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Date December 18, 2017

To all users of AXIOM Artis systems with a flat panel detector from a specific production batch

Important customer safety notice regarding corrective field action:

AX025/16/S

Information about corrective action for AXIOM Artis systems with a flat panel detector 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.

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

As a result of a potential leaking of the coolant couplings of the flat panel detector, liquid may escape above the flat panel detector in the FD carriage. This leaking can occur sporadically on AXIOM Artis systems from the production patch affected.

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

If cooling liquid escapes, the liquid can enter into the flat panel detector. This can lead to a failure of the flat panel detector. The clinical treatment must be canceled and the patient must be transferred to a functioning system.

What actions will be taken?

The affected plastic couplings will be replaced by metal couplings.

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How was the issue detected and what is the cause?

The issue was identified during regular maintenance work. A leaking of the coolant couplings of the flat panel detector was detected.

How effective are the corrective actions?

The corrective action eliminates the root cause of the problem and prevents the failure from recurring.

How will the corrective action be implemented?

Our service organization will contact you to arrange a date 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 AX026/16/S.

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

There are no risks for patients who have previously been examined or treated.

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

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President Advanced Therapies

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