

Field Safety Notice, Medical Device Correction #78320 29294

RayStation/RayPlan 6, 7, 8A, 8B, 9A, 9B, 10A, 10B, RayPlan 2, including some service packs

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

May 6, 2021
RSL-P-RS FSN III 78320 29294

Issue

This notice concerns an issue found with the voxelwise worst clinical goals in the Robust evaluation module of RayStation 8B, 9A, 9B, 10A and 10B. Evaluation of a clinical goal for the voxelwise worst dose distributions may be misleading after editing the clinical goal.

It also describes an issue with contouring when the spacing between slices is ≤ 1 mm, present in RayStation/RayPlan versions from 6 up to 10A.

To the best of our knowledge, these issues have not caused any patient mistreatment. However, the user must be aware of the following information to avoid incorrect information during treatment planning.

Intended audience

This notice is directed to:

- all users of RayStation who use the Robust evaluation module in combination with voxelwise worst clinical goals in the evaluation of the robustness of a treatment plan.
- all users of RayStation/RayPlan who use contouring on image data with CT slice spacing ≤ 1 mm.

Product Name and Version

The products affected by this notice are sold under the trade names RayStation/RayPlan 6, 7, 8A, 8B, 9A, 9B, 10A, 10B, RayPlan 2, 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 “6.0.0.24”, “6.1.1.2”, “6.2.0.7”, “6.3.0.6”, “7.0.0.19”, “8.0.0.6”, “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” or “10.1.0.613”. 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 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 8A (8.0.0.6)	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
RayStation 10A (10.0.0.1154)	07350002010303
RayStation 10A Service Pack 1 (10.0.1.52)	07350002010365
RayStation 10B (10.1.0.613)	07350002010310

Description

Voxelwise worst clinical goal in Robust evaluation

This issue affects RayStation 8B, 9A, 9B, 10A, 10B including some service packs.

The issue occurs when editing the volume of a clinical goal of type “Dose at volume”. When this type of clinical goal is evaluated for the voxelwise worst distribution (voxelwise min or max dose distribution depending on the type of clinical goal), the result of the clinical goal is not updated from the previous value. In RayStation 8B, both the symbol (Green check mark/Red exclamation mark) and the dose value will be incorrect. In versions from RayStation 9A, the symbol will be evaluated correctly, while the dose value will be incorrect. Figure 1 gives an example of the behavior in RayStation 10B.









ROI/POI	Clinical goal	Passed	Voxelwise worst	
 CTV	At least 4700 cGy (RBE) dose at 95.00 % volume	 100 %	 4632 cGy (RBE)	Original goal
 CTV	At least 4700 cGy (RBE) dose at 90.00 % volume	 100 %	 4632 cGy (RBE)	After edit
 CTV	At least 4700 cGy (RBE) dose at 90.00 % volume	 100 %	 4739 cGy (RBE)	After triggered update

Figure 1. The evaluation of voxelwise worst clinical goals is not updated correctly after editing the volume in the dose-at-volume criterion. Example from RayStation 10B. The same behavior with the dose value not being updated correctly is present in RayStation 8B to RayStation 10B. In RayStation 8B the symbol is additionally not correctly displayed.

To trigger an update of the evaluation of the clinical goal, the user can toggle between the Scenario view and the Voxelwise min or max views (see Figure 2).

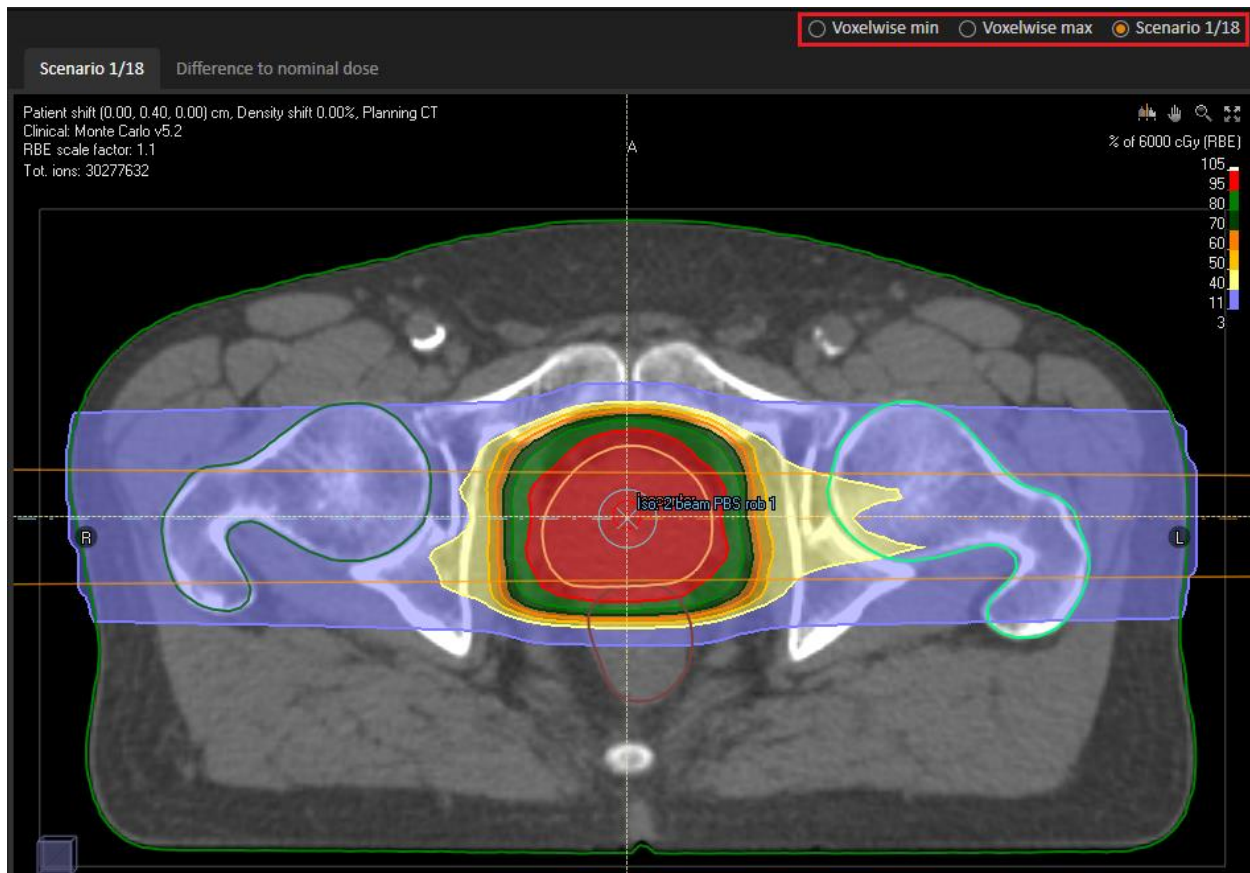


Figure 2. The different dose distribution views in the Robust evaluation module. An update can be triggered by changing between the Scenario view and the Voxelwise min or max views.

Contouring issue

This issue affects RayStation/RayPlan 6, 7, 8A, 8B, 9A, 9B and 10A and RayPlan 2, including some service packs.

Due to the 3D reconstruction effects in RayStation, an issue with contouring might occur in some cases when CT slice spacing is ≤ 1 mm. A reconstructed contour might be displayed on a slice superior or inferior to the contoured ROI geometry, without having been contoured directly on that slice. This could mislead the user to believe that a contour has been drawn on a slice when it has not. The issue can be verified by erasing the contour: if it is a reconstructed contour it will reappear, and if it is a true contour, it will be erased.

The reconstructed contour will not be included when exporting the structure set from RayStation. A workaround is to explicitly convert the ROI geometry from contour representation to voxel- or mesh representation by using for example the keep component tool or the deformation tool. This will trigger a full reconstruction at export, and all visible contours of the ROI geometry will be exported.

Actions to be taken by the user

Voxelwise worst clinical goal in Robust evaluation

- The user is advised to be careful when editing clinical goals in the Robust evaluation module and when evaluating the clinical goals for the voxelwise worst distributions. If a clinical goal needs to

be edited, make sure to toggle between the Scenario view and Voxelwise min and max views to trigger an update.

Contouring issue

- The user is advised to always examine ROI geometries in the transversal view and in the reconstructed sagittal, coronal and 3D views to verify that they have the desired size and shape.
- To avoid displaying a mix of manually drawn and reconstructed contours in the same 2D view, the user can explicitly convert the ROI geometry to voxel- or mesh representation by using the keep component tool or the deformation tool. This way all rendered contours will be reconstructed and also be identical to what will be exported.

All

- Educate planning staff and all users about these issues and the workarounds.
- 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

The voxelwise worst issue will be resolved in the next version of RayStation, scheduled for market release in May 2021 (subject to market clearance in some markets). The contouring issue was resolved in RayStation 10B. 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.

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 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):

