Field Safety Notice, Medical Device Correction #148655

RayStation version 4.5 to 2024B including some service packs

To determine if your version is affected, see build numbers listed in PRODUCT NAME AND VERSION below

January 17, 2025

RSL-P-RS FSN Class III 148655

ISSUE

This notice concerns an issue found with the handling of the density uncertainty in *Robust optimization* and *Plan evaluation* for proton and light ion plans of RayStation version 4.5 to 2024B including some service packs.

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 misleading robust evaluation results during treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation version 4.5 to 2024B, who use *Compute perturbed dose* or *Robust evaluation* for proton or light ion treatment plans in the *Plan evaluation* module.

PRODUCT NAME AND VERSION

The products affected by this notice are sold under the trade names RayStation version 4.5 to 2024B including some 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 “4.5.1.14-5.0.2.35”, “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”, “9.0.1.142”, “9.1.0.933”, “9.2.0.483”, “10.0.0.1154”, “10.0.1.52”, “10.0.2.10”, “10.1.0.613”, “10.1.1.54”, “11.0.0.951”, “11.0.1.29”, “11.0.3.116”, “11.0.4.15”, “12.0.0.932”, “12.1.0.1221”, “12.0.3.68”, “12.0.4.12”, “12.3.0.119”, “13.0.0.1547”, “13.1.0.144”, “13.1.1.89”, “14.0.0.3338”, “15.0.0.430”, “15.1.0.852”, or “16.0.0.847”. If so, this notice applies to your version.

The single registration number (SRN) of the manufacturer: SE-MF-000001908

Product name	Build number	UDI-DI
RayStation 4.5.1 to RayStation 5 Service Pack 2	4.5.1.14-5.0.2.35	N/A
RayStation 5 Service Pack 3	5.0.3.17	073500020100202017050 2
RayStation 6	6.0.0.24	07350002010013201612 14
RayStation 6 Service Pack 1	6.1.1.2	07350002010082201705 29
RayStation 6 Service Pack 2	6.2.0.7	07350002010075201706 30
RayStation 6 Service Pack 3	6.3.0.6	07350002010242201909 23

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Product name	Build number	UDI-DI
RayStation 7	7.0.0.19	073500020100682017113O
RayStation 8A	8.0.0.61	07350002010112201806O8
RayStation 8A Service Pack 1	8.0.1.10	07350002010136201809O8
RayStation 8B	8.1.0.47	07350002010129201812O9
RayStation 8B Service Pack 1	8.1.1.8	07350002010204201902I4
RayStation 8B Service Pack 2	8.1.2.5	07350002010235201905O4
RayStation 9A	9.0.0.113	07350002010174201906I2
RayStation 9A Service Pack 1	9.0.1.142	07350002010488202204O0
RayStation 9B	9.1.0.933	07350002010266201912O0
RayStation 9B Service Pack 1	9.2.0.483	07350002010297202003I0
RayStation 10A	10.0.0.1154	07350002010303202005O6
RayStation 10A Service Pack 1	10.0.1.52	07350002010365202005O6
RayStation 10A Service Pack 2	10.0.2.10	07350002010655202206O8
RayStation 10B	10.1.0.613	07350002010310202012I6
RayStation 10B Service Pack 1	10.1.1.54	07350002010471202201I8
RayStation 11A	11.0.0.951	07350002010389202105I8
RayStation 11A Service Pack 1	11.0.1.29	07350002010433202106I0
RayStation 11A Service Pack 2	11.0.3.116	07350002010440202109I6
RayStation 11A Service Pack 3	11.0.4.15	07350002010631202206I6
RayStation 11B	12.0.0.932	07350002010426202112O8
RayStation 11B Service Pack 1	12.1.0.1221	07350002010495202203I2
RayStation 11B Service Pack 2	12.0.3.68	07350002010501202204I2
RayStation 11B Service Pack 3	12.0.4.12	07350002010600202206I0
RayStation 11B Service Pack Toshiba 1	12.3.0.119	07350002010570202212I2
RayStation 12A	13.0.0.1547	07350002010549202206I6
RayStation 12A Service Pack 1	13.1.0.144	07350002010679202210O7
RayStation 12A Service Pack 2	13.1.1.89	07350002010730202309I3
RayStation 2023B	14.0.0.3338	07350002010556202306I0
RayStation 2024A	15.0.0.430	07350002010723202312I3
RayStation 2024A SP1	15.1.0.852	07350002010761202405O8
RayStation 2024B	16.0.0.847	07350002010778202406I5

DESCRIPTION

This notice is to inform about an inconsistency in the use of *Density uncertainty* in the RayStation functions *Robust optimization*, *Robust evaluation* and *Compute perturbed dose* for proton and light ion treatment plans when a HU-to-mass density CT calibration curve is used.

In *Robust evaluation* and *Compute perturbed dose*, in cases when a HU-to-mass density CT calibration curve is used, the density uncertainty is added to the nominal mass densities of the patient *prior to* the elemental composition assignment of the voxels. This handling is in line with the description in the UI, which states that *"The density uncertainty is modelled by scaling the mass density of the patient"*. However, since the stopping power is not a linear function of the mass densities found in a patient, a scaling of the mass densities prior to the elemental composition assignment of the voxels will not lead to a corresponding scaling of stopping power and water equivalent (WE) range. The result is that the relative change in stopping power and WE range will be less than the given change in mass density. For example, for a

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prostate case with a distal depth of 240 mm, a density change of -3.5% will lead to an increased range of about 6 mm. However, an increase of 6 mm in range corresponds to only -2.5% change in stopping power, and +2.5% in range. If the change of -3.5% is applied to the stopping power instead of the mass density, the resulting change in range would be 8.4 mm, which is 2.4 mm more than the 6 mm resulting from the same change in mass density. While the handling of scaling the patient's mass densities is not incorrect, a user may assume that a change of the mass density in the RayStation UI would lead to a corresponding change in stopping power and WE range.

In *Robust optimization*, on the other hand, the stopping power and WE range of the scenario doses do scale according to the *Density uncertainty* given in the *Robustness settings* dialog. This is explained by the fact that the mass densities used in the dose calculation of the robust optimization are scaled *after* the elemental composition assignment of the voxels. This behavior is inconsistent with the behavior in *Robust evaluation* and *Compute perturbed dose* as described above, but may be more in line with what the user expects (i,e, that the given uncertainty is related to stopping power and WE range, rather than mass density). For RayStation 10A and earlier versions, the density/stopping power uncertainty in the *Optimization Settings Robustness* dialog was correctly labeled as "Range uncertainty". However, from RayStation 10B an onwards, it was relabeled as "Density uncertainty" to harmonize with the labeling in *Plan evaluation*. But, considering the different handling of *Density uncertainty* in *Plan evaluation* as described above, the labeling of the uncertainty in *Robust optimization* as "Density uncertainty" could be misleading.

For plans that are based on a HU-to-SPR CT-calibration curve, the density uncertainty given in *Robust evaluation*, *Compute perturbed* dose and *Robust optimization* is used directly to scale stopping power and therefore WE range. This is in contrast to the description of the functions in the UI, which states that it is the mass density that is scaled (see above).

For patient volumes associated with a material override, only the mass density of those volumes is affected by the density uncertainty while the elemental composition remains unchanged. This means that the stopping power in volumes with a material override will scale according to the user-defined mass density uncertainty for all functions in RayStation and irrespective of type of CT calibration curve.

For a user who evaluates a plan based on a HU-to-mass density CT calibration curve, and who expects that the given uncertainty in density will lead to a corresponding change in stopping power and WE range, the detectability of the inconsistency is likely low since the difference for limited range plans is not that large. Furthermore, if the plan has been robustly optimized, it is more likely to pass a robust evaluation, since the density perturbation in evaluation will lead to smaller changes in dose than in the optimization (assuming that the same density uncertainty was used for robust optimization and evaluation).

ACTIONS TO BE TAKEN BY THE USER

- Inspect your product and identify all installed units with the above software version number(s).
- Educate planning staff and all users on how the density uncertainty is used in RayStation as described in section DESCRIPTION, and about the workarounds suggested below.
- **Confirm you have read and understood this notice by replying to the notification email.**

For users of HU-to-mass density CT calibration curves

If a user wants to evaluate a plan with respect to relative stopping power/WE range error rather than mass density errors, there are two options:

Option 1. Use a HU-to-SPR CT calibration curve instead of a HU-to-mass density curve.

- For evaluation of an existing case, the evaluation can be done on an anonymized and exported copy of the patient and plan.
- Contact RaySearch Service if you need help with the creation of a HU-to-SPR curve from an existing HU-to-mass density curve.

Option 2. Evaluate the plan using a higher (effective) mass density uncertainty that gives similar relative stopping power and WE range change as the nominal value.

- The following values of Effective mass density errors that give similar result as an intended Stopping power error have been deduced from a limited set of patients:

Stopping power error (%)	Effective mass density error (%)
-3.5	-4.7
3.5	4.2
-2.0	-3.0
2.0	2.2

- For other values of intended Stopping power error, interpolate the approximate Effective mass density value from the table above.
- The values are estimates based on a few patients and are expected to vary slightly depending on the mass densities along the beam path.
- Note that the values are not symmetrical around 0.

For users of HU-to-SPR CT calibration curves

Be aware that the density uncertainty given in *Robust evaluation*, *Compute perturbed* dose and *Robust optimization* is used directly to scale stopping power and therefore WE range.

SOLUTION

Starting from RayStation v2025, scheduled for market release in April 2025 (subject to market clearance in some markets), the impact of the mass density uncertainty in *Robust evaluation* and *Compute perturbed dose* when using a HU-to-mass density CT calibration curve will be changed to harmonize with the other use cases. This means that as of RayStation v2025, the impact of mass density uncertainty will be implemented such that the relative change in stopping power and WE range will follow the given change in

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mass density for all RayStation functions and for both types of CT calibration. The description of the functions in the UI and the product documents will be updated to better describe the meaning and effect of the mass density uncertainty.

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. Maintain awareness of this notice as long as any affected version is in use.

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

For regulatory information, please contact quality@raysearchlabs.com.

RaySearch will notify the appropriate regulatory agencies about this Field Safety Notice.

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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.

If you want to attach a signed reply form to the email, please fill in the below. You can also fax this form to Fax: +1-631-828-2137 (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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