

Urgent Device Correction

Use of Previously Delivered Dose During Planning

Dear MRIdian User,

Issue:

ViewRay has become aware of an issue impacting the MRIdian System Treatment Planning and Delivery System (TPDS) software in use at your facility. The issue relates to an optional feature related to using previously delivered dose to make a new plan on MRIdian. ViewRay determined that in some cases dose previously delivered to a patient may not be accurately registered with the daily scan. There have been no reports of this issue affecting a patient.

Background:

The MRIdian TPDS software gives users the ability to import DICOM RT objects (i.e. Images, RT Structures, RT Dose) from previous patient treatments completed on either the MRIdian or on any other system supporting DICOM export. The user may use the TPDS software to sum previously delivered dose and structures to a newly created treatment plan in either the treatment planning or delivery workflows.

ViewRay determined that when the user registers dose and structures in the treatment delivery workflow this could result in an alignment discrepancy between the imported previously delivered dose and the displayed patient anatomy and structures. The TPDS software presents evidence of this misalignment to the user in the predicted DVH. However, depending on the magnitude of the misalignment the impact may not be obvious to the user. As a result, during plan re-optimization the previously delivered dose would be incorrectly accounted for by the software and may result in unexpectedly higher or lower dose than the intended dose calculated for the subsequent treatment plan.

When this issue occurs in the treatment planning workflow registration fails to align the dose with the image. If this behavior is observed, do not proceed with plan summation.

Action Required:

Do not: Sum previously delivered treatment plans in the treatment delivery workflow as it could result in delivery of a higher or lower dose.

Do not: proceed with plan summation if this issue is observed in planning workflow.

Do: contact ViewRay Customer Support for assistance when summing plans in the treatment planning workflow.

ViewRay is developing a resolution for this issue. You will be contacted by ViewRay Customer Support when a software resolution is available. If you have any questions, please do not hesitate to contact ViewRay Customer Support at support@viewray.com or call +1 855-286-8875.

Sincerely,

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