

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Retention of Outdated Information in an Order Set

Product: MOSAIQ

Scope: MOSAIQ Medical Oncology customers using version 2.50.05 and higher.

Notification Released: June 2017

Description of Problem:

Change to an Order Set does not trigger the update of the associated Care Plans.

Details:

In the Care Plan Library, double clicking to add or delete a Component/Procedure to an Order Set does not trigger the update of the associated Care Plans.

Clinical Impact:

The Care Plans in the Care Plan Library remain pointing to an obsolete version of the Order Set.

Recommended User Action:

If the Component/Procedure is edited by selecting it (instead of double clicking), the problem does not occur and the Care Plan updates as expected.

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 the content of this letter

Elekta Corrective Actions:

The issue is resolved in MOSAIQ Releases 2.62 SP8 and 2.64 SP5 and will be resolved in future release 2.65 Beta 01.

This notice has been provided 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 30 days.

Classification: Important Field Safety Notification	FCO Reference Number: 371-01-MSQ-010
Description: Retention of Outdated Information in an Order Set	

Hospital:	
Device Serial No(s): (if applicable)	Location or Site:

I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations.	
Name:	Title:
Customer Signature:	Date:

New installation confirmation to be signed by the installing Elekta engineer or Representative employee when the installed product has a physical IFU/manual:	
I acknowledge that the customer is informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual or added to the record with the applicable User Manual:	
Name:	Title:
Signature:	Date: