Field Corrective Action Reference: **FCA-IMS-0025**
This notice reference: 382-01-ERG-001
HPQC 104

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Incorrect Rotation of the Collimator or Couch

Product: ERGO®

Scope: Sites affected will be those:
1. Running ERGO® version 1.7.3 and higher and,
2. Using a Multileaf Collimator (MLC) device for planning

Notification Released: September, 2017

Description of Problem:
Elekta has become aware of the potential for incorrect DICOM mapping of the exported collimator or couch angles from ERGO®, which would lead to incorrect rotation of the collimator or couch when using a MLC device for planning.

Verification tests are included with this notice. It is recommended that you complete these tests before proceeding with any further patient treatments.

Details:
If the DICOM export values are not mapped correctly, it is possible that treatments could be delivered with the wrong collimator or couch angle.

Clinical Impact:
Patients can be treated with the wrong collimator or couch angle. This would result in a geometric miss with the tumor potentially underdosed and normal structures overdosed.

This document contains important information for the continued safe and proper use of your equipment.

- Please post this notice in a place accessible to all users, e.g. Instructions for Use, until this action is closed.
- Advise the appropriate personnel working with this product the content of this letter

Elekta, Inc.
Tel: 314 993 0003
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FAX: 314 993 0075

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Recommended User Action:
If you are using a MLC for dose planning in ERGO®, please run the verification test below to ensure that your collimator and couch are rotating correctly. If the test passes successfully, please sign the Acknowledgement form and return the form to Elekta. If the test fails please contact your local Elekta Care Support Center for assistance.

If you are not using a MLC in ERGO®, please sign the Acknowledgement form, add a note to confirm that you are not planning with an MLC at your clinic and then return the form to Elekta.

If you have questions about the applicability of this customer notification, please contact your local Elekta Care Support Center before completing and returning the Acknowledgement form to Elekta.

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ERGO Elekta Customer Verification Test

Test Purpose

This document specifies the test for customer verification that collimator and couch angles are configured correctly inside ERGO® and can be delivered consistently when exported to the Linac console.

This verification checklist outlines the necessary tests for Elekta Service personnel and customers to ensure the integrity of the installed applications in the configured environment. The intent is that the site personnel test each item and, if satisfied, initial and date to confirm their verification.

Before running tests it is necessary to make sure that the MLC and Linac in use are properly configured so that angles inside DICOM plans created by ERGO® match those in the actual devices.

Test description and verification checklist

Rows inside the table contain set-up of the beams that must be created with ERGO® Dynamic Multileaf (DMS) module and exported as DICOM plans to the Record & Verify console.

The last two columns of the table must contain results of the verification (passed or failed):

- Record & Verify check
  All plan angles displayed inside the DMS window must be equal to those appearing inside the Record & Verify and MLC controller units

- Light Field check
  Positions of the leaves planned inside DMS must be consistent (field shape and orientation) with those appearing with the light field on the Linac couch. To facilitate execution of this test it is suggested to create shapes with asymmetries like the example in figures 1 and 2.

Test execution

In ERGO® TPS push the images of *Uterus* demo patient (or another patient proven to be *HFS - View From Gantry*) and create a new patient inside the database.

Open DMS module and put a single beam with angles as specified inside the table. Create a separate beam for each row and send the DICOM plan(s) to the controller unit. You can export a single plan with all beams inside the table or a separate plan for each row.

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First perform beam verification on the Record & Verify console and then check shape correctness with the light field.

Light field verifications are only possible using plans with gantry angle 0.

Field Number	Setup			R&V Pass/Fail	Light Field Checks Pass/Fail
	Gantry Angle	Collimator Angle	Couch Angle		
1	0	Default Position	0°		
2	0	Default Position +30°	0°		
3	0	Default Position	30°		
4	0	Default Position + 20°	315°		
5	0	Default Position - 20°	45°		
6	34	Default Position +56	66		**N/A**
7	238	Default Position -37	321		**N/A**

Default collimator angle (Default Position) for integrated BLD is 0°, for APEX is 270°.

For other add-on collimators the default position may change depending on the collimator model in use, refer to documentation applicable to the product.

Tester Name: …….. Tester Signature: …….. Test Date: ……

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Exemplificative figures

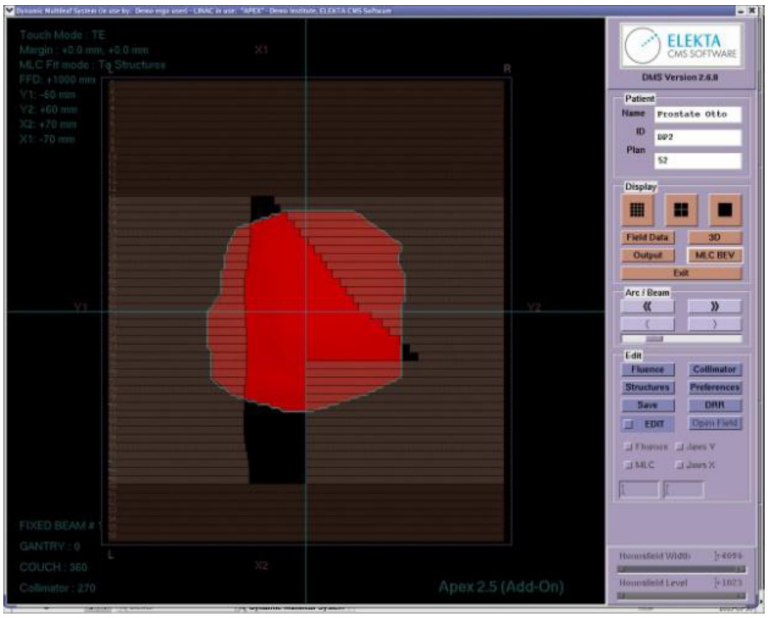

Figure 1 - Screenshot of ERGO®

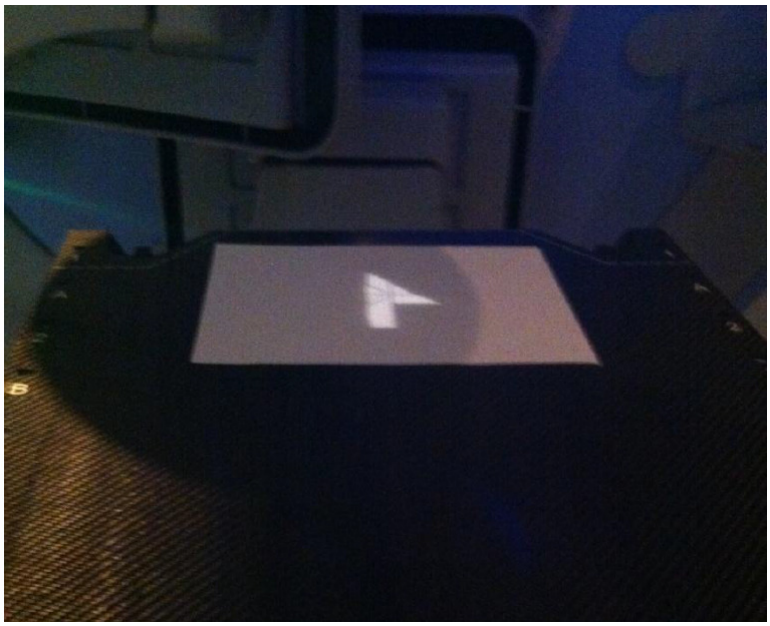

Figure 2 - Light field

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Acknowledgement Form

In order to meet regulatory requirements, you are required to complete this form and return it to Elekta immediately upon receipt but no later than 30 days.

Classification:	Important Field Safety Notification	FCO Reference Number:	382-01-ERG-001
Description	Incorrect Rotation of the Collimator or Couch		

Hospital:	
Device Serial No(s): (if applicable)	Location or Site:

I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations.

Name: Title:

Customer Signature: Date:

New installation confirmation to be signed by the installing Elekta engineer or Representative employee when the installed product has a physical IFU/manual:

I acknowledge that the customer is informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual or added to the record with the applicable User Manual:

Name: Title:

Signature: Date:

Cc: Chairman Medical Board and relevant Head of Departments

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