HITACHI
Inspire the Next

L64 Probe

INSTRUCTION MANUAL
--- For USA ---

Hitachi, Ltd.
Tokyo , Japan

Q1E-EP1444-2

DM 120291 v2

CONTENTS

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 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.**

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:

〈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 "9.1 Probe Care".)
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/Covers™
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.

FDA

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.

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3. General

L64 Probe is of linear array type. 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 List

The components list of L64 is given in Table.1.

Table.1 Probe component list

	Component	Note
1	L64 Probe	1 piece
2	Instruction manual	1 copy
3	Shipping & storage box	1 set

5. Accessories (Option)

5.1 Needle guide bracket EZU-PA7L3

The components list of the EZU-PA7L3 is given in Table.2.

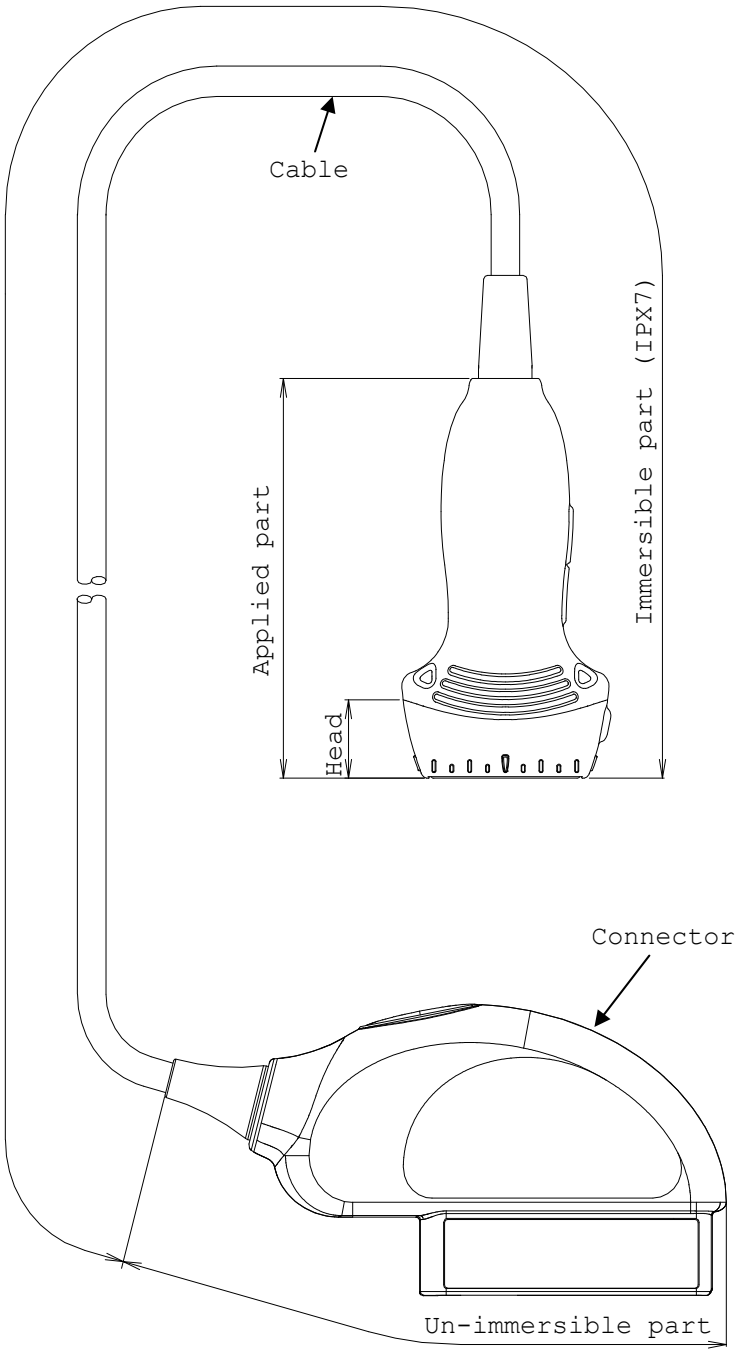
Table.2 Needle guide bracket component list

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

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

6. External View

The external view of L64 is given 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

7. Cleaning and sterilization/high level disinfection of L64

The probe is not sterilized, but must be sterilized or disinfected before 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.)

