PHILIPS

URGENT Field Safety Notice

Zenition 10 and Zenition 30
Arcing in X-ray tube potentially leading to temporary loss of imaging functionality

28-APR-2026

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 identified a potential safety issue affecting a limited number of Zenition 10 and Zenition 30 systems, due to a manufacturing issue in certain X-ray tubes that could lead to temporary loss of imaging functionality. 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 a supplier manufacturing quality issue affecting certain X-ray tubes installed in a limited number of Zenition 10 and Zenition 30 systems, which may increase the likelihood of electrical arcing within the X-ray tube.

When arcing occurs, X-ray generation is interrupted, the system displays error code M 208 (Subsystem error), and for:

- Zenition 10: A system restart is required to resume operation. Such restart takes approximately 5 minutes.
- Zenition 30: The system automatically initiates a recovery sequence, which completes in approximately 10 seconds.

Arcing may recur after the system has completed the restart or recovery cycle.

2. Hazard/harm associated with the issue

This issue may potentially result in or contribute to a delay of therapy, which may result in serious adverse health outcomes. Patients undergoing complex or urgent interventions are most affected, as delays or interruptions could impact clinical workflow and decision-making. The estimated probability of serious adverse health outcomes is improbable. To date, no harm has been reported in relation to this issue.

3. Affected products and how to identify them

Appendix A to this letter includes the intended use of the affected systems and how to identify them.

4. Actions that should be taken by the customer / user that are aimed at lowering 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.

- If the issue described in this letter occurs:
    - Zenition 10 — Restart the system following the instructions in IFU section: 2.2.2- Recovery Procedure.:

      "Use this procedure if the system does not respond.

      1. *To switch off the complete system, click Shutdown on the System menu on the mobile view station. The controlled shut down process may take several seconds to complete. Do not switch the system on again until 30 seconds after the shutdown process is complete.*

      (...)

      2. *Wait 30 seconds.*
      3. *To switch the system on, press either the Power On key on the C-arm stand console (...) or on the mobile view station. A start-up screen is displayed on the examination monitor of the mobile view station and on the C arm stand console."*
    - Zenition 30 — No action is required; the system initiates an automatic recovery process which completes in approximately 10 seconds.
- Keep this URGENT Field Safety Notice with the documentation of the system until Philips corrects your system. Place this notice where it is easily visible to users. If 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.
- 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.

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

A Philips representative will contact you to schedule a visit, during which the X-ray tube will be inspected and subsequently replaced if necessary. In addition, the system software will be updated to enhance arcing error handling through automatic recovery. Philips expects to begin implementation of the correction in September 2026.

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.

Personal information

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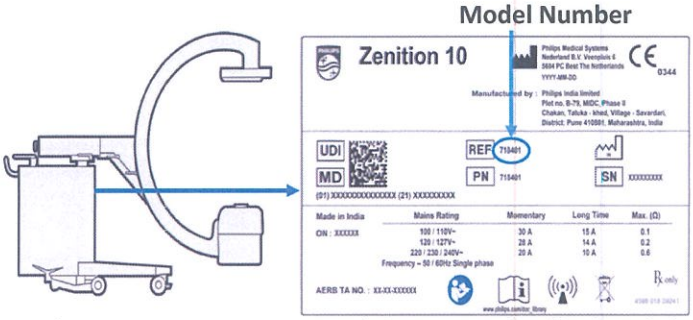
Appendix A

The affected systems are shown in the following table:

Product Name	Model Number
Zenition 10	718401
Zenition 30	718076

The Model Number and Product Name can be found on the System Identification Label (Fig-2). This label is placed on the rear side of the C-arm stand (Fig-1).



*** Fig-1 C-arm stand (System Identification Label location)**

*** Fig-2 System Identification Label**

*Note: Above images are for indication purpose only.

Intended Use:

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.

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.

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URGENT Field Safety Notice Response Form

Reference: Arcing in X-ray tube potentially leading to temporary 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 the issue described in this letter occurs:
    - Zenition 10 — Restart the system following the instructions in IFU section: 2.2.2- Recovery Procedure.:

      "Use this procedure if the system does not respond.

      1. *To switch off the complete system, click Shutdown on the System menu on the mobile view station. The controlled shut down process may take several seconds to complete. Do not switch the system on again until 30 seconds after the shutdown process is complete.*

      (...)

      2. *Wait 30 seconds.*
      3. *To switch the system on, press either the Power On key on the C-arm stand console (...) or on the mobile view station. A start-up screen is displayed on the examination monitor of the mobile view station and on the C arm stand console."*
    - Zenition 30 — No action is required; the system initiates an automatic recovery process which completes in approximately 10 seconds.
- Keep this URGENT Field Safety Notice with the documentation of the system until Philips corrects your system. Place this notice where it is easily visible to users. If 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.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

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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.