IMPORTANT USER NOTICE

We are providing the information in this Notice to notify you of an important 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.

No Interlock Check available in the Workflow without iGUIDE® (3D Workflow)

Product: iGUIDE® 2.2

Reference number (Field Change Order, FCO): 618-03-303-025

Field Corrective Action (FCA) number (if applicable): N/A

Scope:	**All iGUIDE® 2.2.0 Installations**
Description:	**Workflow with iGUIDE (6D Workflow)** The Interlock Check has been implemented to verify if an iGUIDE initiated inhibit results in an External Inhibit at the Linac. The check is done in interaction with the operator, who confirms that the External Inhibit is actually set on the Treatment Control System (TCS). **Workflow without iGUIDE (3D Workflow)** iGUIDE monitors if the HexaPOD is in the pre-defined 3D position. If it is not in this position an inhibit is set. For 3D treatments there is no iGUIDE Interlock Check possible. In the event of a malfunction of the interlock system an inhibit in iGUIDE may not lead to an External Inhibit on the Linac.
Clinical impact:	Potentially unrecognized incorrect position of the treatment couch in 3D workflow, i.e. the HexaPOD has not moved fully to the 3D position.
Solution:	If you do not intend to use iGUIDE for patient positioning, make sure the HexaPOD is at its pre-defined 3D position before treatment. The 3D position is confirmed in the iGUIDE login screen (no inhibit icon) or in the iGUIDE System Overview. In addition the External Inhibit LED at the EnableSwitch Board must be off. It is recommended to perform the Interlock Check in the iGUIDE software on a daily basis.

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IMPORTANT USER NOTICE

Technical Reference:	CLM 02207452
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

1 References

The following warnings and cautions are associated with this notice:
N/A

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IMPORTANT USER 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 an 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.

Classification:	Important User Notice	FCO Ref:	618-03-303-025
Description:	No Interlock Check available in the Workflow without iGUIDE (3D Workflow)		
Scope:	**All iGUIDE® 2.2.0 Installations**		

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:

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