Field Corrective Action Reference: FCA-IMS-0038
This notice reference: 382-01-MON-017
HPQC: 5755

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Unexpected Change in Structure Volume

Product: Monaco®

Scope: Unity sites who have created plans using Monaco® 5.40 or 5.40.01

Notification Released: April 2020

Description of Problem:
When editing a contour and clicking on a Coronal or Sagittal slice, the 3D volume is recreated unnecessarily which could result in a volume change.

Details:
When editing a contour and clicking on a Coronal or Sagittal slice, the 3D volume is recreated and re-sliced when it should not be. The result can be a change in contour shape and volume. Therefore, the patient anatomy might not be accurately represented. The problem can happen with Reshape contour and Replace contour as well as any contouring tool that will activate a contour when the user clicks on the view.

Clinical Impact:
If a significant volume of a structure is missing, the dose distribution displayed will not represent the dose distribution delivered. The DVHs will not reflect the true volumes or the doses within those volumes.

Concave structures which form a keyhole like structure in the Sagittal or Coronal views can show the largest volume change because when the recreated 3D volume is re-sliced, the inner volume will be deleted. Although other structures can have volume changes as well, these changes will be much smaller.

Elekta, Inc.
1450 Beale Street, Suite 205
St. Charles, Missouri 63303
Tel: 314 993 0003 Toll Free: 800 878 4267

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Recommended User Action:
Please follow your standard clinical practice of reviewing plans, including the review of contours and volumes. DVHs that show unexpected overdose or underdose and should be investigated.

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 will be resolved in a future Monaco® release. You will be informed when the resolution is available through a Product Bulletin.

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-017
Description	Unexpected Change in Structure Volume		

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:

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