HITACHI
Inspire the Next

C41V1 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

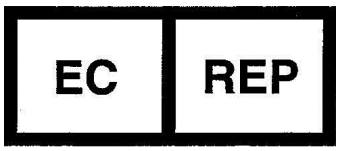
Q1E-EP1432-7

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

Local Distributor:

About this manual

This instruction manual contains safety precautions, the inspection, the operation procedure and the reprocessing procedure of C41V1 Probe. 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 http://www.hitachi.com/businesses/ healthcare/index.html
Authorized Representative in The European Community		Hitachi Medical Systems GmbH Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany
Keep away from Sunlight		Store the probe in a cool place and keep away from high temperature, high humidity, or direct sunlight.
Contains or presence of natural rubber latex		Contains or presence of natural rubber latex
Do not re-sterilize		Do not re-sterilize
Do not reuse		Do not reuse

Definition of symbol

The following symbol is also used for HITACHI Ultrasound Probes.

Location	Symbol	Definition
Probe connector	CE 0123	This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector	IPX7	IPX7 mark See section 1.6.
Probe connector		Type BF APPLIED PART
Probe connector		General warning sign
Probe connector		Warning; dangerous voltage
Probe connector		Caution; Biohazard
Probe connector		Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.
Probe connector		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. Introduction

1.1 Features

C41V1 Probe is a Convex Array Probe.

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 operational manual of each ultrasound diagnostic scanner.

This probe is categorized in class IIa according to Directive 93/42/EEC.

According to IEC60601-1 the probe is classified as type BF.

1.2 Principles of operation

This probe and the ultrasound diagnostic scanner enable image diagnosis using ultrasonic waves. This system operates under the principles described below.

1) When an electric pulse signal is applied from the transmitter to the transducer of the probe, the transducer converts electric signals into mechanical vibration energy for emitting pulse-shaped ultrasonic waves into the body part, liquid or other medium contacting the transducer.
2) The emitted ultrasonic waves are reflected by boundaries with different acoustic characteristics (acoustic impedance) within the body.
3) The transducer is also used to receive reflected ultrasonic waves. The transducer vibrates mechanically due to the received ultrasonic waves and converts mechanical vibrations into electric energy. Electric signals are converted to shades of brightness by brightness modulation to obtain an image.

1.3 Intended Use

C41V1 Probe is designed for observation and diagnosis of the following regions mainly by connecting with the HITACHI ultrasound diagnostic scanner.

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

⚠ WARNING

Never use the probe for following regions.

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

1.4 Components

Components of C41V1 Probe are as follows:

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

⚠ CAUTION

The probe is not sterilized when delivered. Prior to use, be sure to clean, disinfect and sterilize it.

1.5 Accessories (Option)

1.5.1 Sterile Puncture Adapter EZU-PA7V (Disposable)

EZU-PA7V is the attachment for ultrasound guided transvaginal or transrectal biopsy and aspiration of organs, cyst and tumor. The size of needles available is 16 to 19G. Biopsy application requires special care. 24 pieces of Sterile Puncture Adapter EZU-PA7V are packaged in one set as follows:

Component	Model	Note
Sterile Puncture Adapter	EZU-PA7V	24 pcs

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

⚠ CAUTION

A well-trained physician only should perform a biopsy.

1.5.2 Probe cover for Single Use (Disposable)

To protect the probe against contamination, using probe cover is recommended. If using probe cover, lubrication free or dry type probe cover is recommended.
Lubrication may cause a deterioration of the probe surface. Use of non-allergic probe cover is strongly recommended to avoid allergic reactions due to latex rubber.
Discard the used probe cover carefully.

1.5.3 Magnetic Sensor Attachment

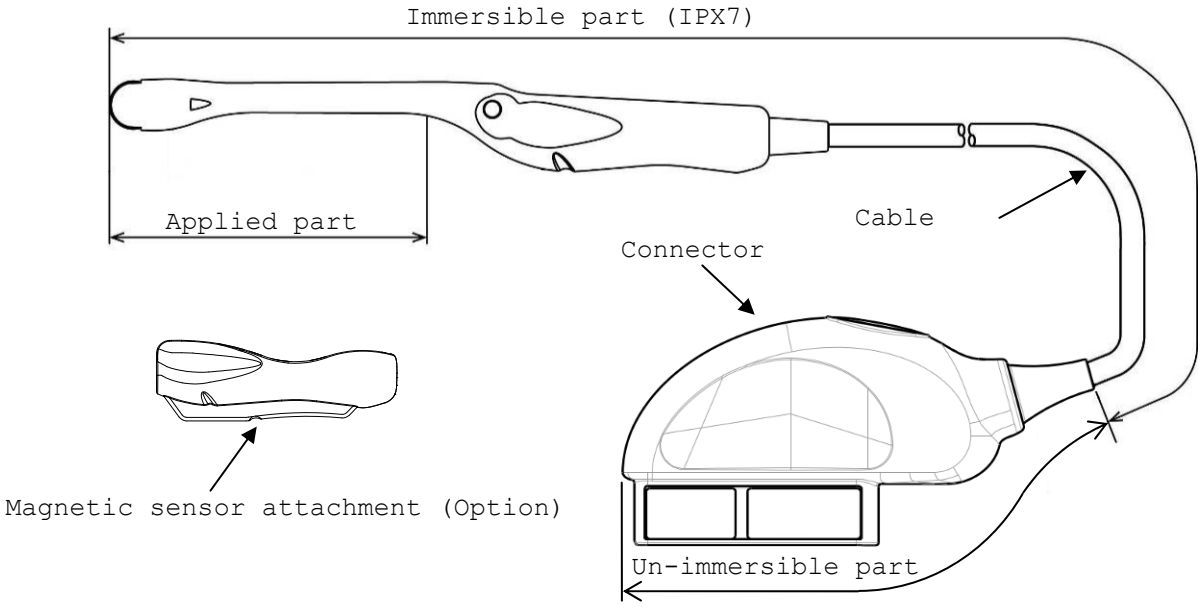
Magnetic Sensor Attachment is needed for Real-time Virtual Sonography (RVS). It is used to fix the magnetic sensor to the probe.

⚠CAUTION

The Magnetic Sensor Attachment is not sterilized when delivered from the factory. Prior to use, be sure to clean, disinfect and sterilize it.

1.6 Construction

The external view of C41V1 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 and accessories must be carefully inspected that they are appropriate for use. If you find any damage, do not use them and contact a service support immediately.

2.1 Inspection for Appropriate Connection

2.1.1 Confirm that the ultrasound diagnostic scanner is correctly operating. Please refer to the instruction manual of the scanner for the operation.

2.1.2 Confirm that any unauthorized device/instrument such as an unauthorized biopsy attachment is not attached or connected to the probe.

2.1.3 Confirm that the Sterile Puncture Adapter and settings of the scanner are appropriate for the probe. Attach the Sterile Puncture Adapter to the probe according to “3. Operation Procedure”. Display the “Needle guide line” on the monitor. (Refer to the operation manual of the ultrasound diagnostic scanner.) Keep the probe head under sterile water and insert a puncture needle in the Sterile Puncture Adapter, then confirm that the needle is inserted smoothly and the echo of the needle is displayed on the “Needle guide line”(dot line) on the monitor.

2.2 Inspection for Material Surface

2.2.1 Visually inspect the surface of the probe head, housing and cable for any crack, scratch or denaturalization.

2.2.2 Visually inspect the envelope of the Sterile Puncture Adapter for any break, deformation, crack or denaturalization. If you find any damage, do not use the Sterile Puncture Adapter.

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.

3. Operation Procedure

3.1 Connection and Settings

1) Confirm that the probe and the Magnetic sensor attachment are disinfected and if necessary sterilized. The Magnetic sensor attachment is needed for Real-time Virtual Sonography(RVS). Regarding the option for RVS, please refer to "4.Option of C41V1 probe".
2) It is recommended to use a disposable probe cover for preventing a patient from infection and the probe cover should be allergy free material to avoid allergic reaction.
3) Connect the probe to the ultrasound diagnostic scanner and operate the scanner and adjust the image according to the instructions given in the operation manual for the ultrasound diagnostic scanner. The relationship between the direction of the probe and the right-left orientation mark on the image is shown in Fig. 2.

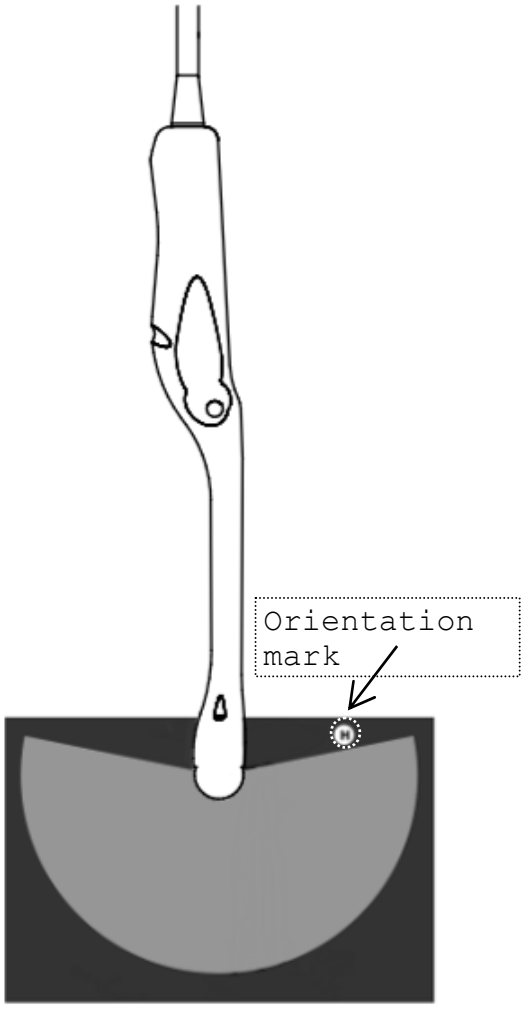


Fig.2 Relationship between the direction of the probe and the Right-left Orientation Mark Direction

4) Put proper quantity of sterilized acoustic jelly on the probe head as a couplant. (See Fig.3.)

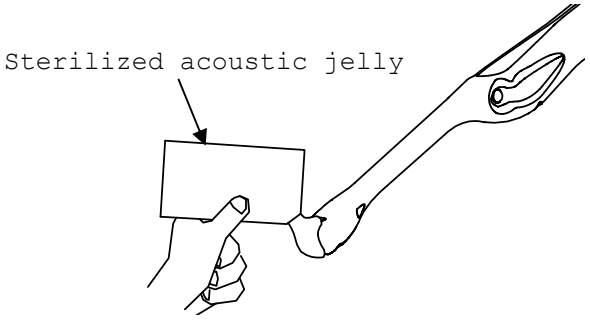


Fig.3 Jelly as a couplant

5) Putting a probe cover onto the probe is recommended. If using probe cover, draw the probe cover until the end of the probe shaft. If air bubbles remain in jelly, remove air bubbles by pushing jelly with finger. (See Fig.4)

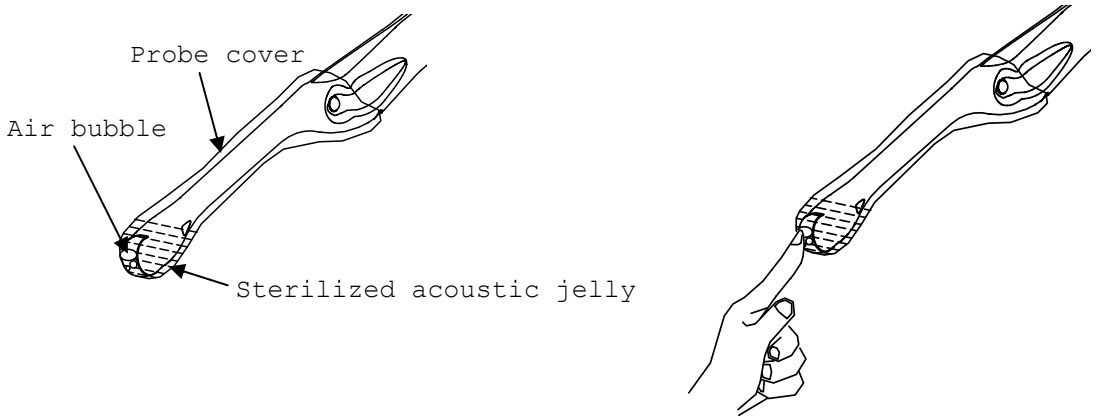


Fig.4 Removal of bubbles in jelly

⚠ WARNING

LATEX

Special attention should be paid for a probe cover made of latex. Latex may cause allergic reactions such as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, depression of blood pressure, and shock.
If you observe any of above-mentioned symptoms in your patient during the operation, stop the use of the latex protective sleeve immediately and take an appropriate treatment to the patient.

