HITACHI
Inspire the Next

Intraoperative Probe

EUP-O54J

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-EP1064-8

CE 0123

Manufacturer:

Hitachi,Ltd
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110-0015, Japan
+81-3-6284-3668
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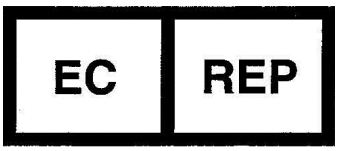
European
Representative:



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 shall provide instructions for using, cleaning, disinfecting, and sterilizing EUP-O54J. It also describes safety considerations and maintenance.
This manual does not include the operation of Hitachi ultrasound diagnostic scanner, so please refer to the operation manual supplied with the scanner for the scanner's operation.
Please read this manual thoroughly before using the probe and keep this manual 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.

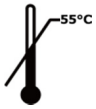
Graphical Symbols for Use in Labeling of Hitachi Ultrasound Probes

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. 2-16-1, Higashi-Ueno, Taito-ku, Tokyo,110-0015, Japan +81-3-6284-3668 http://www.hitachi.com/businesses/ healthcare/index.html
Authorized Representative in The European Community		Hitachi Medical Systems GmbH Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany
Keep away from Sunlight		Store the probe in a cool place and keep away from high temperature, high humidity, or direct sunlight.

Definition of symbol

The following symbol is also used for HITACHI Ultrasound Probes.

Location	Symbol	Definition
Probe connector	CE 0123	This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector	IPX7	IPX7 mark See section 1.6.
Probe connector		Type BF APPLIED PART
Probe connector		General warning sign
Probe connector		Warning; dangerous voltage
Probe connector		Caution; Biohazard
Probe connector		Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.
Probe connector		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	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 probe EUP-O54J is a linear array type.
The acoustic output of this probe when connected to Hitachi ultrasound scanners was measured according to the IEC60601-2-37 standard. The table of measured acoustic output data is contained in the operation manual of each Hitachi ultrasound scanner.
The probe is categorized in class IIa according to Directive 93/42/EEC and classified as type BF according to IEC 60601-1.

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-O54J is designed for observation and diagnosis of the following main regions with connecting to the HITACHI ultrasound diagnostic scanner.

- Intraoperative
- Peripheral vascular
- Musculoskeletal

⚠ WARNING

Never use the probe for following applications.

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

1.4 Components

The components of EUP-O54J are as follows:

1) Probe ····· 1 piece
2) Handle ····· 1 piece
3) Brush ····· 1 piece
4) Instruction Manual ····· 1 copy

⚠ CAUTION

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

1.5 Optional Accessory

The Waterproof Box for the probe connector, EZU-WB1 is applicable and available for EUP-O54J. Using the EZU-WB1 protects the probe connector from contact with liquid such as detergent and disinfectant solution.

1.6 Overview

The overview of EUP-O54J is shown in Fig.1. The immersible part in Fig.1 indicates the part which can be immersed in water or disinfectant. The non-immersible part should not be immersed in any liquid.

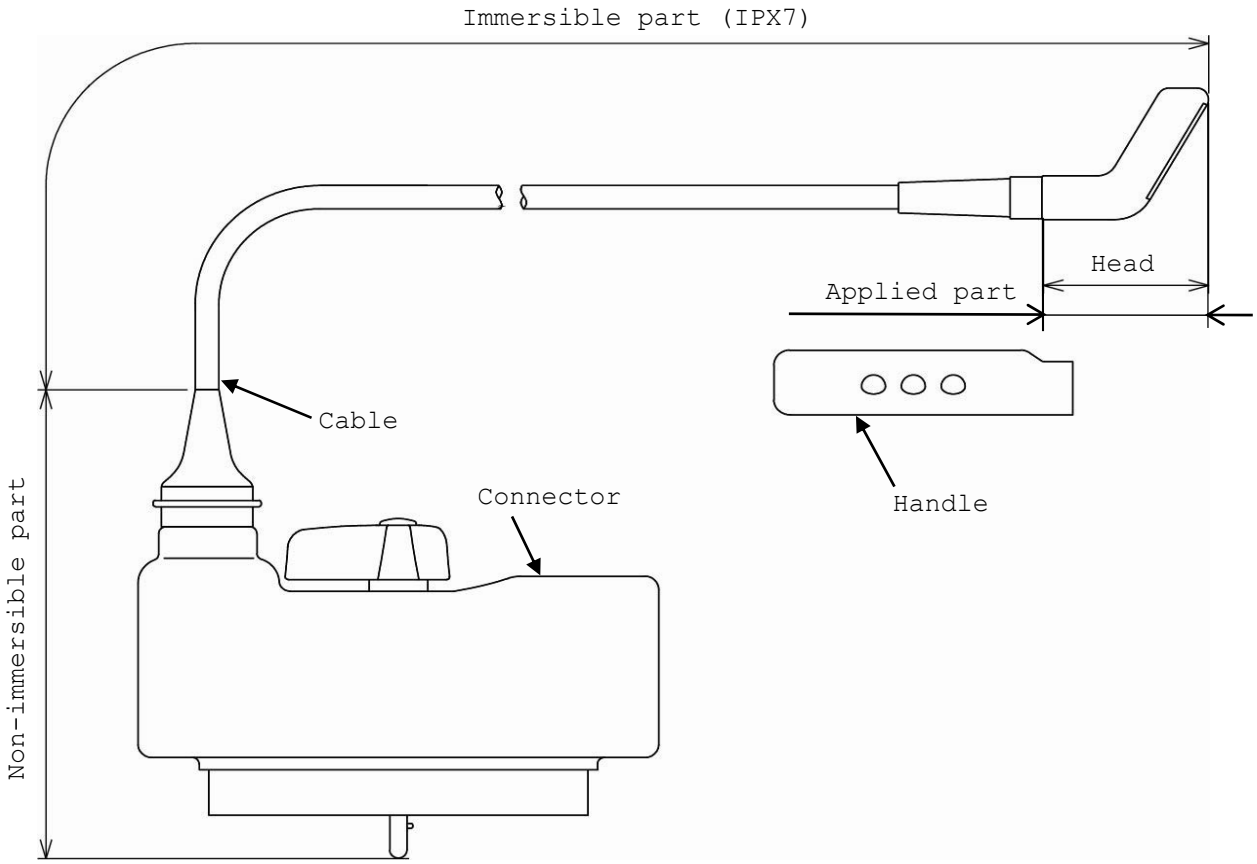


Fig.1 Overview of EUP-O54J

2. Inspection before Use

Prior to each use, the probe must be carefully inspected for any abnormalities. If any abnormalities are found, do not use the probe and immediately contact a service support.

2.1 Inspection for correct operation

Confirm that the scanner is correctly operating. For the scanner's operation, please refer to the operation manual.

Confirm that neither unauthorized devices nor instruments such as unauthorized biopsy attachments are attached to the probe.

2.2 Inspection for material surface

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

3. Operation Procedure

1) Confirm that the probe and the handle are disinfected and sterilized.
2) Connect the probe to the scanner, operate the scanner, and adjust the image according to the instructions given in the operation manual of the scanner.
3) Confirm the direction of the probe. The relationship between the direction of the probe and image is shown in Fig.2. The right-left orientation mark on the image indicates the handle side of the probe.

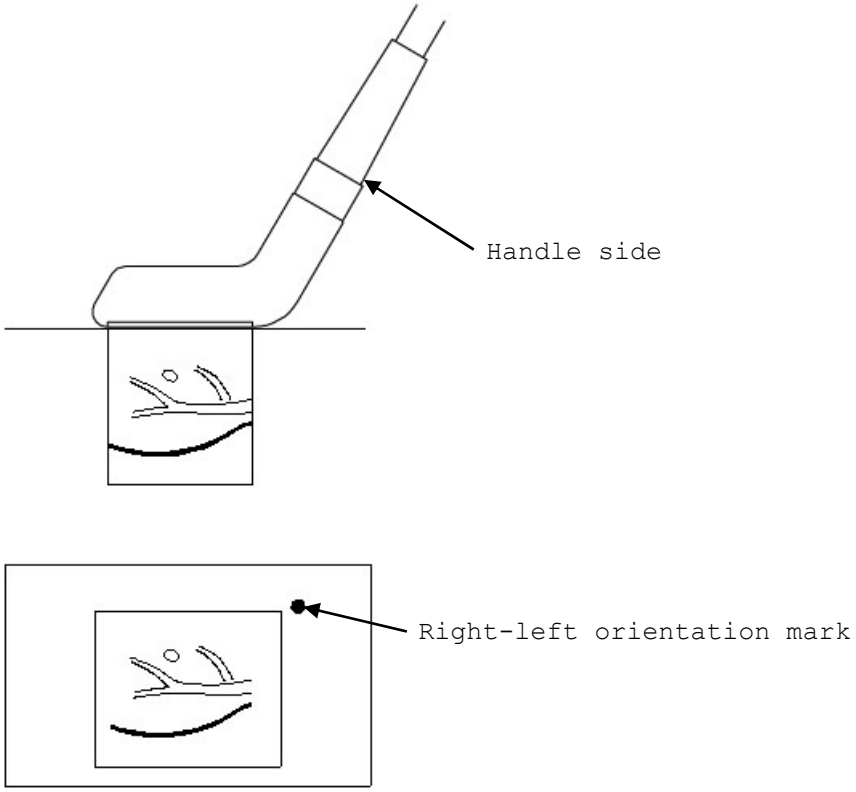


Fig.2 The Relationship between the direction of the probe and the Right-left orientation mark

4) To use the probe with the handle, attach the handle to the probe as shown in Fig.3. First attach the handle to the cable and then slide toward the head. Make sure that the handle is fit to the head properly. For detachment, reverse the procedure.

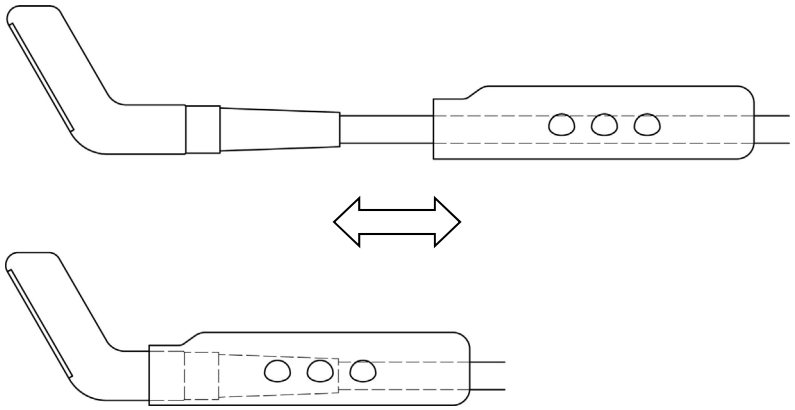


Fig.3 Attachment/detachment of the handle

The handle can be attached multi-directionally as shown in Fig.4.

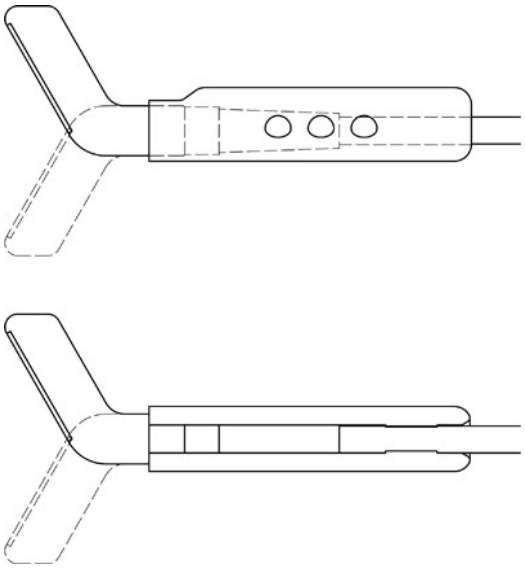


Fig.4 Multidirectional attachment

5) Protecting the probe by using a cover is strongly recommended. Insert the probe into the cover under sterile condition. Please use latex free probe covers to avoid allergic reaction.
6) After using the probe and the handle, perform the reprocessing procedure in accordance with the procedure stated in "4. Cleaning, Disinfection, and Sterilization" every time immediately after completing the ultrasound examination.
7) Store the probe and the handle in the environment indicated in "5. Maintenance and Safety inspection".

4. Cleaning, Disinfection, and Sterilization

The probe and the handle 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. - Temperature should not exceed 60°C during reprocessing. - Probe connector is not water resistant. When a washer-disinfector is used, the waterproof box MUST be used to cover the probe connector.
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.

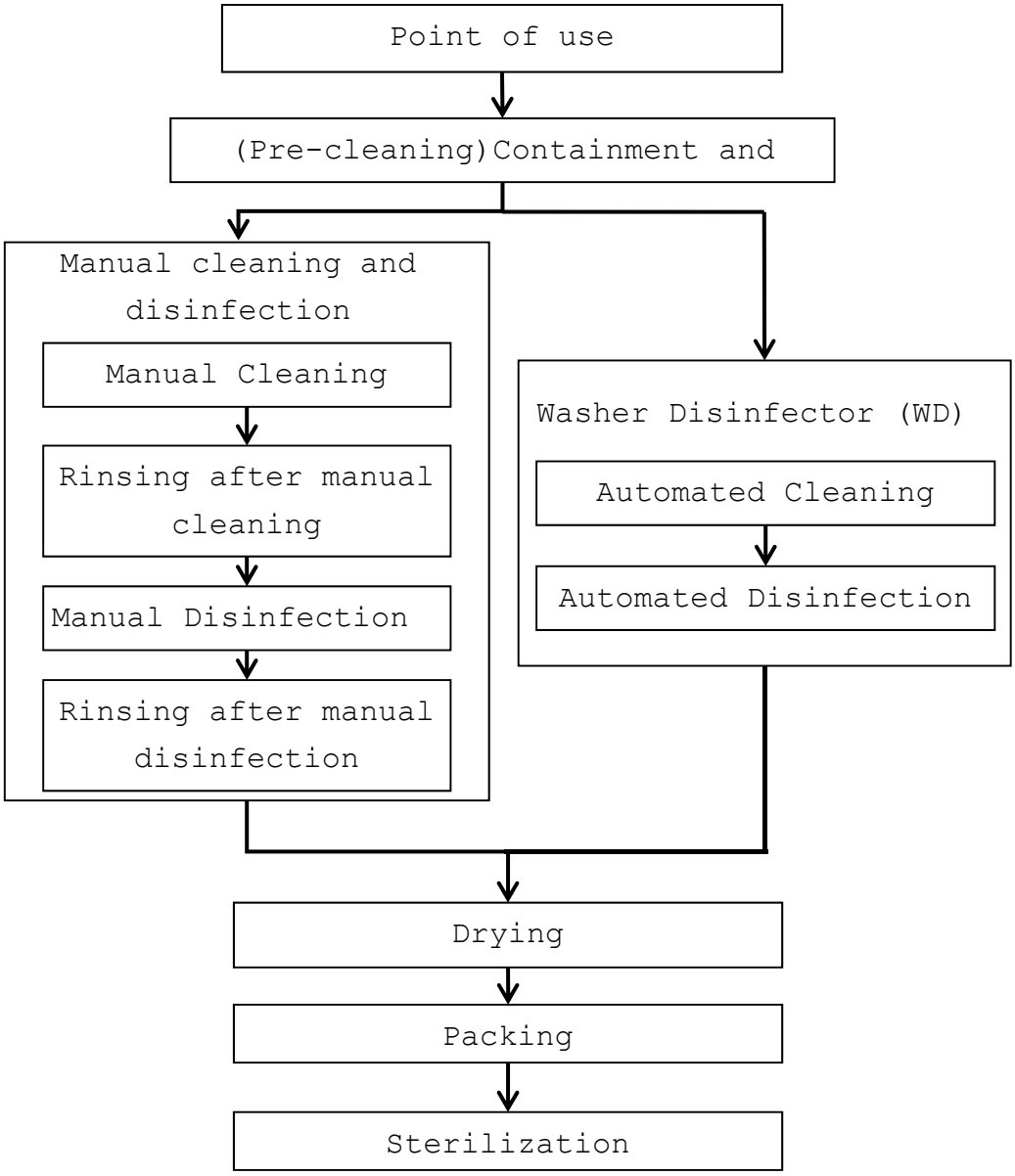
Levels of reprocessing requirements:

