

Field Safety Notice, Medical Device Correction #35469

RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6 and RayStation 7

9/21/18

RSL-D-61-363

ISSUE

This notice concerns an issue found with robust optimization in RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6 and RayStation 7. When using robust optimization functions the background dose is not taken into account, although in some cases it is displayed as such in the user interface.

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 creating treatment plans that are less robust than intended.

INTENDED AUDIENCE

This notice is directed to all users of RayStation who use robust optimization functions.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6 and RayStation 7. 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 "4.5.0.19", "4.5.1.14", "4.5.2.7", "4.7.0.15", "4.7.1.10", "4.7.2.5", "4.7.3.13", "4.7.4.4", "4.7.5.4", "5.0.0.37", "5.0.1.11", "5.0.2.35", "6.0.0.24", "6.1.0.26", "6.1.1.2", "6.2.0.7" or "7.0.0.19". If so, this notice applies to your version.

DESCRIPTION

Robust optimization for plans using beam set + background dose is not supported in RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6 and RayStation 7. It is not possible to define an optimization function as robust if the function relates to beam set + background dose when using these RayStation versions. However, the following cases allow robust functions to be added, which are displayed as if they relate to beam set + background dose:

- Adaptive Replanning (applies only to RayStation 7): When creating an adaptive plan from a plan with robust objectives, these are automatically added to the adaptive plan.
- Function templates: It is possible to use an optimization function template with robust functions for a dependent beam set.
- Scripting: It is possible to use scripting to add robust optimization functions to a dependent beam set.

For these cases, the robust functions are displayed as if they relate to beam set + background dose. However, only the current beam set is taken into account during optimization and background dose will not be considered for the perturbed scenarios. Background dose is only accounted for in the nominal scenario.

This may lead to that a too high dose is allowed in the optimization, since the dose level in the objective function is based on beam set + background dose, but only the beam set dose is considered for that objective function in the perturbed scenarios. The resulting plan is typically less robust than intended. The magnitude of the error depends on the background dose level.

For target objectives, the error will most likely push the optimization to a too high target dose that is easy to detect. For an OAR (Organ At Risk) objective, too high dose may be allowed, and the problem may not always be detectable in the nominal dose. However, detectability is always high when using the Compute Perturbed Dose function in the Plan Evaluation module to evaluate the perturbed scenarios, as recommended in the RayStation Instructions for Use:

WARNING!



Evaluate the dose after robust optimization. After a robust optimization has been performed, the user is strongly advised to evaluate the dose using the perturbed dose tool in the Plan Evaluation module to verify that the dose is robust as intended. (114973)

ACTIONS TO BE TAKEN BY THE USER

- After creating an adaptive plan from a plan with robust objectives, remove all robust objectives that are automatically added to the adaptive plan and replace them with other appropriate objectives before optimizing the adapted plan.
- Do not use an optimization function template with robust functions for a dependent beam set.
- Do not use scripting to add robust optimization functions related to beam set + background dose.

Please educate planning staff and all users about this workaround.

Inspect your product and identify all installed units with the above software version number(s), then confirm that you have read and understood this notice by replying to the notification email.

SOLUTION

This issue is resolved in RayStation 8A, (subject to market clearance in some markets). If customers wish to continue using versions of RayStation affected by this notice, all users must maintain awareness of this notice. Alternatively, customers can choose to upgrade to the new version once it becomes available for clinical use.

TRANSMISSION OF THIS 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 any version of RayStation affected by this issue 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 quality@raysearchlabs.com

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

PLEASE CONFIRM THAT YOU HAVE RECEIVED THIS NOTICE

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

Alternatively, you can email or phone your local support to acknowledge this notice.

If you want to attach a signed reply form to the email, please fill in the below. You can also fax this form to 888 501 7195 (US only).

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):
