Field Safety Notice, Medical Device Correction #93572

RayStation 4-11B, and RayPlan 1, 2, 7-11B including some service packs

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

7th February, 2022

RSL-P-RS FSN Class III 93572

ISSUE

This notice concerns an issue found with the SSD calculation in RayStation 4-11B, and RayPlan 1, 2, 7-11B including some service packs. The SSD displayed and exported may in very rare cases be too high.

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 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 4-11B, and RayPlan 1, 2, 7-11B 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 ‘4.0.0.14’, ‘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’, ’10.0.1.52’, ’10.1.0.613’, ’10.1.1.54’, ’11.0.0.951’, ’11.0.1.29’, ’11.0.3.116’ or ’12.0.0.932’. 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 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

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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/RayPlan 10B Service Pack 1 (10.1.1.54)	07350002010471
RayStation/RayPlan 11A (11.0.0.951)	07350002010389
RayStation/RayPlan 11A Service Pack 1 (11.0.1.29)	07350002010433
RayStation/RayPlan 11A Service Pack 2 (11.0.3.116)	07350002010440
RayStation/RayPlan 11B (12.0.0.932)	07350002010426

DESCRIPTION

RayStation calculates source to skin or surface distance (SSD) 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 SSD calculation algorithm will miss the entry point of the ROI and instead calculate the distance to the exit point, resulting in an incorrect SSD. If this occurs, the 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 are 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 issue may be triggered both when 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 intended SSD will be displayed and exported but the actual SSD of the plan will be shorter than intended.

Dose calculation will not use the displayed SSD, so the calculated dose is correct with respect to the plan. However, if the displayed and exported 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 error depends on the intended SSD and the distance between the beam's entry and exit point.

ACTIONS TO BE TAKEN BY THE USER

- If 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 SSD value is correct.
- If the 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.**

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SOLUTION

This issue will be resolved in the next version of RayStation/RayPlan, scheduled for market release in June 2022 (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.

David Hedfors

I am approving this document
Stockholm, Sweden
2022.02.07 16:56:04 +01'00'

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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):

_____

_____

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