SIEMENS Healthcare

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To all users of Artis zee systems with generator A100Plus or Artis zeego systems with software version VC21B.

Important customer safety notice regarding field safety corrective action

AX075/15/S

Information about a corrective action for Artis zee systems with generator A100Plus or Artis zeego systems with software version VC21B.

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 or equipment.

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

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

- In Artis zeego systems, angulations in the vicinity of the C-arm collision area can cause the cable inlet to become clamped and can result in mechanical damage.
- In Artis systems with A100Plus 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.

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

A fault can result in a spontaneous system malfunction that can only by rectified by our service organization.

What action will be taken?

Additional protection mechanisms will be implemented by means of a system software update.

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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 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 AX076/15/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