HITACHI
Inspire the Next

Convex Array Probe

EUP-CV524

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-EP0737-8

CE 0123

Manufacturer: Hitachi, Ltd.

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

European
Representative: Hitachi Medical Systems GmbH

Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany

EU Importer: Hitachi Medical Systems Europe Holding AG

Address: Sumpfstrasse 13 CH-6300 Zug, Switzerland

Local Distributor:

About this manual

This instruction manual shall provide instructions for using, cleaning, disinfecting and/or sterilizing the HITACHI ultrasound probes. It also describes safety considerations, maintenance. For instructions for operating the main unit, refer to the operation manual for it.
Before using the probe, thoroughly read this manual and keep this book for future reference.
If you have any questions concerning the manual, please contact a service support.
The following conventions are used throughout the manual to denote information of special emphasis.

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

WARNING: "Warning" is used to indicate the presence of a hazard which can cause severe personal injury, death, or substantial property damage if the warning is ignored.

CAUTION: "Caution" is used to indicate the presence of a hazard which will or can cause minor personal injury or property damage if the caution is ignored.

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

Graphical Symbols for Use in Labeling of Hitachi Ultrasound Probes

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

Explanation of Symbol	Symbol	Descriptive Content
Manufacturer Company Name and Address		Hitachi, Ltd. 2-16-1, Higashi-Ueno, Taito-ku, Tokyo,110-0015, Japan +81-3-6284-3668 http://www.hitachi.com/businesses/ healthcare/index.html
Authorized Representative in The European Community		Hitachi Medical Systems GmbH Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany
Keep away from Sunlight		Store the probe in a cool, dustproof and dry environment to avoid high temperature, humidity and direct sunlight.

Definition of symbol

The following symbol is also used for HITACHI Ultrasound Probes.

Location	Symbol	Definition
Probe connector	CE 0123	This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS
Probe connector	IPX7	IPX7 mark See section 1.5.
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		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.

CONTENTS

1. Introduction

1.1 Features

The probe model EUP-CV524 is a Convex Array electronic scanning type.

This probe is able to display Real-time 3D US-image by swinging acoustic part to array cross-section direction by mechanical driving. The acoustic output of this probe when connected to ultrasound scanner was measured according to the IEC60601-2-37 standard. The table of measured acoustic output data is contained in the operation manual of each ultrasound scanner.

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

According to IEC 60601-1 the probe is classified as type BF.

1.2 Principles of operation

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

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

1.3 Intended Use

The Convex Array Probe EUP-CV524 is designed for observation and diagnosis mainly of the following regions by connecting with the HITACHI ultrasound scanner.

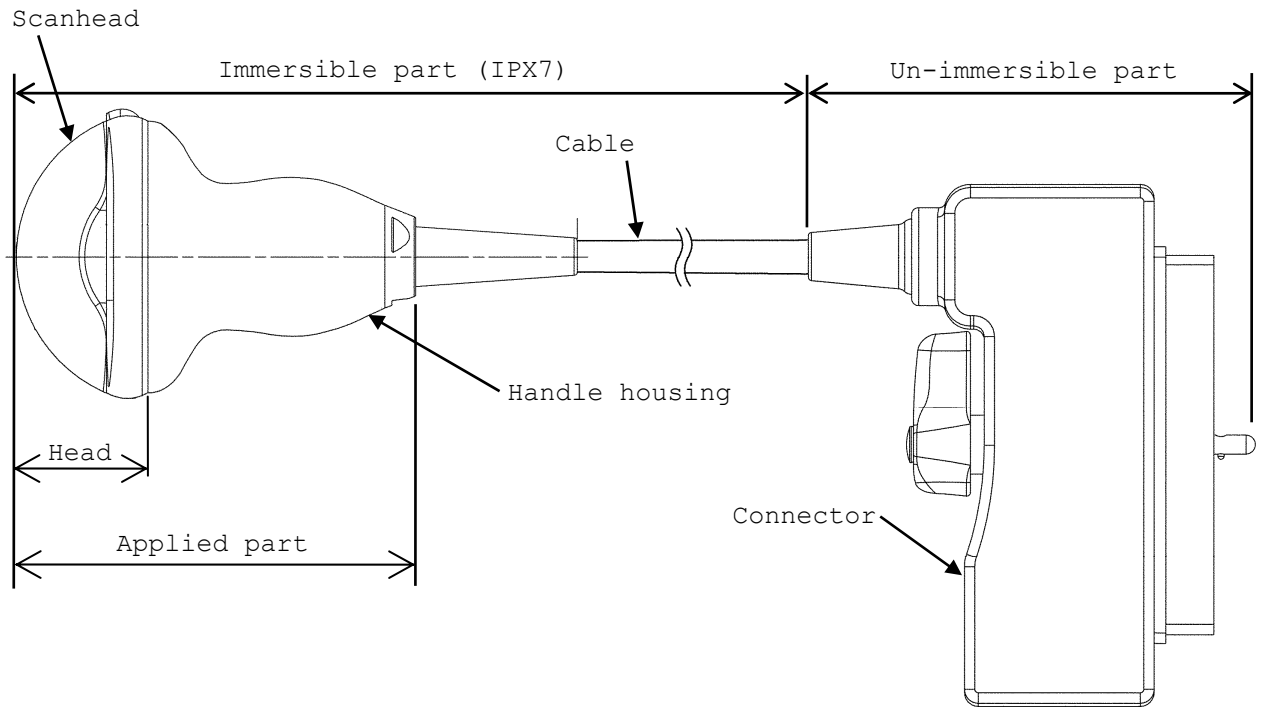
- Abdominal
- Pediatric
- Fetal
- Small organ

1.4 Composition

The probe components of the EUP-CV524 are as follow:

1) Probe EUP-CV524 ..... 1 piece
2) Instruction Manual ..... 1 copy
3) EUP-CV524 Correct Backlash CD-ROM .. 1 piece

1.5 Construction



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 of the EUP-CV524

2. Inspection before Use

Prior to use, the probe must be carefully inspected that it is appropriate for use. If not, do not use the probe and immediately contact a service support.

2.1 Inspection for Appropriate Connection

2.1.1 Do not attach or connect neither unauthorized devices nor instruments on the probe, such as unauthorized biopsy attachments.

2.1.2 Check that the system is correctly operating. Refer to the instruction manual for the main unit.

2.2 Inspection for Material Surface

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

2.3 Inspection for driving

Check whether defects such as mechanical abnormal noise and so on do not occur about the swinging part in the oil case when Real-time 3D mode is selected.

3. Operation Procedure

1) Confirm that the probe is cleaned and disinfected.
2) Connect the probe, operate the main unit, and adjust the image according to the instructions given in the operation manual for the main unit.
3) Relationship between direction of the probe and the image is shown in Fig. 2. The right-left orientation mark on the image indicates the direction of the index mark on the probe.

