URGENT – Field Safety Notice
Medical Device Correction

Azurion Interventional Fluoroscopic X-ray System, with software version 1.2

Poor Image Quality

Dear Customer,

A problem has been detected in the Philips Azurion systems with software version R1.2, 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.

A correction of this problem is being currently executed by Philips through FCO72200430. If your system has already been corrected as part of this FCO, the problem reported in this letter in no longer applicable to your system.

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 of the system until FCO72200430 is implemented.

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

0800 80 3000

This notice has been reported to the appropriate Regulatory Agency.

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	Philips Azurion systems with software version R1.2 **Note:** please note that if Philips has executed the correction with reference FCO72200430 in your system, the problem described in this letter is no longer present in your system.
PROBLEM DESCRIPTION	When performing Cine runs, the Azurion's automatic exposure control software may set technique factors that result in radiation emissions too low to obtain useful diagnostic images. This problem may occur after the following sequence of events: 1. Thickness of the patient is 30 cm or more. 2. A fluoro scan is performed. 3. A field of view (FOV) different than the largest FOV is selected. 4. A cine run is performed. The problem does not occur: • if the largest FOV is selected or • when performing Fluoroscopy or Test Shot Lock In (TSLI) runs.
HAZARD INVOLVED	If the quality of the images obtained during the Cine run is inadequate for diagnostic purposes, the study may have to be repeated, requiring additional x-ray radiation of the patient, the administration of additional contrast agent to the patient, and a prolonged procedure time.
HOW TO IDENTIFY AFFECTED PRODUCTS	The software version of the Philips Azurion system is shown on the start-up screen: If the start-up screen shows software version R1.2, your system has the affected release and FCO72200430 should be implemented on your system. If the start-up screen shows software version R1.2.1, your system has the latest system software release and is not affected by this issue. Philips will also be contacting customers with affected systems directly.
ACTION TO BE TAKEN BY CUSTOMER / USER	Please include this Field Safety Notice with the documentation of the system until Philips implements this correction in your system.

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ACTIONS PLANNED BY PHILIPS	Philips has modified the system software to correct this problem. The updated software (release R1.2.1) will be installed free of charge in all affected systems (reference FCO72200430).
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**