

SIEMENS**Healthcare**

Siemens Healthcare GmbH, HC IM AX MK OPM, Siemensstr. 1, 91301 Forchheim

**To all users of Artis zee Floor, Artis zee Biplane and
Artis zee Multi Purpose systems with SW version
VC21B****BU contact:****Name**

Helene Hübner

Department

HC IM AX MK OPM

Telephone

+49 (9191) 18-6903

Email

Helene.huebner@siemens.com

Date:**Important customer safety notice regarding corrective field action:****AX031/15/S****Information regarding corrective action for Artis zee Floorstand, Artis zee Biplane
Floorstand and Artis zee Multi Purpose systems with SW version VC21B****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 AX031/15/S (Patch 12). Following the installation of this update, the possible speed of the Artis system will be limited to the permissible level.

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Thomas Rathmann, Michael ReitermannSiemensstr. 1
91301 Forchheim
GermanyTel.: +49 (9191) 18 0
Fax: +49 (9191) 18 6999
www.siemens.com/healthcareRegistered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105

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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 AX032/15/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


Dr. Heinrich Kolem
Chief Executive Officer
Wolfgang Hoffmann
Medical Device Safety Officer