URGENT Field Safety Notice

Philips Azurion System

Loss of function due to Certeray generator failure

02-Feb-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 for a limited number of Azurion Systems which may experience a power disruption resulting in the device being unavailable for use. This URGENT Field Safety Notice is intended to inform you about:

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

The Philips Azurion System contains a Certeray generator that may fail due to a potential short circuit in the Printed Circuit Board Assembly (PCBA) in PoInt EVR (Power Invertor). If a short circuit occurs, it will cause the fuses to trip and the system will become non-functional due to power loss. In this case the source of electrical current will stop, preventing further damage. Prior to fuses tripping, users may experience a burning smell coming from the generator.

2. Hazard/harm associated with the issue

A power disruption resulting from a short circuit in the Certeray generator may occur during installation or during clinical use. If this issue occurs during clinical use, it may cause a loss of power, resulting in a potential delay of procedure or termination of procedure.

To date, Philips has not received any complaints or reports of patient or user harm due to this issue.

3. Affected products and how to identify them

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.

Identification of affected systems.

A limited number of Azurion Systems shipped between Sep-2022 to Mar-2023 are in scope of this Letter. There are 175 systems with the following model numbers that may be impacted by this issue.

Model	Description
722221 722222 722280	Azurion 3
722227 722228	Azurion 5
722223 722224 722225 722226	Azurion 7

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

- Circulate this Notice to all clinical staff and any service personnel that may service the system so that they are aware of the issue.
- Keep this Urgent Field Safety Notice with the documentation of the system until Philips implements the correction in your system.
- If the Certeray generator fails, please stop using the system and contact your local Philips representative.
- Place a copy of this Notice in a visible place in the Control and Technical rooms (e.g., posted on the door).
- Please complete and return the attached response form (on page 3) 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 IGT Systems, SRN NL-MF-000001489 to correct the problem

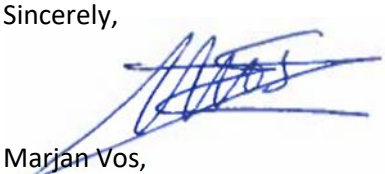
As a remedy, Philips will replace the Power Inverter in the Azurion generator cabinet in all affected Azurion systems through the implementation of Field Change Order (FCO72200544).

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

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. Philips regrets any inconvenience caused by this problem.

Sincerely,



Marjan Vos,
Head of Quality – IGT Systems

URGENT Field Safety Notice Response Form

Reference: 2023-IGT-BST-012 Philips Azurion System Loss of function due to Certeray generator failure (FCO72200544)

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 clinical staff and any service personnel that may service the system so that they are aware of the issue.
- Keep this Urgent Field Safety Notice with the documentation of the system until Philips implements the correction in your system.
- If the Certeray generator fails, please stop using the system and contact your local Philips representative.
- Place a copy of this Notice in a visible place in the Control and Technical rooms (e.g., posted on the door).

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Notice has been properly distributed to all users that handle the 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 Urgent Field Safety Corrective Action.