

Siemens AG, H CP XP MK RFM F, Hartmannstr. 16, 91052 Erlangen

<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

Contact person of
the Business Unit
Department

H CP XP MK RFM F

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Date

2014-03-27

Luminos dRF with potential unintended movement by electrostatic discharges

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients by unintended movement of the Luminos dRF system.

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

Under rare environmental conditions (i.e., extremely dry air in combination with a highly isolated floor) electrostatic discharges (ESD) >8 kV at the system control console may trigger an unintended movement of the system which may cause an emergency situation, danger to the patient (e.g., falling off the table, squeezing), to operating personnel or to the unit.

To date, a sporadic occurrence of this system malfunction has only been reported from two sites.

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

Press one of the red emergency STOP buttons immediately in case of an unintended movement. The system needs to be restarted afterwards to be fully functional again.

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Munich, HRB 6684
WEEE-Reg.-No. DE 23691322

How will the issue finally be resolved?

Siemens is preparing a modification of the Luminos dRF system control console that will resolve this potential malfunction. The field modification will be available from May 2014.

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 until the update has been installed.


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

Siemens Aktiengesellschaft

2014-03-27


CEO
Siemens AG Healthcare
X-ray Products


Head of Quality Management
Siemens AG Healthcare
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