Philips Ultrasound FSN79500527 2019 AUG 28

URGENT – Field Safety Notice

Philips S7-3t & S8-3t Transesophageal (TEE) Transducers
Temperature Display Issue

<Hospital/Clinic Name>
cc: Chairman Medical Board and relevant Head of Departments
Dear Customer,

We detected a problem in the Philips S7-3t & S8-3t Transesophageal (TEE) Transducers, that, if it were to occur, could pose a risk for patients. This Medical Device Correction is intended to explain:

- the problem and under what circumstances it can occur
- the actions that should be taken by a customer or user to prevent risks to patients, and
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy of this letter with the equipment Instructions for Use.

Philips recently discovered an issue associated with a small number of S7-3t and S8-3t Transesophageal (TEE) transducers that were not properly programmed during manufacturing. As a result, the system is unable to correctly measure the temperature on the distal tip of the transducer. This issue will result in affected transducers not initiating auto-cool during use.

If you need any further information or support concerning this issue, please contact your local Philips representative *Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).*

We reported this notice to the appropriate Regulatory Agency.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Ron Nolte
Senior Director, Quality and Regulatory
Philips Ultrasound

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AFFECTED PRODUCTS	S7-3t & S8-3t Transesophageal (TEE) Transducers
PROBLEM DESCRIPTION	A small number of S7-3t and S8-3t TEE transducers were not properly programmed during manufacturing, as a result the system is unable to correctly measure the temperature on the distal tip of the transducer. EPIQ, Affiniti and iE33 systems will show the transducer temperature (TEE T) as <0.0C (<32.0F) on the display. HD11 and CX50 systems will show the transducer temperature (TEE T) as <37.0C (<98.5F) on the display. This issue will result in affected transducers not initiating auto-cool during use, when the transducer distal tip temperature exceeds 41.0°C (105.8°F).
HAZARD INVOLVED	Potential burn of esophageal tissue if the affected TEE transducer distal tip temperature exceeds 42.5°C (108.5°F), and auto-cool is not initiated.

HOW TO IDENTIFY AFFECTED PRODUCTS	The affected S7-3t and S8-3t TEE transducers can be identified by connecting them to an EPIQ, Affiniti or iE33 system, and checking the transducer temperature (TEE T) that appears on the display when enabled. Affected transducers cannot be detected using HD11 or CX50 systems. See instructions below for each system.
	
	<u>For EPIQ, Affiniti, & iE33 systems</u>
	
	• Connect the transducer to the system and ensure that it is secure and locked.
	• If the preset is not already selected by default, select it as follows:
	  o S7-3t - Adult Echo, or
	  o S8-3t - Pediatric.
	• Find the transducer temperature (TEE T) that appears in the lower left corner of the display.
	• If the transducer temperature on the display shows **TEE T <37.0C (<98.5F),** then the transducer was properly programmed, and no actions are required.
	• If the transducer temperature on the display shows **TEE T <0.0C (<32.0F),** then the transducer was not properly programmed (see image below), discontinue using the transducer and contact your local Philips representative.
	• If the transducer temperature (TEE T) does not appear in the lower left corner of the display, follow the instructions below to enable it:
	
	EPIQ & Affiniti
	
	• Swipe to the second touch screen
	• Touch **Temp Display** to display the temperature display
	
	iE33
	
	• Display the **Preset/Transducer** touch screen by touching **Preset/Transducer**
	• Touch **Temp Display** to display the temperature display

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	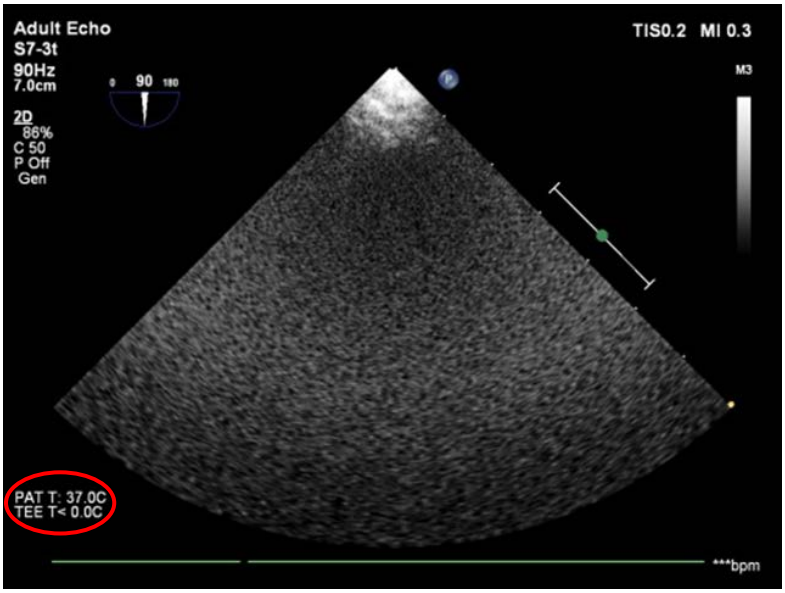 **For HD11 & CX50 Systems** • Discontinue using the transducer immediately and contact your local Philips representative for support.
ACTION TO BE TAKEN BY CUSTOMER / USER	If you have an EPIQ, Affiniti or iE33 system, verify that all your S7-3t and S8-3t TEE transducers are programmed properly by connecting them to the system, checking the transducer temperature (TEE T) on the display, and following the instructions provided on this letter. If you determine that your transducer is not properly programmed, discontinue using the transducer immediately and contact your local Philips representative to schedule an appointment with a field service engineer. If you have an HD11 or CX50 system discontinue using the S7-3t and S8-3t transducer immediately and contact your local Philips representative for support. Please complete the included reply form on the last page and return to Philips as soon as possible via email to ultrasound.corrections@philips.com, or fax to 1-833-512-7756.
ACTIONS PLANNED BY PHILIPS	Philips will resolve the issue by replacing the affected transducers at no cost.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative *Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)*.

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Customer Reply Form

Please complete and email to Philips.

Contact Name	
Telephone Number	
Email Address	
Facility Name	
Street Address City, State, Zip	

CUSTOMER ACKNOWLEDGEMENT:

I acknowledge that I have reviewed and understand this Urgent - Medical Device Correction Letter.

☐ My transducer is not affected, because the system shows the correct TEE T (<37.0C / <98.5F) on the display.

☐ My transducer is affected, because the system shows the incorrect TEE T (<0.0C / <32.0F) on the display. I understand the actions I need to take until my affected transducer is replaced.

☐ I'm unable to check if my transducer is affected; I will contact my local Philips representative for support.

Transducer Model	Serial Number	Affected	
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No
		☐ Yes	☐ No

_____ _____

CUSTOMER NAME (please print) **TITLE**

_____ _____

CUSTOMER SIGNATURE **DATE**

If you experience difficulty carrying out the instructions contained in this communication, please contact your local Philips representative *Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).*