



IMPORTANT FIELD SAFETY NOTICE



PRODUCT: Precise Table™

Date: 03-2013

FCO Ref: 200 01 204 007

Accidental Column Rotations

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: Elekta Precise Tables™ Range 124001 to 126924, 133801 to 133999, 213000 to 213189

Problem: The Column Rotation can accidentally be moved to a different position while in the locked position. This can occur between fields. This can cause clinical mistreatment.

This is an example of how this problem can occur.

1. The column is rotated away from 0°, for example to attach the APEX.
2. The column is rotated back to 0°. The brake can be applied when the column is slightly off the center position. Because the Column Rotation value displays 0°, the user can think that column is in the center position.
3. A patient is then setup, and treatment starts with the treatment table and column in this position.
4. Between treatment fields a manual treatment table isocenter rotation is applied, for example, for non-coplanar treatment techniques. During this movement, the column also moves to be correctly in the indent and at the zero position. The TRM continues to display 0°.
5. The difference in column rotation ($\pm 0.575^\circ$) can equal a maximum of 1 cm lateral shift at the isocenter.
6. The remaining treatment fields are delivered with a 1 cm lateral error. This can cause clinical mistreatment.

It is possible that this problem is not seen, unless imaging is completed between treatment table rotations.

Clinical impact: This problem can cause clinical mistreatment.

This Notice has been notified to the appropriate Regulatory Authority



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Solution:

When you manually rotate the table top to its usual position with column rotation equal to 0°, you feel a spring-loaded bolt lightly engage. You will also hear a 'clunk' as the column goes back into the indent position.

When you do a column rotation, always do this with the brake off. Make sure that the treatment table is correct and stable at 0° before you apply the brake. If you release the column brake and then apply it again, it will cause the treatment table to move to the correct 0° position.

If it is possible to rotate the column with the brakes applied then contact your Service Representative.

Elekta has started work to find the best solution to repair this problem.

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This Notice has been notified to the appropriate Regulatory Authority



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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 01 204 007
FCO description: Accidental Column Rotation	
Scope: Precise Table™ 124001 to 126924, 133801 to 133999, 213000 to 213189	

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

<p>Action on this unit/device was: <i>(select one)</i></p> <p><input type="checkbox"/> Completed as per instructions on: <date day/month/year></p> <p><input type="checkbox"/> Not completed because: <i>(give reasons)</i></p> <p><input type="checkbox"/> Not completed because the unit/device is in storage <i>(if applicable)</i>.</p> <p><input type="checkbox"/> Refused by customer because: <i>(give reasons)</i></p>	<p>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.</p>
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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: _____

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This Notice has been notified to the appropriate Regulatory Authority