

Urgent: Medical Device Correction **Urgent Field Safety Notice**

Re.: Radiation Therapy Simulators of type SimView™ NT

Attention: Radiation Oncology Department

Dear Customer,

This letter is to inform you about a potential safety risk regarding the motion stop function on your SimView NT simulator system.

What is the issue and when does it occur?

In a very rare occurrence an intended movement of the SimView NT simulation system components could not be stopped with usual hand control or the collision detection functionality.

The SimView NT movements are controlled and steered by three PLCs (Programmable Logic Controllers). The hand control is connected to PLC1; the other two PLCs control the motors and sensors. If any movement has been started and the PLC1 hardware fails, the regular motion stop functionality may not work correctly.

What preventive measures can the user take?

To stop the movement in this case, push the emergency button / stop button at control console or push the in-room emergency button. The emergency button/ stop button functionality is described in the User Manual.

There is no preventive measure to avoid this situation. This letter is intended to bring this potential safety issue to your awareness and to ensure that your personnel are trained about the use of the emergency button / stop button inside the simulation room and on the control console. Always monitor any movement of the simulator components.

What will Siemens do to address this issue?

Siemens is working on a solution to mitigate the described situation. You will be informed as soon as the update distributing this solution is available.


Please include this Field Safety Notice in your SimView NT Simulator System Owner Manual chapter "Safety Advisory Letters" where it should remain.

In the interests of safety, we ask that you perform the described preventive measures and inform all affected personnel immediately.

The relevant National Competent Authority has been informed of this Customer Safety Advisory Notice.

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

Sincerely,


General Manager, Radiation Oncology


Head of QM&RA, Radiation Oncology

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