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URGENT Field Safety Notice

Philips Allura Xper R8.1 System with Poly-G Stand
Potential loss of supporting functionality and movement control not performing as intended

31-JUL-2024

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 this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with the Lifetime Extension Kit for Philips Allura Xper R8.1 systems with Poly-G Stand. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

Philips has identified an issue in a limited number of Lifetime Extension (LTE) Kits, for Allura R8.1 systems with a lifetime exceeding 10 years from their installation, where a wrong bolt was included. A half-threaded bolt was included in the LTE kits instead of the correct full-threaded bolt.

In systems utilizing a Poly-G Stand, the full-threaded bolt is intended to fix the propeller motor of the C-arm to the Poly-G Stand. The propeller motor cannot be properly secured with a half-threaded bolt. This improper fixation may lead to an uncontrolled C-arm movement, which can result in unavailability of Cone Beam CT imaging.

2. Hazard/harm associated with the issue

When a half-threaded bolt is used to secure the propeller motor instead of the correct full-threaded one, uncontrolled C-arm movement may occur during clinical use which may contribute to (1) minor physical injury (e.g., minor bruise) due to a collision between the system and patient when the detector is placed in close proximity to the patient, or (2) delay of therapy due to unavailability of Cone Beam CT imaging.

To date, Philips has not received any reports of patient harm due to this issue.

3. Affected products and how to identify them

The **Allura Xper series** are intended for use on human patients to perform:

- Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

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The following systems with lifetimes exceeding 10 years from their installation are affected:

System Product Names	Model Number	Serial number
Allura Xper FD10	722010	111
Allura Xper FD10	722010	138
Allura Xper FD10	722010	467
Allura Xper FD10	722010	817
Allura Xper FD20	722012	2928
Allura Xper FD20 Biplane	722013	269

Affected systems can be identified by their System Product Name, Model Number, and Serial Number (SN), which can be found on the System Identification Label located on the system stand (Figure 1).

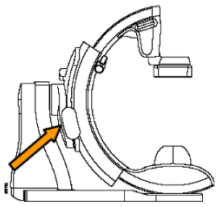

Figure 1: System identification

4. Actions that should be taken by the customer / user in order to prevent risks for patients

a. Affected systems may continue to be used in accordance with their Instructions for Use (IFU).

b. Keep this Urgent Field Safety Notice letter with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.

c. Circulate this notice to all users of the system so that they are aware of the issue.

d. Should you experience uncontrolled C-arm movement, call your local Philips representative to report the event.

e. Return the attached response form to Philips promptly and no later than 30 days from receipt to confirm that the users of the system have reviewed and understood this Field Safety Notice and required actions to be taken.

5. Actions planned by Philips IGT-S to correct the problem

Philips will contact all affected customers to arrange for a Field Service Engineer visit to install an updated Lifetime Extension Kit with the correct full-threaded bolt (reference FCO72200590).

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

Philips regrets any inconvenience caused by this matter.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

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URGENT Field Safety Notice Response Form

Reference: Potential loss of supporting functionality and movement control not performing as intended for Allura Xper R8.1 System with Poly-G Stand, Philips C&R reference number 2024-IGT-BST-005.

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

Customer Actions:

a. Affected systems may continue to be used in accordance with the Instructions for Use (IFU)
b. Keep the Urgent Field Safety Notice letter with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.
c. Circulate this notice to all users of the system so that they are aware of the issue.
d. Should you experience uncontrolled C-arm movement, call your local Philips representative to report the event.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the Philips Allura Xper system.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

It is important that your organization acknowledges receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this Field Safety Notice.