

L441 Probe Instruction Manual Specification MN1-5825 Rev. 6

Notes for operators and responsible maintenance personnel

- ★ *Please read through this Instruction Manual as well as the separate Instruction Manual “Safety (MN1-5982)” and “Cleaning, Disinfection and Sterilization (MN1-5998)” carefully prior to use.*
- ★ *Keep this Instruction Manual together with the ultrasound diagnostic instrument for any future reference.*

FUJIFILM Healthcare Corporation

Introduction

This is the instruction manual for L441 probe. The probe is available by connecting to our company's ultrasound diagnostic instrument and can be mainly used for observation of general abdominal 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.

1. General Information.....	1
1-1. Intended use.....	1
1-2. Classification of ME equipment.....	1
1-3. Standard components	1
1-4. Options	2
2. Specifications and Parts name.....	3
2-1. Specifications.....	3
2-1-1.Specification of the probe	3
2-1-2.Specifications of the holding adjunctive equipment*	4
2-2. Name of each parts.....	5
3. Preparations before use	7
3-1. Visual check	7
3-2. Confirmation of cleaning, disinfection, and sterilization.....	7
3-3. Operation check.....	7
4. Operation.....	9
4-1. Operation.....	9
4-2. How to attach the holding adjunctive equipment	10
4-3. How to release the holding adjunctive equipment.....	11
4-3-1. Removing from the probe	11
4-3-2. Cleaning the holding adjunctive equipment.....	11

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 to be used by doctors or other qualified operators. The probe is placed on the body for observation of 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 L441 probe are as follows.

- L441 Probe 1 set
- Storage case 1 set
- Instruction Manual
 - Specification (MN1-5825) 1 copy
 - Safety (MN1-5982)..... 1 copy
 - Cleaning, Disinfection and Sterilization (MN1-5998) 1 copy

1-4. Options

The following options are available for L441 probe.

- Puncture

Please use the options listed in Table 1 for performing a puncture. Regarding the usage of CIVCO Bracket, please refer to the documentation supplied with the bracket.

Table 1 Options for puncture

Product Name	Product No.
CIVCO Bracket	644-076
CIVCO Probe cover / Biopsy needle guide set	610-608

- Elastography

Please use the options listed in Table 2 for performing Elastography.

Table 2 Options for Elastography

Product Name	Product No.
Hold adjunctive equipment	MP-2804

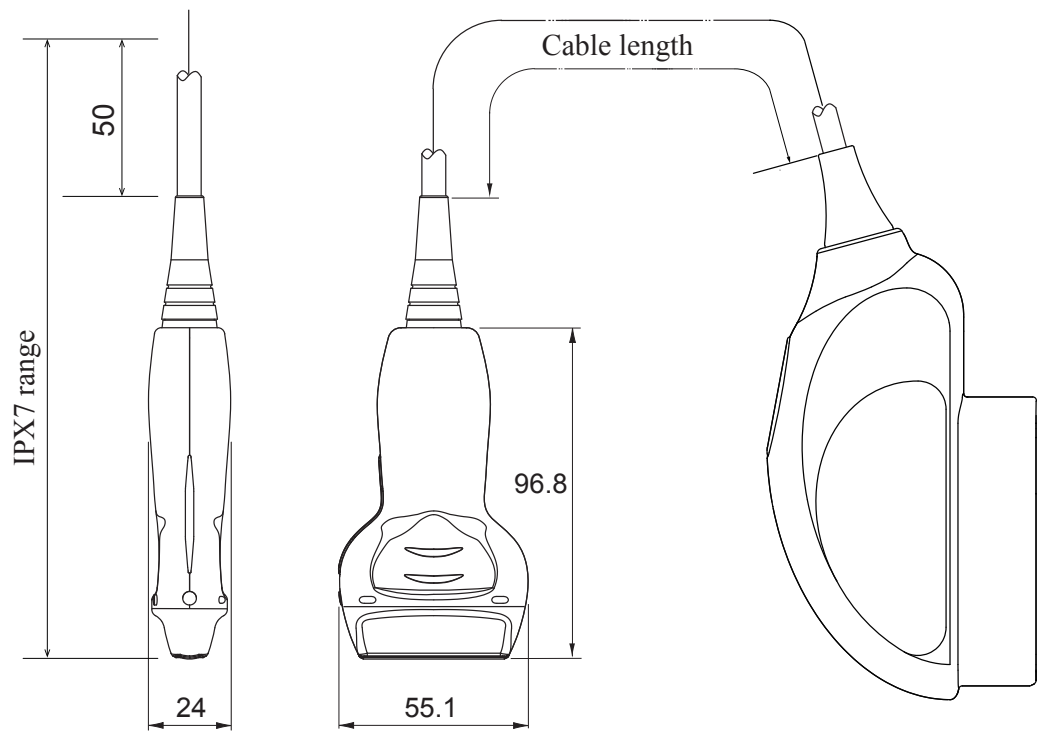
2. Specifications and Parts name

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

2-1. Specifications

2-1-1.Specification of the probe

Application:	Carotid artery
Type of patient contact:	Surface
Connectable instruments:	ARIETTA 70, ARIETTA 60, Noblus, ARIETTA Precision, ARIETTA Prologue, ALOKA ARIETTA 850, ALOKA LISENDO 880
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 our company representative.
Field of view:	38mm
Frequency:	6.0 MHz
Cable length:	2.0 m
Service life:	3 years
Applied part:	Probe tip including ultrasonic radiation part, see the section 2-2
Part treated as Applied part:	Cable up to 1 m length from the probe tip
IPX7 range:	See Figure 1
Measurement accuracy:	Refer to the instruction manual of the ultrasound diagnostic instrument
External dimensions:	See Figure 1



Unit: mm

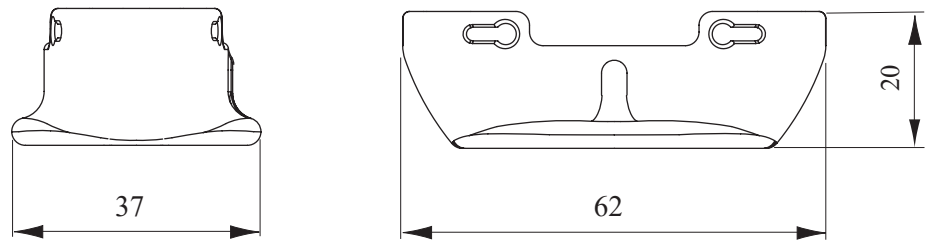
Remark: The tolerance for the dimensions is $\pm 10\%$.

Figure 1 External View

2-1-2.Specifications of the holding adjunctive equipment*

* This equipment is the option of this probe.

Material	Polyethylene
Service life	Three years
External dimensions	As shown in the figure below.



Unit:mm

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

Figure 2 External view of the holding adjunctive equipment

• Safety label

The meaning of each symbol in the safety label (Figure 3) is described in Table 3.



Figure 3 Safety label

Table 3 Mark and meaning of each symbol in the safety label

Mark	Meaning
	Safety warning sign
	Biohazard See the separate instruction manual “Cleaning, Disinfection and Sterilization”.
	Follow the instruction manual to operate this instrument. Improper operation can result in injury, damage to property, or equipment malfunction.

2-2. Name of each parts

The name of each part is shown in Figure 4 and the explanation for each part is listed in Table 4.

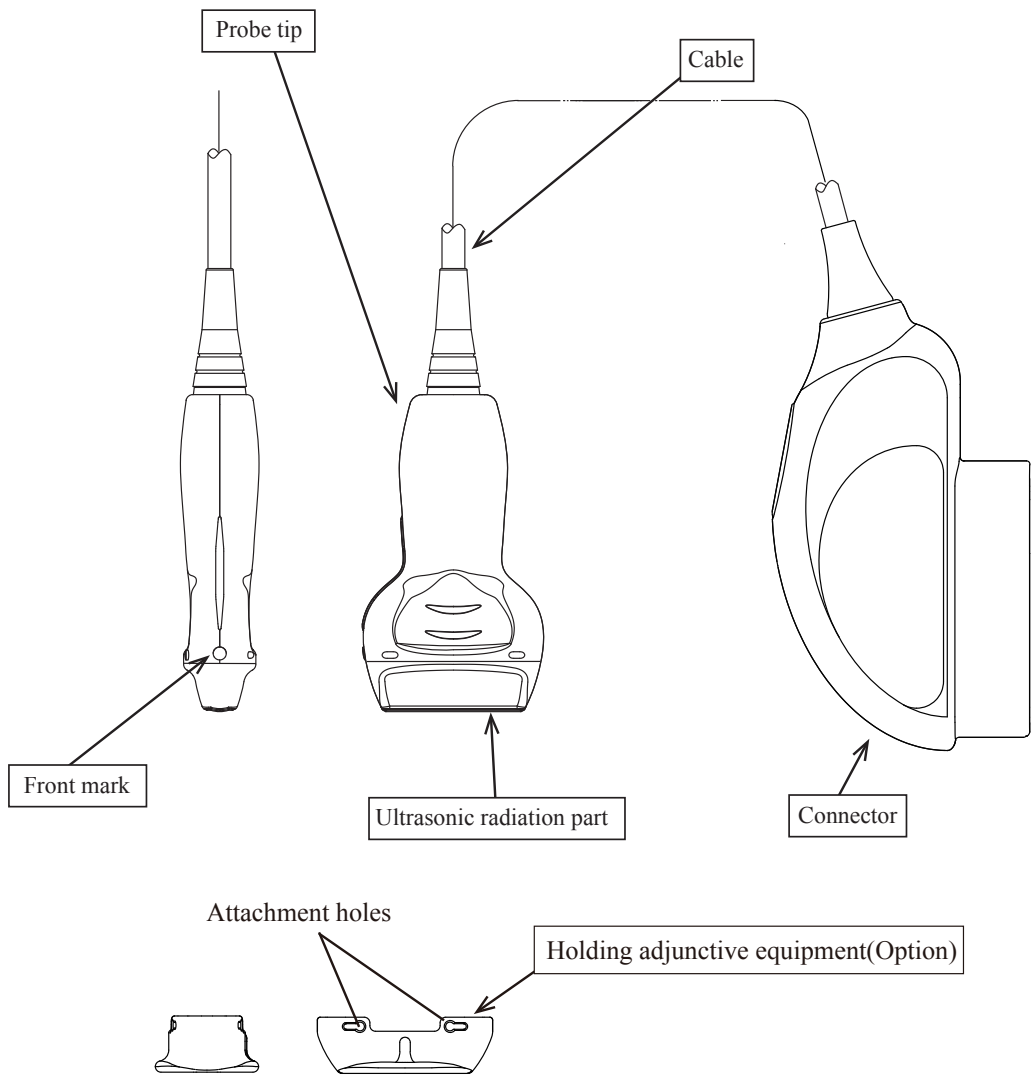


Figure 4 Name of each parts

Table 4 Name of each part and its explanation

Name	Explanation
Ultrasonic radiation part	Ultrasound is radiated from this part. The electronic linear transducer is integrated underneath this part.
Front mark	The side of the front mark corresponds to the side of the orientation mark on the image.
Probe tip	This part is gripped during operation.
Cable	Cable transfers electric input/output signals.
Connector	The connector is the part which is connected to the ultrasound diagnostic instrument.
holding adjunctive equipment	Attaching to the probe provides improved stability during probe operation and enables easier vertical application to the diagnosis region. 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 elastic 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 probe tip, ultrasonic radiation part, cable, and connector.

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

Check also the options as necessary.

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. Check also that options are properly cleaned, disinfected, and sterilized.

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 company 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 company written on the back cover.

4. Operation

This chapter describes the operation of the probe and how to attach/release the holding adjunctive equipment.

4-1. Operation

Place the ultrasonic radiation part of the probe onto the skin surface. An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. For details on displaying and adjusting the 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 attach the holding adjunctive equipment

Attach the holding adjunctive equipment to the probe as shown in the figure below.

Insert the probe into the holding adjunctive equipment by aligning the probe attachment guides with the attachment holes in the holding adjunctive equipment and check that it is locked to the probe.

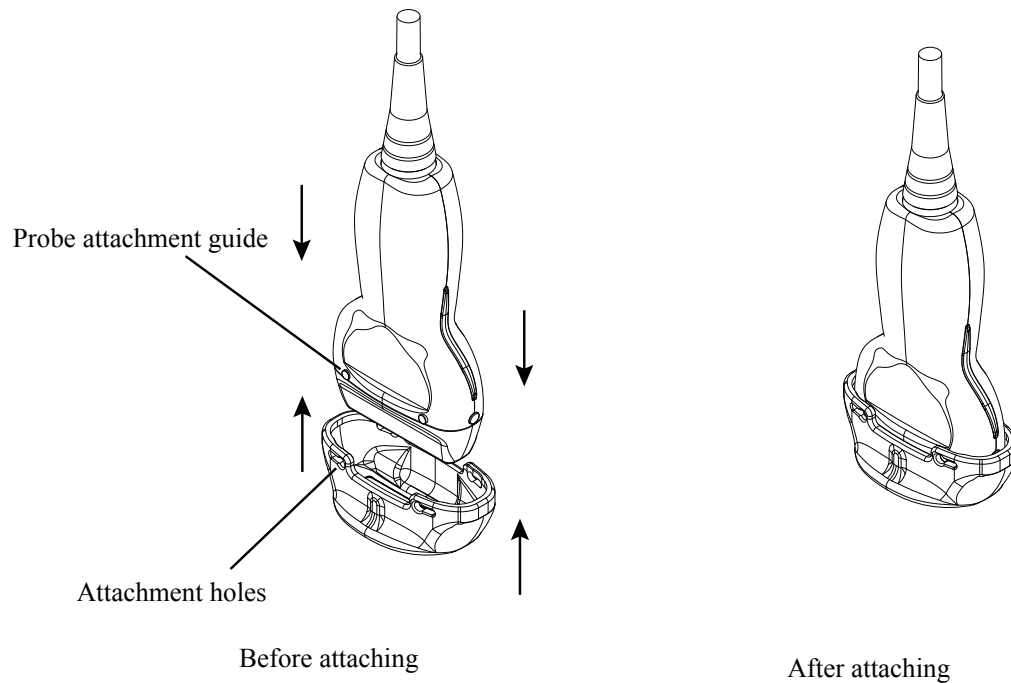


Figure 5 How to attach the holding adjunctive equipment

4-3. How to release the holding adjunctive equipment

4-3-1. Removing from the probe

The holding adjunctive equipment is removed as shown in the figure below.

- (1) Press one end of the holding adjunctive equipment to separate the attachment guide and attachment hole on one side.
- (2) Pull off and remove the probe from the holding adjunctive equipment.

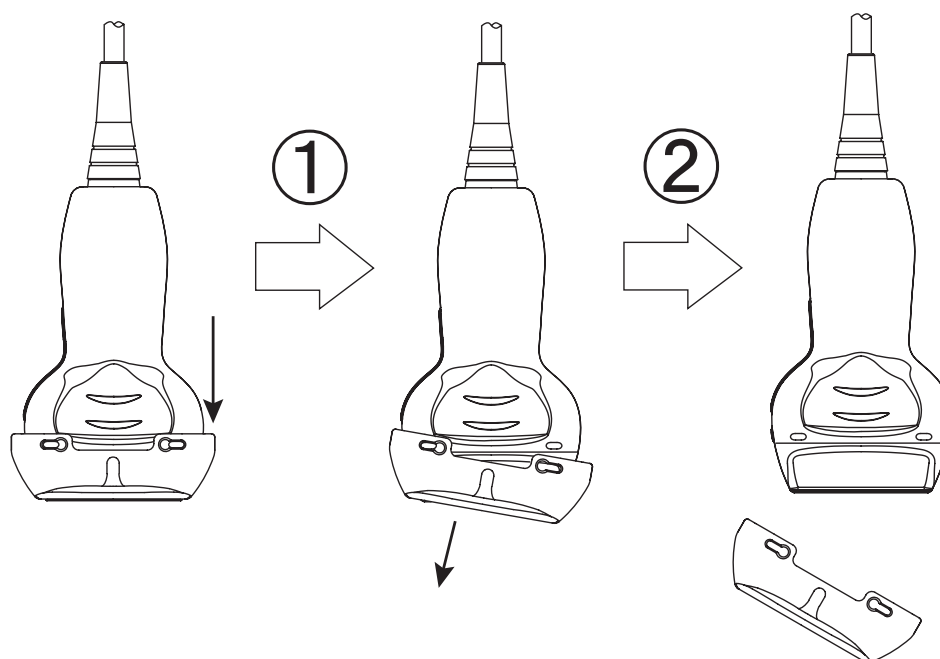


Figure 6 How to release the holding adjunctive equipment

4-3-2. Cleaning the holding adjunctive equipment

Immediately wash the holding adjunctive equipment immediately after it is removed from the probe.

Please refer to the separate instruction manual “Cleaning, Disinfection and Sterilization“ for cleaning, disinfection, and sterilization procedure.

Note

After use of the equipment, immediately care of them.

If the equipment left in uncleaned for a long time after use, the adhered acoustic medium coagulate make difficult to care the equipment.

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