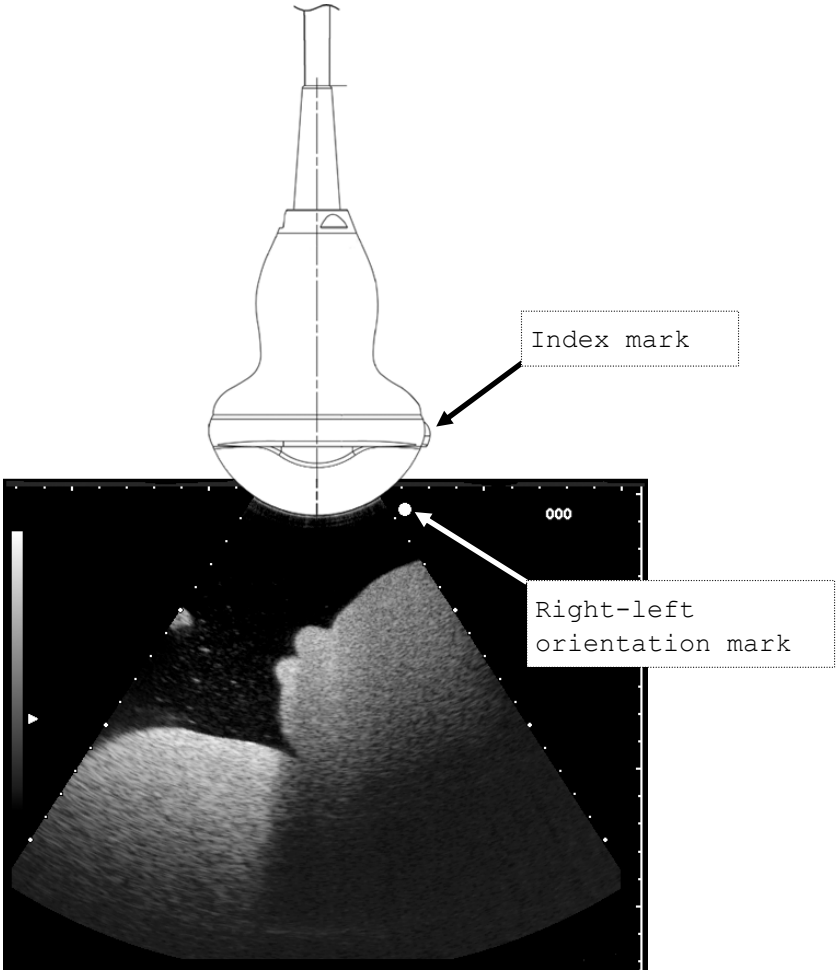


Fig. 2 Relationship between Index Mark and the Right-left orientation mark

4) After disinfecting, protect the probe by using probe covers (Ref. to Suppliers List). Some Latex material may create allergic reaction. Please use allergy free material covers.
5) After the use of the probe, it should be cleaned and disinfected, then store it in an adequate place.

4. Reprocessing Procedure

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

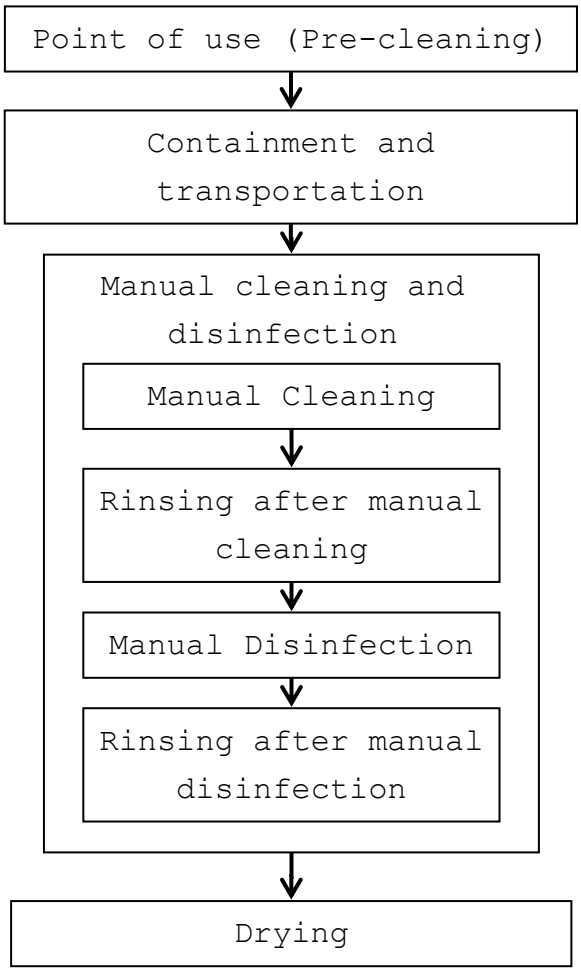
WARNINGS	- The probe is delivered unsterile. Prior to the first use, reprocess the probe. - Temperature should not exceed 40°C during reprocessing. - Probe connector is not water resistant.
Limitations on reprocessing	The probe is not completely submersible. The immersible part is shown in Fig.1. The 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, EUP-CV524 probe is classified as uncritical.

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



4.1 Point of use (Pre-cleaning)

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

Point of use (Pre-cleaning)

1) Remove the probe 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.

4.2 Containment and transportation

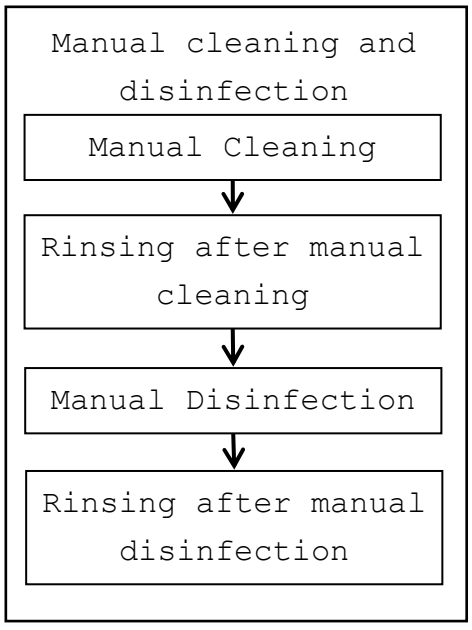
Putting the contaminated equipment into exclusive shock and damage proof container for transportation is recommended. It is recommended that instruments are reprocessed as soon as possible and not later than 4 hours after usage.

Containment and transportation

4.3 Manual Cleaning and disinfection

Prepare following items before manual cleaning and disinfection:

a) Detergent: Cidezyme® (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device.
b) Disinfectant: Cidex® OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device.
c) Two tanks, one for cleaning and one for disinfection - optional:
   1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the submergible part of the probe at full length)
d) Soft, fluff free cloth or single use towel
e) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)



Manual Cleaning:

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

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

2) Immerse the immersible part of the probe without connector into the diluted detergent solution (see Fig. 3). 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-immergible 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. 3) for 5 min.)

6) Visually check the outer surface of the probe for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

Manual disinfection:

1) Prepare the disinfectant solution in a tank with cold water (please follow the instructions of the disinfectant manufacturer regarding application, concentration, microbiological efficiency, service life and contact time).

2) Confirm the concentration of the disinfectant before immersing the probe. Although Cidex® OPA does not need to be diluted, it is recommended to use test strips to verify the concentration. The test strips can indicate whether or not the concentration is above the Minimum Effective Concentration (MEC). Please also note the expiration date of the test stripes. Temperature of disinfectant solution should be minimum 20 °C. The minimum contact time is 5 minutes. If a different disinfectant is used, follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.

3) Immerse the immersible part of the probe into the disinfectant (see Fig. 3). 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. 3) for 5 min.)

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

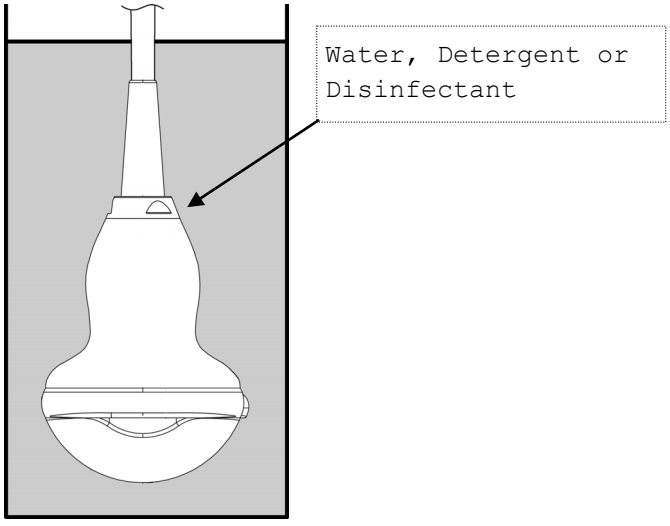


Fig. 3 Immersion of the probe

Drying

4.4 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 probe naturally in an ambient temperature between 15-30°C for a minimum of 4 hours. Alternatively the probe can be dried using a drying heater at a temperature of less than 40°C.

4.5 Inspection

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

4.6 Storage

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

⚠ WARNING

1) Do not sterilize this probe by pressurizing/ depressurizing sterilization system such as ETO and Plasma system. If you sterilize the probe by these systems, the membrane that seals the oil bursts and the probe will not be functional.

2) Do not sterilize this probe by autoclave. If you autoclave the probe, the probe suffers serious damage and will be not functional.

5. Maintenance and Safety Inspection

5.1 Daily Check

1) After using the probe, it should be cleaned and disinfected according to "4. Reprocessing Procedure", store the probe in a cool and dark space to avoid high temperature, humidity and direct sunlight.
2) Visually inspect the surface of the probe head, the housing, the cable and the connector for any crack, scratch or denaturalization. If you find any damage, do not use the probe, and immediately contact a service support.
3) Check whether defects such as mechanical abnormal noise and so on do not occur about the swinging part in the oil case when Real-time 3D mode is selected.

6. Safety Precautions

⚠ WARNING

- Never use the probe if the probe head, housing or cable are cracked or damaged.
- 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 latex-containing medical devices immediately and take an appropriate treatment to the patient.

⚠ CAUTION

- By examination of an early pregnancy the exposure time shall be as short as possible. Start examination with acoustic output power set to L (Low).
- The probe connector is not waterproof. Do not allow liquid to contact the connector.
- Do not drop, hit or bent the probe.
- Use only water, detergents and disinfectants in the suppliers list. Between use store the probe off scanner.
- The probe is not delivered disinfected.

7. Specifications

7.1 Probe

Type	:	EUP-CV524 Convex Array Probe
Center frequency	:	5.0MHz
Technology	:	High density Convex Array Probe
Dimensions	:	See Fig. 4
Weight	:	Approx. 1.0kg (incl. cable and connector)
Scanning angle	:	70° (Refer to Fig. 4)
Volume sweep angle	:	max. 75° (Refer to Fig. 4)
Probe materials	:	Bio-compatible allergy free components
Acoustic output	:	According to IEC60601-2-37 (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.

Operating conditions :

Ambient temperature	;	10 – 35°C
Contact surface temperature (temperature of examinee)	;	max.42°C
Relative humidity	;	30 – 85%

Storage conditions:

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

7.2 Suppliers List

The products listed below are seriously tested and approved for use with the Convex Array Probe EUP-CV524.

Product name	Manufacture	Purpose
ALKAZYME	ALKAPHARM	Cleaner
Klenzyme	KLENZYME	Cleaner
Salvanions ph 7	Laboratories ANIOS	Low-Level Disinfectant
Steranios 2%	Laboratories ANIOS	High-Level Disinfectant
CIDEX	Johnson & Johnson	High-Level Disinfectant
CIDEX plus	Johnson & Johnson	High-Level Disinfectant
CIDEX OPA	Johnson & Johnson	High-Level Disinfectant

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

8. Disposal of the probe

Recycle or dispose this equipment properly in compliance with the Waste Management and Public Cleansing Law.

⚠ CAUTION

Before disposing 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.

