

IMPORTANT USER NOTICE

We are providing the information in this Notice to notify you of an important 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.

Retention of Outdated Information in an Order Set

Product: MOSAIQ

Reference number (Field Change Order, FCO): FCO 371-03-MSQ-001

Field Corrective Action (FCA) number (if applicable): FCA-IMS-0015

HPQC number: 8861

Scope:	MOSAIQ Medical Oncology customers using version 2.50.05 and higher.
Description:	<p>It is possible that a change to an Order Set will not be saved in the current, open Care Plan when the following workflow is utilized:</p> <ol style="list-style-type: none"> 1. Open either the Care Plan Edit form or the Care Plan Instance form and leave the form open. 2. Select an Order Set that is part of the same Care Plan and make a change to the Order Set. This can be a change to the Order Set name or label or a change to the drug, dose, administration instructions, etc. 3. The update made to the Order Set will NOT be saved in the current, open Care Plan.
Clinical Impact:	<p>The old order set information is incorrectly retained in the current, open Care Plan.</p> <p>NOTE: If the order set exists in any Care Plan where a form was not open at the time of the change, the problem does not occur and the Order Set updates as expected.</p>

This Notice has been sent to the appropriate Regulatory Authorities

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Workaround:	All Care Plan windows should be closed prior to making updates to Order Sets.
Solution:	The issue is resolved in MOSAIQ Release 2.64 SP1. A patch is also being developed for the following MOSAIQ releases: 2.50 2.60 2.62
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 User Notice	FCO Ref: 371-03-MSQ-001
Description: Retention of Outdated Information in an Order Set	
Scope: MOSAIQ Medical Oncology customers using version 2.50.05 and higher	
Hospital:	
Device Serial No: (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