

Field Safety Notice, Medical Device Correction #68727 69129

Affected versions: RayStation 4, 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, including all service packs. RayStation 10A and RayPlan 10A are also affected, but not the 10A service pack.

10th November, 2020

RSL-P-RS FSN Class III 68727 69129

ISSUE

This notice concerns two issues found with the treatment plan report. Affected versions: RayStation 4, 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, including all service packs. RayStation 10A and RayPlan 10A are also affected, but not the 10A service pack.

There may be incorrect information for the percent of a region of interest with a clinical goal that is outside the dose grid. For RayStation and RayPlan 9B and 10A, 6D couch angles may be incorrect.

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

INTENDED AUDIENCE

This notice is directed to all users of RayStation and RayPlan who use treatment plan reports.

PRODUCT NAME AND VERSION

Affected versions: RayStation 4, 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, including all service packs. RayStation 10A and RayPlan 10A are also affected, but not the 10A service pack. 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 “4.0.3.4”, “4.5.1.14”, “4.7.2.5”, “4.7.3.13”, “4.7.4.4”, “4.7.5.4”, “4.7.6.7”, “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” 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/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

DESCRIPTION

Percentage outside dose grid

The user can define clinical goals, i.e., evaluation criteria for specific regions of interest (ROIs). A clinical goal is reported in the graphical user interface (GUI) and in the treatment plan report as passed or failed. If an ROI is not completely covered by the dose grid, the pass/fail result reported for the clinical goal on the ROI may be misleading, as only the part of the ROI that is covered by the dose grid will be taken into account during dose computation. As a risk mitigation, the percentage of the ROI that is outside the dose grid (% outside grid) is displayed for each ROI with a clinical goal in the GUI and in the treatment plan report.

In the GUI, this works as intended, but in the treatment plan report the percentage outside dose grid is incorrectly displayed. If up to 50% of the ROI is outside the dose grid, it will be reported as 0% outside grid. If more than 50% of the ROI is outside the dose grid, it is reported as 1% outside grid.

The pass/fail result of clinical goals is the same in the GUI and in the treatment plan report. The error is that in the report the percentage outside the dose grid will never be shown as more than 1%.

Incorrect 6D couch angles in treatment plan report – RayStation/RayPlan 9B and 10A only

6D couch planning is only available with the ray6DCouchPlanning license. With this license couch pitch and couch roll can be set for treatment and setup beams.

The values of couch pitch and couch roll for setup beams may be incorrect in the treatment plan report.

All 6D couch angle values are correct in the exported DICOM files and they are correctly displayed in the GUI.

ACTIONS TO BE TAKEN BY THE USER

- Always verify in the RayStation/RayPlan GUI that all relevant regions of interest (ROIs) are within the dose grid.
- If using the treatment plan report for evaluation of clinical goal results, verify the percentage outside the dose grid (*% outside grid*) for each ROI in the RayStation/RayPlan GUI.
- In the treatment plan report, be aware that the *Couch pitch angle* and *Couch roll angle* values for setup beams may be incorrect.
- Use exported DICOM plans, not the treatment plan report, for transferring treatment parameters to the delivery system.
- Please 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 and RayPlan, scheduled for market release in November 2020 (subject to market clearance in some markets). If customers wish to continue using versions of RayStation and 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. Please maintain awareness of this notice as long as any version of RayStation/RayPlan 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

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

I am approving this document
Stockholm, Sweden
2020.11.10 14:41:34 +01'00'

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):

