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SONOSITE

T8-3 Transducer (P29465)

User Guide

Manufacturer	EC Authorized Representative	Australia Sponsor
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CAUTION
United States federal law restricts this device to sale by or on the order of a physician.

Patent: www.sonosite.com/patents

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Introduction

The T8-3 is a transesophageal echocardiographic transducer designed to operate with the Sonosite PX, Sonosite LX, and Sonosite ZX ultrasound systems built by FUJIFILM Sonosite.

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 T8-3 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 T8-3 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, FUJIFILM Sonosite recommends having this user guide available for reference during all stages of T8-3 transducer handling, and refer to guidelines from the American Society of Echocardiography (ASE) for Point of Care TEE, the American College of Cardiology (ACC), the American Society of Anesthesiologists (ASA), the American College of Emergency Physicians (ACEP), and the Society of Cardiovascular Anesthesiologists (SCA).

Document 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.

Symbols and terms used on the system and transducers are explained in the ultrasound system user guide.

Warranty statement

The T8-3 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 bites, 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.

Getting help

For information on where to order sheaths, bite guards, tip covers, and other supplies, contact FUJIFILM Sonosite or your local representative.

- FUJIFILM Sonosite Technical Support:

United States and Canada	+1 877-657-8118
Europe and Middle East	Main: +31 20 751 2020 English support: +44 14 6234 1151 French support: +33 1 8288 0702 German support: +49 69 8088 4030 Italian support: +39 02 9475 3655 Spanish support: +34 91 123 8451
Asia and Pacific	+61 2 9938 8700
Other regions	+1 425-951-1330 or call your local representative
Fax	+1 425-951-6700
Email	General: ffss-service@fujifilm.com United Kingdom: uk-service@fujifilm.com Europe, Middle East, and Africa: eraf-service@fujfilm.com Asia and Pacific: ffss-apacme-service@fujifilm.com
Web	www.sonosite.com

Getting started

About the T8-3 transducer

WARNING

- 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 T8-3 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 T8-3 transducer.

The T8-3 transducer is an electronically steered phased array ultrasound transducer assembly, mounted in a sealed tip at the end of a conventional endoscope.

The T8-3 transducer is used to generate a set of ultrasound images or slices within a cone from multiple positions in the esophagus. The rotation of the scan plane is driven by a motor in the control handle.

Intended uses

The T8-3 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 T8-3 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 function. The user can also evaluate blood flow direction and velocity via color and spectral Doppler.

Contraindications

WARNING
The physician must consider the following 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

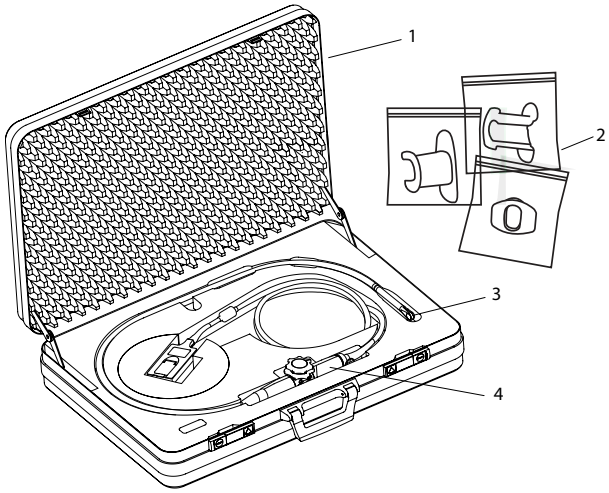
Unpacking the transducer

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.
- The T8-3 transducer must be cleaned, tested for electrical leakage, and disinfected prior to use. See T8-3 Transducer Care [19].

Figure 1. Shipping case with T8-3 transducer



1	T8-3 protective case	3	Transducer tip cover
2	Bite guards (3 sizes, shipped in separate box)	4	T8-3 transducer

Unpack the transducer

1. The T8-3 kit is shipped in one box, and bite guards are shipped separately. Visually inspect both shipping boxes, the transducer case, the T8-3 transducer, and the bite guards 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 boxes contain the components listed on their packing lists:
   - T8-3 transducer shipping box
     - Protective case
     - T8-3 transducer
     - Non-sterile tip cover
   - Bite guard shipping box
     - Bite guards (3 sizes)
     - T8-3 Transducer (P29465) User Guide
     - T8-3 Transducer Care (contains cleaning, testing, and disinfection instructions)

WARNING
To avoid injury to patient:

- Proper care, maintenance, and a detailed understanding of the procedure are essential for safe operation of the T8-3 transducer.
- The medical professional performing the exam must exercise sound medical judgment in selecting this transducer for use in a procedure.

CAUTION

- 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 T8-3 transducer.

Inspecting contents

After unpacking the contents, perform the following on the T8-3 transducer:

- Visual and tactile inspection. See Visually and tactilely inspecting the transducer [8].
- Tip flexion inspection. See Inspecting tip flexion [10].
- Brake inspection. See Inspecting the tip flexion brakes [10].
- Scan plane rotation inspection. See Inspecting the scan plane rotation [12].
- Leakage test. See Testing the transducer for electrical leakage [24].

Contact FUJIFILM Sonosite or your local representative immediately to report any damage or discrepancies. See Getting help [2].

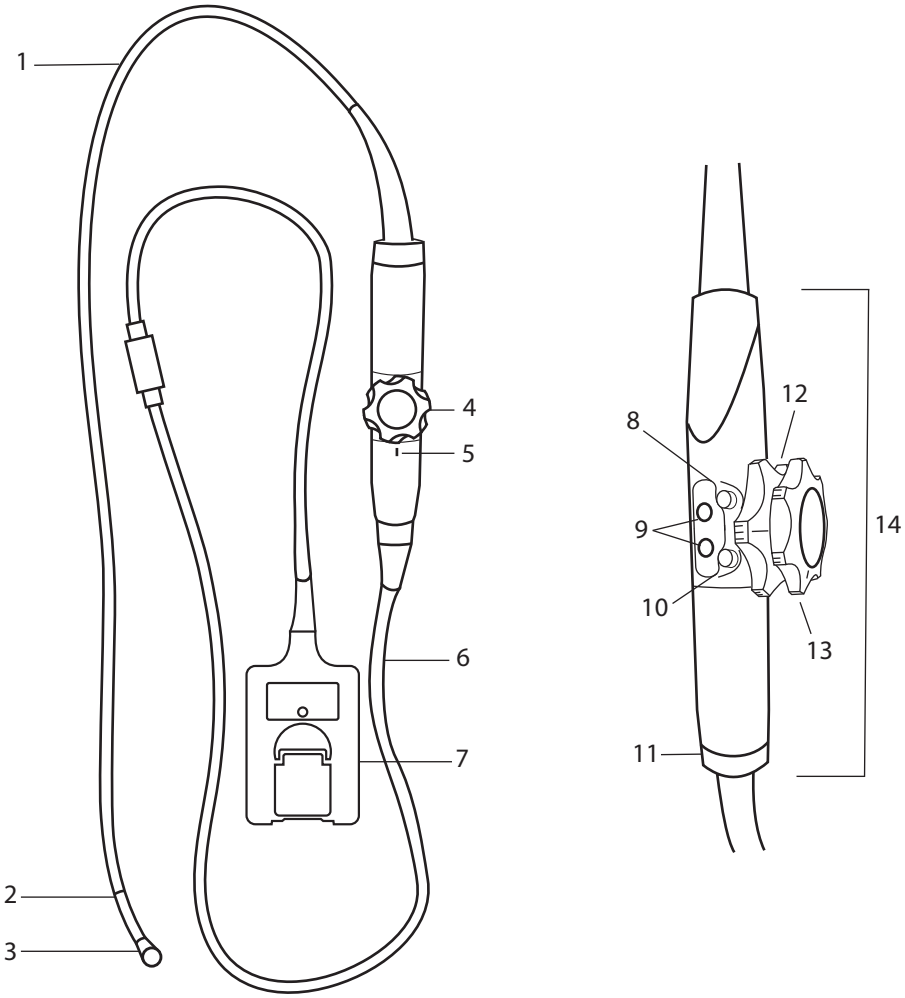
WARNING

To avoid injury to the patient, do not use the T8-3 transducer if any irregularity, substandard function or unsafe condition is observed or suspected.

Transducer and system interface

The T8-3 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, "T8-3 transducer" [7]).

Figure 2. T8-3 transducer



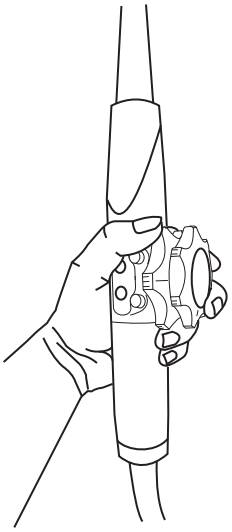
1	Flexible endoscopic shaft	8	Left/right flexion brake
2	Articulation section	9	Scan plane control buttons
3	Transducer tip with scan head	10	Anterior/posterior flexion brake
4	Flexion control wheels	11	Attachment ring
5	Neutral marker	12	Anterior/posterior flexion control
6	Transducer cable	13	Left/right flexion control
7	Transducer connector	14	Handle

T8-3 transducer controls

The transducer is designed for single-handed operation of the flexion and scan plane controls. Figure 3, “Transducer in left hand” [8] 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 3. Transducer in left hand



WARNING
To avoid injury to the patient:

- Do not use the transducer until it has been properly disinfected and has passed its leakage test (see T8-3 Transducer Care [19]).
- Do not use the T8-3 transducer if any irregularity, substandard function, or unsafe condition is observed or suspected.
- Do not use the T8-3 transducer if any metallic protrusions, holes, rough spots, cracks, or dents are found.

Visually and tactilely inspecting the transducer

You should inspect the T8-3 transducer visually and tactilely after taking it out of the box and before disinfecting.

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

Tip flexion

The T8-3 transducer endoscope has two wheels for controlling the transducer tip flexion.

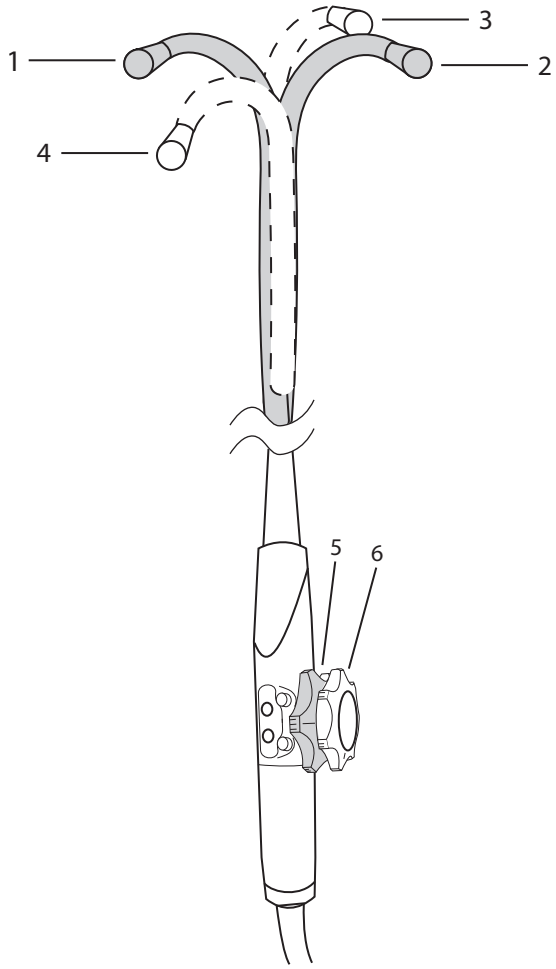
The wheels control anterior/posterior and left/right tip flexion. Figure 4, “Flexion controls” [9] shows the wheels in the neutral (unflexed) position.

The lower wheel controls the anterior/posterior flexion of the tip. The upper wheel controls the left/right flexion of the transducer tip. Controls on the side of the handle can place a brake on either axis independently.

Always have the transducer in a neutral, unbraked position during insertion, advancement, withdrawal, 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 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 lower wheel counterclockwise to move the tip posterior.
2	Turn lower wheel clockwise to move the tip anterior.
3	Turn upper wheel clockwise to move the tip to the right.
4	Turn upper wheel counterclockwise to move the tip to the left.
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.

Inspecting tip flexion

Inspect the tip flexion on the T8-3 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.

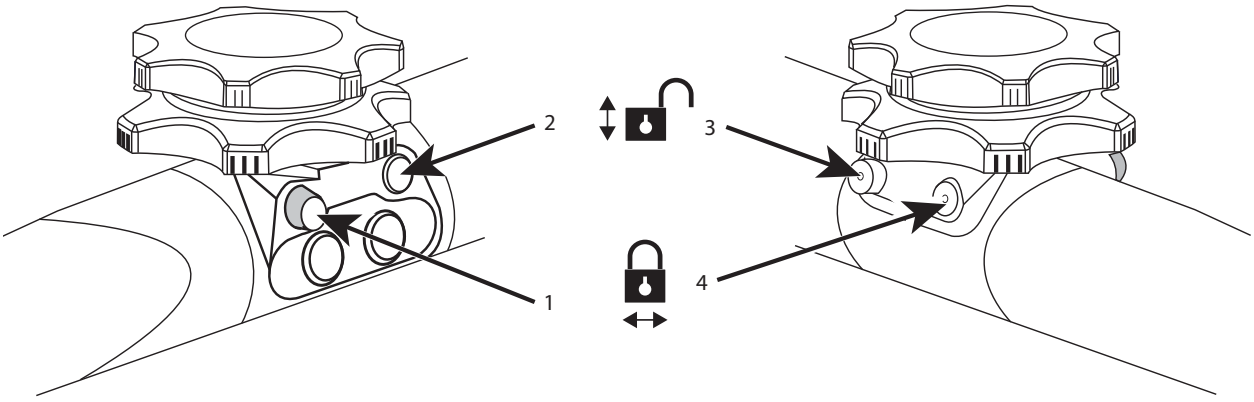
1. Flex the tip in all four directions.
2. Confirm that the flexion controls operate smoothly.
3. Check that when the flexion controls are in the neutral position that the transducer tip is also in a neutral position (unflexed).

Tip flexion brakes

To retain the tip in a flexed position, lock one or both flexion controls.

The flexion brakes are the blue buttons that run through the center of the handle; the anterior/posterior brake is the one closer to the attachment ring, and the left/right brake is the one closer to the transducer tip (see Figure 5, “Tip flexion brake operation” [10].

Figure 5. Tip flexion brake operation



1	Left/right brake in locked position (blue is visible)	3	Back of anterior/posterior brake in unlocked position
2	Anterior/posterior brake in unlocked position (blue is hidden)	4	Back of left/right brake in locked position

Operating the tip flexion brakes

- To lock either brake, push the appropriate brake control to the locked position so that the blue indicator appears.
- To unlock either brake, push the appropriate brake control to the unlocked position so that the blue indicator is hidden.

Inspecting the tip flexion brakes

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

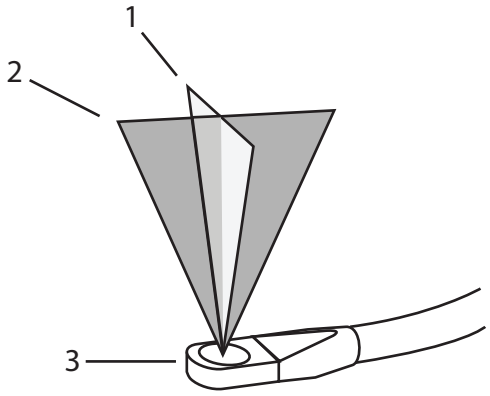
1. Confirm that both brake controls are in their unlocked positions.
2. Flex the tip to the anterior direction.
3. Move the anterior/posterior brake control to the locked position.
4. Confirm that the tip remains in the flexed position.
5. Unlock the control and confirm that the tip straightens easily.
6. Repeat steps 1-5 for the posterior direction.
7. Repeat steps 1-6 with the left/right brake control.

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° on the system screen is the standard monoplane. If you rotate the scan plane 90°, you are now scanning in the longitudinal plane, sweeping through two opposite quadrants of the cone.

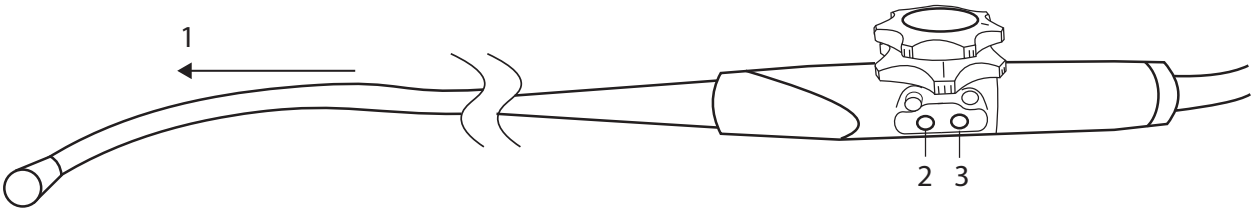
If you continue to rotate the scan plane another 90° in the same direction, scanning occurs in the mirror image of the first transverse plane. The only two planes that are equivalent are the two transverse planes at 0° and 180°, one being the mirror image of the other. As shown in Figure 6, “Rotating to different imaging planes” [11], a 180° rotation of the scan plane fills all four quadrants of the conic imaging volume.

Figure 6. Rotating to different imaging planes



The scan plane rotation is driven by a motor in the transducer handle and is controlled by the white buttons below the brake controls on the handle (see Figure 7, “Scan plane rotation controls” [11]).

Figure 7. Scan plane rotation controls

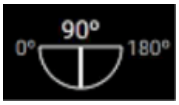


1	Transducer tip
2	Clockwise button (increases angle of rotation)
3	Counterclockwise button (decreases angle of rotation)

The scan plane indicator is shown on the clinical monitor and clearly displays the angle of rotation of the ultrasound plane from the standard monoplane of 0° (see Figure 8, “On-screen scan plane

indicator” [12]). This indicator can assist in obtaining the correct TEE view. Angle ranges are from 0° to 180° and are accurate within +/- 7°.

Figure 8. On-screen scan plane indicator



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

Rotating the scan plane

1. Connect the transducer, and turn on the ultrasound system. (For instructions, see the ultrasound system user guide.)
   The transducer automatically sets the scan plane to 0 degrees.
2. Press the white buttons below the brake controls on the transducer handle:
   - The button closest to the transducer tip rotates the scan plane from 0-180° (scan plane angle increases).
   - The button farthest from the transducer tip rotates the scan plane 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° 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.

Inspecting the scan plane rotation

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

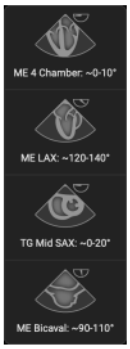
1. Connect the T8-3 transducer to the ultrasound system.
2. Without inserting the transducer, place a small amount of sterile gel on the transducer, and then turn up the gain to obtain an image.
3. Press the scan plane control buttons on the handle to rotate the scan plane from 0° to 180° and backwards from 180° to 0°. See Figure 7, “Scan plane rotation controls” [11].
4. Confirm that the image on-screen changes in relation to the numbers on the scan plane indicator. See Figure 8, “On-screen scan plane indicator” [12].
   While you press the scan plane rotation buttons, the transducer motor should be running as the image is changing.

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

On-screen guidance

This guide is designed to help clinicians obtain transesophageal views that can facilitate performing TEE during cardiac resuscitation.[a] When using the T8-3 transducer with a Cardiac Resuscitation exam type, an on-screen quick reference guide is displayed on the clinical monitor (see Figure 9, “On-screen quick reference guide” [13]).

Figure 9. On-screen quick reference guide



[a]For more information on performing resuscitative transesophageal echocardiography, see the following articles:

- O'Neil, Michael, MD, et al. "How to Perform Resuscitative Transesophageal Echocardiography in the Emergency Department." ACEP Now, 21 July 2020, American College of Emergency Physicians, https://www.acepnow.com/article/how-to-perform-resuscitative-transesophageal-echocardiography-in-the-emergency-department/
- Teran, Felipe, MD, and Amy Zeidan, MD. "Implementation of a Resuscitative TEE Program in the ED-ICU Interface." ACEP, March 2018. American College of Emergency Physicians, https://www.acep.org/how-we-serve/sections/critical-care-medicine/news/march-2018/implementation-of-a-resuscitative-tee-program-in-the-ed-icu-interface/
- Teran, Felipe, MD, et al, "Focused Transesophageal Echocardiography During Cardiac Arrest Resuscitation", J Am Coll Cardiol. 2020 Aug, 76 (6) 745–754, https://www.jacc.org/doi/full/10.1016/j.jacc.2020.05.074

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 via 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 [4].

WARNING

- To avoid trauma to the patient's mouth, throat, esophagus, or stomach, do not use excessive force during insertion, advancement, positioning, or withdrawal.
- To prevent damage to the patient's esophagus when inserting or withdrawing the transducer, the control wheels must be in the freely moving, neutral, and unbraked state. See Figure 5, "Tip flexion brake operation" [10].

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 T8-3 transducer. Call FUJIFILM Sonosite or your local representative immediately.

Perform the following before each exam:

- Visual tactile inspection. See Visually and tactilely inspecting the transducer [8].
- Tip flexion inspection. See Inspecting tip flexion [10].
- Brake inspection. See Inspecting the tip flexion brakes [10].
- Scan plane rotation inspection. See Inspecting the scan plane rotation [12].
- Low-voltage electrical leakage test. See Testing the transducer for electrical leakage [24] .
- Clean and disinfect transducer. See T8-3 Transducer Care [19].

Contact FUJIFILM Sonosite or your local representative to report any damage or discrepancies. See Getting help [2].

WARNING
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 as noted in Transducer specifications [41]), do not use the transducer. Call FUJIFILM Sonosite or your local representative.
- Some gels and disinfectants can cause an allergic reaction in some individuals.

Precautions

Techniques for introducing the T8-3 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 Echocardiography, the American Society of Anesthesiologists, and the American College 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:

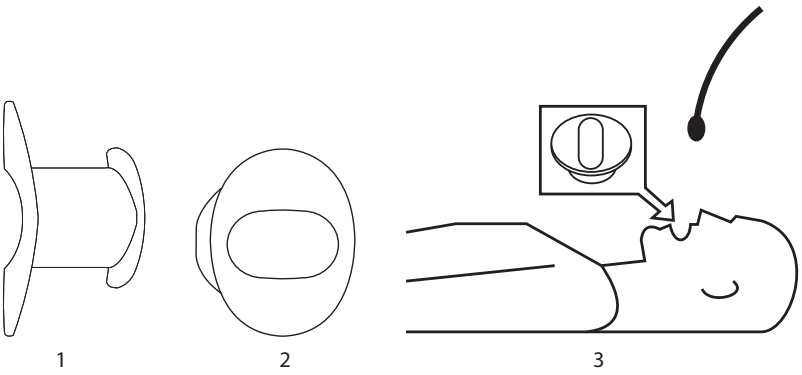
- Maintaining an unobstructed airway is a prime consideration for all patients.
- Prolonged pressure on the esophagus by the tip of the transducer may lead to a pressure necrosis condition. Thus, in operating room monitoring applications, the tip should be removed from the esophagus wall when not scanning 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 T8-3 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 the guidelines set by the ASE, ASA, and ACEP.
- The use of a bite guard/block during all T8-3 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 T8-3 examinations. Biting the endoscope may cause severe, permanent damage to the transducer, making it unsafe for 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 T8-3 transducers (see Figure 10, “Bite guard” [16]). Each T8-3 transducer from FUJIFILM Sonosite is delivered with three different sizes of bite guards. 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 Styrofoam cover still on for patient comfort. If you need help ordering more bite guards, contact FUJIFILM Sonosite or your local representative.

Figure 10. Bite guard



1. Side view 2. Front view 3. Use

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 T8-3 transducer. Contact CIVCO to order sterile sheaths and applicators.

CAUTION
To avoid damaging the T8-3 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.

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

Applying 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 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

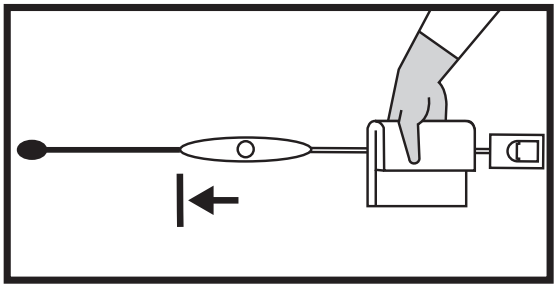
If the transducer tip should become jammed in a deflected position inside the patient, and if all attempts to release the flexed tip should fail, follow these steps to ensure a safe retraction of the transducer:

1. Disconnect the transducer from the ultrasound system.
2. At an accessible location between the transducer handle and the patient, sever the 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.

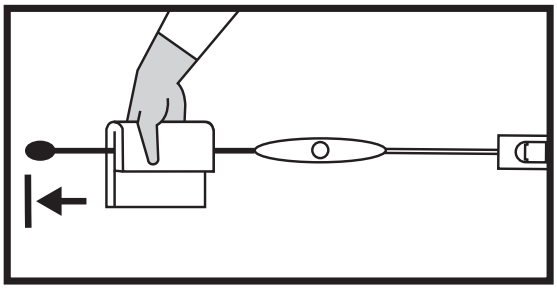
Pre-cleaning following each use

Never allow bodily fluids to dry on the transducer. Perform the following pre-cleaning procedure immediately after removing the transducer from the patient.

1. Disconnect the transducer from the system.
2. Use a clean cloth moistened with water to wipe the cable and controller of the transducer. Do not wipe the connector. Be sure to remove all visible biological material.



3. Use a second clean cloth moistened with water to wipe the endoscopic shaft and scan head. Be sure to remove all visible biological material.



CAUTION
Always disconnect the transducer from the system before cleaning. When disconnecting the transducer from the system, follow the instructions in your ultrasound system's user guide.

NOTE
For information on how to transport a soiled T8-3 transducer, see Transporting a soiled transducer for cleaning [31].

T8-3 Transducer Care

The T8-3 transducer is categorized as semi-critical in the Spaulding classification system, and must be cleaned, tested for electrical leakage, and disinfected prior to use. Follow guidelines from the American Society of Echocardiography and the Academy of Emergency Physicians for transducer cleaning, disinfection, and electrical leakage testing prior to each use.

Before getting started

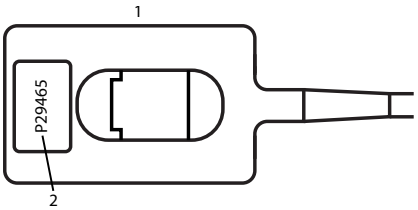
- Follow the disinfectant manufacturer's recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- Inspect the transducer to determine that it is free of any unacceptable deterioration or damage that could lead to fluid leaking into the shaft and exposing the patient to an electrical current. If damage is evident, discontinue use, and contact FUJIFILM Sonosite or your local representative.
- Always handle the transducer with care to minimize the risk of damage.
- 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.

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

Process overview

The following workflow is the recommended process for manual cleaning, electrical leakage testing, and disinfecting the T8-3 transducer, whose part number P29465 is located next to REF on the connector label (see Figure 11, "Location of T8-3 part number" [19]).

Figure 11. Location of T8-3 part number



1. Connector 2. Part number

If using an automated disinfection process, follow manufacturer procedures.

Table 1. Manual workflow

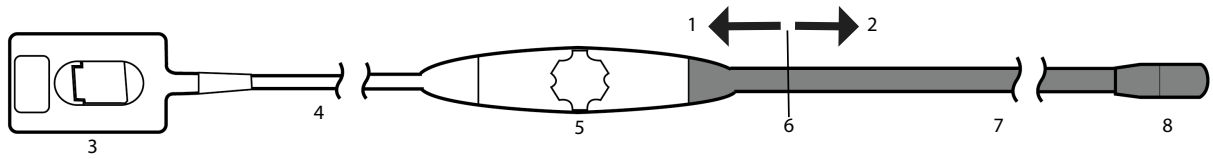
Steps
1. Cleaning
2. Leakage testing
3. Disinfecting

WARNING
Follow all instructions for cleaning, leakage testing, and disinfection. Failure to do so can result in patient injury or infection.

Transducer components

Some components of the T8-3 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 12, “Transducer components” [20] for a diagram of the transducer components.

Figure 12. Transducer components



1	Cannot be submerged	5	Controller
2	Can be submerged	6	90 cm
3	Connector	7	Endoscopic shaft
4	Cable	8	Scan head

Cleaning the transducer

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

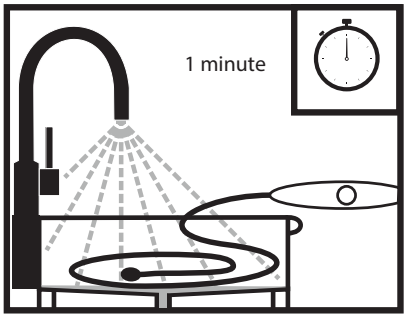
CAUTION

- Always disconnect the transducer from the system before cleaning. When disconnecting the transducer from the system, follow the steps in your ultrasound system's user guide.
- Do not bend the shaft smaller than a 20 cm (8 inch) curve. Exceeding this minimum bend diameter can damage the transducer or its watertight coating.
- Do not use unapproved cleaning agents because they can damage the transducer and void the warranty. For more information about approved cleaners for the shaft and scan head, see Table 2, "Approved cleaners" [21], and for the controller and cable, see Table 3, "Wipes approved for use on transducer cable and controller" [22].
- 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.

To clean the transducer

1. Remove disposable tip cover (if installed).
2. Inspect the transducer and cable for any sign of 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.
3. Rinse the endoscopic shaft and scan head with clean room-temperature running water for a minimum of one minute.



4. At the cleaning station, prepare an approved liquid cleaner for soaking.

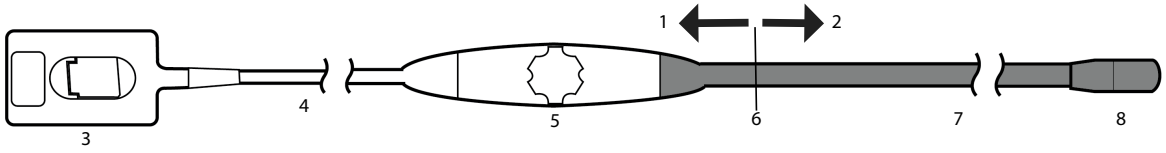
Table 2. Approved cleaners

Approved cleaners[a, b]	
EMPower	Cidezyme or Enzol[c]
Metrizyme	Prolystica 2x conc. Enzymatic Presoak & cleaner[c]
Neodisher MediClean forte	

[a]Refer to the manufacturer's instructions for concentration, temperature, and duration.
[b]Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.
[c]Can be used in the electrical leakage test.

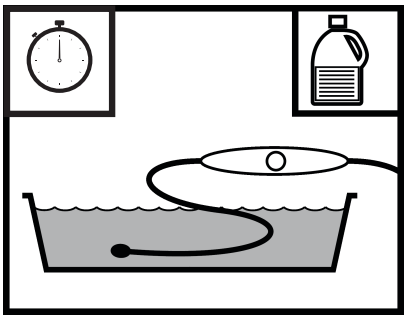
a. **Check** the expiration date on the container to ensure that the cleaner has not expired.
b. **Check** that the cleaner has the concentration recommended by the manufacturer (for example, use a chemical strip test).

5. Secure the control handle so it cannot fall into the cleaning solution, and immerse the shaft and scan head in a plastic container filled with the prepared enzymatic cleaning solution up to the 90 cm mark.



1	Cannot be submerged	5	Controller
2	Can be submerged	6	90 cm
3	Connector	7	Endoscopic shaft
4	Cable	8	Scan head

6. Soak the endoscopic shaft and scan head in approved cleaner in accordance with the cleaning solution manufacturer's instructions.



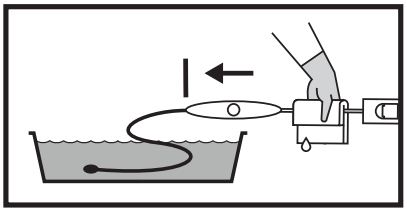
CAUTION
- Do not soak the transducer longer than recommended by the chemical manufacturer.
- Do not immerse the cable, connector, or controller in any fluid.

a. While the shaft is soaking, gently wipe the cable and controller with a wipe from Table 3, "Wipes approved for use on transducer cable and controller" [22]. Do not wipe the connector.

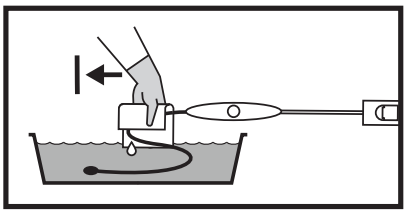
Table 3. Wipes approved for use on transducer cable and controller

Wipes for cable and controller[a, b]	
Oxivir Tb	Sani-Cloth Prime
Sani-Cloth Bleach	

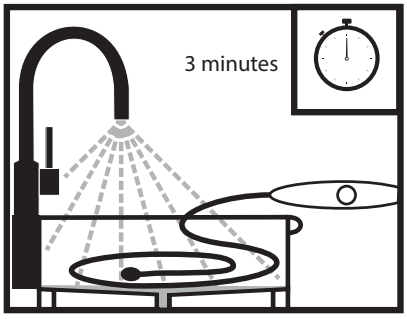
[a]Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.
[b] Refer to the manufacturer's instructions for contact time.



b. Next, moisten a soft cloth or sponge with the prepared cleaner and gently wipe the endoscopic shaft and scan head.

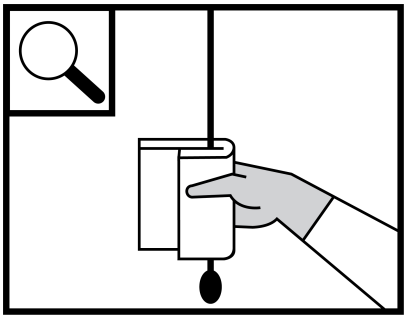


7. After waiting for the cleaner's specified soak time, rinse the endoscopic shaft and scan head with room-temperature running water for a minimum of three minutes to remove residual cleaning solution.



WARNING
Residual cleaners left on the transducer can burn the patient or damage the transducer.

8. Inspect the scan head and shaft for remaining biological material. If any is found, repeat the cleaning process.
9. Dry the transducer with a clean, non-linting towel or medical-grade air.



10. Inspect the transducer and cable a second time for any sign of damage that might have been overlooked during your initial examination or that was previously obscured by biological debris. If damage is evident, discontinue use of the transducer and contact FUJIFILM Sonosite or your local representative.
11. Proceed to Testing the transducer for electrical leakage [24].

NOTE

- If you are cleaning with Cidezyme or Enzol or Prolystica 2x conc. Enzymatic Presoak & cleaner, you may use the same solution for leakage testing.
- Other cleaning chemicals might also be approved for use in leakage testing. See the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.

Testing the transducer for electrical leakage

CAUTION
If the watertight coating on the scan head or 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 surface can be detected using a transducer leakage tester, such as the ULT-2020.

NOTE
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 [39]). You should perform the electrical leakage test on the T8-3 prior to initial use to ensure no damage has occurred during shipment and after every use. You should also maintain a record of test results for each T8-3 transducer.

Required equipment

- Non-conductive container or a container placed on a non-conductive surface
- One of the following leakage testing fluids:
  - Cidezyme or Enzol
  - Prolystica 2x conc. Enzymatic Presoak & cleaner
  - 0.9% saline
- Conductivity probe

NOTE
Only use conductivity probes approved by FUJIFILM Sonosite. Current approved models include BC Biomedical ULT-PC-10, ULT-PC-15, and ULT-PC-30.

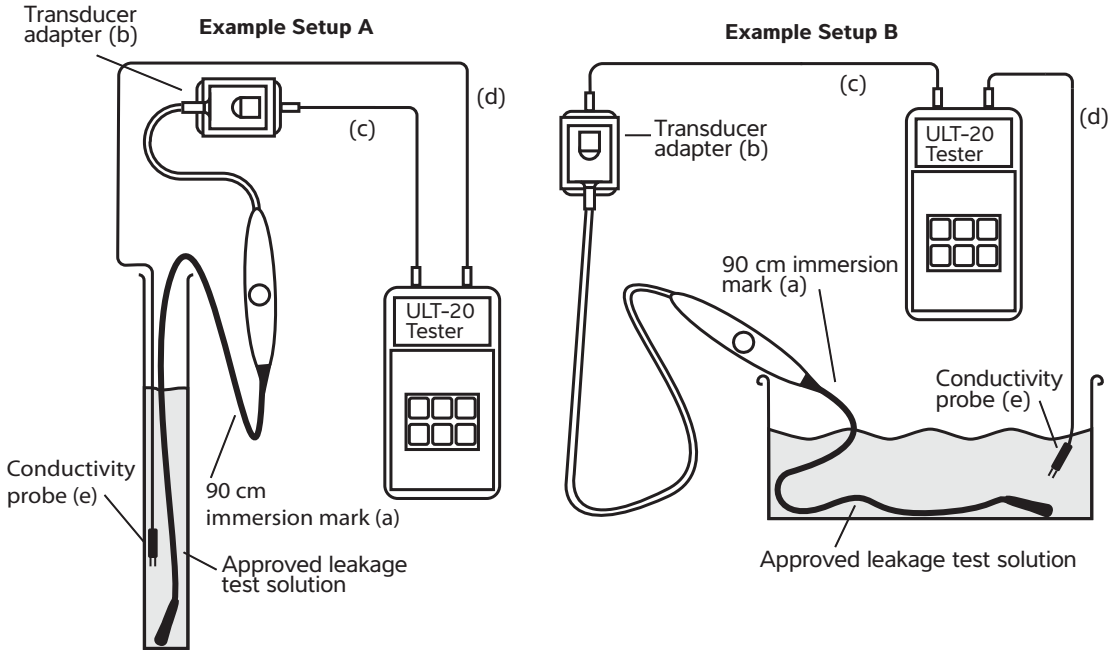
- ULT-2020 leakage tester
- T8-3 transducer adapter

To test the transducer for electrical leakage

> **NOTE**
> If you cleaned the transducer using Cidezyme or Enzol or Prolystica 2x conc. Enzymatic Presoak & cleaner, and are using the same solution for leakage testing, you may skip the first step.

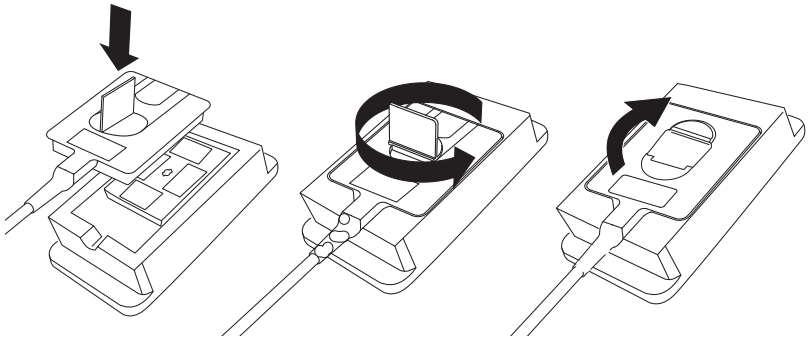
1. Prepare the leakage testing fluid for use:
   a. **Check** the expiration date on the bottle to ensure that the leakage testing fluid has not expired.
   b. **Check** that the leakage testing fluid has the concentration recommended by the manufacturer (for example, use a chemical strip test).
2. Connect the test equipment:

> **NOTE**
> The conductivity probe depicted in the schematics is for illustration purposes only; other types of approved conductivity probes can also be used. The current approved models of conductivity probe include BC Biomedical ULT-PC-10, ULT-PC-15, and ULT-PC-30.
>
> For complete instructions on using the leakage tester, refer to the ULT2000 Series User Manual.



   a. Secure the T8-3 transducer control handle so it cannot fall into the test solution, then immerse the endoscopic shaft up to the 90 cm mark.

b. Insert the transducer connector into the transducer adapter.



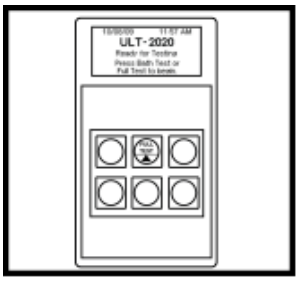
c. Connect the transducer adapter to the leakage tester.
d. Connect the conductivity probe to the leakage tester.
e. Insert the conductivity probe contacts into the container. Make sure that the conductivity probe contacts are completely submerged but do not touch the endoscopic shaft.

3. Power on the ULT-2020 leakage tester.
   a. Press **MODE** repeatedly until Device Configuration appears.
   b. Confirm that the leakage tester is set to the FUJIFILM Sonosite T8-3 transducer. If not, change the setting as required.

> **CAUTION**
> Leakage testers can contain settings for different transducers. Before performing your test, confirm that you have selected **Sonosite T8-3** on the tester.

> **NOTE**
> For information on how to select the appropriate transducer or adjust leakage test parameters in the leakage tester, refer to the ULT2000 Series User Manual.

4. Confirm that the endoscopic shaft, the scan head, and the conductivity probe contacts are all fully submerged in the leakage test fluid.
5. Press the **FULL TEST** button to start the test.



> **CAUTION**
> To ensure accurate test results, monitor the position of the endoscopic shaft, scan head, and conductivity probe contacts throughout the duration of the test. If any part becomes exposed to air during testing, reposition the exposed part so that everything is completely submerged and then re-run the leakage test.

6. Record the test results (Pass/Fail).
   If the result is **Fail**, electrical leakage was detected. **Do not use the T8-3 transducer**. For remediation steps, see If the transducer fails the leakage test [30].
7. Disconnect the T8-3 transducer from the transducer adapter.
8. Rinse the endoscopic shaft and scan head with room-temperature running water for a minimum of three minutes.
9. Dry the transducer with a clean, non-linting towel or medical-grade air.
10. Inspect the transducer for any sign of damage that might have been overlooked during your initial examination.
    If damage is evident, discontinue use of the transducer, and contact FUJIFILM Sonosite or your local representative.
11. Proceed to Disinfecting the transducer [27].

Disinfecting the transducer

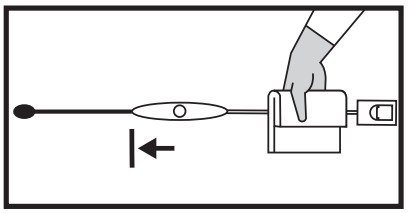
CAUTION
To prevent damage to the transducer, do not steam, autoclave, or expose the transducer to Ethylene Oxide.

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. Follow the manufacturer's instructions for concentration, temperature, and duration.

The following procedure describes the recommended manual disinfection process. If you are using an automated disinfection process, follow the automated endoscope reprocessor manufacturer's procedures.

To disinfect the transducer

1. Verify that the transducer has been cleaned using the procedure described in Cleaning the transducer [20] and has passed the leakage test procedure described in About leakage testing [24].
2. Gently wipe the cable and controller with a wipe from Table 4, "Wipes approved for use on transducer cable and controller" [28]. Do not wipe the connector.



NOTE
The endoscopic shaft will be disinfected later in this procedure with a different disinfectant.

Table 4. Wipes approved for use on transducer cable and controller

Wipes for cable and controller[a, b]	
Oxivir Tb	Sani-Cloth Prime
Sani-Cloth Bleach	

[a]Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.

[b] Refer to the manufacturer's instructions for contact time.

a. Be sure to check the expiration date to ensure that the wipe has not expired.

3. Depending on your facility's policies, you may want to wipe off the disinfectant. If so, wait for the disinfectant's specified contact time, then wipe off the disinfectant with a clean, non-linting cloth or sponge moistened with water.
4. Select an approved disinfectant from Table 5, "Disinfectants approved for immersing endoscopic shaft and scan head" [28] for use on the endoscopic shaft.

Table 5. Disinfectants approved for immersing endoscopic shaft and scan head

Disinfectants for shaft and scan head[a, b]	
Cidex	PeraSafe
Cidex OPA	Rapicide (PA) High-Level Disinfectant (HLD)
Gigasept PAA concentrate	Revital-Ox RESERT XL High Level Disinfectant (HLD)
Metricide	Steranios 2%, 2% N.G., 2% E.C.S.
Metricide 28	TD5
Metricide Plus 30	Tristel Trio Wipes
Metricide OPA Plus	

[a]Refer to the manufacturer's instructions for concentration, temperature, and soak time.

[b]Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.

5. Prepare the disinfectant solution according to the manufacturer's instructions, being sure to:
   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).

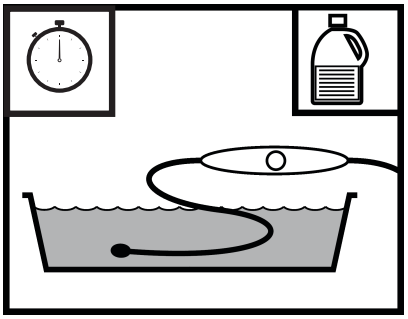
> **NOTE**
> If the same container is used to clean and disinfect, be sure to rinse any residual cleaner from the bath container prior to pouring in the disinfectant.

6. Secure the control handle so it cannot fall into the solution. Disinfect the transducer by soaking the shaft and scan head up to the 90 cm mark (see Figure 12, "Transducer components" [20]) in accordance with the disinfecting solution manufacturer's instructions.

> **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 chemical burns to the patient and damage to the transducer.

CAUTION

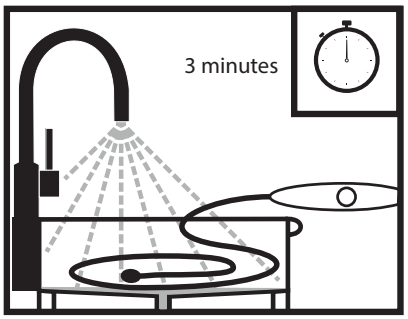
- Do not use unapproved disinfectants because they can damage the transducer. For more information about approved disinfectants, see Table 5, “Disinfectants approved for immersing endoscopic shaft and scan head” [28].
- Do not immerse the cable, connector, or controller in any fluid.



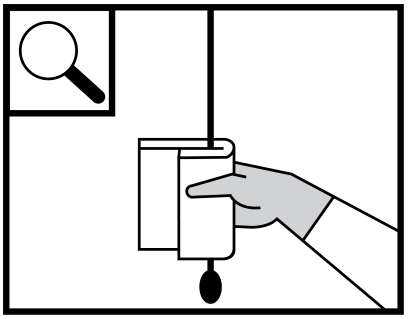
7. After waiting for the disinfectant’s specified soak time, rinse the endoscopic shaft and scan head with room-temperature running water for a minimum of three minutes. Do not rinse the controller or cable. Some disinfectant manufacturers may recommend additional rinsing. See the manufacturer’s guidelines for more information.

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.



8. Dry the transducer with a clean, non-linting towel or medical-grade air.



9. Inspect the transducer 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. Apply a new single-use 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 endoscopic 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.

11. To transport the transducer, refer to the procedures detailed in Transporting the transducer [30].
12. To store the transducer, refer to the procedure detailed in Storing the transducer [32].
13. Dispose of the disinfectant according to the manufacturer's guidelines.

WARNING
Wear the appropriate personal protective equipment (PPE) when handling disinfectants per the manufacturers' guidelines.

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 T8-3 transducer 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 leakage 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 T8-3 transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container that is approved by your organization and whose dimensions are no less than 580 mm (22.83 inches) x 370mm (14.57 inches).

CAUTION

- Do not bend the shaft smaller than a 20 cm (8 inch) curve. Exceeding this minimum bend diameter can damage the transducer or its watertight coating.
- If the transducer is dropped or is subject to physical damage, perform an electrical safety test and temperature calibration prior to use (see Electrical safety test [39]). The transducer should also be cleaned and disinfected prior to use if it is not housed in a protective covering.

Transporting 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 shaft.

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 T8-3 transducer in a sealed container or in its transportation case for long periods of time.

Transporting a clean transducer

A clean transducer is one that has completed the cleaning, leakage testing, 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 Identifying the transducer as clean and safe [30].
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.

Shipping 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 new single-use tip cover over the transducer scan head.

   WARNING
   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 approved T8-3 shipping case provided by FUJIFILM Sonosite 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: -25° C (-13° F) to +55° 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

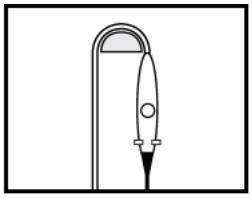
Follow society guidelines and recommendations.

