Field Safety Notice, Medical Device Correction #133261

RayStation RayPlan 7-2024A including some service packs
To determine if your version is affected, see build numbers listed in PRODUCT NAME AND VERSION below
28th March, 2024
RSL-P-RS FSN Class III 133261

Issue
This notice concerns an issue found with the calculation of the reported SSD (i.e., the SSD displayed and exported) in RayStation RayPlan 7-2024A including some service packs. The reported SSD may in very rare cases be too high. The dose calculation is not affected by this issue.

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/RayPlan who use the reported SSD for patient setup or other safety critical tasks.

Product Name and Version
The products affected by this notice are sold under the trade names RayStation RayPlan 7-2024A 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 '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', or '15.0.0.430'. 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 7	7.0.0.19	07350002010068820171130
RayStation/RayPlan 8A	8.0.0.61	07350002010112201180608
RayStation/RayPlan 8A Service Pack 1	8.0.1.10	07350002010136201180928
RayStation/RayPlan 8B	8.1.0.47	07350002010129201181209
RayStation/RayPlan 8B Service Pack 1	8.1.1.8	07350002010204201190214
RayStation/RayPlan 8B Service Pack 2	8.1.2.5	07350002010235201190524
RayStation/RayPlan 9A	9.0.0.113	07350002010174201190612

RSL-P-RS FSN Class III 133261 EN Field Safety Notice, Medical Device Correction #133261

RaySearch Laboratories AB (publ), P.O. Box 45169 SE-104 30 Stockholm Sweden, Visitors: Eugeniavägen 18C, Phone +46 8 510 530 00

www.raysearchlabs.com   Page 1 (5)

RayStation/RayPlan 9A Service Pack 1	9.0.1.142	0735000201048820220420
RayStation/RayPlan 9B	9.1.0.933	0735000201026620191220
RayStation/RayPlan 9B Service Pack 1	9.2.0.483	0735000201029720200310
RayStation/RayPlan 10A	10.0.0.1154	0735000201030320200526
RayStation/RayPlan 10A Service Pack 1	10.0.1.52	0735000201036520200526
RayStation/RayPlan 10A Service Pack 2	10.0.2.10	0735000201065520220608
RayStation/RayPlan 10B	10.1.0.613	0735000201031020201216
RayStation/RayPlan 10B Service Pack 1	10.1.1.54	0735000201047120220128
RayStation/RayPlan 11A	11.0.0.951	0735000201038920210518
RayStation/RayPlan 11A Service Pack 1	11.0.1.29	0735000201043320210610
RayStation/RayPlan 11A Service Pack 2	11.0.3.116	0735000201044020210916
RayStation/RayPlan 11A Service Pack 3	11.0.4.15	0735000201063120220616
RayStation/RayPlan 11B	12.0.0.932	0735000201042620211208
RayStation/RayPlan 11B Service Pack 1	12.1.0.1221	0735000201049520220312
RayStation/RayPlan 11B Service Pack 2	12.0.3.68	0735000201050120220422
RayStation/RayPlan 11B Service Pack 3	12.0.4.12	0735000201060020220620
RayStation/RayPlan 11B Service Pack Toshiba 1	12.3.0.119	0735000201057020221222
RayStation/RayPlan 12A	13.0.0.1547	0735000201054920220616
RayStation/RayPlan 12A Service Pack 1	13.1.0.144	0735000201067920221007
RayStation/RayPlan 12A Service Pack 2	13.1.1.89	0735000201073020230913
RayStation/RayPlan 2023B	14.0.0.3338	0735000201055620230630
RayStation/RayPlan 2024A	15.0.0.430	0735000201072320231213

Description

RayStation calculates source to skin or surface distance (SSD) for display and export. The calculation is performed by tracing from the beam source to the beam center line's intersection with the External ROI, or in the case of source to surface, any bolus, fixation or support ROI.

In very rare cases, the calculation algorithm for the reported SSD (i.e., the SSD displayed and exported) will miss the first ROI in the beam path and instead calculate the distance to the entry point of an ROI that lies further down in the beam path, resulting in an incorrectly reported SSD. If this occurs, the reported SSD will be incorrect in the GUI, in the plan report, in DICOM export and when accessed via scripting. Both treatment beams and setup beams may be affected. It is unlikely that all beams in a beam set are affected, since the issue will only be triggered under special circumstances of ROI geometry and beam angles. The SSD saved to a beam commissioning field to be used with arbitrary photon fields in RayPhysics can also be affected.

The dose calculation uses a separate algorithm to find the patient in relation to the radiation source and is not affected by this issue.

The issue may be triggered both when reported SSD is calculated by RayStation, and when SSD is entered by the user. If the issue is triggered when an intended SSD is entered in RayStation, the reported SSD (i.e., the SSD displayed and exported) would be the SSD intended by the user, but the actual SSD of the plan will be shorter than intended.

RSL-P-RS FSN Class III 133261 EN Field Safety Notice, Medical Device Correction #133261

RaySearch Laboratories AB (publ), P.O. Box 45169 SE-104 30 Stockholm Sweden, Visitors: Eugeniavägen 18C, Phone +46 8 510 530 00

www.raysearchlabs.com   Page 2 (5)

Dose calculation will not use the reported SSD which means that the calculated dose is correct and consistent with the plan. However, if the reported SSD is used for setting up the patient, the calculated dose will not match the delivered dose. The delivered dose will be overall lower than intended, but the irradiated volume will be larger.

The magnitude of the dose error depends on the intended SSD and the distance between the beam's entry points for the omitted ROI and the next ROI in the beam path.

Example:
The reported SSD should in this example be the distance from the radiation source to the beam entry point of the External ROI. If the bug occurs, the External ROI is not included in the calculation and the incorrect reported SSD is the distance from the radiation source to the beam entry point of the couch ROI which is the next ROI in the beam path.

- The intended SSD is 100 cm and the user enters 100 cm SSD.
- If the bug is triggered, the reported SSD will be 100 cm but it will be calculated as the distance to the couch ROI. In this example, it will be displayed as 100 cm in the beam list, but the plan isocenter is in reality placed so that the actual SSD (which is the distance to the entry point of the External ROI) is shorter than 100 cm, see Figure 1 below. In this example, the actual SSD in the plan is 80 cm. All displayed values are correct, except for the reported SSD value in the beam list.
- Dose is calculated based on the plan with SSD 80 cm.
- The reported SSD in the exported RT Plan/RT Ion Plan and the plan report is 100 cm.
- If the patient is treated at SSD 100 cm, the delivered dose will not match the dose that was calculated in RayStation/RayPlan.
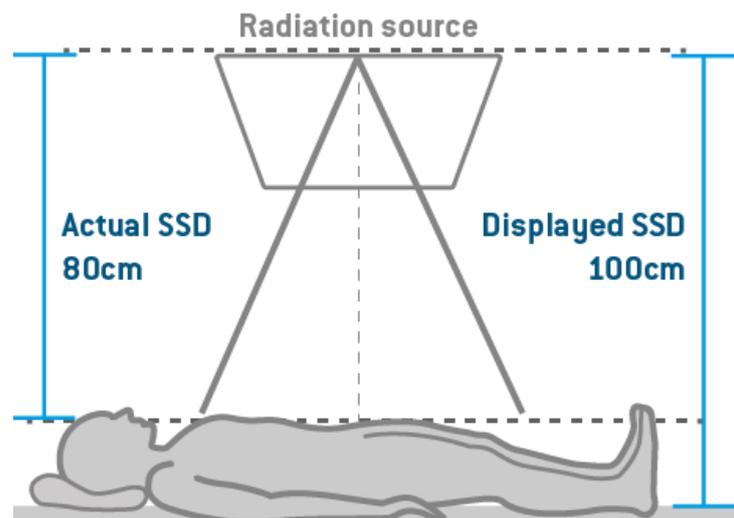

Figure 1. The patient shown in relation to the radiation source. In this example, the reported SSD displayed in RayStation/RayPlan is 100 cm, whereas the actual SSD in the plan is 80 cm.

RSL-P-RS FSN Class III 133261 EN Field Safety Notice, Medical Device Correction #133261

RaySearch Laboratories AB (publ), P.O. Box 45169 SE-104 30 Stockholm Sweden, Visitors: Eugeniavägen 18C, Phone +46 8 510 530 00

www.raysearchlabs.com   Page 3 (5)

Actions to be taken by the user

- If the reported SSD is to be used for patient setup or other critical tasks, use the Measure tool to measure the distance in the patient view to make sure that the reported SSD value is correct.
- If the reported SSD value is found to be incorrect, small changes to isocenter, beam angles or the affected ROI's geometry can be made until the correct value is achieved.
- 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/RayPlan, scheduled for market release in April 2024 (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.

RSL-P-RS FSN Class III 133261 EN Field Safety Notice, Medical Device Correction #133261

RaySearch Laboratories AB (publ), P.O. Box 45169 SE-104 30 Stockholm Sweden, Visitors: Eugeniavägen 18C, Phone +46 8 510 530 00

www.raysearchlabs.com   Page 4 (5)

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):

_____

_____

RSL-P-RS FSN Class III 133261 EN Field Safety Notice, Medical Device Correction #133261

RaySearch Laboratories AB (publ), P.O. Box 45169 SE-104 30 Stockholm Sweden, Visitors: Eugeniavägen 18C, Phone +46 8 510 530 00

www.raysearchlabs.com   Page 5 (5)