***IGT Systems*** **FSN** 2019-IGTBST-019 12-December-2019

# URGENT – Field Safety Notice

## VesselNavigator application in combination with Azurion R1.2.x and R2.0.x.

**Digital Subtraction Angiography (DSA) overlay not visible on VesselNavigator Application.**

Dear Customer,
cc: Chairman Medical Board and relevant Head of Departments

This Field Safety Notice is intended to inform you about a defect identified in the VesselNavigator application when used with a Philips Azurion System R1.2.x or R2.0.x, and the impact it has in the use of this application.

Due to a software defect, when a Digital Subtraction Angiography (DSA) is exported to the VesselNavigator application, the DSA is displayed without subtraction.

This Field Safety Notice 2019-IGTBST-019 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 Instruction for Use until Philips implements the correction.

Philips apologizes for any inconveniences caused by this problem.

[redacted]
R. Rathuna
Head Q&R
Image Guided Therapy Systems

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| **AFFECTED PRODUCTS** | Philips VesselNavigator application when used with the Philips Azurion System R1.2.x and R2.0.x, |
| **PROBLEM DESCRIPTION** | Due to a software defect, when a Digital Subtracting Angiography (DSA) is exported to the VesselNavigator application, the DSA is displayed without subtraction.<br>The unsubtracted images contain more anatomical information than the DSA, which may not be suitable for verification of the registration of a pre-operative CT/MR with X-ray images during the Live Guidance step. |
| **HAZARD INVOLVED** | There are two potential hazards:<br>• Use of the unsubtracted images that contain more anatomical information may result in mismatch between overlay images and live image potentially leading to device misplacement (e.g. stent misplacement).<br>• Unnecessary dose for the patient if the unsubtracted images cannot be used for the registration step.<br><br>**Note:** To date Philips has not been reported any harm that may have occurred due to this problem. |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | Philips VesselNavigator application when used with an Azurion system R1.2.x and R2.0.x are affected.<br>Philips will be contacting customers with affected systems. |
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | Untill Philips implements the software update:<br>• Please suspend the use of Digital Subtraction Angiography images for the verification of the registration during the Live Guidance step.<br>• Please ensure that all staff working with the VesselNavigator application are informed of the content of this safety notice and place a copy of it with the instructions. |
| **ACTIONS PLANNED BY PHILIPS** | The problem will be resolved by a software update, which will be available by the end of December 2019.<br><br>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: Healthcare Representative/Modality Engineer: 1800-744-5477. |