

Field Safety Notice, Medical Device Correction #83773

RayStation 6, 7, 8A, 8B, 9A, 9B, 10A, 10B and 11A, including some service packs

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

September 8, 2021

RSL-P-RS-FSN Class III 83773

ISSUE

This notice concerns an issue found with the optimization of TomoHelical and TomoDirect plans in RayStation 6, 7, 8A, 8B, 9A, 9B, 10A, 10B and 11A, including some service packs. If the dynamic jaw mode is used and an optimization is continued after changing the dose grid or modifying the target ROI, the positions of the jaws may change unexpectedly for some control points.

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 unnecessary jaw openings during treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of TomoHelical and TomoDirect with dynamic jaw mode in RayStation.

PRODUCT NAME AND VERSION

The products affected by this notice are sold under the trade names RayStation 6, 7, 8A, 8B, 9A, 9B, 10A, 10B and 11A, 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 6.1.1.2, 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, 11.0.0.951 or 11.0.1.29. 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 Service Pack 1 (6.1.0.26)	07350002010037
RayStation 6/RayPlan 2 Service Pack 1 v.6.1.1 (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

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RayStation/RayPlan 8B Service Pack 2 (8.1.2.5)	07350002010235
RayStation 9A (9.0.0.113)	07350002010174
RayStation 9B (9.1.0.933)	07350002010266
RayStation 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
RayStation 11A (11.0.0.951)	07350002010389
RayStation 11A Service Pack 1 (11.0.1.29)	07350002010433

DESCRIPTION

For TomoHelical and TomoDirect plans, there are two different jaw modes: static and dynamic. If the dynamic mode is selected and the jaw width is set to 2.5 cm or 5.0 cm, the jaw width of the segment will vary as the superior or inferior edges of the target are irradiated.

If the user changes the dose grid resolution or modifies the target ROI after an optimization and then continues the optimization without Reset, the jaws are repositioned incorrectly for some segments. These segments are typically located in regions where the jaw width varies.

The incorrect jaw positions may lead to irradiation of regions outside the target. The openings formed by the jaws and the leaves are displayed in the Beam's Eye View (BEV) and the positions can be studied in the control points list. The dose distribution is correctly displayed in the different dose views, in the dose statistics and in the clinical goals, so any unwanted dose should be clearly visible when reviewing the plan before delivery.

ACTIONS TO BE TAKEN BY THE USER

- Avoid changing the dose grid after starting an optimization of TomoHelical and TomoDirect plans with dynamic jaw mode.
- Always reset the optimization after editing the dose grid for TomoHelical and TomoDirect plans with dynamic jaw mode.
- Always reset the optimization after modifying the target ROI.
- It is recommended to use the BEV to inspect the jaw positions superior and inferior to the target for plans with dynamic jaw mode.
- 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, scheduled for market release in October 2021 (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. 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):

