SIEMENS Healthcare

Siemens Healthcare GmbH, HC AT IR MK, Siemensstr. 1, 91301 Forchheim

Name Vera Juennemann-Vega
Department HC AT IR MK
Telephone + 49 (9191) 18-8097
E-mail vera.juennemann@siemens.com

To all users of AXIOM Artis, Artis zee and Artis Q/Q.zen systems

Important customer safety notice regarding corrective field action:

AX006/15/S

Information about a corrective action for AXIOM Artis, Artis zee and Artis Q/Q.zen systems

Dear Customer,

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

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

This corrective action addresses a possible cause of a system defect. Contaminants in the form of biomass can develop in the cooling system of Artis systems, which can result in damage to the pump system.

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

The presence of contaminants in the tube cooling circuit impairs the performance of the pump. This fault can even lead to a functional failure of the system. The tube assembly can become overheated so that no radiation can be released.

What action will be taken?

Fitting an additional, external filter in the cooling-water circuit will implement a protective mechanism to prevent the functional failure of the pump system as a result of contamination. During 2016 a second action will be implemented as AX003/16/S that will prevent the development of biomass.

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Thomas Rathmann, Michael Reitermann

Chairman of the Supervisory Board: Siegfried Russwurm
Registered offices: Munich, Germany; Commercial registry: Munich, HRB 213821
WEEE reg. no. DE 64872105

Siemensstr. 1
91301 Forchheim
Germany

Tel.: +49 (9191) 180
siemens.com/healthcare

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How was the issue detected and what is the cause?

The issue was identified during regular field observation.

How effective are the corrective actions?

The action AX007/15/S eliminates the cause of damage to the pump system, ensuring it does not reoccur. AX003/16/S will prevent the development of biomass in the cooling circuit.

How will the corrective action be implemented?

Our service organization will contact you shortly 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 AX007/15/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 defect 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 Advanced Therapies

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