

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Elekta Unity Navigated Scan Protocols

Product: Elekta Unity

Scope: All Elekta Unity systems

Notification Released: February, 2019

Description of Problem:

This notice is intended to provide clarification of the use of Navigated Scan Protocols within the online treatment workflow

Details:

Elekta Unity is supplied with MR scan protocols intended to minimize image artefacts due to respiratory motion by triggering data collection only in a specified part of the breathing cycle. These protocols are:

Anatomy ExamCard	Patient Orientation	Protocol Name
Abdomen	Head First Supine	T2 3D Tra Navigated (NAV)
	Feet First Supine	T2 3D Tra Navigated (NAV)
Thorax	Head First Supine	T2 3D Tra Navigated (NAV)
	Head First Prone	T2 3D Tra Navigated (NAV)

These protocols are designed to acquire data based on the position of the diaphragm and uses a Navigator. The Navigator is positioned over the diaphragm in the MR Console user interface. Data is only acquired when the signal of the Navigator reaches a pre-defined level which is fixed in the protocols (See 'MR Imaging Device Instructions For Use' for more information).

Users need to be aware when using these protocols for daily on line plan adaptation that:

- 1) The images acquired using these protocols do not represent the average position of the anatomy during the respiratory motion cycle. The images are based on data acquired around full expiration.
- 2) The display of the images in the Elekta Unity Application software does not provide information about the protocol used to acquire the image eg. with or without respiratory triggering.

Users must select an appropriate scan protocol that is representative of the respiratory phase used in the reference plan.

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Clinical Impact:

If the pre-treatment image for moving targets is acquired in a different respiratory phase to that of the reference image phase, and is used for plan adaptation, mistreatment could occur

Recommended User Action:

Ensure all staff working with Elekta Unity are aware of this information

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:

None

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.

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Acknowledgement Form

In order to meet regulatory requirements, you are required to 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: 200-01-801-001
Description Elekta Unity Navigated Scan Protocols	

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: