

Field Safety Notice, Medical Device Correction #94224

RayStation 11A, and 11B, RayTreat 5A, and 5B including some service packs

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

February 15, 2022

Issue

This notice concerns an issue found in RayStation 11A, and 11B, RayTreat 5A, and 5B including some service packs. When using RayStation with RayTreat, the RayCare treatment control room application, it is possible to get into a state where a treatment session cannot be completed and it is not possible to record any treatment for that session.

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 incomplete treatment records.

Intended audience

This notice is directed to all users of RayStation who use RayTreat for Accuray TomoTherapy, Radixact or CyberKnife systems.

Product Name and Version

The products affected by this notice are sold under the trade names RayStation 11A, and 11B, RayTreat 5A, and 5B including some service packs. To determine if the version you are using is affected, open the About RayStation dialog in the RayStation or RayTreat application and check if the build number reported there is "11.0.0.951", "11.0.1.29", "11.0.3.116" or "12.0.0.932". 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 11A (11.0.0.951) (used in combination with RayCare 5A)	0735000201038920210518
RayStation 11A Service Pack 1 (11.0.1.29) (with RayCare 5A)	0735000201043320210610
RayStation 11A Service Pack 2 (11.0.3.116) (with RayCare 5A)	0735000201044020210916
RayStation 11B (with RayCare 5B)	0735000201042620211208

Description

When using RayStation with RayTreat, it is possible to get into a state where a treatment session cannot be completed and it is not possible to record any treatment for that session.

In RayCare, the session is displayed as not delivered. The treatment course will never reach a completed state even when all fractions have been delivered. It will not be possible to create new approved setup instructions for the same planning image and to link treatment images to the case in the Offline Image Review workspace.

It has not been feasible to determine all circumstances where it becomes impossible to complete a treatment session. The following combination of steps might cause the issue:

- A continuation session is created for a patient and is cancelled before it is scheduled by the user.
- A user checks in a different treatment appointment for the same patient and the appointment is left checked-in until the next day.

If this error occurs, users shall contact RaySearch support to resolve the situation. Continuing treatment outside RayTreat must only be done when absolutely necessary, since this can lead to incomplete treatment records in RayCare.

Actions to be taken by the user

- If a treatment session is in the state described above, please contact RaySearch support to receive assistance in rectifying the issue.
- Avoid cancelling continuation sessions without first scheduling them.
- 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 2022 (subject to market clearance in some markets). If customers wish to continue using versions of RayTreat and RayCare 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](tel:+16318282137) (US only).

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):
