SIEMENS Healthineers

To all users of ARTIS zee and AXIOM Artis systems systems with generator A100

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Important safety information for customers regarding a field corrective action:

AX038/18/S

Important safety information for customers regarding a field corrective action: ARTIS zee and AXIOM Artis systems with generator A100

Dear Customer,

We would like to inform you about a potential issue with your ARTIS zee and AXIOM Artis system with generator A100.

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

Due to a tolerance problem in the power supply of the generator control above a specific value, the generator A100 may fail. Therefore, the required voltage for the X-ray tube will not be supplied any more.
The problem occurs sporadically and 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 as X-ray is not possible. This may result in a situation where it is necessary to cancel clinical treatment or to continue treatment on an alternative system. Please make sure that an alternative system can be used to continue treatment in these cases.

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

The issue was detected by regular field observation. The root cause is an increased resistor value at certain components at the supply circuit. Due to that it could happen that internally required voltage values are out of tolerance.

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What measures are being taken to mitigate possible risks?

Our service organization will modify the affected supply circuit including a revision of wiring. This modification brings the voltage back to the centre of the tolerance range.

What is the efficiency of the corrective action?

The corrective action mitigates the probability of occurrence of the non-conformity

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 AX039/18/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,

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