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URGENT Field Safety Notice

Philips Azurion R3.1 Systems

Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement may result in a delay or termination of procedure

12-Dec-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 two software issues affecting Azurion R3.1 systems that may result in loss of imaging (X-ray) functionality, and/or loss of motorized movement. 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 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 release R3.1.
Issue 2 - 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.	To date, no complaints have been received reporting harm associated with release R3.1.

Issue Description	Complaints
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.	

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 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 remains in continuous restart mode after the start-up Issue 2 – Longitudinal Position Error

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).

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 - 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 software updates in all affected systems.

Philips expects to have software update 3.1.5 (FCO72200635, FC072200671), that resolves issue 1, released by Q1 2026 (subject to regulatory clearance). The Longitudinal Position Error (issue 2) will not be resolved with software update 3.1.5. The solution for this issue is planned for Q4 2026 (subject to regulatory clearance) with software update 3.1.15 (FCO72200684).

Your local Philips representative will contact you to schedule visits 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:

Telephone	80 30 30 35
Email	philips.service@philips.com

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: Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement which may result in a delay or termination of procedure with Philips Azurion R3.1 Systems, Philips C&R reference number **2025-IGT-BST-014**.

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:

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- 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.

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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.

Please complete and return the response form to **FCO.Nordic@philips.com**

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 R3.1 systems:

Model Number	System Product Name
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
722229	Azurion 3 M12
722230	Azurion 3 M15
722231	Azurion 5 M12
722232	Azurion 5 M20
722233	Azurion 7 M12
722234	Azurion 7 M20
722235	Azurion 7 B12
722236	Azurion 7 B20

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).

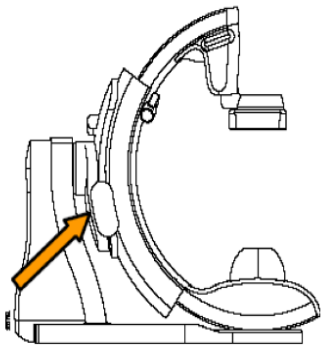

Figure 1- System Identification Label

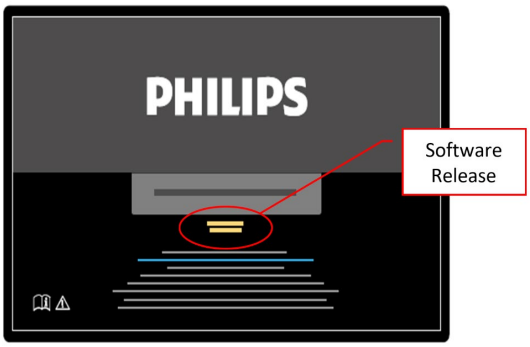

Figure 2- System Startup Screen