

URGENT – Field Safety Notice

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

System Cold Restart Time May Be Prolonged

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 If your system has already been corrected as part of this FCO, the problem reported in this letter is no longer applicable to your system.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 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.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



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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 | The cold restart of Azurion R1.2 systems may take up to 7 minutes if the system is connected to the mains power supply for more than 50 days. |
| HAZARD INVOLVED | A prolonged cold restart time may result in a delay of treatment. If this delay occurs during a critical moment of the procedure, there is a potential for harm for the patient. |
| HOW TO IDENTIFY AFFECTED PRODUCTS | The software version of the 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 | Until Philips corrects your Philips Azurion system, please: <ul style="list-style-type: none"> • At least once every 50 days, briefly disconnect the Azurion system from the mains power supply. Be aware that when an Uninterruptible Power Supply (UPS) is installed, the room emergency power off switch should be used to interrupt the mains power supply to the system. Note that this might also shut down other devices or equipment in the room. • Include this Field Safety Notice with the documentation of the system until Philips implements this correction in your system. |
| 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. |

