IMPORTANT FIELD SAFETY NOTICE

PRODUCT: *XVI*

Date: 01-2012 **FCO Ref:** 200 01 507 042

Using the Edit or enter correction button in the Correction tab can cause an incorrect patient position

This Notice contains important information about the operation of your product. Elekta recommends that all users of the product follow the instructions or recommendations in this Notice.
This Notice must be put in the Important Notice section of the applicable manual.

If you have any queries about this Notice, contact your local Elekta office.

Scope: XVI R4.5 and R4.6 without iGuide®.

Problem: The **Edit or enter correction** button appears in the **Correction** tab after you click **Convert To Correction**. After you click the **Edit or enter correction** button, you can use the spin boxes to change the **Position Error** values. When the changes are completed, you then click **Accept Correction**, and the **Approval** dialog box appears. The problem occurs if you click **Cancel** in the **Approval** dialog box. When you click **Cancel** and then do the approval again, the **Table Correction** values change to their initial values. But, the image panes continue to display the changed **Position Error** values.

The example that follows shows how this problem occurs:

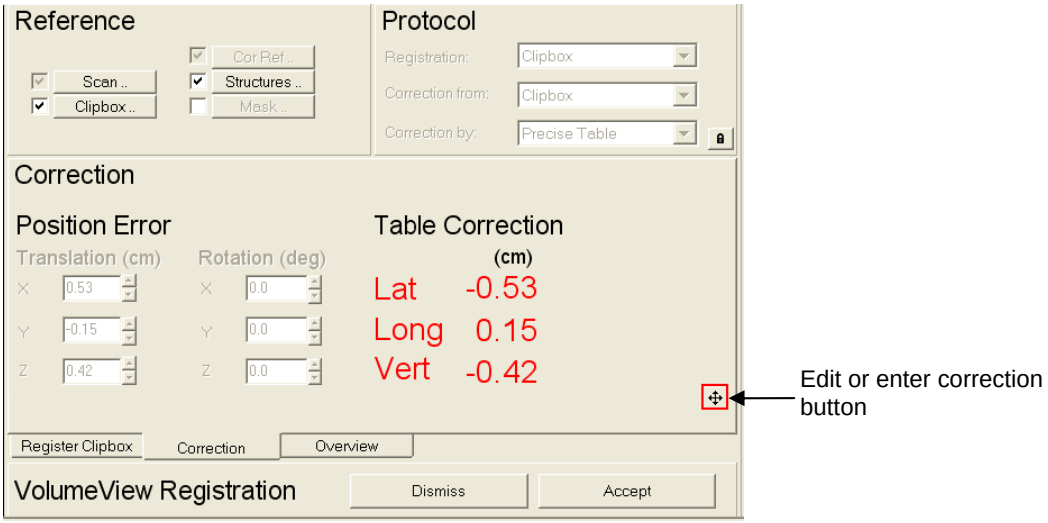

Figure 1: The Correction tab

When you complete the registration and click **Convert To Correction**, the **Edit or enter correction** button (see Figure 1) becomes available.

This Notice has been notified to the appropriate Regulatory Authority

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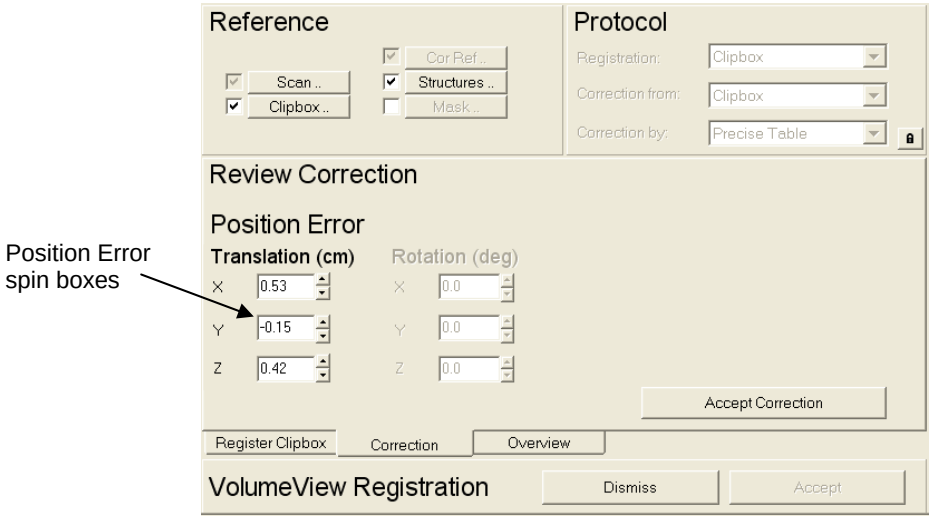

Figure 2: The Correction tab after you click the Edit or enter correction button

After you click the **Edit or enter correction** button, you can then use the spin boxes to manually adjust the registration.

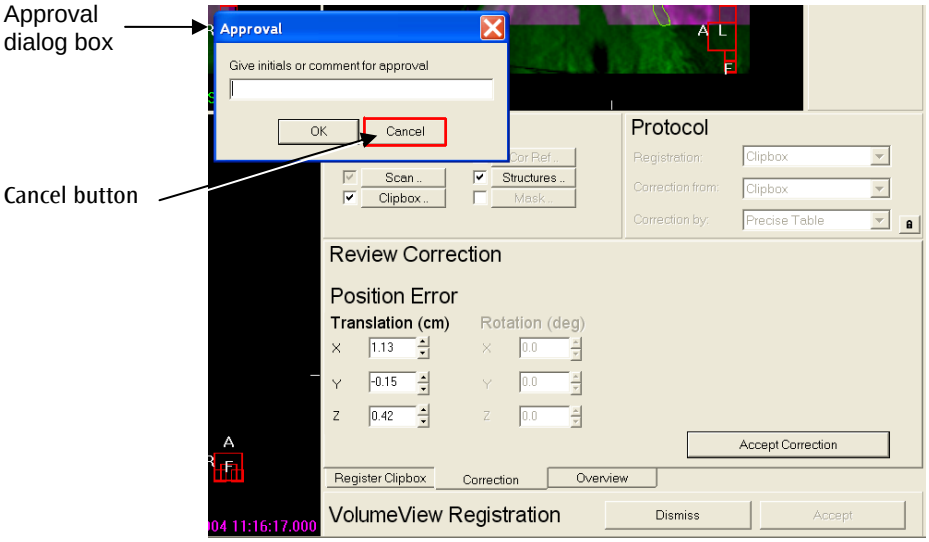

Figure 3: The Approval dialog box

After you click **Accept Correction**, the **Approval** dialog box appears. If you click **Cancel** in this dialog box and then do the approval again, the **Table Correction** values change to their initial values. But, the image panes continue to display the changed **Position Error** values (see Figure 4).

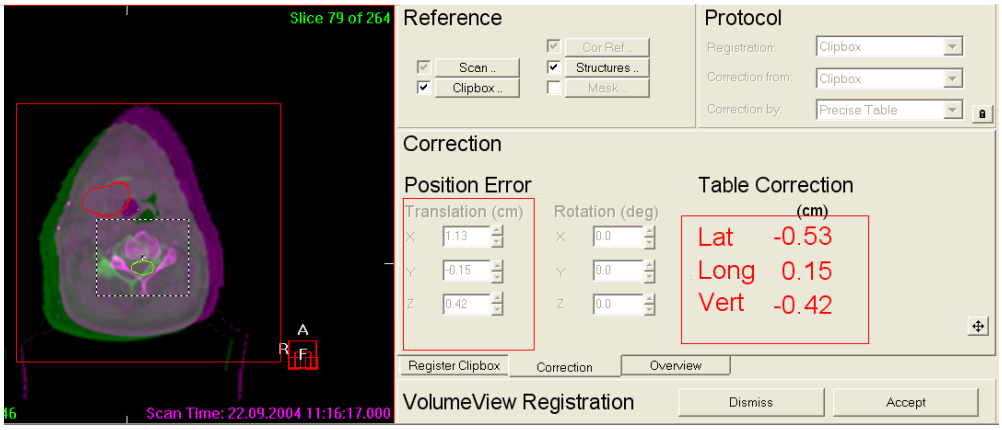

Figure 4: The Table Correction values changed to their initial values, but the image panes and Position Error continue to display the changed Position Error values.

Clinical impact: The patient position in the image pane looks correct, but the **Table Correction** values are not the correct values to move the treatment table to this position. This can cause clinical mistreatment.

Solution: Do not click **Cancel** in the **Approval** dialog box and then do the approval again. If you cancel an approval, always go to the registration tab to do the image registration again.

A later software release of XVI will give a solution to this problem.

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FCO ACTION NOTIFICATION REPORT

<Give this Notice to the customer, and then complete and return this report to your local Elekta Office or Representative for the Configuration Database.>

Classification:	Important Field Safety Notice	**FCO Ref:**	200 01 507 042
FCO description:	Using the Edit or enter correction button in the Correction tab can cause an incorrect patient position		
Scope:	XVI R4.5 and R4.6 without iGuide®		

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

Action on this unit/device was: (*select one*)

Note: If you use a work-order in the CLM configuration database, then you do not have to complete this section. The work-order will be used to add the information to the system.

☐ Completed as per instructions on: <date day/month/year]>

☐ Not completed because: **(***give reasons*)

☐ Not completed because the unit/device is in storage *(if applicable).*

☐ Refused by customer because: **(***give reasons*)

Acknowledgement by customer:
This notification to be signed by the customer.

The REASON and PURPOSE of this notice has been explained.

Name: _____ Title: .....

Signature: _____ Date: .....

This Notice has been notified to the appropriate Regulatory Authority

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