

## Intraoperative Probe

EUP-O732T

### 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-EP1234-7

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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:

Address:

Hitachi Medical Systems Europe Holding AG  
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-0732T. Please read this manual thoroughly to ensure the safety operation. If you have any questions concerning the operation of the probe, please contact a service support.

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

- WARNING:** "Warning" indicates the presence of a hazard which may result in severe personal injury, substantial property damage, or death if the warning is ignored.
- CAUTION:** "Caution" indicates the presence of a hazard which will or can cause minor personal injury or property damage if the caution is ignored.
- NOTICE:** "Notice" indicates information of installation, operation, or maintenance, which is important, but not hazard related.










**Graphical Symbols for Use in Labeling of Hitachi Ultrasound Probes**

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

Explanation of Symbol	Symbol	Descriptive Content
Manufacturer Company Name and Address		Hitachi, Ltd. 2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015, Japan +81-3-6284-3668 <a href="http://www.hitachi.com/businesses/healthcare/index.html">http://www.hitachi.com/businesses/healthcare/index.html</a>
Authorized Representative in The European Community		Hitachi Medical Systems GmbH Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany
Keep away from Sunlight		Store the probe in a cool place and keep away from high temperature, high humidity, or direct sunlight.
Contains or presence of natural rubber latex		Contains or presence of natural rubber latex
Do not re-sterilize		Do not re-sterilize
Do not reuse		Do not reuse

**Definition of symbol**

The following symbol is also used for HITACHI Ultrasound Probes.

Location	Symbol	Definition
Probe connector		This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector	<b>IPX7</b>	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		STERRAD sterilization compatibility mark
Probe connector		Upper Limit of Temperature; 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	<b>Rx Only</b>	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 Intraoperative Probe EUP-0732T is a probe for Convex Array electronic scanning.

The acoustic output of this probe when connected to ultrasound scanner was measured according to IEC 60601-2-37 standard. The table of measured acoustic output data is contained in the operation manual of each ultrasound 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.

#### **WARNING**

Never use the probe for following applications.  
Direct contact to the heart.  
Biopsy to the heart.

#### **WARNING**

Never use the probe with (HF) surgical equipment.

### 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 Intraoperative Probe EUP-0732T is designed for observation and diagnosis of the following regions mainly by connecting with the HITACHI ultrasound scanner.

- Intraoperative

**⚠ WARNING**

Never use the probe for following regions.

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

### 1.4 Compositions

Components of the EUP-0732T are as follows:

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

**⚠ CAUTION**

Sterilization has not been made to the probe shipped from the factory. Prior to use of the probe, be sure to clean, disinfect and sterilize them following this instruction manual.

### 1.5 Accessories (Option)

- 1) Magnetic Sensor Attachment

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

- 2) Spacer for EZU-RV2S

Spacer for EZU-RV2S is the spacer needed to fix the magnetic sensor (EZU-RV2S) to the Magnetic sensor attachment.

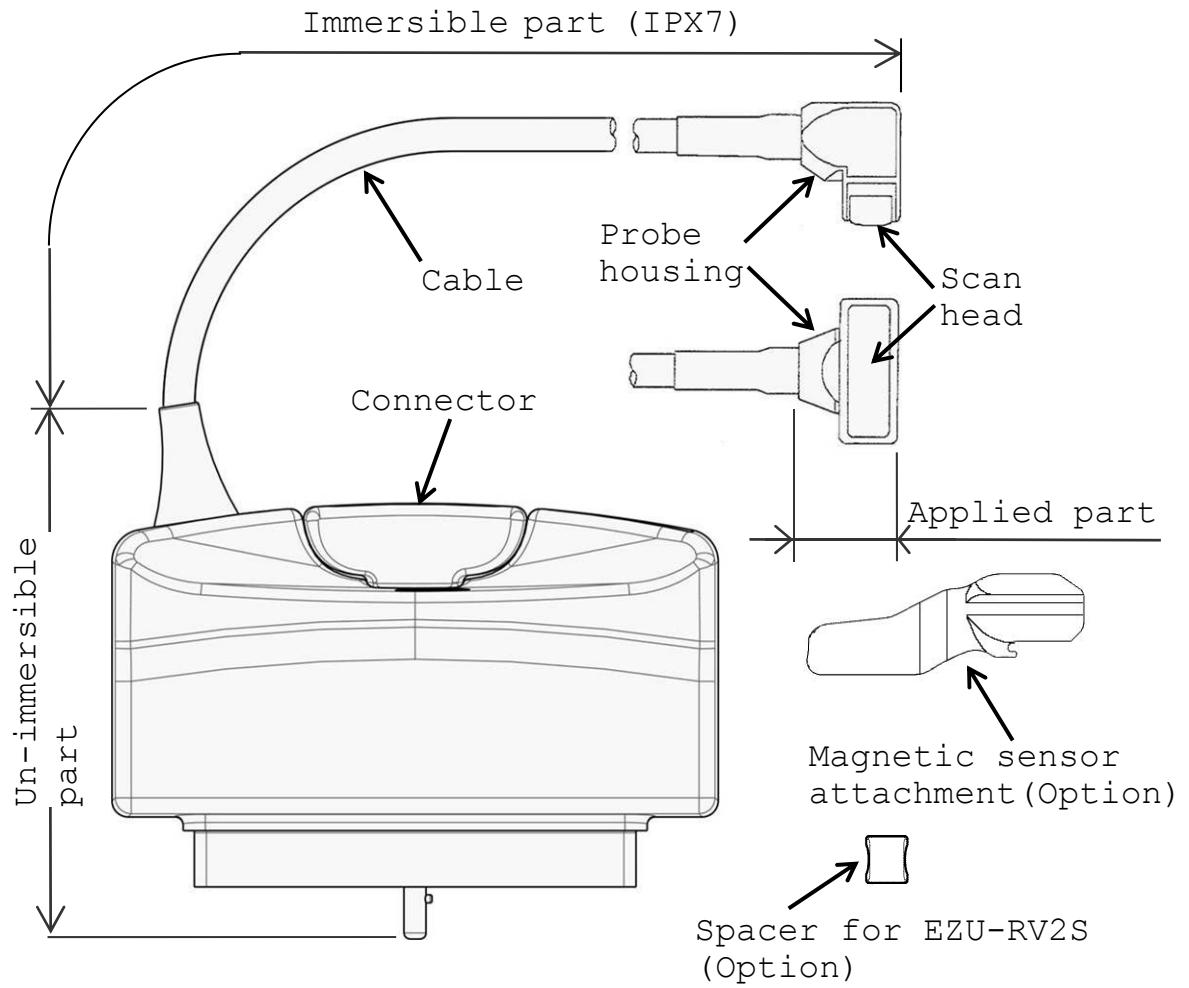
**⚠ CAUTION**

The Magnetic sensor attachment and the Spacer for EZU-RV2S are not sterilized when shipped from the factory. Prior to use, be sure to clean, disinfect and sterilize them.



## 1.6 External View

The external view of EUP-0732T 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 and accessories must be carefully inspected so 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. Please refer to the instruction manual of the Main unit for the operation.
- 2) Confirm that any unauthorized devices or instruments such as an unauthorized biopsy attachment is not attached or connected to the probe.

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

 **CAUTION**

Beware of the Spacer for EZU-RV2S since it is so small.

### 3. Operation Procedure

- 1) Confirm that the probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S are cleaned, disinfected and sterilized. The Magnetic sensor attachment and the Spacer for EZU-RV2S are needed for Real-time Virtual Sonography (RVS). Regarding the option for RVS, please refer to "4.Option of EUP-0732T".
- 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. Then adjust the image according to the instructions given in the operation manual for the scanner.
- 4) The relationship between the direction of the probe and the right-left orientation mark on image is shown in Fig. 2.

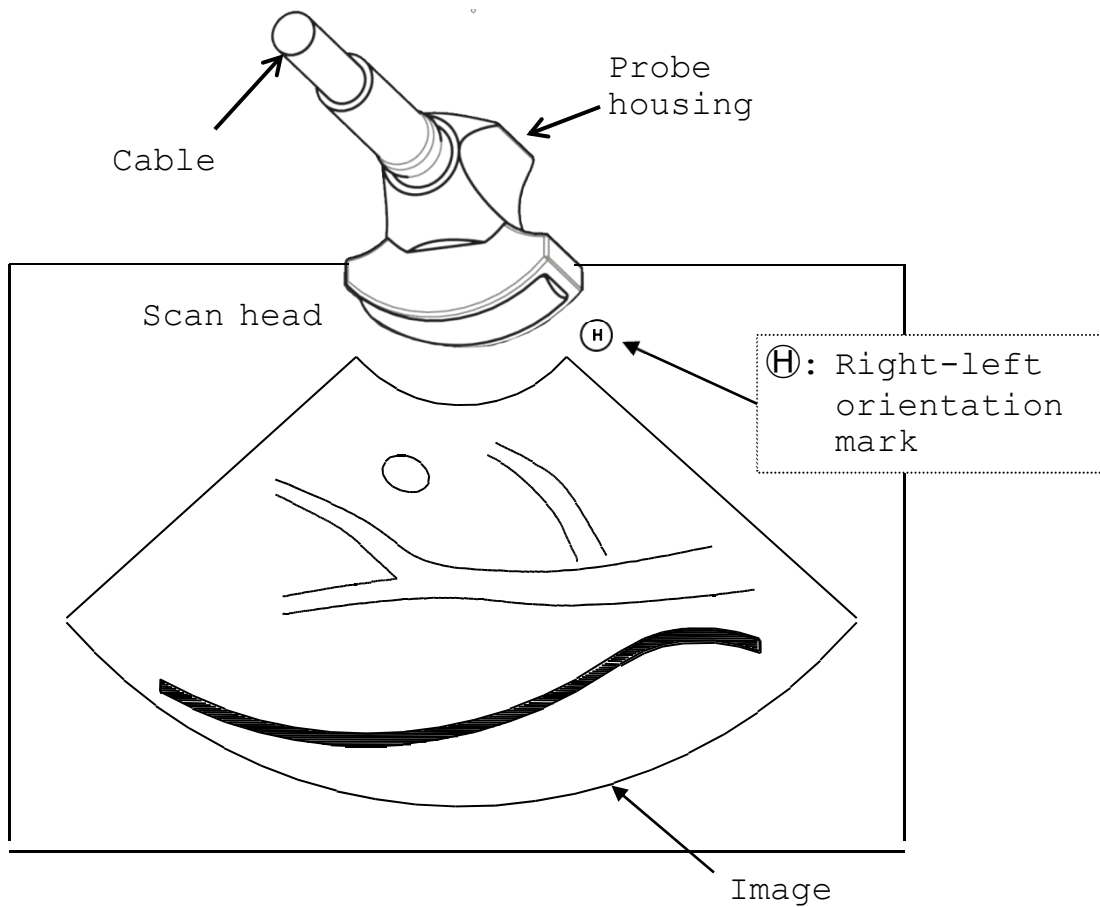


Fig. 2 Relationship between direction of the probe and Right-left orientation Mark



- 5) Use under sterile condition, protecting the probe by using covers is recommend. Some Latex material may create allergic reaction. Please use allergy free material covers.

- 6) After the use of the probe, clean and disinfect and sterilize the probe immediately and using RVS, also clean and disinfect and sterilize the Magnetic sensor attachment. In case of using RVS with an EZU-RV2S, also clean and disinfect and sterilize the Spacer for EZU-RV2S.
- 7) Store the probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S in the environment indicated in "6. Maintenance and Safety Inspection".

 **CAUTION**

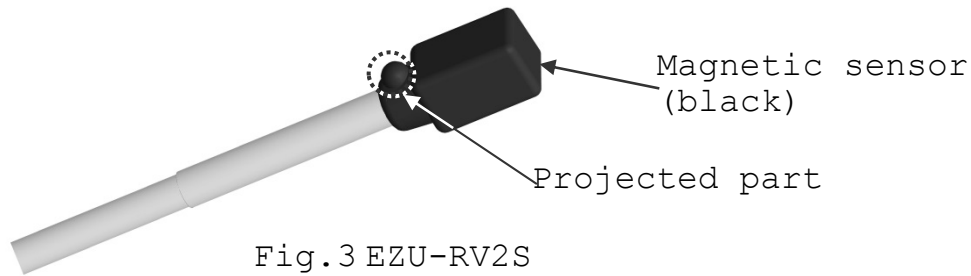
- Do not use the probe if the image and the frequency do not match the probe. An incorrect acoustic output can result in burns or other injuries to the patient.
- Scan for the minimum length of time necessary for the diagnosis and at the lowest possible output. There is the possibility that the patient's tissues could be affected. For details about the acoustic output, please refer to the operation manual of the ultrasound diagnostic instrument.
- The acoustic lens of the probe is very thin and delicate. So if the surface of the acoustic lens is wiped for removing remaining ultrasound jelly or cleaned, use the soft cloth or tissue paper and handle with care.

#### 4. Option of EUP-O732T

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-O732T, EZU-RV2S and EZU-RV3S. EZU-RV2S and EZU-RV3S are shown in Fig.3 and Fig.8. The uses of EUP-O732T with either of the 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.3 is the magnetic sensor (EZU-RV2S) for EUP-O732T.



##### 4.1.1 How to Attach the 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 disinfected and sterilized.
- 2) Connect the probe to the ultrasound diagnostic scanner and operate the scanner. Then adjust the image according to the instructions given in the operation manual for the scanner.
- 3) To use RVS (Real-time Virtual Sonography), attach the magnetic sensor as shown below in the out of operative field.
  - a) Attach the Spacer for EZU-RV2S to Magnetic sensor. Then insert Magnetic sensor into the Magnetic sensor attachment with the correct direction as shown in Fig.4.

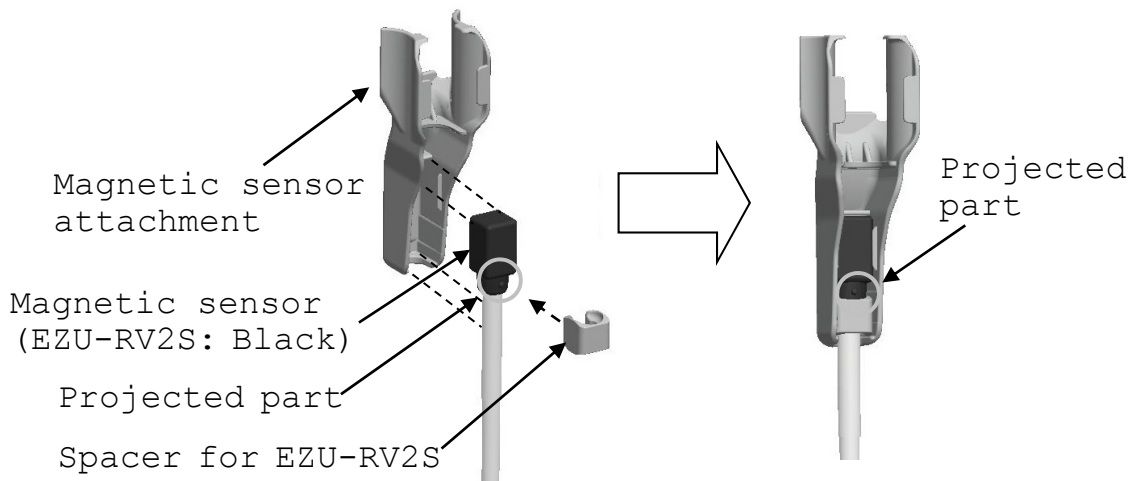


Fig.4 How to attach the Magnetic sensor

**⚠ 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 EZU-RV2S, otherwise it may result in false diagnosis.

b) Attach the Magnetic sensor attachment to the probe as shown in Fig.5.

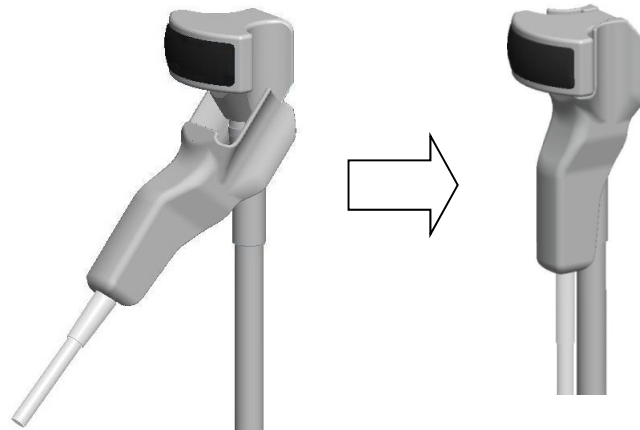


Fig.5 How to attach the Magnetic sensor attachment

**⚠ CAUTION**

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

#### 4.1.2 How to Release the Magnetic Sensor

The procedure of releasing the Magnetic sensor is as follow.

- 1) Detach the Magnetic sensor attachment from the probe as shown Fig.6 in the out of operative field.

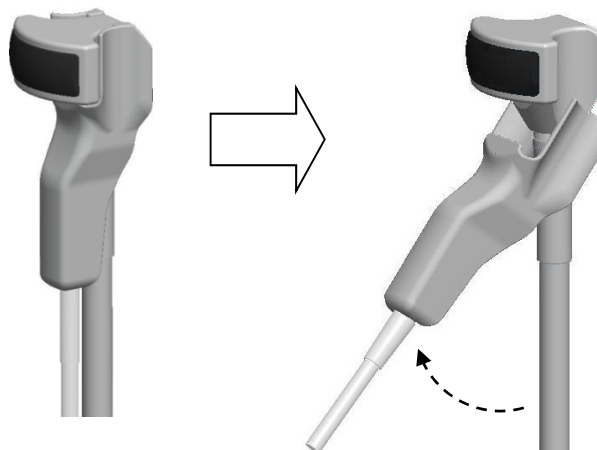


Fig.6 How to release the Magnetic sensor attachment from the probe

- 2) Detach the magnetic sensor and the Spacer for EZU-RV2S from the Magnetic sensor attachment as shown Fig.7 in the out of operative field.

