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URGENT Field Safety Notice

Philips Azurion Systems
Mechanical wear of the Float Tabletop control potentially leading to limited availability or loss of longitudinal and transverse table movements and/or lacerations

24-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 Philips Azurion systems, where longitudinal and transverse table movements may be impacted due to mechanical wear of the Float Tabletop control on the control module. This Urgent Field Safety Notice is intended to inform you about:

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

Philips has identified that the Float Tabletop control on the control module of Azurion systems may experience mechanical wear over time.

The Float Tabletop control is located on the control module at the table-side. When the control is actuated, the table brakes disengage, allowing adjustment of the longitudinal or transverse position of the table.

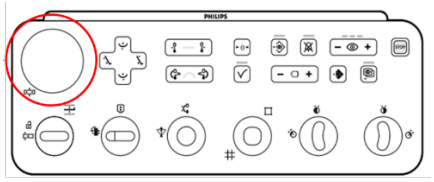

Figure 1. Float Tabletop control on the control module

Over time, mechanical wear may lead to detachment, cracking, or breakage of the Float Tabletop control, which may lead to reduced availability or unavailability of longitudinal and transverse tabletop movement, as well as the formation of sharp edges.

2. Hazard/harm associated with the issue

Reduced or unavailable longitudinal and transversal tabletop movement during clinical use may contribute to a delay of therapy, potentially resulting in serious adverse health outcomes. Patients at the highest risk are those undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia, life-threatening bleeding).

Mechanical damage to the Float Tabletop control may also result in the formation of sharp edges, which may cause minor injury (e.g., laceration) to the user upon contact.
The probability of serious adverse health outcomes is improbable. To date, no harm to patients or users has been reported in relation to this issue.

3. Affected products and how to identify them

This issue applies to Azurion systems not configured with an optional auxiliary pan handle. Systems equipped with an auxiliary pan handle provide an alternative means of controlling longitudinal and transverse table movement.
Appendix A to this letter lists the system codes, commercial names, and intended use of the affected systems.

4. Actions that should be taken by the user in order to reduce risks for patients or users

- Circulate this Urgent Field Safety Notice to all users of the system so that they are aware of the issue.
- Affected systems may continue to be used in accordance with their Instructions for Use (IFU) and the instructions below.
- If the required position cannot be achieved using the Float Tabletop control for table movement, use alternative system movements (e.g., stand movement) where clinically feasible to adjust the relative position between the system and the patient.
- Avoid contact with sharp edges in the event that the Float Tabletop control is damaged.
- Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure that the notice is in a place likely to be seen/viewed.
- 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.
- Please complete and return the attached Response Form attached 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.
- Should you experience the issue reported in this letter, please report the event to Philips through your local Philips representative.

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

Philips will install an auxiliary pan handle on all affected systems. A Philips representative will contact you to schedule the implementation of this correction. Philips expects to begin implementation of the correction by July 2026.

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:

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

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

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Appendix A - Affected Systems and Intended Use

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
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
722280	Azurion 3 M15
722281	Azurion 5 M20
722282	Azurion 7 M20

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

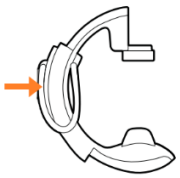

Figure 2- System Identification Label

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.
- 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 specifications of the patient table.

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URGENT Field Safety Notice Response Form

Reference: Philips Azurion Systems, Mechanical wear of Float Tabletop control potentially leading to limited availability or loss of longitudinal and transverse table movements and/or lacerations, C&R 2024-IGT-BST-023

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:

- Circulate this Urgent Field Safety Notice to all users of the system so that they are aware of the issue.
- Affected systems may continue to be used in accordance with their Instructions for Use (IFU) and the instructions below.
- If the required position cannot be achieved using the Float Tabletop control for table movement, use alternative system movements (e.g., stand movement) where clinically feasible to adjust the relative position between the system and the patient.
- Avoid contact with sharp edges in the event that the Float Tabletop control is damaged.
- Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure that the notice is in a place likely to be seen/viewed.
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- Please complete and return the attached Response Form attached 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.
- 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 systems.

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

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