

## Customer Information

**Re.: PRIMUS™/ONCOR™/ARTISTE™ Linear Accelerator Device Modification**

Attention: Radiation Oncology Department

Dear Customer,

this letter is intended to inform you about the solution of a potential safety issue that may cause an unintended rotation of the Gantry of the Linear Accelerator.

### What is the issue and when does the issue occur?

Siemens has received reports where the gantry started to rotate without receiving a movement command. These incidents have been identified to be caused by an overload within the drive signal power line. This resulted in the gantry rotating in a clockwise direction at a very low speed, much slower than any normal commanded gantry motion. This rotation will stop, when the Motion Stop is pressed by the operator or when the electrical end stops are reached.

### What will Siemens do to address this issue?

Siemens has developed a new version of the Motor Control PCB G31V7 to improve the inherent safety of the system. In order to resolve the potential problem, input voltage surveillance has been implemented within the Motor Control Logic on the G31 Motherboard. The failure of the input voltage will result in the inhibition of the gantry rotation during the persistence of the fault. The gantry will no longer rotate in case of this particular fault and therefore no user intervention will be required.

Siemens has arranged for a modification of your system to make sure this additional safety mechanism is fully functional. This has been carried out successfully within the context of this safety update TH023/11/S for your affected system(s).

Please include this Customer Information in your Digital Linear Accelerator System Owner manual chapter 'Safety Advisory Letters' where it should remain.

The relevant National Competent Authority will be informed of this update.

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

Sincerely,

signed Ghada Trotabas  
General Manager, Radiation Oncology

signed Stefan Leidenberger  
Vice President, QM, Radiation Oncology

This document is valid without original signature.

Siemens AG  
Healthcare Sector  
Radiation Oncology

Doris-Ruppenstein-Str. 4  
D-91052 Erlangen  
Germany