

Electronic Convex Sector Scanner

ASU-1014

Instruction Manual

MN1-5933 Rev.5

Notes for operators and responsible maintenance personnel

- ★ *Please read through this Instruction Manual carefully prior to use.*
- ★ *Keep this Instruction Manual together with the ultrasound diagnostic instrument for any future reference.*



 **Hitachi, Ltd.**

© Hitachi, Ltd. 2013, 2017. All rights reserved.

Introduction

This is an instruction for model ASU-1014, an ultrasound scanner.

Read the manual carefully before using the instrument. Take special note of the items in section 1, "Safety Precautions".

Keep this manual securely for future reference.

The CE mark on the scanner indicates that this scanner is valid when it is connected to equipment bearing the CE mark that is specified as available in section 2 of this document. Therefore, if a scanner bearing the CE mark is connected to equipment that is specified as available but does not have a CE mark, part of this instruction manual may not apply.

Symbols used in this document

The terms below are used in the safety information provided to prevent hazards and injuries to the operator or patients. The severity of the hazard and injury that can occur when failing to observe the displayed safety information are indicated in four levels: "Danger", "Warning", "Caution" and "Note".

 Danger

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury to the operator or patient.

 Warning
--

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury to the operator or patient.
--

 Caution
--

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the operator or patient, or property damage only.
--

 Note

Indicates a strong request concerning an item that must be observed in order to prevent damage or deterioration of the equipment and also to ensure that it is used efficiently.
--

The type of safety information is indicated by the symbols below.

 This symbol means attention is required.
--

 This symbol means that the described action is prohibited.
--

 This symbol means the described action is mandatory.
--

CONTENTS

1. Safety Precautions	1
1-1. Intended use	1
1-2. Usage precautions	1
1-2-1. Warnings and safety information	2
1-2-2. Cleaning, disinfection and sterilization precautions	3
1-2-3. Labels	4
2. Specifications and Parts name	9
2-1. Principles of operation	9
2-2. Specifications	10
2-3. Performance	11
2-4. Name of each parts	11
2-5. Environmental conditions	12
2-5-1. Operating environmental conditions	12
2-5-2. Storage environmental conditions	12
2-6. Classification of ME equipment	12
3. Preparations for Use	13
3-1. Start up check	13
3-1-1. Visual check	13
3-1-2. Verification of cleaning, disinfection and sterilization	13
3-1-3. Verification of operation	13
4. Usage	15
4-1. Operation	15
4-2. Connecting to the ultrasound diagnostic instrument	16
4-3. Removing from the ultrasound diagnostic instrument	17
4-4. Actions to be taken when an abnormal state is detected	18
4-4-1. Ensuring safety of patients	18
4-4-2. Handling the instrument	18
5. Cleaning, disinfection and sterilization	19
5-1. Precautions for cleaning, disinfection and sterilization	20
5-2. Reprocessing instruction according to ISO 17664	21
5-3. Point of use (Pre-cleaning)	23
5-4. Containment and transportation	23
5-5. Manual cleaning and disinfection	24

5-5-1. Manual cleaning	24
5-5-2. Manual disinfection	25
5-5-3. Cable and connector	25
5-6. Automated cleaning and disinfecting	26
5-7. Applicable cleaners and disinfectants / Suppliers List	27
5-8. Drying	29
5-9. Maintenance, inspection and testing.....	29
5-10. Packaging	29
5-11. Sterilization.....	30
5-11-1. Liquid sterilization (USA only).....	30
5-12. Storage.....	30
6. Storage	31
6-1. Actions before storing the scanner.....	31
6-2. Environmental conditions for storage.....	31
7. Moving and Transporting.....	33
7-1. Moving and transporting.....	33
7-2. Preparing the scanner and accessories for moving.....	33
7-3. Packing for transportation.....	33
7-4. Environmental conditions during transportation	33
8. Periodic Inspection.....	35
8-1. Safety tests.....	35
8-2. Testing of measurement tolerances.....	36
8-2-1. Conducting tests	36
8-2-2. Result judgement	36
9. Configuration	37
9-1. Standard configuration.....	37
10. Disposal of the Device.....	39


This Instruction Manual contains the main body of 40pages and 5pages until the CONTENTS.

1. Safety Precautions

1-1. Intended use

This scanner is intended for use by a doctor or other qualified operator when placed into direct contact with the skin making ultrasonic observations of surrounding organs.

Caution

 Do not use this equipment for other than its intended purpose.
Use for other purposes can cause burns or other injuries to the patient or operator.

1-2. Usage precautions

The terms below are used in the safety information provided to prevent hazards and injuries to the operator or patients. The severity of the hazard and injury that can occur when failing to observe the displayed safety information are indicated in four levels: "Danger", "Warning", "Caution" and "Note".

Danger

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury to the operator or patient.

Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury to the operator or patient.

Caution

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the operator or patient, or property damage only.

Note

Indicates a strong request concerning an item that must be observed in order to prevent damage or deterioration of the equipment and also to ensure that it is used efficiently.











The type of safety information is indicated by the symbols below.





 This symbol means attention is required.




 This symbol means that the described action is prohibited.

 This symbol means the described action is mandatory.








1-2-1. Warnings and safety information



 Warning	
	Follow the information in this manual and the documentation supplied with any equipment used together with this scanner. Use that is not in accordance with the supplied documentation can result in a serious or moderate injury, equipment breakdown, or physical damage that impairs operation.
	Be sure to preparations for use. Use of the scanner while failing to notice an abnormal condition can result in injury to the operator or patient. If any abnormalities are noted on the scanner in the start up inspection, immediately stop using it and contact one of our offices and/or distributor's offices listed on the back cover. See section 3-1 "Start up check" for the start up inspection content and procedure.
	Do not use on the eyes. This scanner is not intended for use on the eyes. The acoustic output can have an adverse effect on the eyes.
	Do not attempt to disassemble, modify, or repair the scanner. Electric shock or other unforeseen accidents could result. Contact one of our offices and/or distributor's offices listed on the back cover to request repair.
	Clean, disinfect and sterilize before using the scanner. Perform proper cleaning, disinfection and sterilization after use. Otherwise, there is a risk of infection. Note that the scanner is not sterilized at the factory. Before using the scanner first, be sure to clean, disinfect and sterilize it.
	Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
	Dispose the scanner used for patients with Creutzfeldt-Jakob disease. Otherwise, there is a risk of infection to the operator or patient. Our scanner is not compatible with any disinfection/sterilization method for Creutzfeldt-Jakob disease.
	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.
	Do not use the scanner fallen on to floor. Otherwise, there is a risk of infection. Stop the operation and perform the procedure in section 8 "Periodic Inspection" section 5 "Cleaning, disinfection and sterilization" and section 3-1 "Start up check".

 Caution	
	Constantly check for anything abnormal about the patient's condition and scanner. Continued use without noticing that an abnormal condition has occurred can result in an electric shock and injury to the operator or patient. If an abnormal condition occurs, immediately move the scanner away from the patient and stop use of the scanner.
	The scanner is vulnerable to damage by impact. Therefore, handle it with care. There is a risk of damage to the scanner when the scanner is fallen or hit somewhere.
	Do not use this scanner 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 scanner and the other equipment.

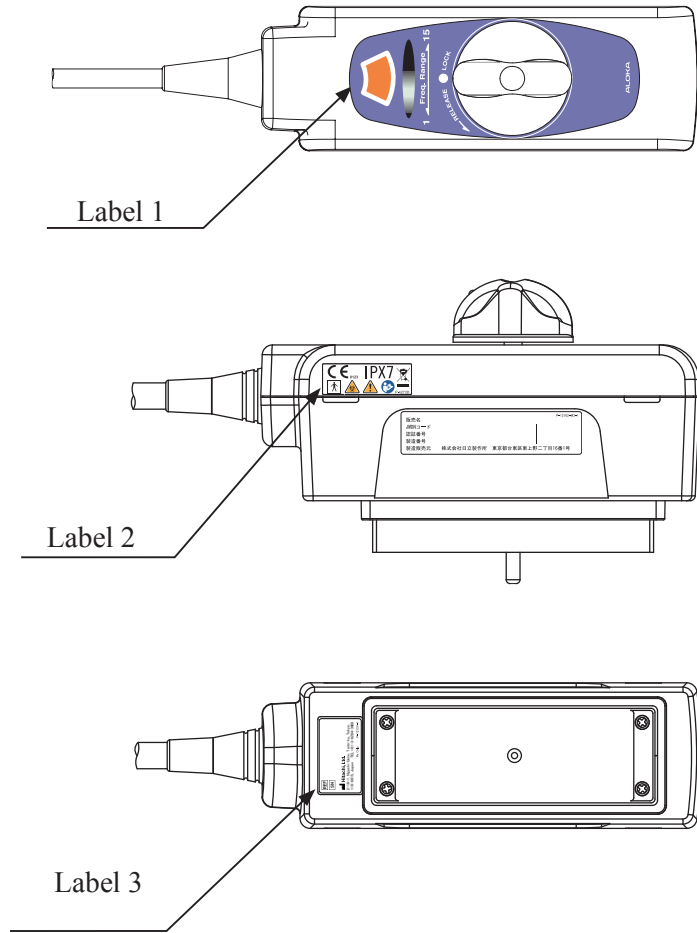
	<p>Scan for the minimum length of time necessary for the diagnosis and at the lowest suitable output. Overuse can adversely affect the internal tissues of the patient. For details about the acoustic output, please refer to the documentation supplied with the ultrasound diagnostic instrument.</p>
	<p>Regularly perform maintenance inspection and safety tests of the ultrasound diagnostic instrument and scanner. If you use equipment for a long period of time, it can reduce the performance, or cause smoke or fire. If anything unusual occurs, immediately stop using it and contact one of our offices and/or distributor's offices listed on the back cover.</p>
	<p>Use, move and transport the scanner under the environmental conditions specified in this manual. Otherwise, it may be damaged. See section 2-5 "Environmental conditions" and section 7-4 "Environmental conditions during transportation".</p>

1-2-2. Cleaning, disinfection and sterilization precautions

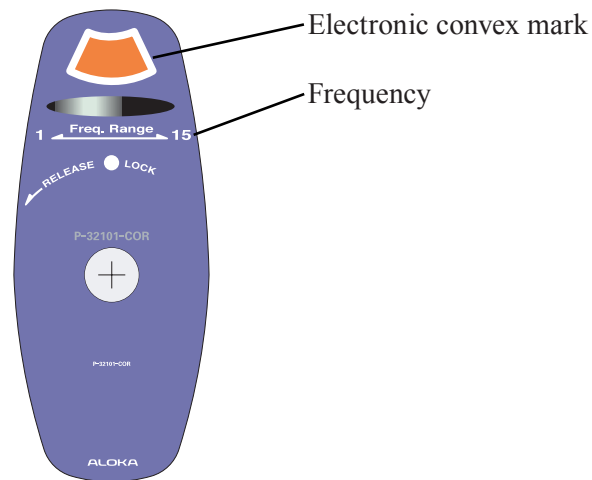
 Warning	
	<p>Wear protective gloves and other protective gear during cleaning, disinfection and sterilization. Handling of the scanner with your bare hands before disinfection can result in an infection.</p>
	<p>After soaking in cleaning agents, thoroughly wash the scanner with running water. Residual cleaning agents can cause an adverse reaction on the bodies of the operator or patient.</p>
	<p>After soaking in a disinfectant, thoroughly wash the scanner with deionized water. Leavings of the disinfectant can cause an adverse reaction on the bodies of the operator or patient.</p>
	<p>Perform aeration completely after gas disinfection. Residual gas can cause an adverse reaction on the bodies of the operator or patient.</p>
	<p>Do not clean, disinfect or sterilize using procedures other than those specified in this manual. Infection could result due to incomplete cleaning, disinfection and sterilization. It can also result in damage to the scanner or reduced performance. The scanner cannot withstand autoclave sterilization or boiling and other types of sterilization at temperatures exceeding 50°C (122°F).</p>
	<p>For details on the usage conditions of chemicals procedures, refer to the documentation supplied with the respective chemical equipment. Infection could result due to incomplete disinfection. This could also cause deterioration of the scanner.</p>

 Caution	
	<p>Do not immerse the probe in any liquids beyond the range of IPX7 shown in section 2-2 "Specifications". Use when liquid has gotten inside the connector can result in a risk of electric shock to the operator or patient. If liquid gets inside the connector, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.</p>

1-2-3. Labels
(1) Scanner unit



Label 1



Label2



This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS.



IPX7 mark
See section 2-2, "Specifications".



Type BF applied part



Do not waste the instrument as general waste. Comply with a local regulation.
See section 10.



Safety warning sign



Biohazard
See section 5.



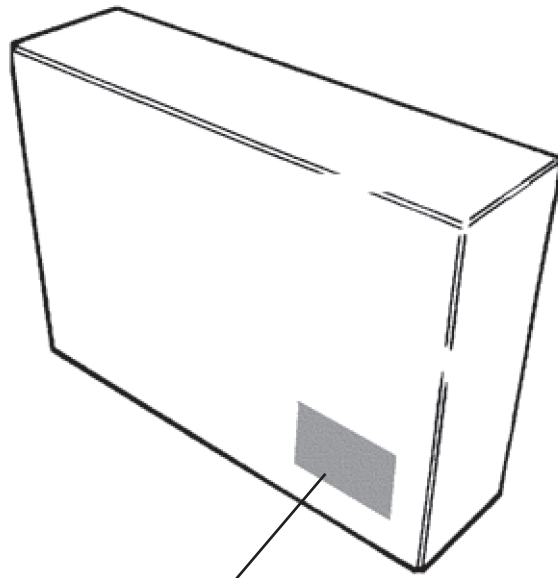
Follow the instruction manual to operate this instrument.
If not avoided, may result in injury, property damage, or the equipment trouble.

