

Medical Device Correction **Field Safety Notice of Improvement**

**Re.: Digital Linear Accelerators of type PRIMUS™, ONCOR™ and ARTISTE™ -
550 TxT™ Treatment Table**

Attention: Radiation Oncology Department

Dear Customer,

This letter is to inform you about an update to the software for the 550 TxT Treatment Table of your Digital Linear Accelerator (LINAC).

What is the issue?

The following safety issues have been addressed with this new software version:

1. In very rare instances, the actual table position may significantly deviate from the position at the table side control and the LINAC control console, but no interlock occurs.
2. In sporadic cases the following issue for the table axis lateral, longitudinal and isocentric rotation occurs:
 - After a manual table movement with released brake an immediate automatic movement for the same table axis is not possible.

What has SIEMENS done to address this issue?

In order to avoid the occurrence of such errors and in order to improve the inherent safety of your system, SIEMENS has developed a new version of the 550 TxT Treatment Table software, VD00C. In addition to the software update Siemens provides you with a 550 TxT Treatment Table Addendum (TH05-100.623.01.01) that describes new table error codes. SIEMENS has arranged for the updating of your 550 TxT Treatment Table software. The SIEMENS Service Representative will ensure that the new software version VD00C is installed on your system.

By installation of this software update the issues were solved by the following actions:

1. A plausibility check was introduced for comparing the two independent encoder systems of each table axis.
2. The time between two encoder comparisons was reduced to 50ms and an error code was introduced.

Please include this Field Safety Notice in your Digital Linear Accelerator System Owner Manual chapter "Safety Advisory Letters" where it should remain.

The relevant National Competent Authority has been informed of this update.

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

Sincerely,

signed Dr. Gabriel Haras
General Manager, Radiation Oncology

signed René Lennert
Head of QM&RA, Radiation Oncology

This document is valid without original signature