



# URGENT

## IMPORTANT FIELD SAFETY NOTICE

**We are providing the information in this Notice to notify you of an important safety issue that may exist on your equipment, and to inform you of any actions needed to safeguard both your staff and your patients. We ask that you please read and understand the content of this notice and implement any recommendations provided.**

**We also need you to acknowledge and accept this Notice by signing and returning the statement on the Acknowledgement page.**

**We advise you to insert this Notice in the applicable copy of the User Manual.**

### Unintended Change to Plan-of-the-Day Selection

**Product: MOSAIQ**

Reference number (Field Change Order, FCO): FCO 371-01-MSQ-006

Field Corrective Action (FCA) number (if applicable): FCA-IMS-0014

HPQC number: 8782

Scope:	MOSAIQ Radiation Oncology customers using version 2.62 and higher with the IQ Scripts license enabled.
Description:	Clicking on the Treat button in the Treatment Chart window will trigger the Plan-of-the-Day IQ script to run. The Plan-of-the-Day window will open and the treatment plan can be selected by clicking on the radio button. It is possible that the selected Plan-of-the-Day could be accidentally changed by scrolling the mouse wheel up and down and inadvertently selecting another plan.
Clinical Impact:	Though the wrong Plan-of-the-Day selected for one fraction would likely not result in Critical harm, if the wrong plan were selected multiple times it could result in serious injury.

This Notice has been sent to the appropriate Regulatory Authorities

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Workaround:	There is no workaround, but the problem can be avoided by careful use of a mouse with a wheel (or using a mouse without a scroll wheel) and verifying that the correct plan is chosen before selecting OK on the Plan-of-the-Day form.
Solution:	The issue is corrected in the general release of MOSAIQ 2.64.  A patch is also being developed for MOSAIQ release 2.62 and you will be notified when this release is available.
Technical Reference:	None
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

This Notice has been sent to the appropriate Regulatory Authorities

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Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

**\*The information in this Notice has been provided to address a safety issue and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take, and may require Elekta to report to the Regulatory Authorities in your country.**

Classification:	Important Field Safety Notice	FCO Ref:	371-01-MSQ-006
Description:	Unintended Change to Plan-of-the-Day Selection		
Scope:	MOSAIQ Radiation Oncology customers using version 2.62 and higher with the IQ Scripts license enabled.		
Hospital:			
<b>Device Serial No:</b> (e.g. linac - if applicable)	Location or Site No:		
Acknowledgement to be signed by customer*: I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations:			
Name:	Title:		
Signature:	Date:		

This Notice has been sent to the appropriate Regulatory Authorities