

C41L47RP Probe

INSTRUCTION MANUAL
--- For USA ---



Tokyo , Japan

Q1E-EP1452-2

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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	IPX7	IPX7 mark See section 5.
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.

1 Foreword

Before using the probe, carefully read this instruction manual for correct and safe handling of the probe as well as for making the most of the performances of the probe and the ultrasound scanner with which the probe is to be used.

Notes to Users

To ensure safe operation, it is essential that you fully understand the function, operating and maintenance instructions by thoroughly reading and understanding this manual and the manuals that accompany probes and accessories before operating this equipment, paying particular attention to all warnings, cautions, and notes incorporated herein. Please contact a service support if you have any questions concerning the operation of equipment.

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.

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

2 General caution

For safe use of the ultrasound scanner and probe, it is advisable to strictly observe the following:

WARNING

- 1) Never use the probe for following regions.
 1. The heart (Do not contact directly)
 2. The eyeball
- 2) When use this Probe (C41L47RP) for biopsy purpose, use Puncture Guide Fixture EZU-PA3U (Option) certainly.

CAUTION

- 1) Federal law restricts this device to use by or on the order of a physician.
- 2) Be sure to read and observe the "General Cautions in Operation" stated in the operation manual for the ultrasound scanner with which the probe is to be used.
- 3) The probe and ultrasound scanner with which it is used should never be operated in an environment at a higher or lower temperature, under a higher or lower pressure and a higher humidity, than the specified operating ambient conditions. (Also see the paragraph "10. Specifications".)
- 4) Never try to remodel the probe and ultrasound scanner; if they are remodeled, a fault will possibly be caused.
- 5) Do not use chemicals or organic solvents such as thinner for wiping the probe. (See the paragraph "11. Supplier's List".)
- 6) Do not hit or drop the probe because the inside of the probe head is easily broken by mechanical shocks.
- 7) Keep the probe head off substances containing fatty acid (hydrocarbon of methane series, paraffin). Because it soaks into the inside of the probe head through the surface of the probe head and cause a fault.
- 8) If the ultrasound scanner and probe malfunction, contact our service personnel.
- 9) The use of a sterile probe sheath is recommended with this probe.
- 10) Use only sterilized acoustic gel during examinations in which sterile techniques are used.

NOTE: The warranty period of the probes is one year from their delivery to the user. If they become faulty within this period and it is evident that Hitachi is responsible for the fault, they will be repaired or replaced with normal ones free of charge.

NOTE: This warranty does not cover accidental damage on your site or improper handling, such as wear, extreme temperature, damages caused by chemical acids and solvents.

 WARNING

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is now advising health-care professionals to screen their latex-sensitive patients, and be prepared to treat allergic reactions promptly. Please read and become familiar with the FDA Medical Alert report of March 29, 1991, titled, "Allergic Reactions to Latex-Containing Medical Devices", reprinted on the following pages.

In certain applications, the use of a protective sheath is recommended. Because of the possibility of latex-sensitive patients, Hitachi and HAMA are now recommending the use of non-latex covers. Specifically, we are recommending that the end user utilize the following devices:

Device: CIVCO PRO/CoversTM

Manufacturer: CIVCO Medical Instruments Company, Inc.

We recommend that the end user contact CIVCO directly for obtaining sizing and pricing information, samples, and local distribution information.



Medical Alert

March 29, 1991
MDA91-1

Lenore Gelb
(301) 443-3220

Allergic Reactions to Latex-Containing Medical Devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex-cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex-sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.



FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service
5600 Fishers Lane, Rockville, Md. 20857

FDA's recommendations to health professionals in regard to this problem are:

- When taking general histories of all patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients, and health-care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged.
- If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "hypoallergenic" may not always prevent adverse reactions.)
- Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
- Advise patients to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

FDA is asking health professionals to report incidents of adverse reactions to latex or other materials used in medical devices. (See the October 1990 *FDA Drug Bulletin*.) To report an incident, call the FDA Problem Reporting Program, operated through the U.S. Pharmacopeia toll-free number: 800-638-6725. (In Maryland, call collect 301-881-0256.) For further information on the clinical aspects of latex sensitivity, call Claudia Gaffey, M.D., Office of Health Affairs, Center for Devices and Radiological Health, at (301) 427-1060.

For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.



3 General

C41L47RP Probe is of convex array and linear array electronic scanning. This is designed for use as connected with Hitachi Ultrasound scanner.

Clinical Intended Use

Please refer to the Instruction Manual (Supplement - Safety and Effectiveness) of the scanner with which this probe is combined.

NOTE: Do not use this probe for a purpose out of the specified intended use, and the intended use of this probe is limited each device.

Please contact your local Hitachi representative with any question on this probe availabilities and intended uses.

Acoustic output

Please refer to the Instruction Manual (Supplement - Safety and Effectiveness) of the scanner with which this probe is combined.

Clinical Measurement Accuracy

In case of using measurement function with this probe, please refer to the Instruction Manual (Supplement - Safety and Effectiveness) of the scanner with this probe is combined with regard to the clinical measurement accuracy.

4 Probe Components and Accessories

4.1 Components

Table.1 Probe component list

Component		Note
1	Probe	1 piece
2	Instruction Manual	1 copy

4.2 Accessory

1)Puncture Guide Fixture EZU-PA3U

(Gauge size available:14G and 18G)

If you need a Puncture Guide Fixture EZU-PA3U,
please contact a service support.

5 External View

The external view of C41L47RP Probe is given in Fig.1.

