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URGENT Field Safety Notice

Philips Azurion System R1.x
Potential Loss of Imaging (X-ray) Functionality and/or Longer Time to Perform Cold Restart

11-JUL-2024

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 two (2) potential safety issues with the Philips Azurion system with software version R1.x that may result in the system exhibiting a loss of imaging (X-ray) functionality and/or a prolonged restart time. This Urgent Field Safety Notice intends to inform you about:

1. What the issues are and under what circumstances they can occur

Philips has identified two issues in software version R1.x of the Philips Azurion system that may affect:

a) Management of the system Log Trace Files:
The mechanism that is present in the system to manage the number and size of the system Log Trace Files does not function properly, as a result of which the Log Trace Files related to remote connection logging may occupy the full hard disk capacity of the Philips Azurion R1.x system. When the full disk capacity is reached, imaging (X-ray) functionality will cease to be available without an advance warning to the user. A restart of the system will not resolve the issue.

Note: This issue only impacts the Philips Azurion R1.x systems that are currently connected to Philips Remote Service or that were connected in the past.

b) Time to Perform a Cold Restart:
A cold restart of the Philips Azurion R1.x system may take up to 6 minutes as stated in the Instructions for Use of the system (Section 4.2). This time includes the time required for the system to shut down and the system to start up. However, there are instances where the shutdown of the system may be prolonged (with up to 4 minutes) resulting in the cold restart taking longer (up to 10 minutes in total).

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2. Hazard/harm associated with the issues

a) Management of the system Log Trace Files:
If the Log Trace Files occupy the full hard disk capacity, the imaging (X-ray) functionality of the Philips Azurion system will not be available. If the issue occurs during a procedure, it may result in a sudden interruption of the procedure.

To date, Philips has received one (1) complaint related to this issue.

b) Time to Perform a Cold Restart:
If a cold restart is required during a procedure, there could be a delay in the procedure if the "Prolonged system restart" issue occurs.

To date, Philips has received thirty-seven (37) complaints related to this issue.

Philips has not received any reports of adverse events resulting from these issues.

3. Affected products and how to identify them

Intended Use

The Azurion series (within the limits of the operation room table) are 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 following systems with software R1.x are affected:

System Product Name	Model Number
Azurion 3M12	722063
Azurion 3M15	722064
Azurion 7B12	722067
Azurion 7B20	722068
Azurion 7M12	722078
Azurion 7M20	722079

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 system can be identified during startup (*Figure2*).

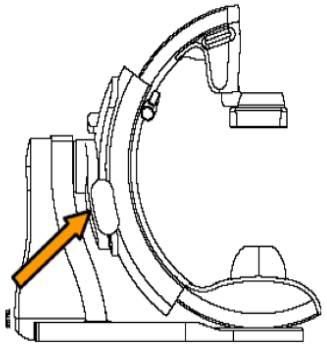

Figure 1- System Identification Label

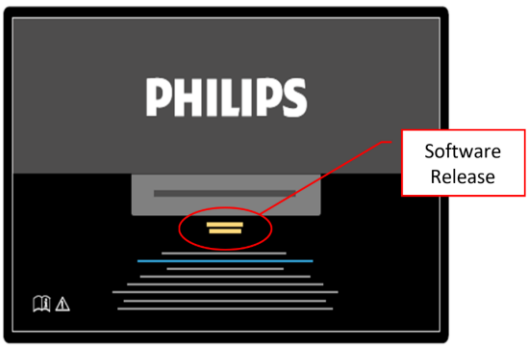

Figure 2- System Startup Screen

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

- Circulate this Urgent Field Safety Notice to all users of the system so that they are aware of the issue.
- 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.
- Should you experience a loss of imaging (X-ray) functionality or a prolonged system restart time, call your local Philips representative to report the event.
- Complete and return the attached response form (page 4) to Philips promptly and no later than 30 days from receipt. This confirms that the users of the system have reviewed and understand this Urgent Field Safety Notice and required actions to be taken.

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

Philips is working on a software release (R2.2.10) that will correct these two issues (ref. FCOs: FCO72200548, FCO72200580, FCO72200582, FCO72200583, FCO72200584, FCO72200592). For those systems that have an Interventional Workspot (IW) and/or EchoNavigator, Philips will upgrade the software version of the IW and/or EchoNavigator to maintain compatibility with the updated Philips Azurion system software (R2.2.10).

Your local Philips representative will contact you to schedule a visit to install the software update once available. Philips expects this software to be released by Q1 2025.

This notice has been reported to the appropriate Regulatory Agencies.

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.

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: 2024-IGT-BST-008 Philips Azurion System R1.x.
Potential Loss of Imaging (X-ray) Functionality and/or Longer Time to Perform Cold Restart

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 issues, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Circulate the Urgent Field Safety Notice to all users of the system so that they are aware of the issue.
- Keep the 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.
- Should you experience a loss of imaging (X-ray) functionality or a prolonged system restart time, call your local Philips representative to report the event.

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 impacted 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 Corrective Action.