Transrectum Mechanical Radial Scanner

ASU-67

Instruction Manual

MN1-1083 Rev.15

CE 0123

Hitachi Aloka Medical, Ltd.

Introduction

This is an instruction for model ASU-67, 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

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 rectum and making ultrasonic observations of the prostate 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".

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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.

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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 as necessary. Perform properly wash, disinfect and sterilize 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 wash, disinfect and sterilize it as required.
❗	Wear medical gloves during examination. Conducting examinations with the bare hands can expose the operator to a risk of infection.
❗	Dispose of scanners used for patients with Creutzfeldt-Jakob disease. Otherwise, there is a risk of infection to the operator or patient. Currently, there are no methods for washing, disinfecting and sterilizing scanners which have been used on patients afflicted by Creutzfeldt-Jacob 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 "Washing, 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 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 somewere.
⃠	Do not use this scanner with other equipment except for those specifically approved in the manual. Use with unapproved equipment can result in burn or other injury to the patient or operator and damage to the scanner and the other equipment.
❗	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.
❗	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.
❗	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".
❗	Take care to avoid splashing water on ultrasound diagnostic instrument or other equipment nearby. Splashed water could cause other equipment to malfunction, or cause accidents.

1-2-2. Option usage precautions

⚠ Warning	
❗	Use by covering the balloon over the insertion portion. If the balloon is not used, residual pathogens on the scanner could infect the patient.
❗	Use Aloka-approved balloons only. Use of an item lacking biocompatibility can cause an adverse reaction by the body of the patient.
❗	Check that the balloon is sterilized and white rubber band is disinfected or sterilized same as scanner. Use of an infected item could spread infection to the patient. Note that the white rubber band is not sterilized at the factory. Before using the scanner first, be sure to wash, disinfect and sterilize it as required. See section 5.
⃠	Do not reuse the balloon and white rubber band. Use of an infected item could spread infection to the patient.
⃠	Do not apply unsterilized acoustic medium to the outer surface of the balloon. 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 balloon for these types of patients could result in anaphylactic shock. Ask the patient about allergy history beforehand.

⚠ Caution	
❗	Check the balloon for abnormalities before use. Store the balloons in a cool, dry location not exposed to direct sunlight and do not use balloons that have exceeded their expiration date (for items where the expiration date is not displayed; 2 years from the displayed sterilization date) or severe discoloration, cracks, or other visible defects finds.
❗	Check that the acoustic medium has no air bubbles inside the balloon that is covering the scanner. Air bubbles inside the balloon can result in misdiagnosis caused by overlooking or misinterpreting lesions due to poor image quality or improper rendering.
⃠	Do not tighten the cock too hard. The cock or insertion tube can be damaged.

⚠ Note
Attach the cock correctly to prevent water leakage.

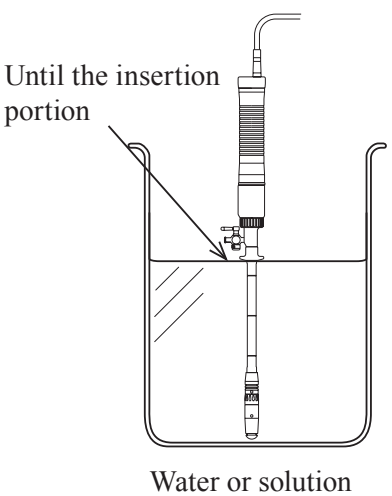
1-2-3. Washing, disinfection and sterilization precautions

⚠ Warning

- Wear protective gloves and other protective gear during washing, 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 chemical disinfection, thoroughly wash the scanner with sterilized water.
  Residual chemicals can cause an adverse reaction on the bodies of the operator or patient.
- Perform aeration completely after gas disinfection and sterilization.
  Residual gas can cause an adverse reaction on the bodies of the operator or patient.
- Do not wash, disinfect or sterilize using procedures other than those specified in this manual.
  Infection could result due to incomplete washing disinfection or 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.

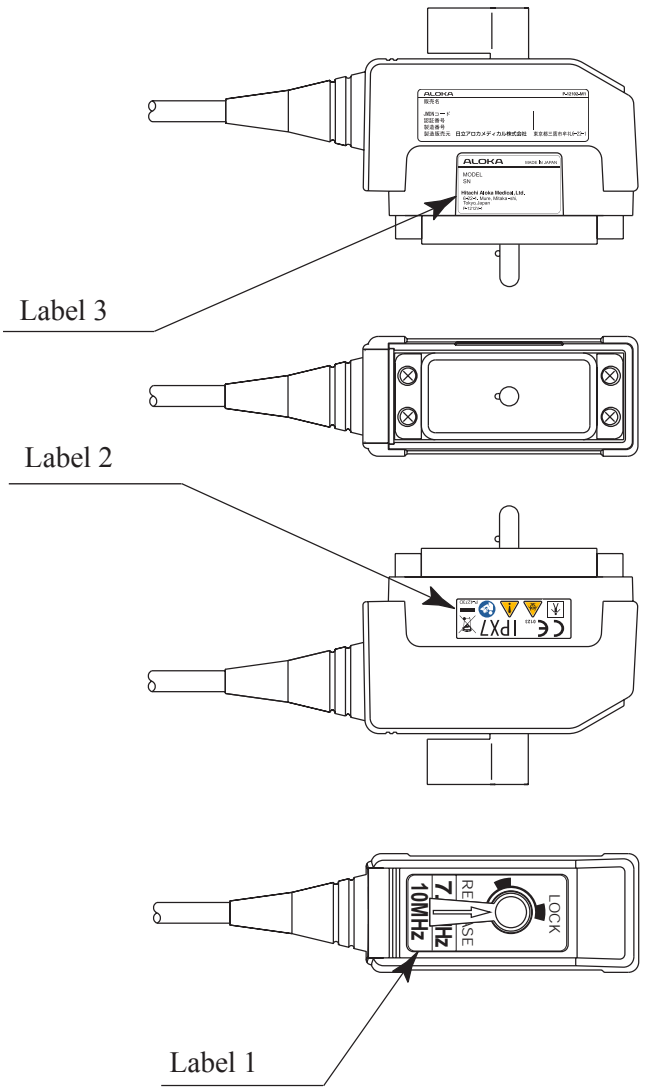
⚠ Caution

- 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.

