

C41B Probe
Instruction Manual
Specification
MN1-6019 Rev.5

Notes for operators and responsible maintenance personnel

- ★ *Please read through this Instruction Manual as well as the separate Instruction Manual “Safety (MN1-5990)” 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.*



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Introduction

This is the instruction manual for C41B probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be used as a vaginal probe for observation of uterus and surrounding organs or used as a transrectal probe for observation of prostate and surrounding organs. It can also be used for ultrasound-guided puncture under the condition that the optional puncture guide tube is attached to it.

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.

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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 a doctor or other qualified operator for inserting into a human vagina and making ultrasound observations of uterus and surrounding organs or for inserting into a human rectal and making ultrasound observations of 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 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 C41B probe are as follows.

- C41B Probe 1 set
- Storage case 1 set
- Instruction Manual
 - Specification (MN1-6019) 1 copy
 - Safety (MN1-5990) 1 copy
 - Cleaning, Disinfection and Sterilization (MN1-6161) 1 copy

1-4. Option

The following options are available for C41B probe.

- Puncture

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

Table 1 Option for puncture

Product Name	Product No.
Puncture Guide Tube	MP-2445

- Probe cover

Please use the option listed in Table 2 for probe cover. Please refer to the section 4-2 for how to mount/remove the probe cover.

Table 2 Option for probe cover

Product Name	Product No.
Rubber Boot	RB-945BP-NS

- Real Time Virtual Sonography (RVS)

Please use the option listed in Table 3 for performing RVS. Please refer to the section 4-3.

Table 3 Option for RVS

Product Name	Product No.
Magnetic Position Sensor Attachment	RV-013

- Reprocessing by liquid detergent, disinfectant or sterilant

Whole the probe is able to immerge into the liquids by putting the connector of the ultrasound probe to the waterproof case WP-001 as below table 4.

Precautions about the waterproof case, please refer to the instruction manual.

Table 4 Accessory for reprocessing by liquid detergent, disinfectant or sterilant

Product Name	Product No.
Waterproof case	WP-001

2. Specifications and Parts name

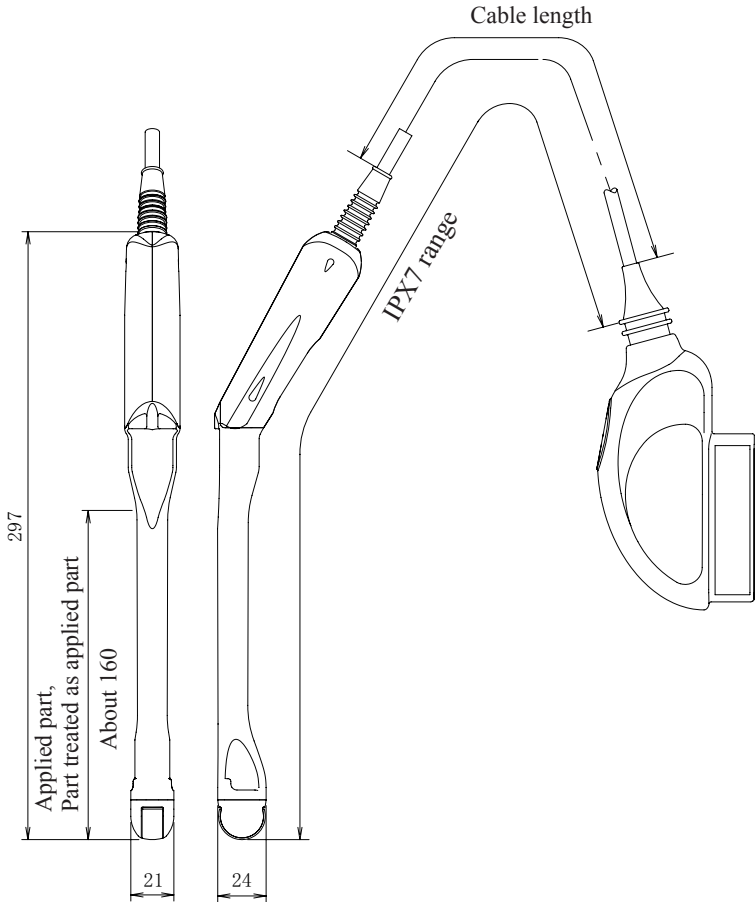
The specifications and the name of each part are provided below.

2-1. Specifications

- Application: Obstetric and gynecological areas, Urological applications
- Type of patient contact: Transvaginal, Transrectal ultrasound
- Connectable instruments: ARIETTA 60, ARIETTA 70, Nobls, ARIETTA Prologue

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: 200°
- Frequency: 6.5 MHz
- Cable length: 2.5 m
- Service life: 3 years
- Applied part: See Figure 1
- Part treated as applied part: See Figure 1
- IPX7 range: See Figure 1 (In case that not putting the waterproof case to the ultrasound probe connector)
In case that putting the waterproof case to the ultrasound probe connector, whole the probe from the tip of the ultrasound probe to the connector with Waterproof Case WP-001 is IPX7. range
- Measurement accuracy: Refer to the instruction manual of the ultrasound diagnostic instrument
- External dimensions: See Figure 1



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

Figure 1 External View

Unit: mm

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 5.

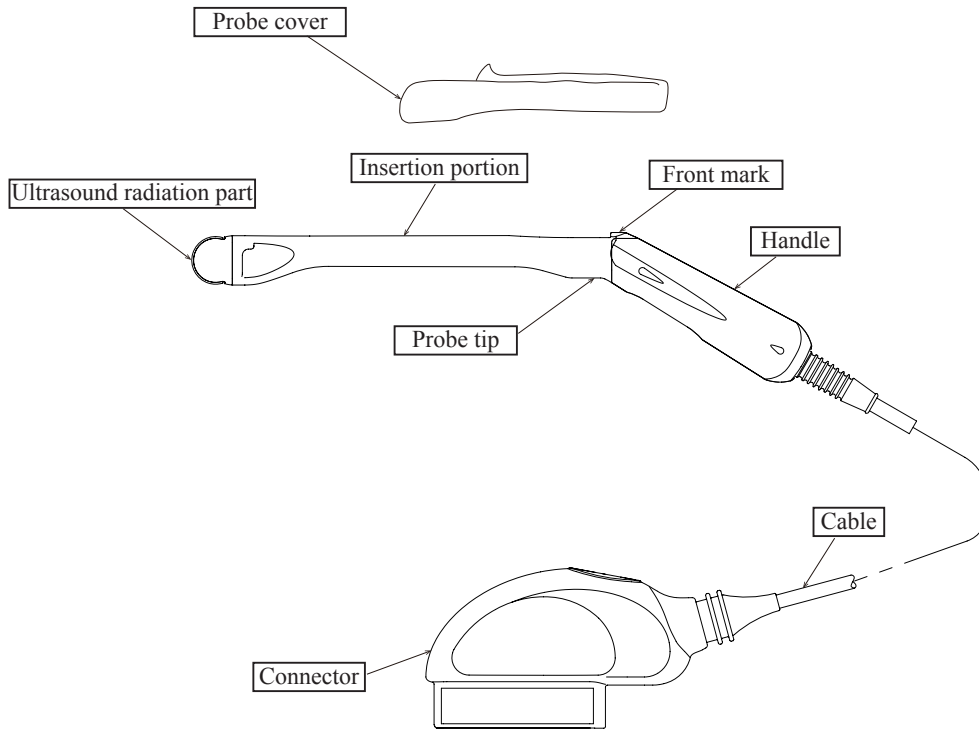


Figure 2 Name of each parts

Table 5 Name of each part and its explanation

Name	Explanation
Ultrasound radiation part	Ultrasound is radiated from this part. The electronic convex transducer is integrated underneath this part.
Insertion portion	This part is inserted into the patient.
Handle	This part is held during operation.
Probe tip	The probe tip is the part includes both the insertion portion and the handle.
Front mark	Correspond to the side of the orientation mark on the image.
Cable	Cable transfers electric input/output signals.
Connector	The connector is the part which is connected to the ultrasound diagnostic instrument.
Probe cover	This covers the insertion portion for preventing infection. Follow the instructions in section 4-2.

<p>⚠ Caution</p>	
<p>⊘ Do not pull, bend, twist, or apply excessive force to the cable. The probe may malfunction due to cable disconnection.</p>	
<p>⊘ Do not subject the ultrasound 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 ultrasound radiation part itself is not damaged because the part is made of elastic material.</p>	

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 ultrasound radiation part, insertion portion, handle, cable, connector and probe cover.

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.



Confirm 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 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, how to mount/remove the probe cover and how to attach/release the magnetic position sensor and the magnetic position sensor attachment.

4-1. Operation

Mount the 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.

In the case of using RVS, mount the probe cover on the probe after attaching the magnetic position sensor and the magnetic position sensor attachment to the probe according to 4-3-1.

 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/remove the probe cover

4-2-1. How to mount the probe cover

Apply a suitable amount of ultrasound gel on the ultrasound radiation part and then mount the probe cover on the probe.

Remove air bubbles in the ultrasound gel or wrinkles of the probe cover on the ultrasound radiation part.

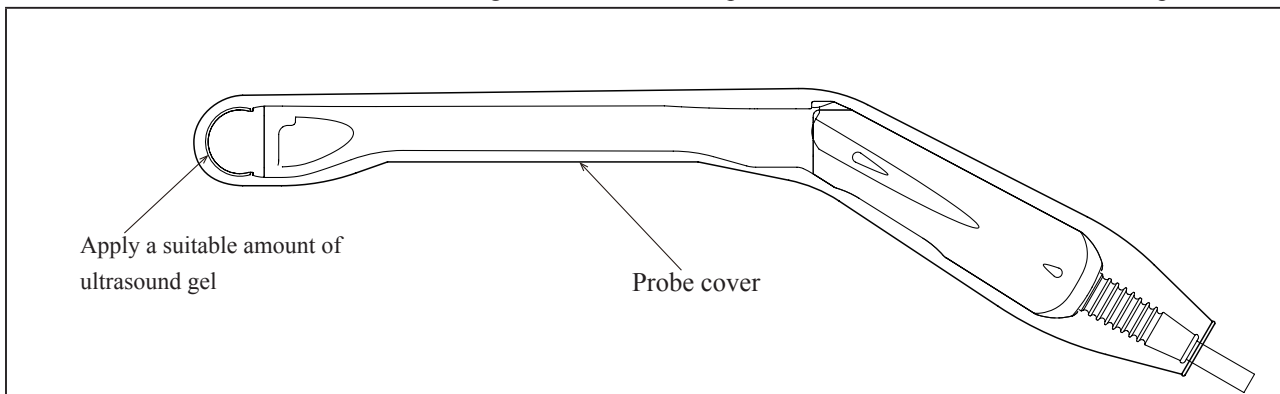




Figure 3 How to mount the probe cover

⚠ Warning	
❗	Mount the probe cover on the insertion portion. If the probe cover is not mounted, residual pathogens on the probe could infect the patient.
❗	Use Hitachi-approved probe covers only. Use of non biocompatible probe covers can cause an adverse reaction.
❗	Use only sterile probe covers. Use of non sterile probe covers could cause infection to the patient.
⊘	Do not reuse the probe cover. Reuse of probe covers may cause infection to the patient.
⊘	Do not apply non sterile acoustic medium on the probe cover. Use of non sterile acoustic medium can cause infection to the patient.
⊘	Do not use latex probe covers for patient who may have an allergic reaction. Use of the latex probe covers 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 probe cover according to its instruction. Do not use the probe 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.

4-2-2. How to remove the probe cover

- (1) Wrap the probe cover in tissue and remove the probe cover from the probe.
- (2) Dispose tissue and the probe cover 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.

4-3. How to attach/release the magnetic position sensor and the magnetic position sensor attachment

This section provides how to attach/release the magnetic position sensor and the magnetic position sensor attachment to the probe.

4-3-1. How to attach the magnetic position sensor and the magnetic position sensor attachment

- (1) Confirm that the magnetic position sensor attachment is sterilized or disinfected.
- (2) Insert the magnetic position sensor into the magnetic position sensor attachment with the correct direction as shown in Figure 4.
- (3) Attach the magnetic position sensor attachment to the probe as shown in Figure 5.

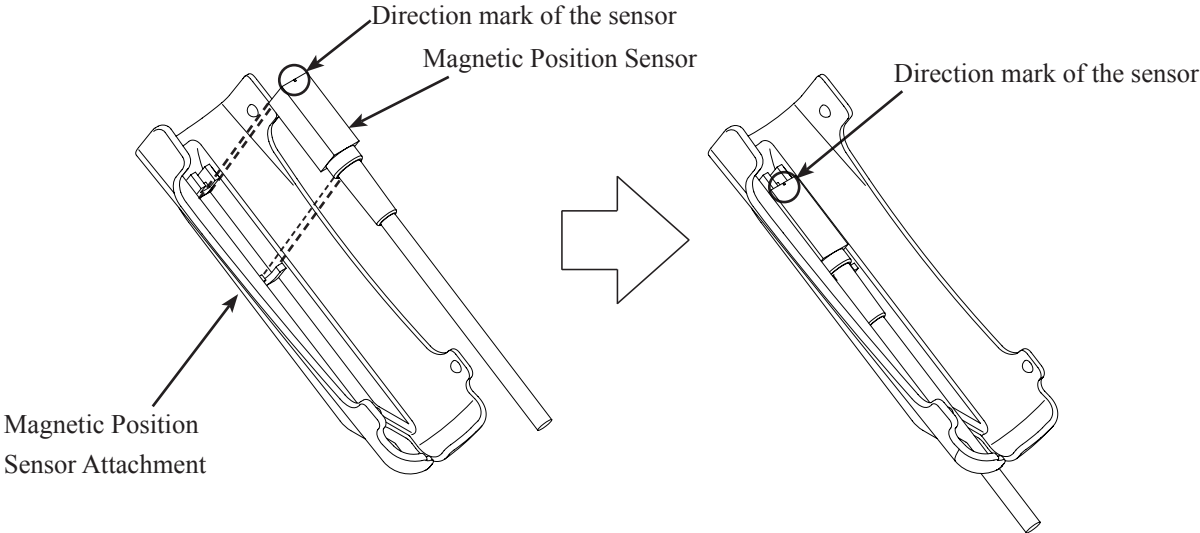


Figure 4 How to attach Magnetic Position Sensor

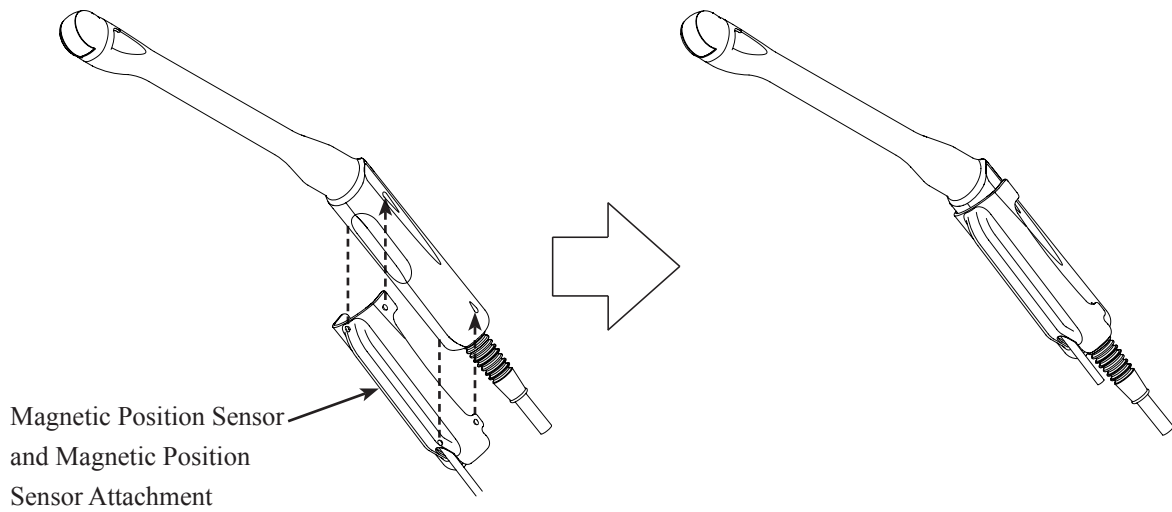


Figure 5 How to attach Magnetic Position Sensor Attachment

<p>⚠ Caution</p>	
<p>!</p>	<p>Never attach the magnetic position sensor attachment to the probe in the incorrect direction, otherwise it may result in false diagnosis.</p>
<p>!</p>	<p>Be careful not to put your fingers between the magnetic position sensor attachment and the probe when attaching the attachment to the probe.</p>
<p>⊘</p>	<p>Do not use the magnetic position sensor attachment if it fell on the floor, otherwise there is a risk of infection. Stop using it and perform the reprocessing procedure described in the separate instruction manual “Cleaning, Disinfection and Sterilization” and make preparations before use described in this manual.</p>

4-3-2. How to release the magnetic position sensor and the magnetic position sensor attachment

- (1) Release the magnetic position sensor attachment from the probe as shown in Figure 6.
- (2) Release the magnetic position sensor from the magnetic position sensor attachment as shown in Figure 7.

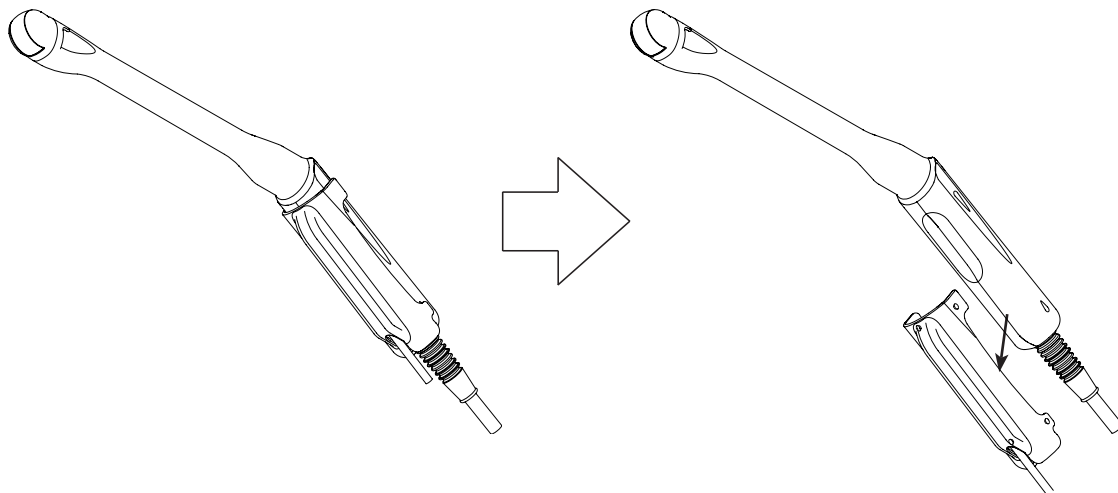


Figure 6 How to release Magnetic Position Sensor Attachment

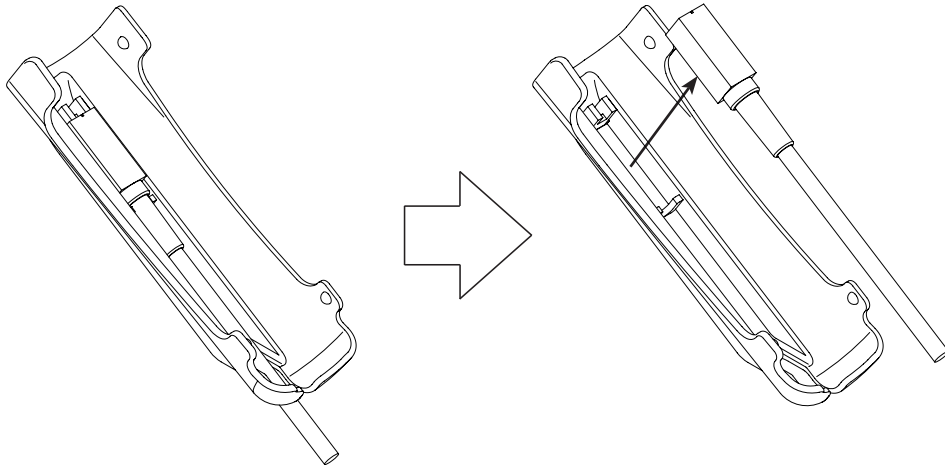


Figure 7 How to release Magnetic Position Sensor

■ Manufacturer



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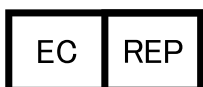
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