TEE Transducer
User Guide


**Caution:** Federal (United States) law restricts this device to sale by or on the order of a physician.

"MicroMaxx" is a trademark of SonoSite, Inc.

Non-SonoSite product names may be trademarks or registered trademarks of their respective owners.

SonoSite products may be covered by one or more of the following U.S. patents: 4454884, 4462408, 4469106, 4474184, 4475376, 4515017, 4534357, 4542653, 4549690, 4552607, 4561807, 4566035, 4567895, 4581636, 4591355, 4603702, 4607642, 4644795, 4670339, 4773140, 4817618, 4883059, 4887306, 5016641, 5050610, 5095910, 5099847, 5123415, 5158088, 5197477, 5207225, 5215094, 5226420, 5226422, 5233994, 5255682, 5275167, 5287753, 5305756, 5353354, 5369299, 5381795, 5386830, 5390674, 5402793, 5423220, 5438994, 5450851, 5456257, 5471989, 5471990, 5474073, 5476097, 5479930, 5482045, 5482047, 5485842, 5492134, 5517994, 5529070, 5546946, 555887, 5603323, 5606972, 5617863, 5634465, 5634466, 5663631, 5645066, 5669824, 5706819, 5715823, 5718229, 5720291, 5722412, 5752517, 5762067, 5782769, 5800356, 5817024, 5833613, 5846200, 5860924, 5893363, 5916168, 5931478, 6036643, 6102863, 6104126, 6113547, 6117085, 6142946, 6203498 B1, 6371918, 6135961, 6364839, 6383139, 6416475, 6447451, 6471651, 6569101, 6575908, 6604630, 6648826, 6835177, D0280762, D0285484, D0285325, D0300241, D0306343, D0328095, D0369307, D0379231, D456509, D461895. Other patents pending.

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# Chapter 6: Transducer Specifications
Chapter 1: Overview

Please read the information in this user guide before using the transesophageal echocardiogram transducer (TEE/8-3 MHz) for the SonoSite® MicroMaxx™ ultrasound system.

About the User Guide

This user guide provides information on the TEE/8-3 transducer. It is designed for a reader familiar with ultrasound and proper esophagogastoscopic techniques; it does not provide training in sonography, cardiology, or clinical practices. This user guide does not include instructions on how to operate the ultrasound system or how to evaluate clinical data. For information about the ultrasound system, see the MicroMaxx Ultrasound System User Guide and other appropriate literature. To aid in safeguarding the patient and ensuring reliable transducer operation, SonoSite recommends that this user guide is available for reference during all stages of TEE transducer handling.

Conventions

These conventions are used in this user guide:

- A WARNING describes precautions necessary to prevent injury or loss of life.
- A Caution describes precautions necessary to protect the products.
- When the steps in the operating instructions must be performed in a specific order, the steps are numbered.
- Bulleted lists present information in list format, but they do not imply a sequence.

Symbols and Terms

For labeling symbols used with SonoSite products, see the ultrasound system user guide.

About the TEE Transducer

**WARNING:** To avoid injury to a patient, the TEE transducer is intended for use by a licensed physician 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.

**Caution:** To avoid inadvertent damage to the transducer, read this user guide before handling and cleaning the TEE transducer.

The TEE transducer is an electronically steered phased array ultrasound transducer assembly, mounted in a sealed tip at the end of a conventional endoscope.
Chapter 1: Overview

The TEE 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 scanplane is driven by a motor in the endoscope handle, controlled by push-buttons on the endoscope housing.

For orientation purposes, the user may choose to start scanning in one of the transverse planes, for instance the standard monoplane indicated as 0° on the system monitor. After rotating the scanplane 90°, scanning occurs in the longitudinal plane, sweeping through two opposite quadrants of the cone. When the scanplane rotates 90° further 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; one being the mirror image of the other. As shown in Figure 1, a 180° rotation of the scanplane fills all four quadrants of the conic imaging volume.

The direction of the tip of the endoscope is easily steered using the deflection control wheels on the handle of the instrument to allow exact positioning of the transducer in the esophagus.

![Figure 1 Multiplane Imaging](image)

### Table 1: Multiplane Imaging

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>90° rotation sagittal to mirror image of transverse plane</td>
</tr>
<tr>
<td>2</td>
<td>90° rotation transverse to longitudinal plane</td>
</tr>
<tr>
<td>3</td>
<td>Conic imaging volume</td>
</tr>
<tr>
<td>4</td>
<td>Quadrants filled by first 90° rotation</td>
</tr>
<tr>
<td>5</td>
<td>Quadrants filled by second 90° rotation</td>
</tr>
</tbody>
</table>
Intended Uses

The TEE/8-3 MHz transducer is designed for 2D, M Mode, color Doppler (Color), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler by applying ultrasound energy through the esophagus or stomach of the patient into the heart. The TEE transducer is intended to be used on adults only. Backscattered ultrasound energy from the patient’s heart is used to form 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 take into account all possible factors before starting the examination.

Contraindications for using the TEE transducer are:
- 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 of the patient to swallow or accommodate the transducer
  - History of gastroesophageal diseases
  - Other therapies the patient may be undergoing

Standards Compliance

The TEE 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. The TEE transducer conforms to the requirements in the following standards.
- Medical Device Directive, 93/42/EEC.
- IEC 1157/EN61157: 1994, Requirements for declaration of the acoustic output of medical diagnostic ultrasonic equipment.
• EN 60601-2-37: 2001, European Norm, Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

Warranty Statement

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

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

Specifically the warranty does not cover:
• Issues caused by external influences
• Accidents involving impact to the scanhead
• Dropped connector
• Pinched endoscope
• Bite marks or holes
• Discoloration or chemical breakdown of endoscope
• Transducer connector or scanhead opened by unauthorized persons

Contact Information

If you encounter difficulty with the system, contact SonoSite technical support at the following numbers or addresses:

Technical Support (USA, Canada) 1-877-657-8118
Technical Support fax: 1-425-951-6700
Technical Support e-mail: service@sonosite.com
SonoSite website: www.sonosite.com and select Support
International Technical Support: Contact your local representative or call (USA) +425-951-1330
European Service Center +44-(0)1462-444-800
e-mail: uk.service@sonosite.com
Japan Service Center +81-3-5304-5337
e-mail: sonositejapan@sonosite.com

Contact CIVCO for sheaths, biteguards, tip covers, and other supplies at www.civco.com.
Chapter 2: Getting Started

Overview

Read the user guide including the applicable referenced pages before using the TEE transducer. It is important that the user establishes and uses a check-out procedure to assure 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, the TEE transducer should not be used. Call SonoSite or your local representative immediately.

Unpacking

Proper care and maintenance is essential. Follow the unpacking procedures. Contact 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

1. Visually examine the shipping carton and the TEE 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 carton contains the components listed on the packing list.
The shipping case contains the following items:
• TEE transducer
• TEE Transducer User Guide
• TEE Care Instructions
• Bite Guards (3)
• Non-sterile tip covers (3)

Figure 1 Shipping Case with TEE Transducer

**WARNING:** To avoid injury to patient, proper care and maintenance is essential for safe operation of the TEE transducer.

To avoid injury to a patient, the physician conducting the examination must exercise sound medical judgment in the selection of patients for this transducer.

**Caution:** To avoid damaging the transducer, do not deflect the transducer tip using finger pressure directly on the tip, as this may permanently damage the internal control wires.

To avoid inadvertent damage to the transducer, read this user guide before handling and cleaning the TEE transducer.
### Out-of-Box Inspection

The following inspections should be performed on the TEE transducer after unpacking the contents.

<table>
<thead>
<tr>
<th>Inspection/Activity</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform visual and tactile inspection.</td>
<td>See “Visual and Tactile Inspection” on page 10.</td>
</tr>
<tr>
<td>Perform tip deflection inspection.</td>
<td>See “Tip Deflection Inspection” on page 12.</td>
</tr>
<tr>
<td>Perform brake inspection.</td>
<td>See “Tip Deflection Brake Inspection” on page 13.</td>
</tr>
<tr>
<td>Perform scanplane rotation inspection.</td>
<td>See “Scanplane Rotation Inspection” on page 15.</td>
</tr>
<tr>
<td>Contact SonoSite or your local representative immediately to report any damage or discrepancies.</td>
<td>See “Contact Information” on page 4.</td>
</tr>
</tbody>
</table>

**WARNING:** To avoid injury to the patient, if any irregularity, substandard function or unsafe condition is observed or suspected, the TEE transducer should not be used.
Transducer and System Interface

The TEE transducer consists of an electronically steered phased array ultrasound transducer assembly, mounted in a sealed tip at the end of a conventional endoscope. It is connected to the ultrasound system with a cable and connector. See Figure 2.

Figure 2 TEE Transducer
Table 1: TEE Transducer

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Flexible shaft</td>
</tr>
<tr>
<td>2</td>
<td>Articulation section</td>
</tr>
<tr>
<td>3</td>
<td>Distal tip with transducer</td>
</tr>
<tr>
<td>4</td>
<td>Deflection brake</td>
</tr>
<tr>
<td>5</td>
<td>Deflection control wheels</td>
</tr>
<tr>
<td>6</td>
<td>Neutral marker</td>
</tr>
<tr>
<td>7</td>
<td>Transducer cable</td>
</tr>
<tr>
<td>8</td>
<td>Transducer connector</td>
</tr>
<tr>
<td>9</td>
<td>Scanplane control buttons</td>
</tr>
<tr>
<td>10</td>
<td>Attachment ring</td>
</tr>
</tbody>
</table>
TEE Transducer Controls and Inspection

The endoscope is designed for one-hand operation of the deflection and scanplane controls. The mechanical operation and physical integrity of the transducer should be checked after taking it out of the box and prior to each exam.

**WARNING:** To avoid injury to the patient, if any irregularity, substandard function or unsafe condition is observed or suspected, the TEE transducer should not be used.

Visual and Tactile Inspection

The visual and tactile inspection should be performed on the TEE transducer after taking it out of the box and prior to each exam.

**WARNING:** To avoid injury to the patient, do not use the transducer if any metallic protrusions, holes, rough spots, cracks, or dents are found.

<table>
<thead>
<tr>
<th>Inspect Contents</th>
<th>1</th>
<th>Visually examine and feel the entire surface of the flexible shaft and deflection section with the transducer in both straight and deflected position.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>Examine the transducer tip for any holes or dents.</td>
</tr>
</tbody>
</table>

Tip Deflection

The TEE transducer endoscope has two control wheels for deflection of the tip. The deflection wheels control anterior/posterior and left/right tip deflection. In Figure 3, the deflection wheels are shown in the neutral (undeflected) position.
Figure 3  Operation of the Deflection Controls

For orientation purposes, hold the transducer with control wheels up and the flexible shaft pointing away.

Table 2: Operation of the Deflection Controls

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Turn upper wheel counterclockwise to move the tip to the left, 40° minimum, 60° maximum</td>
</tr>
<tr>
<td>2</td>
<td>Turn upper wheel clockwise to move the tip to the right, 40° minimum, 60° maximum</td>
</tr>
<tr>
<td>3</td>
<td>Turn lower wheel counterclockwise to move the tip posterior, 40° minimum, 60° maximum</td>
</tr>
<tr>
<td>4</td>
<td>Turn lower wheel clockwise to move the tip anterior, 120° minimum, 130° maximum</td>
</tr>
<tr>
<td>5</td>
<td>Lower deflection control wheel</td>
</tr>
<tr>
<td>6</td>
<td>Upper deflection control wheel</td>
</tr>
</tbody>
</table>
**Tip Deflection Inspection**

The tip deflection inspection should be performed on the TEE transducer after taking it out of the box and prior to each exam.

**WARNING:** To avoid injury to the patient, if during this checkout procedure a sharp “U-turn” of the transducer tip is observed, i.e. that the transducer tip angle exceeds the maximum deflection angles given above, do not use the transducer.

### Tip Deflection Inspection

1. Deflect the tip in all four directions and confirm that the angle is within the ranges specified in Table 2 on page 11 (with reference to the endoscope shaft).
2. Confirm that the deflection controls operate smoothly.
3. Check that when the deflection controls are in the neutral position that the transducer tip is also in a neutral position ( undeflected).

---

**Tip Deflection Brake**

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

The brake for the anterior/posterior deflection is a handle under the deflection wheel (see Figure 4). There is no brake for the right/left deflection.

![Figure 4 Deflection Brake Operation](image)

---

**Table 3: Operation of the Deflection Brake**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Deflection brake for tip control in unlocked position</td>
</tr>
<tr>
<td>2</td>
<td>Deflection brake for tip control in locked position</td>
</tr>
<tr>
<td>3</td>
<td>Wheel position markers</td>
</tr>
</tbody>
</table>
Tip Deflection Brake Inspection

The tip deflection brake inspection should be performed on the transducer after taking it out of the box and prior to each exam.

<table>
<thead>
<tr>
<th>Tip Deflection Brake Inspection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Confirm the brake is in the unlocked position.</td>
</tr>
<tr>
<td>2</td>
<td>Deflect the tip to the anterior direction.</td>
</tr>
<tr>
<td>3</td>
<td>Move the brake to the locked position.</td>
</tr>
<tr>
<td>4</td>
<td>Confirm that the tip is locked in the deflected position.</td>
</tr>
<tr>
<td>5</td>
<td>Unlock the brake and confirm the tip straightens easily.</td>
</tr>
<tr>
<td>6</td>
<td>Repeat steps 1-5 for the posterior direction.</td>
</tr>
</tbody>
</table>

Scanplane Rotation Control

The scanplane rotation is driven by a motor located in the transducer handle. The scanplane rotation is controlled by the two outer push buttons on the handle (see Figure 5).

- The button closest to the transducer tip rotates the scanplane counterclockwise (scanplane angle increases).
- The button farthest from the transducer tip rotates the scanplane clockwise (scanplane angle decreases).

The scanplane rotates 180° from a standard transverse plane (short axis) to the longitudinal plane (long axis), ending at the mirror image of the first transverse plane (short axis). The angular position is displayed on the system monitor. The 0° short axis reference position is defined as follows: when viewing the transducer through the acoustic window of the transducer tip, the transducer is in the extreme clockwise position.
Chapter 2: Getting Started

Figure 5 Scanplane Rotation Control

Table 4: Operation of the Scanplane Rotation Control

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Transducer tip</td>
</tr>
<tr>
<td>2</td>
<td>Counterclockwise button (increases angle)</td>
</tr>
<tr>
<td>3</td>
<td>Center button (rotates angle to orthogonal biplane)</td>
</tr>
<tr>
<td>4</td>
<td>Clockwise button (decreases angle)</td>
</tr>
</tbody>
</table>

Scanplane Indicator

For orientation purposes, a scanplane indicator has been incorporated on the system display. The actual scanplane angle is indicated by a marker, and the value is also displayed as shown in Figure 6. The display shows the angle relative to the standard monoplane, displayed as 0°. The scanplane angle ranges from 0° to 180°.

Figure 6 Scanplane Angle Indication
Scanplane Rotation Inspection

The scanplane rotation inspection on the transducer should be performed after taking it out of the box and prior to each exam.

1. Connect a TEE transducer to the ultrasound system.
2. Prior to inserting the transducer, obtain an image, e.g., Rest the transducer on a surface and adjust the gain to visualize the image on the ultrasound display.
3. Press the scanplane control buttons on the handle to rotate the scanplane counterclockwise (0° to 180°) and clockwise (180° to 0°). See Figure 5.
4. Confirm the image on the screen changes in relation to the numbers on the scanplane indicator. See Figure 6.

While pressing the scanplane control buttons, the transducer motor should be running as the image is changing.

Note: Do not rely only on the scanplane indicator on the screen to verify that the scanplane is rotating.

Biplane Functionality

The center button on the endoscope handle rotates the scanplane at full speed to the orthogonal position. See Figure 7.

Changing Biplane Functionality

Press the center button to rotate the scanplane from the current position to the orthogonal position. (E.g. if the present position is 22°, the scanplane rotates to 112°. If the present position is 162°, the scanplane rotates to 72°). If the center button is pressed again, the scanplane rotates back to the original position.
Connecting TEE Transducer to System

Caution: To avoid damaging the transducer connector, do not allow foreign material in the connector.

Figure 8 Connect the Transducer to System

1. Turn the system upside down (if not in docking system).
2. Pull the transducer latch up and rotate it clockwise.
3. Align the transducer connector with the connector on the bottom of the system.
4. Insert the transducer connector into the system connector.
5. Turn the latch counterclockwise.
6. Press the latch down, securing the transducer connector to the system.

Note: If using the mini-dock or Triple Transducer Connect (TTC), see the applicable SonoSite accessory user guide.

Turn System On/Off

1. Locate the Power key on the top left side of the system.
2. Press the Power key once to turn on and once to turn off.

Scanplane Calibration

A scanplane positioning calibration test is automatically performed when the transducer is connected and the ultrasound system is turned on. This calibration cycle lasts 5 to 10 seconds. After the calibration test is completed, the transducer temperature sensor is activated, and the transducer temperature is displayed, indicating the transducer is ready for use.

If the calibration test of the transducer fails, (no response from the scanplane buttons after calibration), re-connect the transducer to repeat the calibration test.

Remove Transducer

1. Pull the latch up and rotate it clockwise.
2. Pull the transducer connector away from the system.
Chapter 3: Examination

While echocardiographs from the transesophageal or transgastric position will provide important clinical data not available from any other view, there are a number of conditions the examining physician must consider when selecting a patient for safe use of the transducer. 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 3.

Pre-Exam Inspection

The following inspections should be performed prior to each exam.

<table>
<thead>
<tr>
<th>Inspection/Activity</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform visual tactile inspection.</td>
<td>See “Visual and Tactile Inspection” on page 10.</td>
</tr>
<tr>
<td>Perform tip deflection inspection.</td>
<td>See “Tip Deflection Inspection” on page 12.</td>
</tr>
<tr>
<td>Perform brake inspection.</td>
<td>See “Tip Deflection Brake Inspection” on page 13.</td>
</tr>
<tr>
<td>Perform scanplane rotation inspection.</td>
<td>See “Scanplane Rotation Inspection” on page 15.</td>
</tr>
<tr>
<td>Perform leakage test or bite-hole inspection test.</td>
<td>See “Electrical Leakage Current Test” on page 31 or “Bite-Hole Inspection Test” on page 32.</td>
</tr>
<tr>
<td>Clean and disinfect transducer.</td>
<td>See “Clean, Disinfect, and Storage” on page 23.</td>
</tr>
<tr>
<td>Contact SonoSite or your local representative to report any damage or discrepancies.</td>
<td>See “Contact Information” on page 4.</td>
</tr>
</tbody>
</table>

**WARNING:** To avoid injury to the patient, SonoSite recommends performing the above procedures prior to each exam.

To avoid injury to the patient, do not use the transducer if any metallic protrusions, holes, rough spots, cracks, or dents are found.

To avoid injury to the patient, if during the deflection test, a sharp “U-turn” of the transducer tip is observed (the transducer tip angle exceeds the maximum deflection angles), do not use the transducer. Call SonoSite or your local representative.

Some gels and sterilants can cause an allergic reaction in some individuals.
Examination

The actual techniques for introduction of the TEE transducer into the patient are beyond the scope of the user guide. There are numerous medical texts and articles which thoroughly address this topic. Observe the following precautionary measures when conducting an exam.

- Maintenance of 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 re-positioned often.
- Long term exposure to ultrasound should be minimized. Although there have never been any bioeffects demonstrated at the acoustic output levels of the TEE transducer, it is prudent to minimize patient exposure to ultrasound according to the principle of ALARA (As Low As Reasonably Achievable). Please see the ultrasound system user guide.
- In consideration of the above 2 points, the user should freeze the image, which turns the power to the transducer off, and allow the endoscope deflection controls to be disengaged whenever active scanning is not desired.
- Proper patient preparation is essential for successful examinations. This includes restrictions on food and liquid intake as well as a thorough explanation of the examination procedure and other instructions as the particular situation warrants.
- The use of a bite guard during all TEE 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, the use of a protective sheath may provide an even higher level of protection against contamination of the probe. Contact CIVCO for protective sheaths and applicators for protective sheaths.

Bite Guard

Caution: To avoid damaging the transducer, use a bite guard during all TEE examinations. Biting the endoscope may cause severe, permanent damage to the transducer, rendering it unusable in the future, and unsafe in the present by creating electrical and mechanical failure mechanisms.

The use of a bite guard during all TEE examinations is mandatory to protect the transducer from possible damage. Damage to the transducer which results from the failure to use a bite guard will void the transducer warranty.

Note: Damage to the transducer due to biting is not covered under the transducer’s warranty or any service contract.

Each TEE transducer from SonoSite is delivered with three bite guards. Use of a bite guard is mandatory. Contact a local SonoSite representative if you need help in ordering more bite guards.
Re-use, cleaning, and sterilization of the bite guards should be done according to instructions provided by the manufacturer of the bite guard.

![Side view](image1)
![Front view](image2)

**Figure 1 Bite Guard**

**Sterile Sheath**

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

**Caution:**

Ensure that the TEE transducer 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 TEE transducer may occur.

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

**Install Transducer Sheath**

1. Place gel inside the sheath.

2. Insert the transducer into the sheath.

   *Note: To lessen the risk of contamination, install the sheath only when you are ready to perform the procedure.*

3. Pull the sheath over the transducer and cable 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.

   *Note: If any bubbles are present between the footprint of the transducer and the sheath, the ultrasound image may be affected.*

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

---

**Chapter 3: Examination**
Operation of Deflection Controls

The endoscope is designed for one-hand operation. Figure 2 shows the operator holding the endoscope handle in the left hand. Thumb, first and second fingers interact with the deflection and scanplane controls.

Figure 2 Holding the Transducer

There are two wheels for controlling the transducer tip deflection. The lower wheel has brake and freely-moving modes. In the braked mode, the movement of the deflection wheel is restrained. This is used to hold the tip in a certain position.

Special care should be taken when inserting and removing the transducer.

**WARNING:** To avoid injury to the patient, using excessive force during insertion, positioning, or withdrawal may cause trauma to the stomach or esophagus.

To prevent damage to the esophagus when inserting or withdrawing the transducer, the control wheel must be in the freely moving, neutral, and un-braked state (Figure 3).

**Caution:** To avoid damaging the transducer, do not deflect the distal tip of the transducer by direct application of force. Use the deflection wheels for this task.

Figure 3 Deflection Brake
Emergency Retraction

If the transducer tip should get jammed in a deflected position inside the patient, and all attempts to release the deflected tip should fail, follow the procedure “Retract Transducer” on page 21 to assure a safe retraction of the transducer.

<table>
<thead>
<tr>
<th>Retract Transducer</th>
<th>1</th>
<th>Disconnect the transducer from the ultrasound system.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>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 deflection mechanism is now released and the transducer may be safely retracted.</td>
</tr>
</tbody>
</table>
Chapter 4: Clean, Disinfect, and Storage

Disinfecting Solution
Disinfection is required for the TEE transducer. In order to provide users with options in choosing a germicide, SonoSite routinely reviews new medical disinfectants for compatibility with the materials used in the transducer housing, cable and lens. Although a necessary step in protecting patients and employees from disease transmission, liquid chemical disinfectants must also be selected to minimize potential damage to the transducer.

See the TEE Care Instructions enclosed in the transducer case for the latest list of compatible disinfectants. Carefully follow the manufacturer's instructions for preparation, use, and recommended solution.

**WARNING:** Use only disinfectants that are listed in the TEE Care Instructions enclosed with the transducer. In addition, see local/national regulations.

Cleaning and Disinfecting Instructions
The cleaning and disinfecting procedures must be performed on the transducer prior to each exam.

**Caution:** To avoid damaging the transducer, do not immerse the system connector or adapter in any fluid.

DO NOT soak or saturate transducers with solutions containing: alcohol, bleach, ammonium chloride compounds, or hydrogen peroxide.

<table>
<thead>
<tr>
<th>Clean Transducer</th>
<th>Use the following instructions to clean the transducer and remove residues before disinfection. The transducer handle is sealed and may be immersed and wiped with a saturated gauze pad.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Clean the transducer in mild soapy water.</td>
<td>2 Wipe the transducer with a gauze pad saturated in one of the compatible disinfectants.</td>
</tr>
<tr>
<td>2 Wash the transducer in lukewarm running water.</td>
<td>3 Wipe dry with a soft towel or air dry the transducer.</td>
</tr>
</tbody>
</table>
WARNING: To avoid injury to the patient, you must follow the manufacturer's recommendation for rinsing.

Caution: To avoid damaging the transducer, the transducer should not be exposed to the disinfectant longer than specified to achieve the desired effect, but never longer than one hour.

To avoid damaging the transducer, do not steam autoclave or subject the transducer to Ethylene Oxide (ETO).

To avoid damaging the transducer, do not immerse the transducer in a solution containing ethanol.

### Disinfect Transducer

1. Immerse the flexible shaft of the cleaned TEE transducer in one of the recommended disinfectants for the time duration specified by the manufacturer.
   - The transducer handle is sealed and may be immersed and wiped with a pad, saturated with the disinfecting solution.
2. Thoroughly rinse the part of the transducer that was in contact with the disinfectant with water in a quantity recommended by the disinfectant manufacturer.
3. Wipe dry with a soft towel and air dry the transducer.
4. If residue is present after air drying, remove residue by wiping the transducer with a soft cloth moistened in an ethanol solution. Do not immerse the transducer in a solution containing ethanol.

WARNING: To avoid injury to the patient, if residue from the disinfectant is not removed it can cause irritation and/or burning of the mouth and esophageal tissue.
Storage

Transducer

Caution: To avoid damaging the transducer, do not use the shipping case for other than short term storage or to ship the transducer from one place to another. When the shipping case is used to transport the transducer, do not allow any part of the transducer to protrude beyond the case. Never store a moist TEE transducer in the shipping case.

Store Transducer

1. Clean and disinfect the transducer. See “Cleaning and Disinfecting Instructions” on page 23.
2. Thoroughly dry the transducer with a clean cloth.
3. Store the TEE transducer in a vertical orientation on a wall rack.
   - Avoid direct sunlight, and exposure to x-rays. Recommended storage temperature range: between 0° C and +45° C.
   - When a wall mounted rack is used for storage, ensure that it is securely mounted, that the storage slots do not mar the scope and are sized to prevent the instrument from inadvertently falling.

Tip Cover

The tip cover encloses and protects the distal end/scanhead of the endoscope from being exposed to mechanical strain during transportation and storage.

Caution: To avoid damaging the transducer, the tip cover is a single use device. Discard after use.

Shipping

To reduce the risk of spreading diseases, the following safety precautions must be followed carefully.

WARNING: Shipping temperature range: between -40° C and +70°C.

The shipping container in which the TEE transducer was delivered, must never come in contact with a non-disinfected transducer.

To disinfect a transducer, use the procedure described in “Disinfect Transducer” on page 24.

Before returning a transducer to SonoSite or your local representative, always disinfect the transducer. This disinfection must be documented on the “Certificate of Cleanliness,” and attached to the packing list.
Disposal

**WARNING:** The transducer shall not be destroyed by incinerating or burning. The transducer connector contains a battery which may explode if exposed to very high temperatures. Return the transducer to SonoSite or your local SonoSite representative for disposal.
Chapter 5: Safety

Patient safety is ensured only when a well-designed product is used in a safe and responsible manner. Maintaining and determining the mechanical and electrical integrity of the transducer on a regular basis will keep the safety of the patient at a maximum. It is important that the user establishes and uses a check-out procedure to assure that the instrument is safe to use and functions properly prior to each use. If any irregularity, substandard functioning, or unsafe condition is observed or suspected, the TEE transducer should not be used. Call SonoSite or your local representative immediately.

Annual Inspection

The following tests should be performed on the TEE transducer.

<table>
<thead>
<tr>
<th>Inspection/Activity</th>
<th>Location</th>
</tr>
</thead>
</table>

Safe Operational Use

**WARNING:** 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.

To avoid injury to the patient, the TEE transducer is intended for use by a licensed physician 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.

To avoid injury to the patient, 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, the TEE transducer should not be used. Call SonoSite or your local representative. See “Pre-Exam Inspection” on page 17.

To avoid injury to the patient, if the transducer tip should get jammed in a deflected position inside the patient, and all attempts to release the deflected tip should fail, follow procedure “Retract Transducer” on page 21 to assure a safe retraction of the transducer. The deflection mechanism is designed to provide safe operation during normal use.
**WARNING:**

To avoid injury to the patient, perform a bite hole inspection test on the transducer at the end of each disinfecting period or before each exam. See “Bite-Hole Inspection Test” on page 32.

To avoid injury to the patient, do not use conventional coupling gel intended for external use.

To avoid injury to the patient and damage to the transducer, use a bite guard during all transesophageal exams.

To avoid injury to the patient, avoid forceful intubation pressure which can cause lacerations of the gastrointestinal tract with attendant and subsequent perforation.

To avoid injury to the patient, remove the transducer from the patient when using a defibrillator.

To avoid patient injury, SonoSite recommends cleaning and disinfecting transducers after each use. See Chapter 4, “Clean, Disinfect, and Storage.”

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.

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**Caution:**

To avoid damaging the equipment, clean and disinfect the transducer using the recommended procedures only. Do not steam autoclave or Ethylene-Oxide sterilize the transducer as permanent damage is likely to occur.

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

*Note: An applicator for a protective sheath can be ordered through CIVCO.*

To avoid damaging the transducer, the TEE transducer shall be handled only by trained personnel. The TEE transducer is a precision instrument and can be inadvertently damaged.
Thermal Safety

Maintaining a safe thermal environment for the patient has been a design priority at SonoSite. It is generally agreed that to avoid damage to body tissues, for long term exposures, tissue contact transducer tip temperatures should be less than 43° C. The ultrasound system incorporates an elaborate thermal safety system which informs the physician of the operating temperature of the transducer, and prevents the operative temperature from exceeding given limits. Whenever the TEE transducer is connected to the system, the transducer tip temperature is always on the system display.

If the temperature sensor is not working properly when you connect the transducer to the system, the transducer will not be accepted and scanning will not be possible.

Figure 1  Transducer Tip Temperature on System Display

Thermal Limits

The system has two levels of upper thermal limit: the first high limit is set at 41.0° C, and the second high limit is set at 42.5° C. If the temperature of the transducer tip reaches 41.0° C, the temperature display turns reverse highlight and a warning appears on a frozen image. This warning will only appear once per exam. If the temperature reaches 42.5° C, the system will freeze unconditionally. The user will not be allowed to scan until the temperature has decreased below 42.0° C. To restart scanning, the user must press the Freeze key.

The system has a lower thermal limit of 17.5° C. If the temperature of the transducer tip reaches 17.5° C, the temperature display turns reverse highlight and the system will freeze unconditionally. The user will not be allowed to scan until the temperature has increased above 18.0° C. To restart scanning, the user must press the Freeze key.
Control Settings, Temperature

The following are general guidelines for reducing temperature in 2D or Doppler modes.

• In general, imaging in 2D mode results in the lowest transducer surface temperature.
• When imaging in 2D mode, selecting the Res or Gen optimization settings and increasing the image depth generally reduces the transducer surface temperature.
• When imaging in color mode, there are no imaging changes that reduce the transducer surface temperature.
• When imaging in PW Doppler mode, decreasing the PRF and/or positioning the Doppler sample gate to a shallower depth generally reduces the transducer surface temperature.
• When imaging in CW Doppler mode, increasing the depth of the CW Doppler sample line (2D image depth prior to turning on Doppler trace mode) generally reduces the transducer surface temperature.
• In any imaging mode, freezing the image will temporarily reduce the transducer surface temperature.

Temperature Calibration Test

The temperature measurement function should be verified to the specifications at least once a year. See "Thermal Safety" on page 29.

**Test Setup**

Assemble the following items for the test.

- Temperature stabilized water bath
- Temperature gauge with accuracy of +/- 0.1°C

**Temperature Calibration Test**

1. Adjust the water bath temperature to 41.8° +/- 0.1°C and monitor the temperature with the gauge.

   If an accurate and stable water bath is not available, the added inaccuracy must be taken into account when the temperature is read from the ultrasound system. Deviation of more than +/- 0.5°C is not acceptable. Maintaining this accuracy without temperature regulation may be difficult.

2. Connect the TEE transducer to the ultrasound system or select it if you are using the Triple Transducer Connect.

3. Press Freeze.

4. Put the transducer tip in the water bath.

   At least 10 cm of the distal end must be submerged.

5. Observe the temperature indicated on the system monitor.

6. Wait until the temperature display is stabilized at 41.8° +/- 0.5°C plus/minus any water bath temperature deviation.

7. Observe that the Warning pop-up window is displayed.

If both steps 6 and 7 are passed the temperature shutdown works as stated. If not, contact SonoSite or your local SonoSite representative.
**Electrical Safety**

The electrical leakage current test should be performed on the TEE transducer after taking it out of the box and prior to each exam, alternatively, if the bite-hole inspection test is done prior to each exam, then the electrical leakage current test should be done yearly at a minimum.

**Electrical Leakage Current Test**

SonoSite ultrasound systems with accessories are designed to meet the requirements for patient safety described in IEC 60601-1:1988 Medical Electrical Equipment-Part1. General Requirements for Safety. To maintain patient safety it is important to have a low electrical leakage current in the product.

The endoscope shaft has no electrically conducting surfaces, and is covered with a layer of material, which permits neither fluids nor electricity to pass through it. Electrical safety is maintained for the transducer by keeping this material intact. Each TEE transducer is tested for electrical isolation and leakage current before it is shipped to a customer.

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

Checking the integrity of the insulating material cannot always be accomplished by visual inspections. A program for measuring the electrical leakage current on a regular basis should be established. As a minimum, leakage tests according to EN 60601-1/IEC 60601.1 §19 must be performed once a year, or as required by local regulation. The leakage limits associated with Type BF Applied Part must be met. The test requires access to the ultrasound system and to standardized test equipment. The transducer has to be immersed in a Normal Saline solution (50g NaCl per liter water) to above the 40 cm mark (but below the handle).

SonoSite recommends keeping a written log of the results.

| WARNING: | Measuring electrical leakage current should only be done by qualified personnel. Take all necessary precautions to avoid contact with non-insulated parts that have applied voltage. |
**Bite-Hole Inspection Test**

Bite-holes or other damages of the endoscope surface can alternatively be detected by a simplified test without the access to the ultrasound system, by using the following procedure. The objective of this test is to detect bite-holes. It is safe and easy to perform, but is not an isolation or leakage current test as described in EN 60601-1. The test equipment is shown in Figure 2.

![Figure 2: Equipment Used to Detect Bite-Holes in the Endoscope Shaft](image)

**Table 1: Equipment Used to Detect Bite-Holes in the Endoscope Shaft**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Water bath</td>
</tr>
<tr>
<td>2</td>
<td>Copper or aluminum sheet</td>
</tr>
<tr>
<td>3</td>
<td>Multimeter</td>
</tr>
<tr>
<td>4</td>
<td>TEE transducer</td>
</tr>
<tr>
<td>5</td>
<td>Positive lead</td>
</tr>
<tr>
<td>6</td>
<td>Negative lead</td>
</tr>
</tbody>
</table>
### Test Setup

Assemble the following items for the test.

- Water bath with a 1 Normal saline solution (50g NaCl/1 liter water)
- Copper or aluminum sheet with an area of at least 25 cm²
- Digital multimeter with 40 MOhm scale (calibrated to NIST).

### Bite-Hole Test

1. Submerse the TEE transducer with the endoscope shaft in liquid to above the 40 cm mark (but below the handle).
2. Connect the leads of the multimeter. See Figure 2.
   - *Note:* The multimeter can be connected to transducer and copper or aluminum sheet using alligator clips.
   - Connect the positive lead to the bare metal of the system connector housing.
   - Connect the negative lead to the copper or aluminum sheet in the salt-water bath.
3. Set the multimeter to measure resistance (range > 40 MOhms).
4. Wait at least 2 seconds and verify that the resistance is acceptable (greater than 10 MOhms).
   - *Note:* If there is a bite hole, the resistance may vary considerably during the measurement and between different multimeters.

### WARNING:

To avoid injury to the patient, do not use the transducer if the resistance value is less than 10 MOhms. Endoscope insulation may be damaged and should be verified by a SonoSite representative.

To avoid injury to the patient, SonoSite recommends that leakage current measurements be carried out on a regular basis. In addition, a bite-hole inspection should be conducted prior to the use of the transducer in any surgical procedure.

### Acoustic Output

See the ultrasound system user guide for acoustic output information.

### Cleaning and Disinfectants

For cleaning and disinfectant information see the TEE Care Instructions.
# Chapter 6: Transducer Specifications

## Table 1: 8-3 MHz Transducer

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endoscope</strong></td>
<td>External Diameter: 10.5 mm</td>
</tr>
<tr>
<td></td>
<td>Length: 110 cm</td>
</tr>
<tr>
<td><strong>Steering Orientation</strong></td>
<td>Clockwise rotation of the inner deflection control wheel will deflect the tip anterior. Counterclockwise rotation of the deflection wheel will deflect the tip posterior.</td>
</tr>
<tr>
<td></td>
<td>Clockwise rotation of the outer deflection control wheel will deflect the tip to the right.</td>
</tr>
<tr>
<td></td>
<td>Counterclockwise rotation of the deflection wheel will deflect the tip to the left.</td>
</tr>
<tr>
<td><strong>Maximum deflection</strong></td>
<td>Anterior: 120° minimum, 130° maximum</td>
</tr>
<tr>
<td></td>
<td>Posterior: 40° minimum, 60° maximum</td>
</tr>
<tr>
<td></td>
<td>Right and Left: 40° minimum, 60° maximum</td>
</tr>
<tr>
<td><strong>Scanplane Rotation</strong></td>
<td>The transducer scans images in any plane within a 180° (nominal) cone from a transverse plane, through the longitudinal plane and ending at the mirror of the first transverse plane.</td>
</tr>
<tr>
<td></td>
<td>The scanplane rotation is motor-driven, with speed and direction selected with buttons on the endoscope handle. Maximum speed: 180° in approximately 5 seconds.</td>
</tr>
<tr>
<td><strong>Scan Angle</strong></td>
<td>90° max.</td>
</tr>
<tr>
<td><strong>Transducer tip dimensions</strong></td>
<td>Length: 40 mm</td>
</tr>
<tr>
<td></td>
<td>Cross-section maximum: 14 mm x 12.5 mm</td>
</tr>
<tr>
<td><strong>Electrical Safety</strong></td>
<td>Conforms to applicable UL, CSA, IEC requirements for class BF.</td>
</tr>
<tr>
<td><strong>Temperature Accuracy</strong></td>
<td>±0.5° C within the range of 35° to 45° C</td>
</tr>
<tr>
<td><strong>Transducer tip temperature limits</strong></td>
<td>Upper: 42.5° C</td>
</tr>
<tr>
<td></td>
<td>Lower: 17.5° C</td>
</tr>
<tr>
<td><strong>Transducer</strong></td>
<td>Center Frequency 5.0 MHz</td>
</tr>
<tr>
<td><strong>Acoustic Output</strong></td>
<td>Dependent on system software. See the ultrasound system user guide for information.</td>
</tr>
<tr>
<td>Table 1: 8-3 MHz Transducer (Continued)</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Cable length</td>
<td>2 m</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>All patient contact materials of the TEE transducer/endoscope system comply with ISO 10993-1. The transducer is latex free.</td>
</tr>
<tr>
<td>Shipping temperature</td>
<td>Between -40° and +70° C</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>Between 0° and +45° C</td>
</tr>
</tbody>
</table>

  a. Defined as the length of the inflexible distal part of the transducer.