PHILIPS

URGENT Field Safety Notice

Philips Azurion Systems R1.x and R2.x
Software issue potentially resulting in loss of imaging (X-ray) functionality

28-MAY-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 a software issue affecting Azurion R1.x and R2.x systems equipped with a Certeray X-ray generator. This issue may lead to temporary loss of imaging (X-ray) functionality. This Urgent Field Safety Notice intends to inform you about:

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

Philips has identified a software issue in the internal communication process between the system software and the X-ray generator firmware. This issue may be triggered under either of the following situations:

- **Situation 1 - Pedal Tap:** When the foot switch is pressed and released rapidly without generating X-rays (due to a short duration of contact), the system may enter a state where X-ray generation is inhibited. When this occurs, the system does not show any message to the user indicating that X-ray is not possible. A warm restart may resolve the situation in some cases. A cold restart will always resolve the situation.
- **Situation 2 – Phase Fault:** Azurion systems are designed to automatically recover from phase faults (a phase fault is an abnormal condition in which one or more phase voltages drop to (near) zero). When a phase fault occurs, the X-ray generator software initiates an automatic recovery process to restore fully system functionality, during which imaging (X-ray) functionality is not available for approximately 5 seconds. When the identified software issue occurs during this recovery, communication with the system software is lost, resulting in the system not recognizing that the generator has recovered and is ready for operation. In this situation, the system shows the user message *"Generator is busy starting up, no X-ray possible"*. If the phase fault is detected by the generator during acquisition, the system also shows the message *"Run Aborted: Tube Problem"*. To restore system functionality a cold restart of the system is required.

2. Hazard/harm associated with the issue

Loss of imaging (X-ray) functionality caused by the software issue in either of the two situations 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).

In the period from Dec-2023 to Apr-2025, Philips has received:

- Fifty-four (54) complaints related to the Pedal Tap situation. None of these complaints reported any harm to the patient.
- Six (6) complaints related to the Phase Fault situation. According to one (1) complaint procedure was stopped and patient later transferred to a different facility. The patient died two days later.

3. Affected products and how to identify them

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 R1.x and R2.x systems:

Model Number	System Product Names
722063	Azurion 3 M12
722064	Azurion 3 M15
722067	Azurion 7 B12/12
722068	Azurion 7 B20/15
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 B12/12
722226	Azurion 7 B20/15
722227	Azurion 5 M12
722228	Azurion 5 M20
722280	Azurion 3 M15
722281	Azurion 5 M20
722282	Azurion 7 M20

The System Product Name and Model Number can be found on the System Identification Label located on the System stand (Figure 1). The software version of the Philips Azurion systems can be identified during start-up (Figure 2).

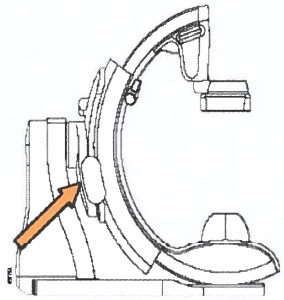

Figure 1- System Identification Label

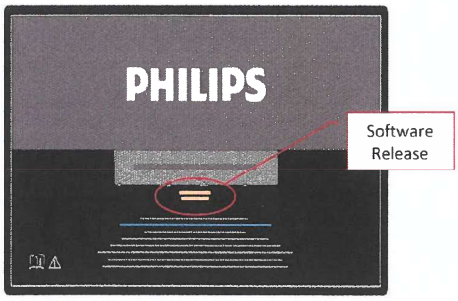

Figure 2- System Startup Screen

4. Actions that should be taken by the customer / user in order to prevent 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.
- Avoid rapidly pressing and releasing the footswitch pedals.
- In case X-ray functionality is not available following the situations described in this letter, perform a cold system restart of the system, as follows:
  - 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: Do not operate any of the controls while the system is powering on, as this may inhibit the start-up process
- In case the affected system has been transferred to another organization, please send a copy of this Urgent Field Safety Notice letter to that organization and inform Philips about this transfer through your local Philips representative.
- Keep this Urgent Field Safety Notice letter 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 letter and understanding of the issue and required actions to be taken.
- If you experience the issue described in this letter, please report it to your local Philips representative.

5. Actions planned by Philips IGT Systems to correct the issue

Philips will address the identified issue by implementing a software update in all affected systems. For systems featuring an Interventional Workspot and/or EchoNavigator, Philips will upgrade the Interventional Workspot and/or EchoNavigator software version to ensure compatibility with the updated Philips Azurion system software.

Philips expects to have the updated software released by June 2025. Your local Philips representative will contact you to schedule a visit to install the software update once available.

This notice has been reported to the appropriate Regulatory Agencies.

If you need any further information or support concerning this issue, contact your local Philips representative:

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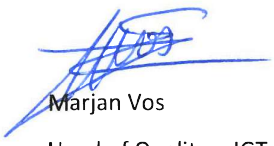
Philips regrets any inconvenience caused by this matter.

Sincerely,



Marjan Vos

Head of Quality – IGT Systems

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URGENT Field Safety Notice Response Form

Reference: Software issue potentially resulting in loss of imaging (X-ray) functionality with Philips Azurion Systems R1.x and R2.x, Philips C&R reference number 2024-IGT-BST-015.

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 letter, 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.
- Avoid rapidly pressing and releasing the footswitch pedals.
- In case X-ray functionality is not available following the situations described in this letter, perform a cold system restart of the system, as follows:
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- If you experience the issue described in this letter, please report it to 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 that handle 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 organization's reply is the evidence required to monitor the progress of this Urgent Field Safety Notice.