

IMPORTANT PRODUCT NOTICE

9th September 2025

Reference: C&R 2024-IGT-BST-022 - Potential temporary loss of motorized movements due to firewall router not installed

Dear Customer,

Philips has identified that, in certain instances, the firewall router might not be installed in specific Azurion R2.x or R3.x systems. This Important Product Notice is intended to inform you about:

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

Philips has identified that the firewall router might not be installed in specific Azurion systems.

The firewall router separates the internal Azurion network from the hospital network. If this router is not installed, there could be interference between the Azurion and the hospital network. When this occurs, the Azurion will initiate an automatic restart of the positioning software, during which all motorized movements will be disabled and the message “The geometry is restarting” will be displayed on the screen. The restart will take approximately 90 seconds to complete, after which motorized movements will be fully available. X-ray imaging is not impacted by this issue and remains available during the positioning software restart.

There is no security risk to the Azurion system when the firewall is not installed.

Due to the temporary nature of the positioning software restart and the continued availability of X-ray imaging, no adverse impact on the procedure and no health consequences are expected. Philips has received no reports of patient harm related to this issue.

2. Affected products and how to identify them

The Product Name and Model Number of the specific Azurion systems affected is shown in the following table:

System Product Name	Model Number
Azurion 3 M12	722063
Azurion 3 M15	722064
Azurion 7 B12	722067
Azurion 7 B20	722068
Azurion 7 M12	722078
Azurion 7 M20	722079
Azurion 3 M12	722221
Azurion 3 M15	722222
Azurion 7 M12	722223
Azurion 7 M20	722224
Azurion 7 B12	722225
Azurion 7 B20	722226
Azurion 5 M12	722227
Azurion 5 M20	722228

Azurion 3 M12	722229
Azurion 3 M15	722230
Azurion 5 M12	722231
Azurion 5 M20	722232
Azurion 7 M12	722233
Azurion 7 M20	722234
Azurion 7 B12	722235
Azurion 7 B20	722236
Azurion 3 M15	722280
Azurion 5 M20	722281
Azurion 7 M20	722282

The System Product Name and Model Number can be found on the System Identification Label located on the System stand (refer to Figure 1). The software version of the Philips Azurion system can be identified during startup (refer to Figure 2).

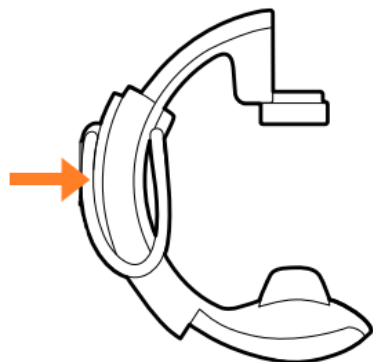


Figure 1: System Identification label

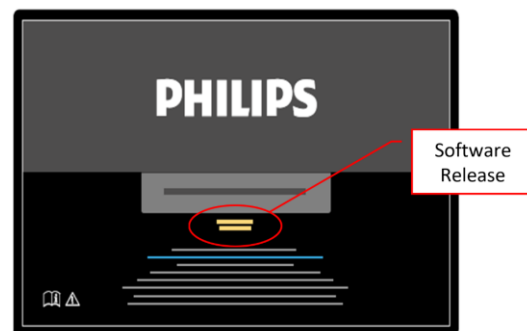


Figure 2: System Startup Screen

3. The actions that you as a customer can take to minimize the effect of the issue

- Circulate this Important Product Notice to all users so that they are aware of the issue.
- Keep this Important Product Notice with the documentation of the system until Philips corrects your system.
- Complete and return the attached response form included with this Important Product Notice to Philips promptly, and no later than 30 days from receipt. Completing this form confirms receipt of the Important Product Notice and understanding of the issue and required actions to be taken.

4. The actions planned by Philips to correct the issue

Philips will inspect all specific Azurion systems to confirm that the firewall router is installed and if not, Philips will be installing the firewall router free of charge.

Philips expects to start this activity in December 2025. Your local Philips representative will contact you to schedule this activity.

5. Additional Information and Support

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact compliance@triomed.com.mt

Philips regrets any inconvenience caused by this issue.

Sincerely,

Marjan Vos

Head of Quality – IGT Systems

IMPORTANT PRODUCT NOTICE RESPONSE FORM

Reference: Potential temporary loss of motorized movements due to firewall router not installed – Philips Azurion Systems R2.x and R3.x - Philips reference: C&R 2024-IGT-BST-022

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 Important Product Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Circulate this Important Product Notice to all users so that they are aware of the issue.
- Keep this Important Product Notice with the documentation of the system until Philips corrects your system.

We acknowledge receipt and understanding of the accompanying Important Product Notice and confirm that the information from this notification has been properly distributed to all users who handle the Azurion R 2.x and R 3.x systems without a firewall router.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

It is important that your organization acknowledges receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this Important Product Notice.