

To all users of the SIEMENS AXIOM Iconos R100
(non-tomography) systems

BU contact:
name Gerben ten Cate
department H IM MK PDRF
E-Mail gerben.tencate@siemens.com

RU contact: **designated person**
name <name>
department <department>
E-Mail <e-mail>
phone <phone>
date: YYYY-MM-DD

Urgent Field Safety Notice

Customer Safety Advisory Notice

UI-S AX043/10/S

Potential malfunction on AXIOM Iconos R100 systems due to a mechanical problem of the motor axis for longitudinal movement of X-ray tube stand (column) or movement of the spot film device (SFD)

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard or potential hazard when using the AXIOM Iconos R100 (Material Number 5895151, Serial Number 1001-1156 and Serial number 3001-3740).

When does this malfunction occur and what is the potential risk?

Component failure may lead to a situation where the axle of the column motor drive or SFD motor drive may break. If the motor drive enabling longitudinal movement of the X-ray tube stand or motor drive for the SFD movement has a broken axle and the system is operated in an upright position or tilted, it may occur that the column or SFD moves downward.

That movement is associated with the risk that the column or the SFD collides with persons or parts positioned in the moving range of the column or SFD. The intensity of the collision depends on how far the system is tilted from the horizontal position.

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

Siemens is currently working on a modification. Until your system has received the safety upgrade we ask you to take special precautions. Please do not use the system for so-called bed exposures with

Siemens AG
Healthcare Sector; Management: Hermann Requardt
Division Imaging & IT Division; Management: Bernd Montag
Angio-, Fluoroscopic- & Radiographic Systems; Management: Heinrich Kolem

Siemensstr. 1
91301 Forchheim
Germany

Tel.: +49 (9191) 18 0
Fax: +49 (9191) 18 9999

Siemens Aktiengesellschaft: Chairman of the Supervisory Board: Gerhard Cromme;
Managing Board: Peter Loescher, Chairman, President and Chief Executive Officer; Wolfgang Dehen, Heinrich Hiesinger,
Joe Kaeser, Barbara Kux, Hermann Requardt, Siegfried Russwurm, Peter Y. Solmsen
Registered offices: Berlin and Munich, Germany; Commercial registries: Berlin Charlottenburg, HRB 12300, Munich, HRB 6684
WEEE-Reg.-No. DE 23691322

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patients underneath the column when the table is tilted. Please do not allow staff, patients or other persons in the column moving range (see figure 1) when the table is tilted.

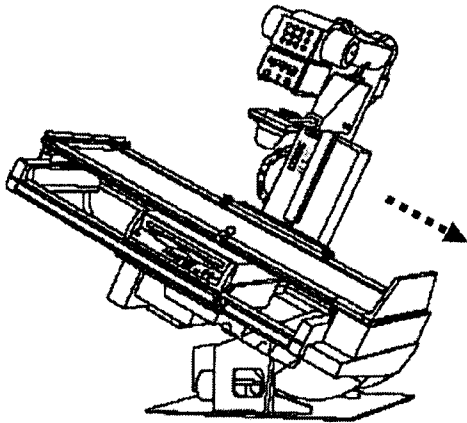


figure 1

How will the issue finally be resolved?

Siemens is preparing a modification of AXIOM Iconos R100 that will resolve this potential malfunction. The field modification UI-S AX049/10/S will be available in the fourth quarter of 2010.

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 over an appropriate defined period.

The manufacturer's National Competent Authority has been informed accordingly.


Please confirm on the enclosed form that you have received this Customer Safety Advisory Notice and send it back to us.

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

Best regards,
SIEMENS AG Healthcare Sector



Dr. Heinrich Kolem
CEO H IM AX



Safety Officer Medical Devices H IM AX