IGT Systems FSN for 2018-IGTBST-006 DHF315242 / XCR609-180031 11-June-2018

URGENT - Field Safety Notice
Medical Device Correction

Allura Xper, UNIQ and Centron

Unexpected Shutter Reset

Dear Customer,

A problem has been detected in the Philips Allura Xper, UNIQ and Centron, that, if it were to re-occur, could pose a risk for patients.

This Field Safety Notice 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 Instructions for Use until the problem is solved by Philips.

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

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Rajesh Kathuria
Head of Q&R
Image Guided Therapy Systems

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AFFECTED PRODUCTS	Allura 8.1.25 Allura 8.1.25.1 Allura 8.1.25.5 Allura 8.2.25 Allura 8.2.25.5 Allura 8.2.27 UNIQ 1.0.10 UNIQ 1.0.10.5 Centron 1.0.10 Centron 1.0.10.1 Centron 1.0.10.5
PROBLEM DESCRIPTION	The first time an operator selects a new procedure type during a single examination, the shutter position resets to the open position for the new procedure type. If the shutters had previously been changed during the examination, that setting is not retained after the first time the procedure type is changed during a single examination.
HAZARD INVOLVED	The X-ray run after the first selection of a procedure during an examination may be created with an unintended open shutter position. Although any unintended shutter position will be detected during this run, this may result in additional radiation exposure the patient and additional scatter radiation exposure for the staff. If the X-ray run does not need to be repeated with adjusted shutter positions, it may still have been generated with less shuttering than intended, resulting in additional X-ray exposure. No injuries attributed to the problem have been reported.
HOW TO IDENTIFY AFFECTED PRODUCTS	The software version of the system is listed on the start-up screen.

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ACTION TO BE TAKEN BY CUSTOMER / USER	Until a software revision that corrects this issue becomes available, users should verify that the desired shutter position is set when performing the run after the first time the procedure type is changed during a single examination. This can be accomplished by first selecting a different procedure and then reselect the original procedure on the Xper Module or on the Data Monitor. Customer shall ensure that all staff with access to the affected systems are informed of the contents of this Field Safety Notice. A copy of this Field Safety Notice shall be placed 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 a software update, which is expected to be available by the second half of 2018. You will be notified by your local Philips representative when the software update is available for installation.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative.