

CC to Chairman Medical  
Board and relevant Head of  
Departments

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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.

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WEEE reg. no. DE 64872105

**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?**

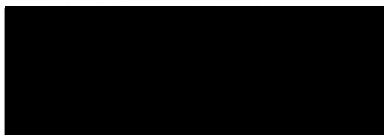
We do not consider it necessary to re-examine any patients in this case. This is a possible hardware defect that had no influence on the treatment of patients.

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.

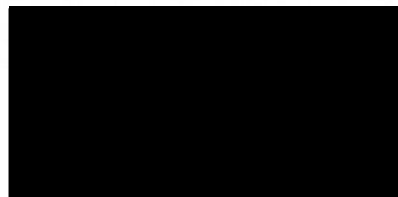
If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

Best regards,

Siemens Healthcare GmbH  
Business Area Advanced Therapies



Dr. Heinrich Kolem  
President



Wolfgang Hofmann  
Safety Officer Medical Devices

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

Name: Philip Stenner  
Department: HC AT IR MK

Email: [REDACTED]  
Date: 04.10.18

**To all users of AXIOM Artis, Artis zee,  
and Artis Q/Q.zen systems delivered after 07/2016**

### Customer information regarding field measure AX003/16/S:

You are receiving this customer information letter because measure AX003/16/S will be implemented on your system in the near future. The measure consists of introducing an additive to the X-ray tube cooling circuit of your system. This will stabilize the quality of the cooling water for an extended period of time.

This measure AX003/16/S supplements measure AX006/15/S listed in the enclosed safety notification AX007/15/S. Your system was manufactured after this measure AX006/15/S was published, which means that this measure was already implemented at the factory.

The Siemens Healthcare Service Organization will contact you to arrange an appointment to implement measure AX003/16/S for your system.

**Siemens Healthcare GmbH**  
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