

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Brainlab Radiation Treatment Planning Software:
 For use in the Brainlab software, image sets other than CT must only contain the same pixel values calibration for all images/slices of the set.

Product Reference: iPlan RT Image (below v.4.1.2) / iPlan RT; and BrainSCAN (discontinued).

Date of Notification: September 7, 2015

Individual Notifying: [REDACTED], Senior MDR & Vigilance Manager

Brainlab Identifier: **CAPA-20150727-001458**

Type of action: Advice regarding use of device; Device modification.



We are writing to advise you of a requirement of the Brainlab Radiation Treatment Planning Software. Except for CT or PET normalized to SUV (*Standard Uptake Value*), the Brainlab software supports only image sets that contain a uniform calibration of pixel values assigned by the imaging device (scanner) for all images, i.e. for all slices of the set.

The only image sets that are supported by the Brainlab Radiation Treatment Planning Software even when containing varying calibrations of pixel values in between image slices are:

- CT image sets, and
- PET image sets normalized to SUV (*Standard Uptake Value*) with SUV also loaded in and displayed by the Brainlab SW (Figure 1).

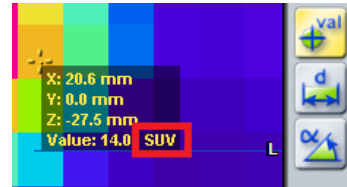


Figure 1 SUV displayed by Brainlab SW

The only other image modality than the above that Brainlab has ever observed to actually contain different pixel value calibrations of different slices within one image set, is PET (without SUV). There has been no negative effect on a patient treatment due to this specific issue reported to Brainlab by any user site.

This notification letter is to provide you with the relevant user information, and to advise you of the actions Brainlab is taking to address the issue.

Effect:

If such an unsupported image set is used with the Brainlab software, the Brainlab software applies the same pixel value calibration as contained in the middle image slice of the set to all slices. If varying pixel value calibrations are contained in the other slices of the unsupported set, these pixel values are set to the same uniform calibration upon loading: in a PET image set such uniform calibrated pixels might then have a different activity value, thus displayed with a different brightness and color, compared to the image slices as displayed by the scanner using varying calibrations.

If this effect occurs when using an unsupported image set, it can be misleading to the user during treatment planning and, for example, result in an incorrect definition of volumes of interest in the planning software. The objects created for these volumes of interest might differ in location or dimension from the actual desired definition of the structure. If not detected by the user during treatment planning, as a consequence target volumes could be erroneously defined for an irradiation plan. This could ultimately result in **ineffective treatment, serious patient injury or even death of the patient.**

Figure 2 below illustrates how this effect could influence the appearance of e.g. a sagittal reconstruction of an unsupported axial PET image set. The areas of the highest and lowest activity might seem to be located in a different region of the reconstruction.

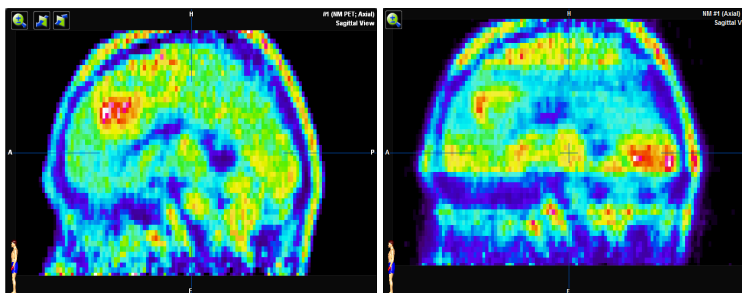


Figure 2 Sagittal reconstructions of axial PET images (without SUV) illustrating the possible effect: Left - display of supported set with uniform calibration. Right - display of unsupported set containing varying calibrations.

Details:

The parameters used to calibrate the raw pixel value from a DICOM file to their actual values are:

Rescale Slope (0028,1053)

Rescale Intercept (0028,1052)

Usually the same calibration is applied to all images of one image set, but in some cases this might be set up differently at the imaging device. If *Rescale Slope/Intercept* differs in between slices of one set, the image set is not supported by the Brainlab planning software except for CT and PET used with SUV. When using such an unsupported image set with the Brainlab software, areas in different slices that would have the same physical or anatomical properties when displayed by the scanner using varying calibrations, might have different values in the Brainlab software due to the uniform calibration to all slices (refer to Figure 3).

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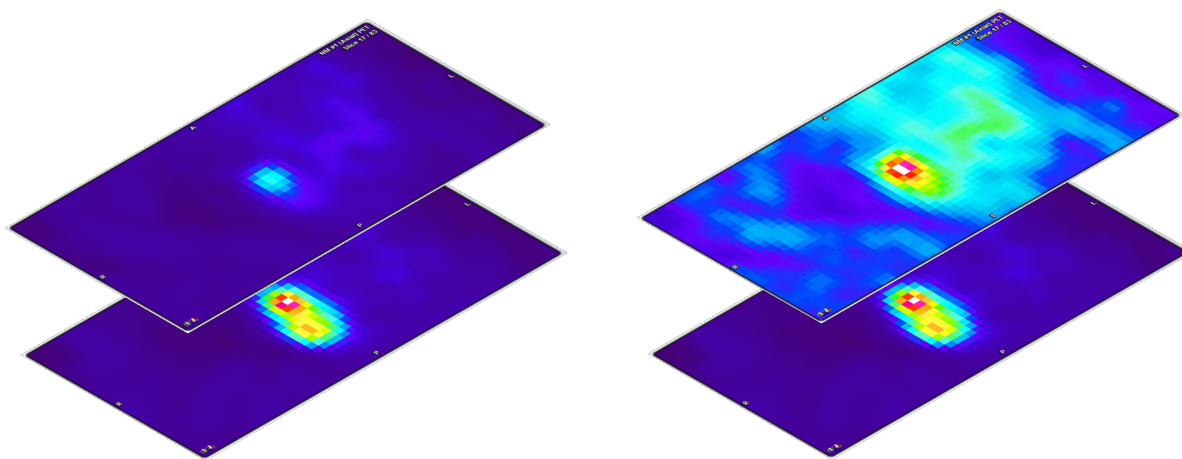


Figure 3 Example of axial PET images (without SUV) illustrating the possible effect:

Left - display of supported slices (uniform calibration). Right - display of unsupported upper slice (varying calibration).

Note: In such an unsupported PET, in the reconstruction (see Figure 2) the area of the highest activity might appear to be located in different regions (other slices of the set) - in comparison to the display by the scanner using varying calibrations - whereas within each single image slice the areas of the highest and lowest activities still remain at the same place.

The information displayed by the Brainlab treatment planning software with uniform calibration, especially for an unsupported PET, can significantly differ from the display by the scanner. Due to the nature of PET or SPECT images - showing activities rather than physical anatomy - such a display of reconstructions with areas of activity seemingly located differently might still appear plausible to the user. If not compared to the images as displayed by the scanner, this could lead to erroneous definitions of volumes of interest by the user within that dataset.

A further, less significant effect to the treatment planning could be a slightly inferior automatic fusion result, whereas any deviation of the automatic fusion exceeding acceptable limits should be detectable by the user during the mandatory visual verification of the result in the Brainlab software.

Image datasets representing the physical anatomy – e.g. MRI – theoretically could also have this unsupported behavior, although this has never been observed by Brainlab. If such a dataset had varying calibrations of pixel values in between slices, the unsupported behavior should be recognizable to the user within the reconstruction when used in the Brainlab software, with different image slices appearing darker or brighter in comparison to the adjacent slices. With a further use of such an unsupported dataset representing physical anatomy, inferior automatic fusion or auto-segmentation results could occur, or the result of the *Band Thresholding* function, if used to outline structures, could be less than ideal. Nevertheless, since the anatomical structure (pixel relation) is still contained in each single image, any deviation exceeding acceptable limits should be detectable by the user during the mandatory verification of the automatically created objects or the automatic image fusion.

If any unsupported image set is processed within the Brainlab treatment planning software (iPlan RT) and later on exported to a third party device, the image set will remain after export as was displayed by the Brainlab software.

Please note: The Brainlab Elements do not require image sets to have the same pixel value calibration of all image slices in one set, as well as image sets loaded within the Brainlab Elements environment and then used with the iPlan RT Image integrated there.

Treatment verification and (retrospective) review:

The display of any image dataset loaded in the Brainlab treatment planning software can at any time be compared by the user to the original images as created by the imaging device (scanner), using a different display media approved and available to the hospital other than the Brainlab software.

Commonly available DICOM attribute viewers can also be used to check whether images will not be supported by the Brainlab software.

Please refer to the Appendix for details upon how to detect image sets not supported by the Brainlab software.



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User Corrective Action:

- Except for CT and PET used with SUV, only load and use image sets in iPlan RT / iPlan RT Image that have the same pixel value calibration for all images of the set.
- Before using image datasets loaded into the Brainlab Radiation Treatment Planning Software, always compare the images displayed in the Brainlab application to the images as displayed by the imaging device (scanner), e.g. using a different display media approved and available to the hospital other than the Brainlab software. Delete and do not use the image sets within iPlan RT in case any deviation is detected and contact Brainlab support.

Brainlab Corrective Action:

- 1) Brainlab provides existing potentially affected customers with this product notification information.
- 2) Brainlab will provide a software solution with the corresponding new feature for affected iPlan RT / iPlan RT Image customers to prevent the described scenario from occurring. Brainlab will actively contact affected customers tentatively starting January 2016 to schedule the update.

Note for BrainSCAN customers: Brainlab discontinued the development of additional functions for BrainSCAN in 2002. A corresponding end-of-life communication was sent in 2013, stating that service and support related to the BrainSCAN will terminate on April 30, 2014. Consequently, Brainlab will not provide a software update for BrainSCAN. Brainlab strongly recommends customers still using BrainSCAN clinically to phase out the use of this software as soon as possible but in no event later than January 2016.

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.

September 7, 2015

Kind Regards,




Senior MDR & Vigilance Manager

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

Appendix

Verification of image sets loaded into the Brainlab Radiation Treatment Planning Software

1. Compare images loaded in the Brainlab software with the images as displayed by the scanner:

- Use a different display media approved and available to the hospital with identical display as the scanner other than the Brainlab software.
- All images of a dataset must be compared in between the different display media and the Brainlab software.
- Ideally compare one pixel value in each single image (measure the value) to ensure to be identical in both independent displays.

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2. Use DICOM attribute viewer to check whether DICOM files are supported

The parameters used to scale the raw pixel value from a DICOM file are:

- Rescale Slope (0028,1053)
- Rescale Intercept (0028,1052)

With a commonly available DICOM attribute viewer these values of the image files can be reviewed and compared.

Any other image set than a CT or a PET loaded with SUV, will be not supported by the Brainlab treatment planning software if these parameter values vary within one image dataset.

3. (Additional option) To check an existing dataset within iPlan RT

All datasets that Brainlab is aware of that are not supported showed the same behavior in the Brainlab application at Brainlab tests: for all these image slices the largest (hottest/brightest) pixel has the same value.

This unusual behavior clearly indicates that a dataset is not supported.

The following describes how to check in iPlan RT Image whether the largest pixel value is identical for all images of one dataset:

1. Open the image set in iPlan RT Image > Viewing
2. In the Options dialog, deselect "Display Interpolation"
3. Open the Windowing dialog
4. Manually move the upper threshold (right value) to the very right (to the largest value possible)
5. Manually adjust the lower threshold (left value) to: [largest value] – 1
6. In the Slices tab if there is now at least one pixel in every image (slice) then the data set is not supported (refer also to the example picture below).

Note: Theoretically image sets still could be not supported even if they do not show this behavior, but Brainlab is not aware of any such image sets.

