

Siemens Healthcare GmbH, HC DI MR QT DCU, Allee am Roethelheimpark 2,
91052 Erlangen

To all users of
SIEMENS MAGNETOM Combi Suite Neurosurgery

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Date	October 10 ⁿ ¹ , 2016

SAFETY ADVISORY NOTICE

Re: Combi Dockable Table Neurosurgery

Dear customer,

This letter is to inform you that we had reasons to believe that in some cases the Combi Dockable Table Neurosurgery may have not been properly manufactured.

Due to a potential manufacturing error in some cases a potential risk exists for a sudden drop in table height. This can happen with or without user interaction. The maximum drop in height is 5cm.

Therefore, it was necessary to check whether the table of your system was manufactured in a manner that ensures safe operation. Siemens considers the safety of patients and users our highest priority; therefore, we initialized this inspection.

When does this issue occur?

The issue could have occurred any time with or without user interaction.

What are the possible risks to health?

Depending on the condition of the patient positioned on the Combi Dockable Table Neurosurgery, the risk of serious injury cannot be excluded.

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

Chairman of the Supervisory Board: Siegfried Russwurm
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How will the issue finally be resolved?

Siemens has inspected your system with the following result (please tick result):

- D** 1.) no safety deficiencies have been found, no correction had been required,
System is safe to use
- D** 2.) not all safety features concerning vertical movement of the table had been in place.
Correction has been performed immediately. System is safe to use.
- D** 3.) not all safety features concerning vertical movement of the table had been in place.
System is not safe to use until the safety issue is resolved.

Date, Name, Signature of CSE performing the inspection and correction

Acknowledge Receipt of this Safety Advisory Notice

In case, option "3" **is selected**, please sign the attached "Acknowledgment of Receipt" and handover to the Siemens Service-Engineer.

The National Competent Authority will be informed of this notice.

We apologize for the inconvenience caused by this issue.

Sincerely Yours

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Siemens Healthcare GmbH

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Siemens Healthcare GmbH

Acknowledgement of receipt

Customer address:

I hereby confirm as the owner / responsible operator of the Combi Dockable Table Neurosurgery with the Serial number _____ that I have read and understood that the Combi Dockable Table Neurosurgery is not safe to use until the safety issue is resolved and I accept the implementation of the recommended measures.

Dissemination of the content of this notice

I ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.

I will instruct my personnel accordingly. This safety advisory will be retained in my product related records appropriately. I will keep this information at least until the measures have been finalized.

I acknowledge this letter,

Place,

Date-----

Name-----

Signature

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