

Transvaginal Electronic Convex Sector Scanner

ASU-1012

Instruction Manual

MN1-5179 Rev.16

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.**

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## Introduction

This is an instruction for model ASU-1012, 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".

 <b>Danger</b>
---

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

 <b>Warning</b>
--

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

 <b>Caution</b>
--

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.
--

 <b>Note</b>
---

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.
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 This symbol means the described action is mandatory.
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This Instruction Manual contains the main body of 44pages 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 for inserting into a human vagina and making ultrasonic observations of the uterus and 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








 <b>Warning</b>	
	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".




 <b>Caution</b>	
	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. Option usage precautions

 <b>Warning</b>	
	Use by covering the rubber boot over the insertion portion. If the rubber boot is not used, residual pathogens on the scanner could infect the patient.
	Use Hitachi-approved rubber boots only. Use of an item lacking biocompatibility can cause an adverse reaction of the human body.
	Check that the rubber boot is sterilized. Use of an infective item could spread infection to the patient.
	Do not reuse the rubber boot. Use of an infective item could spread infection to the patient.
	Do not apply unsterilized acoustic medium to the outer surface of the rubber boot. Use of an acoustic medium that is contaminated by a pathogen can cause an infection on the patient.
	Do not use on patients who may have an allergic reaction to latex products. Use of the rubber boot for these types of patients could result in anaphylactic shock. Ask the patient about allergy history beforehand.

 <b>Caution</b>	
	Check the rubber boot for abnormalities before use. Store the rubber boots in a cool, dry location not exposed to direct sunlight and do not use rubber boots that have exceeded their expiration date (for items where the expiration date is not displayed; 2 years from the displayed sterilization date). Also do not use the rubber boot when there are severe discolorations, cracks or other visible effects.
	Check that the acoustic medium has no air bubbles inside the rubber boot that is covering the scanner. Air bubbles inside the rubber boot can result in misdiagnosis caused by overlooking or misinterpreting lesions due to poor image quality or improper rendering.

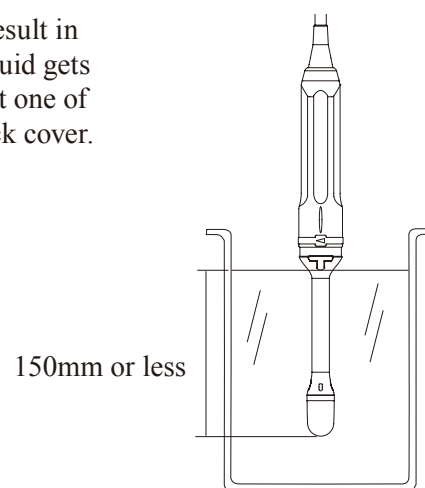
## 1-2-3. Cleaning, disinfection and sterilization precautions

**⚠ Warning**

- !** Wear protective gloves and other protective gear during cleaning, disinfection and sterilization. Handling of the scanner with your bare hands before disinfection or sterilization can result in an infection.
- !** 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.
- !** After soaking in a disinfectant, thoroughly wash the scanner with deionized water. Residuals of the disinfectant can cause an adverse reaction on the bodies of the operator or patient.
- !** Perform aeration completely after gas disinfection. Residual gas can cause an adverse reaction on the bodies of the operator or patient.
- ⊘** 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 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 could result due to incomplete disinfection or sterilization. This could also cause deterioration of the scanner.

**⚠ Caution**

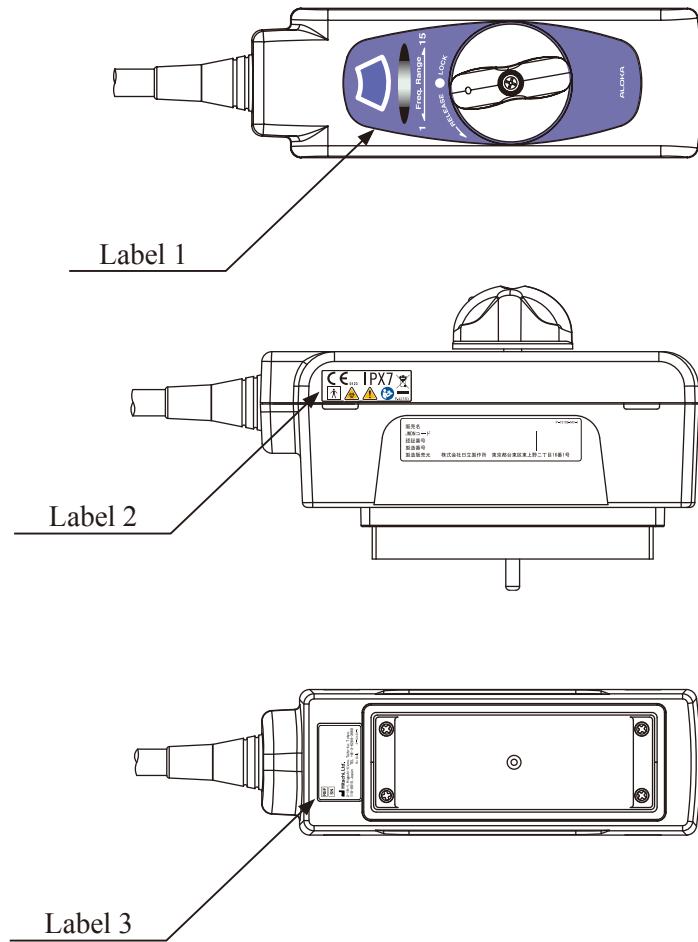
- ⊘** Do not place the insertion portion and handle in any liquids beyond the range shown in the figure right. Use when liquid has gotten inside the connector can result in a risk of electric shock to the operator or patient. If liquid gets inside the connector, immediately stop use and contact one of our offices and/or distributor's offices listed on the back cover.



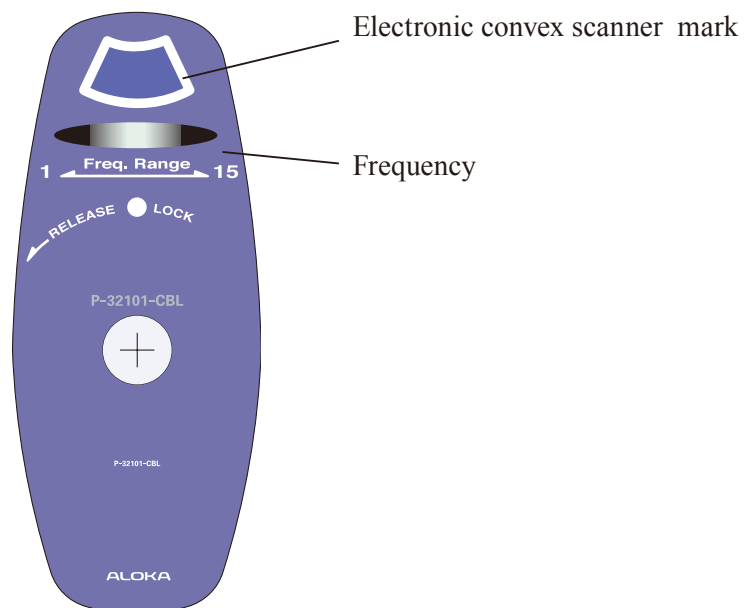
Water or chemical solution

1-2-4. Labels

(1) Scanner unit



Label 1



Label 2



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.



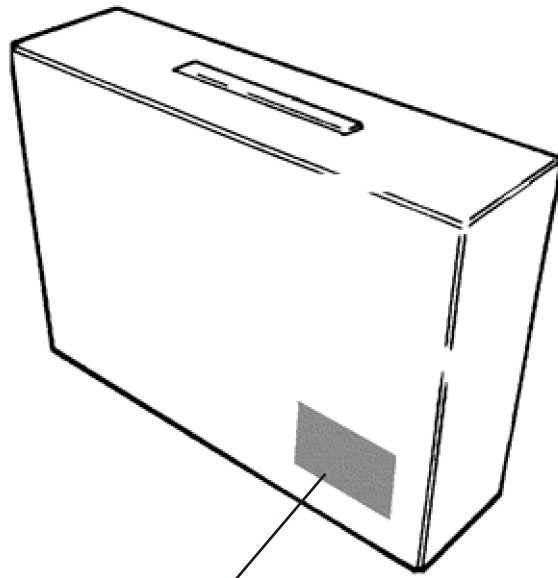
Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.

Label 3

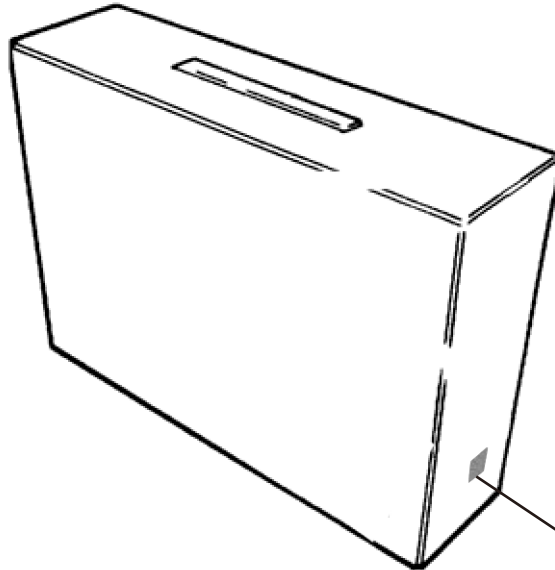


Model  
Serial No.  
Manufacturer  
Address  
Rx Only:  
By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.

(2) Storage case

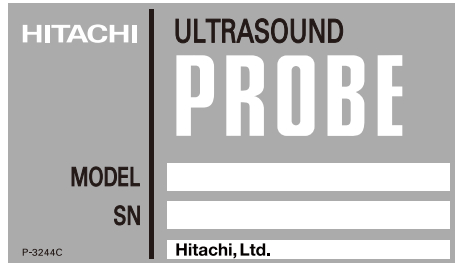


Label A



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)



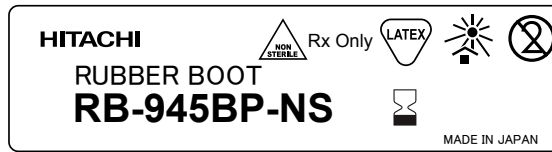
MANUFACTURER



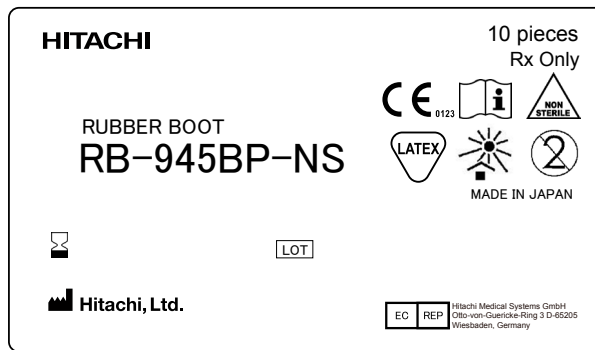
AUTHORISED REPRESENTATIVE IN EUROPEAN  
COMMUNITY

(3) Rubber boot

Label for 1 piece



Label for 10 pieces



Non sterile



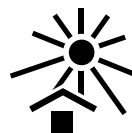
Contains or presence natural rubber latex



Use by



Do not reuse



Keep away from sunlight



Lot number

Rx Only

By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.



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## 2. Specifications and Parts name

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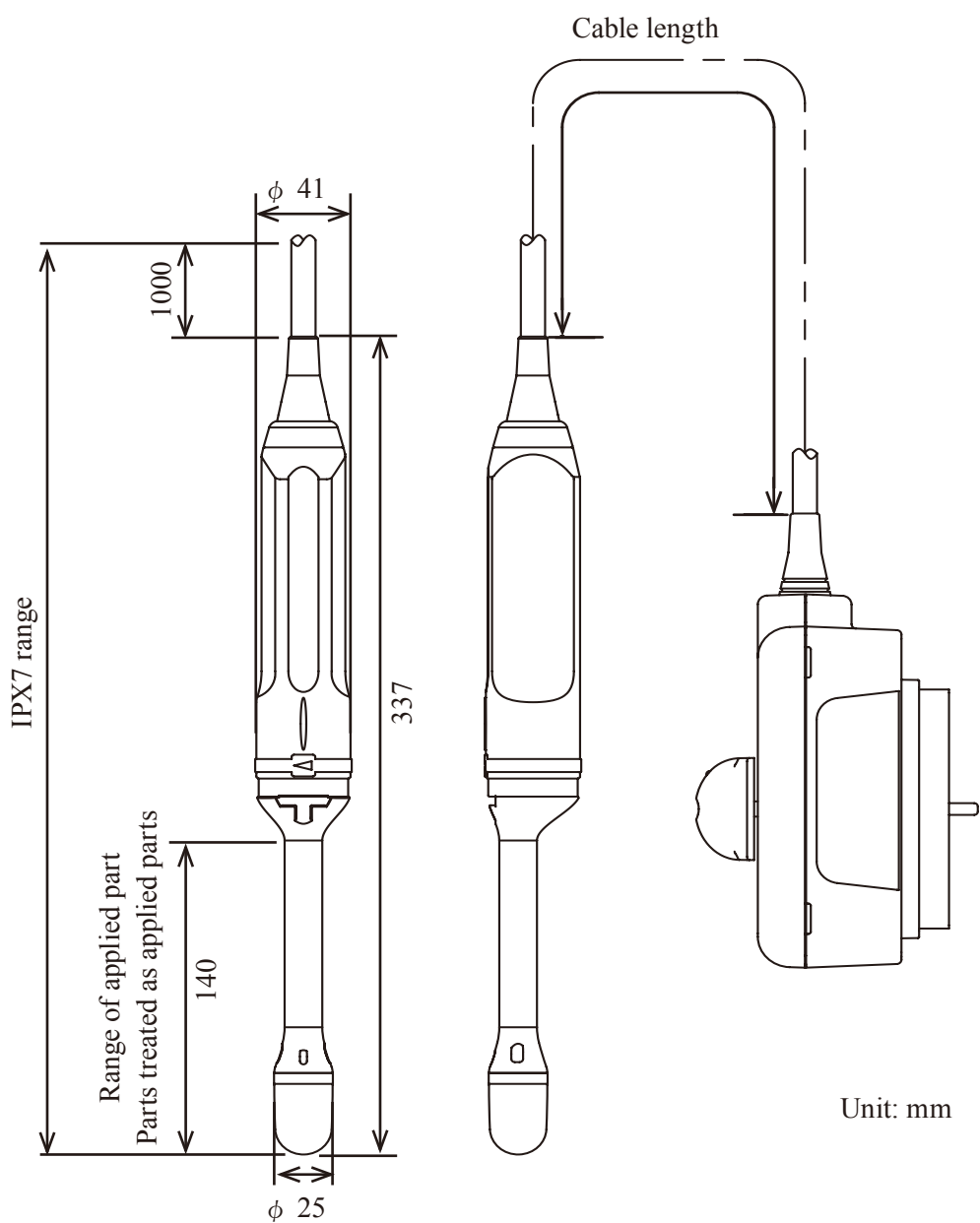
### 2-1. Principles of operation

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:	Obstetric and gynecological areas
Form of application to patient:	Transvaginal
Connectable instruments:	SSD- $\alpha$ 10, Prosound $\alpha$ 7, Prosound $\alpha$ 6, Prosound F75, F37
Electronic scan field of view:	140 °
Mechanical scan field of view:	90 °
Frequency:	6 MHz
Cable length:	2.0 m
Weight:	1,350 g
Service life:	Three years
Range of applied part	As shown in the figure below.
Parts treated as applied parts	As shown in the figure below
IPX7 range	As shown in the figure below.
External dimensions:	As shown in the figure below.



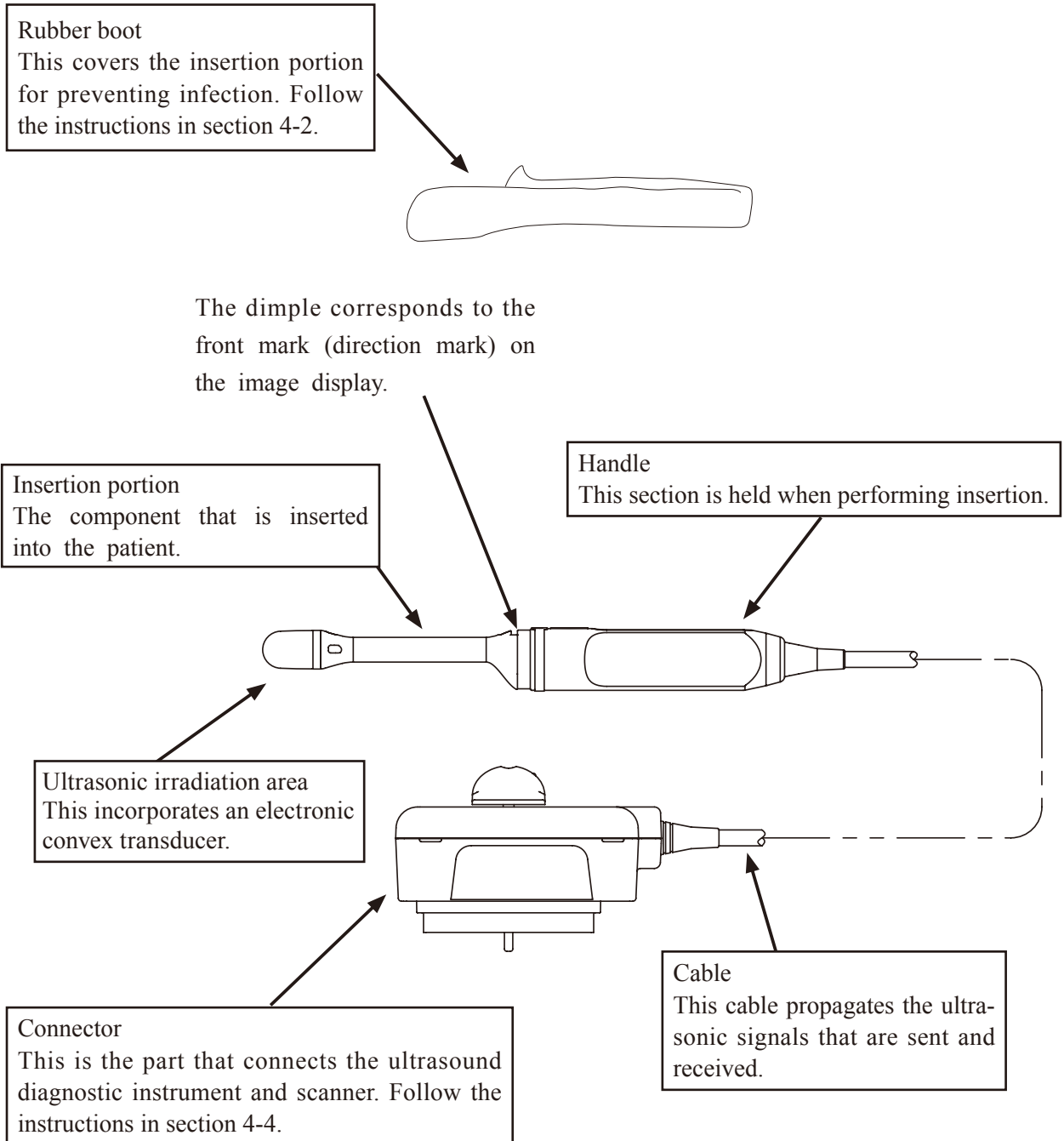
### Remarks

The dimensions and weight are within  $\pm 10\%$  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><b>⚠ Caution</b></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 radiation part 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 radiation part 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:	15°C to 40°C 59°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:	0°C to 50°C 32°F to 122°F
Relative humidity:	10% to 90%
Atmospheric pressure:	700 hPa to 1060 hPa

#### Caution

 Avoid operating or storing the scanner in the following locations.

- 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

Storage in these locations can result in a breakdown or reduced performance.

 Avoid rapid temperature change which may cause condensation. Avoid using in locations where condensation or water droplets can form.

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.

## 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 sterilization ..... 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 insertion portion, handle, 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 4-4, "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

Check that the rubber boot is mounted and insert the scanner into the vaginal cavity. 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.

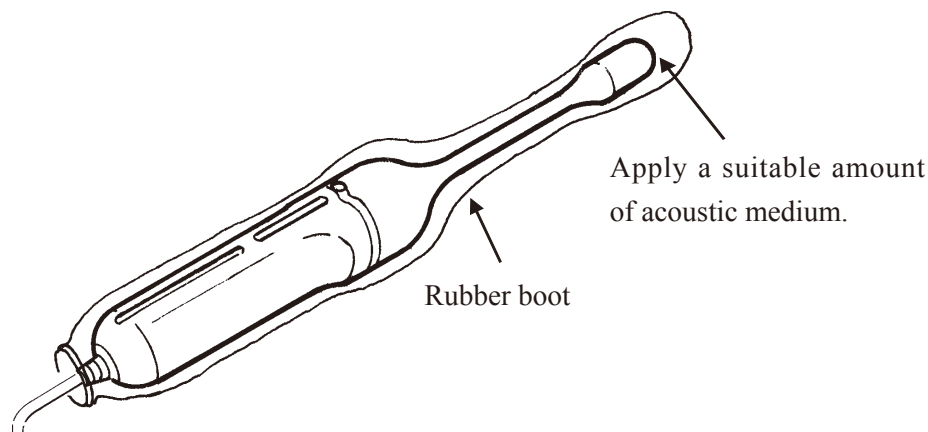
#### Caution

- |  |   |
|--|---|
|   | Do not move the scanner with excessive force.<br>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.<br>There is the possibility that the patient's internal tissues could be affected.<br>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.<br>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.<br>It can cause electric shock to the patient.   |

## 4-2. Mounting of rubber boot

Apply a suitable amount of acoustic medium to the ultrasonic irradiation area of the scanner and then cover it with the rubber boot.

Remove the air bubbles or wrinkles formed on the ultrasonic irradiation area of the scanner.



⚠ Warning	
❗	Use by covering the rubber boot over the insertion portion. If the rubber boot is not used, residual pathogens on the scanner could infect the patient. Also, the puncture guide tube could become loose during puncturing, resulting in puncturing of an unintended body part.
❗	Use Hitachi-approved rubber boots only. Use of an item lacking biocompatibility can cause an adverse reaction of the human body.
❗	Check that the rubber boot is sterilized. Use of an infective item could spread infection to the patient.
⊘	Do not reuse the rubber boot. Use of an infective item could spread infection to the patient.
⊘	Do not apply unsterilized acoustic medium to the outer surface of the rubber boot. Use of an acoustic medium that is contaminated by a pathogen can cause an infection on the patient.
⊘	Do not use on patients who may have an allergic reaction to latex products. Use of the rubber boot for these types of patients could result in anaphylactic shock. Ask the patient about allergy history beforehand.


⚠ Caution	
❗	Check the rubber boot for abnormalities before use. Store the rubber boots in a cool, dry location not exposed to direct sunlight and do not use rubber boots that have exceeded their expiration date (for items where the expiration date is not displayed, 2 years from the displayed sterilization date). Also do not use the rubber boot when there are severe discolorations, cracks or other visible effects.
❗	Check that the acoustic medium has no air bubbles inside the rubber boot that is covering the scanner. Air bubbles inside the rubber boot can result in misdiagnosis caused by overlooking or misinterpreting lesions due to poor image quality or improper rendering.



#### 4-3. Removal of rubber boot

1. Wrap the rubber boot in tissue paper and remove it from the probe.
2. Dispose used tissue paper and rubber boots using infection prevention procedures based on the rules of your facility.

 <b>Caution</b>
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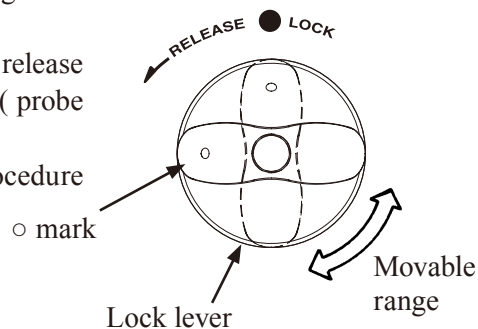
- |  |
|--|
|  Before disposing the equipment, disinfect or take other infection-prevention measures.<br>Disposal of the equipment without taking the proper preventative measures can lead to infection. |
|--|

#### 4-4. 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 electronic probe connecting socket of the diagnostic instrument ( probe connector ).

Connect the scanner to the probe connector by following the procedure below.



- Connection procedure

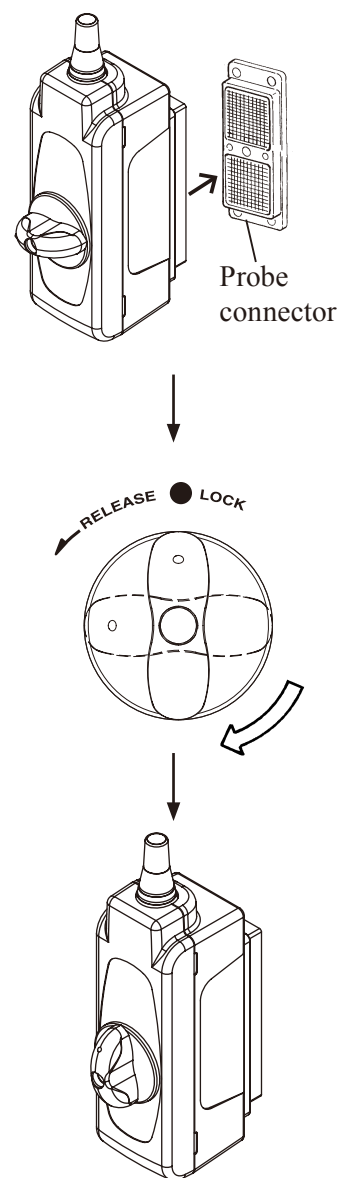
The scanner is connected when in one of the following states.

