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URGENT Field Safety Notice

Zenition 50 and Zenition 70 systems

Potential Loss of X-ray Imaging Functionality and C-arm Height Movement

26-Sep-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 Zenition 50 and Zenition 70 systems. 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 an issue with the Zenition 50 and Zenition 70 systems where the 5-Ampere Mains Control Unit (MCU) board fuse may blow out during the system start-up or during an ongoing procedure. This issue may occur due to fluctuations in the power supply outside of the specifications mentioned in the Instructions for Use (Section 9.3.18 Power Supply) leading to a fuse blowout and to subsequent loss of power and eventually to the system becoming unavailable.

When this issue occurs, the system will display a combination of error messages M326, M050 and M501 during a system start-up and M370, and M501 during an ongoing procedure, as further specified below:

Error Code	Description
M 050	System initialization Problem. Switch system off/on Call service if problem is persistent.
M 370	X-Ray Generator not available. Switch system off/on Call service if problem is persistent.
M 326	X-Ray Generator not available. Switch system off/on Call service if problem is persistent.
M 501	Hight Movement error. Call service if problem persistent.

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2. Hazard/harm associated with the issue

Unavailability of the system for clinical use due to a fuse blowout may result in a potential delay or termination of the clinical procedure.

The potential delay and / or termination of the procedure may result in serious adverse health outcomes.

To date, Philips has not been reported any adverse event resulting from this issue.

Based on the complaint data collected and the number of procedures per system, Philips estimates that 0.0037% of the systems may experience this issue.

3. Affected products and how to identify them

The affected Zenition 50 and Zenition 70 systems are included in the table below.

Product Code	Product Description	Product UDI
718096	Zenition 50	(01)00884838091535(21)
718133	Zenition 70	(01)00884838091528(21)

The system product name and model number are found on the system identification label (Fig-2). This label is on the rear side of the Mobile Viewing Station (MVS) (Fig-1).

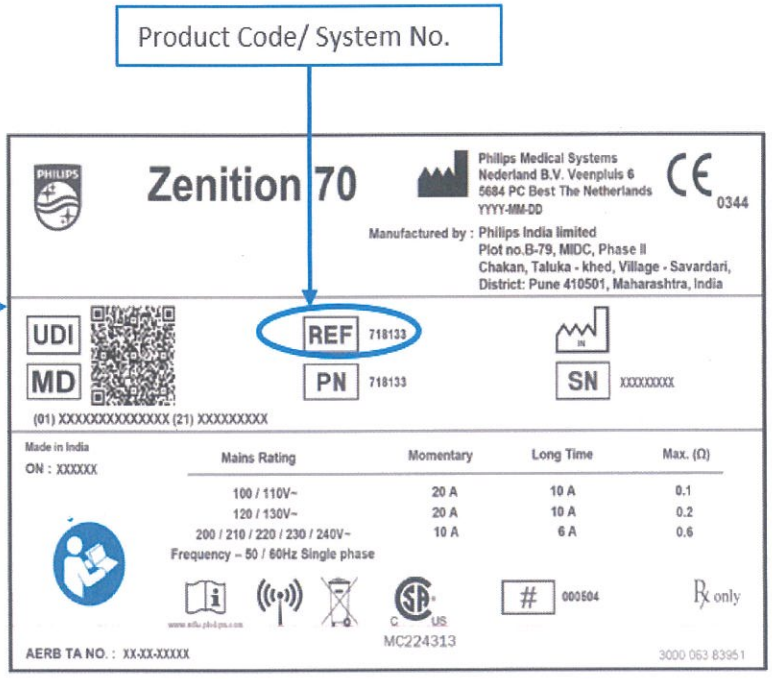

***Fig-1 Mobile Viewing Station (System Identification Label location)**

***Fig-2 System Identification Label**

*Note: Above images are for indication purpose only.

The above images are applicable for both systems Zenition 50 and Zenition 70.

Intended Use:

The Zenition 50 and Zenition 70 devices are used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month),

within the limits of the devices. The devices are to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.
Applications: Orthopedic, Neuro, Abdominal, Vascular, Thoracic, Cardiac.

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

- Affected systems may continue to be used in accordance with their intended use and Instructions for Use (IFU).
- 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 implements the correction in your system. Ensure that the letter is in a place likely to be seen / viewed.
- If you experience a power loss issue with your system, report the event to Philips.
- Complete and return the attached response form (on page 04) 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 (Image Guided Therapy) systems* to correct the problem

Philips will replace the 5-Ampere MCU board fuse with a 10-Ampere MCU board fuse in all affected systems.

Philips will contact customers to schedule a visit to perform this action free of charge (reference FCO71800109).

This notice has been reported to the appropriate Regulatory Agencies.

Be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this issue, contact your local Philips representative. *<Philips representative contact details to be completed by the Market/Business>*

Philips regrets any inconvenience caused by this problem.

Sincerely,

Neena Sonavane
Director -Quality, IGT-Systems, MoS (Mobile Surgery).

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URGENT Field Safety Notice Response Form

Reference: 2024-IGT-PUN-001

Potential Loss of X-ray Imaging Functionality and C-arm Height Movement

Instructions: 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 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 implements the correction in your system. Ensure that the letter is in a place likely to be seen/viewed.
- If you experience loss of power issue with your system, report the event to Philips.

We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice. We confirm that the information from this letter has been properly distributed to all users that handle the affected 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 evidence required to monitor the progress of this URGENT Field Safety Notice.

<provide instructions here for the customer regarding returning the form to Philips, e.g. fax #, email address. For example, "Please fax this completed form to Philips at (xxx)xxx-xxxx>