SIEMENS

ID number: UI TH012/14/S

Urgent Medical Device Correction

Field Safety Notice

Re.: Digital Linear Accelerators of type ARTISTE™, ONCOR™ and PRIMUS™ with Automatic Sequenced Treatment Delivery Option

Attention: Radiation Oncology Department

Dear Customer,

This letter is to remind you about safety risks regarding the use of automatically sequenced treatment delivery technique using the SIMTEC™- Auto Field Sequence option, where movement of gantry and/or table is involved.

Automatic movements of the gantry and/or the treatment table during an auto-sequenced treatment have the potential to lead to a collision with the patient.

What is the issue and when does it occur?

Siemens became aware of an incident where a patient was pinched between the moving gantry and the tabletop during an auto-sequenced treatment. In this case, an automatic gantry movement during an auto-sequenced treatment led to the collision because:

- The auto-sequenced treatment has been created including beams with table angles.
  AND
- No dry run has been performed.
  AND
- The therapist did not monitor the patient during treatment delivery.

What preventive measures can the user take?

The user must be aware of any movement of the gantry and the treatment table during an auto-sequence delivery and the applied table offsets or overrides according to the treatment plan by following these suggestions:

- **Beam Placement -** No beams with table angles should be included in an auto-sequence to minimize the risk for collisions of the gantry or attached accessory with the patient.
- **Dry Run -** Before initiating an auto-sequenced treatment, a dry run should be performed prior to the first treatment of the patient to ensure that ample clearance exists between the patient and all components of the treatment delivery system during the auto-sequenced motion.

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- The dry run must be repeated after any modification of the treatment plan (i.e. the beam order) or modification of the patient positioning.
- **Treatment Interruption -**If the table or the patient is repositioned during an INTERRUPTED SIMTEC – Auto-Field Sequence (AFS) or mARC treatment, the previous set up tolerances regarding a potential collision may be compromised. The therapist should re-verify the clearance to the patient, treatment table, and accessories before continuing with an auto-sequenced treatment.
- **Patient Monitoring -** During the treatment delivery, the therapist must closely monitor the patient with closed circuit television monitors. This is not only required to prevent from the risk of collision due to the moving gantry and treatment table, but also because of any patient movement during an automated treatment delivery that can result in mistreatment due to misalignment of the treatment isocenter.
- **Collision Prevention -** When observing a potential collision of the gantry with the patient or the table the therapist should use one of the following options to stop any motion of the system:
    - Motion stop button at the Control Console
    - Rad-off button at the Control Console
    - Emergency stop button in the control room.
- **OPTIGARD -** If your LINAC is equipped with a collision avoidance system such as OPTIGARD, we strongly recommend activating it during any patient treatment. The OPTIGARD system will assist in detecting a potential collision and will stop the movement of any component if necessary.

Options to interrupt or avoid auto field sequence treatment

- Implement pauses where a user interaction is required, i.e. for moving the patient out of the potential collision area (applicable for RTT 4.x systems)
- Avoid entering fields with potential for collision into an auto field sequences (applicable for RTT 2.x systems).

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What will Siemens do to address this issue?

Siemens is evaluating a new method where automated movement of the LINAC gantry or treatment table are checked by the control console and this check may determine there is a significant probability for a risk of collision of the gantry with the patient or the treatment table.

Please note: The preconditions of this method implementation are:

1. LINAC has serial number 3094 or higher and
2. The control console communicates with the treatment table.

In this way, the control console knows the physical position of the gantry and treatment table.

According to our files, your LINAC system configuration supports this method implementation, when your LINAC communicates with the treatment table.
You will be informed by the local customer service organization as soon as an update for your system is available. If you have any questions about the content of this letter please contact your local customer service representative.

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 has been informed of this Field Safety Notice.

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

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

Sincerely,

[redacted]
General Manager, Radiation Oncology

[redacted]
Head of QM&RA, Radiation Oncology

This document is valid without original signature

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