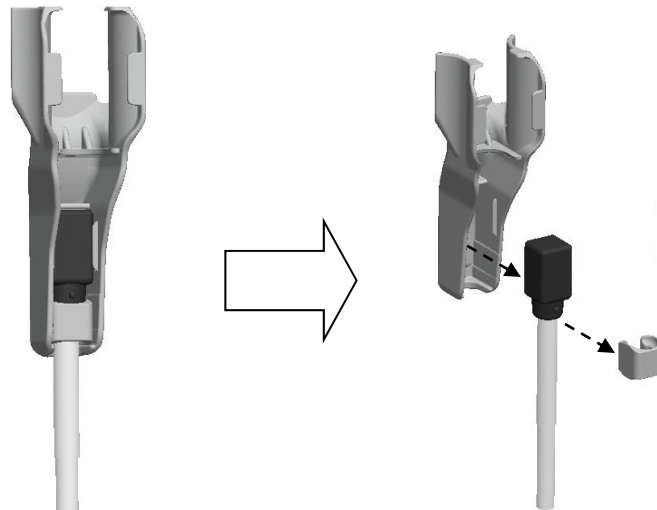


Fig.7 How to release magnetic sensor from the Magnetic sensor attachment

**⚠ CAUTION**

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

#### 4.2 Magnetic Sensor (EZU-RV3S)

Magnetic sensor (EZU-RV3S) as shown in Fig.8 is the magnetic sensor for EUP-0732T.

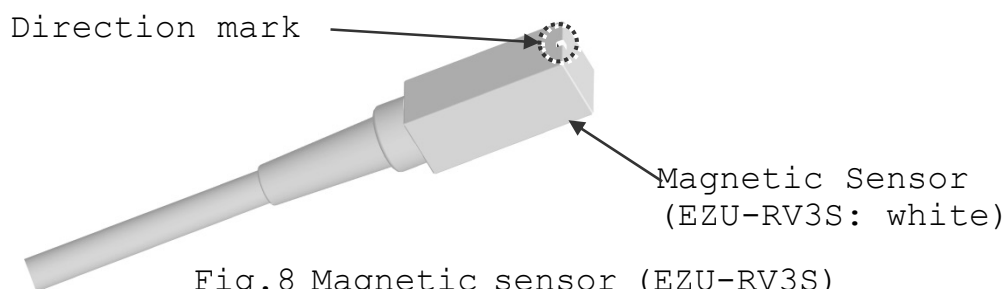


Fig.8 Magnetic sensor (EZU-RV3S)

##### 4.2.1 How to Attach the Magnetic Sensor EZU-RV3S

The procedure of attaching Magnetic sensor is as follow.

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

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

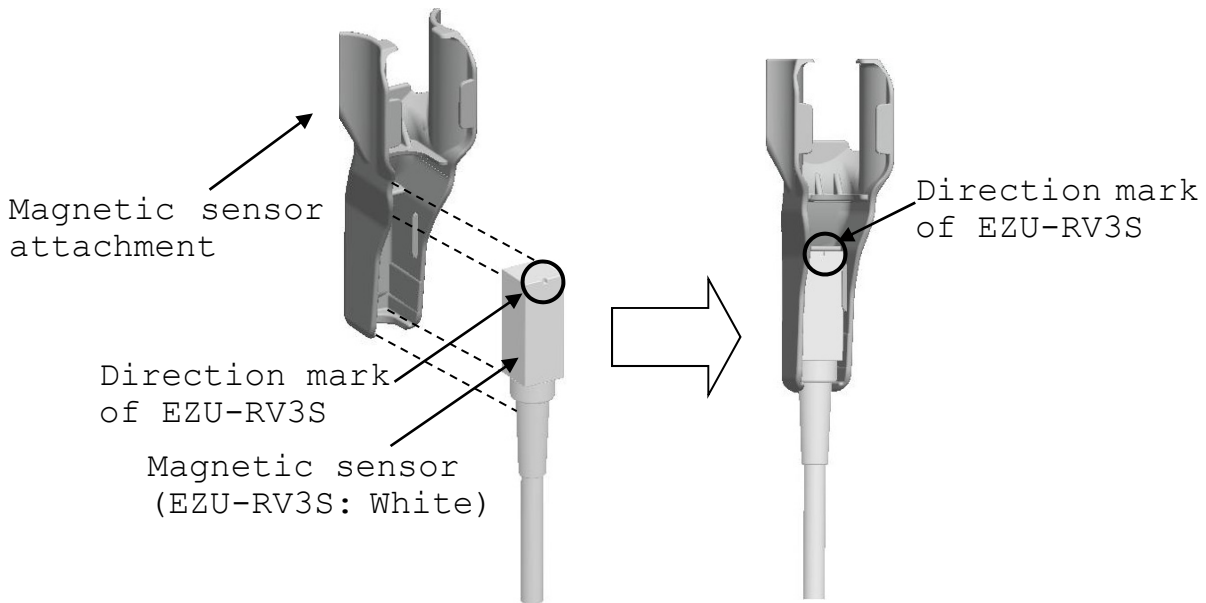


Fig.9 How to attach the Magnetic sensor

**⚠ CAUTION**

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.10.

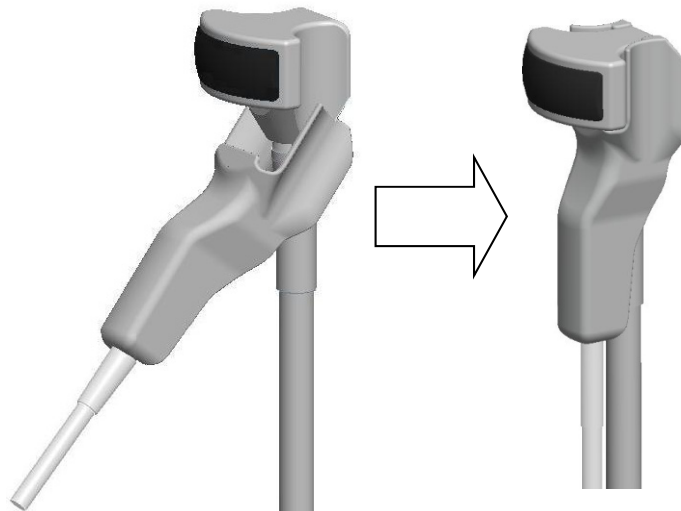


Fig.10 How to attach the Magnetic sensor attachment

**⚠ CAUTION**

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



#### 4.2.2 How to Release the Magnetic Sensor

The procedure of releasing the Magnetic sensor is as follow.

- 1) Detach the Magnetic sensor attachment from the probe as shown Fig.11 in the out of operative field.

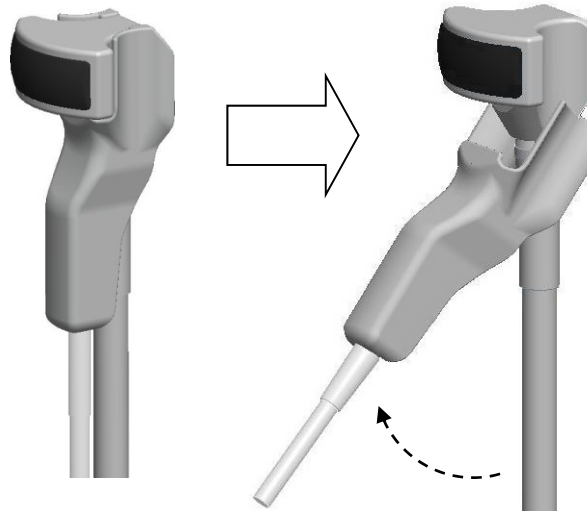


Fig.11 How to release the Magnetic sensor attachment from the probe

- 2) Detach the magnetic sensor from the Magnetic sensor attachment as shown Fig.12 in the out of operative field.

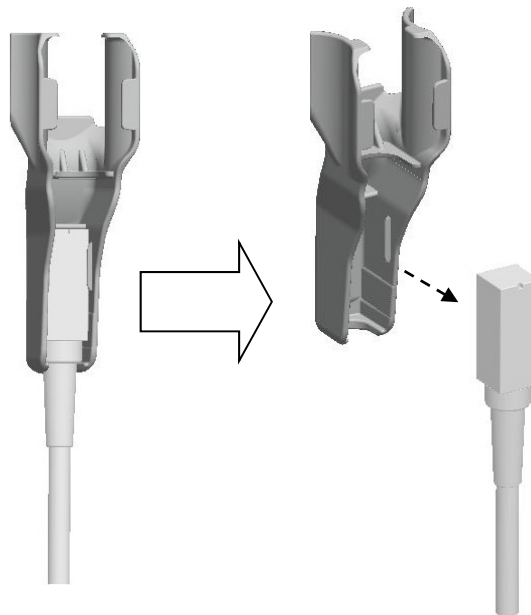


Fig.12 How to release magnetic sensor from the Magnetic sensor attachment

#### CAUTION

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

## 5. Cleaning and Disinfection and Sterilization



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

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

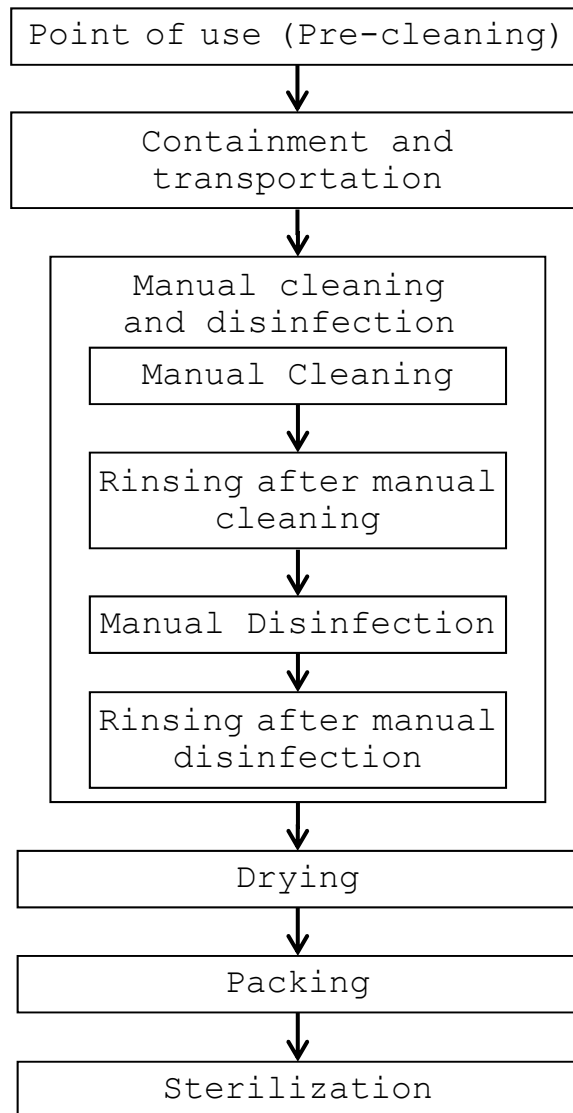
Levels of reprocessing requirements:

Depending on the application of the product and with regard to risk evaluation, the user has to classify the medical device according to the current Medical Device Directive for processing of medical devices as uncritical, semi-critical or critical. Supporting information concerning this topic is listed in the table below. The user is responsible for correct classification of the medical device.

Classification	Definition	Processing
uncritical	Application part only contacts intact and uninjured skin	Cleaning Disinfection
semicritical	Application part contacts mucosa (intracavitary application)	Cleaning Disinfection (Disinfectant with virucidal effect)
critical	Application part contacts intracorporeal tissue directly (operative application)	Cleaning Disinfection (Disinfectant with virucidal effect - minimum) Sterilization

According to the intended use, EUP-0732T probe is classified as critical.

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-0732T 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 and from its surface.

5.2 Containment and transportation

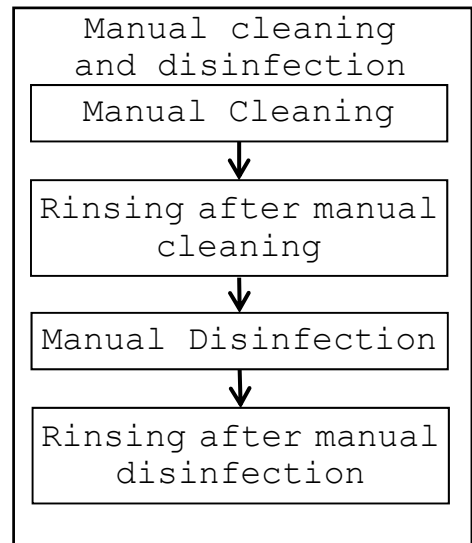
Containment and  
transportation

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 submersible 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-0732T 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. 13). 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-immersible 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.) 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.) 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-0732T 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. 13). 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. 13) 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.). 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. 13) for 5 min.)

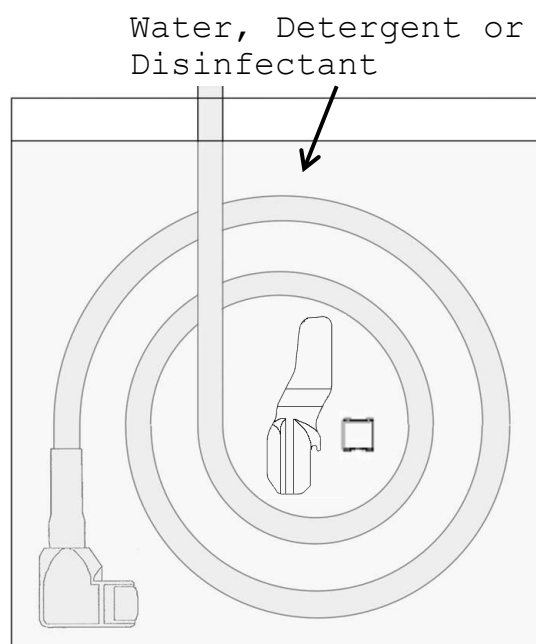


Fig. 13 Immersion of the probe and the Attachment.

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

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

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

**! WARNING**

- 1) Before performing sterilization, check that the operation data of sterilizer are in conjunction with min. and max. data applicable for the probe and the Attachment.
- 2) Do not sterilize the probe and the Attachment 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.

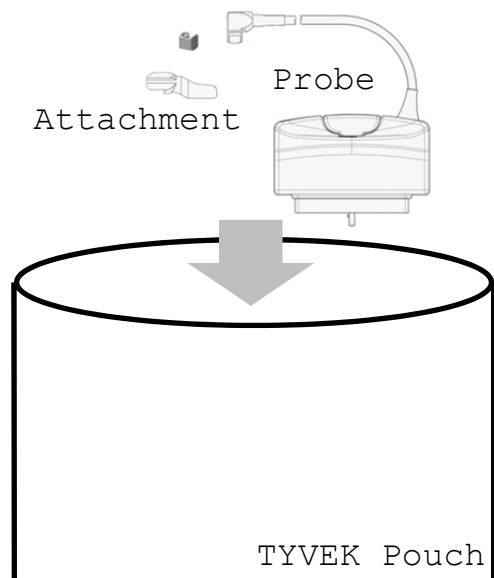


Fig. 14 Packaging in the pouch

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

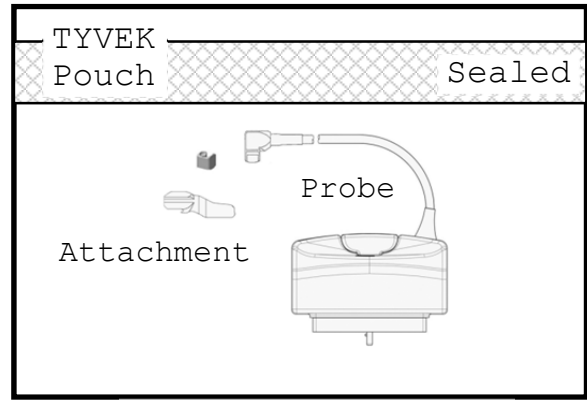


Fig. 15 Sealing

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

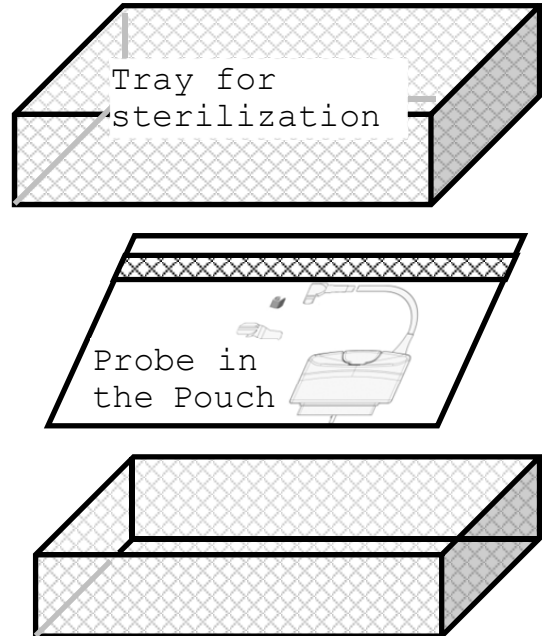


Fig. 16 Packaging in a tray

## 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 the Magnetic sensor attachment and contact a service support immediately.

### 6.2 Storage



After the using the probe, the Magnetic sensor attachment and the Spacer for EZU-RV2S, They should be cleaned and disinfected and sterilized following **"5. Cleaning, and disinfection and Sterilization"**. Then store them in a cool and dark place avoid high temperature and humidity direct sunlight.

## 7. Safety Precautions

### **WARNING**

- Never use the probe if the probe head, housing or cable are cracked or damaged.
- 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.
- The ultrasound gel attached to the ultrasound scanner as one of accessories is not sterile so never use it with EUP-0732T.
- Do not attempt to disassemble, modify, or repair the probe. Electric shock or other unforeseen accidents could result.
- Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
- Do not use the probe fallen on to floor. Otherwise, there is a risk of infection. Stop the operation and perform the inspection, cleaning and disinfection and sterilization according to section 2 "Inspection before Use" and section 5 "Cleaning and Disinfection and Sterilization".
- When using ultrasound contrast agent, follow the supplied documentation. Unexpected accidents could result. Check the state of the patient and take appropriate precautions to avoid side effects.

**⚠ CAUTION**

- Keep the acoustic power low and minimize the ultrasound exposure time for the examination of an early pregnancy.
- Do not expose the connector to water or other liquids. The connector is not waterproof.
- Do not hit or drop the probe. The probe is easily damaged by mechanical shock.
- Do not use detergents and disinfectants other than listed in "8.2 Supplier's list of the Probe" and "8.3 Supplier's List of the Magnetic sensor attachment and the Spacer for EZU-RV2S".
- Use a sterile probe cover to avoid staining or damaging the acoustic lens.
- Clean, disinfect and sterilize the probe, Magnetic sensor attachment and Spacer for EZU-RV2S before the first use as they are not sterilized in the factory.
- Use only the soft cloth or tissue to clean the acoustic lens.
- Do not use this probe with other equipment except for those specifically approved in the manual. Use with unapproved equipment can result in an electric shock, burn, or other injury to the patient or operator and damage to the probe and the other equipment.
- Do not wash, disinfect or sterilize using procedures other than those specified in this manual. Infection could result due to incomplete washing disinfection or sterilization. It can also result in damage to the probe or reduced performance.

## 8. Specifications

### 8.1 Probe

Type:	EUP-O732T Intraoperative probe
Acoustic working frequency:	7.5MHz±30%
Technology:	Convex Array Probe
Dimensions:	See Fig.17
Weight:	Approx. 0.65kg (Including cable and connector)
Probe materials:	Biocompatible allergy free components
Acoustic output:	According to IEC 60601-2-37 (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 supplier's list
Disinfection:	Applicable disinfectants are listed in the supplier's list
Sterilization:	ETO gas sterilization Plasma sterilization
Operating conditions:	
Ambient temperature:	+10 - +40°C
Contact surface temperature (Temperature of examinee):	Max. 42°C
Relative humidity:	30 - 85% (subject to no condensation)
Atmospheric pressure:	700hPa to 1060hPa
Storage conditions:	
Temperature:	-10 - +50°C
Relative humidity:	10 - 90% (subject to no condensation)
Atmospheric pressure:	700hPa to 1060hPa

## 8.2 Supplier's List of the Probe

The products listed below are seriously tested and approved for use with the Intraoperative Probe EUP-0732T.

Product name	Manufacturer	Purpose
ENZOL™	Johnson&Johnson	Cleaner
Cidex® OPA	Johnson&Johnson	Disinfectant
Detergicide®	BIOMARK	Disinfectant
PERASAFE™	DuPont	Disinfectant
CIV-Flex™ Covers 610-575	CIVCO	Probe cover

## 8.3 Supplier's List of the Magnetic Sensor Attachment and the Spacer for EZU-RV2S

The products listed below are seriously tested and approved for use with the Magnetic sensor attachment and the Spacer for EZU-RV2S.

Product name	manufacturer	purpose
Cidezyme®/ENZOL	Johnson & Johnson	Cleaner
Meliseptol BV-Tücher	B.Braun	Disinfectant
STERANIOS 2%	ANIOS	Disinfectant
ANIOXYDE1000	ANIOS	Disinfectant
CIDEX	Johnson & Johnson	Disinfectant
CIDEX® plus™ 28	Johnson & Johnson	Disinfectant
CIDEX® OPA	Johnson & Johnson	Disinfectant
WAVICIDE-01®	Medical Chemical Corp	Disinfectant/ sterilize
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 of equipment properly in compliance with your organizational rules and your local laws.

### CAUTION

Before disposing of the equipment, disinfect or take other infection-prevention measures. Disposal of the equipment without taking the proper preventative measures can lead to infection.

