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URGENT Field Safety Notice

MD Eleva systems
Potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch

15-August-2023

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 the wired foot switch used with the Philips MD Eleva systems, where no or only intermittent X-ray radiation is possible.

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

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

The wired foot switch is used to control fluoroscopy, exposure, and other functions, such as single shot, light control, and toggle between X-ray planes (for bi-plane systems).

Philips has identified instances where no or only intermittent X-ray radiation initiation is possible through use of the wired foot switch, as a result of:

- A damaged foot switch cable or cable connector caused by large external force on the cable such as:
  - The cable being run over by other medical equipment.
- Supplier manufacturing issues associated with the production of certain components of the foot switch.

2. Hazard/harm associated with the issue

When no or only intermittent X-ray radiation initiation is possible, loss of imaging functionality can occur which may result in delayed diagnosis or interruption of procedure.

The segment of the population most at risk are patients undergoing complex/high risk, and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia). In an extremely remote situation where all clinical factors that may mitigate the risk are unavailable (e.g. using the wired foot switch in the control room, transfer of

patient to another room) or insufficient (e.g. using the exposure hand switch, continued monitoring of the patient, and guided restoration and maintenance of tissue oxygen delivery, medication administration), a delay of therapy in the population requiring urgent interventions may contribute to further deterioration of their already critical condition that may potentially lead to death (i.e., critical, and catastrophic delay effects).

The probability that use of the product causes or contributes to health consequences is estimated to be remote. As of the date of this letter, one event has been reported to Philips alleging that loss of imaging functionality caused or contributed to a patient's injury. Philips estimates that 0,008% of footswitches may experience an issue leading to no or only intermittent X-ray radiation when the footswitch is activated by the user.[1]

3. Affected products and how to identify them

Intended use
See Appendix A for detailed information on the intended use of the MD Eleva system.

The wired foot switch is a user input device with different foot pedals to:

- initiate X-ray radiation (fluoroscopy, series exposure or single shot); and
- control other functions like examination room light, or, in case of a bi-plane system, toggle between frontal and lateral X-ray planes.

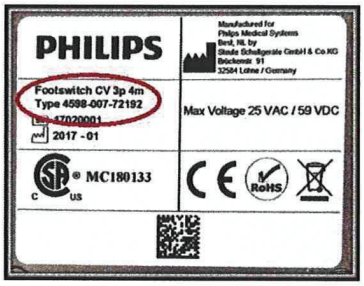
Identification of affected systems.
Appendix B to this letter provides a table with the references/types and model descriptions of the affected wired foot switches.

The reference/type of the wired foot switch can be found on the label located on the bottom of the wired foot switch, as shown in Figure 1.

Figure 1.

Top view

Bottom view



Label identification

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

- Circulate this Urgent Field Safety Notice to all users so that they are aware of the issue and follow the instructions below.

- Follow the instructions provided in Instructions for Use (IFU) Addendum attached to this letter for handling the foot switch, including:

    - Avoid driving over the foot switch cable with other devices or equipment.
    - Perform daily verification tests before using the system to

[1] Estimate based on complaint data collected from September 2020 to May 2023 and number of procedures per device.

- inspect the foot switch and the foot switch cable for damage, such as tears, cuts, or abrasions,
- inspect proper connection of the foot switch to the system,
- test all pedals on all connected foot switches for proper functioning.

If any damage is found or if any step fails, do not use the system, and contact technical support immediately.

- In case of failure of the foot switch to initiate X-ray, continue with image acquisition using an alternative X-Ray activation switch, such as foot switch or hand switch (for exposure) in the control room.

- Keep this Field Safety Notice and the Instructions for Use Addendum with the documentation of the system.

- Please complete and return the attached response form 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 (NL-MF-000001489) to correct the problem

Philips will be inspecting all affected systems to check the foot switch cable.

Philips will contact you to schedule a visit to perform this inspection (reference FCO72200534).

If you need additional 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.

Sincerely,

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URGENT Field Safety Notice Response Form

Reference: 2023-IGT-BST-004: MultiDiagnost-Eleva systems.
Potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.

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 the Urgent Field Safety Notice to all users so that they are aware of the issue and follow the instructions provided in the Instructions for Use with regards to daily verification tests.
- Keep this Field Safety Notice and the Foot Switch Instructions for Use Addendum with the documentation of the system.

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 system(s).

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 Field Safety Corrective Action.

<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

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APPENDIX A

Intended use

The **MultiDiagnost-Eleva** is a multifunctional / universal imaging application system, General R/F, Fluoroscopy, Radiography and Angiography can be performed along with more specialized interventional applications on human patients. This includes the following general areas:

- Digestive system: Swallowing studies, Esophagus, Stomach, Small intestine, Colon, Defecography, ERCP, T-tube cholangiogram, Liver biopsies, Trans jugular Intrahepatic Portosystemic Shunts (TIPS)
- Skeletal system: Bone studies
- Urinary system: IVP, Cystograms, Percutaneous Nephrolithotomy, Nephrostomy tube replacement
- Reproductive system: Hysterosalpingogram, Vena spermatica, Cavernography
- Respiratory system: Thorax, Bronchoscopy, Pulmonary biopsies
- Circulatory system: Venography, Arteriography, Thrombolytic Therapy, Embolizations, Embolectomy, IVC filter placement, Dilatations, Stent placement
- Various: Arthrograms, Myelograms, Facet joint injections, Discography, Sialography

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APPENDIX B

Product information to identify an affected foot switch.

Wired foot switch

12 NC	Description
452270000151	Footswitch MD 3p 6m
452270000152	Footswitch MD 3p 6m
452270000153	Footswitch MD 3p 6m
452270000154	Footswitch MD 3p 6m