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URGENT Field Safety Notice

Philips Allura Systems
Potential Loss of Motorized Movement

03-SEP-2025

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 affecting specific Philips Allura Xper and Allura CV20 Systems that include in their configuration a Geo PC of the model Wolfdale (Q35 generation). This URGENT Field Safety Notice is intended to inform you about:

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

The Geo PC of the model Wolfdale (Q35 generation) that controls the geometry movements of Philips Allura Systems may not perform as intended due to the deterioration of certain internal components (the CMOS battery, hard disk drive, and/or power supply unit). If this deterioration occurs, motorized movements of the system will become unavailable, and the following message will be displayed to the user: *"WARNING: Motorized movement not available"*. Manual movements of the stand (longitudinal, transversal and rotational for ceiling mounted systems and rotational for floor mounted systems) and table longitudinal movements are available. Imaging (X-ray) functionality remains available. The issue may be intermittent and may be resolved by performing a system cold restart. However, a system cold restart may not always resolve the issue. A system warm restart will not resolve the issue.

2. Hazard/harm associated with the issue

Loss of motorized movements during clinical use can contribute to a delay of therapy for patients. The potential delay of therapy may result in serious adverse health outcomes, including the possibility of death, especially when the system is used with patients undergoing complex and/or urgent interventions for potentially life-threatening conditions (e.g., acute ischemic stroke, ST-segment elevation myocardial ischemia, life-threatening bleeding).

In the period from January 2021 to June 2025, Philips received 376 complaints related to this issue. None of these complaints reported any harm to the patient.

3. Affected products and how to identify them

Philips Allura Xper and Allura CV20 Systems that include in their configuration a Geo PC of the model Wolfdale (Q35 generation) are affected by this issue.

Appendix A to this letter provides a table with the System Codes and Commercial Names, and the intended use of the affected systems.

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 and follow the instruction below.
- Perform a system cold restart every day before starting the first procedure, as follows:
  - On the Review Module, press and hold “Power Off”.
  - Release the button when the indicator light begins to flash.
  - When the indicator light stops flashing, wait for 10 seconds.
  - On the Review Module, press and hold “Power On”.
    NOTE: Do not operate any of the controls while the system is powering on, as this may inhibit the start-up process.
- In case the user message “WARNING: motorized movement not available” is shown, perform a system cold restart following the instructions above. A cold restart may temporarily resolve the issue, but it can take up to 6 minutes from initiation until full system functionality is available again.

  After completion of the procedure, do not use the system and contact your local Philips representative immediately.
- In case motorized movements are unavailable, the stand can be manually repositioned using the handgrips and brake controls located on both sides of the stand. For ceiling mounted systems, manual longitudinal (1), transversal (2) and rotational (3) stand movements are available. Note: Transversal stand movement (2) are only available for ceiling mounted systems with FlexMove option. For floor-mounted systems, only rotational (3) stand movements are available. The table longitudinal position (4) can be adjusted manually, when the table is not tilted.

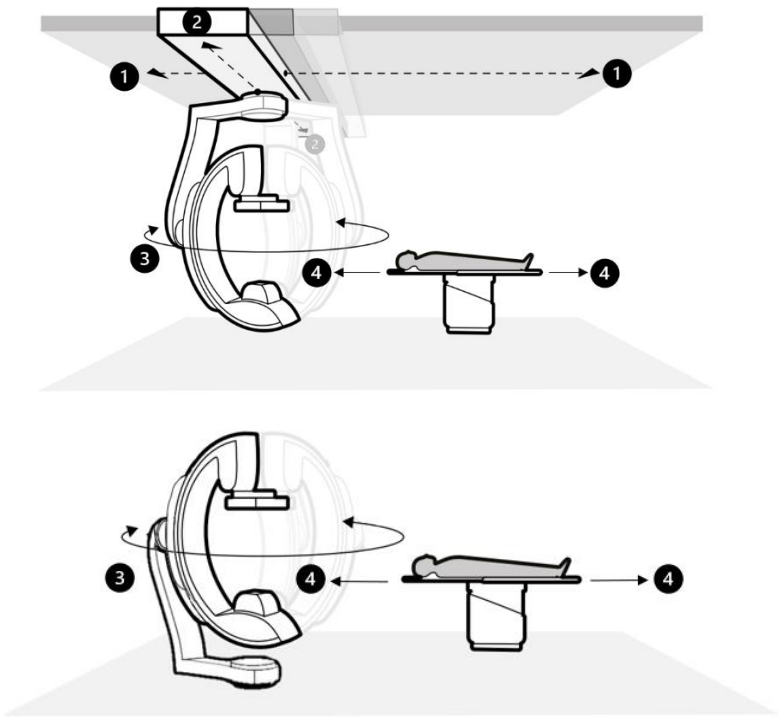


Figure 1 – Manual movements of the ceiling mounted system (top) and floor mounted system (bottom)

For those systems connected under a remote monitoring agreement, until implementation of the correction (see Section 5), Philips will be remotely evaluating log files of the Geo PC for this issue. If

a delayed startup of the Geo PC is detected through remote monitoring, Philips will contact you to schedule a visit to replace the Geo PC.

NOTE: Regardless of such remote evaluation, Philips cannot guarantee that Geo PC issues can be prevented and/or alerted (in due time).

  - In case your system is not connected under a remote monitoring agreement with Philips, sign up for free remote monitoring by contacting your local Philips representative.[1]

- 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 Image Guided Therapy Systems to correct the issue

Philips will be replacing the Geo PC in all affected systems.

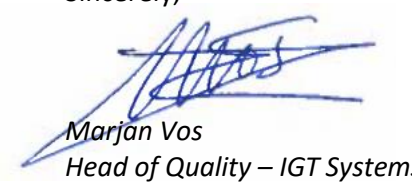
Philips expects to start replacing the Geo PC units by September 2025. Your local Philips representative will contact you to schedule a visit to confirm If your system has a model Wolfdale (Q35 generation) Geo PC and to plan the replacement of the Geo PC once available.

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 any further information or support concerning this issue, please contact your local Philips representative:

Philips regrets any inconvenience caused by this matter.

Sincerely,



Marjan Vos
Head of Quality – IGT Systems

[1] Subject to technical feasibility, applicable laws, and customer's agreement with the applicable terms and conditions.

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URGENT Field Safety Notice Response Form

Reference: Potential Loss of Motorized Movement with Philips Allura Systems. Philips C&R reference number 2024-IGT-BST-024.

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 and follow the instruction below.
- Perform a system cold restart every day before starting the first procedure, as follows:
    - On the Review Module, press and hold “Power Off”.
    - Release the button when the indicator light begins to flash.
    - When the indicator light stops flashing, wait for 10 seconds.
    - On the Review Module, press and hold “Power On”.
      NOTE: Do not operate any of the controls while the system is powering on, as this may inhibit the start-up process.
- In case the user message “WARNING: motorized movement not available” is shown, perform a system cold restart following the instructions above. A cold restart may temporarily resolve the issue, but it can take up to 6 minutes from initiation until full system functionality is available again.

  After completion of the procedure, do not use the system and contact your local Philips representative immediately.
- In case motorized movements are unavailable, the stand can be manually repositioned using the handgrips and brake controls located on both sides of the stand. For ceiling mounted systems, manual longitudinal, transversal and rotational stand movements are available. Note: Transversal stand movement are only available for ceiling mounted systems with FlexMove option. For floor-mounted systems, only rotational stand movements are available. The table longitudinal position can be adjusted manually, when the table is not tilted.

For those systems connected under a remote monitoring agreement, until implementation of the correction (see Section 5), Philips will be remotely evaluating log files of the Geo PC for this issue. If a delayed startup of the Geo PC is detected through remote monitoring, Philips will contact you to schedule a visit to replace the Geo PC.

NOTE: Regardless of such remote evaluation, Philips cannot guarantee that Geo PC issues can be prevented and/or alerted (in due time).

- In case your system is not connected under a remote monitoring agreement with Philips, sign up for free remote monitoring by contacting 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.

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- 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.

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 affected Philips Allura 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

Product Code	Product Description
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
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

The Product Code and Product Description can be found on the System Identification Label located on the System stand (see Figure 2).

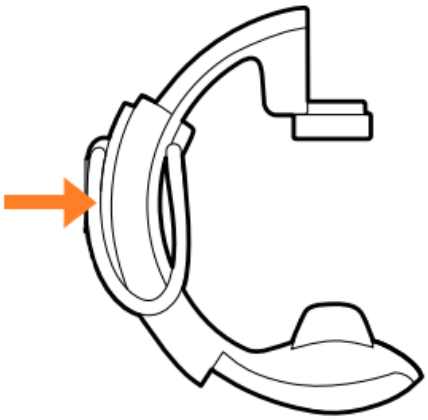

Figure 2 - System Identification Label

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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 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 series 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.