

URGENT Field Safety Notice

Philips Azurion R2.1.x System
APC table lock-up when using Azurion R2.1.x system

Oct-2021

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.

Dear Customer,

A problem has been identified in the Philips Azurion R2.1.x system that could pose a risk for patients. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

In the Azurion R2.1.x system, the user can use Automatic Position Control (APC) to move the stand and table based on live or reference images, to previously stored positions, or to predefined projections.

Philips has discovered that when pressing or releasing both the APC (accept) button and the Float Tabletop (panning) button at the same time, there is a possibility that the system stops reacting to movement requests (table lock-up) and X-ray imaging becomes unavailable. This problem is caused by a software defect.

2. Describe the hazard/harm associated with the issue

If this problem occurs, there will be a delay in procedure.

To date, Philips has not received any reports of harm associated with this problem.

3. Affected products and how to identify them

The following products, with a software version 2.1.x, are affected:

Product name	Model number
Azurion 3 M12	722063
Azurion 3 M12	722221
Azurion 3 M15	722064
Azurion 3 M15	722222
Azurion 5 M12	722227
Azurion 5 M20	722228
Azurion 7 B12	722067
Azurion 7 B12	722225
Azurion 7 B20	722068
Azurion 7 B20	722226

Azurion 7 M12	722078
Azurion 7 M12	722223
Azurion 7 M20	722079
Azurion 7 M20	722224

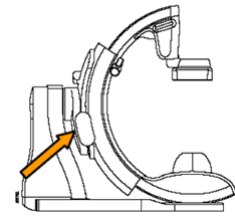


Fig. 1: System identification

The system product name and model number can be found in the System Identification Label located on the system stand (Fig. 1). The users can identify the software version of the Philips Azurion system during the start-up. If the Azurion has software version 2.1.x installed, it is affected by the problem.

Philips will also contact all customers with affected systems.

4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients or users

- Do not press or release both the APC (accept) button and the Float Tabletop (panning) button at the same time during the procedure.
- If the table locks-up, do not perform a cold restart*. It will take 6 minutes until the system is fully available again.
- If the tablet locks-up, perform a warm restart*. With a warm restart the system will be fully functional after 90 seconds. Fluoroscopy will be available after 60 seconds.
- Place this Field Safety Notice with the documentation of the system until the Philips has installed a software update in your system.
- Return the attached reply form to Philips to confirm that the users of the system have reviewed and understood this Field Safety Notice.

* The system restart options are described in section 4.2 of the Instructions for Use.

5. Describe the actions planned by Philips IGT Systems to correct the problem

The problem will be resolved by a software update. You will be contacted by your local Philips representative to schedule the software update for your system.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information, please contact your local Philips representative at the UK Philips Customer Care Service Centre on 0870 532 9741 or Ireland Philips Customer Care Service Centre on +353 1 7640229 (reference to FCO72200494).

Sincerely,

Rajesh Kathuria
Head Q&R – IGT-Systems



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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: 2021-IGT-BST-018

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/County/Post Code /Country: _____

Customer Actions:

- Do not press or release both the APC (accept) button and the Float Tabletop (panning) button at the same time during the procedure.
- If the table locks-up, do not perform a cold restart. It will take 6 minutes until the system is fully available again.
- If the table locks-up, perform a warm restart. With a warm restart the system will be fully functional after 90 seconds. Fluoroscopy will be available after 60 seconds.
- Place this Field Safety Notice with the documentation of the system until the correction has been implemented in your system.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the Azurion R2.1.x system.

Name of person completing this response form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date
(DD/MM/YYYY): _____

Please send this completed form to: **safetynoticeuki@philips.com**