To all user of the following systems

Product/Trade Name: ARTIS pheno

UDI-DI: 4056869046877

EU-SRN DE-MF-000006122

E-mail [redacted]

Date August, 2025

Corrective Action ID AX032/25/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Limited system movement after startup

Dear Customer,

We would like to inform you about a potential issue with your ARTIS pheno system and a corrective action that will be performed.

What is the issue and when does it occur?

Initiating a shutdown of the system can sporadically lead to a state in which the robotic C-arm stand cannot be moved after the next system startup. Other movements (e.g. table movements) are still available with reduced speed.
The system may show the following generic messages "Reduced stand/table speed" and "Limited stand movement, wait".

What is the impact on the operation of the system and what are the possible risks?

In case the error occurs the C-arm stand will not move anymore. Therefore, the C-arm cannot be moved into the required position. This may result in a situation where it is necessary to cancel the clinical procedure or to begin or continue the procedure on an alternative system.

How was the issue identified and what is the root cause?

The issue was reported from the field. The root cause is a software issue.

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Which steps have to be taken by the user to avoid the possible risks associated with this issue?

The user shall test system movements after each system startup, according to the daily checks described in the operator manual. In case the robotic C-arm stand cannot be moved, and the described system messages are displayed please call the service.

What actions are being taken by the manufacturer to mitigate possible risks?

The firmware of the affected components will be updated.

What is the efficiency of the corrective action(s)?

The corrective action mitigates the probability of occurrence of the issue.

How will the corrective action be implemented?

A service technician will update the affected component on site.
Our service organization will get in contact with you for an appointment to perform the corrective action. Please feel free to contact our service organization for an earlier appointment.
This letter will be distributed to affected customers as update AX034/25/S.

What risks are there for patients who have previously been examined or treated using this system?

The manufacturer does not consider this system to bear risks for patients who have previously been examined or treated.

Please ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.
Please forward this safety information to any other organizations that could be affected by this measure.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

With best regards,

Siemens Healthineers AG
Business Area Advanced Therapies (AT)