IGT Systems FSN for 2017-IGTBST-021 DHF297966 / XCR609-170038 13-March-2018

URGENT - Field Safety Notice
Medical Device Correction

Allura Xper R9 and Azurion R1.1

Distance measurements not correctly exported

Dear Customer,

A problem has been detected in the Philips Allura Xper R9 systems and Azurion R1.1 systems, that, if it were to re-occur, could pose a risk for patients.

This 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.

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 Instructions for Use until the problem is solved by Philips.

When using the downscale option, the measurements performed with the Allura Xper R9 system or Azurion R1.1 system using the QA Basic Measurement tool will not be correctly exported to the external DICOM destination. Only these measurements when using the downscale option and exported are affected.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

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	Allura Xper R9 and Azurion R1.1 systems with the QA Basic Measurement tool. Product names: Allura Xper R9 7M12, Allura Xper R9 7M20, Azurion 7M12; Azurion 7M20; Azurion 3M12; Azurion 3M15.
PROBLEM DESCRIPTION	In order to save archiving space, the Allura Xper R9 systems and Azurion R1.1 systems include the option of downscaling the image when exporting images to the external DICOM destination (e.g., PACS). When using the downscale option, the measurements performed with the Allura R9 system or Azurion R1.1 system using the QA Basic Measurement tool will not be correctly exported to the external DICOM destination. The difference between the original measurement and the exported measurement can vary. The distance value after export is factor 1 to 4 smaller than the original value. The difference will depend on the acquired image (e.g., X-ray protocol, field of view) and the used archive settings (i.e., downscale settings). If the measurement is re-performed at the external DICOM destination, the result will also be incorrect unless a recalibration of the image is executed. **Note:** The QA Basic Measurement tool is used to perform distance measurements, so that the user has an indication on the size of anatomical structures or devices. Measurements performed using the Quantitative Vascular Analysis, the Quantitative Coronary Analysis, the Left Ventricular Analysis or the Right Ventricular Analysis packages are NOT affected by this issue.

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HAZARD INVOLVED	The QA Basic Measurement tool is post processing software intended to provide the user an indication of the size of the anatomical structures or devices from angiographic X-ray images during cardiovascular procedures and for post procedural evaluation. When using the downscale option in order to save archiving space, the images are exported with incorrect measurements to the external DICOM destination. If these exported downscaled images are used during or in preparation of an interventional procedure, these incorrect measurement values could result in the selection of an incorrect sized device (e.g., stent or valve). The same applies if a measurement is re-performed at the external DICOM destination without executing a recalibration of the image. **Note:** To date Philips is not aware of any injuries that may have occurred due to this issue.

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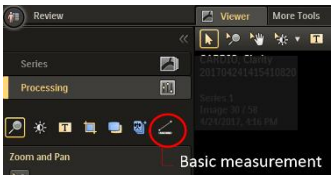
HOW TO IDENTIFY AFFECTED PRODUCTS	During the cold startup of the system the splash screen identifies the production version of the system. After startup, the system version details are shown in the product information screen on the Help menu by clicking About. Refer to Instruction for Use chapter 17.3 (System Version). When QA Basic Measurement option is enabled, the icon highlighted below is shown in the post-processing screen. Chapter 8.14 (Creating Measurements) describes processing. 
ACTION TO BE TAKEN BY CUSTOMER / USER	The Downscale option should be disabled in all Export protocols until Philips corrects this issue. To accomplish this, you may refer to Chapter 13.8 (Configuring Export Protocols) of the system instructions for use that describes how to perform this action. You may also contact your Philips local representative for assistance in performing this action. All archived images exported using the downscale option would be affected by this issue, therefore such measurements from archived images should not be relied on. Additional precaution could be taken by re-performing measurements during the actual interventional procedure.
ACTIONS PLANNED BY PHILIPS	The problem will be resolved by a software update, which is expected to be available by the end of 2017. In the interim, a similar notice will be provided along with newly manufactured devices shipped for use. You will be notified by your local Philips representative when the software update is available for installation.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.