

Urgent Field Safety Notice

Re.: Therapy Simulator of type MEVASIM™, MEVASIM S™, SIMVIEW 3000™ and SIMVIEW NT™

Attention: Radiation Oncology Department

Dear Customer,

This letter is to inform you about a safety risk of using your Siemens Simulator system in combination with the software ProSim by Tiger software GmbH or other third-party components that have not been authorized by Siemens.

What is the issue and when does it occur?

It has come to Siemens' Radiation Oncology attention that some institutions are using the Siemens Simulator system in combination with the software ProSim by Tiger software GmbH which has not been validated by Siemens as being compatible with Siemens Simulator models.

It has been reported that a SIMVIEW system combined with the software ProSim by Tiger software GmbH performed an unintended isocentric table rotation exceeding 90° reaching its mechanical end position. Depending on the gantry position an unintended table rotation might lead to a collision. In worst case the patient might suffer a critical injury when colliding with the gantry.

Siemens cannot ensure that Siemens Simulator systems will operate in a safe manner or otherwise function as intended if used in conjunction with the software ProSim by Tiger software GmbH or with other unauthorized third-party components. Consistent with this Siemens cannot be responsible for any incidents directly caused by, or associated with the use of the software ProSim by Tiger software GmbH or other unauthorized third-party components with the SIMVIEW Simulator system.

This letter is to inform you furthermore that the use of any unauthorized third-party components on Siemens Simulator systems may lead to patient or operator injury, or damage to the Simulator, and can potentially compromise your warranty.

Siemens Healthcare GmbH
Henkestraße 127
D-91052 Erlangen
Germany

What preventive measures can the user take?

Users are advised to use only components authorized by Siemens on Simulator systems for patient treatments as described in the operator's manual. Kindly review the appropriate safety procedures for the use of any authorized Siemens components with your Simulator system.

What will Siemens do to address this issue?

IMPORTANT

Due to the potential for hazards while continuing to operate the Siemens Simulator system with the software ProSim by Tiger software GmbH or other unauthorized third-party components, Siemens advises discontinuing use of such third-party components in conjunction with the Simulator system unless the third party component has been tested and validated proving that the Siemens Simulator system will operate in a safe manner if it is used in conjunction with the third party components.

Furthermore when customers continue to use third party components not authorized by Siemens in conjunction with a Siemens Simulator system, Siemens shall have no liability for the use thereof and you shall indemnify Siemens in full against any claims, losses, costs or demands incurred by Siemens in relation to your use of these unauthorized third-party components.

Please include this Field Safety Notice in your Siemens Simulator System Owner Manual, where it should remain.

The relevant National Competent Authority will be informed of this Field Safety Notice.

We regret any inconvenience that this may cause, and we thank you in advance for your understanding.

Sincerely,

signed Dr. Gabriel Haras
Head of Business Segment RO

signed René Lennert
Head of RO Segment Quality Management

This document is valid without original signature.

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