Philips Ultrasound FSN79500546 January 2021

URGENT – Field Safety Notice

Philips EPIQ Control Panel Arm Failure

Dear Customer,

We detected a problem in the Philips EPIQ Control Panel Arm, that, if it were to occur, could pose a risk for patients and users. 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 EPIQ Ultrasound Systems where the control panel arm assembly could have missing or loose screws. In these cases, if undue force, pressure or weight is applied, the control panel mechanism can fail and break off. We are aware of three instances where the control panel arm with missing/loose screws broke and collapsed, one of them causing a minor injury to the operator.

If you need any further information or support concerning this issue, please contact your local Philips representative at **0800 80 3000**

We reported this notice to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Ron Nolte
Q&R Leader
Philips Ultrasound

Philips Ultrasound FSN79500546 January 2021

URGENT – Field Safety Notice

Philips EPIQ Control Panel Arm Failure

AFFECTED PRODUCTS	All EPIQ Systems (models EPIQ Elite, EPIQ 5G, EPIQ 5C, EPIQ 5W, EPIQ 7G, EPIQ 7C, EPIQ 7W, EPIQ CVx & EPIQ CVxi) shipped between 1/16/2019 and 10/22/2020.
PROBLEM DESCRIPTION	EPIQ Ultrasound Systems could have 1-4 missing or loose screws on the base of the arm. There is a potential for the control panel arm to break and collapse if pressure is applied while adjusting or moving the control panel.
HAZARD INVOLVED	User and/or patient injury may occur if the control panel collapses.
HOW TO IDENTIFY AFFECTED PRODUCTS	All EPIQ Systems (models EPIQ Elite, EPIQ 5G, EPIQ 5C, EPIQ 5W, EPIQ 7G, EPIQ 7C, EPIQ 7W, EPIQ CVx, & EPIQ CVxi) shipped between 1/16/2019 and 10/22/2020. Our records indicate you have one or more of the above systems potentially affected.
ACTION TO BE TAKEN BY CUSTOMER / USER TO ENSURE SAFE SYSTEM USE PRIOR TO INSPECTION	WHEN USING THE SYSTEM: • Do not apply downward force on your EPIQ Ultrasound system cart or control panel when the control arm is locked or in the lowest position. This includes leaning/bracing yourself with the system, such as when reaching across the system to the patient. WHEN POSITIONING THE SYSTEM: • Appropriately position the control panel next to the patient for better ergonomic rather than over the patient during scanning procedures. • When adjusting heights of bed rails and/or stretchers confirm all are clear of the control panel to avoid excessive load. WHEN TRANSPORTING THE SYSTEM: • Do not make any twisting or jerking motions with the control panel when adjusting or steering the system. • When transporting the system, push the system from behind using the back handles on control panel. When starting to move the system or stopping movement of the system avoid sudden downward pressure on the control panel. Please complete the included reply form on the last page and return to Philips as soon as possible via email to **customercare.ch@philips.com**
ACTIONS PLANNED BY PHILIPS	Philips will resolve the issue by inspecting and correcting as needed all the affected EPIQ systems 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 **0800 80 3000**

Philips Ultrasound FSN79500546 January 2021

URGENT – Field Safety Notice

Philips EPIQ Control Panel Arm Failure

Customer Reply Form

Please complete and email to customercare.ch@philips.com

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 – Field Safety Notice.

_____ _____

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 **0800 80 3000**