Field Safety Notice,
Medical Device Correction #13529

RayStation 5

2016-10-11
RSL-D-61-305

ISSUE

This notice concerns an issue found with the display of dose computed on images other than the planning CT (auxiliary CT) when using multiple patient cases in RayStation 5. If a CT image set with the same Frame of Reference as the displayed auxiliary CT set exists in another case, the dose display may be incorrect.

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 possible mistreatment.

INTENDED AUDIENCE

This notice is directed to all users of RayStation 5.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 5. 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 "5.0.0.37", "5.0.1.11" or "5.0.2.35". If so, this notice applies to your version.

DESCRIPTION

The problem can only occur when a patient has multiple cases, and when there are image sets that reside in different cases but share the same Frame of Reference (FoR). The issue occurs when a plan in one case is used to compute dose on another image set, and when that image set has the same FoR as an image set in another case. This happens when using the function "Compute Dose on Other Data Set" in the Plan Evaluation module or when computing fraction doses in the Dose Tracking module. The visual display of dose in the patient views can be incorrect and can be shifted and/or rotated.

In some scenarios when the error has occurred, the RayStation system may crash, e.g., when exporting the evaluation dose or when attempting to create an adapted plan. In other scenarios it is possible to continue operation without apparent problems.

When the error occurs, the display of dose in patient views, including the maximum dose position, the dynamic isodose lines and the dose grid may be incorrect. The dose value normally displayed in the upper left corner when pointing in the 2D view may be incorrect or missing.

However, the dose calculation is not affected. The DVHs, dose statistics and line doses are correct. The beam outline is correctly displayed in the 2D view. Deformable registration is not affected. In the Dose Tracking module, accumulated dose and total dose are correctly displayed.

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Detectability of the problem is usually high since the displayed dose does not match the beam outline, and the DVH and other evaluation tools show the correct dose statistics. However, there may be cases where the error is less visible.

ACTIONS TO BE TAKEN BY THE USER

Be aware that when a patient has multiple cases, the following may be incorrect if there are image sets that share the same Frame of Reference residing in different cases:

- Display of evaluation dose computed on another CT image set
- Dose tracking fraction dose and deformed dose

In these cases, the display of the dose values in the 2D view, including the dose value shown when pointing in the view, maximum dose position, dynamic isodose lines and dose grid display may be incorrect. Please educate planning staff and all users about this.

Inspect your product and identify all installed units with the above software version number, then confirm you have read and understood this notice (contact information below).

SOLUTION

This issue will be resolved in the next version of RayStation, scheduled for market release December 2016. In the meantime, this field safety notice is distributed to all customers. Until a corrected version has been installed, all affected users must maintain awareness of this field safety notice.

TRANSMISSION OF THIS FIELD SAFETY 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 this version of RayStation 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 David Hedfors, at +46 8 510 530 12 or david.hedfors@raysearchlabs.com

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

David Hedfors

Digitally signed by David Hedfors
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REPLY FORM

URGENT FIELD SAFETY NOTICE, MEDICAL DEVICE CORRECTION #13529
RAYSTATION 5
RSL-D-61-305

Preferably, reply to the same email address that sent you this notice, stating you have read and understood it.

You can also email or phone your local support or support@raysearchlabs.com, +46 8 510 533 33 to acknowledge this notice.

If you want to fill in this reply form, please send it to:

☐ Americas market: Freddie Cardel, freddie.cardel@raysearchlabs.com, fax 888 501 7195

☐ Rest of the world: RaySearch Support, support@raysearchlabs.com, no fax number

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):

_____

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