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-O54J is classified as critical.

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



4.1 Point of use (Pre-cleaning)

Point of use (Pre-cleaning)

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

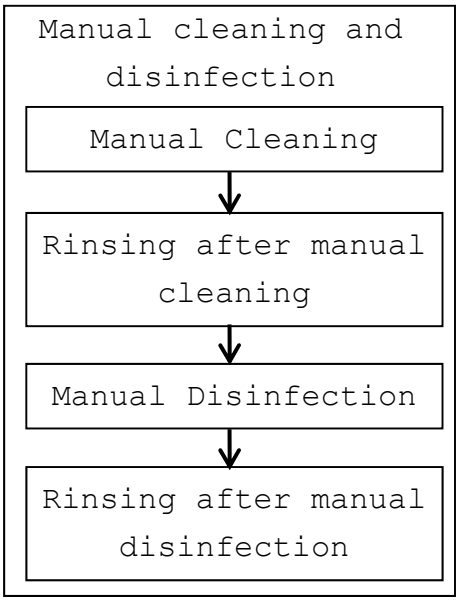
1) Remove the protective cover.
2) Clean the probe and the handle of all patient's blood or fluid with running tap water until the surface of the probe and the handle looks visually clean.
3) Wipe the whole surface of the probe and the handle with gauze pad and remove superficial visible impurities.

4.2 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.

4.3 Manual Cleaning and disinfection



Prepare following items before manual cleaning and disinfection:

a) Detergent: Cidezyme (Johnson & Johnson, #2258)or another cleaning agent with approved material compatibility for this medical device.

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

c) Two tanks, one for cleaning and one for disinfection - optional:
1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the immersible part of the probe at full length)

d) Soft, fluff free cloth or single use towel

e) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)

Manual Cleaning:

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

1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer's instruction. If a differing detergent is used, please also note the approved material compatibility for the medical device.

2) Immerse the immersible part of the probe without connector into the diluted detergent solution (see Figure 6). 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. The inside of the handle should be cleaned with the supplied brush in detergent solution (Fig.5).

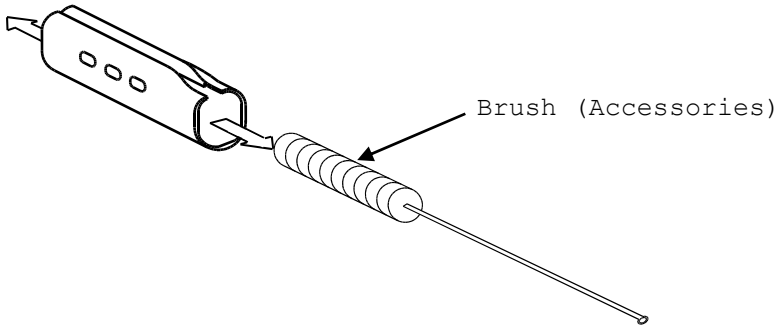


Fig.5 Cleaning for the inside of the Handle

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

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

5) Rinse the immersible part of the probe with running tap water for 1 minute. (alternatively: immerse the immersible part of the probe in a tray filled with deionized water/tap water (see Fig.6) 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.

Manual disinfection:

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. 6). 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.6) for 5 min.)

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

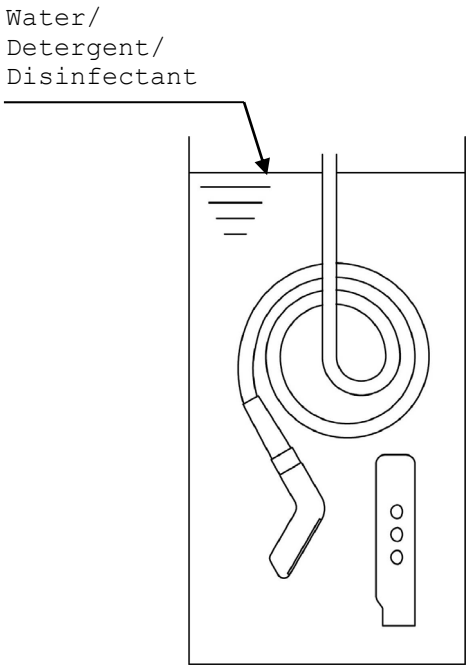
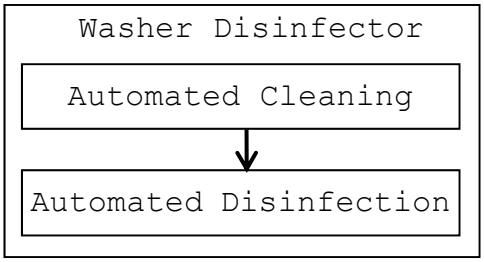


Fig.6 Immersion of the Probe and the Handle

4.4 Automated cleaning and disinfection



The following items must be provided prior to automated cleaning and disinfection:

a) Washer disinfector: according to DIN EN ISO 15883 with chemo-thermal program (temperature: max 60° C).

b) Waterproof box EZU-WB1

c) Detergent: Korsolex Endo-Cleaner (Bode Chemie; # 972 020) or another cleaning agent with approved material compatibility for this medical

device

d) Disinfectant: Korsolex Endo-Disinfectant (Bode Chemie; # 972 030) or another disinfectant with approved material compatibility for this medical device

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

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

2) Connect the waterproof box EZU-WB1 to the probe connector and use the tester to confirm that there is no air leak.

   Refer to the instruction manual of the waterproof box EZU-WB1 for detail information.

3) Place the probe and accessories (handle) in the baskets of the washer disinfector.

4) Close the door of the washer disinfector and start the chemo-thermal program.

5) Open the door after the process is done.

6) Take the probe out of the washer disinfector and check that it is dry. If not, dry it as described in the chapter drying.

4.5 Drying

Drying

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

2) Dry the equipment naturally in an ambient temperature between 15-30°C for a minimum of 4 hours. Alternatively the equipment can be dried using a drying heater at a temperature of less than 60°C.

4.6 Inspection

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

4.7 Packaging

Packaging

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

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

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

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

4.8 Sterilization

Sterilization

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

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

The sterilization method and operating conditions are as follows.

Sterilization Method	Condition
Plasma Sterilization: STERRAD® 50, 100S or 200 (*)	Short Cycle
ETO Sterilization	➢ Gas Type: 10% EO/ 90% HCFC ➢ Temperature: 50-55°C ➢ Exposure Time: More than 120 minutes ➢ Pressurization: 162-200kPa Depressurization: 13-8kPa ➢ Relative humidity: 40-90% ➢ Aeration is minimum 12 hours

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

⚠ WARNING

1) Before performing sterilization, check that the operation data of sterilizer are in conjunction with min. and max. data applicable for the probe and the handle.
2) Do not sterilize the probe and the handle by Steam Autoclaving. If you autoclave them, they suffers serious damage and will be not functional.
3) This probe is not applicable with Sterrad NX and 100NX system. Do not sterilize this probe by Sterrad NX and 100NX system.

The packaging before sterilization is as follows.

1) Put the probe into TYVEK pouch.

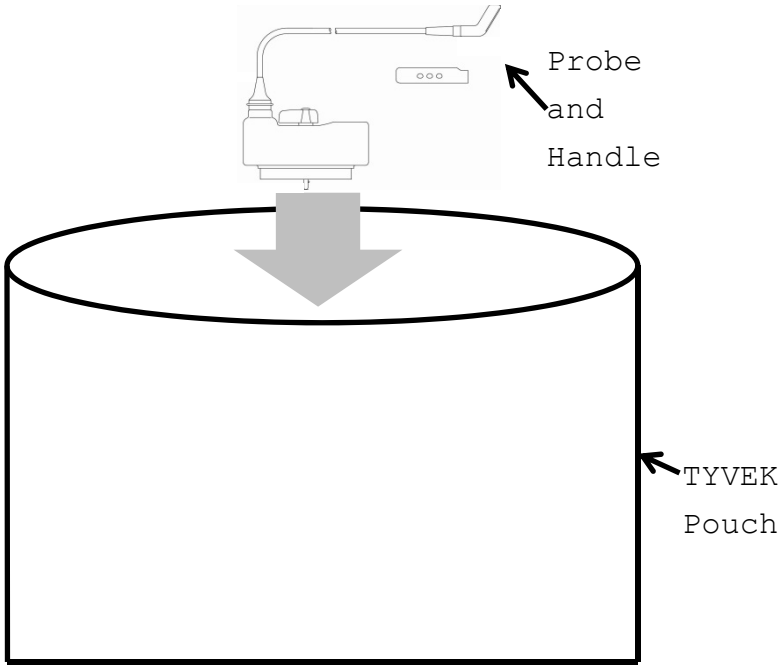


Fig.7 Packaging in the pouch

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

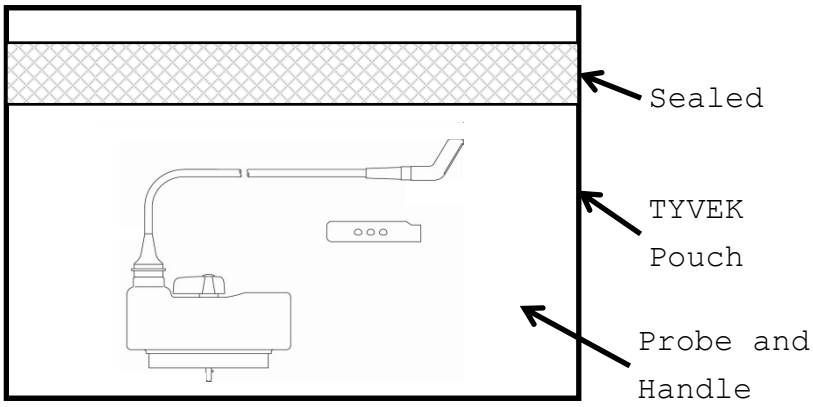


Fig.8 Sealing

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

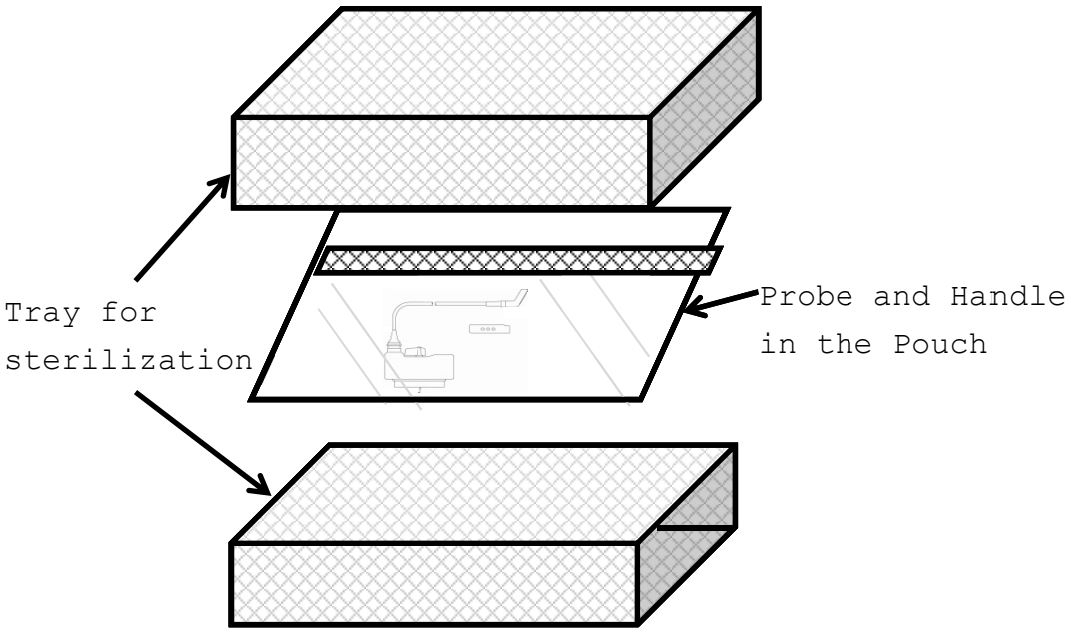


Fig.9 Packaging in a tray

4.9 Storage

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

5. Maintenance and Safety Inspection

1) After each use, the probe and the handle should be cleaned, disinfected and/or sterilized by following the chapter "4.Cleaning, Disinfection and Sterilization", then stored in a cool and dark place to avoid high temperature, humidity and direct sunlight.
2) Visually inspect the probe head, the handle, the cable, and the connector for any crack, scratch or denaturalization. If you find any damage on a daily basis. If you find the damage, do not use the probe and immediately contact a services support.

6. Safety Precaution

⚠ WARNING

- Do not use the probe if the probe is damaged.
- Do not use the latex probe cover for latex sensitive patients. The probe cover, which contains latex may cause allergic reactions such as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, and depression of blood pressure, and shock.

⚠ 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 "7.2 Suppliers list".
- Use a sterile probe cover to avoid staining or damaging the probe.
- Clean, disinfect, and sterilize the probe and the handle before initial use as they are not sterilize in the factory.
- Use only soft cloth or tissue to clean the acoustic lens of the probe's head.
- Do not attach unapproved devices to the probe.

7. Specification

7.1 Probe

Type	:	EUP-O54J Intraoperative probe
Center frequency	:	10MHz
Technology	:	Linear Array Probe
Dimensions	:	See Fig.10
Weight	:	Approx. 0.65kg (including cable and connector)
Scanning width	:	25mm
Probe materials	:	Bio-compatible allergy free components
Acoustic output	:	According to IEC60601-2-37 (See the operation manual of Hitachi ultrasound diagnostic scanner.)
Applicable system	:	Depending on production and upgrade status. For detailed information contact a service support.
Classification	:	MDD classification IIa.
Cleaning	:	Applicable detergents are listed in the "7.2 Suppliers list".
Disinfection	:	Applicable disinfectants are listed in "7.2 Suppliers list".
Sterilization	:	ETO gas sterilization Plasma sterilization

Operating conditions:

Ambient temperature	; +10 – +40°C
Contact surface temperature (temperature of examinee)	; max. 42°C
Relative humidity	; 30 – 85%

Storage conditions:

Temperature	; 0 – +60°C
Relative humidity	; 30 – 85% (Subject to no condensation)

7.2 Suppliers List

The products listed below are seriously tested and approved for use with the Intraoperative probe EUP-O54J.

Product name	manufacturer	purpose
Cidezyme	Johnson & Johnson	Enzymatic detergent
CIDEX	Johnson & Johnson	Disinfectant
CIDEX plus 28	Johnson & Johnson	Disinfectant
CIDEX OPA	Johnson & Johnson	Disinfectant
CIDEX OPA test strips	Johnson & Johnson	Test strip for verifying concentration of Cidex OPA
Korsolex Endo-Cleaner	Bode Chemie	Detergent for Washer-disinfector
Korsolex Endo-Disinfectant	Bode Chemie	Disinfectant for Washer-disinfector
NU-CIDEX	Johnson & Johnson	Disinfectant
Steranios	Laboratories ANIOS	Disinfectant
ALKAZYME	ALKAPHARM	Cleaner
KLENZYME	STERIS	Cleaner

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

8. Disposal of the probe

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

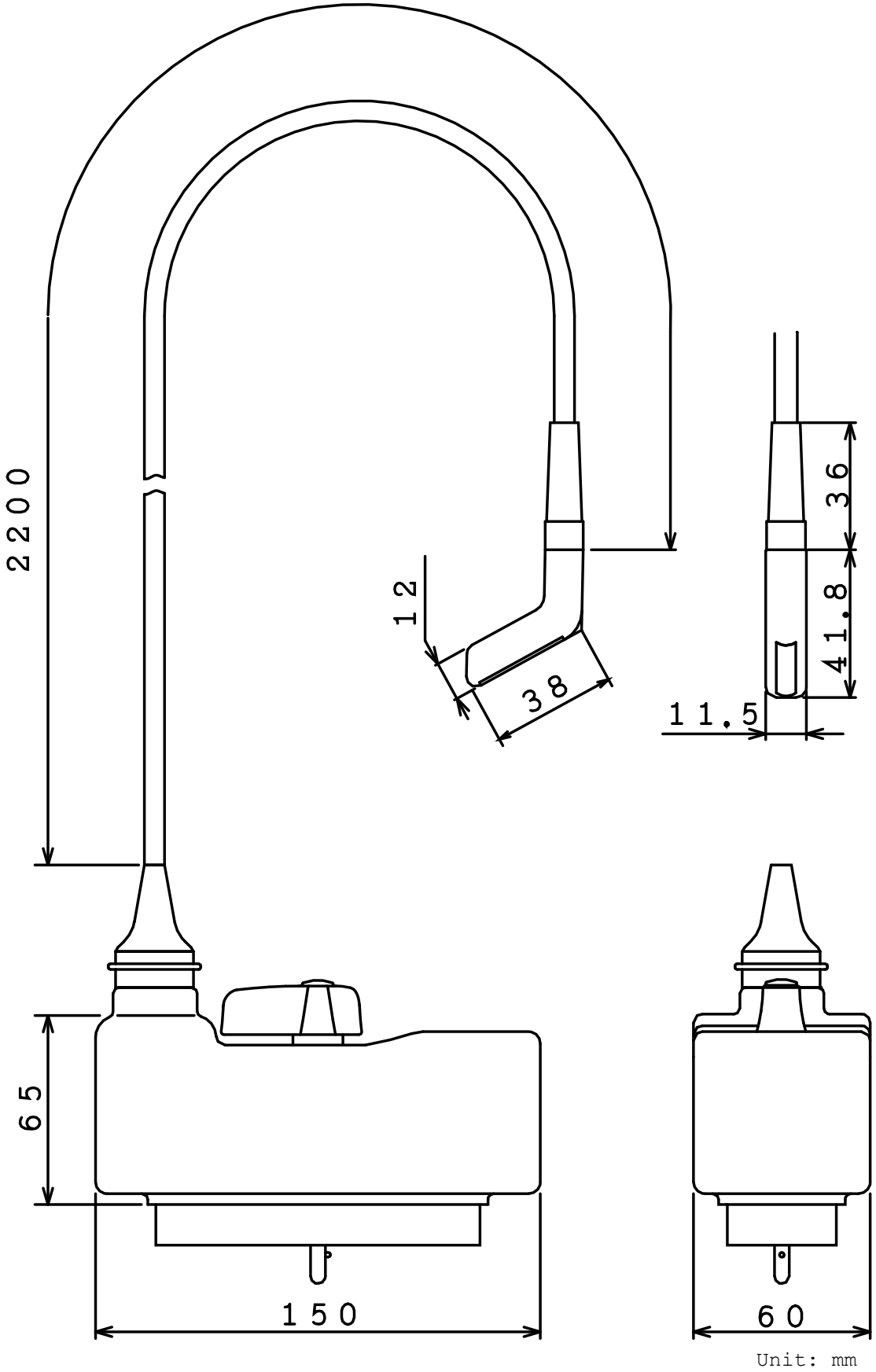
⚠ CAUTION

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

Waste Electrical and Electronic Equipment (WEEE) Directive

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

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



Unit: mm

Fig.10 Dimensions

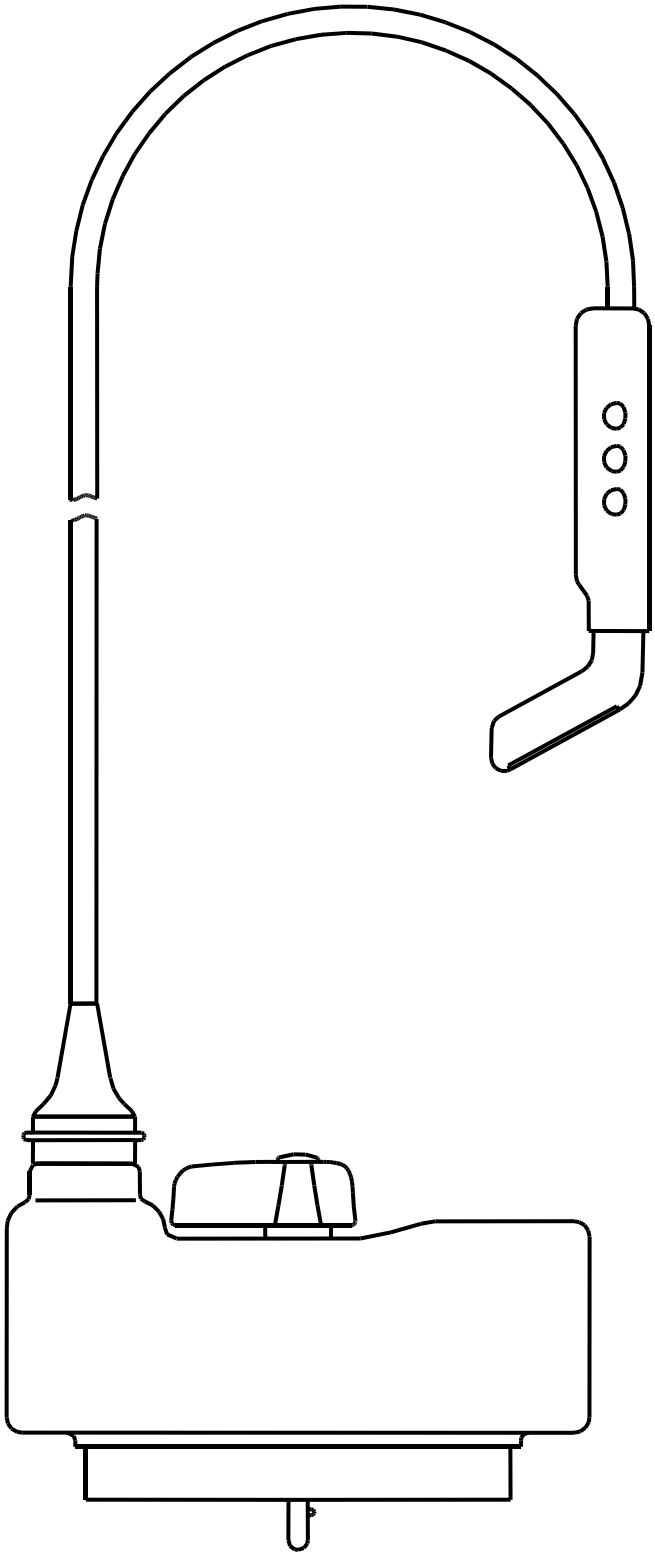


Fig.11 External View of the probe with the handle