SIEMENS

ID number: TH001/15/S and TH002/15/S

# Medical Device Correction

## Field Safety Notice

**Re.: Digital Linear Accelerators of type Primus™, ONCOR™ and ARTISTE™ running Control Console software version 12.0.25 or 13.0.65 and *syngo* RT Therapist™ running software version 4.2.110 or 4.3.SP1**

Attention: Radiation Oncology Department

Dear Customer,

This Field Safety Notice is to inform you about a bundled update of the *syngo* RT Therapist™ 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™ 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™ 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.

### Re-positioning of 160 MLC after motion stop interlock

With the Field Safety Notice TH008/11/S Siemens has informed you about a potential risk related to the behavior of the 160 MLC when using the ‘Motion Stop’ Button followed by a ‘Reset’ several times during the treatment delivery of one beam or one segment.

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Print number TH11-400.691.03.01.02

After a motion stop was cleared, the 160 MLC performed a self-check and moved slightly all leaves and carriages in order to resolve a possible leaf collision. This could cause a deviation between planned and actual leaf positions resulting in a slightly incorrect treatment field shape.

This behavior is now corrected in the new software version.

**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.

**Support of fractional monitor units for Virtual Wedge**

With the version currently installed on the Control Console the system could not deliver Virtual Wedge with fractional Monitor Units, e.g. 10.2. As a workaround the Monitor Units had to be adapted by the user manually in the Oncology Information System (OIS) which could have led to typos and in consequence to an incorrect dose to the patient.

The new software version now enables the systems to deliver Virtual Wedge beams with fractional monitor units.

**Lost information after plan UID change in Oncology Information System (OIS)**

If a treatment plan will be changed in the OIS a new plan UID is created for the updated plan and thus considered by the system as a new treatment plan.

With the current software version of *syngo* RT Therapist™ any changes made on the previous treatment plan in the Workflow Edit Tab (for example imaging options, pauses, gating flags) were no longer active for the new plan. The necessary changes had to be re-done manually for each session. Should the user forget to properly set these attributes, there was potential for mistreatment of the patient or an injury by moving parts.

The new software now provides a beam merging concept which allows you to transfer user-defined attributes from one session to another session in *syngo* RT Therapist™. Details can be found in the User Manual in the Chapter “Beam Merging Concept”.

**Incorrect automatic offset calculation in combination with images acquired with CTVision™**

With Field Safety Notice TH006/15/S Siemens has informed affected customers, running Adaptive Targeting Option on *syngo* RT Therapist™ 4.3.SP1 in combination with images acquired on CTVision™, about wrong offset calculation. Applying an incorrect offset to the patient´s position could have resulted in mistreatment in terms of delivery of dose at the wrong location.

The problem is solved with the new *syngo* RT TherapistTM software provided with this update.

## 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™ software update.

## Interrupt of Cone Beam reconstruction

In some cases memory handling problems caused errors during image acquisition which have led to an interruption of the Cone Beam image reconstruction. This created the need to acquire new images for position verification of the patient and thus an additional dose had to be applied to the patient.

With the software update, the memory handling was improved in order to reduce the risk of additional imaging dose to the patient.

## Table rotation values for Relative setup

With TH009/12/S Siemens has informed you about the risk of unexpected table movement during auto-sequenced treatments when using position verification beams in an Absolute setup. An unexpected table movement might result in an injury of the patient due to a collision or a mistreatment in terms of delivery of dose at the wrong location.

In previous versions *syngo* RT Therapist™ required all table values to be 0 (zero) for a Relative Setup. Therefore, in cases where any table value in any beam has been unequal 0, the setup switched to Absolute Setup which required a table move.

With this version, *syngo* RT Therapist™ interprets a setup as Relative setup, when the lateral, longitudinal, and vertical treatment table positions have the value 0 (zero) in all beams. Isocentric and eccentric table values unequal 0 (zero) will be ignored. In this case the setup will be interpreted as a Relative setup and no table move will occur.

## Wrong in-session resumption in case of 0 (zero) delivered monitor units

In case an IMRT beam has been interrupted before the system has delivered radiation the treatment record for the affected segment beam contained ‘0 delivered MUs. The value “0” had caused incorrect behavior of the *syngo* RT Therapist™ related to the identification of the correct segment(s) for the in-session resumption of the affected beam.
It could have happened that segments would have been treated more than one time because of this incorrect behavior of the *syngo* RT Therapist™. This could result in an overdose to the patient.

This error has been corrected with the software version provided with this update.

**Unexpected table movement after internal error message on syngo RT Therapist**

Due to an internal error in *syngo* RT Therapist™ during the delivery of an auto sequence *syngo* RT Therapist™ and Control Console where nonsynchronous. In this situation *syngo* RT Therapist™ has lost the information about previously overridden table axis positions. This has caused the *syngo* RT Therapist™ to continue the treatment incorrectly with the original table axis positions provided with the treatment plan and thus has performed a table movement which was not expected by the user. This behavior might lead to an injury of the patient due to collision with the gantry and/or a mistreatment due to the delivery of dose at the wrong location.

With this software update, the synchronization process of *syngo* RT Therapist™ and Control Console have been improved. In case the synchronization is lost, the system will cancel the treatment and Interlock #96 “R&V INTERFACE” will be displayed on the Control Console screen, which informs the user that the communication needs to be established again.

**Dose Linearity Quality Assurance procedure for IMRT (Update of user documentation “Physics Primer”)**

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.

**Configuration of autosequence for bolus fields (Update of user documentation “Addendum for syngo RT TherapistTM with MOSAIQ”)**

In case an autosequenced treatment has the potential for a collision, some customers are using the bolus feature for creating an automatic Pause for manually rotating the gantry. Depending on the chosen kind of Pause and the order of the Pause relative to the treatment beams the behavior of the system is different. If a Pause is not appropriately programmed by the user, the Pause does not occur at the expected point of time. This might cause a collision, which could lead to a serious injury of the patient.

The “Addendum for *syngo* RT Therapist™ with MOSAIQ” has been updated with information for bolus fields in the chapter “Dividing an Auto-Sequence” and is provided with this update package.

**Workflow information for moving patient for treatment from one to another Digital Linear Accelerator (Update of user documentation “Customer Release Notes”)**

If a patient has to be moved from one Digital Linear Accelerator (LINAC) to another LINAC, changes performed in Workflow Edit during treatment on the one LINAC will not be transferred automatically to the other LINAC (for example imaging options, pauses, gating flags). The necessary changes have to be re-done manually. Should the user forget to properly set these attributes, there was potential for mistreatment of the patient.

The “Customer Release Notes” have been updated with information for moving patients from one Digital Linear Accelerator to another between treatment sessions. Please read carefully the updated document.

**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,

signed Gabriel Haras
Head of Business Segment RO

signed René Lennert
Head of RO Segment Quality Management

This document is valid without original signature.