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URGENT Field Safety Notice

Philips Allura and Azurion systems

Deaeration hose of tube cooling unit may degrade over time and develop oil leakage, potentially leading to loss of imaging functionality or exposure of users and/or patients to fumes

24-APR-2026

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 Allura and Azurion systems equipped with a tube cooling unit of type CU3101. The deaeration hose in the tube cooling unit may degrade over time and develop oil leakage, which could potentially lead to loss of imaging functionality or, in rare cases, exposure of users and/or patients to fumes. 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 that the deaeration hose in X-ray tube cooling units type CU3101, manufactured between February 2016 and May 2020, may degrade over time, potentially resulting in oil leakage.

Oil leakage may affect the cooling performance of the X-ray tube. When the oil flow drops below a certain threshold, the system automatically switches to low-dose fluoroscopy and displays the message "*Low load fluoroscopy flavor selected: Tube cooler problem*". This condition cannot be resolved by restarting the system.

Under normal conditions, any leaked oil is contained within the system. In rare cases of more significant leakage, oil may extend beyond the intended containment area. If oil then comes into contact with hot surfaces, fumes may be generated. These fumes may activate environmental detection systems.

2. Hazard/harm associated with the issue

This issue may result in loss of imaging functionality, potentially resulting in or contributing to a delay of therapy which may result in serious adverse health outcomes. Most at risk are patients undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia, life-threatening bleedings).

In rare cases, oil leakage may lead to the generation of fumes, which could result in temporary exposure to fumes for people in the surrounding area. This may cause irritation of the skin, eyes, or respiratory system. Most at risk are individuals with pre-existing respiratory conditions (e.g., asthma, chronic obstructive pulmonary disease) as well as critically ill and immuno-compromised individuals.

The estimated probability of serious adverse health outcomes is improbable. To date, no harm to patients, users, or service personnel has been reported in relation to this issue.

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3. Affected products and how to identify them

Philips Allura and Azurion systems are potentially affected by this issue.

Appendix A to this letter includes the intended use of the affected systems and how to identify them.

4. Actions that should be taken by the customer / user that are aimed at lowering risks for patients or users

- Circulate this Urgent Field Safety Notice to all users of the system so that they are aware of the issue.
- In case the affected system has been transferred to another organization, please send a copy of this Urgent Field Safety Notice to that organization and inform Philips about this transfer through your local Philips representative.
- Keep this Urgent Field Safety Notice with the documentation of the system until Philips corrects your system. Ensure that the letter is in a place likely to be seen/viewed.
- Complete and return the response form included in this Urgent Field Safety Notice to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice and understanding of the issue and required actions to be taken.
- If you experience the issue described in this letter, please report it to your local Philips representative.

5. Actions planned by Philips IGT Systems to correct the issue

Starting in Q1 2027, Philips will replace the deaeration hose in the CU3101 tube cooling unit in all affected systems. Your local Philips representative will contact you to schedule a visit to replace the deaeration hose once available

This notice has been reported to the appropriate Regulatory Agencies.

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,

[redacted]

Marjan Vos
Head of Quality – IGT Systems

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URGENT Field Safety Notice Response Form

Reference: Deaeration hose of tube cooling unit may degrade over time and develop oil leakage, potentially leading to loss of imaging functionality or exposure of users and/or patients to fumes in Philips Allura and Azurion systems. Philips C&R reference number is **2025-IGT-BST-020**.

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:

- Circulate this Urgent Field Safety Notice to all users of the system so that they are aware of the issue.
- In case the affected system has been transferred to another organization, please send a copy of this Urgent Field Safety Notice letter to that organization and inform Philips about this transfer through your local Philips representative.
- 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.
- Complete and return the response form included in this Urgent Field Safety Notice to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice letter and understanding of the issue and required actions to be taken.
- If you experience the issue described in this letter, please report it to your local Philips representative.

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 affected Philips Allura and Azurion systems.

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.

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Appendix A - Affected Systems and Intended Use

Affected Systems

The following Allura and Azurion systems equipped with a CU3101 Cooling Unit are potentially affected by this issue.

Model Number	System Product Name
722001	Allura Xper FD10C
722002	Allura Xper FD10F
722003	Allura Xper FD10
722005	Allura Xper FD10/10
722006	Allura Xper FD20
722008	Allura Xper FD20 Biplane
722010	Allura Xper FD10
722011	Allura Xper FD10/10
722012	Allura Xper FD20
722013	Allura Xper FD20 Biplane
722015	Allura Xper FD20 OR Table
722016	Integris H5000 C / Allura 9C
722018	Integris Allura 9
722021	INTEGRIS Allura 9 (biplane)
722023	Allura Xper FD20 OR Table
722025	Allura Xper FD20 Biplane OR Table
722026	Allura Xper FD10
722027	Allura Xper FD10/10
722028	Allura Xper FD20
722029	Allura Xper FD20/10
722030	Integris CV Cesar-Powerpack-Visub-Nicol
722035	Allura Xper FD20 OR Table
722038	Allura Xper FD20/20
722039	Allura Xper FD20/20 OR Table
722043	Integris Allura 15 & 12 (monoplane)
722044	INTEGRIS Allura 15-12 (biplane)
722058	Allura Xper FD20/15
722059	Allura Xper FD20/15 OR Table
722063	Azurion 3 M12
722064	Azurion 3 M15
722067	Azurion 7 B12
722068	Azurion 7 B20
722078	Azurion 7 M12
722079	Azurion 7 M20
722223	Azurion 7 M12
722224	Azurion 7 M20
722225	Azurion 7 B12
722226	Azurion 7 B20
722228	Azurion 5 M20
722400	Cardio Vascular-Allura Centron

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The System Product Name and Model Number can be found on the System Identification Label located on the System stand (Figure 1).

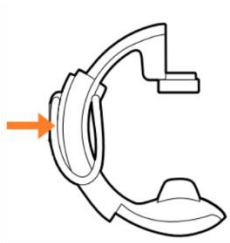

Figure 1- System Identification Label

Intended Use

The **Azurion series** 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.

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.
- Additionally:
    - The Allura Xper series is compatible with a hybrid Operating Room.
    - The Allura Xper FD 10 Systems are compatible with specified magnetic navigation systems.
    - The Allura Xper series is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.

The **Allura Centron** consists of a monoplane system with 15” detector size. It uses X-Ray Fluoroscopy and Acquisition imaging for Cardiac and Peripheral procedures:

- Vascular diagnostic and interventional procedures (Angiogram, Balloon Angioplasty, Stenting)
- Cardiac diagnostics and interventions (PCI)
- Pacemaker implantations and implantable defibs

- Electrophysiology (EP) and RF ablation
- Non-vascular interventions such as drainages, biopsies and vertebroplasty procedure

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

The Philips **Integris-Allura** is a dedicated X-ray system for vascular diagnostic and interventional procedures.

The system is intended for:

- Peripheral, Abdominal, Cerebral diagnostic and interventional angiography, neuro applications, cardiac applications, and non-vascular interventions.