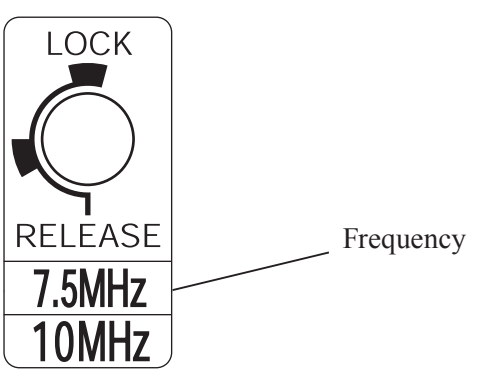


1-2-4. Labels

(1) Scanner unit



Label 1



Label 2

This equipment complies with Directive 93/42/EEC relating to Medical Device.

IPX7

IPX7 mark
See section 2-2, “Specifications”.

Type BF applied part

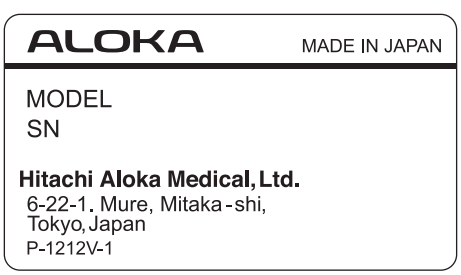
Do not waste the instrument as general waste. Comply with a local regulation.
See section 10.

Safety warning sign

Biohazard
See section 5.

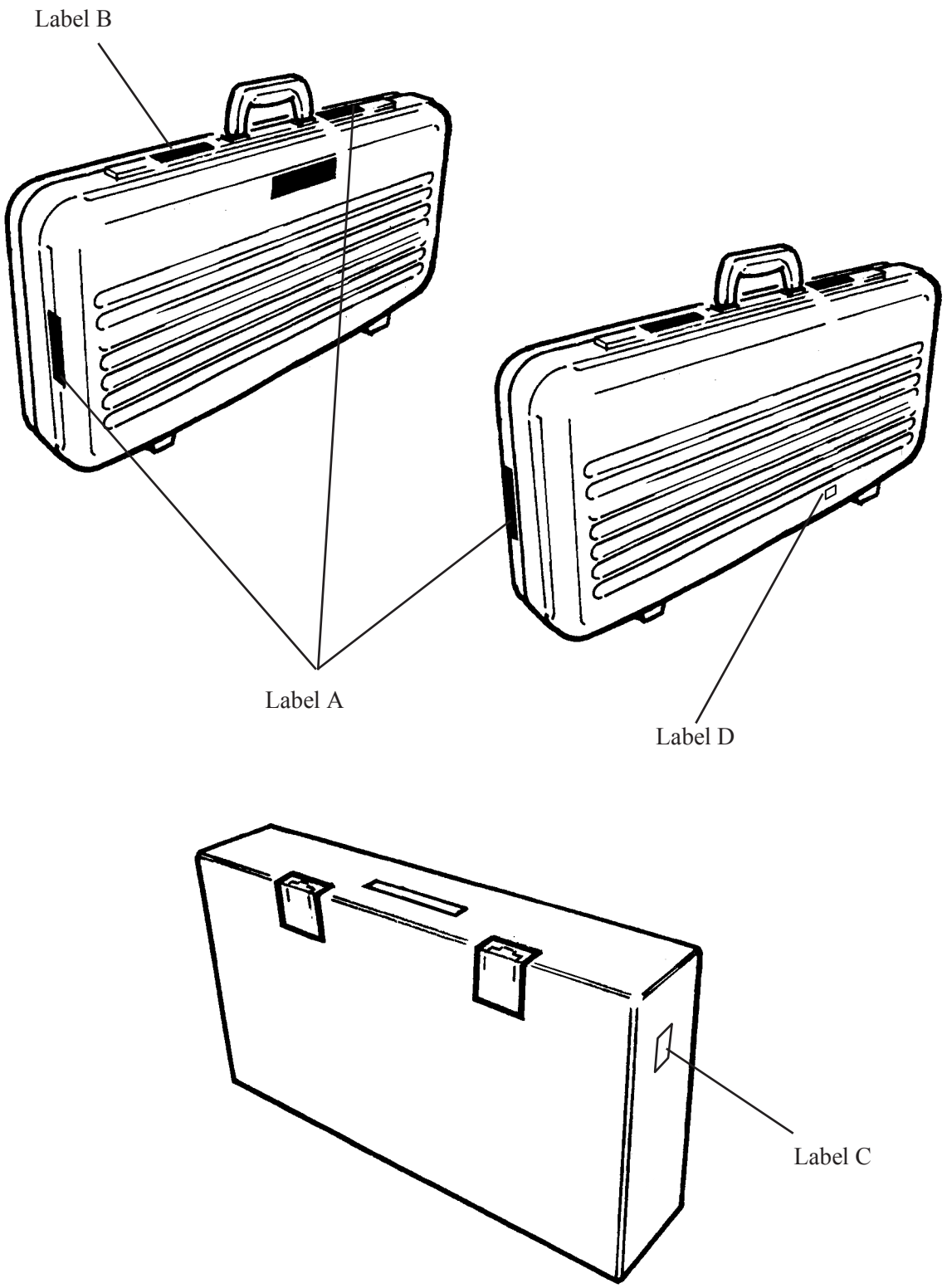
Follow the instruction manual to operate this instrument. If not avoided, may result in injury, property damage, or the equipment trouble.

Label 3



Manufacturer
Model, Serial No.