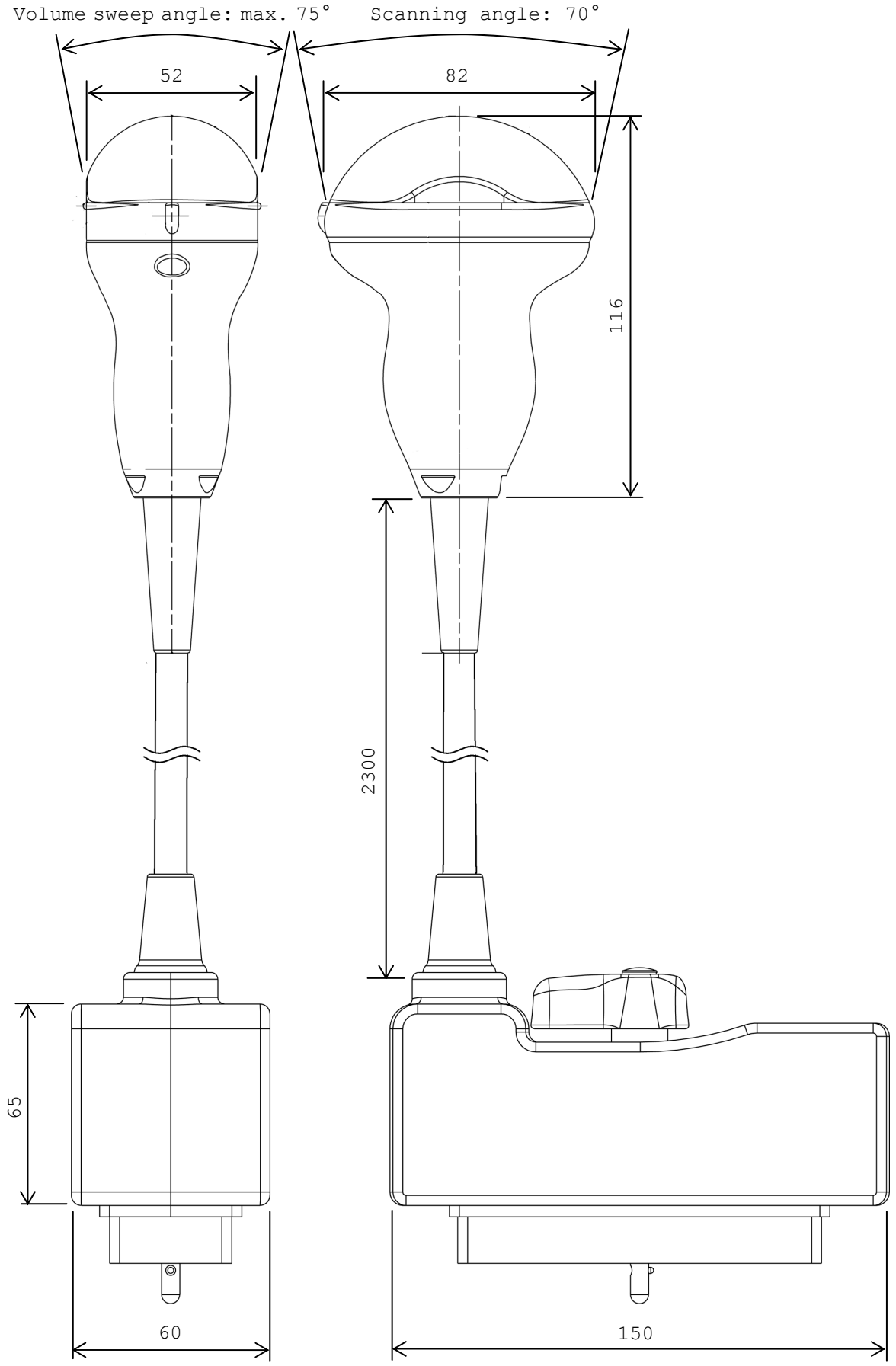


Fig. 4 Dimensions diagram of EUP-CV524

Unit:mm