HITACHI
Inspire the Next

# L64 Probe

# INSTRUCTION MANUAL

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

Hitachi, Ltd.

Tokyo , Japan

Q1E-EP1366-6



CE 0123

Manufacturer:

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

European Representative:


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

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

Local Distributor:

About this manual

This instruction manual shall provide instructions for using, cleaning, and disinfecting and/or sterilizing the HITACHI ultrasound probes.
It also describes safety considerations, maintenance.
For instructions for operating the ultrasound diagnostic scanner, refer to the operation manual for it.
Before using the probe, thoroughly read this manual and keep this book for future reference.
If you have any questions concerning the manual, please contact a service support.

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

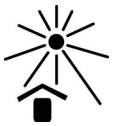
WARNING: "Warning" is used to indicate the presence of a hazard which can cause severe personal injury, death, or substantial property damage if the warning is ignored.

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

NOTICE: "Notice" is used to notify people of installation, operation, or maintenance information which is important, but not hazard related.

**Graphical Symbols for Use in Labeling of 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,<br>Tokyo, 110-0015, Japan<br>+81-3-6284-3668<br>http://www.hitachi.com/businesses/<br>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 place and keep away from high temperature, high humidity, or direct sunlight. |

**Definition of symbol**

The following symbol is also used for HITACHI Ultrasound Probes.

| Location | Symbol | Definition |
|---|---|---|
| Probe connector | CE 0123 | This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS |
| Probe connector | IPX7 | IPX7 mark<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 |   | STERRAD sterilization compatibility mark |
| Probe connector |  | Do not waste the instrument as general waste. Comply with a local regulation. |
| Probe connector | Rx Only | By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only. |

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# 1. General

## 1.1 General

L64 Probe is a Linear Array type.
The acoustic output of this probe when connected to ultrasound diagnostic scanner was measured according to the IEC60601-2-37 standard.
The table of measured acoustic output data is contained in the operation manual of each ultrasound diagnostic scanner.
This probe is categorized in class IIa according to Directive 93/42/EEC.
According to IEC 60601-1 the probe is classified as type BF.

## 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

L64 Probe is designed for observation and diagnosis mainly of the following regions by connecting with the HITACHI ultrasound diagnostic scanner.

- Mammary gland
- Thyroid
- Superficial organs

**⚠ WARNING**

Never use the probe for following applications.

1) Direct contact to the heart.
2) Biopsy to the heart.
3) Direct contact to the eye

## 1.4 Components

The probe components of L64 Probe are as follows:

1) Probe ····· 1 piece
2) Instruction Manual ····· 1 copy

**⚠ CAUTION**

Sterilization has not been made to the probe and the elasto coupler shipped from the factory.
Prior to use, be sure to clean, disinfect and sterilize them.

## 1.5 Accessories

### 1.5.1 Elasto Coupler (Option)

### 1.5.2 Needle Guide Bracket EZU-PA7L3 (Option)

1) Needle guide bracket .....1 piece
2) Brush .....1 piece
3) Spring (Spare) .....2 pieces
4) Instruction manual .....1 copy
5) Case .....1 piece

Please refer to the instruction manual of EZU-PA7L3 about the method of handling, cleaning and disinfecting the needle guide bracket EZU-PA7L3.

### 1.5.3 Acoustic coupler attachment EZU-TEATC2 (Option)

1) Cover .....1 piece
2) Case .....1 piece
3) Instruction manual .....1 copy

Acoustic coupler attachment EZU-TEATC2 fixes the acoustic coupler (EZU-TECPL1 or SF-001) to the probe.

The SF-001 and EZU-TECPL1 are intended to be used for having a clear superficial image by keeping a certain distance between the probe and the skin.EZU-TECPL1 is also used when the operator compares the tissue elasticity of the living body with the Acoustic coupler's one.

Please refer to the instruction manual of EZU-TEATC2 about the method of handling and cleaning EZU-TEATC2, EZU-TECPL1 and SF-001.

### 1.5.4 Magnetic Sensor Attachment (Option)

**⚠ CAUTION**

Elasto coupler, magnetic sensor attachment and needle guide bracket EZU-PA7L3 are not sterilized when shipped, so they must be cleaned, disinfected and sterilized prior to use.

**⚠ CAUTION**

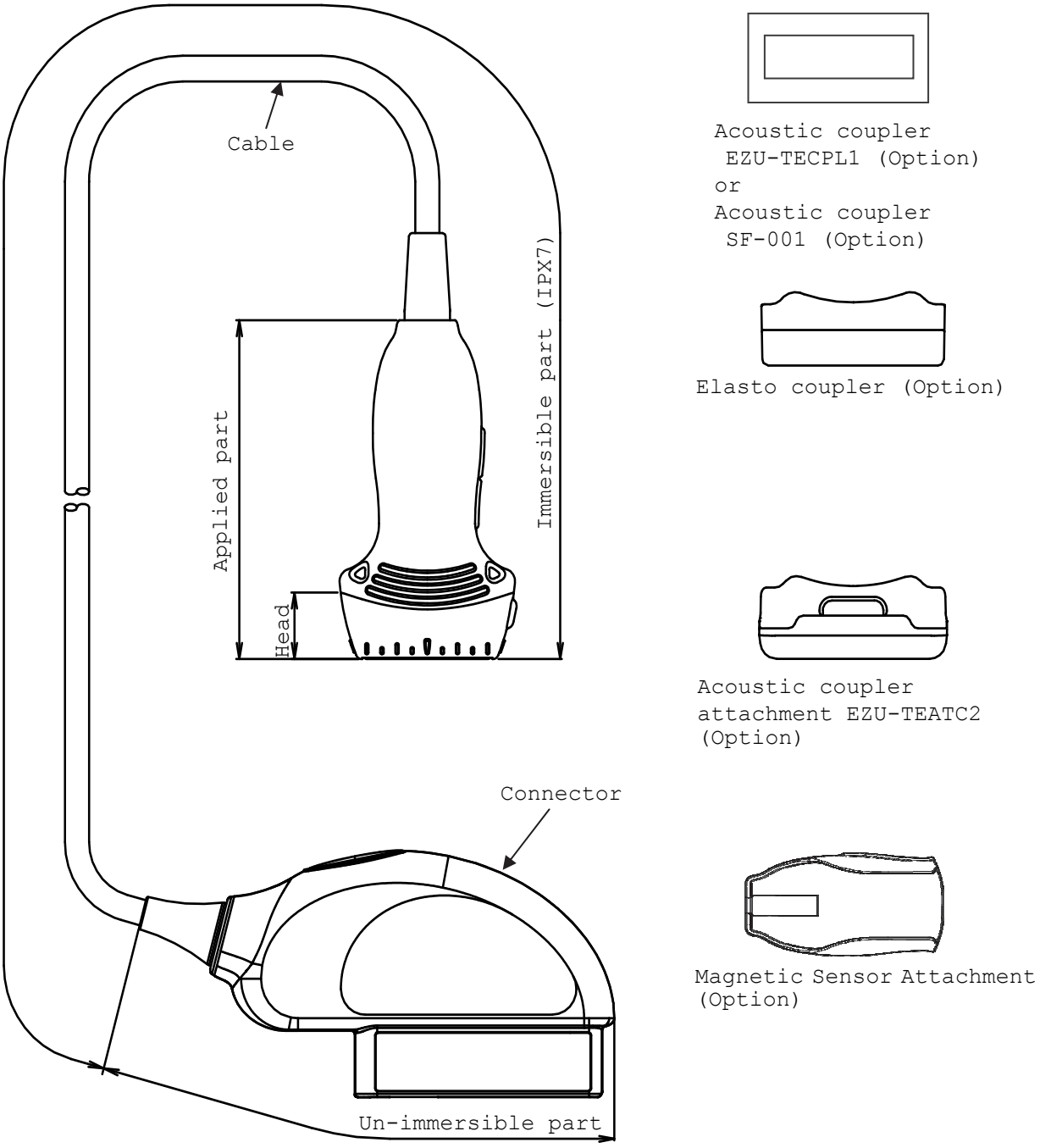
A biopsy should be performed only by a well-trained physician.

**⚠ CAUTION**

Before performing a biopsy, display the needle echo in sterile water, and confirm that the needle echo at each angle overlaps with the correspondent needle guideline. For the confirmation procedure in detail, refer to the instruction manual of EZU-PA7L3.

## 1.6 External View

The external view of L64 Probe 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 can not be cleaned by water.

Fig. 1 External View

## 2. Inspection before Use

Prior to use, the probe must be carefully inspected that it is appropriate for use.

### 2.1 Inspection of 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 nor instruments on the probe, such as unauthorized biopsy attachments.

### 2.2 Inspection of material surface

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

2.2.2 Visually inspect the elasto coupler for any crack, deformation, or denaturalization. If you find any damage, do not use the elasto coupler and contact a service support immediately.

2.2.3 Visually inspect the magnetic sensor attachment for any crack, deformation, or denaturalization. If you find any damage, do not use the magnetic sensor attachment and contact a service support immediately.

## 3. Operation Procedure

1) Confirm that the probe, the magnetic sensor attachment and the elasto coupler are cleaned, disinfected and/or sterilized.
2) It is recommended to use a disposable probe cover for preventing a patient from infection.
3) Connect the probe to the ultrasound diagnostic scanner, operate the scanner, and adjust the image, all according to the instructions given in the operation manual for the ultrasound diagnostic scanner with which the probe is used as connected.
4) Relationship between direction of the probe and the image is shown in Fig. 2. The right-left orientation mark on the image indicates the index mark on the probe.

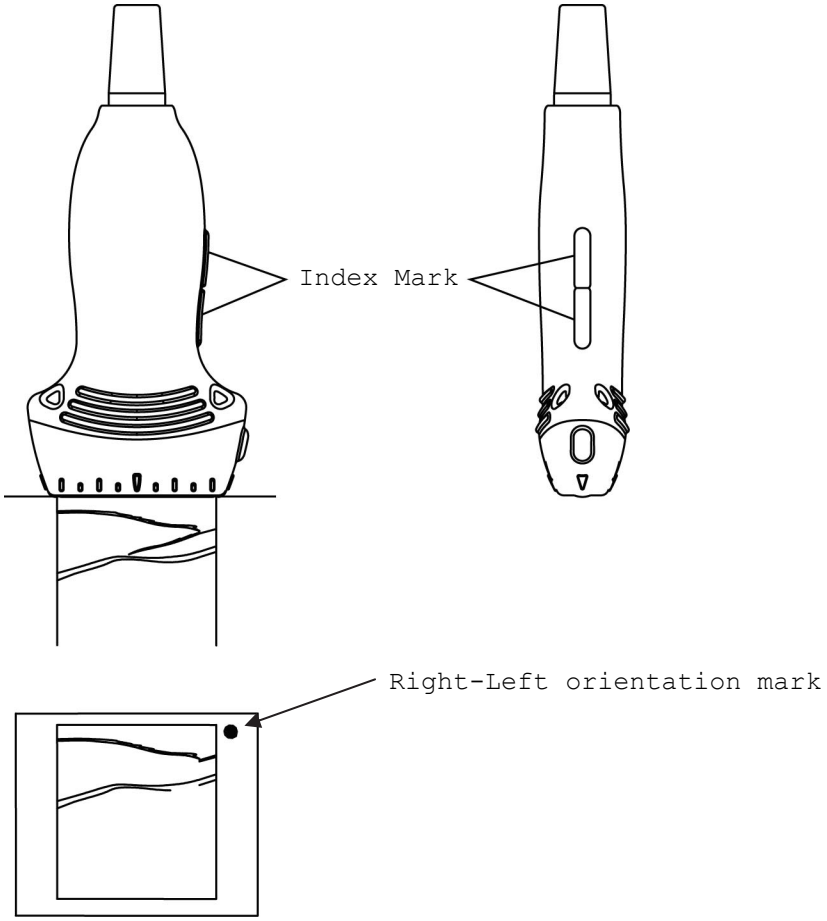



Fig. 2 Relationship between direction of the probe and Right-left orientation Mark

5) Marking Assist as shown in Fig. 3 is a function to help marking the surface of the body.

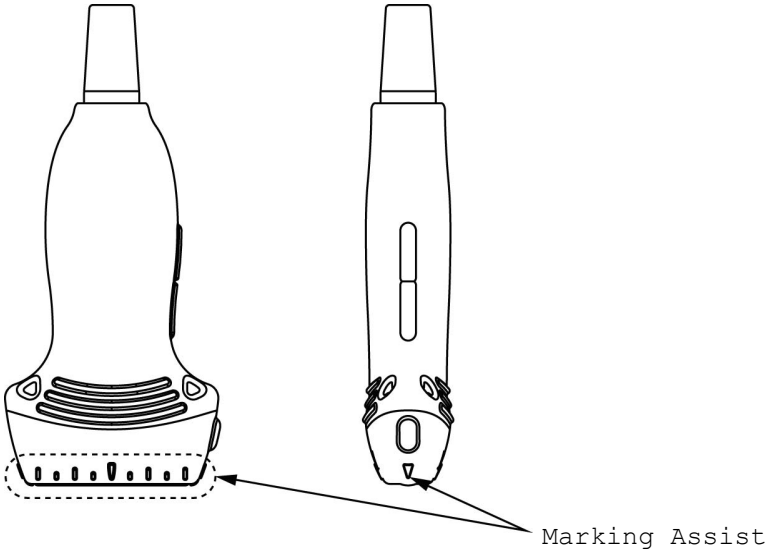
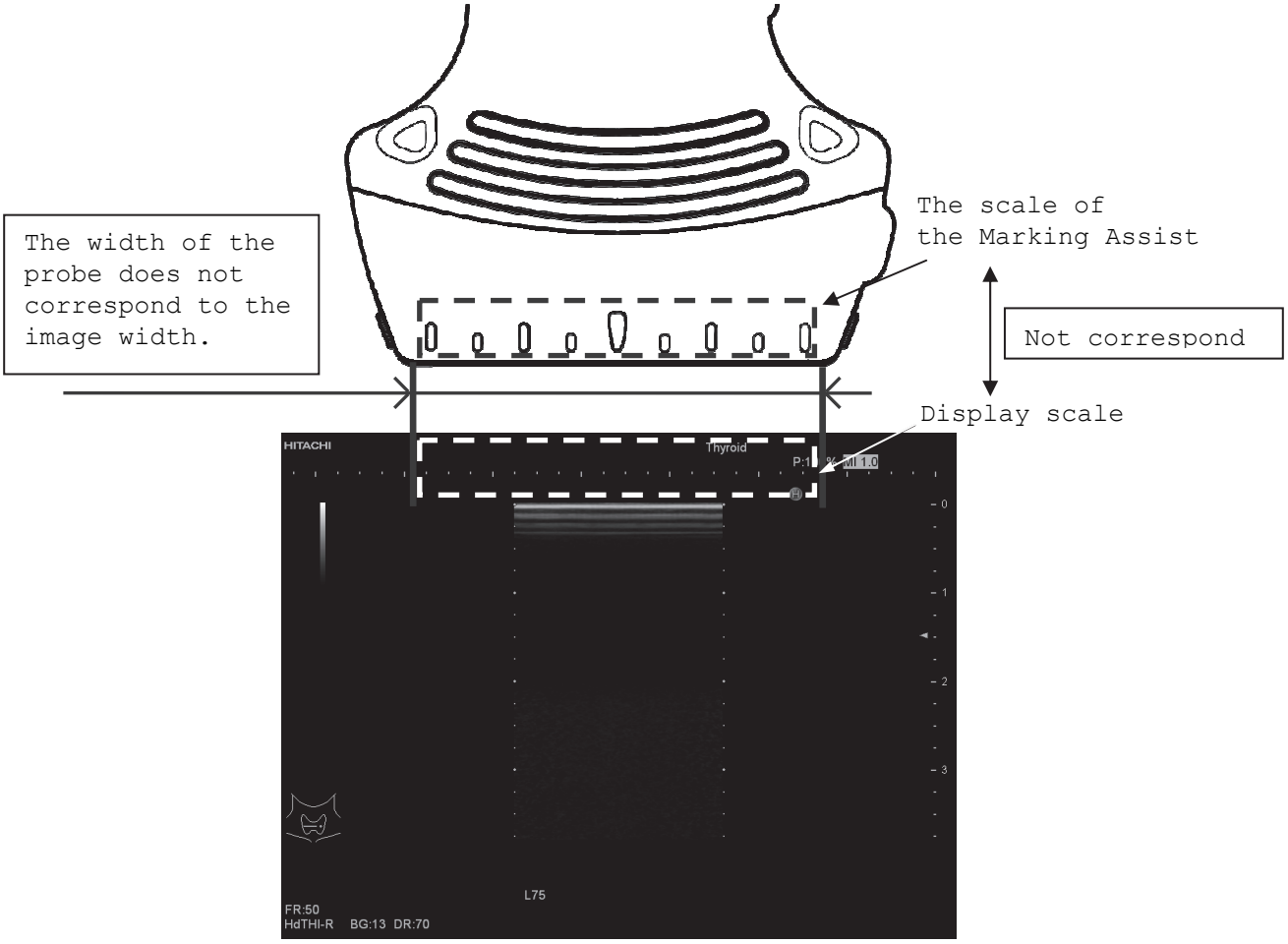



Fig. 3 Marking Assist

6) Use under sterile condition, protecting the probe by using covers is recommended. Some Latex material may create allergic reaction. Please use allergy free material covers.
7) After the use of the probe, the magnetic sensor attachment and the elasto coupler, it should be cleaned and disinfected and/or sterilized, then store it in an adequate place.
8) Store the probe, the magnetic sensor attachment and the elasto coupler in the environment indicated in "6.Maintenance and Safety inspection".

## ⚠ CAUTION

The Marking Assist is intended to be used to only mark. The scale of Marking Assist does not correspond to the display scale and the width of the probe does not correspond to the image width displayed in the image (see the Figure below).



Caution in case of wiping off the ultrasound jelly or cleaning the surface of the acoustic lens.

**⚠ CAUTION**

The acoustic lens of the probe is manufactured very thin and delicate to get the high resolution. Therefore, in case of wiping off the ultrasound jelly or cleaning the surface of the acoustic lens, please use the soft cloth or tissue paper and handle with care. (See Fig. 4)

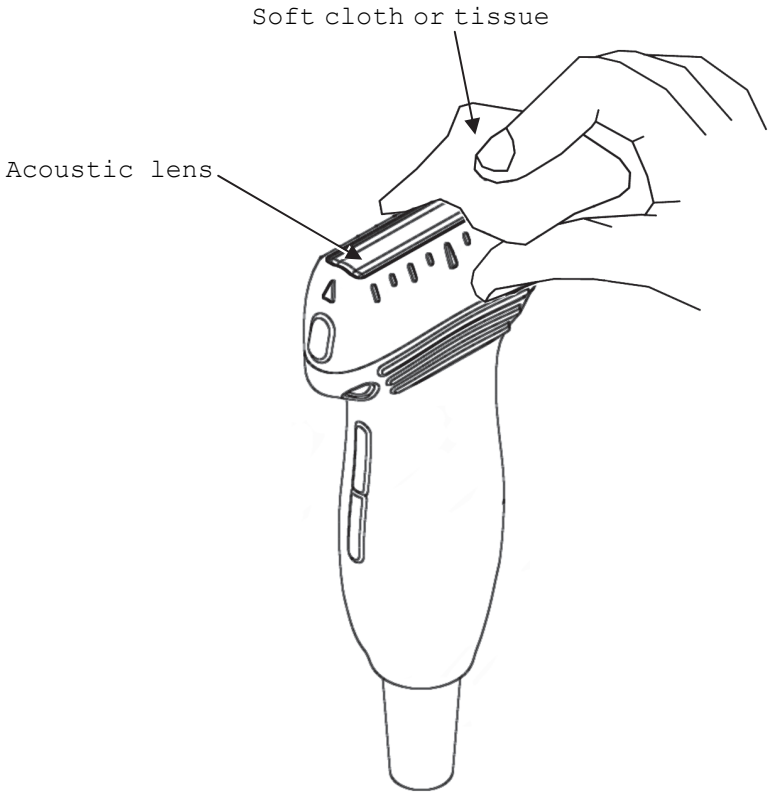



Fig. 4 Wiping off the ultrasound jelly or cleaning the surface of the acoustic lens

# 4. Option of L64 Probe

## 4.1 Elasto coupler

### 4.1.1 How to attach the Elasto coupler

To use elastography, attach the elasto coupler as shown below.

Attach the elasto coupler on the probe as straight as possible as shown in Fig. 5.

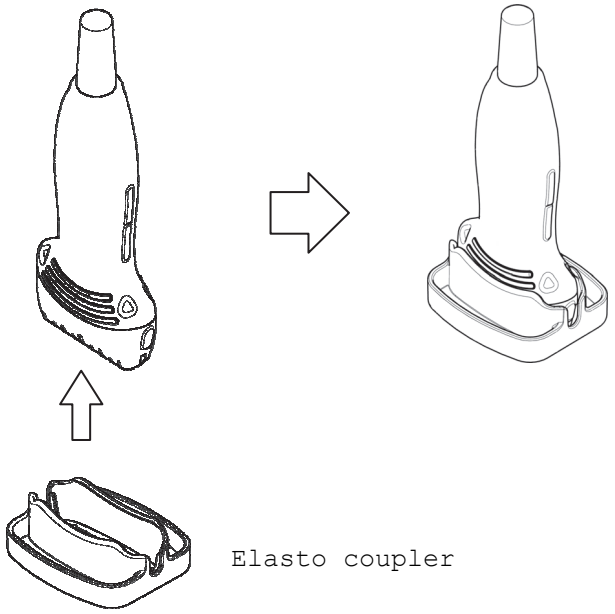



Fig. 5 How to attach the Elasto coupler

### 4.1.2 How to release the Elasto coupler

Release the elasto coupler from the probe as shown in Fig. 6.

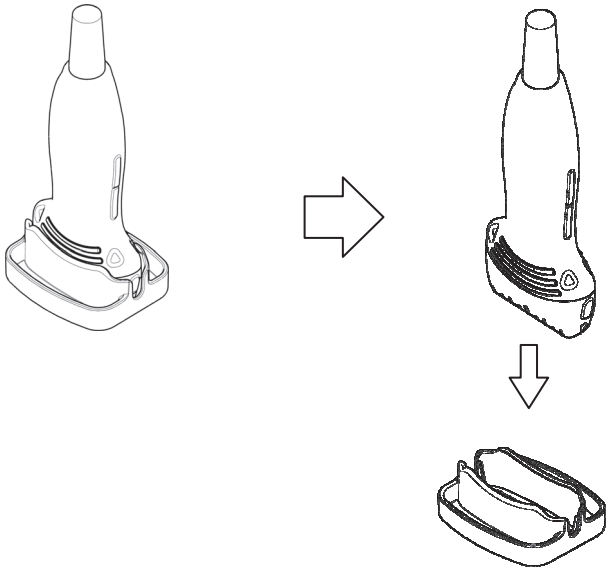


Fig. 6 How to release the Elasto coupler

## 4.2 Magnetic sensor

### 4.2.1 How to attach the Magnetic sensor

The procedure of attaching the magnetic sensor is as follows.

1) Confirm that the probe and the magnetic sensor attachment are cleaned, disinfected and/or sterilized.
2) Connect the probe, operate the ultrasound diagnostic scanner, and adjust the image according to the instructions given in the operation manual for the ultrasound diagnostic scanner.
3) To use Real-time Virtual Sonography (RVS), attach the magnetic sensor as shown below.

a) Attach the magnetic sensor into the probe at the correct direction as shown in Fig. 7.

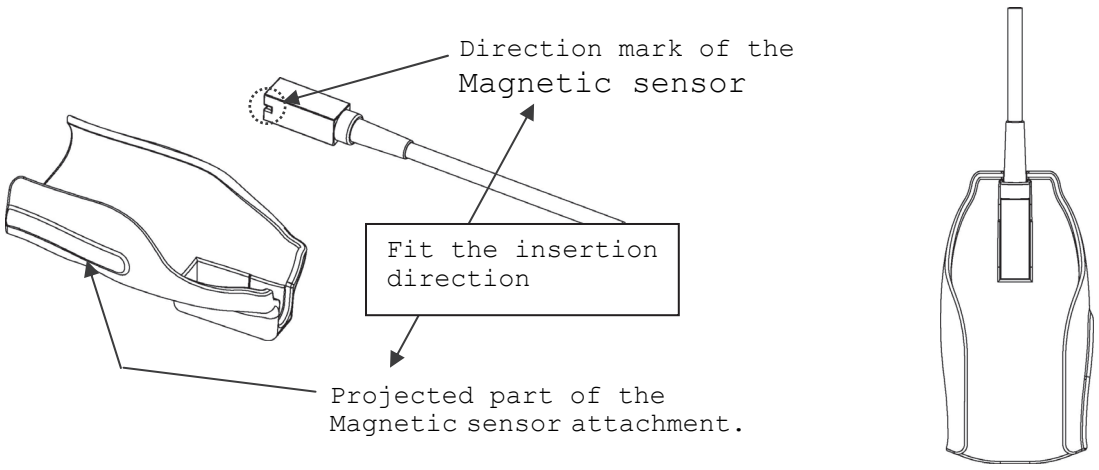



Fig. 7 How to attach the Magnetic sensor

b) Place the magnetic sensor attachment on the probe as shown in Fig. 8. Fit the projected part of the magnetic sensor attachment in the index mark of the probe.

