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URGENT Field Safety Notice

Philips **Azurion System** R1.0, R1.1, R1.2, R2.0, R2.1, and R2.2
Potential loss of imaging functionality and clinical data stored in the system

January 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 a potential safety issue with the Philips Azurion systems R1.0, R1.1, R1.2, R2.0, R2.1, and R2.2, where the system may exhibit a loss of imaging functionality and data. This URGENT Field Safety Notice is intended to inform you about:

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

Philips has identified a potential issue which can cause the system to continuously restart (restart loop). This is likely to occur when the patient database gets too big over time (>500 studies). If this issue occurs, a potential for data loss may be expected.

2. Hazard/harm associated with the issue

If this issue occurs, the Philips Azurion system might not recover from this fault situation causing the system to not be available. If the issue occurs during a procedure, there may be a delay and/or abortion of the procedure.

To date, Philips has received sixty-seven (67) complaints related to this issue. In one (1) of these cases, data loss was reported. No harm to patients or bystanders was reported.

3. Affected products and how to identify them

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.

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The following systems are affected:

System Product Names	Model Number
Azurion 3M12	722063, 722221
Azurion 3M15	722064, 722222
Azurion 5M12	722227
Azurion 5M20	722228
Azurion 7B12/12	722067, 722225
Azurion 7B20/15	722068, 722226
Azurion 7M12	722078, 722223
Azurion 7M20	722079, 722224
Azurion 3 M15 (China)	722280

Affected systems can be identified by their System Product Name, Model Number, and Serial Number (SN), which can be found on the System Identification Label, as shown below.

The system product name and model number can be found on the System Identification Label located on the system stand (Figure 1).

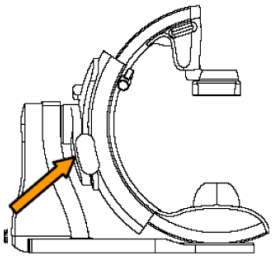

Figure 1: System identification

The software version of the Philips Azurion system can be identified during start-up (Figure2).

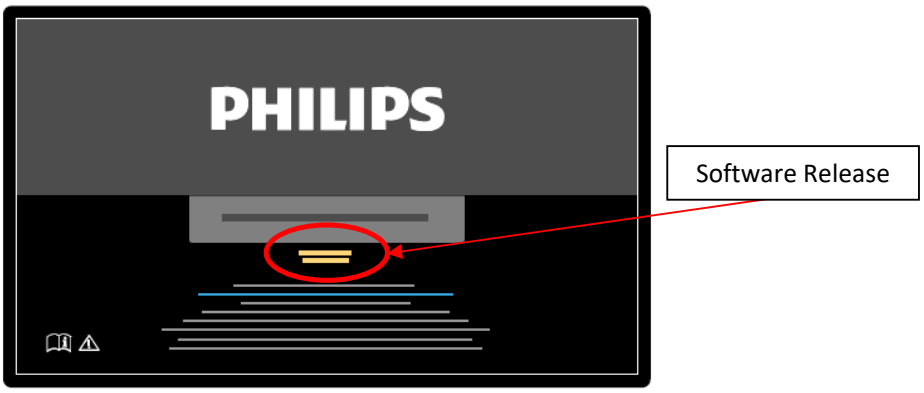

Figure 2: System start-up screen

Philips is sending this notification directly to customers that have (an) affected system(s).

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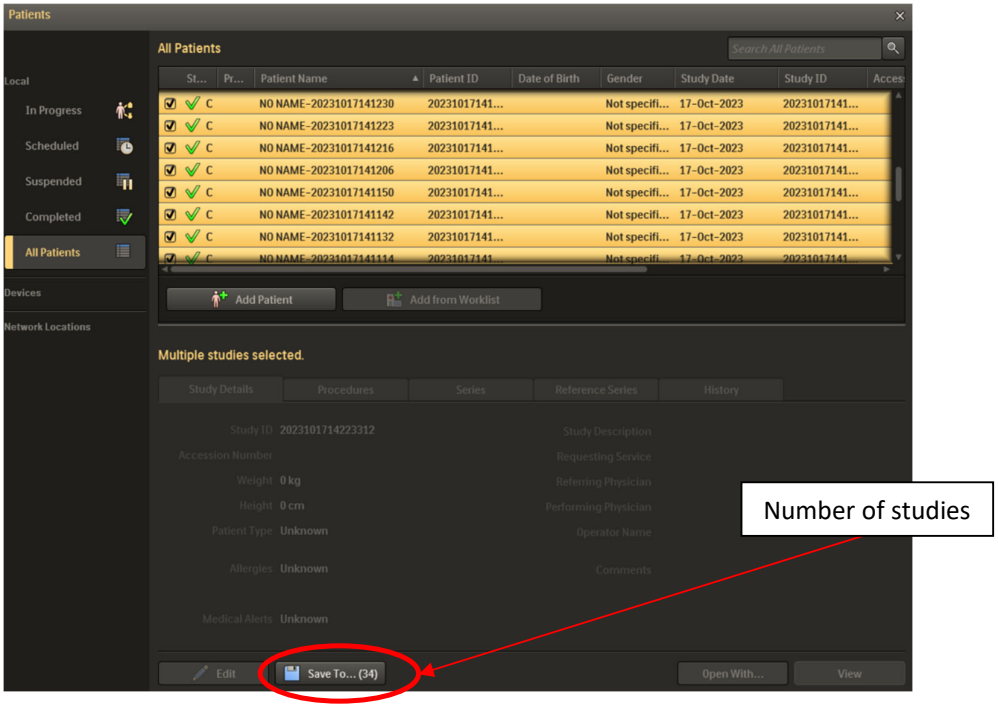
4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

- Keep this Urgent Field Safety Notice letter with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.

- Keep the number of studies in the patient database as low as possible, but at least below 500.

  The number of studies can be determined by selecting all studies in the table (Ctrl+A). The number of studies is displayed at the lower part of the screen, see image below.

  Note: There is no direct relation to the image disk space used. The number of studies can be high while the image disk is only partially filled, in case only a few images are saved for each patient.



- When deleting studies, ensure the studies are archived and delete the studies in small batches (<10).

- Circulate this notice to all users of the system so that they are aware of the issue.

- Return the attached response form (page 5) to Philips promptly and no later than 30 days from receipt to confirm that the users of the system have reviewed and understood this Field Safety Notice and required actions to be taken.

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5. Actions planned by Philips IGT-S to correct the problem

Philips is working on a software release that will correct this issue (reference: FCO72200525, FCO72200528, FCO72200535, and FCO72200548).

You will be contacted by your local Philips representative to schedule these activities.

If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**

This 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: Potential loss of imaging functionality and clinical data stored in the system, Philips C&R reference number 2023-IGT-BST-005.

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:

- Keep the Urgent Medical Device Correction letter with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.
- Keep the number of studies in the patient database as low as possible, but at least below 500.
- When deleting studies, ensure the studies are archived and delete the studies in small batches (<10).
- Circulate this notice to all users of the system so that they are aware of the issue.

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 Philips Azurion system.

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 corrective action.

Please mail this completed form to Philips: **dach.cs.pmplanning.gbs@philips.com**