

URGENT Field Safety Notice

EPIQ CVxi Diagnostic Ultrasound Systems
EchoNavigator System Error

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.

13-SEP-2021

Dear Customer,

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

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

Philips has become aware of a software issue that can potentially cause the EPIQ CVxi system to issue an error notification and become unresponsive during clinical use.

This issue can occur during ultrasound-guided Transesophageal Echocardiogram (TEE) procedures with EPIQ CVxi EchoNavigator, but only if secondary screen capture is enabled (recording real-time fusion of echocardiography and X-ray) and the user presses other buttons on the EPIQ system before the secondary capture has been completed.

If the above sequence causes the system to become unresponsive, the user will be prompted to restart the system. Once restarted the system is available for normal clinical use.

As of September 2021, there have been no reports of harm associated with this issue.

2. Describe the hazard/harm associated with the issue

If the EPIQ system becomes unresponsive during clinical use, there is a potential for delay of therapy/treatment (due to restart of the system), and/or administration of unnecessary therapy/treatment to the patient (due to the need to use an alternative imaging method).

3. Affected products and how to identify them

Our records indicate you have one or more of the potentially affected systems.

Product Code	Product Description	Software Version
795232	EPIQ CVxi Ultrasound System	6.0, 7.0, 7.0.3

All EPIQ CVxi Ultrasound Systems with the software versions listed above are affected by this issue.

Instructions for how to determine the software version of your EPIQ CVxi 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,

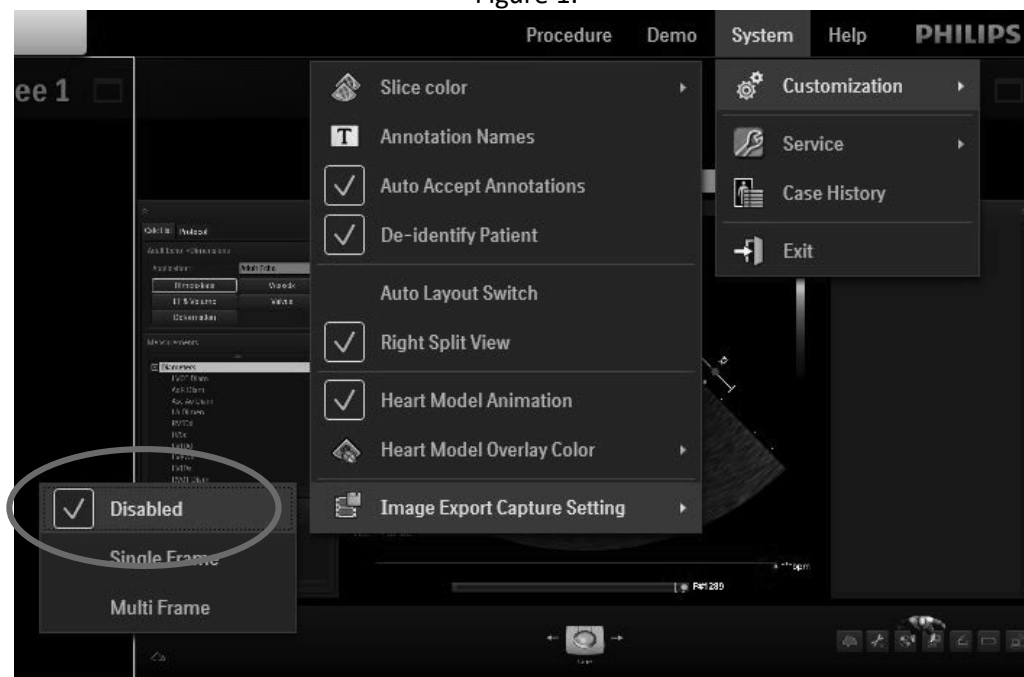
3. Under **System Management**, click **System Information**,
4. The software version is listed in the **Software Information Section**.

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

- Philips recommends that you disable the secondary screen capture feature (i.e., *Image Export Capture Setting*) in the EchoNavigator system settings to prevent the system from becoming unresponsive due to this issue (as shown in Figure 1).

NOTE: The secondary screen recording feature is enabled as a default setting for all EPIQ CVxi EchoNavigator based TEE exams.

Figure 1.



- < Please complete and return the attached 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

A Philips Field Service Engineer will contact you to schedule a software update to permanently resolve the issue (reference FCO79500548).

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: < *Philips representative contact details to be completed by the Market* > and reference FCO79500548.

Sincerely,

Thuy Nguyen
Quality & Regulatory Leader – Philips Ultrasound

URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: EPIQ CVxi EchoNavigator System Error (FCO79500548)

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: _____

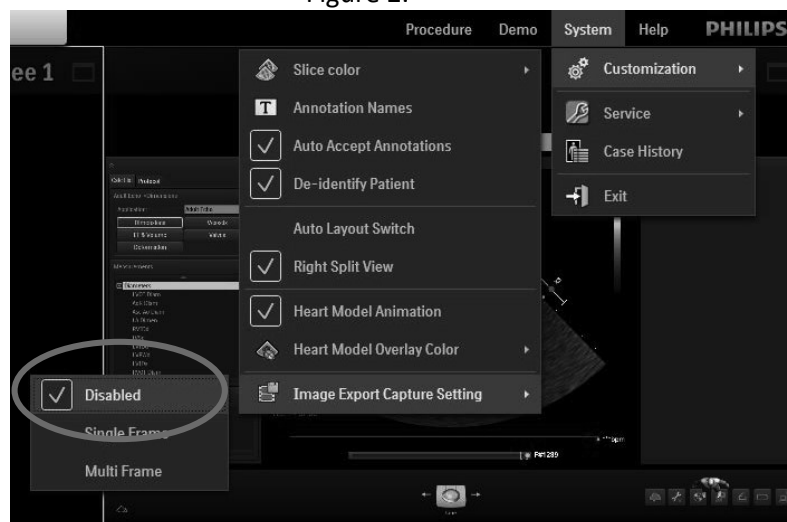
City/State/ZIP/Country: _____

Customer Actions:

Philips recommends that you disable the secondary screen capture feature (i.e., *Image Export Capture Setting*) in the EchoNavigator system settings to prevent the system from becoming unresponsive due to this issue (as shown in Figure 2).

NOTE: The secondary screen recording feature is enabled as a default setting for all EPIQ CVxi EchoNavigator based TEE exams.

Figure 2.



We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the EPIQ CVxi EchoNavigator 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>