

**URGENT - Field Safety Notice**  
**Allura Xper Systems**  
**Bent pedal of footswitch might cause**  
**interruption of live Fluoroscopy imaging or exposure.**

Dear Customer,

A problem has been detected in the Philips Allura Xper Systems that, might intermittently lead to interruption of live fluoroscopy imaging or exposure. This Field Safety Notice 72200248 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 or users
- 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.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

M. Borger  
Sr. Director Quality Assurance & Regulatory (a.i.)  
BIU IXR, Imaging Systems



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AFFECTED PRODUCTS	Productcode:	System:
	722001	Allura Xper FD10 C
	722002	Allura Xper FD10 F
	722003	Allura Xper FD10
	722005	Allura Xper FD10/10
	722006	Allura Xper FD20
	722008	Allura Xper FD20 Biplane
	722010	Allura Xper FD10
	722011	Allura Xper FD10/10
	722012	Allura Xper FD20
	722013	Allura XPER FD20 BIPLANE
	722014	Allura Xper FD10 OR Table
	722015	Allura Xper FD20 OR Table
	722019	Allura Xper FD10/10 OR Table
	722020	Allura Xper FD20 Biplane OR Table
	722022	Allura Xper FD10 OR Table
	722023	Allura Xper FD20 OR Table
	722024	Allura Xper FD10/10 OR Table
	722025	Allura Xper FD20 Biplane OR Table
	722026	Allura Xper FD10
	722027	Allura Xper FD10/10
	722028	Allura Xper FD20
	722029	Allura Xper FD20/10
	722031	Allura CV20
	722033	Allura Xper FD10 OR Table
	722034	Allura Xper FD10/10 OR Table
	722035	Allura Xper FD20 OR Table
	722036	Allura Xper FD20/10 OR Table
	722038	Allura Xper FD20/20
	722039	Allura Xper FD20/20 OR Table
	722058	Allura Xper FD20/15
	722059	Allura Xper FD20/15 OR Table
	722123	Field extensions Xper cardio systems
	722124	Field extensions Xper vascular systems



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	<p>722126 SmartPath to AlluraClarity cardio</p> <p>722127 SmartPath to AlluraClarity vascular</p> <p>722133 Field ext. Xper cardio systems R7.6</p> <p>722134 Field ext. Xper vascular systems R7.6</p> <p>722400 Cardio Vascular-Allura Centron</p> <p>889006 Diamond Select Allura Xper FD10</p>
<b>PROBLEM DESCRIPTION</b>	If a Footswitch is frequently used on an anti-fatigue mat, on a not flat surface or in the pedestal, the footswitch pedals may get bent. This might cause an intermittent or continuous inability of making live fluoroscopy images or exposures.
<b>HAZARD INVOLVED</b>	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. This will lead to a higher dose but it outweighs a possible safety risk.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	All Philips – Allura Xper- Systems as indicated in the “Affected Products” section mentioned above. A Unit Affected List (UAL) is provided to the local Philips representatives. Customers with affected systems will be contacted directly by the local Philips Organization.
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	Before the start of a procedure check the footswitch for possible bent pedals. See images below. If bent pedals are found the procedure should not continue and Local Service should be contacted.



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Left pedal is correct. Third pedal from left is bent.  
Distance to floor should be approx. 12mm or 0,47inch.

<p><b>ACTIONS PLANNED BY PHILIPS</b></p>	<p>A Mandatory Field Safety Corrective Action will be issued to solve this problem. This Field Change Order (FCO) will be identified as FCO72200248 and will be free of charge. Planned issue date is end of December 2014 latest. This FCO consists of a Mechanical Hardware update of the Footswitch in order to prevent bent pedals and therefore prevents an intermittent or continuous inability of making live fluoro images or exposures.</p>
<p><b>FURTHER INFORMATION AND SUPPORT</b></p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Centre on 0870 532 9741.</p>

