

## **URGENT**

# **IMPORTANT FIELD SAFETY NOTIFICATION**

**Subject:** Potential for uncontrolled extension of XVI / iViewGT™ detector arms

**Product:** Digital Accelerator

**Scope:** Digital Accelerators with XVI or iViewGT™ systems prior to machine number 154585.

**Notification Released:** October 2023

**UDI Reference:** N/A

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### **Description of Problem:**

Elekta has identified that if the microswitch within the middle arm is incorrectly setup, there is a potential for an uncontrolled extension of iViewGT™ / XVI detector arms.

When the detector arm is fully deployed there is no risk of uncontrolled extension.

This notice relates to the previous IFSN 200-01-103-082. This notice is a repeat and an announcement of additional corrective measures.

### **Details:**

iViewGT™

1. The micro-switch assembly within the PCB assembly, solenoid limit switch, of the middle arm is activated AND
2. The detector-locked solenoid is not fully engaged in the interface bracket AND
3. The detector arm is closed / folded above the patient when the gantry angle is at  $180^\circ \pm 45^\circ$

XVI

1. The micro-switch within the PCB assembly, solenoid limit switch, of the middle arm assembly is activated AND
2. The detector-locked solenoid is not fully engaged in the interface bracket AND
3. The detector arm is closed / folded above the patient, when the gantry angle is at  $90^\circ \pm 45^\circ$ .

### **Clinical Impact:**

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There is a potential for serious injury to the patient or user due to a potential collision with the extending detector arm.

### Recommended User Action:

Elekta recommends that the user does not open or close the detector arm whilst it is positioned above the patient, as specified in the Instructions for Use (IFU), as shown below:

#### iViewGT™

*Elekta recommends that the detector panel should not be opened or closed when the gantry is at 180° ( $\pm 45^\circ$ ), especially when a patient is on the treatment table. The movement of the MV detector panel at these angles could disturb a patient who is underneath the detector panel iViewGT™.*

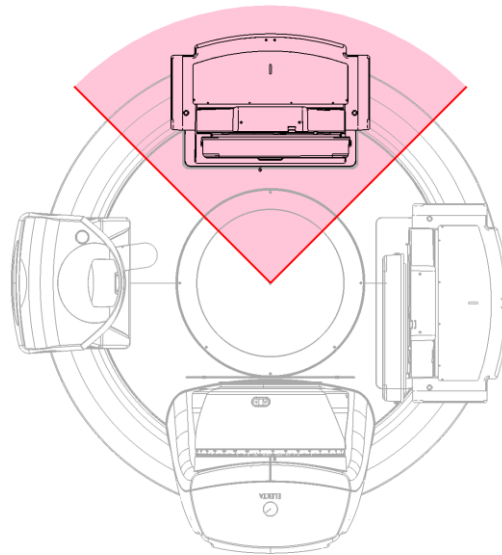


Figure 1 – Non-recommended open and close positions of the MV detector arm

XVI

## URGENT IMPORTANT FIELD SAFETY NOTIFICATION

*Elekta recommends that you do not open or close the detector arms when they are in a position above the patient.*

*Clinical use: set gantry at 0 degrees, unfold the kV imager, use the system XVI.*

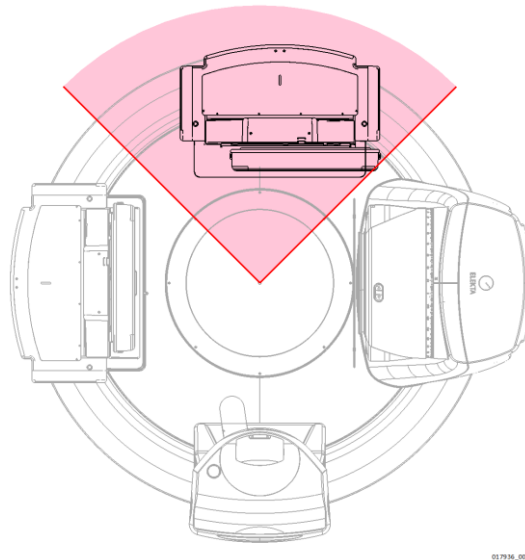


Figure 2 – Non-recommended open and close positions of the kV detector arm.

**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 Field Service Representatives will be fitting a bracket to the middle arm assembly in order to ensure that the micro-switch will activate only when the detector-locked solenoid is fully engaged in the interface bracket. If you have any concerns, please contact your Elekta Field Service Representatives who will be aware of how to complete this work.

**NOTE:** Only customers with the original design of XVI / iViewGT will require this corrective action.

This notice has been submitted to the appropriate Regulatory Authorities. We sincerely apologize for any inconvenience this action may cause and thank you in advance for your cooperation.

## URGENT IMPORTANT FIELD SAFETY NOTIFICATION

### 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: 200-01-103-088
Description: Elekta has identified that in certain situations there is a potential for an uncontrolled extension of iViewGT / XVI detector arms during clinical use.	

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:

<b>New installation confirmation</b> 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: