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To the users of Artis zee and Artis Q systems in conjunction with the DCS Extended monitor suspension system from a specific production batch.

E-mail AdvancedTherapies-FSCA@siemens-healthineers.com

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Important customer safety notice regarding corrective field action:

AX023/18/S

Information about corrective action for Artis zee and Artis Q systems in conjunction with a display suspension system (DCS Extended) from a specific production batch.

Dear Customer,

This letter is to inform you of corrective action that will be performed to prevent a possible hazard to patients, operators, other persons or equipment.

What is the issue to be rectified, and when does it occur?

On the DCS Extended display suspension system, it is possible for individual screws of the screwed connection joining the pivot bearing to the ceiling-mounted support to work loose or snap off. The problem occurs sporadically and is dependent on the frequency of use of the monitor suspension system.

How does the problem affect system operation, and what are the potential risks?

If one or two screws have worked loose or snapped off, the DCS Extended assumes a slanted position, which tends to allow independent movement of the monitor bracket. If other screws are affected, the rotary motion becomes sluggish until the axis of rotation is blocked with a clearly visible inclination of the cantilever arm. In this state, it is no longer possible to use the display suspension system for its intended purpose. In case you face this state, please refrain from moving the DCS including the monitor bracket to prevent further harms.

If the DCS Extended will be used despite this functional restriction, it cannot be excluded that further screws may work loose or snap off, and that the bracket arm including the monitor bracket may become detached from the ceiling-mounted support. This can cause severe injuries to patients and operating personnel.

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What action will be taken?

Our service representative will replace the screwed connection of the ceiling support according to specifications / instructions.
In case the bolt connection cannot be replaced as planned due to technical conditions, the complete bearing will be replaced.

How was the issue detected?

The issue was detected during our field observation.

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 AX024/18/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 this case. This is a possible hardware fault that had no influence on treatment of patients.

We thank you for your cooperation in dealing with this customer safety notice, and request that you immediately notify all the staff at your facility who need to be aware of this problem, and instruct them accordingly. Please also forward this safety information to any other facilities that could also be affected by this action.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the current owner. If possible, please notify us of the identity of the current owner.

Best regards,

Siemens Healthcare GmbH
Business Area Advanced Therapies

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