SIEMENS Healthcare Sector

To all Users of AXIOM Artis or Artis zee systems

BU - Ansprechpartner:
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Important Safety Information in regards to the corrective action: AX008/14/S

Information in regards to a safety relevant corrective action for Axiom Artis or Artis zee systems in connection with the hand switch material number 3771750 operated at the patient table to release a x-ray image.
This safety information is being distributed to all affected customers via update AX 009/14/S.

Dear Sir and Madam,

With this letter we are informing you about a potential problem with your AXIOM Artis or Artis zee system in connection the with hand switch material number 3771750 operated at the patient table to release a x-ray image.

When does this problem occur and what are the risks?

The hand switch to release a x-ray image at the patient table is equipped with a cable extension inside the table. A problem may occur if the connection between cable connection and hand switch is contaminated with an extraordinary large amount of fluid. In a worst case situation, uncontrolled release of a x-ray image may happen. If this situation occurs, the system terminates uncontrolled x-ray after a short period.

What are the measures that are taken to avoid possible risks for the future?

The cable extension installed in the field will be removed from the patient table. The hand switch will be connected directly inside the patient table. Therefore recurrence of the problem is prevented.
Our service organization will contact you for an appointment of the above described action. You may also contact our service organization independently for an appointment.

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What are the risks for the patients that have previously been examined with the system?

This matter has no consequences for patients who have previously been examined or treated using this system. We do not consider it necessary to re-examine these patients due to this hardware issue.

We thank you for your cooperation in dealing with this safety notice and request that you promptly notify and instruct accordingly all the staff at your organization who have to be aware of this problem. Please also forward this safety information to other organizations that could be affected by this measure. Please observe this safety notice, and comply with the corresponding measures until the update has been fully completed.

If the device has been sold and is therefore no longer in your possession, please forward this safety note to the new owner. We would also request that you inform us of the identity of the device's new owner where possible.

With best regards,
SIEMENS AG Healthcare Sector
Business Unit AX

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