SIEMENS **Healthcare**

To users of SIEMENS
Artis zee systems with Card Collimator

BU contact:

name	Michael Greiffenhagen
department	H IM AX MK PDI
E-Mail	michael.greiffenhagen@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 Information UI-S AX 028/12/S

Information regarding a field safety corrective action for Artis zee systems equipped with a card collimator from a specific lot.

Dear Customer,

This letter is to inform you of a potential issue on Artis zee systems bearing material numbers 10094135; 10094137 and 10094141; equipped with a card collimator from a specific lot. At the card collimators of these systems, a dislocation of the scatter radiation filter inside the card collimator (material number 10092591, 10092593, 10092601, 10092631 and 10092632) may occur.

To resolve this issue, the update AX 027/12/S has been made available from 2013-01-22 on. With the distribution of this Urgent Field Safety Notice we would highly recommend securing an appointment with our Customer Service organization in order to have the update AX 027/12/S realized.

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

This potential malfunction may occur randomly after system installation or replacement of a card collimator during a repair session. The scatter radiation filter inside the collimator may become dislocated on a specific manufacturing lot. As a result the filter may be displayed on images overlaying clinical relevant information. Upon occurrence, the system may not be functioning correctly until service technician executed referred field update instruction.

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What steps will be taken to eliminate the potential risk of this issue?

The potential problem will be eliminated by properly attaching the scatter radiation filter inside the collimator. The appropriate update is provided as AX027/12/S.

What is the risk associated to patients previously processed/treated with this system?

There are no risks associated to patients previously processed or treated with this system.

We appreciate your understanding and cooperation with this Customer Safety Information and ask you to immediately pass this information to all those who need to be aware and instruct your personnel accordingly. Please transfer this notice to other organizations on which this action has an impact. Please also maintain awareness on this notice and resulting action unless the problem is solved by performing the update AX 027/12/S.

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
Business Unit AX

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Dr. Heinrich Kolem	Wolfgang Hofmann
CEO H IM AX	Safety Officer Medical Devices