

URGENT - Field Safety Notice

Philips EPIQ Ultrasound Systems
Control Panel Arm Swivel Locking Failure

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.

28-JUL-2021

Dear Customer,

A problem has been identified in the Philips EPIQ 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

The EPIQ Ultrasound Systems control panel arm locking mechanism, intended to prevent side-to-side movements, could fail, preventing it from locking properly. If the control arm fails to lock, this could cause the control panel and monitor to swivel freely while a user is positioning the monitor for better viewing or while a user is transporting or moving the system. Philips has received reports of 2 minor injuries related to this issue.

2. Describe the hazard/harm associated with the issue

If the control panel arm locking mechanism fails while a user is positioning the monitor or transporting the system, musculoskeletal injury may occur to either the patient or the user.

3. Affected products and how to identify them

System	Model	Manufactured
EPIQ	EPIQ Elite EPIQ 5G EPIQ 5C EPIQ 5W EPIQ 7G EPIQ 7C EPIQ 7W EPIQ CVx EPIQ CVxi	Between 2020-02-27 to 2021-05-25 (Refer to the main system label shown below for the manufactured date)



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

When Positioning or Transporting/Moving the EPIQ Ultrasound System:

- Prior to positioning or transporting/moving the system, ensure the control panel locking mechanism is engaged to prevent the control panel and monitor from swiveling freely.
- To ensure the control panel locking mechanism is working properly:
 1. Engage the system brake.
 2. Observe the lock/unlock button on the system handle. It should not be illuminated.
 3. If it is illuminated press button to lock arm. Illumination should cease and arm should lock.
 4. Using the system handle, attempt to rotate the control panel. If the control panel does not rotate, the system is locked and ready to be transported/moved.
 5. Release the brake and transport/move the system as needed.
- Do not make any twisting or sudden motions with the control panel when adjusting or steering the system.
- When transporting/moving the system, push from behind using the back handles on the control panel.

Please complete and return the attached form to Philips promptly and no later than 30 days from receipt via email to safetynoticeuki@philips.com

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

A Philips Field Service Engineer will visit your site and inspect your EPIQ system(s). Any systems that fail the inspection will be corrected.

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 or the UK Philips Customer Care Service Centre on 0870 532 9741 and reference FCO79500549.

Sincerely,

Thuy Nguyen Quality & Regulatory Leader - Philips Ultrasound

URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: Philips EPIQ Ultrasound Systems Control Panel Arm Swivel Locking Failure FCO79500549.

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 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:

When Positioning or Transporting/Moving the EPIQ Ultrasound System:

- Prior to positioning or transporting/moving the system, ensure the control panel locking mechanism is engaged to prevent the control panel and monitor from swiveling freely.
- To ensure the control panel locking mechanism is working properly:
 1. Engage the system brake.
 2. Observe the lock/unlock button on the system handle. It should not be illuminated.
 3. If it is illuminated press button to lock arm. Illumination should cease and arm should lock.
 4. Using the system handle, attempt to rotate the control panel. If the control panel does not rotate, the system is locked and ready to be transported/moved.
 5. Release the brake and transport/move the system as needed.
- Do not make any twisting or sudden motions with the control panel when adjusting or steering the system.
When transporting/moving the system, push from behind using the back handles on the control panel.

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 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 safetynoticeuki@philips.com