(2) Storage case



Label A

Model

Label B

Serial No.

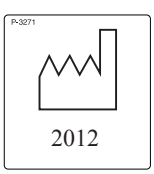
Label C

This equipment complies with Directive 93/42/EEC relating to Medical Device.

DATE OF MANUFACTURE
(in case of 2012)

MANUFACTURER

Label D

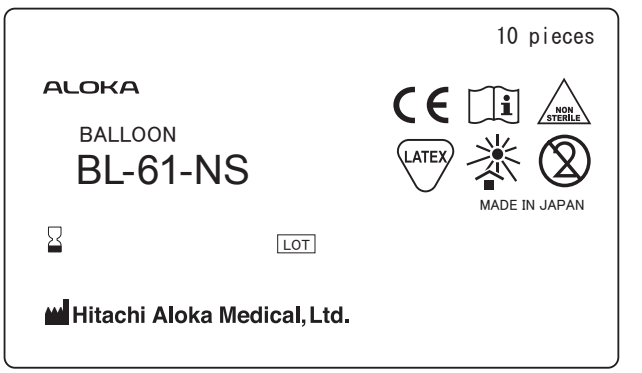


DATE OF MANUFACTURE
(in case of 2012)

(3) balloon

Label for 1 piece

Label for 10 pieces

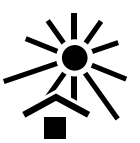


Non sterile

Contains or presence natural rubber latex

Use by

Do not reuse



Keep away from sunlight

Lot number

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.

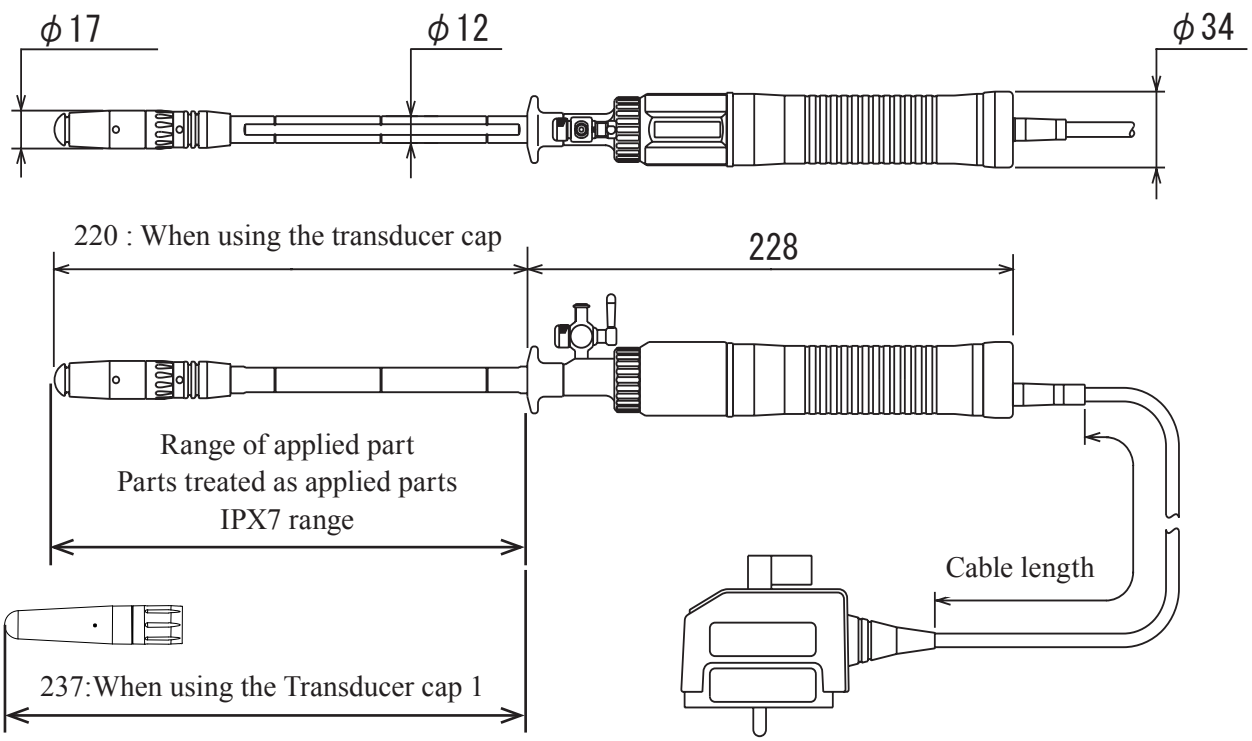
(2) The emitted ultrasonic waves are reflected by boundaries with different acoustic characteristics (acoustic impedance) within the body.

(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 rotates mechanically to enable construct sliced images.

2-2. Specifications

Application regions:	Prostate gland and pelvic organs
Form of application to patient:	Transrectum
Connectable instruments:	SSD-900,SSD-1000,SSD-4000,SSD-α10,SSD-α5,Prosound 6
Field of view:	360 ° Radial Scan (The image from the caudal direction)
Frequency:	7.5MHz, 10MHz
Cable length:	2.0 m
Weight:	870 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.



Unit: mm

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

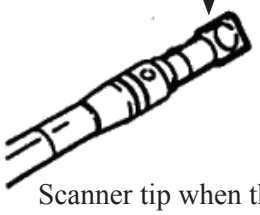
2-3. Performance

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

2-4. Name of each parts

Balloon
This covers the insertion portion for preventing infection. Follow the instructions in section 4-2.

Transducer unit
This unit has two ultrasound irradiation area in each side, featuring different frequency.



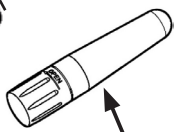
Scanner tip when the transducer cap is removed

Transducer cap (MP-2747)
This is used to protect the transducer unit rotating on scanner tip. See section 4-2.

Scale marks
The scale marks indicate insertion depth.

Cock
This is the cock where the extension tube for supplying water to the balloon and draining water from the balloon is connected. This can be removed from the insertion tube.

Insertion portion



Handle
This section is held when performing insertion.

Transducer cap 1(MP-2782)
This is used to protect the transducer unit rotating on scanner tip. It uses it to diagnose the short distance part such as the anal sphincters. See section 4-2.

Insertion tube
The component that is inserted into the patient's rectum.

Fixing nut
This fixes the insertion tube to handle

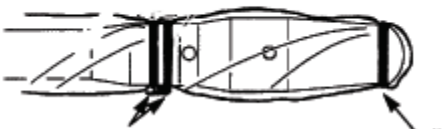
Connector
This is the part that connects the ultrasound diagnostic instrument and scanner. See section 4-7.

Cable
This cable propagates the ultrasonic signals that are sent and received.

⚠ Caution
⊘ Do not pull, bend, twist, or apply excessive force to the cable. The conductors may break and the cable may become unusable.
⊘ Do not subject the ultrasonic irradiation area of the transducer unit to hard impact. This could make the scanner unusable.

・White rubber band

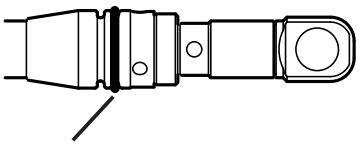
This is used to keep water in the ballon.



White rubber band

・Black O ring

This is used to seal water with the transducer cap 1.

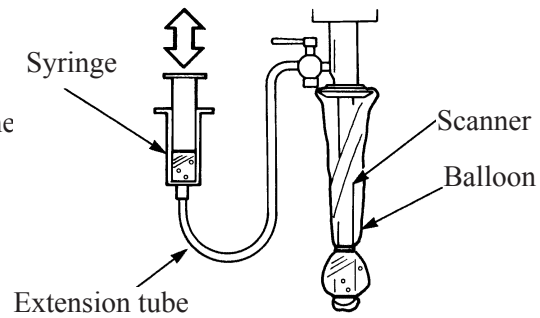


Black O ring

・Extension tube

・Syringe

These are used to inject water to the balloon through the insertion tube. Follow the instructions in section 4-2.



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:	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 “Washing, 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 transducer cap or transducer cap 1, insertion tube, cock, handle, cable, connector and fixing nut.
If any holes, indentations, abrasion, cracks, deformation, looseness, discoloration, or other abnormalities are found, do not use the equipment.

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

Verify that washing, 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 4-7, “Connecting to the ultrasound diagnostic instrument” and check that the selected scanner match the radial display and the displayed frequency and check the image for errors.
Verify that there are no abnormal vibrations or noise.
Verify that the scanner starts rotation when reduce of freeze.

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

⚠ 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

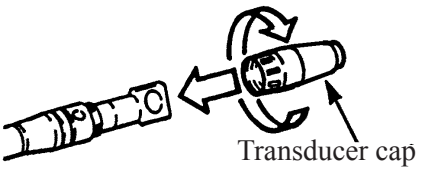
Check that the balloon is mounted and insert into the rectum. An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. Furthermore, this scanner enables observation of two frequency: 7.5MHz and 10MHz. The operator can switch over from one section to the other on 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. Attaching the transducer cap

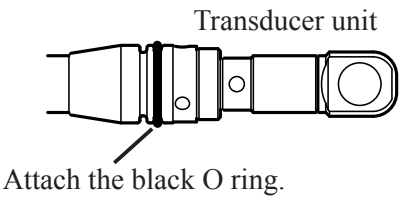
4-2-1. Attaching the transducer cap

Attach the transducer cap and rotate counterclockwise.

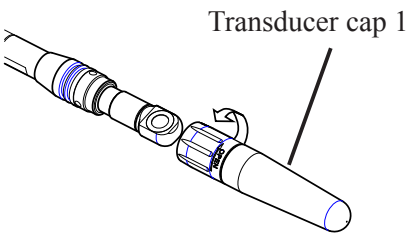


4-2-2. Attaching the transducer cap 1

1. Attach the black O ring to the insertion tube.



2. Attach the transducer cap 1 and rotate counterclockwise.



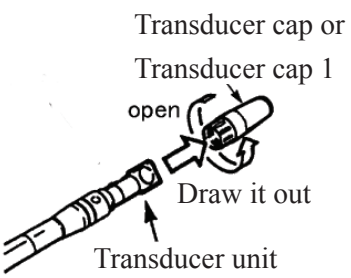
4-3. Removal the transducer cap

4-3-1. Removal the transducer cap

Detach the transducer cap by turning it in the arrowindicated OPEN direction.

[Remarks]

Hold a metal part of the transducer cap when drawing.



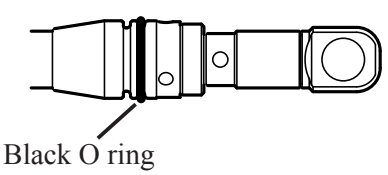
4-3-2. Removal the transducer cap 1

1. Detach the transducer cap 1 by turning it in the arrowindicated OPEN direction.

[Remarks]

Hold a metal part of the transducer cap when drawing.

2. Detach the black O ring.



⚠ Caution
⃠ Do not subject the ultrasonic irradiation area of the transducer unit to hard impact. This could make the scanner unusable.

4-4. Mounting of balloon

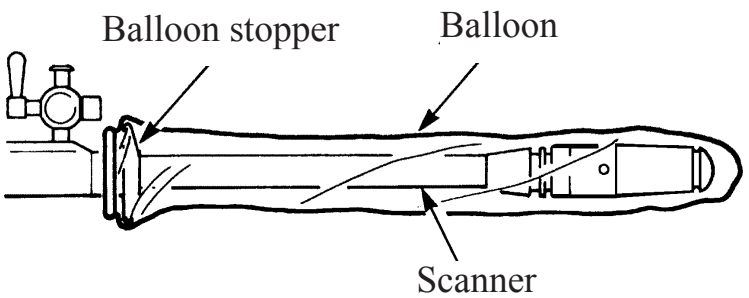
⚠ Warning	
❗	Use by covering the balloon over the insertion portion. If the balloon is not used, residual pathogens on the scanner could infect the patient.
❗	Use Aloka-approved balloons only. Use of an item lacking biocompatibility can cause an adverse reaction by the body of the patient.
❗	Check that the balloon is sterilized and white rubber band is disinfected or sterilized same as scanner. Use of an infected item could spread infection to the patient. Note that the white rubber band is not sterilized at the factory. Before using the scanner first, be sure to wash, disinfect and sterilize it as required. See section 5.
⃠	Do not reuse the balloon and white rubber band. Use of an infected item could spread infection to the patient.
⃠	Do not apply unsterilized acoustic medium to the outer surface of the balloon. 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 balloon for these types of patients could result in anaphylactic shock. Ask the patient about allergy history beforehand.

⚠ Caution	
❗	Check the balloon for abnormalities before use. Store the balloons in a cool, dry location not exposed to direct sunlight and do not use balloons that have exceeded their expiration date (for items where the expiration date is not displayed; 2 years from the displayed sterilization date) or severe discoloration, cracks, or other visible defects finds.
❗	Check that the acoustic medium has no air bubbles inside the balloon that is covering the scanner. Air bubbles inside the balloon can result in misdiagnosis caused by overlooking or misinterpreting lesions due to poor image quality or improper rendering.
⃠	Do not tighten the cock too hard. The cock or insertion tube can be damaged.

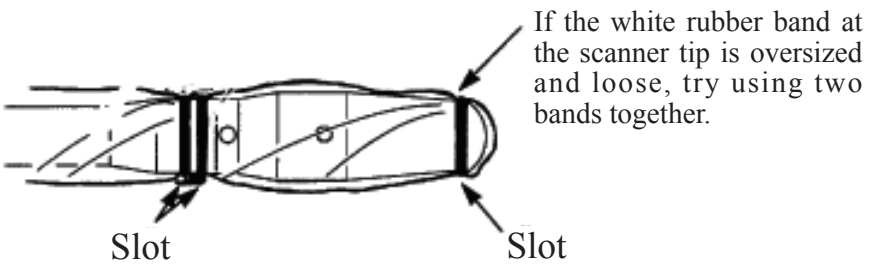
⚠ Note
Attach the cock correctly to prevent water leakage.

4-4-1. Mounting of balloon when the transduder cap is used

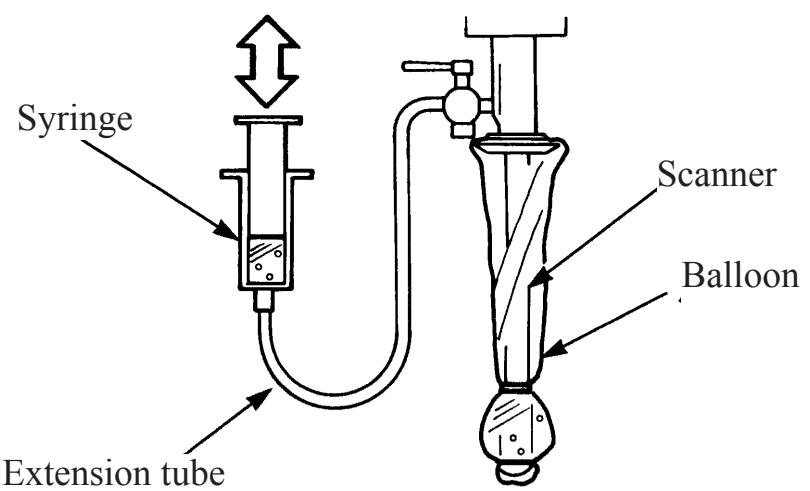
1. Attach the cock to insertion tube.
2. Put water in the balloon to verify that there is no hole or break in the balloon.
3. Completely wash powder off inside of the balloon with deaerated water.
4. Insert the scanner in the balloon and catch on the balloon stopper.



5. Fasten the balloon by inserting the white rubber band into the three slots.

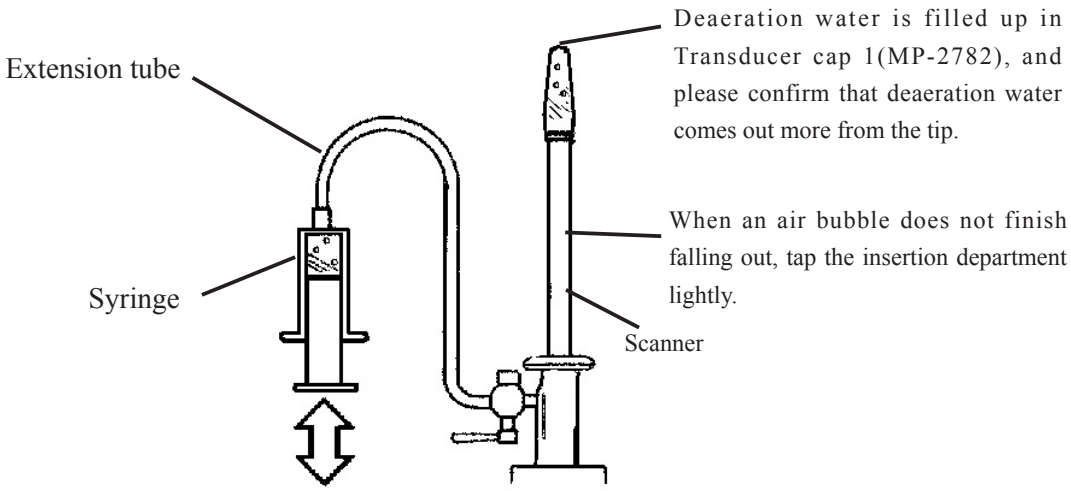


6. Put about 50cc of deaerated water into the accessory syringe and connect it to the cock using the extension tube.
7. Face the tip of the scanner down and inject all the water from the syringe.
8. Pull the syringe and take the bubbles in the balloon into the syringe.
9. Repeat Steps 7 and 8 two or three times and remove any bubbles in the balloon and transducer cap.

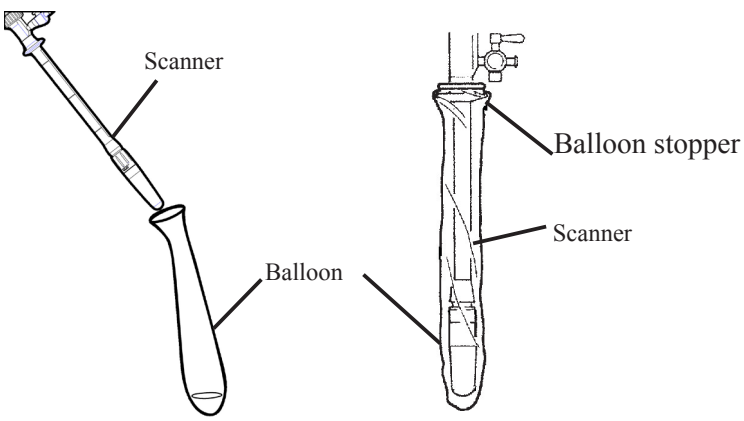


4-4-2. Mounting of balloon when the transduder cap 1 is used

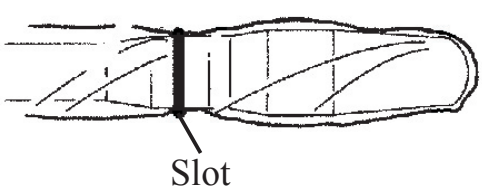
1. Attach the cock to insertion tube.
2. Put about 50cc of deaerated water into the accessory syringe and connect it to the cock using the extension tube.
3. Do the scanner tip upward and flood it slowly till deaeration water goes out of the tip.
4. Tap the insertion tube with having made the scanner tip the top. Move air bubbles left inside to transducer cap 1(MP-2782) and flood it again and remove air bubbles.
5. Repeat operation of 3,4 from 2 or 3 times and pull out air bubbles in the insertion portion and transducer cap 1.
6. Close a cook of a valve after flooding was completed.



7. Put in water into a balloon and confirm that there are not a hole and a tear.
8. Wash off powder sticking in a balloon with deaerated water well.
9. Put deaeration water in 10cc in a balloon and insert a scanner, and a balloon stopper can scratch.



10. While an air bubble does not enter in a balloon, fix a balloon with a white rubber band in one place of slot.

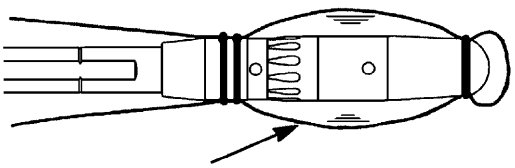


11. Open a valve and pull water in a balloon so that a balloon adheres to transducer cap 1(MP-2782).

4-5. Insertion of the scanner

4-5-1. When the transduder cap is used

1. Return deaerated water to the syringe until the balloon becomes deflated, with only a small amount of water remaining in it. Then,insert the scanner into the rectum.



A small amount of water remains in the balloon

2. After inserting the scanner in the rectum, load deaerated water into the balloon in order to inflate it.

3. The balloon is used to provide the distance needed between the scanner and the region to be observed to produce sharp and clear images. With the scanner inserted in the body, adjust the amount of deaerated water in the balloon to obtain the best level of inflation.

4. Before pulling the scanner out of the body,drain the water from the balloon.

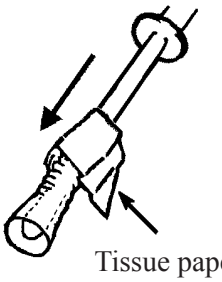
4-5-2. When the transduder cap 1 is used

Use the scanner with the balloon not inflated and adhered to transducer cap 1.

⚠ Caution
⃠ Do not move the scanner with excessive force. Pressing down with more force than necessary can cause injury to the patient. Be aware not to injure patients so that tip of the transducer cap 1 is 36.5mm distance from center of ultrasound irradiation area.

4-6. Removal of balloon

1. Wrap balloons and white rubber bands in tissue paper and remove from the scanner.
2. Dispose of used tissue paper, balloons and white rubber bands using infection prevention procedures based on the rules of your facility.



Tissue paper

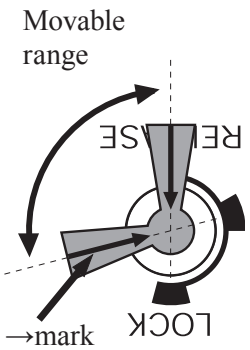
⚠ Caution
Before disposing of the equipment, disinfect or take other infection-prevention measures. Disposal of the equipment without taking the proper preventative measures can lead to infection.
After remove the equipment from the patient, check for anything abnormal about the balloon and the rubber band. If the balloon and the rubber band stay inside of the patient's body, the balloon and the rubber band can cause injury to the patient. When the balloon and the rubber band stay inside of the patient's body, perform the required medical treatment.

4-7. 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

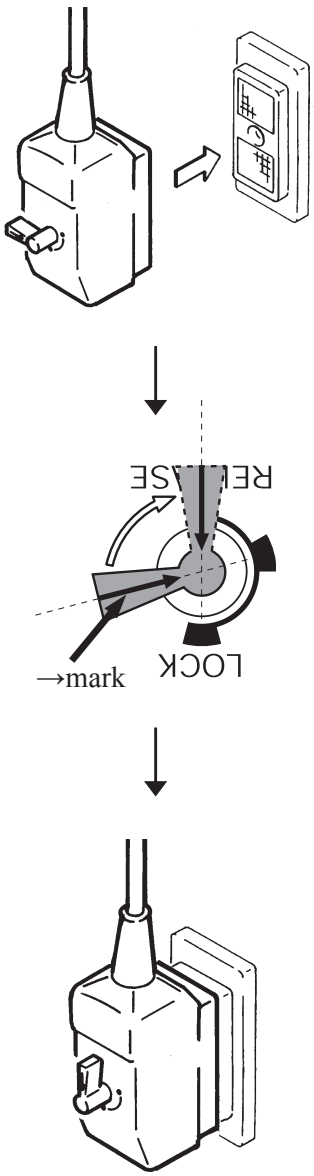
The scanner is connected when in one of the following states.

- 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.
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.

   This completes connection of the scanner.

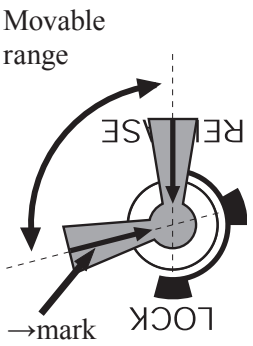


[Remarks]
The transducer unit may rotates momentary when connecting the scanner to probe connector, but this is normal.

⚠ 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.

4-8. 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.



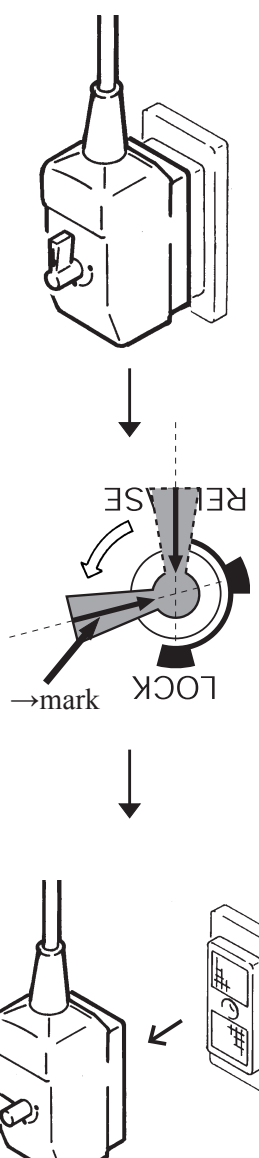
- Removal procedure

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.



This completes the removal of the scanner.
After use, perform washing, disinfection and sterilization of the scanner by following the procedure in section 5 “Washing, 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”.

[Remarks]
The transducer unit may rotates momentary when removing the scanner from probe connector, but this is normal.

4-9. Actions to be taken when an abnormal state is detected

4-9-1. 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.

4-9-2. 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.

⚠ 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.

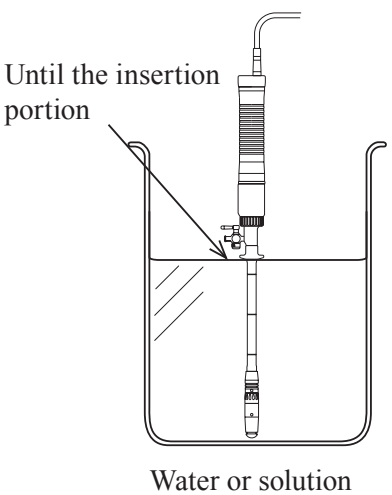
5. Washing, Disinfection and Sterilization

⚠ Warning

- Wear protective gloves and other protective gear during washing, 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 chemical disinfection, thoroughly wash the scanner with sterilized water.
  Residual chemicals can cause an adverse reaction on the bodies of the operator or patient.
- Perform aeration completely after gas disinfection and sterilization.
  Residual gas can cause an adverse reaction on the bodies of the operator or patient.
- Do not wash, disinfect or sterilize using procedures other than those specified in this manual.
  Infection could result due to incomplete washing disinfection or 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.



5-1. Washing

Remove the transducer cap or transducer cap 1 and wash the transducer cap and insertion portion immediately after use with water or soak in a cleaning agent.
Washing before disinfection and sterilization is very important.

5-1-1. Transducer cap and insertion portion

Applicable cleaning agents

General name	Trade name	Manufacturer
Enzyme cleaning agent	ENZOL™ Practical liquid 0.8V/V%	ADVANCED STERILIZATION PRODUCTS® A Johnson & Johnson company Division of Ethicon, Inc.

Washing procedure

Water rinsing - - - - - - - - - - - Rinse the transducer cap or transducer cap 1 and insertion portion with running water. Wash off blood, mucus and other substances adhering to the insertion portion and handle using a sponge or gauze.

or

Soaking in cleaning agent - - - - - - - - - - - Minimize the soaking time.

↓

Water rinsing - - - - - - - - - - - Sufficiently rinse the insertion portion and handle using running water to remove all traces of chemicals.

⚠ Warning

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.

5-1-2. Handle, cable and connector

Gently wipe the cable with gauze dipped in ethyl alcohol or water each divided into approximately 20 cm and dry.
Gently clean the connector and other parts of the scanner that must not be soaked in liquid with gauze dipped in ethyl alcohol and dry.

⚠ Note

Wiping the entire length of the cable at once can result in wrinkled surface.
If this occurs, pull the wrinkled part in the opposite direction to undo it.

5-2. Disinfection

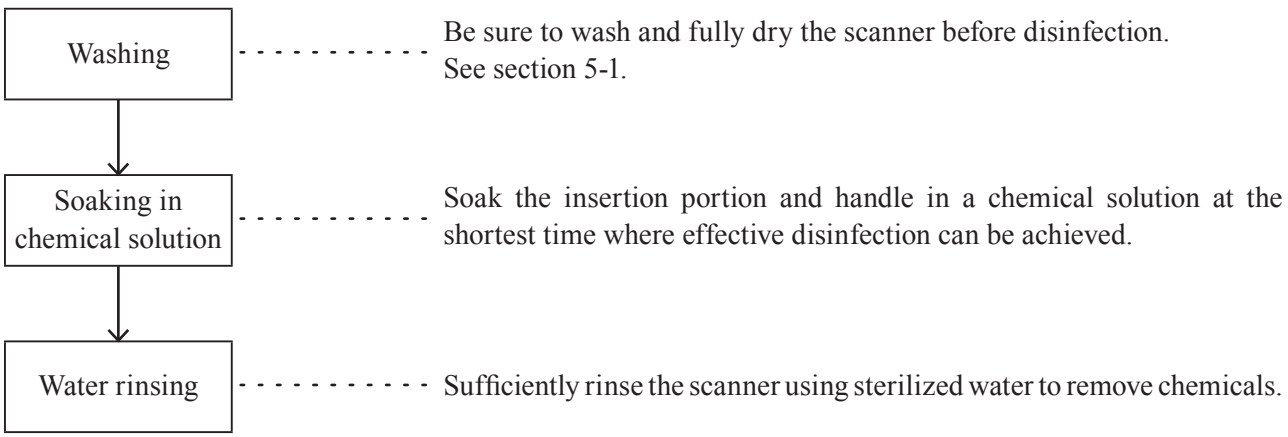
Either chemical disinfection or gas disinfection is performed as necessary.

5-2-1. Chemical disinfection

Applicable chemicals

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	STERIHYDE™ Practical liquid 2W/V%	Maruishi Pharmaceutical Co., Ltd.
Benzalkonium chloride	DETERGICIDE™ Practical liquid 0.2W/V%	Yufu Itonaga Co., Ltd.
Benzethonium chloride	HYAMINE™ Practical liquid 0.1W/V%	DAIICHI SANKYO Co., Ltd.

Disinfection procedure



Remarks

Soaking the insertion portion and handle in CIDEX OPA™ solution 0.55% may result in discoloration of the silicone, but this does not affect performance or safety.

⚠ Warning

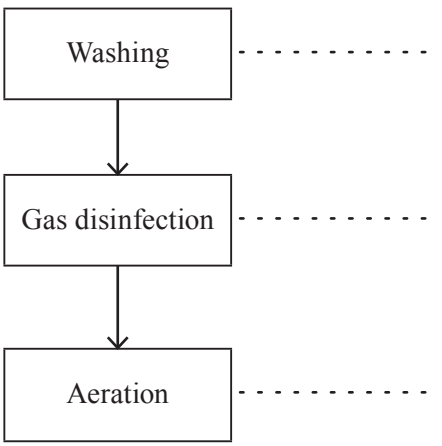
After chemical disinfection, thoroughly wash the scanner with sterilized water.
Residual chemicals can cause an adverse reaction on the bodies of the operator or patient.

5-2-2. Gas disinfection

Applicable gases

General name	Trade name	Manufacturer
Formalin gas	F. gen (14% formaldehyde)	Aso Pharmaceutical Co., Ltd.

Disinfection procedure



Be sure to wash and fully dry the scanner before disinfection.
See section 5-1.

Disinfection the following conditions:

Temperature:	Room temperature
Humidity:	Normal humidity
Atmospheric pressure:	Normal pressure

Aerate the following conditions to ensure that no gases remain.

Temperature:	10°C to 60°C 50°F to 140°F
Humidity:	30% to 85%
Compression	to +101.175kPa
Decompression	to -100.000kPa
Period:	5 days (natural aeration)

⚠ Warning

Perform full aeration after gas disinfection.
Residual gas can cause an adverse reaction on the bodies of the operator or patient.

5-3. Sterilization

Perform Ethylene oxide gas (EOG) sterilization as necessary.

5-3-1. Ethylene oxide gas (EOG) sterilization

Applicable gases

General name	Trade name	Manufacturer
Ethylene oxide gas	AMPROLENE™ 84% density	Central Uni Co., LTD.

Sterilization procedure

Washing

Be sure to wash and fully dry the scanner before sterilization.
See section 5-1.

EOG sterilization

Sterilize the following conditions:

Temperature:	10℃ to 60℃
	50°F to 140°F
Humidity:	30% to 85%
Compression	to +101.175kPa
Decompression	to -100.000kPa

Aeration

Aerate the following conditions to ensure that no gases remain.

Temperature:	10°C to 60°C
	50°F to 140°F
Humidity:	30% to 85%
Compression	to +101.175kPa
Decompression	to -100.000kPa
Period:	5 days (natural aeration)

⚠ Warning

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

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 “Washing, 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 “Washing, Disinfection and Sterilization”.

7-3. Packing for transportation

Store in the storage case after performing the procedure in section 5 “Washing, 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

⚠ 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 require an appropriate qualified technician, Aloka trained service personnel can conduct a test at the user's expense. Contact one of our offices and/or distributor's offices listed 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 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 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 µA or less 100 µA or less	 50 µA or less 500 µA or less
(2) Patient leakage current caused by an external voltage on the patient connection of an F-type applied part		5000 µA 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-67	1 set
(Including transducer cap MP-2747)		
Transducer cap 1	MP-2782	1
White rubber band	SR6 × 1.5	80
Black O ring	ϕ 13.1×W1.6	5
Syringe	SS-50LZ	1
Extension tube	SF-ET3825L	1
Cleaning brush	74-050-01	1
Storage case	STB-45-PA2	1 set
Instruction manual	MN1-1083	1 copy

9-2. Options

- Balloon BL-61-NS (unsterilized)

10. Disposal of the Device

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

⚠ Caution
Before disposing of the equipment, take infection-prevention measures. Disposal of the equipment without taking the proper preventative measures can lead to infection.

Waste Electrical and Electronic Equipment (WEEE) Directive

This products is a duty of the display of WEEE marking is imposed,
into the European Union (EU) .
In case you dispose this products in the EU member nation,
please contact any of the offices or agencies, should follow the law of each country
or your local legislation.

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EC REP

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