

IMPORTANT PRODUCT NOTICE

7 December 2023

RE: Roadmap pro dark image

Dear Customer,

A problem has been detected in the Philips Azurion Systems, that, if it were to occur, could affect the performance of the equipment. This Important Product Notice is intended to inform you about:

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

During the device phase of Roadmap Pro, a user may experience a dark image that is not clinically usable. The dark image may result after the user performs a pedal tap (shortly touching the footswitch pedal without generating an Xray image). The pedal tap may cause a dark image with the next fluoroscopy run.

Roadmap Pro allows you to superimpose a mask image of the vessel tree to improve visibility of catheters, devices, and materials.

Roadmap Pro is 2D subtracted fluoroscopy and is acquired in two phases:

- The first phase is the vessel mask. This is used to create the mask onto which the live fluoroscopy is superimposed.
- The second phase is the device phase. This phase is to view the device, for example a catheter, wire, or coil, under fluoroscopy over the vessel mask.

2. Affected products and how to identify them

The following systems with software release R2.2.0, R2.2.1, R2.2.3, R2.2.5 and R2.2.6 are affected:

System product name	Model number
Azurion 3M12	722063, 722221
Azurion 3M15	722064, 722222
Azurion 5M12	722227
Azurion 5M20	722228
Azurion 7B12/12	722067, 722225
Azurion 7B20/15	722068, 722226
Azurion 7M12	722078, 722223
Azurion 7M20	722079, 722224

The system product name and model number can be found on the System Identification Label located on the system stand (Figure 1).

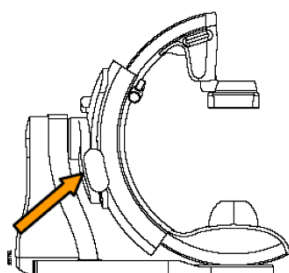


Figure 1: System identification

The software version of the Philips Azurion system can be identified during start-up (Figure 2).

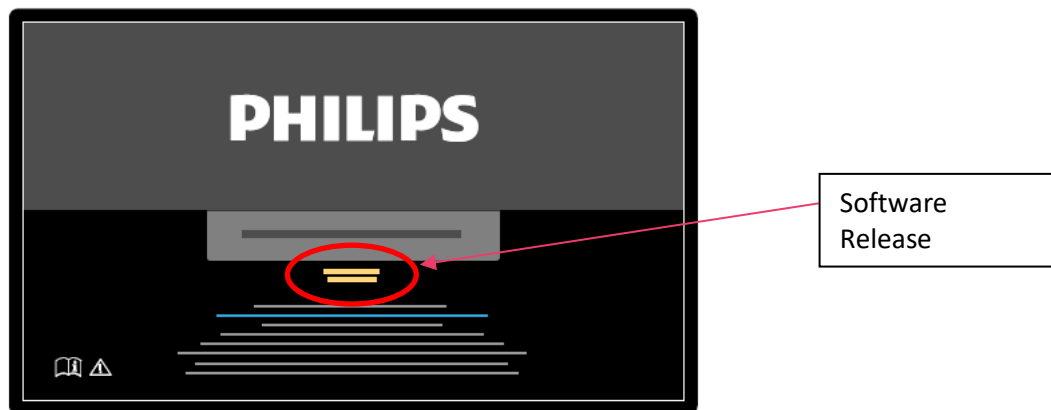


Figure 2: System start-up screen

This issue only happens on Philips Azurion systems with Roadmap Pro.

The availability of the Roadmap Pro functionality can be identified on the Touch Screen Module (TSM) (Figure 3).



Figure 3: System with Roadmap Pro

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

- Prevent pedal tapping (i.e. pressing the footswitch and releasing it before the first X-ray image has been created)
- In case of an inadvertent pedal tap during the device phase, restart the device phase by using the 'Reset Device' button in the Roadmap menu on the TSM (Figure 4).

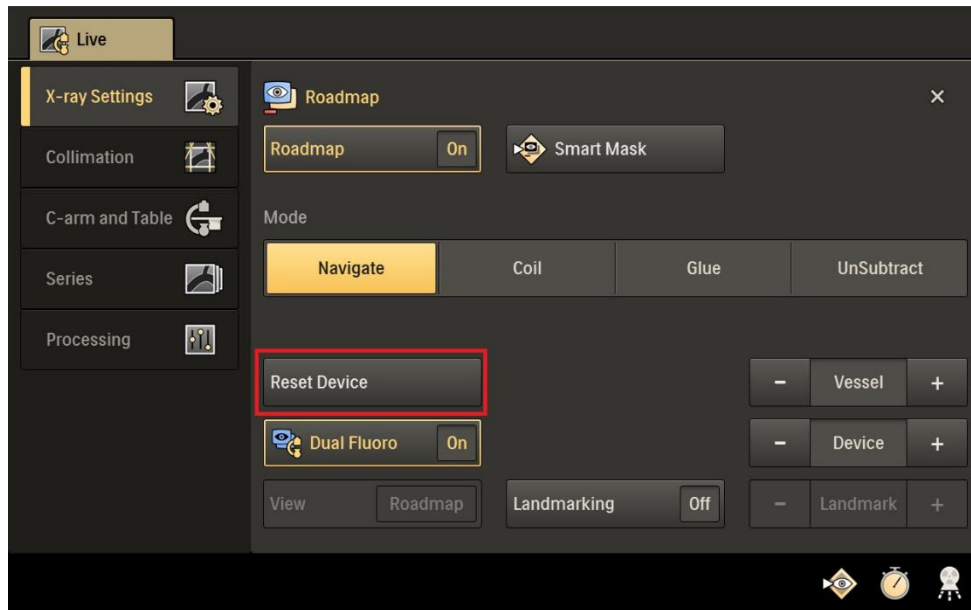


Figure 4: Location of “Reset Device” button on the TSM.

- Keep this Important Product Notice with the documentation of the system until Philips corrects your system.
- Circulate this notice to all users of the system so that they are aware of the issue.
- Return the attached reply form to Philips to confirm that the users of the system have reviewed and understood this Important Product Notice.

4. The actions planned by Philips to correct the problem

Philips is working on a software release that will correct this issue (reference FC072200528).

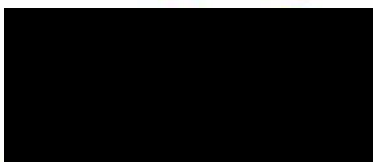
You will be contacted by your local Philips representative to schedule these activities.

5. Additional Information and Support

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

Philips regrets any inconvenience caused by this problem.

Sincerely,



Marjan Vos
Head of Quality – IGT Systems

IMPORTANT PRODUCT NOTICE RESPONSE FORM

Reference: Roadmap pro dark image

Instructions: Please complete and return this form to Philips Healthcare promptly upon receipt and no later than 30 days from receipt. Completing this form confirms receipt of the Important Product Notification, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Prevent pedal tapping (i.e. pressing the footswitch and releasing it before the first X-ray image has been created)
- In case of an inadvertent pedal tap during the device phase, restart the device phase by using the 'Reset Device' button in the Roadmap menu on the TSM.
- Keep this Important Product Notice with the documentation of the system until Philips corrects your system.
- Circulate this notice to all users of the system so that they are aware of the issue.

We acknowledge receipt and understanding of the accompanying Product Notice and confirm that the information from this Notification has been properly distributed to all users that handle the Philips Azurion system with Roadmap Pro.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date

(DD/MM/YYYY): _____