

Field Safety Notice, Medical Device Correction #11905

**RayStation 3.0, RayStation 3.5,
RayStation 4.0, RayStation 4.5,
RayStation 4.7 and RayStation 5
July 1st, 2016
RSL-D-61-298**

ISSUE

This notice concerns an issue found with the evaluation of biological clinical goals in RayStation 3.0, RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7 and RayStation 5. Biological clinical goals for an adapted plan based on another planning CT than the original planning CT will show incorrect values.

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 plan evaluation during treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation 3.0, 3.5, 4.0, 4.5, 4.7 and 5, who uses adaptive replanning (rayAdaptive) in combination with biological models (rayBiology). The issue can only occur for a user licensed for rayAdaptive and rayBiology concurrently.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 3.0, RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7 and 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 "3.0.0.251", "3.5.0.16", "3.5.1.6", "4.0.0.14", "4.0.1.4", "4.0.2.9", "4.0.3.42", "4.5.0.19", "4.5.1.14", "4.5.2.7", "4.7.0.15", "4.7.1.10", "4.7.2.5", "4.7.4.4", "4.7.5.4", "5.0.0.37", "5.0.1.11" or "5.0.2.35". If so, this notice applies to your version.

DESCRIPTION

Biological clinical goals for an adapted plan based on a new CT (not the planning CT used for the original plan) are evaluated using incorrect dose values and will therefore display incorrect values. The issue is present in all views displaying biological clinical goals, for adapted plans based on a new CT.

The magnitude of the error is irregular and largely dependent on the differences between the original planning CT and the new CT. The computed TCP/NTCP values may be smaller or larger than the correct values.

The error affects biological clinical goals, both TCP and NTCP. Neither the biological evaluation views, nor the biological objective functions are affected. Physical clinical goals are not affected.

ACTIONS TO BE TAKEN BY THE USER

- Do not use the values displayed for biological clinical goals in clinical decision making when performing adaptive replanning.
- The user is referred to using corresponding biological objective functions or biological functions defined in the Biological Evaluation module. These are evaluated correctly.
- As stated in the RayStation Instructions for Use, always evaluate the physical 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, then confirm 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 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

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

REPLY FORM

FIELD SAFETY NOTICE, MEDICAL DEVICE CORRECTION #11905 RAYSTATION 3.0, RAYSTATION 3.5, RAYSTATION 4.0, RAYSTATION 4.5, RAYSTATION 4.7 AND RAYSTATION 5 RSL-D-61-298

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, +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, fax 888 501 7195
- Rest of the world: RaySearch Support, 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):
