To all user of the following systems with software version VD12 Artis zee / Artis Q / Artis Q.zen

Product/Trade Name: See attachment 1

Model number: See attachment 1

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

Date October, 2021

Corrective Action ID AX069/21/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Potential software issue on Artis zee /Q /Q.zen systems with software version VD12

Dear Customer,

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

What is the issue and when does it occur?

If SID (source-to-image distance) lift movement is activated and X-ray shall be released simultaneously then X-ray is not possible and the message “NO X-ray, try again” is displayed.

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

X-ray is not possible. However, after stopping SID lift movement and releasing the X-ray switch, X-ray is possible again. This may result in a short delay in procedure.

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

The problem was identified by regular field observation. The root cause is a software issue.

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

To avoid the problem, it is recommended to position the SID first and then release X-ray.

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

The software of the affected systems will be updated.

Siemens Healthcare GmbH
Management: Bernhard Montag, President and Chief Executive Officer;
Darleen Caron, Jochen Schmitz, Christoph Zindel

Chairman of the Supervisory Board: Ralf P. Thomas
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105
SCF V12

What is the efficiency of the corrective action)?

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 AX070/21/S.

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

The manufacturer does not consider 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 Healthcare GmbH

Business Area Advanced Therapies (AT)

i.V.

Electronically signed by: Carsten Bertram
Reason: I am approving this document
Date: Oct 15, 2021 14:19 GMT+2

Carsten Bertram

President Advanced Therapies

i.V.

Electronically signed by: Johann Boeck
Reason: I am approving this document
Date: Oct 15, 2021 13:16 GMT+2

Johann Böck

Person Responsible for Regulatory Compliance

Attachment 1

Product/Trade Name	Model number
Artis zee floor	10094135
Artis zee ceiling	10094137
Artis zee multi-purpose	10094139
Artis zee biplane	10094141
Artis Q floor	10848280
Artis Q ceiling	10848281
Artis Q biplane	10848282
Artis Q.zen floor	10848353
Artis Q.zen ceiling	10848354
Artis Q.zen biplane	10848355
Artis zeego	10280959