

## **Urgent: Medical Device Correction** **Customer Safety Advisory Notice**

**Re.: Digital linear accelerators of type ARTISTE™ *syngo*® RT Therapist version 4.3**

Attention: Radiation Oncology Department

Dear customer,

This letter is intended to inform you about a potential safety issue when using the “In-session resumption” feature of the *syngo* RT Therapist 4.3 software.

### What is the issue and when does it occur?

The *syngo* RT Therapist 4.3 (RTT) provides several mechanisms to fully administer a treatment beam whose delivery has been previously interrupted for any reasons. The “in-session resumption” feature of *syngo* RT Therapist 4.3 consists in the possibility to select in the Treatment Visualization tab one or several partially delivered beams and send them for delivery to the control console of the linear accelerator. This mechanism will send for delivery an amount of Monitor Units (MU) equivalent to the planned MUs minus the already delivered MUs for each of the selected beams.

In the following very rare scenario, however, the RTT will send again the complete beam or segment for delivery to the control console:

- An interlock of the control console or a user-performed treatment termination has occurred when less than 0.5 MU were remaining for the complete delivery of a certain treatment beam
- and**
- The user selects to not perform an immediate resumption when prompted by the associated pop-up menu in the *syngo* RT Therapist
- and**
- This beam, although appearing as treated in the *syngo* RT Therapist UI, is selected for in-session resumption (alone or in combination with other treatment beams)

If **all** the conditions stated above are fulfilled, the system will send the already treated beam again to the control console of the linear accelerator for full delivery.

Siemens AG  
Healthcare Sector  
Radiation Oncology

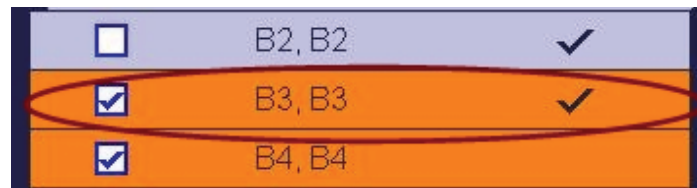
Doris-Ruppenstein-Strasse 4  
D-91052 Erlangen  
Germany

TH11-400.680.07.01.02

## What preventive measures can the user take?

In case an interlock happens near the completion of the treatment beam, please ensure the following before performing in-session resumption:

- Do not attempt to make in-session resumption for any beams that are indicated in the UI as fully delivered (solid checkmark on the right of the beam). In the example below, this will correspond to beam "B3, B3". In this case deselect the beam manually.



## What will Siemens do to address this issue?

We are currently working on a new version of the *syngo* RT Therapist software that will solve this problem.

**In the interests of safety, we ask that you perform the above preventive measures and inform all affected personnel immediately.**

Please include this Customer Safety Advisory Notice in your System Owner Manual chapter "Safety Advisory Letters" where it should remain until the measures defined above are implemented.

The relevant National Competent Authority has been informed of this Customer Safety Advisory Notice.

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

Sincerely,

████████████████████  
General Manager, Radiation Oncology

████████████████████  
Vice-President, QM, Radiation Oncology

This document is valid without original signature.

Siemens AG  
Healthcare Sector  
Radiation Oncology

Doris-Ruppenstein-Strasse 4  
D-91052 Erlangen  
Germany