

Field Safety Notice, Medical Device Correction #90375

RayStation/RayPlan 6, 7, 8A, 8B, 9A, 9B including some service packs

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

29 December, 2021
RSL-D-RS FSN Class III 90375

Issue

This notice concerns an issue found with the display of secondary image sets in a side-by-side view in RayStation/RayPlan 6, 7, 8A, 8B, 9A, 9B including some service packs. The primary image set may be displayed instead of the secondary image set.

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 missing information during treatment planning.

Intended audience

This notice is directed to all users of RayStation/RayPlan who use 4D image sets in patient modeling.

Product Name and Version

The products affected by this notice are sold under the trade names RayStation/RayPlan 6, 7, 8A, 8B, 9A, 9B 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 “6.0.0.24”, “6.1.0.26”, “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”. 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 (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
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

Description

In the Structure definition module, registered image sets can be viewed in a side-by-side layout. A 4D image set can be shown as a “cine loop”, running through the 3D image sets as a sequence. The cine loop is started by clicking the play button in the lower left corner of the view displaying the 4D image set.

If a cine loop is started in the view of the primary image set, the same cine loop will be displayed in all side-by-side views, i.e., also in the view of the secondary image set, regardless of which image set is selected as secondary.

If a new primary image set is selected while the cine loop is running, the primary image set will be displayed as both primary and secondary image set in all side-by-side views. This will also be true for any new patient or case opened while the cine loop is running. The error will persist until the affected instance of RayStation/RayPlan is closed.

Actions to be taken by the user

- Do not change the primary image set while the cine loop is running.
- If the primary image set has been changed while the cine loop is running, restart RayStation/RayPlan to restore correct behavior.
- 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 is resolved in RayStation/RayPlan versions 10A and higher (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.

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):

