IMPORTANT FIELD SAFETY NOTICE

PRODUCT: DMLC

Date: 08-2013 **FCO Ref:** 200 01 406 030

Changes to your system to improve the safe operation of DMLC

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.

IMPORTANT CUSTOMER NOTICE

In view of the potential for clinical errors (as set out in this IFSN) while continuing to operate the DMLC outside of the solution configuration prerequisites and the FCO upgrade, Elekta advises customers who do not wish to take advantage of this FCO upgrade, to discontinue with the clinical use of these devices.

For customers who continue to use these devices clinically, Elekta shall have no liability for the use thereof and you shall indemnify Elekta in full against any claims, losses, costs or demands incurred by Elekta in relation to your use of these devices.

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

Should I choose not to take the upgrade FCO, I, being the authorised representative of the hospital/institute sign to acknowledge and accept liability for the continued clinical use of this product as set out in this IFSN.

Please sign and return one copy of this IFSN to acknowledge that you have read, understood and accepted these terms and conditions.

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

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

Scope: All DMLC systems on an Elekta digital accelerator.

Problem: Although stereotactic radiosurgery has not replaced open surgery for most brain lesions, it is necessary to use it for more brain conditions, which include some tumors and some arteriovenous malformations. The general use of the applicable technologies caused a fast move from specialised institutes to the general use of SRT technologies. Manufacturers must therefore develop products which can be used with a larger range of clinical use and skills.

Therefore, Elekta have designed a solution to further the product integration into the stereotactic clinical workflow. This reduces the dependencies which have been placed on highly skilled and highly trained individual users for almost 25 years.

This Notice has been notified to the appropriate Regulatory Authority

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Clinical impact: With the current design, it is necessary for the stereotactic practitioner to implement processes and protocols, to manage the clinical application of these devices, and to be fully trained and current on the complete process of stereotactic radiosurgery. The likely contributing factors to errors in the clinical workflow which fall under this management are:

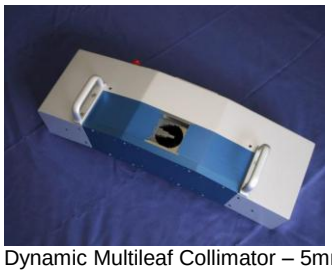
- No DMLC system installation at the necessary time.
- An incorrect diaphragm setting in the Treatment Planning System.
- An incorrect diaphragm setting in Standard Therapy.
- Different patients and/or beams selected in MOSAIQ® and MCS.

A failure to manage these conditions can cause clinical mistreatment.

Solution: The DMLC is an add-on microMLC system. It is an accessory to the linear accelerator used for radiation therapy. It is intended to shape the X-ray field both in static (fixed) or dynamic mode with rotating gantry as a function of the gantry angle. It is provided to assist the radiation oncologist to deliver radiation to the target tissue while sparing the surrounding normal tissues. There are three almost the same DMLC systems. The primary different parts are the:

- Dynamic Multileaf Collimator (see Figure 1).
- Linac attachment plates – for different types of host machine (see Figure 2).
- Controller box (see Figure 3).


Dynamic Multileaf Collimator – 3mm


Dynamic Multileaf Collimator – 5mm


Dynamic Multileaf Collimator – 7mm

Figure 1 Dynamic Multileaf Collimator

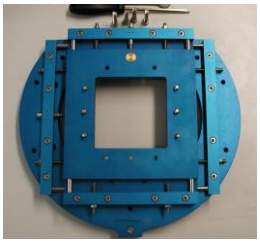

LINAC attachment Philips/Elekta

Figure 2 Attachment plate


DMLC IV Controller Box


DMLC V Controller Box

Figure 3 Controller box

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The new design includes:

- The use of bar codes for device recognition during the clinical workflow.
- Changes to the ERGO++™ or Monaco® TPS and MOSAIQ® OIS systems to operate with the new functions.
- Changes to DMLC control software (MCS).

These changes can be applied to the current design of the DMLC system.

These functions help to prevent these possible errors:

ID	Function	Possible Error
1	The TPS automatically transfers the DMLC identifier to the R&V system and the R&V system automatically loads the DMLC identifier.	This prevents: • No DMLC system installation at the necessary time.
2	Each DMLC is identified by a unique bar code.	This prevents: • No DMLC system installation at the necessary time. • A diaphragm size incorrectly set in the TPS.
3	If a DMLC is indicated for use for a treatment, the correct bar code scan data must be available before treatment is permitted by the system.	This prevents: • No DMLC system installation at the necessary time.
4	MOSAIQ® does a check that the prescribed diaphragm settings are the same as for the DMLC, and prevents treatment delivery if it is not correct.	This prevents: • A diaphragm size incorrectly set in the TPS.
5	The diaphragm settings for the DMLC cannot be changed in MOSAIQ®.	This prevents: • A diaphragm size incorrectly set in the TPS.
6	Standard Therapy must be blocked by DMLC MCS.	This prevents: • A diaphragm incorrectly set in Standard Therapy
7	The system must prevent treatment delivery if the DMLC cannot find the EPID file.	This prevents: • A diaphragm incorrectly set in Standard Therapy • Different patients and/or beams selected in MOSAIQ® and MCS.

System configuration

To benefit from these improvements in the DMLC system clinical workflow, the Treatment System must be in compliance with the following configuration:

- MOSAIQ® 2.4.1 or later software release
- ERGO++™ 1.7.7 or Monaco® 3.3 (or later)
- Desktop Pro™ R7.01 (Service Pack 2) or Integrity™ R1.1
- DMLC system workstation HP6600 or Z210.

If you wish to upgrade your Treatment System to take advantage of this upgrade, please contact your local Elekta office to discuss your requirements.

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Customer system configurations which are in compliance with these prerequisites can receive a free FCO upgrade with a bar code scanner. For Elekta Digital Linear Accelerators, refer to FCO 200 02 406 025.

The kit includes:

- **MCS 2.5.4 patch release –** this:
  - Makes sure a Record and Verify (R&V) system is always present in the Treatment System configuration.
  - Provides connectivity to the R&V system.
  - Supports the operation of the bar code functions.
- **Unique bar codes** – which are printed on approved label material and applied to each collimator.
- **Bar Code Scanner** – this is used in the treatment room to do a scan of the collimator.
- **An Important Field Safety Modification (IFSM)** - which gives the upgrade and the new clinical workflow instructions.

Contact your local Elekta representative to prepare for this upgrade.

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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 01 406 030
FCO description:	Changes to your system to improve the safe operation of DMLC		
Scope:	All DMLC systems on an Elekta digital accelerator		

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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