SIEMENS Healthcare

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To all users of Artis zee systems with SW VD11 and A100 generator

Important customer safety notice regarding corrective field action:

AX016/17/S

Information about corrective action for Artis zee systems with SW version VD11 and A100 generator

Dear Customer,

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

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

As a result of a software fault in Artis zee systems with software version VD11 and generator A100, it may be that, following the failure of a tube assembly focus, the Artis system only functions properly until the next reactivation. Following reactivation, the system no longer initializes as intended.

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

If the fault occurs, the high-voltage generator can no longer be accessed by the control system. It will then no longer be possible for any radiation to be released.
If this fault occurs, then the problem can only be resolved by our service organization.
Because this fault can only occur following a restart of the Artis system, we assume that it will not cause an ongoing treatment to be aborted. Should treatments be scheduled at this time or become necessary at short notice, they must be transferred to an alternative facility.

What action will be taken?

The software of the affected systems will be corrected with an update.

How was the issue detected and what is the cause?

The issue was identified during regular field observation. In this case, a corresponding error occurred in the situation described.

How effective are the corrective actions?

The cause will be eliminated following the software update, 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 **AX017/17/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 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]