

Urgent Field Safety Notice, Medical Device Correction #99333

RayStation 9B SP1, 10A SP1, 11A SP1 and 11A SP2

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

May 31, 2022

RSL-P-RS FSN Class II 99333

Issue

This notice concerns an issue found with the propagation of treatment course information from RayStation RayTreat to RayCare.

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 clinical decisions based on incorrect or incomplete information.

Intended audience

This notice is directed to all users of RayTreat.

Product Name and Version

The products affected by this notice are sold under the trade names RayStation 9B SP1, 10A SP1, 11A SP1 and 11A SP2. 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 “9.2.0.483”, “10.0.1.52”, “11.0.1.29” or “11.0.3.116”. 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 9B SP1 (9.2.0.483)	0735000201029720200310
RayStation 10A SP1 (10.0.1.52)	0735000201036520200526
RayStation 11A SP1 (11.0.1.29)	0735000201043320210610
RayStation 11A SP2 (11.0.3.116)	0735000201044020210916

Description

An issue with propagation of treatment course information from RayStation with RayTreat to RayCare has been identified. During some workflows, information may not be propagated to RayCare. Workflows where safety related information may not be propagated are:

1. When treatment has been performed and is to be recorded, either online (normal) or offline through manual recording or offline import of treatment record(s), RayCare might not receive information about the performed treatment.
2. Adding a continuation session in RayStation might not be reported to RayCare. As an additional consequence, RayCare may crash repeatedly in this scenario.
3. Plan assignment in RayStation may not be updated in RayCare.
4. Fractions added to end of treatment course in RayStation may not be propagated to RayCare.

Some other, not safety related workflows may also be affected.

A software upgrade that will eliminate the issue is being prepared and will be made available to affected clinics as soon as possible.

Actions to be taken by the user

- Be aware that treatment course information in RayCare may not always be up to date.
- Verify critical information in RayStation or RayTreat, before treatment course information in RayCare is used for critical decisions
- Please contact RaySearch support if any issues are seen.
- Educate all RayCare and RayTreat 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 mandatory software updates for RayStation, scheduled for market release in June 2022 .

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):

