

Siemens AG, HC CP XP MK, Allee am Röthelheimpark 2, 91052 Erlangen

<To the person in charge of the unit where the SIEMENS product is operated, and the administrative head of organization>

Contact person of
the Regional Unit
Department

Telephone
Fax
E-Mail

Date

Safety Advisory Notice

To all users of the
SIEMENS AXIOM Aristos FX

Contact person of Volker Biermann
the Business Unit
Department HC CP XP MK IN RFM

Telephone + 49 9131 18-9908
Fax + 49 9131 18-8893
E-Mail Volker.j.biermann@siemens.com

Date

Re: AXIOM Aristos FX systems; possible drop of the cable holder

Dear Customer,

This letter is to inform you of a possible hazard to patients or operators when moving ceiling suspension of all AXIOM Aristos FX systems (7414803) with serial numbers up to and including 1168.

When does this malfunction occur and what are the potential risks?

In case, the 3 wheeled cable cart moves behind the point of the fixed cable holder, the corrugated hose may get stuck behind the hose from the fixed cable holder (picture 1).

In case the cable cart and the corrugated hose cannot move freely, the cable cart may get pushed out of the ceiling suspension if pulled into the direction of the tube stand. If this occurs, there is a potential for the cable holder to drop down and hit patients or system operators.

What steps can the user take to avoid the potential risk of this issue

Please ensure, that the corrugated hose does not get caught behind the hose from the fixed cable holder and that it can move freely (picture 2).

Special attention should be paid to avoid possible risk of injury to patients or operators.



picture 1



picture 2

Siemens AG
Healthcare Sector; Management: Bernd Montag

Allee am Röthelheimpark 2
91052 Erlangen
Deutschland

Tel.: +49 (9131) 84 0

Siemens Aktiengesellschaft: Chairman of the Supervisory Board: Gerhard Cromme; Managing Board: Joe Kaeser, Chairman, President and Chief Executive Officer; Roland Busch, Lisa Davis, Klaus Helmrich, Janina Kugel, Siegfried Russwurm, Ralf P. Thomas; Registered offices: Berlin and Munich, Germany; Commercial registries: Berlin Charlottenburg, HRB 12300, Munich, HRB 6684; WEEE-Reg.-No. DE 23691322

Only the cable holders with 3 wheels are affected (picture 3). Cable holders with 4 wheels are not affected by this malfunction.



picture 3

How will the issue finally be resolved ?


- Siemens is preparing a field modification (UI XP091/14/S) for all AXIOM Aristos FX systems that will resolve this potential malfunction.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is placed in the system's instructions for use. Your personnel should maintain awareness until the modification has been implemented.

If you have sold this device/equipment and it is no longer in your possession, we kindly ask that you forward this safety advisory notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.

Sincerely Yours


Andre Hartung
CEO H CP XP

i. V. 
Jürgen Buckow
H CP XP QM

Acknowledgement of receipt

Customer address:

I hereby confirm as the owner / responsible operator of the AXIOM Aristos FX with the Serial number _____ (optional) that I received the following document:

Safety Advisory Notice

AXIOM Aristos FX systems; possible drop of the cable

Place, Date _____

Name _____

Signature _____