Label 3

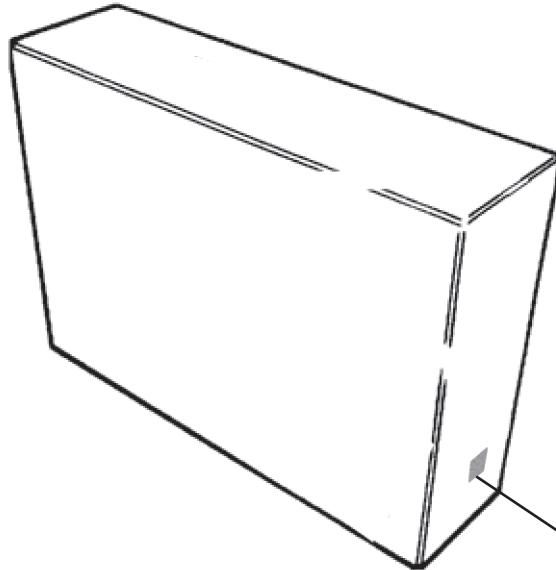


Model
Serial No.
Manufacturer
Address
Rx Only:
By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.

(2) Storage case

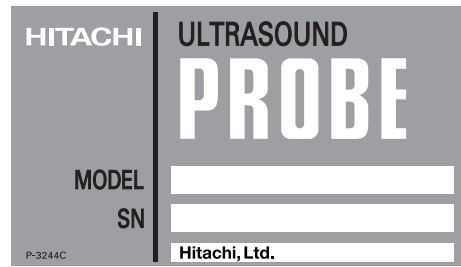


Label A



Label B

Label A



Model
Serial No.

Label B



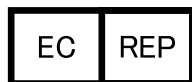
This instrument complies with Directive 93/42/EEC relating to Medical Device and Directive 2011/65/EU relating to RoHS.



DATE OF MANUFACTURE
(in case of 2016-09)



MANUFACTURER



AUTHORISED REPRESENTATIVE IN EUROPEAN
COMMUNITY

2. Specifications and Parts name

2-1. Principles of operation

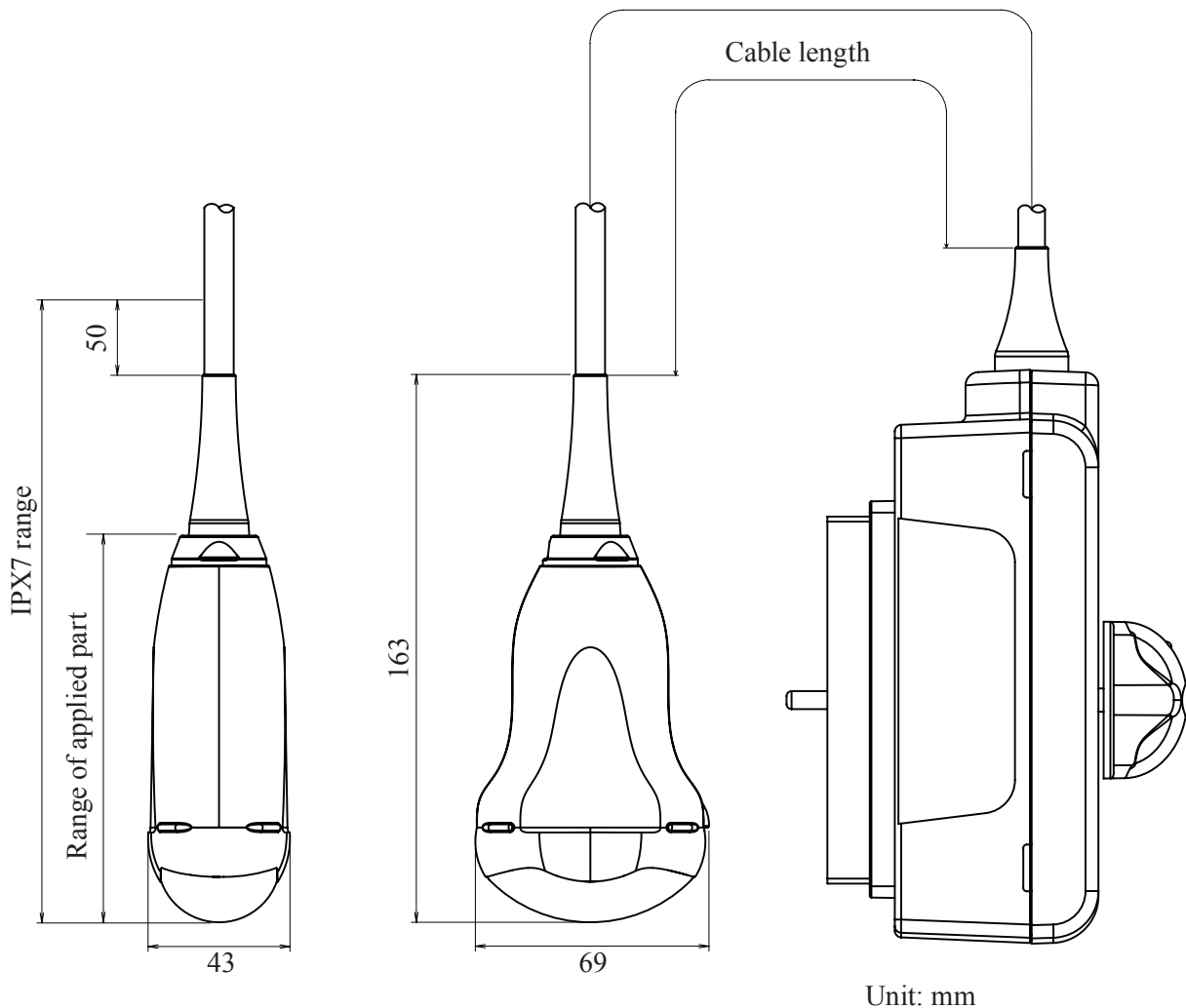
This scanner and the ultrasound diagnostic instrument enable image diagnosis using ultrasonic waves. These instruments operate under the principles described below.

- (1) When an electric pulse signal is applied from the transmitter to the transducer of the scanner, the transducer operates by converting electrical vibrations to mechanical vibration energy for emitting pulse-shaped ultrasonic waves into the body part contacting the transducer or into liquid or other medium.
- (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 vibrations and uses an electro-mechanical conversion operation to convert the received mechanical vibrations to electric energy. The received echo is also converted to electric signals and a brightness modulation operation is used to convert the electric pulses to shades of brightness for forming an image.
- (4) The transducer is moved mechanically to enable changing of the scanning surface for sliced images.

2-2. Specifications

Application regions:	Obstetrics areas
Form of application to patient:	Surface
Connectable instruments:	F37
Electronic scan field of view:	67°
Mechanical scan field of view:	Max 75°
Frequency:	5 MHz ± 30%
Cable length:	2.3 m
Weight:	1,250 g
Service life:	Three years

Range of applied part	As shown in the figure below.
Parts treated as applied parts	Scanner tip itself and 1 m of the cable near the scanner tip.
IPX7 range	As shown in the figure below.
External dimensions:	As shown in the figure below.



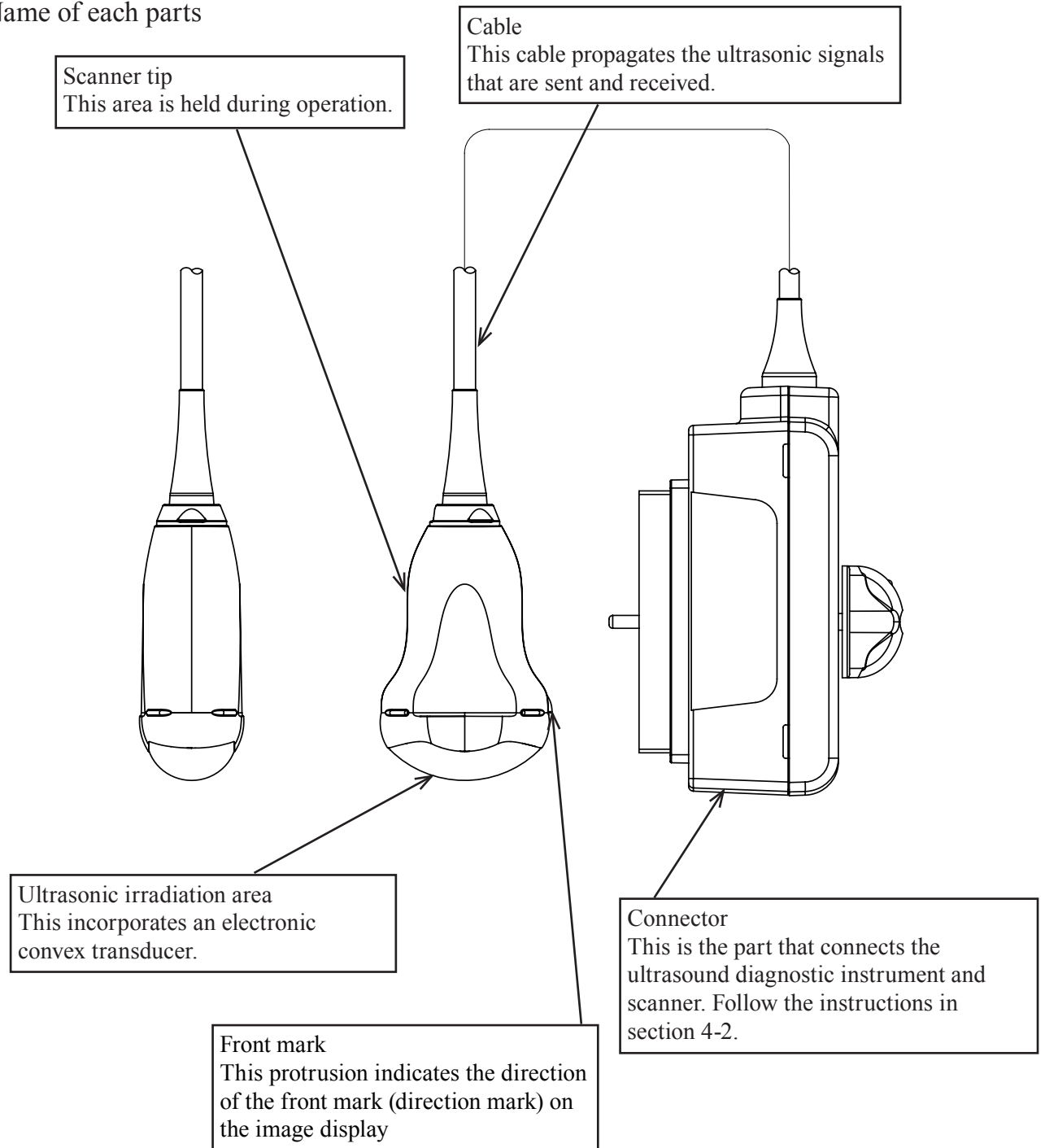
Remarks

The dimensions and weight are within ±10% of the indicated values.

2-3. Performance

For measurement tolerances, operating tolerances and other data, refer to the instruction manual for the ultrasound diagnostic instrument.

2-4. Name of each parts



<p>⚠ Caution</p>	
<p>⊘</p>	<p>Do not pull, bend, twist, or apply excessive force to the cable. The conductors may break and the cable may become unusable.</p>
<p>⊘</p>	<p>Do not subject the ultrasonic irradiation area to hard impact. The impact may cause damage to the transducer, and that results in noise or no echo in the image. In most cases, the ultrasonic irradiation area itself is not damaged because the part is made of plastic material.</p>

2-5. Environmental conditions




Use and store the scanner under the following conditions.

2-5-1. Operating environmental conditions

Ambient temperature:	10°C to 40°C 50°F to 104°F
Relative humidity:	30% to 75%
Atmospheric pressure:	700 hPa to 1060 hPa
Altitude:	3,000 m or less

2-5-2. Storage environmental conditions

Ambient temperature:	-10°C to 50°C 14°F to 122°F
Relative humidity:	10% to 90%
Atmospheric pressure:	700 hPa to 1060 hPa

 Caution	
	<p>Avoid operating or storing the scanner in the following locations.</p> <ul style="list-style-type: none"> • Locations exposed to water or other liquids • Locations subject to adverse conditions such as air pressure, temperature, humidity, ventilation, direct sunlight, dust, or air containing salt, sulfur, or other corrosive substances • Locations where chemical substances are stored or where gases are generated <p>Storage in these locations can result in a breakdown or reduced performance.</p>
	<p>Avoid rapid temperature change which may cause condensation. Avoid using in locations where condensation or water droplets can form.</p> <p>Condensation can occur when moving the scanner from a cool location to a warm one. Use when condensation has occurred can result in a breakdown or reduced performance.</p>

2-6. Classification of ME equipment

- Classification based on degree of protection against electric shock . Type BF applied part
- Classification for protection against ingress of liquids IPX7 (Watertight equipment)
- Operation mode Continuous operation
- Method of disinfection See section 5 “Cleaning, disinfection and sterilization”

For the range of applied parts, parts treated as applied parts and the range of IPX7, see section 2-2.

3. Preparations for Use

3-1. Start up check

3-1-1. Visual check

Visually check the scanner tip, ultrasonic irradiation area, cable and connector.

If any holes, indentations, abrasion, cracks, deformation, looseness, discoloration, or other abnormalities are found, do not use the equipment.

3-1-2. Verification of cleaning, disinfection and sterilization

Verify that cleaning, disinfection and sterilization are conducted according to the intended use.

3-1-3. Verification of operation

Connect to the ultrasound diagnostic instrument by following the instructions in section 4-2, "Connecting to the ultrasound diagnostic instrument" and check that the selected scanner match the convex display and the displayed frequency and check the image for errors.

Verify that there are no abnormal vibrations or noise.

Remarks

For details on the displayed screens, see the documentation supplied with the ultrasound diagnostic instrument.

If the probe is operated in still air, brightness on the top of the image may be non uniform, but this does not affect the performance of the probe.

Warning



Be sure to preparations for use.

Using the scanner without noticing an abnormal condition can result in injury to the operator or patient. If an inspection finds an abnormal condition in the scanner, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.

