

SIEMENS

Medical Solutions

**To all users of the Siemens MAGNETOM
Espree Systems with swiveling OR Table**

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Your letter of
Our reference 07-07830-MR-0608
Date 23.10.2007

Customer Safety Advisory

Re: MAGNETOM Espree System with swiveling OR Table

Dear MAGNETOM Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the swiveling OR Table of the Siemens MAGNETOM Espree system.

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

During the transfer of the OR tabletop from the OR tabletop carrier to the MR tabletop carrier and the transfer from the MR tabletop carrier back to the OR tabletop carrier a complete locking of the OR table and the MR patient table may occur in certain circumstances.

If this malfunction occurs it is no longer possible to move the OR table and the patient needs to be removed from the OR table top manually. This might present an increased risk to the patient depending on his/her condition.

The operation of the MR system is not affected.

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

You can avoid the potential risk, if the transfer of the OR tabletop to the MR system is executed as follows:

Before you rotate the OR table into the magnet position, please adjust the table height and tilt position, so there is a visible **significant difference from the Zero Position**. The height is adjusted by pressing the control buttons 'Raise/transfer' or 'Lower/transfer' for approximately 1 second.

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SCF 2007-05/OP-Liege Anweisung v4_en

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The Tilt (Trendelenburg) can be adjusted by pressing the control buttons 'Tilt up' or 'Tilt down', dependant on the situation of the patient, for approximately 1 second.
Now set the OR Table to the zero position by pressing and holding the control button 'Zero Position' until you hear a beep signal.
Now press the button 'Unlock' and rotate the OR table to the magnet position.

Please make sure that no control buttons are pressed after the Zero Position has been reached and before unlocking the OR table.

How will the issue finally be resolved?

Siemens is preparing a modification of the OR table control software that will resolve this potential malfunction. The field modification will be available from the middle of November 2007.

- We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is placed in the System Operating Manual.
Thank you for your patience and we apologize for any inconvenience this may cause.

Sincerely yours



President
Magnetic Resonance Division



Vice President
MR Quality Management

SIEMENS

Medical Solutions

Acknowledgement of receipt

Customer address:

I hereby confirm as the owner / responsible operator of the system MAGNETOM Espree.
Serial number

that I received the following document:

Customer Safety Advisory

MAGNETOM Espree System with swiveling OR Table

Place, Date

Name

Signature