Philips Ultrasound FSN79500545 December 3, 2020

URGENT – Field Safety Notice

Philips EPIQ Image Boost with xPlane Color Flow or Doppler with X8-2t Transducer Issue

Dear Customer,

We detected a problem with the Philips EPIQ Image Boost with xPlane Color Flow or Doppler when used with the X8-2t transducer, that, if it were to occur, could pose a risk for patients. This Field Safety Notice 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 the EPIQ Image Boost with xPlane and Color Flow or Doppler while using the X8-2t TEE Transducer. If Image Boost is enabled the color box shows flow visualization not accurately represent the fluid flow. Similarly, if Image Boost is enabled, both CW and PW Doppler traces will not accurately represent the fluid flow.

To date, no adverse events have been reported.

If you need any further information or support concerning this issue, please contact your local Philips representative at *<Philips representative contact details to be completed by the Market>*

We will report 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 (www.fda.gov/medwatch/report.htm), by regular mail or by fax.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Ron Nolte
Q&R Leader
Philips Ultrasound

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AFFECTED PRODUCTS	All EPIQ Systems (models EPIQ Elite, EPIQ 5G, EPIQ 5C, EPIQ 7G, EPIQ 7C, EPIQ CVx & EPIQ CVxi) with software version 7.0 when using the X8-2t TEE Transducer. EPIQ products running any other software versions are not affected.
PROBLEM DESCRIPTION	If the Image Boost feature is enabled with xPlane and Color Flow or Doppler while using the X8-2t TEE Transducer the blood flow will not be represented accurately. Color Flow visualization will be inaccurate and the Doppler traces, both CW and PW will be incorrect.
HAZARD INVOLVED	• Potential risk to miss the severity of the pathology, when this is related to regurgitant flow due to incorrect visualization or incorrect Doppler trace. • Potential risk to get incorrect assessment during device implant due to incorrect xPlane color visualization or incorrect Doppler trace.
HOW TO IDENTIFY AFFECTED PRODUCTS	To determine the software version of your Ultrasound system: • Power up the system and allow it to finish the boot sequence • Press “Support” on the right side of the control panel • Under “System Management” click “System Information” The software version is listed in the Software Information Section.
ACTION TO BE TAKEN BY CUSTOMER / USER	Do not use the Image Boost feature on your EPIQ Ultrasound System when using the X8-2t transducer. Ensure that the Image Boost Feature is disabled using the following steps: • Select the “2D” tab • Check that the “Image Boost” control button is not selected. (If not selected will say it is “off”) • If the “Image Boost” control button is selected, then unselect. Note: By default, the Image Boost feature is disabled. All other functions of the system will operate normally with Image Boost disabled. 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 providing a software update, at no cost.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative at *<Philips representative contact details to be completed by the Market>*

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Customer Reply Form

Please complete and email to *<Philips representative contact details to be completed by the Market>*

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 device is not affected, because it is running a software version other than 7.0**

☐ **My device is affected because it is running software version 7.0. I understand what actions I need to take until my system software is updated.**

_____ _____

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 at *<Philips representative contact details to be completed by the Market>*