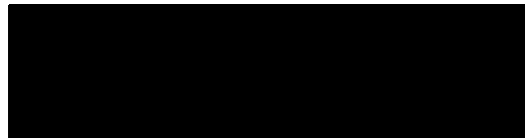


Siemens Healthcare GmbH, HC AT IR MK, Siemensstr. 1, 91301 Forchheim

To all users of Artis zee systems with specific delivery lots of the A100Plus generator in combination with 2-focus Megalix Cat Plus tube units.



Date 2017-01-24

Important customer safety notice regarding corrective field action:

AX016/16/S

Information regarding corrective action for Artis zee systems shipped with specific delivery lots of the A100Plus generator in combination with 2-focus Megalix Cat Plus tube units.

Dear Customer,

This letter is to inform you of 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?

Due to a component defect on Artis systems with an A100Plus generator of a certain delivery lot and 2-focus Megalix Cat Plus tube unit, a module in the high voltage generator can fail.

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

If the fault occurs, the result can be failure of the large focus. The small focus will still be available for continued operation.

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WEEE Reg. No. DE 64872105

What action will be taken?

The modules with defective components will be replaced.

How was the issue detected and what is the cause?

The issue was identified during quality assurance. Breakdowns have occurred during production or installation. System failures during regular clinical operation are not known.

How effective are the corrective actions?

The cause will be eliminated after replacement of the potentially faulty module, 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 AX015/16/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

