CC Chairman Medical Board and relevant Head of Departments

To users of patient table of Artis zee and Artis Q systems within a specific production lot.

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

Date July 2019

Important safety information for customers regarding a field corrective action:

AX010/19/S

Information about a corrective action (Inspection) of patient table of Artis zee and Artis Q systems within a specific production lot.

Dear Customer,

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

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

A specific number of patient tables of Artis zee/Q systems may be affected by a cracked table mainframe.

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

In case the table mainframe is cracked, the load capacity is reduced regarding possible weight overload of the table.
The reduction of the rigidity of the table due to the crack has no effect on operation within maximum allowed total weight.
However, in very unlikely cases an extreme overload of the table may lead to a crack of the table mainframe. In this case the table top mechanics might become detached and may hurt patient and staff.

What action will be taken?

Our service organization will test all potentially affected tables and determine whether the table mainframe is cracked. If the mainframe is cracked the table will be replace in a second step.

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What is the efficiency of the corrective actions?

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

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

The problem was noted during manufacturing process of the patient table. As a root cause a change in the production process has been identified.

How will the corrective action be implemented?

Our service organization will contact you to arrange a date to perform this corrective action. Please feel free to contact our service organization for an earlier appointment.
This letter will be distributed as update AX011/19/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.

We thank you for your cooperation in dealing with this customer safety notice. We request you to promptly notify and instruct all staff in your organization, who need to be aware of this problem. 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.

Best regards,

SIEMENS Healthcare GmbH
Business Area Advanced Therapies

[redacted]

Michel Therin
Head of Business Area AT

[redacted]

Johann Böck
Safety Office Medical Devices AT