SIEMENS

Healthcare

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To users of Artis zee, Artis Q, and Artis Q.zen systems with software version VD11B.

Important customer safety notice regarding corrective field action:

AX001/16/S

Information regarding a corrective action for Artis zee, Artis Q, and Artis Q.zen systems with software version VD11B.

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?

This corrective action addresses 2 possible, mutually independent causes of a system defect.

- In Artis systems with A100Plus or A100G generators, an attempt to resume operation following detection of a fault (such as a short circuit in the X-ray tube) can result in the failure of a module in the high-voltage generator.

- For biplane systems delivered with software version VD11B since April of this year, software problems in conjunction with the graphics card may in rare cases result in the loss of image display in the examination room.

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

A generator fault can result in a spontaneous system malfunction that can only by rectified by our service organization. If the clinical treatment requires imaging, it may be necessary to cancel or restart the treatment or transfer the patient to an alternative system.

The software problem can be corrected by restarting the system. It can take up to 8 minutes to restart the system. The hazard posed to the patient as a result of the delay depends on the type of the clinical treatment and the point at which the failure occurs during a treatment.

Standard emergency processes in case of system failure should be implemented. Please have these processes prepared in advance until the update can be applied.

What action will be taken?

A system software update will implement additional protective mechanisms for the generator and correct the software problem.

How was the issue detected and what is the cause?

The issues were identified during regular field observation.

How effective are the corrective actions?

Following the system software update, the causes are eliminated and a recurrence of the fault is prevented.

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 AX002/16/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,

Ronan Kirby
Head of Service Ireland

Adrian Cronin
Service Supervisor AX/XP ROI