

IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Incorrect Energy Used in Dose Calculation

Product: Monaco[®]

Scope: Sites affected will be those who:

- Have created plans using Monaco[®] version 5.40 and above

Notification Released: November 2019

Description of Problem:

Monaco[®] is using the incorrect energy when optimizing and calculating dose.

Details:

If a Monaco[®] plan has at least two beams, and the beams have different energies, the optimization and subsequent dose calculation are incorrectly using the energy from the first beam only. However, the exported RTPlan file will indicate that mixed energies were calculated by Monaco[®]. Monaco[®] plans that are created without optimization are not impacted.

Clinical Impact:

An approved plan in Monaco[®] that used only a single energy will be delivered with different energies. Therefore, the dose delivered will not match the planned dose.

Recommended User Action:

Do not use multiple energies within the same plan. Please check patient plans created with the affected versions to make sure multiple energies have not been used.

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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-016
Description: Incorrect Energy Used in Dose Calculation	

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: