Urgent Field Safety Notice, Medical Device Correction #31383

RayStation 2.5, RayStation 3.5, RayStation 4.0, RayStation 4.3 (InverseArc 1.0), RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7)

2018-06-05
RSL-D-61-352

ISSUE

This notice is a reminder to follow the instructions listed in the product documentation when creating a photon beam model in RayStation/RayPlan. It is the user's responsibility to validate the beam model for all clinically relevant fields before the system is used to create clinical treatment plans.

This information is already present in the Instructions For Use, the Reference Manual and the RayPhysics/RayPlan Physics Manual, but it has come to our attention that some RayStation/RayPlan users have commissioned machines with erroneous Beam profile correction parameters. These parameters affect the dose calculated in corners of large or off-axis fields.

To the best of our knowledge, the issue has not caused any patient mistreatment. 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 photon planning.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 2.5, RayStation 3.5, RayStation 4.0, RayStation 4.3 (InverseArc 1.0), RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7). 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 "2.5.1.89", "3.5.0.16", "3.5.1.6", " 4.0.0.14", "4.0.1.4" 4.0.2.9", "4.0.3.4", "4.3.0.14", "4.5.0.19", "4.5.1.14", "4.5.2.7", "4.7.0.15", "4.7.1.10", "4.7.2.5", "4.7.3.13", "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", "7.0.0.19". If so, this notice applies to your version.

DESCRIPTION

Beam profile correction parameters affect the dose calculated in corners of large or off-axis fields. This effect cannot be seen in the Beam Commissioning module and dose in large or off-axis fields needs to be validated using the Beam 3D Modeling module in RayPhysics/RayPlan Physics.

RSL-D-61-352 EN Urgent Field Safety Notice, Medical Device Correction #31383

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www.raysearchlabs.com   Page 1 (6)

Inappropriate parameter values may occur after auto-modeling in RayPhysics/RayPlan Physics and all beam model parameters must be reviewed before a treatment machine is commissioned. This applies even if the beam model is based on a template machine provided with RayStation/RayPlan.

The Reference Manual describes the Beam profile corrections:
"… fluence that originates in the primary source is further scaled with a radial beam profile correction. In beam modeling the radial beam profile correction is used to obtain the characteristic central field dip of conventional Elekta LINACs or to model the forward peaked energy fluence of flattening filter-free beams. It can also be used to model more subtle effects; one example being the primary collimator which can decrease the fluence at the corners of large fields."

Similar information can be found in the RayPhysics/RayPlan Physics Manual:
"The fluence from the primary source is scaled with a rotationally symmetric profile, the Beam profile correction. The beam profile correction can be used to create a dip or an increase in the fluence intensity for small radii. It can also be used to create fall-offs at the corners."

The RayPhysics/RayPlan Physics Manual defines the typical in-field values for Beam profile correction as 0.95 – 1.05 and defines a limit of 10% where the parameter values need to be subject to extensive investigation:
"For the Beam profile correction, all factors should not deviate from 1.0 with more than approximately 10% in the in-field region for machines with flattening filter. If the beam profile correction factors show larger differences, review the beam model parameters."

Furthermore, it is stated that the auto-modeling may generate unrealistic Beam profile correction values for radii points larger than the measured curves:
"The auto modeling may generate values which are unreasonable from a physical point of view for radii points larger than the measured curves. Therefore, some manual tuning is often necessary after the auto modeling; continue the gradient or set this region to a constant extrapolated value."

In RayStation 7, a warning is displayed before commissioning, if such unreasonable Beam profile correction values are present.

The following information concerning review of parameters after auto-modeling can be found in the RayPhysics/RayPlan Physics Manual:
"Review of parameter values after auto-modeling. The user must always review beam model parameter values after auto-modeling. The user must have proper training and be familiar with the beam model process. Results must be verified using professional standards of QA or alternative calculations."

The beam models must be validated for all relevant clinical situations before clinical use. This is a user responsibility as stated in the Instructions For Use:

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www.raysearchlabs.com   Page 2 (6)

> **WARNING!**
>
> **Beam models must be validated before clinical use.** It is the responsibility of the end-user to validate and commission RayStation/RayPlan before the system is used to create clinical treatment plans. RayStation/RayPlan is developed to be used by trained Radiation Oncology professionals. We strongly suggest that users adhere to recommendations published in AAPM TG40, TG142, TG53, IAEA 430 and other standards to assure accurate treatment plans.
>
> - Computed dose accuracy depends directly on beam model quality. Beam model insufficiency may lead to deviations between approved and delivered dose.
>
> - All parameter values and plan QA and QC shall be reviewed and approved by qualified physicists.
>
>   The computed dose shall be validated for all relevant clinical situations; e.g., variation in SAD, SSD, field-size, off-axis fields, collimation type and patient/phantom geometry. The dose calculations shall be validated using all commissioned CT machines. (508815)
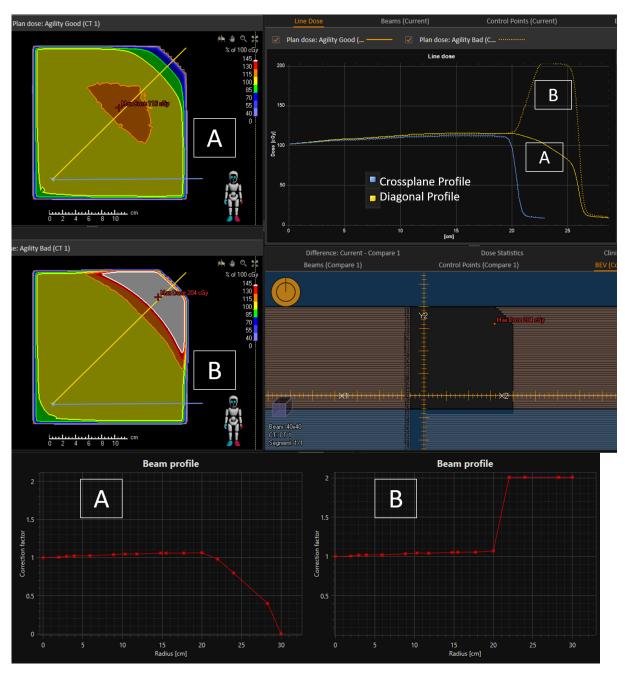
> **WARNING!**
>
> **Beam model parameters.** The accuracy of the dose computation depends critically on the beam model parameters established during beam commissioning. Before a machine is commissioned, all beam model parameters must be carefully reviewed by a person with proper training. (508983)

The following images show an example of how improper beam profile corrections may influence the dose for an extremely asymmetric field. Note that the error cannot be seen in the cross-plane profile (blue) but is obvious in the diagonal profile (yellow).

- Images marked with "A" display a properly modeled (correct) Beam profile correction for an Elekta LINAC with the Agility head.

- Images marked with "B" display the results following the auto-modeling step "Beam Profile Corrections" (incorrect) without a subsequent review of the results.

Similar effects will be seen for other LINAC types.

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www.raysearchlabs.com   Page 3 (6)

Detectability of this problem is high when validating the beam model for large or off-axis fields in the Beam 3D module in RayPhysics/RayPlan Physics.

RSL-D-61-352 EN Urgent Field Safety Notice, Medical Device Correction #31383

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www.raysearchlabs.com   Page 4 (6)

ACTIONS TO BE TAKEN BY THE USER

- Always validate the beam model for all clinically relevant fields, including, but not limited to, large and off-axis fields, before the system is used to create clinical treatment plans.

- Carefully review all beam model parameters before commissioning.

- Be aware that the Beam profile correction values may need to be adjusted in order to correctly model the primary collimator that limits the dose in the corners of large or off-axis fields.

- Review any existing photon beam models to ensure that the actions above have been properly performed.

Please educate physics staff about these user responsibilities.

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

Safe use relies on careful validation of the beam model for all clinically relevant fields before the system is used to create clinical treatment plans. This information is already present in the Instructions For Use, the Reference Manual and the RayPhysics/RayPlan Physics Manual for the existing product versions. To further reduce the risk of using improper beam models, the safety warnings within the product documentation will be updated in the next version of RayStation/RayPlan, scheduled for market release in June 2018.

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 information and continuously educate new and existing staff about the user responsibility to validate beam models for all clinically relevant treatment setups.

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

For regulatory information, please contact David Hedfors, at david.hedfors@raysearchlabs.com

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

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www.raysearchlabs.com   Page 5 (6)

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.

_____

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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www.raysearchlabs.com   Page 6 (6)