

## **URGENT Field Safety Notice**

### **Philips Azurion and Allura Systems**

Potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.

26-FEB-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 the wired foot switch used with the Philips Azurion and Allura systems, where no or only intermittent X-ray radiation initiation is possible through the wired foot switch. This Urgent Field Safety Notice is intended to inform you about:

#### **1. What the issue is and under what circumstances it can occur**

Philips has identified instances where X-ray imaging may not be initiated or may occur intermittently when using the wired foot switch due to:

- Intermittent or absent electrical contact when the foot switch pedal is pressed due to gradual formation of silicon oxide layers on the microswitch<sup>1</sup> contact surfaces.
- Internal damage to the foot switch cable.
- Application of strain relief<sup>2</sup> on the connector that may not fully mitigate mechanical load, which could potentially result in connector damage and/or intermittent or complete loss of connection.

#### **2. Hazard/harm associated with the issue**

Loss of imaging during clinical use may result in, or contribute to, procedural complications and/or a delay of therapy.

The segment of the population most at risk are 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). A delay of therapy in the population requiring urgent interventions may contribute to further deterioration of their already critical condition, and that may potentially lead to death. Loss of imaging during critical phases of technically demanding interventions may contribute to procedural complications, potentially resulting in critical injuries or lead to death.

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<sup>1</sup> The microswitch is a component inside the foot switch that closes the electrical circuit when pressing the pedal and activates X-ray.

<sup>2</sup> The strain relief on the connector is a plastic tie that holds the foot switch cable to take strain off the connection between the foot switch cable and the Allura or Azurion system.

Between January 2023 and December 2025, Philips received 3554 complaints potentially associated with this issue. Philips received two reports of serious injuries and one report of death potentially related to this issue.

### 3. Affected products and how to identify them

Philips Azurion and Allura series are affected by this issue. Appendix A to this letter provides a table with the System Codes and Commercial Names, and the intended use of the affected systems.

### 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 issue and follow the instructions below.
- Perform the daily check before starting the first procedure, as described in the device labelling:  
*“Perform the following check every day before starting the first procedure. If you find any damage or if any step fails, stop using the system immediately and contact technical support. Check the functionality of all foot switches (primary and additional) that are connected to the system.*
  - 1 Inspect each foot switch and foot switch cable for damage, such as tears, cuts, or abrasions.*
  - 2 (...).*
  - 3 Inspect each foot switch for proper connection to the system.*
  - 4 Ensure that foot switch cables do not interfere with activities in the examination room.*
  - 5 Test all pedals on each connected foot switch for proper function.”*
- Should you experience a foot switch activation issue, please report it to your local Philips representative.
- 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 issue and required actions to be taken.

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

Philips will perform the following actions in the affected systems:

- Installation of a redesigned strain relief in all wired foot switches.
- Installation of an additional wired foot switch with a redesigned microswitch, for systems with a table that supports the connection of two wired foot switches.
- Installation of a wired foot switch with redesigned microswitch and redesigned cable for systems with a table that does not support the connection of two wired foot switches.

The table below summarizes the actions taken considering the type of system table and number of footswitches currently installed:

<b>System tables that support connection of two wired foot switches</b>		
<b>System Table*</b>	<b>Number of foot switches installed</b>	<b>Actions by Philips**</b>
AD7XT or AD7XNT table	One wired foot switch	Installation of the redesigned strain relief. Installation of an additional wired foot switch.  Philips anticipates commencing this activity in May 2026.
	One wired foot switch and a wireless foot switch	Installation of the redesigned strain relief.  Philips anticipates commencing this activity in May 2026.
AD7XT or AD7XNT table with accessory rail kit AD5G table or hybrid operating room table	One wired foot switch	Installation of the redesigned strain relief. Installation of an additional wired foot switch.  Philips anticipates commencing this activity in Q3 2026.
	One wired foot switch and a wireless foot switch	Installation of the redesigned strain relief.  Philips anticipates commencing this activity in Q3 2026.
<b>System tables that support connection of one wired foot switch</b>		
AD7, AD7NT, or AD5i table	One wired foot switch	Replacement of the foot switch with the redesigned wired foot switch that includes a redesigned microswitch, and redesigned cable with integrated strain relief.  Philips anticipates commencing this activity in Q4 2026.
	One wired foot switch and a wireless foot switch	Installation of the redesigned strain relief.  Philips anticipates commencing this activity in Q3 2026.

\* Details to identify the System Table type are provided in Appendix B

\*\* Anticipated availability dates subject to regulatory clearance

Your 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 additional information or support concerning these issues, contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Marjan Vos', with a horizontal line drawn through it.

Marjan Vos  
Head of Quality – IGT Systems

## URGENT Field Safety Notice Response Form

**Reference:** 2024-IGT-BST-026: Azurion and Allura Systems - Potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.

**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 issue and follow the instructions below.
- Perform the daily check before starting the first procedure, as described in the device labelling:  
*“Perform the following check every day before starting the first procedure. If you find any damage or if any step fails, stop using the system immediately and contact technical support. Check the functionality of all foot switches (primary and additional) that are connected to the system.*
  - 1 Inspect each foot switch and foot switch cable for damage, such as tears, cuts, or abrasions.*
  - 2 (...).*
  - 3 Inspect each foot switch for proper connection to the system.*
  - 4 Ensure that foot switch cables do not interfere with activities in the examination room.*
  - 5 Test all pedals on each connected foot switch for proper function.”*
- Should you experience a foot switch activation issue, please report it to your local Philips representative.
- 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.

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 Philips Azurion and Allura 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 organization’s reply is the evidence required to monitor the progress of this Urgent Field Safety Notice.

## Appendix A - Affected Systems and Intended Use

System Code	Commercial Name
722001	Allura Xper FD10C
722002	ALLURA Xper FD10
722003	Allura Xper FD10
722005	Allura Xper FD10/10
722006	Allura Xper FD20
722008	Allura Xper FD20 Biplane
722010	Allura Xper FD10
722011	Allura Xper FD10/10
722012	Allura Xper FD20
722013	Allura Xper FD20 Biplane
722015	Allura Xper FD20 OR Table
722020	Allura Xper FD20 Biplane OR Table
722022	Allura Xper FD10 OR Table
722023	Allura Xper FD20 OR Table
722025	Allura Xper FD20 Biplane OR Table
722026	Allura Xper FD10
722027	Allura Xper FD10/10
722028	Allura Xper FD20
722029	Allura Xper FD20/10
722031	Allura CV20
722033	Allura Xper FD10 OR Table
722035	Allura Xper FD20 OR Table
722038	Allura Xper FD20/20
722039	Allura Xper FD20/20 OR Table
722058	Allura Xper FD20/15
722059	Allura Xper FD20/15 OR Table
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
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
722400	Cardio Vascular-Allura Centron

The System Code and Commercial Name can be found on the System Identification Label located on the System stand (see Figure 1).

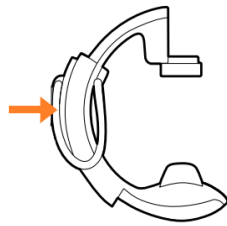


Figure 1 - System Identification Label

## **Intended Use**

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 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.

The **Allura Xper series** is intended for use on human patients to perform:

- Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

Additionally:

- The Allura Xper series is compatible with a hybrid Operating Room.
- The Allura Xper FD 10 Systems are compatible with specified magnetic navigation systems.

The Allura Xper series is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.

The **Allura Centron** system (within the limits of the used operating room table) is intended to perform:

- Vascular diagnostic and interventional procedures (Angiogram, Balloon Angioplasty, Stenting)
- Cardiac diagnostics and interventions (PCI),
- Pacemaker implantations and implantable defibs
- Electrophysiology (EP) and RF ablation
- Non-vascular interventions such as drainages, biopsies and vertebroplasty procedures

The Allura Centron is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.

The **Allura CV20** is intended for physicians (e.g. cardiologists and radiologists), assisted by trained hospital staff (e.g. nurses and lab technicians), who are qualified to perform medical procedures on humans (having a maximum weight of 250 kg.) with probable internal diseases or injuries for:

- Dedicated vascular and carotid imaging applications, including diagnostic and interventional procedures.
- Cardiac imaging applications including diagnostics, interventional procedures, pacemaker implantations and electrophysiology (EP).

Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.



## Appendix B – Identification of Table Type

The table below provides information to identify the table type. The identification label of the table is located at the table base (see Figure 2).

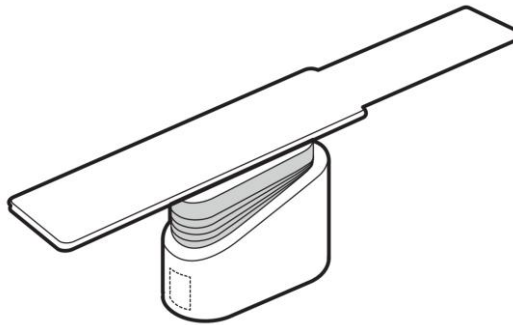
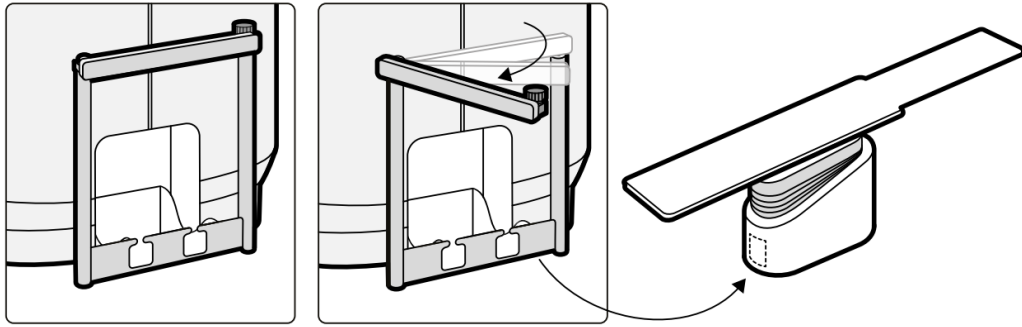


Figure 2 – Table Identification Label

Table Type	Model Number
AD7	989600204431 989600204432 989600204433 989600204434 989600204435 989600204436 989600204437 989600204438
AD7NT	989710003451 989710003452 989710003453 989710003454 989710003455 989710003456 989710003457
AD7XT*	459800605311 459800605312 459800605313 459800605314 459800249151 459800249152 459800249153 300010125981
AD7XNT*	459800605321 459800605322 459800605323 459800605324 459800249231 459800249232 459800249233 459800249234 300008753261 300008753291 300009062011
AD5i	459800254061 459800547941 459800614931
AD5G	989600205131 989600205132

\*To identify if the AD7XT or AD7XNT has the optional table base accessory rail, check the base of the table as shown in Figure 3.



*Figure 3 - Table base accessory rail*