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<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 Luminos dRF with software version VD10 or Luminos dRF Max with software version VE10

Contact person of
the Business Unit
Department

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Date

Re: Luminos dRF / Luminos dRF Max with possible infiltration of fluids into the tableside control panel

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients and personnel when exposing the tableside control panel of the Luminos dRF / Luminos dRF Max system to fluids. This malfunction affects all Luminos dRF systems with software version VD10 and Luminos dRF Max systems with VE10.



Figure 1: tableside control panel

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Siemens Aktiengesellschaft; Chairman of the Supervisory Board: Gerhard Cromme;
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Hermann Requardt, 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

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

In case of exposure to fluids, the tableside control panel may be infiltrated by fluids. As a result malfunctions of the tableside control panel may occur when buttons on the control panel are pressed.

If a malfunction of the tableside control panel does occur, the panel needs to be replaced and it should not be used in the meantime. Nevertheless the Luminos dRF / Luminos dRF Max remains functional and can be operated via the remote control panel.

In the very unlikely case of the infiltrated fluid causing a permanent short circuit within the control panel the Luminos dRF / Luminos dRF Max will automatically disable the affected button(s) with the start-up of the system.

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

- When using the system, please try to avoid extensive exposure of fluids to the tableside control panel.
- When cleaning the system, please make sure that you do not apply excessive fluids; e.g., only use damp towels, in accordance with the product manual.
- The remote control panel is not affected by any malfunction of the tableside control panel and can reliably be used at any time. In case of a malfunction of the tableside control panel, please switch to solely using the remote control panel(s). Thereby it is ensured that the Luminos dRF / Luminos dRF Max remains completely functional.



Figure 2: remote control panel

How will the issue finally be resolved?

We are working intensely on providing a near-term solution which eliminates any risk for a potential malfunction of the tableside control panel due to infiltration of fluids. As soon as this solution is available the tableside control panel of all affected systems will be replaced.

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



Jürgen Buckow
H CP XP QM

Acknowledgement of receipt

Customer address:

I hereby confirm as the owner / responsible operator of the **<product name>** with the Serial number _____ (optional) that I received the following document:

Safety Advisory Notice

<product name> with **<short description of the malfunction>**

Place, Date _____

Name _____

Signature _____