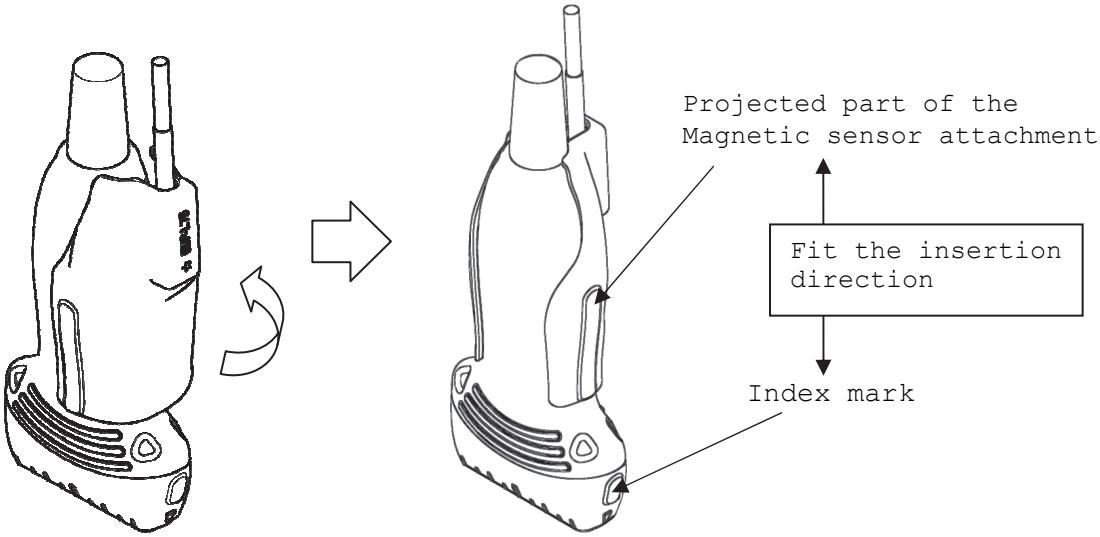



Fig. 8 How to attach the Magnetic sensor attachment

⚠ CAUTION

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

4.2.2 How to release the Magnetic sensor

The procedure of releasing the magnetic sensor is as follows.

1) Turn around the magnetic sensor attachment and remove it from the probe as shown in Fig. 9.

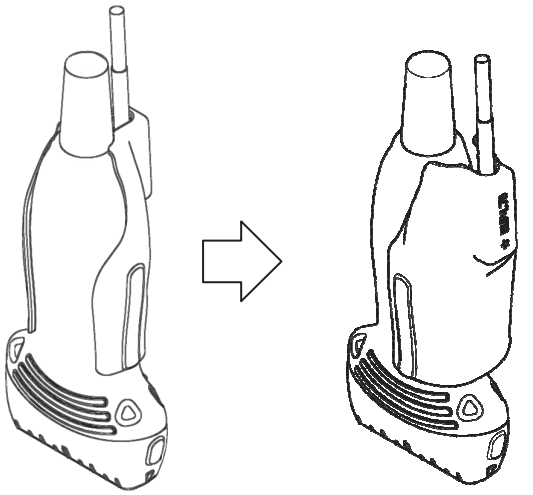


Fig. 9 How to release the Magnetic sensor attachment from the probe

2) Release the magnetic sensor from the magnetic sensor attachment as shown in Fig. 10.

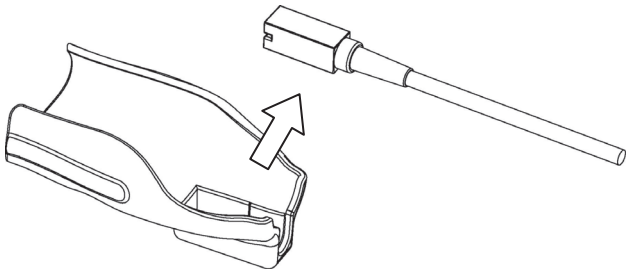


Fig. 10 How to release the Magnetic sensor from the Magnetic sensor attachment

## 5. Reprocessing Procedure

The probe must be reprocessed after each use. Refer to the reprocessing instruction in this chapter. For reprocessing of the needle guide bracket EZU-PA7L3 refer to the instruction manual of the needle guide bracket.

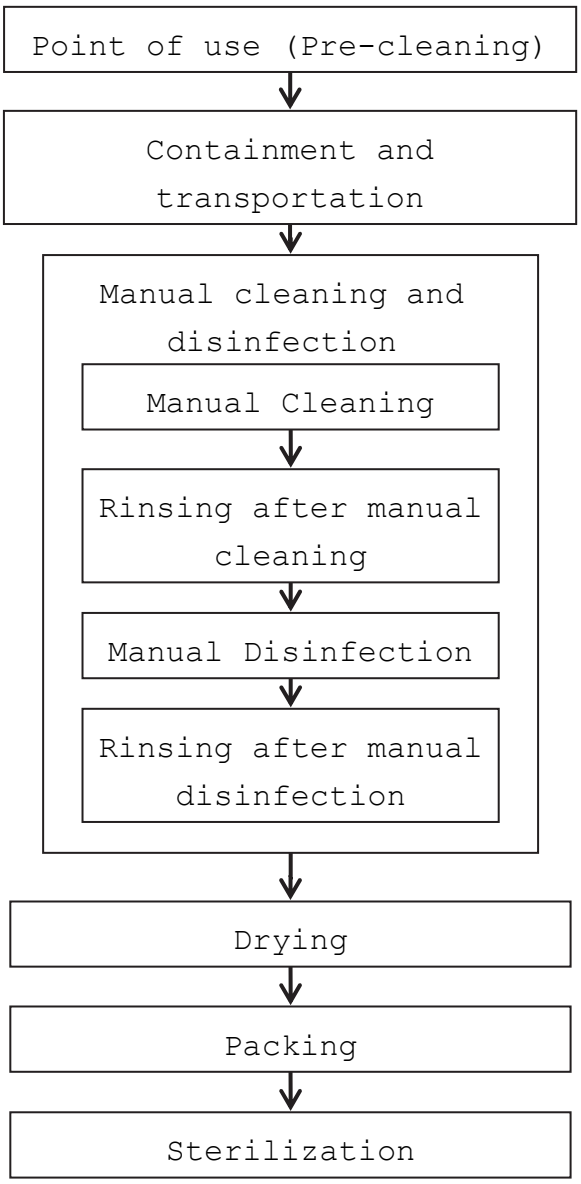
| | |
|---|---|
| WARNINGS | - The probe is delivered unsterile. Prior to the first use, reprocess the probe.<br>- Temperature should not exceed 60°C during reprocessing.<br>- Probe connector is not water resistant. |
| Limitations on reprocessing | The probe is not completely submersible. The immersible 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<br>(Disinfectant with virucidal effect) |
| critical | Application part contacts intracorporeal tissue directly (operative application) | Cleaning<br>Disinfection<br>(Disinfectant with virucidal effect - minimum)<br>Sterilization |

According to the intended use, EUP-L64 is classified as uncritical.

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) L64 probe

1) Remove the probe cover and any accessories from the probe.
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

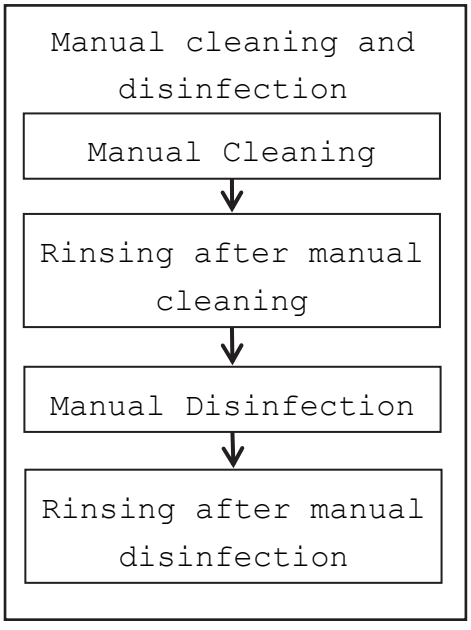
1) Remove the attachment and the magnetic sensor from the probe.
2) Immerse the attachment in sufficient amount of high quality tap water. Scrub it using a soft cloth to remove all visible soil and from its surface.

5.2 Containment and transportation

Containment and transportation

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

5.3 Manual Cleaning and disinfection




Prepare following items before manual cleaning and disinfection:

a) Detergent: Cidezyme® (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device.
b) Disinfectant: Cidex® OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device.
c) Two tanks, one for cleaning and one for disinfection - optional:
   1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the 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) L64 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. 11). 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. 11) 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. 11) 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) L64 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. 11). 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. 11) 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. 11). 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. 11) for 5 min.)

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

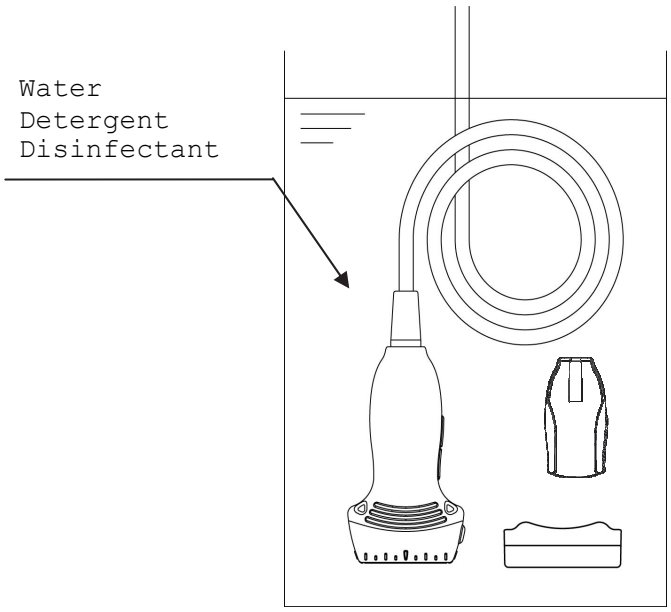



Fig. 11 Immersion of the Probe, the Magnetic sensor attachment and the elasto Coupler

## 5.4 Drying

Drying

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

2) Dry the 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 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.
2) Do not sterilize the probe by Steam Autoclaving. If you autoclave it, it suffers serious damage and will be not functional

The packaging procedure is as follows.

1) Put the probe into TYVEK pouch.

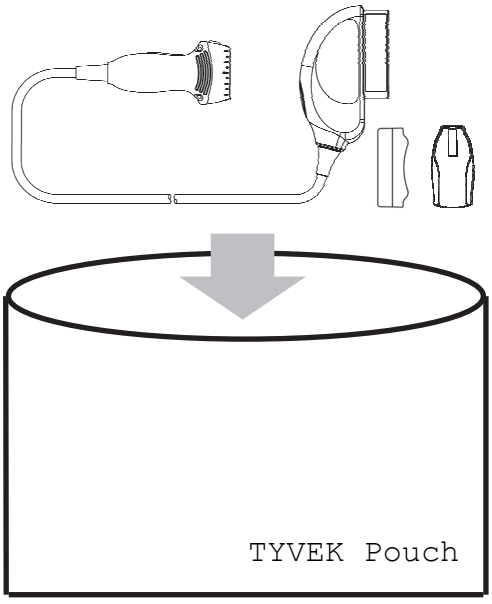



Fig. 12 Packaging in the pouch

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

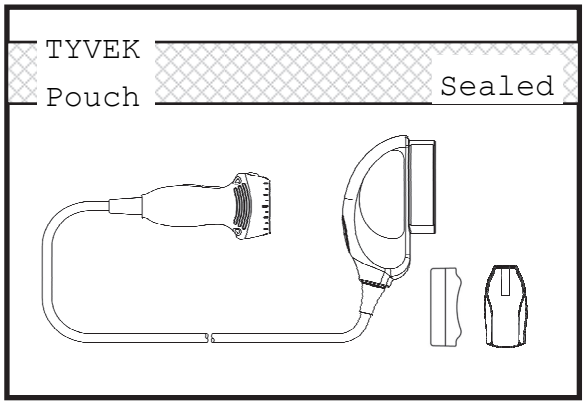



Fig. 13 Sealing

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

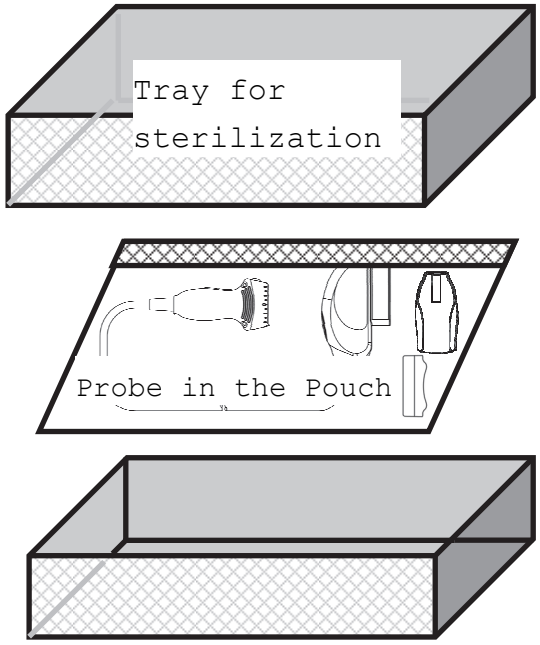



Fig. 14 Packaging in a tray

## 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

1) After using the probe, it should be cleaned and disinfected and sterilized according to "5. Reprocessing Procedure", then store it in a cool and dark place avoid high temperature and humidity, direct sunlight.
2) After using the magnetic sensor attachment and the elasto coupler, it should be cleaned and disinfected and sterilized according to "5. Reprocessing Procedure", then store them in a cool and dark place avoid high temperature and humidity, direct sunlight.
3) 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.
4) Visually inspect the surface of the elasto coupler for any crack, deformation or denaturalization. If you find any damage, do not use it and contact a service support immediately.
5) Visually inspect the surface of the magnetic sensor attachment for any crack, deformation or denaturalization. If you find any damage, do not use it and contact a service support immediately.

## 7. Safety Precautions

### ⚠ WARNING

- Never use the probe if the probe head, housing or cable are cracked or damaged.
- When using this probe (L64 Probe) for biopsy purpose, use the needle guide bracket EZU-PA7L3 (Option) certainly.
- Warning is case of using probe covers which latex is contained to. The latex may cause such allergic reactions as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, and depression of blood pressure, shock and so on. For the patients suspected of latex allergy, do not use the latex-containing medical devices. If you observe any of above mentioned symptoms in your patient during the operation, stop the use of the latex-containing medical devices immediately and take an appropriate treatment to the patient.

### ⚠ CAUTION

- By examination of an early pregnancy the exposure time shall be as short as possible. Start examination with acoustic output power set to L (Low).
- The probe connector is not waterproof. Do not allow liquid to contact the connector.
- Do not drop, hit or bent the probe.
- Use only water, detergents and disinfectants in the suppliers list.
- Between uses store the probe holder of scanner.
- Under sterile condition use appropriate protection for probe and cable. Some Latex material may create allergic reactions.
- The probe, the magnetic sensor attachment and the elasto coupler are not delivered disinfected or sterilized.
- The acoustic lens of the probe is manufactured very thin and delicate to get the high resolution.
  Therefore, in case of wiping off the ultrasound jelly or cleaning the surface of the acoustic lens, please use a soft cloth or tissue paper and handle with care.

# 8. Specifications

## 8.1 Probe

| | |
|---|---|
| Type | : L64 Probe |
| Acoustic working Frequency | : 10MHz |
| Technology | : Linear Array Probe |
| Dimensions | : See Fig. 15. |
| Weight | : Approx. 0.46kg (Including cable and connector) |
| Probe materials | : Biocompatible allergy free components |
| Acoustic output | : According to IEC60601-2-37 (See Main Unit manual) |
| Applicable systems | : Depending on production and upgrade status for detailed information, contact a service support. |
| Classification | : MDD classification IIa. |
| Cleaning | : Applicable detergents are listed in the suppliers list |
| Disinfection | : Applicable disinfectants are listed in the suppliers list |
| Sterilization | : ETO gas sterilization Plasma sterilization |

Operating conditions:

| | |
|---|---|
| Ambient temperature: | +10 - +35°C |
| Contact surface temperature: (Temperature of examinee) | max. 42°C |
| Relative humidity: | 30 - 85% (subject to no condensation) |

Storage conditions:

| | |
|---|---|
| Temperature: | -10 - +55°C |
| Relative humidity: | 10 - 95% (subject to no condensation) |

8.2 Suppliers List

The products listed below are seriously tested and approved for use with L64 Probe.

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

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

⚠ CAUTION

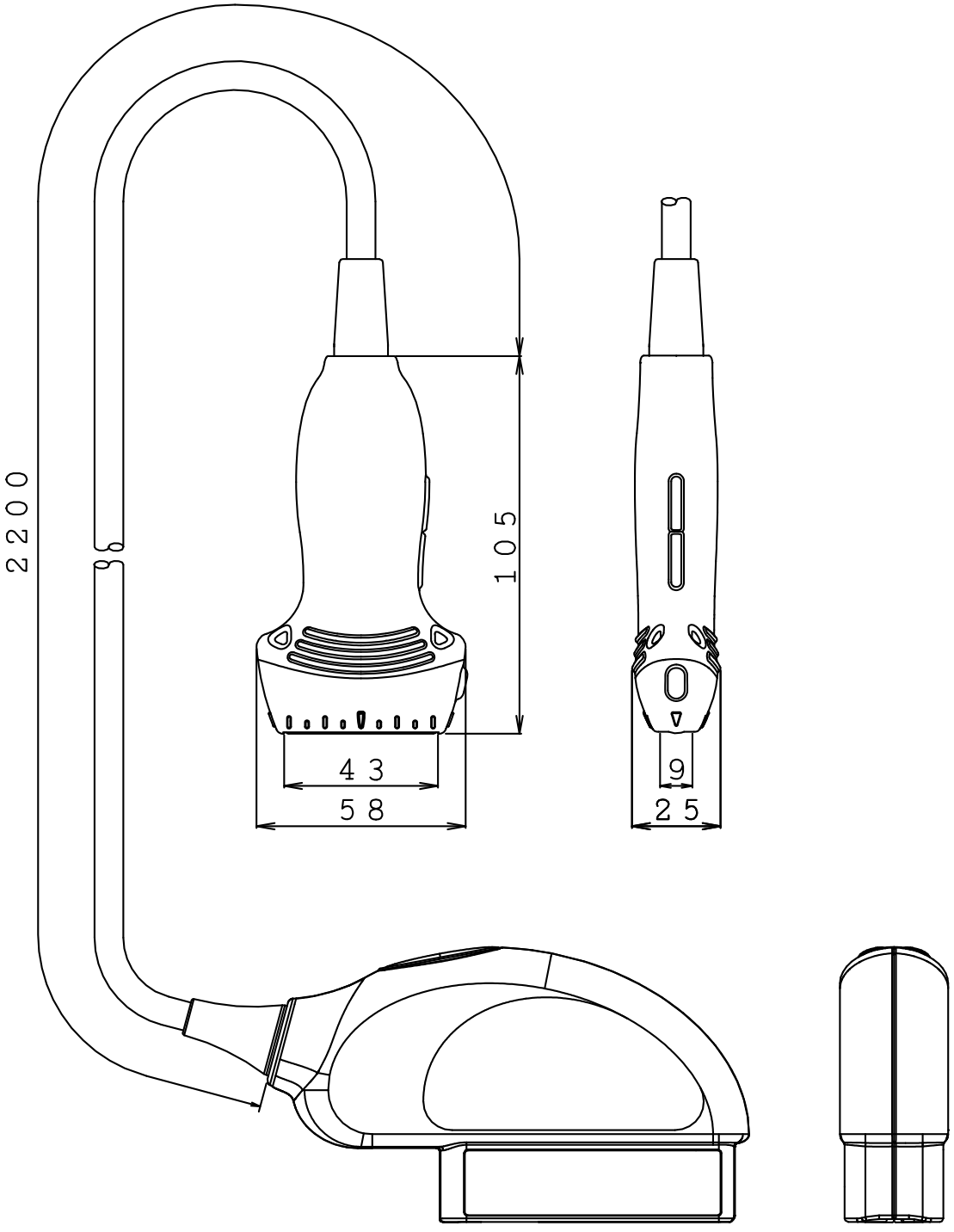
Before disposing the equipment, disinfect or take other infection-prevention measures.

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

Waste Electrical and Electronic Equipment (WEEE) Directive

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

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




Unit:mm

Fig. 15 Dimensions

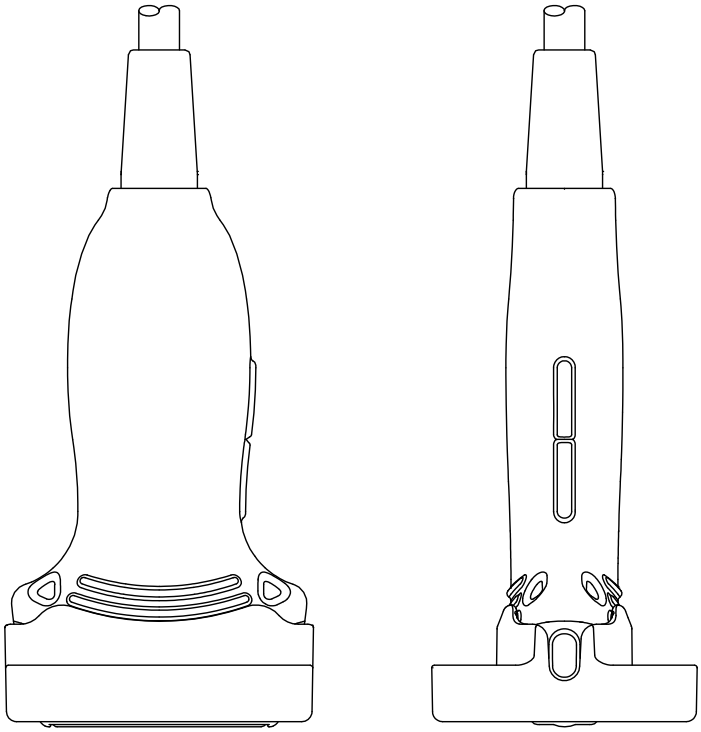


Fig. 16 External View (with the Elast coupler)

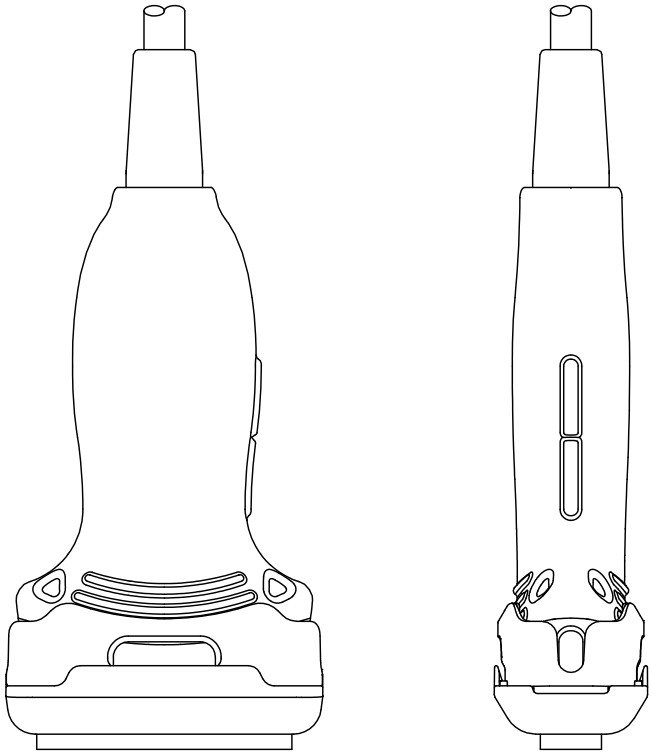


Fig. 17 External View (with the Acoustic coupler attachment EZU-TEATC2 and the Acoustic coupler (EZU-TECPL1 or SF-001))

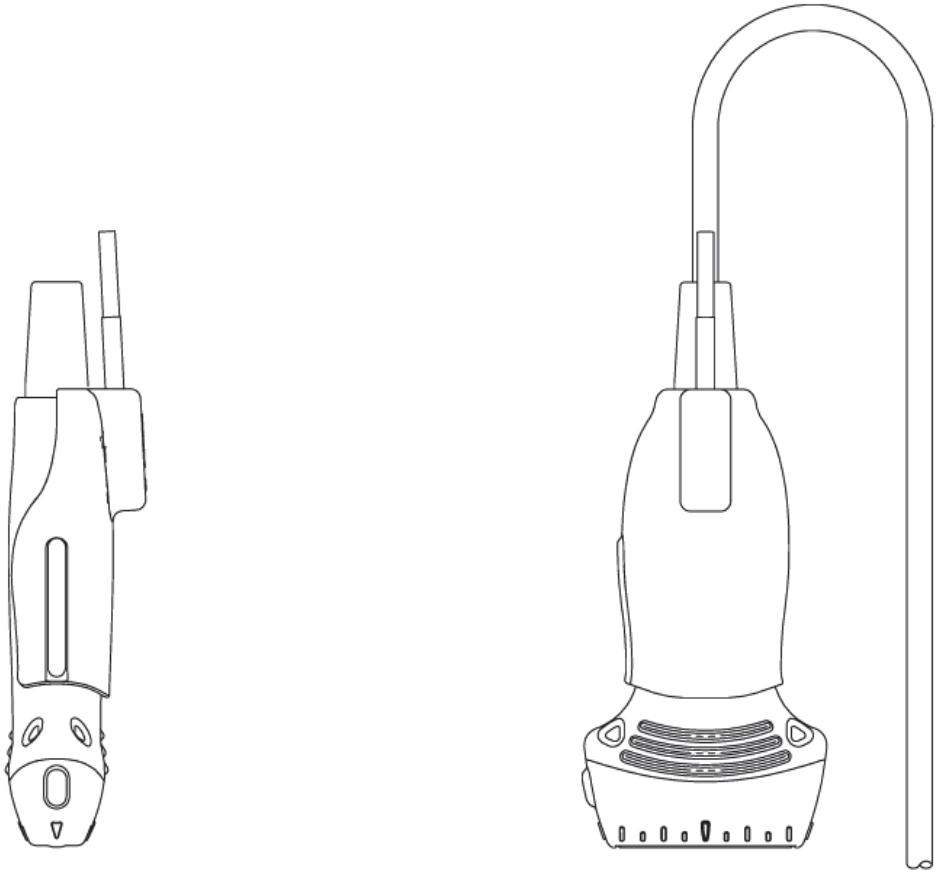


Fig.18 External view (with the Magnetic sensor attachment)

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