

## Field Safety Notice, Medical Device Correction #11262

**RayStation 5**  
**May 24<sup>th</sup>, 2016**  
**RSL-D-61-293 v2**

### ISSUE

This notice concerns an issue found with the treatment plan report in RayStation 5. For a treatment plan with multiple beam sets, the table for ROI plan dose statistics in the report may show the statistics for a beam set dose.

To the best of our knowledge, the issue has not caused any patient mistreatment or other incidents. However, the user must be aware of the following information to avoid incorrect assessment of treatment plan dose levels.

### INTENDED AUDIENCE

This notice is directed to all users of RayStation 5.

### PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 5. To determine if the version you are using is affected, open the About RayStation dialog in the RayStation application and check if the build number reported there is "5.0.0.37", "5.0.1.11" or "5.0.2.35". If so, this notice applies to your version.

### DESCRIPTION

For a treatment plan consisting of multiple beam sets, the table for ROI plan dose statistics in the report may show the statistics for a beam set dose. The error can only be triggered when using a report template where statistics for a beam set dose is included as the last dose statistics prior to the plan dose statistics. For such a report template, all reports for multiple beam set plans would always be affected. The default template provided with RayStation 5 does not trigger the error as long as it has not been modified.

The error affects only the ROI plan dose statistics table and only in the plan report. If some other plan dose statistics section is included as the last dose statistics prior to the ROI dose statistics table, the error is not triggered.

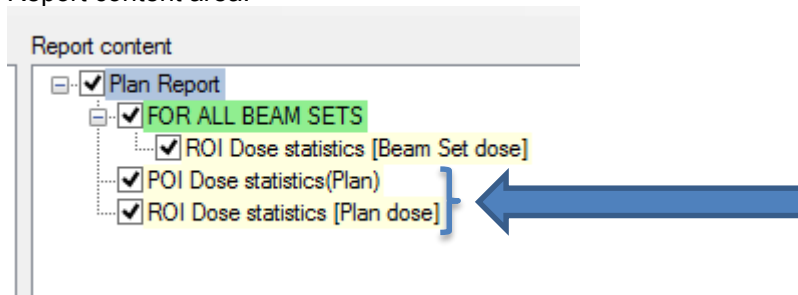
All information in the report except the ROI plan dose statistics will be correct. Evaluation information in the user interface is not affected by the error.

In the unlikely event that a clinical decision is based only on the erroneous ROI plan dose statistics in the plan report, this could lead to the approval of an inappropriate dose plan. A possible scenario would be if a risk organ had received close to the maximum allowed dose in an already delivered plan but due to the

error was displayed with a significantly lower pre-treated dose. This could lead to local over-dose in the risk organ from allowing too high of a dose in a future plan.

## ACTIONS TO BE TAKEN BY THE USER

Inspect all report templates that are intended to be used for plans with multiple beam sets. Make sure that “POI Dose statistics (Plan)” is included immediately before “ROI Dose statistics [Plan dose]” in the Report content area.



Please educate planning staff and all users about this workaround.

Inspect your product and identify all installed units with the above software version number, then confirm that you have read and understood this notice (contact information below).

## SOLUTION

This issue will be resolved in the next version of RayStation, scheduled for market release in December 2016. In the meantime, this field safety notice is distributed to all customers.

## TRANSMISSION OF THIS FIELD SAFETY NOTICE

This notice needs to be passed on to all those who need to be aware within your organization. Please maintain awareness of this notice as long as this version of RayStation is in use to ensure effectiveness of the workaround.

Thank you for your cooperation, and we apologize for any inconvenience.

For regulatory information, please contact David Hedfors, at +46 8 510 530 12 or [david.hedfors@raysearchlabs.com](mailto:david.hedfors@raysearchlabs.com)

The undersigned confirms that the appropriate Regulatory Agencies will be notified.

## REPLY FORM

### FIELD SAFETY NOTICE, MEDICAL DEVICE CORRECTION #11262 RAYSTATION 5 RSL-D-61-293 V2

Preferably, reply to the same email address that sent you this notice, stating you have read and understood it.

You can also email or phone your local support or [support@raysearchlabs.com](mailto:support@raysearchlabs.com), +46 8 510 533 33 to acknowledge this notice.

If you want to fill in this reply form, please send it to:

- Americas market: Freddie Cardel, [freddie.cardel@raysearchlabs.com](mailto:freddie.cardel@raysearchlabs.com), fax 888 501 7195
- Rest of the world: RaySearch Support, [support@raysearchlabs.com](mailto:support@raysearchlabs.com), no fax number

From: \_\_\_\_\_ (name of institution)

Contact person: \_\_\_\_\_ (please print)

Telephone no: \_\_\_\_\_

Email: \_\_\_\_\_

I have read and understood the notice.

Comments (optional):

---