HITACHI
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R41RL Probe
Instruction Manual
Specification

MN1-6033 Rev. 6

Notes for operators and responsible maintenance personnel

★ *Please read through this Instruction Manual as well as the separate Instruction Manual "Safety (MN1-5988)" and "Cleaning, Disinfection and Sterilization (MN1-6161)" carefully prior to use.*

★ *Keep this Instruction Manual together with the ultrasound diagnostic instrument for any future reference.*

CE 0123

Hitachi, Ltd.

Introduction

This is the instruction manual for R41RL probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be mainly used as a transrectal probe for observation of prostate and surrounding organs.
Prior to use, read this manual as well as the separate instruction manual “Safety” in which information for safe use is provided.

The probe bears the CE mark but the mark is valid only when the probe is connected to the ultrasound diagnostic instrument bearing the CE mark.

Symbols used in this document

Safety information is classified into Danger, Warning, Caution, and Note according to the level of hazard. Those terms are used in safety information provided to prevent hazards and injuries to the operator or patient.

⚠ 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 that attention is required.
⃠	This symbol means that the described action is prohibited.
❗	This symbol means that the described action is mandatory.

CONTENTS

This instruction manual contains 4 pages of front matter and 16 pages of the main content.

1. General Information

General information for the probe is provided below.

1-1. Intended use

This probe is intended to be used by a doctor or other qualified operator for ultrasonic observations of the prostate and surrounding organs.

Please refer to the ultrasound diagnostic instrument instruction manual used with this probe for the probe intended use information.

Regarding with the connectable instrument, please refer to section 2-1. Specifications of this manual.

⚠ Warning

Do not use this equipment for other than its intended use.
Otherwise it could cause burns or other injuries to the operator or the patient.

1-2. Classification of ME equipment

This probe is classified as follows according to IEC60601-1.

Please refer to the section 2-1 for the applied part, the part treated as the applied part, and the range of IPX7.

- Classification based on the 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····· Refer to the separate instruction manual "Cleaning, Disinfection and Sterilization"

1-3. Standard components

The standard components of R41RL probe are as follows.

R41RL Probe ····· 1 set
Storage case ····· 1 set
Instruction Manual
- Specification (MN1-6033) ····· 1 copy
- Safety (MN1-5988)····· 1 copy
- Cleaning, Disinfection and Sterilization (MN1-6161) ····· 1 copy

1-4. Option

- Reprocessing by liquid detergent, disinfectant or sterilant

  The following options are available for this probe.

  The whole probe can be immerged into liquid or be reprocessed automatically by attaching the waterproof case WP-001 to the probe connector. Regarding the precautions about the waterproof case, please refer to the its instruction manual.

Accessory for automated reprocessing or immersion into liquid

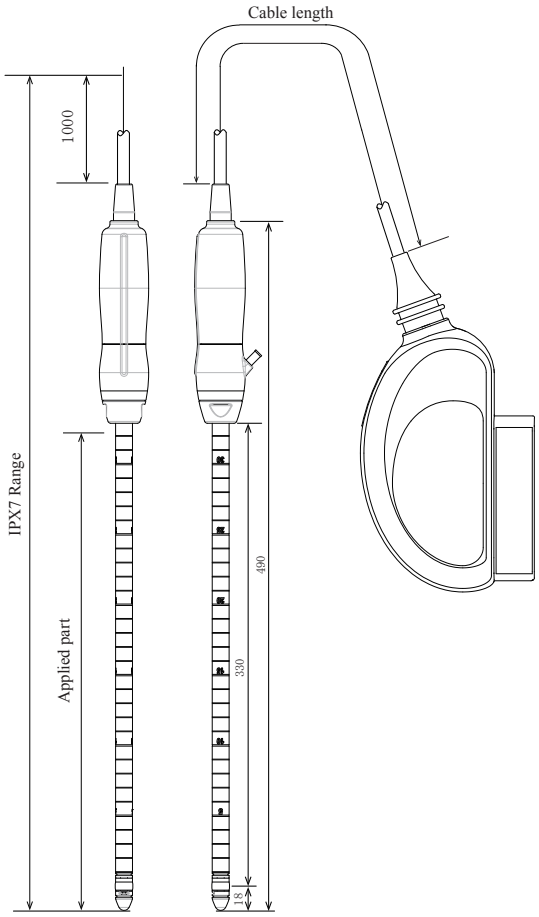
Product Name	Product No.
Waterproof case	WP-001

2. Specifications and Parts name

The specifications and the name of each part are provided below.

2-1. Specifications

Application:	Urological
Type of patient contact:	Transrectal
Connectable instruments:	ARIETTA 70, ARIETTA 60, ARIETTA Precision, ALOKA ARIETTA 850 NOTE: At the time of publication of this manual, the connectable diagnostic ultrasound instrument or instrument software version available with this probe is different for each country, please refer to the instrument instruction manual or contact your local Hitachi representative.
Field of view:	360°
Frequency:	7.5 MHz
Cable length:	2.1 m
Service life:	3 years
Applied part:	See Figure 1
Part treated as Applied part:	See Figure 1
IPX7 range:	See Figure 1 (when not using the waterproof case WP-001) When attaching the waterproof case WP-001 to the probe connector the IPX7 range of the probe is extended from the tip to the connector.
Measurement accuracy:	Refer to the instruction manual of the ultrasound diagnostic instrument
External dimensions:	See Figure 1



Unit: mm

Remark: The tolerance for the dimensions is ±10%.

Figure 1 External View

2-2. Name of each parts

The name of each part is shown in Figure 2 and the explanation for each part is listed in Table 1.

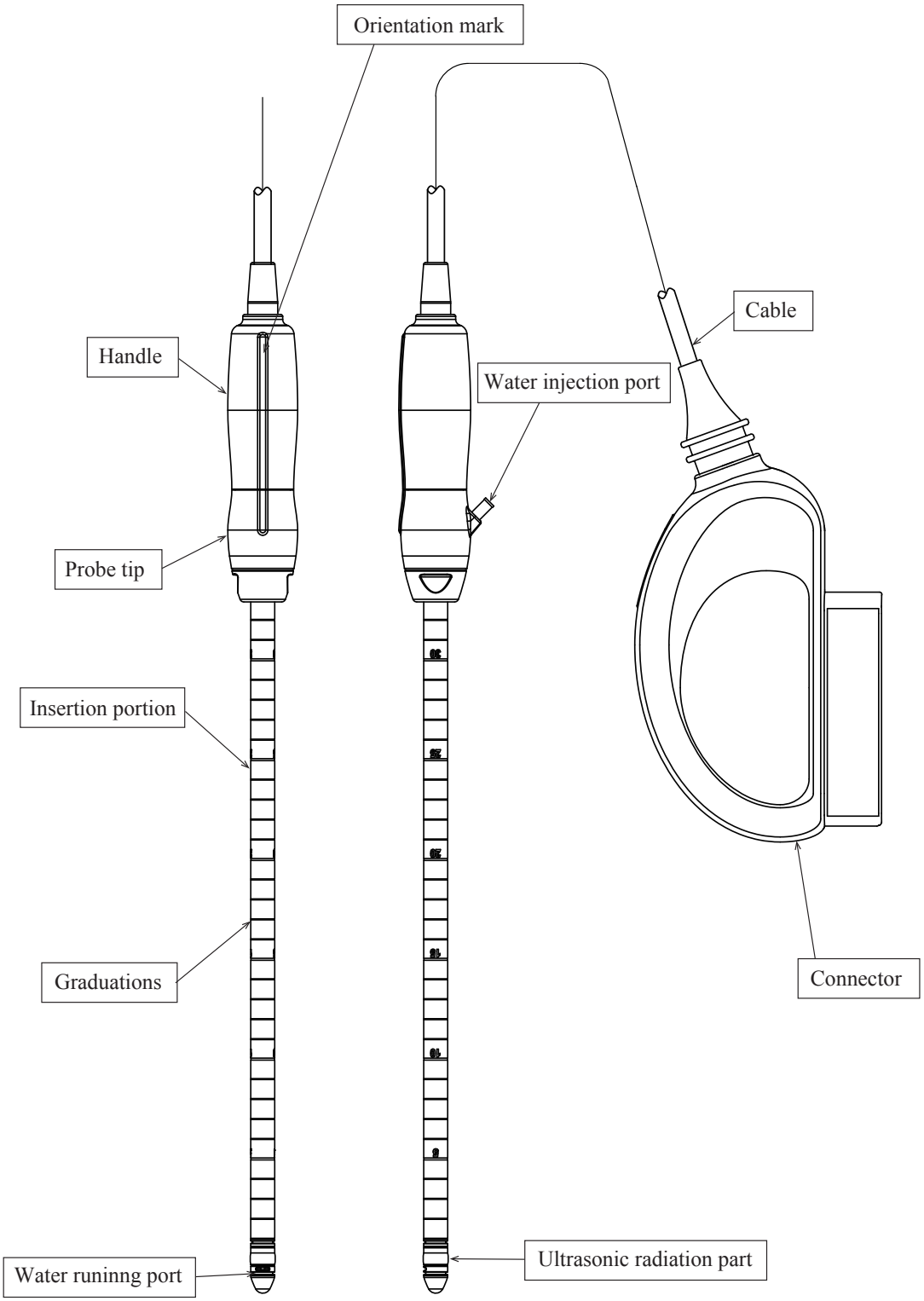


Figure 2 Name of each parts

Table 1 Name of each part and its explanation

Name	Explanation
Ultrasonic radiation part	Ultrasound is radiated from this part. The electronic radial transducer is integrated underneath this part.
Orientation mark side	The side of the orientation mark corresponds to the side of the orientation mark on the image.
Probe tip	The probe tip includes both the insertion portion and the handle.
Handle	This part is held during operation.
Insertion portion	This part is inserted into the patient.
Graduations	Graduations are marked 1cm increments for a rough indicator
Water injection port	This port is connected to the extension tube. Please refer to the section 4-2 for how to connect the extension tube to the port.
Water running port	Water injected from the injection port comes out of this port.
Cable	Cable transfers electric input/output signals.
Connector	The connector is the part which is connected to the ultrasound diagnostic instrument.

⚠ Caution	
⃠	Do not pull, bend, twist, or apply excessive force to the cable. The probe may malfunction due to cable disconnection.
⃠	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 elastic material.
⃠	Do not wipe the insertion portion with alcohol. Alcohol could damage the part.

3. Preparations before use

This chapter describes preparations needed to use the probe safely. Please prepare the probe prior to each use by following the instructions below.

3-1. Visual check

Visually check the ultrasonic radiation part, insertion portion, handle, cable, and connector.

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

3-2. Confirmation of cleaning, disinfection, and sterilization

Confirm that the probe is certainly cleaned, disinfected, and sterilized. The degree of reprocessing depends on the intended use. Please refer to the separate instruction manual “Cleaning, Disinfection and Sterilization“ for cleaning, disinfection, and sterilization procedure.

3-3. Operation check

Connect the probe to the ultrasound diagnostic instrument and check that the displayed scan type and frequency correspond to those of the probe. Check also that there is no abnormality in the image.

Remark: Please refer to the documentation supplied with the ultrasound diagnostic instrument for how to connect the probe and information displayed on the monitor.

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

Make preparations prior to each use.
The operator and the patient may be injured if the equipment has any abnormality.
If any abnormality is found in the equipment, stop using it and contact our office written on the back cover.

⚠ Caution

Do not use the probe if the displayed scan type and frequency do not correspond to those of the probe.
Incorrect acoustic output can result in burns or other injuries to the patient. Contact our office written on the back cover.

3-4. Preparation for diagnosis

Please prepare following items before diagnosis.

- Short probe cover or condom (Length: approx. 100mm, Inner diameter: over 13mm)
  - sterile if possible
  - not latex if possible

  e.g. Cross Healthcare, Ltd./samcoCover REF 7.584.420, Size: FU 100

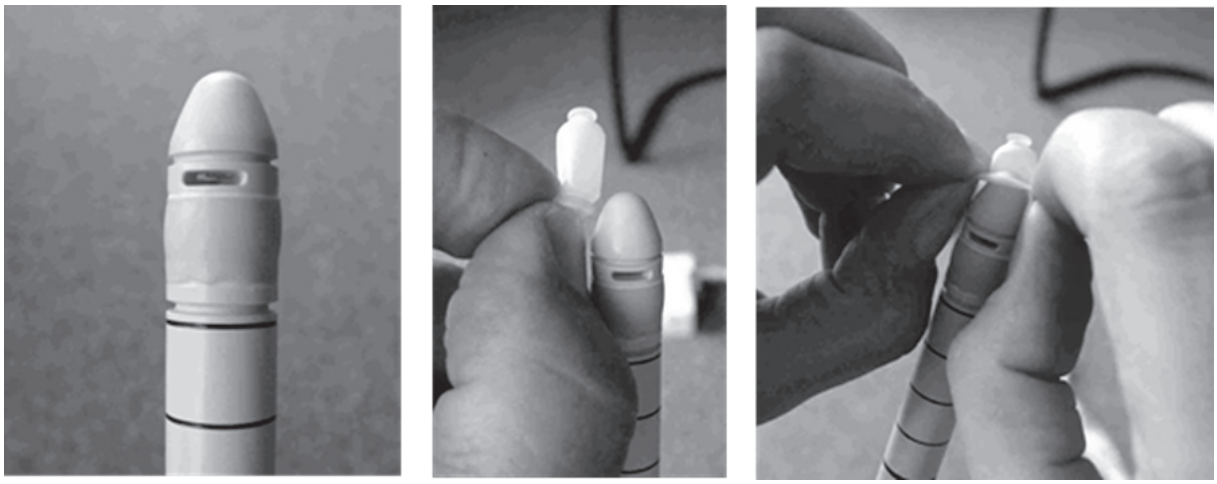


Figure 6: Application of first protective sheath (e.g. Cross Healthcare, Ltd./samcoCover REF 7.584.420)

⚠ Caution
Both sides of the rings of Cross Healthcare, Ltd./samcoCover REF 7.584.420 balloon are little bit tight against the grooves of the tip of probe. Handle with care when mounting and removing it to/ from the probe. If the cover is mounted or remove roughly, the acoustic part may suffer serious damage and be unfunctional.

- Long probe cover or condom (Length: approx. 400mm, Inner diameter: over 15mm)
  - sterile if possible
  - not latex if possible

  e.g. Cross Healthcare, Ltd. cover REF: 220.00.04 Size: 26x300mm, non-sterile

  e.g. Cross Healthcare, Ltd. cover REF: 7.206.040 Size: 26x300mm, sterile

- Sterile tape
- Extension tube
- Syringe
- Sterile saline

4. Operation

This chapter describes the operation of the probe and how to attach/release a probe cover.

4-1. Operation

Mount a probe cover on the probe and insert the probe into the rectal. Please refer to the next section for how to mount a probe cover to the probe.

An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. For details on displaying and adjusting the image, refer to the documentation supplied with the ultrasound diagnostic instrument.

⚠ Caution
Do not operate the probe with excessive force. Use with excessive force could result in injury to the patient.
Scan for minimum time necessary at the lowest possible acoustic output. Acoustic output may affect the patient's internal tissues. 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 probe. Electrostatic discharge may result in malfunction of the probe.
Do not touch the probe connector of the ultrasound diagnostic instrument and the patient at the same time. It can cause electric shock to the patient.

4-2. How to mount probe covers

Please mount probe covers by following the instruction below.

(1) Mount a short probe cover on the probe tip and tie the short probe cover by adhesive tape.
(2) Apply sterile ultrasound gel to the short probe cover on the ultrasonic radiation part (Figure 3).
(3) Mount a long probe cover on the probe and cover the acoustic part of the probe. (Figure 4)
(4) Inject physiological saline in the short probe cover by the syringe to remove air bubbles.
(5) After removing air bubbles, draw all physiological saline back into the syringe.

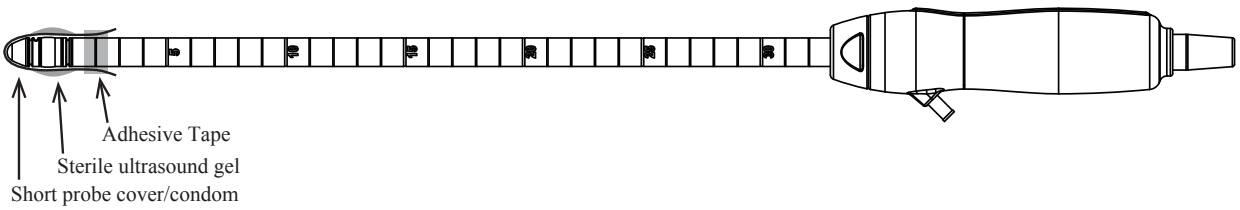


Figure 3 Mounting a short probe cover

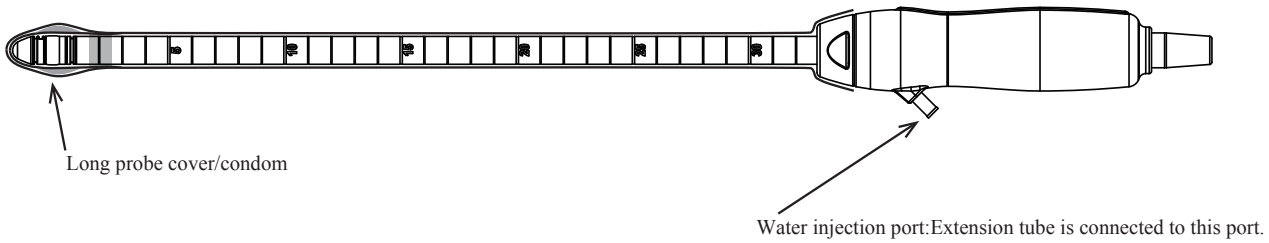


Figure 4 Mounting a long probe cover

⚠ Warning	
❗	Mount the probe cover on the insertion portion. If the probe cover is not used, residual pathogens on the probe could infect the patient.
❗	Use only biocompatible probe covers. The use of non biocompatible probe covers can cause an adverse reaction.
❗	Use only sterile probe cover. The use of non sterile probe cover could cause infection to the patient.
⃠	Do not reuse the transducer cover. The reuse of the transducer cover may cause infection to the patient.
⃠	Do not apply unsterile acoustic medium to the outer surface of the probe cover. The use of unsterile acoustic medium can cause infection to the patient.
⃠	Do not use the latex probe cover for patient who may have an allergic reaction. The use of the latex probe cover could result in anaphylactic shock. Ask the patient about allergy history before diagnosis.

⚠ Caution	
❗	Confirm the storage condition and the expiration date of the probe cover. Store the transducer cover according to its instruction. Do not use the transducer cover if the expiration date has passed, if it is discolored, or if there is visible damage, such as a tear.
❗	Confirm that there is no air bubbles in the ultrasound gel on the ultrasound radiation part. Air bubbles on the ultrasound radiation part can result in misdiagnosis due to poor image quality or improper rendering.

4-3. Diagnosis

(1) Insert the probe into anus.

(2) Inject the physiological saline into the short probe cover by the syringe.

(3) Locate the probe at the observation site by turning the probe and adjust the insertion depth.

(4) The relationship between the scan position and the image is that,

- if “PROX“ is displayed, the image from the insertion direction is shown (Figure 5),
- if “DISTAL“ is displayed, the image from the opposite direction of the insertion direction is shown.

(5) After observation, draw physiological saline in the short probe cover into the syringe.

(6) After drawing all physiological saline back into the syringe, remove the probe from anus.

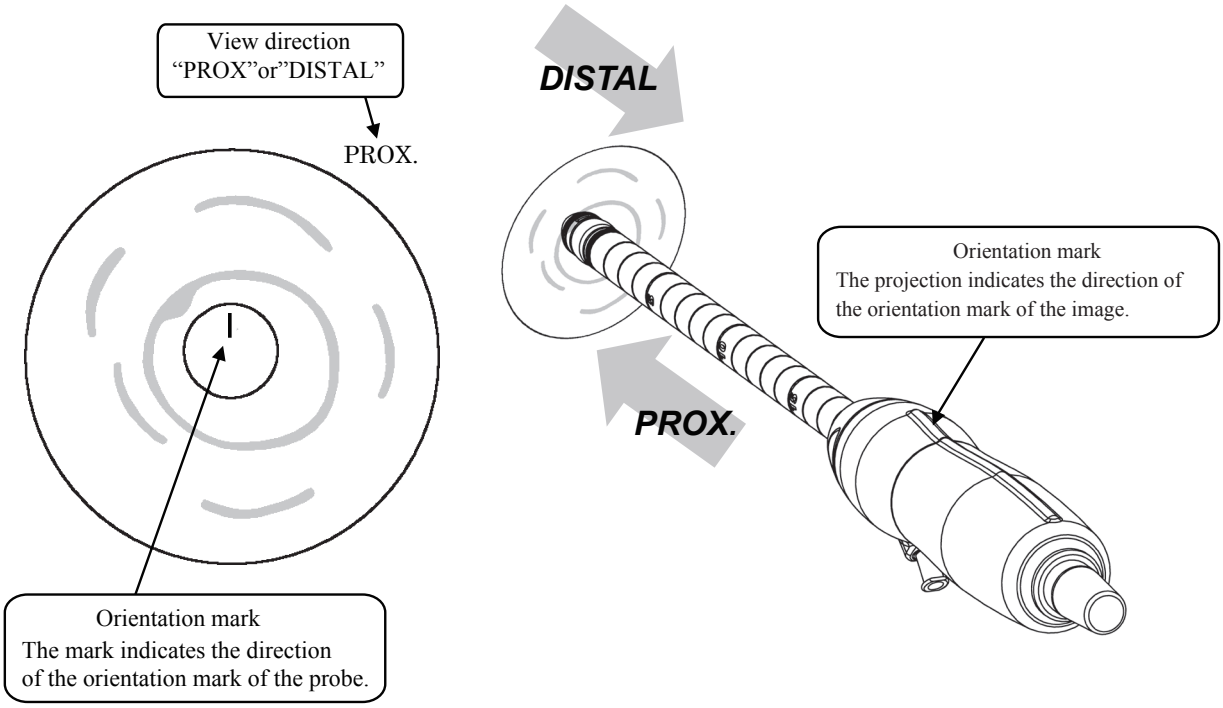


Figure 5 Direction of the image

4-4. Procedure after use

(1) Remove the long probe cover/condom first.

(2) Untie adhesive tape and remove the short probe cover/condom.

(3) Clean and disinfect or sterilize the probe according to the separate instruction manual “Cleaning, Disinfection and Sterilization”.

(4) Store the probe under the conditions specified in the separate instruction manual “Safety”.

⚠ Warning
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.
Do not use any sharp object such as a pincet to remove the probe cover or the condom. Do not scratch the ultrasound radiation part and the insertion portion.
Do not hold the insertion portion to remove the probe cover or the condom. The insertion portion may be damaged due to excessive force.

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