⚠ **IMPORTANT SAFETY NOTICE**

Couch Move Assistant – Unintended Change in the Shift Direction and Offset

MOSAIQ®, FCA0008

Correct Functioning of the System	When using MOSAIQ Couch Move Assistant (CMA), the Direction and Offset options should only change if the user intentionally modifies these values.
What is the problem?	When using CMA, if the user hovers the mouse pointer exactly above the Direction dropdowns and then uses the mouse thumbwheel or touchpad scroll bar, the Direction selection might change when the intention was only to move the mouse pointer to a different area of the screen. Likewise, if the user hovers the mouse pointer exactly above the Site dropdown and uses the mouse thumbwheel or touchpad scroll bar, the Site could change and the Direction and Offset will change depending on the Site selected. An inadvertent change can also occur if either the Direction or Site dropdown is selected, the mouse pointer is anywhere on the dialog, and the mouse thumbwheel or touchpad scroll bar is used.
When does this occur?	The problem occurs when the mouse thumbwheel or touchpad scroll bar is used when the mouse is either hovering exactly above the Direction or Site dropdowns or when these dropdowns are selected.
Why does this occur?	The problem occurs because movement of the mouse thumbwheel or touchpad scroll bar is changing the Direction or Site options when it should not.
What is the clinical impact?	The patient could be shifted incorrectly leading to a geometric miss or treatment of the incorrect area. It is likely that the target would be underdosed and normal tissues overdosed.

What is the workaround?	There is no workaround, but the problem can be avoided by moving the mouse pointer away from the Direction or Site dropdowns or by making sure these options are not selected when using the thumbwheel or touchpad scroll bar.
What is the resolution?	The problem was introduced in MOSAIQ version 1.4 and is present in all released builds of versions 1.40 – 2.50 inclusive. The issue will affect users with Elekta linacs that have the Linac Remote Table License turned on. The problem will be resolved in a future MOSAIQ release and your site will be notified when the fix is available.

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Please distribute this notice to all users of MOSAIQ software at your organization who are potentially affected by this issue. The applicable regulatory agencies have been notified of this corrective field action.

Confirmation of Receipt

Product	MOSAIQ®
Subject	Couch Move Assistant – Unintended Change in the Shift Direction and Offset
Reference	FCA0008

Please sign and date this form and return it in one of the three ways indicated below

☐ I have read and understood this notice.

Site Name _____

Site Number _____

Recipient's Name _____

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Signature _____

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