IGT Systems **Reference: 2020-IGTBST-017** **23-April-2021**

URGENT - Field Safety Notice

Allura Xper and UNIQ systems

Increased failure rate observed for low-voltage DC Power Supplies

Dear Customer,

Analysis of service reports conducted as part of Philips' quality management system has detected a problem with a component of the Xper R8.2.x and UNIQ R1.0.x systems, which 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 product

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 product Instructions for Use until the problem is solved by Philips.

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 Agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Rajesh Kathuria,
Head Q&R
IGT Systems.

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AFFECTED PRODUCTS	A limited number of Allura Xper R8.2 and UNIQ R1.0 Systems are affected. The Philips product numbers for these systems are: **Product name:** — **Product code:** **Allura Xper** Allura Xper FD10 — 722026 Allura Xper FD10/10 — 722027 Allura Xper FD20 — 722028 Allura Xper FD20/10 biplane — 722029 Allura Xper FD20 OR Table — 722035 Allure Xper FD20/20 — 722038 Allura Xper FD20/15 — 722058 **UNIQ** UNIQ FD20 — 722028
PROBLEM DESCRIPTION	Philips Healthcare has discovered through trend analysis an increase in the failure rate of certain low-voltage DC power supplies (“DCPS”) used in these products. Each system contains multiple DCPS, some of which may be subject to an increased probability of failure. Failure of a DCPS may result in the sudden loss of imaging functionality or mechanical movement, depending on what subsystems the DCPS is powering.
HAZARD INVOLVED	The loss of key imaging functionality or mechanical movement during a diagnostic or therapeutic procedure may interrupt or require the abandonment of the procedure. In rare instances, unavailability of live imaging might lead to a possible injury to the patient when the system fails during a critical phase of the procedure. **Note:** To date Philips Healthcare is not aware of any potential injuries that may have occurred due to failure of DCPS.
HOW TO IDENTIFY AFFECTED PRODUCTS	For systems mentioned above, If 'Rev 8.2.16 or ‘Rev 8.2.17’ appears in the lower (black) area of the start-up screen, the system is affected. Philips will be notifying customers with affected systems.
ACTION TO BE TAKEN BY CUSTOMER / USER	The likelihood of a system failure occurring is remote, and the users are recommended to follow their pre-established procedures for managing potential patient safety in the event that the system shuts down.

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ACTIONS PLANNED BY PHILIPS	Philips will replace the affected DCPS. This service will be provided free of charge for all affected systems. A Philips Healthcare service representative will contact customers with affected devices to arrange for the service.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative.

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Customer Facility Name	
Address	
Phone number	
Our facility has received the above referenced Field Safety Notice, will take recommended actions and will inform staff working with the affected product of the content of this correction.	
Name	
Title/Function	
Signature	
Date	

Please send this confirmation form to your local Philips representative.