To all user of 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 August, 2022

Corrective Action ID AX028/22/S
AX039/22/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Issue in the tube's error detection mechanism

Dear Customer,

We would like to inform you about the following potential issue with your Artis system in combination with a specific lot of X-ray tubes and a corrective action that will be performed.

What is the issue and when does it occur?

The Artis system is provided with a dedicated error detection mechanism. In rare cases of failure of this error detection mechanism it will not be possible to release X-ray anymore until system shutdown.

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

If this issue occurs, the system message “No X-ray, tube too hot!” is shown without an additional audible sound and the operator is unable to release X-ray. A system shutdown is required to enable the release of X-ray. 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 problem was identified by regular field observation. The root cause is an issue in the tube's error detection mechanism.

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

If this issue occurs the user should try to recover the normal operation by a shutdown and restart of the system.

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

A hardware modification will be performed for the affected systems to correct the issue.

What is the efficiency of the corrective action?

The corrective action 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 AX029/22/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)

..

Reason: I am approving this document
Date: Aug 4, 2022 16:48 GMT+2

...
President Advanced Therapies

..

Reason: I am approving this document
Date: Aug 4, 2022 16:47 GMT+2

...
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 China	10848460
ARTIS pheno	10849000
ARTIS icono biplane	11327600
ARTIS icono floor	11327700
ARTIS icono ceiling	11328100