Re.: Digital Linear Accelerators of type ARTISTE™, ONCOR™ and PRIMUS™ running
- Control Console from software version 13.0.302 and higher
- Control Console from software version 9.2.400 and higher
- Control Console from software version 11.0.400 and higher

Attention: Radiation Oncology Department
CC: Chairman of Medical Board & Heads of Departments

Dear Customer,

This Field Safety Notice is to inform you about the consequences of disabling the

"Auto Field Sequence (AFS) Automatic Motion Protection (AMP)" function

implemented at the Control Console of your Digital Linear Accelerator.

The "Auto Field Sequence (AFS) Automatic Motion Protection (AMP)" was introduced in order to reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table using the SIMTEC™-Auto Field Sequence.

Please refer to the FSN (TH001/19/S) enclosed.

Yours Sincerely,

[redacted]

Chua Link Soon
Customer Service Head
Siemens Healthcare Pte Ltd

Siemens Healthcare Pte. Ltd.
Management : Elisabeth Staudinger-Leibrecht
Michael Mueller

Henkestr. 127
91052 Erlangen
Germany

Tel.: +49 (9131) 84 0
Fax: +49 (9131) 84 0
www.siemens.com/healthcare

RC: 201504514R

ID number: TH001/19/S

FIELD SAFETY NOTICE

Re.: Digital Linear Accelerators of type ARTISTE™, ONCOR™ and PRIMUS™ running
- Control Console from software version 13.0.302 and higher
- Control Console from software version 9.2.400 and higher
- Control Console from software version 11.0.400 and higher

Attention: Radiation Oncology Department

Dear Customer,

This Field Safety Notice is to inform you about the consequences of disabling the

"Auto Field Sequence (AFS) Automatic Motion Protection (AMP)" function

implemented at the Control Console of your Digital Linear Accelerator.

The "Auto Field Sequence (AFS) Automatic Motion Protection (AMP)" was introduced in order to reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table using the SIMTEC™-Auto Field Sequence.

For detailed information please refer to TH005/16/S (software version 13.1.002), TH010/17/S (software version 9.2.502), or TH005/15/S (software version 11.0.400) respectively.

IMPORTANT CUSTOMER NOTICE

In view of the potential for collisions of LINAC equipment with patients, Siemens Healthcare GmbH advises customers to not induce to disable or bypass the AMP function.

Customers who decide to disable or bypass the AMP function, do so on their own responsibility, duly weighing patient benefit and risk. Disabling or bypassing for reasons of comfort is not permitted. Siemens Healthcare GmbH shall have no liability for the safe use of the system in the event of any automatically sequenced treatments with respect to any kind of collision between any part of the LINAC and patient.

Customer shall indemnify and hold harmless Siemens Healthcare GmbH from and against any and all third party claims arising from or related to damage suffered from switching off the safety function AMP.

The REASON and PURPOSE of this notice has been explained. I have read and understood the terms and conditions of this Field Safety Notice.

Should I choose to disable or bypass the AMP function, I, being the authorized representative of the hospital/institute sign to acknowledge and accept liability for the continued clinical use of this product as set out in this Field Safety Notice.

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Jochen Schmitz, Michael Reitermann

Siemens Healthcare GmbH
Henkestraße 127
D-91052 Erlangen
Germany

Print number: T2-000.680.26.01.02

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

Sincerely,

Gabriel Haras
Head of Business Segment RO Management

René Lennert
Head of RO Segment Quality

☐ I confirm that the disabling/bypassing of the AMP function is for medical reasons and the patient benefit outweighs the risk.

Please sign and return one copy of this Field Safety Notice to acknowledge that you have read, understood and accepted these terms and conditions in case of disabling/bypassing the AMP function.

Linac Type: _____ Serial number: _____

Name: _____ Title: _____

Signature: _____ Date: _____

Please return the copy of this Field Safety Notice to:

e-mail: csslmro.team@siemens-healthineers.com

Fax number: +49 (0) 9131 84 4363

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Jochen Schmitz, Michael Reitermann

Siemens Healthcare GmbH
Henkestraße 127
D-91052 Erlangen, Germany

Print number: T2-000.680.26.01.02