

Urgent Medical Device Correction **Field Safety Notice**

**Re.: Update for Digital Linear Accelerators of type MEVATRON™,
PRIMUS™, ONCOR™ and ARTISTE™**

Attention: Radiation Oncology Department

Dear Customer,

This letter is to inform you about a corrective action on your Linear Accelerator (LINAC) in terms of the replacement of the Head Driver Printed Circuit Board (PCB) by a redesigned board.

What is the issue and when does the issue occur?

Siemens has received reports from one electric board (G41) located inside of the linac gantry showing signs of overheating. After a detailed analysis the root cause was found to be one of the components that belong to this board (Head Driver PCB).

What will Siemens do to address this issue?

Siemens has redesigned the Head Driver PCB to further mitigate the risk of local overheating on the G41 motherboard. The present corrective action comprises the replacement of the Head Driver PCB by a redesigned component on your LINAC.

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 will be informed of this update.

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

Sincerely,

signed Gabriel Haras
General Manager, Radiation Oncology

signed René Lennert
VP of QM&RA, Radiation Oncology

This document is valid without original signature.

Siemens AG
Healthcare
Radiation Oncology

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