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All users of Artis systems with a wireless foot switch

Important customer safety notice regarding corrective field action:

AX009/17/S

Information regarding a corrective action for Artis system wireless foot switches

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 or equipment.

What is the problem and when can it occur?

The wireless foot switch can fail due to impacts by external factors, such as electrostatic discharge that exceeds a certain intensity. Troubleshooting actions have been implemented (resetting the affected assembly) but have no effect in this case.

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

If the wireless foot switch fails, it will no longer be possible to use it to release radiation. It will still be possible to trigger exposures if a wired foot switch or hand switch is present. Fluoroscopy with the hand switch is not possible. This may result in a situation in which it is necessary to cancel or restart clinical treatment or transfer it to a functioning system.

What actions will we take?

The affected control assembly will be replaced with a new version as a corrective action. With the new version, the entire assembly is reset to a defined basic status once the power plug is inserted in the appropriate socket. This ensures that the wireless foot switch can be returned to an operational state when such error states occur.

How effective are the corrective actions?

After completing these actions there is no further risk of a permanent wireless foot switch failure should the factors noted above occur.

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 to arrange a convenient appointment. This letter will be distributed to affected customers as Update **AX013/17/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. This is a possible hardware defect that has 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 affected device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also ask you to inform us of the identity of the device's new owner where possible.

Best regards,

Siemens Healthcare GmbH
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