

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Re-optimization, After Adding Contours Without Forced Density Outside the External Structure, May Result in Inaccurate Dose Presentation

Product: Monaco®

Scope: Monaco® customers who have created plans with Versions 5.11.xx using the specific workflow described below. Other Monaco® releases are not affected.

Notification Released: February 2023

UDI Reference: (01)00858164002169(10)5.11.00, (01)00858164002169(10)5.11.01,
(01)00858164002169(10)5.11.02, (01)00858164002169(10)5.11.03

Description of Problem:

A sequence of steps performed by the user, consisting of an initial optimization, expansion of a structure or the creation of a new margin structure outside of the external contour and without forced density, change of the optimization criteria, and continuation of the optimization, may result in apertures that deliver doses on an incorrectly shifted position of the target – a geometrical miss. Moreover, after the final optimization, it is possible that the dose distribution in Monaco® looks like it is conforming to the target at the original location, as desired. However, if the plan is delivered to the patient, the delivered dose may be shifted and will not match the dose distribution calculated in Monaco®.

Details:

The problem can be reproduced using the following workflow steps:

1. A plan is optimized.
2. A contoured region, without a forced density, is added to a structure set outside of the external contour, causing the calculation extents to expand to cover the new structure. Monaco does not recognize that the dose calculation grid and the structure occupancy grids used by the optimizer should be reset.
3. Optimization criteria are modified, for example by changing the reference dose of a cost function or by adding / deleting a cost function that contains a reference dose while the optimization results are still in memory (i.e., the plan has not been unloaded since the previous optimization finished).
4. At this point, the calculation extents are expanded but the grid in the optimizer is not expanded to match the modified calculation extents.
5. Continue the optimization.

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This problem was identified when the above workflow was utilized with a margin to the external structure to evaluate for changes visible in the cone beam CT.

Once the plan is re-optimized (Step 5 above, Details), the target position within the optimizer will be shifted with respect to the calculated dose. Once the optimization is complete, the calculated dose may be shifted with respect to the MLC positions. If the plan is exported and delivered at this point, the delivered dose will be consistent with the shifted MLC shapes and will not reflect the dose displayed in Monaco®.

Clinical Impact:

The clinical impact of such an error is directly affected by the size of the geometrical miss (shift), which can range from zero or negligible to a few centimeters, depending on how much the dose calculation extent is expanded after adding the contour outside the patient in (Step 2 above, Details).

A problematic plan will be identified if a dose recalculation is forced in Monaco® or by using a secondary dose calculation for quality assurance (QA). However, a measurement-based QA procedure, such as delivering the plan on a phantom and measuring the dose, will **not** identify a problematic plan as the dose delivered to the phantom will match the calculated QA plan dose.

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Recommended User Action:

The problem will not occur if the added contour outside the external contour has an assigned density. If you believe that patient plans at your site could have been affected by this workflow, please contact Elekta Care Support if help is needed to identify those patients.

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:

The issue has been fixed in Monaco® releases 5.40 and above. If you are running a 5.11.xx version, please contact Elekta Care Support to upgrade to a newer software version.

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 either acknowledge receipt of this notification via the [Elekta Care™ Community](#) or 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-023
Description: Re-optimization, After Adding Contours Without Forced Density Outside the External Structure, May Result in Inaccurate Dose Presentation	

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:

Signature Manifest

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382-01-MON-023

Document Approval

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