



## IMPORTANT FIELD SAFETY NOTICE



### PRODUCT: Digital Accelerator

Date: 07-2012

FCO Ref: 200 01 103 049

### Release of the Field Change Order to install the Modulator Reverse Diode Cover

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. Put this notice in the Important Notice section of the applicable manual.

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

**Scope:** This Notice is applicable to machine range 105071 to 105360. It replaces Important Notice A349.

**Problem:** Malfunction of the Modulator Reverse Diode. Elekta thinks that the cause of the malfunction is a defect in the diode that occurred during the manufacturing process. The defect can increase the pressure in the diode and cause it to malfunction during radiation delivery, or after radiation delivery is terminated. If a malfunction occurs, the ceramic body of the diode can burst into pieces.

**Clinical impact:** This can cause ceramic material and silicone oils to eject from the modulator assembly. This can cause injury to Service personnel when they do work in Area 30 of the Digital Accelerator.

**Solution:** As a failure of the diode cannot be prevented, this notice tells Users that the modification kit (FCO 200 02 103 050) is available. The modification kit is installed to prevent injury if the Modulator Reverse Diode fails.

Until the Modulator Reverse Diode cover is installed, Elekta recommends that service personnel always wear protective safety glasses when they do work on the modulator assembly with the covers removed. Elekta also recommends that users make sure that the modulator cover is installed when the digital accelerator is in operation.

The local Business Unit representative will contact you to organize the installation of the cover.

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.>

<b>Classification:</b> Important Field Safety Notice	<b>FCO Ref:</b> 200 01 103 049
<b>FCO description:</b> Fitting of the Modulator Reverse Diode Cover	
<b>Scope:</b> This notice is applicable to machine range 105071 to 105360. It replaces A349.	

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

<b>Action on this unit/device was:</b> <i>(select one)</i>	<b>Note:</b> 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>	

<b>Acknowledgement by customer:</b> This notification to be signed by the customer.	
<b>The REASON and PURPOSE of this notice has been explained.</b>	
Name: .....	Title: .....
Signature: .....	Date: .....

This Notice has been notified to the appropriate Regulatory Authority