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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Potential inaccuracy of BrainSCAN Pencil Beam Dose Algorithm
Product Reference:	BrainSCAN versions 5.31 and 5.32 only
Date of Notification:	Oct. 28, 2011
Individual Notifying:	Alexander Schwiersch, Regulatory Affairs Manager
Brainlab Identifier:	11-08-30.FIS.1
Type of action:	Advice regarding use of device.

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We are writing to advise you of a potential undesirable effect that might occur with the Pencil Beam Dose Algorithm of BrainSCAN version 5.31 or version 5.32 under the specific conditions as described below.

This 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 BrainSCAN Pencil Beam Dose Algorithm may overestimate the dose delivered to the target region if both of the following conditions are met:

- The scatter measurements have been performed according to the Technical Reference Guide (TRG) “Brainlab Physics” (any revision), i.e. the scatter table was measured and implemented without values for equal jaw and MLC field sizes. **AND**
- In the treatment plan, the margin between jaw position and MLC field shape is set to a value smaller than the default margin of 8mm in leaf movement direction and 2mm in direction perpendicular to leaf movement.

As a consequence, a dose lower than planned and intended might be delivered to the patient, **potentially resulting in ineffective treatment.**

In general, the magnitude of the effect increases with decreasing margin between jaw and MLC field shape.

Details:

The linear accelerator’s primary jaws are used to reduce the inter- and intra-leaf leakage. Therefore they are positioned relatively close to the Multi-Leaf-Collimator (MLC) field. However, for most linear accelerators, the primary jaws have a broader penumbra than the MLC and cannot be positioned as accurately as the MLC. As a consequence, during treatment planning the jaws are not directly aligned with the MLC field shape, but are positioned with a certain margin behind the MLC field shape.

If treatment planning is performed as outlined in the previous paragraph, the effect of the described inaccuracy is very small or non- existent. Our calculations have shown that the dose calculation is correct if jaw margins equal or larger than the default jaw margins are used. The default margin between jaws and MLC shape in BrainSCAN is 8mm in leaf movement direction and 2mm in direction perpendicular to leaf movement for all MLCs.

If the user decides to use smaller or no margins then the following applies:

For accurate dose calculation, the algorithm used in BrainSCAN 5.31 and 5.32 requires scatter measurements where, for each jaw field size (column), there is one **identical** MLC square field size (row) (e.g. jaw size = 6 x 6 mm^2 and MLC square field of 6 x 6 mm^2).

Other software versions do not have this specific requirement.

Before the first release of the TRG, measurement instructions described the measurements in a way that was compatible to this requirement of the Pencil Beam algorithm in BrainSCAN version 5.31 and 5.32.

Scatter Factors

Jaw Size [mm]

Square Field [mm] / Color	8.0	14.0	20.0
6.0	0.5007	0.6098	0.7302
12.0	~~0.5313~~	0.7027	0.7327
18.0	~~0.5313~~	~~0.7225~~	0.7793
24.0	0.5313	0.7225	0.7882
30.0	0.5313	0.7225	0.7882
36.0	0.5313	0.7225	0.7882
42.0	0.5313	0.7225	0.7882
60.0	0.5313	0.7225	0.7882
80.0	0.5313	0.7225	0.7882
100.0	0.5313	0.7225	0.7882

Image 1. Example of a scatter table measured according to the TRG with different jaw and MLC field size.

Potentially affected – if margins smaller than the default ones are used

Scatter Factors

Jaw Size [mm]

Square Field [mm] / Color	6.0	12.0	18.0
6.0	0.6008	0.7819	0.7863
12.0	~~0.6095~~	0.8799	0.9065
18.0	~~0.6097~~	~~0.8832~~	0.9316
24.0	0.6097	0.8832	0.9332
30.0	0.6097	0.8832	0.9332
36.0	0.6097	0.8832	0.9332
42.0	0.6097	0.8832	0.9332
60.0	0.6097	0.8832	0.9332
80.0	0.6097	0.8832	0.9332
100.0	0.6097	0.8832	0.9332

Image 2. Example of a scatter table measured with equal jaw and MLC field size.

Not affected – even if margins smaller than the default ones are used

User Corrective Action:

- In the scatter table of your implemented dose data for BrainSCAN version 5.3.1 or 5.3.2: Make sure that, for each jaw field size (column), there is one **identical** MLC square field size (row). **AND**
- During treatment planning: Position the jaws with a certain distance of a few mm behind the MLC leaves and for automatic jaw adaption use jaw margin values that are large enough (e.g. the original default margins). **AND**
- For all treatment plans: Follow the Quality Assurance measures described in section 13.4 of the Software User Guide “BrainSCAN” version **5.31 and 5.32**

Brainlab Corrective Action:

1. Potentially affected customers receive this Product Notification letter.
2. Brainlab will provide revised Instructions for Use for BrainSCAN dose data measurements to potentially affected customers. Tentatively planned availability: March 2012.

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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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Oct. 28, 2011

Kind Regards,

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