To store the transducer

1. Clean, test, and disinfect the T8-3 transducer. See T8-3 Transducer Care [19].
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.

     WARNING
     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 -25° C (-13° F) and +55° C (149° F).
- If the transducer is stored in an open room, it must be stored in a plastic sleeve; otherwise it can be mounted in an enclosed cabinet with the following requirements:
  - The storage rack is securely mounted.
  - The storage slots do not mar the transducer or the 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. Please report any serious safety incident that occurs in relation to the transducer and ultrasound system to FUJIFILM Sonosite and to the competent authority of the country in which the user and patient are located.

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 T8-3 transducer. Call FUJIFILM Sonosite or your local representative.

WARNING
The T8-3 transducer has no protection in the event of a neutral electrode fault of a high frequency surgical device. When using the T8-3 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

For a list of applicable standards and requirements, see the ultrasound system's user guide.

Annual inspection

In addition to the regular inspections described elsewhere in this document, perform the following tests at least annually on the T8-3 transducer:

- Temperature calibration test. See Temperature calibration test [38].
- Electrical safety test. See Electrical safety test [39].

Safe operational use

WARNING
To avoid injury to the patient:

- Remove the transducer from the patient when using a defibrillator.
- 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 T8-3 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 T8-3 transducer. Call FUJIFILM Sonosite or your local representative. See Pre-exam inspection [14].
- Always have the transducer in a neutral, unbraked position during insertion, advancement, withdrawal, and removal of the transducer.
- If the transducer tip should become jammed in a flexed position inside the patient, and all attempts to release the tip should fail, follow procedure Emergency retraction [17] 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 [24].
- Do not use conventional coupling gel intended for external use.
- Avoid forceful intubation pressure which can cause lacerations or perforation of the gastrointestinal tract.
- FUJIFILM Sonosite recommends cleaning and disinfecting transducers after each use. See T8-3 Transducer Care [19].
- To avoid injury to the patient and damage to the transducer, use a bite guard/block during all transesophageal exams.
- To prevent cross-contamination, 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.

CAUTION

- To avoid damaging the equipment, clean and disinfect the transducer using the recommended procedures only.
- To avoid damaging the transducer, the T8-3 transducer should be handled only by trained personnel. The T8-3 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 will freeze, and a warning will be displayed.

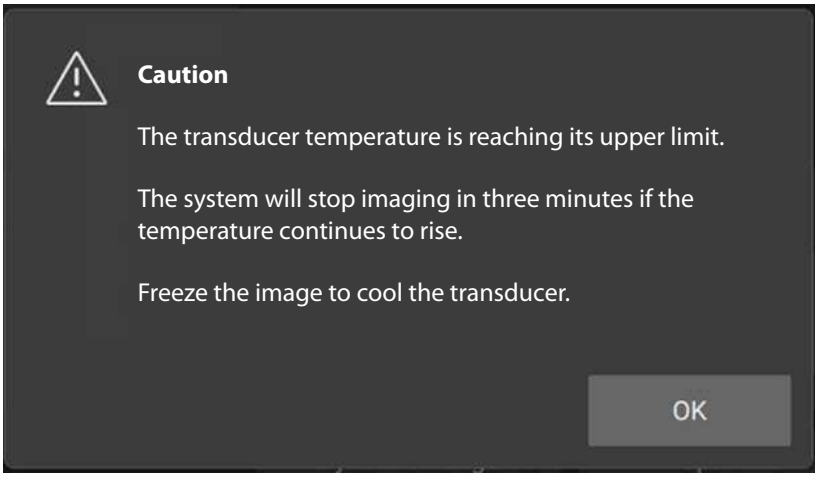
Thermal limits

The imaging temperature range for the T8-3 transducer is between 0° C and 45° C. The ultrasound system includes safety features designed to assist the user in modifying treatment to prevent thermal damage to the patient during use.

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:

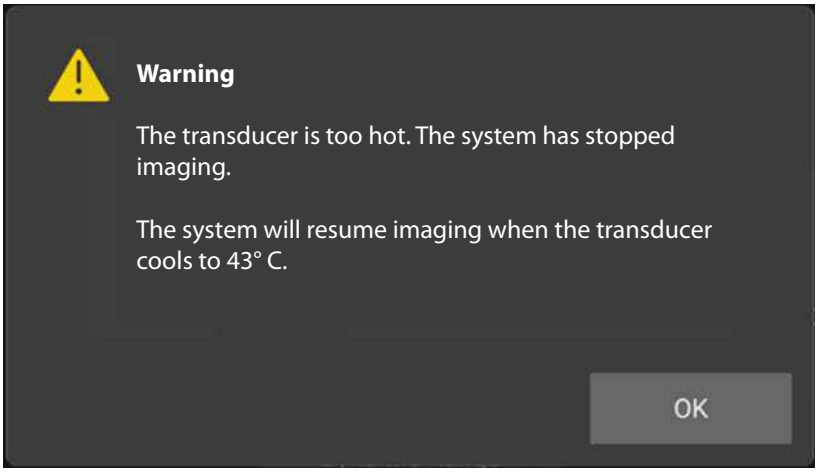
Figure 13. High temperature caution message



As indicated by the message in Figure 13, "High temperature caution message" [36], the system will stop imaging in three minutes if the scan head temperature stays above 43° C. Tap **OK** to dismiss the message, then either freeze the image to begin cooling the transducer or complete any remaining imaging within three minutes.

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:

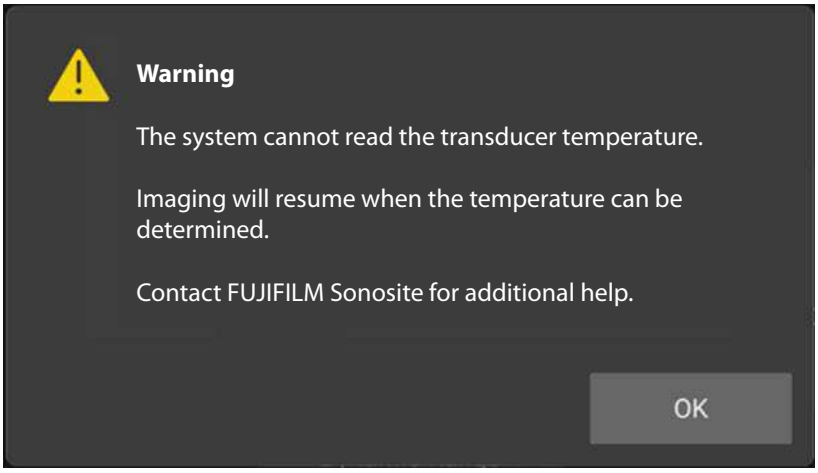
Figure 14. High temperature warning message



As indicated by the message in Figure 14, “High temperature warning message” [37], the system stops imaging if the scan head temperature remains above 43° C for more than three minutes or if it ever exceeds 45° C. Tap **OK** to dismiss the message and wait for the temperature to drop before resuming imaging.

If a communication error occurs and the system cannot determine the T8-3 scan head temperature, the scan is halted and will not resume until the temperature can be read and is within operating limits (see Figure 15, “Transducer communication error message” [37]).

Figure 15. Transducer communication error message



As indicated by the message in Figure 15, “Transducer communication error message” [37], the system stops imaging if the system cannot determine the scan head temperature. Tap **OK** to dismiss the message and contact FUJIFILM Sonosite or your local representative for assistance.

Reducing temperature

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

- In any imaging mode, freezing the image temporarily reduces the transducer surface temperature.
- In any imaging mode, use the system's Power control to lower the acoustic output, which decreases transducer temperature.

> **NOTE**
> To learn how the Power control directly controls acoustic output, see your system's user guide.

- Staying in 2D mode will typically result in the lowest transducer surface temperature.

Output display

Table 6, "MI or TI ≥1.0" [38] indicates whether, for each operating mode, the value of TI or MI is greater than or equal to 1.0, thus requiring display.

Table 6. MI or TI ≥1.0

Transducer	Index	2D/M-Mode	CPD/Color	PW Doppler	CW Doppler
T8-3	MI	Yes	No	No	No
	TIB, TIC, or TIS	No	No	Yes	Yes

MI and TI output display accuracy

Table 7, "MI and TI output display accuracy" [38] lists the accuracy of the displayed MI and TI for the T8-3 transducer. The accuracy values are stated statistically as 95% tolerance interval limits and should be interpreted as follows: with 95% confidence, 95% of the measured MI/TI values are within the specified percentage of the displayed value or 0.1 of the displayed value, whichever is larger.

Table 7. MI and TI output display accuracy

Transducer	MI display accuracy	TI display accuracy
T8-3	+19% to -19%	+19% to -24%

Transducer surface temperature rise

Table 8, "Maximum transducer surface temperature rise, non-external use (°C)" [38] lists the measured surface temperature rise from ambient (23°C ± 3°C) of the T8-3 transducer used on the ultrasound system. The temperatures were measured in accordance with IEC 60601-2-37 with controls and settings positioned to give maximum temperatures.

Table 8. Maximum transducer surface temperature rise, non-external use (°C)

Test	°C rise
Still air	10.1 (≤27)
Simulated use	4.9 (≤6)

Temperature calibration test

At least once a year, verify the temperature measurement function to the specifications. This test can be performed along with the electrical safety test (see Electrical safety test [39]).

Setting up the calibration test

Assemble the following items for the test:

- Temperature stabilized water bath

- Temperature gauge with accuracy of +/- 0.1° C

Testing temperature calibration

1. Adjust the water bath temperature to 43° +/- 0.1° 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 +/- 1° C is not acceptable. Maintaining this accuracy without temperature regulation may be difficult.
3. Connect the T8-3 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.
   At least 10 cm of the distal end must be submerged.
6. Observe the temperature indicated on the system screen.
7. Wait three minutes, or until the temperature display is stabilized at 43° +/-0.5° C plus/minus any water bath temperature deviation.
8. Observe that the Warning pop-up window appears.

If the temperature warning works as described in Thermal limits [36], the transducer passes the test. If not, contact FUJIFILM Sonosite or your local representative.

Electrical safety

FUJIFILM 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 T8-3 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 Testing the transducer for electrical leakage [24] and Electrical safety test [39].

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 T8-3 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 T8-3 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

T8-3/8-3 MHz transducer

Endoscopic shaft	External diameter: 11.4 mm Length: 100 cm
Steering orientation	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.
Tip deflection	Anterior: ≥120° Posterior: ≥90° Right and left: ≥45°
Scan plane rotation	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.
Field of view	90° maximum
Transducer tip dimensions	Length: 31 mm Cross-section maximum: 14 mm x 11 mm
Disinfection classification	Spaulding class, semi-critical
Electrical safety	Conforms to applicable UL, CSA, IEC requirements for class BF.
Temperature accuracy	±1° C within the range of 41°C° to 45° C
Transducer tip temperature limits	Upper: 45° C Lower: 0° C
Transducer	Center frequency 5.1 MHz nominal
Maximum cable length	5.74 ft/1.75 m (as measured between the strain reliefs)
Biocompatibility	All patient contact materials of the T8-3 transducer comply with ISO 10993-1. The transducer is manufactured without natural rubber latex.
Environmental limits (shipping and storage)	Temperature: Shipping: -25° to +55° C Storage: -25° to +55° C Humidity: 5% to 95% R.H. Pressure: 500 to1060 hPA (0.49 - 1.06 ATM)

Acoustic output

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

Table 9. Acoustic output table key

(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.)
—	Not applicable for this transducer/mode.

T8-3 acoustic output tables

Table 10. Transducer model: T8-3 Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.48	0.34		0.34		(b)
Index component value			0.34	0.34	0.34	0.34	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.79					
	P (mW)		10.4		10.4		#
	P_{1x1} (mW)		10.4		10.4		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	2.25					
	$z_{pii,\alpha}$ (cm)	2.25					
	f_{awf} (MHz)	3.54	6.81		6.81		#
Other information	prr (Hz)	540					
	srr (Hz)	60.0					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$(W/cm^2)	494.9					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	38.1					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	47.4					
	p_r at z_{pii} (MPa)	3.57					
Operating controls	Exam type	Cardiac	Cardiac		Cardiac		
	Optimization	Pen	Gen		Gen		
	Depth (cm)	6.2	4.0		4.0		
	MB/THI	Off / On	Off / Off		Off / Off		
	AQ Zoom	Small-Middle	Max-Middle		Max-Middle		
	Variable Sector	Off	Off		Off		

Table 11. Transducer model: T8-3 Operating mode: 2D+MM

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.48	0.34		0.43		(b)
Index component value			0.34	0.33	0.29	0.43	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.83					
	P (mW)		10.5		16.5		#
	P_{1x1} (mW)		10.5		16.5		
	z_s (cm)			1.1			
	z_b (cm)					1.1	
	z_{MI} (cm)	0.95					
	$z_{pii,\alpha}$ (cm)	0.95					
	f_{awf} (MHz)	3.65	6.83		3.73		#
Other information	prr (Hz)	560					
	srr (Hz)	40.0					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$(W/cm^2)	361.6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	42.5					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	48.5					
	p_r at z_{pii} (MPa)	2.95					
Operating controls	Exam type	Cardiac	Cardiac		Cardiac		OB
	Optimization	Pen	Gen		Gen		
	Depth (cm)	4.0	4.0		4.0		
	MB/THI	Off / On	Off / Off		Off / On		
	AQ Zoom	Small-Middle	Max-Middle		Small-Middle		
	SNP	Off	Off		Off		
	Variable Sector						

Table 12. Transducer model: T8-3 Operating mode: Color

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.70	0.39		0.39		(b)
Index component value			0.39	0.39	0.39	0.39	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.35					
	P (mW)		21.6		21.6		#
	P_{1x1} (mW)		21.6		21.6		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.5					
	$z_{pii,\alpha}$ (cm)	0.5					
	f_{awf} (MHz)	3.73	3.78		3.78		#
Other information	prr (Hz)	4687					
	srr (Hz)	12.5					
	n_{pps}	7					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$(W/cm^2)	64.4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	20.9					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	24.0					
	p_r at z_{pii} (MPa)	1.43					
Operating controls	Exam type	Cardiac	Cardiac		Cardiac		
	Mode	Color	Color		Color		
	2D Opt/Depth (cm)	Gen / 11.5	Gen / 8.3		Gen / 8.3		
	THI	Off	Off		Off		
	Color Opt/ PRF (Hz)	Low / 2604	Low / 1543		Low / 1543		
	Colorbox Position/Size	Top / Wide-Short	Def / Narrow-Short		Def / Narrow-Short		
	AQ Zoom	On	On		On		
	Variable Sector	Off	Off		Off		

Table 13. Transducer model: T8-3 Operating mode: CW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.05	0.43		1.48		(b)
Index component value			0.43	0.32	0.40	1.48	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.10					
	P (mW)		22.6		21.1		#
	P_{1x1} (mW)		22.6		21.1		
	z_s (cm)			1.1			
	z_b (cm)					0.8	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{awf} (MHz)	4.00	4.00		4.00		#
Other information	prr (Hz)	1					
	srr (Hz)	—					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$(W/cm^2)	0.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	331.4					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	387.8					
	p_r at z_{pii} (MPa)	0.11					
Operating controls	Exam type	Cardiac	Cardiac		Cardiac		
	Gate position	Zone 1 (1.6 cm)	Zone 3 (3.3 cm)		Zone 1 (1.6 cm)		

Table 14. Transducer model: T8-3 Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.67	0.48		1.46		(b)
Index component value			0.48	0.32	0.42	1.46	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.28					
	P (mW)		26.9		24.0		#
	P_{1x1} (mW)		26.9		24.0		
	z_s (cm)			1.5			
	z_b (cm)					0.55	
	z_{MI} (cm)	0.6					
	$z_{pii,\alpha}$ (cm)	0.6					
	f_{awf} (MHz)	3.68	3.73		3.70		#
Other information	prr (Hz)	1563					
	srr (Hz)	—					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$(W/cm^2)	60.0					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	122.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	142.4					
	p_r at z_{pii} (MPa)	1.39					
Operating controls	Exam type	Cardiac	Cardiac		Cardiac		
	Gate Size (mm)	1	1		1		
	Gate Position	Zone 1 (1.6 cm)	Zone 4 (4.2 cm)		Zone 1 (1.6 cm)		
	PRF (Hz)	1526	10417		20833		
	TDI	Off	Off		Off		

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