Field Safety Notice, Medical Device Correction #167168

RayStation/RayPlan 10B, 11A, 11B, 12A, 2023B, 2024A, 2024B and v2025 including some service packs

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

November 28, 2025

RSL-P-RS FSN Class III 167168

ISSUE

This notice concerns an issue found with the dose invalidation in RayStation/RayPlan 10B, 11A, 11B, 12A, 2023B, 2024A, 2024B and v2025 including some service packs.

In rare cases, the invalidation for calculated radiation dose does not work as intended for certain Regions of Interest (ROIs). This issue occurs for some ROI(s) which have no contours and either have a material override defined, or are of type Bolus, Fixation, or Support. In these cases, adding geometry to the ROI, subsequently modifying geometry, or removing the material override does not invalidate dose as intended.

To the best of our knowledge, the issue has not caused any patient mistreatment. 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 edit Regions of Interest with material override or type Bolus, Fixation or Support.

PRODUCT NAME AND VERSION

The products affected by this notice are sold under the trade names RayStation/RayPlan 10B, 11A, 11B, 12A, 2023B, 2024A, 2024B and v2025 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 one of the build numbers listed in the table below. 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/RayPlan 10B	10.1.0.613	073500020103102020121 6
RayStation/RayPlan 10B SP1	10.1.1.54	07350002010471202201 31
RayStation/RayPlan 11A	11.0.0.951	07350002010389202105 18
RayStation/RayPlan 11A SP1	11.0.1.29	07350002010433202106 10
RayStation/RayPlan 11A SP2	11.0.3.116	07350002010440202109 16

RayStation/RayPlan 11A SP3	11.0.4.15	073500020106312022061 6
RayStation/RayPlan 11B	12.0.0.932	073500020104262021120 8
RayStation/RayPlan 11B SP1	12.1.0.1221	073500020104952022031 2
RayStation/RayPlan 11B SP2	12.0.3.68	073500020105012022042 2
RayStation/RayPlan 11B SP3	12.0.4.12	073500020106002022062 0
RayStation/RayPlan 11B SPT1	12.3.0.119	073500020105702022122 2
RayStation/RayPlan 12A	13.0.0.1547	073500020105492022061 6
RayStation/RayPlan 12A SP1	13.1.0.144	073500020106792022100 7
RayStation/RayPlan 12A SP2	13.1.1.89	073500020107302023091 3
RayStation/RayPlan 2023B	14.0.0.3338	073500020105562023063 0
RayStation/RayPlan 2024A	15.0.0.430	073500020107922024052 3
RayStation/RayPlan 2024A SP1	15.1.0.852	073500020107612024050 8
RayStation/RayPlan 2024A SP2	15.2.0.107	073500020108082024121 7
RayStation/RayPlan 2024A SP3	15.1.3.10	073500020108842025012 9
RayStation/RayPlan 2024B	16.0.0.847	073500020107782024062 5
RayStation/RayPlan v2025	17.0.0.1270	073500020108222025042 3
RayStation/RayPlan v2025 SP1	17.0.1.113	073500020109452025070 2

DESCRIPTION

In rare cases, the invalidation for calculated radiation dose does not work as intended for certain Regions of Interest (ROIs).

This issue occurs for ROI(s) which has no contours and either has a material override defined, or is of type Bolus, Fixation, or Support. It only occurs for ROI(s) that have no contours defined on the image set but have a PrimaryShape. An ROI geometry can reach this state when, e.g., all contours for the ROI have been removed from an image set using a contouring tool, or when a derived ROI is updated or overridden in a way that results in an empty geometry (for example when a derived ROI is the intersection of two ROIs that have no overlap in the image set). After the dose is computed, adding geometry to the ROI, subsequently modifying geometry, or removing the material override does not invalidate dose as intended.

The user will get a warning that dose statistics are not up to date, but when these are recomputed, they are based on the obsolete dose distribution.

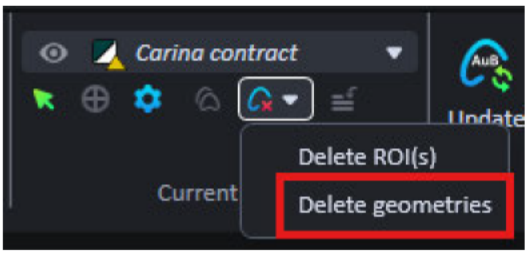
The treatment plan can be approved and exported with the dose in this inconsistent state.

Dose cannot be recomputed unless the user makes another change that invalidates the dose. However, if dose is recomputed or optimization is redone, the ROI material and geometry will be used correctly.

To avoid the error:

When a plan or dose exists on an image set and changes are needed to an ROI that has no geometry defined on the image set and has MO, or is of type Bolus, Fixation or Support, do the following before adding geometry to the ROI:

1. Use ‘Delete geometry’ (RayStation 10B-12A) or ’Delete geometries’ (RayStation 2023B-v2025) for the ROI on the image set:



This will remove the PrimaryShape of the geometry.

2. Add the desired geometry

Dose will be invalidated when adding the geometry and invalidation will work as expected if further changes are made to the ROI.

ACTIONS TO BE TAKEN BY THE USER

- Follow the steps above when adding geometry to an empty ROI with MO or of type Bolus, Fixation or Support.

- 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 December 2025 (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.

The upgrade to an unaffected software version will be scheduled in coordination with the authorized personnel, considering the specific circumstances and requirements of each individual case. The upgrade may be conducted remotely or onsite, as deemed appropriate.

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.

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.

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):

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