

## **FIELD SAFETY NOTICE**

**Re.: Field Safety Notice - Applicable to your ARTISTE, ONCOR or PRIMUS  
with syngo RT Therapist (RTT) software version 4.3.1 MR3**

Attention: Radiation Oncology Department

Dear Customer,

This letter is intended to inform you about the planned rollout of the new *syngo* RT Therapist (RTT) software version 4.3.1 MR4 related to patient treatment when using **ARTISTE, ONCOR or PRIMUS with ARIA connectivity** that will avoid a (potential) safety issue.

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

With our Field Safety Notice TH001/21/S (*syngo* RT Therapist (RTT) software version 4.3.1. MR3) we informed you that Siemens Healthineers has identified a potential safety issue with the possibility that a user selects the wrong site for treatment resulting in dose being delivered to a wrong isocenter. Depending on the fraction dose and the planned volumes, this may lead to a serious injury.

For detailed information please refer to TH001/21/S (*syngo* RT Therapist (RTT) software version 4.3.1. MR3) respectively:

“.....

*Siemens Healthineers has identified a potential safety issue with the possibility that a user selects the wrong site for treatment. Therefore, there is a possibility to deliver dose to wrong isocenter.*

*This potential issue could occur if the following preconditions are met:*

- Patient plan includes multiple sites.*
- User downloads multiple sites from ARIA to syngo RT Therapist (RTT). As a result, all sites get downloaded to syngo RT Therapist (RTT) at the same time.*
- User acquires imaging setup beams first and then modifies the site fraction group. As a result, RTT reorders the site list. The User may not recognize that the last modified site is now displayed at the top.*
- Beam names between different fraction groups could be identical or similar.*
- When selecting the site fraction group for treatment the User may not verify the site name. As the site fraction group order is changed by RTT after the user modification, the user may select the wrong site fraction group for download.*

*With the above preconditions the User could unintentionally select the wrong site fraction group of a different site, resulting in delivery of a wrong plan to the actual positioned isocenter.*

... “

### How will the issue finally be resolved?

As already stated in the previous letter TH001/21/S, the systems **ARTISTE, ONCOR or PRIMUS with syngo RT Therapist (RTT) "in ARIA environment"** work as intended.

Due to another recently reported occurrence, Siemens Healthineers has decided to modify the *syngo* RT Therapist (RTT) software version 4.3.1 MR3 and change the current behavior in order to avoid this potential safety issue. Availability of the new *syngo* RT Therapist (RTT) software version RTT 4.3.1 MR4 and UI ID number is not known yet.

With the new ***syngo* RT Therapist (RTT) software version RTT 4.3.1 MR4** only one site can get loaded at a time, therefore the user cannot confuse multiple displayed sites. If the user would try to download multiple sites from ARIA to *syngo* RT Therapist (RTT), the RTT will reject the complete patient loading.

Users should immediately change their workflow by preparing in ARIA one scheduler per planned site.

### Dissemination of the content of this notice

Please ensure that all users of **ARTISTE, ONCOR or PRIMUS with *syngo* RT Therapist (RTT)** in ARIA environment 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 **ARTISTE, ONCOR or PRIMUS** System Owner Manual.

### What if you no longer have this device/equipment?

If this **ARTISTE, ONCOR or PRIMUS with *syngo* RT Therapist (RTT)** in ARIA environment is no longer in your possession, please forward this Safety Advisory Notice to the new owner of the **ARTISTE, ONCOR or PRIMUS with *syngo* RT Therapist (RTT)** in ARIA environment. If applicable, please inform us about the new owner of the device.

#### Note:

Multi-Isocenter plans are not affected by these changes and still can get loaded.

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

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

Sincerely,

[Redacted signature]

[Redacted signature]