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URGENT FIELD SAFETY NOTICE
UPDATED

Philips EPIQ & Affiniti Ultrasound Systems
System Lock-Up Issue and PW Doppler
Signal Dual Mode 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.

04 - OCT - 2021

Dear Customer,

This notice contains updates to our previous Urgent Field Safety Notice dated 05-August-2021.
This notice is intended to supersede the previous version and contains the following updates:

- Provides information on a second issue identified with the EPIQ and Affiniti Ultrasound Systems
- *Actions taken by Philips* (section 5) has been updated to indicate that Philips will be providing a software solution that will address both issues.

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

- Issue #1: Potential lock-up in x-plane
- Issue #2: Potential Compromise of Pulse Wave Doppler Signal using Dual Mode

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

Issue #1: Potential lock-up in x-plane

Due to a software issue, when reviewing or adjusting xPlane exam results, there is a potential for EPIQ & Affiniti Ultrasound systems to become unresponsive (Lock-up) preventing users from continuing clinical use. The lock-up can occur if the user changes imaging controls (for example: Tilt, Rotate, Gain etc.) while the loop capture is in progress, then proceeds to leave the live imaging modes, goes into “Review” mode, reviews the image(s) and goes back to live imaging modes during the same procedure. If the user follows these steps, the lock-up could potentially occur when they return to live imaging modes during the same procedure. If this occurs, 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.

Issue #2 - Pulse Wave Doppler Signal Dual Mode

Issue Description
Philips Ultrasound has identified an issue where the Pulse Wave (PW) Doppler signal, both visual and

audio can be compromised under specific workflows.

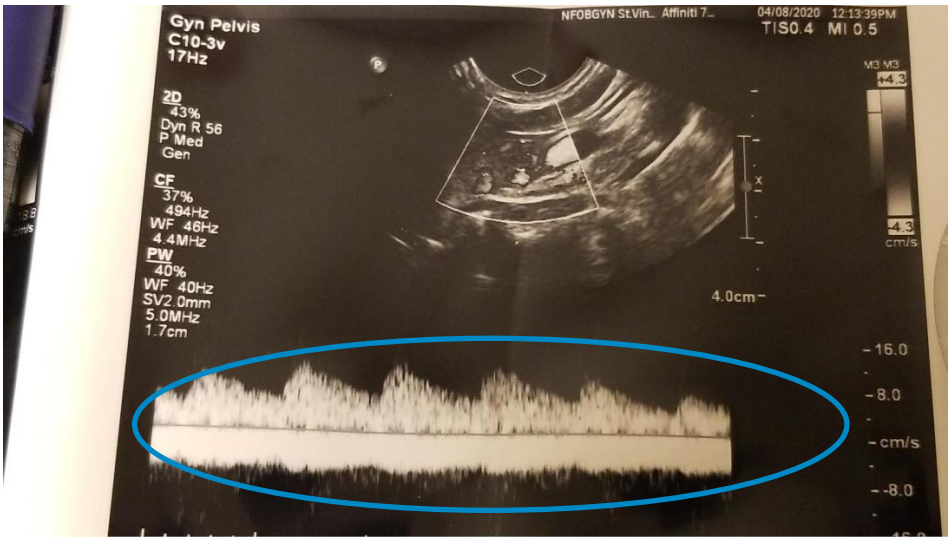

Figure 1

Figure 1 shows a normal PW Doppler signal, highlighted in the blue oval.
When the issue occurs, this signal is compromised as shown in Figure 2 below, highlighted by the red oval.

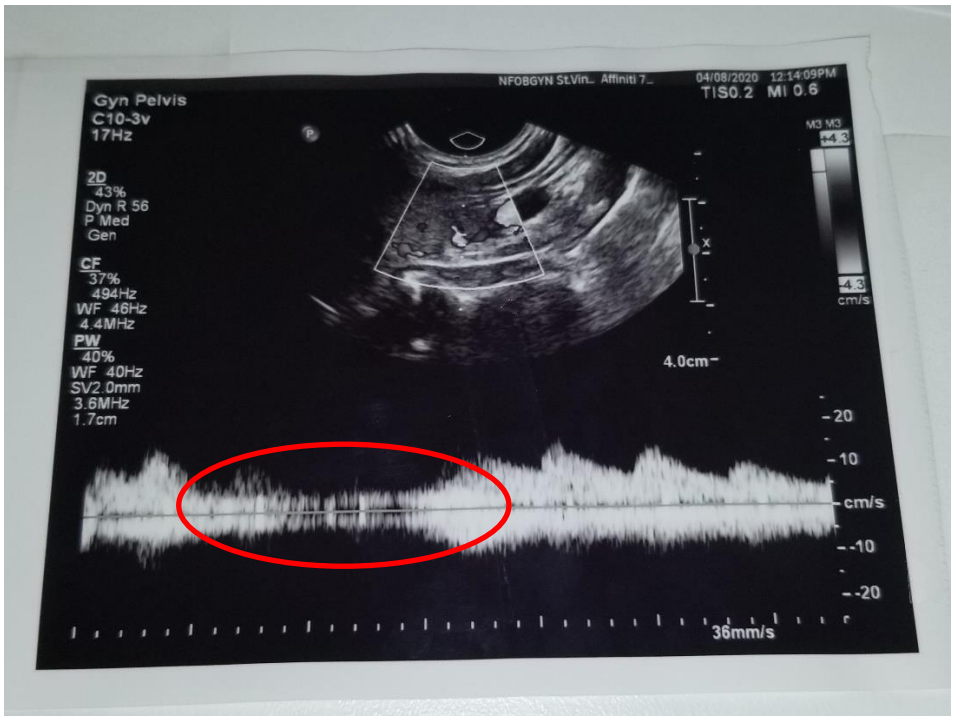

Figure 2

Issue Reproduction
The issue occurs if a user enters Dual Mode, exits Dual Mode and then turns on the PW Doppler signal. The PW Doppler signal cannot be engaged while in Dual Mode, so the user must leave this Mode to use PW Doppler. At this point, having been in Dual Mode creates the issue in the PW Doppler Signal.

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

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2. Describe the hazard/harm associated with the issue

Issue #1: Potential lock-up in x-plane

If imaging failure were to occur during open-heart surgery while the patient is on cardiac bypass, the time the patient remains on cardiac bypass will be prolonged while the system 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.

Issue #2 - Pulse Wave Doppler Signal Dual Mode

Clinical Risk Scenario
Based on the nature of the issue, the specific scenario which incurs Clinical Risk is if the user is attempting to image blood flow which is present, but the issue indicates that it is not.

More specifically, the stated harms may occur if the below three elements are applicable in a given procedure:

- PW Doppler is the sole imaging modality to determine if blood flow is present,
- There is no other method for the user to validate that blood flow is present and
- The user concludes from the image that the patient does not have blood flow

This may lead to:

- Misdiagnosis of the clinically significant condition
- Wrong treatment / delay of treatment
- Incorrect therapy being ordered
- Unnecessary therapy/ treatment

3. Affected products and how to identify them

Issue #1: Potential lock-up in x-plane

Table 1

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

Issue #2 - Pulse Wave Doppler Signal Dual Mode

Table 2

System	Model	Affected Software Version	Affected Transducers
EPIQ	EPIQ 5C EPIQ 5G EPIQ 5W EPIQ 7C EPIQ 7G EPIQ 7W EPIQ CVx	5.0 5.0.1 5.0.2	C10-3v C10-4ec C5-1 C8-2 C9-2 eL18-4

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System	Model	Affected Software Version	Affected Transducers
	EPIQ CVxi		L12-3 L12-3ergo L12-5 L15-7io S7-3t S8-3t V9-2 X6-1 X7-2t
Affiniti	Affiniti 30 Affiniti 50 Affiniti 70	5.0 5.0.1 5.0.2	BP10-5ec C10-3v C10-4ec C5-1 C6-2 C8-5 C9-2 C9-4v L12-3 L12-3ergo L12-4 L12-5 L15-7io V9-2

For both Issue #1 and Issue #2

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**.
5. If you have software versions 5.0, 5.0.1 or 5.0.2 proceed with the actions in step 4.

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

1. Circulate this notice to all users of this device so they are aware of the product issue and associated hazard/harm.
2. Post this notice near the affected EPIQ or Affiniti unit(s) for ease of reference.
3. Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt via email to: ultrasound.corrections@philips.com or fax to 1-833-512-7756.

Until Philips has updated your systems with FCO79500535, please continue to follow the instructions below to mitigate the identified issues.

Issue #1: Potential lock-up in x-plane

Because the software issue may intermittently cause the system to lock-up when exiting Review mode, please take the following steps to minimize the likelihood of occurrence. The following steps can also be found in the device user manual:

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.

NOTE: 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.

Issue #2 - Pulse Wave Doppler Signal Dual Mode

Prevention
The user has an option for preventing the effect of the issue.

The PW Doppler function can be used prior to entering Dual Mode. This avoids the issue by **preventing** the Dual Mode from impacting the use of the PW Doppler function.

Mitigation
The user has two options for mitigating the effect of the issue.

1) The user can reselect the transducer after exiting Dual Mode which will resolve the issue in the signal allowing normal use of the PW Doppler function. Note, this mitigation would need to be used each time the user goes into and exits Dual Mode. Note, any function which reselects the transducer, such as closing and opening the exam will also solve the problem.
2) The user can validate their PW Doppler signal using a different Doppler Mode such as Color Doppler. Color Doppler is not affected by this issue. Note, Color Doppler is a different clinical function. However, its output correlates to the PW Doppler output to indicate to the user there is a problem.

These mitigations can be applied within a few seconds.

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 the potential issues.

A Philips Field Service Engineer or Representative will contact you to schedule a software update for all ultrasound systems that have VMQ5.0., 5.0.1 or 5.0.2 software to permanently resolve these issues (reference FCO79500535).

This notice has been reported to the appropriate Regulatory Agencies. 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, or by regular mail, or by fax.

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 System Lock-Up Issue and PW Doppler Signal Dual Mode 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:

1. Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm.

2. Attach this notice as an addendum to the EPIQ or Affiniti IFU (User Manual) for ease of reference.

3. Until Philips has installed your update in the system, continue to follow the mitigations provided in section 4 of the Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this notice 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***>**