

## Field Safety Notice, Medical Device Correction #37483

**RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7,  
RayStation 5, RayStation 6, RayStation 7 and RayStation 8A**

**11/12/18**

**RSL-D-61-365**

### ISSUE

This notice concerns an issue found with isocenter shifts when using dose tracking in RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6, RayStation 7 and RayStation 8A. In these versions, isocenter shifts in dose tracking are incorrectly interpreted according to the DICOM patient coordinate system.

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 fraction dose estimation in dose tracking.

### INTENDED AUDIENCE

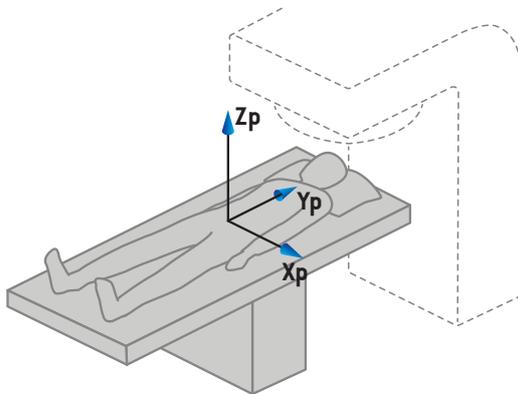
This notice is directed to all users of RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6, RayStation 7 and RayStation 8A who use dose tracking.

### PRODUCT NAME AND VERSION

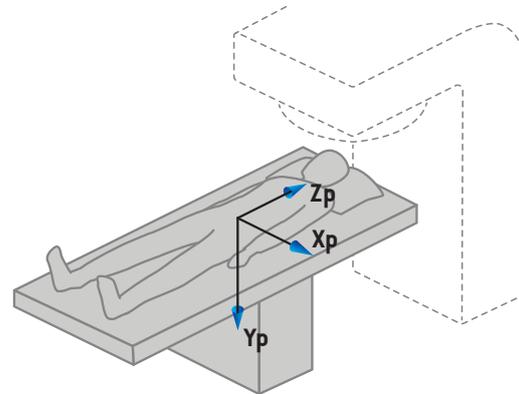
The product affected by this notice is sold under the trade name RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6, RayStation 7 and RayStation 8A. To determine if the version you are using is affected, open the About RayStation dialog in the RayStation application and check if the build number reported there is "3.5.0.16", "3.5.1.6", "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", "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", "7.0.0.19", "8.0.0.61" or "8.0.1.10". If so, this notice applies to your version.

### DESCRIPTION

When estimating fraction doses in the Dose Tracking module, it is possible to enter isocenter shifts as X, Y, Z in the Estimate Fraction Dose dialog. The coordinate system is not specified in the user interface, but the user manuals state that values in RayStation shall be entered according to the IEC patient coordinate system. However, in the Estimate Fraction Dose dialog, coordinates are interpreted according to the DICOM patient coordinate system. This means that Y and Z values will be used incorrectly.



**Figure 1) IEC patient coordinate system**



**Figure 2) DICOM patient coordinate system**

The incorrect isocenter shifts will be visible in the dose views in the Dose Tracking module. The estimated fraction dose can be used as background dose for treatment adaptation. If the isocenter shifts are incorrect the background dose will also be incorrect, and the new adapted plan may not be as intended.

The error only applies to the Dose Tracking module. The same function is available in the Plan Evaluation module when computing perturbed doses, but in this module X, Y, Z are correctly interpreted according to the IEC patient coordinate system.

## ACTIONS TO BE TAKEN BY THE USER

- In the Dose Tracking module, be aware that isocenter shifts X, Y, Z in the Estimate Fraction Dose dialog are interpreted according to the DICOM patient coordinate system.
- Make sure that isocenter shifts are as intended when using estimated fraction dose as background dose for treatment adaptation.

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, scheduled for market release in December 2018 (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](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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