URGENT - Field Safety Notice

Medical Device: Azurion R2.0

<Date>
<Hospital/Clinic Name>

Detector Cable Set Inspection

cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

A problem has been detected in the Philips Azurion R2.0 system that, if it were to re-occur, 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
- 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.

During manufacturing of an Azurion R2.0, it was found that the cable set in the C-arc was not according to specifications. Philips initiated an investigation and confirmed that Azurion R2.0 systems in the field have to be inspected and corrected if the cable set is found to be not according to specifications.

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

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

R. Kathuria
Head Q&R IGT systems

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AFFECTED PRODUCTS	Azurion R2.0 with [redacted]
PROBLEM DESCRIPTION	During manufacturing of an Azurion R2.0 system, it was found out that the cable set was not according to specification. This resulted in damage of the 24V power cable of the detector.
HAZARD INVOLVED	When the cable set is not manufactured according to specification, in extreme positions of the C-Arc roll, cables of the C-Arc may get damaged. If a cable is damaged, the attached part of the system such as the detector, collimator or tube may cease to function leading to loss of key image functionality or mechanical movement. This could result in interruption or delay of a procedure and potentially lead to injury to the patient if the system fails during a critical phase of the procedure.
HOW TO IDENTIFY AFFECTED PRODUCTS	The two serial numbers identified in the section "Affected Products" above are affected. Philips is contacting directly customers with an affected system.
ACTION TO BE TAKEN BY CUSTOMER / USER	A copy of this Field Safety Notice shall be placed together with the documentation of the system until the system has been inspected and corrected if applicable by Philips.
ACTIONS PLANNED BY PHILIPS	Philips will inspect the affected systems free of charge. If the system is not according to specification, Philips will correct the system to bring it back to specification. You will be contacted by your local Philips representative to schedule these actions. This action will start effective from February 2019.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative.