IGT Systems FSN for 2018-IGTBST-006 DHF315242 / XCR609-180031 vs01 June 2018

URGENT - Field Safety Notice
Medical Device Correction

Allura Xper, UNIQ and Centron

Unexpected Collimator 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:

0800 80 3000

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

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 purpose of the collimator shutters is to restrict the exposed patient area to the region of interest. When for the first time an operator selects a new procedure type during a single examination, the collimator shutter position will incorrectly reset to the edge of the imaging area. Because of this, any previously set collimator shutter position will not be retained.
HAZARD INVOLVED	The incorrect collimator shutter reset to the edge of the imaging area might result in additional radiation exposure for the patient and additional scatter radiation exposure for the staff. If the X-ray run needs to be repeated because of the wrong collimation this retake will also lead to additional radiation for the patient. 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.
ACTION TO BE TAKEN BY CUSTOMER / USER	Until a software revision that corrects this issue becomes available, users should verify that the collimator shutter position is set correctly when performing a 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 reselecting 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.

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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: **0800 80 3000**