FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Brainlab RT Elements Radiation Treatment Planning Software: Potential incorrect dose distribution calculation when using the Pencil Beam algorithm on GPU for large tissue models
Product Reference:	Cranial SRS 1.0.0/1.5.0; Spine SRS 1.0.0/1.5.0; Multiple Brain Mets SRS 1.5.0; RT QA 1.0.0/1.5.0
Date of Notification:	March 11, 2019
Individual Notifying:	Andrea Miller, Vigilance Manager
Brainlab Identifier:	CAPA-20190306-002261
Type of action:	Advice regarding use of device; Device modification

We are writing to advise you of potentially incorrect dose distribution calculation by Brainlab RT Elements software (for affected versions, see above) under specific circumstances when using the Pencil Beam algorithm on the GPU (graphics card), as is the default system setting.

There has been no report to Brainlab by any user site of undesirable dose distribution delivered to a patient due to this issue at the time of writing.

The purpose of this Product Notification letter is to provide you with the technical details and to inform you of the corrective actions Brainlab is taking to address this issue.

Effect:

The implementation of the Pencil Beam algorithm for the GPU is affected by an anomaly that prevents the algorithm from retrieving correct tissue model values. The tissue model provides the electron density (derived from the Hounsfield Units (HU) contained in the CT scan) of all materials in the entire region of interest (e.g. patient and couch top) used for dose calculation. It is stored as a large continuous data block. When its size exceeds 512 MB (e.g.: a cranial CT with very small pixel size including a couch top), values stored in the exceeding part are clipped and therefore treated as electron density zero (equivalent to air). Because the tissue model values are always retrieved from top to bottom (head to feet) of the volume, the affected region is always located in the bottom (feet) part of the CT scan, see Figure 1 a).

This effect leads to deviations in dose distribution calculation for the tissue region represented by this clipped part of the data block and for all beams passing through it. Resulting potentially incorrect dose distribution values are displayed by the software in the isodose lines, 3D Volume Dose, DVH and exported plan dose. The Point Dose value measured with the point measurement tool is not affected by this anomaly, see Figure 1 b).
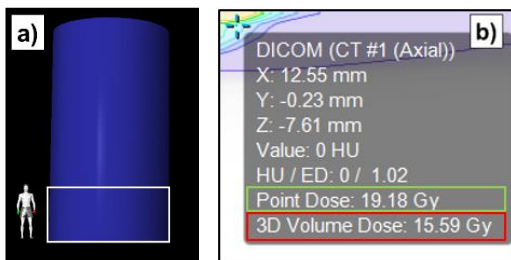

Figure 1 a) Tissue model example. White rectangle shows the clipped region assuming a phantom with a tissue model volume of 700 MB.

Figure 1 b) Point Measurement box as shown in RT Elements software. Inside the green rectangle, the correct Point Dose value is shown. Inside the red rectangle the affected 3D Volume Dose is shown.

If dose deviations are not recognized by the user, the irradiation of such a treatment plan **might lead to adverse clinical outcome**.

The following details the specific conditions for this error to occur, along with the magnitudes of potential deviations that may result.

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Details:

Due to this effect, calculated dose distribution could be higher or lower than expected and deviations could exceed 10% under specific circumstances. Dose deviation strongly depends on the geometric parameters: tumor location, beam path and number of beams with respect to the clipped region. Furthermore the beam modeling (contained in the machine profile) and other plan parameters such as field sizes may also affect the dose deviation.

Potentially incorrect dose would be delivered to the patient if ALL of the following conditions apply:

- The GPU calculation is activated. See appendix for additional information.
- Pencil Beam dose calculation is used.
- Calculated tissue model for a clinical plan exceeds 512 MB. See appendix for a detailed explanation on how this is computed and a graphic with reference values.
- The region of clinical interest is within the clipped region or the plan contains beams passing through that clipped region.
- The deviation is not detected during plan quality assurance.

The RT QA Element, in its three flavors (Patient Specific QA, Beam Model Verification and RT QA Recalculation) is also affected by this issue. Since Patient Specific QA application needs a different CT scan (phantom) than the one used clinically (patient), it is not certain that it could reliably detect the issue. On the other hand, a correctly calculated clinical plan could potentially fail Patient Specific QA because a phantom with tissue model exceeding 512 MB would be used.

For clarification, the following parts of the RT Elements software are NOT affected by the anomaly:

- The implementation of the Pencil Beam algorithm for the CPU (central processor).
- The implementation of the Monte Carlo algorithm.
- The graphical representation of the tissue model in the software is correct, since it is calculated using the CPU and not the GPU. For the same reason also the Point Dose value shown using the point measurement tool and the arc plane view in the software are correct.
- The following RT Elements versions are NOT affected: Multiple Brain Mets SRS 1.0.0/1.0.1/1.0.2 and 2.0.0, Cranial SRS 1.5.1, Spine SRS 1.5.1, Dose Review (all versions) and RT QA 2.0.0.

Retrospective review:

For plans calculated using the affected Pencil Beam algorithm on the GPU, the following data can be reviewed in order to determine whether a patient treatment plan (or QA plan) is affected.

1. Determine if the CT scans regularly used in your clinic potentially reach tissue model sizes larger than 512 MB by reviewing the reference graph in the appendix.
2. For an accurate evaluation of all calculated plans, you can determine the exact size of the tissue model stored in the log file, see appendix for detailed explanation on how to find this value.
3. If you find a log file referring to a tissue model bigger than 512 MB refer to the plans created on the date of the log file entry.

User Corrective Action:

Ensure for all affected applications that the clinically used CT scans do not create tissue models bigger than 512 MB as explained in points 1 and 2 above.

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Brainlab Corrective Action:

1. Existing potentially affected customers receive this product notification information.
2. Brainlab will disable the Pencil Beam GPU calculation in the settings of the affected RT Elements Radiation Treatment Planning Software, and thus correct the described issue for all affected customers. Brainlab will actively contact you, starting in April 2019 to schedule the settings change.

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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March 11, 2019
Kind Regards,

A. Miller

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

APPENDIX

GPU Usage for dose calculation

RT Elements installations have the GPU dose calculation option enabled per default. In some cases (non-supported GPU versions or virtual machines) the GPU is not used for dose calculation. The following line appears in the log files when the GPU dose calculation is enabled:

```
AMP dose calculations enabled.
```

Log files are located in your system in `\%BRAINLAB_PATH%\Appls\Logfiles\`. Refer to the following folders for each application:

- Cranial SRS 1.0.0 and Spine SRS 1.0.0 are located in `\VMATPlanning_1.0.0\`
- Cranial SRS 1.5.0 and Spine SRS 1.5.0 are located in `\VMATPlanning_1.5.0\`
- Multiple Brain Mets SRS 1.5.0 are located in `\ MultipleBrainMetsSRS_1.5.0\`
- RT QA 1.0.0 are located in `\RTQA_1.0.0\`
- RT QA 1.5.0 are located in `\RTQA_1.5.0\`

Tissue Model Data Block computation

Several parameters affect the size of the tissue model data block: size of the region of interest, the number of slices and the pixel size of the CT dataset. Below you can see how the tissue model data block size is computed.

$$Data\ Block\ size\ [MB] = n°\ slices \cdot \frac{4}{1024^2} \cdot \frac{x}{ps_x} \cdot \frac{y}{ps_y}$$

x refers to the left right (L-R) size of the field of view in the CT and y refers to the anterior posterior (A-P) size. If an additional couch top is used, this extends the size of the CT in L-R and A-P directions. ps_x and ps_y refer to the pixel sizes in the corresponding directions assumed to be equal since only square pixels are supported.

Reference Graph

The following graph illustrates under which conditions a tissue model size is larger than 512 MB for A-P of 30 cm (average cranial CT) and A-P of 50 cm (average spine CT) scenarios with L-R 54 cm (general couch top size) for different pixel sizes and number of slices.

The area above the curves corresponds to the tissue model data block being bigger than 512 MB. For reference see the reference points below with the corresponding explanation.
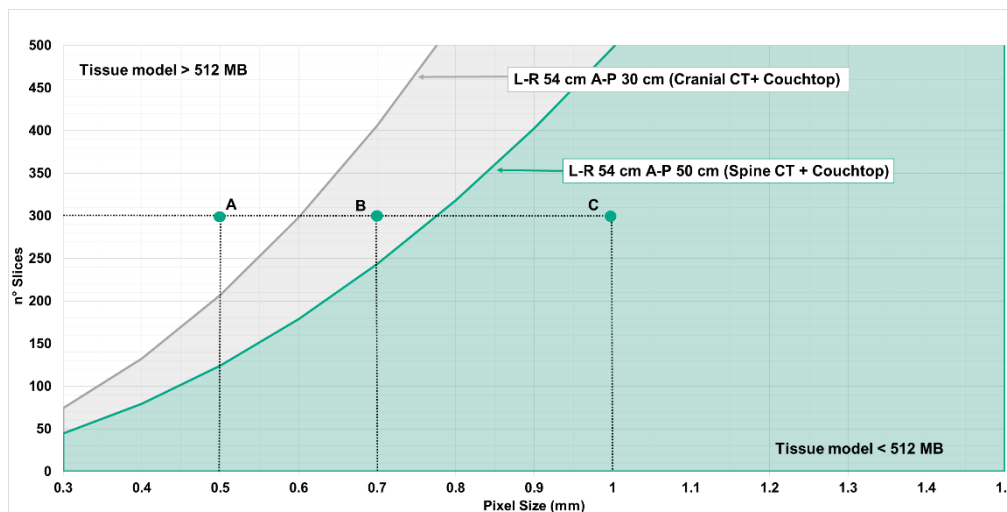

Figure 2: Translation of graph labeling: Tissue model = …, Cranial CT = …, Spine CT = …, Couch top = …, n°Slices = …, Pixel size = …

Point A: Refers to a CT scan of 300 slices and a pixel size of 0.5 mm. For both A-P of 30 cm (Cranial) and A-P of 50 cm (Spine) this CT scan would result in a tissue model bigger than 512 MB.

Point B: Refers to a CT scan of 300 slices and a pixel size of 0.7 mm. For an A-P of 30 cm (Cranial) this CT scan would result in a tissue model smaller than 512 MB. For A-P of 50 cm (Spine) this CT scan would result in a tissue model bigger than 512 MB.

Point C: Refers to a CT scan of 300 slices and a pixel size of 1 mm. For both A-P of 30 cm (Cranial) and A-P of 50 cm (Spine) this CT scan would result in a tissue model smaller than 512 MB.

Tissue model sizes in the log files:

Log files of the different applications show the tissue model computed size in the following line with varying values within the parenthesis:

```
AMP ray tracer successfully initialized (instance pointer: 0x0000028EC315EEB0 / size: 512 x 337 x 208 => 136 MB).
```

TOGETHER WE ARE MAKING MEDICAL TECHNOLOGY AND KNOWLEDGE MORE IMPACTFUL AND ACCESSIBLE TO PHYSICIANS AND THEIR PATIENTS.