

URGENT

IMPORTANT FIELD SAFETY NOTIFICATION

Subject: For service user: precautions to be taken when handling diode D1

Product: Digital Linear Accelerator

Scope: All Linacs

Notification Released: September 2021

UDI Reference: **Elekta Infinity (01) 05060191071543**

Versa HD (01) 05060191071574

Elekta Harmony Pro (01) 05060191071604

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Description of Problem:

Two events have been reported where, after removal from the machine, Diode D1 has ruptured, spraying shattering pieces in the area where it was stored.

Details:

There is a risk that the Diode D1 in the Modulator can fail in a destructive manner, and that the protective tube surrounding the diode may fail to contain the ejected matter. As the destructive event results in the release of silicon oil and ceramic fragments, further mitigating actions need to be taken when dealing with the diode failure, to reduce the risk of injury to users in the immediate vicinity.

Elekta is currently working on a solution to eliminate this failure mode, which when released, will replace the current diode in production and field failures as they occur.

Clinical Impact:

No Clinical impact

Recommended User Action:

No user actions

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.

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Elekta Corrective Actions:

Removing the modulator covers

The engineer must be wearing suitable Personal Protective Equipment (PPE) before removing any Modulator covers. This includes safety visor, protective jacket and gloves.

The PPE should continue to be worn during any maintenance work with any modulator cover removed.

As a minimum the safety standard rated PPE should be used.

Gloves (These protect against any mechanical & Chemical hazards)

EN 388:2016 levels 4-5-4-4-F, EN ISO Cut level F protection, PPE Regulation (EU) 425/2016

Example <https://www.supertouch.com/deflector-f>

Face shields (These will protect against high-speed particle with medium energy impact)

EN166 - 1B

Example <https://www.portwest.com/products/view/PW96/CLR>

Protective jacket (Provides multi standard protection for hazardous environments)

EN ISO 11611 Class 2 A1 – Protective jacket (Provides multi standard protection for hazardous environments)

Example <https://www.portwest.com/products/view/SW34/TAR>

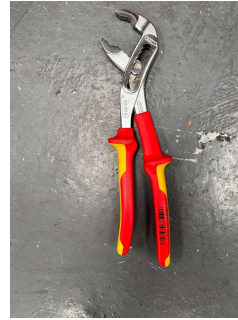
Instructions for removing the RDO diode (D1)

In addition to wearing the PPE the system must be shut down and left for a minimum 4 hours.

While PPE is being worn, the retaining nuts should be loosened. Using a tool, such as the water pump pliers shown below. Set the jaw size to between 28mm to 35mm to ensure it correctly grips the tube and remove the diode safely and place in container whilst wearing described PPE.

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Example <https://uk.rs-online.com/web/p/pliers/1585439/>



Once the diode has been removed from the Linac, it must be stored inside a suitable container as there is still a risk of the device rupturing within the protective tube and forcing out the end caps, or breaking the protective tube and ejecting matter over a wider area.

A suitable container could be a multiwall cardboard box, wooden crate or metal toolbox that can be securely sealed and remain closed in the event of the diode rupturing. The containers role is to prevent matter being ejected over a wide area if the diode rupturing whilst in storage/disposal.

A safe method for disposal is being confirmed and will be communicated as soon as possible. In the meantime the diode must be retained in the container.

Any container used must have a warning notice attached to it, to warn other users against opening the container unless they are wearing suitable PPE (visor, jacket, and gloves).



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: 200-01-103-084,
Description For service user: precautions to be taken when handling diode D1	

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:

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Signature:

Date: