

IMPORTANT USER NOTICE

We are providing the information in this Notice to notify you of an important issue 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.

Contour Edits and Deletions not Saved

Product: Monaco

Reference number (Field Change Order, FCO): FCO 382-03-MON-003

Field Corrective Action (FCA) number (if applicable): FCA-IMS-0016

HPQC number: 3694

Scope:	Monaco customers using version 3.1 and higher.
Description:	<p>In a specific workflow where contours are edited (enlarged, moved, copied, etc.) and then the contour is deleted on some slices and saved in the same session, it is possible that the deleted contours are still present which would not be the intent of the planner. If the patient is not saved and recalled, in a subsequently created plan the BEV will show the contours as still present while the Transverse, Sagittal and Coronal views will show the contours as deleted. The total volume of the structure reported in the DVH and the Structure Control will not match.</p> <p>If the study set is saved and reopened before plan creation the total volume of the structure reported in the DVH and the Structure Control will be corrected.</p> <p>A similar workflow could trigger the defect if contour deletions and edits are performed while a plan is loaded.</p>
Clinical Impact:	If the user bases their clinical decisions on incorrect contours it could lead to dose errors and potential patient mistreatments.

This Notice has been sent to the appropriate Regulatory Authorities

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Workaround:	<p>The problem does not always occur when the delete function is used in combination with contour editing tools. Additionally, due to the complex nature of the problem, it is not practical to enumerate all possible workflows in which it occurs. However, it is possible for a user to avoid triggering the defect by incorporating one of the following sequences of steps into his/her general contouring workflow:</p> <ol style="list-style-type: none">1. Delete before edit: For newly generated contours, delete any unwanted contours and save before making edits (move, rotate, reshape)2. If further deletions are required after edits are performed, save and unload the data. Then reload the data before deleting. This will allow the affected code to locate all the coordinate points of the contour.3. Delete Contour and start over.4. Clear Contour and start over.
Solution:	This issue will be resolved in a future Monaco release.
Technical Reference:	None
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

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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 a safety issue 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 User Notice	FCO Ref: 382-03-MON-003
Description: Contour Edits and Deletions not Saved	
Scope: Monaco customers using Release 3.1 and higher	
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 sent to the appropriate Regulatory Authorities