SIEMENS Healthineers

Name: Philip Stenner
Department: SHS AT IR MK

E-Mail: Philip.stenner@siemens-healthineers.com
Date: 15. May 2018

To all users of AXIOM Artis and Artis zee systems with specific lot of detector cooling unit.

Important safety information for customers regarding a field corrective action:
AX076/17/S

Important safety information for customers regarding a field corrective action: AXIOM Artis and Artis zee systems with a specific production lot of Detector Cooling Units

Dear Customer,

We would like to inform you about a potential issue with your Artis system.

What problem is behind this corrective action and when does the problem occur?

The Artis system may shut down suddenly due to a technical problem which affects the detector cooling unit.
The problem occurs very sporadically. It might occur during an ongoing procedure.

What is the impact to the operation of the system and what are the possible risks?

In case the problem occurs, the system cannot be operated normally. This may result in a situation where it is necessary to cancel clinical treatment or to continue treatment on an alternative system.

How was the subject identified and what is the root cause?

The issue was detected by regular field observation. The root cause is a defective sealing and a change in the production process of the cooling unit which would allow coolant to inflow into the electrical parts of the system cabinet which might cause a short-circuit and a sudden shutdown of the Artis system.

What measures are being taken to mitigate possible risks?

Our service organization will replace all affected cooling units.

What is the efficiency of 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 get in contact with you for an appointment 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 AX077/17/S.

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

The manufacturer does not consider risks for patients who have previously been examined or treated.

We thank you for your cooperation in dealing with this customer safety notice. We request you to promptly notify and instruct all staff in 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 Advanced Therapies

Siegfried Quinger
Safety Officer Medical Devices