Urgent Device Correction

Dear MRIdian User,

ViewRay has identified a potential safety issue with the Treatment Planning and Delivery Software (TPDS) in use with the MRIdian System at your facility.

ViewRay received a report of a partially-completed patient treatment regimen moved from a non-ViewRay system to a MRIdian System for completion. The user created a new treatment plan for the full treatment course, including dose already delivered on the non-ViewRay system, with the TPDS software for evaluation. At this point the remaining dose and fractions were altered to account for the previously delivered dose, however the plan was not rescaled when optimizing target dose. The user changed the prescription with the expectation that the treatment plan would automatically be rescaled however the TPDS software requires the user to rescale the plan. This resulted in a higher dose per fraction than the physician intended.

Required Actions:

If you want to move a treatment plan from one system to another and still show the total original prescribed dose on the MRIdian TPDS you have multiple ways to do this.

1. Once you have evaluated the plan at the full dose, ensure the prescription matches the dose and number of fractions to be delivered on the MRIdian, and scale the dose to the target by either renormalizing or changing the target objective in the optimizer.

2. Keep the original total number of fractions (including those delivered elsewhere) in the prescription but when the plan is assigned to the fractions in the delivery calendar, "Discontinue" the number of fractions that have already been delivered on another system.

3. Import the previously delivered dose files into MRIdian as RTDose and fuse with the plan images. Optimize to the remaining target dose you want to deliver on MRIdian. Include the imported dose as Previously Delivered Dose and 'Calculate' in the Finish screen to display the full dose which has and will be delivered. Ensure the prescription matches the dose and number of fractions to be delivered on the MRIdian.

4. Import the previously delivered dose files into MRIdian as RTDose and fuse with the plan images. Optimize to the original total dose, including the Previously Delivered Dose as part of the optimization. Ensure the prescription matches the total dose and number of fractions including those treated elsewhere and those to be delivered on the MRIdian.

While we will address this issue in the next release of software, we recommend that you take note that the isodose values and DVH dose in the plan (excluding any dose

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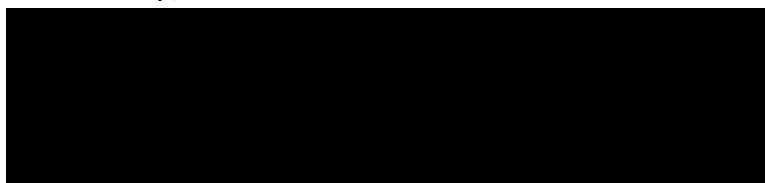Phone: +1 440.703.3210   Phone: +1 440.703.3210
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applied as 'Previously Delivered Dose') is what the system will deliver, and the daily dose per fraction will be that dose divided by the number of fractions in the prescription. The dose value in the prescription does not influence the optimizer at all.

Please confirm receipt of this document by sending an email to Debra Cavallaro at dcavallaro@viewray.com.

If you have any questions or concerns regarding this issue, please do not hesitate to contact ViewRay Customer Support at support@viewray.com or call the ViewRay Customer Support center at +1 855-286-8875.

Sincerely,

ViewRay, Inc.

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