

Field Safety Notice

Re.: Digital Linear Accelerators of type ARTISTE™, ONCOR™ and PRIMUS™ with serial number equal or higher than 3094

Attention: Radiation Oncology Department

Dear Customer,

This Field Safety Notice is to inform you about a hardware update regarding the collimator position detection and the mechanic of the overhead suspension of your Digital Linear Accelerator.

With the present hardware update Siemens is addressing the following issues.

Incorrect values for the rotational collimator position displayed due to mechanical problems of the sensor slide

It has come to our attention that incorrect values for the rotational collimator position have been displayed. This can happen, if the slide, on which the sensors used to detect the rotational collimator position are mounted, is not in its fully latched position.

If the user is not aware of the incorrect values the patient can be mistreated by dose at the wrong location.

To keep the sensor slide in its latched position, a locking plate shall be mounted to the sensor slide. This will significantly reduce the risk that the sensor slide might be mechanically misaligned and cause incorrect values being displayed for the rotational collimator position.

Improper weld seam at the overhead suspension

Siemens got aware of a defective weld seam at overhead suspensions. Due to such defect the weld seam might break and the overhead suspension might fall down. This can lead to a severe injury of the patient or any other person.

As reinforcement a bracket will be added to the overhead suspension to ensure the stability of the connection. This will prevent the overhead suspension from falling down.

Siemens Healthcare GmbH
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Germany

Please include this Field Safety Notice in your System Owner Manual chapter “Safety Advisory Letters” where it should remain.

If required 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,

signed Dr. Gabriel Haras
Head of Business Segment RO

signed René Lennert
Head of RO Segment Quality Management

This document is valid without original signature.