Field Safety Notice, Medical Device Correction #106572

RayStation RayTreat 5A, RayTreat 5B, and RayTreat 6A

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

1st December, 2022

Issue

This notice concerns an issue found in RayStation RayTreat 5A, RayTreat 5B, and RayTreat 6A including service packs. When using RayTreat (the RayCare treatment control room application) in combination with the Accuray Radixact or Accuray CyberKnife treatment delivery devices, there is a risk to deliver a different session than the checked in session in 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 mistreatment.

Intended audience

This notice is directed to all RayTreat users delivering treatment plans on Accuray Radixact or Accuray CyberKnife treatment delivery devices.

Product Name and Version

The products affected by this notice are sold under the trade names RayStation RayTreat 5A, RayTreat 5B, and RayTreat 6A. To determine if the version you are using is affected, open the About RayStation dialog in the RayTreat application and check if the build number reported there is “11.0.4.15”, “12.0.4.12” or “13.1.0.144”. 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 SP3 (11.0.4.15)	073500020106312022061 6
RayStation 11B SP3 (12.0.4.12)	073500020106002022062 0
RayStation 12A SP1 (13.1.0.144)	073500020106792022100 7

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Description

When using RayTreat to deliver Radixact and CyberKnife treatment plans, there is a risk to deliver a different session from the Radixact or CyberKnife treatment delivery console than the checked in session in RayCare.

If a treatment session has been partially delivered for a patient and any following session for that patient is checked in in RayCare, the user can intermittently end up in two different scenarios on the Radixact or CyberKnife treatment delivery console:

- The user can only select one session, and this session does not correspond to the checked in session in RayCare.
- The user can select between the makeup session (terminology used in Accuray software for what is referred to as continuation session in RayTreat) and the next full treatment session(s).

For both scenarios: If the user selects the session that does not correspond to the checked in session in RayCare, the delivered meterset will not correspond to the planned meterset of the checked in session. The delivered meterset will be correctly recorded, but the treatment result will indicate an over- or underdelivery. The session status will be set to 'Invalid' and no continuation session can be created.

The following are two examples of situations that may occur:

- A partial delivery for session 1 was performed where 40% of the planned meterset was delivered. The currently checked in session in RayCare is the next treatment session (session 2) and not the continuation session (session 1.1). The makeup session is the only available session for selection on the Radixact or CyberKnife delivery console and is delivered to the patient. The delivered meterset is correctly recorded in RayTreat and RayCare as 60% of the planned meterset of the total session. Compared to the planned meterset of the checked in session, an underdelivery will be recorded in RayTreat and RayCare. The session status will be invalid.

- A partial delivery for session 1 was performed where 40% of the planned meterset was delivered. In RayCare, the continuation session (session 1.1) with 60% of the planned meterset remaining is checked in. The next full treatment session (session 2) is selected and delivered on the Radixact or CyberKnife treatment device. The delivered meterset (100%) is correctly recorded in RayTreat and RayCare on the checked in continuation session (session 1.1). Compared to the planned meterset of the checked in continuation session, an overdelivery of 40% will be recorded in RayTreat and RayCare. The session status will be invalid.

All beam delivery results are recorded correctly in RayTreat and RayCare. Treatment results cannot be removed or moved between sessions which means that treatment results for a non-corresponding session cannot be corrected retrospectively. Do not use fraction numbers to verify consistency of the treatment delivery since the fraction numbers are not consistent between RayCare, RayTreat and the Radixact and CyberKnife treatment delivery consoles. When non-corresponding sessions have been delivered, they can be identified by the 'Invalid' session status and the non-corresponding metersets.

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Actions to be taken by the user

- Ensure that the **plan** and **planned meterset** match the current session in RayTreat and the Radixact or CyberKnife treatment delivery console.
- If the checked in session in RayCare is a full fraction delivery, always deliver a full fraction on the Radixact or CyberKnife treatment delivery console.
- If the checked in session in RayCare is a partial continuation session, always deliver a makeup session on the Radixact or CyberKnife treatment delivery console.
- Deliver all treatment sessions in the correct order, i.e. the continuation session must always be delivered before the next full treatment session.
- 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 a coming version of RayStation, scheduled for market release in 2023 (subject to market clearance in some markets). Customers must 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.

David Hedfors

I am approving this document
Stockholm, Sweden
2022.12.01 17:38:44 +01'00'

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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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