# URGENT - Field Safety Notice
# Medical Device Correction

## *Software for Philips Azurion 2.0 Interventional Fluoroscopic X-ray system*
### *XperGuide application hosted in Interventional Workspot 1.5*

Dear Customer,

Philips has identified an issue in the Philips Azurion 2.0 systems that have the XperGuide application enabled in the Interventional Workspot platform. This issue could pose a risk for patients.

This Field 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 or users
- 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 the problem is solved by Philips.

Philips will correct this issue by installing a software upgrade (Interventional Workspot 1.5.1) in all affected systems. No patient harm arising from this issue has been reported to Philips to date.

If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Rajesh Kathuria
Head Q&R
IGT Systems

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| **AFFECTED PRODUCTS** | XperGuide Software hosted in Interventional Workspot 1.5, when used with the following Philips Azurion 2.0 system:<br><br>**Product code - System description:**<br>722079 - Azurion 7 M20 |
| **PROBLEM DESCRIPTION** | When a user acquires XperCT scan on an Azurion 2.0 system, enters the XperGuide guidance step and moves the L-arm away from the initial scan position before starting the live guidance, a warning message is displayed in the main screen directing the user to move the L-arm stand back to the initial XperCT scan position. Although the software generates this message, it does not prevent the use of live guidance if the L-arm stand is not repositioned. Using live guidance with a mispositioned L-arm can result in the display of an incorrect overlay and needle path. |
| **HAZARD INVOLVED** | Tissue damage due to incorrect overlay and needle path. However, no harm has been reported to Philips to date. |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | The users can identify the software version of the Philips Azurion system during the start-up. The version is displayed in the splash screen. Interventional Workspot software release is displayed in the splash screen during start-up of Interventional Workstation. The XperGuide application will only be visible in the Interventional Workspot platform if enabled. If the Azurion has software version 2.0 installed and XperGuide is enabled, the system is affected and will be corrected.<br>Philips will be contacting directly customers with affected systems. |
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | To avoid this hazardous situation, the users should:<br>• Use XperGuide live guidance with the L-arm positioned in the XperCT scan position.<br>• Move the L-arm back to the initial XperCT scan position if the system displays the warning "*Live 3D roadmap not possible. Please move stand to the [acquisition position] position*".<br>At any stage during needle guidance, the user can perform a verification run to verify if the needle position is correct.<br><br>Please ensure that all staff working with the XperGuide application are informed of the content of this letter and place a copy of this letter as an addendum to the Instructions for Use. |

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| **ACTIONS PLANNED BY PHILIPS** | Philips will correct this issue by installing a software upgrade to Interventional Workspot 1.5.1 in all affected systems. This upgrade will prevent the use of XperGuide live guidance when the L-arm is positioned away from the XperCT scan position. This upgrade will be available at the beginning of April 2020. You will be contacted by our local Philips representative to schedule an appointment. |
| **FURTHER INFORMATION AND SUPPORT** | If you need any further information or support concerning this issue, please contact your local Philips representative:<br><br>**0800 80 3000** |