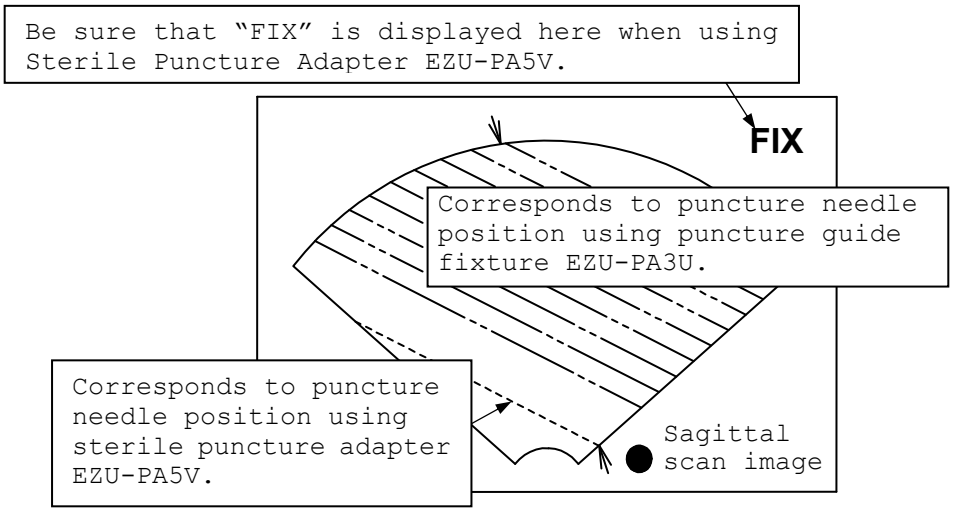


Fig. 6 Position of Puncture Needle Guide Line

NOTE: In case of switching over depth of the needle guideline on the screen, turn the periphery of "ANGLE key encoder" to switch over depth.

⚠ WARNING

1) When displaying the needle guideline of the Sterile Puncture Adapter EZU-PA5V, never use the Puncture Guide Fixture EZU-PA3U. So, use the Sterile Puncture Adapter EZU-PA5V without fail.
2) When displaying the needle guideline of the Puncture Guide Fixture EZU-PA3U, never use the Sterile Puncture Adapter EZU-PA5V. So, use the Puncture Guide Fixture EZU-PA3U without fail.

4 Magnetic Sensor for EUP-CC531S

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 EUP-CC531S, EZU-RV2S and EZU-RV3S.
The Magnetic sensor (EZU-RV2S) and the Magnetic sensor (EZU-RV3S) are shown in Fig.7 and Fig.12.
The uses of EUP-CC531S with wither 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 EUP-CC531S.

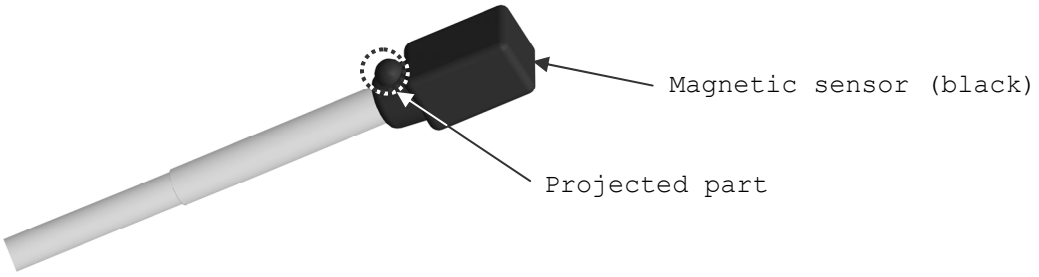


Fig.7 Magnetic sensor (EZU-RV2S)

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 and the Spacer for EZU-RV2S are disinfected and if necessary 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 RVS (Real-time Virtual Sonography), 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.

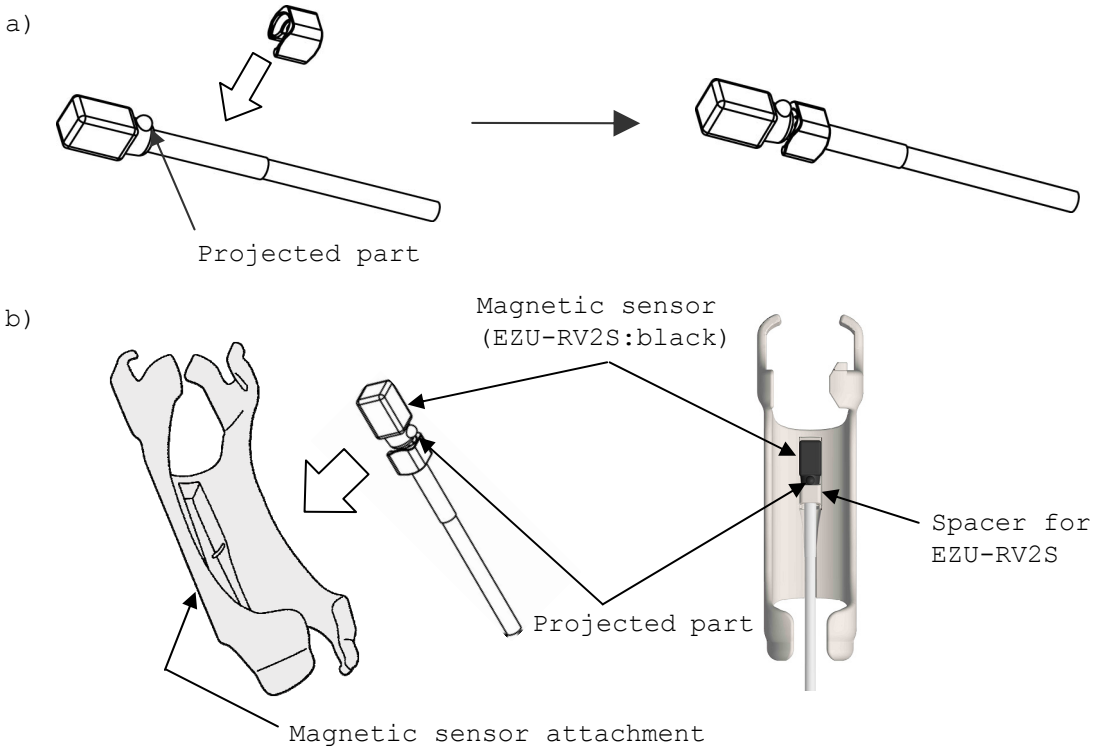


Fig.8 How to attach the Magnetic sensor

⚠ CAUTION

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

c) Attach the Magnetic sensor attachment to the probe as shown in Fig.9.

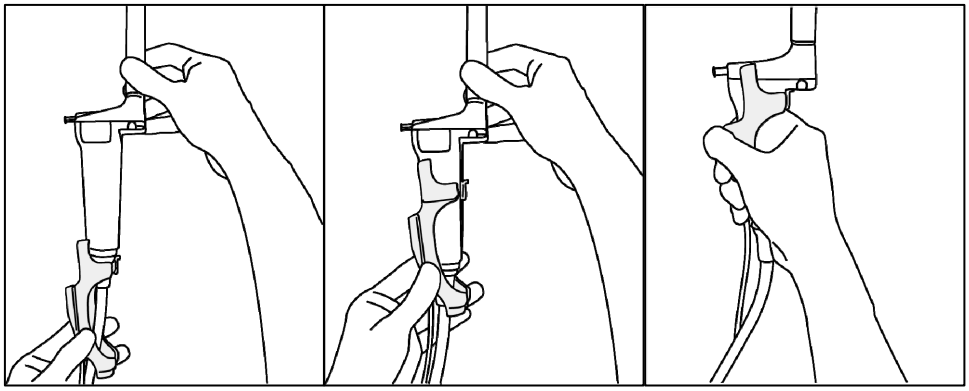


Fig.9 How to attach the Magnetic sensor attachment

⚠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) Release the Magnetic sensor attachment from the probe as shown in Fig.10.

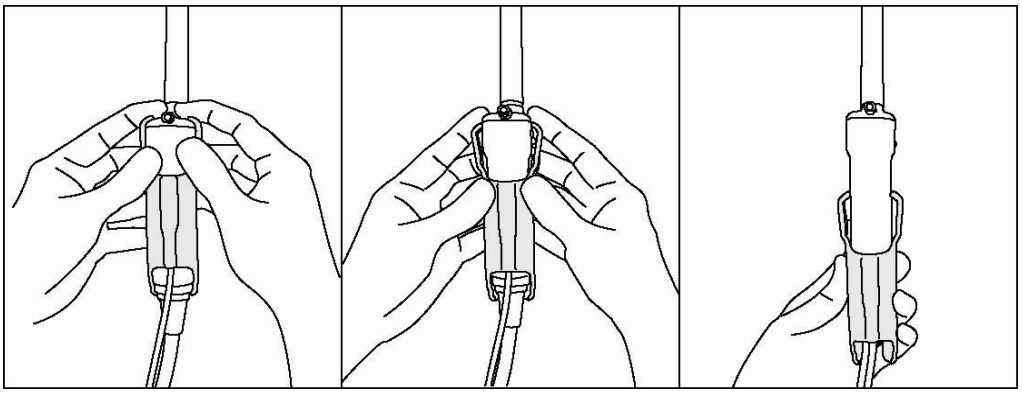


Fig.10 How to release the Magnetic sensor attachment from the probe

2) Release the Magnetic sensor and the Spacer for EZU-RV2S from the Magnetic sensor attachment as shown in Fig.11.

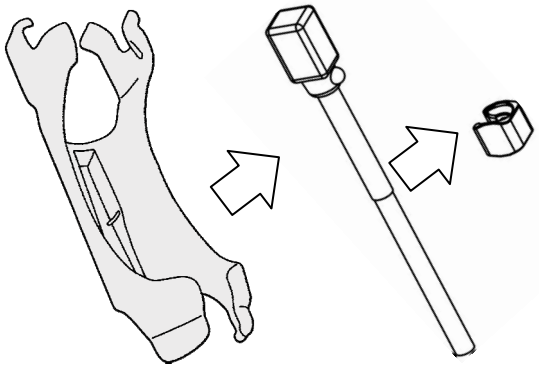


Fig.11 How to release the Magnetic sensor from the Magnetic sensor attachment

⚠ CAUTION

Clean, disinfect and sterilize the Magnetic sensor attachment and the Spacer for EZU-RV2S before the first use as there are not sterilized in the factory.

4.2 Magnetic Sensor (EZU-RV3S)

The Magnetic sensor (EZU-RV3S) as shown in Fig.12 is the Magnetic sensor for EUP-CC531S.

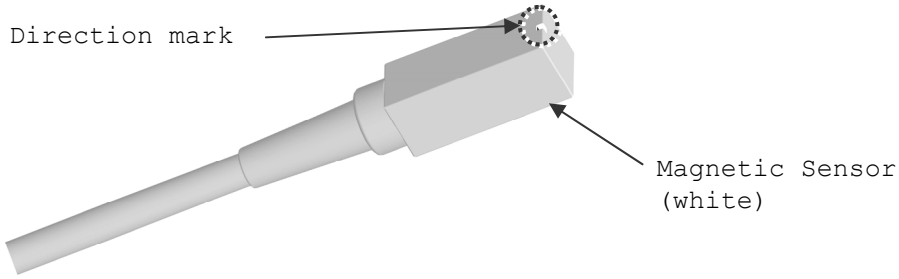


Fig.12 Magnetic sensor (EZU-RV3S)

4.2.1 How to attach the Magnetic Sensor

The procedure of attaching the Magnetic sensor is as follow.

1) Confirm that the Magnetic sensor attachment and the Spacer for EZU-RV3S are disinfected and if necessary 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 RVS (Real-time Virtual Sonography), attach the Magnetic sensor as shown below.

a) Attach the Spacer to the Magnetic sensor.
b) Insert the Magnetic sensor into the Magnetic sensor attachment with the correct direction as shown in Fig.13.

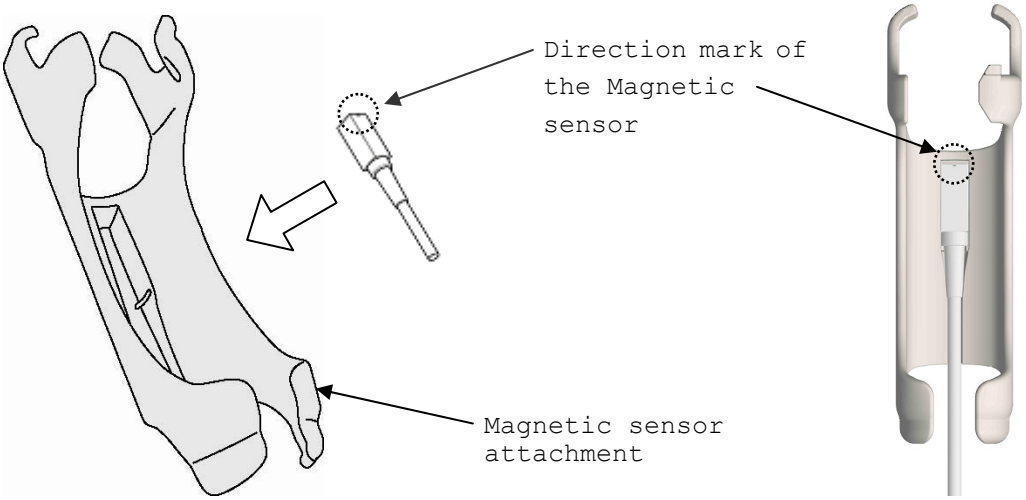


Fig.13 How to attach the Magnetic sensor

⚠CAUTION

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

c) Attach the Magnetic sensor attachment to the probe as shown in Fig.14.

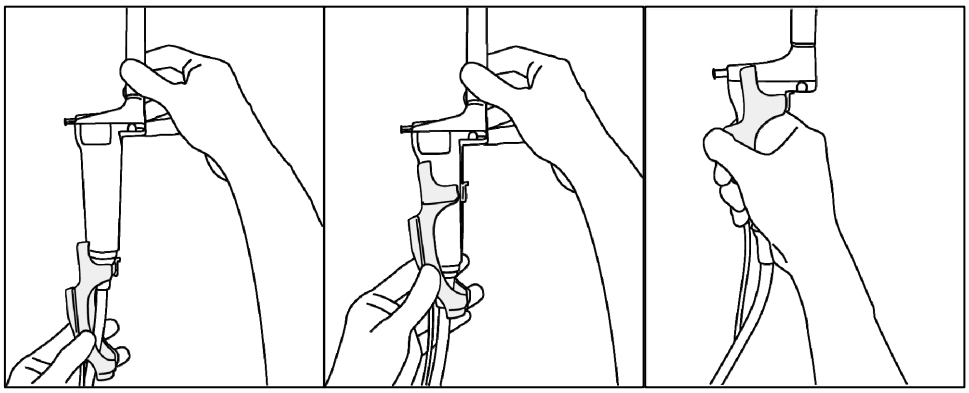


Fig.14 How to attach the Magnetic sensor attachment

⚠CAUTION

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

4.2.2 How to release the Magnetic Sensor

The procedure of releasing the Magnetic sensor is as follow.

1) Release the Magnetic sensor attachment from the probe as shown in Fig.15.

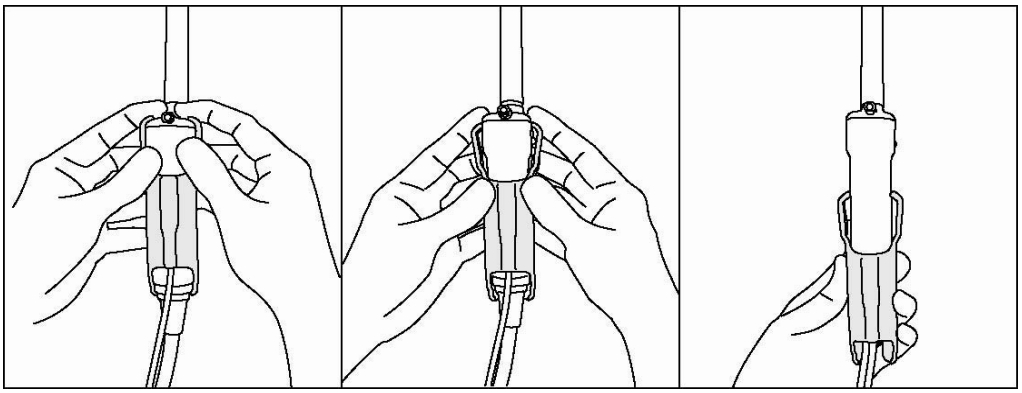


Fig.15 How to release the Magnetic sensor attachment from the probe

2) Release the Magnetic sensor from the Magnetic sensor attachment as shown in Fig.16.

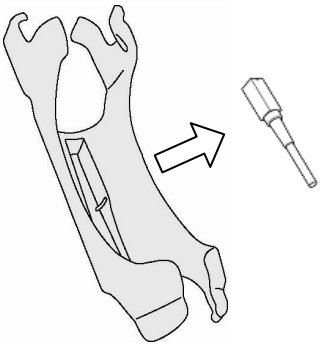


Fig.16 How to release the Magnetic sensor from the Magnetic sensor attachment

⚠CAUTION

Clean, disinfect and sterilize the Magnetic sensor attachment before the first use as there are not sterilize in the factory.

5 Cleaning, Disinfection and Sterilization

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

WARNINGS	- Particular attention is required when reprocessing probes with lumen. - The probe is delivered unsterile. Prior to the first use, reprocess the probe. - Temperature should not exceed 60°C during reprocessing. - Probe connector is not water resistant.
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.

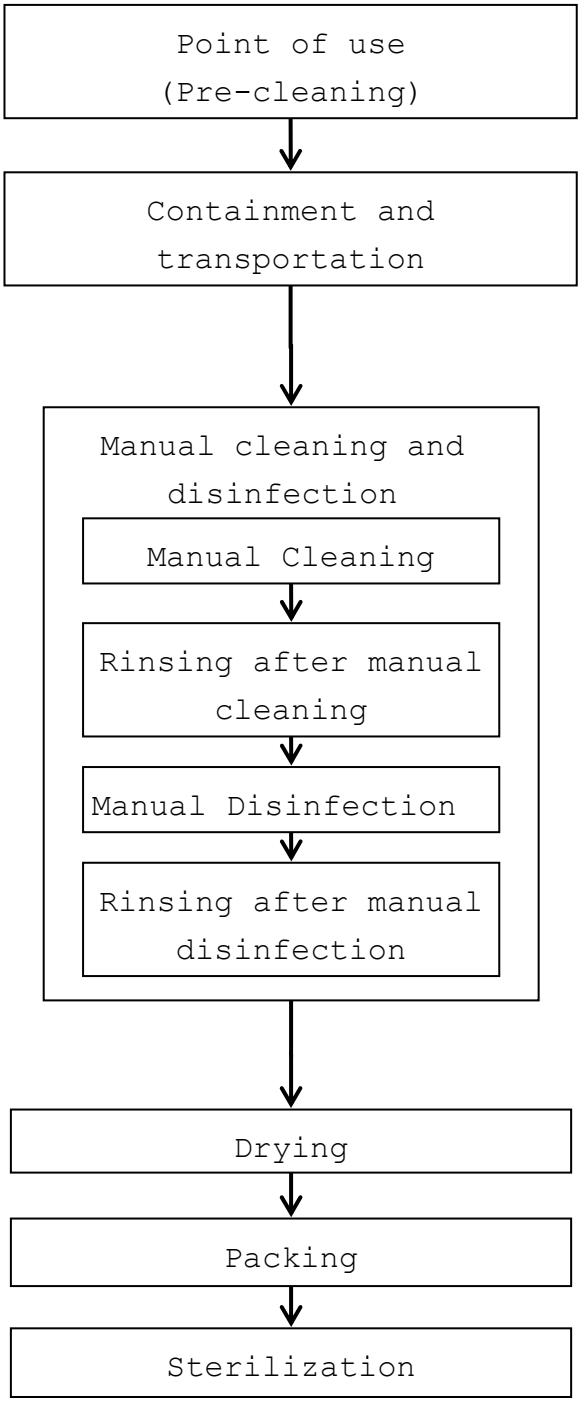
Levels of reprocessing requirements:

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, EUP-CC531S 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) EUP-CC531S

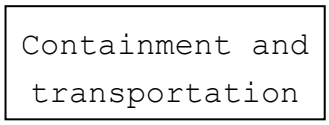
1) Remove the protective cover.
2) Flush the lumen of the probe directly after use with 50 ml deionized water/tap water using a 50 ml syringe (adaptation of the syringe to the Luer inlet of the probe).
3) Clean the probe of all patient's blood or fluid with running tap water until the surface of the probe looks visually clean.
4) Wipe the whole surface of the probe with gauze pad and remove superficial visible impurities.

B) Magnetic sensor attachment and Spacer for EZU-RV2S

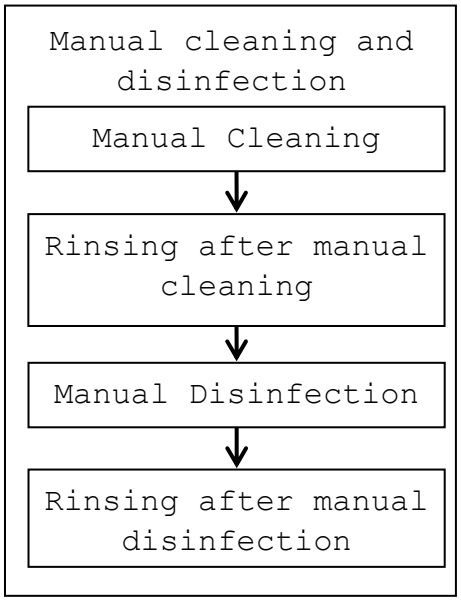
1) Remove the Magnetic sensor attachment and the magnetic sensor from the probe. Remove the Spacer for EZU-RV2S from the magnetic sensor if the sensor is EZU-RV2S.
2) Immerse the Magnetic sensor attachment and the Spacer for EZU-RV2S in sufficient amount of high quality tap water. Scrub them using soft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

5.2 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® or another cleaning agent with approved material compatibility for this medical device (Johnson & Johnson, #2258)

b) Disinfectant: Cidex® OPA or another disinfectant with approved material compatibility for this medical device (Johnson & Johnson, # 20391)

c) Cleaning brushes if applicable, i.e. Olympus Model Nr. BW-400L (cleaning the lumen of the water channel)

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 immersible part of the probe at full length)

e) Syringe 50 ml with Luer-lock

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:

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) EUP-CC531S

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. Wipe the immersible part of the probe under the surface of the detergent solution with a soft cloth to remove all visible soil.

3) Use the syringe via the Luer inlet to fill and rinse the lumen with the detergent solution. The lumen of the probe is rinsed 5 times under the surface of the detergent solution with 50 ml diluted detergent. Drain the detergent out of the lumen by using the syringe. Afterwards, remove the syringe from the probe.

4) Insert the cleaning brush into the lumen via the Luer inlet until the end of the channel is reached. Brush the whole length of the lumen 5 or more times. In addition all immersible parts of the probe are wiped with a soft cloth until visually clean.

⚠ CAUTION

The inside of the water channel is very sensitive, so if the water channel is cleaned, cleaning brush should be operated carefully. If brushing is rough, water channel may suffer serious damage.

5) Rinse the lumen 5 times with 50 ml detergent solution by using the syringe.

6) The immersible part of the probe should be left in the detergent solution according to the specified contact time of the detergent manufacturer.

7) Wipe the un-immersible parts of the probe with a soft cloth dipped with the detergent solution.

8) Rinse the probe and the lumen with running tap water for 1 minute, ensuring that the lumen is rinsed properly.
(alternatively: immerse the immersible part of the probe in a tray filled with tap water (see Fig.17) for 5 min. and rinse the lumen of the probe with 50 ml deionized water/tap water 5 times by using the syringe)

9) 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 and Spacer for EZU-RV2S

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 and the Spacer for EZU-RV2S into the diluted detergent solution. Wipe them under the surface of the detergent solution with a soft cloth to remove all visible soil.

3) The Magnetic sensor attachment and the Spacer for EZU-RV2S should be left in the detergent solution according to the specified contact time of the detergent manufacturer.

4) Rinse the Magnetic sensor attachment and the Spacer for EZU-RV2S with running tap water for 1 minute. (alternatively: immerse them in a tray filled with deionized water/tap water (see Fig.17) 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.

Manual disinfection:

A) EUP-CC531S

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.17). Use the syringe via the Luer inlet to fill and rinse the lumen with the disinfectant solution. The lumen of the probe is rinsed 5 times under the surface of the disinfectant solution with 50 ml disinfectant. Set a clock to insure the recommended contact time which is 5 minutes. Note that air inside the lumen should be removed to disinfect properly.

4) Rinse the immersible part of the probe and the lumen of the probe with deionized water for 1 minute, ensuring that the lumen is rinsed properly.

   (alternatively: immerse the immersible part of the probe in a tray filled with deionized water (see Fig.17) for 5 min. and rinse the lumen of the probe with 50 ml deionized water 5 times by using the syringe)

5) Visually check the outer surface of the probe for leavings of the disinfectant. If necessary, repeat the rinsing.

B) Magnetic sensor attachment and Spacer for EZU-RV2S

1) Prepare the disinfectant solution as stated in the procedure for the probe.

2) Immerse the Magnetic sensor attachment and the Spacer for EZU-RV2S into the disinfectant (see Fig. 17). Set a clock to insure the recommended contact time which is 5 minutes.

3) Rinse the Magnetic sensor attachment and the Spacer for EZU-RV2S with deionized water for 1 minute. (alternatively: immerse them in a tray filled with deionized water (see Fig.17) for 5 min.)

4) Visually check the outer surface of the Magnetic sensor attachment and the Spacer for EZU-RV2S for leavings of the disinfectant. If necessary, repeat the rinsing.

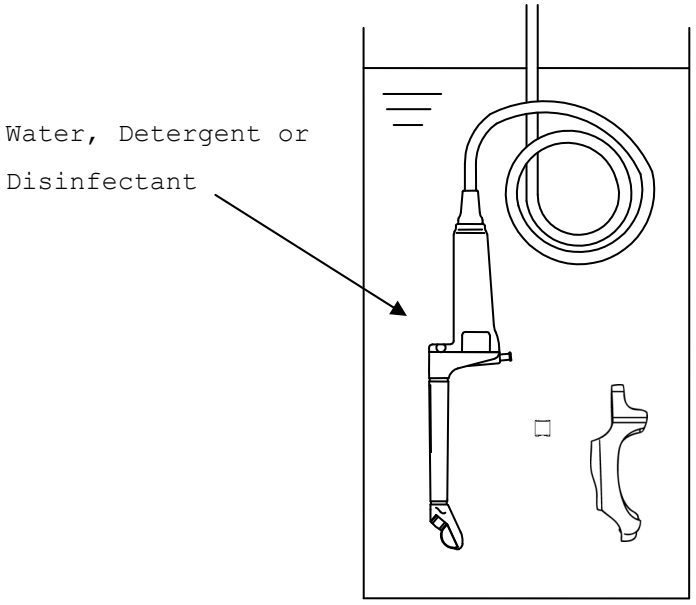


Fig.17 Immersion of the Probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S

5.4 Drying

Drying

1) Wipe the probe with a single-use, fluff-free wipe or towel to remove moisture from the surface of the probe.

2) Dry the lumen by applying compressed air. The compressed air should be filtered by a sterile filter that removes air particles of less than 0.2 µm. Dry until no visible moisture is left.

3) Dry the probe naturally in an ambient temperature between 15-30°C for a minimum of 4 hours. Alternatively the probe 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.

5.7 Sterilization

Sterilization

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	➢ Gas Type: 10% EO/ 90% HCFC ➢ Temperature: 50-55˚C ➢ Exposure Time: More than 120 minutes ➢ Pressurization: 162-200kPa Depressurization: 13-8kPa ➢ Relative humidity: 40-90% ➢ Aeration is minimum 12 hours

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

⚠ WARNING

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

2) Do not sterilize the probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S by Steam Autoclaving. If you autoclave them, they suffers serious damage and will be not functional.

The packaging procedure is as follows.

1) Put the probe into TYVEK pouch.

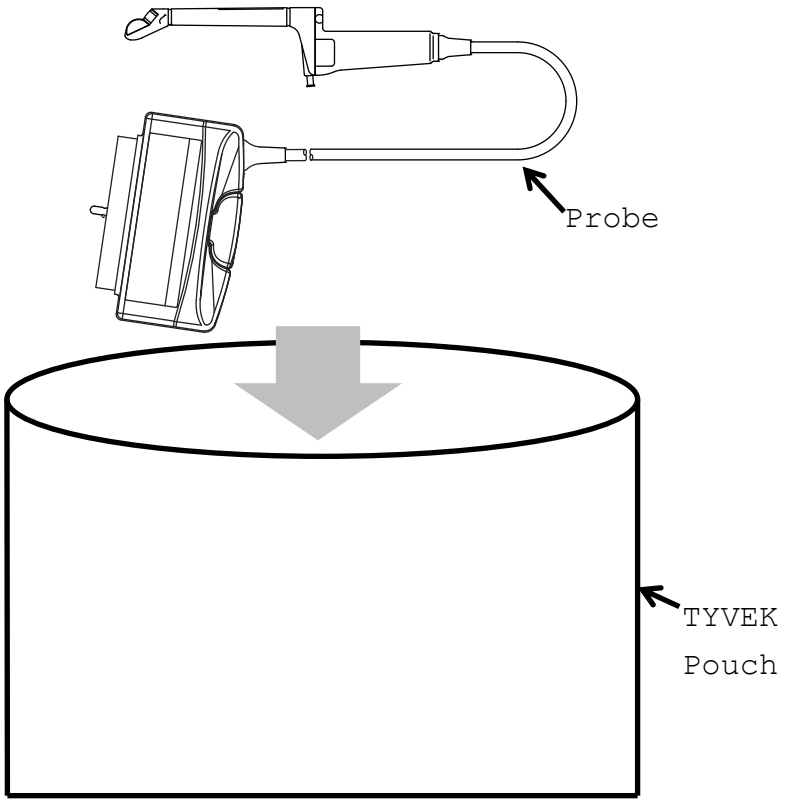


Fig.18 Packaging in the pouch

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

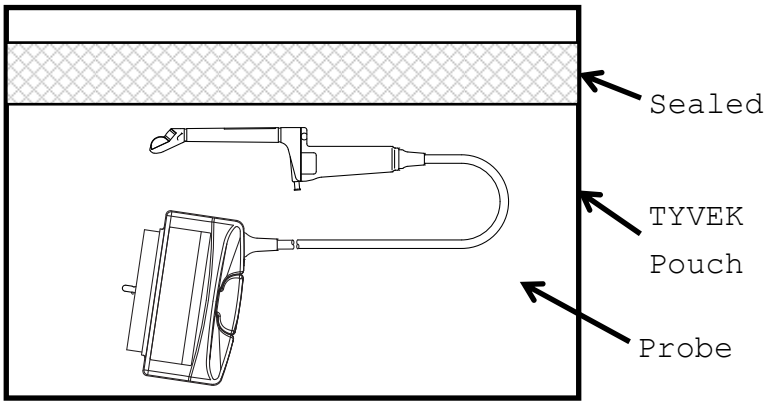


Fig.19 Sealing

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

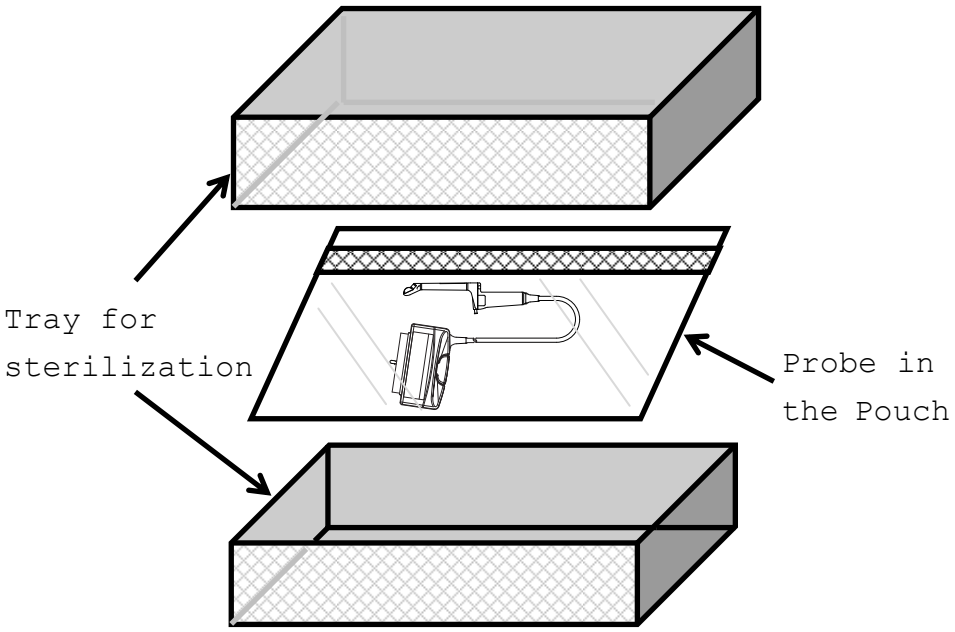


Fig.20 Packaging in a tray

5.8 Storage

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

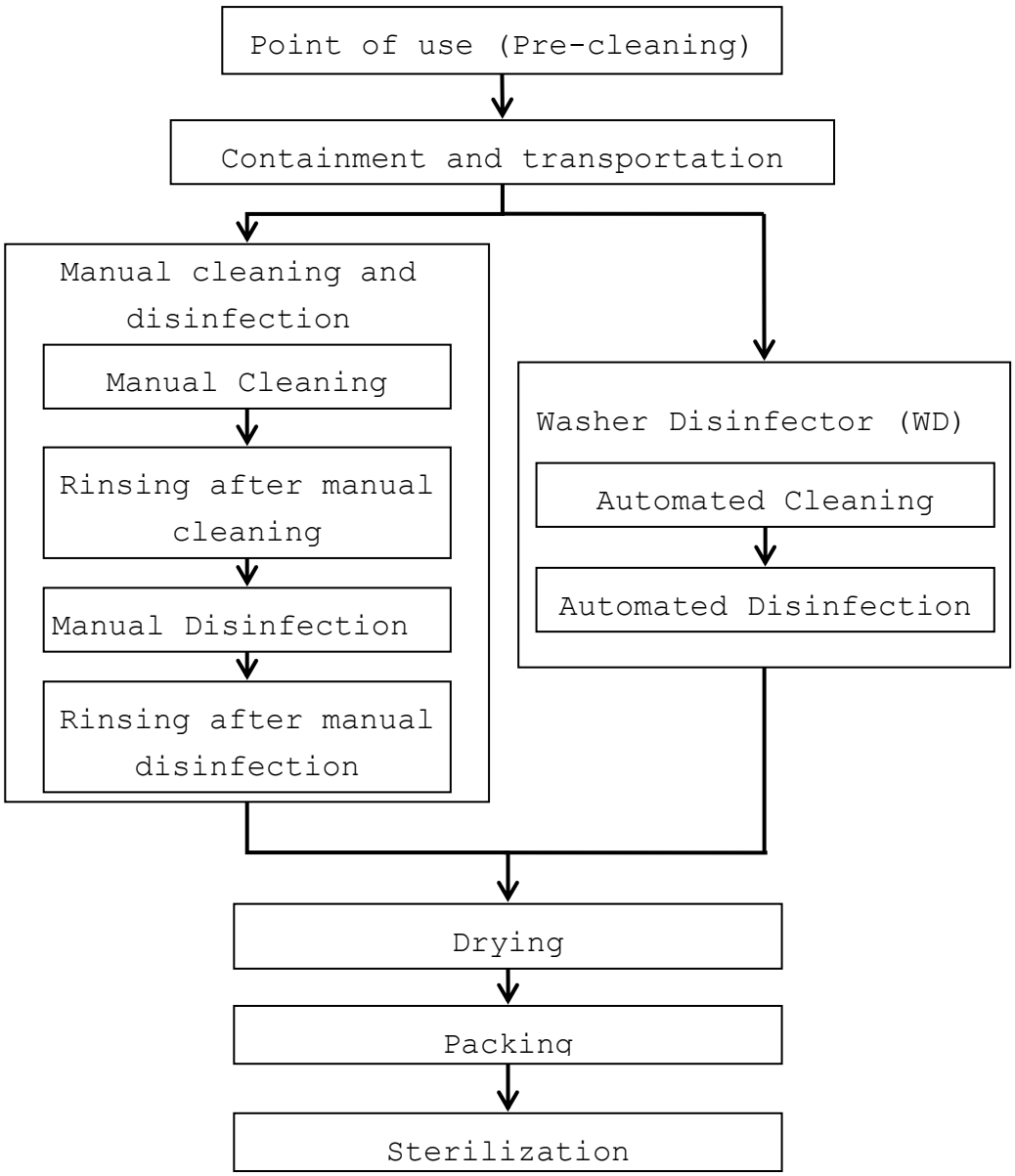
6 Cleaning, Disinfection and Sterilization of EZU-PA3U

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. The cavities of the puncture guide fixture require particular attentions during all processes. The puncture guide fixture must be dismantled into single parts before reprocessing.
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) Flush patient's blood or fluid by tap water from the puncture guide fixture directly after use, until the surface looks visually clean.

3) Disassemble the EZU-PA3U (Fig.21) 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.

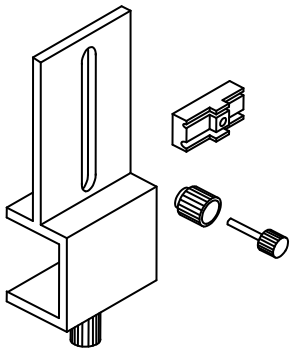


Fig.21 Disassembly of EZU-PA3U

6.2 Containment and transportation

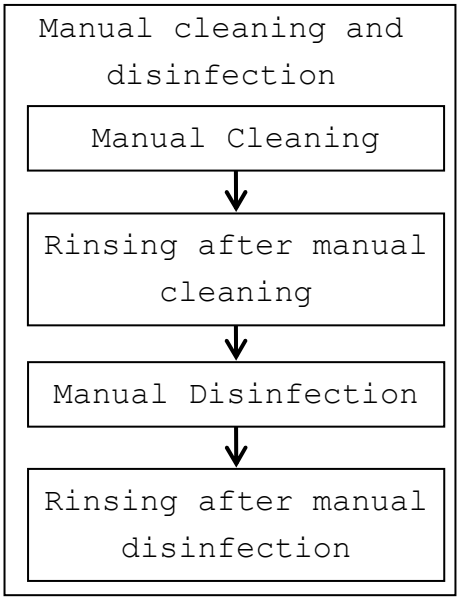
Refer to 5.2.

6.3 Manual Cleaning and disinfection

<u>Prepare following items before manual cleaning and disinfection:</u>

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, e.g. REF 09098 (Interlock)

d) Two tanks, one for cleaning and one for disinfection - optional: 1 additional tank for rinsing with deionized/tap water

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:

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. Brush the whole length of the cavity at least 5x using an applicable brush.

3) Using a syringe flush the cavity of the puncture guide fixture 5x under the surface of the detergent solution with 50 ml diluted detergent.

4) Wipe the parts of the puncture guide fixture under the surface of the detergent solution with a soft, fluff free cloth. Be sure that all grooves of the puncture guide fixture are implemented during the cleaning process.

5) The parts of the EZU-PA3U should be left in the detergent solution according to the specified contact time of the detergent manufacturer.

6) 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.17) for 5 min. and rinse the cavity of the puncture guide fixture with 50 ml tap water. Repeat this 5x.)

7) 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:

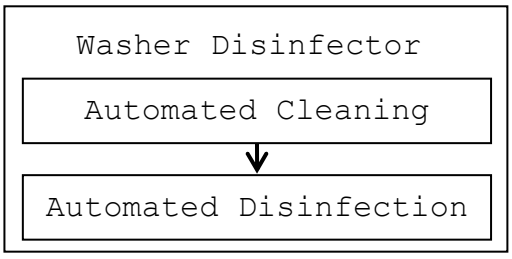
1) Prepare the disinfectant solution as stated in the procedure for the probe.

2) Immerse the parts of the EZU-PA3U into the disinfectant. Rinse the cavity of the puncture guide fixture with 50 ml disinfectant solution. Repeat this 4x. 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. and rinse the cavity of the puncture guide fixture with 50 ml deionized water. Repeat this 5x.)

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.

b) Detergent: Korsolex Endo-Cleaner (Bode Chemie; # 972 020)

c) Disinfectant: Korsolex Endo Disinfectant (Bode Chemie; # 972 030)

d) Washer disinfector accessories:

Basket for holding the puncture guide fixture

Basket with lid for holding the dismantled small parts (e.g. screws) of the puncture guide fixture

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 disinfector. Smaller parts like the screws must be placed in a strainer basket with lid.

3) Close the door of the washer disinfector 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 disinfector 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.

6.8 Sterilization

Sterilization

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	➢ Gas Type: 10% EO/ 90% HCFC ➢ Temperature: 50-55°C ➢ Exposure Time: More than 120 minutes ➢ Pressurization: 162-200kPa Depressurization: 13-8kPa ➢ Relative humidity: 40-90% ➢ Aeration is minimum 12 hours
Steam Autoclaving (that is applicable to only EZU-PA3U)	➢ Temperature: min. 132°C ➢ Chamber Pressure:41.7-44.7psia(27-30psig or 3bar) ➢ Exposure time: Minimum 10 minutes.

* 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 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.

7.2 Storage

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 and dark place avoid high temperature and humidity direct sunlight.

8 Safety Precautions

⚠ WARNING

1) Never use the probe if the probe head, housing or cable are cracked or damaged.
2) When use EUP-CC531S for biopsy purpose, use Sterile Puncture Adapter EZU-PA5V (Option) or Puncture Guide Fixture EZU-PA3U (Option) certainly.
3) Never use the Sterile Puncture Adapter or Puncture Guide Fixture if the adapter 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, such 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.
5) The ultrasound gel attached to the ultrasound scanner as one of accessories is not sterile so never use it with EUP-CC531S.

⚠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 and disinfect/sterilize the probe, syringe kit, the Magnetic sensor attachment and the Spacer for EZU-RV2S before the first use as it is not sterilize in the factory.
7) Use only the soft cloth or tissue to clean the acoustic lens.
8) A well-trained physician should only perform a biopsy.
9) Do not attach unapproved devices to the probe.
10) The probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S are delivered without being disinfect or sterilized.

9 Specifications

9.1 Probe

Type : Biplane Transrectal/Vaginal Probe EUP-CC531S

Acoustic working frequency

- Sagittal scan head : 6.5MHz
- Axial scan head : 6.5MHz

Technology : Convex Array Probe

Dimensions : See Fig.22

Weight : Approx.0.95kg (Including cable and connector)

Scanning angle

- Sagittal scan head : 100°
- Axial scan head : 120°

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

Operating conditions:

- Ambient temperature : +10 – +35°C
- Contact surface temperature (Temperature of examinee) : max. 42°C
- Relative humidity : 30 – 85%
- Atmospheric Pressure : 700 – 1060hPa

Storage conditions:

- Temperature : –10 – +55°C
- Relative humidity : 10 – 95% (Subject to no condensation)
- Atmospheric Pressure : 700 – 1060hPa

Transport conditions:

Temperature	: -10 – +55°C
Relative humidity	: 10 – 95% (Subject to no condensation)
Atmospheric Pressure	: 700 – 1060hPa

9.2 Needle Guides (Option)

Needle guideline display of main unit is not accepted change of following two systems. So, if you need for changing of following two systems, please contact a service support.

9.2.1 Sterile Puncture Adapter EZU-PA5V

Type	: EZU-PA5V
Dimension	: See Fig.23
Acceptable needle gauge	: 16G to 19G
Materials	: Bio-compatible allergy free components
Classification	: MDD classification IIa
Package	: 24 Sterile Puncture Adapters for single use
Sterilization method	: Sterilized with gamma irradiation
Operating conditions:	
Temperature	: -10 – 40°C
Relative humidity	: 10 – 95°%
Atmospheric Pressure	: 700 – 1060hPa
Storage conditions:	
Temperature	: -10 – 40°C
Relative humidity	: 10 – 95°%
Atmospheric Pressure	: 700 – 1060hPa
Transport conditions:	
Temperature	: -10 – 60°C
Relative humidity	: 10 – 95°%
Atmospheric Pressure	: 700 – 1060hPa

9.2.2 Puncture Guide Fixture EZU-PA3U

Type	: EZU-PA3U
Dimension	: See Fig.24
Acceptable needle gauge	: 14G to 18G
Materials	: Bio-compatible allergy free components
Classification	: MDD classification IIa
Cleaning	: Applicable detergents are listed in the suppliers list
Sterilization method	: ETO gas sterilization, Autoclave
Operating conditions:	
Temperature	: -10 – 40°C
Relative humidity	: 10 – 95°%
Atmospheric Pressure	: 700 – 1060hPa
Storage conditions:	
Temperature	: -10 – 55°C
Relative humidity	: 10 – 95°%
Atmospheric Pressure	: 700 – 1060hPa
Transport conditions:	
Temperature	: -10 – 55°C
Relative humidity	: 10 – 95°%
Atmospheric Pressure	: 700 – 1060hPa

9.3 Suppliers List

The products listed below are seriously tested and approved for use with the biplane transrectal/vaginal probe EUP-CC531S.

Product name	manufacturer	purpose
Cidezyme	Johnson & Johnson	Enzymatic detergent
Meliseptol HBV-Tücher	Braun	Disinfectant
Incidin Liquid	Henkel Hygiene GmbH	Disinfectant
Incidur Spray	Henkel Hygiene GmbH	Disinfectant
STERANIOS 2%	ANIOS	Disinfectant
CIDEX plus	Johnson & Johnson	Disinfectant
CIDEX OPA	Johnson & Johnson	Disinfectant
ALKACIDE	ALKAPHARM	Disinfectant
Bacillol 25	BODE CHEMIE	Disinfectant
ALKAZYME	ALKAPHARM	Cleaner
Balloon kit, part number: 1450303A	Hitachi, Ltd.	Probe cover

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 this equipment properly in compliance with the Waste Management and Public Cleansing Law.