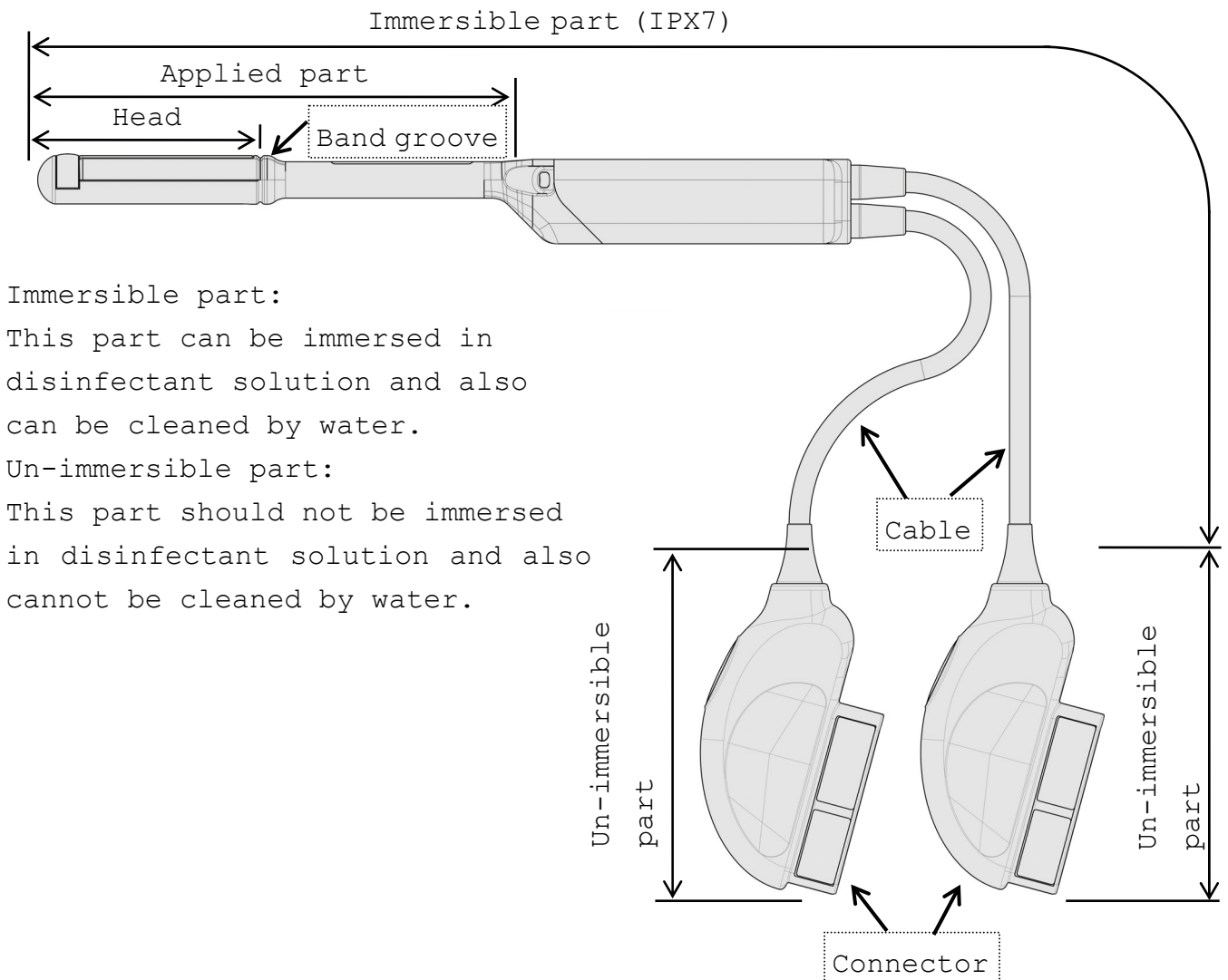


Fig.1 External view

6 Cleaning and sterilization/high level disinfection

The probe and the puncture guide fixture are not sterilized, but must be sterilized or disinfected before the initial use, and after each subsequent use, following the directions given below and working in accordance with standard hospital practice. (For reference, consult "Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Devices: ANSI/AAMI ST35-1991", published by the Association for the Advancement of Medical Instrumentation.)

6.1 Levels of Disinfection Requirement

To choose an appropriate disinfectant, the user must determine the required level of disinfection, based on the following classification (See Table.2) and the regulation of each country.

Table.2 Levels of Disinfection Requirements

Classification	Definition	Levels of disinfection
Critical	Device directly contacts tissue (Intraoperative applications)	Sterilization
Semi-critical	Device contacts mucous membranes (Intracavity applications)	Sterilization or minimally High
Non-critical	Device contacts intact skin	Intermediate or low



CAUTION

Do not clean, disinfect or sterilize by the 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.

6.2 Reprocessing Procedure

After each use of the probe, the reprocessing procedure including cleaning, disinfection, and sterilization must be performed immediately. A flow diagram showing the steps of the reprocessing procedure is given in Fig.2 and Fig.3. The reprocessing procedure must be performed even after the probe was used with a probe sheath.

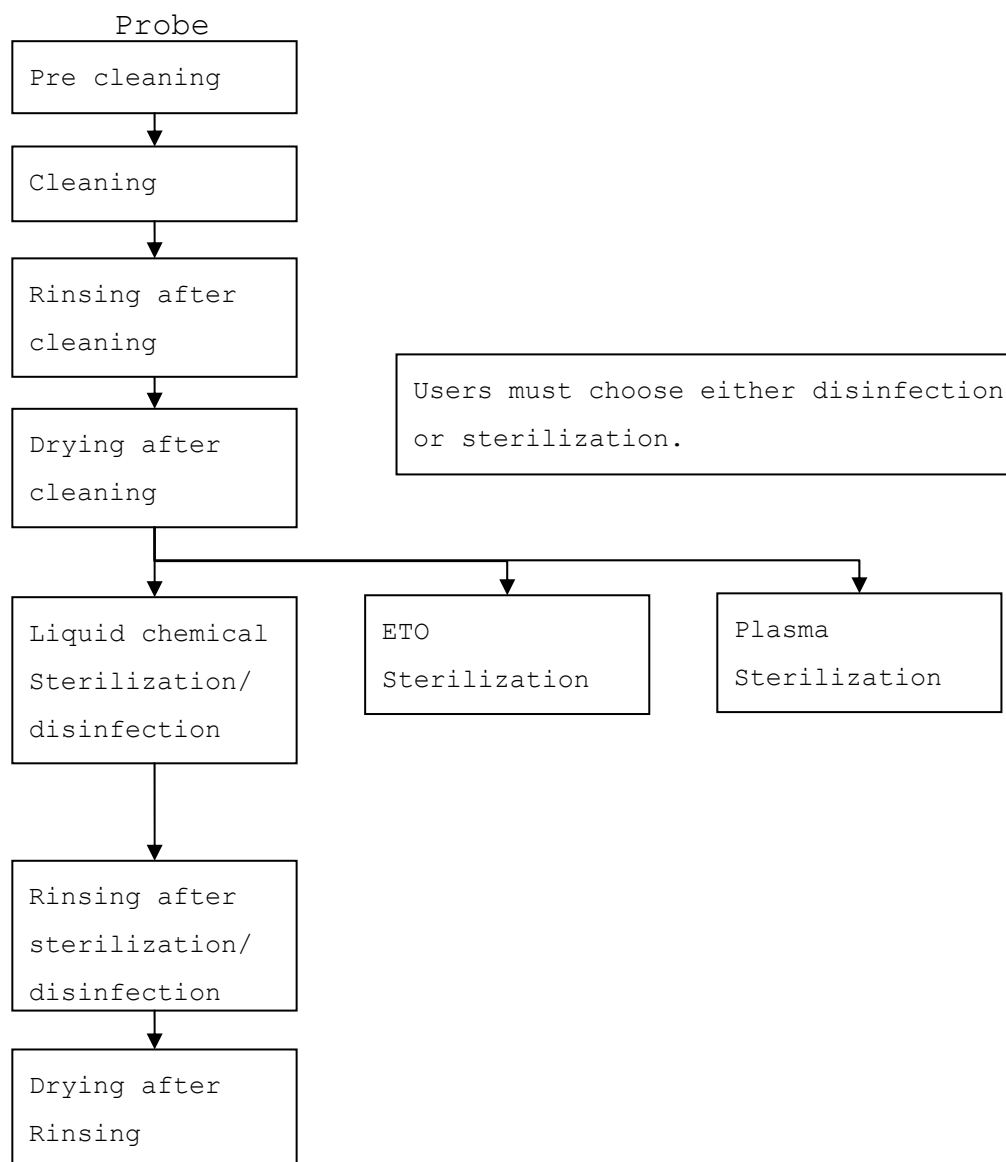


Fig.2 Reprocessing Procedure of the probe

⚠ WARNING

Do not sterilize the probe by Autoclave.
Autoclave sterilization causes the probe to malfunction.

Puncture Guide Fixture

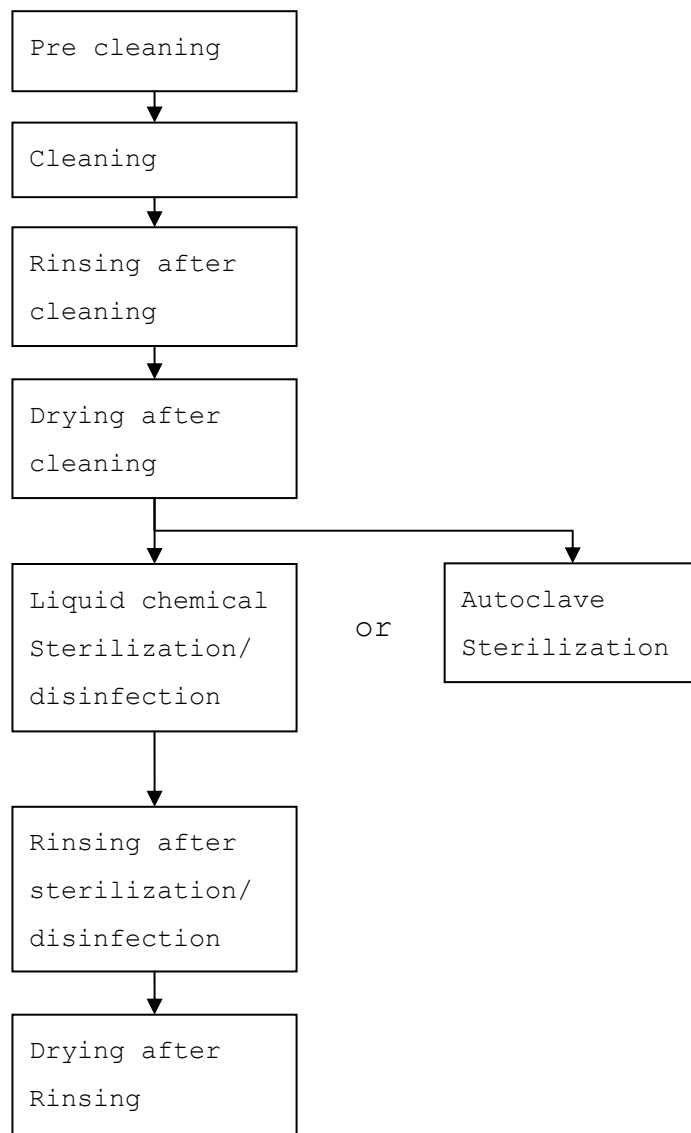


Fig.3 Reprocessing Procedure of the Puncture Guide Fixture

6.3 Cleaning of the probe

Prior to liquid chemical sterilization/high level disinfection process, the probe and the puncture guide fixture must be cleaned.

Immerse the probe in an enzymatic detergent (Enzol®) solution (as shown in Fig.4) for more than 30 minutes or until the visible residue is removed.

If needed, scrub the probe using a soft sponge, gauze, or cloth to remove visible residue from the surface of the probe.

WARNING

Follow the instructions of the enzymatic detergent manufacturer regarding recommended dilution, temperature and soak time. Using insufficiently diluted detergent may damage the probe.

After cleaning, the probe must be thoroughly rinsed with high quality tap water or sterile water for more than 10 minutes to remove all residue of the detergent solution (as shown in Fig.5). After rinsing the probe, air-dry it completely.

WARNING

Remove all debris and residue of detergent solution from the surface of the probe sufficiently.

Debris and residue of detergent solution on the surface of the probe may affect patient health.

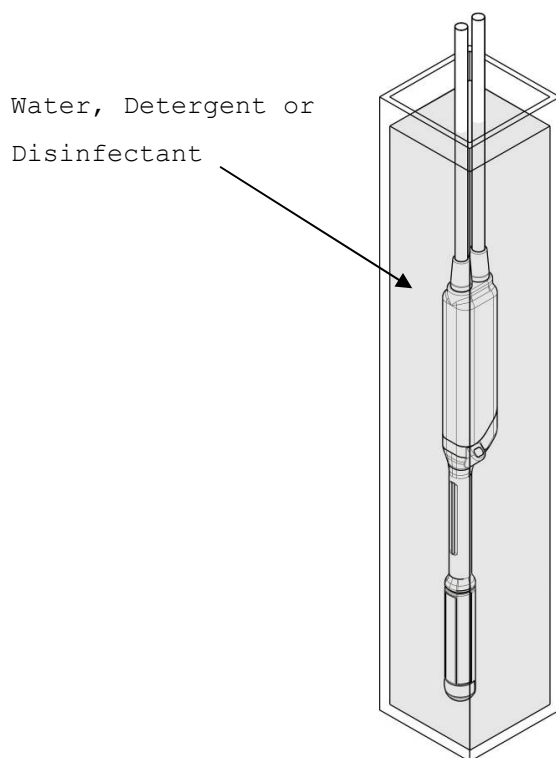


Fig.4 Immersion of the Probe

Rinse with sterile water or high quality tap water after cleaning.

Rinse with sterile water after Disinfection/Liquid chemical sterilization.

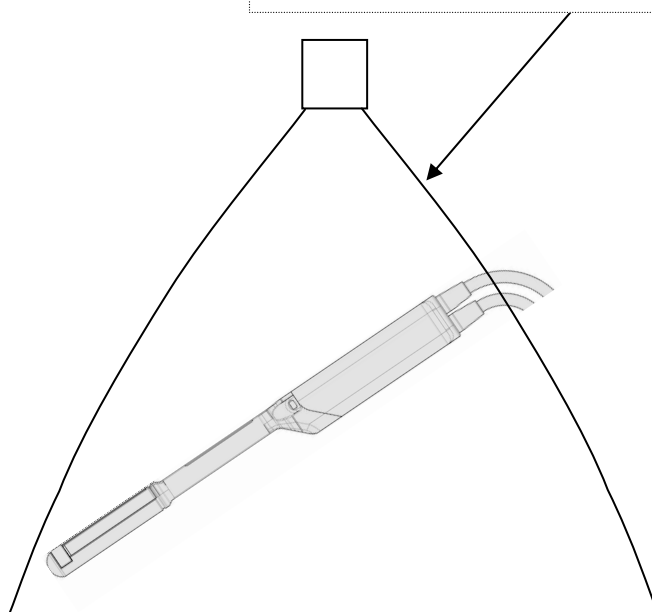


Fig.5 Rinse of the probe

6.4 Liquid Chemical Sterilization/Disinfection of the probe

For liquid chemical sterilization/high level disinfection of the probe, follow the procedures as indicated in this paragraph. (For reference, consult "Chemical Sterilants and sterilization Methods - A Guide to Selection and Use: AAMI TIR7-113", published by the Association for the Advancement of Medical Instrumentation).

