Field Safety Notice, Medical Device Correction #106232

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

6th December, 2022

RSL-P-RS FSN Class III 106232

ISSUE

This notice concerns an issue found with registration of MR images in the Fundus view in the Eye modeling workspace in RayStation 10A, 10B, 11A, 11B and 12A including service packs. The Fundus view always uses the Frame-of-reference registration between the MR and CT images, even when another image registration has been selected for viewing the MR image in the 2D views in the Eye modeling workspace.

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 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 workspace.

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)	073500020103032020526
RayStation 10A SP1 (10.0.1.52)	073500020103652020526
RayStation 10A SP2 (10.0.2.10)	073500020106552022608
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

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RayStation 11B (12.0.0.932)	073500020104262021 1208
RayStation 11B SP1 (12.1.0.1221)	07350002010495202 20312
RayStation 11B SPC1 (12.1.1.41)	07350002010587202 20330
RayStation 11B SP2 (12.0.3.68)	07350002010501202 20422
RayStation 11B SPC2 (12.1.2.91)	07350002010617202 20517
RayStation 11B SP3 (12.0.4.12)	07350002010600202 20620
RayStation 11B SPC3 (12.1.3.162)	07350002010662202 21003
RayStation 12A (13.0.0.1547)	07350002010549202 20616
RayStation 12A SP1 (13.1.0.144)	07350002010679202 21007

DESCRIPTION

An MR image in RayStation can be registered to a CT image by a Frame-of-reference (FoR) registration, Image to image registration (from 11B), or Deformable image registration. There can be several registrations for the same MR-CT image pair.
The image registration is selected in a drop-down list in the Image set library tab in the Eye modeling workspace. However, the MR data seen in the Fundus view will always use the FoR registration, even when another registration has been selected. The selected registration will only be used in the 2D views and there is no indication that the FoR registration is used in the Fundus view.

Below is an example workflow where the error occurs:

1. A Frame-of-reference (FoR) registration between MR1 and CT is created.
2. The user decides that the FoR registration is not sufficient for MR2 and creates a new image registration between MR2 and CT.
3. In the Eye modeling workspace, MR2 is used as secondary image with the new image registration. Everything looks good in the 2D views when toggling between primary image (CT) and secondary image (MR2).
4. An eye model is created based on CT and MR2.
5. The MR2 image in the Fundus view uses the FoR registration and the tumor seen on the MR in the Fundus view will be positioned incorrectly in relation to the eye model.
6. If the MR data is used to delineate the tumor directly in the Fundus view, the tumor volume may be incorrect. This is a rare use case, but it is possible.

Detectability of this issue is usually high, since the incorrect tumor volume created in the Fundus view will be displayed in the 2D views and it does not match the tumor in the MR data in the 2D views.
If the error is not detected, it could lead to the approval of an inappropriate dose plan. This could lead to local overdose outside the intended target and local under-dosage in the intended target.

ACTIONS TO BE TAKEN BY THE USER

- Always define the FoR registration between MR and CT for the MR image that will be used for tumor definition in the Eye modeling workspace in the Patient modeling module.
- Be aware that if another registration than FoR registration is selected in the Eye modeling workspace (or anywhere else in the system), the FoR registration will still be used in the Fundus view.
- 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, scheduled for market release in February 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.

For regulatory information, please contact quality@raysearchlabs.com.

RaySearch will notify the appropriate regulatory agencies about this Field Safety Notice.

[redacted]

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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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