

Siemens Healthcare GmbH, HC DI XP MK, Siemensstr. 3, Healthcare Building 1,
91301 Forchheim

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

Customer Safety Advisory Notice

To all users of the SIEMENS Uroskop Omnia and Uroskop
Omnia Max operated with a monitor support arm with
mat. no.10999410

Contact person of
the Business Unit
Department

Telephone
Fax
E-Mail

Re: Possibility that the swivel arm of the Uroskop Omnia/Uroskop Omnia Max detaches from the carrying arm

Dear customer,

This letter is to inform you of a potential problem and hazard to persons when positioning the monitors of the monitor support arm (Mat. No.10999410) of the Uroskop Omnia and Uroskop Omnia Max directly above the patient.

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

Due to a manufacturing error of the monitor support arm, the swivel arm holding the monitors may become dislocated from the carrying arm. The probability of this problem occurring will increase during the lifetime of the system.

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

The risk from this malfunction can be mitigated by not moving and positioning the monitors above the system table. As an alternative and if clinically applicable, the monitors can also be operated when they are supported in the parking position.

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Thomas Rathmann, Michael Reitermann

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

How will the issue finally be resolved?

Siemens is preparing a field corrective action issued as Update XP006/19/S to modify affected Urooskop Omnia and Urooskop Omnia Max systems so that the dislocation cannot occur. The update is planned to be available starting end of Feb 2019. This Update will be provided to you free of charge.

Our service organization will get in contact with you for an appointment to perform the corrective action Update XP006/19/S. Please feel free to contact our service organization for an earlier appointment.

This letter will be distributed to affected customers as Update XP004/19/S.

- 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. Your personnel should maintain awareness until the modification has been implemented.

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,

