ID number: **TH002/20/S**

Field Safety Notice

Re.: Field Safety Notice- Applicable to all digital LINAC systems

ONCOR-, PRIMUS- and ARTISTE product families

Attention: Radiation Oncology Department

Dear Customer,

We would like to inform you about the importance to observe safety interlocks related to patient treatment when using any Control Console Software (CCSW) version (V6, V7, V9, V11, V13) of your digital LINAC system.

What is the issue and when does it occur?

We have identified a potential safety issue in case one of the following safety interlocks occurs and users clear the interlock without having the interlock immediately analysed by a skilled staff member (e.g. medical physicist) and handled as set forth in this letter:

#1	Name:	MONITOR 2
	Description:	Monitor 2 total dose coincidence
	Intent:	This interlock is intended to prevent overdose when the primary dose monitoring system fails to complete the treatment.
#2	Name:	TREATMENT TIME
	Description:	Preset treatment time coincidence with actual treatment time
	Intent:	This interlock is intended to prevent overdose if preset treatment time is exceeded.
#3	Name:	MONITOR SYNC (SW)
	Description:	Excessive accumulated dose deviation detected between the primary and the secondary dose monitoring systems.
	Intent:	This interlock is intended to prevent patient mistreatment due to inaccurate monitoring of delivered dose.

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When one or more of the above described interlocks occur, it is assumed that there is an error in the dose monitor system.
Therefore treatment should be stopped and the instuctions set forth below (under "**What steps have to be taken by the user to avoid the possible risks associated with this issue?"**) have to be followed. Furthermore, Siemens Healthineers service organization should be contacted immediately.

In case the interlock is cleared without following such instructions this may lead to an incorrect recording of dose values in the OIS and to the application of an overdose for the respective segment during following treatment resumption.

Warning

Incorrect handling of occurred interlocks can lead to an incorrect recording of dose values in the OIS and to the application of an overdose for the respective segment during following treatment resumption.

GENERAL MISTREATMENT AND/OR PHYSICAL INJURY

What are the possible risks to health?

For #1 (MONITOR 2) an overdose of up to 15% can occur per segment
For #2 (TREATMENT TIME) an overdose of max. 20% depending on the dose rate can occur per segment
For #3 (MONITOR SYNC (SW) an overdose of max. 10 % can occur per segment

All three can lead to a critical injury.

What steps have to be taken by the user to avoid the possible risks associated with this issue?

To avoid the possibility of an overdose treatment comply with the following:

- Stop actual treatment (do not perform an immediate or in-session resumption) in case one of the above listed interlocks (#1, #2, or #3) occurs
- Don't clear the interlock, call a skilled staff member (e.g. medical physicist) immediately
- Clarify if the dose chambers display identical or different values
- Document displayed actual values – ("MONITOR 1", "MONITOR 2", "TIME") separately
- Call the Siemens Healthineers service organization
- Perform an error analysis (with the support of Siemens Healthineers service organization) After comparing the values of the dose chamber with the displayed actually delivered values, any values from the dose chamber that have been automatically recorded in the OIS but are deviating from the actually delivered values have to be manually corrected in the OIS .
- Perform a late resumption of the remaining MUs after interruption of the treatment for correct treatment completion

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How will the issue finally be resolved?

The safety interlocks work as required. Siemens Healthineers is not planning a correction for this (potential) issue. The intent of this Field Safety Notice is to make you aware of the importance of these safety interlocks and appropriate handling of such.

Dissemination of the content of this notice

Please ensure that all users of all the digital LINAC systems with the affected CCSW versions within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.
We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly.

Please include this Field Safety Notice in your LINAC System Operator Manual.

What if you no longer have this device/equipment?

If the digital LINAC System is no longer in your possession, please forward this Field Safety Notice to the new owner of the digital LINAC System. If applicable, please inform us about the new owner of the device.

The relevant National Competent Authority will be informed of this Field Safety Notice, if required.

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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