URGENT - Field Safety Notice
FCO72200276

All Allura Xper, AlluraClarity, Allura CV, Allura Centron and UNIQ systems

Still image indications

Dear Customer,

This Field Safety Notice is intended to inform you about a situation on how a customer misinterpreted still images as live Images.

If it were to re-occur it could adversely affect the outcome of a clinical procedure.

This Field Safety Notice is applicable for all Allura XPER, Allura Clarity, Allura CV, Allura Centron and UNIQ systems. where a customer live images and still images can misinterpreted as live Images although the system is working within specificaton and fully according its intended use.

This Field Safety Notice is distributed to all affected customers and is intended to inform you about:

- The circumstances in which this situation can occur.
- Actions that you as a customer can take to minimize the effect of 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:
<Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

H. Weusten 2015 OCT 30
Head Q&R IGT systems

URGENT - Field Safety Notice
FCO72200276

All Allura Xper, AlluraClarity, Allura CV, Allura Centron and UNIQ systems

Still image indications

AFFECTED PRODUCTS	**System:** All Allura Xper, AlluraClarity, Allura CV, Allura Centron and UNIQ systems **Productcode:** 722001, 722002, 722003, 722005, 722006, 722008, 722010, 722011, 722012, 722013, 722015, 722019, 722020, 722022, 722023, 722025, 722026, 722027, 722028, 722029, 722031, 722033, 722034, 722035, 722038, 722039, 722058 and 722400.
PROBLEM DESCRIPTION	The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images. This can happen when: 1. While doing fluoroscopy, the user presses the single shot exposure pedal, resulting in a single shot still image being displayed on the screen. The user does not realize that the single shot exposure pedal is still active, and that exposure therefore is still active. By design, exposure imaging takes priority over fluoroscopy imaging, so no fluoroscopy is started until the exposure pedal is released. At the same time the user does not realize that live X-ray imaging is not active, although the still image icon is displayed and all legally required live X-ray indicators (such as dose rate, X-ray active icon, fluoro timer, and audible signal –X-ray buzzer-) are inactive. 2. While a fluoroscopy pedal is pressed and fluoroscopy is active, the user (accidently) presses a second fluoroscopy pedal and then releases the first fluoroscopy pedal. Upon releasing the first fluoroscopy pedal, the system stops live imaging. The user does not realize that the first fluoroscopy pedal was still pressed when pressing the second fluoroscopy pedal. At the same time the user does not realize that live X-ray imaging is not active, although the still image icon is displayed and all legally required live X-ray indicators (such as dose rate, X-ray active icon, fluoro timer, audible signal –X-ray buzzer-) are inactive.
HAZARD INVOLVED	Live images and still images can lead to still images being interpreted as live Images.
HOW TO IDENTIFY AFFECTED PRODUCTS	All systems as mentioned above with all above mentioned components. The affected systems will be clearly identified by the local Philips organization.

URGENT - Field Safety Notice

FCO72200276

All Allura Xper, AlluraClarity, Allura CV, Allura Centron and UNIQ systems

Still image indications

ACTION TO BE TAKEN BY CUSTOMER / USER	The following advice should be followed by the user / customer: • The user must ensure the audible signal (X-ray buzzer) is enabled. • The user must be aware of the indicators related to X-ray ON as described in the Instructions for Use (IFU). • The user must activate only ONE fluoroscopy pedal at time. • To prevent two fluoroscopy pedals being used simultaneously, design measures are in place for all footswitch models and available for use with the system. • Users are strongly advised to configure the footswitch to the default Philips configuration. • The user must be aware that pressing a single shot exposure pedal results in a still exposure image being displayed as long as the single shot exposure pedal is pressed, as described in the Instructions for Use (IFU).
ACTIONS PLANNED BY PHILIPS	• Philips will inform customers via this Field Safety Notice (FSN) about the presence of the live and still image indications on the system as mentioned in the Instructions for Use. (IFU) • Philips will strongly advise customers via this Field Safety Notice (FSN) to ensure the audible signal (X-ray buzzer) is always enabled. • Philips will remind customers via this Field Safety Notice (FSN) to activate only ONE fluoroscopy pedal at time. • Philips will strongly advise customers via this Field Safety Notice (FSN) to configure the footswitch to the default Philips configuration. • The system is working fully within specification and accordance with its intended use.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>