**Brainlab AG**
Kapellenstraße 12 • 85622 Feldkirchen • Germany

phone: +49 89 99 15 68 0
fax: +49 89 99 15 68 33

## FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

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| | |
|---|---|
| **Subject:** | Software accuracy limitations for very small Multi-Leaf-Collimator (MLC) field sizes |
| **Product Reference:** | All Brainlab BrainSCAN and iPlan RT treatment planning software versions |
| **Date of Notification:** | March 9, 2012 |
| **Individual Notifying:** | [redacted] MDR & Vigilance Manager |
| **Brainlab Identifier:** | 12-01-13.FIP.1 |
| **Type of action:** | Advice regarding use of device. |

Brainlab has become aware of events where the accuracy of the Brainlab Radiotherapy treatment planning software was not within clinically desirable limits for very small Multi-Leaf-Collimator (MLC) field sizes.

We are writing to remind you of the software accuracy limitations for very small MLC field sizes, and to provide further specific recommendations.

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.

The definition of a 'very small MLC field size' depends on the MLC type used (i.e. leaf thickness), the smallest field size measured for Scatter and Depth Dose tables, and the resolution of the dose calculation grids used.

**Effect:**

The Brainlab BrainSCAN and iPlan RT treatment planning software have unavoidable technical limitations in regard to the appropriate dose simulation for certain kinds of treatment set-up. The following information is related to the use of the Brainlab Radiotherapy treatment planning software when simulating very small MLC shaped fields.

The Brainlab user guides already today provide you with general information about these limitations. With this Product Notification we intend to give you additional background information and more specific recommendations.

The dose calculation accuracy of treatment plans for very small MLC field sizes can be affected by several aspects. Those aspects include, but are not limited to:

- Extrapolation outside the measured range of tabulated values
- Pencil Beam kernel resolution
- Monte Carlo calculation grid resolution
- 3D-dose volume resolution
- Radiological corrections (e.g. corrections for tongue and groove leaf design and rounded leaf ends)

The combination of those factors may result in a dose calculation less accurate than the generally accepted standards.

If not recognized by the user with the recommended treatment plan quality assurance, the irradiation of such a treatment plan **might lead to serious injury of the patient and/or ineffective treatment.**

**Details**:

*Extrapolation outside the range of tabulated values*:

The Brainlab Pencil Beam algorithm relies on tabulated values for Depth Dose, output factors (Scatter Factors) and off-axis profiles (Radial Factors). Arbitrary values retrieved from the tables are interpolated accordingly. If the range of tabulated values is exceeded, certain approximations are necessary in order to allow the display of extrapolated dose values. Naturally, the accuracy of extrapolated values is reduced and has to be verified prior to treatment.



Brainlab generally does not recommend to use extrapolated values like small field sizes below the measured range of tabulated values. Please refer also to the applicable warnings in the Technical Reference Guide - Brainlab Physics.

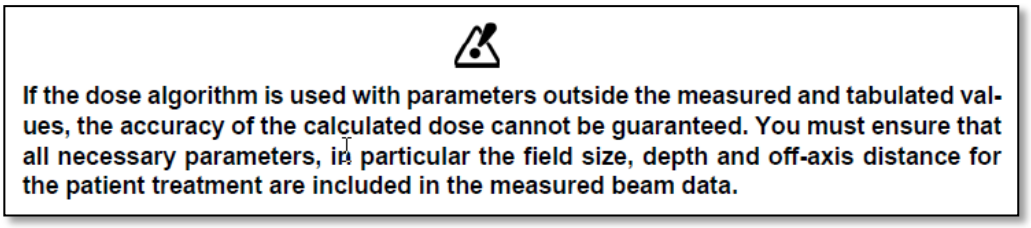



**Figure 1** **Warning from Technical Reference Guide - Brainlab Physics - Revision 1.4 - section *3.3.2 Extrapolation Outside the Range of Measured Values*.**

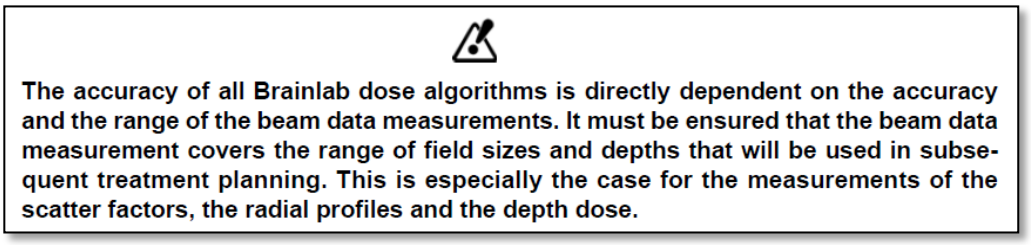



**Figure 2** **Warning from Technical Reference Guide - Brainlab Physics - Revision 1.4 - section *4.2.1 Getting Started*, section *7.2.1 Overview* and section *10.2.1 Overview*.**

*Resolution of calculation grids:*

Similar to other treatment planning systems, the Brainlab BrainSCAN and iPlan RT treatment planning software use several calculation grid resolutions relevant for the accuracy of the dose calculation (depending on the licensed features and the TPS version):

1. Pencil Beam kernel resolution
2. Monte Carlo calculation grid resolution, and
3. 3D-dose volume resolution.

In general, the resolution of the calculation grid has to be fine enough to represent the main characteristics of the dose distribution.

Figure 3 shows exemplarily a dose profile of a very small radiation field, sampled with only 2 grid elements within the nominal MLC edge. As a result the amplitude of the peak and the penumbra cannot be represented with acceptable accuracy.

Radiological corrections, like the Tongue-and-Groove shift (dotted green line in Figure 3) make this effect even stronger.

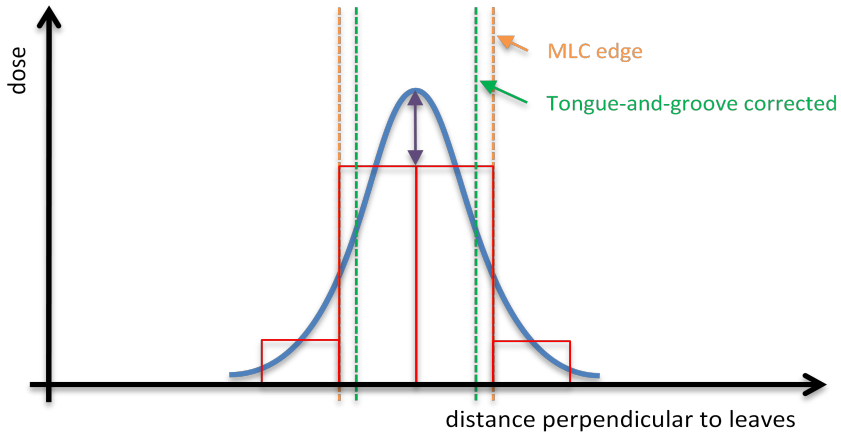



**Figure 3** **Dose profile of a very small radiation field. The outer vertical line (dotted orange) represents the nominal MLC edge, while the inner vertical line (dotted green) shows the radiologic field size (position of the 50% isodose level). The red bars represent the profile with only two grid elements within the nominal MLC edge.**

To avoid unacceptable differences between the calculated and the actual dose distribution, the field size shall not be smaller than four times the grid resolution, irrespective of the dose calculation grid type (Pencil beam kernel, Monte Carlo or 3D-dose volume). The improvement is schematically shown in Figure 4.

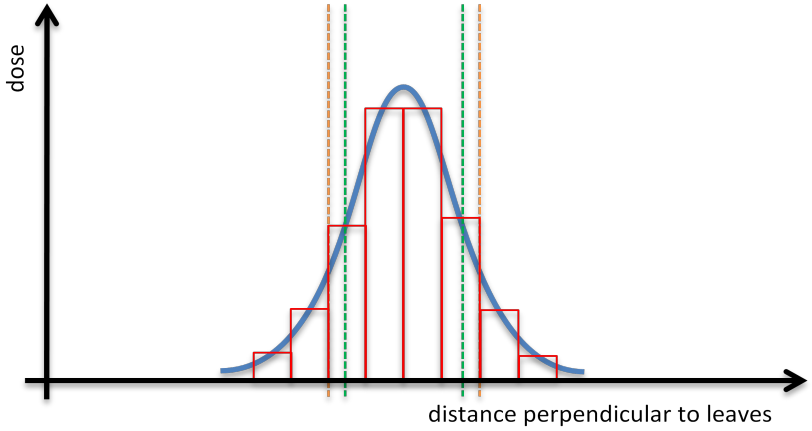



**Figure 4** **Same profile as in Figure 3, now sampled with four grid elements within the nominal MLC edge.**

Brainlab recommends to always consider the calculation grid resolution. Please refer also to the applicable warnings in the technical documentation.

**Depending on the MLC type, the pencil beam algorithm uses kernels of a certain resolution that define the overall resolution of the dose calculation perpendicular to the beam axis. In the case of small structures in combination with a insufficient kernel grid size, the pencil beam dose calculation may be too coarse to identify every detail of the delivered dose distribution.**

**Figure 5** **Warning from Technical Reference Guide - Brainlab Physics - Revision 1.4 - section *3.3.3 Other Limitations*.**

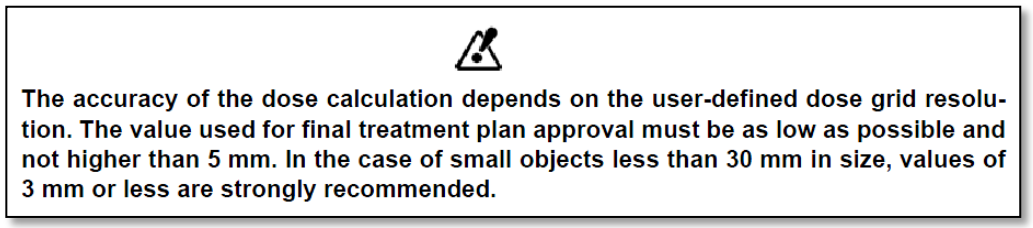



**Figure 6** **Warning from iPlan RT Version 4.5 - Clinical User Guide - Revision 1.1 - section *5.3.5 Adjusting the Dose Resolution* and section *7.6.3 Monte Carlo Calculation*.**



**User Corrective Action:**

1. Avoid extrapolation; do NOT plan radiation fields with an equivalent field size smaller than the smallest field size included in the tables of measured values.

2. Avoid inaccuracies caused by grid resolution effects. Therefore always consider the:
   - Pencil Beam kernel resolution
   - Monte Carlo calculation grid resolution, and
   - 3D-dose volume resolution.

   The minimum field extension shall not be smaller than four times the poorest grid resolution (largest size of a single grid element).

   *field extension (width or height) ≥ 4 × grid resolution*

   *Note: Please be aware that different versions of Brainlab Radiotherapy treatment planning software have slightly different flexibility influencing the diverse grid resolutions.*

3. For more information on how to retrieve the necessary information for your treatment plan, please see the appendix.

4. If field sizes below the minimum values described above would be desired, Brainlab recommends to use conical collimators instead of the MLC as the beam shaping device or, as an alternative to perform additional extended quality assurance tests that allow the user to assess and consider the software accuracy limitations for each treatment plan.

**Brainlab Corrective Action:**

1. Potentially affected customers receive this Product Notification letter.
2. Brainlab will provide updated Instructions for Use to potentially affected customers. Tentatively planned availability: June 2012.

**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.

**Customer Hotline:** +49 89 99 15 68 44 or +1 800 597 5911 (for US customers) or by

**E-mail:** support@brainlab.com (for US customers: us.support@brainlab.com)

Fax Brainlab AG: + 49 89 99 15 68 33

**Address:** Brainlab AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

www.brainlab.com

March 9, 2012

Kind Regards,

[redacted]

MDR & Vigilance Manager

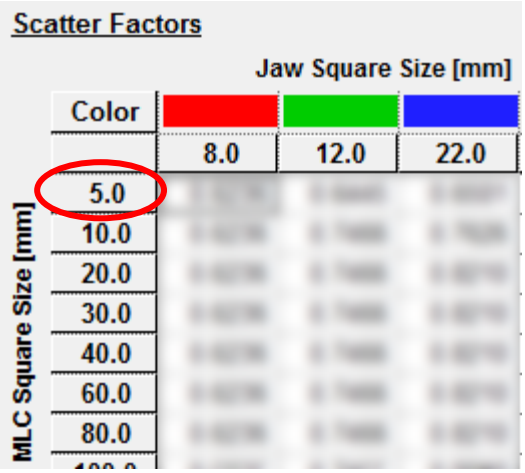
[redacted]

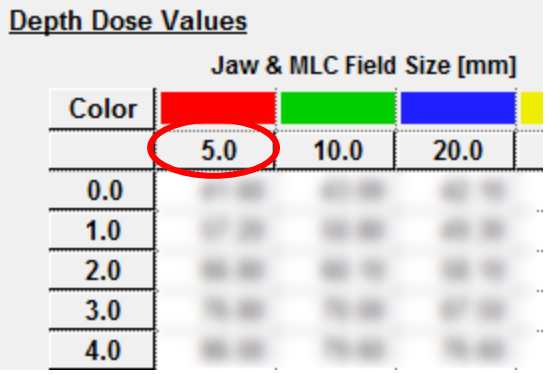
Europe: The undersign confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.

## Appendix

1. How to find the smallest field size measured for Scatter and Depth Dose tables.

   Information can be found in Beam Profile Editor / Physics Administration for every beam profile / machine profile.



2. How to find the Pencil Beam kernel resolution for your treatment plan.

- **BrainSCAN**: Open the Parameters printout - section Dosimetry Specifications:

**Dosimetry Specifications**

| | |
|---|---|
| Multileaf | :BrainLab m3 |
| Prescribed treatment dose (= 100 %) | :1.00 Gy |
| Dose algorithm | :Pencilbeam |
| Kernel type info | :128 * 128 Pixels / 1.5 mm |
| Nominal output | :0.876 Gy / 100MU |
| Tissue inhomogeneity correction | :On |
| Av. tissue depth (eq. path length) | :78.4 mm |
| Target volume (Lesion) | :13.74 ccm |
| Total number of isocenters | :1 |
| Total number of beams | :6 |

- **iPlan RT Dose**: Open the Treatment Parameters printout - section Machine

**Machine :** [redacted]

| | | |
|---|---|---|
| Linac Name | : | NOVALIS TX |
| Linac Convention | : | IEC |
| Linac Energy [MV] | : | 6 |
| Flattening Filter Mode | : | Stereotactic |
| Blocking Device Type | : | MLC - Varian MLC-120 HD SRS mode |
| Dose Algorithm | : | BrainLAB.PencilBeam.X, Kernel Resolution : 1.25 mm |

3. How to find the Monte Carlo calculation grid resolution for your treatment plan.

   Open the Treatment Parameters printout - section Monte Carlo Specifications.

**Monte Carlo Specifications**

| | |
|---|---|
| Spacial Resolution [mm³] | : 4.0 x 4.0 x 4.0 |

4. How to find the 3D-dose volume resolution.

   Open the RTPlan Properties - section Dose Calculation.