Field Corrective Action Reference: See below
This notice reference: 382-01-MON-018

URGENT

IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Issues to be Fixed in Monaco® Release 5.51.10

Product: Monaco®

Scope: Unity sites who have created plans using Monaco® 5.40.00 or 5.40.01

Notification Released: July 2021

Elekta wishes to reassure our users that patient safety remains in the forefront of our concerns. With that in mind, we are sending this notification to remind you that if you are running Monaco® 5.40.00 or 5.40.01 on your Unity machine the following workarounds remain in place to ensure safe usage of the machine.

Incorrect Electron Density Information Used in Dose Calculation
Reference number (Field Change Order, FCO): 382-01-MON-015
Field Corrective Action number (FCA), if applicable: FCA-IMS-0033
Relates To: HPQCs 5485 and 5494

Description:	Monaco® is calculating incorrect electron density (ED) information in specific situations. The dose calculation is also affected. **Details:** It is possible that the forced electron density settings will be changed for some structures unintentionally and this can result in incorrect dose calculation. Three specific issues are discussed below. Issues 1 and 3 are specific to MR-Planning. The magnitude of the error in dose calculation is influenced by Issue 1. The specific situations that can lead to the unintended forced electron density behavior are described in Issues 2 and 3. Issue 1: Erroneous MR Pixel to ED conversion Depending on the properties of the structure set, the contour shapes and the plan settings, an incorrect Electron Density grid can be calculated. The incorrect ED will be calculated for any voxel that lies within a contour or contours for which the Force ED option on the "Contoured" tab is unchecked and either: a) at least one of the contours containing the voxel is set as the External, or b) at least one of the contours containing the voxel is used as on the "IMRT Constraint" tab. The incorrect ED will result in incorrect dose calculation. This can occur Online or Offline and in reference or adapted plans. Issue 2: Incorrect Creation of New Structures Using Adapt Anatomy Due to Erroneous Letter-Case Logic

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	Adapt Anatomy can be used to deform structures from a “reference” image to a “target” image. When this is done, Monaco® performs a check to determine if each structure from the reference set exists and is contoured in the target structure set. The check for name equivalence is currently case sensitive, and it should not be. Structure names should be unique and case insensitive (for example, Patient and patient should be recognized as the same structure). Thus, the use of Adapt Anatomy can result in the unintended situation where the target structure set contains multiple structures whose names differ only by letter case. Monaco® is not designed to operate in this state and the user should not proceed. This may result in Force ED settings that do not match what the user intends and can result in dose calculation errors. <u>Issue 3: Force ED Flag on Adapt Setup Not Applied in Adapt Anatomy as Shown in GUI</u> For Internal or Target type structures, the "Force ED on MR" checkbox on the Adapt Setup Tab is editable. If this box is unchecked for a structure and the user subsequently redefines that structure to be of type External, then the "Force ED on MR" setting for that structure will appear as checked in the GUI and it will not be possible to uncheck it. However, the information displayed in the GUI is not stored and the “Force ED on MR” setting will be unchecked when Adapt Anatomy is performed. This situation can lead to dose calculation errors. If an anatomical group that has the “Force ED on MR” checkbox unchecked is applied within a plan to a structure set that does not contain an existing External, then the External in the plan will be set to what is defined in the anatomical group. Again, there could be a mismatch shown on the Adapt Setup tab between the Force ED information shown in the GUI and what is stored internally, resulting in dose calculation errors. Note that by default, new structures created directly from the Auto Margin Dialogue will have Force ED unchecked on the Adapt Setup tab. In the three workflows described above, incorrect electron density information can be used in the dose calculation resulting in incorrect dose delivery.
Recommended User Action:	Manually review the electron density grid to ensure that densities are being correctly applied.

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Incorrect Energy Used in Dose Calculation
Reference number (Field Change Order, FCO): 382-01-MON-016
Field Corrective Action number (FCA), if applicable: FCA-IMS-0035
Relates To: HPQC 5575

Description:	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. 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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Unexpected Change in Structure Volume
Reference number (Field Change Order, FCO): 382-01-MON-017
Field Corrective Action number (FCA), if applicable: FCA-IMS-0038
Relates To: HPQC 5794

Description:	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. 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.
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 should be investigated.

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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:
These issues will be resolved in Monaco® Release 5.51.10. 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-018
Description	Issues to be Fixed in Monaco® Release 5.51.10		

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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