Field Safety Notice, Medical Device Correction #84236

RayStation/RayPlan versions 4 - 11A, including service packs
To determine if your version is affected, see build numbers listed in PRODUCT NAME AND VERSION below
September 22, 2021
RSL-P-RS FSN Class III 84236

ISSUE

This notice concerns an issue in the density handling of voxels intersected by both the External ROI and an ROI of type Support, Fixation or Bolus in all RayStation/RayPlan versions 4 - 11A, including 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 incorrect dose calculations during treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation who use RayStation for electron, proton, helium and carbon planning and to all users of RayPlan who use RayPlan for electron planning. For photons the effect of the error will be negligible compared to other uncertainties.

PRODUCT NAME AND VERSION

The products affected by this notice are sold under the trade names RayStation/RayPlan versions 4 - 11A, including service packs. To determine if the version you are using is affected, open the About RayStation dialog in the RayStation/RayPlan application and check if the build number reported there is 4.0.0.14, 4.0.3.4, 4.3.0.14, 4.5.1.14, 4.7.2.5, 4.7.3.13, 4.7.4.4, 4.7.5.4, 4.7.6.7, 4.9.0.42, 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, 9.2.0.483, 10.0.0.1154, 10.0.1.52, 10.1.0.613, 11.0.0.951 or 11.0.1.29. If so, this notice applies to your version.

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

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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/RayPlan 2 (6.0.0.24)	07350002010013
RayStation 6/RayPlan 2 Service Pack 1 (6.1.1.2)	07350002010082
RayStation 6/RayPlan 2 Service Pack 2 (6.2.0.7)	07350002010075
RayStation 6/RayPlan 2 Service Pack 3 (6.3.0.6)	07350002010242
RayStation/RayPlan 7 (7.0.0.19)	07350002010068
RayStation/RayPlan 8A (8.0.0.61)	07350002010112
RayStation/RayPlan 8A Service Pack 1 (8.0.1.10)	07350002010136
RayStation/RayPlan 8B (8.1.0.47)	07350002010129
RayStation/RayPlan 8B Service Pack 1 (8.1.1.8)	07350002010204
RayStation/RayPlan 8B Service Pack 2 (8.1.2.5)	07350002010235
RayStation/RayPlan 9A (9.0.0.113)	07350002010174
RayStation/RayPlan 9B (9.1.0.933)	07350002010266
RayStation/RayPlan 9B Service Pack 1 (9.2.0.483)	07350002010297
RayStation/RayPlan 10A (10.0.0.1154)	07350002010303
RayStation/RayPlan 10A Service Pack 1 (10.0.1.52)	07350002010365
RayStation/RayPlan 10B (10.1.0.613)	07350002010310
RayStation 11A (11.0.0.951)	07350002010389
RayStation 11A Service Pack 1 (11.0.1.29)	07350002010433

DESCRIPTION

For all dose computations, a density is assigned to each dose grid voxel. The density in a voxel is a combination of underlying CT voxels resampled to the dose grid resolution, and density from ROIs with material override that cover at least part of the voxel.

This notice concerns an issue where the combined density in a dose grid voxel partially covered by the External ROI and also partially covered by an ROI of type Bolus, Support or Fixation may be unexpected. The density in the voxel can be both under- and overestimated. An example where the density is overestimated at the border between a Bolus ROI and the External ROI is shown in Figure 1.

The magnitude of the issue will depend on how the External ROI contour cuts the dose grid voxels at the CT density/air border. The issue will be smaller or non-existent, if the External ROI corresponds well with the CT density/air border. See Figure 2 for an example of the effect for different External ROI contours.

It is recommended to use the automatic tool in RayStation/RayPlan to create the External ROI, but the issue might still be present. Larger problems can occur if the External ROI is imported from another system or manually edited.

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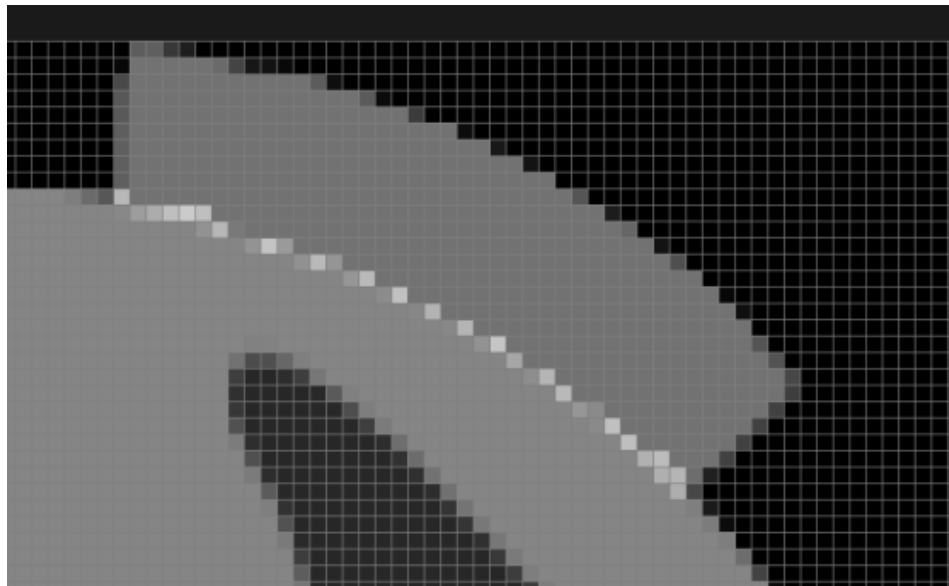www.raysearchlabs.com   Page 2 (6)

Figure 1. An example where the density is overestimated at the border between a Bolus ROI and the External ROI. The image shows density re-sampled to dose grid voxel resolution. This is the resolution used during dose computation.
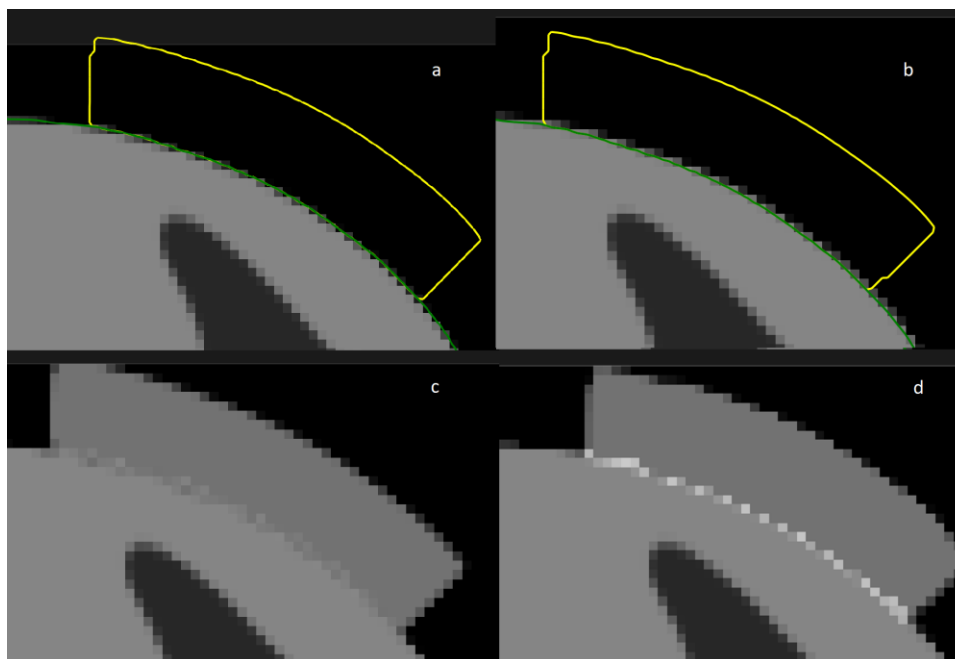

Figure 2. Density at the External ROI/Bolus ROI border for different External ROI contours. (a) External ROI contour (green) in relation to the CT data for an External ROI created with the automatic tool with default settings in RayStation/RayPlan. (b) External contour (green) in relation to the CT data for an External ROI not created with the automatic tool function. (c) The combined density of the CT data and the Bolus ROI (yellow contour) for case (a), with mixed density at the border. (d) The combined density of the CT data and the Bolus ROI (yellow contour) for case (b). The density is clearly overestimated at the border between the External ROI and the Bolus ROI. The images show density re-sampled to dose grid voxel resolution. This is the resolution used during dose computation.

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The same issue as described above for density handling exists when stopping power ratios are used instead of densities.

The users have previously been informed about this issue in RayStation/RayPlan Physics training courses, but only for the combination of electron planning and Bolus ROIs. It has come to our attention that it has not been adequately described for the combination of electron planning and Support and Fixation ROIs, and not described at all for other charged particles, such as protons and carbon ions. In addition, no information about this issue can be found in the RayStation/RayPlan labeling.

The issue could lead to a maximum density of a surface voxel that equals the sum of the CT density and the bolus/support/fixation density in that voxel. In most cases, the effect will be much smaller.

ACTIONS TO BE TAKEN BY THE USER

- Use the automatic tool in RayStation/RayPlan to create the External ROI.
- When using a Support or Fixation ROI of tissue-like material (density around 1), extend this ROI a few millimeters inside the External ROI to cover the surface voxels of the patient.
- If the Support or Fixation ROI differs significantly from the adjacent body tissue, an extra help ROI with material override set to a suitable material, for example, *Skin*, can be created inside the External ROI. The help ROI must have a width of a few millimeters and extend along the part of the patient surface connected to the Support or Fixation ROI. The same workflow can be used for Bolus ROIs in combination with electron beams. See Figure 3 for an example.
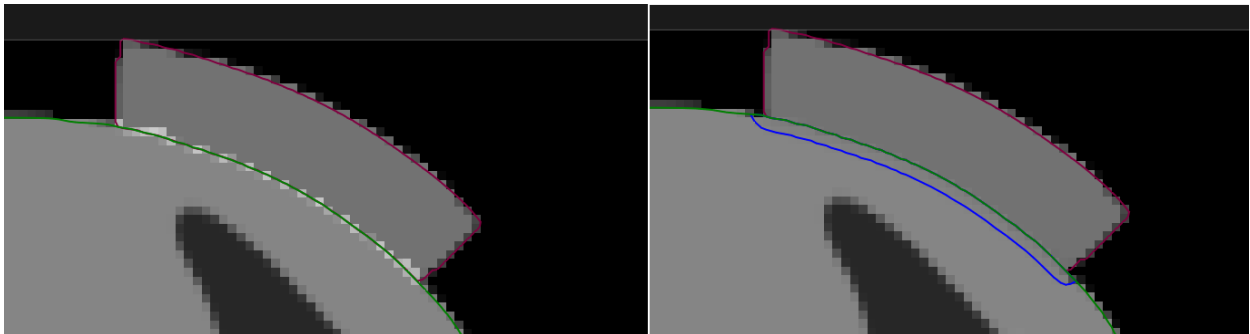

Figure 3. To the left, CT density is used for the entire External ROI (green contour) and a material override is set on the Bolus ROI (purple contour), with the resulting overestimated density at the border. To the right, a help ROI (blue contour) with material override has been added inside the External ROI so that the External/Bolus ROI border is between two material overrides instead of CT density and material override. In the second case, the density is not overestimated. The images show density re-sampled to dose grid voxel resolution. This is the resolution used during dose computation.

- If the bolus/support/fixation device is part of the CT data, an alternative solution is to include its structure inside the External ROI. In this case the structure should not be defined as a Bolus, Support or Fixation ROI, but as a normal ROI, by setting the ROI type to, for example "Other". When included in the External ROI, the user can choose to use the CT densities or to apply a material override to the structure. If this method is applied for a bolus, the user must make sure that only the applicable beams pass through the structure.
- For protons and light ions, the user should consider using a higher density uncertainty than normal in robust optimization for active scanning techniques and larger proximal and distal margins for the target in passive techniques, when shooting through a Fixation or Support ROI.
- 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.**

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SOLUTION

This issue will be resolved in the next version of RayStation/RayPlan, scheduled for market release in December 2021 (subject to market clearance in some markets). If customers wish to continue using versions of RayStation/RayPlan 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

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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