

URGENT Field Safety Notice

Philips Azurion Systems

Potential loss of imaging functionality, loss of motorized movement, and/or loss of data due to SSDs that are not specified in the Medical Device File

06-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 Philips Azurion systems and is initiating a Field Safety Corrective Action (FSCA) to address this issue. This URGENT Field Safety Notice provides important information regarding the nature of the issue, the potential risks to patients and users, and the required actions.

1. Issue Description

Philips Azurion systems use Solid-State Drives (SSDs) in various PCs to store the operating system and image data and to support system functionality.

Philips has identified that, during certain repair or service actions, SSDs that are not specified in the Medical Device File may have been installed. These SSDs may have different performance characteristics, which may include reduced reliability over time.

When an SSD does not perform as intended, the symptoms depend on the PC in which the SSD is installed and the function being used. This may result in loss of imaging functionality or motorized movement, a blank or black display, and/or the inability to store newly acquired images or access previously acquired images.

2. Hazard/harm associated with the issue

This issue may potentially result in or contribute to a delay in diagnosis, delay in therapy/treatment, and/or procedural complications. Depending on the clinical situation and the patient's condition, the associated health consequences may range from negligible or temporary effects to serious adverse health outcomes.

Patients undergoing complex and/or urgent interventions or potentially life-threatening conditions, such as acute ischemic stroke, acute myocardial ischemia, or life-threatening bleeding, may be most at risk. In these patients, a delay in diagnosis or therapy/treatment may contribute to deterioration of the patient's condition, potentially resulting in serious injury, permanent impairment, or death. Procedural complications may also result in serious injury and, in severe circumstances, permanent impairment or death.

Although serious adverse health outcomes are possible, the estimated probability of such outcomes is 'improbable.' Philips has not received any reports of harm associated with this issue.

3. Affected products and how to identify them

Certain serial numbers of Philips Azurion systems may be affected by this issue. Appendix A to this letter provides the System Codes and Commercial Names of the affected product models. Philips is notifying customers whose systems have been identified as potentially affected.

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

- Affected systems may continue to be used in accordance with their Instructions for Use (IFU) and the instructions below.
- If motorized movements become 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).

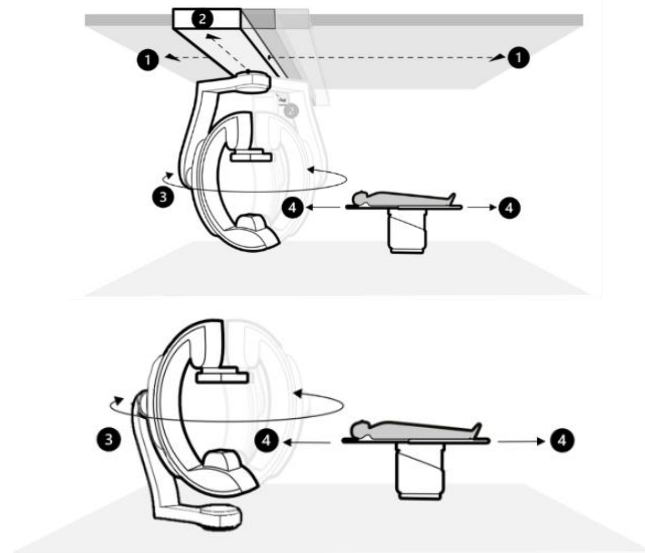


Figure 1 – Manual movements of the ceiling-mounted system (top) and floor-mounted system (bottom)

- 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 devices for ease of reference, where applicable.
- If the affected product has been transferred to another organization, please forward this notice to that organization and inform Philips through your local representative.
- Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system.
 - If you experience the issue described in this letter, please report it to your local Philips representative.
 - Complete and return the response form included in the 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.

5. Actions planned by Philips Image Guided Therapy Systems

Philips will inspect all systems in scope of this FSCA and replace SSDs that are not specified in the Medical Device File. Philips expects to start the implementation of this correction in December 2026. A local Philips representative will contact you to schedule a visit for a Field Service Engineer to perform these activities.

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

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

URGENT Field Safety Notice Response Form

Reference: Potential loss of imaging functionality, loss of motorized movement, and/or loss of data due to SSDs that are not specified in the Medical Device File, Philips Azurion Systems, C&R 2026-IGT-BST-004

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:	

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 Philips Azurion 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 response helps us ensure that this communication has been received and that appropriate actions can be effectively implemented.

Please return this signed form.

Appendix A - Affected Systems

System Code	Commercial 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
722285	Azurion S

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

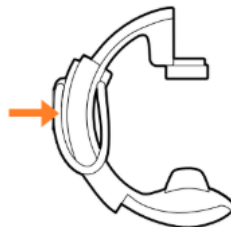


Figure 2- System Identification Label