- 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.

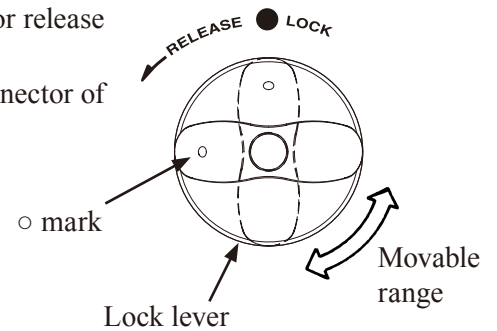
Forcibly turning the lever may damage the connector and the probe connector on the instrument.

#### 4-5. 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 probe connector of the ultrasound diagnostic instrument.



- Removal procedure

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

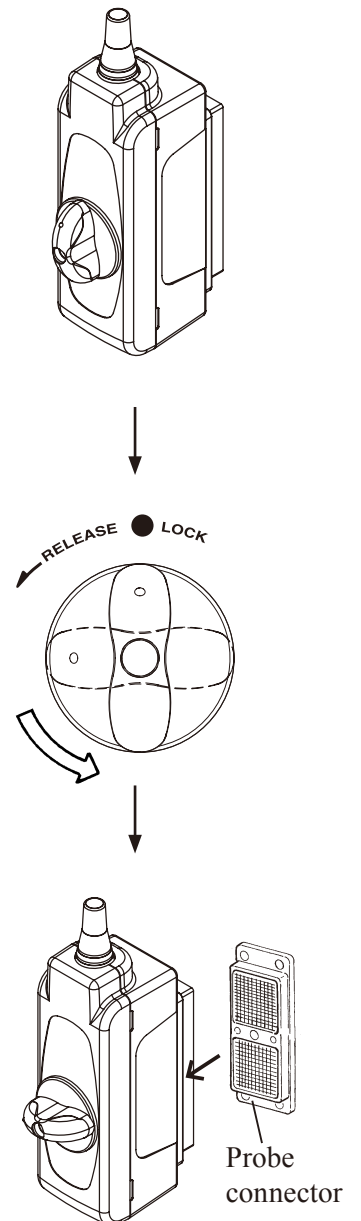
- The power switch is set to OFF.
- The image displayed on the ultrasound diagnostic instrument is frozen.

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”.



#### 4-6. Actions to be taken when an abnormal state is detected

##### 4-6-1. 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.

##### 4-6-2. Handling the instrument

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

 <b>Caution</b>
 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-1012	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.

 <b>Warning</b>	
	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.

 <b>Caution</b>	
	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"> <li>• The scanner is delivered unsterile. Prior to the first use, reprocess the scanner.</li> <li>• Do not exceed 60 °C [140 °F].</li> <li>• Scanner connector has no water resistance.</li> </ul>
Limitations on reprocessing	The scanner is not completely submergible (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 submergible 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.

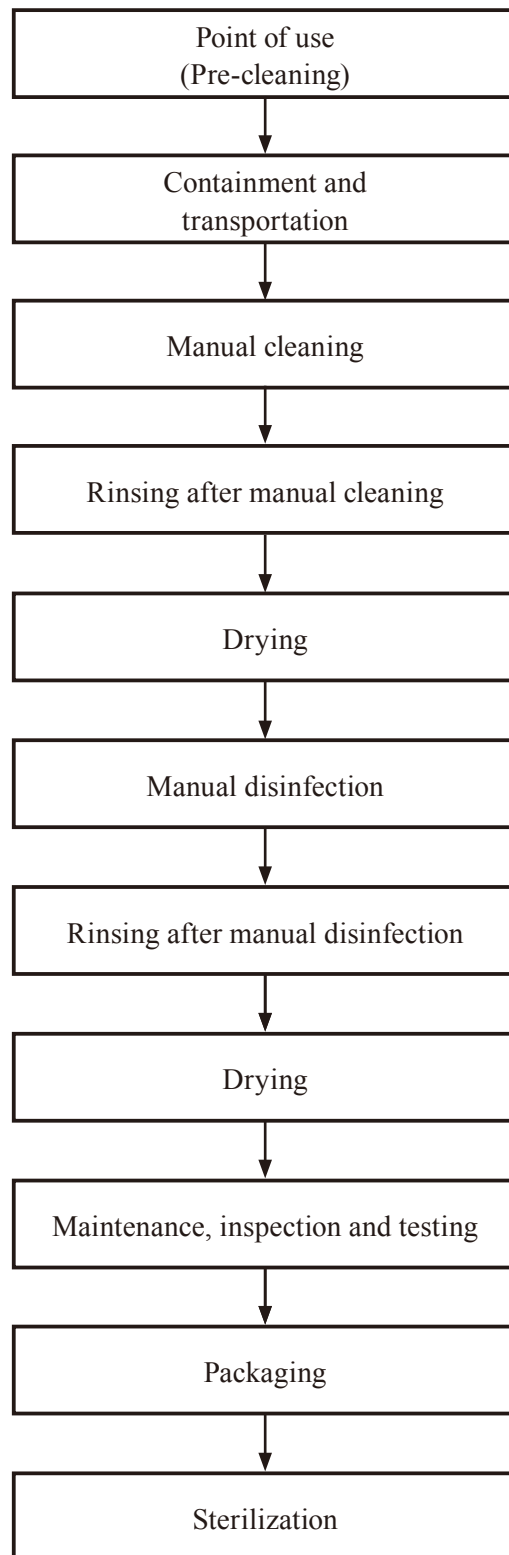
The CDC (Centers for Disease Control and Prevention) in the USA and the RKI (Robert Koch Institute) in Germany classify medical devices according to their use. For each classification, they specify the level of disinfection/sterilization processing that is required before use. Table 3 summarizes this 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 * <sup>1</sup>

\*<sup>1</sup>. 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) Remove any accessories from the scanner like rubber boot.
- 2) Flush patient's blood or fluid by tap water directly after use until the surface looks visually clean.
- 3) 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.

 <b>Caution</b>
 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<sup>®</sup>/Cidezyme<sup>®</sup> (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device.
- 2) Disinfectant: Cidex<sup>®</sup> 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.

 <b>Caution</b>
--

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

## 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.

 <b>Note</b>
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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.
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## 5-6. Automated cleaning and disinfecting

### Scanner

 <b>Warning</b>
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- |   |
|---|
|  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 <sup>®</sup> /Cidezyme <sup>®</sup> Practical liquid 0.8V/V%	ADVANCED STERILIZATION PRODUCTS <sup>®</sup> A Johnson & Johnson company Division of Ethicon, Inc.
Alkylpolyalkylenglykolether	Korsolex <sup>®</sup> Endo-Cleaner	BODE Chemie GmbH

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

 <b>Warning</b>
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 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. Ethylene oxide (EtO) gas sterilization

Sterile conditions of applicable sterilization methods are as follows.

Regarding the operation of the sterilizer, refer to the documentation supplied with the sterilizer.


#### Warning

 The probe cannot withstand ethylene oxide gas sterilization.

#### RB-945BP-NS

Perform sterilization in the following conditions:	
Gas Type:	30% EO/ 70% CO <sub>2</sub>
Temperature:	45 - 55°C
	113 - 131°F
Exposure Time:	More than 240 minutes
Pressurization:	89 - 108kPa
Depressurization:	13 - 8kPa
Relative humidity:	30 - 60%
Aeration is minimum	12 hours

#### Warning



 Perform full aeration after gas sterilization.  
Residual gas can cause an adverse reaction to the operator or patient.

5-11-2. 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
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.

 <b>Warning</b>
 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”.



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## 6. Storage

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### 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: 0°C to 50°C  
 32°F to 122°F  
 Relative humidity: 10% to 90%  
 Atmospheric pressure: 700 hPa to 1060 hPa

 <b>Note</b>
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 insertion portion and handle 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 insertion portion and handle 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 $\mu$ A or less 100 $\mu$ A or less	50 $\mu$ A or less 500 $\mu$ A or less
(2) Patient leakage current caused by an external voltage on the patient connection of an F-type applied part	/	5000 $\mu$ 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.

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## 9. Configuration

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### 9-1. Standard configuration

Scanner	ASU-1012 .....	1 set
Storage case	CB-UST1-P7.....	1 set
Instruction manual	MN1-5179 .....	1 copy

### 9-2. Options

- Rubber boot                      RB-945BP-NS (unsterilized)






## 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



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