PHILIPS

URGENT Field Safety Notice

Philips Allura Xper, Allura CV20, Allura Centron, and MultiDiagnost-Eleva systems
Hand switch button may not fully release, potentially leading to loss of imaging functionality or unintended radiation exposure and additional contrast injection

18-MAY-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 identified a potential safety issue involving the hand switch used with Philips Allura Xper, Allura Centron, Allura CV20, and MultiDiagnost-Eleva systems. Under certain conditions, the hand switch button may not fully release after being pressed, potentially resulting in loss of imaging functionality or unintended radiation exposure and potentially additional contrast medium injection. 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 observed occurrences in which the hand switch button, used for activating exposure from the control room, did not fully release after being pressed due to mechanical resistance within the button mechanism.

The hand switch has three mechanical positions (see Figure 1 below):

1) Neutral – the button is not pressed.
2) Prepare – the button is partially pressed (first actuation point), during which the system enters a preparation phase for exposure imaging. During this phase, imaging functionality is not available.
3) Expose – the button is fully pressed (second actuation point), activates exposure imaging.

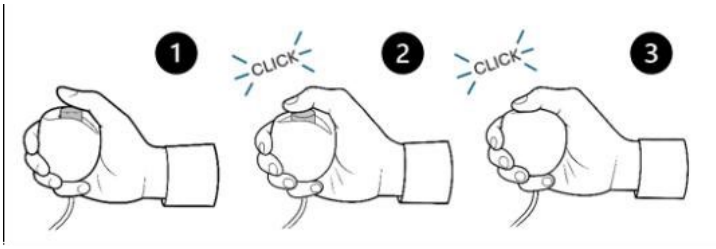

Figure 1 – Exposure Hand Switch positions.

If the button, upon release, returns only to the Prepare position, the system remains in the exposure-prepare state, and imaging functionality is disabled. No system message is displayed to indicate this state.

If the button, upon release, does not return and remains in the Expose position, exposure X-ray imaging continues until the system completes the programmed acquisition (for example, completion of a rotational scan) or until the button is manually released (e.g., by pulling, tapping, or repeatedly pressing the button).

When exposure imaging is used in conjunction with an integrated injector, contrast injection continues until the preset contrast volume is delivered or until exposure imaging is interrupted.

2. Hazard/harm associated with the issue

This issue may result in loss of imaging functionality, unintended radiation exposure, or additional contrast medium injection.

Loss of imaging functionality may contribute to a delay of therapy, potentially resulting 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). Unintended radiation exposure may lead to limited or transient radiation effects. Most at risk are pediatric patients, pregnant women, and patients with existing radiation-related conditions. Long-term effects are not expected. Additional contrast medium injection may lead to mild or moderate kidney-related effects requiring medical intervention to prevent temporary impairment. Most at risk are patients with pre-existing kidney conditions.

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

3. Affected products and how to identify them

All Philips Allura Xper, Allura Centron, Allura CV20, and MultiDiagnost-Eleva 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 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.
- Before starting a procedure, verify that the hand switch button returns smoothly to the neutral position after being pressed. If you notice a delay in return or abnormal friction when pressing the button, avoid using the hand switch and contact your Philips representative.
- If the issue occurs during an ongoing procedure, try to release the button by manually pulling the button upwards, tapping or repeatedly pressing the button.
- If you experience the issue described in this letter, please report it to your local Philips representative.
- 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.

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

Philips will replace the hand switch with a new design hand switch in all affected systems. Philips will start hand switch replacement by Q3 2026 for Allura systems and by Q4 2026 in MD-Eleva systems. Your local Philips representative will contact you to schedule a visit to perform this activity on your system once available.

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

Telephone 80 30 30 35
Email philips.service@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this issue.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

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URGENT Field Safety Notice Response Form

Reference: Hand switch button may not fully release, potentially leading to loss of imaging functionality or unintended radiation exposure and additional contrast injection in Allura Xper, Allura CV 20, Allura Centron and MultiDiagnost-Eleva systems. Philips C&R reference number is **2024-IGT-BST-025**.

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.
- Before starting a procedure, verify that the hand switch button returns smoothly to the neutral position after being pressed. If you notice a delay in return or abnormal friction when pressing the button, avoid using the hand switch and contact your Philips representative.
- If the issue occurs during an ongoing procedure, try to release the button by manually pulling the button upwards, tapping or repeatedly pressing the button.
- If you experience the issue described in this letter, please report it to your local Philips representative.
- 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.

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, Allura CV20, Allura Centron, and MultiDiagnost-Eleva 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.

Please complete and return this form via email to: **FCO.Nordic@philips.com**

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Appendix A - Affected Systems and Intended Use

Affected Systems

Model Number	System Product Name
708032	MultiDiagnost Eleva
708034	MultiDiagnost Eleva with Flat Detector
708036	MultiDiagnost Eleva
708037	MultiDiagnost Eleva with Flat Detector
708038	MultiDiagnost Eleva with Flat Detector
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
722019	Allura Xper FD10/10 OR Table
722020	Allura Xper FD20 Biplane OR Table
722022	Allura Xper FD10 OR Table
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
722031	Allura CV20
722033	Allura Xper FD10 OR Table
722035	Allura Xper FD20 OR Table
722038	Allura Xper FD20/20
722039	Allura Xper FD20/20 OR Table
722058	Allura Xper FD20/15
722059	Allura Xper FD20/15 OR Table
722400	Cardio Vascular-Allura Centron

The System Product Name and Model Number can be found on the System Identification Label located on the System stand (see Figure 2 below).

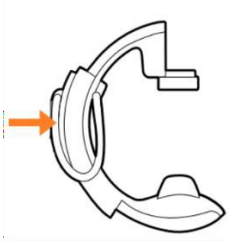

Figure 2 – System Identification Label

Intended Use

The **Allura Xper** is 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).
- No n-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

  Additionally:

  - The Allura Xper series is compatible with a hybrid Operating Room.

The Allura 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 **Allura CV20** is a monoplane system with a floor mounted C-arm stand with a 20” detector size. The Allura CV20 is intended for physicians (e.g. cardiologists and radiologists), assisted by trained hospital staff (e.g. nurses and lab technicians), who are qualified to perform medical procedures on humans (having a maximum weight of 250 kg.) with probable internal diseases or injuries for:

- Dedicated vascular and carotid imaging applications, including diagnostic and interventional procedures.
- Cardiac imaging applications including diagnostics, interventional procedures, pacemaker implantations and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

The **MultiDiagnost Eleva series** is intended to be used as a multifunctional / universal system. General R/F, Fluoroscopy, Radiography and Angiography can be performed along with more specialized interventional applications. This includes the following general areas:

- Digestive system
- Skeletal system
- Urinary system

- Reproductive system
- Respiratory system
- Circulatory system
- Stent placement
- Various: Arthrograms, Myelograms, Facet joint injections, Discography, Sialograph