7.1 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.3) and the regulation of each country.

Table.3 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

7.2 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. The reprocessing procedure must be performed even after the probe was used with a probe sheath.

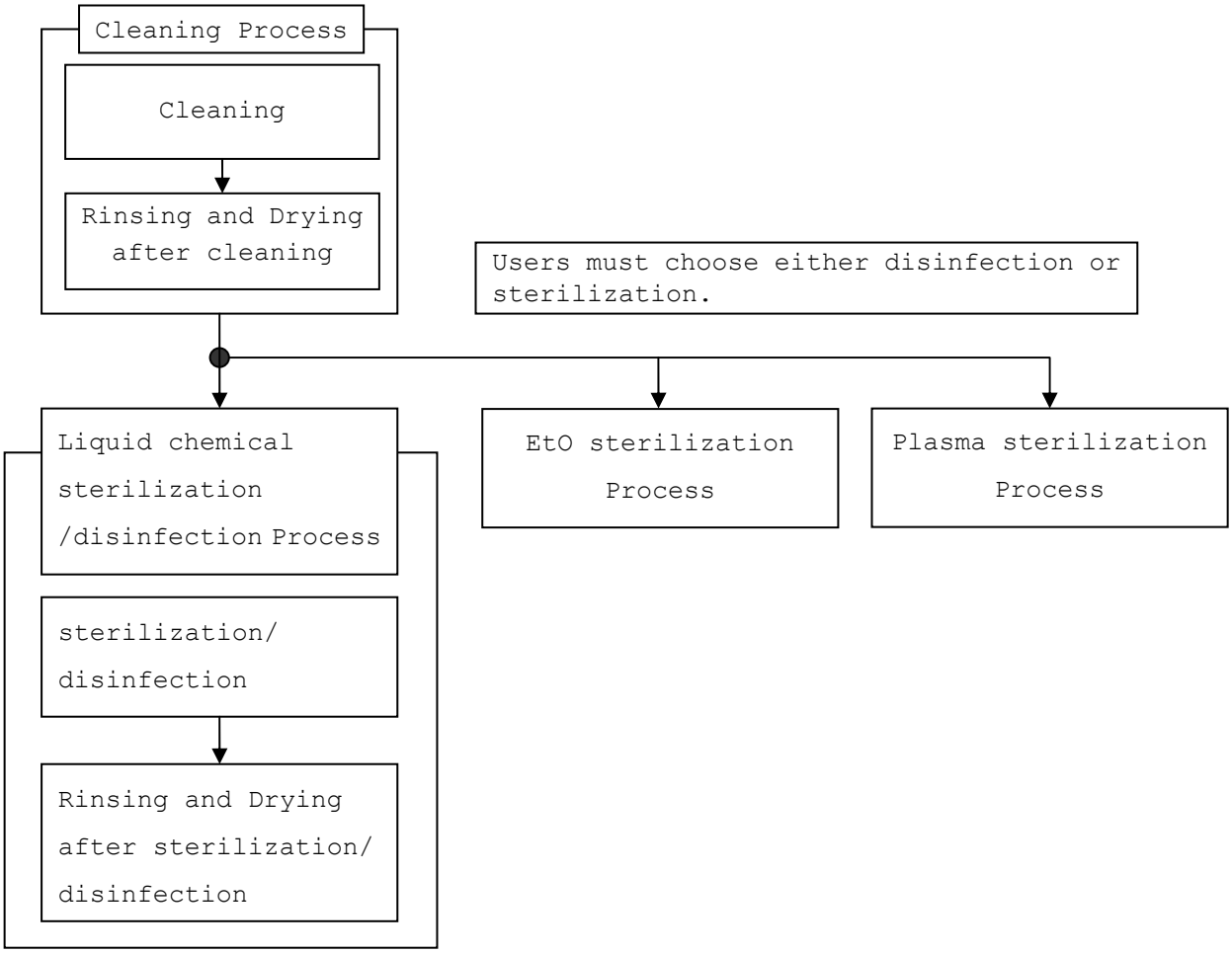


Fig.2 Reprocessing Procedure

〈 WARNING 〉

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

7.3 Cleaning Process

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

7.3.1 Cleaning

Immerse the probe in an enzymatic detergent (Enzol®) solution (as shown in Fig. 3) 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.

7.3.2 Rinsing and Drying after Cleaning

After cleaning and prior to liquid chemical sterilization/high level disinfection, the probe must be thoroughly rinsed with deionized running water or sterile water for more than 10 minutes to remove all residue of the detergent solution (See Fig.4). After rinsing the probe, air-dry it completely.

〈 WARNING 〉

Remove all debris and residue of sterilant/detergent solution from the surface of the probe sufficiently.
Debris and residue of sterilant/detergent solution on the surface of the probe may affect patient health.

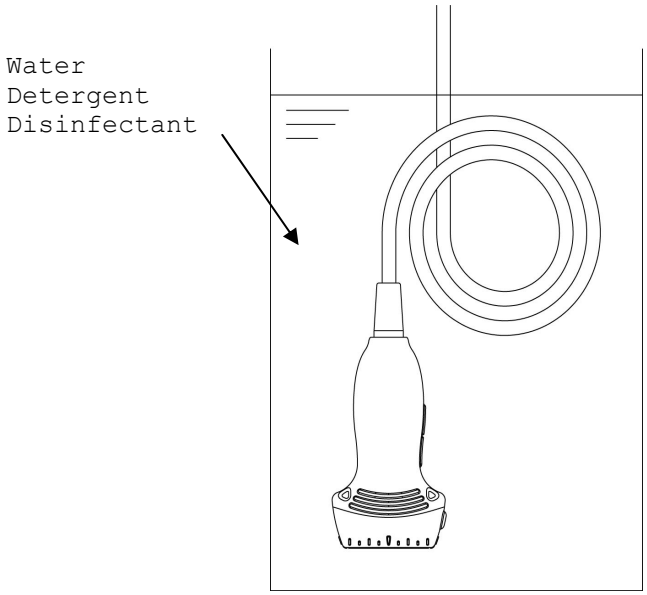


Fig.3 Immersion of the Probe

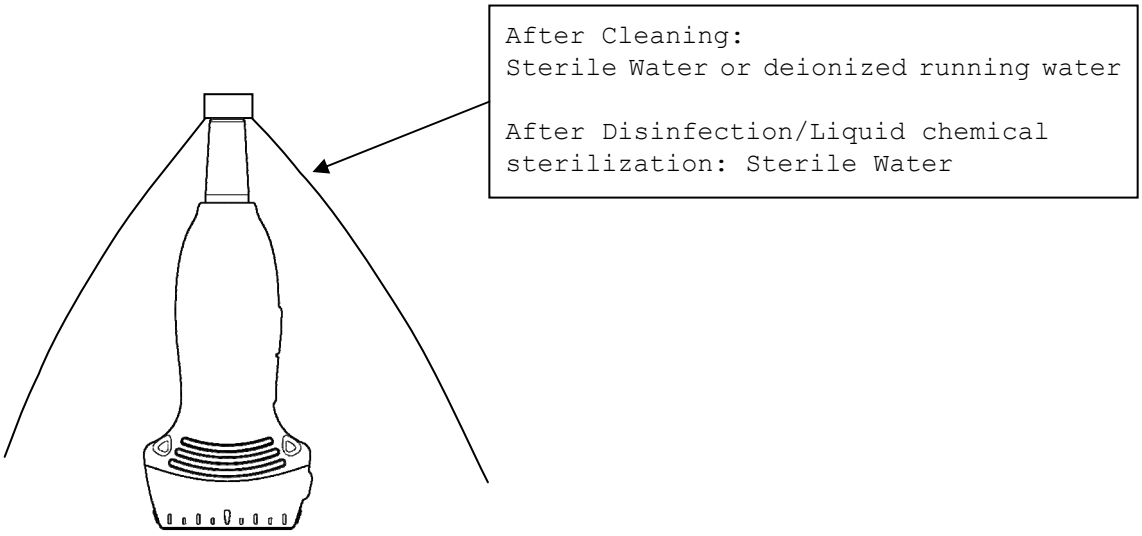


Fig.4 Rinse of L64

7.4 Liquid Chemical Sterilization/Disinfection Process

For sterilization/high level disinfection of L64 using liquid chemicals, follow the procedures as indicated in this section. (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).

7.4.1 Sterilization / High Level Disinfection

Immerse the probe in a sterilant/high level disinfectant (Refer to 11.Supplier's List) following the manufacturer's directions regarding preparation and soak time (Fig.3). The contact condition of recommended solutions is given in Table 4.

Table.4 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.

7.4.2 Rinsing and drying

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 (See 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 sufficiently. 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.

7.5 EtO Sterilization Process

L64 is compatible with Ethylene Oxide (EtO) Sterilization. This manual does not describe the instruction of EtO sterilizer, therefore, follow the instructions of your sterilizer regarding the operation.

7.5.1 EtO Sterilization

Ensure that the probe is cleaned in accordance with the procedure stated in "7.3 Cleaning Process" before the sterilization. Perform sterilization operations with the condition given in Table 5.

Table.5 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

7.6 Plasma Sterilization Process

L64 is compatible with STERRAD® Plasma Sterilization (STERRAD® 50,100S and 200). This manual does not describe the instructions of STERRAD® system, therefore, follow the instructions of your STERRAD® system regarding the operation.

7.6.1 STERRAD® Sterilization (Johnson & Johnson Product)

Ensure that the probe is cleaned in accordance with the procedure stated in "7.3 Cleaning Process" 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.

8. Operating Procedure

8.1 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〉

Set the ultrasound diagnostic scanner to "FREEZE ON" mode when replacing the probe.

〈CAUTION〉

Prior to each use, ensure that the probe is cleaned and sterilized/ disinfected in accordance with the procedure stated in "7.2 Reprocessing Procedure".

8.2 Orientation of the image

The Relationship between the direction of the probe and the B-Mode image is shown in Fig.5. 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.)

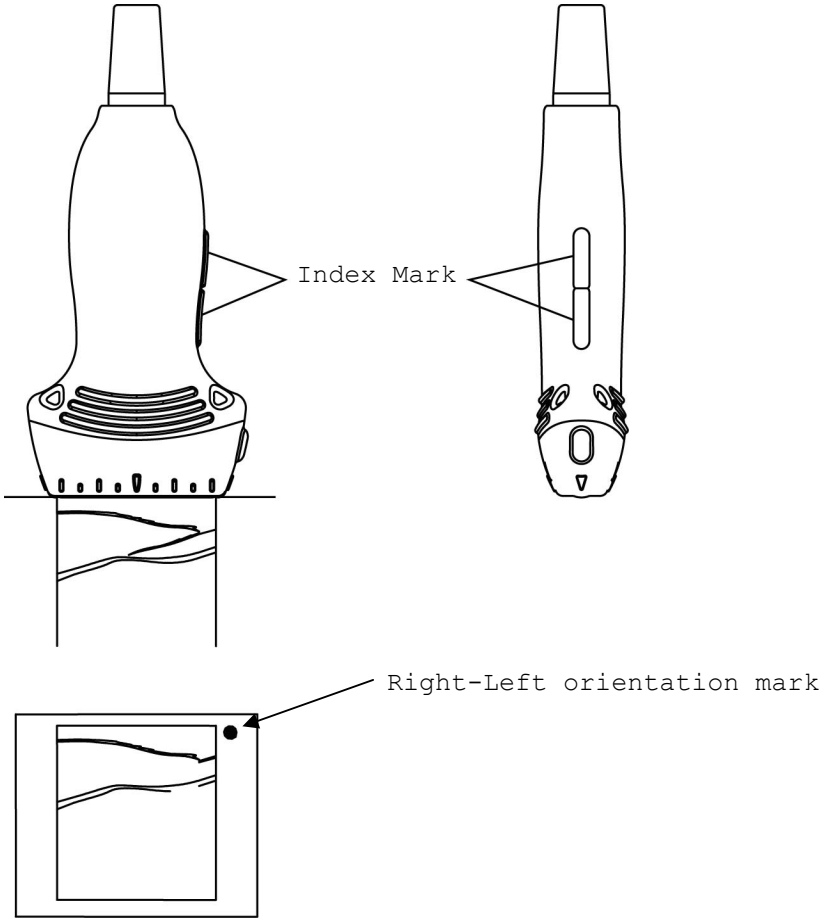


Fig.5 Relationship between direction of the probe and Right-left orientation Mark

8.3 Marking Assist

Marking Assist as shown in Fig.6 is the function to help marking the surface of the body.

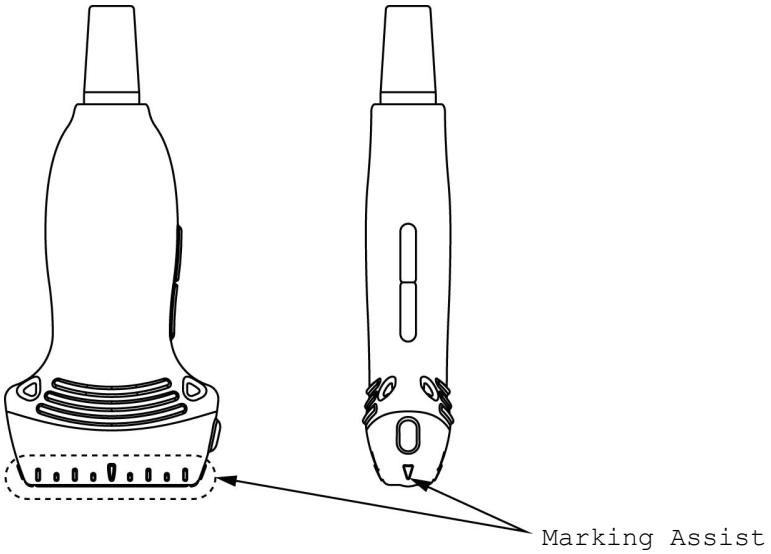
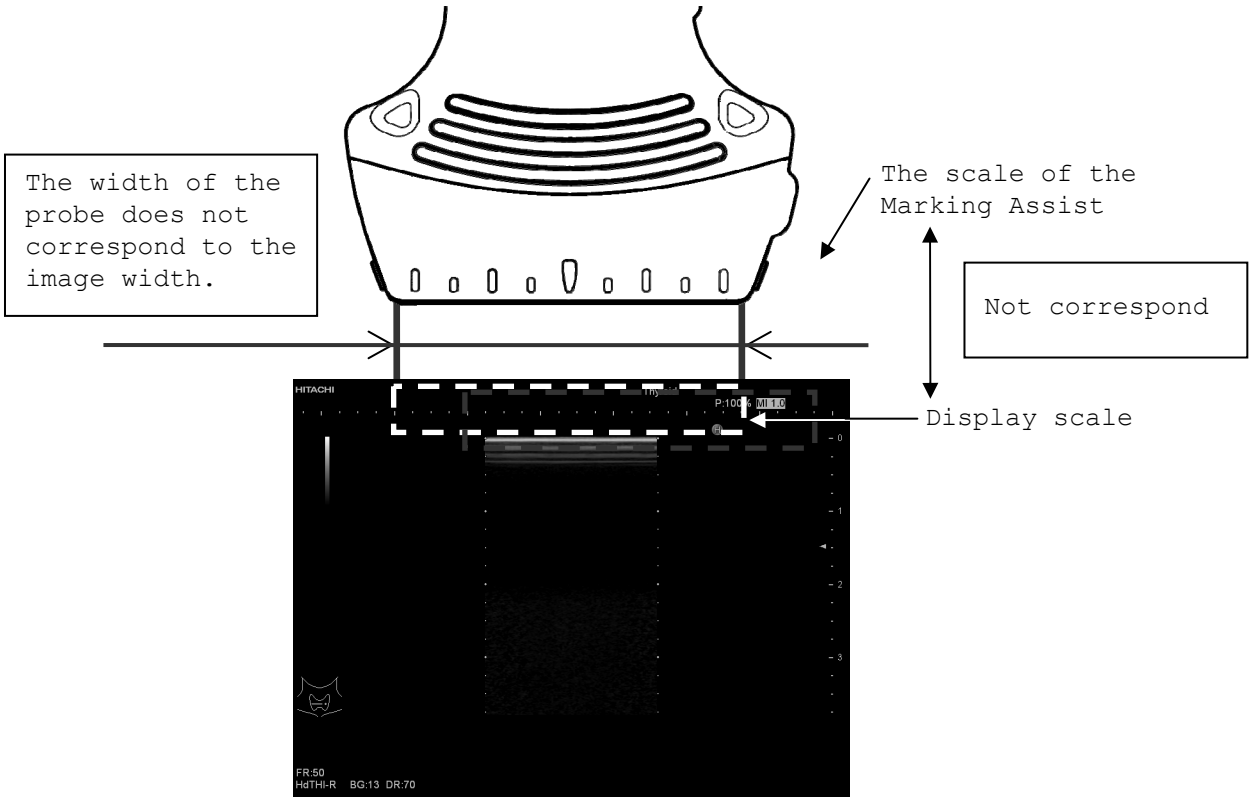


Fig.6 Marking Assist

〈CAUTION〉

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



〈CAUTION〉

The acoustic lens of the probe is manufactured very thin and delicate to get the high resolution. Therefore, in case of wiping out the ultrasound jelly or cleaning the surface of the acoustic lens, please use the soft cloth or tissue paper and handle with care. (See Fig. 7)

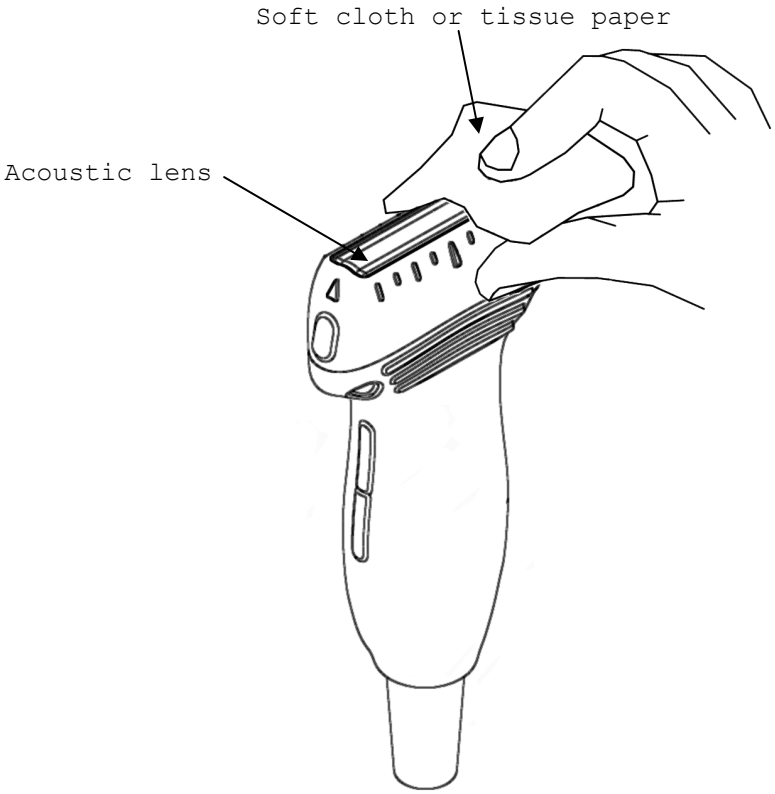


Fig. 7 Wiping out the ultrasound jelly or cleaning the surface of the acoustic lens

8.4 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 〉

Some Latex material may create allergic reaction.
See "2. General caution" for more detail.

8.5 Diagnosis

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

8.6 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.

9. Maintenance and Safety Inspection

9.1 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.

9.2 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.

10. Specifications

Type	: L64 Probe
Acoustic working Frequency	: 10MHz
Technology	: Linear Array Probe
Dimensions	: See Fig.8.
Weight	: Approx. 0.46kg (Including cable and connector)
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 - +35°C
Contact surface temperature: (Temperature of examinee)	max. 42°C
Relative humidity:	30 - 85% (subject to no condensation)

Storage conditions:

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

11. Supplier's List

The products listed bellow are seriously tested and approved for use with the linear array probe L64.

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

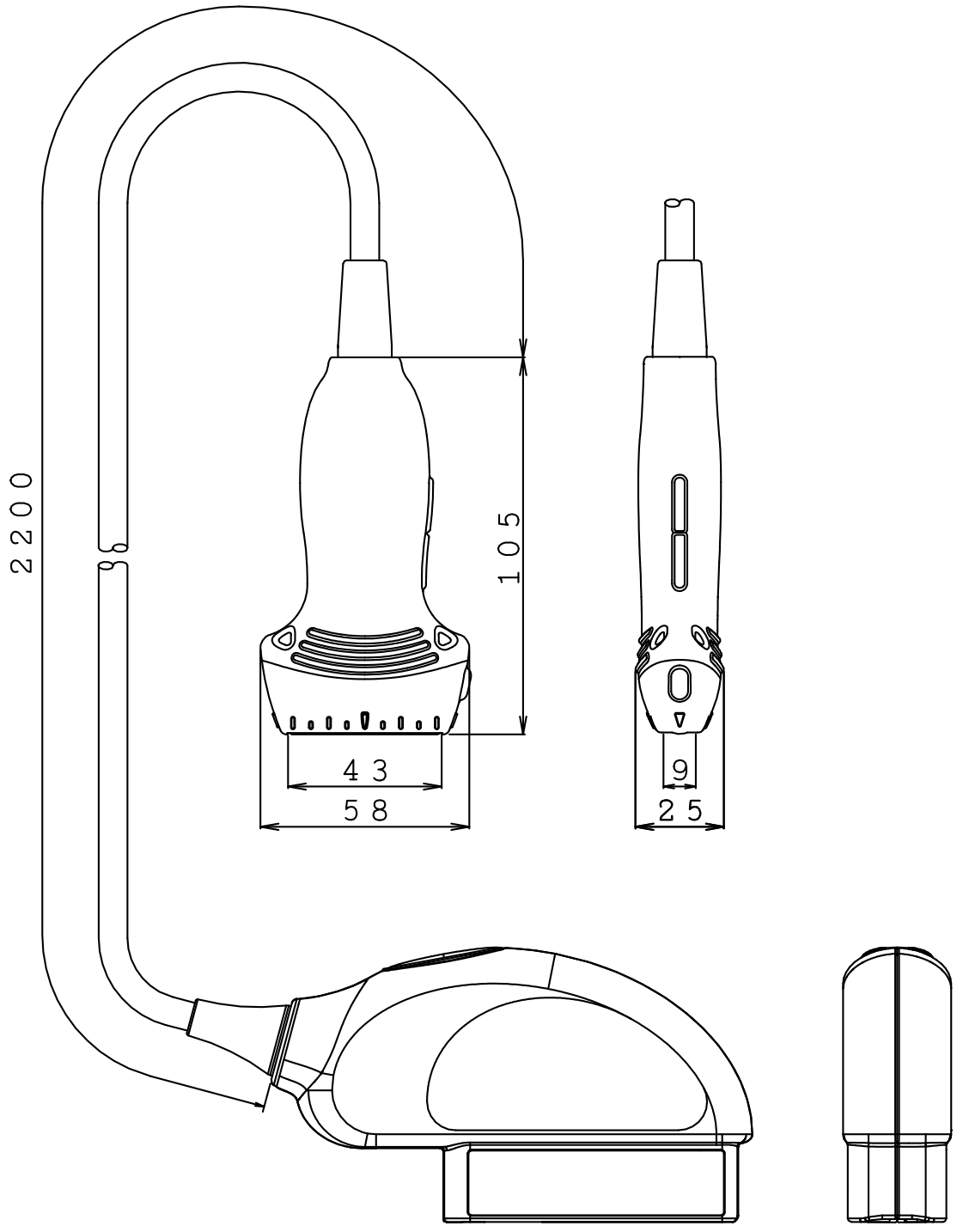
12. Disposal of the probe

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.



Unit:mm

Fig.8 Dimensions

Manufacturer

Hitachi,Ltd.

2-16-1, Higashi-Ueno,Taito-ku,Tokyo,110-0015,Japan

Contact

+81-3-6284-3668

http://www.hitachi.com/businesses/healthcare/index.html

Representative

Hitachi Aloka Medical America, Inc.

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