

Field Safety Notice, Medical Device Correction #66704

RayStation 4, 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, 10A, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, 10A, including all service packs
October 7, 2020
RSL-D-61-433

ISSUE

This notice concerns an issue found with the DICOM import in RayStation 4, 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, 10A, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, 10A, including all service packs. If a region of interest (ROI) or point of interest (POI) that is referenced from an imported plan is missing in the imported RT Structure Set, the reference may become linked to the wrong ROI or POI. The imported RT Structure Set must be corrupt for the bug to be triggered, i.e., the referenced ROI/POI must not exist in the imported RT Structure 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 incorrect ROI or POI references during treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation who import RT Structure Sets with references from RT Plans/RT Ion Plans.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 4, 4.5, 4.7, 4.9, 5, 6, 7, 8A, 8B, 9A, 9B, 10A, RayPlan 1, 2, 7, 8A, 8B, 9A, 9B, 10A, including all 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 “4.0.0.14”, “4.0.3.4”, “4.5.1.14”, “4.7.2.5”, “4.7.3.13”, “4.7.4.4”, “4.7.5.4”, “4.7.6.7”, “4.9.0.42”; “5.0.1.11”, “5.0.2.35”, “5.0.3.17”, “6.0.0.24”, “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”, or “10.0.0.1154”. If so, this notice applies to your version.

The UDI-DI of the affected products:

Product name (build number)	UDI-DI
RayStation 4.0 (4.0.0.14) to RayStation 5 Service Pack 2 (5.0.2.35)	N/A
RayStation 5 Service Pack 3 (5.0.3.17)	07350002010020
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
RayStation/RayPlan 10A (10.0.0.1154)	07350002010303

DESCRIPTION

The references from a RT Plan/RT Ion Plan to a RT Structure Set that can be affected by this issue are bolus ROIs and prescription ROIs or POIs. Material override and other ROI or POI properties are not affected by this bug.

If the RT Plan/RT Ion Plan, RT Structure Set and CT set are imported all at the same time, the incorrect references can only be set up to an ROI or a POI that does not have any definition on the CT set. This means that the ROI contours or the POI coordinates of the incorrectly referenced ROI or POI would not be defined.

If the CT set is imported first and some ROIs/POIs are defined before importing the RT Plan/RT Ion Plan and RT Structure Set, the incorrectly referenced ROI/POI could be defined on the CT.

Prescription ROI or POI

Input data that may trigger the error is a plan that references to a prescription ROI or POI that does not exist in the RT Structure Set. RayStation version 5 and above may produce such data if excluding the prescription ROI/POI when exporting with the "Exclude from export" option.

The incorrect prescription reference can then be set at import when an existing ROI/POI in the case has the same ROI/POI number as the missing ROI. It is not possible to link an ROI prescription to a POI or vice versa.

If the prescription is set for an ROI or a POI which is defined on the CT, it would be possible to scale the plan, i.e., change the MU to match the incorrect prescription. Auto-scale to prescription would not be selected by default, so any scaling would need to be initiated by the user. If the incorrect ROI/POI is not defined on the CT, scaling to prescription is not possible.

Bolus ROI

Input data that may trigger the error is a plan that references to a bolus ROI that does not exist in the RT Structure Set. RayStation will not allow export that creates such data.

The incorrect bolus reference will occur when an existing ROI in the case has the same ROI number as the missing Bolus ROI. The existing ROI must also be of type Bolus, making an incorrect match very unlikely.

If the incorrect link is made to a bolus ROI without contours on the CT set, the dose could be calculated without the intended bolus. There will be a warning at export and approval of a plan with dose calculated with a bolus without contours.

If the link is made to an incorrect ROI with contours, the dose would be calculated with a bolus for beams that were intended to have a bolus, but the bolus could be in the wrong place or with unintended thickness.

ACTIONS TO BE TAKEN BY THE USER

- Do not exclude the prescription ROI or POI when exporting from RayStation with the “Exclude from export” option.
- If an RT Structure Set where it is not certain that all referenced bolus and prescription ROIs or POIs are present is imported to RayStation, make sure to check that any intended references to bolus and prescription are correct after import.
- Please 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 November 2020 (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. Please maintain awareness of this notice as long as any version of RayStation affected by this issue is in use to ensure effectiveness of the workaround.

Thank you for your cooperation, and we apologize for any inconvenience.

For regulatory information, please contact quality@raysearchlabs.com

The undersigned confirms that the appropriate Regulatory Agencies will be notified.

.....  I am approving this document
Stockholm, Sweden
2020.10.07 13:01:47 +02'00'

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 888 501 7195 (US only).

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):

