HITACHI
Inspire the Next

# Transvaginal Probe

EUP-V53W

# 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-EP0325-15



CE 0123

Manufacturer:

Hitachi, Ltd.
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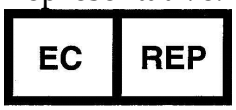


Hitachi Medical Systems GmbH
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EU Importer: Hitachi Medical Systems Europe Holding AG
Address: Sumpfstrasse 13 CH-6300 Zug, Switzerland

Local Distributor:

About this manual

This instruction manual contains safety precautions, the inspection, the operation procedure and the reprocessing procedure of EUP-V53W. 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 Symbols
The following conventions are used throughout the manual to denote special emphasis.

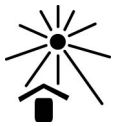
WARNING: "Warning" indicates the presence of a hazard which may result in severe personal injury, substantial property damage, or death if the warning is ignored.

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.

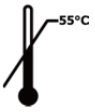
Graphical Symbols for Use in Labeling of Hitachi Ultrasound Probes

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.<br>2-16-1, Higashi-Ueno, Taito-ku, TOKYO, 110-0015, Japan<br>+81-3-6284-3668<br>http://www.hitachi.com/businesses/healthcare/index.html |
| Authorized Representative in The European Community |  | Hitachi Medical Systems GmbH<br>Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany |
| Keep away from Sunlight |  | Store the probe in a cool, dustproof and dark, dry environment to avoid high temperature and humidity and 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<br>See section 1.6. |
| Probe connector |  | Type BF APPLIED PART |
| Probe connector |  | General warning sign |
| Probe connector |  | Warning; dangerous voltage |
| Probe connector |  | Caution; Biohazard |
| Probe connector |  | Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble. |
| Probe connector | Compatible STERRAD Sterilization System | STERRAD sterilization compatibility mark |
| Probe connector |   | Upper Limit of Temperature;<br>The probes that are applicable to Ethylene Oxide Gas Sterilization use symbol of "Upper Limit of Temperature: 55 degrees". |
| Probe connector |  | Do not waste the instrument as general waste. Comply with a local regulation. |
| Probe connector | 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 transvaginal probe EUP-V53W is Convex Array electronic scanning.

The acoustic output of this probe when connected to ultrasound scanner was measured according to the IEC60601-2-37 standard. The table of measured acoustic output data is contained in the operational manual of each ultrasound 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 Transvaginal Probe EUP-V53W is designed for observation and diagnosis of the following regions mainly by connecting with the HITACHI ultrasound diagnostic scanner.

- General OB/GYN organs
- Biopsy (with a Sterile Puncture Adapter)
- Transrectal

**⚠WARNING**

Never use the probe for following regions.

1) The heart (Do not contact directly.)

2) The eyeball

## 1.4. Components

Components of EUP-V53W are as follows:

1) Transvaginal Probe EUP-V53W ·· 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. Sterile Puncture Adapter EZU-PA5V (Disposable)


Attachment for ultrasound guided transvaginal or 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. Mechanical Compression Unit for Elastography EZU-TEMC1 and balloon set for Elastography EZU-TEBL2

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-TEBL2.

### 1.5.3. Condom or Protection Sleeve for Single Use (Disposable)

To protect the probe against contamination, use only lubrication free condom or protective tube sleeve, which is dry type.


Lubrication may cause a deterioration of the probe surface. And latex rubber may create allergic reactions, use of non-allergic condom or sleeve is strongly recommended.

Take care for the handling of used condom or protection sleeve.

### 1.5.4. Magnetic Sensor Attachment

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 and electronic scanning ultrasound tomography system.

### 1.5.5. Spacer for EZU-RV2S

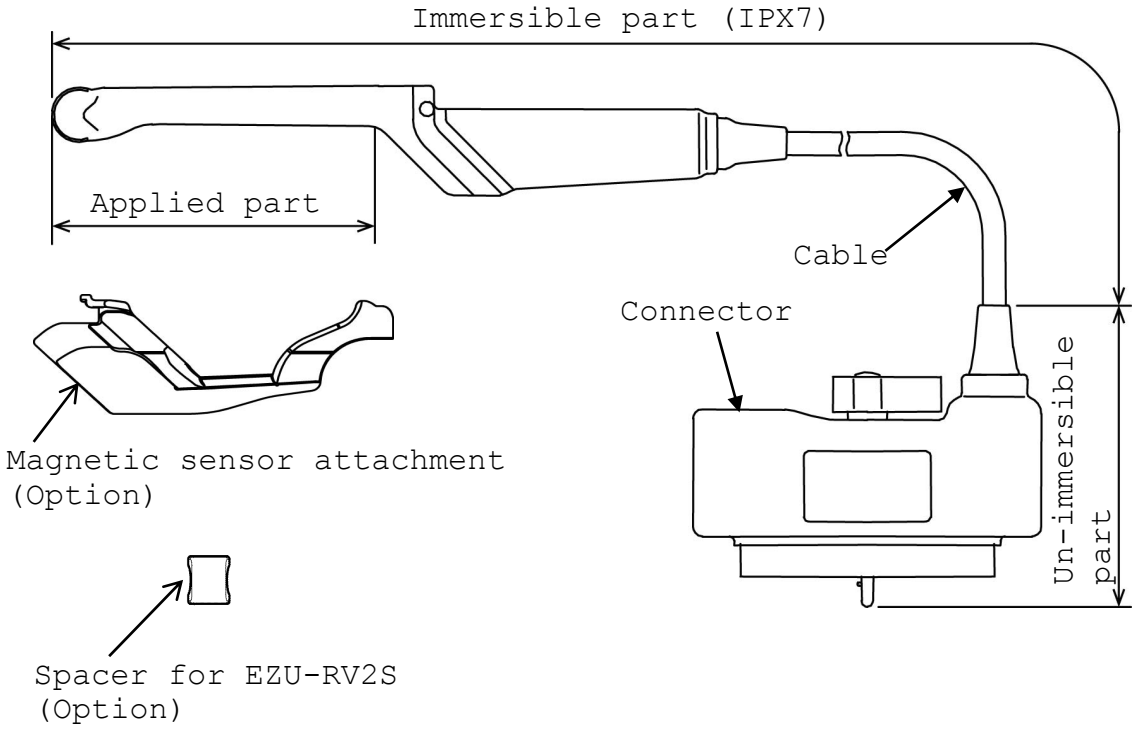
Spacer for EZU-RV2S is used for Real-time Virtual Sonography (RVS) with EZU-RV2S. By using the Spacer, the magnetic sensor for EZU-RV2S is attached to the magnetic sensor attachment.

**⚠CAUTION**

Sterilization has not been made to the Magnetic sensor attachment and the Spacer for EZU-RV2S shipped from the factory. Prior to each use, be sure to clean, disinfect and if necessary sterilize them following this instruction manual.

1.6. Construction

The external view of EUP-V53W is shown in Fig. 1.




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

1) Confirm that the system is correctly operating. Refer to the instruction manual for the Main unit.
2) Do not attach or connect unauthorized devices or instruments on the probe, such as unauthorized biopsy attachments.
3) Confirm that the Sterile Puncture Adapter and software version and then settings of the scanner are appropriate for the probe. Attach the Sterile Puncture Adapter 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. 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

1) Visually inspect the surface of the probe head, housing and cable for any crack, scratch or denaturalization.
2) Visually inspect the envelope of the Sterile Puncture Adapter for any break, deformation, crack or denaturalization. If you find any damage, do not use the Sterile Puncture Adapter.
3) Visually inspect the Magnetic sensor attachment and the Spacer for EZU-RV2S for any crack, deformation or denaturalization.

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

4) Put proper quantity of sterilized acoustic jelly on the probe head as a couplant. (See Fig. 2.)

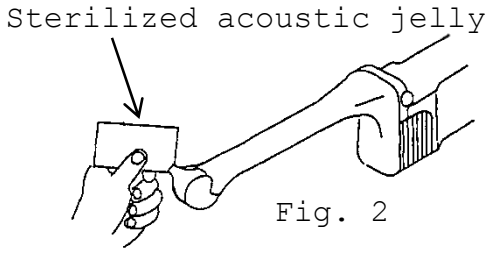


Fig. 2

5) Put a probe cover on the probe and draw the probe cover until the end of the probe shaft. To avoid air bubbles, be careful to press the probe cover gently against probe head and to keep jelly on the probe head. If air bubbles appear on the probe head, remove air bubbles by pushing jelly with finger. (See Fig. 3 and Fig. 4.)

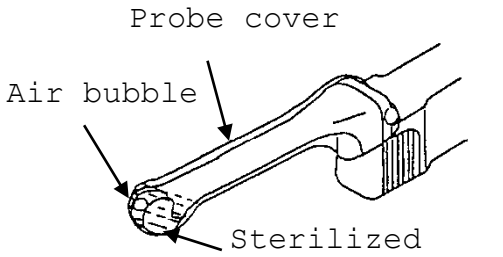


Fig. 3

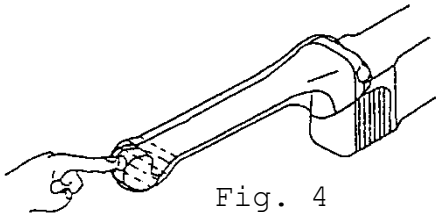


Fig. 4

**⚠WARNING**

LATEX

Be careful with a probe cover made out of latex. Latex may cause such allergic reactions as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, and depression of blood pressure, shock and so on.

If your patient shows any of above mentioned symptoms during the operation, stop the use of protective sleeve immediately and take an appropriate treatment to the patient.

6) Fix jelly on the top of the probe with sterile adhesive tape. (See Fig. 5.)

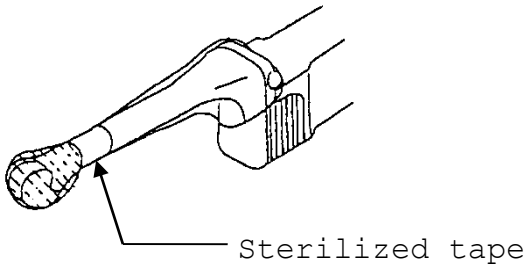



Fig. 5

7) Insert the probe gentry and adjust the probe's position for a clear view of the desired image. By turning or tilting the probe, a "turn around" imaging is possible. If the image is unsufficient, use sterile saline solution. This solution improves the contact between probe and organ.
8) After using the probe, clean, disinfect and if necessary sterilize the probe immediately and using RVS, also clean, disinfect and sterilize the Magnetic sensor attachment. In case of using RVS with an EZU-RV2S, also clean, disinfect and sterilize the Spacer for EZU-RV2S.
9) Store the probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S in the environment indicated in "6. Maintenance and Safety Inspection".

### 3.2. 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 is used, careful handling is necessary to avoid damage of the probe cover. During open or minimal invasive surgery, use the protection sleeve to cover probe and cable.

1) Attach a sterile probe cover to the probe. (See "3.1 Connection and Settings")
2) Put the picks of the Sterile Puncture Adapter to the grooves on the tip of the probe. (See Fig. 6.)

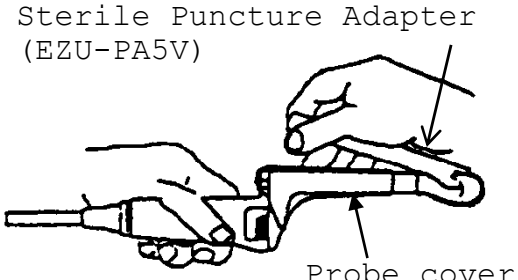



Fig. 6

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. 7.)

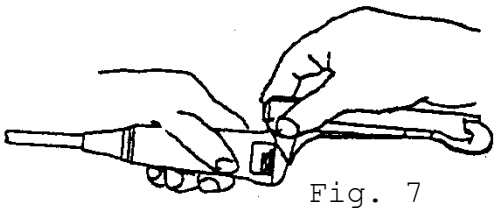


Fig. 7

3.3. Display of Needle Guide Line

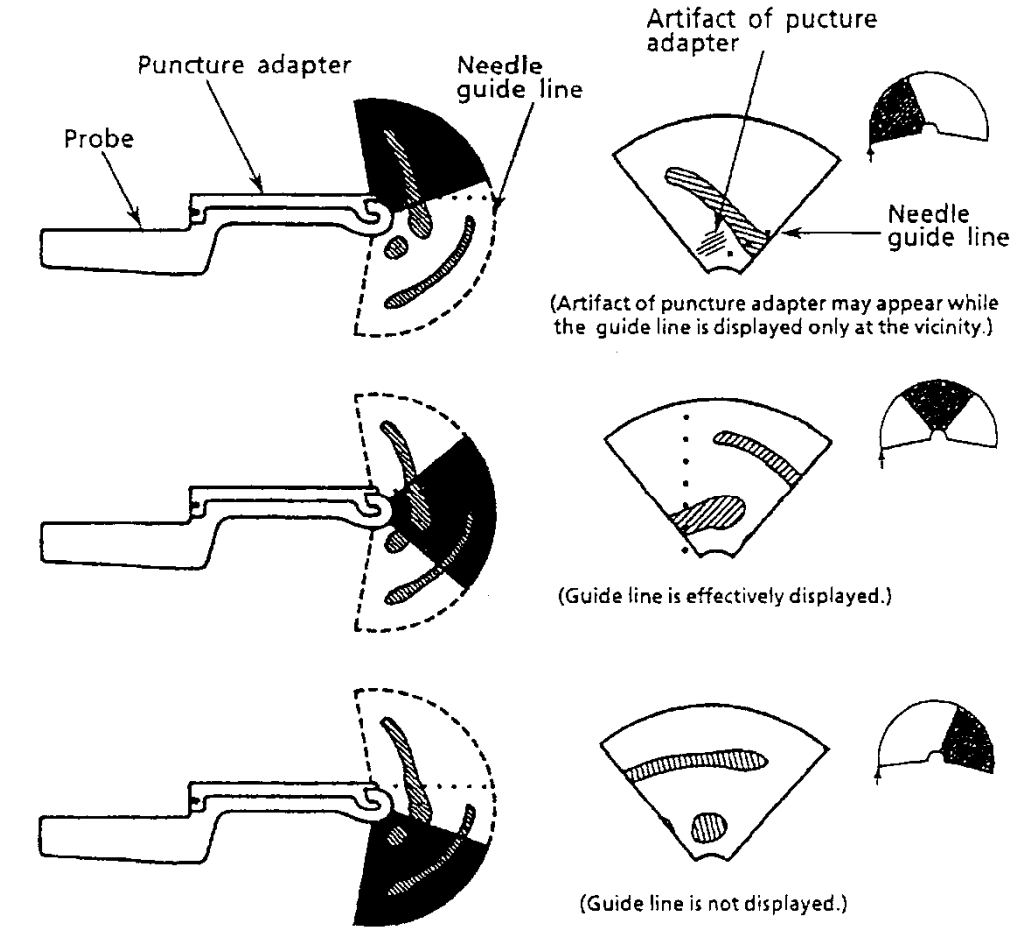
When puncture is to be conducted, the needle guideline can be displayed by dot marks. Operation procedure for displaying the needle guideline on the main unit must be referred to the part of "Needle guide line" in the manual of the connected ultrasound scanner.

NOTE: The needle guide line 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.

**⚠CAUTION**

The needle guide line can be displayed with this probe; however, some image display may not be appropriate for puncture procedure according to the location of observation field-of-view.

Use observation field-of-view that is appropriately according to the location of puncture.



## 4. Option of EUP-V53W

In case of using RVS (Real-time Virtual Sonography), confirm the type of the magnetic sensor.

There are two types of the magnetic sensors for EUP-V53W, EZU-RV2S and EZU-RV3S. EZU-RV2S and EZU-RV3S are shown in Fig.8 and Fig.13. The use of EUP-V53W with both magnetic sensors enables the user to perform RVS (Real-time Virtual Sonography).

### 4.1. Magnetic sensor (EZU-RV2S)

Magnetic sensor (EZU-RV2S) as shown in Fig. 8 is the magnetic sensor (EZU-RV2S) for EUP-V53W.

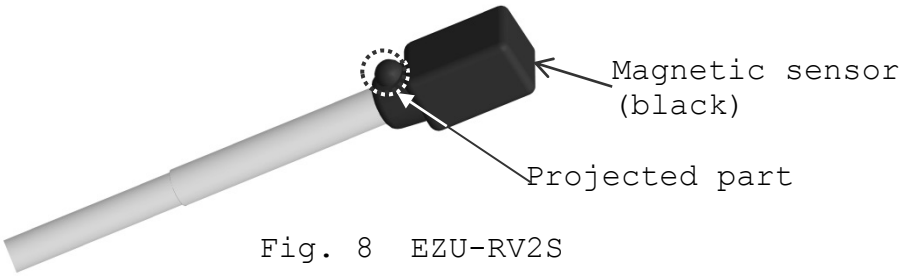



Fig. 8 EZU-RV2S

#### 4.1.1. How to attach magnetic sensor

The procedure of attaching magnetic sensor is as follow.

1) Confirm that the magnetic sensor attachment and the Spacer for EZU-RV2S are cleaned, disinfected and 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 Magnetic sensor.

b) Insert Magnetic sensor into the Magnetic sensor attachment with the correct direction as shown in Fig. 9.

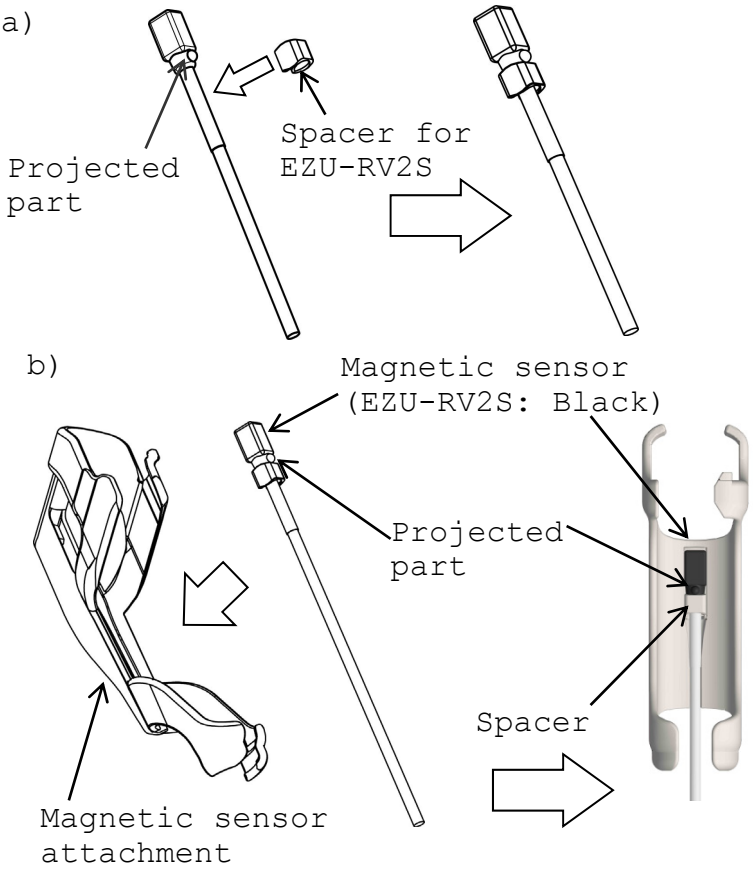



Fig. 9 How to attach the Magnetic sensor

**⚠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 when using RVS with magnetic sensor, otherwise it may result in false diagnosis.

c) Attach the Magnetic sensor attachment to the probe as shown in Fig.10.

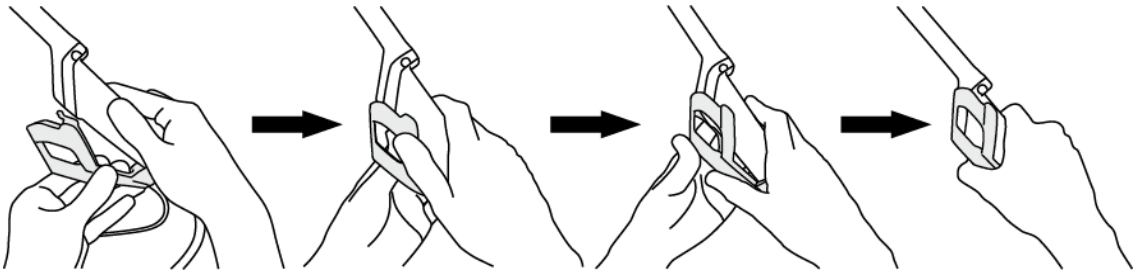


Fig.10 How to attach the Magnetic sensor attachment

**⚠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 Magnetic sensor

The procedure of releasing Magnetic sensor is as follow.

1) Detach the Magnetic sensor attachment from the probe as shown Fig.11.

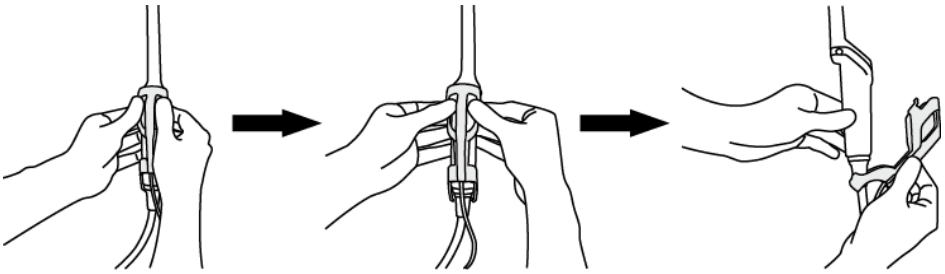


Fig.11 How to release the Magnetic sensor attachment from the probe

2) Detach the magnetic sensor and the Spacer for EZU-RV2S from the Magnetic sensor attachment as shown Fig. 12.

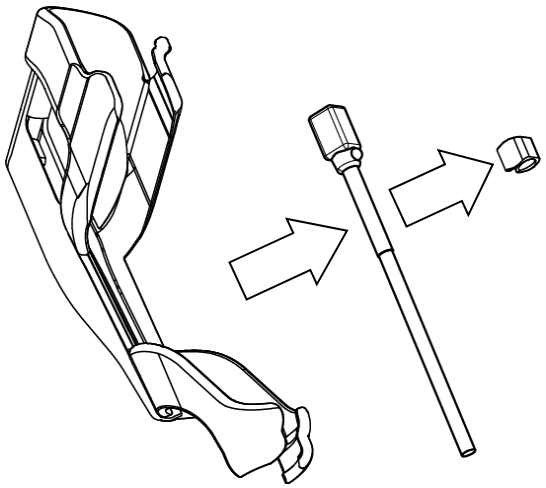


Fig. 12 How to release magnetic sensor from the Magnetic sensor attachment

**⚠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)

Magnetic sensor as shown in Fig. 13 is the magnetic sensor for EUP-V53W.

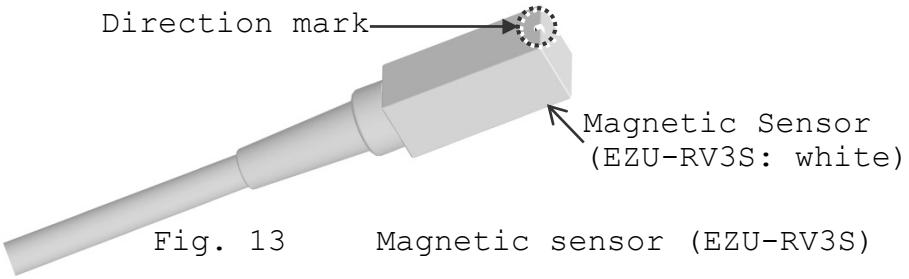



Fig. 13 Magnetic sensor (EZU-RV3S)

4.2.1. How to attach Magnetic sensor

The procedure of attaching Magnetic sensor is as follow.

1) Confirm that the Magnetic sensor attachment is cleaned, disinfected and 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) Insert Magnetic sensor into the Magnetic sensor attachment with the correct direction as shown in Fig. 14.

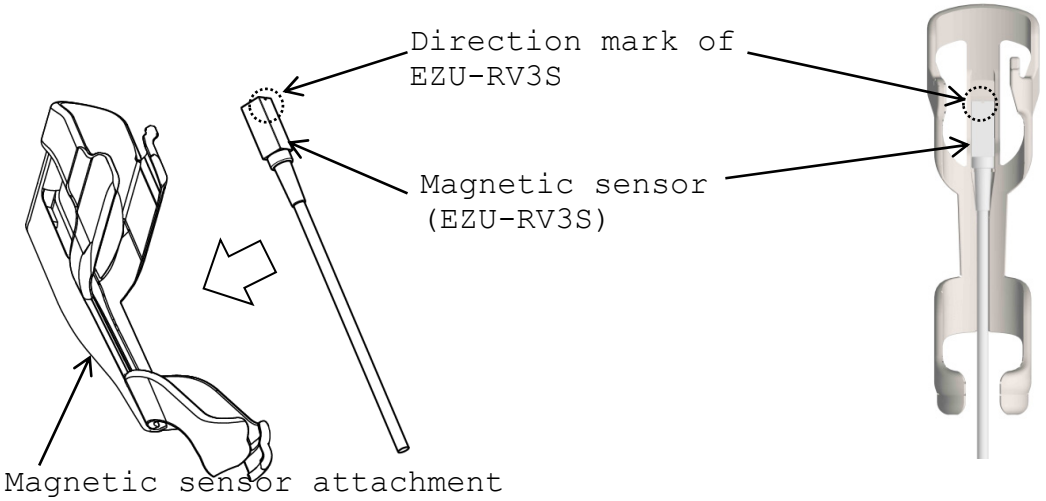



Fig. 14 How to attach the Magnetic sensor

**⚠CAUTION**

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

b) Attach the Magnetic sensor attachment to the probe as shown in Fig.15.

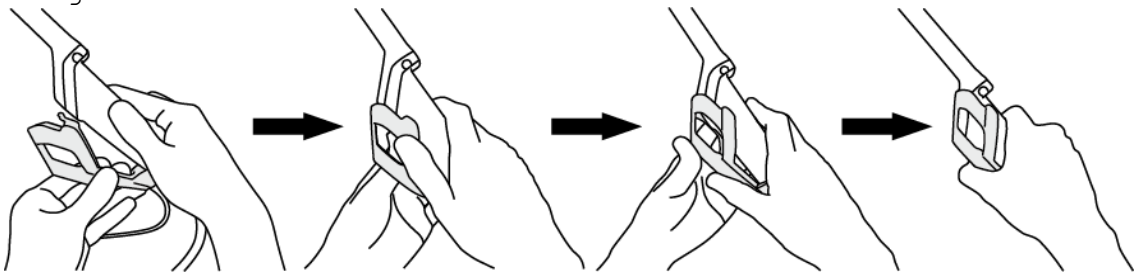


Fig.15 How to attach the Magnetic sensor attachment

**⚠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 Magnetic sensor

The procedure of releasing Magnetic sensor is as follow.

1) Detach the Magnetic sensor attachment from the probe as shown Fig.16.

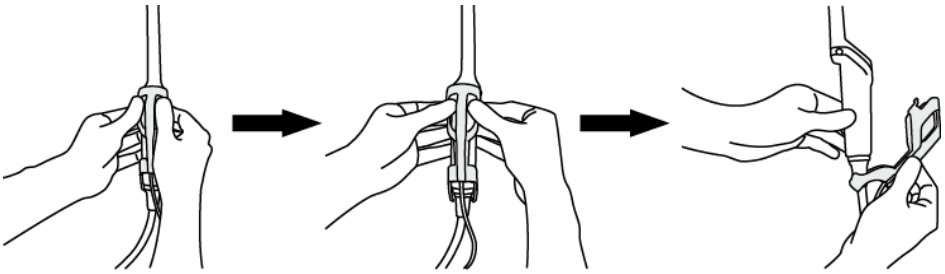


Fig.16 How to release the Magnetic sensor attachment from the probe

2) Detach the magnetic sensor and the Spacer for EZU-RV3S from the Magnetic sensor attachment as shown Fig. 17.

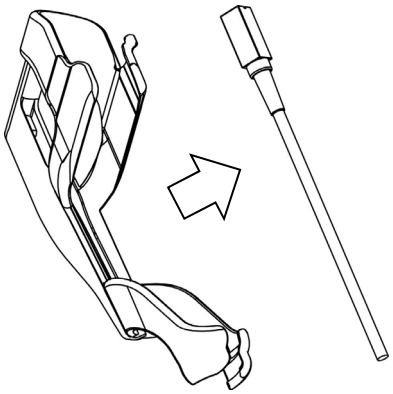


Fig. 17 How to release magnetic sensor from the Magnetic sensor attachment

**⚠CAUTION**

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

## 5. Reprocessing Procedure

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

| | |
|---|---|
| WARNINGS | - The probe is delivered unsterile. Prior to the first use, reprocess the probe.<br>- Temperature should not exceed 60°C during reprocessing.<br>- 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. |

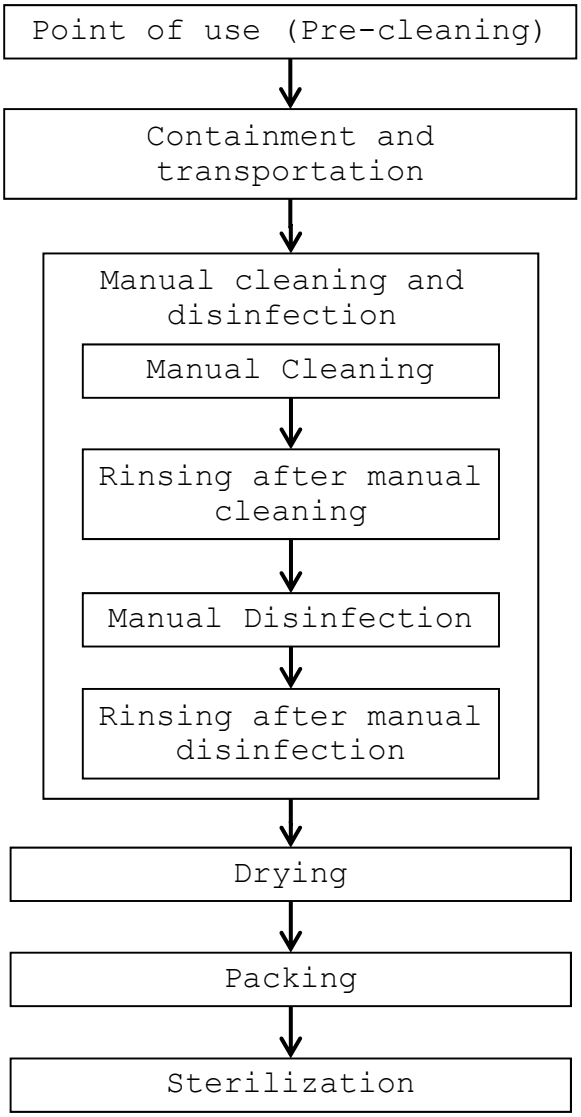
Levels of reprocessing requirements:

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<br>Disinfection |
| semicritical | Application part contacts mucosa (intracavitary application) | Cleaning<br>Disinfection (Disinfectant with virucidal effect) |
| critical | Application part contacts intracorporeal tissue directly (operative application) | Cleaning<br>Disinfection (Disinfectant with virucidal effect - minimum)<br>Sterilization |

According to the intended use, EUP-V53W probe is classified as semicritical.

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



Point of use (Pre-cleaning)

## 5.1. Point of use (Pre-cleaning)

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

A) EUP-V53W 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) Attachment

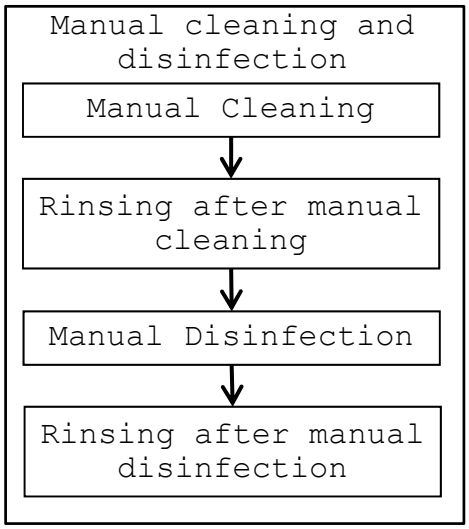
1) Remove the Attachment and the magnetic sensor from the probe.
2) Immerse the Attachment in sufficient amount of high quality tap water. Scrub it using soft cloth to remove all visible soil from its surface.

Containment and transportation

## 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 (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 submergible 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) EUP-V53W 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 Fig. 18). Wipe the immersible part of the probe under the surface of the detergent solution with a soft cloth to remove all visible soil. Be sure that all grooves of the probe are implemented during the cleaning process.
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-immergible parts of the probe with a soft cloth dipped with the detergent solution.
5) Rinse 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. 18) 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) 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 Attachment into the diluted detergent solution. Wipe it under the surface of the detergent solution with a soft cloth to remove all visible soil. Be sure that all grooves of the attachment are implemented during the cleaning process.
3) The Attachment should be left in the detergent solution according to the specified contact time of the detergent manufacturer.
4) Rinse the Attachment with running tap water for 1 minute. (alternatively: immerse it in a tray filled with deionized water/tap water (see Fig. 18) for 5 min.)
5) Visually check the outer surface of the Attachment for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

Manual disinfection:

A) EUP-V53W 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. 18). 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. 18) for 5 min.)
5) Visually check the outer surface of the probe for leavings of the disinfectant. If necessary, repeat the rinsing.

B) Attachment

1) Prepare the disinfectant solution as stated in the procedure for the probe.
2) Immerse the Attachment into the disinfectant (see Fig. 18). Set a clock to insure the recommended contact time which is 5 minutes.
3) Rinse the Attachment with deionized water for 1 minute. (alternatively: immerse it in a tray filled with deionized water (see Fig. 18) for 5 min.)
4) Visually check the outer surface of the Attachment for leavings of the disinfectant. If necessary, repeat the rinsing.

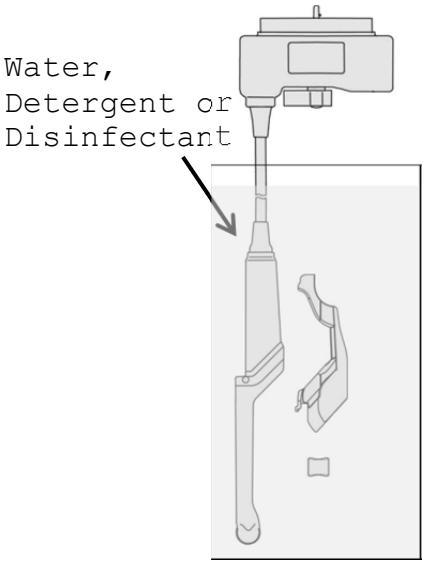



Fig. 18 Immersion of the probe and the Attachment.

## 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 probe 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 55 °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 probe 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 probe can be placed on plastic mesh wires supplied for plasma sterilization and then packed as mentioned above.

The probe 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 in the next page). 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<br>➢ Temperature: 50-55°C<br>➢ Exposure Time: More than 120 minutes<br>➢ Pressurization: 162-200kPa<br>Depressurization: 13-8kPa<br>➢ Relative humidity: 40-90%<br>➢ 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 and the Attachment.
2) Do not sterilize the probe and the Attachment by Steam Autoclaving. If you autoclave them, they suffer serious damage and will not be functional.

The packaging procedure is as follows.

1) Put the probe into TYVEK pouch.

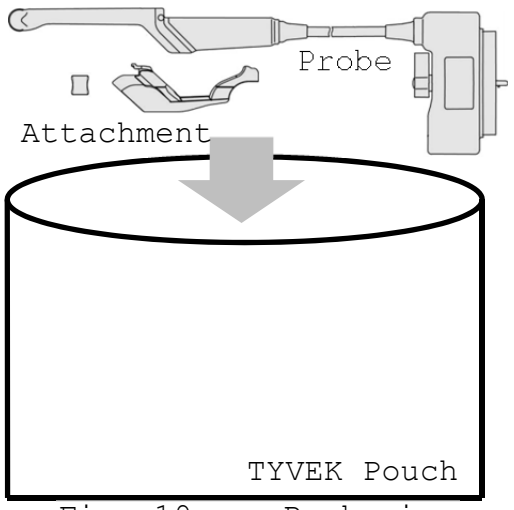



Fig. 19 Packaging in the pouch

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

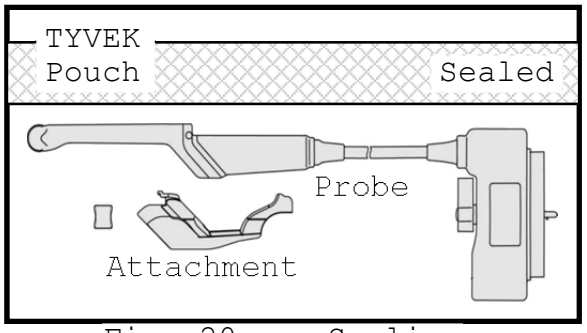



Fig. 20 Sealing

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

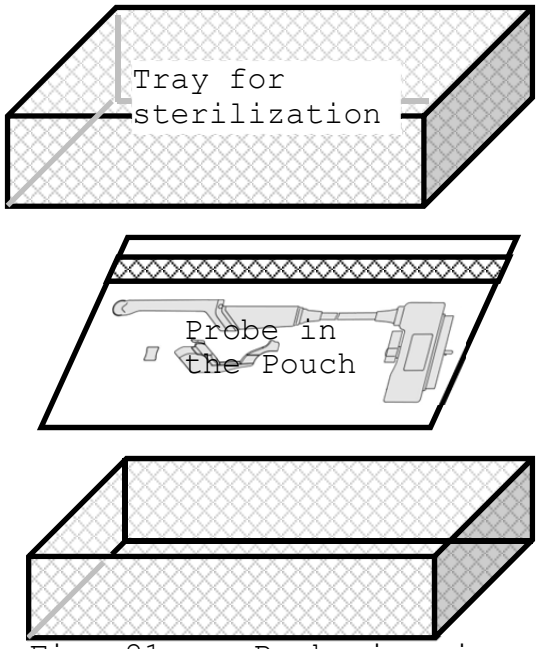



Fig. 21 Packaging in a tray

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. Maintenance and Safety Inspection

6.1. Daily Inspection

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.
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 immediately.

7. Safety Precautions

**⚠WARNING**

1) Never use the probe if the probe head, shaft or cable are cracked or damaged.
2) When use EUP-V53W for biopsy purpose, use Sterile Puncture Adapter EZU-PA5V (Option) certainly.
3) Never use the Sterile Puncture Adapter 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, 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 EUP-V53W.

**⚠CAUTION**

1) By OB/GYN applications of the probe during surgical or minimal-invasive procedures, take care that electro cauter devices are out of range. In case of using defibrillation, take the probe out or away from the body.
2) Keep the acoustic power low and minimize the ultrasound exposure time for the examination of an early pregnancy.
3) Do not expose the connector to water or other liquids. The connector is not waterproof.
4) Do not hit or drop the probe. The probe is easily damaged by mechanical shock.
5) Do not use detergents and disinfectants other than listed in “8.3 Suppliers list”.
6) Use a sterile probe cover to avoid staining or damaging the acoustic lens.
7) Clean, disinfect and sterilize the probe, Magnetic sensor attachment and Spacer for EZU-RV2S before the first use as it is not sterilized in the factory.
8) Use only the soft cloth or tissue to clean the acoustic lens.
9) Only a well-trained physician should perform a biopsy.
10) Do not attach unapproved devices to the probe.

# 8. Specifications

## 8.1. Probe

| | |
|---|---|
| Type: | EUP-V53W Transvaginal probe |
| Center frequency: | 6.5MHz |
| Technology: | High density Convex Array Probe |
| Dimensions: | See Fig. 22 |
| Weight: | Approx.1kg (Including cable and connector) |
| 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 a service supports. |
| 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 or Plasma sterilization |
| Operating conditions: | |
| Ambient temperature: | +25 – +35°C |
| Contact surface temperature (Temperature of examinee): | max. 42°C |
| Relative humidity: | 30 – 85% |
| Storage conditions: | |
| Temperature: | –10 – +55°C |
| Relative humidity: | 10 – 95% (Subject to no condensation) |

8.2. Sterile Puncture Adapter EZU-PA5V

| | |
|---|---|
| Type: | EZU-PA5V |
| External view: | 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 |
| Storage conditions: | |
| Temperature: | -10 – +40°C |

8.3. Suppliers List

The products listed below are seriously tested and approved for use with the transvaginal probe EUP-V53W.

| Product name | manufacturer | purpose |
|---|---|---|
| Cidezyme | Johnson & Johnson | Enzymatic detergent |
| Meliseptol HBV-Tücher | Braun | Disinfectant |
| Incidin Liquid Spray | Henkel Hygiene GmbH | Disinfectant |
| Incidur Spray | Henkel Hygiene GmbH | Disinfectant |
| STERANIOS 2% | ANIOS | Disinfectant |
| CIDEX | Johnson & Johnson | Disinfectant |
| CIDEX plus | Johnson & Johnson | Disinfectant |
| CIDEX OPA | Johnson & Johnson | Disinfectant |
| Gigasept FF | Schülke & Mayr | Disinfectant |
| ALKACIDE | ALKAPHARM | Disinfectant |
| ALKAZYME | ALKAPHARM | Cleaner |

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

9. Disposal of the probe

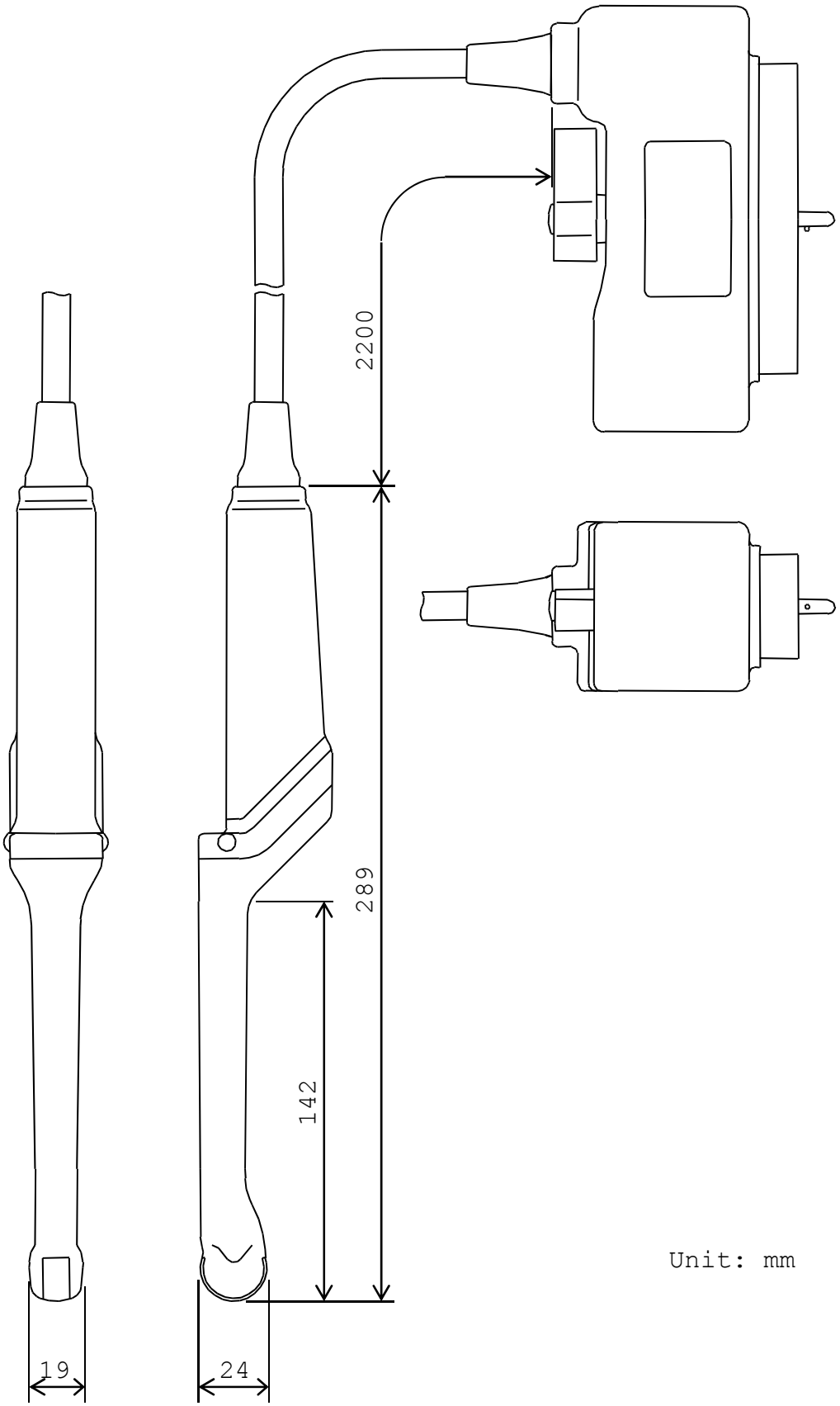
Recycle or dispose the equipment properly in compliance with your organizational rules and your local laws.

**⚠CAUTION**

Before disposing the equipment, disinfect or take other infection-prevention measures. Disposal of 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 of Probe EUP-V53W

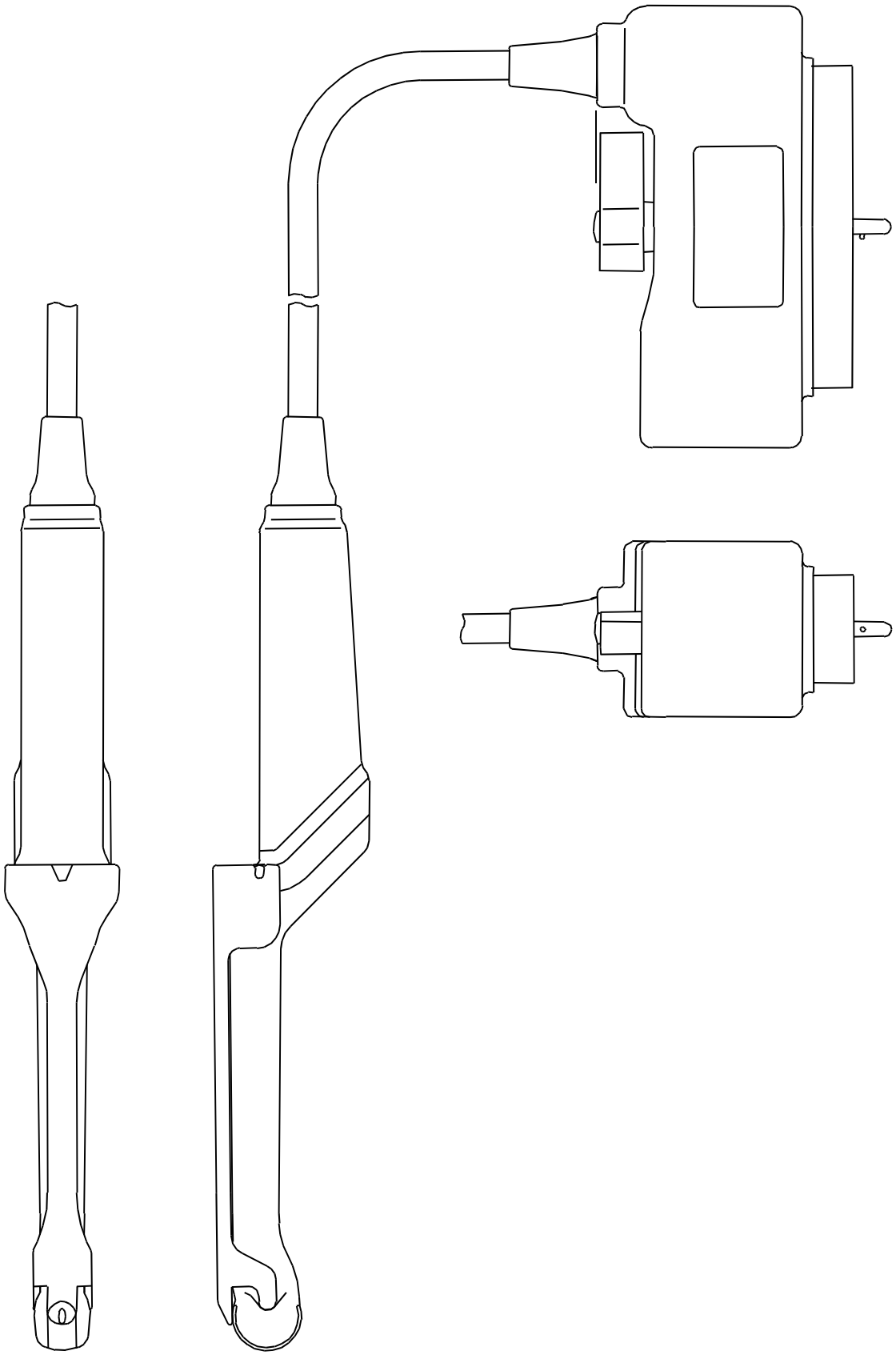


Fig. 23 External view of the probe EUP-V53W with Sterile Puncture Adapter (EZU-PA5V)

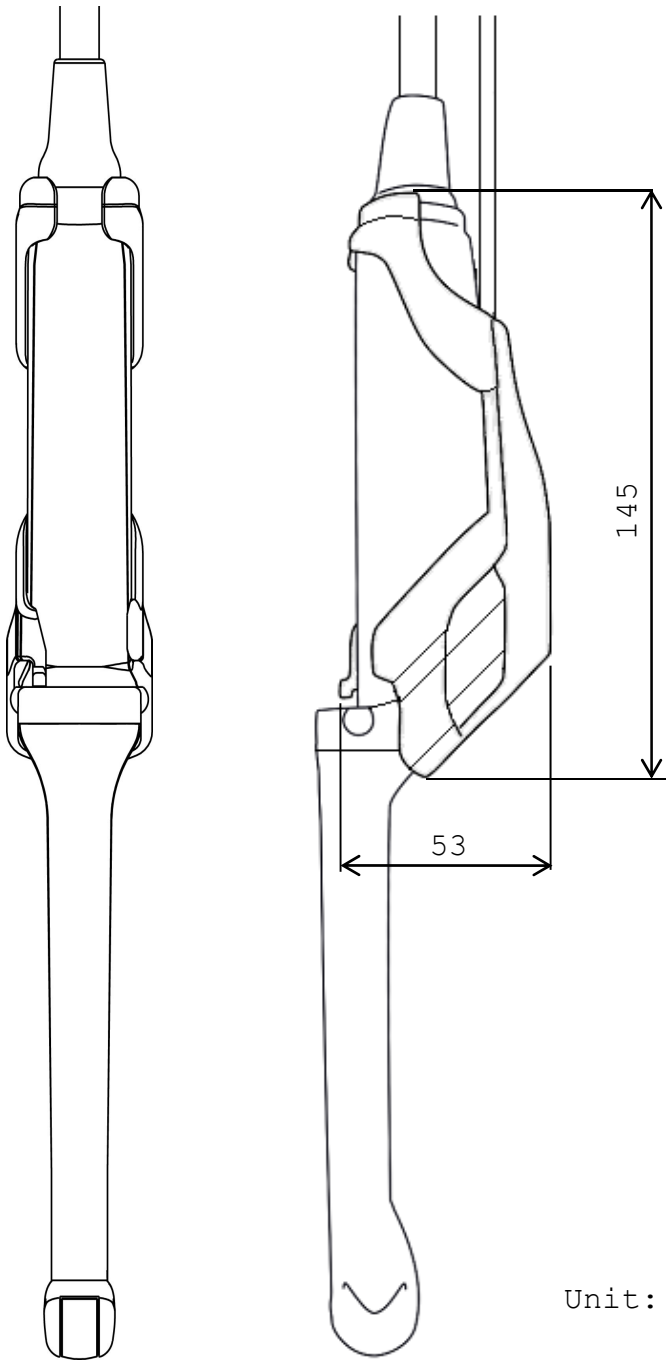



Fig. 24 Dimension of the probe EUP-V53W with the Magnetic Sensor Attachment (Option)