SIEMENS

ID number: TH004/15/S

Medical Device Correction

Field Safety Notice

Re.: Digital Linear Accelerators of type PRIMUS™ and ONCOR™ - Control Console Software Update to Version 9.2.400

Attention: Radiation Oncology Department

Dear Customer,

this letter is to inform you about an update of the Control Console software. The corrective measures described in this field safety notice affect the Control Console with your digital Linear Accelerator.

With this update the following safety issues have been addressed:

Prevention from automatic movements in case of significant risk for collision

With TH012/14/S Siemens 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 LINAC gantry or treatment table is checked (for isocentric and excentric rotation) by the Control Console to determine if there might be a significant probability for a risk of collision of the LINAC gantry with the patient or the treatment table. In case the Control Console detects a significant risk for collision the system will prevent 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 (AFS Motion Protection System) which is provided with this update package.

Motor stall interlock did not occur

The rotation limit switches are designed to trip after collimator or gantry rotate past certain limits and cause FC#0 to activate an Interlock and power off the motor. In some cases the Interlock was not activated and the power off of the motor did not function. This has now been corrected. In case a limit switch is activated FC#0 will activate IL #63 and hence, power off the motor.

Physics Primer update

The user documentation (Physics Primer) was extended by a description of a Dose Linearity Quality Assurance procedure for IMRT similar to the mARC procedure. The Physics Primer is being provided with this update package.

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Restart of Control Console

In cases where an accepted treatment was simultaneously cleared by using the CLEAR key and rejected by the V&R system, a reboot was required to re-enable DMIP communication. With this version this communication problem has been solved.

Jaw potentiometer / encoder sensor mismatch (Interlock 63)

The system checks whether the position of the jaws is changed after a power off or a Left Hand Key Reset. If so, a message is displayed that a mismatch was detected and the user has to confirm that the field size has been verified. No treatment is possible till the message is confirmed.
This mechanism was optimized with this SW version.

Incorrect resumption

In the very rare case that a Function Controller sends an incorrect treatment completion dose to the Control Console, a wrong dose will be reported to the V&R system.

With this version the handling of an incorrect reported dose was corrected. Control Console now asserts an Interlock and reports the last correct dose to the V&R system.

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.

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