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URGENT Field Safety Notice

Zenition 50

Potential loss of imaging functionality and/or poor image quality

29-Sep-2025

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 in a limited number of Image Intensifier Televisions (IITV) used in Zenition 50 which could lead to loss of imaging functionality or clinically unusable images.

This URGENT Field Safety Notice is intended to inform you about:

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

Philips has become aware that over time some Zenition 50 systems may experience loss of imaging functionality and/or poor image quality due to potential corrosion of the Image Intensifier Television (IITV) control board.

2. Hazard/harm associated with the issue

Loss of imaging functionality or reduced image quality may result in delay of therapy. The potential delay may result in serious adverse health outcomes, including the possibility of death, especially when the system is used with 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).

Until 10-Jul-2025, Philips has not received any complaints related to this issue.

3. Affected products and how to identify them

The Product impacted is Zenition 50, model number 718096.

Product Number	Product Description	Product UDI
718096	Zenition 50	(01)00884838091535

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

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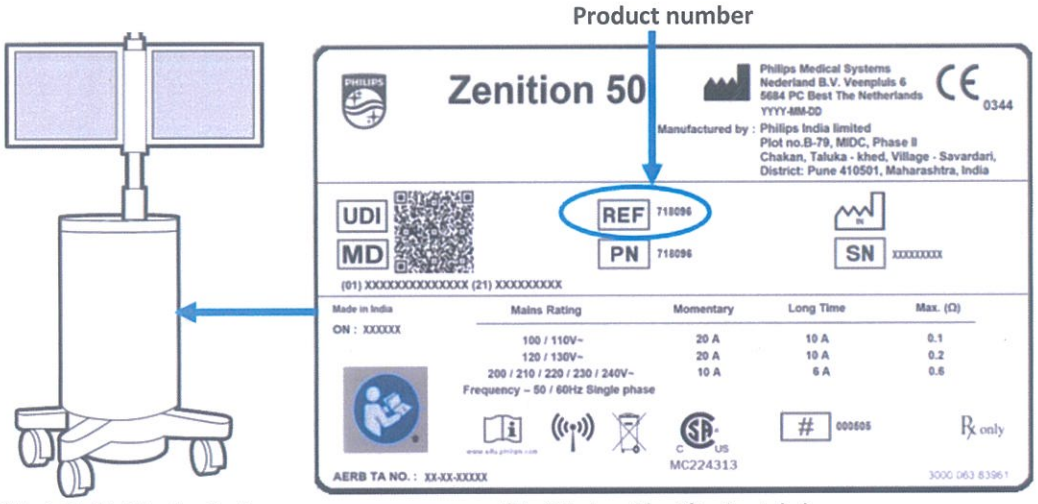

***Fig-1 Mobile Viewing Station (System Identification Label location)**

***Fig-2 System Identification Label**

*Note: Above images are for indication purpose only.

Intended Use:

The Zenition 50 device is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device.

The device is 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 device. The device is 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 or users

- Circulate this URGENT Field Safety Notice to all users so that they are aware of the issue and follow the instructions below.
- Affected systems may continue to be used in accordance with their intended use and Instructions for Use (IFU).
- Keep this URGENT Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.
- In case the affected system has been transferred to another organization, please send a copy of this URGENT Field Safety Notice to that organization and inform Philips about this transfer through your local Philips representative.
- Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt. Completing this form confirms the receipt of the URGENT Field Safety Notice and understanding of the issue and required actions to be taken.
- If you experience the issue described in this letter, please report it to your local Philips representative.

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

Starting in October 2025, Philips will replace the IITV control board of the affected Zenition 50 systems.

Your local Philips representative will contact you to schedule a visit to perform this activity in your system.

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 issue.

Sincerely,
Neena Sonavane
Director- Quality, IGT-Systems, MOS (Mobile Surgery)

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URGENT Field Safety Notice Response Form

Reference: Potential loss of imaging functionality and/or poor image quality with Zenition 50. Philips Reference C&R 2024-IGT-PUN-004.

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 users so that they are aware of the issue and follow the instructions below.
- Affected systems may continue to be used in accordance with their intended use and Instructions for Use (IFU).
- Keep this URGENT Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.
- In case the affected system has been transferred to another organization, please send a copy of this URGENT Field Safety Notice to that organization and inform Philips about this transfer through your local Philips representative.
- If you experience the issue described in this letter, please report it to your local Philips representative.

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 Zenition 50.

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.