PHILIPS

URGENT FIELD SAFETY NOTICE

Philips EPIQ & Affiniti Ultrasound Systems
System Lock-Up Issue

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.

21-JUL-2021

Dear Customer,

A problem has been identified in the Philips EPIQ & Affiniti Ultrasound Systems that could pose a risk for patients. This Field Safety Notice is intended to inform you about:

1. **What the problem is and under what circumstances it can occur**

   Due to a software defect, when reviewing or adjusting xPlane exam results, there is a potential for EPIQ & EPIQ Affiniti Ultrasound systems to become unresponsive (Lock-up) preventing users from continuing clinical use. The ultrasound system provides an error notification including method to restart and bring system back to normal use.

   Philips received a report of an EPIQ Ultrasound system locking up multiple times during an open cardiac procedure while using a Transesophageal Echocardiogram (TEE) transducer. Each lock-up required at least one system reboot to regain functionality. The procedure was successfully completed with no adverse effects to the patient.

   Philips has not been made aware of any reported injuries related to this issue.

2. **Describe the hazard/harm associated with the issue**

   If imaging failure were to occur during open-heart surgery while the patient is on cardiac bypass, time on bypass will be prolonged while the machine is replaced or rebooted, adding to the time during which known complications of cardiac-bypass may occur. Complications may include: stroke, kidney damage, bleeding, cardiac arrhythmias, embolism, and pulmonary/respiratory issues.

3. **Affected products and how to identify them**

System	Model	Software Version
EPIQ	EPIQ 5C EPIQ 5G EPIQ 7C EPIQ 7G EPIQ CVx EPIQ CVxi	5.0 5.0.1 5.0.2
Affiniti	Affiniti 30 Affiniti 50 Affiniti 70	5.0 5.0.1 5.0.2

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Instructions for how to determine the software version of your Ultrasound system:

1. Power up the system and allow it to complete the boot sequence
2. Press ***Support*** on the right side of the control panel
3. Under **System Management,** click ***System Information***
4. The software version is listed in the **Software Information Section**.

4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients or users

Because the software defect may intermittently cause the system to lock-up when exiting Review mode, please take the following steps to minimize the likelihood of occurrence:

1. Acquire a loop while in xPlane, xPlane Doppler, or Dual mode.
2. Do NOT adjust an imaging control (for example: Rotate, Tilt, Gain) while the loop capture is in progress.*
3. Allow the loop capture to complete normally. The system will indicate when it has completed the capture.

*If the imaging controls have been adjusted during the loop capture, Philips recommends that the system be rebooted prior to reviewing the loop in Review mode.

At this point the loop can be viewed in Review mode and imaging controls can be applied normally.

<Please complete and return this form to Philips promptly and no later than 30 days from receipt via email to: > < ***Philips representative contact details to be completed by the Market*** >

5. Describe the actions planned by Philips Ultrasound to correct the problem

Philips is providing this customer letter containing guidance and alternative process steps to mitigate potential issues.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. 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*** > and reference FCO79500535.

Sincerely,

Thuy Nguyen
Quality and Regulatory Leader – Ultrasound

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: Philips EPIQ & Affiniti Ultrasound Systems Lock Up Issue FCO79500535.

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:

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*If the imaging controls have been adjusted during the capture, Philips recommends that the system be rebooted prior to reviewing the loop in Review mode.

At this point the loop can be viewed in Review mode and imaging controls can be applied normally.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the EPIQ & Affiniti Ultrasound Systems.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please send this completed form to <***Philips** representative contact details to be completed by the Market***>**