

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Large objects with fine resolution are potentially displayed cropped when imported into Brainlab Brain Metastases 1.0.0 or Adaptive Hybrid Surgery Analysis 1.0.0
Product Reference:	Brain Metastases version 1.0.0 Adaptive Hybrid Surgery Analysis version 1.0.0
Date of Notification:	November 5, 2015
Individual Notifying:	Julia Mehlretter, Manager MDR & Vigilance
Brainlab Identifier:	CAPA-20151029-001528
Type of action:	Advice regarding use of device; Device modification.



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We are writing to advise you of the following potential effect that has been identified when importing large objects with fine resolution from SmartBrush to Brain Metastases version 1.0.0 or Adaptive Hybrid Surgery Analysis version 1.0.0.

Please note that version 1.0.0 is not the latest version of Brain Metastases / Adaptive Hybrid Surgery Analysis.

There has been no negative effect on a patient due to this issue reported to Brainlab by any user site.

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

Effect:

Brainlab *SmartBrush* and the contained *Atlas Segmentation Performer* are used for outlining anatomical structures and pathologies in medical images. The outlined structures are stored as objects and can be used e.g., for further surgery or treatment planning in Brainlab Elements.

Typically the objects are stored with the same slice distance as the reference image data set in which they are drawn. However, to provide a more precise and smoother display of objects, the contour information of specific objects may be stored on slices with a smaller slice distance than the reference image data set. Whether the structures are stored in slices with smaller slice distance depends on the object type, certain settings and the workflow used (please see below for further details).

If the amount of slices used for the structure exceeds the amount of slices of the whole reference image data set, the object is displayed cropped when loaded in Brain Metastases version 1.0.0 or Adaptive Hybrid Surgery Analysis version 1.0.0.

The potential effect of this error depends on the software application:

Brain Metastases 1.0.0

In the Brain Metastases workflow (selected in the *Content Manager*) all objects created or modified manually in SmartBrush have a slice distance of 0.3 mm and therefore potentially a finer resolution than the reference image data set.

Additionally following objects created by the Atlas Segmentation Performer have a slice distance of 0.3 mm:

- Chiasm, 0.3mm
- Lens (Left/Right), 0.3mm
- Optic Nerve (Left/Right), 0.3mm
- Optic Tract (Left/Right), 0.3mm

All other objects created by the Atlas Segmentation Performer have the same slice distance as the reference image data set and are therefore not affected, unless they are modified with SmartBrush.

If an image data set with outlined tumors and other objects is imported into Brainlab Brain Metastases, all anatomical objects defined in the data set correspond to one of the following object type categories: *Treated Metastases*, *Untreated Metastases*, *Original Metastases* or *Others*. Depending on the Object Type, the object may be affected by the error:

Object Type: **Treated Metastases or Untreated Metastases**

These objects are **not affected** by this issue; they are displayed correctly. All software dose calculations for plan optimization and dose volume histograms (DVH) are based on *Treated Metastases* or *Untreated Metastases* and are therefore correct.

Object Type: **Original Metastases**

These objects may be displayed cropped in the Brain Metastases software. Although this structure is not used for calculations of plan optimization, if the *Original Metastases* is displayed and the structure is cropped, also the corresponding DVH of this object is incorrectly calculated. This can be detected when comparing the Original Metastases with the Treated Metastases or Untreated Metastases by selecting the two objects at the same time.

Object Type: **Others** (e.g. Organs at risk)

These objects may be displayed cropped in the Brain Metastases software. The Brain Metastases software does not consider other objects, e.g., Organs at risk (OAR), in the optimization algorithm used to create the radiotherapy treatment plan. Nevertheless, the DVH for the other objects are calculated and displayed in the software to allow detection of potential overdosage in any object. If due to this error the other object is cropped, the DVH for this object will be calculated based on the cropped object, and therefore if the error occurs, the **calculated DVH may not correctly reflect the actual dose.**

If the cropped object is not recognized by the user before the plan is used for treatment and the deviation exceeds clinically acceptable limits, **this could result in ineffective radiation treatment, serious patient injury, or even death of the patient.**

When exporting the treatment plan to DICOM – e.g., for transfer to a Record and Verify system, to Dose Review or *Quentry Dose Review*, and to *ExacTrac* – all structures (visible and invisible) are exported by Brain Metastases. **Structures that are cropped in Brain Metastases are also cropped in the exported DICOM RT Structure Set files.**

Adaptive Hybrid Surgery Analysis 1.0.0

In the Adaptive Hybrid Surgery workflow (selected in the *Content Manager*) all objects created or modified in SmartBrush, e.g. tumors, per default have the same slice distance as the reference image data set and are therefore not affected. Accordingly the **result of the tumor analysis is not affected.**

However, following objects created by the Atlas Segmentation Performer have a slice distance of 0.3 mm and therefore potentially a finer resolution than the reference image data set:

- Chiasm, 0.3mm
- Lens (Left/Right), 0.3mm
- Optic Nerve (Left/Right), 0.3mm
- Optic Tract (Left/Right), 0.3mm

All other objects created by the Atlas Segmentation Performer have the same slice distance as the reference image data set and are therefore not affected.

If an image data set with the above mentioned objects created by the Atlas Segmentation Performer is imported into Brainlab Adaptive Hybrid Surgery Analysis, the objects may be displayed cropped. A cropped displayed organ-at-risk (OARs) also has an effect on the dose calculation performed by AHSA.

For each OAR in the image data set, Adaptive Hybrid Surgery Analysis displays an analysis of the potential effect of the intended radiation treatment. If the error occurs **the actual values, their relation to the constraint values and the visual indicators for the OARs are displayed incorrectly as the calculated values may not correctly reflect the actual dose.**

If determination regarding the potential for radiotherapy is made, **the incorrect information displayed can have an effect on clinical decisions.** If the determination is done during



surgery this could even, in a worst case scenario, **mislead the user in regards to assessing the extent of resection during this surgery.**

User Corrective Action:

Users of Brain Metastases Version 1.0.0 or Adaptive Hybrid Surgery Analysis 1.0.0 shall adhere to the following:

After import always carefully review and verify all objects for correctness and validity.

For reviewing an object, select the image set which was used to outline or to modify the objects in the **Data** menu.

Also compare the contours of an object in Brain Metastases or Adaptive Hybrid Surgery Analysis software to the contours in SmartBrush.

Please note that **the error will not be visible in SmartBrush**. Always verify the correct shape of the objects in Brain Metastases or Adaptive Hybrid Surgery Analysis software.

If possible do not use image data sets with large slice distance and/or with a low amount of slices.

To retrospectively identify if cropped objects have been used for treatment planning, the object contours of a specific treatment plan can be reviewed in Brainlab Dose Review, where the error will also be visible.

Brainlab Corrective Action:

1. Existing potentially affected customers receive this product notification information.
2. Brainlab will provide a software update with this issue solved to affected customers. Brainlab will actively contact affected customers tentatively starting February 2016 to schedule the update.

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)

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November 5, 2015

Kind Regards,



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

