

## URGENT IMPORTANT FIELD SAFETY NOTIFICATION

**Subject:** Margin tool systematically overestimates margin in certain areas of the volume

**Product:** Leksell GammaPlan 11.1

**Scope:** Leksell Gammaplan 11.1

**Notification Released:** July 2018

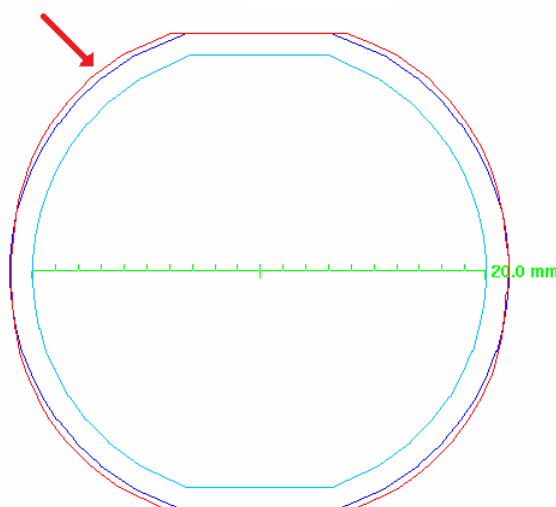
**Description of Problem:**

The margin tool in Leksell GammaPlan 11.1 systematically overestimates margin in certain areas of the volume.

**Details:**

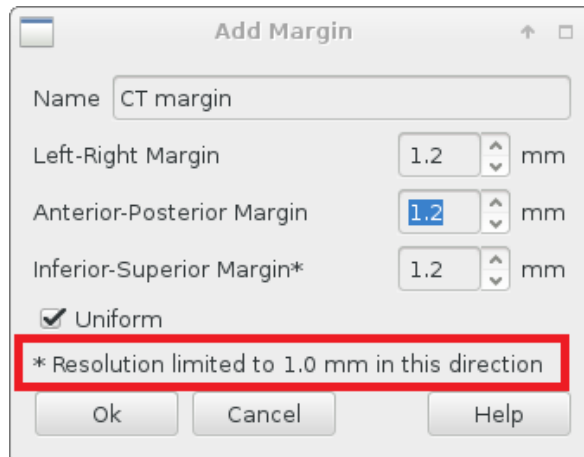
The root cause is that the margin algorithm calculates the expanded volume at a resolution limited to the original images resolution in the contours normal direction, resulting in an overestimation of the resulting margin volume in areas oblique to the contouring plane.

The following figure illustrate an example of overestimated margin in a sagittal view for a 1 mm margin applied to a 20 mm sphere (in light blue) defined in an axial CT with 1 mm slice distance. As can be seen, the resulting margin volume (in red) is overestimated compared to the ideal result (in blue) at oblique angles.



The overestimation in the normal direction to the volume surface is limited to half the image resolution in the direction normal to the contouring plane. The easiest way to determine the limit of the overestimation is to look at the resolution notice in the “Add Margin” dialog and divide it by two.

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Note that since volumes are represented by a stack of contours outlined on images, the resolution of volumes in the normal direction to the contouring planes is inherently limited to the distance between these images.

The following table summarizes the volumetric overestimation of margins for a spherical shape of different sizes defined in a tomographic image study with various slice distances compared to the ideal result.

Image slice distance [mm]	Volumetric overestimation of margin compared to ideal result		
	Sphere Ø10 mm	Sphere Ø20 mm	Sphere Ø30 mm
0.5	+4.7%	+3.0%	+2.3%
1.0	+7.9%	+4.8%	+3.7%

### Clinical Impact:

With the described inaccuracy, the margin tool in Leksell GammaPlan may still be considered useful.

### Recommended User Action:

Consider implications of the described inaccuracy in use of the margin tool in Leksell GammaPlan.

**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:

Elekta will distribute information regarding the Margin tool to all affected users.

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 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: 100-01-102-017
Description Margin tool systematically overestimates margin in certain areas of the 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:

<b>New installation confirmation</b> 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: