

To all user of the following systems Artis zee/Q/Q.zen systems with Siemens Healthineers table (Tilt/Step, OR) and with software version VD11E

Product/Trade Name: *see Attachment 1*

Part number: *see Attachment 1*

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

Date: November 2020

Corrective Action ID: AX056/19/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Blocked or limited table movement in case of a defective Safety Limit Switch

Dear Customer,

We would like to inform you about a potential issue with your Artis zee/Q/Q.zen systems with Siemens Healthineers table (Tilt/Step, OR) and with software version VD11E system and a corrective action that will be performed.

What is the issue and when does it occur?

Blocked or limited table movement may occur in case of a defective Safety Limit Switch which is activated by default as long as the table has not reached the end position. The function of the Safety Limit Switch is to prevent table movements beyond defined limits.

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

If this problem occurs, the system performs a safety stop. All table movements are blocked and can only be reactivated by a field service engineer.

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

The problem was identified by regular field observation. The root cause for the blocked tabletop movement (horizontally and vertically) is a software error of the stand control unit.

Siemens Healthcare GmbH

Management: Bernhard Montag, President and Chief Executive Officer;
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

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

We strongly recommend to establish appropriate emergency procedures until the corrective action has been performed. In any case, please make sure that patient treatment can be continued in other ways if there is any possible danger for the safety of the patient.

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

The software of the affected systems will be updated.

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

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

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 AX057/19/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)



Dr. Reinmar Killmann
Vice President Project & Portfolio Management



Johann Böck
Safety Officer Medical Devices AT

Attachment 1

Product/Trade Name	Part number
Artis zee floor	10094135
Artis zee ceiling	10094137
Artis zee biplane	10094141
Artis zeego	10280959
Artis zee III floor	10502501
Artis zee III ceiling	10502502
Artis zee III biplane	10502504
Artis Q floor	10848280
Artis Q ceiling	10848281
Artis Q biplane	10848282
Artis zeego	10848283
Artis Q.zen floor	10848353
Artis Q.zen ceiling	10848354
Artis Q.zen biplane	10848355