

**Philips Healthcare
Ultrasound**

CIL AfP-FCO79500322

2014 NOV 14

**Field Safety Notice
Philips Model MPT7-4 Transesophageal Transducer**

Use of Transducer After End of Service Life

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Dear Customer,

Philips Healthcare is committed to providing the highest level of support to our customers; however we need to inform you that the MPT7-4 Transesophageal (TEE) Transducer has reached the end of its service life.


The MPT7-4 transducer was introduced in 1995, and Philips ceased marketing new transducers in 2007. Because Philips can no longer procure a key service part for the transducer, and the performance of this part may degrade with time and use, we can no longer service or replace this transducer. Hence, we are removing the MPT7-4 from any service contracts.

Philips does not recommend the continued use of TEE transducers beyond their service life. However, because there are few replacement TEE options for certain older ATL and Philips ultrasound scanners, some users may find it necessary to temporarily continue use of the MPT7-4 transducer before obtaining an alternative TEE solution. Should this be the case, it is particularly important to have a back-up imaging strategy and to carefully inspect and test the transducer before use. This letter is intended to provide you with Philips' most current recommendations for standard testing and operational procedures for TEE transducers.

If you need any further information concerning this issue, please contact your local Philips representative or Philips Customer Service at 1-800-722-9377.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,


Senior Director, Quality and Regulatory
Philips Healthcare - Ultrasound

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AFFECTED PRODUCTS	MPT7-4 Transesophageal Echocardiograph (TEE) Transducer 4000-0317-01 thru 4000-0317-19
PROBLEM DESCRIPTION	Philips can no longer service or replace this TEE transducer, and in particular, Philips can no longer procure a key service part for the transducer, and the performance of this part may degrade with time and use, leading to a reduction in the range of articulation of the transducer.
HOW TO IDENTIFY AFFECTED PRODUCTS	The model number (MPT7-4) and part number (4000-0317-01 thru 4000-0317-19) is printed on the transducer System Connector Housing. This product is used on the ATL UM9, ATL HDI 3000, ATL HDI 3500, ATL HDI 5000, and the Philips 5000 ultrasound systems.
ADVICE ON ACTIONS BY CUSTOMER / USER	Philips does not recommend the continued use of the product beyond its service life. However, because there are few replacement TEE options for certain older ATL and Philips ultrasound scanners, some users may find it necessary to temporarily continue use of the MPT7-4 transducer before obtaining an alternative TEE solution. Should this be the case, it is particularly important to carefully inspect and test the transducer before use. To provide assistance, we have included Philips' current general recommendations for testing and operational procedures for TEE transducers (see Attachment A). It is also considered good practice in TEE imaging to have a backup imaging strategy.
ACTIONS PLANNED BY PHILIPS	Philips is providing this Customer Information Letter to notify customers of the issue, and provide Philips' current general recommendations for testing and operational procedures for TEE transducers. Please contact your local Philips representative to discuss alternate options.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Customer Service at 1-800-722-9377.

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Attachment A – Recommended Pre-Procedure Inspection Process

Operators of TEE Transducers

TEE transducers are designed to be used by physicians who are properly trained in esophagogastrosopic techniques according to currently approved relevant medical practices. Philips recommends that physicians who operate a TEE transducer have the following qualifications:

- Proficiency in recognizing and interpreting transesophageal imaging patterns.
- Thorough familiarity with the safe operation, care, and maintenance of the ultrasound system and the TEE transducer.
- Thorough familiarity with the latest TEE methods through literature and seminars

Patient Safety During TEE Exams

This section provides information on patient safety when using a TEE transducer.

NOTE

Philips recommends that you practice using the controls before performing any procedure mentioned in this section. You must also be thoroughly familiar with the safe operation, care, and maintenance of the ultrasound imaging system used with the TEE transducer, as well as proficient at interpreting the images generated. You can help ensure patient safety when using a TEE transducer by following these guidelines:

- Use informed judgment when selecting patients for TEE exams.
- Scrutinize the entire transducer and test all of the controls before each use.
- Ensure that the transducer handle does not rest on or touch the patient.
- Use protective equipment, such as a bite guard and a market-approved sterile transducer cover during a TEE exam.
- Do not allow water or other liquids to come in contact with the transducer connector or the interior of the system, or to drip onto the keyboard.
- Minimize the possibility of transducer tip fold-over. This problem has occurred rarely, but its consequences can be serious.

Checking the TEE Transducer

Before each TEE exam, carefully inspect the transducer and try the controls, as described in the following topics.

Inspecting the Transducer

Carefully inspect the entire surface of the distal tip and flexible shaft for protrusions, holes, dents, abrasions, cuts, burrs, or cracks that could be extremely hazardous to both you and your patient.

Also check for excessive flexibility in the tip, particularly in the medial/lateral direction. *Do not* use the transducer if the tip is extremely flexible. If you have any questions about tip flexibility, contact your Philips service representative.

Verifying Operation of the Controls

Use the deflection controls to position the tip in every possible direction and amount of articulation, both to ensure that the controls work properly and to get used to the feel of the TEE transducer. Make sure that the controls operate smoothly without binding, and that you can achieve all possible positions easily before introducing the TEE transducer into the patient. Test the detent brake and freewheeling mode. Remember that

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the controls must be in freewheeling mode (no deflection and no brake resistance) when repositioning or withdrawing the transducer, as well as whenever you are not imaging.

Special Considerations for TEE Exams

Special considerations regarding TEE exams are advisable for patients with existing gastroesophageal abnormalities, such as esophageal varices, hiatal hernia, tumor, diverticula, esophageal webs and rings, fistulae, or peptic ulcers, as well as for patients who have had anti-reflux procedures. In addition, you should do the following:

- Consider the patient's size and ability to accommodate the transducer tip and shaft.
- Check the patient's history for gastroesophageal disease or difficulty swallowing.
- Evaluate the potential overall effects of any treatment that the patient is undergoing, such as mediastinal radiation, chemotherapy, anticoagulation, or steroid therapy.
- Be aware that you may discover unsuspected esophageal pathology during an exam. Be alert for congenital problems with the esophagus or stomach, particularly with pediatric patients.
- This list is not comprehensive. Rather, it suggests areas to investigate when considering TEE for a particular patient.

Minimize the possibility of pressure necrosis (tissue death). *Do not* let the distal tip displace any one segment of tissue for more than 5 consecutive minutes. Also make sure the deflection area and the distal tip are in the position of least potential pressure. Be sure that the transducer is in a freewheeling mode and unplugged whenever you are not imaging.

- Prevent potential esophageal damage. Philips recommends that you stop TEE scanning and unplug the transducer from the system during periods of poor perfusion, circulatory arrest, or the hypothermic phase of open heart surgery. To discontinue scanning, unlock the transducer connector.
- Before each TEE exam, carefully inspect the transducer, as described above thorough inspection procedure is required for the safety of the patient and yourself, and to ensure the continued correct functioning of the transducer.
- Never use excessive force when inserting, operating, or withdrawing a transducer, and make sure the deflection area is straight during insertion and withdrawal. Forceful insertion, manipulation, or withdrawal of a transducer can result in lacerations, bleeding, perforation, tearing of adhesions, and ligament damage. Also be aware that the tip can fold over, causing similar damage.
- Refrain from handling the distal tip whenever possible. If you must handle the distal tip, grasp it on the sides. Do not touch the top or bottom. Support the transducer's proximal head, either by having an assistant hold the steering mechanism or by clamping the transducer at the steering mechanism. However, be sure that the clamp does not interfere with steering, and do not clamp any part of the flexible shaft, as this will damage the transducer.