URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Potential image to contour mismatch during Motion Monitoring

Product: Elekta Unity

Scope: The machine numbers it is applicable to are: 600002, 600005, 600007 to 600014, 600016 to 600040, 600042, 600044, 600047, 600048.

Notification Released: February 2021

Description of Problem:
This notice replaces IFSN 200-01-801-010, in which Elekta notified Elekta Unity customers that 2D Contours overlaid on top of 2D MR Cine images for visual Motion Monitoring may be incorrectly calculated.

Details:
Based on phantom images, Elekta has become aware that in some cases 2D Contours overlaid on top of 2D MR Cine images for visual Motion Monitoring may not be calculated correctly. This can lead to incorrect 2D Overlay Contour positions and 2D Overlay Contour scaling errors.

The original IFSN described in detail that for some 2D MR Cine protocols, calculations generating the 2D Contour Overlay used the wrong Field-of-View, resulting in a scaling issue. Based on further analysis, Elekta would like to generally increase the fidelity of the 2D Contour Overlay calculations and to fully re-verify and validate them.

In addition, Elekta received feedback that the detailed explanation in the original IFSN was in places too technical and did not sufficiently outline which capabilities and workflows are **not** affected. Elekta is therefore issuing this update to the IFSN to provide a simpler, generic message regarding the problem:

The 2D Cine Overlay Contours used for Motion Management may be calculated incorrectly and may therefore be misleading.

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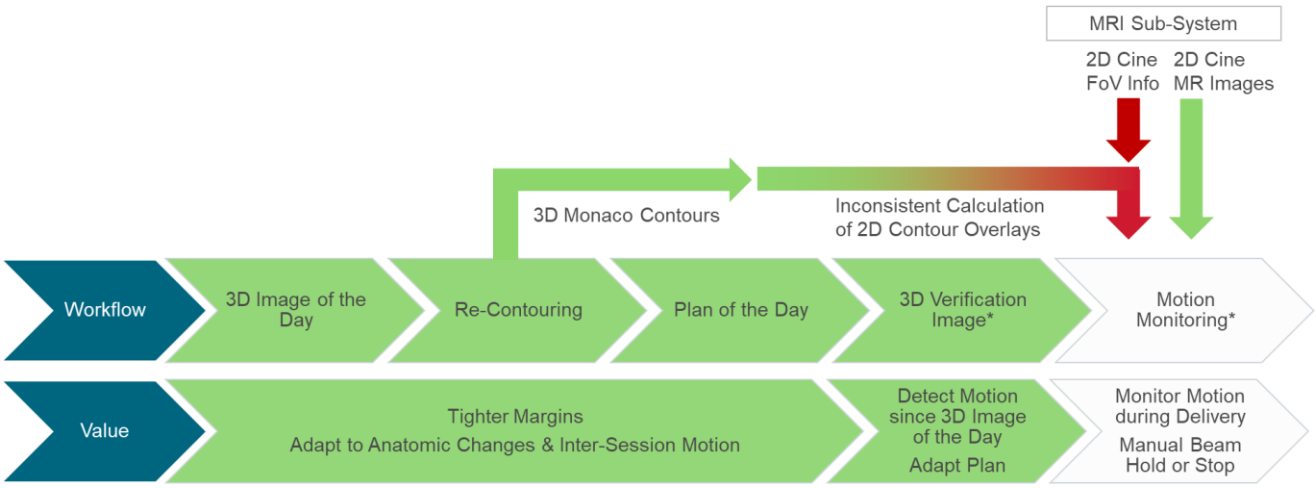
The following are **not impacted**:

1. 3D MR images, planning contours, dose calculation, RT plans
2. 2D MR Cine images
3. Any workflows outside of Motion Monitoring, such as Plan Adaptation or Verification Imaging.

In particular, it should be clarified that the 2D MR Cine images themselves are not impacted.

- The original IFSN stated that "…the system is incorrectly scaling the 2D MR Cine image and subsequently passing to TSM the incorrect image dimensions".
- More precisely stated: the MR sub-system correctly provides the 2D MR Cine images according to the "Reconstructed Field-of-View" declared in the ExamCard, but in some cases the wrong Field-of-View is used in the 2D Cine Overlay Contour calculation.
- The 2D MR Cine images themselves are not impacted; they are correctly acquired and displayed.



Schematic Representation of the Elekta Unity Clinical Workflow showing that both the Field-of-View information used in the calculation of the 2D Contour Overlays as well as the calculation itself are impacted (red). The steps preceding visual Motion Monitoring, as well as the 2D MR Cine images are not impacted (green).

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Clinical Impact:

There are two use cases for visual motion monitoring:

1. Viewing the images to confirm that no gross patient or anatomic motion has occurred
2. Careful visual assessment of the 2D contour overlays and 2D MR Cine images to determine more closely whether the organs are the desired position during treatment

Gross patient or anatomic motion should be apparent from the 2D MR Cine images themselves. The bigger risk emanates from cases where margins were adapted assuming that the clinician would carefully visually control the 2D MR Cine images against the 2D overlay contours with a high degree of precision in order to either hold the beam manually or to discontinue treatment.

Recommended User Actions:

Based on these clarifications, Elekta would also like to update the Recommended User Actions.

The 2D Cine Overlay Contours used for Motion Management may be calculated incorrectly and may therefore be misleading – they should not be used to make clinical judgements.

Option 1: Deliver without Motion Monitoring

Visual motion monitoring is an optional capability. Elekta Unity still provides the capabilities to adapt the plan for inter-session motion and soft tissue changes via the image and plan of the day workflow. In addition, 3D verification imaging can be used to confirm organ positions match the positions used during planning. Furthermore, the user can acquire additional images on the MR console and compare them to previous datasets acquired during the online session as outlined in the User Manual, Marlin 1.5T for Elekta Unity - Instructions for Use Release 5 Marlin.

Option 2: Deliver with Visual Motion Monitoring for Gross Motion Detection

The 2D MR Cine images are correctly displayed and in themselves convey anatomic positions. In order to initiate 2D MR Cine imaging, the central position of the imaging plane(s) need to be chosen through the selection of a structure for display. If the selected structure is a non-anatomic arbitrary structure, such as a sphere, the user can still focus on the gross-anatomic changes presented by the 2D MR Cine imaging. The user should not use 2D Overlay Contours to visually control the 2D MR Cine images in order to either hold the beam manually or to discontinue treatment.

Read and understand additional RCMs

Additional risk control measures (Risk Control Measures), which have been added since the delivery of the system. Please read and understand the following RCMs before imaging, and add them to your Elekta Unity IFU in the section: **“Using the system > Prerequisite tasks”.**

RCM: RTIS-1012: Do not use an irregular motion monitoring structure with large changes in shape through the imaging planes. An irregular shape can result in changes to the intersection of the imaging plane and tracking structure, due to residual gradient non-linearity geometrical distortion. These changes can affect how the

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motion monitoring structure and images are displayed, which can be misleading. Motion monitoring structures that change shape slowly through the imaging planes, such as spherical or rectangular volumes, are recommended. If you ignore this warning, you can cause clinical mistreatment.

RCM: RTIS-1013: Do not use bifurcated or split tracking structures for motion monitoring. Bifurcated or split structures are not supported. Bifurcated or split structures can cause misleading placement of the imaging planes and are susceptible to residual gradient non-linearity geometrical distortion errors. If you ignore this warning, you can cause clinical mistreatment.

While gradients are optimized for linearity, small gradient non-linearities exist. For cine imaging, Unity fully corrects for the gradient non-linearity errors at the center of the tracking structure. Away from the center of the tracking structure, residual through-plane distortions can remain. To correct for these residual distortions, data adjacent to the plane are required. To enable fast cine imaging, these data are not acquired. Consequently, a through-plane correction is not possible.

This recommendation applies to all customers with the Clinical IFU with the following references:

- 1503128_01/02/03/04/06/06/07/08
- 1503128NE_01/02

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 via a software release including an Exam Card upgrade as an absolute priority to Elekta. You will be informed regularly on our progress. A site-specific plan will be made to roll this fix out to you as quickly and efficiently as possible.

In addition, the RCMs numbered RTIS1012 and RTIS 1013 have been added to the user documentation.

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

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:	200-01-801-010
Description	Update: Potential image to contour mismatch during Motion Monitoring		

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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