To all user of following systems

Product/Trade Name:	see Attachment 1
UDI-DI:	see Attachment 1

EU-SRN	DE-MF-000038456
E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
Date	March, 2024
Corrective Action ID	AX005/23/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Ensuring the correct coolant level of the X-ray tube assembly without a coolant level sensor

Dear Customer,

We have already informed you with CSI AX006/20/S of a possible issue with your Artis system related to the tube cooling unit and of the corrective actions. Unfortunately, the solution does not fit to your local building setup. The necessary cable routing between cooling device and system cabinet cannot be established according to our knowledge. Therefore, we would like to inform you about the further procedure.

The following explanations have already been provided to you with the CSI AX006/20/S.

What is the issue and when does it occur?

If the coolant level in the tube cooling circuit drops below a certain level, this may result in a situation in which the X-ray tube is no longer sufficiently cooled and the Artis system will display the message “TUBE HOT, have a break”. Several minutes later the Artis system will block X-ray to prevent further damages and displays the message “NO XRAY: TUBE TOO HOT”.

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

In case the issue occurs, the system cannot be operated normally. This may result in a situation where it is necessary to cancel clinical treatment or to continue treatment on an alternative system.

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

The issue was detected by regular field observation. The root cause is a coolant loss of the tube cooling unit which occurs over time.

Siemens Healthineers AG
Chairman of the Supervisory Board: Ralf P. Thomas;
Managing Board: Bernhard Montag, President and Chief Executive Officer;
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Which steps have to be taken by the user to avoid the possible risks associated with this issue?

As also described in the Operator Manual, we recommend that the system operator checks the water level of the cooling circuit at least every three months and refills water, if necessary:

1. Open the filling gland of the cooling unit. The water surface must be clearly visible above the cooling ribs.
2. Replenish with water (drinking water quality) if cooling liquid is lacking.

Please inform the service technician in case of lacking cooling liquid.

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

The announced measure to install a water level sensor from the CSI AX006/20/S is not applicable for your site because it does not fit to your local building setup.
We have informed and advised our customers to check and refill the cooling unit according to the provided instruction for use of the Artis system. In addition, a label will be affixed on the start-up console of the Artis system in the control room to remind the user of checking cooling levels. As a courtesy, our service organization will check the water level once outside the regular maintenance interval. Prospectively, the check of the cooling level is part of each maintenance.

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

Probability of occurrence of the issue will be mitigated by taking the above measures.

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 AX034/23/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 relation with the issue described above.

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: Mar 20, 2024 17:15 GMT+1

Carsten Bertram
President Advanced Therapies

Electronically signed by: Christian Dittmar
Reason: I am approving this document
Date: Mar 20, 2024 16:13 GMT+1

Christian Dittmar
Person Responsible for Regulatory Compliance

Attachment 1

Product/Trade Name	UDI-DI
Artis Q floor	4056869009971
Artis Q ceiling	4056869009988
Artis Q biplane	4056869009995
Artis Q zeego	4056869010007
Artis Q.zen floor	4056869010014
Artis Q.zen ceiling	4056869010021
Artis Q.zen biplane	4056869010038
Artis Q zeego	4056869012711
Artis zee floor	4056869010045
Artis zee ceiling	4056869010052
Artis zee multi-purpose	4056869010076
Artis zee biplane	4056869010069
Artis zee floor MN	4056869010090
Artis zee biplane MN	4056869010106
Artis zeego	4056869010083
Artis zee III floor	4056869012643
Artis zee III ceiling	4056869012650
Artis zee III multi-purpose	4056869012667
Artis zee III biplane	4056869012674
Artis zeego III	4056869012681
Artis zee III floor MN	4056869012698
Artis zee III biplane MN	4056869012704