Field Safety Notice, Medical Device Correction #180167

RayStation 4.7 to v2026 including some service packs

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

October 1, 2026

RSL-P-RS FSN 180167

ISSUE

This notice concerns an issue found with dose deformation. When a dose is deformed using a deformable registration that expands outwards near the boundary of the original dose grid, parts of the deformed dose may extend beyond the boundary, meaning clinically relevant dose may be lost.

To the best of our knowledge, the issue has not caused any patient mistreatment. However, the user must be aware of the information in this notice to avoid unintended underestimation of dose when using the deformed dose for further evaluation or planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation who use the deformable registration and dose deformation functionality.

PRODUCT NAME AND VERSION

The products affected by this notice are sold under the trade names RayStation 4.7 to v2026 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 one of the build numbers listed in the table below. If so, this notice applies to your version.

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

Product name	Build number	UDI
RayStation 4.7.0 to RayStation 5 SP2	4.7.0 - 5.0.2.35	N/A
RayStation 5 SP3	5.0.3.17	073500020100202017050 2
RayStation 6	6.0.0.24	07350002010013201612 14
RayStation 6 SP2	6.2.0.7	07350002010075201706 30
RayStation 6 SP3	6.3.0.6	07350002010242201909 23
RayStation 7	7.0.0.19	07350002010068201711 30
RayStation 8A	8.0.0.61	07350002010112201806 08
RayStation 8A SP1	8.0.1.10	07350002010136201809 28
RayStation 8B	8.1.0.47	07350002010129201812 09

RayStation 8B SP1	8.1.1.8	073500020102042019021 4
RayStation 8B SP2	8.1.2.5	073500020102352019052 4
RayStation 9A	9.0.0.113	073500020101742019061 2
RayStation 9A SP1	9.0.1.142	073500020104882022042 0
RayStation 9B	9.1.0.933	073500020102662019122 0
RayStation 9B SP1	9.2.0.483	073500020102972020031 0
RayStation 10A	10.0.0.1154	073500020103032020052 6
RayStation 10A SP1	10.0.1.52	073500020103652020052 6
RayStation 10A SP2	10.0.2.10	073500020106552022060 8
RayStation 10B	10.1.0.613	073500020103102020121 6
RayStation 10B SP1	10.1.1.54	073500020104712022012 8
RayStation 11A	11.0.0.951	073500020103892021051 8
RayStation 11A SP1	11.0.1.29	073500020104332021061 0
RayStation 11A SP2	11.0.3.116	073500020104402021091 6
RayStation 11A SP3	11.0.4.15	073500020106312022061 6
RayStation 11B	12.0.0.932	073500020104262021120 8
RayStation 11B SP1	12.1.0.1221	073500020104952022031 2
RayStation 11B SP2	12.0.3.68	073500020105012022042 2
RayStation 11B SP3	12.0.4.12	073500020106002022062 0
RayStation 11B SPT1	12.3.0.119	073500020105702022122 2
RayStation 12A	13.0.0.1547	073500020105492022061 6
RayStation 12A SP1	13.1.0.144	073500020106792022100 7
RayStation 12A SP2	13.1.1.89	073500020107302023091 3
RayStation 2023B	14.0.0.3338	073500020105562023063 0
RayStation 2024A	15.0.0.430	073500020107922024052 3
RayStation 2024A SP1	15.1.0.852	073500020107612024050 8
RayStation 2024A SP2	15.2.0.107	073500020108082024121 7
RayStation 2024A SP3	15.1.3.10	073500020108842025012 9
RayStation 2024B	16.0.0.847	073500020107782024062 5
RayStation v2025	17.0.0.1270	073500020108222025042 3
RayStation v2025 SP1	17.0.1.113	073500020109452025070 2
RayStation v2025 SP2	17.2.0.165	073500020109692025112 6
RayStation v2025 SP1B	17.3.0.43	073500020110722026041 7
RayStation v2026	18.0.0.2189	07350002010952260624*

*According to the GS1 Production date format (11), the production date has been updated from YYYYMMDD to YYMMDD, effective from v2026 and applicable to all subsequent versions.

DESCRIPTION

When a dose is deformed using a deformable registration that expands outwards near the boundary of the original dose grid, parts of the deformed dose may extend beyond the boundary, meaning clinically relevant dose may be excluded from the deformed dose distribution. If this deformed dose is subsequently used as background dose, the missing dose contribution will be treated as zero dose, potentially resulting in an underestimation of the accumulated dose.

This situation requires substantial anatomical differences between the reference and target image sets, or that the deformation vector field is used not only for deformations but also for rigid alignment. Examples include significant weight gain, growth in pediatric patients, or other anatomical changes that increase the extent of the anatomy beyond the region covered by the original dose grid.

For reirradiation planning, the issue may lead to underestimation of the accumulated dose to organs at risk. For adaptive planning, it may lead to underestimation of the accumulated dose to the target and/or organs at risk. An illustration of the latter is shown in Figure 1 below, using the scenario of swelling occurring during the treatment. To the left, the planned dose is shown on the planning image. In the middle, the dose has been deformed to an image taken midway through the treatment. Due to substantial deformations in the high dose region close to the dose grid border, the deformed dose is clipped at the anterior aspect of the anatomy, even though the new dose grid for the adapted plan, to the right, covers its planning image. If the adapted plan is optimized with the deformed dose as background dose, it will cause an unnecessarily high dose in this region.

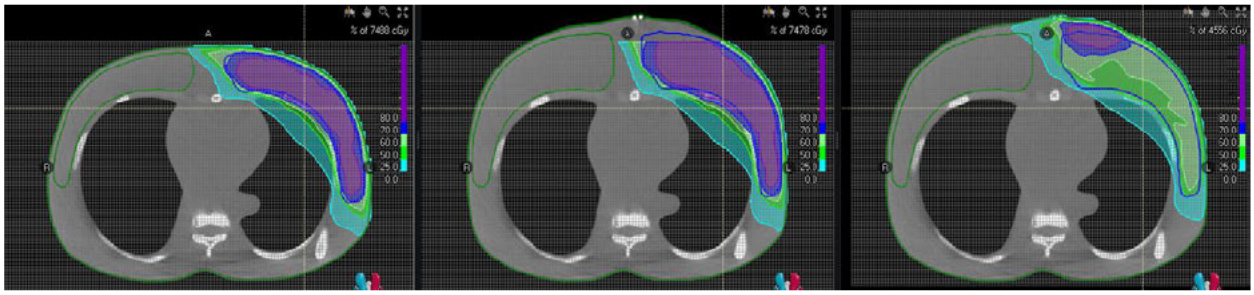


Figure 1.

The deformation vector field used for this case is shown in Figure 2 below. Note that the arrows show the direction from which the deformed dose should be interpolated. In this case, voxels outside of the original image point to positions inside the high dose region, and should receive high dose.

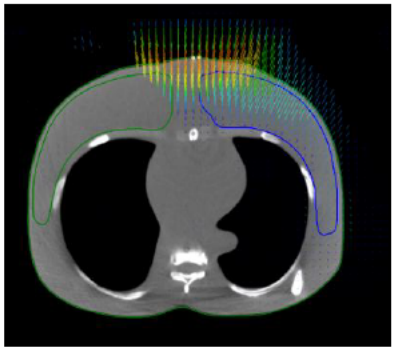


Figure 2.

ACTIONS TO BE TAKEN BY THE USER

- Exercise caution when deforming dose using a deformable registration that is expanding outwards in the region close to the boundary of the original dose grid.
- Review deformed dose carefully before using it for dose accumulation or treatment evaluation.
- Ensure that the dose grid extends with a sufficient margin around regions where the deformable registration may expand outward.

- 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 that 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, scheduled for market release in December 2026 (subject to market clearance in some markets). 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.

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):

_____

_____