#### Waste Electrical and Electronic Equipment (WEEE) Directive

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

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





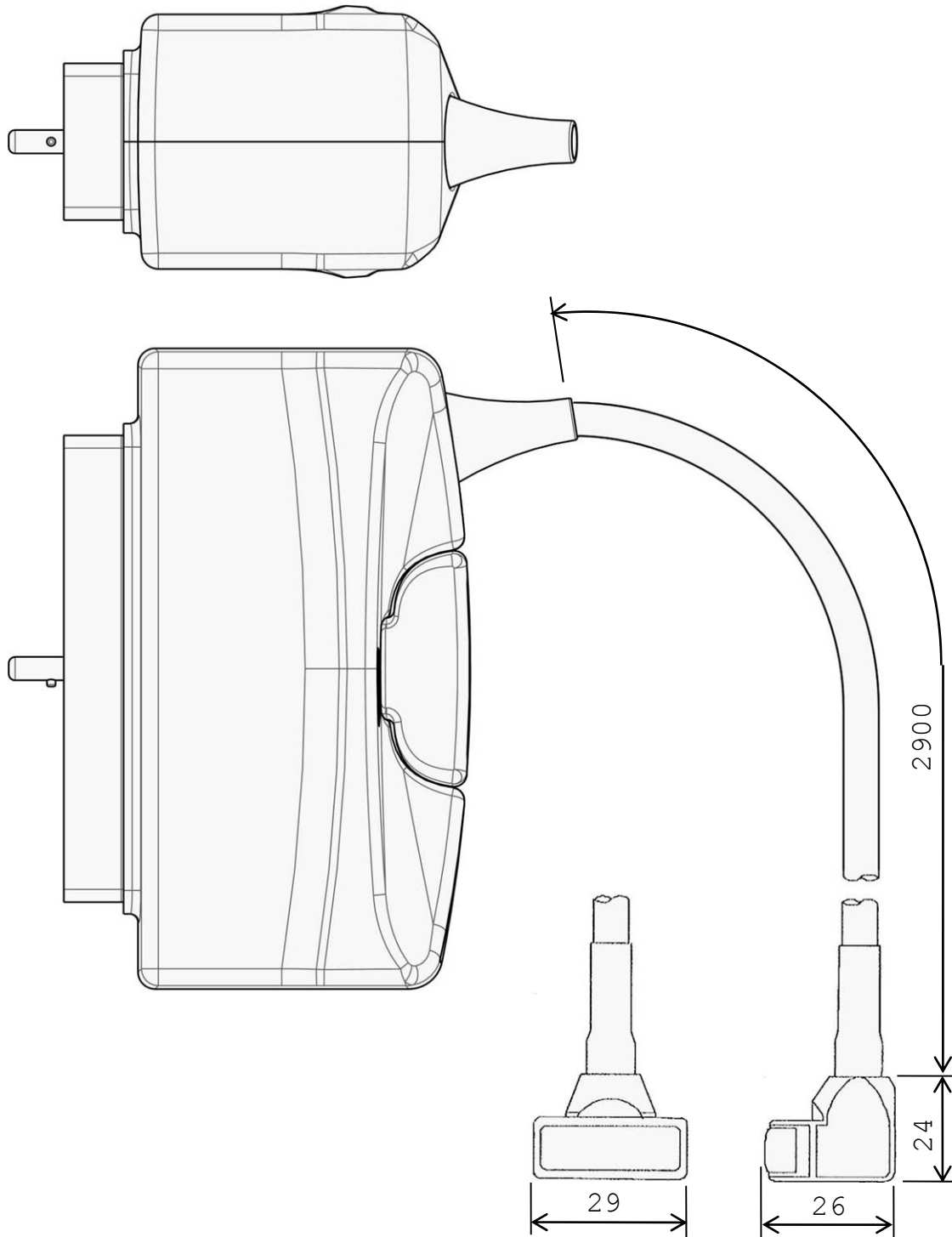


Fig.17 Dimensions

Unit: mm

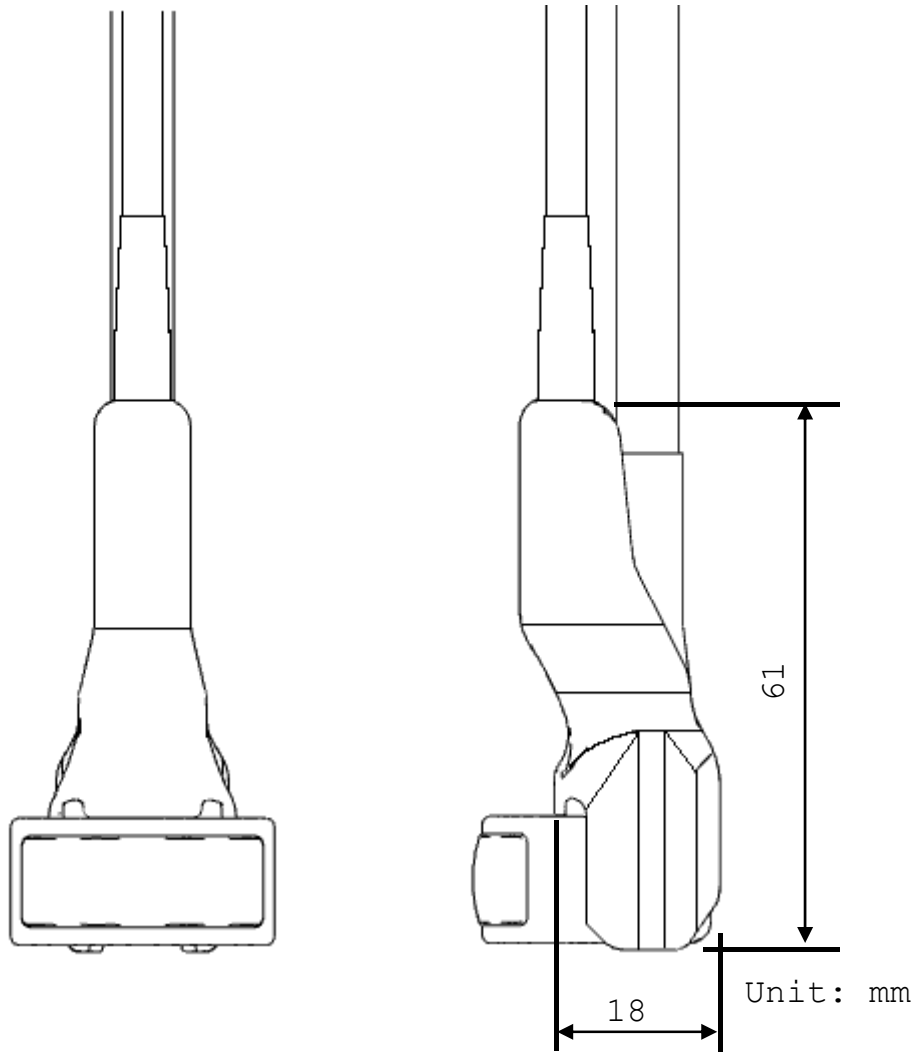


Fig.18 External view of the probe EUP-0732T with the Magnetic Sensor Attachment (Option)

