To all users of the following systems

Product/Trade Name: ARTIS icono ceiling

UDI-DI: 4056869295923

EU-SRN DE-MF-000006122

E-mail advancedtherapies-fsca.team@siemens-healthineers.com

Date June, 2026

Corrective Action ID AX022/26/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Information regarding a possible DCS issue for ARTIS icono ceiling systems

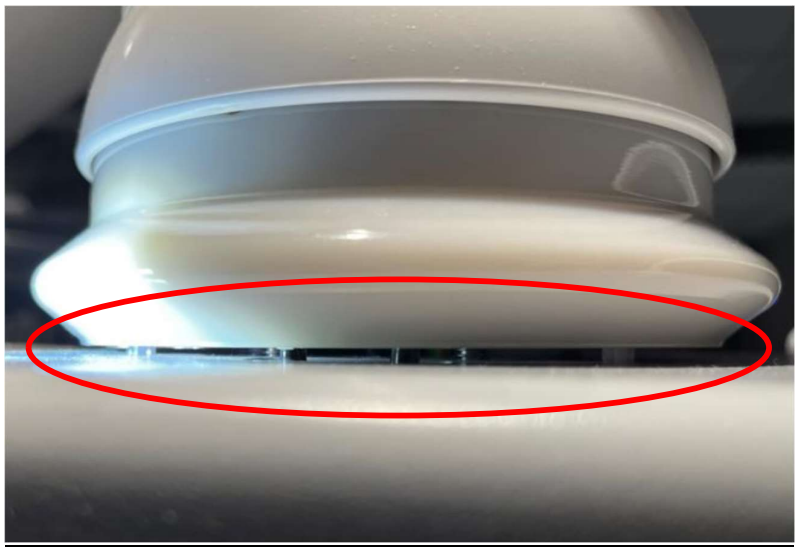
Dear Customer,

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

What is the issue and when does it occur?

The affected part is the Display ceiling suspension (DCS Fix XL) that holds the monitor in place. Over time, some screws that keep the monitor attached may slowly become loose. This happens near the X-ray indicator light. As the screws loosen gradually, a small gap can be seen underneath the indicator light. This gap increases slowly and can be noticed over a longer period of time.

This issue has been observed sporadically and appears to correlate with the frequency of use of the monitor suspension system.



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

The monitor carrier is attached to the supporting arm using multiple screws, providing a high level of mechanical redundancy. If one or more screws at this connection loosen, a visible gap may appear between the monitor carrier and the X-ray indicator light. Because several screws secure the connection, the system includes built-in safety redundancy if an individual screw begins to loosen.

If operation continues while screws are loosening, internal cables routed within the arm may become damaged. This damage can result in loss of the displayed image. If the condition is not detected in time or is ignored, additional screws may progressively loosen over time.

In the worst-case scenario, complete loosening of the connection could occur. This may result in separation of the monitor carrier from the supporting arm and a downward drop. Such an event poses a significant risk of serious injury to patients and operating room staff.

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

The issue was identified during field observations.

The screw tightening torque can be insufficient in certain practical situations. Frequent impacts against the DCS end stops may lead to a loosening of the screws.

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

To minimize risk, regular inspection of the gap between the monitor carrier and the ceiling-mounted arm should be performed. If a gap is observed, promptly contact our service organization for guidance. Additionally, be attentive to any unusual noises, shaking, wobbling, or other unexpected behavior during operation, as these may indicate loose screws. If you observe any such signs, limit movements of the DCS and contact our service organization immediately for further instructions.

Always ensure that the DCS is positioned for safe use.

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

Our service representative will correct the screwed connection of the monitor ceiling support according to the adapted specifications and instructions.

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

The corrective action mitigates the probability of occurrence of the non-conformity.

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 AX023/26/S.

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

We do not consider it necessary to re-examine any patients in this case as this possible hardware fault has no influence on treatment of patients.

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: Philipp Fischer
Reason: I am approving this document
Date: Jun 5, 2026 11:35:36 GMT+2

Dr. Philipp Fischer
President Advanced Therapies

Electronically signed by: Christian Dittmar
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Christian Dittmar
Person Responsible for Regulatory Compliance