Philips Ultrasound FSN79500532 October 27, 2020

URGENT – Field Safety Notice

Philips EPIQ & Affiniti Ultrasound Systems
Patient Data Error

Dear Customer,

A problem has been detected in the Philips EPIQ & Affiniti Ultrasound Systems that, if it were to re-occur, could pose a risk for patients. This Medical Device Correction is intended to inform you about:

- the problem and under what circumstances it can occur
- the actions that the customer / user should take to prevent risks for patients

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.

Please retain a copy with the equipment Instructions for Use.

Philips has determined that with certain uncommon workflows there is potential for incorrect patient data to be displayed and saved into an exam. The issues manifest differently for different versions of software, the details of which are provided in this letter. In each case, the recommended workflows are standard-of-care and avoid the issue.

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 or the UK Philips Customer Care Service Centre on 0870 532 9741.

Philips 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 (www.fda.gov/medwatch/report.htm), 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 *All products listed are affected by one or more of the issues identified in this letter.*	All EPIQ and Affiniti Ultrasound Systems (models EPIQ 5G, EPIQ 5C, EPIQ 5W, EPIQ 7G, EPIQ 7C, EPIQ 7W, EPIQ CVx, Affiniti 30, Affiniti 50, and Affiniti 70) running any of the following software versions: Software versions affected worldwide: 1.0.x, 1.1.x, 1.2.x, 1.3.x, 1.4.x, 1.5.x, 1.7.x, 1.8.x, 2.0.x, 3.0.x, 4.0.x, 5.0, 5.0.1. Software versions affected China only: 1.0.x, 1.1.x, 1.2.x, 1.3.x, 1.4.x, 1.5.x, 1.7.x, 1.8.x, 1.9.x, 2.1.x.
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.

ISSUE 1

PRODUCTS IMPACTED	All EPIQ and Affiniti Ultrasound Systems (models EPIQ 5G, EPIQ 5C, EPIQ 5W, EPIQ 7G, EPIQ 7C, EPIQ 7W, EPIQ CVx, Affiniti 30, Affiniti 50, and Affiniti 70) running software versions: 1.0.x, 1.1.x, 1.2.x, 1.3.x, 1.4.x, 1.5.x, 1.7.x, 1.8.x, 2.0.x, 3.0.x, 4.0.x, 5.0, 5.0.1 worldwide, or 1.0.x, 1.1.x, 1.2.x, 1.3.x, 1.4.x, 1.5.x, 1.7.x, 1.8.x, 1.9.x, 2.1.x. China Only.
THIS IS ONLY RELEVANT TO YOU IF	You start a new patient exam and you accidentally enter the details for a different patient for whom you already have exams saved in your system.
ISSUE WORKFLOW	An error may occur if you attempt to correct the mistake by editing the patient information or selecting a different patient from the worklist.
ERROR DESCRIPTION	This can result in the mixing of patient data between exams for the two patients. This can include patient demographic information, images, measurements, and calculations.
SUGGESTED WORKFLOW TO PREVENT ERROR	If you accidentally enter the details for the incorrect patient when starting an exam, immediately end and delete the erroneous exam. Check the other patient’s exams to confirm that the action did not inadvertently change the patient name. Then start a new patient exam for the intended patient through the **Patient Data** form or **Worklist** tab as usual.

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ISSUE 2

PRODUCTS IMPACTED	All EPIQ and Affiniti Ultrasound Systems (models EPIQ 5G, EPIQ 5C, EPIQ 5W, EPIQ 7G, EPIQ 7C, EPIQ 7W, EPIQ CVx, Affiniti 30, Affiniti 50, and Affiniti 70) running software versions 1.5.x, 1.7.x, 1.8.x, 2.0.x, 3.0.x, 4.0 worldwide, or 1.5.x, 1.7.x, 1.8.x, 1.9.x, 2.1.x. China Only.
THIS IS ONLY RELEVANT TO YOU IF	• You have the Single Report per Study setting enabled in Setups. And • You use Modality Worklist.
ISSUE WORKFLOW	• You attempt to start a new exam from the worklist while you are reviewing an exam for a different patient. And • The new patient selected from the worklist happens to already have a previous exam stored on the system.
ERROR DESCRIPTION	The system will mix the patient data between the previous exam and the exam currently open for review. This can include patient demographic information, images, measurements, and calculations.
SUGGESTED WORKFLOW TO PREVENT ERROR	Always close and/or end an exam before attempting to start a new one.

ISSUE 3

PRODUCTS IMPACTED	All EPIQ and Affiniti Ultrasound Systems (models EPIQ 5G, EPIQ 5C, EPIQ 5W, EPIQ 7G, EPIQ 7C, EPIQ 7W, EPIQ CVx, Affiniti 30, Affiniti 50, and Affiniti 70) running software versions 1.0.x, 1.1.x, 1.2.x, 1.3.x, 1.4.x, 1.5.x, 1.7.x, 1.8.x, 2.0.x, 3.0.x worldwide, or 1.0.x, 1.1.x, 1.2.x, 1.3.x, 1.4.x, 1.5.x, 1.7.x, 1.8.x China Only.
ISSUE WORKFLOW	• You exit the **Patient Data** form by means other than clicking the **Done** button (such as pressing **Setups** or **Support**). Or • You start exams using the Temporary ID feature.
ERROR DESCRIPTION	When you start a new patient exam, you may see the last frozen image from the previous patient's exam on the display.
SUGGESTED WORKFLOW TO PREVENT ERROR	If you see a frozen image of the previous patient, simply unfreeze the image and return to live imaging. Then perform your new exam as usual.

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ISSUE 4

PRODUCTS IMPACTED	All EPIQ and Affiniti Ultrasound Systems (models EPIQ 5G, EPIQ 5C, EPIQ 5W, EPIQ 7G, EPIQ 7C, EPIQ 7W, EPIQ CVx, Affiniti 30, Affiniti 50, and Affiniti 70) running software versions 1.0.x, 1.1.x, 1.2.x, 1.3.x, 1.4.x, 1.5.x, 1.7.x, 1.8.x, 2.0.x, 3.0.x, 4.0.x, 5.0, 5.0.1 worldwide, or 1.0.x, 1.1.x, 1.2.x, 1.3.x, 1.4.x, 1.5.x, 1.7.x, 1.8.x, 1.9.x, 2.1.x. China Only.
ISSUE WORKFLOW	You put the system into Sleep mode or disconnect the power cord, after you have filled out the **Patient Data** form and before you have captured any images.
ERROR DESCRIPTION	When you restart the system, the **Patient Data** form may still show the Height, Weight, and BSA for the previous exam.
SUGGESTED WORKFLOW TO PREVENT ERROR	When starting a new patient exam, make sure to review the Height, Weight, and BSA fields to ensure that they correctly show the information for the current patient.

ASSOCIATED HEALTH RISKS	If a user is unaware of the patient data error, there is a potential for the following risks: • Delay of treatment • Loss of patient data • Misdiagnosis
ACTIONS PLANNED BY PHILIPS	Philips is providing this customer letter with guidance and suggested workflow instructions to prevent the potential issues.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741

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Customer Reply Form

Please complete and email to safetynoticeuki@philips.com

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

CUSTOMER ACKNOWLEDGEMENT:

☐ **I reviewed and understand this Urgent Medical Device Correction Letter.**

_____ _____

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 or the UK Philips Customer Care Service Centre on 0870 532 9741.