⚠ CAUTION

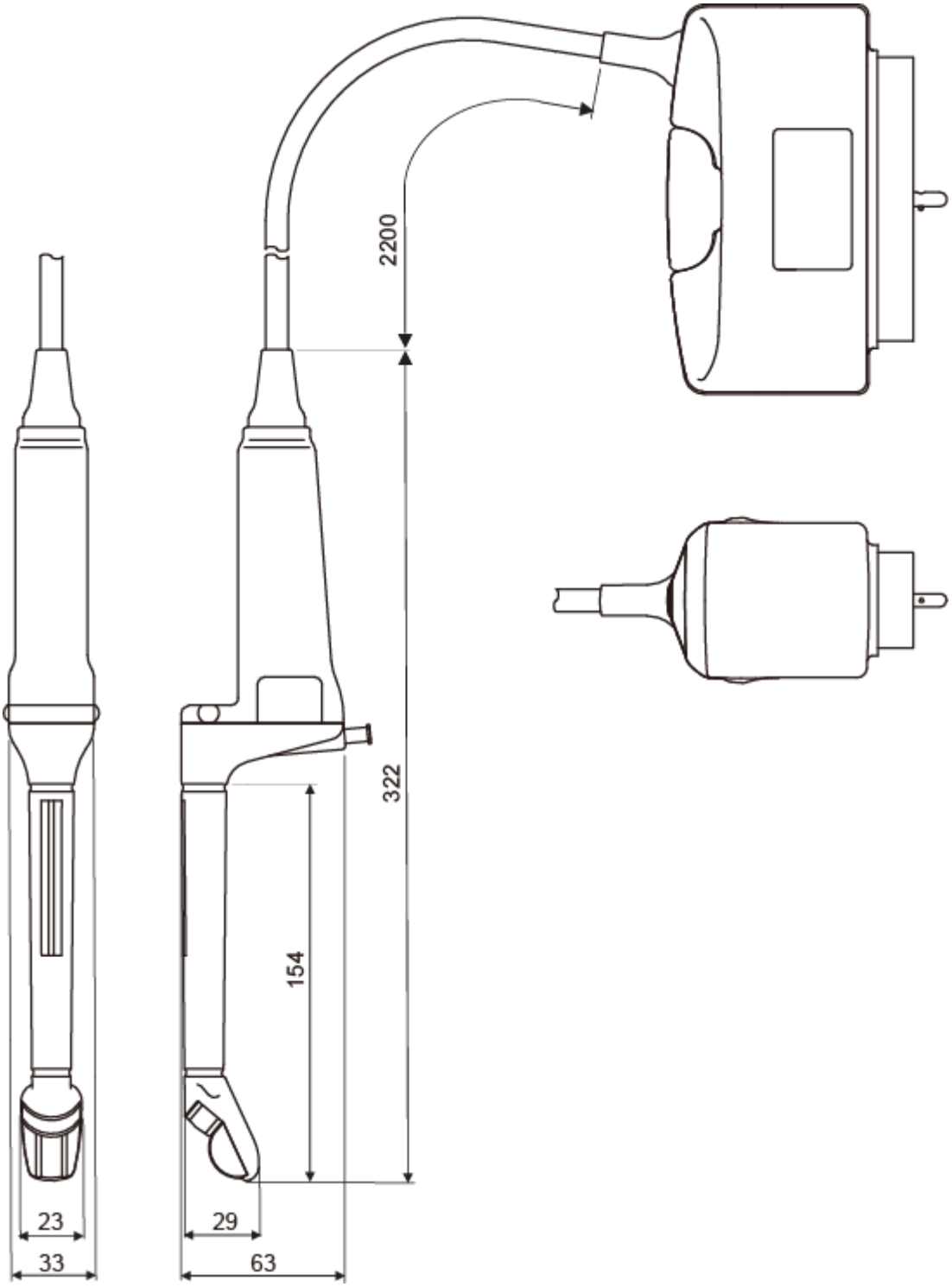
Before disposing of the equipment, disinfect or take other infection-prevention measures.

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

Waste Electrical and Electronic Equipment (WEEE) Directive

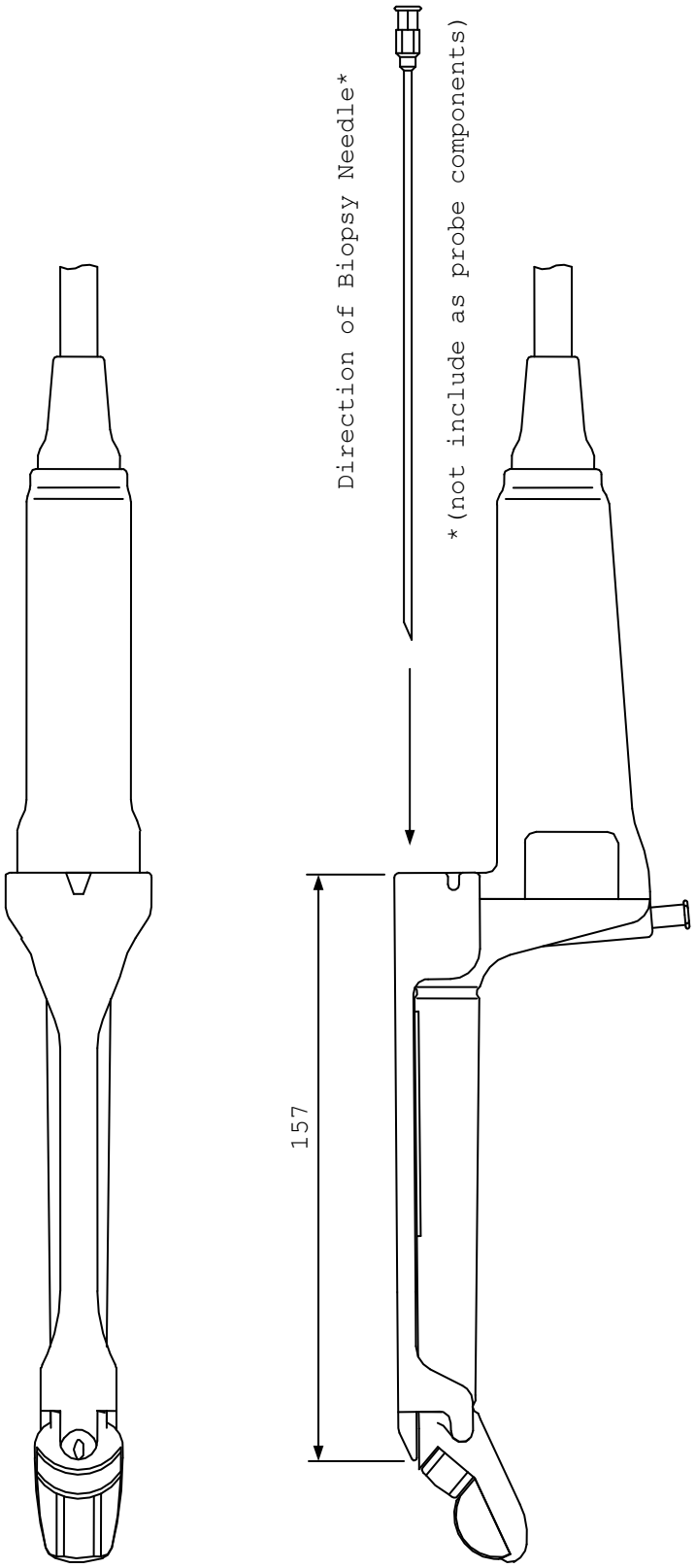
The illustration on the right is required by the EU WEEE Directive to appear on all electrical and electronic equipment.

For proper disposal of this product in an EU nation, contact an EU office or agency and observe appropriate local and national regulations and laws.



