

Field Safety Notice, Medical Device Correction #99834

RayStation 11B including some service packs

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

June 8, 2022

RSL-P-RS FSN Class III 99834

Issue

This notice concerns two issues found related to the display of Linear Energy Transfer (LET) in RayStation 11B including some service packs. First, when using a dose threshold for an evaluation dose, LET display might be misleading. Second, a displayed beam-specific LET distribution can sometimes be out of sync with the selected beam.

To the best of our knowledge, these issues have not caused any patient mistreatment or other incidents. However, the user must be aware of the following information to avoid incorrect LET evaluation during treatment planning.

Intended audience

This notice is directed to all users of RayStation who use LET for plan evaluation.

Product Name and Version

The products affected by this notice are sold under the trade names RayStation 11B 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 “12.0.0.932”, “12.1.0.1221”, or “12.0.3.68”. 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 11B (12.0.0.932)	0735000201042620211208
RayStation 11B SP1 (12.1.0.1221)	0735000201049520220312
RayStation 11B SP2 (12.0.3.68)	0735000201050120220422

Description

Issue 1

When evaluating LET, a user-defined dose threshold can be used to hide LET values for areas with low dose. When evaluating LET for perturbed doses or doses on other datasets, the mask for determining where LET will be displayed is incorrectly based on the nominal dose. This means that high LET in areas with a dose above the threshold might potentially not be displayed.

Only the visualization of LET in the 2D views is affected by this issue. The value displayed on mouse over in the 2D views, as well as other views and quantities related to the LET distribution (statistics, LVH, and line dose) do not take the dose threshold into account and are correctly displayed. If no dose threshold is used, LET display will also be correct in the 2D views.

Issue 2

When viewing the LET distribution for a single beam, the user can switch beam by selecting a different one in the beam list, the BEV, or using the scroll tool. In this case, the LET distribution and all quantities derived from it (2D views, statistics, LVH, and line doses) are not correctly updated, but will still refer to the originally selected beam. The beam list, energy layer list and BEV will refer to the newly selected beam.

By selecting to view another distribution from the Dose tree (e.g., the beamset LET) and then selecting the beam LET, all views will be up to date.

Note that all LET-related quantities will be correctly labeled with the name of the beam to which they refer.

Actions to be taken by the user

- Be aware that when using a dose threshold, LET display for perturbed doses and doses on additional image sets may be misleading
- Do not use a dose threshold when evaluating the LET distribution for an evaluation dose.
- Be aware that a displayed beam-specific LET distribution could refer to another beam than indicated by the selection in the beam list, the energy layer list and the BEV.

- 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 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.

XXX

I am approving this document
RaySearch Stockholm, Sweden
Laboratories 2022.06.08 17:31:30 +0200

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):

