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URGENT Field Safety Notice

Philips Azurion Systems
Unexpected table movement

26-JAN-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 become aware of a potential safety issue with Philips Azurion systems, where under certain conditions, the table may move unexpectedly when the Reset Geometry button is pressed – even when a table lock is active. This URGENT Field Safety Notice is intended to inform you about:

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

The Reset Geometry function (activated through the Reset Geometry button, see Figure 1) resets the table and stand of the Azurion system to their default position to provide all-around access to the patient. Movement continues while the button is pressed or until the default position is reached.

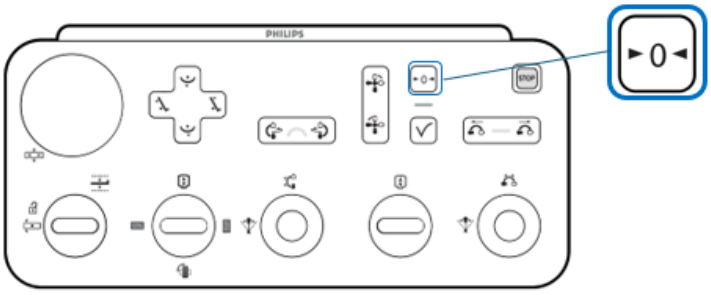

Figure 1: Reset Geometry button on the control module

To prevent unintended table movement, the system provides table lock options. When a table lock is active, any table movement request from the user interface is blocked. Depending on how the Reset Geometry button is configured, pressing this button may override the table lock (as further explained in Appendix A).

Philips has identified a potential safety issue when the Reset Geometry button is configured to overwrite the table lock, while the Philips system is being used with a stand-alone third-party device or a stationary accessory not synchronized with the table (e.g., a floor-mounted device, a head stabilizer, a robotic arm with a biopsy needle). If the Reset Geometry button is then (accidentally) pressed, unintended table movement may cause the patient to move relative to the stand-alone third-party device or stationary accessory, posing a risk to the patient (e.g., if a needle is inserted into the patient).

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The configuration of the Reset Geometry button is not described in the Instructions for Use. Philips has also identified that, in the Instructions for Use, the Reset Geometry button is the only method described to get all-around access to the patient during a clinical emergency, while there are other ways to get such all-around access (as further explained in Appendix A).

Between January 2021 and October 2025, Philips has received 3 (three) complaints regarding this issue. One of them reported a potential injury to the patient.

2. Hazard/harm associated with the issue

Unexpected table movement when using stand-alone third-party devices or stationary accessories may cause the patient to move relative to the stand-alone third-party device or stationary accessory, posing a risk of procedural complications. The potential health consequences may result in serious adverse health outcomes, including the possibility of death, especially when the system is used to treat frail or elderly patients with multiple comorbidities due to their lower physiological reserve, and patients on anticoagulation or with coagulopathy due to increased bleeding risk. The estimated probability of serious adverse health outcomes is 'improbable'.

3. Affected products and how to identify them

All Philips Azurion systems (R1.X, R2.X, R3.X, R4.0) are affected.

Product Name	System Model Number
Azurion 3 M12	722063
Azurion 3 M15	722064
Azurion 7 M12	722078
Azurion 7 M20	722079
Azurion 7 B12	722067
Azurion 7 B20	722068
Azurion 3 M12	722229
Azurion 3 M15	722230
Azurion 5 M12	722231
Azurion 5 M20	722232
Azurion 7 M12	722233
Azurion 7 M20	722234
Azurion 3 M15	722280

Product Name	System Model Number
Azurion 3 M12	722221
Azurion 3 M15	722222
Azurion 5 M12	722227
Azurion 5 M20	722228
Azurion 7 M12	722223
Azurion 7 M20	722224
Azurion 7 B12	722225
Azurion 7 B20	722226
Azurion 5 M20	722281
Azurion 7 M20	722282
Azurion 7 B12	722235
Azurion 7 B20	722236

The System Model Number and Product Name are found on the System Identification Label. The location of the System Identification Label is shown in Figure 2 below.

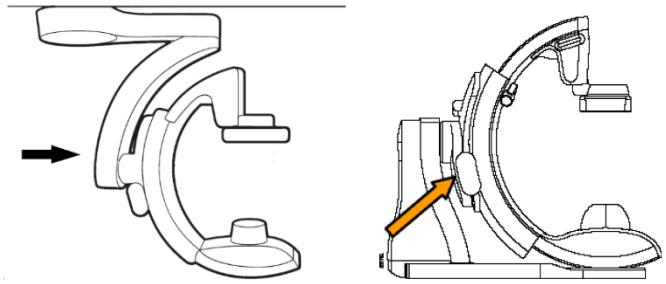

Figure 2: Location of the System Identification Label on the system

The **Azurion series** (within the limits of the used operating room table) 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 several 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.

4. Actions that should be taken by the customer /user with the aim of lowering risks for patients

- Circulate this URGENT Field Safety Notice to all users of the system so that they are aware of the issue.
- Read and follow the additional instructions in Appendix A regarding the use and configuration of the Reset Geometry function. Appendix A explains how table movement behavior changes based on the Reset Geometry function settings and the recommended configuration when using the system with a stand-alone third-party device or a stationary accessory.
- Keep Annex A together with the documentation of the system. Ensure that the letter is in a place likely to be seen/viewed.
- Confirm the Reset Geometry function that best suits your clinical workflow. If required, you may request Philips to change the settings. When using a third-party stand-alone device or a stationary accessory, Philips recommends configuring the Reset Geometry function without automatic table movement. You can request a configuration change free of charge within six (6) months from the date of this Urgent Field Safety Notice by contacting your local Philips representative (reference 2024-IGT-BST-020). If you requested a configuration change, please indicate this in the response form by checking the box.
- 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 Response form attached to Philips promptly and no later than 30 days from receipt. Please confirm whether you have requested a free-of-charge change to the configuration of the Reset Geometry function. 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 is informing customers of this issue through this Urgent Field Safety Notice.

Philips will provide the configuration change of the Reset Geometry function free of charge for any customer who requests it within six (6) months from the date of this Urgent Field Safety Notice.

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 issue, please contact your local Philips representative:

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

This Urgent Field Safety 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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URGENT Field Safety Notice Response Form

Reference: Unexpected table movement with Philips Azurion systems, C&R 2024-IGT-BST-020

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. Also, please select the box below in red if you have requested to change the configuration of the Reset Geometry function.

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.
- Read and follow the additional instructions in Appendix A regarding the use and configuration of the Reset Geometry function. Appendix A explains how table movement behavior changes based on the Reset Geometry function settings and the recommended configuration when using the system with a stand-alone third-party device or a stationary accessory.
- Keep Annex A together with the documentation of the system. Ensure that the letter is in a place likely to be seen/viewed.
- Confirm the Reset Geometry function that best suits your clinical workflow. If required, you may request Philips to change the settings. When using a third-party stand-alone device or a stationary accessory, Philips recommends configuring the Reset Geometry function without automatic table movement. You can request a configuration change free of charge within six (6) months from the date of this Urgent Field Safety Notice by contacting your local Philips representative (reference 2024-IGT-BST-020). If you requested a configuration change, please indicate this in the response form by checking the box.
- 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 Response form attached to Philips promptly and no later than 30 days from receipt. Please confirm whether you have requested a free-of-charge change to the configuration of the Reset Geometry function. 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 affected system.

☐ **I have requested to change the configuration of the Reset Geometry function.**

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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 this form via email to: **FCO.Nordic@philips.com**

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Appendix A

Reset Geometry and Table movements

- The Reset Geometry (Reset Geo) function is configured at installation of the system to suit the clinical workflow and may or may not include an automatic movement of the table to the default position. This configuration may be changed by a Philips service representative upon customer request.

  The following table describes the expected table and stand behavior when using the Reset Geometry function with or without automatic table movement:

Applied Lock		Reset Geo WITH Automatic Table Movement	Reset Geo WITHOUT Automatic Table Movement
	**Table**	**Reset Geo** unlocks the table. The table and stand move to the default position if not already at this position.	**Reset Geo** unlocks the table. The table does not move automatically. The stand moves to the default position if not already at this position.
	**Table Lateral**	**Reset Geo** unlocks the table. The table and stand move to the default position if not already at this position.	**Reset Geo** unlocks the table. The table does not move automatically. The stand moves to the default position if not already at this position.
	**All**	**Reset Geo** does not unlock the table. The table and stand do not move.	**Reset Geo** does not unlock the table. The table and stand do not move.

  In either configuration (with or without automatic table movement), the table lock is disabled after pressing the Reset Geometry button (except when the "All" lock option is applied in the X-ray Settings task).

- To check the current configuration of the Reset Geometry button:
  - Move the table in any direction.
  - Engage the ‘Table’ lock.
  - Press the ‘Reset Geometry’ (>0<) button.
  - Observe whether the table moves automatically after pressing ‘Reset Geometry’.

  Note: Ensure that this check is carried out when the system is not in clinical use.

- Use/Exercise care with table movements when the patient is connected to a stand-alone third-party device or stationary accessory (for example, a surgical robot) that is positioned on the floor. Table movements are independent of the stand-alone third-party device. In this situation, table movements may cause harm to the patient.
- When using a stand-alone third-party device with the system, it is recommended to configure the Reset Geometry function WITHOUT Automatic Table Movement.
- Ensure all staff are aware that table movements may be caused by certain functions on the system. This includes, but is not limited to, the Reset Geometry function or Automatic Position Control.

Access to the patient in the event of a clinical emergency

In the event of a clinical emergency, use this procedure to reset the system to its default position and provide all-around access to the patient.

- Move the stand and/or tabletop to provide access to the patient following one of the options below:
  - Using the controls on the control module to move the stand and tabletop independently.
  - Press and hold the Reset Geometry button on the control module to move the stand and table to the default position.
  - Recalling a position using Automatic Position Control.