PHILIPS

URGENT Field Safety Notice

Philips Allura Xper R8.1.x and R8.2.x systems with FlexVision monitor
Software issue causing a blank screen or frozen FlexVision display, potentially resulting in delay of therapy, procedural complications, and/or inadequate or inappropriate treatment.

01-OCT-2026

This document contains important information for the continued safe and proper use of your device

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.

Dear Customer,

Philips has become aware of a potential safety issue affecting Allura Xper R8.1.x and R8.2.x systems with a FlexVision monitor and is initiating a Field Safety Corrective Action to address this issue.

This URGENT Field Safety Notice (FSN) provides important information regarding the nature of the issue, the potential risks to patients, and the actions required to mitigate those risks until Philips implements the Field Safety Corrective Action.

1. Issue Description

Philips has identified a software issue that may cause the FlexVision software application to become unresponsive during clinical use. When this occurs, the FlexVision monitor may either:

- turn blank and no longer display live images or other information shown on the FlexVision monitor; or
- freeze on the last displayed screen and no longer update live images or other information shown on the FlexVision Monitor.

A cold system restart is required to restore normal FlexVision display functionality.

2. Hazard/harm associated with the issue

A blank or frozen FlexVision monitor may contribute to a delay of therapy. Additionally, when the FlexVision monitor freezes on the last displayed screen, the displayed image may appear valid while no longer reflecting the current clinical situation. This may not be recognized immediately and could result in procedural complications, and/or inadequate or inappropriate treatment.

The patient population most at risk includes those undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial infarction, life-threatening bleeding). For patients requiring urgent intervention, a delay in therapy may contribute to further deterioration of an already critical condition and could potentially lead to death.

To date, Philips has received one report of death potentially associated with this issue.

3. Affected products and how to identify them

Philips Allura Xper systems with software releases R8.1.x or R8.2.x and configured with a FlexVision monitor are affected. **Appendix A** to this letter includes instructions on how to identify the affected system.

4. Actions that should be taken by the customer / user

- Customers may continue to use affected systems in accordance with their intended use, subject to the actions below.
- If the FlexVision monitor becomes blank or freezes on the last displayed screen during a procedure, suspend image-guided device manipulations, and perform a cold system restart following the steps described in the instructions for Use:
  - Press the System OFF button on the Xper review module for more than 10 seconds.
  - The system performs a controlled shutdown
  - Press the System ON button on the Xper review module

  NOTE: A cold restart of the system takes up to 6 minutes from initiation of the cold restart until all system functionality is available.
- Ensure this notice is distributed to all relevant users and retained with the device documentation until corrective actions are completed.
- Post this notice near affected systems for ease of reference, where applicable.
- If the affected system has been transferred to another organization, please forward this notice to that organization and inform Philips through your local representative.
- Keep this FSN with the documentation of the system until Philips corrects your system.
- If you experience the issue described in this notice, report it to your local Philips representative.
- Complete and return the response form included in FSN to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the FSN and understanding of the issues and required actions to be taken.

5. Actions planned by Philips Image Guided Therapy Systems

Philips will be implementing a software correction free of charge to address the issue. Philips is planning to commence implementation of this software update by July 2028. A Philips representative will contact you to schedule the correction.

If you need any further information or support concerning this matter, please contact your local Philips representative at the Philips Customer Care Service Centre by:

Telephone: UKI: +448000260086
NI: +448000260430
ROI: +3531800832340

Email: UKFCO@philips.com

This notice has been reported to the appropriate regulatory authorities, in accordance with applicable regulations.

Philips regrets any inconvenience caused by this matter.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

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URGENT Field Safety Notice Response Form

Reference: 2026-IGT-BST-002 Philips Allura Xper R8.1.x and R8.2.x systems with FlexVision monitor: Software issue causing a blank screen or frozen FlexVision display, potentially resulting in delay of therapy, procedural complications, and/or inadequate or inappropriate treatment.

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 FSN, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:	
Street Address:	
City/Postcode:	

We acknowledge receipt and understanding of the accompanying FSN and confirm that the information from this notice has been properly distributed to all users that handle the Philips affected Allura Xper system(s).

Name of person completing this form:

Signature:	
Printed Name:	
Title:	
Telephone Number:	
Email Address:	
Date (DD / MMM / YYYY):	

It is important that your organization acknowledges receipt of this notice. Your response helps us ensure that this communication has been received and that appropriate actions can be effectively implemented.

Please return the completed and signed reply form to **UKI_Quality_CR@philips.com**

Appendix A - Affected Systems

This correction applies to the Allura Xper systems with software releases R8.1.x or R8.2.x and a FlexVision monitor listed in Table 1 below.

Model Number	System Product Name
722003	Allura Xper FD10
722005	Allura Xper FD10/10
722006	Allura Xper FD20
722008	Allura Xper FD20 Biplane
722010	Allura Xper FD10
722011	Allura Xper FD10/10
722012	Allura Xper FD20
722013	Allura Xper FD20 BIPLANE
722022	Allura Xper FD10 OR TABLE
722023	Allura Xper FD20 OR TABLE
722024	Allura Xper FD10/10 OR Table
722025	Allura Xper FD20 Biplane OR Table
722026	Allura Xper FD10
722027	Allura Xper FD10/10
722028	Allura Xper FD20
722029	Allura Xper FD20/10
722033	Allura Xper FD10 OR Table
722034	Allura Xper FD10/10 OR Table
722035	Allura Xper FD20 OR Table
722036	Allura Xper FD20/10 OR Table
722038	Allura Xper FD20/20
722039	Allura Xper FD20/20 OR Table
722058	Allura Xper FD20/15
722059	Allura Xper FD20/15 OR Table

Table 1 – List of affected systems

The System Product Name and Model Number can be found on the System Identification Label located on the System stand (Figure 1). The software release version of the Philips Allura system can be identified during start-up (Figure 2).

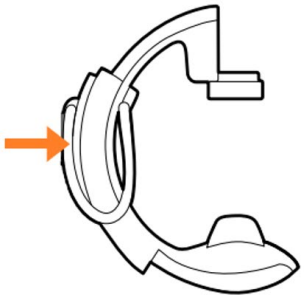


Figure 1 - System Identification Label

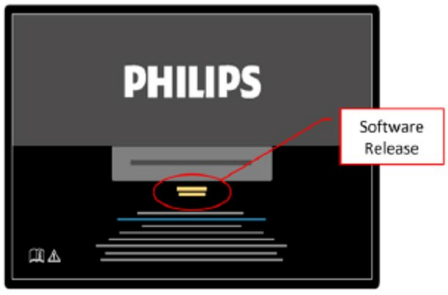


Figure 2 - System Start-up Screen