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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Brainlab Radiation Treatment Planning Software: Potential inaccurate dose calculation for small MLC-shaped fields when using the Pencil Beam algorithm
Product Reference:	iPlan RT and iPlan RT Dose (all versions), BrainSCAN (discontinued)
Date of Notification:	November 23, 2016
Individual Notifying:	Andrea Miller, MDR & Vigilance Manager
Brainlab Identifier:	CAPA-20161121-001828
Type of action:	Advice regarding use of device; Device modification.

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We are writing to advise you of the following effect that has been identified for the Brainlab radiation treatment planning software iPlan RT, iPlan RT Dose and BrainSCAN (all versions) when using the Pencil Beam algorithm for dose calculation of small MLC-shaped fields.

The purpose of this Product Notification letter is to provide you with corrective action information and to advise you of the actions Brainlab is taking to address the issue.

Effect:

The Pencil Beam algorithm refers to beam data which is acquired by performing dose measurements for Multileaf Collimator (MLC) fields at predefined field sizes and which are stored using the iPlan RT Physics Administration / BrainSCAN Beam Profile Editor.

For each beam contained in a radiation treatment plan, dose calculation is performed based on these tabulated measurement values. If a beam's equivalent field size does not correspond to the measured field size, the measured values are interpolated accordingly. Due to an inaccurate implementation in the Brainlab radiation treatment planning software, this interpolation between two measured values is less accurate

a) the smaller the field and
b) the further away the equivalent field size is from the measured value.

For certain treatment setups, this leads to the effect that an insufficient amount of Monitor Units (MU) is calculated and that consequently the delivered dose is lower than the planned dose. For clarity, the delivered dose does not exceed the planned dose due to the described issue.

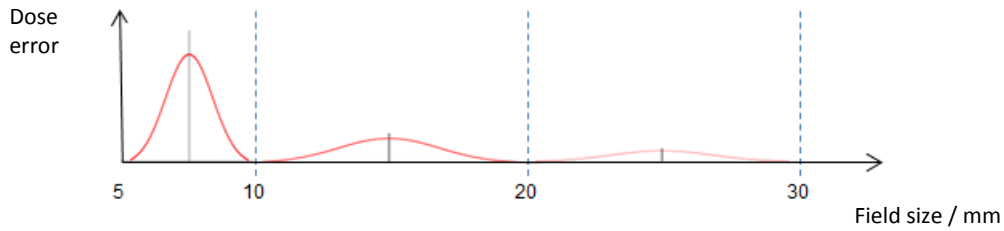

Figure 1 Schematic illustration of the possible dose error (calculated minus measured) over the field size. Measured field sizes are 5, 10, 20 and 30 mm, in this example of a Varian HD120 MLC. For the specific amount of dose error please see below.

The deviation between planned and delivered dose is largest if MLCs with small leaf width (e.g. Varian HD120 or Brainlab m3) are used and if the beam's equivalent field size is in the middle between two measured fields' sizes (refer to figure 1 above for an example). There is no deviation if the equivalent field size of a calculated field equals the size of a measured field, e.g. for a 5 mm or 10 mm field in above mentioned example. Interpolation is less accurate with growing distance from a measured field, and is least accurate if the equivalent field size is in the middle of two measured fields, e.g. for a 7.5 mm or 15 mm field in the example above.

Round-shaped volumes are affected to a larger extent, since the size of corresponding beams remains constant for different beam directions. Elongated or irregular shapes are not affected as much, because the equivalent field size varies with different beam angles.

The dose deviation is caused by a software module responsible for the phantom scatter calculation using the convolution of the Pencil Beam kernels. Therefore, the specific amount of dose deviation is depending on the combination of source function correction values (width and amplitude). For technical details of the algorithm please refer to the Technical Reference Guide.

Brainlab analysis (based on data from more than 140 beam data sets for different MLCs) determined that the **maximum dose deviation for a set of beam data for fields smaller than 10 mm is typically below 5%** and only in **rare cases between 5% and 10%**. Larger deviations are theoretically possible, but not expected. Furthermore the analysis showed for all MLCs that **for fields larger than 10 mm the maximum dose deviation is typically below 3%** and only in **rare cases between 3% and 4%**.

If dose deviations are not recognized by the user with the recommended treatment plan quality assurance, the irradiation of such a treatment plan **might lead to ineffective radiation treatment**.

User Corrective Action

As a workaround, to reduce the described dose deviation to less than 2% using the Pencil Beam algorithm in iPlan RT 4.5.x Brainlab recommends to modify the machine profile following the instructions outlined in the Appendix.

For all Brainlab treatment planning systems, as recommended by Brainlab, perform proper pre-treatment quality assurance for every treatment plan. Independent calculation of the dose using 3rd party QA Software or dose measurements inside a phantom is suitable to judge the accuracy of the dose calculation. Refer to the Brainlab Physics Technical Reference Guide for details.

Treatment verification and (retrospective) review

To determine to which degree a certain treatment plan is affected by the issue described above, review the results of your pre-treatment quality assurance. Even if no quality assurance was performed before patient treatment, this can also be performed anytime, retrospectively. Refer to the Brainlab Physics Technical Reference Guide for details.

Brainlab Corrective Action

1) Brainlab provides existing potentially affected customers with this product notification information.
2) Brainlab will provide a software solution (iPlan RT) to prevent the described scenario from occurring. Brainlab will actively contact affected customers tentatively starting September 2017 to schedule the update.

Note for BrainSCAN customers: Brainlab discontinued the development of additional functions for BrainSCAN in 2002. A corresponding end-of-life communication was sent in 2013, stating that service and support related to BrainSCAN will terminate on April 30, 2014. Consequently, Brainlab will not provide a software update for BrainSCAN. Brainlab strongly recommends customers still using BrainSCAN clinically to phase out the use of this software with immediate effect.

Please advise the appropriate personnel working in your department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation.

If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

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November 23, 2016
Kind Regards,

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Europe: The undersign confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.

APPENDIX

For potentially affected MLCs, extend the Scatter Factor table to include two additional rows, following the according instructions in the iPlan RT Physics Administration software user guide.

Note: Applicable only for iPlan RT versions 4.5.x (i.e. 4.5.0, 4.5.1, 4.5.2, 4.5.3, 4.5.4).

- The field sizes for the rows to be added correspond to the middle values between the three smallest existing measured MLC field sizes (e.g. for a MLC with 2.5 mm leaf width typically the rows for the 7.5 mm and 15.0 mm square fields are to be added).
- The values to be entered in the new rows are not measured, but determined by directly interpolating the existing measured values (e.g. the values for the 7.5 mm square field result from directly interpolating the 5.0 and 10.0 mm square field measurements).
- Note that if new dose data measurements are taken (for the whole Scatter Factor table), the values for the additional rows can be measured as well (and don't have to be interpolated manually as described above).

SAMPLE: How to extend the Scatter Factor table

The instructions below explain how to add two MLC square fields to an existing Scatter Factor table in iPlan RT Physics Administration.

The two rows that will be added correspond to the two middle values between the three smallest measured MLC square fields. The example below is for a MLC with 2.5 mm leaf width, where the three smallest MLC square fields measured are 5.0 mm, 10.0 mm and 20.0 mm. Rows are to be added for the 7.5 mm and 15.0 mm square fields.

Please note that the values are only representative. Your machine profile values may differ. **Do not use this example clinically.**

Step	Instructions
1.	Open Physics Administration
2.	Under Machine Profiles, click on "Open"
3.	Select the Machine profile you wish to adapt
4.	Select the tab "Scatter" Scatter | Depth Dose | Radial Factors
5.	The Scatter Factor table should look similar to the one below
6.	Under MLC Square Size, click on "Add Row …"
7.	Enter the new MLC Size, in this example 7.5 mm, and click "OK"
8.	A new row with zeros will be added
9.	Replace the zeros with the new values that result from linearly interpolating the rows above and below. Example for a MLC Square Size of 7.5 mm and Jaw Square Size of 8.0 mm: $SF_{(7.5\ ,\ 8.0)} = \frac{SF_{(10.0\ ,\ 8.0)} + SF_{(5.0\ ,\ 8.0)}}{2} = \frac{0.6850 + 0.6208}{2} = 0.6529$
10.	Repeat the calculation for the remaining Jaw Square Sizes

Jaw Square Size [mm]

MLC Square Size [mm]	8.0	12.0	22.0	32.0	42.0	60.0
5.0	0.6208	0.6296	0.6340	0.6356	0.6372	0.6376
10.0	0.6850	0.7303	0.7372	0.7396	0.7420	0.7428
20.0	0.6850	0.7448	0.7913	0.8018	0.8074	0.8106
30.0	0.6850	0.7448	0.7970	0.8295	0.8399	0.8511
40.0	0.6850	0.7448	0.7970	0.8339	0.8628	0.8792
60.0	0.6850	0.7448	0.7970	0.8339	0.8680	0.9173
80.0	0.6850	0.7448	0.7970	0.8339	0.8680	0.9173
100.0	0.6850	0.7448	0.7970	0.8339	0.8680	0.9173

	8.0	12.0	22.0	32.0	42.0	60.0
5.0	0.6208	0.6296	0.6340	0.6356	0.6372	0.6376
7.5	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
10.0	0.6850	0.7303	0.7372	0.7396	0.7420	0.7428
20.0	0.6850	0.7448	0.7913	0.8018	0.8074	0.8106

		8.0	12.0	22.0	32.0	42.0	60.0
	5.0	0.6208	0.6296	0.6340	0.6356	0.6372	0.6376
	7.5	0.6529	0.6800	0.6859	0.6876	0.6896	0.6902
	10.0	0.6850	0.7303	0.7372	0.7396	0.7420	0.7428
	20.0	0.6850	0.7448	0.7913	0.8018	0.8074	0.8106
11.	Repeat steps 6 to 10 for the 15.0 mm MLC Square Size						
		8.0	12.0	22.0	32.0	42.0	60.0
	5.0	0.6208	0.6296	0.6340	0.6356	0.6372	0.6376
	7.5	0.6529	0.6800	0.6859	0.6876	0.6896	0.6902
	10.0	0.6850	0.7303	0.7372	0.7396	0.7420	0.7428
	15.0	0.6850	0.7376	0.7642	0.7707	0.7747	0.7767
	20.0	0.6850	0.7448	0.7913	0.8018	0.8074	0.8106
12.	Save the machine profile						
13.	After proper verification of the modification within iPlan RT the new machine profile may be approved.						