ELEKTA

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.

Treatment Table position errors

Product: Precise Treatment Table™

Reference number (Field Change Order, FCO): 200 01 204 011
Field Corrective Action (FCA) number (if applicable): FCA-EL-0001

Scope:	Precise Treatment Table™ Serial Numbers: (124001-125803, 125807-880, 125883-899, 125902-917, 125920-949, 125952-963, 125967-125153, 126158-170, 126174-208, 126212-230, 126232-261, 126269-281, 126293-309,126318-330, 126338-126373, 126375-397, 126400-133999, 213000+)
Description:	Elekta have identified that it is possible to get a positional error with the Precise Treatment Table™. This can occur if the positional sensors are not correctly installed during corrective maintenance. The system has a software check for large positional errors which is intended to find faults, but it is possible to position the Treatment Table with errors greater than 5mm and no inhibits are displayed.
Clinical impact:	It is possible to cause clinical mistreatment if the patient is not in the correct position.

This Notice has been notified to the appropriate Regulatory Authorities

Elekta Limited, Linac House, Fleming Way, Manor Royal
Crawley, West Sussex, RH10 9RR
Tel: +44 (0) 1293 544422 Fax: +44 (0) 1293 654321

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Solution:	The procedure to check for this error is in the Precise Treatment Table™ Instructions For Use (1502625_02 and later). Elekta recommends that a procedure to verify the accuracy of the treatment table position as shown by the treatment room monitor (TRM) is done daily as part of the daily machine checks. The procedure that follows is one example of how to do this. When you do this check, it is necessary to record measurements to the accuracy of one millimeter. A test object, such as a cube or steel ruler can be used. 1. Rotate the gantry to 0°. 2. Put the test object/steel ruler at isocenter, and align it to the room lasers at the central axis. Note the treatment table longitudinal (X) TRM as d_1 3. Use the user interface module to move the treatment table 20 mm in a longitudinal direction. 4. Do a check to make sure that the distance moved, as measured by the test object/steel ruler, is the same as the change in the TRM. If the error is >1 mm, contact your local service representative. Record the value as d_2 5. Use the user interface module to move the test object/steel ruler to its initial position (isocenter), and align it to the room lasers at the central axis. Record of the value in the TRM as d_3. 6. Calculate the difference between d_3 and d_1. This is the positional error. If the error is >1 mm, contact your local service representative. 7. Do step 1 to step 6 again for treatment table movements in the Lateral (Y) and Height (Z) directions. Elekta will supply an improved method of installation for positional sensors that your local field service engineer can use when the part is replaced.
Technical Reference:	01824773
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

1 Safety reference

The following warnings and cautions are associated with this notice:
None

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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.

Classification:	Important Field Safety Notice	FCO Ref:	200 01 204 011
Description:	Treatment Table position errors		
Scope:	Precise Treatment Table™ Serial Numbers: (124001-125803, 125807-880, 125883-899, 125902-917, 125920-949, 125952-963, 125967-125153, 126158-170, 126174-208, 126212-230, 126232-261, 126269-281, 126293-309,126318-330, 126338-126373, 126375-397, 126400-133999, 213000+)		

Hospital:	
Device Serial No: (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:

This Notice has been notified to the appropriate Regulatory Authorities

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