



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.

Incorrect Treatment Delivery Using Third Party Fixed Wedges

Product: XiO

Reference number (Field Change Order, FCO): FCO 382-01-XiO-001

Field Corrective Action (FCA) number (if applicable): FCA-IMS-0008

HPQC number: 12215

Scope:	<p>Sites affected will be those:</p> <ol style="list-style-type: none">1. Running XiO Release 4.51 and higher, and2. Using Elekta linacs, and3. Using third party fixed wedges in combination with MLCs
Description:	<p>When fixed wedges are defined in Source File Maintenance, the user defines a maximum field size allowed for each wedge. This maximum field size is being ignored by the software when both fixed wedges and MLCs are present in a beam. The result is incorrect calculation and delivery of dose outside the physical extent of the wedge. The dose distribution calculated by XiO will not match the dose delivered to the patient in regions beyond the physical dimension of the wedge.</p> <p>Varian and Siemens linacs will prevent delivery. Elekta linacs with motorized wedges will prevent delivery. Elekta linacs with third party fixed wedges will not prevent delivery.</p>

This Notice has been notified to the appropriate Regulatory Authorities

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Clinical impact:	XiO will calculate wedged dose in the region outside of the physical wedge and the linac will deliver open dose. The patient will receive dose that is different from the planned dose and that dose difference can exceed 5%. There is a remote probability of serious injury resulting from this issue.
Solution:	The problem will be resolved in a patch to XiO Release 5.10.
Technical Reference:	None
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

This Notice has been notified to the appropriate Regulatory Authorities

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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:	382-01-XIO-001
Description:	Incorrect Treatment Delivery When Using Third Party Fixed Wedges		
Scope:	Sites affected will be those: <ol style="list-style-type: none"> 1. Running XiO Release 4.51 and higher, and 2. With Elekta linacs, and 3. Using third party wedges in combination with MLCs 		
Hospital:			
Device Serial No: (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:		

This Notice has been notified to the appropriate Regulatory Authorities