



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.

XVI generator faults

Product: XVI

Reference number (Field Change Order, FCO): 200 01 304 054

Field Corrective Action (FCA) number (if applicable): n/a

Scope:	All XVI systems
Description:	Elekta is aware of multiple occurrences of generator faults. Elekta are investigating this issue.
Clinical impact:	<p>This will cause scan termination. This can cause an interruption to the workflow until the fault is cleared.</p> <p>A terminated scan can cause an increase in the dose to the patient if the images acquired are not satisfactory and more scans are necessary.</p>
Solution:	<p>If the XVI system cannot deliver kV radiation, it is possible that there is a fault on the kV generator. The fault is usually corrected when you reset the generator:</p> <ul style="list-style-type: none"> • In the XVI window, click the kV generator status indicator. A Generator Fault dialog box appears. • Click Yes. • If the reset fails, a second Generator Fault dialog box appears, click OK. • After approximately 15 seconds, do these steps again. • If this fault continues, contact your local Elekta Service representative. <p>If the terminated scan produces a reconstructed image, do a check to make sure that the image is clinically acceptable. If the image is clinically acceptable, continue with the workflow.</p> <p>If the terminated scan does not produce a clinically acceptable reconstructed image, acquire the image again.</p> <p>Elekta are investigating possible solutions.</p> <p>If you continue to experience this fault, contact your local Elekta Service representative.</p>
Technical Reference:	Case Nos. 01689309, 01646877
Contact:	If you have any queries about this Notice, contact your local Elekta office.

This Notice has been notified to the appropriate Regulatory Authorities

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Safety reference

The following warnings and cautions are associated with this notice:

None - 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 01 304 054
Description: XVI generator faults	
Scope: All XVI systems	

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:	
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