PHILIPS

URGENT Field Safety Notice

Philips Azurion and Allura Systems
Potential loss of imaging functionality (Allura/Azurion), loss of motorized movement (Allura), or loss of data (Allura) due to aging Hard Disk Drives

30-APR-2026

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.

Please retain this letter for your records.

Dear Customer,

Philips has identified a potential safety issue with the Hard Disk Drives (HDDs) used in Philips Azurion and Allura systems. As HDDs age, particularly beyond six years of service, the likelihood of a performance issue that may lead to loss of imaging functionality (Allura and Azurion systems) and, for Allura systems, also loss of motorized movement or loss of data, may increase. This URGENT Field Safety Notice is intended to inform you about:

1. What the issue is and under what circumstances it can occur
Philips has identified that HDDs used in the PCs of Azurion and Allura systems may show a decrease in performance as they age, particularly beyond six years of service. Issues with an HDD may, depending on the specific system PC in which the affected HDD is installed, result in loss of imaging functionality. Additionally, in Allura systems, this may lead to loss of motorized movement, or loss of data. In some cases, a system restart may temporarily restore functionality.

2. Hazard/harm associated with the issue
This issue may potentially result in or contribute to procedural complications and/or a delay of therapy, potentially resulting in serious adverse health outcomes. Patients undergoing complex or urgent interventions may be most affected, as delays or interruptions could impact clinical workflow and decision-making.

The estimated probability of serious adverse health outcomes is improbable. Philips has not received any reports of harm associated with this issue.

3. Affected products and how to identify them
Philips Azurion and Allura series are affected by this issue. Appendix A to this letter provides a table with the System Codes, Commercial Names, and the intended use of the affected systems.

PHILIPS

4. Actions that should be taken by the customer / user that are aimed at lowering risks for patients

- Circulate this Urgent Field Safety Notice to all users of the system so that they are aware of the issue and follow the instructions below.
- In case motorized movements are unavailable, the stand can be manually repositioned using the handgrips and brake controls located on both sides of the stand. For ceiling-mounted systems, manual longitudinal (1), transversal (2) and rotational (3) stand movements remain available. Note: Transversal stand movements (2) are only available for ceiling-mounted systems with the FlexMove option. For floor-mounted systems, only rotational (3) stand movements remain available. The table longitudinal position (4) can be adjusted manually, when the table is not tilted (see Figure 1 below).

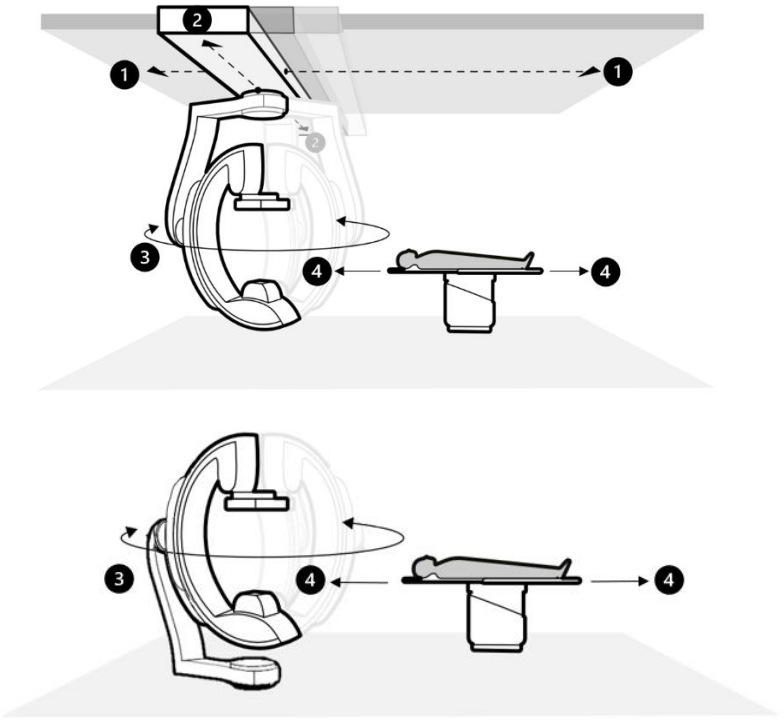

Figure 1 – Manual movements of the ceiling-mounted system (top) and floor-mounted system (bottom)

- In case the affected system has been transferred to another organization, please send a copy of this Urgent Field Safety Notice to that organization and inform Philips about this transfer through your local Philips representative.
- Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure that the letter is in a place likely to be seen/viewed.
- Complete and return the response form included in this Urgent Field Safety Notice to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice and understanding of the issue and required actions to be taken.
- If you experience the issue described in this letter, please report it to your local Philips representative.

5. Actions planned by Philips Image Guided Therapy Systems to correct the issue

Philips will replace the HDDs in all affected systems. Philips expects to start replacing the HDDs in September 2026. A local Philips representative will contact you to schedule a visit to replace the HDDs in your system.

PHILIPS

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this matter, contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this matter.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

PHILIPS

URGENT Field Safety Notice Response Form

Reference: 2025-IGT-BST-005: Potential loss of imaging functionality (Allura/Azurion), loss of motorized movement (Allura), or loss of data (Allura) due to aging HDDs.

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:

- Circulate this Urgent Field Safety Notice to all users of the system so that they are aware of the issue and follow the instructions below.
- In case motorized movements are unavailable, the stand can be manually repositioned using the handgrips and brake controls located on both sides of the stand. For ceiling-mounted systems, manual longitudinal (1), transversal (2) and rotational (3) stand movements remain available. Note: Transversal stand movements (2) are only available for ceiling-mounted systems with the FlexMove option. For floor-mounted systems, only rotational (3) stand movements remain available. The table longitudinal position (4) can be adjusted manually, when the table is not tilted (see Figure 1 below).

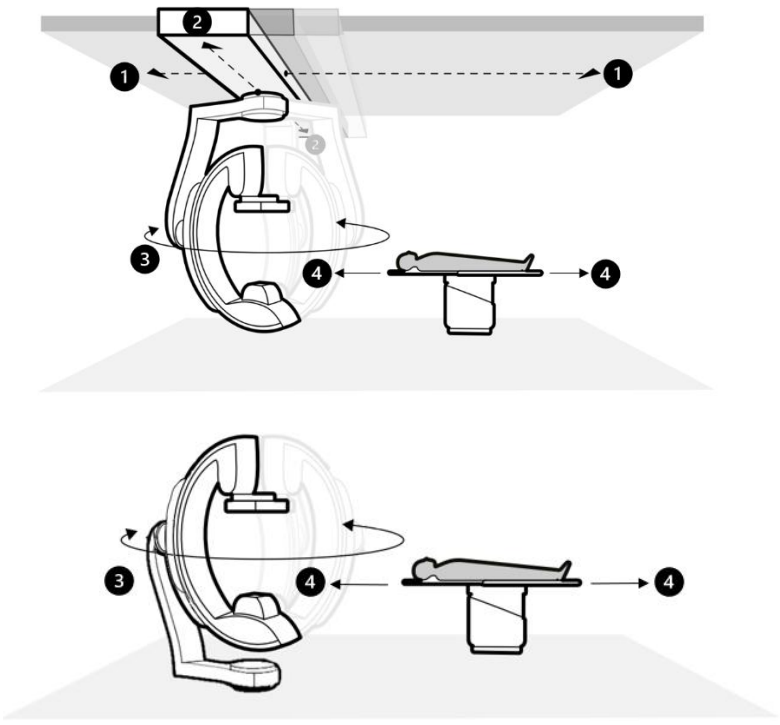

Figure 1 – Manual movements of the ceiling-mounted system (top) and floor-mounted system (bottom)

- In case the affected system has been transferred to another organization, please send a copy of this Urgent Field Safety Notice to that organization and inform Philips about this transfer through your local Philips representative.
- Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure that the letter is in a place likely to be seen/viewed.

PHILIPS

- If you experience the issue described in this letter, please report it to your local Philips representative.

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 affected Philips Azurion and/or Allura systems.

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 letter. Your organization's reply is the evidence required to monitor the progress of this Urgent Field Safety Notice.

PHILIPS

Appendix A - Affected Systems and Intended Use

System Code	Commercial 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
722015	ALLURA XPER FD20 OR TABLE
722022	ALLURA XPER FD10 OR TABLE
722023	ALLURA XPER FD20 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
722035	Allura Xper FD20 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
722063	Azurion 3 M12
722064	Azurion 3 M15
722067	Azurion 7 B12
722068	Azurion 7 B20
722078	Azurion 7 M12
722079	Azurion 7 M20
722221	Azurion 3 M12
722222	Azurion 3 M15
722223	Azurion 7 M12
722224	Azurion 7 M20
722225	Azurion 7 B12
722226	Azurion 7 B20
722227	Azurion 5 M12
722228	Azurion 5 M20
722400	Allura Centron

The System Code and Commercial Name can be found on the System Identification Label located on the system stand (see Figure 2).

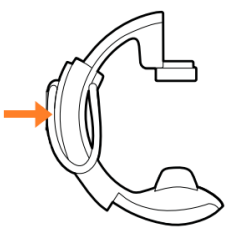

Figure 2 - System Identification Label

PHILIPS

Intended Use

The Azurion series (within the limits of the used operating room table) is intended for use to perform:

- Image guidance in diagnostic, interventional, and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular, and neuro procedures.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures.

Additionally:

- The Azurion series can be used in a hybrid operating room.
- The Azurion series contains a number of features to support a flexible and patient-centric procedural workflow.

The Azurion series is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.

The **Allura Xper series** is intended for use on human patients to perform:

- Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

Additionally:

  - The Allura Xper series is compatible with a hybrid Operating Room.
  - The Allura Xper FD 10 Systems are compatible with specified magnetic navigation systems.

The Allura Xper series is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.

The **Allura Centron** system (within the limits of the used operating room table) is intended to perform:

- Vascular diagnostic and interventional procedures (Angiogram, Balloon Angioplasty, Stenting)
- Cardiac diagnostics and interventions (PCI)
- Pacemaker implantations and implantable defibs
- Electrophysiology (EP) and RF ablation
- Non-vascular interventions such as drainages, biopsies and vertebroplasty procedures

The Allura Centron is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.