6) Fix the probe cover with sterile adhesive tape as shown in Fig.5.
Visually inspect the probe cover for any hole or tears.

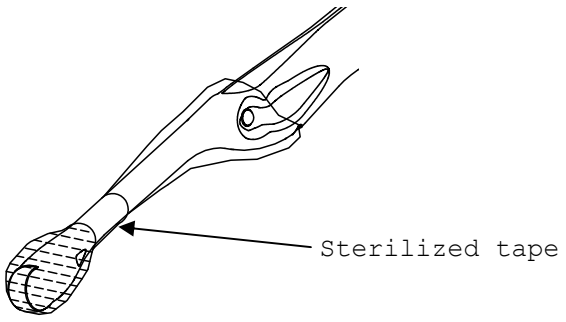


Fig.5 Fix by sterile adhesive tape

7) Insert the probe gentry and adjust the probe's position for a clear view of the desired image. If the image is not clear enough, use sterile saline solution to have a better image.

8) After using the probe, clean, disinfect and if necessary sterilize the probe immediately. If RVS is carried out, clean and disinfect and if necessary sterilize the Magnetic sensor attachment.

9) Store the probe and the Magnetic sensor attachment under the conditions written in "6. Maintenance and Safety Inspection" and "8.Specification".

⚠ 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.

3.2 How to attach the Sterile Puncture Adapter (EZU-PA7V)

How to attach the Sterile Puncture Adapter (EZU-PA7V) to the probe is instructed below.

1) Put the picks of the Sterile Puncture Adapter to the projection on the probe. (See the top of Fig.6)
2) Push the other end of the Sterile Puncture Adapter until the dents of the Sterile Puncture Adapter are fixed at the grooves of the probe. (See the bottom of Fig.6)
3) Visually inspect the probe cover for any hole or tears.

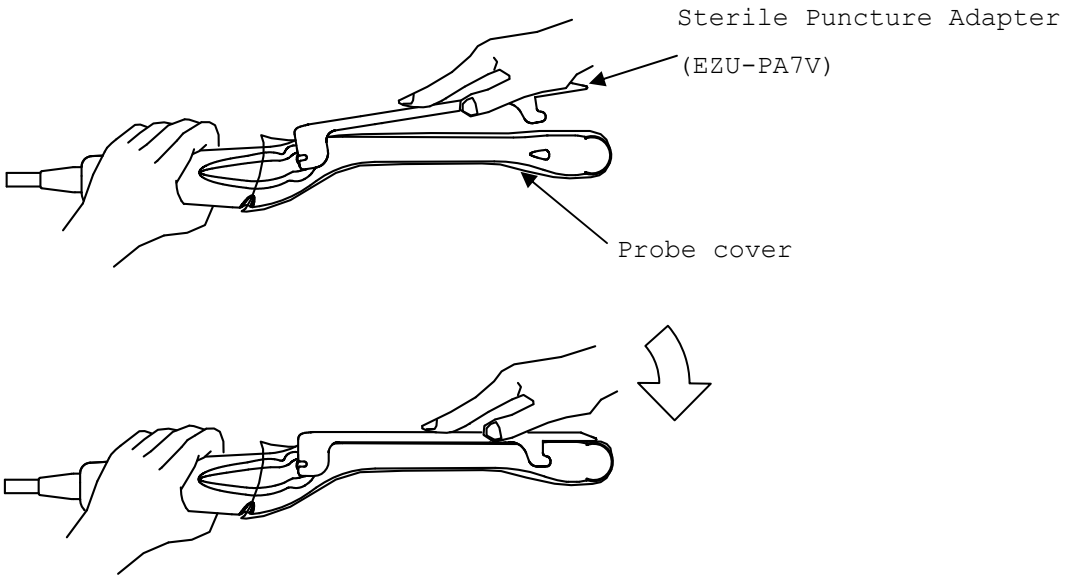


Fig.6 how to attach the Adapter

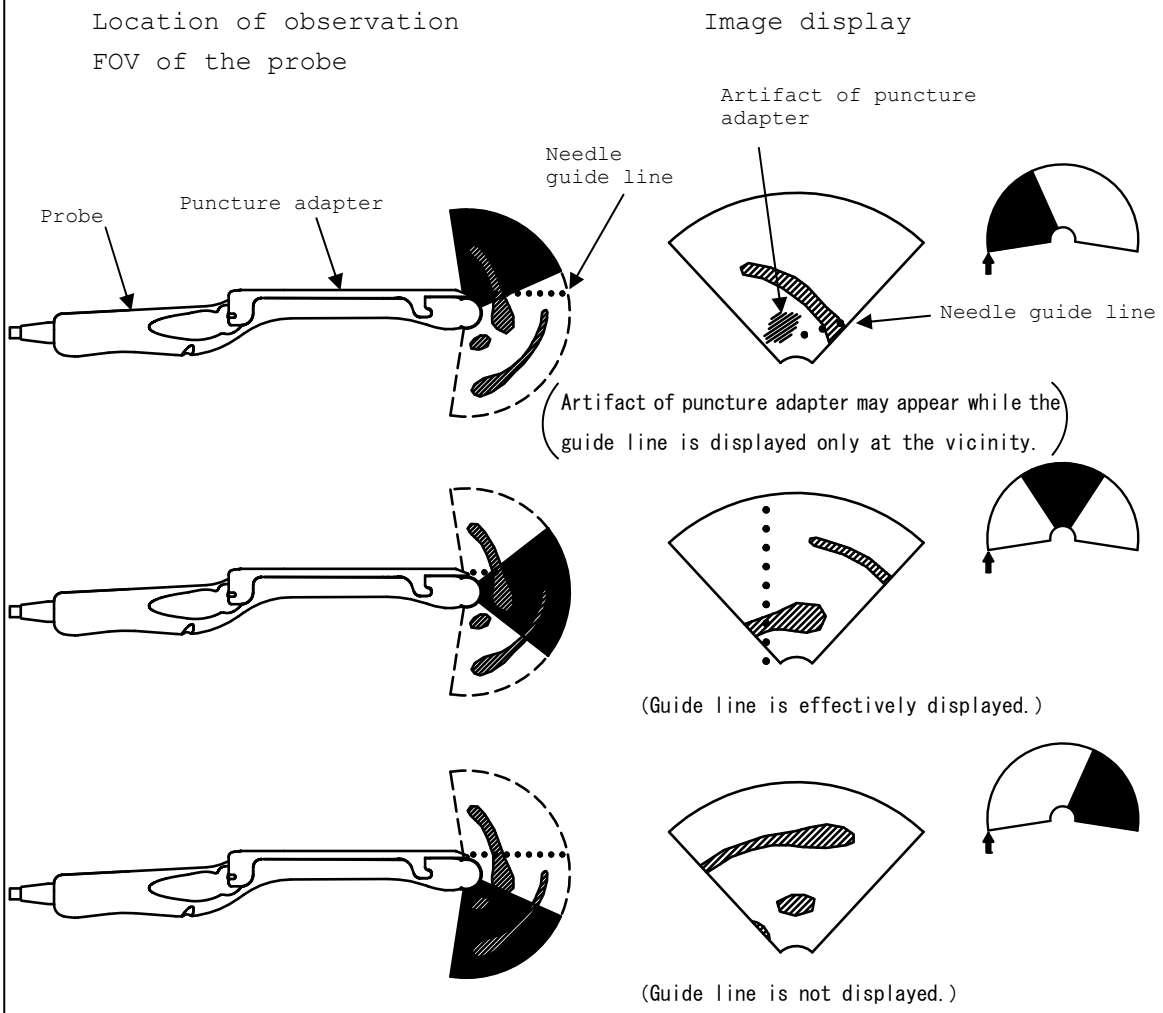
3.3 Display of Needle Guide Line

The needle guideline in dot marks can be displayed on the monitor for biopsy. Regarding the needle guideline, refer to the operation manual of the ultrasound diagnostic scanner.

NOTE: The needle guide line is intended to provide a visual guide to the direction of the puncture needle pathway. Be sure to check the actual needle position on the ultrasound image when performing the puncture operation.

⚠ CAUTION

The needle guide line can be displayed for this probe, but if the image is displayed at some angle (see the figures below), the image displayed may not be appropriate for biopsy.
Confirm that the image displayed is appropriate prior to biopsy.



⚠ WARNING

1) Special attention should be paid for a probe cover made of latex. Latex may cause allergic reactions such as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, depression of blood pressure, and shock.
   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.
2) The puncture adapter EZU-PA7V and the recommended probe covers are disposable and must not be reused.
3) Sterilize/disinfect the probe and disinfect the puncture adapter when the probe cover is torn.
4) Be careful about the use of a needle cannula with the puncture adapter. If the insulation coating of the needle cannula is damaged, it may cause a burn to tissue.
5) Use a needle whose size is appropriate for the puncture adapter, otherwise looseness or tightness of the needle could result in biopsy at an unintended part and injury to the patient.
6) Display the needle guideline during biopsy. Regarding the needle guideline, refer to the operation manual of the ultrasound diagnostic scanner.

4. Option of C41V1 Probe

4.1 Magnetic sensor

4.1.1 How to attach the Magnetic sensor

The procedure of attaching the magnetic sensor is as follow.

1) Confirm that the Magnetic sensor attachment is sterilized or disinfected.

2) Insert Magnetic sensor into the Magnetic sensor attachment in the correct direction as shown in Fig.7.

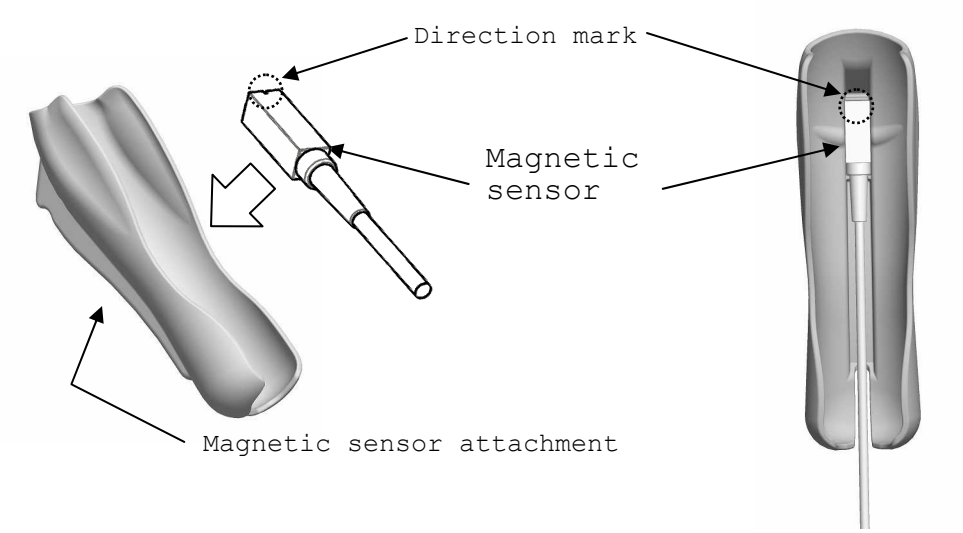


Fig.7 How to attach the Magnetic sensor

⚠ CAUTION

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

3) Attach the Magnetic sensor attachment to the probe as shown in Fig.8.

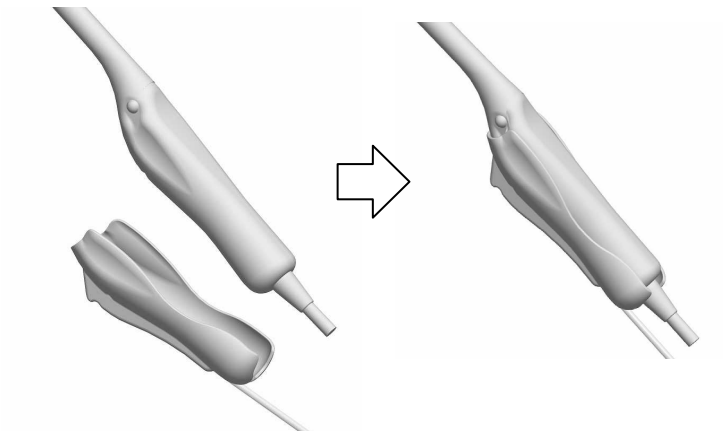


Fig.8 How to attach the Magnetic Sensor Attachment

⚠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 in Fig.9.

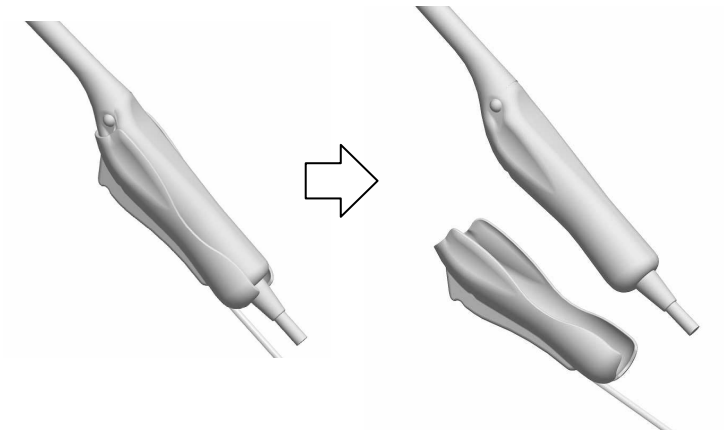


Fig.9 How to release the Magnetic sensor attachment from the probe

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

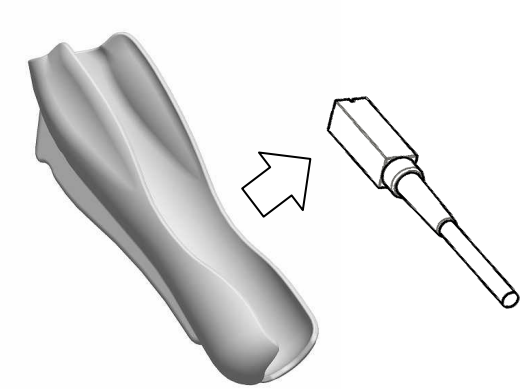


Fig.10 How to release magnetic sensor from the Magnetic sensor attachment

⚠CAUTION

Clean, disinfect and sterilize the Magnetic sensor attachment prior to the first use as it is not sterilized when delivered.

5. Cleaning, Disinfection and Sterilization

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

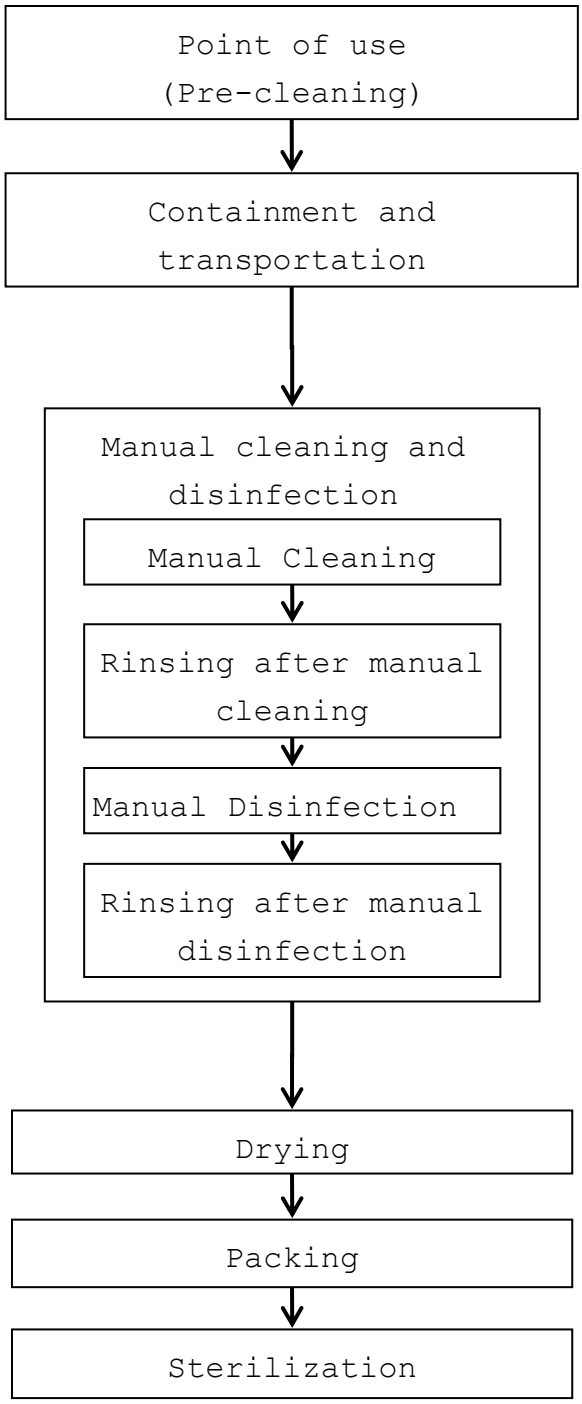
WARNINGS	- The probe is delivered unsterile. Prior to the first use, reprocess the probe. - Temperature should not exceed 60°C during reprocessing. - Probe connector is not water resistant.
Limitations on reprocessing	The probe is not completely submersible. The immersible part is shown in Fig.1. The un-immersible part should be disinfected by wipe disinfection.
Transportation before using	The probe should be packed in a sterile pouch or container to transport from Central Sterile Supply Department (CSSD) to an operating room. Be careful not to damage the sterile pouch or container during transportation.

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

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

According to the intended use, C41V1 probe is classified as semicritical.

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



5.1 Point of use (Pre-cleaning)

Point of use (Pre-cleaning)

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

A) C41V1 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.

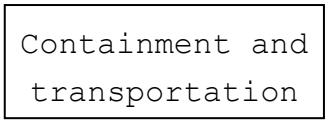
3) Wipe the whole surface of the probe with gauze pad and remove superficial visible impurities.

B) Magnetic sensor attachment

1) Remove the Magnetic sensor attachment and the magnetic sensor from the probe.

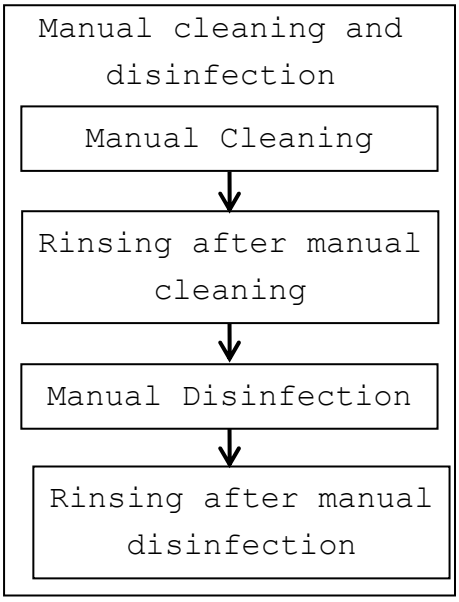
2) Immerse the Magnetic sensor attachment in sufficient amount of high quality tap water. Scrub it using soft cloth to remove all visible soil from its surface.

5.2 Containment and transportation



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

5.3 Manual Cleaning and disinfection



Prepare following items before manual cleaning and disinfection:

a) Detergent: Cidezyme (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).

A) C41V1 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 Figure 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-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.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) Magnetic sensor 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 Magnetic sensor attachment into the diluted detergent solution. Wipe it under the surface of the detergent solution with a soft cloth to remove all visible soil.

3) The Magnetic sensor attachment should be left in the detergent solution according to the specified contact time of the detergent manufacturer.

4) Rinse the Magnetic sensor 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 Magnetic sensor attachment for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

Manual disinfection:

A) C41V1 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) Magnetic sensor attachment

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

2) Immerse the Magnetic sensor attachment into the disinfectant (see Fig. 11). Set a clock to insure the recommended contact time which is 5 minutes.

3) Rinse the Magnetic sensor 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 Magnetic sensor attachment for leavings of the disinfectant. If necessary, repeat the rinsing.

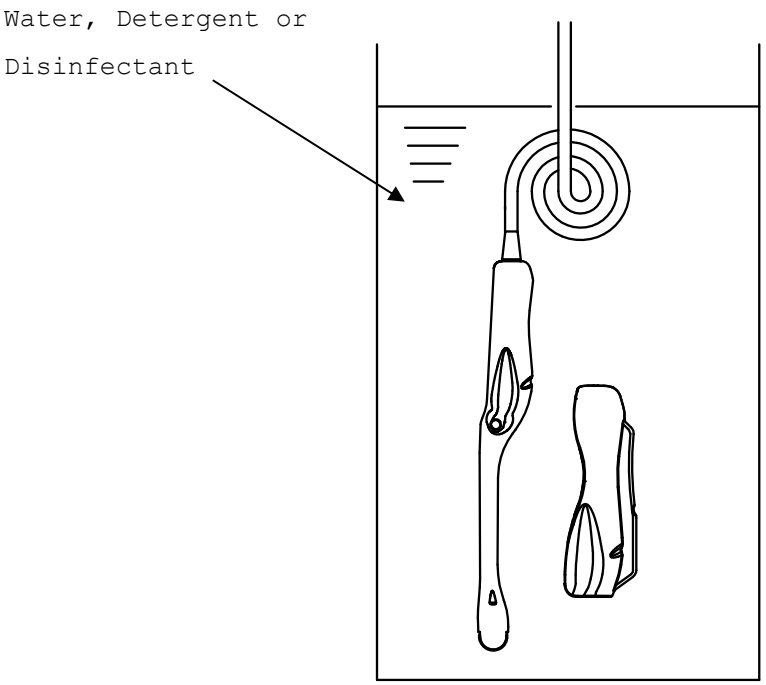


Fig.11 Immersion of the Probe and the Magnetic sensor attachment

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 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.

5.5 Inspection

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

5.6 Packaging

Packaging

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

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

The equipment can be packed in a simple or double packing.

Please note that the size of a sterile barrier should be large enough to be able to pack the equipment leaving sufficient space to seal it completely.

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

5.7 Sterilization

Sterilization

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

Sterilization Method	Probe and Magnetic sensor attachment
Plasma Sterilization	Applicable
ETO Sterilization	Applicable

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

The sterilization method and operating conditions are as follows.

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

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

⚠ WARNING

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

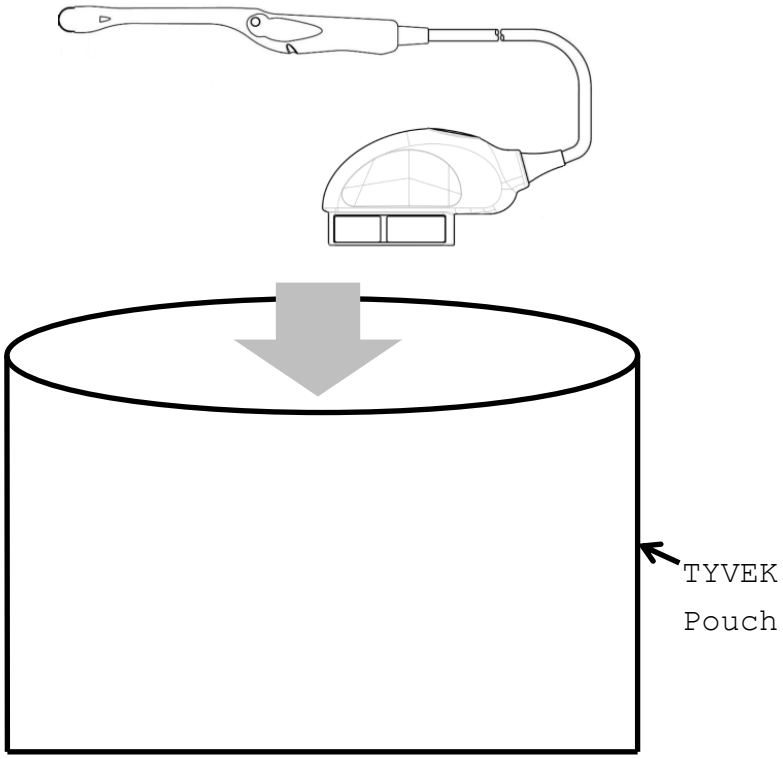


Fig.12 Packaging in the pouch

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

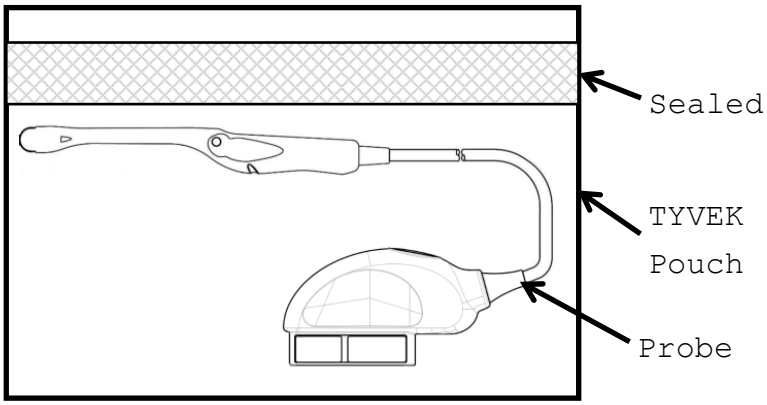


Fig.13 Sealing

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

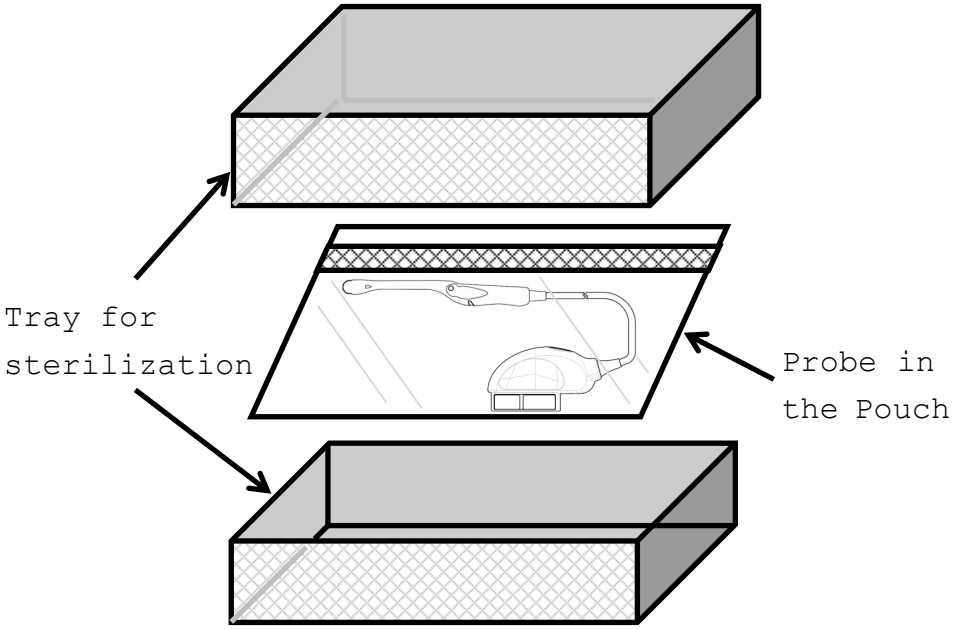


Fig.14 Packaging in a tray

5.8 Storage

Store the equipment in a cool, dustproof and dark, dry 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

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

6.1.2 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.

6.2 Storage

After using the probe and accessory, they should be cleaned and disinfected/sterilized according to "5. Cleaning, disinfection and Sterilization" immediately. Then store them in a cool and dark place, and keep out of high temperature, humidity and direct sunlight.

7. Safety Precautions

⚠ WARNING

1) Never use the probe if the probe head, shaft or cable are cracked or damaged.
2) Use Sterile Puncture Adapter EZU-PA7V (Option) certainly for biopsy.
3) Never use the Sterile Puncture Adapter if the adapter is deformed, cracked or damaged.
4) Do not use a probe cover made of latex for latex sensitive patients. The latex probe cover may cause allergic reactions such as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, depression of blood pressure, and shock.
5) The ultrasound jelly which is an accessory of Hitachi ultrasound scanner is not sterile jelly, so never use it for C41V1.
6) Do not disassemble, modify, or repair the probe. Electric shock or other unforeseen accidents could result.
7) Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
8) 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 or sterilization according to section 2 "Inspection before Use" and section 5 “Cleaning, Disinfection and Sterilization".
9) When using ultrasound contrast agent, follow the supplied document of the contrast agent, otherwise unexpected accidents could result. Check the state of the patient and take appropriate precautions to avoid side effects.
10) During a biopsy, use sterilized physiological saline for the acoustic medium. Using an unsterilized ultrasound medium can cause an infection on the patient.
11) For details about the reuse and disposal of the biopsy needle, follow the instructions in the documentation supplied with the biopsy needle. Reuse of disposable biopsy needle or improper disposal could result in an infection.

⚠ CAUTION

1) When the probe is used for surgical or minimal-invasive procedures, keep electrocautery away from the probe. When defibrillator is used, take the probe out of the body.
2) Keep the acoustic power low and minimize the ultrasound exposure time for the examination of an early pregnancy.
3) Do not expose the connector to water or other liquids. The connector is not waterproof.
4) Do not hit or drop the probe. The probe is easily damaged by mechanical shock.
5) Do not use detergents and disinfectants other than listed in "8.3 Supplier's list".
6) Use a sterile probe cover to protect the acoustic lens against staining or damaging.
7) Clean, disinfect and sterilize the probe and the Magnetic sensor attachment prior to the first use as they are not sterilized when delivered.
8) Use only the soft cloth or tissue to clean the acoustic lens.
9) Only a well-trained physician should perform a biopsy.
10) Do not 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 other equipment.
11) Do not clean, disinfect or sterilize using procedures other than those specified in this manual. Infection could result due to incomplete cleaning,disinfection or sterilization. It can also result in damage to the probe or reduced performance.

8. Specifications

8.1 Probe

Type	: C41V1 Probe
Acoustic working frequency	: 6.5MHz
Technology	: Convex Array Probe
Dimensions	: See Fig.15
Weight	: Approx.0.80kg (Including cable and connector)
Probe materials	: Bio-compatible allergy free components
Acoustic output	: According to IEC 60601-2-37 (See Main Unit manual.)
Applicable system	: Depending on production and upgrade status For detailed information 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 – +40°C
Contact surface temperature (Temperature of examinee)	: max. 42°C
Relative humidity	: 30 – 75%

Storage conditions:

Temperature	: –10 – +50°C
Relative humidity	: 10 – 90% (Subject to no condensation)

8.2 Sterile Puncture Adapter EZU-PA7V

Type	: EZU-PA7V
External view	: See Fig.16
Acceptable needle gauge	: 16G to 19G
Materials	: Bio-compatible allergy free components
Classification	: MDD classification IIa
Package	: 24 Sterile Puncture Adapters for single use
Sterilization method	: Sterilized with gamma irradiation

Operating conditions:

Temperature	: -10 – +40°C

Storage conditions:

Temperature	: -10 – +40°C

8.3 Suppliers List

The products listed below are seriously tested and approved for use with C41V1 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/ sterilant
WAVICIDE-01	Medical Chemical Corp	Disinfectant/ sterilant

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.

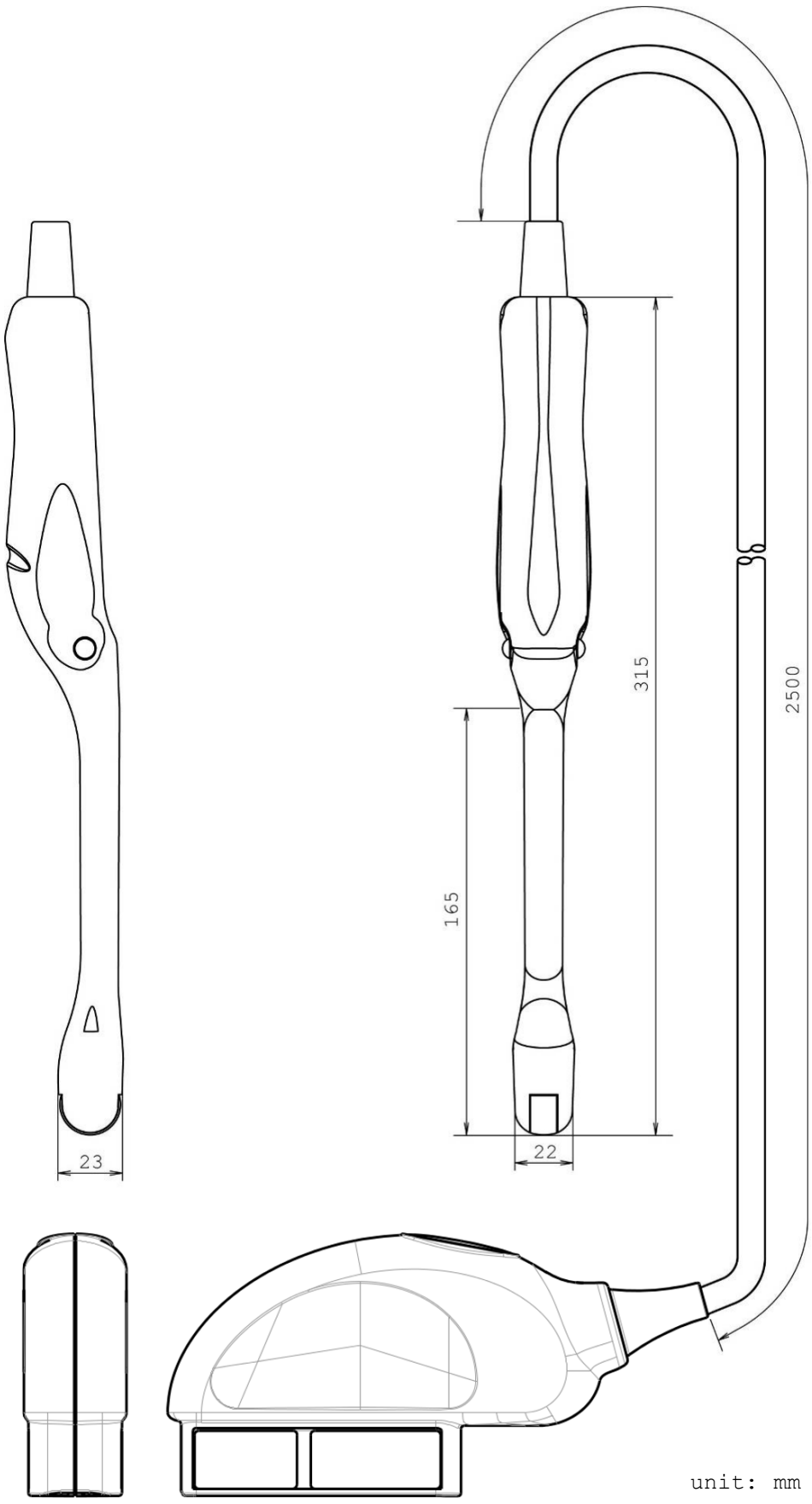


Fig.15 External view of C41V1 Probe

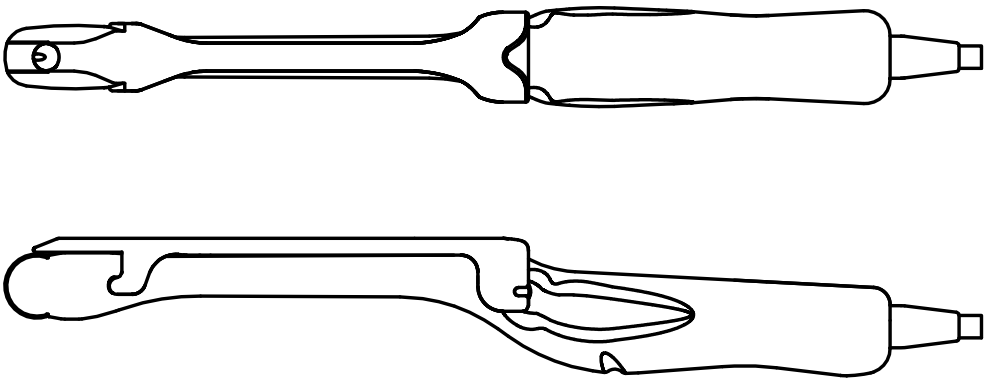


Fig.16 External view of C41V1 Probe with
Sterile Puncture Adapter (EZU-PA7V)