

Medical Device Correction

Field Safety Notice

Re.: syngo RT Oncologist™ with software version 4.2.X or 4.3.X

Attention: Radiation Oncology Department

Dear Customer,

This Field Safety Notice is to inform you about an update of the syngo RT Oncologist™ software.

With this update the following safety issues have been addressed:

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 Oncologist™ 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 Oncologist™ software update.

Problems with structure name in case of using structure operation functionality in Segmentation

In special scenarios within the Structure Operation functionality of the Segmentation tab, the system did not store the selected name from the list of predefined names when creating a new structure. After reloading the data, the system replaced the name of this structure by the name of the former last deleted structure. If the user was not aware of this problem, an incorrect structure might be chosen for treatment planning which could result in mistreatment of the patient.

The *syngo* RT Oncologist™ software update corrects now this behavior.

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

This document is valid without original signature.


Head of RO Segment Quality Management