SIEMENS Healthineers

CC Chairman Medical Board and relevant Head of Departments

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To all users of Artis zee and Artis Q systems with software version VD11C.

Important customer safety notice regarding corrective field action:

AX051/17/S

Information about corrective action for Artis zee and Artis Q systems with software version VD11C.

Dear Customer,

This letter is to inform you of corrective action that will be performed to prevent a possible hazard to patients.

What is the underlying issue requiring this corrective action and when does the issue occur?

In the application "DSA Roadmap" the Artis system's intended behavior is to reject the stored Vesselmap from previously acquired DSA if the patient table was moved during the Roadmap workflow. In rare cases the system does not reject the DSA Vesselmap and uses it for the further Roadmap workflow steps.

What is the impact on system operation and what is the potential risk?

Depending on the amount of table movement which was applied during the Roadmap workflow, the DSA Vesselmap might be overlaid as vessel tree at a position which does not fulfill our requirements for accuracy. If the displacement of the vessel tree is very large , it might be recognized by the user. However, if the displacement is slight or at an unfavorable plane the user might rely on incorrect visualization of the catheter relative to the Vesselmap. This might imply danger for the patient. A similar risk exists in case of patient movement between acquiring the DSA Vesselmap and using it.

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What action will be taken?

The software in the affected systems will be updated to correct the issue.

How was the issue detected and what is the cause?

The issue was identified during internal extended test of the system behavior.

How effective are the corrective actions?

The cause will be eliminated once the software has been updated, thus preventing a recurrence of the fault.

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 to affected customers as Update **AX020/17/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 software defect that has no influence on previous diagnosis and treatment of patients in all cases where the outcome was deemed to be sufficient by the physician responsible.

We thank you for your cooperation in dealing with this customer safety notice, and request that you promptly notify and instruct accordingly all the staff at 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
AT Business Area

[redacted]

Dr. Heinrich Kolem
President Advanced Therapies

[redacted]

Wolfgang Hofmann
Safety Officer Medical Devices