

URGENT

IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Use of Contrast Agents with Elekta Unity

Product: Elekta Unity

Scope: All Elekta Unity systems

Notification Released: March, 2019

Description of Problem:

This notice is to inform clinical users of Unity that the instructions for use of Gadolinium-Based Contrast Agents (GBCA) must be consulted prior to using in Unity clinical workflows.

Details:

When using Gadolinium-Based Contrast Agents (GBCA) always refer to the manufacturer's guidance for safe use, particularly for repeated use of contrast agents for patients who may be at higher risk for gadolinium retention (e.g. a fractionated course of radiotherapy treatment or repeated courses of treatment).

Clinical Impact:

Consult the Gadolinium-Based Contrast Agents (GBCA) manufacturer instructions for use for potential clinical impact regarding repeated use of the agent based on the patient's treatment requirements.

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: 200-01-801-003
Description Use of Contrast Agents with Elekta Unity	

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: