

10 Aug 2017

ATTN: Risk Manager Biomedical Engineering, Chief Medical Physicist

cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,

Please kindly refer to the relevant Urgent Important Field Safety Notification with

Notice reference: 382-01-MON-009

Subject:

Incorrect Dose After Editing Beam Number and Wedge Angle

Description of Problem:

Calculated dose from wedged beams can be assigned to the wrong beam.

The attached Urgent Important Field Safety Notification contains important information for the continued safe and proper use of your equipment. The details and impact of the problem have been clearly described. The recommended user action has been provided. Please kindly return the acknowledgement form in the Urgent Important Field Safety Notification in order to represent your understanding and awareness.

By signing the acknowledgment form, the customer representative confirms that this notice has been read and understood and communicated to the appropriate employees within the organization. If you have any questions, please feel free to contact our Elekta Application Specialist to provide you with additional information and/or guidelines if necessary.

Tel. 62212322 e-mail: Fareast.Support@elekta.com.

Sincerely,



Henry Hou

Regulatory Affairs Manager

Elekta Limited

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Tel. + 852 2892 4359



Field Corrective Action Reference: **FCA-IMS-0022**

This notice reference: 382-01-MON-009
HPQC 3965

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Incorrect Dose After Editing Beam Number and Wedge Angle

Product: Monaco®

Scope: Sites affected will be those:

1. Running Monaco®:
 - a. V 5.10.00 (including 5.10.01, 5.10.02), or
 - b. V 5.11.00 (including 5.11.01), or
 - c. V 5.20.00, and
2. Using Elekta Motorized Wedges

Notification Released: December, 2016

Description of Problem:

Calculated dose from wedged beams can be assigned to the wrong beam.

Details:

This can occur for a plan with at least two beams using the Elekta motorized wedge. The user must change the beam index numbers belonging to the two wedged beams, such that the index numbers have been exchanged for these beams, then edit the wedge angle of one of the beams. The beam index numbers are located in the first column of the Beams Spreadsheet.

Clinical Impact:

The dose distribution will not reflect what is delivered to the patient. A geometric miss would result.

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



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URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Recommended User Action:

If a recalculation is forced after the beam numbers are edited and the wedge angle is modified, the problem will resolve itself.

Elekta Corrective Actions:

This problem will be resolved in patches to the following Monaco® releases:

5.10

5.11

The problem will also be resolved in major release 5.30.00.

This notice has been provided to the appropriate Regulatory Authorities.

We sincerely apologize for any inconvenience this action may cause and thank you in advance for your cooperation.



URGENT IMPORTANT FIELD SAFETY NOTIFICATION

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-MON-009
Description: Incorrect Dose After Editing Beam Number and Wedge Angle	

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