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URGENT Field Safety Notice

Philips Allura Xper R7.6- R8.1 systems

Delay of installation of the Lifetime Extension (LTE) kit in Allura Xper R7.6-R8.1 systems may lead to a broken propeller motor clamping bolt and a broken X-ray tube locking bolt.

Date: 11-NOV-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 potential safety issues in Allura Xper R7.6- R8.1 systems where the Lifetime Extension (LTE) kit is not installed in a timely manner. This URGENT Field Safety Notice is intended to inform you about:

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

Philips has identified potential safety issues with delayed LTE kit installations for Allura R7.6-R8.1 systems exceeding 10 years of life. The kit includes a propeller motor clamping bolt (see Figure 1) and the X-ray tube locking bolt (see Figure 2). If one of these bolts breaks, part of the system will not function as expected.

If the installation of the LTE kit is delayed, breakage of the propeller motor clamping bolt and/or the X-ray tube locking bolt may be expected. If this occurs,

- The broken propeller motor clamping bolt may cause erratic C-arm movements, and potentially colliding with patients or bystanders (see Figure 3). These unbalanced movements may also cause the system to falsely detect a collision, consequently blocking motorized C-arm movements.
- The broken X-ray tube locking bolt may cause the tube to hit the cover, causing unexpected noise and the appearance of a black area (maximum up to 25%) on the X-ray image. Consequently, the area of interest in the X-ray image may be obscured, leading to the need for an additional scan.

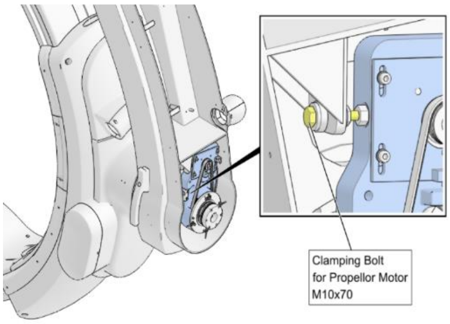

Figure 1: Clamping bolt of the C-arm propeller drive

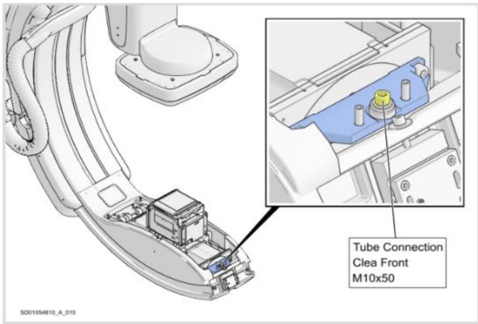

Figure 2: Locking bolt of the X-ray tube

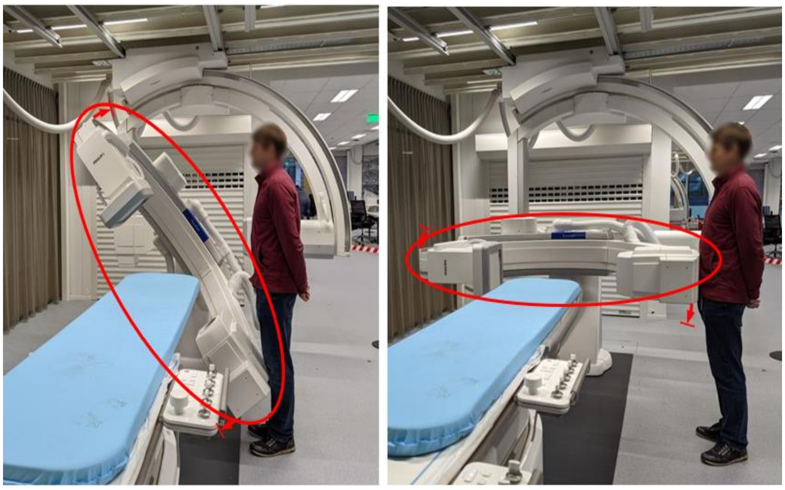

Figure 3: Erratic movements of C-arm (red circle) due to broken propeller motor clamping bolt.

2. Hazard/harm associated with the issue

A broken propeller motor clamping bolt could cause erratic C-arm movements, potentially resulting in the tube or the detector hitting staff or patients, leading to minor physical injuries (Example: hematoma/bruises, scratches, small cuts, or skin abrasions). Additionally, these erratic movements may trigger false collision detections, blocking all C-arm motorized movements and potentially delaying diagnosis or treatment.

A broken X-ray tube locking bolt could cause a black area to appear on the X-ray image, which may obscure the area of interest. This may require repeat imaging (up to 1 or 2 additional X-ray images or 3D scans), leading to additional radiation exposure. However, this additional radiation is not expected to exceed the thresholds for tissue reactions set by the International Commission on Radiological Protection (ICRP) for the risk of illness or injury.

To date, Philips has received one (1) complaint related to a broken propeller motor clamping bolt and no complaints related to the broken X-ray tube locking bolt.

To date, Philips has not received any reports of patient harm due to these issues.

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, for example, 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.

The following Allura Xper R7.6-R8.1 systems are affected.

Product Name	**Model Number**
Allura Xper FD10	722010
Allura Xper FD10 OR Table	722022
Allura Xper FD10/10	722011
Allura Xper FD20	722012
Allura Xper FD20 OR Table	722023
Allura Xper FD20 Biplane	722013
Allura Xper FD20 Biplane OR Table	722025

Affected systems can be identified by their Product Name and Model Number. These can be found on the System Identification Label on the frontal stand (see Figure 4)

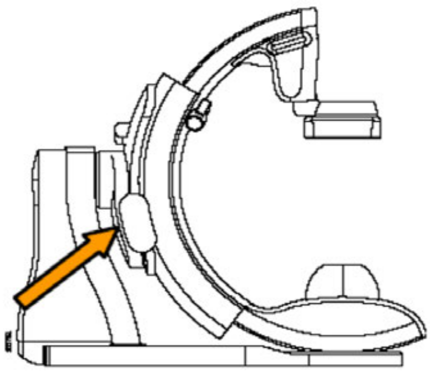

Figure 4: Position of labels on the frontal stand

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

- Affected systems may continue to be used in accordance with their Indications for Use and Instructions for Use (IFU).
- Keep this Urgent Field Safety Notice letter with the documentation of the system until Philips corrects your system. Ensure that the letter is in a place likely to be seen/viewed.
- Circulate this notice to all users of the system so that they are aware of the issue.

- If you experience erratic movements of the C-arm and/or if you see a portion of black area on the X-ray image, please call your local Philips representative to report the event.
- Complete and return the attached response form (refer to page 05) 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 a Lifetime Extension Kit (reference FCO72200598). As of the date of this Urgent Field Safety Notice, Philips expects the solution to be available by Q1 2025.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning these issues, contact your local Philips representative.

Philips regrets any inconvenience caused by this problem.

Sincerely,

[redacted]

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URGENT Field Safety Notice Response Form

Reference: 2024-IGT-BST-010: Delay of installation of the Lifetime Extension (LTE) kit in Allura Xper R7.6-R8.1 systems may lead to a broken propeller motor clamping bolt and a broken X-ray tube locking bolt.

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, understanding of the issues, and required actions to be taken.

Customer/Consignee/Facility Name: ______________________

Street address: ______________________

City/State/ZIP/Country: ______________________

Customer Actions:

- Affected systems may continue to be used in accordance with their Indications for Use and Instructions for Use (IFU).
- Keep this Urgent Field Safety Notice letter with the documentation of the system until Philips corrects your system. Ensure that the letter is in a place likely to be seen/viewed.
- Circulate this notice to all users of the system so that they are aware of the issue.
- If you experience erratic movement of the C-arm and/or if you see a portion of black area on the X-ray image, please call your local Philips representative to report the event.

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

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 Urgent Field Safety Notice.