HITACHI
Inspire the Next

VC41V Probe
Instruction Manual
Specification

MN1-5863 Rev.5

Notes for operators and responsible maintenance personnel

★ *Please read through this Instruction Manual as well as the separate Instruction Manual "Safety (MN1-5994)" and "Cleaning, Disinfection and Sterilization (MN1-6002)" 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 VC41V probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be mainly used for observation of the uterus 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 the safety information provided to prevent hazards and injuries to the operator or patients.

⚠ 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 12 pages of the main content.

1. General Information

General information for the probe is provided below.

1-1. Intended use

This probe 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.

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 patient or operator.

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 range of applied part, the part treated as 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 VC41V probe are as follows.

VC41V Probe ····· 1 set
Storage case ····· 1 set
Instruction Manual
- Specification (MN1-5863)····· 1 copy
- Safety (MN1-5994) ····· 1 copy
- Cleaning, Disinfection and Sterilization (MN1-6002) ····· 1 copy

1-4. Option

The following options are available for VC41V probe.

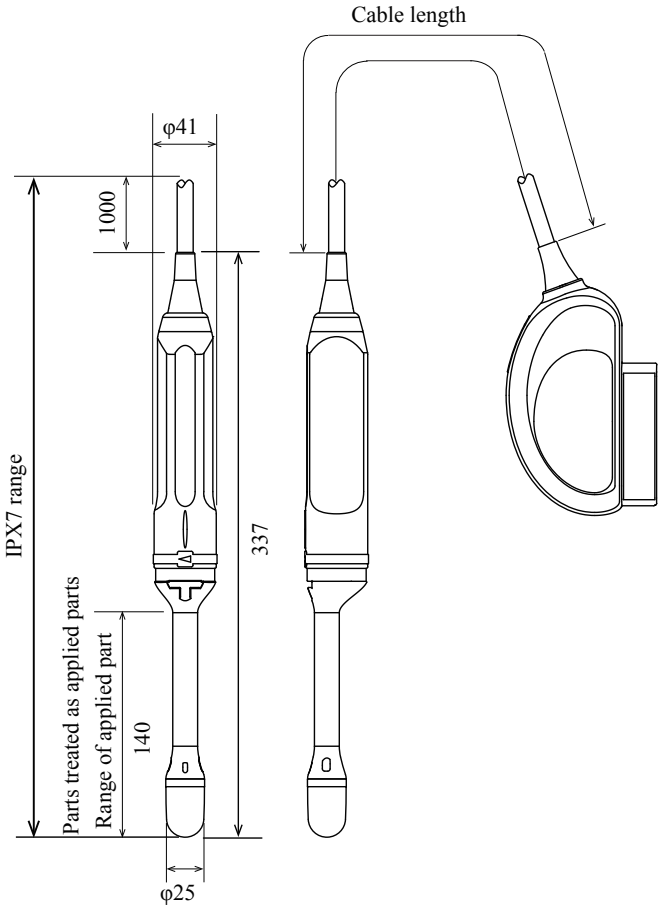
- Rubber boot RB-945BP-NS (non-sterile)

2. Specifications and Parts name

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

2-1. Specifications

Application:	Obstetric and gynecological areas
Type of patient contact:	Transvaginal
Connectable instruments:	ARIETTA 70, ARIETTA 60 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.
Electronic scan field of view:	140°
Mechanical scan field of view:	90°
Frequency:	6.0 MHz
Cable length:	2.0 m
Service life:	3 years
Applied part:	See Figure 1
Part treated as applied part:	See Figure 1
IPX7 range:	See Figure 1
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.

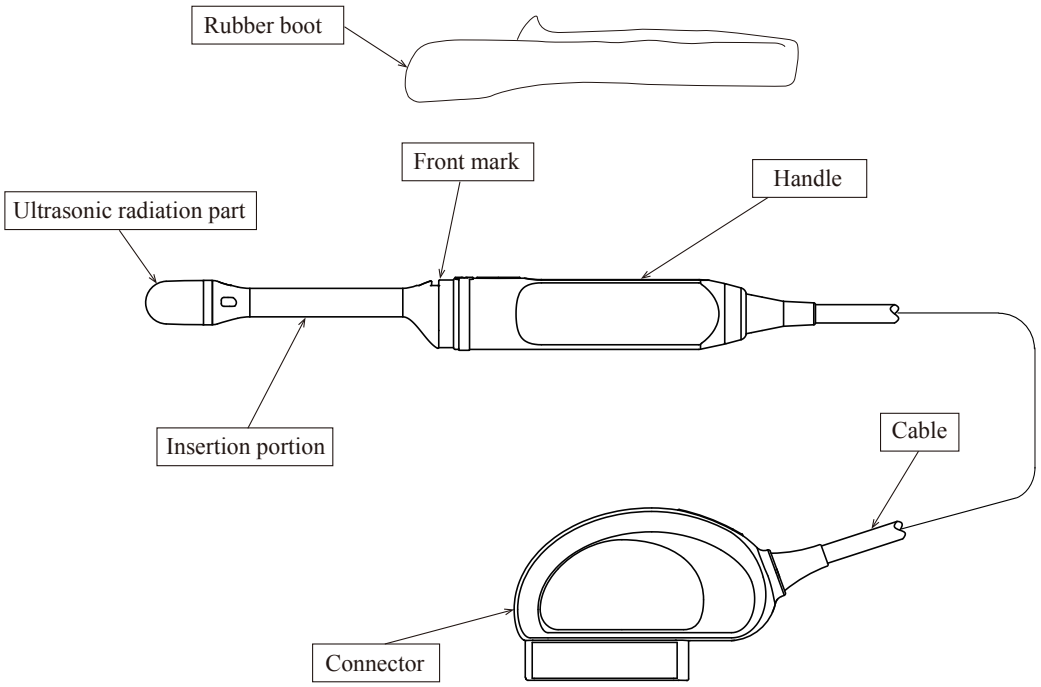


Figure 2 Name of each parts

Table 1 Name of each part and its explanation

Name	Explanation
Ultrasonic radiation part	Ultrasound is radiated from this part. The electronic convex transducer is integrated underneath this part.
Insertion portion	The component that is inserted into the patient.
Front mark	The dimple corresponds to the side of the orientation mark on the image.
Handle	This section is held when performing insertion..
Cable	Cable transfers electric input/output signals.
Connector	The connector is the part which is connected to the ultrasound diagnostic instrument.
Rubber boot	This covers the insertion portion for preventing infection. Follow the instructions in section 4-2

⚠ 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 plastic material.

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, connector and rubber boot.
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.

4. Operation

This chapter describes the operation of the probe and how to mount/remove the rubber boot.

4-1. Operation

Mount a probe cover on the probe and insert the probe into the body 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 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 the rubber boot

Apply a suitable amount of ultrasound gel on the ultrasonic radiation part and then cover it with the rubber boot.
Remove air bubbles or wrinkles on the ultrasonic radiation part.

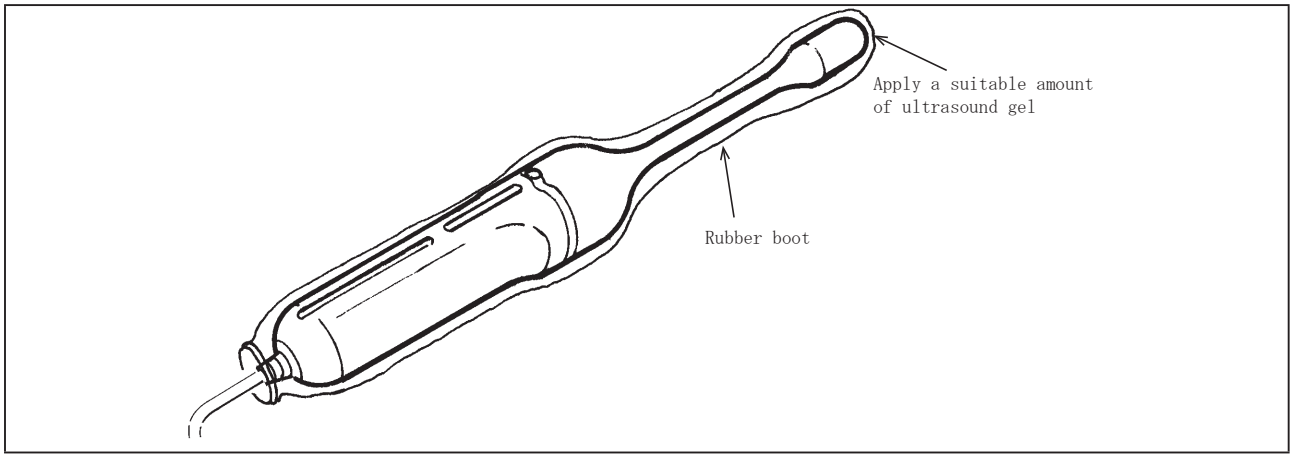


Figure 3 How to mount the rubber boot

⚠ 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.
❗	Use Hitachi-approved rubber boots only. Use of an item lacking biocompatibility can cause an adverse reaction by the body of the patient.
❗	Check that the rubber boot is sterilized. Use of an infected item could spread infection to the patient.
⃠	Do not reuse the rubber boot. Use of an infected 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) or severe discoloration, cracks, or other visible defects finds.
❗	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. How to remove the rubber boot

(1) Wrap the rubber boots in tissue paper and remove the rubber boots from the probe.

(2) Dispose tissue paper and the rubber boots according to the infection prevention procedures of your facility.

⚠ 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.

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