Field Safety Notice, Medical Device Correction #24138

RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6, RayPlan 1 (RayStation 4.9) and RayPlan 2 (RayStation 6)
November 17, 2017
RSL-D-61-342

ISSUE

This notice concerns an issue found with the electron dose calculation in RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6, RayPlan 1 (RayStation 4.9) and RayPlan 2 (RayStation 6). When calculating electron Monte Carlo dose with a very large number of histories, the dose calculation may be wrong.

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 dose calculations during beam modelling and treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation and RayPlan who use electron dose calculation.

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, RayPlan 1 (RayStation 4.9) and RayPlan 2 (RayStation 6). 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”, “4.9.0.42”, “5.0.0.37”, “5.0.1.11”, “5.0.2.35”, “5.0.3.17”, “6.0.0.24”, “6.1.0.26”, “6.1.1.2”, or “6.2.0.7”. If so, this notice applies to your version.

DESCRIPTION

Electron dose calculation in RayStation uses a Monte Carlo dose engine, where a large number of particles are simulated. Each simulated particle is called a history, adding to the simulated dose. The number of histories can be adjusted for each dose calculation. Generally, a higher number of histories leads to a better dose accuracy due to lower statistical uncertainty, but adds to the calculation time. In beam modeling, using a higher number of histories may also be desired to determine an appropriate normalization value for commissioning the treatment machine.

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When starting the dose calculation, the data variable representing the number of histories is erroneously converted to a number format which cannot handle sufficiently large values. This means that when a very large number of histories is requested, the Monte Carlo dose engine may use a lower number of histories than requested. At the end of the dose calculation, the resulting dose is divided by the *intended* number of histories. This leads to a calculated dose that is lower than the actual dose. The shape of the dose distribution will be correct but the absolute dose level will be wrong.

In detail, the error occurs when the total number of histories (area × histories per cm^2) is above the maximum number a variable of type "unsigned long" can represent, which is 4,294,967,295 (2^{32}-1). For example, for a 25 × 25 open applicator (area of 625 cm^2), the dose will be incorrect if the number of histories is above 6,871,947 histories/cm^2. For smaller openings, a larger number of histories per cm^2 is required to trigger the error:

Applicator dimensions [cm]	Area [cm^2]	Max number of histories / cm^2
25 × 25	625	6 871 947
20 × 20	400	10 737 418
15 × 15	225	19 088 743
10 × 10	100	42 949 672
6 × 6	36	119 304 647

The table shows the max number of histories below which the dose is correct.

The error can arise during treatment planning in RayStation and in RayPlan, as well as during beam commissioning in RayPhysics and in RayPlanPhysics. When the number of histories during treatment planning is above the limit, the computed dose is underestimated which leads to overdosage.

Commissioning a machine with a normalization value determined by an erroneous calculation would scale the monitor units so that too few monitor units are prescribed. This results in an underdosage to all patients, regardless of the number of histories used in treatment planning.

If the large number of histories which is required to trigger the error is used, this would result in very long calculation times. This large number of histories is also well above the required number of histories to get a clinically acceptable dose accuracy.

For an individual treatment plan, the error could be detected by common clinical knowledge of the expected dose per monitor unit relationship for electron beams or by secondary calculations. For beam commissioning, the error could be detected by validation of the beam model.

ACTIONS TO BE TAKEN BY THE USER

- Do not use a number of histories above 6 million for electron dose calculation.
- Inspect all commissioned electron beam models for any applicator calculated with greater than 6 million histories.
- Contact customer support if you have any further questions.

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 you have read and understood this notice (contact information below).

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SOLUTION

This issue will be resolved in the next version of RayStation, scheduled for market release in December 2017 (subject to market clearance in some markets). 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 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 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, c=SE, ou=Stockholm, ou=Users, cn=David Hedfors
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REPLY FORM

FIELD SAFETY NOTICE, MEDICAL DEVICE CORRECTION #24138 RAYSTATION 3.5, RAYSTATION 4.0, RAYSTATION 4.5, RAYSTATION 4.7, RAYSTATION 5, RAYSTATION 6, RAYPLAN 1 (RAYSTATION 4.9) AND RAYPLAN 2 (RAYSTATION 6) RSL-D-61-342

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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