HITACHI
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L44LA Probe

Instruction Manual

Specification

MN1-6013 Rev.4

Notes for operators and responsible maintenance personnel

★ *Please read through this Instruction Manual as well as the separate Instruction Manual "Safety (MN1-5984)" and "Cleaning, Disinfection and Sterilization (MN1-6000)" 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 L44LA probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be mainly used for observation of human internal organs through the trocar .
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 when placed into direct contact with human internal organs through the trocar during surgery making ultrasonic observations.

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 L44LA probe are as follows.

L44LA Probe ····· 1 set
Protect tube(MP-2485B) ····· 1 set
Storage case ····· 1 set
Instruction Manual
- Specification (MN1-6013) ····· 1 copy
- Safety (MN1-5984) ····· 1 copy
- Cleaning, Disinfection and Sterilization (MN1-6000) ····· 1 copy

1-4. Options

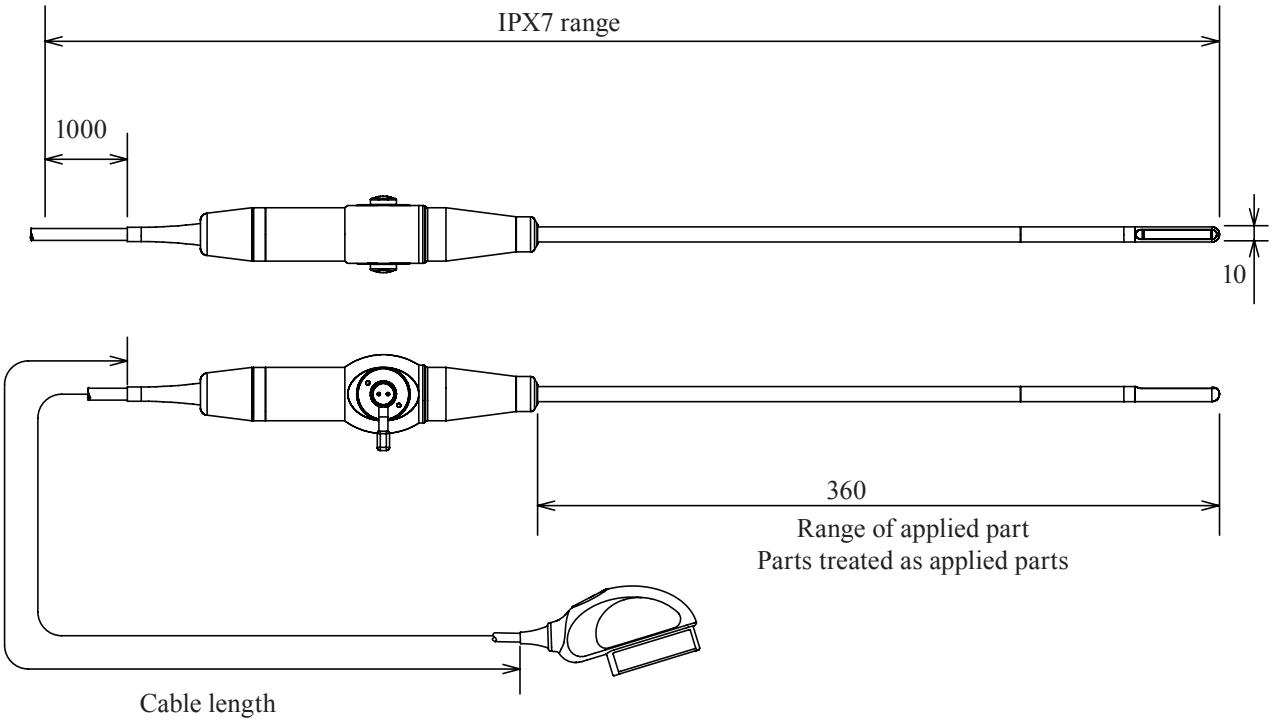
There is no option available for L44LA probe.

