

## **TEExp Transducer**



### ***User Guide***

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**Caution**

United States federal law restricts this device to sale by or on the order of a physician.

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## Introduction

The TEEp transducer is a transesophageal echocardiographic transducer designed to operate with the SonoSite X-Porte ultrasound system built by FUJIFILM SonoSite, Inc.

Transesophageal procedures carry a variety of inherent risks to the patient. The information and instructions in this user guide are intended to help you minimize those risks. In addition, the TEEp transducer is a highly complex and delicate precision instrument. Misuse or poor handling may severely shorten the service life.

### **WARNING**

To help avoid conditions that may cause harm to the patient or damage to the transducer, it is important that personnel using or handling this transducer read and understand the instructions, warnings, cautions, and training material contained in this user guide. If you have questions about any of the information contained in this user guide, contact FUJIFILM SonoSite or your local representative.

## About the user guide

This user guide provides information on the TEEp transducer. It is designed for a reader familiar with ultrasound and proper endoscopic techniques; it does not provide training in sonography, cardiology, echocardiography, or clinical practices. For information about the ultrasound system, see its user guide and other appropriate literature.

To aid in safeguarding the patient and ensuring reliable transducer operation, SonoSite recommends having this user guide available for reference during all stages of TEEp transducer handling, and refer to guidelines from the American Society of Echocardiography for Point of Care TEE (ASE) and the Academy of Emergency Physicians (ACEP).

## Changes in this version

| Change                | Description                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Added references      | Added references to ACEP, ASE, and SCA guidelines.                                                                                            |
| Clarified terminology | Changed the term “deflection” to “flexion,” which describes the behavior of the probe more appropriately.                                     |
| Bite guard/bite block | Added “bite block” as an additional term to prevent confusion. Emphasized bite guard use.                                                     |
| Leakage tester update | Updated the leakage test procedure to support the new leakage tester. Integrated the leakage test into the cleaning and disinfection process. |

## Conventions

The document follows these conventions:

- ▶ A **WARNING** describes precautions necessary to prevent injury or loss of life.
- ▶ A **Caution** describes precautions necessary to protect the products.
- ▶ A **Note** provides supplemental information.
- ▶ Numbered and lettered steps must be performed in a specific order.
- ▶ Bulleted lists present information in list format but do not imply a sequence.
- ▶ For labeling symbols used, see the ultrasound system user guide.

## Warranty statement

The TEEexp transducer is warranted for material and workmanship only, for a period of 12 months from date of shipment from FUJIFILM SonoSite.

The warranty does not cover damage caused by patient bite, misuse by the end user, disinfecting incorrectly or with chemicals not approved by FUJIFILM SonoSite, or circumstances beyond what is considered normal for the product’s intended application.

## Technical Support

To order sheaths, bite guards, tip covers, and other supplies, see [www.civco.com](http://www.civco.com).

For technical support, contact FUJIFILM SonoSite as follows.

|                                               |                                                                                                                                                                                                            |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Phone<br/>(U.S. or Canada)</b>             | 877-657-8118                                                                                                                                                                                               |
| <b>Phone<br/>(outside U.S. or<br/>Canada)</b> | 425-951-1330, or call your local representative                                                                                                                                                            |
| <b>Fax</b>                                    | 425-951-6700                                                                                                                                                                                               |
| <b>Email</b>                                  | ffss-service@fujifilm.com                                                                                                                                                                                  |
| <b>Web</b>                                    | www.sonosite.com                                                                                                                                                                                           |
| <b>Europe Service Center</b>                  | Main: +31 20 751 2020<br>English support: +44 14 6234 1151<br>French support: +33 1 8288 0702<br>German support: +49 69 8088 4030<br>Italian support: +39 02 9475 3655<br>Spanish support: +34 91 123 8451 |
| <b>Asia Service Center</b>                    | +65 6380-5581                                                                                                                                                                                              |



## Getting started

### About the TEEexp transducer

#### WARNINGS

- ▶ FUJIFILM SonoSite does not recommend the use of high-frequency electromedical devices in proximity to its systems. FUJIFILM SonoSite equipment has not been validated for use with high-frequency electrosurgical devices or procedures. Use of high-frequency electrosurgical devices in proximity to its systems may lead to abnormal system behavior or shutdown of the system.
- ▶ To avoid the risk of a burn hazard, do not use the transducer with high-frequency surgical equipment. Such a hazard may occur in the event of a defect in the high-frequency surgical neutral electrode connection.
- ▶ To avoid injury to a patient, the TEEexp transducer is intended for use by a medical professional who has received appropriate training in endoscopic techniques as dictated by current relevant medical practices, as well as in proper operation of the ultrasound system and transducer. Adhere to the standards and protocols from the American Society of Echocardiography for Point of Care TEE and the American College of Emergency Physicians.

#### Caution

To avoid inadvertent damage to the transducer, read this user guide before handling and cleaning the TEEexp transducer.

The TEEexp transducer is an electronically steered phased array ultrasound transducer assembly, mounted in a sealed tip at the end of a conventional endoscope.

The TEEexp transducer is used to generate a set of ultrasound images or slices within a cone from the same position in the esophagus. The rotation of the scan plane is driven by a motor in the control handle.

## Intended uses

The TEEp transducer is an endoscopic transducer designed for 2D, M Mode, color Doppler (Color), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler imaging by applying ultrasound energy through the esophagus or stomach of the patient into the heart. The TEEp transducer is intended to be used on adults only. Backscattered ultrasound energy from the patient's heart forms images of the heart to detect abnormalities in structure or motion, to evaluate the velocity of blood flowing within the heart, and to obtain a color depiction of the velocities of blood flowing in the heart.

## Contraindications

### **WARNING**

The physician must consider all possible factors before starting the examination.

Contraindications for using a transesophageal transducer include, but are not limited to, the following:

- ▶ Fetal imaging
- ▶ Pediatric imaging
- ▶ Imaging when the patient exhibits the following or similar conditions:
  - ▶ Esophageal stricture, spasms, lacerations, and trouble swallowing (dysphagia)
  - ▶ Esophageal diverticula, esophageal varices (swollen veins)
  - ▶ Gastrointestinal bleeding
  - ▶ Peptic ulcers, hiatal hernia, esophageal webs and rings
  - ▶ Recent radiation treatment to the esophagus
  - ▶ Inability to swallow or accommodate the transducer
  - ▶ History of gastroesophageal diseases

## Unpacking

Proper care and maintenance are essential. Follow the unpacking procedures. Contact FUJIFILM SonoSite or your local representative immediately to report any damage or discrepancies.

### **WARNING**

To avoid injury to patient/operator, carefully inspect all equipment after receipt and prior to each use.

## Unpack the transducer

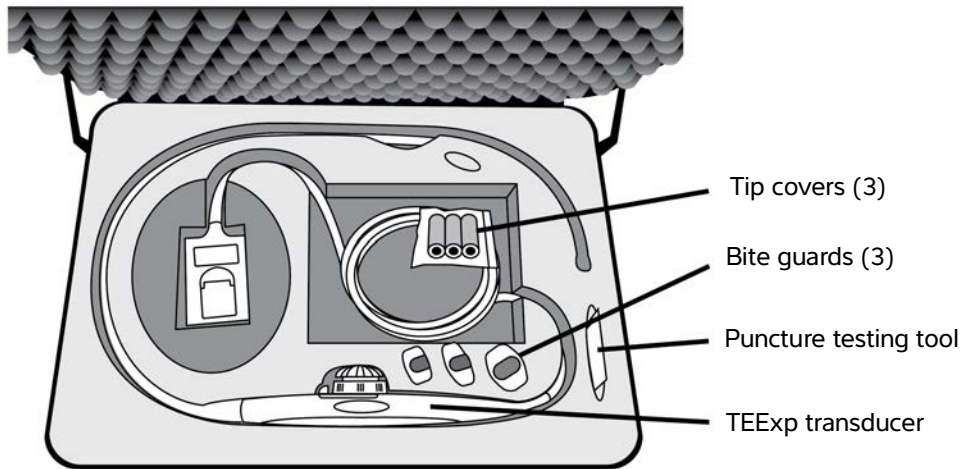


Figure 2-1 Shipping case with TEEp transducer

- 1 Visually examine the shipping box, shipping case, and the TEEp transducer for any damage.
- 2 Note any breakage or other apparent damage, retain the evidence, and notify the carrier or shipping agency.
- 3 Verify that the shipping case contains the components listed on the packing list:
  - ▶ TEEp transducer
  - ▶ *TEEp Transducer User Guide*
  - ▶ *TEE Transducer Care* (contains cleaning, testing, and disinfection instructions)
  - ▶ Bite guards/blocks (3)
  - ▶ Puncture test tool
  - ▶ Non-sterile tip covers (3)

### **WARNING**

To avoid injury to patient:

- ▶ Proper care, maintenance, and a detailed understanding of the procedure are essential for safe operation of the TEEp transducer.
- ▶ The medical professional performing the exam must exercise sound medical judgment in selecting this transducer for use in a procedure.

### Cautions

- ▶ To avoid permanently damaging the transducer's internal control wires, do not manually flex the tip in any direction. Use the control wheels only for this purpose.
- ▶ To avoid inadvertent damage to the transducer, read this user guide before handling and cleaning the TEEexp transducer.

## Inspecting contents

After unpacking the contents, perform the following on the TEEexp transducer:

- ▶ Visual and tactile inspection. See **"To visually and tactilely inspect the transducer"** on page 2-6.
- ▶ Tip flexion inspection. See **"To inspect tip flexion"** on page 2-8.
- ▶ Lock inspection. See **"To inspect the tip flexion lock"** on page 2-9.
- ▶ Scan plane rotation inspection. See **"To inspect the scan plane rotation"** on page 2-11.
- ▶ Leakage test. See **"Testing the transducer for electrical leakage"** on page 4-5.

Contact FUJIFILM SonoSite or your local representative immediately to report any damage or discrepancies. See **"Technical Support"** on page 1-2.

### WARNING

To avoid injury to the patient, do not use the TEEexp transducer if any irregularity, substandard function or unsafe condition is observed or suspected.

# Transducer and system interface

The TEEp transducer consists of an electronically steered phased array ultrasound transducer assembly mounted in a sealed tip at the end of a conventional endoscope. It connects to the ultrasound system with a cable and connector (see [Figure 2-2](#)).

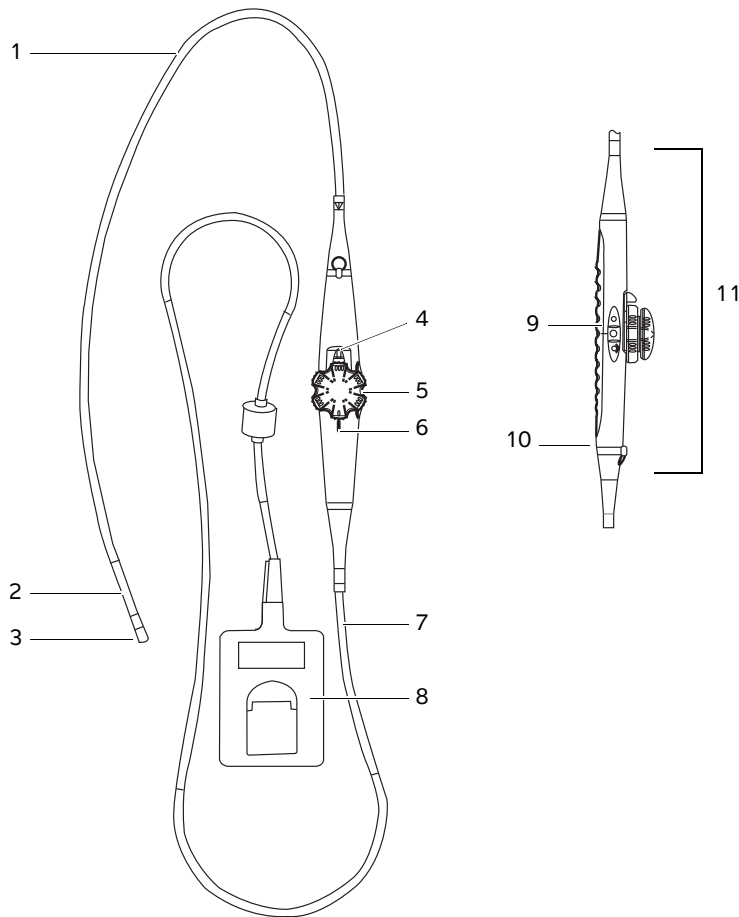


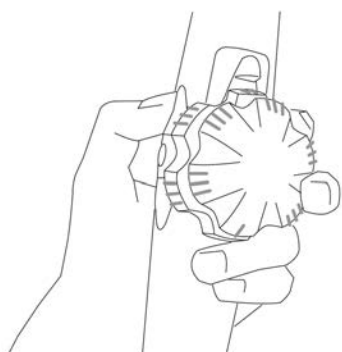
Figure 2-2 TEEp transducer

- |   |                                 |    |                            |
|---|---------------------------------|----|----------------------------|
| 1 | Flexible endoscopic shaft       | 7  | Transducer cable           |
| 2 | Articulation section            | 8  | Transducer connector       |
| 3 | Transducer tip with scan head   | 9  | Scan plane control buttons |
| 4 | Anterior/posterior flexion lock | 10 | Attachment ring            |
| 5 | Flexion control wheels          | 11 | Handle                     |
| 6 | Neutral marker                  |    |                            |

## TEExp transducer controls

The endoscope is designed for single-handed operation of the flexion and scan plane controls. **Figure 2-3** shows the user holding the endoscope handle in the left hand. Thumb and first and second fingers operate the flexion and scan plane controls.

Check the mechanical operation and physical integrity of the transducer after taking it out of the box and before each exam.



**Figure 2-3** Transducer in left hand

### **WARNING**

To avoid injury to the patient:

- ▶ Do not use the TEEp transducer if any irregularity, substandard function, or unsafe condition is observed or suspected.
- ▶ Do not use the TEEp transducer if any metallic protrusions, holes, rough spots, cracks, or dents are found.

### **To visually and tactilely inspect the transducer**

You should inspect the TEEp transducer visually and tactilely after taking it out of the box and before disinfecting.

- 1** Visually examine and feel the entire surface of the flexible shaft and flexion section with the transducer in both the straight and flexed position.
- 2** Examine the transducer tip for any holes or dents.

## Tip flexion

The TEEp transducer endoscope has two wheels for controlling the transducer tip flexion.

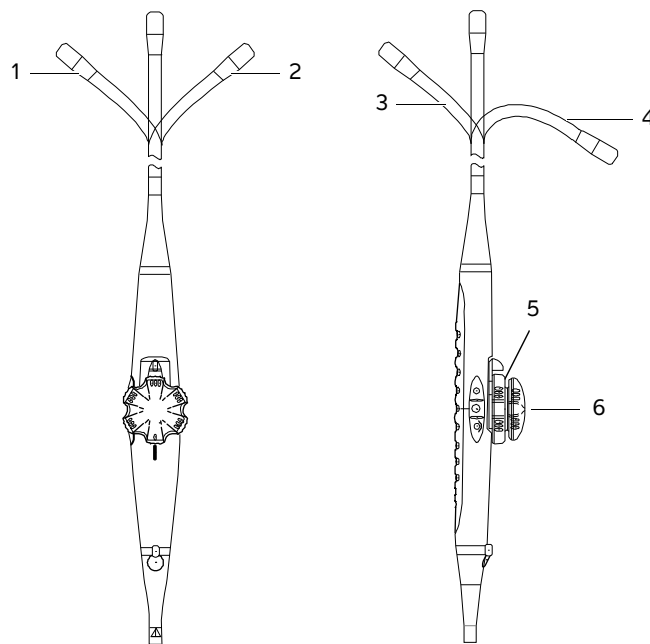
The wheels control anterior/posterior and left/right tip flexion. **Figure 2-4** on page 2-7 shows the wheels in the neutral (unflexed) position.

The lower wheel controls the anterior/posterior flexion of the tip. You can lock this control into position. The upper wheel controls the left/right flexion of the probe tip, and cannot be locked.

Always have the probe in a neutral, unlocked position during insertion and removal of the transducer.

**Caution**

To avoid damaging the transducer, do not flex the distal tip of the transducer by direct application of force. Use the flexion wheels for this task.



**Figure 2-4** Flexion controls. For orientation purposes, hold the transducer pointing away with control wheels up and the flexible shaft in a straight position.

- 1 Turn upper wheel counterclockwise to move the tip to the left.
- 2 Turn upper wheel clockwise to move the tip to the right.
- 3 Turn lower wheel counterclockwise to move the tip posterior.
- 4 Turn lower wheel clockwise to move the tip anterior.
- 5 Anterior/posterior flexion control (lower wheel)
- 6 Left/right flexion control (upper wheel)

## WARNING

To avoid injury to the patient, if you observe a sharp “U-turn” of the transducer tip during the tip flexion inspection, do not use the transducer.

### To inspect tip flexion

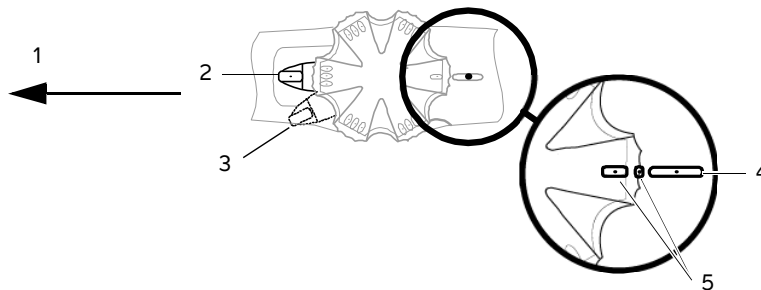
Inspect the tip flexion on the TEEExp transducer after taking it out of the box and before each exam. For orientation purposes, hold the transducer pointing away with control wheels up and the flexible shaft in a straight position.

- 1 Flex the tip in all four directions.
- 2 Confirm that the flexion controls operate smoothly.
- 3 Check that when the flexion controls are in the neutral position that the transducer tip is also in a neutral position (unflexed).

### Tip flexion lock

To retain the tip in a flexed position, friction can be applied to the anterior/posterior flexion control.

The lock for anterior/posterior flexion is a handle located under the lower control wheel (see [Figure 2-5](#)). There is no lock for left/right flexion.



**Figure 2-5** Tip flexion lock operation

- |   |                                  |   |                         |
|---|----------------------------------|---|-------------------------|
| 1 | Transducer tip                   | 4 | Neutral position marker |
| 2 | Tip control in unlocked position | 5 | Wheel position markers  |
| 3 | Tip control in locked position   |   |                         |

## To inspect the tip flexion lock

Inspect the tip flexion lock on the transducer after taking it out of the box and before each exam.

- 1 Confirm that the lock control is in the unlocked position.
- 2 Flex the tip to the anterior direction.
- 3 Move the lock control to the locked position.
- 4 Confirm that the tip is locked in the flexed position.
- 5 Unlock the control and confirm that the tip straightens easily.
- 6 Repeat steps 1-5 for the posterior direction.

## Scan plane rotation

To familiarize yourself with scan plane rotation, you may choose to start scanning in one of the transverse planes — for example,  $0^\circ$  on the system screen is the standard monoplan. If you rotate the scan plane  $90^\circ$ , you are now scanning in the longitudinal plane, sweeping through two opposite quadrants of the cone.

If you continue to rotate the scan plane another  $90^\circ$  in the same direction, scanning occurs in the mirror image of the first transverse plane. The only two planes that are equivalent are the two transverse planes at  $0^\circ$  and  $180^\circ$ , one being the mirror image of the other. As shown in [Figure 2-6](#), a  $180^\circ$  rotation of the scan plane fills all four quadrants of the conic imaging volume.

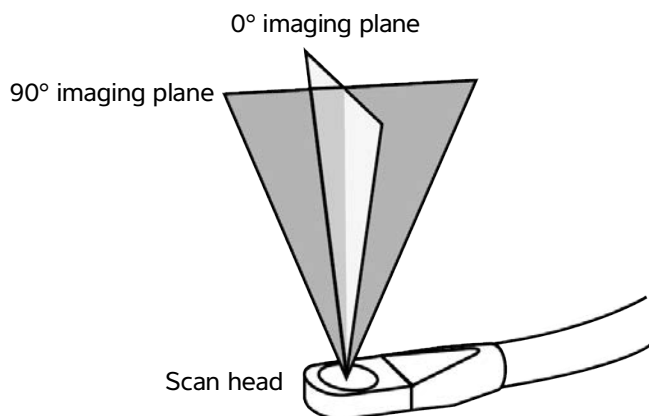
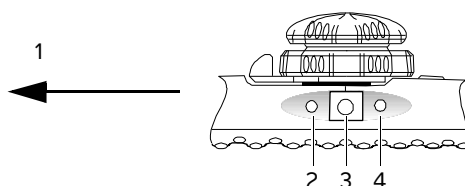


Figure 2-6 Rotating to different imaging planes

The scan plane rotation is driven by a motor in the transducer handle and is controlled by buttons on the handle (see [Figure 2-7](#)).



**Figure 2-7** Scan plane rotation controls

- 1 Transducer tip
- 2 Counterclockwise button (increases angle)
- 3 Biplane button (rotates angle to orthogonal biplane)
- 4 Clockwise button (decreases angle)

A scan plane indicator on the system screen shows the orientation. The scan plane angle is indicated by a marker and a value (see [Figure 2-8](#)). The screen shows the angle relative to the standard monoplane, displayed as **0°**. The nominal scan plane angle ranges from 0° to 180° and is accurate within  $\pm 7^\circ$ .



**Figure 2-8** Scan plane indicator

**Caution**

To avoid damaging the transducer connector, protect the connector from dirt and moisture.

**To initialize the scan plane to 0 degree plane**

- 1 Connect the transducer, and turn on the ultrasound system. (For instructions, see the ultrasound system user guide.)
- 2 Press the scan plane rotation buttons.

**To rotate the scan plane**

Press the outer buttons on the transducer handle:

- The button closest to the transducer tip rotates the scan plane counterclockwise from 0-180° (scan plane angle increases).

- ▶ The button farthest from the transducer tip rotates the scan plane clockwise from 180-0° (scan plane angle decreases).

Full rotation of the imaging plane can be rotated forward from the standard transverse 0° plane to 180° (mirror image of the standard transverse plane). You can then rotate backward from 180° back to 0°. You may need small incremental degree changes to optimize your view. Note the on-screen display of your current rotations and degree settings.

### **To change the biplane**

Press the biplane button (the center button) on the endoscope handle. See [Figure 2-7](#) on page 2-10.

The scan plane rotates at full speed from the current position 90° to the orthogonal position (For example, if the present position is 22°, the scan plane rotates to 112°. If the present position is 162°, the scan plane rotates to 72°.)

Pressing the button again rotates the scan plane back to the previous position.

### **To inspect the scan plane rotation**

Inspect the scan plane rotation on the transducer after taking it out of the box and before each exam.

- 1 Connect the TEEp transducer to the ultrasound system.
- 2 Without inserting the transducer, place a small amount of sterile gel on the transducer, and then turn up the gain to obtain an image.
- 3 Press the scan plane control buttons on the handle to rotate the scan plane counterclockwise (0° to 180°) and clockwise (180° to 0°). See [Figure 2-7](#) on page 2-10.
- 4 Confirm that the image on-screen changes in relation to the numbers on the scan plane indicator. See [Figure 2-8](#) on page 2-10.

While you press the scan plane rotation buttons, the transducer motor should be running as the image is changing.

Do not rely only on the on-screen scan plane indicator to verify that the scan plane is rotating.



## Examination

TEE is a semi-invasive procedure that offers improved image access to the heart and surrounding vessels due to the close proximity to the heart from the esophagus. Careful consideration for its use should be made by the examining physician. Follow ASE, SCA, and ACEP guidelines. The list of contraindications and considerations do not constitute a complete list of all possible factors the examining physician must consider before starting the examination. They are presented only as examples. See **“Contraindications”** on page 2-2.

### WARNINGS

- ▶ To avoid trauma to the patient’s stomach or esophagus, do not use excessive force during insertion, positioning, or withdrawal.
- ▶ To prevent damage to the patient’s esophagus when inserting or withdrawing the transducer, the control wheel must be in the freely moving, neutral, and unlocked state. See **Figure 2-5** on page 2-8.

## Pre-exam inspection

It is important to establish and use a check-out procedure to ensure that the transducer is safe to use and functions properly prior to each use. If you observe or suspect any irregularity, substandard functioning, or unsafe condition, do not use the TEEp transducer. Call FUJIFILM SonoSite or your local representative immediately.

Perform the following before each exam:

- ▶ Visual tactile inspection. See **“To visually and tactilely inspect the transducer”** on page 2-6.
- ▶ Tip flexion inspection. See **“To inspect tip flexion”** on page 2-8.
- ▶ Lock inspection. See **“To inspect the tip flexion lock”** on page 2-9.
- ▶ Scan plane rotation inspection. See **“To inspect the scan plane rotation”** on page 2-11.

- ▶ Low-voltage electrical leakage test. See **“Testing the transducer for electrical leakage”** on page 4-5 .
- ▶ Clean and disinfect transducer. See **“Transducer Care”** on page 4-1.

Contact FUJIFILM SonoSite or your local representative to report any damage or discrepancies. See **“Technical Support”** on page 1-2.

## WARNINGS

To avoid injury to the patient:

- ▶ FUJIFILM SonoSite recommends performing the above procedures prior to each exam.
- ▶ Do not use the transducer if any metallic protrusions, holes, rough spots, cracks, or dents are found.
- ▶ If, during the flexion test, a sharp “U-turn” of the transducer tip is observed (the transducer tip angle exceeds the maximum flexion angles), do not use the transducer. Call FUJIFILM SonoSite or your local representative.
- ▶ Some gels and sterilants can cause an allergic reaction in some individuals.

## Precautions

Techniques for introducing the TEEp transducer into the patient are beyond the scope of the user guide. Guidelines for training and procedural protocols are set forth by the American Society of Echocardiograph and the American Academy of Emergency Physicians. A complete understanding of the risks and complications, along with optimal training are recommended to perform this procedure.

Observe the following precautionary measures when conducting an exam:

- ▶ Maintaining an unobstructed airway is a prime consideration for all patients.
- ▶ Prolonged pressure on the esophagus by the tip of the transducer may lead to a pressure necrosis condition. Thus, in operating room monitoring applications, the tip should be removed from the esophagus wall when not scanning by releasing it in the neutral position. If continuous monitoring is required, the transducer tip should be repositioned often.
- ▶ Long-term exposure to ultrasound should be minimized. Although there have never been any bio-effects demonstrated at the acoustic output levels of the TEEp transducer, it is prudent to minimize patient exposure to ultrasound according to the principle of As-Low-As-Reasonably-Achievable (ALARA). Please see the ultrasound system user guide.
- ▶ In consideration of the above two points, you should freeze the image, which turns off the power to the transducer, and allow the endoscope deflection controls to be disengaged whenever active scanning is not desired.
- ▶ Proper patient preparation is essential for successful examinations. Refer to guidelines.

- ▶ The use of a bite guard/block during all TEEexp examinations is mandatory to protect the transducer from possible damage.
- ▶ The use of protective gloves during the examination is encouraged. Please see the U.S. Food and Drug Administration's Medical Alert on Latex Products (FDA 1991).
- ▶ In addition to the high-level disinfection, a protective sheath may provide even greater protection against contamination of the transducer. Contact CIVCO for protective sheaths and applicators for protective sheaths.

## Bite guard/block

### Caution

To avoid damaging the transducer, use a bite guard/block during all TEEexp examinations. Biting the endoscope may cause severe, permanent damage to the transducer, making it unsafe for future patient use. Damage to the transducer from failure to use a bite guard voids the transducer warranty.

Use of a bite guard is mandatory for TEEexp transducers. Each TEEexp transducer from FUJIFILM SonoSite is delivered with three bite guards (**Figure 3-1**). For patients with dentures, you must still use a bite guard. Remove the dentures before placing the bite guard in the patient's mouth. After removal of dentures, place the bite guard with the soft syrofoam cover still on for patient comfort. If you need help ordering more bite guards, contact CIVCO Medical Solutions.

Re-use, cleaning, and sterilization of the bite guards should be done according to instructions provided by the manufacturer of the bite guard.

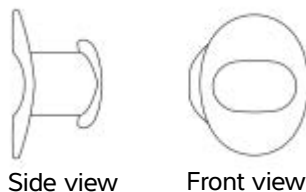


Figure 3-1 Bite guard

## Sterile sheath

Use a sterile sheath whenever examining a patient that poses an isolation risk.

There are various sterile sheaths available to eliminate direct contact between the patient and the endoscope. Follow the user instructions for a particular sheath when applying and removing the sheath from the TEEExp transducer. Contact CIVCO to order sterile sheaths and applicators.

### Caution

To avoid damaging the TEEExp transducer, ensure that the tip is straight during application and removal of the sheath. During removal of the sheath, be careful not to use excessive force on the transducer tip; otherwise, permanent damage to the TEEExp transducer may occur.

To provide suitable acoustic coupling within the sheath, FUJIFILM SonoSite recommends using a sterile gel.

### To apply a transducer sheath

FUJIFILM SonoSite recommends the use of market-cleared, transducer sheaths for intracavitary applications. To lessen the risk of contamination, apply the sheath only when you are ready to perform the procedure.

- 1 Place gel inside the sheath.
- 2 Insert the transducer into the sheath.
- 3 Pull the sheath over the transducer endoscope shaft until the sheath is fully extended.
- 4 Secure the sheath using the bands supplied with the sheath.
- 5 Check for and eliminate bubbles between the footprint of the transducer and the sheath.

Any bubbles between the footprint of the transducer and the sheath can affect the ultrasound image.

- 6 Inspect the sheath to ensure that there are no holes or tears.

## Emergency retraction

If the transducer tip should get jammed in a deflected position inside the patient, and if all attempts to release the flexed tip should fail, follow the procedure **“To retract the transducer”** on page 3-4 to ensure a safe retraction of the transducer.

### To retract the transducer

- 1 Disconnect the transducer from the ultrasound system.
- 2 At an accessible location between the transducer handle and the patient, cut the entire endoscope shaft, including all internal wiring, using heavy duty cutting pliers or another suitable tool.

The flexion mechanism is now released and the transducer may be safely retracted.

# CHAPTER 4

## Transducer Care

The TEEp transducer is categorized as semi-critical in the Spaulding classification system, and must be cleaned, tested for electrical leakage, and disinfected after each exam. Follow guidelines from the American Society of Echocardiography and the Academy of Emergency Physicians for probe cleaning, disinfection, and electrical leakage testing prior to each use.

### Before getting started

- ▶ Follow the disinfectant manufacturer's recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the transducer to determine that it is free of any unacceptable deterioration or damage that could lead to fluid leaking into the endoscopic shaft and exposing the patient to an electrical current. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility's use. FUJIFILM SonoSite routinely tests cleaners and disinfectants for use with FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for efficacy and material compatibility with the products.
- ▶ Ensure that the disinfectant type, concentration, and contact time are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

#### WARNINGS

- ▶ Ensure that cleaners and disinfectants are not expired.
- ▶ Some cleaners and disinfectants can cause an allergic reaction in some individuals.

Process overview

For manual cleaning, electrical leakage testing, and disinfecting the transducer, the following workflow is recommended.

If using an automated disinfection process, follow manufacturer procedures.

Table 4-1: Manual workflow

| Steps             |
|-------------------|
| 1 Cleaning        |
| 2 Leakage testing |
| 3 Disinfecting    |

Transducer components

Some components of the TEEp transducer have different cleaning requirements and restrictions than others. The cleaning, testing, and disinfection procedures frequently refer to specific components of the transducer. See [Figure 4-1](#) for a diagram of the transducer components.

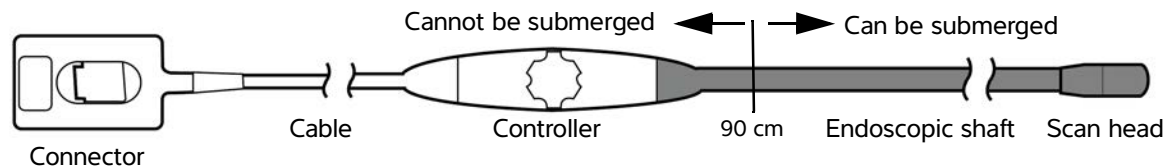


Figure 4-1 Transducer components

# Cleaning the transducer

- WARNING**

Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as protective eyewear and gloves.
- Cautions**

- ▶ Always disconnect the transducer from the system before cleaning. When disconnecting the transducer from the system, follow the steps in the *SonoSite X-Porte User Guide*.
  - ▶ Do not bend the endoscopic shaft smaller than a 20 cm (8 inch) curve. Exceeding this minimum bend diameter can damage the endoscope or its watertight coating.
  - ▶ Do not use unapproved cleaning agents, such as alcohol or bleach (for example, Sani-Cloth wipes) as these can damage the transducer and void the warranty. For more information about approved cleaning agents, see [Table 4-2](#).
  - ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.

Cleaners and disinfectants not listed on FUJIFILM SonoSite's website have not been evaluated for compatibility and may cause damage to the transducer. For approved chemicals, follow the manufacturer’s instructions for concentration, temperature, and duration.

**Table 4-2: Approved cleaners**

| Cleaner <sup>a, b</sup>                                                                                                                                                                                                                                     |                                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| Prolystica                                                                                                                                                                                                                                                  | Cidezyme/Enzol <sup>c</sup>              |
| Hexanios G+R                                                                                                                                                                                                                                                | Medizime LF                              |
| Aniosyme DD1                                                                                                                                                                                                                                                | Revital-Ox Enzymatic Detergent           |
| Salvanios pH7                                                                                                                                                                                                                                               | TEEZyme sponge                           |
| Gigazyme                                                                                                                                                                                                                                                    | Simple2 Multi-Tiered Enzymatic Detergent |
| Gigazyme X-tra                                                                                                                                                                                                                                              |                                          |
| <sup>a</sup> Refer to the manufacturer’s instructions for concentration, temperature, and duration.                                                                                                                                                         |                                          |
| <sup>b</sup> Refer to the cleaners and disinfection tool available at <a href="http://www.sonosite.com/support/cleaners-disinfectants">www.sonosite.com/support/cleaners-disinfectants</a> for a more complete list of approved cleaners and disinfectants. |                                          |
| <sup>c</sup> Can be used in the electrical leakage test.                                                                                                                                                                                                    |                                          |

## To clean the transducer

- 1 Immediately after extracting the TEEp from the patient, wipe the cable, controller, endoscopic shaft, and scan head of the transducer with a cloth or wipe moistened with water. Be sure to remove all visible biological material. Do not wipe the connector.
- 2 At the cleaning station, prepare the cleaner for use:
  - a **Check** the expiration date on the bottle to ensure that the cleaner has not expired.
  - b **Check** that the cleaner has the concentration recommended by the manufacturer (for example, use a chemical strip test).
  - c **Check** that the temperature of the cleaner is within the manufacturer's recommended limits.
- 3 Secure the control handle so it cannot fall into the cleaning solution, and immerse the endoscopic shaft and scan head in a plastic container filled with enzymatic cleaning solution up to the 90 cm mark (see [Figure 4-1](#) on page 4-2).
- 4 Soak according to the manufacturer's instructions.

### Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer cable, connector, or controller in any fluid.

- 5 While the endoscope is soaking:
  - a Scrub the endoscopic shaft for at least three minutes using a soft brush or single-use endoscopic sponge moistened with enzymatic cleaner.
  - b Clean the control handle and cord by wiping with a clean, non-linting cloth or single-use endoscopic sponge moistened with the approved cleaner. To remove any residual cleaner, wipe both components again with a clean, non-linting cloth or single-use endoscopic sponge moistened with clean water. Do not wipe the connector.
- 6 Rinse the endoscopic shaft by soaking it in a large volume of clean, lukewarm water (for example, eight liters) for at least three minutes to remove residual cleaning solution.
- 7 Rinse the endoscopic shaft by soaking it in a large volume of clean, lukewarm water (for example, eight liters) for at least three minutes to remove residual cleaning solution.
- 8 Visually inspect the scan head and endoscopic shaft for remaining biological material. If any is found, repeat the cleaning process.

### Caution

Residual cleaners left on the transducer can cause damage.

- 9 Dry the transducer with a clean, non-linting towel. Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

10 Proceed to “[Testing the transducer for electrical leakage](#)” on page 4-5.

## Testing the transducer for electrical leakage

### Caution

If the watertight coating on the scan head or endoscopic shaft has been damaged or punctured, contact FUJIFILM SonoSite for instructions on cleaning and returning the transducer for repair.

### About leakage testing

Electrical leakage caused by bite holes or other damages to the endoscope surface can be detected using a transducer leakage tester, such as the ULT-2000 series. For complete instructions on using the leakage tester, refer to the *ULT2000 Series User Manual*.

The electrical leakage test is not the same test as the electrical safety test (see “[Electrical safety test](#)” on page 5-8). You should perform the electrical leakage test on the TEEExp before or after every use, and maintain a record of test results for each TEEExp transducer.

### Required equipment

- ▶ Container with one of the following:
  - ▶ Cidezyme/Enzol
  - ▶ 0.9% saline
- ▶ Conductivity probe
- ▶ ULT-2000 series leakage tester (preset to test the TEEExp probe)
- ▶ TEEExp transducer adapter
- ▶ Fork adapter
- ▶ Splitter

### To test the transducer for electrical leakage

- 1 Insert the transducer connector into the transducer adapter as shown in [Figure 4-2](#).

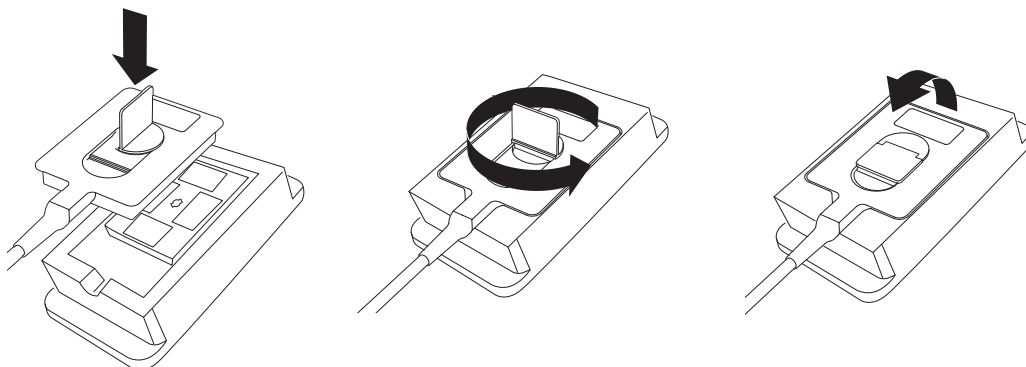


Figure 4-2 Insertion of the transducer connector

- 2 Insert the fork adapter securely in between the flexion control wheels as shown in [Figure 4-3](#). You will feel the fork adapter snap into position and may hear a click.

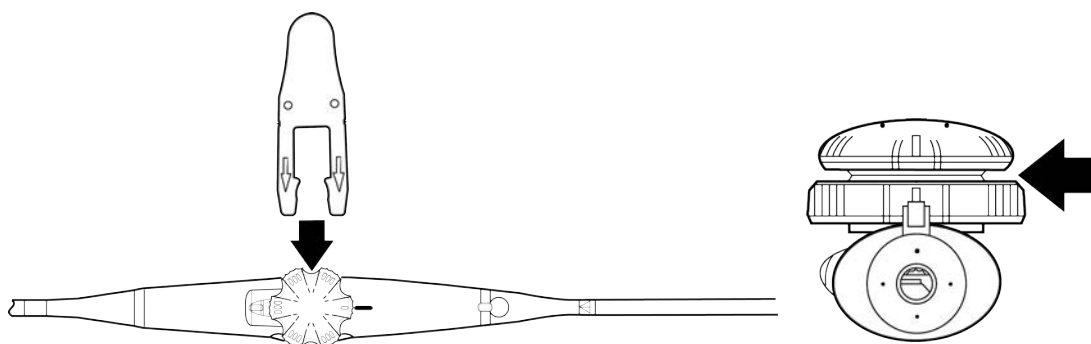


Figure 4-3 Insertion of the fork adapter

#### Note

Do not allow the fork adapter to swivel during the test.

- 3 Attach the splitter to the leakage tester, then attach the transducer adapter and the fork adapter to the splitter as shown in **Figure 4-4**.

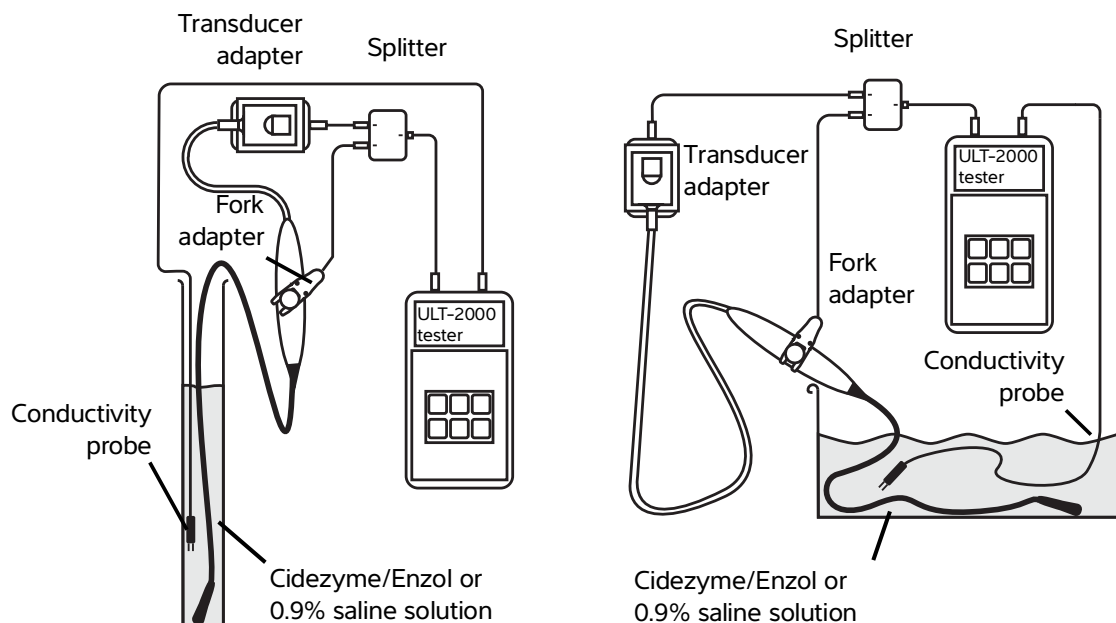


Figure 4-4 Two electrical test setup examples

- 4 Attach the conductivity probe to the leakage tester and insert the contacts into the container. Make sure the contacts are completely submerged.
- 5 Submerge between 70 cm and 90 cm of the endoscopic shaft.
- 6 Power on the ULT-2020.
- 7 If the screen does not display **Ready for Testing**, press the **RESET** key.
- 8 Press the **FULL TEST** button to start the test.
- 9 Record the test results (Pass/Fail).
- 10 If it passes, repeat steps 7 and 8 to complete three tests. If any of the results are **Fail**, electrical leakage was detected. **Do not use the TEEp transducer**. For remediation steps, see **"If the transducer fails the test"** on page 4-10.
- 11 Rinse the transducer in a large volume of clean water (for example, eight liters) for at least three minutes. and visually inspect it for damage before proceeding to **"Disinfecting the transducer"** on page 4-8.
- If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

# Disinfecting the transducer

Caution

Do not steam, autoclave, or expose the transducer to Ethylene Oxide.

Cleaners and disinfectants not listed on FUJIFILM SonoSite's website have not been evaluated for compatibility and may cause damage to the transducer. For a list of approved disinfectants, see [www.sonosite.com/support/cleaners-disinfectants](http://www.sonosite.com/support/cleaners-disinfectants). Follow the manufacturer’s instructions for concentration, temperature, and duration.

Table 4-3: Approved disinfectants

| Disinfectant <sup>a, b</sup>                                                                                                                                                                                                                                |                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Anioxyde 1000                                                                                                                                                                                                                                               | Opal                       |
| Anioxy - Twin                                                                                                                                                                                                                                               | Opaster'Anios              |
| Cidex                                                                                                                                                                                                                                                       | PeraSafe                   |
| Cidex OPA                                                                                                                                                                                                                                                   | Rapicide HLD & Sterilant   |
| Cidex Plus                                                                                                                                                                                                                                                  | Rapicide OPA 28            |
| DisOPA                                                                                                                                                                                                                                                      | Rapicide PA                |
| Gigasept PAA Concentrate                                                                                                                                                                                                                                    | Revital-Ox Resert HLD      |
| Gigasept Pearls                                                                                                                                                                                                                                             | Sekusept Aktiv             |
| McKesson OPA 28                                                                                                                                                                                                                                             | Steranios 2%               |
| Metricide                                                                                                                                                                                                                                                   | TD-100 & TD-5              |
| Metricide 28                                                                                                                                                                                                                                                | TD-100 & TD-8              |
| Metricide Plus 30                                                                                                                                                                                                                                           | Tristel Generator Solution |
| Metricide OPA Plus                                                                                                                                                                                                                                          | Wavicide-01                |
| Nu-Cidex                                                                                                                                                                                                                                                    |                            |
| <sup>a</sup> Refer to the manufacturer’s instructions for concentration, temperature, and soak time.                                                                                                                                                        |                            |
| <sup>b</sup> Refer to the cleaners and disinfection tool available at <a href="http://www.sonosite.com/support/cleaners-disinfectants">www.sonosite.com/support/cleaners-disinfectants</a> for a more complete list of approved cleaners and disinfectants. |                            |

## To disinfect the transducer

- 1 Verify that the transducer has been cleaned using the procedure described in **“Cleaning the transducer”** on page 4-3.
- 2 At the disinfection station, prepare the disinfectant for use:
  - a **Check** the expiration date on the bottle to ensure that the disinfectant has not expired.
  - b **Check** that the disinfectant has the concentration recommended by the manufacturer (for example, use a chemical strip test).
  - c **Check** that the temperature of the cleaner is within the manufacturer’s recommended limits.
- 3 Disinfect the cable and controller by wiping them with a sterile, non-linting cloth or single-use endoscopic sponge moistened with disinfectant.
- 4 Rinse the cable and controller by wiping them with a sterile, non-linting cloth or single-use endoscopic sponge moistened with sterile water.
- 5 Secure the control handle so it cannot fall into the solution. Disinfect the transducer by soaking the shaft and scan head in the disinfectant up to the 90 cm mark. See **Figure 4-1** on page 4-2.

### WARNING

Follow the chemical manufacturer’s instructions. Do not soak the transducer longer than recommended by the chemical manufacturer. Prolonged soaking in chemical disinfectants can cause damage to the transducer and chemical burns to the patient.

### Cautions

- ▶ Do not use unapproved disinfectants, such as alcohol or bleach (for example, Sani-cloth wipes) as these can damage the transducer. For more information about approved disinfectants, see **Table 4-3** on page 4-8.
- ▶ Do not immerse the transducer cable, connector, or controller in any fluid.

- 6 Continue with **“To rinse the transducer”** on page 4-9.

## To rinse the transducer

- 1 Rinse the transducer by soaking it for at least one minute, in a large volume of sterile, deionized water (for example, eight liters). Discard the rinse water.

### WARNING

Chemical disinfectants can cause harm to the patient if not completely removed from the transducer. For more information, see the disinfectant manufacturer’s instructions.

- 2 **Important:** To ensure that no residual disinfectant remains on the scan head or endoscopic shaft, repeat **step 1** at least two more times for a minimum total of **three rinse cycles**. Dispose of the water after each rinse. Some disinfectant manufacturers may recommend additional rinsing. See the manufacturer’s guidelines for more information.
- 3 Dry the transducer with a sterile, non-linting towel or medical-grade air.

- 4 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

- 5 If not already in place, apply a clean tip cover over the transducer scan head. The tip cover encloses and protects the scan head from mechanical strain and impact during transportation and storage. Keep the tip cover on until preparing the transducer for use.

**WARNING** When handling a clean transducer, always take appropriate precautions to prevent cross-contamination. You can place the probe shaft in a clean sleeve.

**Caution** The tip cover is a single-use device. Do not reuse tip covers. Doing so can result in contamination of, or damage to the scan head.

- 6 To transport the transducer, refer to the procedures detailed in **“Transporting the transducer”** on page 4-11.
- 7 To store the transducer, refer to the procedure detailed in **“Storing the transducer”** on page 4-12.
- 8 Dispose of the disinfectant according to the manufacturer’s guidelines.

**WARNING** Wear the appropriate personal protective equipment (PPE) when handling disinfectants.

## Identifying the transducer as clean and safe

To identify the transducer as clean, containers used to transport clean transducers should carry a verification sticker or certificate that include the date cleaned and the name (or other identification) of the person who performed the cleaning. Check the guidelines for proper record keeping on your TEE probe cleaning, disinfecting and electrical leakage testing.

### If no electrical leakage is detected

To identify the transducer as safe, you should include a sticker or certificate that travels with the transducer that includes the date of the test, the name or other identification of the tester, and the outcome of the test. If the test was performed as part of the cleaning process, continue to clean and disinfect the transducer.

### If the transducer fails the test

First, verify that you correctly set the test up and connected the equipment properly. If your test setup is correct, do not use the transducer or connect the transducer to an ultrasound system. Contact FUJIFILM SonoSite for repair.

To identify the transducer as unsafe to use, you should include a sticker or certificate that travels with the transducer that includes the date of the test, the name or other identification of the tester, and the outcome of the test.

## Transporting the transducer

When transporting the TEEp transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

### Caution

Do not bend the endoscopic shaft smaller than a 20 cm (8 inch) curve. Exceeding this minimum bend diameter can damage the endoscope or its watertight coating.

### To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

### WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



### Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector and endoscope.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

### Caution

Do not leave the TEEp transducer in a sealed container for long periods of time.

### To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate. For more

information, see **“Dispose of the disinfectant according to the manufacturer’s guidelines.”** on page 4-10.

- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

### To ship a transducer

#### WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned, tested, and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a “Declaration of Cleanliness,” and attach it to the packing list.

- 1 If not already in place, insert a tip cover over the transducer scan head.

#### Caution

The tip cover is a single-use device. Do not reuse tip covers. Doing so can result in contamination of, or damage to, the scan head.

- 2 Place the transducer in the shipping case and seal it.

#### Caution

When shipping the transducer in the shipping case, do not allow any part of the transducer to protrude beyond the case.

- 3 Ship the transducer using the following precautions:

- ▶ Clearly label the case as fragile.
- ▶ Do not stack items on top of the case.
- ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
- ▶ Do not open the case until it reaches its final destination.

After arrival, the transducer must be cleaned, tested, and disinfected using the procedures detailed in this chapter before it can be used.

## Storing the transducer

Follow society guidelines and recommendations.

### To store the transducer

- 1 Clean, test, and disinfect the TEEp transducer. See **“Transducer Care”** on page 4-1.
- 2 Store the transducer so that it hangs freely and vertically, and observe the following precautions:
  - ▶ Store the transducer away from any contaminated transducers.

- ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
- ▶ Use a tip cover when storing the transducer to prevent damage to the scan head. The tip cover encloses and protects the scan head from mechanical strain and impact during storage. Keep the tip cover on until preparing the transducer for use.

### Caution

The tip cover is a single-use device. Do not reuse tip covers. Doing so can result in contamination of, or damage to, the transducer.

- ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
- ▶ If using a wall-mounted rack for storage, ensure that:
  - ▶ It is securely mounted.
  - ▶ The storage slots do not mar the transducer or the endoscopic shaft.
  - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
- ▶ Make sure the connector is supported and secure.

## Disposing of the transducer

### WARNING

Do not destroy the transducer by incinerating or burning it. Return the transducer to FUJIFILM SonoSite or your local representative for disposal.



## Safety

Patient safety is ensured only when a well-designed product is used in a safe and responsible manner. Follow guidelines and protocols provided by the American Society of Echocardiography and the Academy of Emergency Physicians.

It is important that you establish and use a check-out procedure to ensure that the transducer is safe to use and functions properly prior to each use. If any irregularity, substandard functioning, or unsafe condition is observed or suspected, do not use the TEEp transducer. Call FUJIFILM SonoSite or your local representative.

### WARNING

The TEEp transducer has no protection in the event of a neutral electrode fault of a high frequency surgical device. When using the TEEp transducer with high frequency surgical equipment, monitor the scan head temperature and remove the transducer from the area if you observe an increase in temperature.

## Standards compliance

The TEEp transducer conforms to the Medical Device Directive 93/42/EEC. It is a class IIA medical device. Symbols and terms used on the transducer are explained in the ultrasound system user guide.

For a list of applicable standards and requirements, see the *SonoSite X-Porte User Guide*.

## Annual inspection

In addition to the regular inspections described elsewhere in this document, perform the following tests at least annually on the TEEp transducer:

- ▶ Temperature calibration test. See “**Guidelines for reducing MI and TI**” on page 5-5
- ▶ Electrical safety test. See “**Electrical safety**” on page 5-7.

## Safe operational use

### WARNINGS

To avoid injury to the patient:

- ▶ Consult the medical literature regarding techniques, complications, and hazards prior to transesophageal procedures. Study this user guide thoroughly prior to performing a transesophageal procedure.
- ▶ The TEEExp transducer is intended for use by a medical professional who has received appropriate training in endoscopic techniques as dictated by current relevant medical practices, as well as in proper operation of the ultrasound system and transducer.
- ▶ Check the transducer prior to each use to assure that it is safe to use and functions properly. If any irregularity, substandard functioning, or unsafe condition is observed or suspected, do not use the TEEExp transducer. Call FUJIFILM SonoSite or your local representative. See **“Pre-exam inspection”** on page 3-1.
- ▶ If the transducer tip should get jammed in a flexed position inside the patient, and all attempts to release the tip should fail, follow procedure **“To retract the transducer”** on page 3-4 to assure a safe retraction of the transducer. The mechanism is designed to provide safe operation during normal use.
- ▶ Perform a low-voltage electrical leakage test after cleaning the transducer, but before disinfecting it. If leakage is detected, do not use the transducer. See **“Testing the transducer for electrical leakage”** on page 4-5.
- ▶ Do not use conventional coupling gel intended for external use.
- ▶ Avoid forceful intubation pressure which can cause lacerations or perforation of the gastrointestinal tract.
- ▶ Remove the transducer from the patient when using a defibrillator.
- ▶ FUJIFILM SonoSite recommends cleaning and disinfecting transducers after each use. See **“Transducer Care”** on page 4-1.

### WARNINGS

- ▶ To avoid injury to the patient and damage to the transducer, use a bite guard/block during all transesophageal exams.
- ▶ To maintain proper level of sterility, the use of a protective sheath in addition to the high level disinfection, may provide the proper level of protection against contamination of the transducer.
- ▶ Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. See 21 CFR 801.437, User labeling for devices that contain natural rubber.

### Cautions

- ▶ To avoid damaging the equipment, clean and disinfect the transducer using the recommended procedures only.
- ▶ To avoid damaging the transducer, the TEEExp transducer shall be handled only by trained personnel. The TEEExp transducer is a precision instrument and can be inadvertently damaged.

## Thermal safety

Experts generally agree that to avoid damage to body tissues during long-term exposures, the temperature of the transducer tip where contacting tissue should be less than 43° C.

A thermal-safety system in the ultrasound system displays the transducer's operating temperature on-screen and prevents it from exceeding given limits.

If the temperature sensor is not working properly when you connect the transducer to the system, the image freezes, and a warning appears.

## Thermal limits

The imaging temperature range for the TEEExp transducer is between 18° C and 43° C. The X-Porte system includes safety features designed to assist the user in modifying treatment to prevent thermal damage to the patient during use.

When the scan head temperature is below 17.5° C, the scan is stopped, the scan head temperature flashes on the screen, and the following message appears:

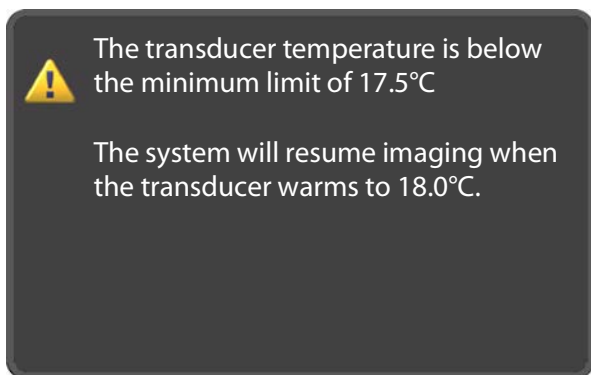


Figure 5-1 Low temperature warning message

If the temperature exceeds 41° C, the scan head temperature is highlighted on the screen to indicate that you are close to the maximum safe operating temperature.

If the temperature exceeds 43° C, the scan head temperature flashes on the screen and the following message appears:

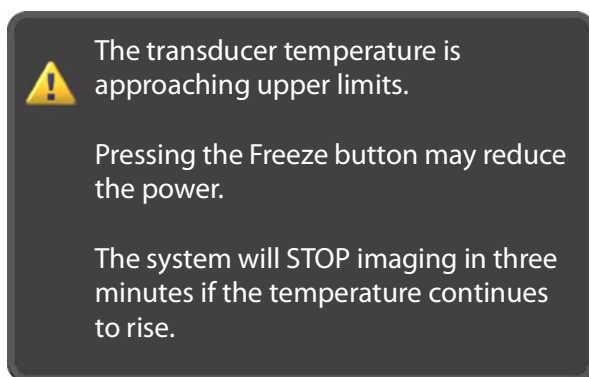


Figure 5-2 High temperature caution message

If the scan head temperature stays above 43° C for more than three minutes, or if it exceeds 45° C at any time, the scan is halted and the following message appears:

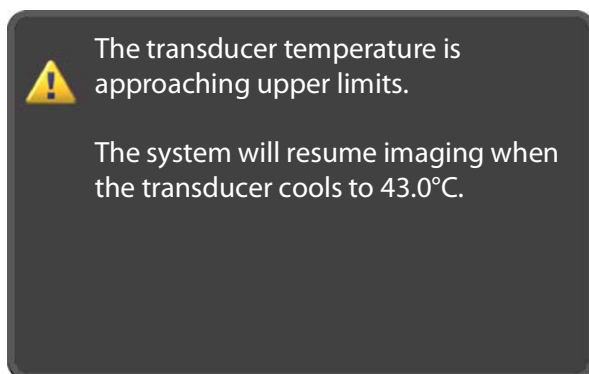


Figure 5-3 High temperature warning message

If a communication error occurs and the TEEp thermistor cannot be read, the scan is halted and will not resume until the thermistor can be read and the temperature is within operating limits.



Figure 5-4 Transducer communication error message

Reducing temperature

- ▶ The following are general guidelines for reducing temperature in 2D or Doppler imaging modes:
- ▶ Scan using 2D mode (2D imaging typically results in the lowest transducer surface temperature).
- ▶ In 2D imaging, select the average optimization setting and increase the image depth.
- ▶ In PW Doppler imaging, position the Doppler sample gate to a deeper depth.
- ▶ In CW Doppler imaging, no imaging changes reduce the transducer surface temperature.
- ▶ In any imaging mode, freezing the image temporarily reduces the transducer surface temperature.

Guidelines for reducing MI and TI

To reduce MI, increase depth.

Table 5-4: Guidelines for reducing TI (TIS, TIC, TIB)

| Transducer                                                | CPD/Color settings |            |           |     |       |          | PW settings |
|-----------------------------------------------------------|--------------------|------------|-----------|-----|-------|----------|-------------|
|                                                           | Box width          | Box height | Box depth | PRF | Depth | Optimize | Depth       |
| TEExp                                                     |                    |            | ↑         | ↓   |       |          | ↑           |
| ↓<br>Decrease or lower setting of parameter to reduce TI. |                    |            |           |     |       |          |             |
| ↑<br>Increase or raise setting of parameter to reduce TI. |                    |            |           |     |       |          |             |

## Output display

The following table indicates whether, for each operating mode, the value of TI or MI is greater than or equal to 1.0, thus requiring display.

**Table 5-5: MI or TI value by operating mode**

| Operating mode | MI         | TIC, TIB, or TIS |
|----------------|------------|------------------|
| 2D/M Mode      | $\geq 1.0$ | $< 1.0$          |
| CPD/Color      | $< 1.0$    | $< 1.0$          |
| PW Doppler     | $\geq 1.0$ | $\geq 1.0$       |
| CW Doppler     | $< 1.0$    | $\geq 1.0$       |

## Transducer surface temperature rise

**Table 5-6: Surface temperature rise**

| Test          | °C rise                          |
|---------------|----------------------------------|
| Still air     | 10.7                             |
| Simulated use | 3.6 ( $\leq 6^{\circ}\text{C}$ ) |

## Temperature calibration test

At least once a year, verify the temperature measurement function to the specifications.

### To set up the test

Assemble the following items for the test:

- ▶ Temperature stabilized water bath
- ▶ Temperature gauge with accuracy of  $\pm 0.1^{\circ}\text{C}$

### To test the calibration

- 1 Adjust the water bath temperature to  $43.3^{\circ} \pm 0.1^{\circ}\text{C}$  and monitor the temperature with the gauge.
- 2 If an accurate and stable water bath is not available, account for the added inaccuracy when reading the temperature from the ultrasound system. Deviation of more than  $\pm 0.5^{\circ}\text{C}$  is not acceptable. Maintaining this accuracy without temperature regulation may be difficult.

- 3 Connect the TEEexp transducer to the ultrasound system or select it if you are using the Triple Transducer Connect.
- 4 Freeze the image.
- 5 Put the transducer tip in the water bath.
- 6 At least 10 cm of the distal end must be submerged.
- 7 Observe the temperature indicated on the system screen.
- 8 Wait three minutes, or until the temperature display is stabilized at  $43.3^{\circ} \pm 0.5^{\circ} \text{C}$  plus/minus any water bath temperature deviation.
- 9 Observe that the Warning pop-up window appears.

If the temperature warning works as described in **“Thermal limits”** on page 5-3, the transducer passes the test. If not, contact FUJIFILM SonoSite or your local representative.

## Electrical safety

SonoSite ultrasound systems with accessories are designed to meet the requirements for patient safety described in IEC 60601-1. To maintain patient safety it is important to have a low electrical leakage current in the product. FUJIFILM SonoSite tests each TEEexp transducer for electrical isolation and leakage current before it is shipped to a customer.

The endoscopic shaft does not have any electrically conducting surfaces and is covered with a layer of material that does not permit fluids nor electricity to pass through it. The transducer's electrical safety is maintained by keeping this material intact. Punctures in this material, such as those resulting from bites or improper handling, can result in fluids entering the endoscopic shaft and the patient being exposed to an electrical current. You must test for such damage before or after every use. See **“Proceed to “Testing the transducer for electrical leakage” on page 4-5.”** on page 4-5.

It is important that you establish and use a standardized procedure to ensure that the transducer is safe to use and functions properly prior to each use. If any irregularity, substandard functioning, or unsafe condition is observed or suspected, do not use the TEEexp transducer. Call FUJIFILM SonoSite or your local representative.

### **WARNING**

To avoid injury to the patient, do not use the transducer if the insulating material has been punctured or otherwise compromised.

## Electrical safety test

You should establish a program for measuring the electrical leakage current on a regular basis. As a minimum, electrical current leakage tests according to IEC 60601-1 must be performed once per year, or as required by local regulation. The leakage limits associated with Type BF (Body Floating) Applied Part must be met. You should maintain a record of the test results for each TEEp transducer.

### **WARNING**

Only qualified personnel should perform the electrical safety test. Take all necessary precautions to avoid contact with non-insulated parts that have applied voltage.

## Transducer specifications

### TEExp/8-3 MHz transducer

|                                    |                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Endoscopic shaft</b>            | <p>External Diameter: 10.5 mm</p> <p>Length: 110 cm</p>                                                                                                                                                                                                                                                                                                     |
| <b>Steering orientation</b>        | <p>Clockwise rotation of the lower control wheel will flex the tip anterior. Counterclockwise rotation of the lower wheel will flex the tip posterior. Clockwise rotation of the upper control wheel will flex the tip to the right. Counterclockwise rotation of the upper wheel will flex the tip to the left.</p>                                        |
| <b>Tip deflection</b>              | <p>Anterior: ≥120°</p> <p>Posterior: ≥40°</p> <p>Right and Left: ≥40°</p>                                                                                                                                                                                                                                                                                   |
| <b>Scan plane rotation</b>         | <p>The transducer scans images in any plane within a nominal 180° cone from a transverse plane, through the longitudinal plane and ending at the mirror of the first transverse plane. The scan plane rotation is motor-driven, with speed and direction selected with buttons on the endoscope handle. Maximum speed: 180° in approximately 5 seconds.</p> |
| <b>Field of view</b>               | <p>90° maximum</p>                                                                                                                                                                                                                                                                                                                                          |
| <b>Transducer tip dimensions</b>   | <p>Length: 35 mm</p> <p>Cross-section maximum: 14 mm x 12.5 mm</p>                                                                                                                                                                                                                                                                                          |
| <b>Disinfection classification</b> | <p>Spaulding class, semi-critical</p>                                                                                                                                                                                                                                                                                                                       |
| <b>Electrical safety</b>           | <p>Conforms to applicable UL, CSA, IEC requirements for class BF.</p>                                                                                                                                                                                                                                                                                       |
| <b>Temperature accuracy</b>        | <p>±0.5° C within the range of 35° to 45° C</p>                                                                                                                                                                                                                                                                                                             |

|                                                    |                                                                                                                                                                |
|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Transducer tip temperature limits</b>           | Upper: 45° C<br>Lower: 17.5° C                                                                                                                                 |
| <b>Transducer</b>                                  | Center Frequency 5.0 MHz                                                                                                                                       |
| <b>Maximum cable length</b>                        | 7.2 ft/2.2 m (as measured between the strain reliefs)                                                                                                          |
| <b>Biocompatibility</b>                            | All patient contact materials of the TEEexp transducer/ endoscope system comply with ISO 10993-1. The transducer is manufactured without natural rubber latex. |
| <b>Environmental limits (shipping and storage)</b> | Temperature:<br>Shipping: -35° to +65° C<br>Storage: 0° to +45° C<br>Humidity: 15 to 95% R.H.<br>Pressure: 700 to 1060 hPA (0.7 - 1.05 ATM)                    |

## Acoustic output

For acoustic output information, see the ultrasound system user guide.

**Table 6–1: Transducer model: TEEExp Operating mode: 2D**

| Index label                  |                                                                                 | MI     | TIS        |               | TIB        |               | TIC        |
|------------------------------|---------------------------------------------------------------------------------|--------|------------|---------------|------------|---------------|------------|
|                              |                                                                                 |        | At surface | Below surface | At surface | Below surface | At surface |
| <b>Maximum index value</b>   |                                                                                 | 1.2    | (a)        |               | (a)        |               | (b)        |
| <b>Index component value</b> |                                                                                 |        | #          | #             | #          | #             |            |
| Acoustic parameters          | $p_{r,\alpha}$ at $z_{MI}$ (MPa)                                                | 2.60   |            |               |            |               |            |
|                              | $P$ (mW)                                                                        |        | #          |               | #          |               | #          |
|                              | $P_{1 \times 1}$ (mW)                                                           |        | #          |               | #          |               |            |
|                              | $z_s$ (cm)                                                                      |        |            | —             |            |               |            |
|                              | $z_b$ (cm)                                                                      |        |            |               |            | —             |            |
|                              | $z_{MI}$ (cm)                                                                   | 1.7    |            |               |            |               |            |
|                              | $z_{pii,\alpha}$ (cm)                                                           | 1.7    |            |               |            |               |            |
|                              | $f_{awf}$ (MHz)                                                                 | 4.60   | #          |               | #          |               | #          |
| Other information            | $pr$ (Hz)                                                                       | 1750   |            |               |            |               |            |
|                              | $srr$ (Hz)                                                                      | 50.0   |            |               |            |               |            |
|                              | $n_{pps}$                                                                       | 1      |            |               |            |               |            |
|                              | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm <sup>2</sup> )                        | 366    |            |               |            |               |            |
|                              | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm <sup>2</sup> ) | 26.3   |            |               |            |               |            |
|                              | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm <sup>2</sup> )                      | 33.5   |            |               |            |               |            |
|                              | $p_r$ at $z_{pii}$ (MPa)                                                        | 3.38   |            |               |            |               |            |
| Operating controls           | Exam type                                                                       | Crd    |            |               |            |               |            |
|                              | Optimization                                                                    | Pen    |            |               |            |               |            |
|                              | Depth (cm)                                                                      | 4.0    |            |               |            |               |            |
|                              | Sector width                                                                    | Narrow |            |               |            |               |            |

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

# No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)

— Data are not applicable for this transducer/mode.

**Table 6-2: Transducer model: TEEExp Operating mode: 2D + M Mode**

| Index label           |                                                                                 | MI   | TIS        |               | TIB        |               | TIC        |
|-----------------------|---------------------------------------------------------------------------------|------|------------|---------------|------------|---------------|------------|
|                       |                                                                                 |      | At surface | Below surface | At surface | Below surface | At surface |
| Maximum index value   |                                                                                 | 1.0  | (a)        |               | (a)        |               | (b)        |
| Index component value |                                                                                 |      | #          | #             | #          | #             |            |
| Acoustic parameters   | $p_{r,\alpha}$ at $z_{MI}$ (MPa)                                                | 2.09 |            |               |            |               |            |
|                       | $P$ (mW)                                                                        |      | #          |               | #          |               | #          |
|                       | $P_{1 \times 1}$ (mW)                                                           |      | #          |               | #          |               |            |
|                       | $z_s$ (cm)                                                                      |      |            | #             |            |               |            |
|                       | $z_b$ (cm)                                                                      |      |            |               |            | #             |            |
|                       | $z_{MI}$ (cm)                                                                   | 1.75 |            |               |            |               |            |
|                       | $z_{pii,\alpha}$ (cm)                                                           | 1.75 |            |               |            |               |            |
|                       | $f_{awf}$ (MHz)                                                                 | 4.60 | #          |               | #          |               | #          |
| Other information     | $prr$ (Hz)                                                                      | 400  |            |               |            |               |            |
|                       | $srr$ (Hz)                                                                      | 30.8 |            |               |            |               |            |
|                       | $\eta_{pps}$                                                                    | 1    |            |               |            |               |            |
|                       | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm <sup>2</sup> )                        | 244  |            |               |            |               |            |
|                       | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm <sup>2</sup> ) | 31.5 |            |               |            |               |            |
|                       | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm <sup>2</sup> )                      | 54.9 |            |               |            |               |            |
|                       | $p_r$ at $z_{pii}$ (MPa)                                                        | 2.74 |            |               |            |               |            |
| Operating controls    | Exam type                                                                       | Crd  |            |               |            |               |            |
|                       | Optimization                                                                    | Pen  |            |               |            |               |            |
|                       | Depth (cm)                                                                      | 4.0  |            |               |            |               |            |

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

# No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)

— Data are not applicable for this transducer/mode.

**Table 6-3: Transducer model: TEEExp Operating mode: PW Doppler**

| Index label           |                                                                                 | MI                | TIS        |               | TIB            |               | TIC        |
|-----------------------|---------------------------------------------------------------------------------|-------------------|------------|---------------|----------------|---------------|------------|
|                       |                                                                                 |                   | At surface | Below surface | At surface     | Below surface | At surface |
| Maximum index value   |                                                                                 | 1.3               | (a)        |               | 1.9            |               | (b)        |
| Index component value |                                                                                 |                   | #          | #             | 0.6            | 1.9           |            |
| Acoustic parameters   | $p_{r,\alpha}$ at $z_{MI}$ (MPa)                                                | 2.64              |            |               |                |               |            |
|                       | $P$ (mW)                                                                        |                   | #          |               | 32.8           |               | #          |
|                       | $P_{1 \times 1}$ (mW)                                                           |                   | #          |               | 32.8           |               |            |
|                       | $z_s$ (cm)                                                                      |                   |            | #             |                |               |            |
|                       | $z_b$ (cm)                                                                      |                   |            |               |                | 0.60          |            |
|                       | $z_{MI}$ (cm)                                                                   | 0.6               |            |               |                |               |            |
|                       | $z_{pii,\alpha}$ (cm)                                                           | 0.6               |            |               |                |               |            |
|                       | $f_{awf}$ (MHz)                                                                 | 4.01              | #          |               | 4.01           |               | #          |
| Other information     | $pr$ (Hz)                                                                       | 1008              |            |               |                |               |            |
|                       | $srr$ (Hz)                                                                      | —                 |            |               |                |               |            |
|                       | $n_{pps}$                                                                       | 1                 |            |               |                |               |            |
|                       | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm <sup>2</sup> )                        | 289               |            |               |                |               |            |
|                       | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm <sup>2</sup> ) | 327.5             |            |               |                |               |            |
|                       | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm <sup>2</sup> )                      | 386.0             |            |               |                |               |            |
|                       | $p_r$ at $z_{pii}$ (MPa)                                                        | 2.86              |            |               |                |               |            |
| Operating controls    | Exam type                                                                       | Crd               |            |               | Crd            |               |            |
|                       | Sample volume size (mm)                                                         | 1                 |            |               | 2              |               |            |
|                       | Sample volume position                                                          | Zone 1<br>(16 mm) |            |               | Zone 1 (16 mm) |               |            |
|                       | PRF (Hz)                                                                        | 1008              |            |               | 1562           |               |            |
|                       | TDI                                                                             | On                |            |               | Off            |               |            |

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

# No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)

— Data are not applicable for this transducer/mode.

**Table 6-4: Transducer model: TEEExp Operating mode: CW Doppler**

| Index label           |                                                                                 | MI  | TIS        |               | TIB            |               | TIC        |
|-----------------------|---------------------------------------------------------------------------------|-----|------------|---------------|----------------|---------------|------------|
|                       |                                                                                 |     | At surface | Below surface | At surface     | Below surface | At surface |
| Maximum index value   |                                                                                 | (a) | (a)        |               | 1.3            |               | (b)        |
| Index component value |                                                                                 |     | #          | #             | 0.5            | 1.3           |            |
| Acoustic parameters   | $p_{r,\alpha}$ at $z_{MI}$ (MPa)                                                | #   |            |               |                |               |            |
|                       | $P$ (mW)                                                                        |     | #          |               | 25.9           |               | #          |
|                       | $P_{1 \times 1}$ (mW)                                                           |     | #          |               | 25.9           |               |            |
|                       | $z_s$ (cm)                                                                      |     |            | #             |                |               |            |
|                       | $z_b$ (cm)                                                                      |     |            |               |                | 0.90          |            |
|                       | $z_{MI}$ (cm)                                                                   | #   |            |               |                |               |            |
|                       | $z_{pii,\alpha}$ (cm)                                                           | #   |            |               |                |               |            |
|                       | $f_{awf}$ (MHz)                                                                 | #   | #          |               | 4.00           |               | #          |
| Other information     | $p_{rr}$ (Hz)                                                                   | #   |            |               |                |               |            |
|                       | $s_{rr}$ (Hz)                                                                   | #   |            |               |                |               |            |
|                       | $n_{pps}$                                                                       | #   |            |               |                |               |            |
|                       | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm <sup>2</sup> )                        | #   |            |               |                |               |            |
|                       | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm <sup>2</sup> ) | #   |            |               |                |               |            |
|                       | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm <sup>2</sup> )                      | #   |            |               |                |               |            |
|                       | $p_r$ at $z_{pii}$ (MPa)                                                        | #   |            |               |                |               |            |
| Operating controls    | Exam type                                                                       |     |            |               | Crd            |               |            |
|                       | Sample volume position                                                          |     |            |               | Zone 5 (53 mm) |               |            |

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

# No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference global maximum index value line.)

— Data are not applicable for this transducer/mode.





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