Field Corrective Action Reference: **FCA-ESAB-0005**

This notice reference: 371-01-MSQ-019

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Image offsets calculated by the 2D Image Review Application may be incorrect for LINACs not characterized at IEC61217 scale.

Product: MOSAIQ®

Scope: MOSAIQ customers who have run version 3.1.2, 3.1.3, 3.2.1 and use the 2D Image Review Application for online image matching on a Linear Accelerator not scaled to IEC61217.

Notification Released: January 2025

UDI Reference:

3.1.2.0 (01)07340201500026(10)3.1.2.0
3.1.3.0 (01)07340201500026(10)3.1.3.0
3.1.3.1 (01)07340201500026(10)3.1.3.1
3.1.3.2 (01)07340201500026(10)3.1.3.2
3.1.3.3 (01)07340201500026(10)3.1.3.3
3.1.3.4 (01)07340201500026(10)3.1.3.4
3.2.1.0 (01)07340201500071(10)3.2.1.0
3.2.1.1 (01)07340201500071(10)3.2.1.1
3.2.1.2 (01)07340201500071(10)3.2.1.2
3.2.1.3 (01)07340201500071(10)3.2.1.3
3.2.1.4 (01)07340201500071(10)3.2.1.4

Description of Problem:

MOSAIQ 2D Image Review Application may provide incorrect image offsets when a 2D verification image is taken at a patient support angle (couch rotation) other than 0 degrees, AND if the treatment machine is characterized at a scale that is not IEC61217.

Details:

During the patient setup and treatment delivery workflow, the Image Review Application may be used to view 2D verification images taken while the patient is on the table to derive any necessary shifts prior to radiation delivery. Calculated offsets shown in the Image Offsets pane may be incorrect. It is possible these incorrect values would be sent to Couch Move Assist.
If the patient support angle (couch angle) is 0 the issue does not occur.
If the Linac is scaled at IEC61217 the issue does not occur.

Clinical Impact:

Incorrectly calculated image offsets could lead to incorrect position of the treatment field(s). This could result in an overdose or underdose of the patient.

Recommended User Action:

Customers included in the scope of the Field Safety Notice, should not calculate shifts from 2D verification images taken at a non-zero patient support angle (couch angle).

Elekta Solutions AB Hagaplan 4, Stockholm, 11368, Sweden
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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:
Elekta will shortly release a Field Safety Modification detailing corrective actions available. The estimated release time is within 60 days.

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 either acknowledge receipt of this notification via the Elekta Care™ Community or 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-019
Description	Image offsets calculated by the 2D Image Review Application may be incorrect for LINACs not characterized at IEC61217 scale.		

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:

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