⚠ IMPORTANT SAFETY NOTICE January 25, 2022

Subject: Unintended Isocenter change between Setup and Treatment Fields

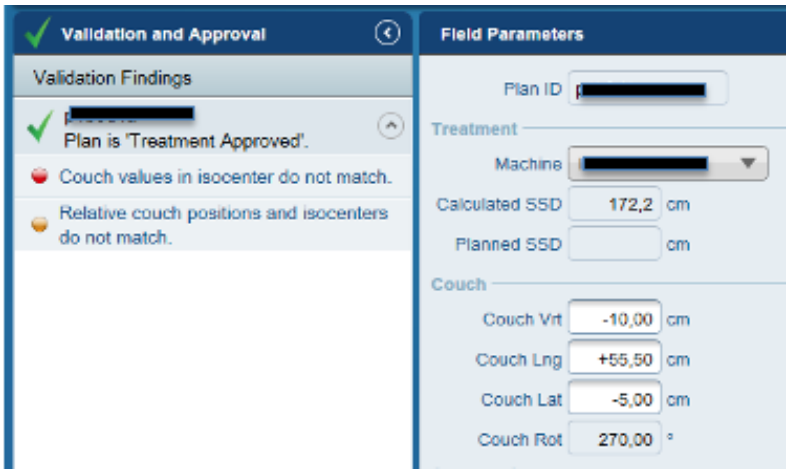
Statement of Problem

Within an OIS, a user may change only the Setup field isocenter of a treatment plan. When manually modifying the Setup field isocenter of a plan, the changes must be propagated to all Treatment fields
There are workflows to achieve this, such as:

- using the 'Couch Capture' function during a treatment session
- reapproving plans in the OIS after an isocenter change

Mevion was informed of an instance where a user changed only the Setup isocenter in ARIA in a previously approved plan, without propagating the change to all Treatment fields. The system generated a warning (shown here) which was ignored, and the OIS permitted the plan to be saved and the modified plan was used to treat additional times.

In such a situation a mistreatment may occur.



In addition, the Therapy Console (TC) checks for consistency of isocenter between all fields before allowing a plan to load. This check in the TC uses a tolerance table imported from the OIS through DICOM. The tolerance table used is the one associated with the first field in the field selection screen, typically the Setup field.

Mevion observed that the values in the OIS tolerance tables can be, and sometimes are, set to be so large they render the TC check meaningless. A user error of changing Setup isocenter without redoing the Treatment isocenters can

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result in a treatment which passes Setup imaging but delivers the treatment to the wrong location. If this error is not caught during chart reviews or noticed in the room during treatment, then multiple geographic misses may occur.

Determination of Cause

There are 2 factors identified when analyzing and determining the cause:
The User

- did not propagate the modification of the Setup field isocenter to all other fields and
- ignored the onscreen warning in the OIS and
- set the OIS tolerance tables to tolerances that render the TC check meaningless

The OIS

design permits Setup isocenter to be different from Treatment isocenters without plan reapproval.

Description of Potential Harm

A single normal fractionated treatment with a geographic miss may produce harm from marginal to critical depending on the area and size of the miss. Multiple fractions or a single hyper-fractionated treatment with a significant geographic miss may produce harm which could be lethal in some cases.

Containment or Mitigation

Containment

A notice will go out to all sites imminently to alert them to values in OIS tolerance tables which may currently be used in this TC check exceeding a 2 cm limit.

Mitigation

A software change to use internal values in the TC check on isocenter consistency between fields in a plan will not allow treatments where the isocenter differences are greater than a minimal value will be in the next release. Fields with planned iso-shifts will be properly accounted for.

Required User Action

1. Until a software upgrade is installed to correct the defect:
   - Physics needs to read and understand this notice
   - Physics needs to pay attention to our forthcoming notice(s) concerning the tolerances we find in their DICOM files
   - Therapists should use Couch Capture or Plan Re-approval for any changes in Setup field coordinates
2. When a software upgrade is offered with this change, it should be installed promptly.

Corrective Action

1. All users will be notified of this condition and the proper response.

2. A Mevion software upgrade (as described in the mitigation section) 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.

Lauren Baker
Project Manager, Clinical Applications and Training

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: robyn.walker@mevion.com