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To all users of Artis systems with SW version VC14J

Important customer safety notice regarding corrective field action:

AX008/15/S

Information about corrective action for Artis systems with SW version VC14J

Dear Customer,

This letter is to inform you of corrective action that will be performed to prevent the possible loss of the image generation function.

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

Your Artis system has an X-ray locking function that prevents any accidental release of radiation. However, in case a system error occurs and the system enters the "Bypass Fluoro" mode while the X-ray locking function is active, it won't be possible to exit the X-ray locking function any longer. The only way to exit the X-ray locking function, would be to either resolve the root cause of the system being in "Bypass Fluoro" or to restart the system.

What effect does this system behavior have on the operation of the system and what potential risks are associated with this?

In the situation described, no radiation release is possible. This means that no fluoroscopic images can be acquired. Potential risks can arise from a delay to procedures resulting from the need for a system restart.

What action will be taken?

This issue will be remedied by a software update (Patch 11). Following the installation of the software update, your Artis system will automatically unlock the radiation release in "Bypass Fluoro" mode so that imaging is possible in all cases.

How was the issue detected?

The issue was identified during regular field observation.

How effective are the corrective actions?

Following the installation of the software update, the cause of the undesired system behavior is remedied and the error is prevented from recurring.

Do the corrective actions have additional implications?

The resulting change in system behavior is detailed in an Addendum to the Operator Manual. The Addendum will be distributed for affected systems as the corrective action is performed.

How will the corrective action be implemented?

Our service organization will contact you to arrange a date for the installation of the software update. Please feel free to contact our service organization for an earlier appointment. This letter will be distributed to affected customers as Update AX 009/15/S.

What risks are there for patients who have previously been examined or treated using this system?

This system behavior had no influence on the treatment of patients.

Please forward this information to all the staff at your organization that needs to be aware of this problem. If you have sold the device, please forward this safety notice to the new owner. We would also request that you inform us of the identity of the device's new owner where possible.

Best regards,

SIEMENS Healthcare GmbH
Business Unit AX

[redacted]

Dr. Heinrich Kolem
Chief Executive Officer

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Wolfgang Hofmann
Medical Device Safety Officer