To all user of the following systems

Product/Trade Name:	ARTIS icono floor, ARTIS icono biplane, ARTIS icono ceiling
UDI-DI:	4056869149325, 4056869063317, 4056869295923

EU-SRN	DE-MF-000038456
E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
Date	May, 2026
Corrective Action ID	AX018/26/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Information regarding a possible issue for ARTIS icono systems delivered with software version VE40A and VE40B

Dear Customer,

We would like to inform you about a potential issue with your ARTIS icono system delivered with software version VE40A and VE40B and a corrective action that will be performed.

What is the issue and when does it occur?

In very rare situations, after increasing the detector lift height to its maximum or minimum, the system may lose its movement capability. A reboot may not reestablish movement control. This failure can be resolved only by qualified service personnel.

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

If this issue occurs, the system will report a failure of movement control and request a service call. It will not be possible to move the stand other than by emergency salvage procedures, manual unmotorized table movements as well as fluoroscopy and acquisition will be still available. This may result in a situation where it is necessary to cancel the clinical procedure or to continue or begin the procedure on an alternative system.

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

The issue was detected during regular field observation. The root cause is a position mismatch within the movement supervision.

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

If the issue occurs an ongoing procedure might need to be terminated.
Please follow the instructions for emergency rescue in the instructions for use.

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

The software of the affected systems 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?

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 AX019/26/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)

Electronically signed by: Carsten Bertram
Reason: I am approving this document
Date: May 18, 2026 10:48:10 GMT+2

Carsten Bertram
President Advanced Therapies

Electronically signed by: Christian Dittmer
Reason: I am approving this document
Date: May 15, 2026 18:46:57 GMT+2

Christian Dittmer
Person Responsible for Regulatory Compliance