



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.

Specific Catch-up Workflow Leads to Inaccurate Positioning

Product: iGUIDE® 2.1, iGUIDE® 2.2

Reference number (Field Change Order, FCO): 618-01-303-025

Field Corrective Action (FCA) number (if applicable): FCA-MI-0001

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| Scope: | iGUIDE® 2.1.0 and iGUIDE® 2.2.0 installations |
| Description: | <p>If by mistake the initial pre-treatment imaging was performed BEFORE the HexaPOD was moved to the DRIVE (*START) position, iGUIDE offers the possibility to branch into a specific catch-up workflow, which was implemented to use the initial scan data. This should avoid the need to redo imaging with HexaPOD in DRIVE (*START) position. In this scenario the software may prompt you several times to move the HexaPOD to its DRIVE (*START) position. If you follow this request the HexaPOD will move to DRIVE (*START). In a consecutive step iGUIDE shows hints to move the couch top with the Precise Table back to the initial imaging position. However, this position is reached only with a coarse movement. A final fine adjustment move, executed by the HexaPOD, is missing. The coarsely reached imaging position becomes the new registered position for the actual position error correction (PEC) movement to the target position. A theoretical additional error of max. ± 2 mm in three dimensions, in respect to the true target position, can occur due to the missing fine movement.</p> <p style="text-align: right;"><i>*iGUIDE 2.1 wording</i></p> |
| Clinical impact: | Inaccurate positioning of max. ± 2 mm in three dimensions - Risk of mistreatment. |
| Solution: | <p>Prevention:</p> <p>Avoid imaging in the PARK (*LOAD) position!</p> |

This Notice has been notified to the appropriate Regulatory Authorities

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| | <p>Workaround:</p> <p>If you have performed imaging when the HexaPOD is not in the DRIVE (START*) position, cancel all move to DRIVE (START*) requests. Thus the HexaPOD remains in the imaging position. If you then apply the PEC the HexaPOD will reach the target in the specified accuracy. The movement to the target will be a combination of Precise Table and HexaPOD moves.</p> <p>Check: In case of any doubts perform a verification scan.</p> <p>Final solution:</p> <p>A software update will correct the behavior of the affected iGUIDE versions 2.1 and 2.2. As soon as available it will be installed at no charge.</p> |
| Technical Reference: | ECO 2016-011 |
| Contact: | If you have any queries about this Notice, please contact your local Elekta office. |

Safety reference

The following warnings and cautions are associated with this notice:

N/A

This Notice has been notified to the appropriate Regulatory Authorities

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.

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| Classification: Important Field Safety Notice | FCO Ref: 618-01-303-025 |
| Description: Specific Catch-up Workflow Leads to Inaccurate Positioning | |
| Scope: iGUIDE® 2.1.0 and iGUIDE® 2.2.0 installations | |

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

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| 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: |

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| 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