

P7-3T/P7-3Ts/P7-3TE/P7-3TU/P8-2Ts/P8-2TU/P8-3Ts/XP8-2TU

Ultrasonic Transducer

Operator's Manual

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Introduction

This operator's manual describes the operating procedure for the transducer. To ensure safe and correct operation of the transducer, read the operator's manual carefully and understand the transducers clearly before operation.

For the operating procedures for the ultrasonic diagnostic system and other devices, please refer to the relevant manuals.

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All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

Note

This equipment must be operated by skilled/trained clinical professionals.

Warning

It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray or repairs by people other than Mindray authorized personnel.

This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible.
- Others not caused by instrument or part itself.

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Tel:	+1 (201) 995-8000

Toll Free:	+1 (800) 288-2121
Fax:	+1 (800) 926-4275

Important Information: Customer Responsibility

- The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product.
- When the transducer is sent to MINDRAY for warranty or repair, you must disinfect it and keep it in the original shipping/carrying case to prevent infection.
- The warranty does not cover:
 - Damage to the transducer due to patient biting,
 - Damage to the transducer caused by disinfecting incorrectly or with chemicals not recommended by Mindray
- The warranty will be void if the transducer is not returned in its original Mindray carrying case.
- This equipment shall not be used by persons other than fully qualified and certified medical personnel.
- Do not make changes or modifications to the software or hardware of this product.
- In no event shall MINDRAY be liable for problems, damage, or loss caused by relocation, modification, or repair performed by personnel other than those designated by MINDRAY.
- The purpose of this system is to provide physicians with data for clinical diagnosis. The responsibility for diagnostic procedures lies with the physicians involved. MINDRAY shall not be liable for the results of diagnostic procedures.
- MINDRAY shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
- This manual contains Warnings regarding foreseeable potential dangers. Be alert at all times to dangers other than those indicated. MINDRAY shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions contained in this operator's manual.
- On the occasion of change of the administrator or manager for this system, be sure to hand over this operator's manual.
- When disposing of this system, contact your MINDRAY Customer Service Department or sales representative. Do not dispose of this system without consulting MINDRAY Customer Service Department or sales representative first. MINDRAY does not assume any responsibility for damage resulting from disposal of this system without consulting MINDRAY. A replacement transducer will not be sent to customer until the defective transducer is received.

Meaning of Signal Words

In this operator's manual,  **DANGER**,  **WARNING**,  **CAUTION** and **NOTE** are signal words used to indicate safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal Word	Meaning
 DANGER	Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.
 WARNING	Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
NOTE	Indicates a potentially hazardous situation that, if not avoided, may result in property damage.

1 Safety Information

1.1 Safety Classification

Please refer to the safety classification information

- To avoid injury to the patient, avoid forceful intubation pressure which can cause lacerations of the gastrointestinal tract with attendant and subsequent perforation.
- The deflection may after prolonged use develop an unwanted amount of free play. In that case, contact the Mindray Customer Service Department or sales representative to readjust the steering of the transducer. In this way, the risk of “buckling” or “U-turning” of the transducer in the esophagus is minimized.
- Confirm that the transducer and cable are normal before and after each examination. A defective transducer may cause electric shock to the patient.
- When using intra-cavity transducers, do not activate the transducer outside the patient’s body.
- The connector is not watertight, and should always be kept dry. The control unit, although spray-watertight, should not be immersed.
- Do not subject the transducer to shock. A defective transducer may cause electric shock to the patient.
- This equipment contains no operator serviceable components. To prevent electric shock, do not remove any covers or panels.
- DO NOT use the transesophageal probe with the defibrillator.

CAUTION

- When using this transducer, wearing medical gloves can help to prevent infection.
- To avoid inadvertent damage to the transducer, read this user guide before handling and cleaning the TEE transducer.
- Be sure to use ultrasound gel. Please use the ultrasound gel compliant with the relevant local regulations. Proper management and use of the ultrasound gel is essential to ensure that it will not become a source of infection.
Only use water-based coupling gel.
- Under normal conditions at full acoustic power the temperature of the tip does not exceed 43°C. Follow the instruction in this user manual to check this regularly.
- If the TEE probe is faulty, freeze the image and stop using the transducer, and then slowly remove the transducer from the patient. Do not use the TEE transducer before maintenance.
- Before each use or after a change of viewing modes/settings, pay attention to the status of the ultrasound image. Do not use the probe to perform image acquisition when the image is frozen. Ensure that the orientation of the ultrasound image is correct. Check the orientation prior to the examination
- Before each use, the outer surface of the portions of TEE probe which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.
- Do not use the carrying case for storing the transducer. If the carrying case is used for storage, it may become a source of infection.

- It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.
- The transducer and accessories supplied with it are not delivered disinfected. High-level disinfection is recommended before use.
- Disposable components are packaged sterile and are single-use only. Do not use if integrity of packaging violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.
- Please use the disinfection solution that recommended in this operator's manual, otherwise Mindray will not be liable for damage caused by other solutions. If you have any questions, please contact Mindray Customer Service Department or sales representative.
- Before introducing the transducer: do not rub or spray the tip of the transducer with an anesthetic agent.
- The damage of the transducer may be caused by the contact of improper gel or cleaner:
 - DO NOT dip the transducer in the strong polar solutions of ethanol, chloride of lime, ammonium chloride, acetone and formaldehyde.
 - DO NOT contact the transducer with solution or ultrasound gel containing oily medium such as mineral oil or lanoline.

NOTE:

- Read the following precautions to prevent the transducer from malfunction.
 - Before connecting or disconnecting the transducer, freeze or turn off the ultrasonic diagnostic system.
 - Clean and disinfect the transducer before and after each examination.
- Repeated disinfection will eventually damage the transducer, please check the transducer's performance periodically.

1.3 Ambient conditions

To prevent the transducer from being damaged, do not use it where it will be exposed to:

- Direct sunlight or X-rays
- Sudden changes in temperature
- Dust
- Excessive vibration
- Heat generators

Table 1-1 Environmental Conditions

Probe model	Conditions	Ambient temperature	Relative humidity (no condensation)	Atmospheric pressure
P7-3T	Operating	0 °C to 40 °C	10% to 85%RH	700 hPa to 1060 hPa
P7-3Ts P7-3TE P7-3TU	Storage and transportation	-10 °C to 45 °C	30% to 90%RH	700 hPa to 1060 hPa
P8-3Ts	Operating	0 °C to 45 °C	10% to 90%RH	700 hPa to 1060 hPa
	Storage and transportation	-25 °C to 55 °C	5% to 95%RH	700 hPa to 1060 hPa
P8-2Ts/ P8-2TU	Operating	17.5 °C to 42.7 °C	20% to 85%RH	700 hPa to 1060 hPa
	Storage and transportation	-20 °C to 55 °C	20% to 95%RH	700 hPa to 1060 hPa
XP8-2TU	Operating	10 °C to 40 °C	30% to 85%RH	570 hPa to 1060 hPa
	Storage and transportation	-20 °C to 40 °C	30% to 95%RH	570 hPa to 1060 hPa

1.4 Symbols

This system uses the symbols listed in the following table. Their meanings are explained as follows.

Symbol	Description
	General warning sign
	Type-BF applied part
	Serial number
	Date of manufacture
	Indicates the direction of the lock handle. The top symbol indicates the position of locked handle, the left symbol indicates the position of the unlocked handle.
	Manufacturer
IPX7	Protection against temporary immersion in water
	Comply with the requirements of the Council Directive 93/42/EEC "

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

Geometric shape	Meaning	Safety color	Contrast color	Graphical symbol color
	Warning	Yellow	Black	Black

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2 Overview

2.1 Applications

The TEE transducer is used together with the diagnostic ultrasound system, and is intended for clinical ultrasound diagnosis and examination. Refer to the operator's manual of the diagnostic ultrasound system.

2.2 Precautions For Use

WARNING

The physician must take into account all possible factors before starting the examination.

Precautions for using the TEE transducer are:

- P7-3T/P7-3Ts/P7-3TE/P7-3TU/P8-2Ts/P8-2TU/XP8-2TU is intended to be used on adults only, fetal imaging and pediatric imaging are not permitted.
- P8-3Ts is not intended for fetal 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

2.3 Out-of-Box Inspection

2.3.1 Accessories Inspection

The following items are supplied with each transducer.

Item	Quantity	Description
Ultrasonic transducer	1	/
Operator's Manual	1	Describes the basic functions and operations of the probe, safety precautions, etc.

Item	Quantity	Description
Cleaning and Disinfection Guide	1	Describes the probe cleaning and disinfection procedures in figure and text.
TEE Transducer Leakage Current Safety Testing Guide	1	Describes the leakage current test procedures.
Carrying case	1	/
Tip cover	1	/
Probe connector seal cover	1	Prevents liquid splashing during cleaning and disinfection. NOTE: • Only the "s" probe (the model name ends with letter "s") contains the probe connector seal cover. • Since the probe connector is not waterproof, if the probe is configured with probe connector seal cover, be sure to put the seal cover on the connector to prevent the liquid from entering the connector during the cleaning and disinfection process.
Transducer cover suite	1	

2.4 Structure

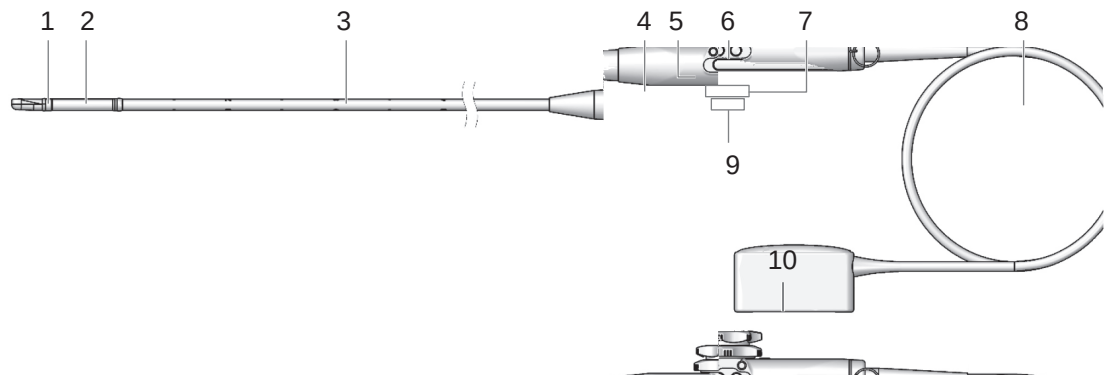
TEE transducer is a phased array transducer, mounted in a sealed tip at the end of a gastroscope. The transducer is intended for imaging of the heart through the esophagus and the stomach. Among them, the tip of P7-3T/P7-3Ts/P7-3TE/P7-3TU/P8-2Ts/P8-2TU rotates using the motor control push-button on the control handle, the tip of P8-3Ts rotates using the scanplane rotation wheel on the control handle, and the tip of XP8-2TU rotates using the control push-buttons on the control handle electronically.

The probe tip rotates using the deflection control wheel on the handle for accurate positioning in the esophagus.

2.4.1 P7-3T/P7-3TE Transducer Functions by Part

No.	Name	Function
10	Connector	Connects the transducer to the ultrasonic diagnostic system.

2.4.2 P7-3Ts/P7-3TU Transducer Functions by Part

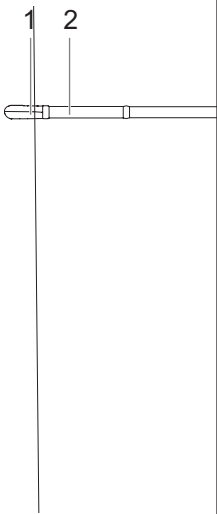


No.	Name	Function
1	Distal tip with transducer	Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts it into an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens for correct operation.
2	Defection section	Defects to obtain an overall scanning.
3	Flexible shaft	Inserts into the mouth cavity or esophagus. Depth is marked on the flexible shaft, unit: cm.
4	Control handle	Operates on the transducer defection or rotation.
5	Up/Down Defection control wheel	Used for controlling the transducer up/down tip defection.
6	Left/Right Defection control wheel	Used for controlling the transducer left/right tip defection.
7	Defection lock	Restrain the defection

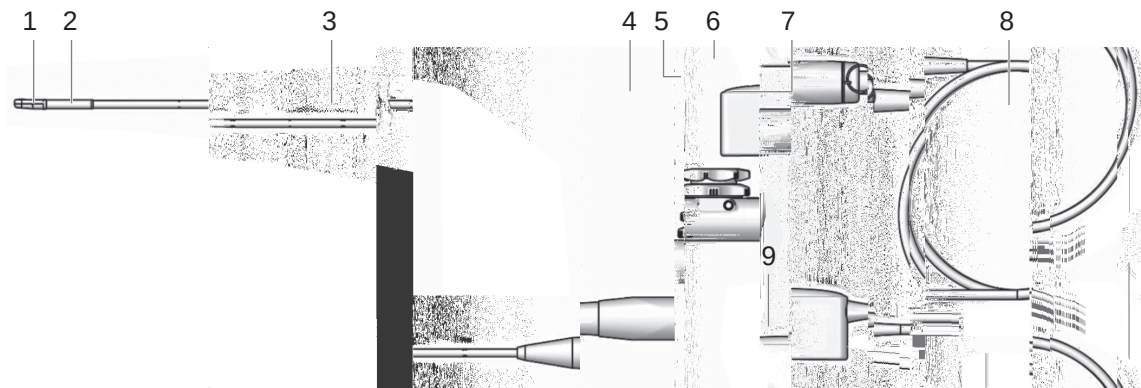
2.4.3

P8-2Ts/P8-2

art

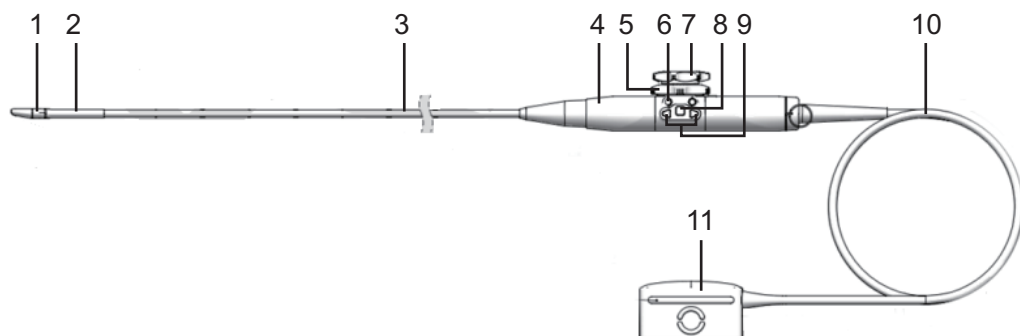


2.4.4 P8-3Ts Transducer Functions by Part



No.	Name	Function
1	Distal tip with transducer	Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts it into an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens for correct operation.
2	Deflection section	Deflects to obtain an overall scanning.
3	Flexible shaft	Inserts into the mouth cavity or esophagus. Depth is marked on the flexible shaft, unit: cm.
4	Control handle	Operates on the transducer deflection or rotation.
5	Deflection control wheel	The larger wheel on the handle is for controlling the probe tip deflection.
6	Scanplane rotation wheel	The wheel on top is the scanplane rotation control wheel. Controls to scanplane rotation. Range: 0°-180°.
7	Deflection lock	Restrain the deflection wheel adjustment.
8	Cable	Transmits electrical signals between the transducer body and connector.
9	Connector	Connects the transducer to the ultrasonic diagnostic system.

2.4.5 XP8-2TU Transducer Functions by Part



No.	Name	Function
1	Distal tip with transducer	Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts it into an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens for correct operation.
2	Deflection section	Deflects to obtain an overall scanning.
3	Flexible shaft	Inserts into the mouth cavity or esophagus. Depth is marked on the flexible shaft, unit: cm.
4	Control handle	Operates on the transducer deflection or rotation.
5	Up/Down Deflection control wheel	Used for controlling the transducer up/down tip deflection.
6	Deflection lock lever	Restrain the deflection wheel adjustment.
7	Left/Right Deflection control wheel	Used for controlling the transducer left/right tip deflection.
8	User-defined key	Set by the user in the Ultrasound system preset
9	Control push-buttons	Controls to scanplane rotation. Range: 0°–360°
10	Cable	Transmits electrical signals between the transducer body and connector.
11	Connector	Connects the transducer to the ultrasonic diagnostic system.

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3 Transducer Controls and Inspection

3.1 Inspection before Use

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.

If any abnormality is found, immediately stop using the transducer and contact MINDRAY Customer Service Department or sales representative.

3.1.2 Tip Deflection Control

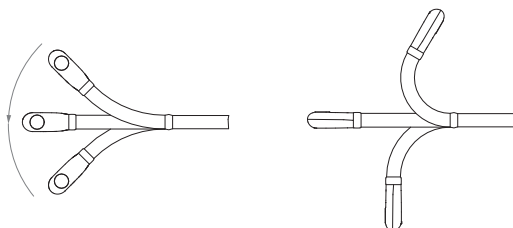
WARNING

- If the deflection shows an unwanted amount of free play, do not use the transducer. Contact the service organization to re-adjust the steering of the transducer. In this way, the risk of "buckling" or "U-turning" of the transducer in the esophagus is minimized.
- 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.

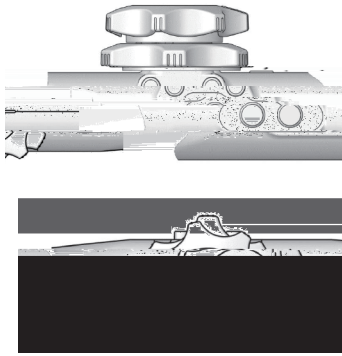
The tip deflection brake inspection should be performed on the transducer after taking it out of the box and prior to each exam.

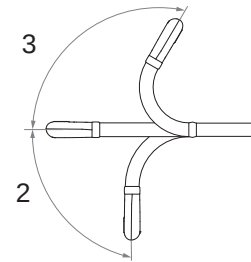
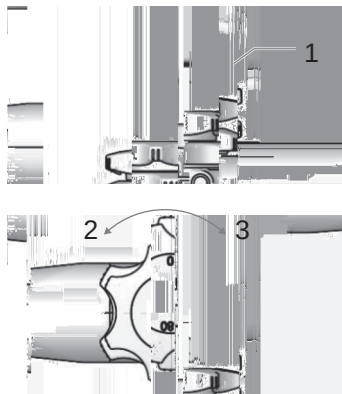
1. Deflect the tip in all four directions (P8-3Ts: up/down) and confirm that the angle is within the ranges specified above (with reference to the endoscope shaft).
2. Confirm that the deflection controls operate smoothly.
3. Check that when the deflection controls are in the neutral position that the transducer tip is also in a neutral position (undeflected).

P7-3T/P7-3TE

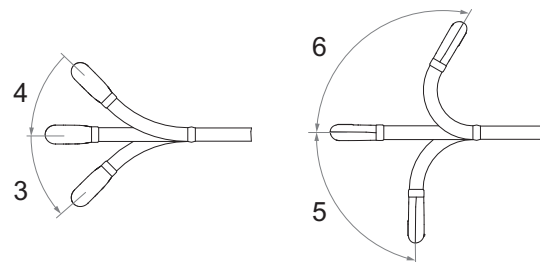
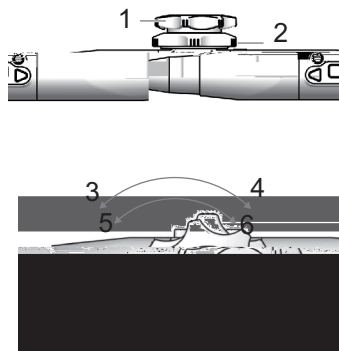


P7-3Ts/P7-3TU



P8-3Ts

1	Up/Down Deflection control wheel
2	Turn lower wheel counterclockwise to move the tip down, 90° minimum
3	Turn lower wheel clockwise to move the tip up, 120° minimum

XP8-2TU

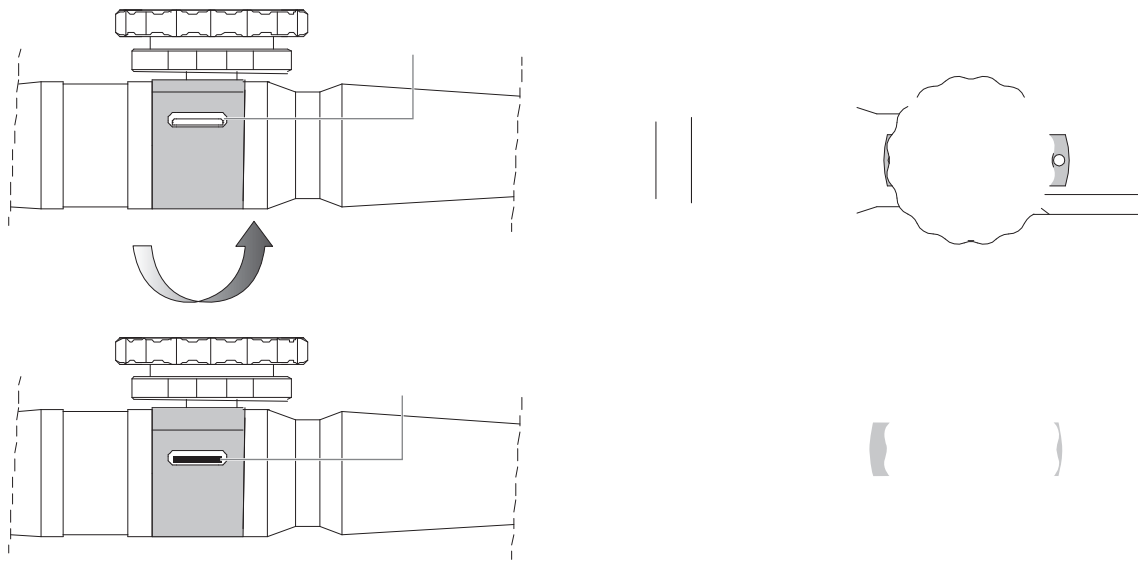
1	Left/Right Deflection control wheel
2	Up/Down Deflection control wheel
3	Turn upper wheel counterclockwise to move the tip left, 45° minimum
4	Turn upper wheel clockwise to move the tip right, 45° minimum
5	Turn lower wheel counterclockwise to move the tip down, 90° minimum
6	Turn lower wheel clockwise to move the tip up, 120° minimum

3.1.3 Brake Operation

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

1. Confirm the brake is in the unlocked position.
2. Deflect the tip to the anterior direction.
3. Move the brake to the locked position.
4. Confirm that the tip is locked in the deflected position.
5. Unlock the brake and confirm the tip straightens easily.
6. Repeat steps 1-5 for the other directions.

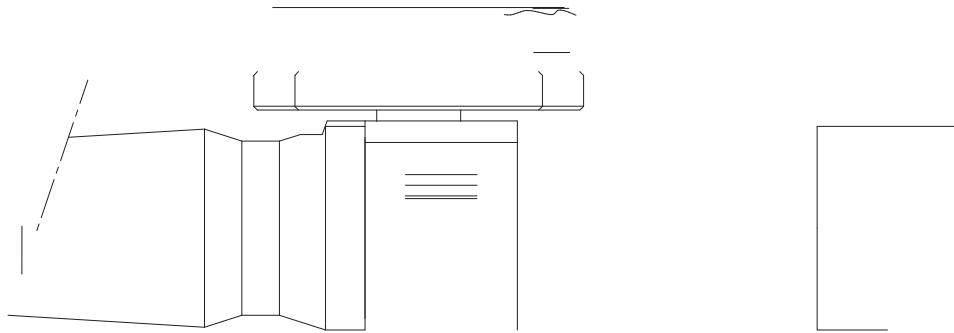
P7-3T/P7-3TE

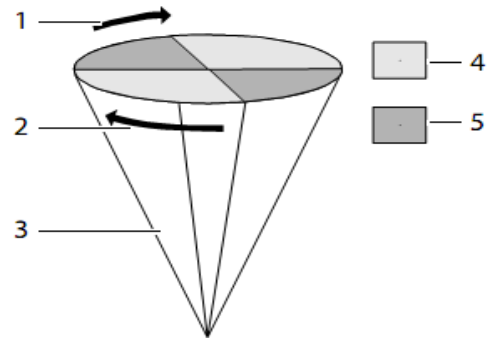


1	Left/Right/Up/Down deflection lock: 

Rotation Control

Figure 3-1 P7-3T/P7-3TE





1	90°rotation sagittal to mirror image of transverse plane
2	90°rotation transverse to longitudinal plane
3	Conic imaging volume
4	Quadrants filled by first 90°rotation
5	Quadrants filled by second 90°rotation



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 TE 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°).
4. Confirm the image on the screen changes in relation to the numbers on the scanplane indicator.
 - While pressing the motor control push-buttons (not available for P8-3Ts and XP8-2TU), the transducer motor should be running as the image is changing.
 - For P8-3Ts: use the scanplane rotation wheel to control the rotation.
 - For XP8-2TU: use the control push-buttons to control the rotation.

3.2 Connecting and Disconnecting the Transducer

TEE transducer should be used only with Mindray compatible ultrasonic diagnostic systems.

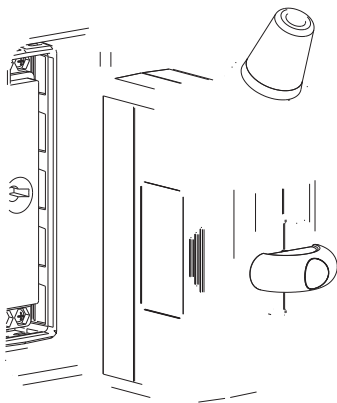
NOTE:

- Before connecting or disconnecting a transducer, freeze or turn off the ultrasonic diagnostic system, otherwise the ultrasonic diagnostic system or the transducer may malfunction.
- Place the cable properly to avoid being treaded or wrapping with other devices. DO NOT allow the transducer head to hang free.

3.2.1 TEE Transducer connector with Lock Handle

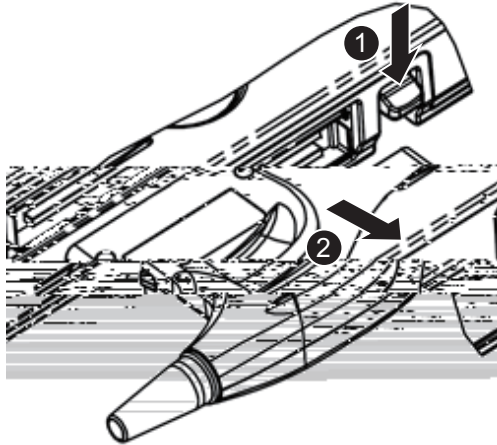
Connecting the Transducer

1. Turn the lock handle horizontally, and insert the connector fully into the connector.
2. Turn the lock handle 90° clockwise to lock it securely.



Disconnecting the Transducer

1. After freezing or turning off the ultrasonic diagnostic system, toggle the locking lever to the unlock position to unlock the connector of the probe.
2. Pull the probe connector straight out as shown in the figure below.



3.3 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-guard inspection test is done prior to each exam, then the electrical leakage current test should be done yearly at a minimum.

3.3.1 Electrical Leakage Current Test

Mindray ultrasound systems with accessories are designed to meet the requirements for patient safety described in IEC 60601-1 Medical Electrical Equipment-Part 1. 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.
- 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.

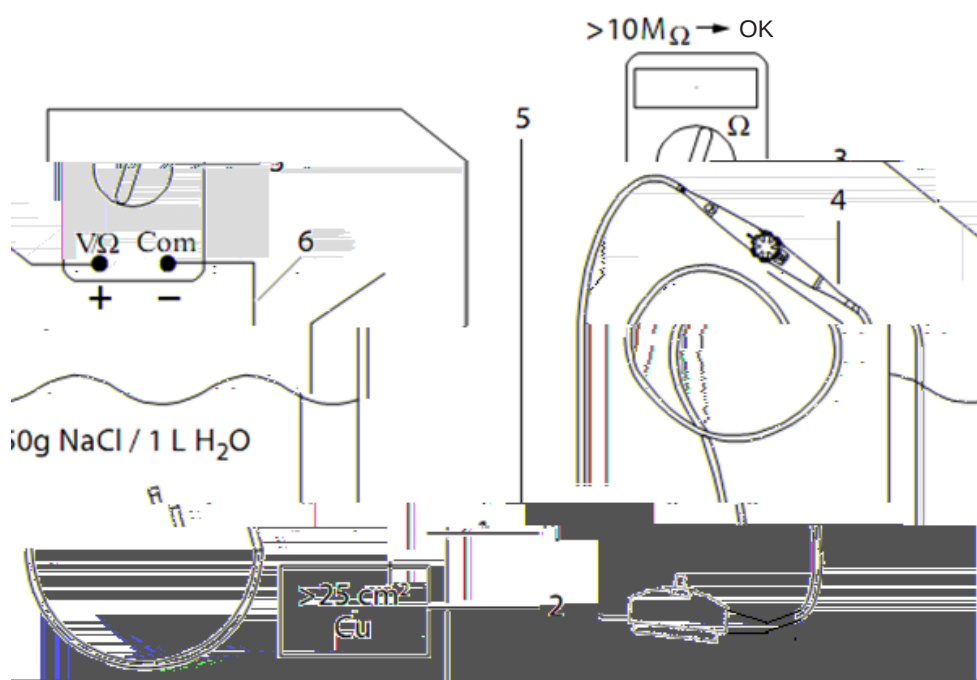
Checking the integrity of the insulating material cannot always be accomplished by visual inspections. A program for measuring the electrical leakage current on a regular basis should be established. As a minimum, leakage tests according to EN 60601-1/IEC 60601.1 §19 must be performed once a year, or 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).

Mindray recommends keeping a written log of the results.

3.3.2 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 below.

Figure 3-4 Connection with test equipment (for reference only)



1	Water bath
2	Copper or aluminum sheet
3	Multimeter
4	TEE transducer
5	Positive lead
6	Negative lead

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 M Ω scale (calibrated to NIST).

Bite-hole Test

1. Submerge 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 3-4.
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 M Ω).
4. Wait at least 2 seconds and verify that the resistance is acceptable (greater than 10 M Ω).

WARNING

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

 WARNING

To avoid the risk of esophageal burn for adult patients, reduce the time spent imaging at distal tip temperatures in excess of 42 °C (107.6 °F). At 42 °C (107.6 °F) or higher, the exposure time of the P7-3T/P7-3Ts/P7-3TE/P7-3TU/P8-2Ts/P8-2TU/P8-3Ts/XP8-2TU probe for adult applications should be limited to 10 minutes or less. There is no sufficient data to prove the thermal tolerance of the esophagus in neonate and pediatric patients, but it is apparently these patients are more vulnerable than adults. For neonatal or pediatric applications, the P8-3Ts probe should reduce the time spent imaging at distal tip temperatures in excess of 41 °C (105.8 °F).

3.4.2 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, 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.

3.4.3 Temperature Calibration Test

The temperature measurement function should be verified to the specifications at least once a year.

Test Setup

Assemble the following items for the test.

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

Temperature Calibration Test

1. Adjust the water bath temperature to $41^{\circ}\pm 0.1^{\circ}\text{C}$ 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 $\pm 0.5^{\circ}\text{C}$ is not acceptable. Maintaining this accuracy without temperature regulation may be difficult.
2. Connect the TEE transducer to the ultrasound system.
3. Press <Freeze> and set patient temperature to be 41°C on ultrasound system.
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

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4 Examination

The actual examination with the multiplane TEE Transducer is beyond the scope of this manual. There are many medical articles and books, which very thoroughly address this topic. There are however specific cautions that should be considered.

The operator should have adequate clinical experience and received related training.

WARNING

The physician must take into account all possible factors before starting the examination.

4.1 Pre-Exam Inspection

The following inspections should be performed prior to each exam.

- Perform visual tactile inspection, see "3.1.1 Visual and Tactile Inspection".
- Perform tip deflection inspection, see "3.1.2 Tip Deflection Control".
- Perform brake inspection, see "3.1.3 Brake Operation".
- Perform scanplane rotation inspection, see "3.1.4 Scanplane Rotation Operation".
- Perform leakage test or bite-guard inspection test, see "3.3 Electrical Safety".
- Clean and disinfect transducer, see "5 Cleaning and Disinfection".

WARNING

- **To avoid injury to the patient, Mindray 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 Mindray or your local representative.**
- **Some gels and disinfectants can cause an allergic reaction in some individuals.**

4.2 Couple Gel, Sheath, and Bite-guard

4.2.1 Couple Gel

Apply a sufficient amount of water-soluble acoustic coupling gel on the transducer acoustic window.

 CAUTION

Only use water-soluble acoustic coupling gel. Other coupling gels containing ingredients like ethanol, mineral oil, iodine, lotions, lanolin, aloe vera or methyl or ethyl parabenzoic acid can cause transducer damage.

4.2.2 Sheath

For patient protection, a sterile, single-use, latex sheath can be used over the transducer before performing examination. Use a commercially available transducer sheath.

If used, place the latex sheath over the transducer and gastroscope shaft up to but not covering the handle. Rub the tip carefully to ensure that all air bubbles have been removed from the transducer's acoustic window area. In addition to the gel on the acoustic window, apply a sufficient amount of acoustic coupling gel on the outside of the sheath at the tip of the transducer.

 CAUTION

- **Be sure to cover the transducer with a new (unused) transducer sheath to prevent infection during examination. If the package of a transducer sheath is open or broken, the sterilization of the transducer sheath may not be sufficient. Do not use such a transducer sheath.**
- **The sheath contains natural rubber latex and talc that can cause allergic reactions in some individuals. In the USA, refer to FDA Medical Alert MDA91-1.**
- **Do not exert force on the window area.**

Method (for reference):

1. Place an appropriate amount of gel inside sheath or on the transducer surface. Poor imaging may result if no gel is used.
2. Insert the transducer into the sheath.
3. Pull sheath tightly over transducer surface to remove wrinkles and air bubbles, and take care to avoid puncturing the sheath. Secure sheath with the enclosed elastic bands.
4. Inspect the sheath to ensure there are no holes or tears.

4.2.3 Bite-guard

Place the bite-guard on the transducer so that after insertion of the transducer the bite-guard can easily be placed in the patient's mouth. The bite-guard can also be placed in the patient's mouth before inserting the transducer.

 WARNING

- **The use of a bite-guard is mandatory. Failure to use the bite-guard may result in damage to the transducer, which could result in a safety hazard. Damage to the transducer due to biting is not covered by the transducer's warranty.**

- **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 Bite-guard is for single use only, do not re-use the Bite-guard. Otherwise it may become a source of infection .**

4.2.4 Ordering Supplies

You can order transducer sheath, bite-guard and necessary accessories from the following manufacturer.

To order a transducer sheath, you may contact:

CIVCO Medical Instruments Co.

102 First Street South, Kalona, IA 52247-9589 USA

E-mail: info@civco.com

<http://www.civco.com>

Call 1-800-445-6741 within the United States or 1-319-656-4447 outside of the United States. To fax orders call: 1-319-656-4451

For details, please contact your local Mindray representative for assistance.

4.3 Examination

The operator should adopt proper ultrasonic scanning procedures and methods according to different target organs.

NOTE:

It is required to practice ALARA when operating ultrasonic diagnostic system.

4.3.1 Cautions

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 manual.

 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.

4.3.3 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 following procedure to assure 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, 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.

4.4 After Examinations

After the examination is completed, turn OFF the ultrasonic diagnostic system, remove the bite-guard and disconnect the transducer, and then clean and disinfect the transducer.

After disinfecting the transducer, confirm that the transducer is in good condition and store it in a suitable place.

For details about clean and disinfect, see "5 Cleaning and Disinfection".

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5

Cleaning and Disinfection

This section describes the methods and precautions for cleaning and disinfection of TEE probes. After completing each examination, clean, disinfect the TEE probes as required. If necessary, repeat the cleaning, disinfection process before next use.

 WARNING

- **Keep the control handle and system connector out of any cleaning or disinfection solutions. The control handle and cable may be cleaned with a damp cloth, but only the distal end of the transducer up to the 100 cm marker on the shaft (70 cm for P8-3Ts) may be placed into a disinfection solution.**

5.1 Before Processing

This step is to remove the ultrasound gel or other visible dirt.

1. Wear a pair of gloves to prevent infection through the whole cleaning, disinfection process.
2. Disconnect the probe from the system. If the sheath is used, take off the sheath and dispose it as directed by the hospital.
3. Wipe away the ultrasound gel or other visible dirt on the surface of the probe by using a damp piece of disposable lint-free soft cloth or tissue.

5.2 Cleaning

Only the following cleaners are recommended by Mindray to clean the TEE transducers. For the biological effectiveness and the correct use of the cleaners, see the information of the cleaner's manufacturer.

5.2.1 Compatible Detergents

Cleaner	Active ingredient	Concentration	Applicable for
Cidezyme/Enzol	Proteolytic enzymes	< 5%	P7-3T
Neodisher MediClean forte	Trisodium nitrilotriacetate	5-10%	P7-3Ts
	2,2-Iminodiethanol diethanolamine	1-2%	P7-3TU P7-3TE
Prolystica 2x conc. Enzymatic Presoak & cleaner	Ethanolamine	1-5%	P8-3Ts
	Protease	0.1-1%	P8-2Ts
	Ethoxylated alcohol	1-5%	P8-2TU
	Polyalkylene glycol	1-5%	XP8-2TU
	Glycerine	1-5%	
EMpower	Proteolytic enzymes	< 2%	P7-3T
Metrizyme	Proteolytic enzymes	< 2%	P7-3Ts P7-3TU P7-3TE P8-3Ts P8-2Ts P8-2TU
WIP'ANIOS CLEAN'UP	Association of surfactants, excipients	/	P8-2Ts P8-2TU
Intercept™ Detergent	Diethylene glycol monoethyl ether, Quaternary ammonium compounds, benzyl-C12-18- alkyldimethyl, chlorides	1-5%	
TEEZyme	Ethoxylated Alcohols	0.1-1%	XP8-2TU
	Proteolytic enzymes	0.1-1%	
	Amylase	0.1-0.5%	
TEEZyme Sponge	Proteolytic enzymes	0.1-1%	

5.2.2 Cleaning Procedure for TEE Probe

1. Select an appropriate cleaner include cleaning wipes and sprays, mild detergents, enzymatic cleaners and specially designed enzymatic sponges.
2. Follow the cleaner manufacturer's instructions to prepare and use the cleaner. Select an appropriate method:
 - Soaking: Soak the probe in the cleaner solution for a duration according to the cleaner manufacturer's instructions. Wipe and wash the probe surface gently by using a piece of lint-free soft cloth or soft sponge until no dirt is visible. When necessary, wash the locating groove and other items by using disposable cotton swabs.

Avoid using a brush to wash the lens because it may damage the probe.

Only the section from distal end to the 100 cm marker (70 cm for pediatric TEE probe) on the flexible shaft can be immersed in the cleaner solution. The handle, cable and connector can only be cleaned with a wrung out soft cloth moistened with cleaners.
 - Wiping: Use a commercially available cleaning wipe, cleaning sponge, or a soft cloth soaked with a cleaning spray to wipe and clean all surfaces of the probe thoroughly for at least 1 minute or follow the cleaner manufacturer's instructions until the probe is clean. When necessary, wash the locating groove and other items by using disposable cotton swabs.
3. Rinse the probe insertion part thoroughly with plenty of clean flowing water (about 7.5L) at room temperature for about 1 minute to remove the residual dirt and cleaning solvent. Or follow the rinsing method specified by the cleaner manufacturer. Use moistened soft cloth to wipe the residual cleaners on the handle, cable, and connector.
4. Dry the probe with a disposable lint-free soft cloth or tissue. Do not dry the probe by heating.
5. Inspect the probe. If visible dirt still exists, repeat the preceding steps to wash the probe until it is all clean.

5.3 Disinfections

Only the following disinfectants are recommended by Mindray to disinfect the TEE transducers. For the biological effectiveness and the correct use of the disinfectants, see the information of the disinfectants' manufacturer.

5.3.1 Compatible Disinfectants

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Disinfectant	Active ingredient	Concentration	Applicable for
Metricide Plus 30	Glutaraldehyde	3.40%	P7-3T P7-3Ts P7-3TU P7-3TE P8-3Ts
CIDEX [®] OPA (applicable for FDA region only)	Ortho-phthalaldehyde	0.55%	P7-3T P7-3Ts
Metricide OPA Plus (applicable for FDA region only)	Ortho-phthalaldehyde	0.60%	P7-3TU P7-3TE P8-3Ts P8-2Ts P8-2TU XP8-2TU
Revital-Ox [®] Resert [®] HLD	Hydrogen Peroxide	1.4-2.3%	P7-3T
	2-Fluoroic Acid	≤2.50	P7-3Ts P7-3TU P7-3TE
UltrOx [™] HLD	Hydrogen Peroxide	1.4-2.3%	P8-3Ts
	2-Fluoroic Acid	≤2.50	XP8-2TU
Rapicide OPA-28	Ortho-phthalaldehyde	0.575%	P8-2Ts P8-2TU
TD-8	Ortho-phthalaldehyde	0.59%	XP8-2TU

5.3.2 Disinfection Procedure

- Select an appropriate high-level disinfectant to disinfect the probe. Follow the disinfectant manufacturer's instructions to use the high-level disinfectant. Prepare a disinfectant by using sterile distilled or softened water when necessary.
- Select an appropriate method:
 - Soaking: Soak the probe in the disinfectant solution and shake the probe properly to remove bubbles on the surface of the probe. For the probe soaking duration, see the disinfectant manufacturer's instructions.
Only the section from distal end to the 100 cm marker (70 cm for pediatric TEE probe) on the flexible shaft can be immersed in the disinfectant solution. The handle, cable and connector can only be disinfected with a wrung out soft cloth moistened with disinfectants.
 - Wiping: Use a commercially available disinfecting wipe, or a disposable sterile lint-free soft cloth soaked with a disinfecting spray to wipe and disinfect all surfaces of the probe thoroughly for the time specified in the disinfectant manufacturer's instructions.

Model	Manufacturer	Compatible Reagents	Compatible Probes
ASTRA TEE®	CIVCO Medical Solutions	Cidex OPA	P7-3T/P7-3Ts/P7-3TU/P7-3TE/P8-3Ts/P8-2Ts/P8-2TU/XP8-2TU
		Metricide OPA Plus	
		Revital-Ox® Resert® HLD	P7-3T/P7-3Ts/P7-3TU/P7-3TE/P8-3Ts/XP8-2TU
		UltrOx™ HLD	
Advantage Plus™	Steris (Medivators)	Intercept™ Detergent	P8-2Ts/P8-2TU
		Rapicide™ PA HLD	P8-2Ts/P8-2TU/P8-3Ts/XP8-2TU

6 Storage and Transportation

When all examinations for the day have been completed, confirm that the transducer is in good condition and store it in a suitable place so that the next examination can be conducted smoothly. Make sure the transducer is adequately cleaned and disinfected prior to storage.

 CAUTION

- When transporting 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.



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7 Specifications

P7-3T/P7-3Ts/P7-3TE/P7-3TU		
Shaft length		110 cm (deviation:±10%)
Mechanical dimensions	Shaft external diameter	11 mm (deviation: +10%, the lower limit is not calculated)
	Diameter of the inflexible distal part of the transducer tip	17.5 mm (deviation: +5%, the lower limit is not calculated)
	Maximum insertion portion diameter:	≤17.5 mm
Transducer type		Phased array
Number of elements		64
Scanplane rotation		0 180°
Temperature precision		Temperature range: 17.5~50°C, precision: ±1°C, of which, when the temperature is 43°C, the precision is ±0.5°C
Tip defection		Up/Down/Left/Right: ≥120°/90°/45°/45° (Deviation: -10% mm, the upper limit is not calculated)
Leakage current / Dielectric strength		Meet the requirements of IEC 60601.
Biocompatibility		All external materials of the multiplane TEE Transducer have passed relevant biocompatibility tests according ISO 10993.

P8-3Ts		
Shaft length		72 cm (deviation:±10%)
Mechanical dimensions	Shaft external diameter	7.5 mm (deviation: 10%, the lower limit is not calculated)
	Diameter of the inflexible distal part of the transducer tip	14.5 mm (deviation: +5%, the lower limit is not calculated)
	Maximum insertion portion diameter:	≤14.5mm
Transducer type		Phased array
Number of elements		48
Scanplane rotation		0 180°

P8-3Ts	
Temperature precision	Temperature range: 17.5~50°C, precision: ±1°C, of which, when the temperature is 43°C, the precision is ±0.5°C
Tip deflection	Up/Down: 120°/90° (Deviation: -10% mm, the upper limit is not calculated)
Leakage current / Dielectric strength	Meet the requirements of IEC 60601.
Biocompatibility	All external materials of the multiplane TEE Transducer have passed relevant biocompatibility tests according ISO 10993.

P8-2Ts/P8-2TU	
Shaft length	108 cm (deviation: ±10%)
Mechanical dimensions	Shaft ew $\bar{I} \pm 10\% \dot{W}$ $\dot{q}$ Æ w $\overset{\sim}{3} \frac{3}{4}$ ew



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8 Disposal

NOTES:

- Follow the local regulations or hospital's guideline when disposing this device.
- Be sure to clean and sterilize this device before disposing it.
- Contact your MINDRAY representatives when disposing this device.
- Follow the disposal control policy for your office, department, or hospital when disposing contaminated items such as probe covers or other disposable items.

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