

Siemens Healthcare GmbH, Henkestr. 127, 91052 Erlangen, Germany

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 Fax E-mail

Date

Safety Advisory Notice

To all affected users of the SIEMENS systems Luminos Agile Max, Luminos dRF Max, LUMINOS Lotus Max with display ceiling suspension and Multitom Rax with display wall suspension Contact person of the

Business Unit

Department

SHS DI XP F&U PRM

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Re: Potential risk of unintentional lowering of the support arm for display ceiling suspension / display wall suspension

Dear Customer,

This letter is to inform you about a potential problem with the support arm for the display ceiling suspension / display wall suspension. This issue may result in an injury to persons when they are under the display ceiling/wall suspension while positioning the displays.

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

There is a potential risk that the mounting screw on the support of the display ceiling/wall suspension may loosen or be missing, causing the support arm with displays to lower downwards with continued use. In a worst-case scenario, the support arm could lower suddenly and cause serious injury. During service activities Siemens Healthineers XP became aware of two cases in which the mounting screw was missing. No injuries were associated.

Siemens Healthcare GmbH

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Chairman of the Supervisory Board: Ralf P. Thomas Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821 WEEE-Reg.-No. DE 64872105



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

Please visually inspect the mounting screw on the ceiling tube (Figure 1) or wall tube (Figure 2) of the display suspension as far as this is possible from the ground.

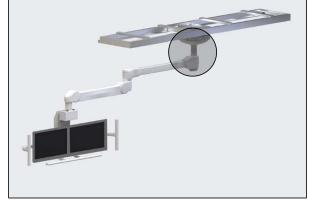


Figure 1 Display ceiling suspension

with ceiling tube circled

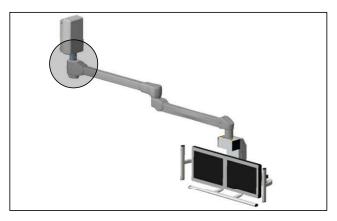


Figure 2 Display wall suspension with wall tube circled

Exemplary illustration of mounting screw and tube attachment on the display ceiling suspension showing the correct (figure 3) versus incorrect (figure 4) tube attachment:



Figure 3 Correct: Mounting screw available and no visible damage



Figure 4 Incorrect: Mounting screw missing and/or lowered support arm

For display wall suspension: The tube attachment on the wall suspension is identical to the tube attachment on the display ceiling suspension.

If the mounting screw is missing, or if the screw head protrudes or is broken, discontinue use of the system immediately. Please inform the Siemens Healthineers customer Furthermore, if the display ceiling/wall suspension has lowered, discontinue use of the system immediately and inform customer service of the issue.

In case the visual inspection of the mounting screw does not show any abnormalities, you can continue to use the system. Nevertheless, until the system has been checked by Siemens Healthineers customer service with the planned field action, we recommend:



- not to swivel the support arm of the display ceiling/wall suspension to the mechanical limit with great force and
- to ensure that there is no one under the display ceiling/wall suspension when positioning the displays.

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

This Customer Safety Advisory Notice (update XP017/24/S) is being distributed to all potentially affected customers. Siemens Healthineers is preparing a field safety corrective action that will be provided with Update XP018/24/S starting in the third quarter of 2024. The corrective action will involve check and replacement of the attachment of the support arm for the display ceiling/wall suspension by a service technician in an onsite visit. In instances where the mounting screw is broken, the support arm will also be replaced with update XP019/24/S. These field actions will be provided to you free of charge.

Once the corrective actions are available, our customer service team will contact you to schedule an appointment to perform the above safety corrective action(s). If you would like to make an earlier appointment, please feel free to contact customer service at any time.

We appreciate your understanding and cooperation with this Customer Safety Advisory Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory notice is retained in your product related records appropriately.

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

Sincerely yours,

Electronically signed by: Verena Schoen Reason: I am approving this document Date: Jun 13, 2024 16:20 GMT+2

Verena Schön Head of Business Line X-Ray Products Electronically signed by: Andreas Herdegen Reason: I am approving this document Date: Jun 13, 2024 15:27

Andreas Herdegen Head of Quality Management X-Ray Products