PHILIPS

URGENT Field Safety Notice

Philips Azurion systems
Power Distribution Unit issue potentially leading to loss of imaging functionality

15-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 identified a safety issue affecting certain Azurion systems potentially leading to loss of imaging functionality. This URGENT Field Safety Notice is intended to inform you about:

1. Issue description

The Power Distribution Unit is an internal assembly of the Philips Azurion system that contains multiple power supplies. Philips has identified that, in certain Azurion systems, one or more of these power supplies can fail due to energy peaks (surge voltages) during start or restart of the system.

When a power supply failure occurs during a start or restart, the Power Distribution Unit does not provide the required direct current power to essential system components. As a result, the system does not successfully complete the (re-)start, imaging functionality is unavailable, and the system remains unavailable for clinical use.

2. Hazard/harm associated with the issue

Loss of imaging during clinical use may result in, or contribute to, procedural complications and/or 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 condition, which may potentially lead to death.

Although serious adverse health outcomes are possible, the estimated probability of such outcomes is ‘improbable.’ To date, Philips has not received any report of serious injury potentially associated with this issue.

3. Affected products and how to identify them

This issue affects Philips Azurion systems listed in Table 1 that were handed over to customers between June 2020 and June 2022:

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System Product Name	Model Number
Azurion 3 M12	722063
Azurion 3 M15	722064
Azurion 7 B12	722067
Azurion 7 B20	722068
Azurion 7 M12	722078
Azurion 7 M20	722079
Azurion 3 M12	722221
Azurion 3 M15	722222
Azurion 7 M12	722223
Azurion 7 M20	722224
Azurion 7 B12	722225
Azurion 7 B20	722226
Azurion 5 M12	722227
Azurion 5 M20	722228

Table 1 – List of Affected Systems

Affected products are identified by the System Product Name and Model Number, which can be found on the System Identification Label located on the system stand (Figure 1).

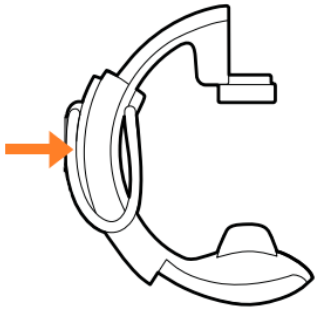


Figure 1 - System Identification Label

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

- Customers may continue to use the affected systems in accordance with their intended use, subject to the actions below.
- 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 notice with the documentation of the system until Philips corrects your system.
- If you experience an 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.

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5. Actions planned by Philips IGT Systems

Philips will replace the existing Power Distribution Unit assembly with a redesigned assembly that includes power-supply redundancy.

With the redesigned assembly, a failure of a single power supply during system start-up may still result in the system not starting correctly. However, upon performing a cold restart of the system, the redundant power supply will automatically take over the function of the failed power supply, allowing the system to start successfully and restoring system functionality. During a subsequent preventive maintenance visit, the affected assembly will be replaced to restore full redundancy.

Philips currently expects the redesigned Power Distribution Unit to be available by Q2 2028. Your local Philips representative will contact you to schedule a visit for implementation of the correction once it becomes available.

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

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URGENT Field Safety Notice Response Form

Reference: Power Distribution Unit issue potentially leading to loss of imaging functionality. Philips C&R reference number is **2025-IGT-BST-024.**

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 affected systems.

Name of person completing this form:

Signature:	
Printed Name:	
Title:	
Telephone Number:	
Email Address:	
Date (DD / MMM / YYYY):	

Please return this signed form