



URGENT

IMPORTANT FIELD SAFETY NOTICE

We are providing the information in this Notice to notify you of two important safety issues that may exist on your equipment, and to inform you of any actions needed to safeguard both your staff and your patients. We ask that you please read and understand the content of this notice and implement any recommendations provided.

We also need you to acknowledge and accept this Notice by signing and returning the statement on the Acknowledgement page.

We advise you to insert this Notice in the applicable copy of the User Manual.

Dose and MU Incorrect When CT Images Viewed From the Head

Dose and MU Incorrect When Using Multiple Prescriptions With Forced Densities

Product: Monaco

Reference number (Field Change Order, FCO): FCO 382-01-MON-002

Field Corrective Action (FCA) number (if applicable): FCA-IMS-0009

Scope:	Sites affected will be those running Monaco 5.10.00.
Dose and MU Incorrect When CT Images Viewed From the Head (HPQC 3131)	
Description:	<p>In Radiation Therapy, CT images are typically presented as if the viewer is standing at the foot of the couch and looking toward the patient's head (if the patient is supine, the patient's left is on the right side of the screen).</p> <p>However, for Neurosurgery, images are often created as if being viewed from the top of the couch looking toward the patient's feet (supine patient's left will be presented on the left of the screen).</p> <p>When CT images are created this latter way and imported in Monaco, the image is displayed correctly but the electron densities are incorrectly flipped in both the right-left and superior-inferior directions.</p>
Clinical impact:	The dose distribution and monitor units will be incorrect. There is a remote probability that serious injury could occur.

This Notice has been notified to the appropriate Regulatory Authorities

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Dose and MU Incorrect When Using Multiple Prescriptions With Forced Densities (HPQC 3130)	
Description:	When using Multiple Prescriptions and the first prescription has forced densities, these forced densities are not being maintained with the second prescription.
Clinical impact:	The dose distribution and monitor units will be incorrect as the initial prescription will use forced densities and the second prescription will use CT densities. Over the range of electron densities commonly found in patients, there is a reasonable probability that non-serious injury would occur.

Solution:	Both problems will be resolved in Monaco Patch Release 5.10.01.
Technical Reference:	None
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

This Notice has been notified to the appropriate Regulatory Authorities

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Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

***The information in this Notice has been provided to address two safety issues and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take, and may require Elekta to report to the Regulatory Authorities in your country.**

Classification:	Important Field Safety Notice	FCO Ref:	382-01-MON-002
Description:	Dose and MU Incorrect When CT Images Viewed From the Head Dose and MU Incorrect When Using Multiple Prescriptions With Forced Densities		
Scope:	Sites affected will be those running Monaco 5.10.00		
Hospital:			
Device Serial No: (e.g. linac - if applicable)	Location or Site No:		
Acknowledgement to be signed by customer*: I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations:			
Name:	Title:		
Signature:	Date:		

This Notice has been notified to the appropriate Regulatory Authorities