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URGENT Field Safety Notice

Philips Azurion R2.1.10 and R2.2.10 Systems
Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement, and/or incorrect image content, and/or loss of data which may result in a delay or termination of procedure and/or procedural complications

<DD-MMM-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 identified six software issues affecting Azurion R2.1.10 and R.2.10 systems that may result in loss of imaging (X-ray) functionality, and/or loss of motorized movement, and/or incorrect image content, and/or loss of data.

Please note that this FSN also applies to Azurion systems currently running earlier software versions (R1.x & R2.x) that are being upgraded to R2.1.10 or R2.2.10 as part of the previously communicated Field Safety Notice C&R 2024-IGT-BST-015. These issues will apply after the upgrade is implemented.

This URGENT Field Safety Notice intends to inform you about:

1. What the issues are and under what circumstances they can occur

Issue Description	Complaints
Issue 1 – System keeps restarting When the Patient database in the Azurion system's Suite PC, which stores metadata about patients, studies, procedures, and series objects, contains more than 50,000 series objects, system functionality becomes unavailable. To address this, the Azurion system initiates a recovery restart. However, because the number of series objects remains unchanged, the issue persists, causing the system to repeatedly perform recovery restarts. No message is displayed to indicate this situation. To resolve this issue, a reinstallation of the Suite PC software is required.	To date, no complaints have been received reporting harm associated with releases R2.1.10 or R2.2.10.
Issue 2 – AMC triple drive Due to a firmware issue in the Advanced Motion Controller (AMC) 3-Axis drive (integrated electronic and mechanical component responsible for the precise movement and positioning of the Azurion's stand):	To date, no complaints have been received reporting harm associated with releases R2.1.10 or R2.2.10.

Issue Description	Complaints
a) Movements of the stand might be slow – when this occurs the message "Adjustment of frontal stand is required" is displayed to the user. When this occurs, 3D scan functionality is not available. The message "Rotational scanning is unavailable. Reselect the X-ray protocol" is displayed to the user. To resolve this issue, a calibration of the system by service is required. b) Motorized movements of the stand might become unavailable – when this occurs the message "Adjustment of frontal stand is required" is shown to the user. A cold restart of the system may temporarily resolve the issue in some cases. Manual movements of the stand remain available. Table movements are not impacted by this issue.	
Issue 3 – C-Partition of Suite PC running out of free space The C-drive of the Azurion Suite PC may gradually lose available space due to the accumulation of printer spool files. The Windows operating system creates a spool file for each print job and deletes it once the job is completed successfully. If a print job fails, these spool files are not removed and accumulate after each system (re)start when the Windows operating system retries the print job, consuming disk space. When the system (re)starts and the C-drive is full, motorized movements are disabled. The following messages appear on the screen "Some geometry movements are not available" and "The geometry is starting. Do not change SID".	To date, no complaints have been received reporting harm associated with releases R2.1.10 or R2.2.10.
Issue 4 - System remains in continuous restart mode after the start-up Due to a software issue, the License Manager – which verifies installed licenses and enables optional functionality in the Azurion system based on the available licenses – expands the Windows registry database at every system start or restart. Over time, the registry may grow beyond the maximum size that the License Manager can load. When this happens, the License Manager cannot start and the system will enter a continuous reboot loop. The Azurion system will not complete booting, and the message "X-ray system is booting…" remains displayed on the screen.	To date, no complaints have been received reporting harm associated with releases R2.1.10 or R2.2.10.
Issue 5 – Misalignment of Marker Tool Overlay – <u>Applicable only to Azurion systems with the Marker Tool option</u> The Marker Tool allows clinical users to draw freehand markers on a previously acquired X-ray image to add guidance or indicate a region of interest. Markers are displayed on all images within the series and on any images acquired after they are created. When geometry movement exceeds predefined thresholds (e.g., angulation or rotation differences greater than 10°, or a Beam-IsoCenter-to-Patient deviation greater than 50 mm), markers are hidden.	To date, no complaints have been received reporting harm associated with releases R2.1.10 or R2.2.10.

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Issue Description	Complaints
When the geometry returns within the threshold, markers reappear. However, they may not be restored to their exact original position and can deviate by several millimeters. If the Marker Tool is used during a clinical procedure to indicate the correct placement of a device, this deviation could lead to incorrect placement of the device.	
Issue 6 - Longitudinal Position Error – <u>Applicable only to Azurion systems with Poly-G3 frontal stand</u> When requesting a movement of the frontal stand in longitudinal direction, the Azurion system may detect a mismatch between the expected longitudinal (set-) position and the measured (actual) position of the stand. This mismatch is caused by a glitch in the longitudinal position value provided by the position sensing potentiometer. When the mismatch is detected, the motion power to the frontal stand is automatically cut off. The message "Some stand movements are not available" is displayed to the user. In this situation, X-ray imaging and table movements will continue to function. This issue can be resolved with a cold restart of the system or by restarting the geometry.	To date, no complaints have been received reporting harm associated with releases R2.1.10 or R2.2.10.

2. Hazard/harm associated with the issues

Potential safety risks associated with these issues are described in the table below.

Potential safety Risk	Issue
Loss of imaging (X-ray) functionality potentially resulting in delay or abort of therapy and procedural complications. The estimated probability of serious adverse health outcomes is 'improbable'.	Issue 1 – System keeps restarting Issue 4 – System remains in continuous restart mode after the start-up
Loss of motorized movement potentially resulting in delay or abort of therapy and procedural complications. The estimated probability of serious adverse health outcomes is 'improbable'.	Issue 1 – System keeps restarting Issue 2 – AMC triple drive Issue 3 – C-Partition of Suite PC running out of free space Issue 4 – System remains in continuous restart mode after the start-up Issue 6 – Longitudinal Position Error
Loss of data potentially resulting in delay of therapy and procedural complications. The estimated probability of serious adverse health outcomes is 'improbable'.	Issue 1 – System keeps restarting

Potential safety Risk	Issue
Incorrect image content potentially leading to procedural complications. The estimated probability of serious adverse health outcomes is 'not expected to occur'.	Issue 5 – Misalignment of Marker Tool Overlay

Harm related to Loss of Imaging (X-ray) Functionality

Loss of imaging (X-ray) functionality could result in a delay of therapy. The potential delay may result in serious adverse health outcomes, including the possibility of death, especially when the system is used with patients undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia, life-threatening bleedings).

Harm related to Loss of Motorized Movement

Loss of motorized movements during clinical use could contribute to a delay of therapy. The potential delay may result in serious adverse health outcomes, including the possibility of death, especially when the system is used with patients undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia, life-threatening bleeding).

Harm related to Loss of Data

Loss of data could result in or contribute to a delay or termination of therapy, require repeat imaging or procedures, or result in incomplete documentation. The potential delay may result in serious adverse health outcomes, including the possibility of death, especially when the system is used with patients undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia, life-threatening bleedings).

Harm related to Procedural Complications

Procedural complications could result in serious adverse health outcomes, including the possibility of death, especially when the system is used with patients undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia, life-threatening bleedings).

3. Affected products and how to identify them

Appendix A to this letter includes the intended use of the affected systems and how to identify them.

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 issues.
- 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 issues and required actions to be taken.
- If you experience an issue described in this letter, please report it to your local Philips representative.

  The table below includes the recommended actions for each issue, where applicable:

Issue	Action
Issue 2 – AMC triple drive	• Perform a cold system restart, as described in the Instructions for Use*.
Issue 5 – Misalignment of Marker Tool Overlay	• Avoid moving the C-arm and/or table after drawing the markers. • If movement occurs, re-verify the position of all markers before proceeding. Note: the marker tool is accurate for changes in digital zoom, magnification, SID (Source to Image Distance) and detector format.
Issue 6 - Longitudinal Position Error	• Perform a cold system restart, as described in the Instructions for Use*; or • Perform a Geometry restart by: - pressing the emergency stop button on the Control Module; and then - pressing the 'Power on' button on the Control Module for 3 seconds NOTE: Geometry restart may take up to 2 minutes to complete.

***** To perform a cold restart:

- On the Review Module, press and hold "Power Off".
- Release the button when the indicator light begins to flash.
- When the indicator light stops flashing, wait for 10 seconds.
- On the Review Module, press and hold "Power On".

NOTE I: Do not operate any of the controls while the system is powering on, as this may inhibit the start-up process.

NOTE II: A cold restart of the system takes 6 minutes from initiation of the cold restart until all system functionality is available.

5. Actions planned by Philips IGT Systems to correct the issues

Philips will address the identified issues by implementing a software update (R2.1.15 or R2.2.15) in all affected systems (FCO72200660 to 2.2.15, FCO72200672 to 2.1.15). Philips expects to have this software update released by Q4 2026 (subject to regulatory clearance).

Your local Philips representative will contact you to schedule a visit to install the software updates once available.

This notice has been reported to the appropriate Regulatory Agencies.

If you need any further information or support concerning any issue, contact your local Philips representative.

Philips regrets any inconvenience caused by this matter.

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Sincerely,

Marjan Vos

Head of Quality – IGT Systems

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URGENT Field Safety Notice Response Form

This FSN also applies to Azurion systems currently running earlier software versions (R1.x & R2.x) that are being upgraded to R2.1.10 or R2.2.10 as part of the previously communicated Field Safety Notice C&R 2024-IGT-BST-015. These issues will apply after the upgrade is implemented.

Reference: Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement, and/or incorrect image content, and/or loss of data which may result in a delay or termination of procedure and/or procedural complications with Philips Azurion R2.1.10 and 2.2.10 Systems, Philips C&R reference number **2025-IGT-BST-012**.

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 issues.
- 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 issues and required actions to be taken.
- If you experience an issue described in this letter, please report it to your local Philips representative.
- The table below includes the recommended actions for each issue, where applicable:

Issue	Action
Issue 2 – AMC triple drive	• Perform a cold system restart, as described in the Instructions for Use*.
Issue 5 – Misalignment of Marker Tool Overlay	• Avoid moving the C-arm and/or table after drawing the markers. • If movement occurs, re-verify the position of all markers before proceeding. Note: the marker tool is accurate for changes in digital zoom, magnification, SID (Source to Image Distance) and detector format.
Issue 6 - Longitudinal Position Error	• Perform a cold system restart, as described in the Instructions for Use*; or • Perform a Geometry restart by:

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Issue	Action
	- pressing the emergency stop button on the Control Module; and then - pressing the 'Power on' button on the Control Module for 3 seconds NOTE: Geometry restart may take up to 2 minutes to complete.

***** To perform a cold restart:

- On the Review Module, press and hold "Power Off".
- Release the button when the indicator light begins to flash.
- When the indicator light stops flashing, wait for 10 seconds.
- On the Review Module, press and hold "Power On".

NOTE I: Do not operate any of the controls while the system is powering on, as this may inhibit the start-up process.

NOTE II: A cold restart of the system takes 6 minutes from initiation of the cold restart until all system functionality is available.

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 system.

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.

Appendix A – Affected Systems and Intended Use

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.
- 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.

This correction applies to the following Philips Azurion R2.1.10 and 2.2.10 Systems:

Model Number	System 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
722280	Azurion 3 M15
722281	Azurion 5 M20
722282	Azurion 7 M20

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 Azurion systems can be identified during start-up (Figure 2).

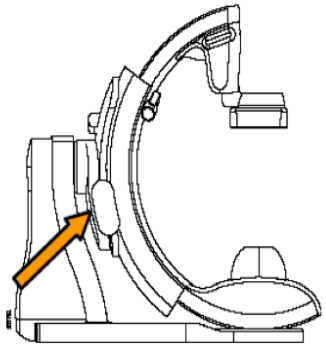


Figure 1- System Identification Label

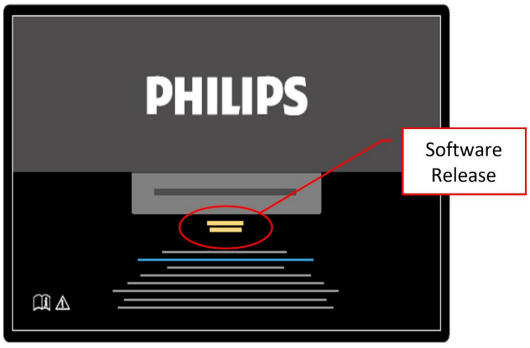
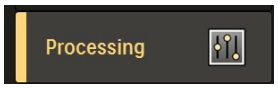


Figure 2- System Startup Screen

Systems affected by Issue 5 – Misalignment of Marker Tool Overlay

The Marker Tool functionality is only available when the license option is installed. To verify whether this option is available on your system, follow the next steps:



a) Select the **Processing** task in the task selection panel on the Touch Screen Module (TSM) or Control room

b) Click **Markers** on the toolbar of the viewport

Note: If the **Markers** icon is not visible, this license is not available on your system.