RaySearch
Laboratories

Field Safety Notice, Medical
Device Correction #12171 #11861

RayStation 2.5, 3.0, 3.5, 4.0, 4.5, 4.7,
5.0 and 4.3 (InverseArc 1.0)
September 5th, 2016
RSL-D-61-301

ISSUE

This notice concerns two issues found with the dose calculation when using a region of interest (ROI) of type Fixation or Support with material override within the patient outline (External ROI) in RayStation 2.5, 3.0, 3.5, 4.0, 4.5, 4.7, 5.0 and 4.3 (InverseArc 1.0). There are two issues:

- When an ROI with material override overlaps a Fixation or Support ROI, the material used for dose calculation in the overlapping region may not be as intended.

- When a Support or Fixation ROI overlaps the patient outline (External ROI) in a dose grid voxel along the outer surface of the patient outline, the density used for dose calculation in that voxel may not be as intended.

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 dose calculations during treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation and InverseArc.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 2.5, 3.0, 3.5, 4.0, 4.5, 4.7, 5.0 and 4.3 (InverseArc 1.0). To determine if the version you are using is affected, open the 'About' dialog in the application and check if the build number reported there is "2.5.0.144", "2.5.1.89", "3.0.0.251", "3.5.0.16", "3.5.1.6", "4.0.0.14", "4.0.1.4", "4.0.2.9", "4.0.3.42", "4.3.0.14", "4.5.0.19", "4.5.1.14", "4.5.2.7", "4.7.0.15", "4.7.1.10", "4.7.2.5", "4.7.4.4", "4.7.5.4", "5.0.0.37", "5.0.1.11" or "5.0.2.35". If so, this notice applies to your version.

DESCRIPTION

The DICOM standard defines SUPPORT and FIXATION ROIs as regions with external patient support, fixation or immobilization devices. Support and Fixation ROIs in RayStation are intended to be used for such devices to allow for material override outside the patient outline.

However, the intended use of Support/Fixation is not defined in the RayStation Instructions for Use and it is possible to use Support or Fixation for any ROI also for regions within the patient outline, e.g., where artefacts need to be removed.
Using Support or Fixation ROIs within the patient outline may lead to the following issues:

RSL-D-61-301, doc version 2.0, Field Safety Notice, Medical Device Correction #12171 #11861

RaySearch Laboratories AB (publ), P.O. Box 3297 SE-103 65 Stockholm Sweden, Visitors: Sveavägen 44 Phone +46 8 510 530 00

www.raysearchlabs.com   Page 1 (4)

Material override overlap

Overlapping ROIs with different material overrides are normally not allowed in RayStation. However, if one of the overlapping ROIs is of type Support or Fixation, it is possible to calculate dose without a warning. In the overlapping region, the material used for dose calculation will be the material of the Support or Fixation ROI. This could lead to an incorrect dose distribution downstream from the overlapping region if the density of the other ROI was intended.

The effect on the dose distribution will depend on the difference in densities between the overlapping ROIs, and on the beam configuration.

Detectability in the dose distribution may be low for some cases. When pointing in the overlapping region in the patient views, a warning about ambiguous material will be displayed in the upper left corner of the patient view.

Surface voxels

For dose calculation, the mass density distribution, as interpreted from the patient images, is resampled to dose grid resolution. The mass density of a dose grid voxel is calculated as a weighted average of the density from the CT data and the density of any material override ROIs that overlap the voxel. For a surface voxel, i.e., a dose grid voxel which lies partially outside the patient outline, the density is adjusted since the voxel shall in part be regarded as air or vacuum.

If the Support/Fixation ROI is <u>outside</u> the External ROI the density will be correct. However, if a Support or Fixation ROI <u>inside</u> the External ROI overlaps the External ROI in a surface voxel, the air part of the voxel is not correctly taken into account, resulting in a too high density in that voxel. If the overlapping voxel does not contain any air, the density will be correct. For details, see Figure 1.
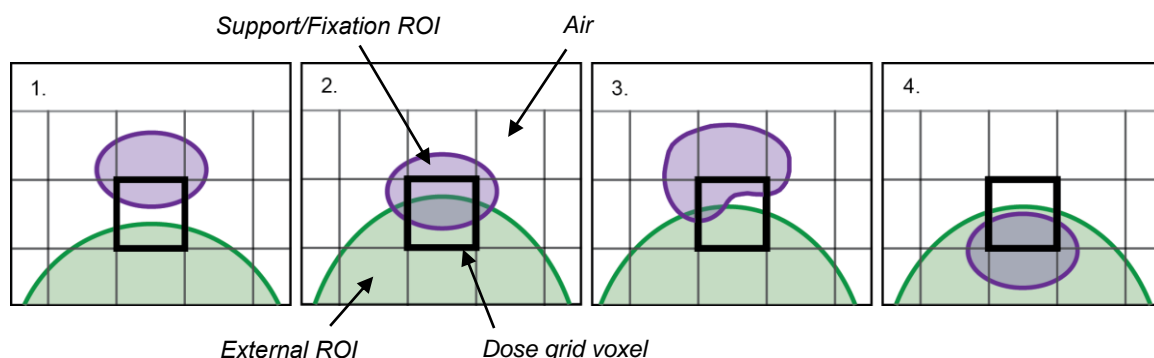

Figure 1: Case 1) The density will be correct. Case 2) The density will be correct. Case 3) The density will be incorrect in the affected voxel, but since it only affects a single voxel, the effect on overall dose will be negligible. Case 4) The density will be incorrect in the affected voxel. For a Support/Fixation ROI mainly inside the External ROI, many surface voxels may be affected, which may result in a non-negligible effect on the overall dose.

The effective density of the surface voxel can be overestimated by a factor of up to 0.5 relative the density of the External ROI material in the surface voxel. The impact depends on the material in the External ROI and the amount of air in the affected voxel. For photon and electron treatment, the effect is negligible. For proton treatment, the range may be affected.

RSL-D-61-301, doc version 2.0, Field Safety Notice, Medical Device Correction #12171 #11861

RaySearch Laboratories AB (publ), P.O. Box 3297 SE-103 65 Stockholm Sweden, Visitors: Sveavägen 44 Phone +46 8 510 530 00

www.raysearchlabs.com   Page 2 (4)

ACTIONS TO BE TAKEN BY THE USER

Do not use ROIs of type Fixation or Support within the patient outline. Always use other ROI types for material override within the External ROI. A small overlap with the External ROI is acceptable if the Fixation or Support ROI is mainly outside the External ROI.

Please educate planning staff and all users about this workaround.

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

A correction of these issues will be available in the next version of RayStation, scheduled for market release in 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.

RSL-D-61-301, doc version 2.0, Field Safety Notice, Medical Device Correction #12171 #11861

RaySearch Laboratories AB (publ), P.O. Box 3297 SE-103 65 Stockholm Sweden, Visitors: Sveavägen 44 Phone +46 8 510 530 00

www.raysearchlabs.com   Page 3 (4)

REPLY FORM

FIELD SAFETY NOTICE, MEDICAL DEVICE CORRECTION #12171 #11861 RAYSTATION 2.5, 3.0, 3.5, 4.0, 4.5, 4.7, 5.0 AND 4.3 (INVERSEARC 1.0) RSL-D-61-301

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):

_____

RSL-D-61-301, doc version 2.0, Field Safety Notice, Medical Device Correction #12171 #11861

RaySearch Laboratories AB (publ), P.O. Box 3297 SE-103 65 Stockholm Sweden, Visitors: Sveavägen 44 Phone +46 8 510 530 00

www.raysearchlabs.com   Page 4 (4)