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URGENT Field Safety Notice

Zenition 10 & Zenition 30
C-Arc Cable issue potentially leading to loss of imaging functionality

31-OCT-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 with a cable connection in the C- Arc of a limited number of Zenition 10 and Zenition 30 systems. 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 identified that during maintenance activities excessive bending forces may be applied to the ethernet cable connector transmitting image data from the detector to the system. This may cause the cable to be pulled out of the connector's strain relief, potentially leading to intermittent disconnections between the internal wires and the connector pins. If one of the connecting pins loses connection, live X-ray image will no longer be displayed, and the error message 393: "Doselink Error – X-ray aborted" will be shown on the user interface. In some instances, a restart of the C-arm stand may temporarily resolve the issue.

2. Hazard/harm associated with the issue
Loss of imaging functionality could result in delay of therapy. The potential delay may result in serious adverse health outcomes, especially when the system is used with patients undergoing complex, and/or urgent interventions for potentially life-threatening conditions (e.g., life-threatening bleedings, acute limb ischemia).

Until September 2025, Philips has received 8 complaints related to this issue. Philips has not received any complaints associated with this issue reporting harm.

3. Affected products and how to identify them
The model number of the affected products are shown in the following table:

Product name	Model Number
Zenition 10	718401
Zenition 30	718076

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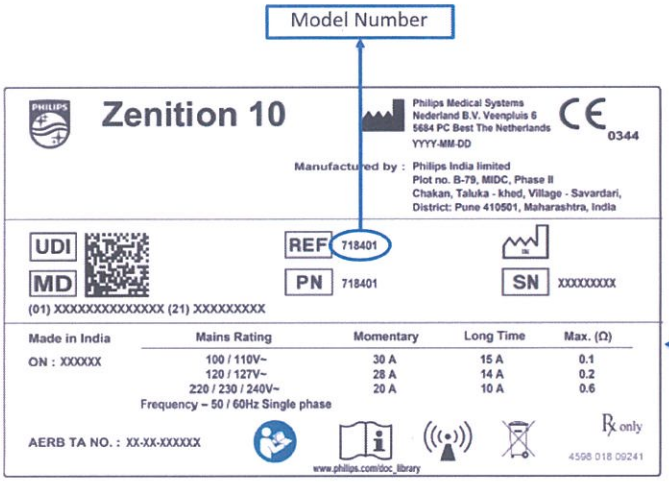
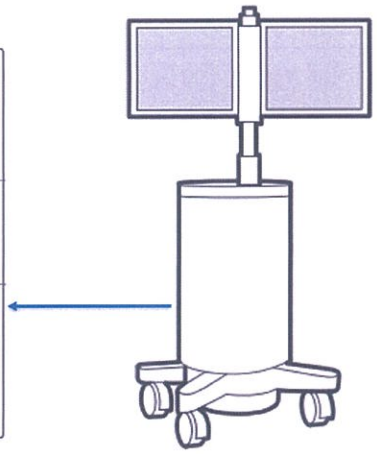
The Model number and Product name can be found on the System Identification Label (Fig-1). This label is on the rear side of the Mobile Viewing Station (MVS) (Fig-2).





*** Fig-1 System Identification Label**

*** Fig-2 Mobile Viewing Station (System Identification Label location)**

*Note: Above images are for indication purpose only.

Intended Use of Zenition 10:
The Zenition 10 system is used for radiological guidance and visualization during interventional and surgical procedures on all human patients.

Applications: Orthopedic, Pain management, Abdominal, Peripheral vascular, General surgery and Thoracic.

Intended Use of Zenition 30:
The Zenition 30 system is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients. 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 and Cardiac.

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

- Circulate this URGENT Field Safety Notice to all users so that they are aware of the issue and follow the instructions below.
- If you experience the issue described in this letter, restart the C-Arm stand as in some cases the issue can be temporarily resolved. Please report it always to your local Philips representative.
- 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.

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- 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.

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

Philips will be replacing the C-Arc Cable in the affected systems. Your local Philips representative will contact you to schedule a visit to replace the C-Arc Cable in the affected systems. Philips will start replacement of the C-arc cables in Q2 2026 (reference FCO71800116).

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 this matter, please contact your local Philips representative.

Philips regrets any inconvenience caused by this matter.

Sincerely,

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

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URGENT Field Safety Notice Response Form

Reference: C-Arc Cable issue potentially leading to loss of imaging functionality

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.
- If you experience the issue described in this letter, restart the C-Arm stand as in some cases the issue can be temporarily resolved. Please report it always to your local Philips representative.
- 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.

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 Zenition 10 and Zenition 30 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 Field Safety Corrective Action.