



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

Telephone
Fax
E-mail

Date

Safety Advisory Notice

To all users of SIEMENS AXIOM Iconos MD, AXIOM Iconos R100, Luminos RF Classic, Luminos Fusion, LUMINOS Impulse

UDI-DI: 04056869281865 (LUMINOS Impulse)

SRN: CN-MF-000013434

Contact person of the Business Unit Department

Persoonsgegevens

SHS DI XP QT

Telephone

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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 footrest detaching from the patient table during an examination.

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

If the footrest 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 footrest 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 footrest must be visible.
- The footrest must only be attached and removed when the table is horizontal.

For attaching the footrest 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 footrest 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,

Shanghai, November 6th 2023

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