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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	iPlan RT Radiation Treatment Planning Software: Potentially incorrect patient positioning when using multiple localized CT image data sets.
Product Reference:	iPlan RT / iPlan RT Dose (all versions)
Date of Notification:	November 19, 2014
Individual Notifying:	Markus Hofmann, MDR & Vigilance Manager
Brainlab Identifier:	**CAPA-20141112-001173**
Type of action:	Advice regarding use of device; Device modification.

www.brainlab.com

We are writing to advise you of potentially incorrect patient positioning at the linear accelerator (linac) when using iPlan RT treatment plans containing multiple localized CT scans under specific circumstances.

Affected Brainlab Software:
All versions of Brainlab iPlan RT / iPlan RT Dose radiation treatment planning software in combination with a localizer and one of the following positioning solutions:
- o Target Positioner
- o ExacTrac v.4.5 or v.5.x
- o ExacTrac Vero (versions 2.1, 3.0, 3.1, 3.1.1, 3.2.0, 3.2.1)

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

Effect:
Incorrect patient positioning at the linac might occur, if all of the following conditions are met:
1. At least two different CT datasets are being used and have been both localized and fused to each other in the same treatment plan.
2. The latest* CT scan used with the localizer is not assigned as both *Reference Set* and *Alignment Set* (for definitions, see the appendix).
3. Patients are positioned at the linac using one of the following positioning solutions:
   - o Target Positioner
   - o ExacTrac v.4.5 or v.5.x
   - o ExacTrac Vero (from v.2.1 up to v.3.2.1)

* Throughout the entire document, the term *latest CT scan* refers to the localized CT scan, for which the identical patient fixation mask or headring position is used for CT scanning and subsequent treatment at the linac. In a typical clinical workflow, this is the latest (i.e., most recent) localized CT scan.

For clarity, this issue does not affect any treatment plan exported via DICOM from Brainlab iPlan RT Dose to an image-guided patient positioning system.

Magnitude of potentially incorrect patient positioning due to this issue:
The magnitude of potentially incorrect patient positioning is given by the difference in patient position inside the localizer during the two CT scans, one of which was assigned to the *Reference Set* and the other to the *Alignment Set*.

Figure 1 (see the following page) illustrates this difference "d" in patient positioning. "d" is shown here as an example from head-to-toe and corresponds to the resulting positioning error under the previously mentioned conditions.

Such a difference in patient position inside the localizer occurs if the fixation of the localizer to the patient is no longer identical, for example, if two different patient masks were used during the acquisition of the two CT scans.

Depending on the magnitude of the potential resulting patient positioning error at the linac, the difference "d" could exceed clinically acceptable limits for a specific treatment. If not detected by the user, **this could result in ineffective radiation treatment, serious patient injury, or even death of the patient**.
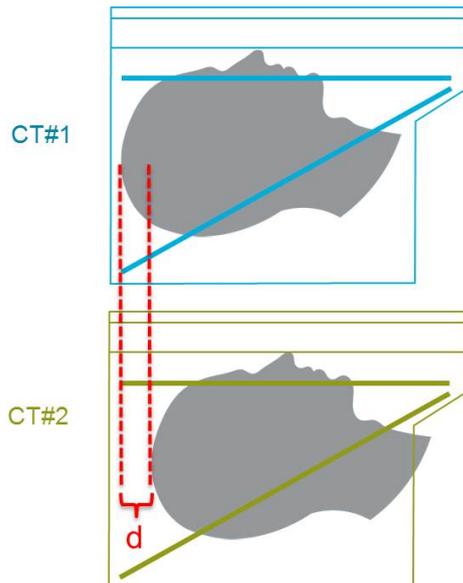
Figure 1: Illustration of the difference "d" that could occur in patient positioning.

Please refer to the appendix for **details** regarding this issue.

User Corrective Action:

1) If clinically not required, do not use multiple localized CT scans within one treatment plan (to avoid potentially incorrect *Reference* and *Alignment Set* assignments in the first place).

2) If you must use multiple localized CT scans, e.g. for recurrent treatment planning of the same patient, always guarantee that the latest (see note *) CT scan is defined as both *Alignment Set* **and** *Reference Set* during treatment planning.

Brainlab Corrective Action:

1) Brainlab provides existing potentially affected iPlan RT / iPlan RT Dose customers with this product notification information.

2) Brainlab will provide a software solution to prevent the described scenario from occurring. Brainlab will actively contact affected customers tentatively starting January 2016 to schedule the update.

3) Brainlab will additionally refine the instructions for use of the iPlan RT treatment planning software in regard to implications of *Alignment Set* and *Reference Set* selections and will provide this user guide update to existing affected customers together with the software 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 cooperation.

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)

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November 19, 2014

Kind Regards,

Markus Hofmann
Senior MDR & Vigilance Manager
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Europe: The undersigned confirms that the appropriate Regulatory Agency in Europe has been notified of this notice.

APPENDIX

Definition of *Reference* and *Alignment Set*
- The fusion root is the first image set in the fusion chain, to which all other image sets are either directly or indirectly fused. This fusion root is identical to the *Alignment Set* and is used for subsequent patient alignment on the treatment table.
- The *Reference Set* is used to define the outer contour and tissue model used by the dose algorithm in iPlan RT Dose.
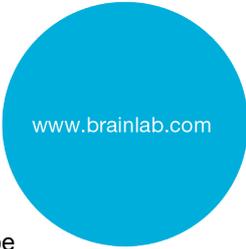
A clinical example on the usage of two localized CT scans
A patient needs to be treated a second time due to a tumor recurrence. For this, a new localized CT scan (CT#2) was acquired and fused to the existing iPlan RT treatment plan (based on the CT#1 (localized)) for reviewing the previously delivered dose. For the new plan, patient alignment and dose calculation should be based on CT#2. Therefore, the latest (see note*) CT set, CT#2, must be defined as both the *Alignment* and *Reference Set*.
In such a scenario, the Brainlab RT planning software is not restrictive and allows the user to freely choose the assignment. For your reference, the correct selection is described in the Clinical User Guide in the chapter covering Alignment and Reference Sets, specifically Case 6 *Update of a Localized Cranial Scan*. You can also find an excerpt of this description in the appendix in the section *Clinical User Guide: Selection of Reference and Alignment Set*.

Assignment of *Reference* and *Alignment Set* (including retrospective identification in existing plans)
You can identify the assignment of the *Reference* and *Alignment Sets* from iPlan RT Dose and from the *Treatment Parameter* printout in the section *Image Set Specifications*. For the clinical example above, the correct selection of *Alignment Set* and *Reference Set* is shown in Fig. 2 below – the latest CT scan, CT#2, was used for both sets. This assignment is correct for both patient positioning with all versions of ExacTrac and for patient positioning using the Target Positioner.

Image Set Specifications

Name	**Reference Set**	**Alignment Set**
Name	CT #2 (Axial)	CT #2 (Axial)
Scan Date	11–Feb-2014	11–Feb-2014
Number of Slices	379	379
Localizer	Brainlab Head&Neck	Brainlab Head&Neck
Pixel Size [mm]	0.9766	0.9766

Figure 2: Correct assignment of *Reference Set* and *Alignment Set* (Patient positioning: **correct**)

Consequences for Patient Positioning

Target Positioner:
For correct patient positioning with the Target Positioner, **the latest (see note *) CT scan** (CT#2 in the clinical example above) **must be strictly assigned to the *Alignment Set.***
Incorrect patient positioning would occur if the old CT scan was set as the *Alignment Set* and the new mask was used for patient treatment. Fig. 3 shows an example.

NOTE: If CT#1 would be selected as the *Reference Set*, patient positioning would be correct. However, dose calculations would then be based on the old CT scan, which is usually clinically not intended. Hence, it is strongly recommended to assign the latest (see note*) CT scan (CT#2) to the *Reference Set* as well.

ExacTrac:
For correct patient positioning with the ExacTrac versions listed on p.1, it is strictly required **that the *Alignment Set* and *Reference Set* are identical**. As mentioned in detail before, both the *Reference* and *Alignment Set* must be assigned **to the latest (see note *) CT scan** (CT#2 in the clinical example above).
Incorrect patient positioning could occur if *Reference Set* and *Alignment Set* are not identical: one example is illustrated in Fig. 3.

NOTE: If CT#1 would be selected as both the *Reference* and *Alignment Set* in the clinical example above, the tissue model and patient positioning would be based on the old patient anatomy.

Image Set Specifications

	Reference Set	Alignment Set
Name	CT #2 (Axial)	CT #1 (Axial)
Scan Date	11–Feb-2014	05-Nov-2013
Number of Slices	379	347
Localizer	Brainlab Head&Neck	Brainlab Head&Neck
Pixel Size [mm]	0.9766	0.9766

Figure 3: Example for wrong selection of the *Reference* and *Alignment Set* (Patient positioning: **incorrect**)

For the clinical example above, the table below summarizes the options for *Reference Set* and *Alignment Set* assignments and the corresponding consequences for patient positioning.

Scenario	CT#1	CT#2	ExacTrac	Target Positioner
1	Reference Set	Alignment Set	**Incorrect**	**Correct** [1]
2	Alignment Set	Reference Set	**Incorrect**	**Incorrect**
3	Alignment Set Reference Set		**Incorrect** [2]	**Incorrect**
4		Alignment Set Reference Set	**Correct**	**Correct**

Table 1: Overview of *Reference Set* and *Alignment Set* assignment scenarios

[1] Note: dose calculations are based on the old CT scan, however, patient positioning is correct.
[2] Note: depends on the clinical scenario. Only if the treatment target/isocenter position in both CT sets is at the same position in relation to the bone anatomy used for X-ray positioning <u>and</u> the bone anatomy of the patient did not change, patient positioning would be not affected.

<u>Clinical User Guide: Selection of *Reference* and *Alignment Set*</u>
The correct selection of *Reference* and *Alignment Set* for the case of multiple localized CT datasets is described in Case 6 *Update of a Localized Cranial Scan*. Below you will find an excerpt of the description from the Clinical User Guide.

Case 6: Update of Localized Cranial Scan

The new localized scan is intended to be used as the alignment set.

Current Assignment of Image Sets (for an approved treatment plan based on CT#1)
- CT#1 is defined as **Alignment Set**
- CT#1 is defined as **Reference Set**

Workflow

Steps	
1.	Add the localized update CT scan (CT#2) to the existing treatment plan.
2.	Fuse both CT image sets in the reverse direction to the default proposal (**iPlan RT Image**). (CT1 ⟶ CT2)
3.	Verify the treatment plan in the **Verification** dialog and approve it in the **Approval** dialog (**iPlan RT Dose**).

Assignment of Image Sets after Workflow
- CT#2 is defined as **Alignment Set**
- CT#2 is defined as **Reference Set**

Excerpt Clinical User Guide – iPlan RT v. 4.5; chapter *Changing Reference Sets*