Field Corrective Action Reference: FCA-IMS-0027
This notice reference: 371-01-MSQ-013
HPQC: 11453

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Wedged Fields Delivered Without Wedges

Product: MOSAIQ

Scope: MOSAIQ Radiation Oncology customers using release version 1.0 and higher and Multi-ACCESS Customers using release version 6.1 and higher.

The problem will occur if these MOSAIQ or Multi-ACCESS customers are using the following:

- Varian 4D Console, TrueBeam, EXCI linacs with either Static or Enhanced Dynamic Wedges (EDW)
- Siemens linacs with either Static or Virtual Wedges (VW)
- Treatment planning systems that don't force Wedge IDs to be defined

Notification Released: December 2018

Description of Problem:
If there are no Wedge IDs included in the DICOM RT PLAN sent from the TPS, the field in MOSAIQ will be created with no wedge.

Details:
MOSAIQ is dependent on the presence of the Wedge ID to assign a wedge to a beam at the time of plan promotion, regardless of the presence of other wedge indicators [e.g. Number of Wedges or Wedge Position]. No warnings are presented if Wedge IDs are not present.

Clinical Impact:
If not discovered, it is possible that fields planned with wedges can be delivered without the wedge. Treatment of a field without the planned wedge will receive more dose than the treatment plan indicates.

100 Mathilda Place, Fifth Floor
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Recommended User Action:
Review your TPS system to verify that Wedge IDs are defined for all wedges. Also, check to make sure that the exported RT Plan information contains the necessary Wedge IDs.

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:
The issue is resolved in MOSAIQ Release 2.80 Beta 01. This update will also be provided in Service Packs to MOSAIQ and Multi-ACCESS. You will be notified with a Product Bulletin when these Service Packs are available and upgrade options will be explained.

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:	371-01-MSQ-013
Description	Wedged Fields Delivered Without Wedges		

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 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:

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