Field Safety Notice, Medical Device Correction #28672

RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7) March 29, 2018 RSL-D-61-349

ISSUE

This notice concerns an issue found with the photon Collapsed Cone dose calculation in RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7). For machines with fixed jaws (e.g., Elekta BM and Vero) and machines with the MLC closer to the source than both x- and y-jaws (e.g., Elekta Synergy with MLCi/MLCi2), the dose calculation accuracy may in some situations be less than expected.

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 treatment planning.

INTENDED AUDIENCE

This notice is directed to all users of RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7) who use photon Collapsed Cone dose calculation for the affected machine types.

PRODUCT NAME AND VERSION

The product affected by this notice is sold under the trade name RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7). 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 6.0.0.24, 6.1.0.26, 6.1.1.2, 6.2.0.7, or 7.0.0.19. If so, this notice applies to your version.

DESCRIPTION

The field measure calculation may be incorrect for certain LINAC types. The error can affect beam commissioning of machines with the MLC closer to the source than both x- and y-jaws (e.g., Elekta Synergy with MLCi/MLCi2). The error can also affect the dose calculation in treatment planning with the same type of machines as well as machines with fixed jaws (e.g., Elekta BM and Vero), for some specific types of treatment plans.

If the Elekta Synergy with MLCi/MLCi2, or a LINAC with similar collimator setup, is commissioned with measurement conditions ‘MLC only’, it may lead to errors in the output factor corrections (OFCs) and dose normalization of the beam model. This is expected to result in a systematic error of 0-2% for most treatment plans and typical variations in the beam model OFCs.

Treatment planning with affected machines (Elekta Synergy with MLCi/MLCi2, Elekta BM and Vero, or a LINAC with similar collimator setup) can give errors of the same magnitude also for correct beam models, but only for some specific types of treatment plans.

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Field measure and output factor corrections

The dose output varies with field size. Output variation caused by phantom scatter is accounted for in the RayStation Collapsed Cone dose calculation as part of the radiation transport and head scatter as fluence originating in extended sources. Remaining field size dependence is accounted for by adjusting the output factor corrections (OFCs) of the beam model. These are given as a function of the field measure, which relates the size of irregularly shaped fields to that of rectangular fields. For more information, see section "Output factor corrections" in the *RayPhysics manual* and section "Field measure" in the *Reference manual*.

Field measure calculation error

For machines with fixed jaws (e.g., Elekta BM and Vero) and machines with backup jaw and the MLC closest to the source (e.g., Elekta Synergy with MLCi/MLCi2), the field measure is calculated as the equivalent square of the MLC x- and y-opening. The x-opening is given by the maximum opening of all leaf pairs that are exposed by jaws. The error is present in the calculation of the y-opening for these machine types. The y-opening is given by the number of open MLC leaf pairs multiplied with their widths, considering only leaf pairs that are exposed by the jaws. A leaf pair should be considered open only if the opening is larger than the 'Minimum static/dynamic tip gap' of the MLC. In the affected products, the value of the 'Minimum static/dynamic tip gap' is disregarded, and all leaf pairs with an opening larger than 0.001 cm and which are not covered by jaws are incorrectly included as open leaves (see Figure 1). The maximum resulting error occurs when jaws are fully retracted.

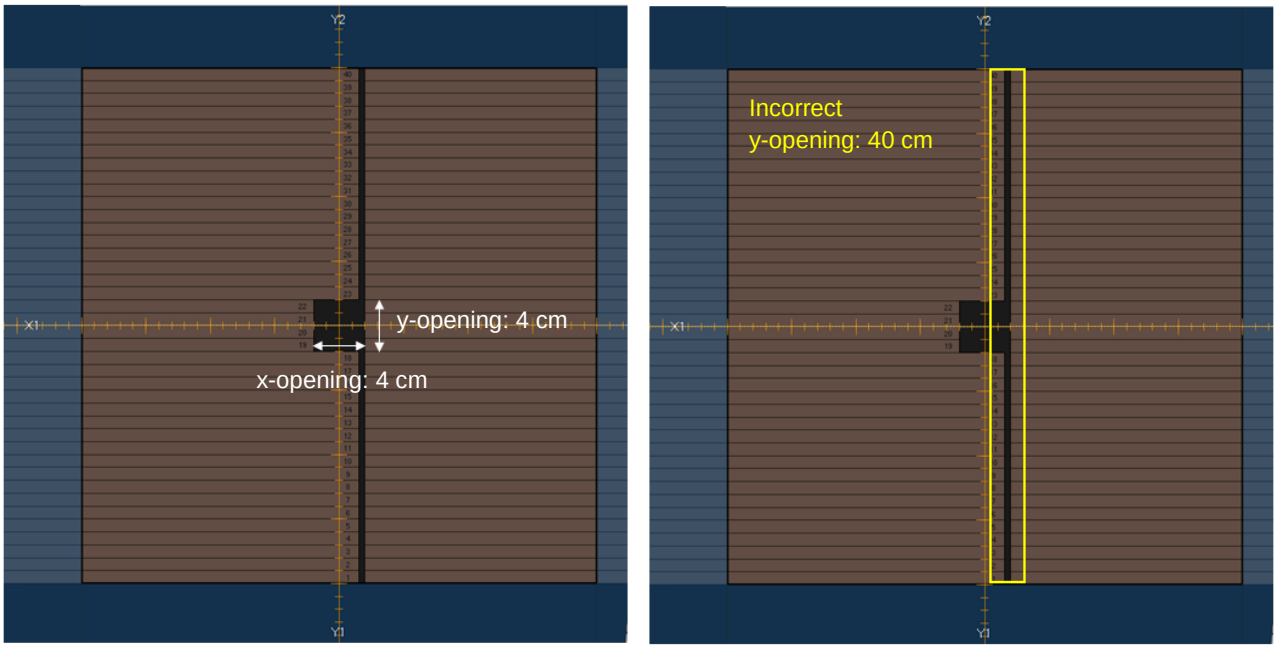

Figure 1. The field measure is incorrectly calculated from the 40 cm jaw field size in y (right image).

Beam commissioning with 'MLC only collimated' fields

Beam commissioning is affected by the error when closed MLC leaves are exposed by jaws. This is the case for the Elekta Synergy with MLCi/MLCi2, when the fields are 'MLC only collimated'. Fixed jaw machines are not affected, since closed leaves are positioned behind x-jaws.

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The error in the field measure calculation during beam commissioning leads to a suboptimal beam model. As an example, consider a machine that was commissioned with 'MLC only collimated' and used to treat fields where jaws conform to the MLC. For a specific MLC field size, the OFC will be adjusted so that measured and computed curves match for the incorrect calculated field measure FM_{BC}. During planning, when the jaws conform to the MLC opening, no closed leaf pairs will be exposed. The OFC for the correct field measure $FM_{Correct}$ will be used for dose calculation.

The beam model was adapted to the incorrect field measure calculation and the error in the dose calculation will be given by the difference between OFCs.

$$Dose\ calculation\ error = OFC\ difference = \frac{OFC(FM_{Correct}) - OFC(FM_{\mathrm{BC}})}{OFC(FM_{\mathrm{BC}})}$$

The resulting dose error for a typical beam model is presented in Table 1. For a typical beam model, with small variations in OFCs (Figure 2), the deviation will be below 2%, where the computed dose is lower than it should be. If large gradients exist in the OFCs, the error could potentially be as large as 5-10%.
In general, for field sizes above 2 x 2 cm, the OFCs should be close to 1.0. According to the *RayPhysics manual*, the OFC graph should be used to assess how good the model is. Variations in OFC of up to +/- 5% are not atypical, but if the corrections are greater than this, additional modeling may be required.

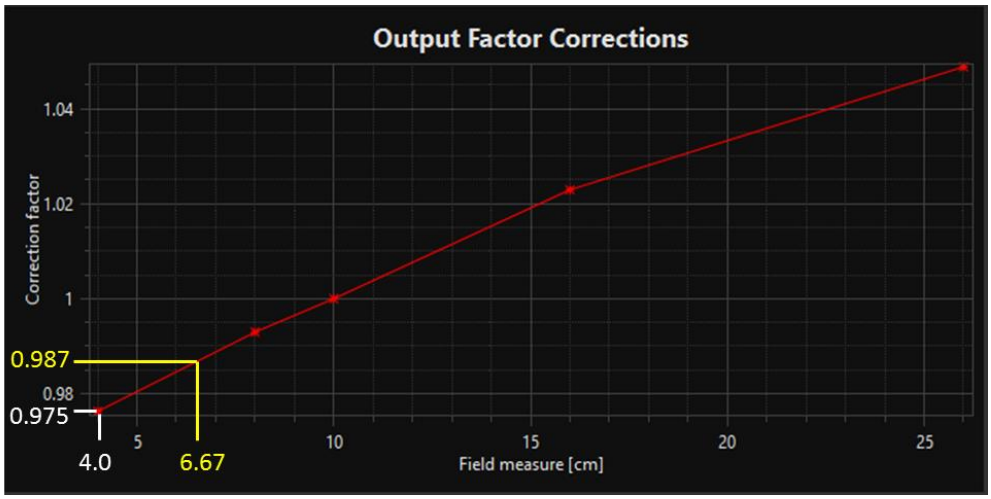

Figure 2. Typical OFCs. The field measure of the 4 x 4 MLC field will be calculated to 6.67 (yellow) for a field with a jaw opening in y of 20 cm, resulting in a 1.2% error in the OFC for the field.

MLC field size [cm]	Jaw y field size [cm]	$FM_{Correct}$ [cm]	FM_{BC} [cm]	OFCs as a function of field measure		Dose calculation error [%]
				$OFC(FM_{Correct})$	$OFC(FM_{BC})$	
4 x 4	20	4	6.67	0.975	0.987	-1.205
8 x 8	20	8	11.43	0.993	1.005	-1.203
10 x 10	20	10	13.33	1.000	1.013	-1.254
16 x 16	25	16	19.51	1.023	1.032	-0.882
26 x 26	26	26	26.00	1.049	1.049	0

Table 1. *Typical OFCs. The field measure of the 4 x 4 MLC field will be calculated to 6.67 (yellow) for a field with a jaw opening in y of 20 cm, resulting in a 1.2% error in the OFC for the field.*

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Treatment planning with Elekta Synergy with MLCi/MLCi2, Elekta BM and Vero machines
Even if the OFCs of the beam model are correct, the error in the field measure calculation may affect treatment plans where closed leaves, positioned to fulfill the 'Minimum static/dynamic tip gap' of the MLC, are exposed by jaws.

For most typical treatment planning situations, the jaws will conform to the MLC field opening (Elekta Synergy with MLCi/MLCi2) or closed leaves will be positioned behind x-jaws (Elekta BM and Vero machines), exposing only a limited number of closed leaves. The effect on dose calculation will then be negligible.

In a worst-case scenario, a large number of closed leaves would be exposed by jaws for all or most beam segments. This could happen for the Elekta Synergy with MLCi if multiple small targets should be treated within the same field. The MLCi does not allow leaves to interdigitate, forcing a channel of closed leaves to be created in between MLC openings. For fixed jaw machines, a worst-case scenario could be realized by some VMAT and Conformal arc setups.

Exact dose deviation for the worst-case scenario will depend on the variation of the OFCs. Most beam models have OFC values close to 1, leading to small deviations. However, it is possible to create a beam model with large OFC variations. Typically, the variation is larger for very small fields than for medium sized to large fields. When attempting to create a worst-case scenario with a typical beam model, the computed doses are up to ~2% higher than for a correctly calculated field measure.

If the OFCs of the beam model are incorrect due to beam commissioning with 'MLC only collimated´ fields, the errors will to some extent cancel out and the dose deviation in treatment planning will be smaller.

ACTIONS TO BE TAKEN BY THE USER

- Do not use 'MLC only collimated' to set output factor corrections (OFCs) in beam modeling of Elekta Synergy machines with MLCi/MLCi2 or any other machine with the MLC closer to the source than both the x- and y-jaws. Always use ´Jaws and MLC collimated´.

- Be aware that there is an error in the field measure calculation for machines with the MLC closer to the source than both the x- and y-jaws, and for machines with fixed jaws. Make sure to perform patient-specific QA before treatment delivery for treatment plans with fields where: 1) closed MLC leaves are positioned inside the jaw field and 2) the minimum static/dynamic tip gap is larger than 0.001 cm.

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 by replying to the notification email.

SOLUTION

This issue will be resolved in the next version of RayStation/RayPlan, scheduled for market release in June 2018 (subject to market clearance in some markets). If customers wish to continue using versions of RayStation/RayPlan affected by this Field Safety Notice, all users must maintain awareness of this Field Safety Notice. Alternatively, customers can choose to upgrade to the new version once it becomes available for clinical use.

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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/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, david.hedfors@raysearchlabs.com

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

David Hedfors

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