SIEMENS Healthineers

To all user of Artis zee systems with VC21C and system serialnumber 140422, 140423, 140430.

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Customer Safety Information (CSI):

AX052/19/S

Subject: Field Safety Notice for: Artis zee systems with VC21C and system serialnumber 140422, 140423, 140430.

Dear Customer,

We would like to inform you about a potential problem with your ARTIS system equipped with a particular motor control unit and system serial number 140422, 140423, 140430.

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.

What measures are being taken 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.

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What is the efficiency of the corrective actions?

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.

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 AX052/19/S.

What about new Products?

New systems are already delivered with the current software version.

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 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,

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