

## **Urgent: Medical Device Correction** **Urgent Field Safety Notice**

**Re.: Digital Linear Accelerators of type ONCOR and ARTISTE**

Attention: Radiation Oncology Department

Dear Customer,

This letter is to inform you about a safety risk regarding a potentially existing dark current phenomenon on your Linear Accelerator (LINAC) in combination with IMRT or mARC treatments using unflat beams.

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

The dark current is a phenomenon that may develop over time during the normal use of a linear accelerator. It is characterized by the presence of a small amount of radiation when the radiofrequency (RF) is applied to the waveguide even if no treatment beam is produced. This is due to occasionally accelerated electrons which are randomly emitted by the gun and is called dark current.

During conventional treatments, the dark current dose is measured by the linear accelerator dosimetry system which terminates the treatment when the programmed dose is reached.

During step and shoot IMRT or mARC treatments, the Siemens linear accelerators have a mechanism that keeps the RF turned on while the jaws or MLC leaves are moving without producing a treatment beam. This allows a more stable and faster beam formation from segment to segment. Because the RF remains switched on during field shape change, a small amount of dark current radiation and thus dose may be generated during these periods without being considered by the dosimetry system. In case there are many long periods of field shape changes in an IMRT or mARC treatment plan, the dose due to dark current may sum up to a significant value.

Note: For step and shoot IMRT the RF is switched off during the time intervals when the gantry, collimator, or treatment table is rotating. This eliminates the possibility of dark current occurring during these time intervals.

## What preventive measures can the user take?

Although there are technical precautions in place to minimize the dark current, Siemens recommends that the responsible medical physicists perform a dosimetric quality control check for any IMRT treatment at very high dose rates (Multiple X) and for mARC treatments. With this measurement an unacceptable additional dose resulting from dark current can be identified. If an inadequate level of dark current dose has been detected during this dosimetric quality control check, please try to optimize and recalculate the affected treatment plan in terms of less field shape changes from segment to segment or call the Siemens Service Center for support.

## What will Siemens do to address this issue?

If a considerable amount of dark current dose is recognized by the medical physicist during the dosimetric quality control check, Siemens will reduce the effect of potential dark current by optimizing specific beam parameters of the LINAC. In very rare cases it might happen that a not acceptable dark current issue persists. In this case, Siemens will get back to the customer in order to discuss possible actions depending on the configuration and age of the affected system.

Please include this Field Safety Notice in your Digital Linear Accelerator System Owner Manual chapter "Safety Advisory Letters" where it should remain.

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

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,



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