

## Field Safety Notice, Medical Device Correction #50327

**RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 4.9  
(RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2),  
RayStation/RayPlan 7, RayStation/RayPlan 8A,  
RayStation/RayPlan 8B and RayStation/RayPlan 9A**

**November 18, 2019**

**RSL-D-61-404**

### ISSUE

This notice concerns an issue found with static arc planning in RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation/RayPlan 7, RayStation/RayPlan 8A, RayStation/RayPlan 8B and RayStation/RayPlan 9A.

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 dose calculations during treatment planning.

### INTENDED AUDIENCE

This notice is directed to all users of RayStation/RayPlan who use static arcs.

### PRODUCT NAME AND VERSION

The products affected by this notice are sold under the trade names RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation/RayPlan 7, RayStation/RayPlan 8A, RayStation/RayPlan 8B and RayStation/RayPlan 9A. To determine if the version you are using is affected, open the About RayStation/RayPlan dialog in the RayStation/RayPlan application and check if the build number reported there is "4.0.0.14", "4.0.1.4", "4.0.2.9", "4.0.3.4", "4.5.0.19", "4.5.1.14", "4.5.2.7", "4.7.0.15", "4.7.1.10", "4.7.2.5", "4.7.3.13", "4.7.4.4", "4.7.5.4", "4.9.0.42", "5.0.0.37", "5.0.1.11", "5.0.2.35", "6.0.0.24", "6.1.0.26", "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", or "9.0.0.113". If so, this notice applies to your version.

UDIs of the affected products:

Product name (build number)	UDI
RayStation 4.0 (4.0.0.14)	N/A
RayStation 4.0 Service Pack 1 (4.0.1.4)	N/A
RayStation 4.0 Service Pack 2 (4.0.2.9)	N/A

Product name (build number)	UDI
RayStation 4.0 Service Pack 3 (4.0.3.4)	N/A
RayStation 4.5 (4.5.0.19)	N/A
RayStation 4.5 Service Pack 1 (4.5.1.14)	N/A
RayStation 4.5 Service Pack 2 (4.5.2.7)	N/A
RayStation 4.7 (4.7.0.15)	N/A
RayStation 4.7 Service Pack 1 (4.7.1.10)	N/A
RayStation 4.7 Service Pack 2 (4.7.2.5)	N/A
RayStation 4.7 Service Pack 3 (4.7.3.13)	N/A
RayStation 4.7 Service Pack 4 (4.7.4.4)	N/A
RayStation 4.7 Service Pack 5 (4.7.5.4)	N/A
RayStation 4.9/RayPlan 1 (4.9.0.42)	N/A
RayStation 5 (5.0.0.37)	N/A
RayStation 5 Service Pack 1 (5.0.1.11)	N/A
RayStation 5 Service Pack 2 (5.0.2.35)	N/A
RayStation 6/RayPlan 2 (6.0.0.24)	0735000201001320161214
RayStation 6/RayPlan 2 Service Pack 1 (6.1.0.26, 6.1.1.2)	0735000201003720170501, 0735000201008220170529
RayStation 6/RayPlan 2 Service Pack 2 (6.2.0.7)	0735000201007520170630
RayStation 6/RayPlan 2 Service Pack 3 (6.3.0.6)	0735000201024220190923
RayStation/RayPlan 7 (7.0.0.19)	0735000201006820171130
RayStation/RayPlan 8A (8.0.0.61)	0735000201011220180608
RayStation/RayPlan 8A Service Pack 1 (8.0.1.10)	0735000201013620180918
RayStation/RayPlan 8B (8.1.0.47)	0735000201012920181209
RayStation/RayPlan 8B Service Pack 1 (8.1.1.8)	0735000201020420190214
RayStation/RayPlan 8B Service Pack 2 (8.1.2.5)	0735000201023520190524
RayStation/RayPlan 9A (9.0.0.113)	0735000201017420190612

## DESCRIPTION

Editing a static arc beam may unexpectedly set the MU of the beam to its initial default value of 200 MU. This may happen in the following scenarios:

1. When editing or viewing a static arc beam with a cone using the Edit beam dialog. The bug is triggered when closing the Edit beam dialog with OK, even if no changes were made in the dialog.
2. When editing the aperture of a static arc beam using the Polygon tool or the Rectangular Field tool.

If the bug is triggered, the dose is invalidated and needs to be recalculated before the plan can be approved or exported. After recalculation the dose will be correct, but the beam weighting can be different than it was before the beam was edited, even if the beam weights were clamped (locked) in the Beam Weighting tab.

## ACTIONS TO BE TAKEN BY THE USER

- Be aware that the MU of static arc beams may change unexpectedly when using the Edit beam dialog or when editing the beam aperture.
- Always review the final dose before approving a plan for treatment:

### WARNING!



**Plan review and approval.** All treatment plan data shall be carefully reviewed and approved by a qualified person before it is used for radiotherapy treatment purposes. A plan (beam set) that is 'optimal' with respect to the optimization goals may still be inappropriate for clinical use. (508826, 508814)

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), then confirm that 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/RayPlan, scheduled for market release in December 2019 (subject to market clearance in some markets). If customers wish to continue using versions of RayStation/RayPlan 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/RayPlan 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](mailto:quality@raysearchlabs.com)

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

**PLEASE CONFIRM THAT YOU HAVE RECEIVED THIS NOTICE**

**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.

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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):

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