

Siemens Healthcare GmbH, HC DI XP QT, Allee am Röthelheimpark 2,
91052 Erlangen

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

Contact person of
the Regional Unit
Department

Telephone
Fax
E-Mail

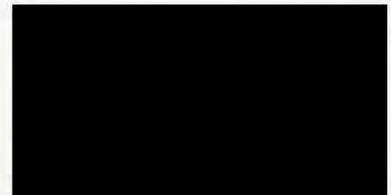
Urgent - Customer Safety Advisory Letter

To all users of the SIEMENS Ysio Max system

Contact person of
the Business Unit
Department

Telephone
Fax
E-Mail

Date



Re: Problem with patient table (Ysio, Ysio Max, Multix Fusion)

Dear Customer,

This letter is to inform you about a possible problem with the patient table of your System Ysio, Ysio Max or Multix Fusion with a potential risk to patients.

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

Siemens identified an issue with a patient table which was caused by a manufacturing error. There is an unlikely risk that an internal part of the table may detach causing the table top to tilt to the left side which could result in an injury to a patient on the table. This issue was identified during the installation of a patient table and this is the only known table with this problem. Siemens is initiating steps to determine if the same problem exists on other patient tables.

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

The affected part is covered and is not visible; therefore your device needs to be inspected by a Siemens technician.

Please do not use the table until it is inspected by our technician.

Siemens Healthcare GmbH
Geschäftsführung: Bernhard Montag, Vorsitzender,
Thomas Rathmann, Michael Reitermann

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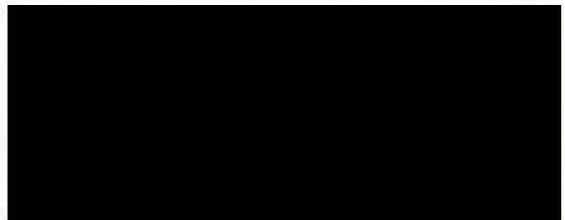
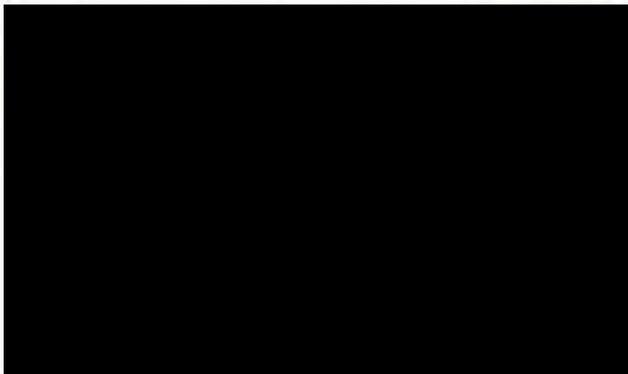
Vorsitzender des Aufsichtsrats: Siegfried Russwurm
Sitz der Gesellschaft: München, Deutschland; Registergericht: München, HRB 213821
WEEE-Reg.-Nr. DE 64872105

How will the issue finally be resolved?

We will send a service technician to your institution to check the affected part of the table. In the unlikely case that your device is affected, the technician will take steps to address the issue. This solution will be provided free of charge to all affected systems.

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 our technician checks your system and the modification, if needed, 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 advisory notice to the new owner of this device/equipment. Please inform us about the new owner of the device/equipment.



Acknowledgement of receipt

Customer address:

I hereby confirm as the owner / responsible operator of the **<product name>** with the Serial number _____ (optional) that I received the following document:

Safety Advisory Notice

<product name> with Problem with patient table (Ysio, Ysio Max, Multix Fusion

Place, Date _____

Name _____

Signature _____