

C42T Probe  
Instruction Manual  
Specification  
MN1-5823 Rev.6

*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.*



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## Introduction

This is the instruction manual for C42T probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be mainly used for observation of human internal organs during surgery.

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 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 doctors. The probe is placed in direct contact with human internal organs during surgery for ultrasonic observation.

This probe can also be used for neurosurgery application if our specified transducer cover is mounted on the probe. Please note that this probe is not allowed to be used for neurosurgery application in Japan. Regarding the precautions for neurosurgery applications, please refer to the section 4-4.

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.

 <b>Warning</b>	
	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 C42T probe are as follows.

- C42T Probe ..... 1 set
- Storage case ..... 1 set
- Instruction Manual
  - Specification (MN1-5823)..... 1 copy
  - Safety (MN1-5984) ..... 1 copy
  - Cleaning, Disinfection and Sterilization (MN1-6000) ..... 1 copy

1-4. Options

The following options are available for C42T probe.

- Real Time Virtual Sonography (RVS)

Please use the option listed in Table 1 for performing RVS. Regarding how to attach/release the attachment, please refer to the section 4.2.

Table 1 Option for RVS

Product Name	Product No.
Magnetic Sensor Attachment	RV-003

- Transducer cover for neurosurgery application

The pyrogen-free transducer cover listed in Table 2 can be used for neurosurgery applications.

If you are unable to purchase it, please contact your local Hitachi Systems representative.

Table 2 Option for neurosurgery application

Product Name	Product No.
CIVCO Transducer cover	610-956
	610-956-EU

- Reprocessing by liquid detergent, disinfectant or sterilant

Whole the probe is able to immerse into the liquids by putting the connector of the ultrasound probe to the waterproof case WP-001 as below table 3.

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

Table 3 Accessory for reprocessing by liquid detergent, disinfectant or sterilant

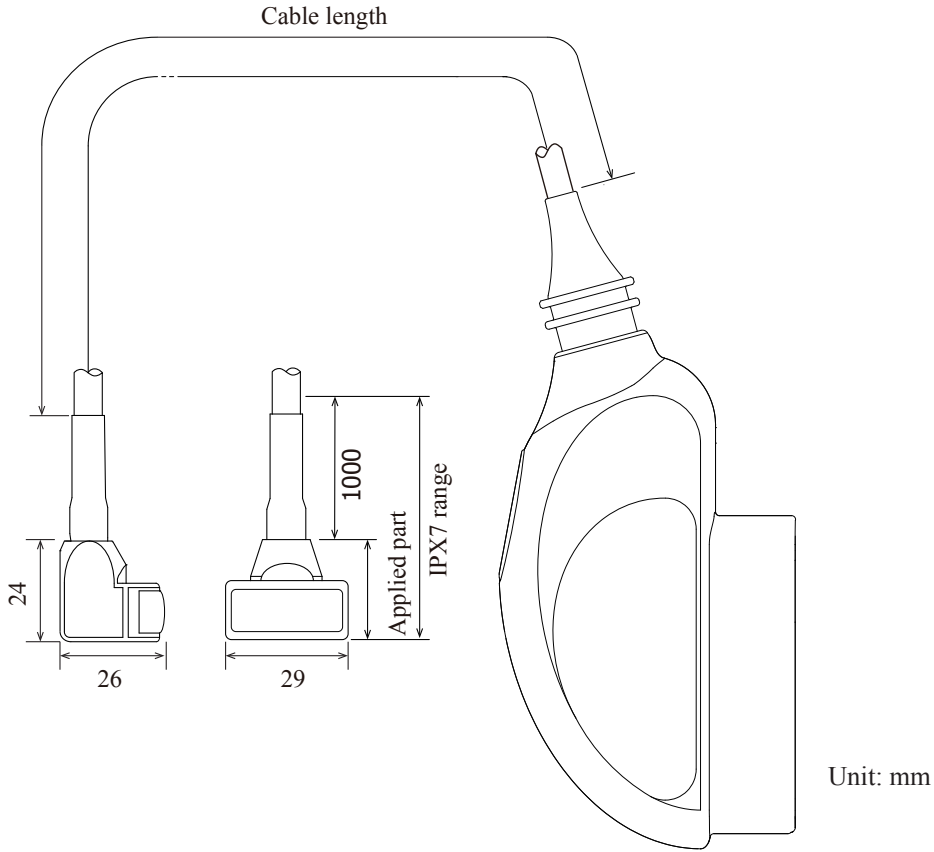
Product Name	Product No.
Waterproof case	WP-001

2. Specifications and Parts name

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

2-1. Specifications

- Application: Intraoperative diagnosis  
Neurosurgery application, see 4-4 for precautions
- Type of patient contact: Intraoperative  
Neurosurgical, see 4-4 for precautions
- 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: 65°
- Frequency: 7.5 MHz
- Cable length: 2.9 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 0.2 m length from the probe tip
- 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

2-1-3. Transducer cover when using the probe in neurosurgery application

CIVCO Transducer cover 610-956 , 610-956-EU

This transducer cover can be used in neurosurgery applications and it is Pyrogen free.

If you are unable to obtain the transducer cover locally, please contact your local Hitachi Medical Systems representative.



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 3.

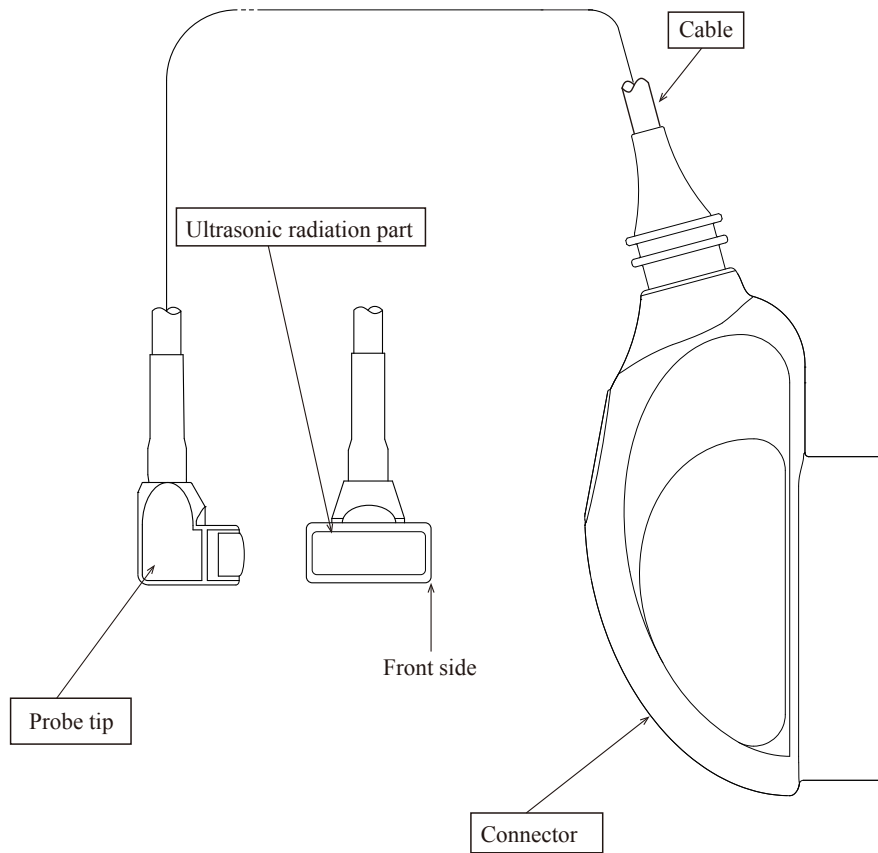


Figure 2 Name of each parts

Table 3 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.
Front side	The side 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.

<b>⚠ Caution</b>	
<b>⊘</b>	Do not pull, bend, twist, or apply excessive force to the cable. The probe may malfunction due to cable disconnection.
<b>⊘</b>	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 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.

#### 3-3. 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 attach/release Magnetic Position Sensor and Magnetic Position Sensor Attachment and how to mount/remove the transducer cover for neurosurgery application.

### 4-1. 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.

 <b>Caution</b>	
	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/release Magnetic Sensor Attachment and Magnetic Position Sensor

Follow the instructions below to attach/release the Magnetic Position Sensor and the Magnetic Position Sensor Attachment. All following procedure must be performed out of operative field.

##### 4-2-1. How to attach Magnetic Position Sensor

- (1) Align the direction mark of the Magnetic Position Sensor and the hole of the Magnetic Position Sensor Attachment, and place the sensor into the attachment (Figure 3).

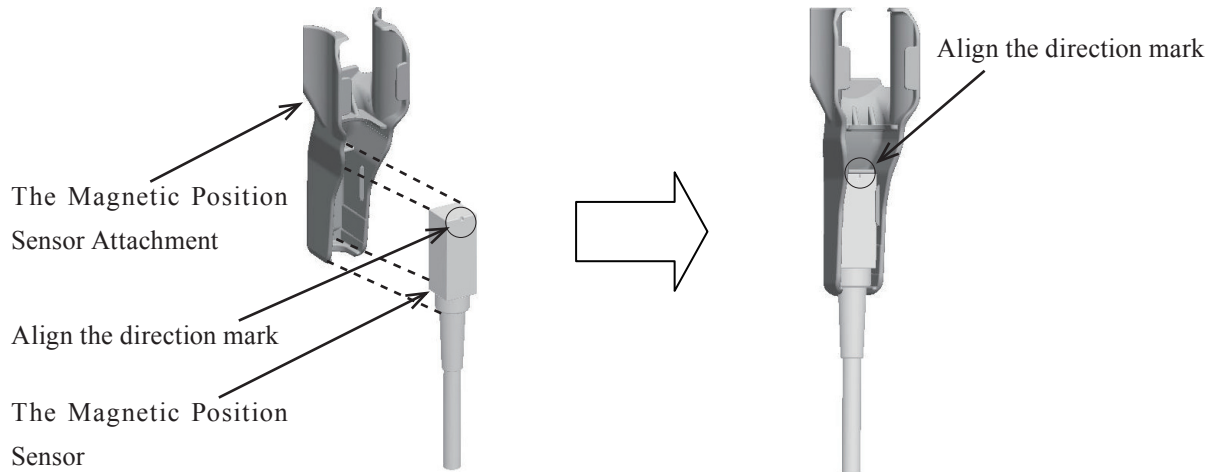


Figure 3 How to attach Magnetic Position Sensor

- (2) Attach the attachment to the probe as shown in Figure 4.

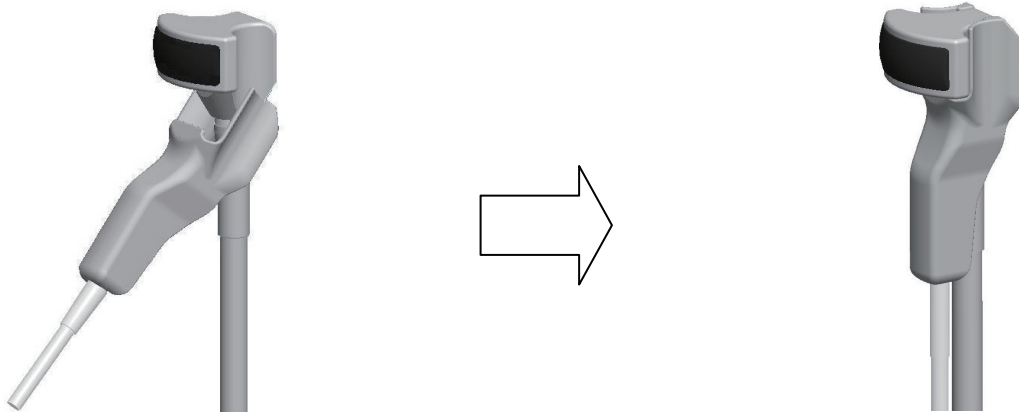


Figure 4 How to attach Magnetic Position Sensor Attachment

#### ⚠ Caution



Attach the Magnetic Position Sensor Attachment to the probe correctly. If the sensor is attached in the wrong direction, this causes false diagnosis.

4-2-2. How to release Magnetic Position Sensor

- (1) Slide the attachment downward and pull it away from the probe.

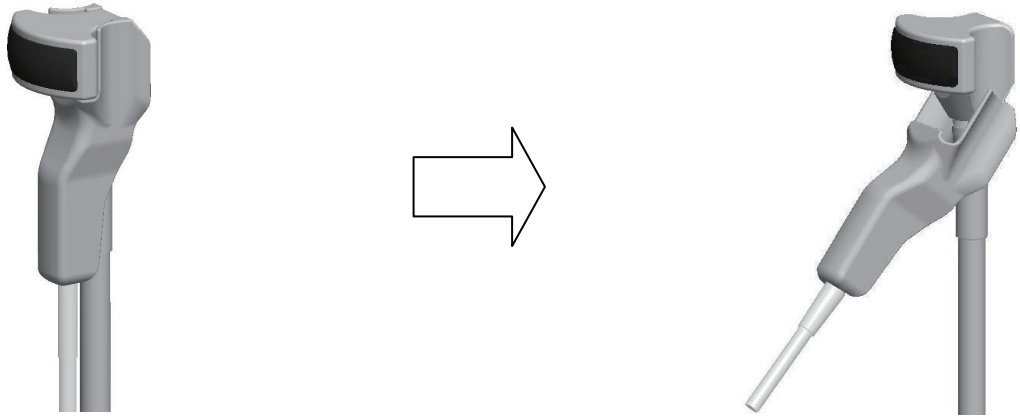


Figure 5 How to release Magnetic Position Sensor Attachment

- (2) Take out the Magnetic Position Sensor from the Magnetic Position Sensor Attachment.

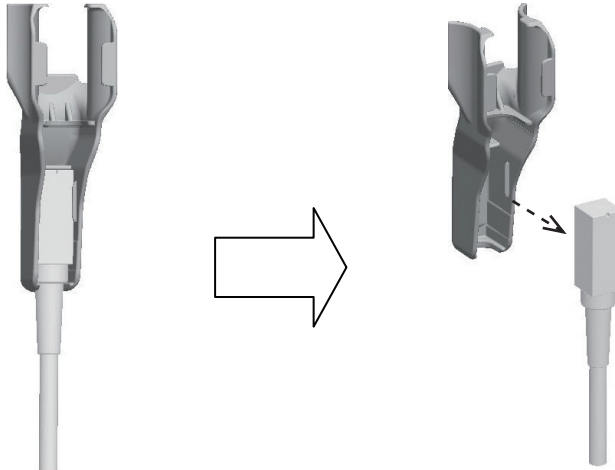


Figure 6 How to release Magnetic Position Sensor

#### 4-3. How to mount/remove the transducer cover

Mount the specified transducer cover by following the instruction below. Please note that the probe must be sterilized before mounting the transducer cover.

##### 4-3-1. How to attach the transducer cover

Apply some sterile ultrasound gel attached to the specified transducer cover to the ultrasound radiation part. Mount the transducer cover on the probe. Remove any bubbles or wrinkles from the ultrasound radiation part of the probe.

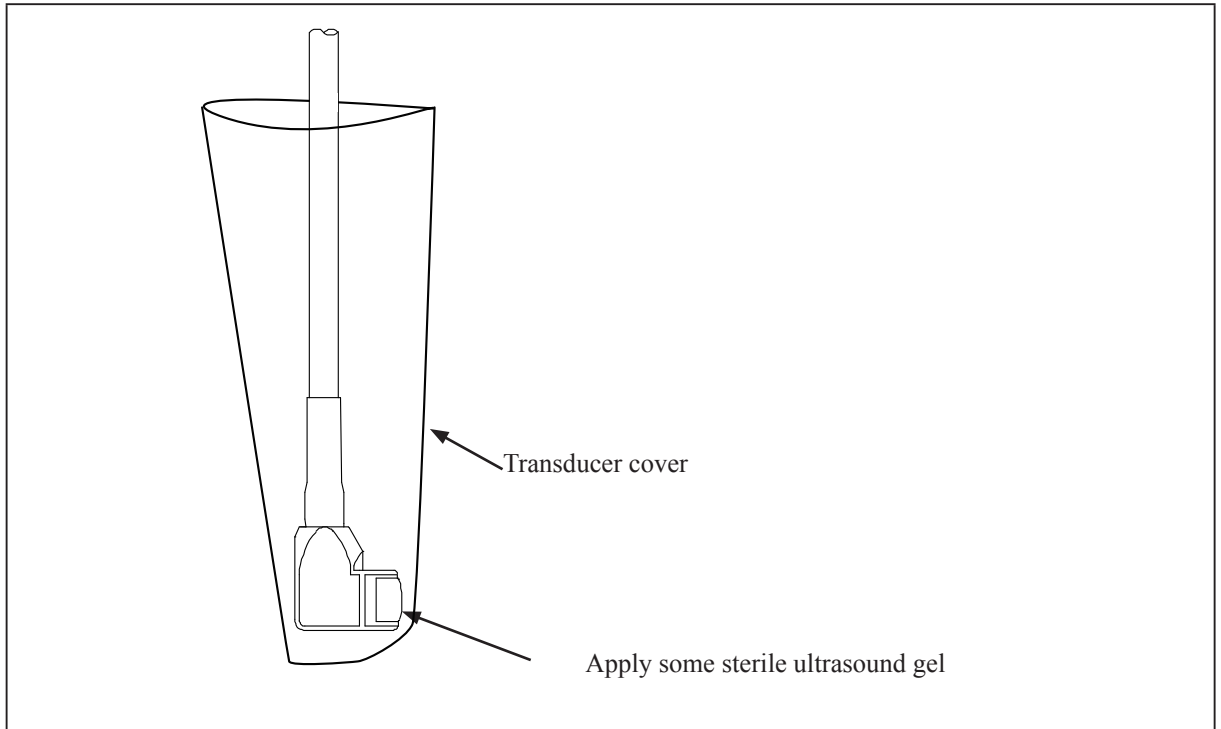


Figure 7 How to attach the transducer cover

##### 4-3-2. How to remove the transducer cover








- (1) Wear surgical gloves to prevent infection and remove the transducer cover from the probe.
- (2) Dispose the surgical gloves and the transducer cover according to the infection prevention procedures of your facility.



#### 4-4. Precautions for neurosurgery application

The following warnings and cautions must be observed when using the probe for neurosurgery application. Please note that this probe is not allowed to be used for neurosurgery application in Japan.

⚠ Warning	
⚠	Mount the transducer cover on the probe properly for use for neurosurgery application.
⚠	The probe can be used for neurosurgery applications if the specified transducer cover is mounted on the probe. The use without the transducer cover may cause harm to the patient.
⚠	Use the specified transducer cover.
⚠	The use of an unspecified transducer cover may cause harm to the patient due to tearing or pyrogen.



	Do not use the transducer cover if the packaging has been opened or damaged. If the packaging has been opened or damaged, the transducer cover is unsterile and it may cause patient infection.
	Confirm the storage condition and the expiration date of the transducer 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.
	Take precaution in handling the transducer cover so as not to break it as this may then result in direct contact with the edge of bone during a craniotomy. If the transducer cover breaks, it may cause harm to the patient.
	Confirm that the probe is sterilized. Use the sterile ultrasound gel attached to the specified transducer cover as the acoustic medium. If the probe and the gel are not sterilized, they may cause patient infection.
	Confirm that there are no bubbles in the ultrasound gel inside the transducer cover. If there are bubbles in the gel on the ultrasound radiation part, they may cause erroneous image and lead to misdiagnosis.
	Do not remove the transducer cover with excessive force. The probe may be damaged by excessive force and/or contaminated material may be scattered.
	Do not reuse the transducer cover. The reuse of the transducer cover may cause patient infection.

 <b>Caution</b>	
	Dispose the transducer cover by taking appropriate measures for prevention of infection. Improper disposal may cause environmental contamination.

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■ Manufacturer



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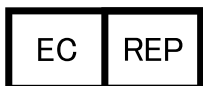
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