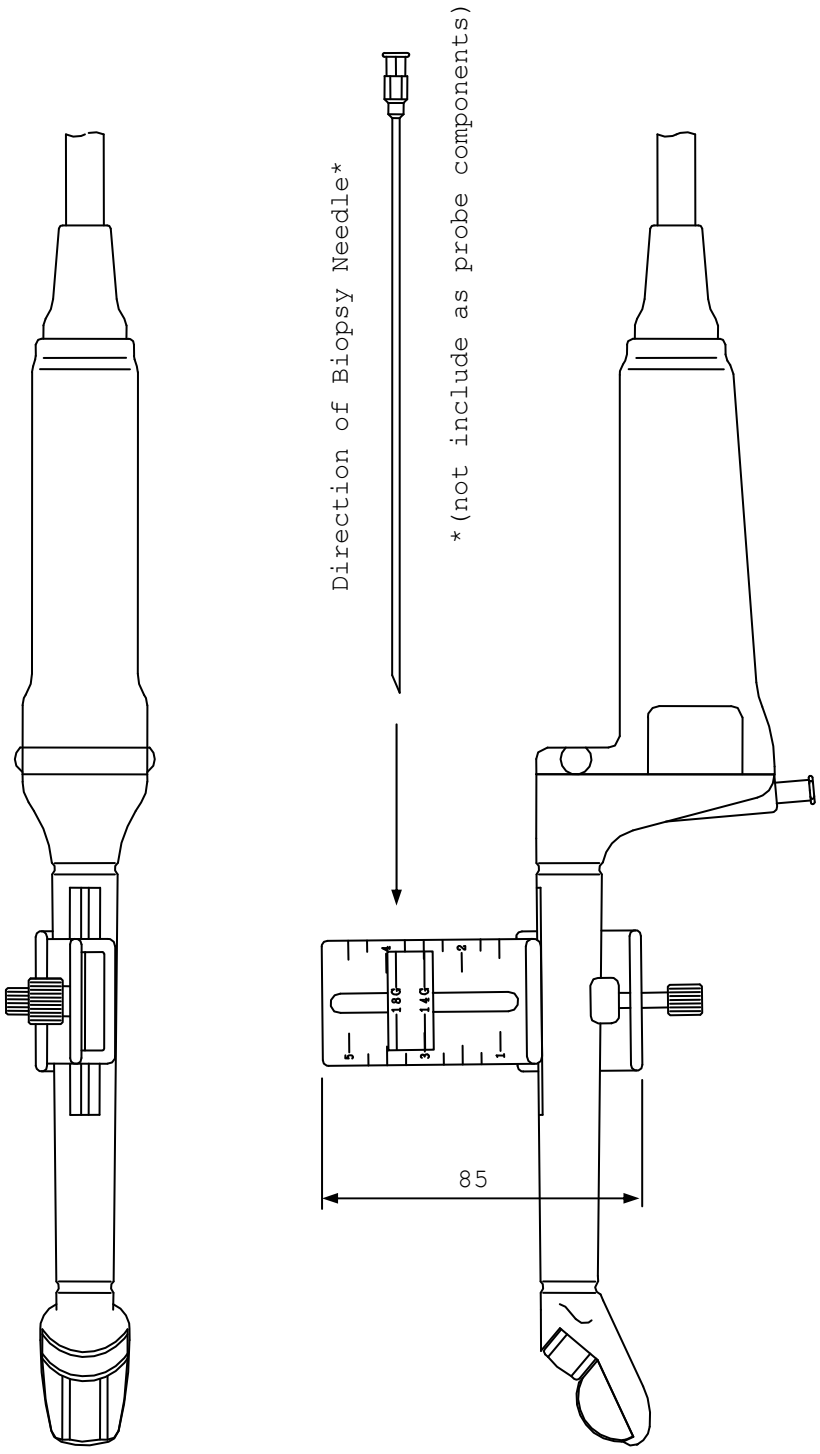
Unit: mm

Fig.22 Dimension Diagram of EUP-CC531S



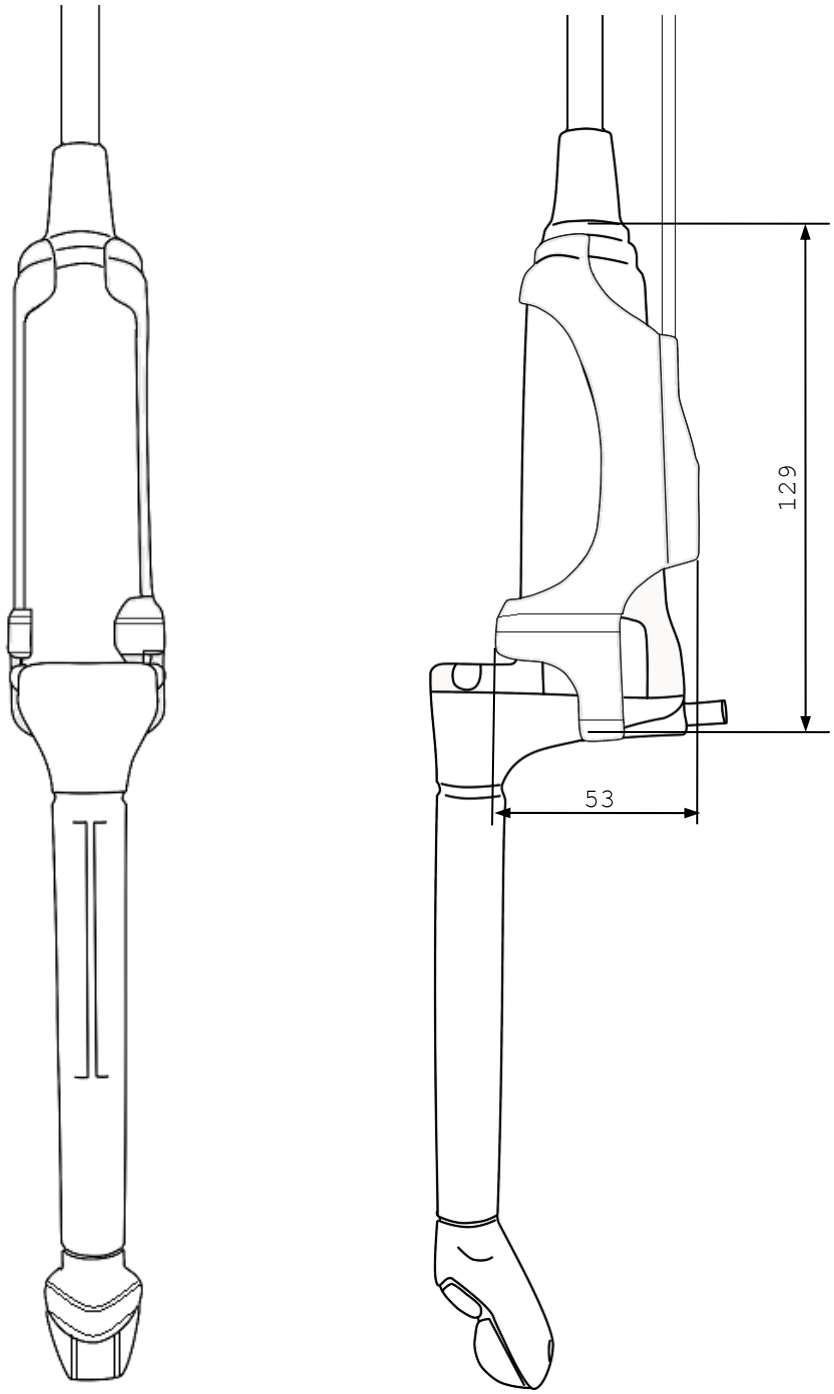
Unit: mm

Fig.23 Dimension Diagram with Sterile Puncture Adapter (EZU-PA5V):Option



Unit: mm

Fig.24 Dimension Diagram with Puncture Guide Fixture (EZU-PA3U): Option



Unit: mm

Fig.25 Dimension Diagram with The Magnetic sensor attachment: Option