IMPORTANT FIELD SAFETY NOTICE

PRODUCT: Digital Accelerator

Date: 03-2013 **FCO Ref:** 200 01 502 032

Integrity™ 1.1 Incorrect Static Tolerances for Linac Geometric Axes

This Notice contains important information about the operation of your product. Elekta recommends that all users of the product follow the instructions or recommendations in this Notice.

If you have any queries about this Notice, contact your local Elekta representative.

Scope: All Integrity™ 1.1 sites

Problem: During beam delivery, the tolerance values are used to do a check for unwanted movements.

These values are known as “static tolerances” which are related to all the digital accelerator geometric movement axes except Table Column.

The problem is that the “static tolerances” from the calibration files (loaded database) are used for beam delivery instead of the machine calculated values.

A fault occurs if the loaded database is incorrect.

Clinical impact: If the tolerances for the unwanted movement during the delivery are incorrect, the unwanted movement may not terminate treatment.

This is only a problem if a malfunction such as a brake failure or an equivalent fault occurs during beam delivery. It can cause clinical mistreatment.

Solution: The solution to this problem is to apply the Integrity™ 1.1 Static Tolerance Updater Tool as detailed in the Field Safety Modification 200 02 502 031.

WARNING: This tool will need to be re-applied, if a new Linac license is applied in the future.

A complete solution will be included in the next release.

This Notice has been notified to the appropriate Regulatory Authority

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FCO ACTION NOTIFICATION REPORT

<Give this Notice to the customer, and then complete and return this report to your local Elekta Office or Representative for the Configuration Database.>

Classification:	Important Field Safety Notice	**FCO Ref:**	200 01 502 032
FCO description:	Integrity™ 1.1 Incorrect Static Tolerances for Linac Geometric Axes		
Scope:	All Integrity 1.1 sites		

Hospital:	
Device Serial No: (e.g. linac - if applicable)	**Location or** **Site No:**

Action on this unit/device was: (*select one*)

Note: If you use a work-order in the CLM configuration database, then you do not have to complete this section. The work-order will be used to add the information to the system.

☐ Completed as per instructions on: <date day/month/year]>

☐ Not completed because: **(***give reasons*)

☐ Not completed because the unit/device is in storage *(if applicable).*

☐ Refused by customer because: **(***give reasons*)

Acknowledgement by customer:
This notification to be signed by the customer.

The REASON and PURPOSE of this notice has been explained.

Name: ..... Title: .....

Signature: ..... Date: .....

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