

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Potential incorrect positioning after verification scan

Product: iGUIDE® Software 2.2

Scope: iGUIDE® 2.2.0, iGUIDE® 2.2.1

Notification Released: June, 2017

Description of Problem:

If the PEC data dialog after a verification scan is cancelled, a re-send of PEC data will lead to incorrect positioning because the 2nd PEC values supersede the 1st PEC values instead of being added.

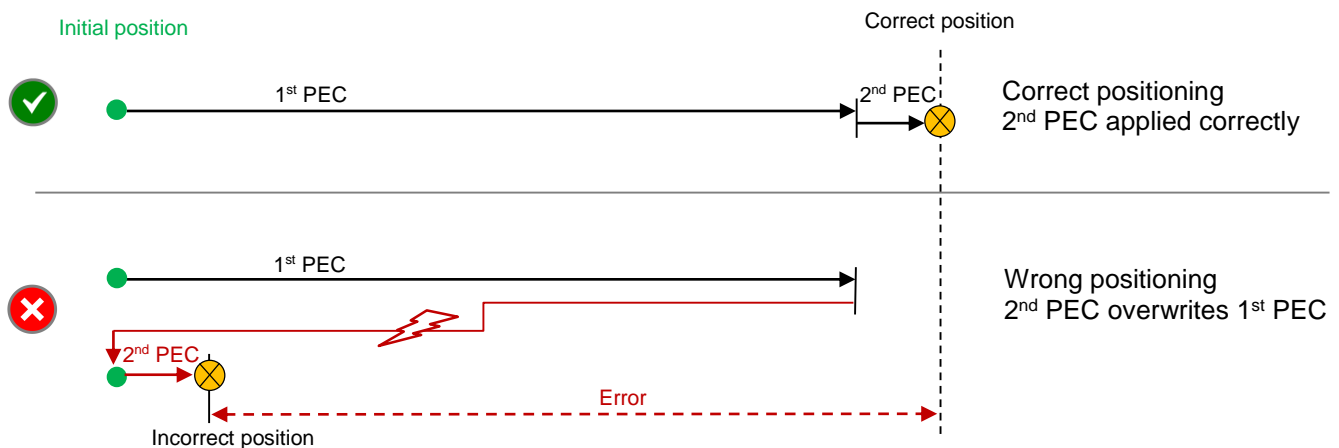
Note:

The workflow as described in the User Manual will not result in this error. The error will only occur under the circumstances described in this document.

Details:

The incorrect positioning will occur in the following unusual scenario:

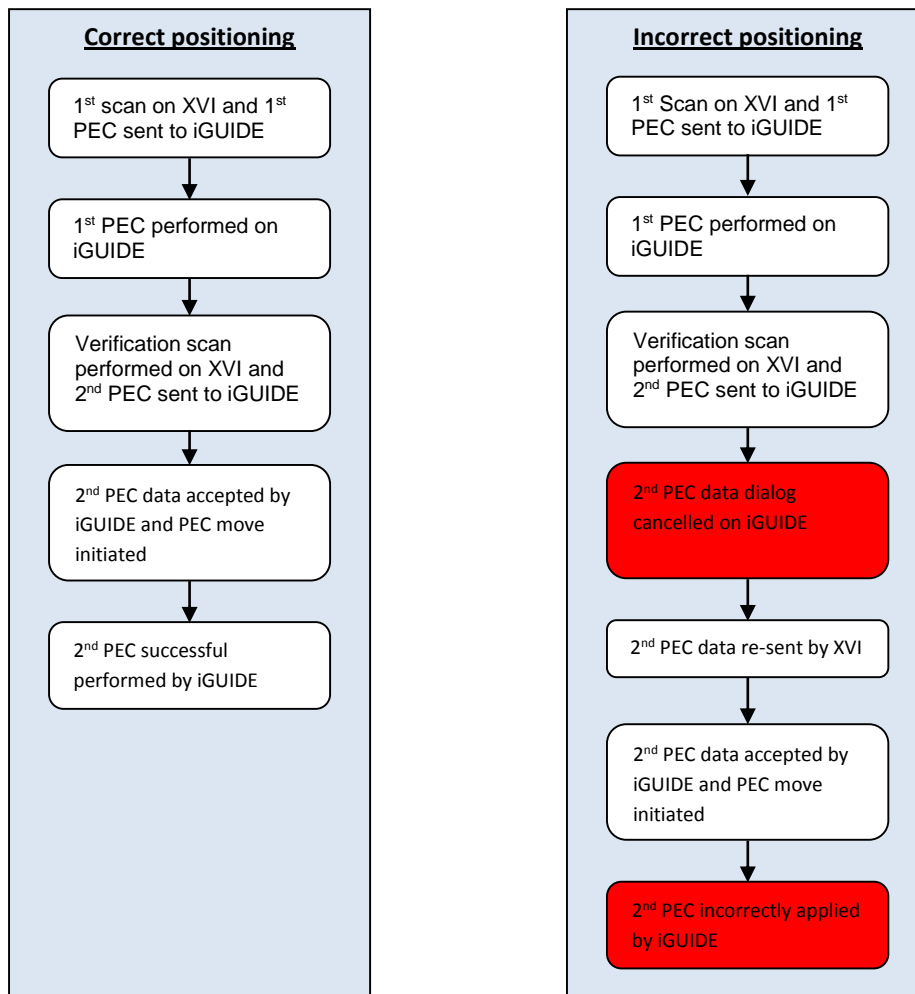
1. In the iGUIDE 6D correction workflow, the 1st XVI scan is executed and the 1st PEC is performed correctly, i.e. the HexaPOD is moved to the specified position.
2. The verification scan is performed on XVI and the 2nd PEC is sent to iGUIDE. The PEC data dialog is cancelled by the user. This cancellation is the trigger for the following incorrect positioning.
3. The user decides to apply the 2nd PEC data and re-sends the values from XVI to iGUIDE. The iGUIDE software does not recognize this data as an additional PEC (to be added) but overwrites the first PEC instead. This wrong behavior of the software leads to a wrong positioning in the order of magnitude of the first PEC.



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The following image compares the iGUIDE workflow scenarios with correct and incorrect positioning.

- On the left a normal workflow including verification scan with correct positioning is shown.
- On the right the unusual workflow with wrong positioning is shown. The error occurs when the 2nd PEC data dialog is cancelled and the re-sent PEC is executed.




Clinical Impact:

Incorrect positioning (values of 1st PEC are overwritten) - Risk of mistreatment.

Recommended User Action:

Do not cancel the 2nd iGUIDE PEC data dialog (and confirm the cancellation) for a verification scan. If you have cancelled the 2nd PEC data dialog, you have to restart the positioning and return to the beginning of

the positioning procedure. To do that, click the  button in the Positioning window.

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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:

A software update will correct the behavior of the affected iGUIDE versions 2.2.0 and 2.2.1. As soon as available it will be installed at no charge.

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: 618-01-303-026
Description: Potential incorrect positioning after verification scan	

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: