

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Compliance issue with Varex PSU's

Product: Varex Part Number 95510354H-01 (Varex serial numbers 354-01H_A0010004PC to 354-01H_A0010269PC).

Scope: 109331, 109333, 109335, 109336, 109339, 109341, 109342, 151879, 152194, 152223, 152483, 153038, 153299, 153410, 153681, 153970, 156073, 156724, 156841, 156849, 156941, 156966, 156968, 156969, 156970, 156971, 156973, 156977, 156978, 156979, 156980, 156981, 156982, 156983, 156984, 156985, 156986, 156987, 156988, 156989, 156990, 156992, 156995, 156996, 156997, 156998

Notification Released: April 2023

UDI Reference: N/A

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Description of Problem:

A component within a limited number of Elekta Linacs has been realized to be non-compliant to IEC 60601. This is notification of the non-compliance and that Elekta will replace the component.

Details:

The non-compliance relates to a power supply unit that does not meet the IEC 60601 requirement for dielectric strength testing. The power supply unit within the iViewGT system (located within Area 44 of the Linac) may become non-compliant under specific fault conditions.

All of the specified power supply units will be inspected and / or replaced.

There is an increased potential of power supply unit failure resulting in loss of imaging functionality.

Power supply unit (PSU) impacted:

Manufacturer: Varex

Part number: 95510354H-01

NOTE: Part number 95510354H is not affected by this issue.

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Clinical Impact:

There is no clinical impact as a result of the non-compliant component. The system remains safe for labelled use. No special measures by the user are required.

Recommended User Action:

No action needed by the user. Elekta will contact the impacted customers to perform the following onsite activities.

The power supply unit will need to be inspected to confirm it is impacted by this non-compliance.

Power supply units that fall within this scope will be removed and replaced with compliant power supply units.

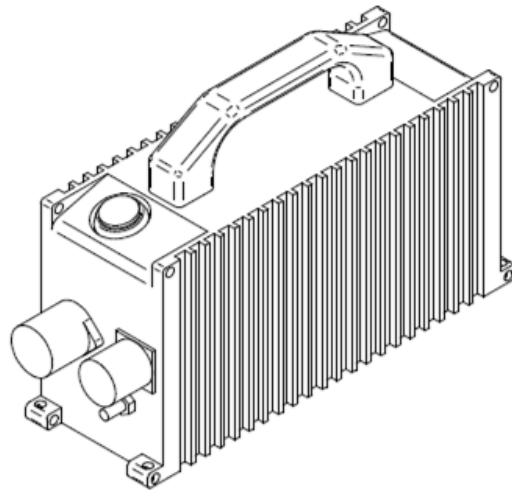


Fig.1 – Image of the Varex PSU

This document contains important information for the continued safe and proper use of your equipment.

- Please post this notice in a place accessible to all users, e.g. Instructions for Use, until this action is closed.
- Advise the appropriate personnel, working with this product, on the content of this letter.

Elekta Corrective Actions:

Elekta will replace all affected power supply units, this will be performed under a modification notice.

This notice has been submitted to the appropriate Regulatory Authorities.

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We sincerely apologize for any inconvenience this action may cause and thank you in advance for your cooperation.

Acknowledgement Form

In order to meet regulatory requirements, you are required to either acknowledge receipt of this notification via the [Elekta Care™ Community](#) or complete this form and return it to Elekta immediately upon receipt, but no later than within 30 days.

Classification: Important Field Safety Notification	FCO Reference Number: <XXX-XX-XXX-XXX>
Description <Enter the title of the document – no more than 2 lines>	

Hospital:	
Device Serial No(s): (if applicable)	Location or Site:

I acknowledge that I have read and understood this Notice and accept the implementation of any given recommendation.	
Name:	Title:
Customer Signature:	Date:

New installation confirmation to be signed by the installing Elekta engineer or a Representative employee, when the installed product has a physical IFU/manual:	
I acknowledge that the customer has been informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual, or added on record with the applicable User Manual:	
Name:	Title:
Signature:	Date: