IGT Systems FSN for 2017-IGTBST-029 2019-February-19

URGENT – Field Safety Notice

Bent pedal of footswitch might cause interruption of live Fluoroscopy imaging or exposure.

<Date>
<Hospital/Clinic Name>
cc: Chairman Medical Board and relevant Head of Departments
Dear Customer,

A problem has been detected in the Philips MultiDiagnost-Eleva with Flat Detector and Allura Xper systems that, might intermittently lead to interruption of live fluoroscopy imaging or exposure.

This Medical Device Correction is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients.
- the actions planned by Philips to correct the problem.

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 a copy with the equipment Instruction for Use until the problem is solved by Philips.

Philips noticed that due to a bent pedal of the footswitch, loss of image functionality is possible (intermittent or continuous inability of making live fluoroscopy images or exposures).
The pedal may get bent when the footswitch is frequently used on an anti-fatigue mat or on a not flat surface or in the pedestal.

In the following pages, detailed information and actions required are provided.

If you need any further information or support concerning this issue, please contact your local Philips representative:

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

[redacted]
Rajesh Kathuria
Head of Q&R
Image Guided Therapy Systems

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AFFECTED PRODUCTS	**System:** MultiDiagnost Eleva with Flat Detector Allura Xper FD10 Ceiling Allura Xper FD10 Floor Allura Xper FD10 Allura Xper FD10/10 Allura Xper FD20 Allura Xper FD20 Biplane Allura Xper FD10 Allura Xper FD10/10 Allura Xper FD20 Allura Xper FD20 Biplane Allura Xper FD10 OR Table Allura Xper FD20 OR Table Allura Xper FD20 Biplane OR Table Allura Xper FD20 OR Table Allura Xper FD10 Allura Xper FD10/10 Allura Xper FD20 Allura Xper FD20/10 Allura CV20 Allura Xper FD20 OR Table Allura Xper FD20/20 Allura Xper FD20/20 OR Table Allura Xper FD20/15 Cardio Vascular-Allura Centron **Productcode:** 708037, 708038 722001, 722003, 722005, 722006, 722008,722010, 722011, 722012, 722013, 722014, 722015, 722020, 722023, 722026, 722027, 722028, 722029, 722031, 722035, 722038, 722039, 722058 and 722400.
PROBLEM DESCRIPTION	If a Footswitch is frequently used on an anti-fatigue mat, on a non-flat surface or in the pedestal, the footswitch pedals may get bent.
HAZARD INVOLVED	A bent pedal of the footswitch might lead to an intermittent or continuous inability of making live fluoroscopy images or exposures. In case the fluoroscopy pedal is bent and live fluoroscopy is not available, the exposure pedal of the footswitch or the hand switch may be used to generate a live image in order to finish a procedure.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips will be contacting directly customers with affected systems.

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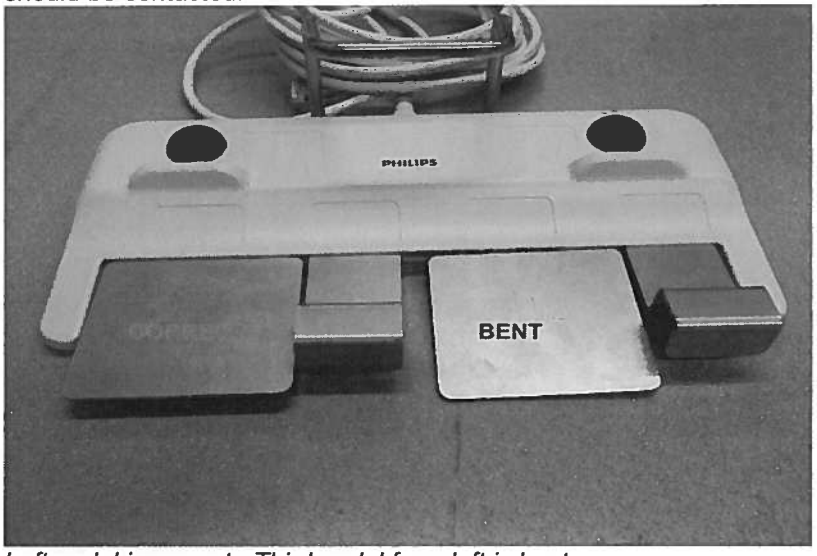
ACTION TO BE TAKEN BY CUSTOMER / USER	• Before the start of a procedure, the user must check the footswitch for possible bent pedals. See images below on how to identify a bent pedal. If bent pedals are found the procedure should not continue and Local Service should be contacted.  *Left pedal is correct. Third pedal from left is bent.* *Distance to floor should be approx. 12mm (0,47inches).* • Do not use the footswitch on an anti-fatigue mat or in the pedestal. • Please ensure that all staff with access to the affected systems are informed of the content of this Field Safety Notice. • Include this Field Safety Notice together with the documentation of the system until the system has been corrected by Philips.
ACTIONS PLANNED BY PHILIPS	The problem will be resolved by an update of the mechanical hardware of the Footswitch that will prevent that the pedals of the footswitch becoming bent. This mechanical hardware is available by February 2019. You will be notified by your local Philips representative to schedule a date for installation of this mechanical hardware update.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)

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