To all user of the following systems

Product/Trade Name: *see Attachment 1*

Model Number: *see Attachment 1*

EU-SRN	DE-MF-000006122
E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
Date	February, 2022
Corrective Action ID	AX002/20/S / AX004/20/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: X-ray tube coolant level and new coolant level sensor

Dear Customer,

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

What is the issue and when does it occur?

If the coolant level in the 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 System will display the message “TUBE HOT, have a break”. Several minutes later the 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.

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 tube cooling unit will be equipped with a water level sensor and the software will be updated accordingly. In case the coolant level drops below a certain threshold the following message will be displayed: “Tube cooling water level low: Refill as per Operator Manual”.

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

The Hardware and software update will mitigate the 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 AX006/20/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 Healthcare GmbH

Business Area Advanced Therapies (AT)

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Electronically signed by: Carsten Bertram Reason: I am approving this document Date: Feb 18, 2022 09:39 GMT+1

Carsten Bertram

President Advanced Therapies

i.V.

Electronically signed by: Johann Boeck Reason: I am approving this document Date: Feb 18, 2022 09:30 GMT+1

Johann Böck

Person Responsible for Regulatory Compliance

Attachment 1

Product/Trade Name	Model number
Artis Q floor	10848280
Artis Q ceiling	10848281
Artis Q biplane	10848282
Artis Q zeego	10848283
Artis Q.zen floor	10848353
Artis Q.zen ceiling	10848354
Artis Q.zen biplane	10848355
Artis Q zeego	10848460
Artis zee floor	10094135
Artis zee ceiling	10094137
Artis zee multi-purpose	10094139
Artis zee biplane	10094141
Artis zee floor MN	10094142
Artis zee biplane MN	10094143
Artis zeego	10280959
Artis zee III floor	10502501
Artis zee III ceiling	10502502
Artis zee III multi-purpose	10502503
Artis zee III biplane	10502504
Artis zeego III	10502505
Artis zee III floor MN	10502506
Artis zee III biplane MN	10502507