

## Urgent Field Safety Notice, Medical Device Correction #60564

**RayStation 4, 4.5, 4.7, 5, 6, 7, 8A, 8B,  
9A and 9B (including all service  
packs)  
May 18, 2020  
RSL-D-61-422**

### ISSUE

This notice concerns an issue found with the proton Pencil Beam Scanning (PBS) and Line Scanning (LS) dose calculation algorithms in RayStation 4, 4.5, 4.7, 5, 6, 7, 8A, 8B, 9A and 9B (including all service packs). The effect of the issue is that robustly optimized plans using tangential fields may exhibit hot spots in the vicinity of the patient surface/skin in the delivered dose. These hot spots would not be visible in dose calculated with the RayStation proton pencil beam dose engine.

The issue can also be relevant for robustness analysis, and dose tracking of non-robust optimized plans using tangential fields. This issue is relevant for any dose computed with the analytical pencil beam (PB) dose engine, and the non-clinical optimization dose of the Monte Carlo (MC) dose engine. The issue is not relevant for the clinical MC dose engine, which handles the tangential fields correctly.

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 treatment planning.

### INTENDED AUDIENCE

This notice is directed to all users of RayStation who use Proton PBS/LS planning.

### PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 4, 4.5, 4.7, 5, 6, 7, 8A, 8B, 9A and 9B (including all service packs). 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 "4.0.3.4", "4.5.1.14", "4.7.2.5", "4.7.3.13", "4.7.4.4", "4.7.5.4", "4.7.6.7", "5.0.1.11", "5.0.2.35", "5.0.3.17", "6.0.0.24", "6.1.1.2", "6.2.0.7", "6.3.0.6", "7.0.0.19", "8.0.0.61", "8.0.1.10", "8.1.0.47", "8.1.1.8", "8.1.2.5", "9.0.0.113", "9.1.0.933" or "9.2.0.483". If so, this notice applies to your version.

The UDI-DI of the affected products:

Product name (build number)	UDI-DI
RayStation 4.0 (4.0.0.14) to RayStation 5 Service Pack 2 (5.0.2.35)	N/A
RayStation 5 Service Pack 3 (5.0.3.17)	07350002010020
RayStation 6 (6.0.0.24)	07350002010013
RayStation 6 Service Pack 1 (6.1.1.2)	07350002010037, 07350002010082
RayStation 6 Service Pack 2 (6.2.0.7)	07350002010075

RayStation 6 Service Pack 3 (6.3.0.6)	07350002010242
RayStation 7 (7.0.0.19)	07350002010068
RayStation 8A (8.0.0.61)	07350002010112
RayStation 8A Service Pack 1 (8.0.1.10)	07350002010136
RayStation 8B (8.1.0.47)	07350002010129
RayStation 8B Service Pack 1 (8.1.1.8)	07350002010204
RayStation 8B Service Pack 2 (8.1.2.5)	07350002010235
RayStation 9A (9.0.0.113)	07350002010174
RayStation 9B (9.1.0.933)	07350002010266
RayStation 9B Service Pack 1 (9.2.0.483)	07350002010297

## DESCRIPTION

An issue has been found in the proton PBS/LS dose engine in which the dose from spots whose central axis does not intersect the External ROI is excluded from the dose calculation, despite the fact that they partially may enter the External ROI and deposit dose in the patient. This issue occurs in the analytical pencil beam dose engine for optimization and final dose calculation. The dose error is also present in the proton Monte Carlo (MC) optimization dose engine, which only generates non-clinical dose. However, all spots are handled correctly in the PBS/LS MC dose engine for clinical final dose calculation.

Spots that fall outside of the External ROI can be generated when performing robust optimization for tangential fields where the target is close to the External ROI surface. Robust optimization here also includes optimization using multiple image sets, for example, 4D optimization. Non-robustly optimized plans will not create spots outside the External ROI. Other possible use cases where spots can end up outside the External ROI include dose computation of perturbed doses (including robust evaluation), and dose computation on additional data sets performed in the Plan evaluation module. Spots can also fall outside the External ROI in the Dose tracking module, since the patient data will differ from the patient data used for the original plan. It is also possible to generate spots outside of the External ROI by manually adding/moving spots, or by manipulating the isocenter, gantry angle or patient orientation for an existing plan.

The effect of this issue is that the delivered dose may exhibit hot spots in the vicinity of the patient surface/skin. These hot spots would not be visible in the planned dose in RayStation when the analytical pencil beam dose engine is used to generate clinical dose. These hot spots may also occur after optimization using the MC dose engine, but they would then be visible in the proton MC dose calculation for final dose. This also holds true for dose calculations in the Plan evaluation and Dose tracking modules.

The detectability of this error is low when the analytical pencil beam dose engine is used since the error is present also in the clinical dose. However, a suboptimal plan will likely be revealed in robustness evaluation analysis of the plan, also when the pencil beam dose engine is used, a fact that increases the detectability of the problem. Robust evaluation analysis of robust plans is part of the clinical practice, and the RayStation Instructions for Use strongly advises the users to evaluate a robustly optimized plan in the Plan evaluation module to verify that the plan is robust as intended.

When using the MC dose engine, detectability of the error in the optimization dose is very high, since the correct dose is computed and displayed in the mandatory final dose computation.

There is an easy workaround to avoid this problem, namely, to expand the External ROI so that the central axis of all spots will intersect with the External ROI.

## ACTIONS TO BE TAKEN BY THE USER

- Always use the MC dose engine for final dose calculation, in robustness analysis, and dose tracking if possible. The MC dose engine is available in versions RayStation 6.0 and later.
- If the pencil beam dose engine is used for final dose calculation, ensure that all spots intersect the External ROI as seen in the Beams Eye View (BEV) of the Plan optimization module. If they do not, expand the External ROI so that all spots do intersect the External ROI, and reoptimize the plan if necessary.
- If the MC dose engine is used for final dose calculation, and hot spots related to tangential fields are observed, expand the External ROI so that the central axis of all spots intersect the External ROI and reoptimize the plan.
- Educate planning staff and all users about this workaround.
- Inspect your product and identify all installed units with the above software version number(s).
- **Confirm you have read and understood this notice by replying to the notification email.**

## SOLUTION

This issue will be resolved in the next version of RayStation, scheduled for market release in June 2020 (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](mailto:quality@raysearchlabs.com)

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

[Redacted signature block]

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# CONFIRMATION OF RECEIPT

**PLEASE CONFIRM THAT YOU HAVE RECEIVED THIS FSN**

**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.

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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):

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