2. Specifications and Parts name

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

2-1. Specifications

Application:	Intraoperative diagnosis
Type of patient contact:	Intraoperative
Connectable instruments:	ARIETTA 70, ARIETTA 60, Noblus, ARIETTA Precision 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:	36mm
Frequency:	7.0 MHz
Cable length:	3.0 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

Remarks

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

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.

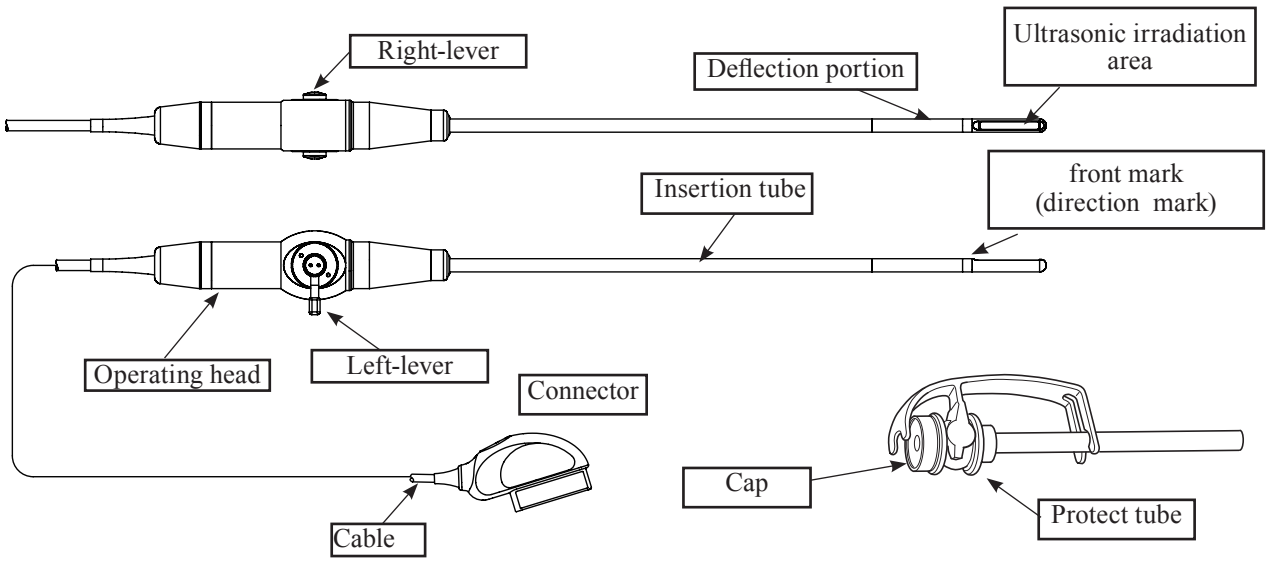


Figure 2 Name of each parts

Table 1 Name of each part and its explanation

Name	Explanation
Ultrasonic irradiation area	This incorporates an electronic linear transducer.
front mark (direction mark)	Near the deflection portion corresponds the front mark (direction mark) on the image display.
Deflection portion	When operate the left-lever , you can bend the tip up-down direction. When operate the right-lever , you can bend the tip left -right direction..
Left-lever,Right-lever	This part is used to operate the deflection portion.
Operating head	When using the probe, hold this part by hand.
Insertion tube	The part is inserted into the patient's body with the ultrasonic irradiation area and deflection portion.
Cable	This cable propagates the ultrasonic signals that are sent and received.
Connector	This cable propagates the ultrasonic signals that are sent and received.
Cap	The cap eliminates the gap with the probe and keeps airtightness.
Protect tube	Protects the probe from the external tube of torocar.

⚠ 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.

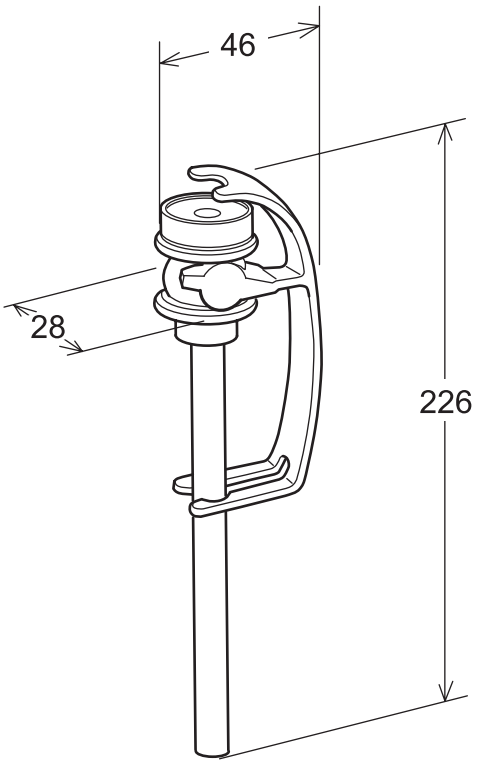
2-3. Specifications of the protect tube

Material: Polyetherimide (Protect tube), Silicon rubber (Cap)

Compatible trocar size: 12mm

Service life: Three years

External dimensions: As shown in the figure below.



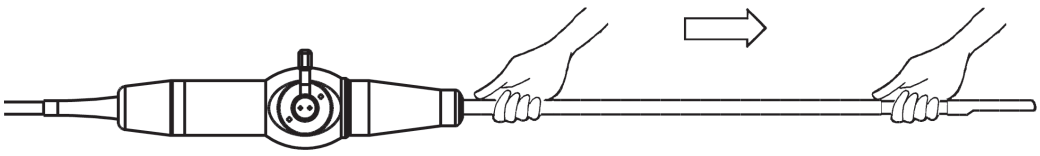
3. Preparations for Use

following the instructions below.

3-1. Visual check

Visually check the ultrasonic irradiation area, deflection portion, insertion tube, operating head, cable and the connector.

- If any holes, indentations, abrasion, cracks, deformation, looseness, discoloration, or other abnormalities are found, do not use the equipment.
- Try to bend the deflection portion in all directions by operating the left-lever and the right-lever and make sure there are no protrusions or cracks.
- Gently grab the insertion tube to the ultrasonic irradiation area by hand, slide it and make sure there are no catching or loose parts.



- Make sure the protect tube has no abnomalities such as scars, cracks or separation.
- Make sure the surface of the connector and the cable has no abnomalities such as scars, cracks or separation.

3-2. Deflection portion operation check

- Gently operate left and right lever till it stops and check the following:

*The lever can be smoothly operate without any excessive force
* Make sure there are no irregularities in force to turn the angle knob such as catching.
* Make sure the deflection portion is bent smoothly in all directions.

3-3.Confirmation of cleaning and sterilization

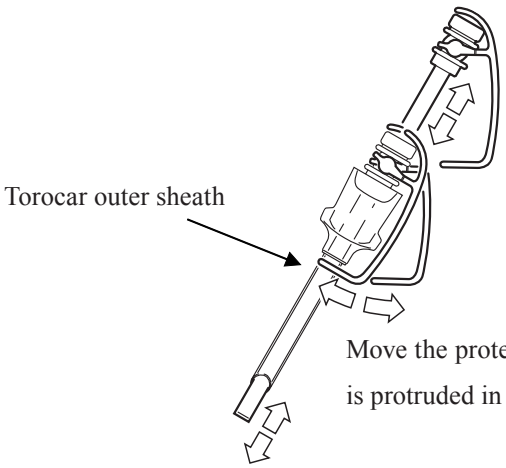
Confirm that the probe is certainly cleaned and sterilized. The degree of reprocessing depends on the intended use. Please refer to the separate instruction manual “Cleaning, Disinfection and Sterilization“ for cleaning and sterilization procedure.

3-4.Verification of operation

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.

3-5.Torocar connection check

• Make sure the protect tube can be smoothly and correctly attached/detached to/from the torocar outer sheath and its tip is protruded from the trocar outer sheath when the protect tube is locked.



Move the protect tube up and down after it is locked and make sure the tip is protruded in all conditions.

