

Field Safety Notice, Medical Device Correction #109890

RayStation 10A, 10B, 11A, 11B and 12A including service packs

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

2nd February, 2023

RSL-P-RS FSN Class III 109890

Issue

This notice concerns an issue found with the visualization and creation of tumor models in the fundus diagram in the Eye modeling module in RayStation 10A, 10B, 11A, 11B and 12A including service packs. When drawing the tumor contour in a different fundus view plane than the plane defined for the tumor model, the contour will not be accurately projected from the drawing plane to the tumor plane when the fundus diagram is shown in “Polar” mode. The result is that the tumor volume may be smaller or larger than anticipated. Furthermore, if the fundus plane of an existing tumor model is changed, the tumor contour is not accurately projected from the existing plane to the new plane. Finally, when the fundus diagram is shown in “Polar” mode, the tumor model contour is not correctly projected from its definition plane to the viewing plane.

To the best of our knowledge, the issue has not caused any patient mistreatment. However, the user must be aware of the following information to avoid incorrect target delineation during treatment planning.

Intended audience

This notice is directed to all users of RayStation of RayStation 10A, 10B, 11A, 11B and 12A including service packs who use the Eye modeling module.

Product Name and Version

The products affected by this notice are sold under the trade names RayStation 10A, 10B, 11A, 11B and 12A including 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 10.0.0, 10.0.1, 10.0.2, 10.1.0, 10.1.1, 11.0.0, 11.0.1, 11.0.3, 11.0.4, 12.0.0, 12.1.0, 12.1.1, 12.0.3, 12.1.2, 12.0.4, 12.1.3, 13.0.0 or 13.1.0. 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 10A (10.0.0.1154)	0735000201030320200526
RayStation 10A SP1 (10.0.1.52)	0735000201036520200526
RayStation 10A SP2 (10.0.2.10)	0735000201065520220608
RayStation 10B (10.1.0.613)	0735000201031020201216

RayStation 10B SP1 (10.1.1.54)	0735000201047120220128
RayStation 11A (11.0.0.951)	0735000201038920210518
RayStation 11A SP1 (11.0.1.29)	0735000201043320210610
RayStation 11A SP2 (11.0.3.116)	0735000201044020210916
RayStation 11A SP3 (11.0.4.15)	0735000201063120220616
RayStation 11B (12.0.0.932)	0735000201042620211208
RayStation 11B SP1 (12.1.0.1221)	0735000201049520220312
RayStation 11B SPC1 (12.1.1.41)	0735000201058720220330
RayStation 11B SP2 (12.0.3.68)	0735000201050120220422
RayStation 11B SPC2 (12.1.2.91)	0735000201061720220517
RayStation 11B SP3 (12.0.4.12)	0735000201060020220620
RayStation 11B SPC3 (12.1.3.162)	0735000201066220221003
RayStation 12A (13.0.0.1547)	0735000201054920220616
RayStation 12A SP1 (13.1.0.144)	0735000201067920221007

Description

- When creating a tumor model showing the fundus diagram in “Polar” mode, the tumor model contour will not be correct if it is defined for a different fundus plane than the plane used in the fundus diagram where the contour is drawn.
 - If the tumor model contour fundus plane is chosen to be deeper than the drawing fundus plane, the contour (and thereby tumor) will be smaller than expected. If it is shallower than the drawing fundus plane, it will be larger than expected.
- When editing the tumor model plane for an existing tumor model, the tumor contour will not follow a projection of the contour.
 - When editing the tumor to a deeper plane, the tumor volume will get effectively smaller, while it gets larger when editing to a shallower plane.
 - This "change" of the edited tumor model will not be visible when showing the fundus diagram in “Polar” mode due to the related viewing issue (see next bullet point), but will be visible when showing the fundus diagram in “Camera” mode, and also in the 2D views.
- The tumor model contour is not correctly projected to the fundus plane when showing the fundus diagram in “Polar” mode.
 - In relation to image data and ROI contours (e.g. clips), the base contour will appear larger than it is if the fundus diagram plane is shallower than the tumor model contour fundus plane, and appear smaller if the fundus diagram plane is deeper than the tumor model contour fundus plane.
- The magnitude of the error will depend on the distance from the posterior pole (with no error at the posterior pole) and the difference between viewing and tumor model fundus plane depths, or the difference in tumor model fundus plane depths before and after editing.
- The tumor model contour is correctly projected to the fundus plane in “Camera” mode.
- All ROI contours visible in the fundus diagram are correctly projected to the chosen fundus plane for both “Camera” and “Polar” modes.

Actions to be taken by the user

- When creating a new tumor in “Polar” mode:
 - Consider using the “Camera” mode instead.
 - In “Polar” mode, always create the contour in the same fundus plane as the plane defined for the tumor model contour.
- When editing the fundus plane of an existing tumor model:
 - Edit the tumor model fundus plane.
 - Delete the existing tumor contour.
 - Draw a new tumor contour in the fundus diagram.
 - If “Polar” mode is used, the new contour must be drawn in the same plane as the new tumor model contour fundus plane.
- When reviewing a tumor model showing the fundus diagram in “Polar” mode, for example to measure distances between tumor contour and clips:
 - Consider using the “Camera” mode instead.
 - If “Polar” mode is used, set the fundus diagram fundus plane to the same value as the tumor model fundus plane.
- 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 June 2023 (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.

 I am approving this document
Stockholm, Sweden
2023.02.02 20:56:25 +01'00'

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):
