Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 105 **dated** 28/7/2024 **Regarding NCMDR Field Safety Notice of Stationary Radiological Equipment from (mfr: Siemens Healthcare GmbH).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 105 / 2024

22-01-1446 H
28-07-2024

Field Safety Notice of Stationary Radiological Equipment from Siemens Healthcare GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21111
Product	Luminos Agile Max, Luminos dRF Max, LUMINOS Lotus Max with display ceiling suspension and Multitom Rax with display wall suspension.
Description	Radiological technology - stationary radiological equipment.
Manufacturer	Siemens Healthcare GmbH.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	All.
Reason	A potential problem with the support arm for the display ceiling suspension / display wall suspension.
Action	1. Please follow the steps in the attachment of what can the user take to avoid the potential risk of the above issue. 2. The corrective action by Siemens will involve check and replacement of the attachment of the support arm, refer to the attachment for more information. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان. وزارة الصحة
مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

SIEMENS Healthineers

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

Contact person of
the Regional Unit
Department

Telephone
Fax
E-mail

Date

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

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: Monika Schwarz
Department: SHS DI XP F&U PRM

Telephone: +49 173 9655243
E-mail: monika.schwarz@siemens-healthineers.com

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 Healthineers

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.

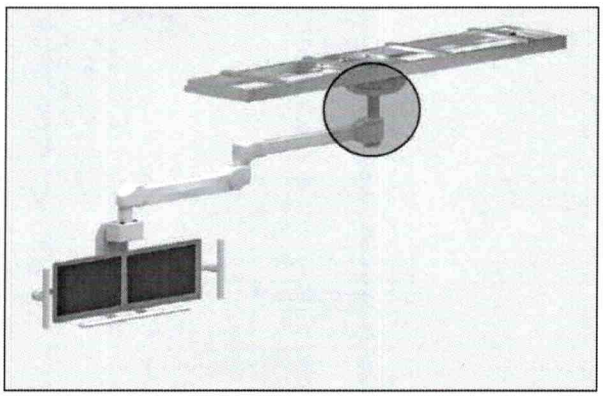

Figure 1 Display ceiling suspension with ceiling tube circled

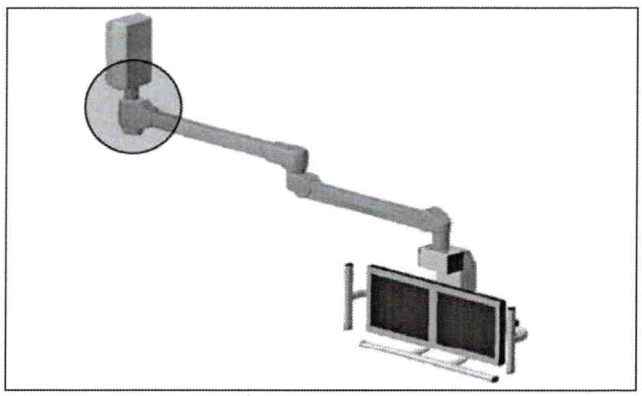

Figure 2 Display wall suspension with wall tube circled

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

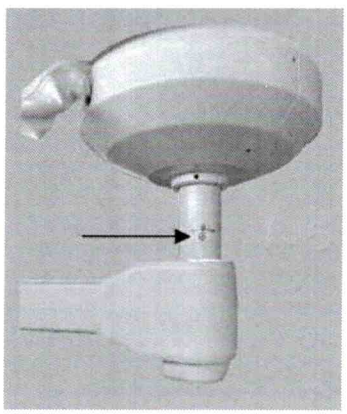

Figure 3 Correct: Mounting screw available and no visible damage

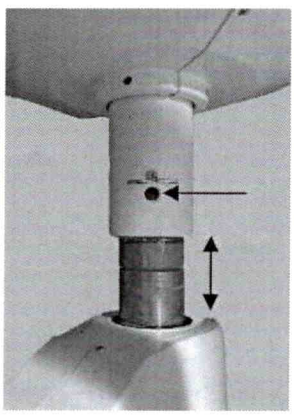

Figure 4 Incorrect: Mounting screw missing and/or lowered support arm

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 service. 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,

[redacted]
Head of Business Line
X-Ray Products

[redacted]
Head of Quality Management
X-Ray Products

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 006 07 24 000
Date submitted: 7/3/2024

Back

Manufacturer:	Siemens Healthcare GmbH
Device Type:	Luminos Agile Max, Luminos dRF Max, LUMINOS Lotus Max with display ceiling suspension and Multitom Rax with display wall suspension
Description:	Radiological technology - stationary radiological equipment
Medical Device Identifier:	All
Reason of Field Safety Corrective Action:	A potential problem with the support arm for the display ceiling suspension / display wall suspension.
Remedy Action:	Please follow the steps in the attachment of what can the user take to avoid the potential risk of the above issue. The corrective action by Siemens will involve check and replacement of the attachment of the support arm, refer to the attachment for more information.
Athorized Representative/Importer/Distributor:	Siemens Medical Solutions
Report Source:	NCMDR
Source Ref. Number:	SA-30-06-24-484
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	Siemens Healthcare GmbH.pdf

View History