SIEMENS Healthcare

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To all users of AXIOM Artis dFA, dFC, dFCM, AXIOM Artis dBA, dBC, dBCM and AXIOM Artis dMP Systems with SW version VB35D

Important customer safety notice regarding corrective field action:

AX047/15/S

Information regarding corrective action for AXIOM Artis dFA, dFC, dFCM, AXIOM Artis dBA, dBC, dBCM and AXIOM Artis dMP Systems with SW version VB35D

Dear Customer,

This letter is to inform you of corrective action that will be performed to prevent a possible hazard to persons and equipment.

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

The issue is caused by a possible position sensor fault in the swivel base axis not being detected by the system software. Following the enabling of movement by the operator, the C-arm system can unexpectedly move faster than normal.

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

In this situation, your Artis system will not move of its own accord, movement must still be initiated by the operator. When moving, however, the system can unexpectedly exceed its usual speed, potentially resulting in a collision.

What action will be taken?

This issue will be remedied with software update AX047/15/S. Following the installation of this update, the possible speed of the Artis system will be limited to the permissible level.

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.

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 AX048/15/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 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