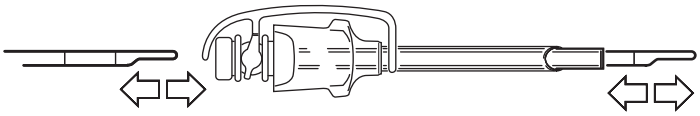
Remark: Please refer to the documentation supplied with the ultrasound diagnostic instrument for how to connect the probe and information displayed on the monitor.
If the probe is operated in still air, brightness on the top of the image may be non uniform, but this does not affect the performance of 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.

3-6. Probe insertion check

With the protect tube locked to the trocar outer sheath, insert the probe into the protect tube and make sure the probe can be smoothly inserted/removed.

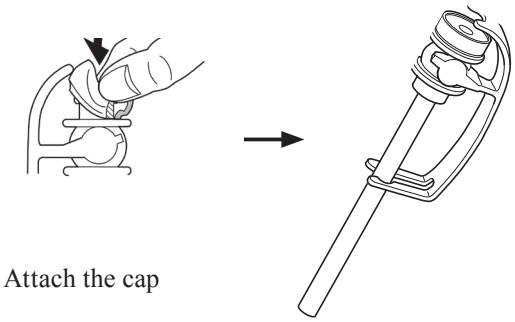


4. Operation

This chapter describes the operation of the probe.

4-1. Preparations of the protect tube

Attach the cap to protect tube.



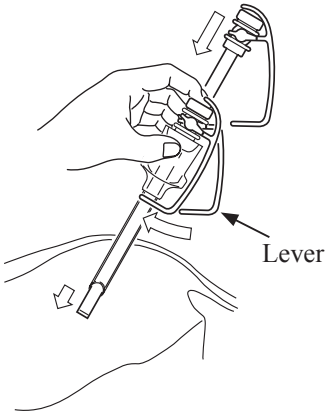
Attach the cap

4-2. Insertion of the probe

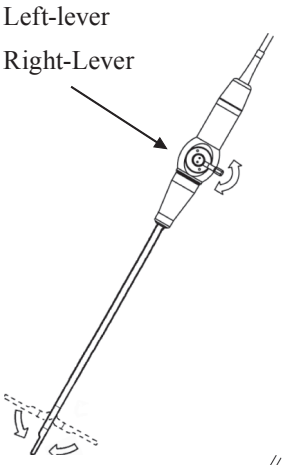
① Insert the protect tube into the torocar outer sheath and fix the lever to the trocar outer sheath.

[Remarks]

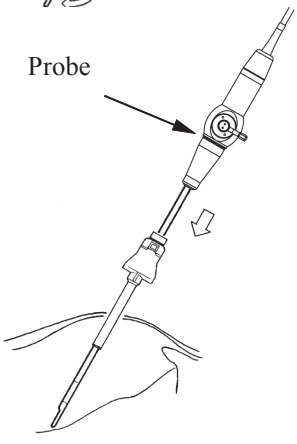
After fixing the lever, cover the insertion opening for the probe by finger to prevent gas leakage.



② Operatig left and right lever , please straight the deflection portion of the probe.



③ Gently insert the tip of the probe into the insertion opening of the protect tube.



4-3. Operation

Place the ultrasonic radiation part of the probe onto the inner organ surface during surgery. 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.

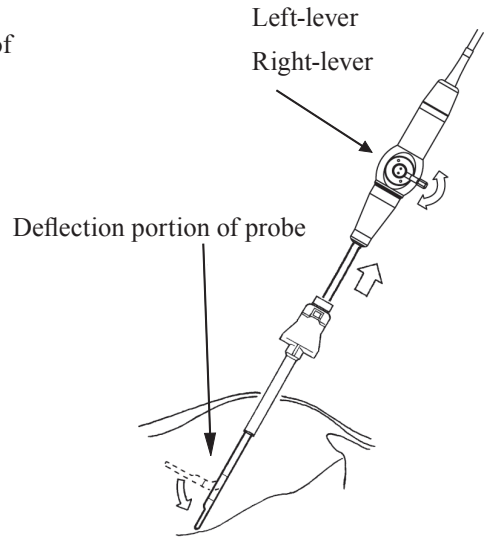
⚠ Warning	
❗	Be sure to wear sterilized medical gloves during handling the equipment to prepare. Handling of the equipment with your bare hands expose the patient to a risk of infection.
❗	Always use a protective tube. If the probe is damaged during operation, the patient can be injured.
❗	Use a trocar outer sheath that is the right size for the protective tube. When the trocar outer sheath is not the right size, the tube can be loose or difficult to insert and could result in a hazardous situation. Use a trocar outer sheath with a diameter of 12 mm and prepare it before operation.
❗	Attach the protective tube correctly to the trocar outer sheath. The patient can be injured if the protective tube moves unexpectedly or comes off during the operation. Also, if the cap is not attached correctly, the filled gas inside the patient's body will be released, making it difficult to perform the procedure.
⃠	Do not try to forcibly perform operations. Excessive force cause injury to the patient. If an abnormal resistance force is felt, stop use of the equipment.

⚠ Caution	
⃠	Do not try to forcibly perform operations. Excessive force cause injury to the patient. If an abnormal resistance force is felt, stop use of the equipment.
❗	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 waterproof connector terminal pin of the probe. The probe may deteriorate or be damaged due to electrostatic discharge.
⃠	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.
⃠	Please do not move the right and left lever at the same time. It may caused the wire of Probe loosens and does not come straight back. In addition, the blurring within 10 degrees is normal from a central axis.

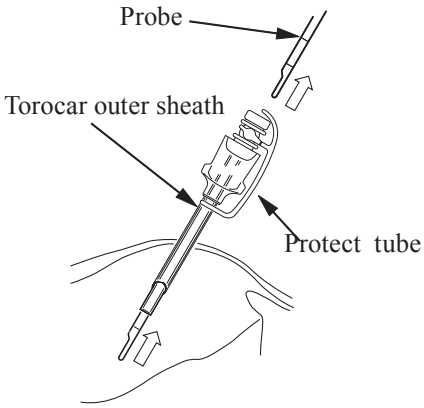
⚠ Note
Before inserting the probe into the body, confirm the deflection portion is straight. When the probe is used for an extended period of time, the deflection portion may not be straightened.

4-4. Pulling out the probe

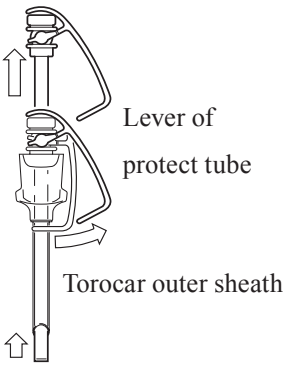
① Operatig left and right lever , please straight the deflection portion of the probe.



② Gently pull out the probe from the protect tube.



③ Take care that the torocar outer sheath does not move and pull out the protect tube by release the lever from the torocar outer sheath.



④ Immediately wash and sterilize the probe, protect tube and cap.

⚠ Warning
When removing the probe, straighten the deflection portion and pull out slowly and carefully. If pulling out the probe with excessive force ,it may cause the harm to a patient. If you feel resistance during operation such as it catching on something, do not operate excessive force and please check patient abdominal cavity with an endoscope.
Be sure to sterilize the probe and accessories which blood adhered. Otherwise, there is a risk of infection. Be sure to remove the cap from protect tube before washing.

■Manufacturer

Hitachi, Ltd.

2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015, Japan

■Contact

+81-3-6284-3668

http://www.hitachi.com/businesses/healthcare/index.html

Overseas Offices:

EC REP Hitachi Medical Systems GmbH

Otto-von-Guericke-Ring 3 D-65205 Wiesbaden, Germany

EU Importer: Hitachi Medical Systems Europe Holding AG

Address: Sumpfstrasse 13 CH-6300 Zug, Switzerland

US Importer: Hitachi Healthcare Americas Corporation

Address: 1959 Summit Commerce Park, Twinsburg, Ohio 44087

Distributor