Caution



Do not use the scanner if the selected scanner and image do not match the frequency.





An incorrect acoustic output can result in burns or other injuries to the patient. Contact one of our offices and/or distributor's offices listed on the back cover.

4. Usage

4-1. Operation

Bring the ultrasonic irradiation area of the scanner into contact with the skin surface. An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. For details on displaying and adjusting the screens, see the documentation supplied with the ultrasound diagnostic instrument.

Caution

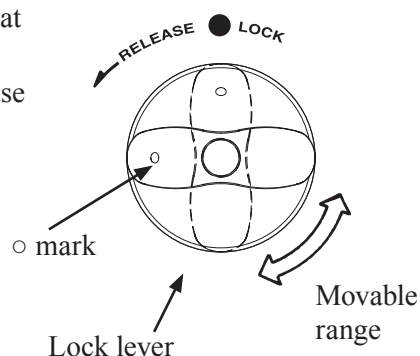
- | | |
|---|---|
|  | Do not move the scanner with excessive force.
Pressing down with more force than necessary can cause injury to the patient. |
|  | Scan for the minimum length of time necessary for the diagnosis and at the lowest suitable output.
There is the possibility that the patient's internal tissues could be affected.
For details about the acoustic output, please refer to the documentation supplied with the ultrasound diagnostic instrument. |
|  | Do not touch the connector terminal pin of the scanner.
The scanner may deteriorate or be damaged due to electrostatic discharge. |
|  | Do not touch the electronic scanner connecting socket of the diagnostic instrument and the patient at the same time.
It can cause electric shock to the patient. |

4-2. Connecting to the ultrasound diagnostic instrument

The lock lever of the connector moves over the range shown in the figure at right.

Align the ○ mark with the LOCK or RELEASE position and lock or release the probe connector.

Connect the scanner to the electronic probe connecting socket of the diagnostic instrument (probe connector) by following the procedure below.



- Connection procedure

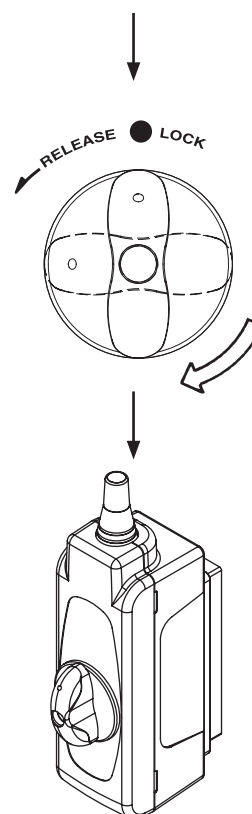
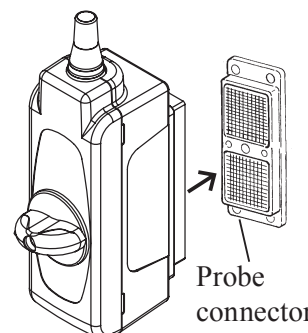
The scanner is connected when in one of the following states.

- The power switch is set to OFF.
- The image displayed on the ultrasound diagnostic instrument is frozen.

Before inserting the scanner into the probe connector, check that the connector pins are not bent.

1. Turn the connector lock lever to align the ○ mark on the lever with the RELEASE position.
2. Firmly insert the connector into the probe connector on the ultrasound diagnostic instrument.
3. Turn the lock lever clockwise by 1/4 turn until the ○ mark is aligned with the LOCK position.
4. Check that the connector is firmly inserted into the probe connector on the instrument.

This completes connection of the scanner.



⚠ Caution

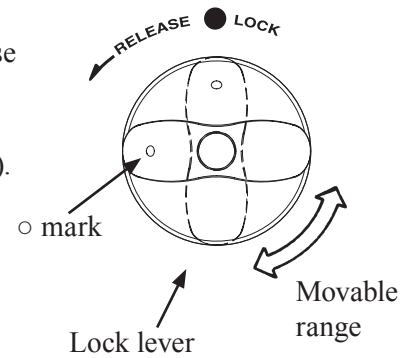
- ❗ If there is resistance when trying to turn the lock lever when connecting the connector, do not forcibly try to connect it. Instead, correctly perform the steps for connecting the connector and firmly insert it into the probe connector.
Forcibly turning the lever may damage the connector and the probe connector on the instrument.

4-3. Removing from the ultrasound diagnostic instrument

The lock lever of the connector moves over the range shown in the figure at right.

Align the ○ mark with the LOCK or RELEASE position and lock or release the probe connector.

Use the procedure below to remove the scanner from the electronic scan probe connector of the ultrasound diagnostic instrument (probe connector).



- Removal procedure

The scanner is removed when in one of the following states.

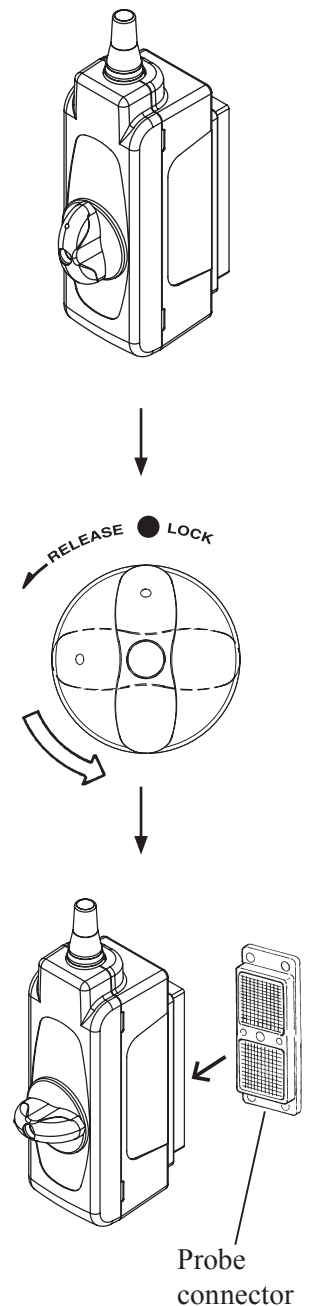
- The power switch is set to OFF.
- The image displayed on the ultrasound diagnostic instrument is frozen.

1. Turn the connector lock lever to align the ○ mark on the lever with the RELEASE position.
2. Firmly grasp the connector unit and pull it out from the probe connector of the ultrasound diagnostic instrument.

This completes the removal of the scanner.

After use, perform cleaning, disinfection and sterilization of the scanner by following the procedure in section 5 “Cleaning, disinfection and sterilization”.

If the scanner will not be used for an extended period of time, store it by following the instructions in section 6 “Storage”.



4-4. Actions to be taken when an abnormal state is detected

4-4-1. Ensuring safety of patients

Immediately move the scanner away from the patient and quit operation.

Keep the patient in safe condition and administer the required medical treatment.

4-4-2. Handling the instrument

Turn off the ultrasound diagnostic instrument, remove its plug from the AC socket and disinfect if it is contaminated. For details, refer to the instruction manual for the ultrasound diagnostic instrument.

 Caution
--



Do not use a scanner where a problem has been found.
--

Using a scanner in an abnormal state can cause injury to the patient. Contact one of our offices and/or distributor's offices listed on the back cover.

5. Cleaning, disinfection and sterilization

Applicable cleaning, disinfection and sterilization methods for each product are listed in the Table 1. The detail of each method is described in Chapter 5-2.

Table 1 Applicable cleaning, disinfection and sterilization methods

Model	Cleaning		Disinfection		Sterilization					Waterproof cover (MP-2790)
	Manual	Automated *1	Manual	Automated *1	EtO	STERRAD®	Liquid *2	Autoclave	STERIS®	
ASU-1014	X		X				X			









Note: X means “Applicable”






*1: Automated Need waterproof cover

*2: Liquid sterilization USA only

5-1. Precautions for cleaning, disinfection and sterilization

The following warnings and cautions must be observed when cleaning, disinfecting and sterilizing the scanner and accessories.

 Warning	
	Wear protective gloves and other protective gear during cleaning, disinfection and sterilization. Handling of the scanner with your bare hands before sterilization can result in an infection.
	After finishing soaking the scanner in cleaning agents, thoroughly wash it with running water. Residual cleaning agents can cause an adverse reaction to the operator or the patient.
	After chemical sterilization, thoroughly wash the scanner with sterile water. Residual chemicals can cause an adverse reaction to the operator or patient. (USA only)
	After disinfecting the scanner, thoroughly wash the scanner with deionized water. Residuals of the disinfectant can cause an adverse reaction on the bodies of the operator or patient. (EU only)
	Perform full aeration after gas sterilization. Residual gas can cause an adverse reaction to the operator or patient.
	Do not clean or sterilize using procedures other than those specified in this manual. Failure to clean and sterilize the equipment can result in an infection. It can also result in damage to the scanner or reduced performance. The scanner is not compatible with autoclave sterilization or boiling and other types of sterilization at temperatures exceeding 60°C [140°F].
	For details on the usage conditions of chemicals and sterilization procedures, refer to the documentation supplied with the respective chemical or sterilization equipment. Infection can be resulted due to incomplete sterilization. Wrong sterilization procedure could cause deterioration of the scanner.

 Caution	
	Do not immerse the scanner into any liquid beyond the range of IPX7. The range is indicated in the section 2-2 "specification". If any liquid enters the connector, immediately stop using the scanner and contact one of our offices and/or distributor's offices listed on the back cover. Liquid in the connector could cause electric shock to the operator or patient.
	Do not wipe the ultrasonic radiation part with alcohol. Alcohol could damage the part.
	Do not use organic solvent such as thinner for cleaning to prevent the scanner from damage.
	Do not use hard or sharp objects to remove residue on the scanner. Such objects may damage the scanner.

Additional information:

The Instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, material and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

5-2. Reprocessing instruction according to ISO 17664

Take care about clean circumstances before using the scanner on the next patients. If processors reprocess this equipment, refer to these instructions.

Table 1

WARNINGS	<ul style="list-style-type: none"> • The scanner is delivered unsterile. Prior to the first use, reprocess the scanner. • Do not exceed 60 °C [140 °F]. • Scanner connector has no water resistance.
Limitations on reprocessing	The scanner is not completely submersible (Do not immerse the scanner into any liquid beyond the range of IPX7. The range is indicated in the section 2-2 "specification".) Parts which are not submersible can only be disinfected by wipe disinfection.
Transportation before using	Sterile pouch or container should be kept between transportation from Central Sterile Supply Department (CSSD) to operating room. Be careful that no damages are applied to sterile pouch or container for transportation.

The level of processing required depends on the type of equipment and its use.

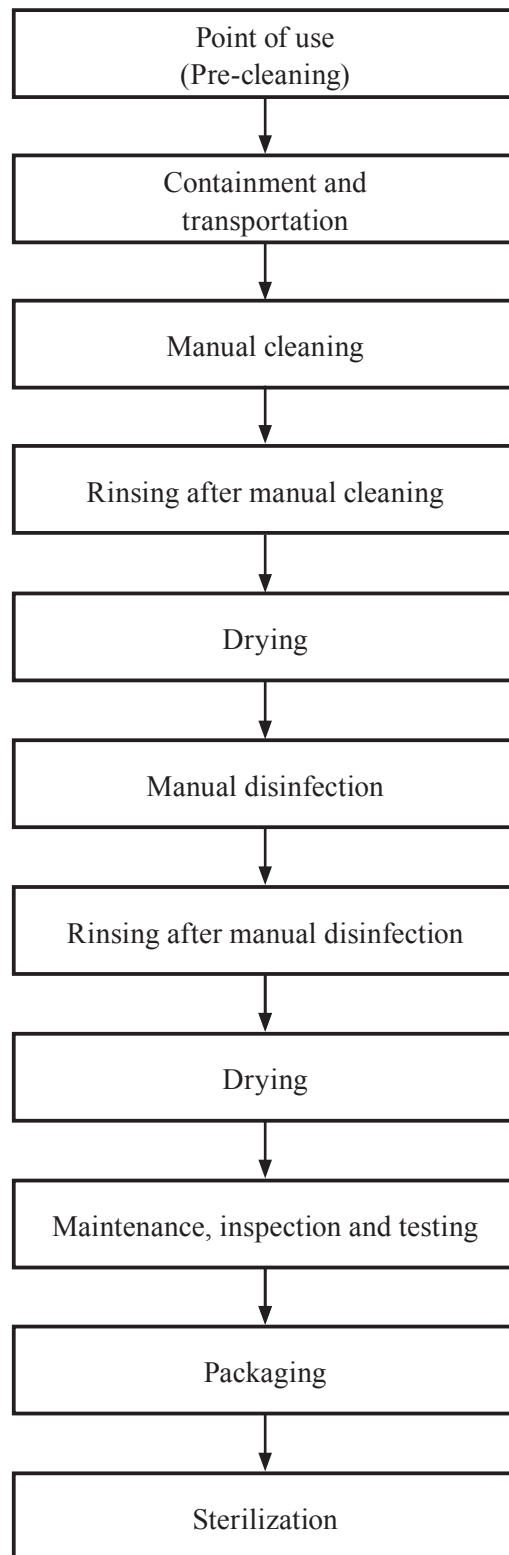
The CDC (Centers for Disease Control and Prevention) in the USA and the RKI (Robert Koch Institute) in Germany classify medical devices according to their use. For each classification, they specify the level of disinfection/sterilization processing that is required before use. Table 3 summarizes this information.

Table 2

Classification	Definition	Processing
Noncritical	Application part only contacts intact and uninjured skin	Cleaning ↓ Disinfection [in the USA, low-level disinfection]
Semicritical	Application part contacts mucosa (intracavitary application)	Cleaning ↓ Disinfection (Disinfectant with bactericidal, fungicidal and virucidal effect) [in the USA, high-level disinfection or sterilization]
Critical	Application part contacts intracorporeal tissue directly (intraoperative application)	Cleaning ↓ Disinfection ↓ Sterilization * ¹

*¹. When sterilization is not possible, the FDA in the USA recognize that disinfection (in the USA, high-level disinfection) and the use of a sterile gel and sterile transducer cover, as described in the instructions provided with the transducer cover, is an accepted method of infection control for scanner.

Flowchart of reprocessing process of this scanner is as follows:



5-3. Point of use (Pre-cleaning)

In the operating room after use of the scanner

Scanner

- 1) Flush patient's blood or fluid by tap water directly after use until the surface looks visually clean.
- 2) Wipe the whole surface of the scanner by gauze pad and remove superficial visible impurities until the surface looks visually clean.

5-4. 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.

 Caution
 Do not immerse the probe in any liquids beyond the range of IPX7 shown in section 2-2 "Specifications". Use when liquid has gotten inside the connector can result in a risk of electric shock to the operator or patient. If liquid gets inside the connector, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.

5-5. Manual cleaning and disinfection

Prepare following items before manual cleaning and disinfection.

Scanner

- 1) Detergent: ENZOL[®]/Cidezyme[®] (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device.
- 2) Disinfectant: Cidex[®] OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device.
- 3) 2 tanks, 1 for cleaning and 1 for disinfection - optional: 1 additional tank for rinsing with deionized/tap water. (sufficient size for immersion of the submergible part of the scanner at full length)
- 4) Soft, fluff free cloth or single use towel
- 5) 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)

5-5-1. Manual cleaning

Scanner


- 1) The temperature of the detergent solution should be between 15-30 °C [59-86 °F], 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 consider the approved material compatibility for this scanner.
- 2) Immerge the submergible part of the scanner (see figure) without connector into the detergent.
- 3) Wipe the submergible part of the scanner under the surface of the detergent solution with a single-use, fluff free soft cloth to remove all visible soil. Be sure that all grooves of the scanner are implemented during the cleaning process. If necessary use an appropriate cleaning brush for this purpose.
- 4) Wipe the non-submergible parts of the scanner with a soft cloth dipped with a detergent.
- 5) Rinse the submergible part of the scanner with running tap water for 1 minute.
- 6) Alternatively to step 5 suspend the submergible part of the scanner in a tray filled with deionized water/tap water for 5 min.
- 7) Visually check the outer surface of the scanner for cleanness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

5-5-2. Manual disinfection


Scanner

- 1) Before immersing the equipment, it is recommended to test the concentration of disinfectant solution before each usage. The solution Cidex® OPA is ready for use and does not need to be diluted. Test strips to verify that the appropriate concentration of Cidex® OPA is correct are available by manufacturer. Test strips will indicate a concentration above the Minimum Effective Concentration (MEC). Temperature of disinfectant solution should be minimum 20 °C[68 °F]. The minimum contact time is 5 minutes. If a differing disinfectant is used follow the manufacturer's instructions. Please also consider the material compatibility for the medical device.
- 2) Wipe the non-submergible parts of the scanner with a soft and fluff free cloth with disinfectant.
- 3) Immerge the submergible part of the scanner (see figure) into the disinfectant. Set a clock to insure the recommended contact time is observed.
- 4) Rinse the submergible part of the scanner with running deionized water for 1 minute.
- 5) Alternatively to step 4 suspend the submergible part of the scanner in a tray filled with deionized water for 5 min.
- 6) Visually check the outer surface of the scanner for that there are no leavings of the disinfectant. If necessary, repeat the rinsing.

 Caution
--

- | |
|---|
|  Do not wipe the ultrasonic radiation part with alcohol.
Alcohol could damage the part. |
|---|

 Warning
--

- | |
|---|
|  After finishing soaking the scanner in the cleaning agent or disinfectant, thoroughly rinse it with running water (after cleaning) and deionized water (after disinfection). Residual agent can cause an adverse reaction to the operator or patient. |
|---|

5-5-3. Cable and connector



Wipe the cable in 20 cm intervals with gauze dipped in ethyl alcohol or water, and dry it after wiping. Clean the connector with gauze dipped in ethyl alcohol, and dry it after cleaning. Clean the other parts of the scanner which must not be soaked in liquid in the same manner as the connector.

 Note

If the entire length of the cable is wiped at once, a part of the cable may be wrinkled. If this occurs, pull the wrinkled part in the opposite direction to smooth it.

5-6. Automated cleaning and disinfecting

Scanner

 Warning
 The scanner cannot withstand Automated cleaning and disinfecting.

5-7. Applicable cleaners and disinfectants / Suppliers List

The applicable chemical solutions are listed below.

General name	Trade name	Manufacturer
Enzyme cleaning agent	ENZOL [®] /Cidezime [®] Practical liquid 0.8V/V%	ADVANCED STERILIZATION PRODUCTS [®] A Johnson & Johnson company Division of Ethicon, Inc.
Alkylpolyalkylenglykoether	Korsolex [®] Endo-Cleaner	BODE Chemie GmbH



General name	Trade name	Manufacturer
Glutaral	CIDEX [®] Solution 2.4%	ADVANCED STERILIZATION PRODUCTS [®] A Johnson & Johnson company Division of Ethicon, Inc.
Ortho-phthalaldehyde	CIDEX [®] OPA Solution 0.55%	
Glutaral	Cidex plus [®]	
Glutaral	STERIHYDE [®] * Practical liquid 2W/V%	Maruishi Pharmaceutical Co., Ltd.
Benzethonium chloride	Hyamine [®] * Practical liquid 0.1W/V%	DAIICHI SANKYO Co., Ltd.
Didecyl dimethylammonium chloride	Cleanisept [®] Wipes * Solution 7.5%	Dr. Schumacher GmbH
Hydrogen peroxide	ANIOXYDE 1000 * Solution 0.15%	Laboratories ANIOS
Dimethyl-dioctyl-ammonium-chloride	Gigasept [®] AF forte * Solution 2.0%	Schülke & Mayr
Glutaral	Korsolex extra *	BODE Chemie GmbH
Glutaral	Korsolex Endo-Disinfectant	BODE Chemie GmbH

Note: * indicates that the marked disinfectant is not applicable in Canada.

High-level disinfection

General name	Trade name	Manufacturer
Hydrogen peroxide	PERASAFE™* Practical liquid 1.62W/V%	ANTEC INTERNATIONAL
Peracetic acid	Acecide®* Solution 6%	Saraya Co., Ltd.
Glutaraldehyde	WAVICIDE®-01* Solution 2.65%	Medical Chemical Corporation
Glutaraldehyde	STERANIOS* Solution 2.0%	Laboratoires ANIOS
Glutaral	Cidex plus® Solution 3.4%	ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc.

Note: * indicates that the marked disinfectant is not applicable in Canada.

 Warning
 After disinfection, thoroughly rinse the scanner with deionized water. Residual disinfectant can cause an adverse reaction to the operator or patient.

5-8. Drying

Scanner

- 1) Wipe the scanner with single use, fluff free wipe or towel for removing moisture on the surface of the equipment.
- 2) If using drying heater for medical equipment, the temperature limit is a maximum of 60 °C [140 °F]. Dry until no visible moisture is left.
- 3) If using natural drying, temperature range should be between 15-30°C[59-86°F] for a minimum time of 4 hours.

