

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Cross profile for Varian 60 degree wedge shows “horns”

Product: Oncentra® External Beam Oncentra® Brachy

Scope: All Oncentra External Beam versions
Please note that this product was formerly known as Oncentra MasterPlan during release of v3.x.

Notification Released: December 2016

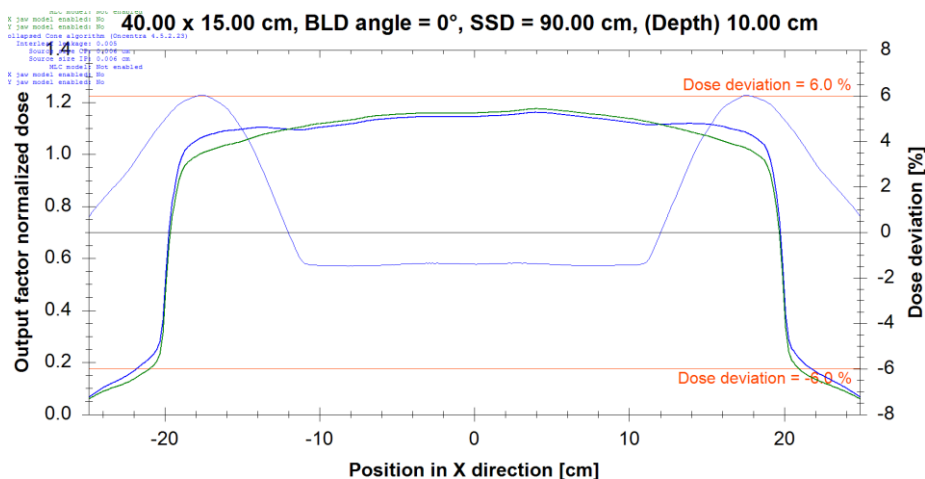
Description of Problem:

If a physical wedge, for which the total field size limit perpendicular to the wedge direction is more than 10 cm larger than the field size limit in wedge direction, is inserted in in-plane direction (as seen with collimator angle 0 degrees), then with very large fields perpendicular to wedge direction a part of the scattered fluence can become unmodulated by the wedge. This will result in profile “horns” close to the edge of the field.

Details:

If a physical wedge, for which the total field size limit perpendicular to the wedge direction is more than 10 cm larger than the field size limit in wedge direction, is inserted in in-plane direction (as seen with collimator angle 0 degrees), then with very large fields perpendicular to wedge direction a part of the scattered fluence can become unmodulated by the wedge.

This will result in profile “horns” close to the edge of the field:



The deviation is most prominent with the Varian 60-degree wedge. The calculated overdose in the affected areas, towards the edges of the field, is typically 6% for clinically used field sizes locally.

Smaller deviations inside the field can also be observed with the Varian 45-degree wedge. With all other inplane wedges, including the Elekta motorized wedge, there is only an insignificant deformation of the cross profile tail, which is outside the treatment field.

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Clinical Impact:

If such large fields are used clinically, then the calculated overdose might suggest a too optimistic target coverage during treatment planning, better than in reality, which might then result in an underdose to the outer parts of the treatment volume.

Recommended User Action:

Until an upgraded version of Oncentra External Beam is available, do not exceed jaw positions of +/- 12cm with the Varian 60-degree wedge and +/- 14.5 cm with the Varian 45-degree wedge in the direction perpendicular to the wedge slope, if the wedge is inserted in in-plane direction (collimator angle 0 degrees).

It is strongly advised to perform proper Quality Assurance for all treatment plans before delivery of the first fraction to the patient.

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 the content of this letter

Elekta Corrective Actions:

This issue will be solved in the next upgrade.

This notice has been provided 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 30 days.

Classification: Important Field Safety Notification	FCO Reference Number: 806-01-ETP-002
Description: Cross profile for Varian 60 degree wedge shows "horns"	

Hospital:	
Device Serial No(s): (if applicable)	Location or Site:

I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations.	
Name:	Title:
Customer Signature:	Date:

New installation confirmation to be signed by the installing Elekta engineer or Representative employee when the installed product has a physical IFU/manual:	
I acknowledge that the customer is informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual or added to the record with the applicable User Manual:	
Name:	Title:
Signature:	Date: