



IMPORTANT FIELD SAFETY NOTICE



PRODUCT: Digital Accelerator

Date: 04-2013

FCO Ref: 200 01 502 029

Incorrect Static Tolerances for Linac Geometric Axes in Integrity™ R3.0

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™ R3.0 sites

Problem: During beam delivery tolerance values are used to do checks of any unexpected movements.

These values are known as “static tolerances” which are related to all Linac 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 will only occur if the loaded database is incorrect.

Clinical impact: If the tolerances for unexpected movement during delivery are incorrect, any amount of unexpected movement can be more than the expected tolerance and therefore not be detected.

This is only possible if a malfunction such as a brake failure or an equivalent fault occurs during beam delivery.

This can cause clinical mistreatment.

Solution: The solution to this problem is to upgrade to Integrity™ R3.1 as soon as it is available. Refer to Important Field Safety Modification 200 02 502 030.

This Notice has been notified to the appropriate Regulatory Authority



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 01 502 029
FCO description: Incorrect Static Tolerances for Linac Geometric Axes in Integrity™ R3.0	
Scope: All Integrity R3.0 sites	

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

Action on this unit/device was: <i>(select one)</i>	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.
<input type="checkbox"/> Completed as per instructions on: <date day/month/year>	
<input type="checkbox"/> Not completed because: <i>(give reasons)</i>	
<input type="checkbox"/> Not completed because the unit/device is in storage <i>(if applicable)</i> .	
<input type="checkbox"/> Refused by customer because: <i>(give reasons)</i>	

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:

This Notice has been notified to the appropriate Regulatory Authority