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>

Customer Safety Advisory Notice

To all users of the SIEMENS systems
UROSKOP Omnia and UROSKOP Omnia Max
with specific serial numbers

Re: UROSKOP Omnia / UROSKOP Omnia Max – Potential risk of overheating of a frequency inverter under very rare circumstances

Dear Customer,

With this letter we inform you about a potential problem and thus potential hazard to users, patients and other persons that may be caused by a component of the drive for longitudinal movement of the patient table on UROSKOP Omnia and UROSKOP Omnia Max systems with specific serial numbers.

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

The problem can occur under very rare circumstances in case of an undetectable defect in the frequency inverter for the longitudinal table movement (defective relay) and when at the same time this movement is activated in frequent succession. This may lead to overheating of a resistor in the frequency converter. If, in addition, several installation-related factors coincide unfavorably, it cannot be ruled out that the plastic housing will catch fire. Should this exceptional case occur, it can potentially result in burns or smoke injuries to patients, users and other persons.

Due to the specific conditions for the error case in combination with the individual system constellation, the occurrence of harm is considered highly unlikely.

Siemens Healthineers AG
Chairman of the Supervisory Board: Ralf P. Thomas;
Managing Board: Bernhard Montag, President and Chief Executive Officer;
Members of the Managing Board: Darleen Caron, Jochen Schmitz,
Elisabeth Staudinger-Leibrecht

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

You can continue to use your system when paying attention for signs of burning smell and/or smoke coming from the device base.
In this case, the system must be immediately disconnected from power supply via room emergency on/off switch and the Siemens Healthineers Service Organization must be informed. If required, initiate further necessary measures.

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

This safety advisory notice (update XP009/25/S) is being distributed to all potentially affected customers.

- Siemens Healthineers is preparing an on-site field safety corrective action to replace the frequency inverter by another type that cannot cause the described problem.
The field safety corrective action will be implemented in the second quarter of 2025 with update XP008/25/S and will be provided to you free of charge.

Our customer service team will contact you to schedule an appointment to perform the safety corrective action. 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: May 14, 2025 12:00 GMT+2

Verena Schön
Head of Business Line
X-Ray Products

Electronically signed by:
Andreas Herdegen
Reason: I am approving this document
Date: May 9, 2025 13:34 GMT+2

Andreas Herdegen
Head of Quality Management
X-Ray Products