

Urgent Medical Device Correction

May 4, 2021

French, Italian, and German language versions of MRIdian Linac Treatment Delivery System Software

Region of Interest Percent and Confidence Value values of the software in these versions cannot be modified by user

Dear MRIdian User,

ViewRay Inc. has identified two software anomalies affecting the French, German, and Italian language versions of the MRIdian Treatment Delivery System (TDS) software. User changes made to the Region of Interest Percent (ROI%) and Confidence Value are used by the system during treatment setup. The ROI% and Confidence Value values are entered by the user and displayed properly but the system in some scenarios does not use the values entered by the user but instead defaults to internally configured values. The actual values used by the system remain the default values. There have been no customer reports that a patient was affected by these issues.

Affected Systems:

- ViewRay is aware of four affected customers using the French version of the TDS software (Serial Numbers 214, 215, 226 and 240).
- ViewRay is not aware of any customers using the German or Italian versions of the TDS software (Serial Numbers 203, 232, 108, 244 and 228)
- These anomalies DO NOT affect the English version of the MRIdian TDS software.

Region of Interest Percent (ROI%) Summary

The first software anomaly involves the Region of Interest percent value (ROI%). The ROI% is the parameter that is used to allow a certain percentage of the target structure to be outside of the gating boundary until the beam is automatically paused off. Sections 6.35.3 and 9.14.2 of the MRIdian Operator's Manual describes the use of the ROI% value.

The user can adjust the ROI% value during RealTarget setup and tracking editing. The default value is zero percent. The ROI% is typically used as a parameter for treatments that involve the tracking of moving targets and customers typically set the ROI% value greater than zero percent. For treatments that involve targets that are stationary, and the target structure does not typically move outside the gating boundary, the ROI% value is less of a factor in treatment delivery.

If the user enters an ROI% value other than 5%, the ROI% value displayed does change to the value the customer entered but the actual ROI% value used by the MRIdian system is set to 5%.

Region of Interest Percent (ROI%) Potential Risks

There are three possible scenarios with potential risks that may result from this issue.

1. For customers that use a ROI% value of 5%, the system works as intended and there is no potential risk to the patient.
2. For customers that enter a ROI% greater than 5%, the system displays the larger value but uses 5% for the ROI%. In this scenario, the system may pause the radiation delivery more frequently using a more conservative ROI% criteria. The potential risk to the patient may be a prolonged procedure as the time needed to complete the radiation delivery may be lengthened.
3. For customers that enter a ROI% less than 5%, the system displays the smaller value but uses 5% for the ROI%. In this scenario, the system may pause the radiation delivery less frequently using a less conservative ROI% criteria. The potential risk to the patient may result in unintended dose to structures adjacent to the treatment target and may shorten the delivery time.

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Confidence Value Summary

The second software anomaly observed involves the Confidence Value. The Confidence Value is a metric that relates to the quality of the image deformation. The user can set a minimum threshold for the Confidence Value for the radiation beam to be triggered on. Section 9.14.5 of the MRIdian Operator's Manual describes the use of the Confidence Value.

The Confidence Value can only be adjusted by the user during tracking editing. The default value is 50. If the user enters a Confidence Value other than 50, the Confidence Value is displayed as entered by the user. However, the system continues to use the Confidence value of 50.

Confidence Value Potential Risks

There are three possible scenarios with potential risks that may result from this issue:

1. For customers that use a Confidence value of 50, the system works as intended and there is no potential risk to the patient.
2. For customers that enter a Confidence value less than 50, the system displays the smaller value but uses 50 for the Confidence Value. In this scenario, the system will not allow lower quality image deformation to be accepted and may pause the radiation delivery more frequently. The potential risk to the patient may be a prolonged procedure as the time needed to complete the radiation delivery may be lengthened.
3. For customers that enter a Confidence Value greater than 50, the system displays the larger value but uses 50 for the Confidence Value. In this scenario, the system will allow lower quality image deformation to be accepted and may pause the radiation delivery less frequently. The potential risk to the patient may result in unintended dose to structures adjacent to the treatment target and may shorten the delivery time.

Actions To Be Taken by Customer:

We will provide an update to customers when new information is available. Until that time:

- ☐ **Customers should be aware of these software anomalies and the behavior of the system described in this letter.**
- ☐ ***Please promptly complete and return the enclosed Customer Response Form to acknowledge receipt of this notification.***

Any device-related incidents should be reported to ViewRay, ViewRay's distributor or local representative. Adverse reactions or quality problems experienced with the use of this product may be reported to the Competent Authority if appropriate or to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

If you have any questions related to this letter, please contact ViewRay Customer Support at support@viewray.com or call +1 855-286-8875 toll free 24 hours a day, 7 days a week.

Sincerely,

Amanda Sequira
Senior Vice President Clinical, Quality and Regulatory
ViewRay Inc.

UDC 2021-001

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Customer Response Form

Please assist us in making this Urgent Medical Device Correction notification follow-up process efficient and convenient for you by completing and returning this form to ViewRay via email or fax. This response form serves as a confirmation that you have read and understood this notification and will take the recommended actions. A cover sheet is not required.

Email: Product Surveillance at ccr@viewray.com. Fax: +1-800-417-3459

(PLEASE PRINT)

Facility Name: _____

Facility Address: _____

Completed By: _____

Title: _____ Phone: _____

Email: _____

Signature: _____ Date: _____

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