IMPORTANT FIELD SAFETY NOTICE

PRODUCT: *MLCi and MLCi2*

Date: 04-2012 **FCO Ref:** 200 01 403 002

It is possible that the backup diaphragms drive mechanism can become loose

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. This Notice must be put in the Important Notice section of the applicable manual.

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

Scope: All MLCi and MLCi2 radiation heads.

Problem: It is possible that the backup diaphragms drive mechanism can become loose after many years in clinical operation. This can cause a backlash between the positioning mechanism and the diaphragm. This backlash can be seen by the usual X-ray and field calibration checks when the field is moved from a small to a large field size. If there is a problem it will be that the backup diaphragm is not in the correct position behind the MLC leaf tips. If you do not do the recommended planned maintenance program, screws can become lost from the positioning mechanism. If you find one or more screws, do not use the machine for clinical operation, and find the cause.

Clinical impact: The problem can cause clinical mistreatment if it is not repaired.

Solution: Do the weekly recommended physics check of the X-ray and light field size calibration. Make sure that the field is moved from a small to a large field size. If an error is found during this check, you must contact your local Elekta service engineer.

Safety reference

The following warnings and cautions are associated with this notice:

WARNING

Do not try to deliver radiation treatment unless the user routine checks have been satisfactorily completed and the planned maintenance program is up to date. The use of equipment where the planned maintenance program is not up to date can result in clinical mistreatment, fatal injury and damage to the equipment.

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 01 403 002
FCO description:	It is possible that the backup diaphragms drive mechanism can become loose.		
Scope:	All MLCi and MLCi2 radiation heads.		

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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