

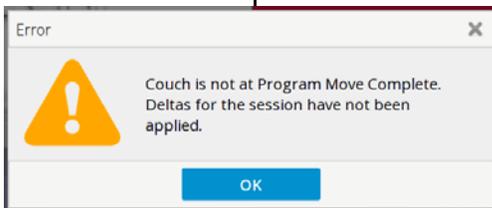
! IMPORTANT SAFETY NOTICE

October 29, 2020

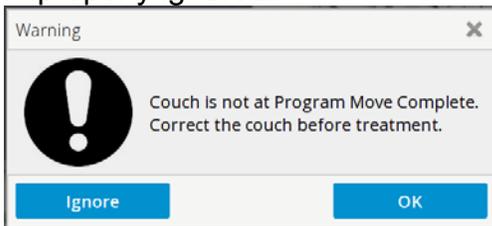
Subject: Auto-Field Sequence workflow fails to prevent treatment after isocenter is lost during setup.

Statement of Problem

In the event that a user action causes isocenter to be lost during the setup workflow, the system will present error messages on the In-Room Monitor and the TC screen indicating that Deltas were not applied during setup or a Program Move Complete (PMC) was not achieved. When the Setup field is closed another Error Message (see below) appears on the TC that informs the user of a problem which they must correct. The user is prevented from proceeding to a treatment field until the setup is corrected and the Setup field is closed with a PMC.



The Auto-Field Sequencing option as currently implemented, automatically loads the first treatment field after the above Error Message is acknowledged. The workflow is permitted to proceed to treatment. Additional Warnings (see below) will appear before each beam can be turned on, but those warnings may be improperly ignored.



If the incomplete move and lost isocenter puts the patient a significant distance away from the prescribed position, a misadministration due to a geographic miss is possible.

Determination of Cause

The use of the Auto-Field Sequencing option fails to check for a 'Program Move Complete' after the Setup field is closed and allows treatments to proceed.

Description of Potential Harm

If the Setup warning messages are not acted upon and a treatment field is loaded, a geographic miss of any magnitude is possible. The subsequent harm will come from irradiation of non-target tissue for some fraction of the total dose. This could possibly happen on multiple days to the same patient. It should be caught during physics check using the off-line review system. Dose deficiencies to the target would need to be corrected with additional irradiation.

Containment or Mitigation

Auto-Field Sequence should not be used until the underlying defect is corrected.

Required User Action

Until a software upgrade is installed to correct the defect:

- **Site physics should assure that Auto-Field Sequence is not used**
- **Therapists should not select the check box for Auto-Field Sequence**
- **Field service engineers have been notified to not set Auto-Field Sequence as the default configuration.**

Corrective Action

All users should be notified of this condition and the proper response.
A Mevion software upgrade will be released to correct the problem.

Please contact Mevion Customer service with any questions or concerns.

Please distribute this notice to all users of the Mevion Medical Systems device at your organization who may be affected by this issue.

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Customer acknowledges receipt of this notice:
I have read and understood the notice.

Signature:

Name:

Title:

Email:

Institution:

Please sign, print and return acknowledgement to Field Service or by Email
to:@mevion.com