Immerse the probe in a sterilant/high level disinfectant (Refer to 10. Supplier's List) following the manufacturer's directions regarding preparation and soak time (as shown in Fig.4). The contact condition of recommended solutions is given in Table 3.

Table.3 Contact condition of sterilant/disinfectant

Solution	Contact condition	Purpose
Cidex®	10 hours at 25°C	Sterilization
Cidex plus®	10 hours at 20-25°C	Sterilization
Cidex® OPA	12 minutes at 20°C	Disinfection

CAUTION

- 1) Do not mix any solution into a disinfectant unless otherwise indicated by the manufacturer.
- 2) Do not use activated disinfectant solution beyond the expiration date.
- 3) Do not immerse the probe in liquid disinfectant more than 15 hours.
- 4) Do not immerse the probe in disinfectant solution exceeding 30°C in temperature.

Use sterile technique when removing the probe from high level disinfectant solution and rinse the probe thoroughly by soaking in sterile water for more than 10 minutes (as shown in Fig.4). After rinsing the probe, air-dry it completely.

⚠ **WARNING**

- 1) Remove all debris and residue of sterilant/disinfectant solution from the surface of the probe. Debris and residue of sterilant/disinfectant may affect patient health.
- 2) The probe connector is not waterproof. Do not allow liquid to contact the connector.

6.5 ETO Sterilization Process of the probe

The probe is compatible with Ethylene Oxide (ETO) Sterilization. This manual does not describe the instructions of ETO sterilizer, therefore, follow the instructions of your sterilizer regarding the operation.

6.5.1 ETO Sterilization

Ensure that the probe is cleaned in accordance with the procedure stated in "6.3 Cleaning of the probe" before the sterilization. Perform sterilization operations with the condition given in Table4.

Table.4 ETO Sterilization condition

Preconditioning:	none
Conditioning in Chamber (Dwell):	
Temperature:	122.0-131.0°F (equivalent of 50-55°C)
Humidity:	40-90 % RH
Prevacuum:	1.93-3.89 PSIA (22-26" Hg, 13.26-26.73kPa)
Time:	30-45 minutes
Exposure:	
Temperature:	122.0-131.0°F (equivalent of 50-55°C)
Sterilant gas:	10% E0/90% HCFC
Gas Concentration	600±30 mg/L
Exposure time:	125 minutes
Post-vacuum:	1.93-3.89 PSIA (22-26" Hg, 13.26-26.73kPa), 2 times
Aeration:	
Temperature:	53°C
Time:	11 hours and 30 minutes to 12 hours

6.6 Plasma Sterilization Process

The probe is compatible with STERRAD® Plasma Sterilization (STERRAD® 50/100S/200/NX/100NX). This manual does not describe the instructions of STERRAD® system, therefore, follow the instructions of your STERRAD® system regarding the operation.

6.6.1 STERRAD® Sterilization (Johnson & Johnson Product)

Ensure that the probe is cleaned in accordance with the procedure stated in "6.3 Cleaning of the probe" before the sterilization. Perform sterilization operations by following the instructions of the manufacturer.

WARNING

Confirm the sterilization condition before performing sterilization. The sterilization by other than the specified condition causes the probe to malfunction.

6.7 Cleaning of the puncture guide fixture

- 1) Dilute enzymatic detergent solution (ref. To Suppliers List) according to the instruction of manufacturer.
- 2) Dismantle the Puncture Guide Fixture (as shown in Fig.6). And immerse parts of the Puncture Guide Fixture more than 30 minutes in the detergent solution completely.
- 3) Wash parts of the Puncture Guide Fixture and remove all visible soil and dried protein with brushes in detergent solution.
- 4) Rinse parts of the Puncture Guide Fixture thoroughly with high-quality tap water to remove all residue of the detergent solution(as shown in Fig.7).
- 5) Thoroughly dry the parts of the Puncture Guide Fixture.

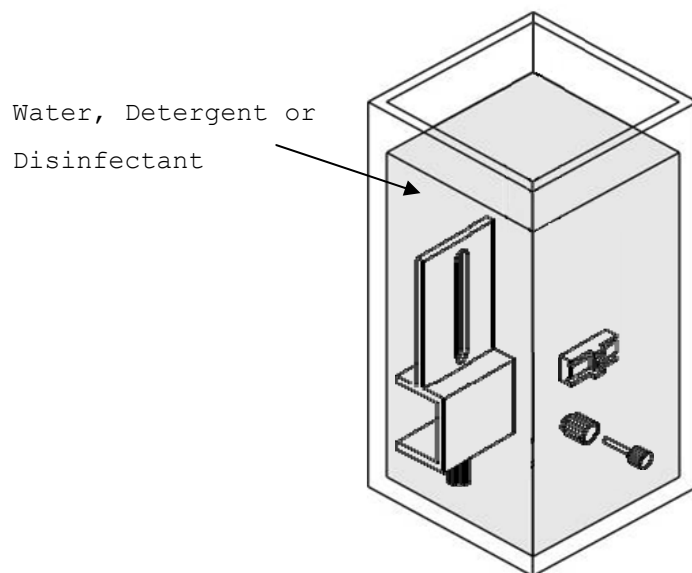


Fig.6 Immersion of the puncture guide fixture

Rinse with sterile water or high quality tap water after cleaning.

Rinse with sterile water after Disinfection/Liquid chemical sterilization.

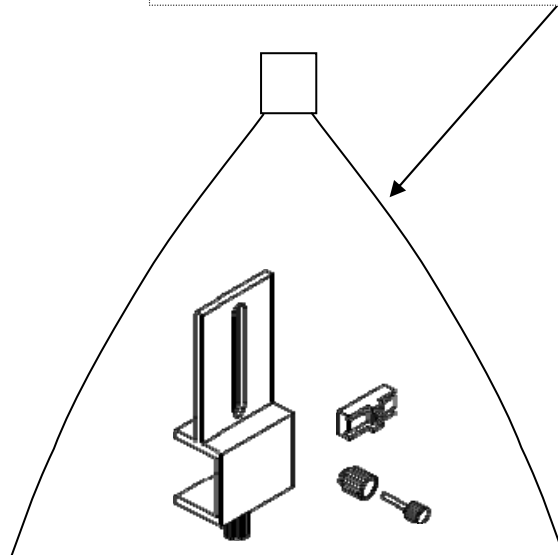


Fig.7 Rinse of the puncture guide fixture

6.8 Liquid Chemical Sterilization/Disinfection of the puncture guide fixture

Immerse the puncture guide fixture in a sterilant/high level disinfectant (Refer to 10. Supplier's List) following the manufacturer's directions regarding preparation and soak time (as shown in Fig.6). The contact condition of recommended solutions is given in Table 3.

CAUTION

- 1) Do not mix any solution into a disinfectant unless otherwise indicated by the manufacturer.
- 2) Do not use activated disinfectant solution beyond the expiration date.

Use sterile technique when removing the puncture guide fixture from high level disinfectant solution and rinse it thoroughly by soaking in sterile water for more than 10 minutes (as shown in Fig.6). After rinsing the puncture guide fixture, air-dry it completely.

WARNING

Remove all debris and residue of sterilant/disinfectant solution from the surface of the puncture guide fixture. Debris and residue of sterilant/disinfectant may affect patient health.

6.9 Autoclave sterilization of the puncture guide fixture

Following sterilization methods are applicable. Handling should be according to operation manual of the sterilizer.

Autoclave

Conditions

- 1) Temperature : 132-148°C
- 2) Time : 10 min. or more

7 Operating Procedure

7.1 Probe

7.1.1 Operation of the ultrasound diagnostic scanner

Connect the probe to the ultrasound diagnostic scanner, operate the scanner, and adjust the image, all according to the instructions given in the operation manual for the ultrasound diagnostic scanner with which the probe is used as connected.

WARNING

- 1) Set the ultrasound diagnostic scanner to "FREEZE ON" mode when replacing the probe.
- 2) Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
- 3) Do not use the probe fallen onto the floor. Otherwise, there is a risk of infection. Stop the operation and perform the cleaning and disinfection or sterilization according to paragraph 6 "Cleaning and sterilization/high level disinfection".

CAUTION

- 1) Prior to each use, ensure that the probe is cleaned and sterilized/ disinfected in accordance with the procedure stated in "6.2 Reprocessing Procedure".
- 2) Do not use the probe if the image and the frequency of the probe are not correctly displayed. An incorrect acoustic output can result in burns or other injuries to the patient.
- 3) Scan for the minimum length of time necessary for the diagnosis and at the lowest suitable 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.
- 4) 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.

7.1.2 Orientation of the image

The Relationship between the direction of the probe and the B-Mode image is shown in Fig.8 and Fig.9. The mark of right-left orientation on the image indicates the direction of the index mark of the probe. (For detail of the right-left orientation mark, refer to the instruction manual of the device to be connected.)

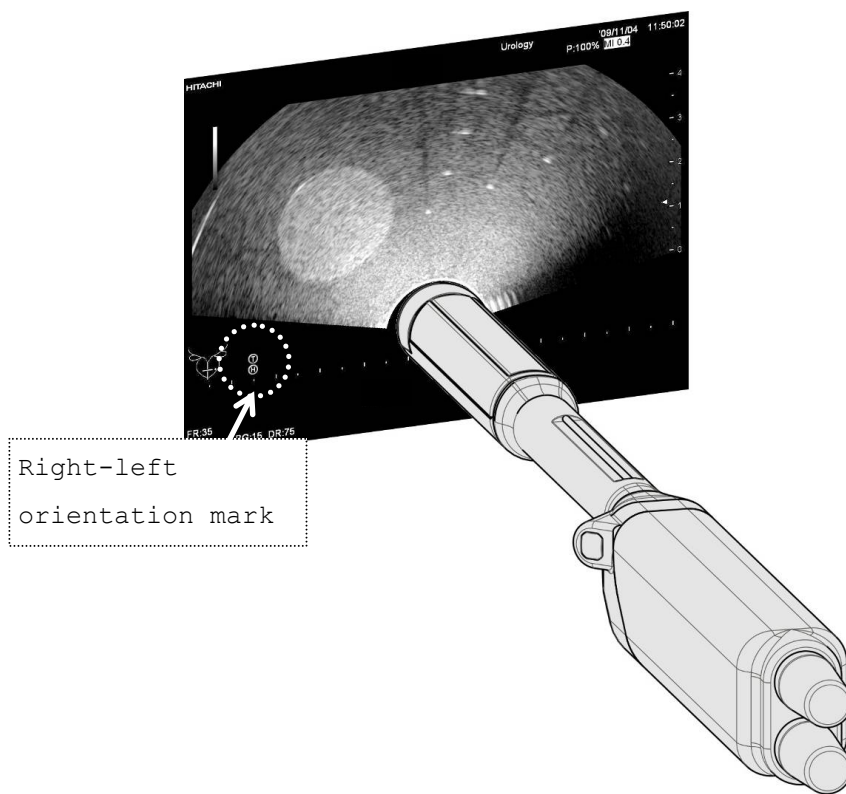


Fig.8 The relationship between the direction of the probe and the Right-left Orientation Mark in Convex US image

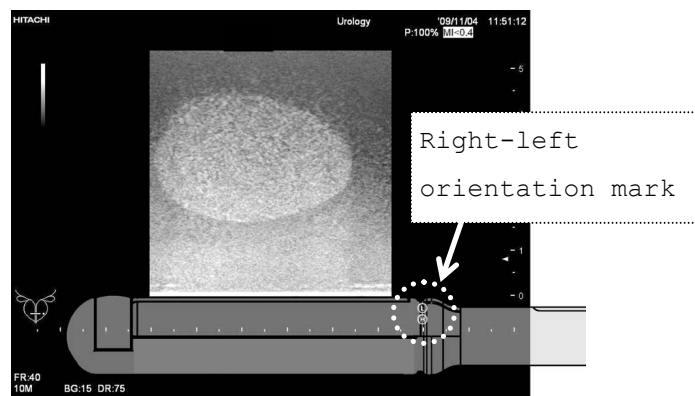


Fig.9 The relationship between the direction of the probe and the Right-left Orientation Mark in Linear US image

7.1.3 Probe Sheath

Use a sterile probe sheath to protect the probe. The probe sheath should be allergy free material to avoid allergic reaction. Between the probe and the probe sheath, acoustic coupling gel is required as a couplant.

WARNING

- 1) Some Latex material may create allergic reaction.
See "2. General Caution" for more detail.
- 2) Use a biocompatible probe cover. Use of a non-biocompatible probe cover can cause the patient an adverse reaction.

7.1.4 Diagnosis

Insert the probe gently and adjust the probe's position for a clear view of the desired image. Place the probe on the examination site and adjust the probe's position for a clear view of the desired image.

WARNING

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

Do not hold the needle cannula of the electrosurgical unit with metal tweezers, forceps, and the like.
[Doing so may damage the insulation section of the needle cannula, and may cause a burn to a non-treated area.]

7.1.5 Care after use

Perform the reprocessing procedure in accordance with the procedure stated in "6.2 Reprocessing procedure" every time immediately after completing the ultrasound examination.

7.2 Use of Puncture Guide Fixture (EZU-PA3U)

The steps to attach the Puncture Guide Fixture (EZU-PA3U) to the probe is as follows.

- 1) Attach a sterile probe cover to the probe.
- 2) Fit the groove of the Puncture Guide Fixture to the projection on the probe. (as shown in Fig.10)
- 3) Screw the Puncture Guide Fixture to attach to the probe firmly. Visually inspect that there is no hole in the probe cover.

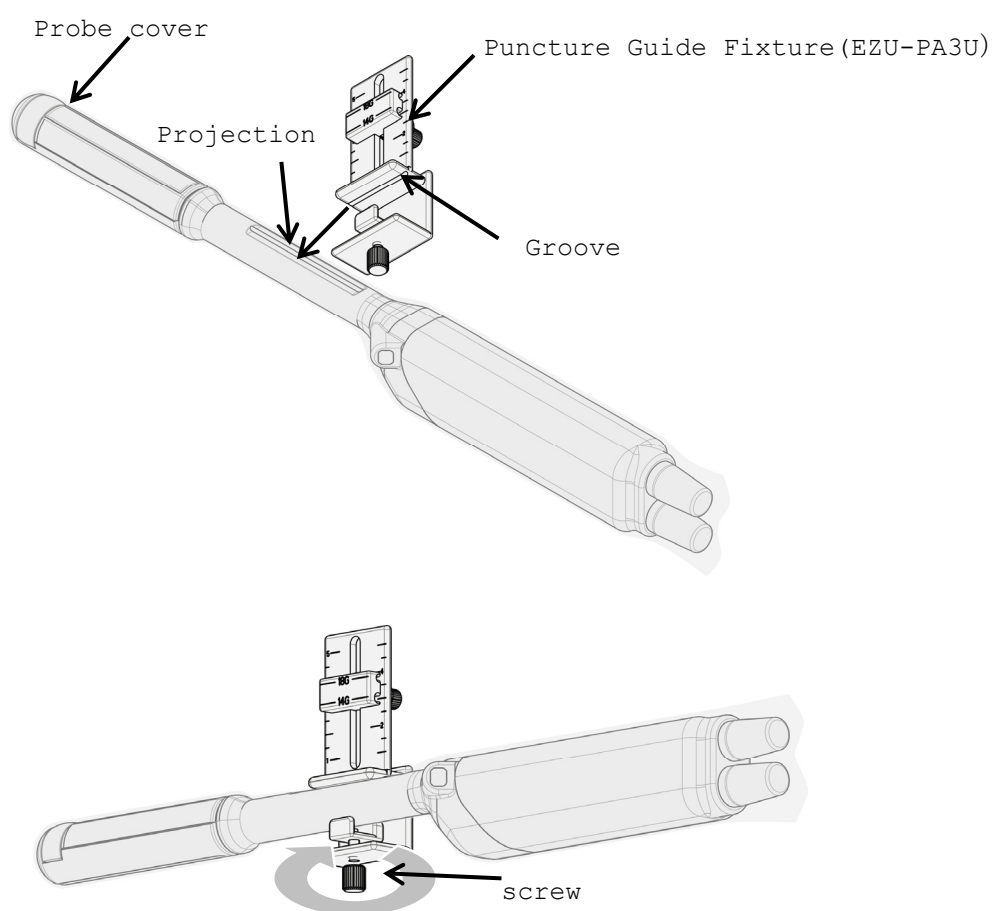


Fig 10. How to attach the EZU-PA3U

7.3 How to adjust Puncture Guide Fixture (EZU-PA3U)

- 1) Loose thumbscrew on the back side of the puncture guide.
- 2) Slide guide groove in the depth on demand.
- 3) Tighten thumbscrew for fixing guide groove.

Following figure is an example that guide groove of 14G is combined with the depth of 30mm

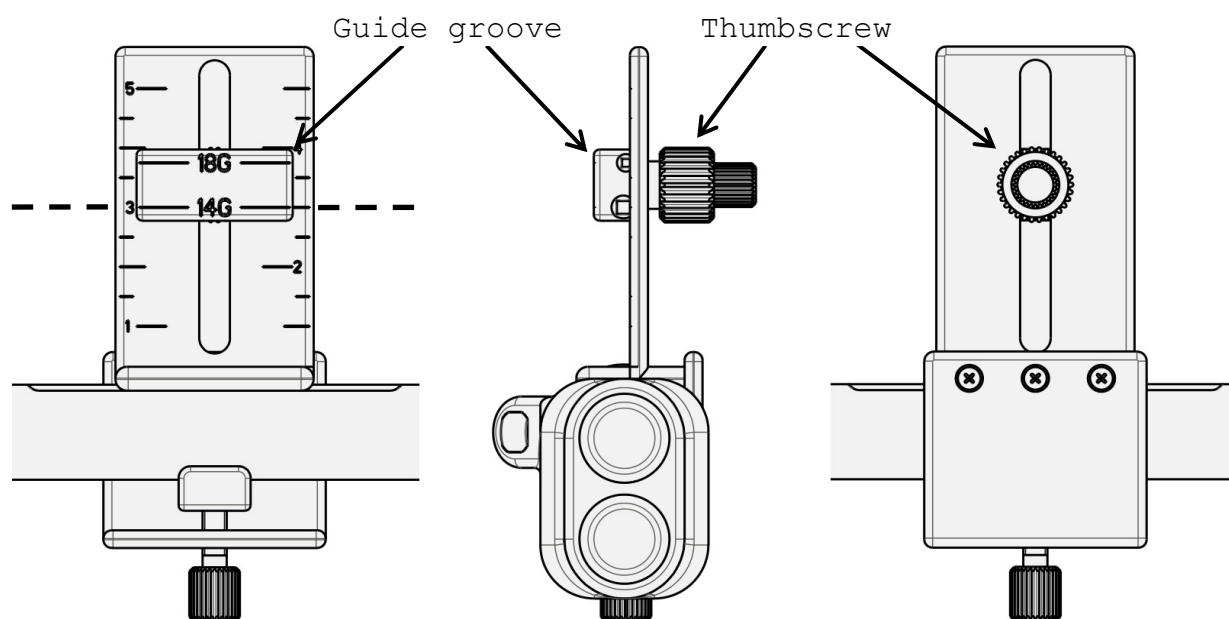


Fig 11. How to adjust Puncture Guide Fixture

 CAUTION

The needle guideline can be displayed on US image for perineal prostate biopsy. This probe can be used for biopsy with the Puncture Guide Fixture EZU-PA3U.

When the needle guideline is displayed, numeric value is displayed on the upper right of the US image. This numeric value means the distance between the surface of acoustic lens and the needle guideline (see the figure in the next page). Regarding the needle guideline, refer to the instruction manual of the ultrasound scanner that the ultrasound probe is connected to.

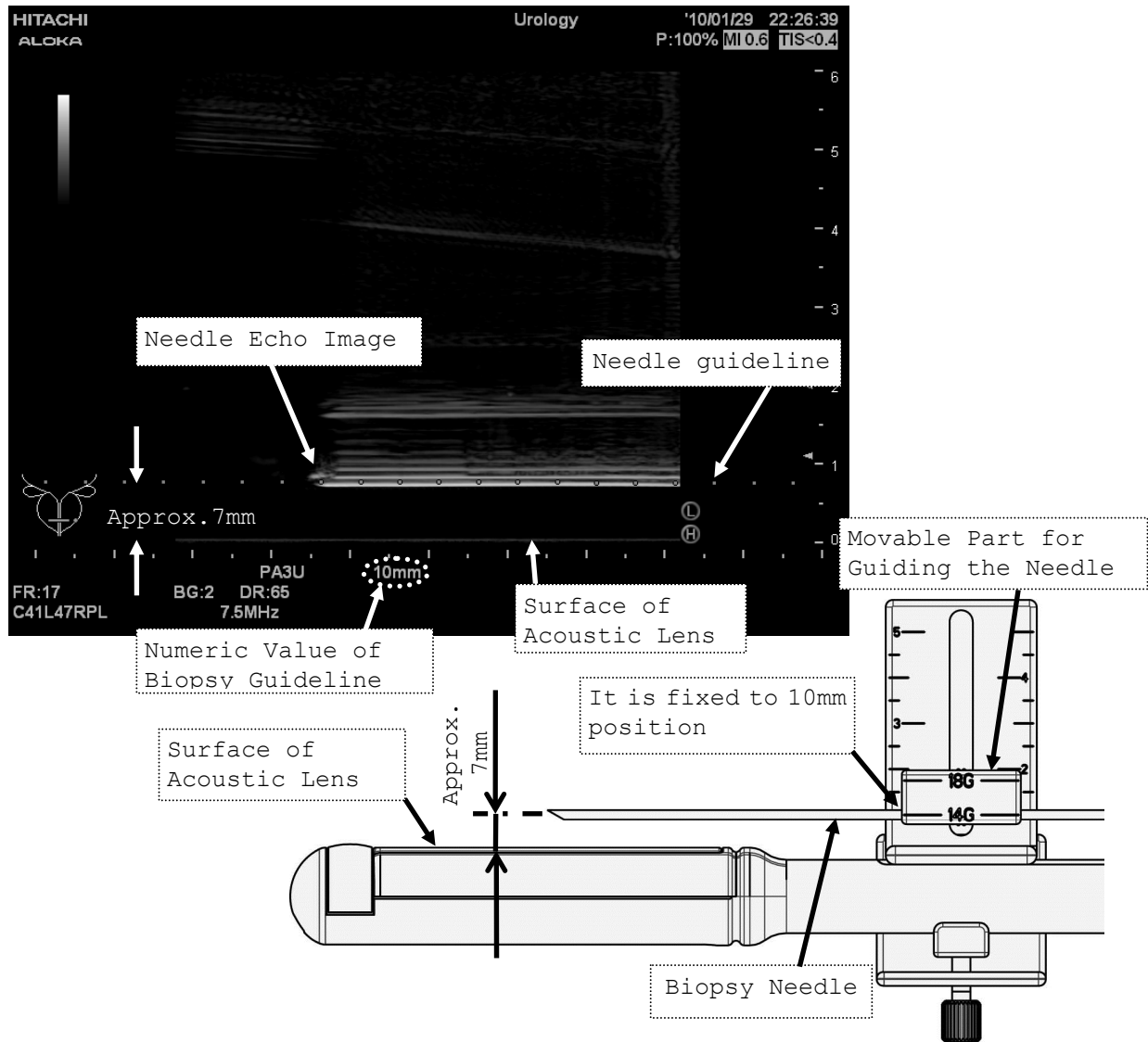
The numeric value on the image corresponds to the numeric value engraved on the Puncture Guide Fixture EZU-PA3U. For example, when the Movable Part for guiding the needle is fixed at 10mm position, then the numeric value in the upper right on US image is needed to be adjusted to 10mm. The Movable Part for guiding the needle and the needle guideline can be fixed at from 10 to 50mm in 5mm steps.

Note that the position of the numeric value on the US image is different in each ultrasound scanner.

Make sure that there is no damage to the Puncture Guide Fixture prior to each use, otherwise the needle or needle cannula might be damaged.

⚠ CAUTION

The needle echo image corresponds with the needle guideline, but the actual distance from the surface of acoustic lens to the needle guideline is approximate 3mm shorter than the numeric value in the upper right on US image, so the numeric value is rough indication for biopsy.



 CAUTION

- 1) Never use the acoustic jelly which is the accessory of the ultrasound diagnostic scanner since it is not sterile acoustic jelly.

 WARNING

- 1) Warning in case of using probe covers which latex is contained to. The latex may cause such allergic reactions as itching, rubor, urticaria, swelling, fever, anhelation, wheezing, depression of blood pressure, shock and so on.
For the patients suspected of latex allergy, do not use the latex-containing medical devices. If you observe any of above mentioned symptoms in your patient during the operation, stop the use of the latex-containing medical devices immediately and take an appropriate treatment to the patient.
- 2) Sterilize/disinfect the probe and disinfect the Puncture Guide Fixture when probes cover tears.

 CAUTION

Perform cleaning and sterilization for the probe and perform cleaning and high level disinfection for the puncture guide fixture when the probe cover is broken.

8 Maintenance and Safety Inspection

8.1 Probe Care

Use gauze soaked in water or in ethyl alcohol to clean the dirt on the surface of the probe.

CAUTION

- 1) Do not attempt to scrape away caked dust on the probe with a hard cloth or knife.
- 2) Do not allow liquid to contact/enter the probe connector, as the probe connector is not waterproof.
- 3) Do not use Ethyl alcohol other than cleaning. Ethyl alcohol is not effective as a disinfectant/sterilant.

8.2 Daily Inspection

- 1) Visually inspect the surface of the probe head, the housing, and the cable for any crack, scratch or denaturalization. If you find damage, do not use the probe, and immediately contact our service personnel.
- 2) Visually inspect the ultrasound image for abnormality or major change from initial state. If you find abnormality or major change, do not use the probe, and immediately contact our service personnel.

9 Specifications

Type	:C41L47RP Probe
Acoustic working	
Frequency	: Convex 6.5MHz : Linear 7.5MHz
Technology	: Convex array and Linear array electronic scanning
Dimensions	: See Fig.12
Weight	: Approx. 1.3kg (Including cable and connector)
Scanning angle	: 200°
Scanning width	: 64mm
Probe materials	: Biocompatible allergy free components
Applicable systems	: Depending on production and upgrade status for detailed information, contact a service support.
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% (subject to no condensation)
Storage/Transportation conditions:	
Temperature:	-10 - +50°C
Relative humidity:	10 - 90% (subject to no condensation)

10 Supplier's List

The products listed below are seriously tested and approved for use with C41L47RP.

Product name	manufacturer	purpose
Enzol [®]	Johnson & Johnson	Enzymatic detergent
Cidex [®]	Johnson & Johnson	Sterilant
Cidex Plus [®]	Johnson & Johnson	Sterilant
Cidex [®] OPA	Johnson & Johnson	disinfectant
Transducer covers	CIVCO Medical	Covers

11 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.

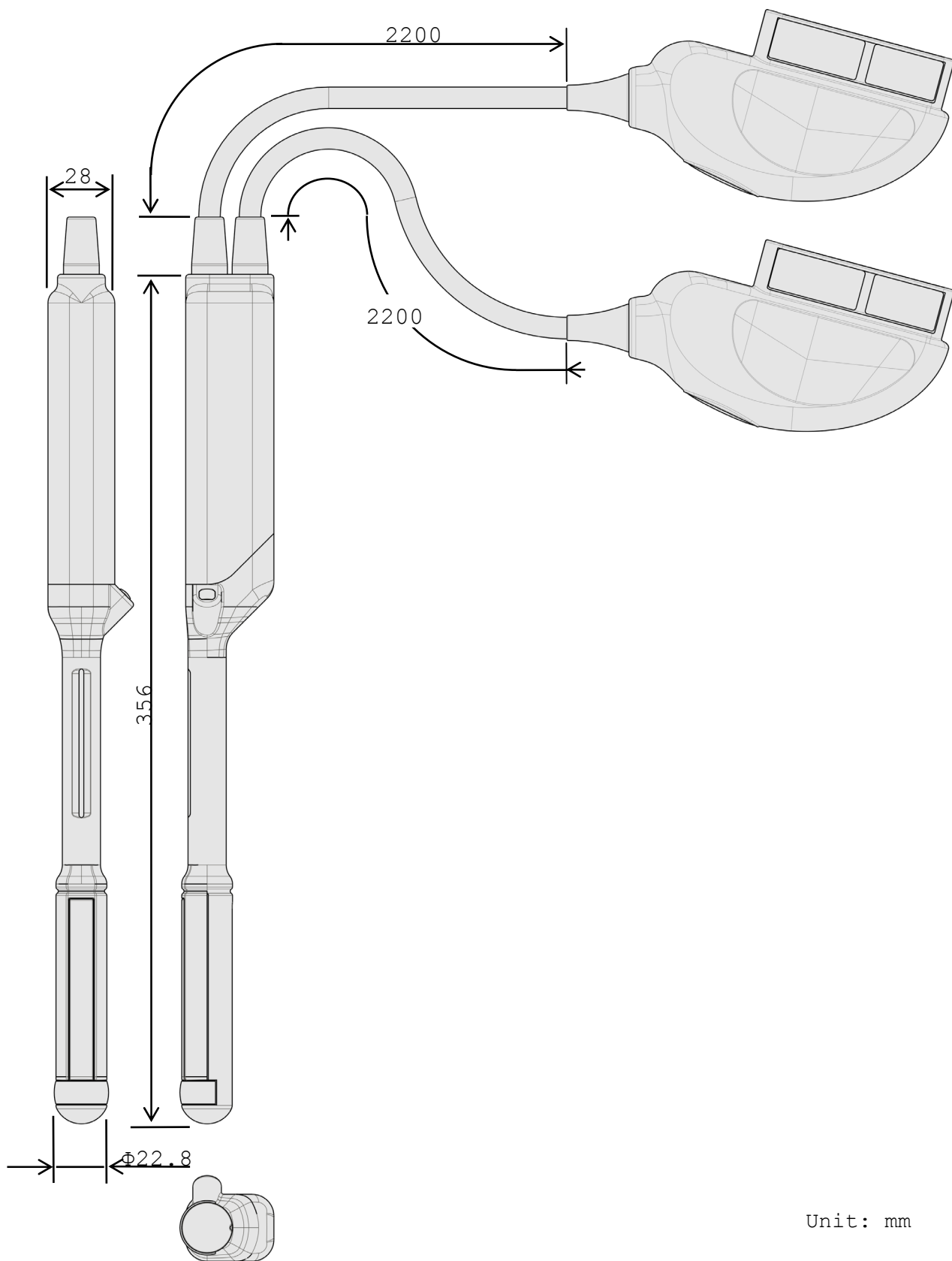


Fig.12 External view of C41L47RP Probe

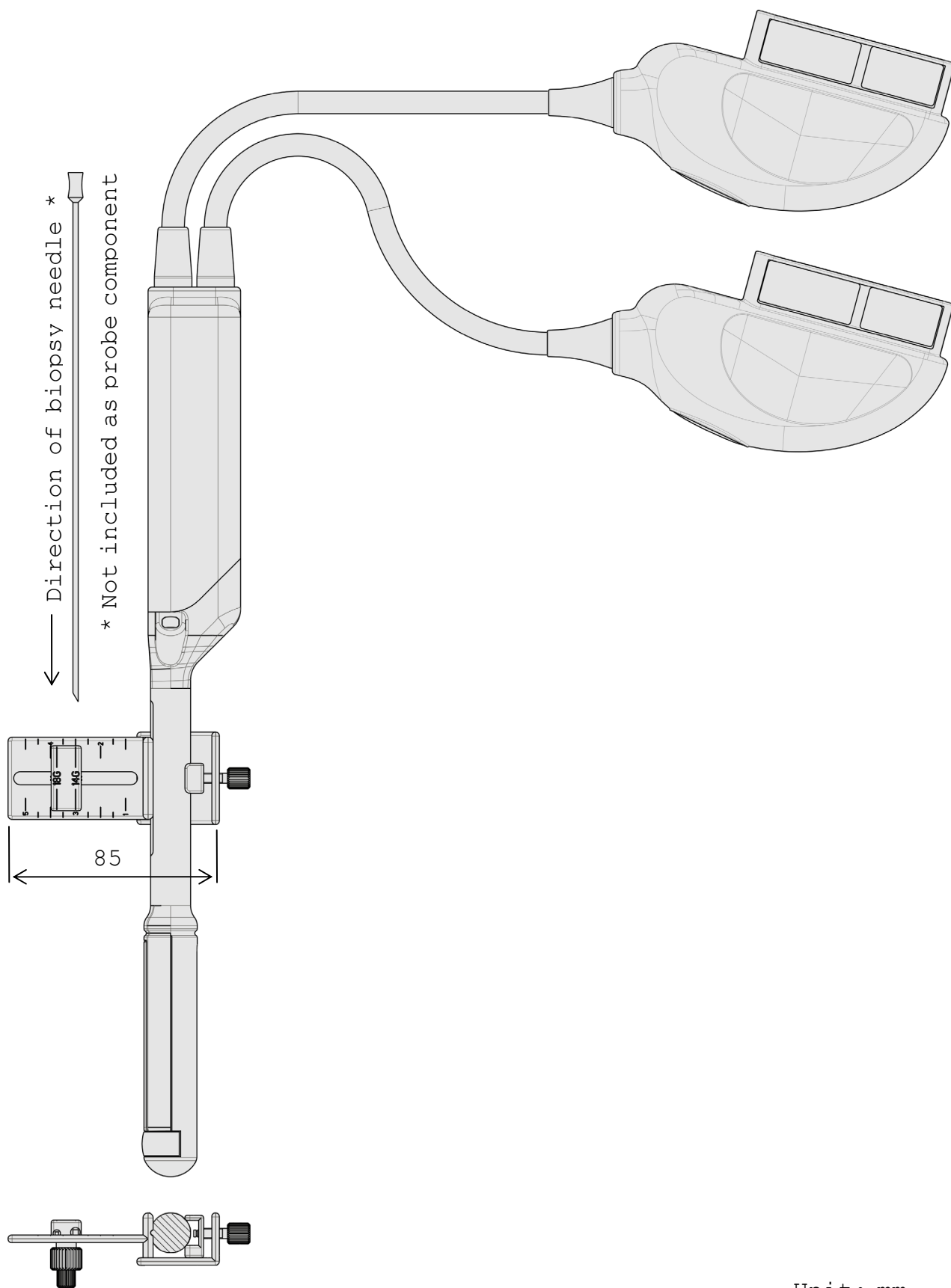


Fig.13 Dimension Diagram with the Puncture Guide Fixture
(EZU-PA3U)

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