

Field Safety Notice, Medical Device Correction #20673

RayStation 6 (including SP1 and SP2) July 14, 2017 RSL-D-61-337

ISSUE

This notice concerns an issue found with the proton QA preparation module in RayStation 6 (including SP1 and SP2). If the Snout Position or Gap is modified in the QA module, the dose in the QA module may be computed for a different setup than what is used for QA measurements.

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 dose calculations during QA preparation.

INTENDED AUDIENCE

This notice is directed to all users of RayStation 6 proton planning.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 6 (including SP1 and SP2). 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 "6.0.0.24", "6.1.0.26", "6.1.1.2" or "6.2.0.7". If so, this notice applies to your version.

DESCRIPTION

When editing Snout Position in the QA Preparation module, either directly or by adjusting Gap, RayStation preserves the geometrical properties of block and compensator projected onto the isocenter plane. This means that the physical size of the block and compensator used for dose computation in the RayStation QA plan changes, and consequently the dose in the QA module may be computed for a physical block and/or compensator setup that differs from the setup that was specified in the treatment plan and used for QA measurements.

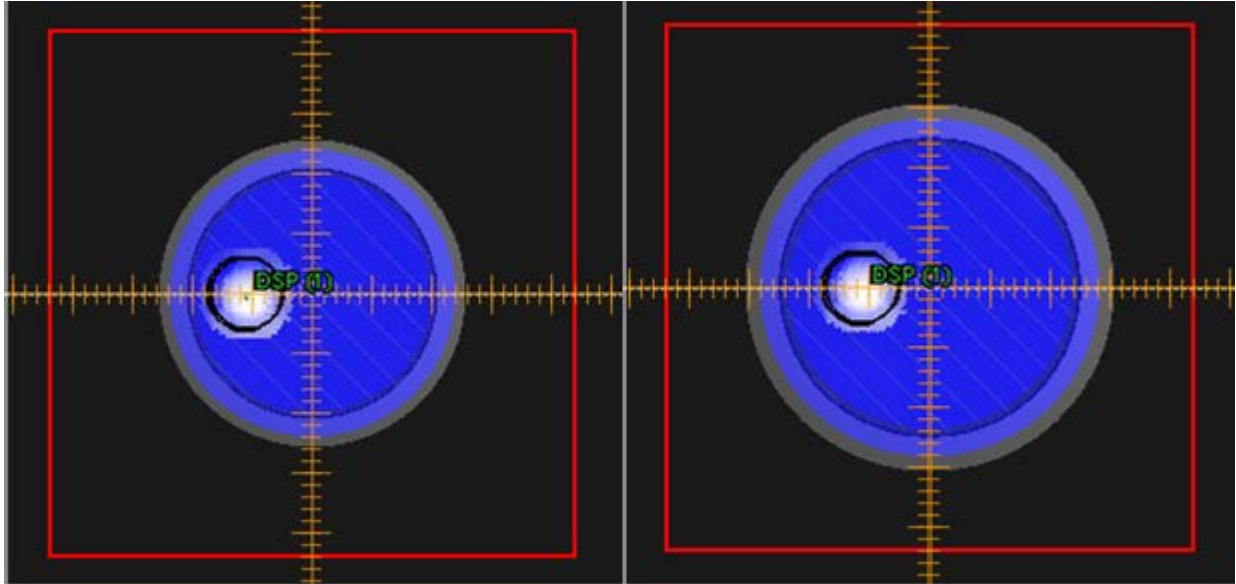


Fig. 1: BEV showing Snout position (i.e. the isocenter to snout position plane distance) = 20 cm (Left) vs Snout position = 50 cm (Right).

Snout is moved relative to the isocenter and the block/compensator geometry at isocenter is maintained, resulting in a change of physical block/compensator size in the QA plan.

For passive proton techniques (Uniform Scanning, Double Scattering, Wobbling), RayStation does not compute absolute dose and the monitor unit (MU) for treatment must be calculated based on measured output. If the calculated dose for a modified QA plan is used for determining the output factor, the resulting treatment MU may be wrong. The magnitude of the error will depend on the size of the snout adjustment and on the beam model and field setup. The maximum deviation found during testing is 4% dose deviation. The error is not easy to detect in RayStation, but should be visible in plan QA if computed dose is compared to 2D or line dose measurements.

In RayStation 6 SP1 and SP2, all proton techniques supporting block and/or compensator are affected. In RayStation 6, it is not possible to edit Snout Position, but Gap can be edited for proton PBS and Line Scanning plans with block.

ACTIONS TO BE TAKEN BY THE USER

- Do not modify Snout Position or Gap for proton QA plans with block and/or compensator.
- If the air gap needs to be adjusted in the QA plan to avoid collision with the phantom, edit the Isocenter position. This will preserve the block and compensator geometry in RayStation to match the block and compensator geometry that was manufactured according to the treatment plan.

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 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 2017. 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 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 David Hedfors, at david.hedfors@raysearchlabs.com

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

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REPLY FORM

FIELD SAFETY NOTICE, MEDICAL DEVICE CORRECTION #20673 RAYSTATION 6 (INCLUDING SP1 AND SP2) RSL-D-61-337

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):
