



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.

Faulty bolts on counterbalance weight assembly

Product: Digital Linear Accelerator

Reference number (Field Change Order, FCO): 200 01 103 079

Field Corrective Action (FCA) number (if applicable): FCA-EL-0002

Scope:	Elekta Digital Linear Accelerators listed below are affected by this IFSN. 152807, 152943, 153060, 153255, 153300, 153348 – 153350, 153359, 153406, 153511, 153530 - 153532, 153534 – 153586, 153588 – 153620, 153622 – 153647, 153649 – 153670, 153672 – 153678, 153680, 153683 – 153685, 153691, 153696, 153699, 153702, 153710, 153712, 153713, 153715, 153717, 153723 – 153728, 153734. Machines outside this serial number range are not affected.
Description:	Elekta have identified an unserviceable batch of bolts supplied to install the counterbalance weight assembly on the gantry drum. Not all bolts in the batch are defective. Elekta will replace all the defective bolts that have the mark 'OF' on the head. If the bolts have a fault, the gantry drum is not stable and can fall and cause fatal injuries to all users. Contact your local Elekta representative to do a check on the bolts on the counterbalance weight assembly. The digital linear accelerator must not be used until these bolts are checked.
Clinical impact:	If the bolts are not serviceable, the gantry drum is not stable and can cause fatal injuries to all users and patients. The digital linear accelerator must not be used until the 'OF' bolts are replaced.
Solution:	The digital linear accelerator must not be used until the 'OF' bolts are replaced. If your system has the serviceable bolts, that is bolts without the 'OF' mark, you do not have to implement this ISFN.

This Notice has been notified to the appropriate Regulatory Authorities

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Fig. 1 Faulty bolt with 'OF' on face of bolt.

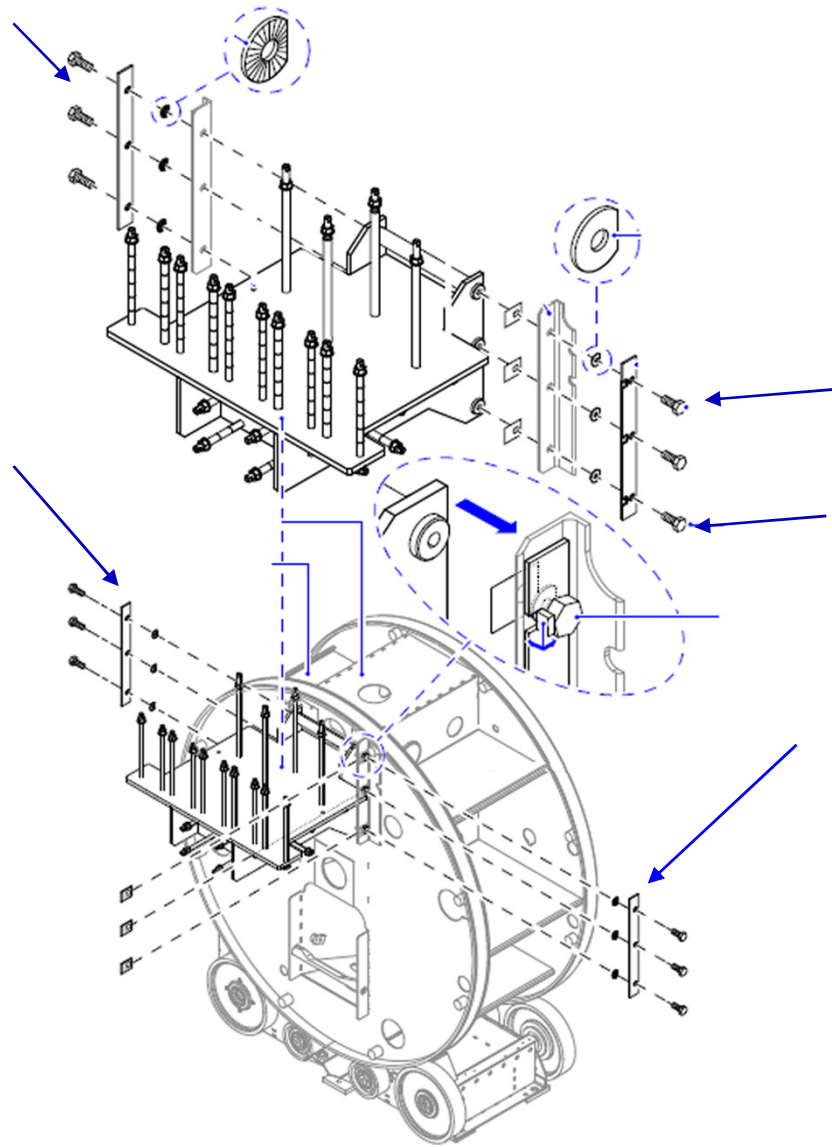


Fig.2 Bolts on counterbalance weight assembly

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	<p>Elekta recommend that you replace the M20 x 50 mm bolts marked 'OF' on the gantry counterbalance frame immediately.</p> <p>The digital linear accelerator must not be used until these 'OF' bolts are replaced. Elekta recommend that you put the machine in a parked position at 0°, and attach the gantry locking straps.</p> <p>A Modification kit will be available as soon as possible which contains the correct bolts.</p>
Technical Reference:	CASE No 01938203
Contact:	If you have any queries about this Notice, contact your local Elekta representative.

1 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.

Classification: Important Field Safety Notice	FCO Ref: 200 01 103 079
Description: Faulty bolts on counterbalance weight assembly	
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Hospital:	
Device Serial No(s): (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:	

This Notice has been notified to the appropriate Regulatory Authorities

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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