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URGENT Field Safety Notice

L-arm rotation cover may fall on Philips Allura and Philips Azurion systems with monoplane fixed ceiling mounts

31-Oct-2023

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 identified a potential safety issue with the Philips Allura and Azurion Product Families with the monoplane fixed ceiling mounted systems. 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 a potential safety issue with the Philips Allura and Azurion Product Families having monoplane fixed ceiling mounted systems. The ceiling mounted L-arm contains a rotation cover that may potentially be susceptible to falling if a collision between the L-arm and other hospital equipment (i.e., an operating light) were to occur. Although the cover is retained by a safety chain, if a collision were to occur the chain may also detach resulting in the cover falling on the patient, user, or bystander. There have been 5 incidents where minor injuries, such as bruises or scratches, were reported. To date, there have been no reported serious injuries or deaths related to this issue.

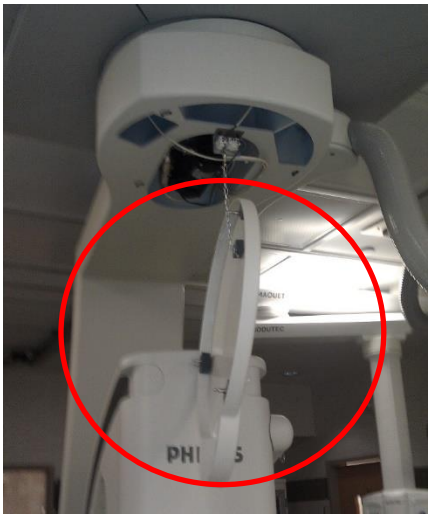

***Figure 1**: Example of a detached L-arm rotation cover*

2. Hazard/harm associated with the issue

<u>Hazards associated with potential sterility issues due to the cover becoming loose:</u>

The cover may fall when there is no patient on the table or operator in the vicinity. In such situations, there will be no adverse health consequences. However, if the cover detaches during a procedure, it may result in dirt/microorganisms coming into contact with a sterile environment. A compromised sterile environment may result in infection, and/or the need to take measures to control infection.

Hazards associated with trauma due to the falling cover:
If the cover falls during a procedure, the device will continue to work, and it is possible to continue treatment. The cover weighs less than 1,14 kilogram (2,51 pounds) and may result in scratches or bruises if it were to come into contact with a patient, user, or bystander.

3. Affected products and how to identify them

All Allura and Azurion Product Families with the monoplane fixed ceiling mounted systems are affected by this issue, as shown in Figure 2 and Table 1 below.

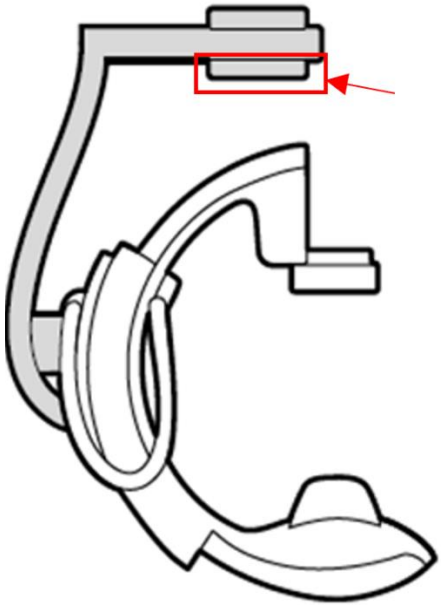

Figure 2: *Only monoplane fixed ceiling mounted systems are impacted (as shown above)*

Table 1: *Impacted Products and Description*

Product Code	Product Description
72246	Poly G - OMCP - VISUB - CCD (H5000)
722001	Allura Xper FD10C
722003	Allura Xper FD10
722006	Allura Xper FD20
722010	Allura Xper FD10
722012	Allura Xper FD20
722015	Allura Xper FD20 OR Table
722016	Integris H5000 C / Allura 9C
722018	Integris Allura 9
722022	Allura Xper FD10 OR Table
722023	Allura Xper FD20 OR Table
722026	Allura Xper FD10
722028	Allura Xper FD20

722033	Allura Xper FD10 OR Table
722035	Allura Xper FD20 OR Table
722043	Integris Allura 15 & 12 (monoplane)
722078	Azurion 7 M12
722079	Azurion 7 M20
722223	Azurion 7 M12
722224	Azurion 7 M20
722227	Azurion 5 M12
722228	Azurion 5 M20

Intended Use

The **Allura Xper** series (including the Poly G H5000) 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, embolization's 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 **Azurion series** (within the limits of the used operating room table) is intended for use to perform:

- Image guidance in diagnostic, interventional, and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular, and neuro procedures.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures.

Additionally:

- The Azurion series can be used in a hybrid operating room.
- The Azurion series contains a number of features to support a flexible and patient-centric procedural workflow.

The Azurion series is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.

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

- Keep this Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.
- Avoid collisions to prevent serious injury to patients and staff, or damage to the equipment. Care should be taken to prevent collisions between hospital equipment and the L-arm rotation cover when moving a ceiling boom (i.e., an operating light) or during motorized movement of the L-arm to avoid collision with a ceiling boom (Refer to the Azurion Instructions for Use, section 2.4 of and the Allura Basic Instructions for Use, section 3.6).
- If the cover falls during a procedure, when no person is harmed, the cover may be reseated, removed, or released and stored and the procedure continued based on medical judgment.
- Circulate this Notice to all users of the system so that they are aware of the issue.
- Please complete and return the attached response form (on page 5) to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notification Letter and understanding of the issue and required actions to be taken.

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5. Actions planned by Philips Image Guided Therapy Systems to correct the problem

As a remedy, Philips is replacing the existing covers of all the affected Philips Allura and Philips Azurion with the monoplane fixed ceiling mounted systems with a redesigned L-arm rotation cover (bolted instead of spring clips) to make sure it is resistant to external collisions.

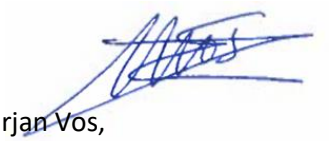
Philips will contact all affected customers to arrange for a Field Service Engineer visit to replace the L-arm rotation cover free of charge (reference FCO72200510 for the Philips Allura systems, including the Philips Poly G H5000, FCO72200511 for the Philips Azurion systems).

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market/Business>*

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. Philips regrets any inconvenience caused by this problem.

Sincerely,



Marjan Vos,
Head of Quality – IGT Systems

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URGENT Field Safety Notice Response Form

Reference: Allura and Azurion Product Families L-arm Rotation Cover May Fall

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 issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure the letter is in a place likely to be seen/viewed.
- Avoid collisions to prevent serious injury to patients and staff, or damage to the equipment. Care should be taken to prevent collisions between hospital equipment and the L-arm rotation cover when moving a ceiling boom (i.e., an operating light) or during motorized movement of the L-arm to avoid collision with a ceiling boom (Refer to the Azurion Instructions for Use, section 2.4 of and the Allura Basic Instructions for Use, section 3.6).
- If the cover falls during a procedure, when no person is harmed, the cover may be reseated, removed, or released and stored and the procedure continued based on medical judgment.
- Circulate this Letter to all users of the system so that they are aware of the issue.

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 Allura and Azurion Product Families.

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 corrective action.

<provide instructions here for the customer regarding returning the form to Philips, e.g. fax #, email address. For example, "Please fax this completed form to Philips at (xxx)xxx-xxxx>