5-9. Maintenance, inspection and testing

Confirm following items

- 1) the function of mechanical moving parts
- 2) the image performance when the scanner is connected to the scanner
- 3) there are no abnormal exterior damages such as cracks on the surface of the equipment
- 4) Safety tests (See section 8-1)

5-10. Packaging

Store the disinfected scanner in a dustproof environment until next application. Before sterilization it is necessary to pack all parts in a pouch suitable for sterilization, or in a tray with wrap according to ISO 11607-1 and ISO 11607-2 “Packaging for terminally sterilized devices” and ISO/TS 16775 “Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2” or the local hospital procedure. Follow the pouch manufacturer’s specifications or the local regulations for how to pack and seal the pouches.

Check the sealing seam after heat sealing for any defects. In case of processing mistakes or defects the package has to be opened again and the device has to be packed and sealed again.

5-11. Sterilization



See “Table 1. Applicable cleaning, disinfection and sterilization methods” for available sterilization methods. Follow the instructions of the sterilizer manufacturer regarding usage, temperature and sterilization-time etc. Handling and maximum input to chamber of sterilizer should be according to operation manual of the sterilizer.

5-11-1. Liquid sterilization (USA only)

- Applicable chemical solution for sterilization
The applicable sterilants are listed below.

General name	Trade name	Manufacturer
Hydrogen peroxide	PERASAFE® * Practical liquid 1.62W/V%	ANTEC INTERNATIONAL
Peracetic acid	Acecide® * Solution 6%	Saraya Co., Ltd.
Glutaraldehyde	WAVICIDE®-01 * Solution 2.65%	Medical Chemical Corporation
Glutaraldehyde	STERANIOS * Solution 2.0%	Laboratoires ANIOS
Glutaral	Cidex plus® Solution 3.4%	ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc.

Note: * indicates that the marked sterilant is not applicable in Canada.

 Warning
 After chemical sterilization, thoroughly rinse the scanner with sterile water. Residual sterilant can cause an adverse reaction to the operator or patient.

5-12. Storage

For details about the storage environmental conditions, see section 2-5-2 “Storage environmental conditions”.

6. Storage

6-1. Actions before storing the scanner

When the scanner will not be used for an extended period of time, perform the procedures described in section 5 "Cleaning, disinfection and sterilization" and then store it in its storage case.

6-2. Environmental conditions for storage

For details about the storage environmental conditions, see section 2-5-2 "Storage environmental conditions".

7. Moving and Transporting

7-1. Moving and transporting

In this section, *moving* refers to "carrying of the scanner within a facility" and *transporting* refers to "transferring using a vehicle or sending the scanner for repairs".

7-2. Preparing the scanner and accessories for moving

Store in the storage case after performing the procedure in section 5 "Cleaning, disinfection and sterilization".

7-3. Packing for transportation

Store in the storage case after performing the procedure in section 5 "Cleaning, disinfection and sterilization" and then put the storage case in a cardboard box for additional protection.

7-4. Environmental conditions during transportation

Ambient temperature: -10°C to 50°C
14°F to 122°F
Relative humidity: 10% to 90%
Atmospheric pressure: 700 hPa to 1060 hPa

 Note
The scanner is a precision equipment and is vulnerable to physical impact. Protect it by packing it properly for transportation.
Contact one of our offices and/or distributor's offices listed on the back cover when transporting the scanner.

8. Periodic Inspection

8-1. Safety tests

The safety tests should be conducted at least once a year by a qualified technician. The test record should be stored for future reference.

Remarks 1

Qualified technician: personnel for conducting safety tests of medical electrical equipment.

If the user requires an appropriate qualified technician, service personnel trained by us can conduct a test at the user's expense. Contact one of our office written on the back cover.

Remarks 2

Make a copy of the Safety Inspection Data Sheet provided in the instruction manual of the ultrasound diagnostic instrument. Use the sheet as a test record.

Procedure for periodic safety tests and judgment

(1) Test of patient leakage current from the patient connection to earth

Using the measuring instruments which usable to the requirement of IEC 60601-1 :2005, conduct the test as shown in Fig. 15 of IEC 60601-1 :2005.

Soak the scanner tip in saline solution and measure the leakage current between the applied part and earth.

Do not soak scanners in saline solution beyond the "IPX7 range" provided in section 2-2.

(2) Test of patient leakage current caused by an external voltage on the patient connection of an F-type applied part.

Using the measuring instruments which usable to the requirement of IEC 60601-1 :2005, conduct the test as shown in Fig. 16 of IEC 60601-1 :2005.


Soak the scanner tip in saline solution and measure the leakage current between the applied part and earth.

Do not soak scanners in saline solution beyond the "IPX7 range" provided in section 2-2.

Item	Normal condition	Single fault condition
(1) Patient leakage current from the patient connection to earth DC AC	10 μ A or less 100 μ A or less	50 μ A or less 500 μ A or less
(2) Patient leakage current caused by an external voltage on the patient connection of an F-type applied part	/	5000 μ A or less

Table. Standard Values for Periodic Safety tests
(Extract from IEC 60601-1 :2005)

Warning

 Perform a safety tests at least once a year and keep a record of the inspection results. Failure to notice an abnormal condition while using the scanner can result in injury to the operator or patient. If an inspection finds an abnormal condition in the scanner, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.

8-2. Testing of measurement tolerances

Perform the measurements specified below using an ultrasonic phantom* at least once per year. The test record should be stored for future reference.

- Sensitivity
- Resolution

Remarks

Make a copy of the Measurement accuracy inspection data sheet provided in the instruction manual for the ultrasound diagnostic instrument. Use the sheet as a test record.

* The ultrasonic phantom is made of a substance which is similar to human tissue in terms of its response to ultrasonic waves.

Regions with different textures and targets spaced at preset intervals are embedded in the phantom. Some phantoms contain a mechanism for Doppler measurement. The phantom is used to check the performance of the scanner and ultrasonic diagnostic instrument, as well as to adjust the image settings.

8-2-1. Conducting tests

Some types of ultrasonic phantoms have targets with narrow gaps between them for confirming the resolution.

This enables you to check the level of detail that images can be viewed on the display. For phantoms with no targets, the resolution determines the fineness of the displayed textures. The sensitivity can be determined by examining the luminance of ultrasonic images. Other factors that affect the resolution include the type of connected scanner, gain, focus and recording instrument. The specific testing conditions must be recorded in detail to enable proper comparison at the next inspection.

8-2-2. Result judgement

Compare the currently-obtained value with the value recorded at the last test. If there is a significant difference between the two values, the current value is considered to be abnormal.

It is important to note that the resolution varies depending on the type of ultrasonic phantom and phantoms generally deteriorate over time.

Caution



Do not use a scanner or ultrasound diagnostic instrument where a problem has been found. This can result in an incorrect diagnosis. Contact one of our offices and/or distributor's offices listed on the back cover.

9. Configuration

9-1. Standard configuration

Scanner	ASU-1014.....	1 set
Storage case	CB-UST1-P1.....	1 set
Instruction manual	MN1-5933.....	1 copy

10. Disposal of the Device

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.



■ 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>

Overseas Offices:



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

Distributor