

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Potential image to contour mismatch during Motion Monitoring

Product: Elekta Unity

Scope: All Elekta Unity systems

Notification Released: July 2020

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Description of Problem:

This notice replaces IFSN 200-01-801-007, 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.**

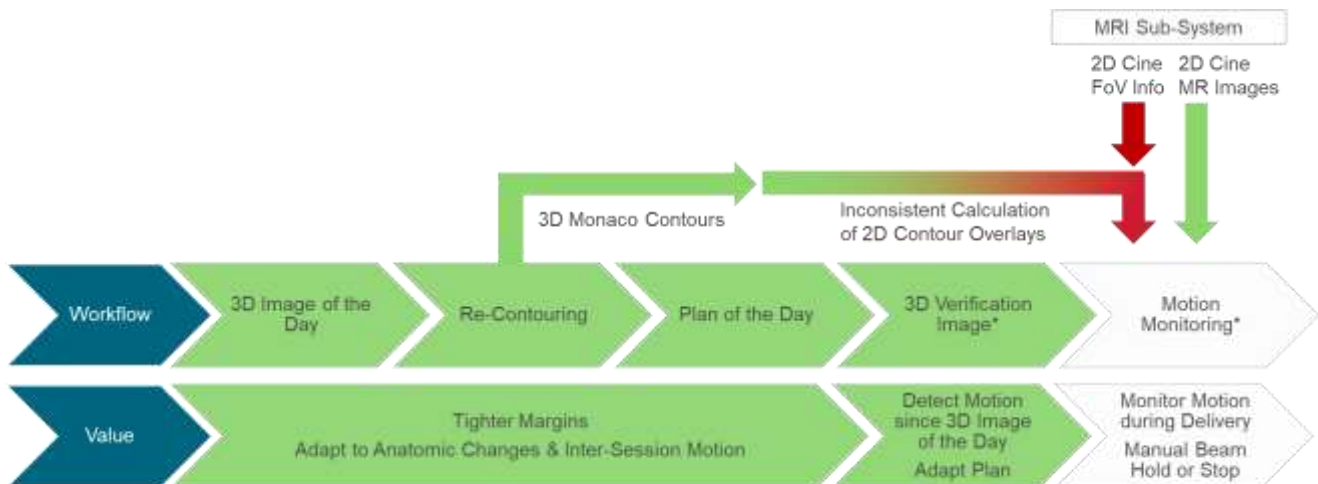
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The following are **not impacted**:

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 Action:

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.

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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:

The issue will be resolved via a software release including an ExamCard 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.

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: 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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IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Potential image to contour mis-match during Motion Monitoring

Product: Elekta Unity

Scope: Unity – Philips Marlin SW versions: R5.3.30, R5.3.31, R6.0.5331, R5.7.0, R5.7.1, R6.1.571

Notification Released: April - 2020

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Description of Problem:

In TSM (Treatment Session Manager) Motion Monitoring workflows, under certain conditions there can be a mismatch between the contour data overlay with respect to the motion monitoring images of the monitored structure.

Details:

For some motion management imaging protocols, the system is incorrectly scaling the Cine image and subsequently passing to TSM the incorrect image dimensions. The result is that the Cine images appear smaller than the contour overlay. The magnitude of the scaling inconsistency varies from 0-10% depending on Field of View (FOV). The FOV changes depending on the protocol used for a particular area of anatomy being imaged.

The scaling impacts both in-plane axes and is realised radially from the center of the image i.e. the centre of the image is at the correct location and not impacted by scaling.

Imaging Protocols impacted by this issue and the percentage value of image scaling are shown in Table 1.

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Table 1 - Imaging protocol and the percentage geometric error of the Cine image compared to the contour overlay.

Anatomy	Protocol Name	FOV p [mm]	FOV m [mm]	Geometric error [%]
Abdomen	btFFE Cor RealTime	424	400	-6.0%
	btFFE Cor Sag RealTime	424	400	-6.0%
	btFFE Cor Sag Tra RealTime	424	400	-6.0%
	btFFE Fast Sag Cor RealTime	441	400	-10.3%
	btFFE Sag RealTime	424	400	-6.0%
HeadNeck L	bFFE Cor RealTime	250	300	Nil
	bFFE Cor Sag RealTime	250	300	Nil
	bFFE Cor Sag Tra RealTime	250	300	Nil
	bFFE Sag RealTime	250	300	Nil
	bFFE Sag Tra RealTime	250	300	Nil
HeadNeck M	bFFE Cor RealTime	250	300	Nil
	bFFE Cor Sag RealTime	250	300	Nil
	bFFE Cor Sag Tra RealTime	250	300	Nil
	bFFE Sag RealTime	250	300	Nil
	bFFE Sag Tra RealTime	250	300	Nil
Pelvis L	bFFE Cor RealTime	436	400	-9.0%
	bFFE Cor Sag RealTime	436	400	-9.0%
	bFFE Cor Sag Tra RealTime	436	400	-9.0%
	bFFE Sag RealTime	436	400	-9.0%
	bFFE Sag Tra RealTime	436	400	-9.0%
Pelvis M	bFFE Cor RealTime	436	400	-9.0%
	bFFE Cor Sag RealTime	436	400	-9.0%
	bFFE Cor Sag Tra RealTime	436	400	-9.0%
	bFFE Sag RealTime	436	400	-9.0%
	bFFE Sag Tra RealTime	436	400	-9.0%
Thorax	btFFE Cor RealTime	424	400	-6.0%
	btFFE Cor Sag RealTime	424	400	-6.0%
	btFFE Cor Sag Tra RealTime	424	400	-6.0%
	btFFE Sag RealTime	441	400	-10.3%
	btFFE Sag RealTime	424	400	-6.0%

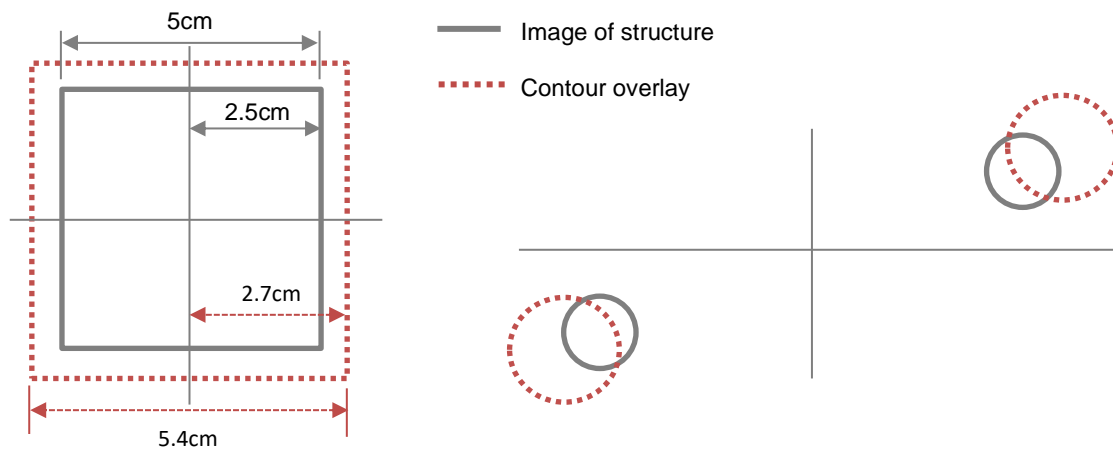
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Clinical Impact:

The clinical impact is that when the scaling inconsistency occurs, the position of the delineated contours with respect to the anatomy that is displayed will be erroneous.

The magnitude of the error ranges from 0-10% depending on the protocol used and the error increases with distance from the center of the image. Centre of the image is correct and is not impacted by scaling errors.

Figure 1 provides a schematic for the purposes of explaining the impact of scaling. Two scenarios are shown, a single structure (Region of Interest, ROI) and a multiple structure ROI.



Single structure: The image will be central to the centroid of the structure. Scaling -9.0%.

Multiple structures: The image will be centered between the two structure's centroids. The effect is 1. Change in distance between centroids; 2. Change in size of structure.

Figure 1 - An example showing a single and a multiple structure scenario with the scaling error applied.

Example: Prostate treatment

The impact on a singular 5cm x 5cm mass that is centered on the image.

Imaging Protocol: Pelvis M/L, all protocols have same scaling; FOV 436mm x 400mm.

Scaling error: -9.0%

Centre of contour shift: 0.0cm (*image center to center of contour*)

Contour dilation: +0.2cm (*change in image center to contour edge*)

The following example (figure 2) is of an example taken using Elekta Unity and a phantom.

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Image in Monaco

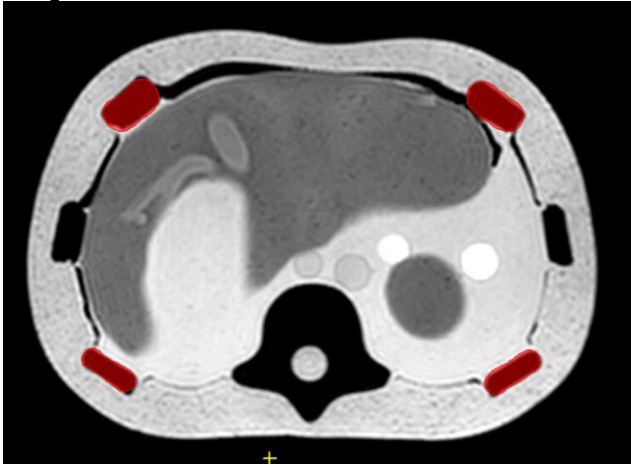


Image as viewed in TSM

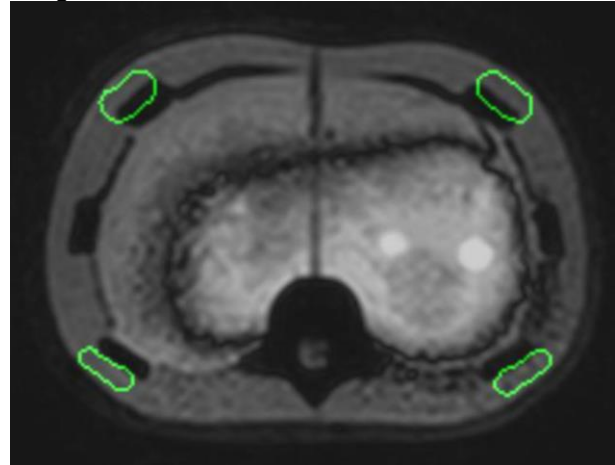


Figure 2 - Images taken to demonstrate the impact of scaling on a phantom in the transverse perspective. Note the shift in target regions relative to the contours.

Recommended User Action:

There is no method to correct the scaling issue for the protocols affected (refer to table 1). However, the following options are available to continue safe and effective treatments:

1. Continue treatments without the use of Motion Monitoring. Motion Monitoring is not mandated for any treatment.
2. Compensation for intra-fraction motion can be done through the acquisition of a 3D Verification MRI. This method is not impacted by the scaling issue.

If you have concerns or queries relating to this issue please contact the local Elekta Customer Care team, the query can then be escalated and answered.

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Elekta Corrective Actions:

This issue has the full attention of Elekta and its partners. The root cause of the issue is understood and a correction is being developed. Once testing has been completed, a future release of exam cards will correct this issue for all protocols. This will be released via a mandatory Important Field Safety Modification.

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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Signature:	Date: