SIEMENS

Medical Device Correction

Field Safety Notice

Re.: **Digital Linear Accelerators of type PRIMUS^{TM}, ONCOR^{TM} and ARTISTE^{TM} with *syngo* RT Therapist^{TM} 4.3.1_AR1**

Attention: Radiation Oncology Department

Dear Customer,

This letter is to inform you about a bundled update of the *syngo* RT Therapist^{TM} software and the Control Console software.

Both updates have to be performed at the same time in order to ensure that the system will run properly. The corrective measures described in this field safety notice affect the combination of the *syngo* RT Therapist^{TM} and the Control Console with your digital Linear Accelerator.

With this bundled update the following safety issues have been addressed:

Prevention from automatic movements in case of significant risk for collision

With the Field Safety Notice TH012/14/S Siemens has informed you about the potential risk of collision in case of automatically sequenced treatment delivery techniques using the SIMTEC^{TM} Auto Field Sequence Option.

Siemens has evaluated a new method where automated movement of the Digital Linear Accelerator gantry or treatment table is checked by the Control Console to determine if there might be a significant probability for a risk of collision of the Digital Linear Accelerator gantry with the patient or the treatment table. In case the Control Console detects a significant probability for a risk for collision, the system will be prevented from automatic movements.

For details please refer to the chapter 6 *Technical Data,* subchapter *AFS Motion Protection System,* of the Digital Linear Accelerator System Owner Manual and chapter 3 *System Overview* as well as chapter 5 *Tasks* of the Operator Manual which is provided with this update package.

Incorrect offset calculation in Adaptive Targeting Option

In rare cases, an identical Region of Interest (ROI) label for the planning isocenter and the treatment isocenter may have been randomly generated during image processing. In this case the offset calculation in Adaptive Targeting during image review has been incorrect. Applying an incorrect offset to the patient´s position could result in mistreatment in terms of delivery of dose at the wrong location.

This behavior is now corrected with this *syngo* RT Therapist^{TM} software update.

Siemens AG
Henkestraße 127
D-91052 Erlangen
Germany　　　　　　　　Page 1 of 2　　　　　　　　Print number TH11-400.680.10

Dose Linearity Quality Assurance procedure for IMRT (user manual update)

The "Physics Primer" was extended by a description of a Dose Linearity Quality Assurance procedure for IMRT similar to the mARC procedure. The affected parameter is called D1_CO. A not adjusted D1_C0 could potentially result in an injury of the patient in terms of an under-/or overdose for every fraction.

The updated "Physics Primer" is being provided with this update package.

Restart of Control Console

In cases where an accepted treatment (by using the ACCEPT key) was simultaneously cleared by using the CLEAR key and rejected by the Verify&Record system, a reboot was required to re-enable DMIP communication. Due to the possibility of patient movements during the time necessary for the reboot, additional imaging for position verification may have been required resulting in additional dose to be applied to the patient.

With this version this communication problem has been solved.

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 will be informed of this update.

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

Sincerely,

███████████████   ██████████████

Head of Business Segment RO   Head of RO Segment Quality Management

This document is valid without original signature.