SIEMENS Healthineers

Siemens Healthcare GmbH, SHS DI XP F&U PRM, Siemensstr. 3, Healthcare Building 1, 91301 Forchheim

Contact person of the Regional Unit Department

Telephone
Fax
E-mail

Date

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

Safety Advisory Notice

To all users of SIEMENS AXIOM Luminos TF, AXIOM Iconos R100, AXIOM Iconos R200, AXIOM Luminos Agile, Luminos Agile Max, AXIOM Luminos dRF, Luminos dRF Max and LUMINOS Lotus Max systems

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SHS DI XP F&U PRM

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Re: Potential risk of foot rest detaching from the patient table

Dear customer,

This letter is to inform you about a preventive measure to exclude any potential risk of patient injury caused by the foot rest detaching from the patient table during an examination.

When could the hazard occur and what are the potential risks?

If the foot rest is not connected and locked properly to the patient table, there is a risk that it could detach and the patient could slide off the table and be injured.

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

- The user must check that the foot rest is locked into position and attached firmly every time before allowing a patient to sit or stand on it.
- The two green bars on each side of the foot rest must be visible.
- The foot rest must only be attached and removed when the table is horizontal.

For attaching the foot rest please follow the instructions in the attached addendum to the operator manual for your system.

How will the issue finally be resolved, and the corrective action be implemented?

This advisory letter is distributed to all affected customers together with an addendum to the operator manual. The addendum contains additional details and illustrations on how to securely attach the foot rest to further improve the understanding of handling the foot rest.

Please make sure that all persons operating the system are informed about the content of this letter and the addendum to the operator manual.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately inform your personnel accordingly. Please ensure that this safety advisory notice and the addendum to the operator manual are placed in the system's instructions for use.

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.

Sincerely yours,

Forchheim, 2022-11-11

i.V.

Verena Schön
Head of Business Line
X-Ray Products

i.V.

Christian Denger
Head of Quality Management
X-Ray Products