Urgent Field Safety Notice, Medical Device Correction #32484 v2.0

RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation 7 (RayPlan 7) and RayStation 8A (RayPlan 8A)

2018-07-17
RSL-D-61-354 v2.0

Note: *Changes since v1.0 are highlighted.*

ISSUE

This notice concerns an issue found with the DMLC "sliding window" photon dose calculation in RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation 7 (RayPlan 7) and RayStation 8A (RayPlan 8A) for machines with x-jaws and where the MLC is below both jaws (i.e., Varian style LINACs). If the beam model has a highly asymmetric or very small primary source, it is not correctly taken into account in the calculation of DMLC fields when the collimator is rotated. This does not apply to VMAT plans.

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 "sliding window" DMLC plans with rotated collimator.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation 7 (RayPlan 7) and RayStation 8A (RayPlan 8A). To determine if the version you are using is affected, open the About RayStation dialog in the RayStation/RayPlan application and check if the build number reported there is "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", "5.0.2.3", "6.0.0.24", "6.1.0.26", "6.1.1.2", "6.2.0.7", "7.0.0.19", "8.0.0.61". If so, this notice applies to your version.

DESCRIPTION

In a photon beam model, the primary source has an elliptical Gaussian intensity profile with the main axes along the x- and the y-directions; hence it is characterized by its widths in the x- and y-directions (perpendicular to the beam). The width of a source is equal to the standard deviation of a Gaussian distribution. The primary source is fixed in the gantry system, i.e., it does not rotate with the collimator.

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In RayStation/RayPlan, a “sliding window” DMLC plan has no jaw motion while the beam is on, and the MLC movement is strictly in one direction. This is the case for Varian style machines, i.e., machines with backup jaw and where the jaws are positioned closer to the source than the MLC. DMLC plans created in RayStation/RayPlan are of "sliding window” type and jaw movement will be per beam for machines that have backup jaw even if the machines are capable of jaw movement per segment. This applies to e.g., Varian TrueBeam with jaw tracking.

In the DMLC fluence calculation for “sliding window” type plans, there are x- and y-limits in the integration of the primary source. These limits are erroneously rotated with the collimator. This means that when the source is asymmetric and the collimator is rotated, there may be parts of the primary source that are not included and the fluence will be underestimated.

The displayed dose will have a correct overall shape, but the absolute dose level will be too low, leading to potentially significant overdosage at delivery. The effect will be most significant for a collimator angle of 90 degrees. The magnitude of the error will depend on the ratio of the primary source widths, see Figure 1 and Figure 2.

The largest error occurs when one of the widths is zero and the other width is larger than zero. This could lead to even larger errors than those displayed in Figure 1. If both widths are zero there is no error.

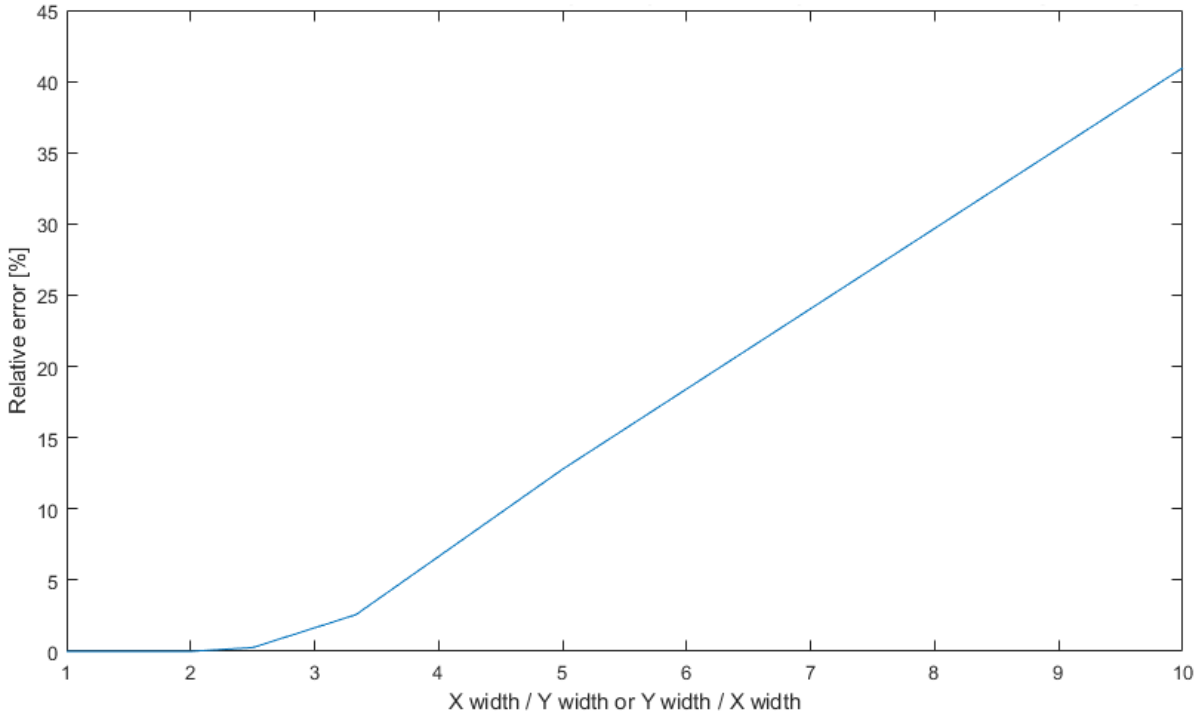

Figure 1: Approximate relative dose error as a function of the asymmetry of the primary source. The results are from a single field with a collimator angle of 90 degrees in a water phantom.

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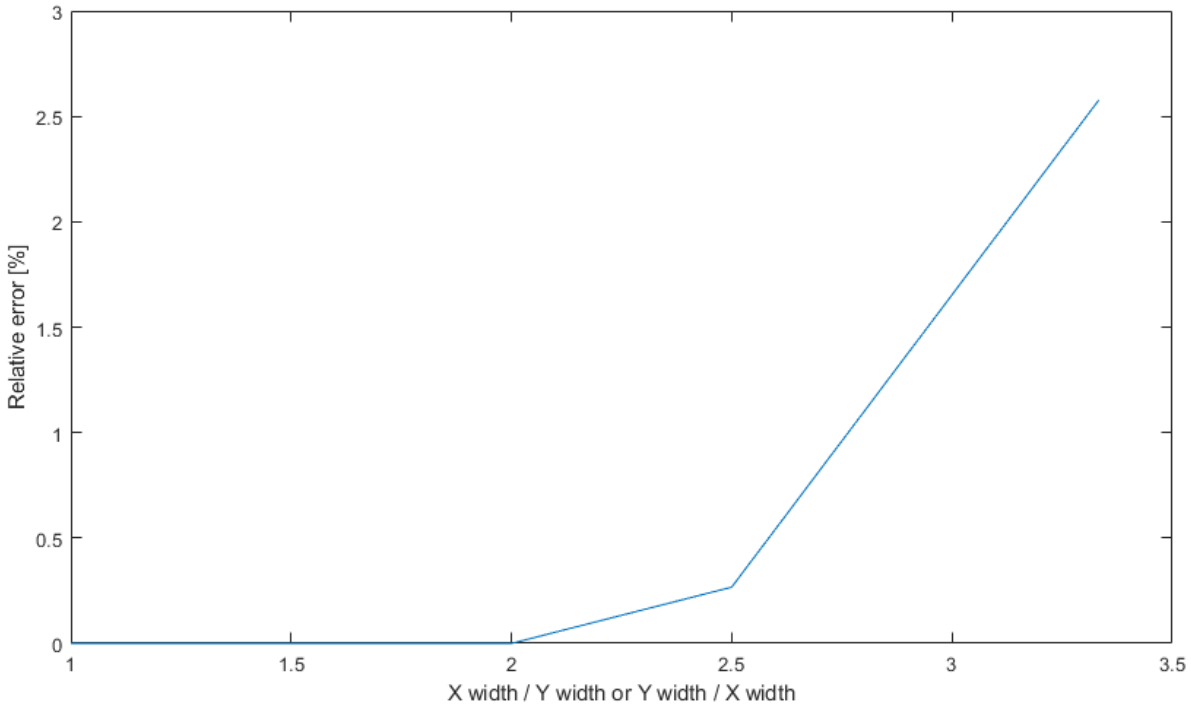

Figure 2: Approximate relative dose error. This figure shows the same data as in Figure 1 zoomed in on the region where the error becomes noticeable.

Detectability of the problem will normally be high in plan QA. However, if the option to collapse collimator angles to zero has been used in the QA Preparation module, the problem can only be detected in QA if the treatment plan, instead of the QA plan, is used for QA delivery.

The ”sliding window” fluence algorithm may also show other artifacts for very small primary source widths in either direction. Artifacts may manifest for source sizes below approximately 0.01 cm.

Note: *RayStation 5/RayPlan 2 and higher also supports DMLC with moving jaws, DMLC for machines without x-jaws, as well as DMLC for machines with x-jaws but where the MLC is positioned closest to the source. For these LINAC types, a different fluence algorithm is used, see section DMLC in the RayStation/RayPlan Reference Manual. This algorithm is not affected by the error.*

ACTIONS TO BE TAKEN BY THE USER

- Inspect the beam model for all LINACs that:
- allow DMLC planning and
- have x-jaws and
- have the MLC below both jaws (i.e., Varian style LINACs).

- If either the x- or y width of the primary source is below 0.01 cm or if they differ with more than a factor 2, do not use this beam model for DMLC. Contact RaySearch support for further assistance in adjusting the beam model and identifying potentially affected patients.

Please educate physics staff about this issue.

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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 2018 (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 David Hedfors, at david.hedfors@raysearchlabs.com

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

David Hedfors

Digitally signed by David Hedfors
DN: dc=com, dc=raysearchlabs, ou=Data, ou=Accounts, ou=Sweden, ou=Stockholm, ou=Users, cn=David Hedfors
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