

IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Incorrect Shift Information Displayed and Exported

Product: Monaco[®]

Scope: Sites affected will be those who:

- Have created plans using Monaco[®] version 5.50 or 5.51

Notification Released: August, 2019

Description of Problem:

Monaco[®] is displaying some incorrect shift information on the Scan and Setup Reference Report and is DICOM exporting incorrect shift information.

Details:

Monaco[®] is displaying the Anatomy and Beam shift direction incorrectly on the Monaco[®] Scan and Setup Reference Report and is DICOM exporting incorrect (Anatomy/Beam) shift directions. Therefore, the (Anatomy/Beam) shifts in all three directions (post/ant, sup/inf and left/right) can be in the opposite direction from what was intended. Note that the Table top shift directions (Operator face to Gantry), as described in the Monaco[®] Scan and Setup Reference Report, are correct.

Clinical Impact:

This could result in a geometric miss of the intended target resulting in an underdose of the tumor and overdose of normal structures.

Recommended User Action:

All shifts should be verified before treatment.

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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, on the content of this letter.

Elekta Corrective Actions:

Your site will be notified when a software fix is available.

This notice has been submitted to the appropriate Regulatory Authorities.

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

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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 within 30 days.

Classification: Important Field Safety Notification	FCO Reference Number: 382-01-MON-014
Description Incorrect Shift Information Displayed and Exported	

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

I acknowledge that I have read and understood this Notice and accept the implementation of any given recommendation.	
Name:	Title:
Customer Signature:	Date:

New installation confirmation to be signed by the installing Elekta engineer or a Representative employee, when the installed product has a physical IFU/manual:	
I acknowledge that the customer has been informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual, or added on record with the applicable User Manual:	
Name:	Title:
Signature:	Date: