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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Image sets and associated outlined objects may become shifted when imported into Brain Metastases 1.0.0 or Adaptive Hybrid Surgery Analysis (AHSA) 1.0.0
Product Reference:	Brain Metastases version 1.0.0 Adaptive Hybrid Surgery Analysis version (AHSA) 1.0.0
Date of Notification:	December 15, 2015
Individual Notifying:	Andrea Miller, MDR & Vigilance Manager
Brainlab Identifier:	CAPA-20151127-001553
Type of action:	Advice regarding use of device; Device modification.

We are writing to advise you of the following potential effect that has been identified when using image datasets fused by Brainlab Image Fusion in Brain Metastases 1.0.0 and Adaptive Hybrid Surgery Analysis (AHSA) 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 Image Fusion is used for co-registration of medical images. When loading the fusion result in Brain Metastases 1.0.0 or Adaptive Hybrid Surgery Analysis (AHSA) 1.0.0, under specific circumstances, the fusion result stored by Image Fusion is disregarded. Instead the image datasets are co-registered based on the scanner-inherent fusion that can potentially result from acquiring the images in one imaging session. In consequence, the image datasets may become shifted in relation to one another.

Anatomical structures and pathologies are outlined in SmartBrush and the contained Atlas Segmentation Performer. Outlined structures (objects) are associated with the image dataset, in which they are drawn. If associated an affected image dataset, e.g. organs at risk (OARs) or planning target volumes (PTVs), may become shifted in relation to their anatomical position.

The magnitude of the shift varies, depending on the shift of the patient position between the affected image datasets. Therefore, for some cases, the shift will be clearly visible when the fusion pair is used in Brain Metastases or Adaptive Hybrid Surgery Analysis. However, a shift could also be non-obvious. If a shift occurred and was not detected during review of the data, the deviation of the information displayed in the Brainlab planning and analysis software could result in incorrect dose planning or mislead the user regarding clinical decisions.

The specific consequences of the described effect depend on the software application:

<u>Brain Metastases 1.0.0</u>

If the shifted objects are 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. **Objects that are shifted in Brain Metastases are also shifted in the exported DICOM RT Structure Set files.**

<u>Adaptive Hybrid Surgery Analysis (AHSA) 1.0.0</u>

When the potential for radiotherapy is assessed, the **incorrect information displayed can have an effect on clinical decisions**. If the assessment is done during surgery, this could even, in a worst case scenario, **mislead the user in regards to assessing the extent of tumor resection during this surgery**.

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Details:

The potential problem arises if all of the following preconditions are met:

1) Multiple patient image datasets are acquired in one imaging session using the same imaging device, whereby both of the following criteria are met

   - The identical coordinate system is assigned to each of these image datasets. Such a coordinate system is called the images' frame of reference (FOR) and is the basis for the scanner-inherent fusion. Whether it is identical or not depends on the configuration and operation of the imaging device.
   - A shift of the patient position occurred during acquisition of these image datasets.

2) These image datasets are co-registered in Image Fusion using e.g. manual or automatic fusion, i.e. not approving the scanner-inherent fusion. The scanner-inherent fusion is called Scanner Fusion and the type of fusion is shown in the Fusion Pair dialog.

3) One of the image datasets (in this fusion pair) is fused directly to the CT, which is used for treatment planning in a later step, or both image datasets are linked to the CT indirectly by multiple fusions. Figure 1 and Figure 2 illustrate two sample fusion scenarios:

   - Figure 1: Two MR image datasets (MR1 and MR2) with the same FOR (FOR2) are fused. MR1 is also fused directly to a CT image dataset (CT1) with a different FOR (FOR1).

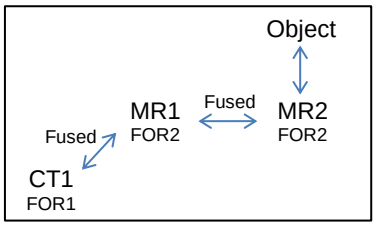

Figure 1: Sample fusion scenario

   - Figure 2: MR1 and MR2 are fused as well, but neither is fused directly to CT1. Instead an additional MR image dataset (MR3) with a different FOR (FOR3) is fused to CT1, and MR1 is fused to MR3, thereby being linked indirectly to CT1.

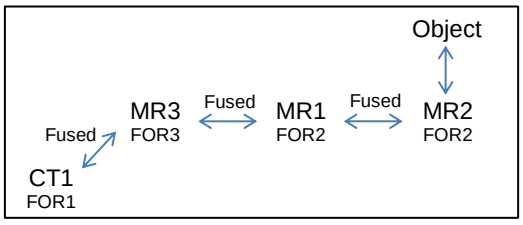

Figure 2: Sample fusion scenario

4) Objects created in SmartBrush are associated to the specific image dataset (of the fusion pair with the same FOR), which is *not* fused directly to the CT or is linked to the CT *later* than its fusion partner by multiple fusions. In Figure 1 and Figure 2 this applies to MR2.

5) Objects associated to the image dataset identified in step 4) are used in Brain Metastases 1.0.0 or Adaptive Hybrid Surgery Analysis (AHSA) 1.0.0

If a fusion pair with the same frame of reference is loaded in Brain Metastases or Adaptive Hybrid Surgery Analysis, a warning message is displayed, notifying the user that the DICOM Registration object (which contains the fusion result stored by Image Fusion) cannot be imported. Figure 3 shows this warning message.

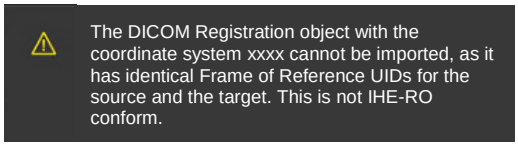

Figure 3: Warning message in Brain Metastases or AHSA

If the preconditions are met and the error occurs (and the user proceeds despite the warning message), the described effect occurs, i.e. the fusion result stored by Image Fusion is replaced by the scanner fusion (according to the frame of reference information). As a result, the affected image dataset and associated objects become shifted. Referring to the sample fusion scenarios illustrated in Figure 1 and Figure 2, MR2 and any object associated to MR2 becomes shifted in relation to CT1, MR1 and MR3.

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A shifted PTV and/or a shifted OAR also have an effect on the dose calculation performed by Brain Metastases or Adaptive Hybrid Surgery Analysis.

The dose planning is based on the outlined PTV. If the error occurs, and the position of the PTV is shifted, dose planning is performed on the basis of this shifted anatomical position.

If the position of the OAR is shifted (but the position of the PTV is not), only the dose calculation of the OAR is affected (dose planning for the PTV is correct).

For the avoidance of doubt:

- Any imaging modality able to assign the same frame of reference to multiple images could be affected, e.g. MR, CT, PET, or CT-PET (if a multi-modality imaging device is used). However, for Brain Metastases, the effect does not occur with CTs, as this product permits only exactly one CT.
- If image datasets with the same frame of reference are not fused, or if scanner fusion is approved for this fusion pair in Image Fusion, the effect does not occur.
- If only image datasets with different frame of reference information are used, the effect does not occur.
- More than two image datasets may be acquired with the same frame of reference and consequently more than one fusion pair with the same frame of reference may exist and can be affected by this issue.

Treatment verification and (retrospective) review for existing plans

To retrospectively identify if treatment planning was based on potentially shifted objects, perform the following steps:

1) Open the potentially affected treatment plan in Brain Metastases 1.0.0 or Adaptive Hybrid Surgery Analysis (AHSA) 1.0.0.
2) Verify if a warning message (as shown in Figure 3) is displayed, which indicates that a fusion pair with a scanner fusion exists and the described effect may have occured.
3) Review the position and dose distribution of the PTVs and OARs in the CT used for treatment planning and in the image datasets with the same frame of reference. If shifts are observed, determine if clinically acceptable limits are exceeded.

Note: The effect is only visible in Brain Metastases version 1.0.0 or Adaptive Hybrid Surgery Analysis (AHSA) version 1.0.0.

User Corrective Action:

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

If possible **do not use image datasets with an identical coordinate system (i.e. same frame of reference information), unless the scanner fusion is acceptable to be approved in Image Fusion**.

Always carefully review and verify the fusion result and all objects for correctness and validity in Brain Metastases or Adaptive Hybrid Surgery Analysis.

Specifically if the error message shown in Figure 3 is displayed by the software, review the position of all objects in the CT used for treatment planning and in the image datasets with the same frame of reference**.**

Please note that **the error will not be visible in SmartBrush, Image Fusion and DICOM Viewer**. Always verify the fusion result and correct position of objects in Brain Metastases or Adaptive Hybrid Surgery Analysis.

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.

www.brainlab.com

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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December 15, 2015

Kind Regards,

[redacted]

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