SIEMENS Healthcare

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To all users of AXIOM Artis and Artis zee systems

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Important customer safety notice regarding corrective field action:

AX004/15/S

Information about a corrective action for AXIOM Artis and Artis zee systems

Dear Customer,

This letter is to inform you of a corrective action that will be performed to prevent a possible leak in the detector cooling system and its possible consequences.

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

Due to a leak in the cooling system, fluids could seep into the equipment cabinet. This leak can occur sporadically in the affected systems.

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

Loss of coolant can result in cooling system failure. Actions will be taken to protect against consequential damage resulting from leaking fluids. In the worst case scenario, this leak can cause system failure.

What action will be taken?

The affected plastic couplings are being replaced with metal couplings, additional actions are being implemented to prevent fluid leaks.

How was the issue detected and what is the cause?

The issue was identified during regular field observation. In this case there was a leak in the hose connections.

How effective are the corrective actions?

The action eliminates the problem, ensuring it does not reoccur.

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 AX005/15/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 the treatment of patients.

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
Business Area AT

[redacted]

Dr. Heinrich Kolem
President Advanced Therapies

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Wolfgang Hofmann
Medical Device Safety Officer