SIEMENS Healthineers

To all users of Artis zee and Artis Q/Q.zen systems delivered since Mai 2018

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Date April 5, 2019

- **Important safety information for customers regarding a field corrective action:**

AX045/18/S, AX006/19/S, AX007/19/S

Important safety information for customers regarding a field corrective action: Artis zee and Artis Q/Q.zen systems delivered since Mai 2018

Dear Customer,

We would like to inform you about a potential issue with your ARTIS system equipped with a particular motor control unit delivered since Mai 2018.

What problem is behind this corrective action and when does the problem occur?

In affected Artis systems the movement of the floating tabletop may be blocked after a collision sensor has been activated during system movement. The collision supervision then displays a user message on the monitor.

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

Usually activation of a collision sensor will cause a block of any system movements but moving the floating tabletop will still be possible. In affected Artis systems the movement of the floating tabletop is blocked as well. This may cause a delay or interruption of patient intervention and rescue procedure if applicable.

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

The subject was identified during regular field observation.

The root cause for the blocked table top movement (horizontally and vertically) is a software error of the stand control unit. This issue came up with the new motor control unit introduced in May 2018.

What is the effect of the corrective action?

The corrective action is an update of the system software. This update will eliminate the underlying cause of the problem and prevents a repetition of the failure.

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What actions can you take to mitigate possible risks?

By using the safety override function and moving out of the collision zone the system movement will be resumed.
In safety override mode you may try to resolve a collision state by moving the stand, the motorized axles of the table (lift, tilt, cradle), rotate the table out of the collision zone or by moving the patient on the tabletop e.g. with pulling the mattress.

What actions will we take?

Our service organization will get in contact with you for an appointment to perform a corrective action. Please feel free to contact our service organization for an earlier appointment.
- This letter will be distributed to affected customers as update AX047/18/S.

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

Currently, we are not aware of any risks for patients who have previously been examined or treated.

Please inform and instruct immediately all staff in your organization and any persons who might use your Artis product concerned who need to be aware of this problem. Furthermore, we kindly request you to 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. In this case, please inform us about the identity of the device's new owner where possible.

We thank you for your cooperation in dealing with this customer safety notice.

Best regards,

Siemens Healthcare GmbH
Business Area Advanced Therapies

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