ELEKTA

URGENT
IMPORTANT FIELD SAFETY NOTICE

We are providing the information in this Notice to notify you of an important safety issue that may exist on your equipment, and to inform you of any actions needed to safeguard both your staff and your patients. We ask that you please read and understand the content of this notice and implement any recommendations provided.
We also need you to acknowledge and accept this Notice by signing and returning the statement on the Acknowledgement page.
We advise you to insert this Notice in the applicable copy of the User Manual.

Potential incorrect dose distribution when using the Tumor Overlap Fraction during VMAT planning

Oncentra® External Beam Oncentra® Brachy
Product: Oncentra® External Beam

Reference number (Field Change Order, FCO): 806-01-ETP-001
Field Corrective Action (FCA) number (if applicable): FCA-NU-0002

Scope:	Oncentra External Beam - VMAT module - all versions. Please note that this product was formely known as Oncentra MasterPlan during the release of version 3.3.
Description:	When using the Tumor Overlap Fraction option in VMAT planning it has been observed that in rare cases the system includes an organ at risk as the target volume. This could result in open MLCs and open jaws in areas away from the target volume.
Clinical impact:	The description above could result in overdosage of the organs at risk outside the intended treatment volume.
Solution:	It is strongly advised to perform proper Quality Assurance for all treatment plans before delivery of the first fraction to the patient. To prevent the issue, the workaround is to not use the Tumor Overlap Fraction option for VMAT planning. The issue will be solved in Oncentra External Beam version 4.5.2.
Technical Reference:	Case 02086358
Contact:	If you have any queries about this Notice, please contact your local Elekta representative.

This Notice has been notified to the appropriate Regulatory Authorities

Telephone: +31 318 557 133
Fax: +31 318 557 208
www.elekta.com

IMPORTANT FIELD SAFETY NOTICE ACKNOWLEDGEMENT

Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

***The information in this Notice has been provided to address a safety issue and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations.**
Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take, and may require Elekta to report to the Regulatory Authorities in your country.

Classification:	Important Field Safety Notice	FCO Ref:	806-01-ETP-001
Description:	Potential incorrect dose distribution when using the Tumor Overlap Fraction option during VMAT planning.		
Scope:	Oncentra External Beam version 3.3 and higher. Please note this product was formerly known as Oncentra MasterPlan during the release of version 3.3.		

Hospital:	
Device Serial No(s): (e.g. linac - if applicable)	Location or Site No:

Acknowledgement to be signed by customer*:

I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations:

Name: Title:

Signature: Date:

New installation confirmation to be signed only by the installing Elekta or Representative employee:

I acknowledge that the customer is informed on content of this notice and has been inserted in the applicable copy of the User Manual:

Name: Title:

Signature: Date:

This Notice has been notified to the appropriate Regulatory Authorities

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