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URGENT Field Safety Notice

Philips Azurion and Allura with 1 Phase UPS
Potential Loss of System Functionality

July 2025

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 become aware of a potential safety issue with Philips Azurion and Allura systems configured with a 1 Phase Uninterruptible Power Supply (UPS). This URGENT Field Safety Notice Letter is intended to inform you about:

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

The 1 Phase UPS is an optional component that can be installed in Allura and Azurion systems to support a controlled shutdown of the PCs (the computers that control the system) in the event of a mains power failure. The 1 Phase UPS provides temporary power to the PCs, allowing the system to save the data of the last acquired run before the PCs shut down.

Philips has identified that some internal components of the 1 Phase UPS may fail. When this occurs, there will be a complete loss of power to the system, causing the system to shut down and/or not start up. The 1 Phase UPS system may fail without warning and prior to any mains power failure.

2. Hazard/harm associated with the issue

If the system does not start up or the system shuts down, there is a potential risk of delay or termination of the procedure. The potential delay in treatment and/or termination of the procedure may result in serious adverse health outcomes, including the possibility of death, especially when the system is used with critical patients, particularly those undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia).

In the period from January 2022 to May 2025, Philips has received 153 complaints related to Azurion systems and 32 complaints related to Allura systems associated with this issue. None of these complaints reported any harm to the patient.

3. Affected products and how to identify them

Affected products are the Philips Azurion and Allura systems that are configured with a 1 Phase UPS. The 1 Phase UPS is an option for the Allura and Azurion systems. The following systems can be configured with a 1 Phase UPS:

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Product Number	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
722023	Allura Xper FD20 OR Table
722026	Allura Xper FD10
722027	Allura Xper FD10/10
722028	Allura Xper FD20
722029	Allura Xper FD20/10
722035	Allura Xper FD20 OR Table
722038	Allura Xper FD20/20
722058	Allura Xper FD20/15
722059	Allura Xper FD20/15 OR Table

Product Number	Product Name
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
722282	Azurion 7 M20

The Product Number and Product Name can be found on the System Identification Label (Figure 1).

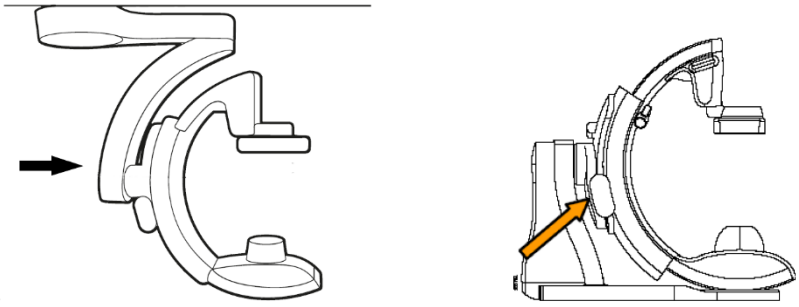

Figure 1: Location of the System identification label

The **Azurion series** 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.

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 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, embolization 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

4. Actions that should be taken by the customer /user in order to prevent risks for patients

- Affected systems may continue to be used in accordance with their Instructions for Use (IFU).
- Circulate this Urgent Field Safety Notice Letter to all users so that they are aware of the issue. Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system.
- Establish an emergency protocol prior to all applicable diagnostics, interventional and minimally invasive procedures to manage the situation should you experience the issue during a procedure.
- In case the affected system has been transferred to another organization, please send a copy of this Urgent Field Safety Notice letter to that organization and inform Philips about this transfer through your local Philips representative.
- Complete and return the attached response form 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 actions required.
- Should you experience the issue reported in this letter, please report the event to Philips through your local Philips representative.

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

Philips will bypass the 1 Phase UPS in the affected systems (disconnecting all connections of the 1 Phase UPS but not removing it physically). This will render the 1 Phase UPS inactive, preventing the occurrence of the above-described issue. Not having the 1 Phase UPS connected will not affect system usage during normal operation.

Once the 1 Phase UPS is bypassed, controlled shutdown and data backup in the event of a hospital mains power interruption will no longer be available, which may cause the last acquired run to be lost when the power failure occurs during the acquisition or shortly after the run was acquired. Data loss from the last run on Azurion systems is not expected, as these systems are equipped with solid state drives (SSD).

Philips will contact all affected customers to schedule the execution of this activity (reference: FCO72200594). As of the date of this Urgent Field Safety Notice, Philips expects to start bypassing the 1 Phase UPS by Q4 2025.

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 additional information or support concerning this issue, please contact your local Philips representative: **UKI_Quality_CR@philips.com**

Philips regrets any inconvenience caused by this matter.

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

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

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Email: UKFCO@philips.com

Sincerely,

PHILIPS

URGENT Field Safety Notice Response Form

Reference: 2024-IGT-BST-009: Philips Azurion and Allura with 1 Phase UPS
Potential Loss of System Functionality

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 the required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Affected systems may continue to be used in accordance with their Instructions for Use (IFU).
- Circulate this Urgent Field Safety Notice Letter to all users so that they are aware of the issue. Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system.
- Establish an emergency protocol prior to all applicable diagnostics, interventional, and minimally invasive procedures to manage the situation should you experience the issue during a procedure.
- In case the affected system has been transferred to another organization, please send a copy of this Urgent Urgent Field Safety Notice letter to that organization and inform Philips about this transfer through your local Philips representative.
- Complete and return the attached response form 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 actions required.
- Should you experience the issue reported in this letter, please report the event to Philips through 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 who handle the Philips Azurion and Allura with 1 Phase UPS.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

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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 Field Safety Notice.

Please complete and return this form via email to: **UKI_Quality_CR@philips.com**