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Contact person of  
the Regional Unit  
Department

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

Telephone  
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Date

### **Safety Advisory Notice**

To users of SIEMENS systems Luminos Agile (VC10),  
Luminos Agile Max (VE10, VF10, VF11), Luminos dRF  
(VD10), Luminos dRF Max (VE10, VF10, VF11), Luminos  
Lotus Max (VF11), Urooskop Omnia (VD10) and Urooskop  
Omnia Max (VE10, VF10, VF11)

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### **Re: Potential risk of ceiling collision**

Dear customer,

This letter is to inform you about a potential risk of a collision with the ceiling or wall which might lead to serious injury for staff or patient.

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

Results of post market surveillance revealed that under certain rare circumstances the room configuration parameters of the system may be set to default values. If these values are larger than the actual room dimensions, a collision with the ceiling or wall cannot be ruled out during system movement. In worst case this could lead to a serious injury if the system were to hit the ceiling and parts were to fall down. So far, SIEMENS Healthineers has not become aware of any injuries caused by this issue.

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

When performing unit movements, the user should pay special attention to the travel range of system parts and stop movement in time to prevent a collision with objects, ceiling, or walls. System movement can be stopped by releasing the movement control or by activating the emergency stop button, as described in the operator manual.

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

This advisory letter (Update XP056/22/S) is distributed to all potentially affected customers.

The field corrective action (Update XP057/22/S for VD10, VE10, VF10 systems) will initiate an onsite visit of a service engineer to check the room configuration parameters currently set for your system and if necessary, restore them to their correct values. Systems with software version VF11 will be addressed with a separate field action (update to VF11H).

The respective corrective actions are planned for Q1 2023 and will be free of charge. Our service organization will contact you for an appointment to perform the corrective action needed for your system. Please feel free to reach out to the service organization for an earlier appointment.

We appreciate your understanding and cooperation with this safety advisory notice and ask you to immediately inform your personnel of the content of this notification. Please ensure this safety advisory notice is maintained in the system's instructions for use.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. Please inform us about the new owner of the device.

Sincerely yours,

Verena Schön  
Head of Business Line  
X-Ray Products

Andreas Herdegen  
Head of Quality Management  
X-Ray Products