Field Corrective Action Reference: **FCA-ESAB-0013**

This notice reference: 371-01-MSQ-022

IMPORTANT FIELD SAFETY NOTIFICATION

URGENT: MEDICAL DEVICE CORRECTION

Subject: MOSAIQ may fail to load adapted Baseline Shift Plan during Unity treatment delivery when a communication error occurs during the send process.

Product: MOSAIQ with Unity

Scope: Unity customers with MOSAIQ v 3.2.1.0 to 3.2.3.2

Notification Released: May 2026

UDI Reference:

UDI Reference	Software Version
07340201500071	3.2.1.0, 3.2.1.1, 3.2.1.2, 3.2.1.3, 3.2.1.4, 3.2.2.0, 3.2.2.1, 3.2.3.0, 3.2.3.1, 3.2.3.2

Description of Problem:
When using Anatomical Position Monitoring (APM) during a Comprehensive Motion Management (CMM) Unity treatment delivery, if the user performs a Baseline Shift (BLS) plan and an error occurs during the plan transfer, in some instances, the BLS plan may not load into MOSAIQ resulting in the original beams being delivered without the new BLS applied.

Details:
The problem only occurs if a background process time-lapse occurs while an adapted BLS plan is being sent from Monaco (not version specific). Time-lapse errors occur when the communication between internal MOSAIQ processes are temporarily blocked, which may occur due to several reasons and result in a time out error. When this application communications time out occurs, an error (see Figure 1) will be displayed. Aside from this, there is no warning that the new adapted BLS plan failed to load into MOSAIQ.

Clinical Impact:
During CMM delivery, when a target drifts outside the specified gating tolerances, the user can create a BLS plan. The BLS plan accounts for the shift in the target's average position and will be used for the remainder of the delivery. The clinical impact of not treating with the intended BLS plan will depend on multiple treatment specific factors such as the magnitude of BLS correction requested, the number of beams treated without the BLS plan, total dose, fractionation pattern, and proximity of organs at risk. The allowable BLS magnitudes are user-configurable per patient, with a maximum system allowable limit of 50mm. Elekta has received one customer complaint from the field that reported an incident that resulted in non-serious patient mistreatment.

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Recommended User Action:
If an “Application Communication Time Out” error message (Figure 1) appears during a BLS plan transfer, click Continue, then:

1. Navigate to the treatment delivery table.
2. Right-click on the relevant field and select Field Delta from the pop-up menu (Figure 2).
3. If the field has changed, as expected, a warning message will be displayed (Figure 3), click Yes to show details.
4. In the details window (Figure 4), check that the timestamp for the last edit matches the time of the last BLS transfer from Monaco.
5. If the Field Delta indicates that the field has changed with the expected timestamp, treatment delivery can continue.
6. If questions remain following review of the Field Delta, end the current treatment session and continue with the Completion Plan workflow.

Figure 1, Machine Interface Error Message

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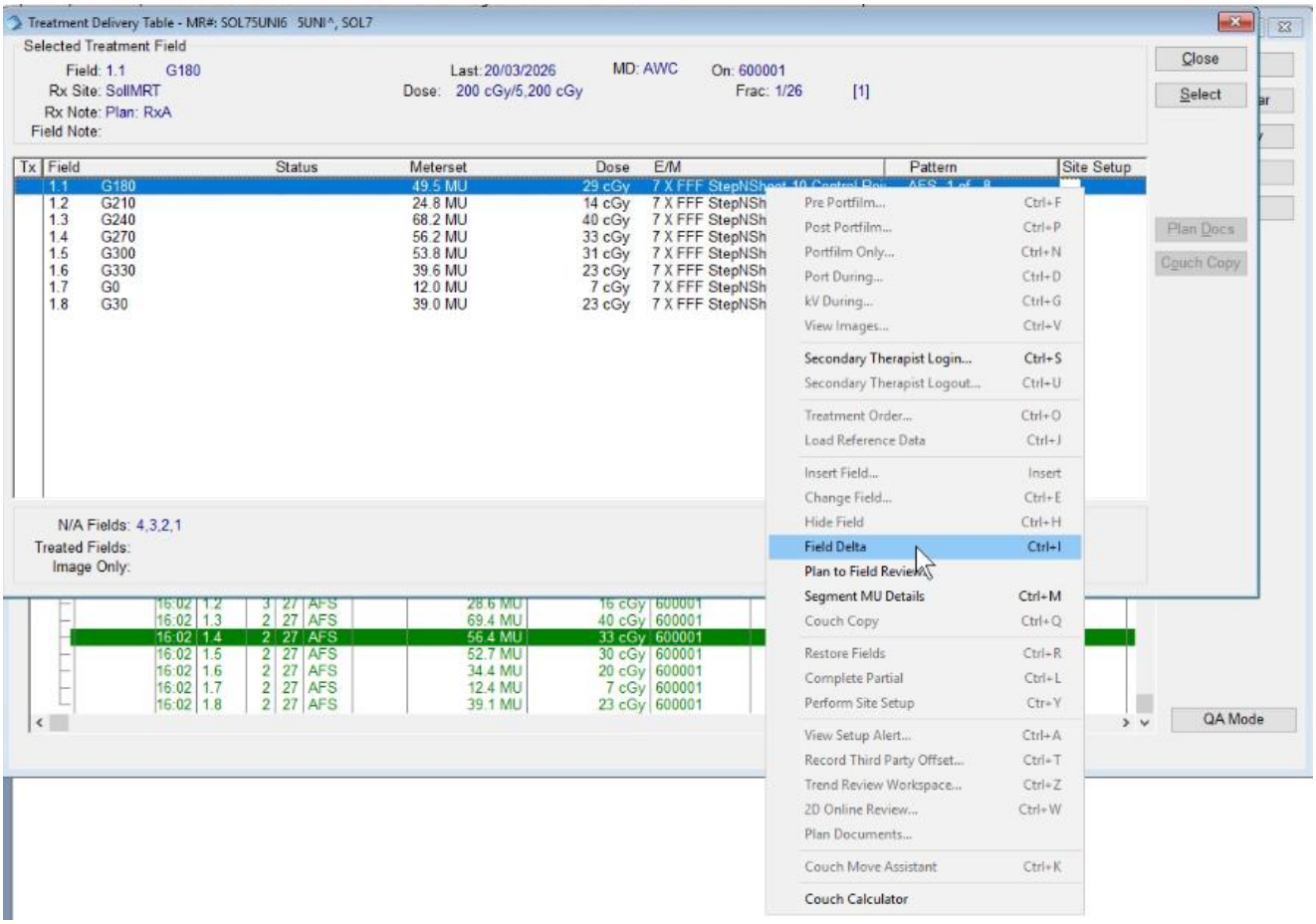

Figure 2, Field Delta selection

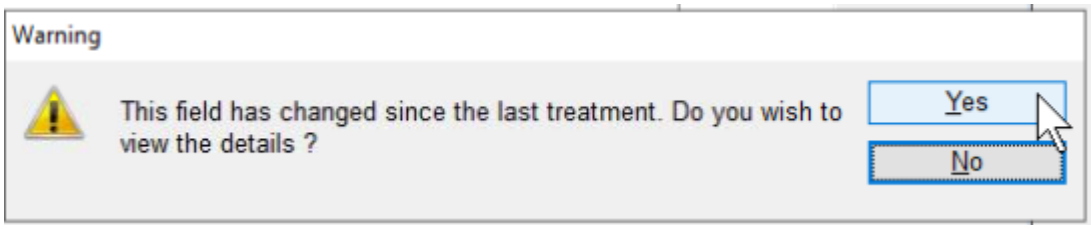

Figure 3, Field change warning message

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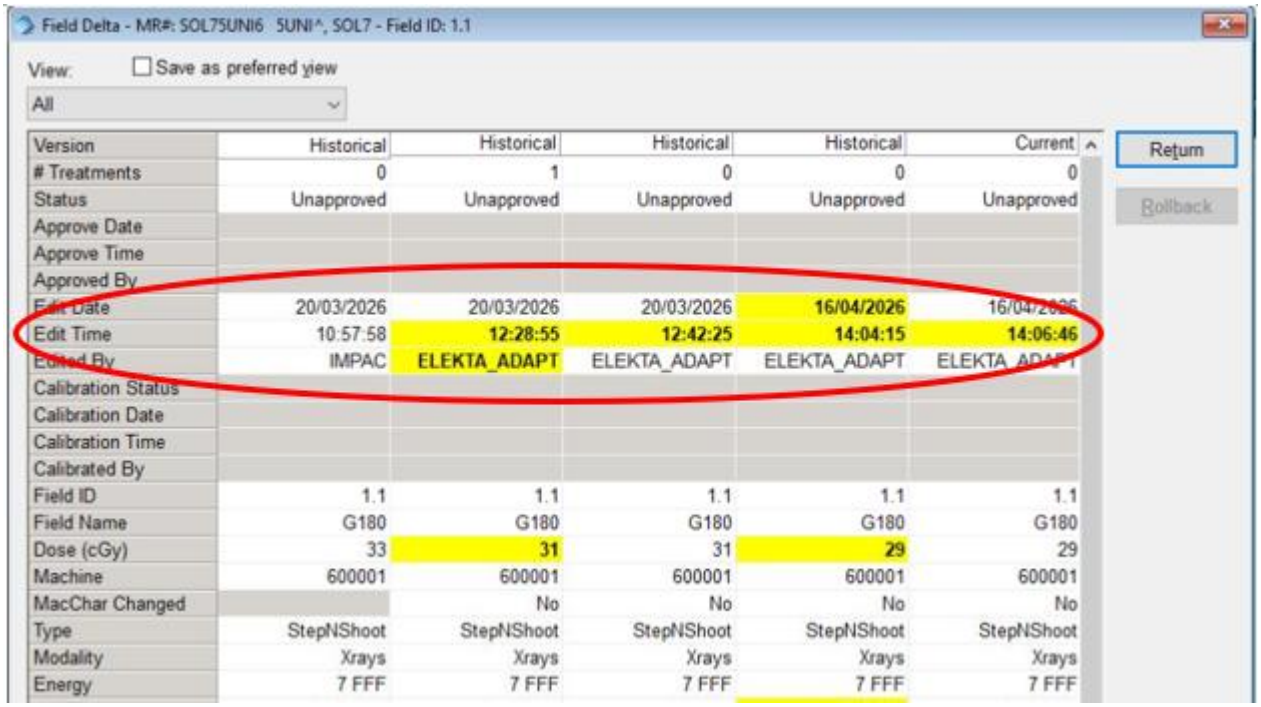

Version	Historical	Historical	Historical	Historical	Current
# Treatments	0	1	0	0	0
Status	Unapproved	Unapproved	Unapproved	Unapproved	Unapproved
Approve Date					
Approve Time					
Approved By					
Edit Date	20/03/2026	20/03/2026	20/03/2026	16/04/2026	16/04/2026
Edit Time	10:57:58	12:28:55	12:42:25	14:04:15	14:06:46
Edited By	IMPAC	ELEKTA_ADAPT	ELEKTA_ADAPT	ELEKTA_ADAPT	ELEKTA_ADAPT
Calibration Status					
Calibration Date					
Calibration Time					
Calibrated By					
Field ID	1.1	1.1	1.1	1.1	1.1
Field Name	G180	G180	G180	G180	G180
Dose (cGy)	33	31	31	29	29
Machine	600001	600001	600001	600001	600001
MacChar Changed		No	No	No	No
Type	StepNShoot	StepNShoot	StepNShoot	StepNShoot	StepNShoot
Modality	Xrays	Xrays	Xrays	Xrays	Xrays
Energy	7 FFF	7 FFF	7 FFF	7 FFF	7 FFF

Figure 4, Field Delta details window with showing Edit Time timestamp

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.

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Elekta Corrective Actions:
Elekta is continually working to reduce the incidence of time lapse errors and a specific fix is being developed to correct this issue. Elekta will release a Field Safety Modification to the field with details of the correction for this issue. The update will be provided via Elekta's Field Change Order process once available.

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-022
Description	MOSAIQ may fail to load adapted Baseline Shift Plan during Unity Treatment Delivery		

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 of 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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