ID number: **TH009/17/S**

Field Safety Notice

Re.: Digital Linear Accelerators of type ONCOR™ and PRIMUS™ running Control Console software version 9.2.400

Attention: Radiation Oncology Department

CC: Chairman of Medical Board & Heads of Departments

Dear Customer,

This Field Safety Notice is to inform you about an update of the Control Console software version 9.2.400 of your Digital Linear Accelerator.

To reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table using the SIMTEC™-Auto Field Sequence Option Siemens has updated the software solution “Auto Field Sequence (AFS) Motion Protection” implemented at the Control Console of your Digital Linear Accelerator.

With the present Control Console software update to version 9.2.502 Siemens is addressing the following issues.

1. Risk of collision due to automatic gantry movements in case of lateral table shifts

The previous “AFS Motion Protection” software did only consider critical settings of isocentric and excentric table positions, but not a lateral shift of the treatment table. In case of a large lateral shift of the treatment table there is a significant risk of collision of the gantry with the patient during automatic gantry movements.

This behavior is now corrected. In the present software update to Control Console software version 9.2.502 the “AFS Motion Protection” software was enhanced in order to consider also the lateral, longitudinal and vertical position of the table.

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2. Unwanted automatic gantry movements in case of table configuration set to “Manually” and the movement order to be “Table first”

The previous AFS Motion Protection software required the table configuration to be set to “automatic” for all parameters. In case the user had configured the isocentric table rotation to be “Manually” and the movement order to be “Table first” the previous software disregarded this configuration. If a gantry and a table movement was required for the next treatment field the software did not stop the AFS in order to allow a manual movement of the table prior to the gantry. The gantry had been automatically moved to the next target position. In this case there is a significant risk for collision of the gantry with the patient.

This behavior is now corrected. With the new software version any table value configuration set to “Manually” and the movement order set to “Table first” will result in a stop of the AFS and requires the manual movement of the treatment table and the gantry.

Additional safety advice

The new “AFS Motion Protection” Software will anticipate a potential collision based on the gantry position, the 4D table positions (x, y, z and isocentric rotation) and a safety margin covering a standard patient volume. If the AFS Motion Protection predicts a potential collision for a certain movement, the movement will not be executed automatically. In such a case, the user may perform the planned movement manually.

You can find more information on these functionalities in the following documents:

- Operator Manual of the Digital Linear Accelerator chapter 5 Tasks "AFS Motion Protection System"
- Digital Linear Accelerator System Owner Manual chapter 6 Technical Data “Automatic Motion Protection System (AMP)”
- Release notes of Digital Linear Accelerator Control Console 9.2.502 and Higher.

These updated manuals are provided with this update package.

In scenarios with significant risk for collision the system will prevent collisions when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table using the SIMTEC™-Auto Field Sequence Option. Despite these safety measures, there might be scenarios which are not covered by the software. Therefore, during an auto-sequence delivery the user must be aware all the time of any movement of the gantry and the treatment table and the applied table offsets or overrides according to the treatment plan.
The measures to be taken by the user are described in detail in the Operator Manual of the Digital Linear Accelerator and briefly summarized in the previously provided Field Safety Notice TH012/14/S.

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In case of any manual movement the system cannot anticipate a potential collision. During a manual movement the user has to monitor the system all the time and stop the movement by releasing the pressed deadman switch (if operated by hand control) or the pressed keys (if operated by Control Console keyboard) in case the gantry is getting too close to the patient.

In the interests of safety, we ask you to continue with these preventive measures described in the Field Safety Notice TH012/14/S.

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

If required 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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