SIEMENS Healthcare

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

Name Philip Stenner
Department HC AT IR MK
E-mail Philip.stenner@siemens.com

To users of Artis Q systems of a defined serial number range

Important customer safety notice regarding corrective field action:

AX007/16/S

Information about corrective action for Artis Q systems with A100G generators, within a defined serial number range.

Dear Customer,

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

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

In Artis systems with A100G generators, a component can be affected by aging, resulting in the failure of a module in the high-voltage generator.

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

When the failure occurs, the system usually responds by providing emergency fluoroscopy. In the worst case, a spontaneous failure of the radiation generation function is conceivable. Currently, we are not aware of either of these scenarios having occurred. If this failure occurs, then the problem can only be resolved by our service organization. In case of a spontaneous failure, it might be necessary to cancel or restart a clinical treatment or transfer it to a functioning system.

What action will be taken?

The potentially affected modules will be replaced. Standard emergency processes should be implemented in case a system failure occurs. Please have these processes carefully prepared in advance until our counter-measure has been implemented.

How was the issue detected and what is the cause?

The issue was identified in the course of regular field observation during scheduled maintenance sessions.

How effective are the corrective actions?

The cause will be eliminated once the potentially faulty modules have been replaced, thus preventing a recurrence of the fault.

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 AX008/16/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
AT Business Area

[redacted]

Dr. Heinrich Kolem
President Advanced Therapies

[redacted]

Wolfgang Hofmann
Safety Officer Medical Devices