

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: ExacTrac 5.x Patient Positioning System:
 Potentially inconsistent positioning information in ExacTrac when used in combination with a non-Brainlab radiation treatment planning system.

Product Reference: ExacTrac versions 5.0, 5.0.1 and 5.0.2
 ExacTrac versions 5.5, 5.5.1 and 5.5.2

Date of Notification: March 12, 2013

Individual Notifying: Markus Hofmann, MDR & Vigilance Manager

Brainlab Identifier: CAPA-20130308-000254

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



We are writing to advise you of an anomaly detected in ExacTrac 5.x when used in combination with a non-Brainlab radiation treatment planning system (TPS). This anomaly can mislead the user when selecting a treatment plan / isocenter (radiation treatment target) in ExacTrac for patient positioning at the linear accelerator (linac).

Potentially affected are the ExacTrac versions 5.0 and 5.5 (v. 5.0, 5.0.1, 5.0.2 and v. 5.5, 5.5.1, 5.5.2).

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

Effect:

When using a specific plan update workflow in combination with a non-Brainlab treatment planning system (TPS), there is a possibility in ExacTrac 5.x to generate an unintended blend of two initially separate plans of the same patient.

If the anomaly occurs, the information displayed by ExacTrac under “External Name” and “Dicom Patient Coordinates” (below marked pink) might not be correctly related to the information simultaneously displayed within the “Image Set Reconstruction” picture and under “BrainLAB Coordinates” (below marked blue).

Select Current Isocenter

Select Isocenter
 Isocenter Number: "External Name"
 Isocenter 1 - 1.1 lame boost re,1.2 r

Assign PTV
 Change PTV Selection

Image Set Reconstruction
 Axial CT #2 Slice: 56
 Isocenter 1

BrainLAB Coordinates
 X: 403.35 Y: -238.99 Z: -188.00

Dicom Patient Coordinates
 X: -130.10 Y: -43.60 Z: -685.00

View
 Axial Coronal Sagittal

Please check the isocenter coordinates.

Back Finish Cancel

External Name of Isocenter and Dicom Patient Coordinates:
 used by operator for comparison with plan at linac and TPS printout

might be inconsistent to

Image Set Reconstruction and BrainLAB Coordinates:
 used by ExacTrac for subsequent patient positioning

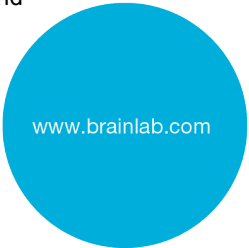
Figure 1 ExacTrac 5.x screenshot explaining the anomaly

Such a display of inconsistent positioning information might mislead the user when selecting a treatment plan / isocenter in ExacTrac for patient positioning. If not detected by the user, this might result in a patient and treatment target position at the linear accelerator (linac) that is different than intended.

As a consequence the treatment dose might be delivered to a region different from the intended target region. If the deviation would exceed clinically acceptable limits, **this could result in ineffective treatment, serious patient injury or even death of the patient.**

For the avoidance of doubt, not affected by this issue are:

- Treatment plans exported from any Brainlab treatment planning system (iPlan RT and BrainSCAN) and imported into ExacTrac.
- ExacTrac versions 6.0 or higher.
- ExacTrac versions 3.5.x or below.



Details:

If all circumstances in the following plan update workflow scenario are met, the described anomaly in ExacTrac 5.x might occur:

- A non-Brainlab radiation treatment planning system (TPS) is used for treatment planning
- And one of the following treatment planning scenarios is true:
 - Multiple plans exist for the same patient, or
 - Existing treatment plan is updated and isocenter related information is changed.
- And one of the following options is chosen during plan import into ExacTrac:
 - Inside the Patient Browser popup “BrainLAB Patient Browser: Images”, user selects “Yes”:

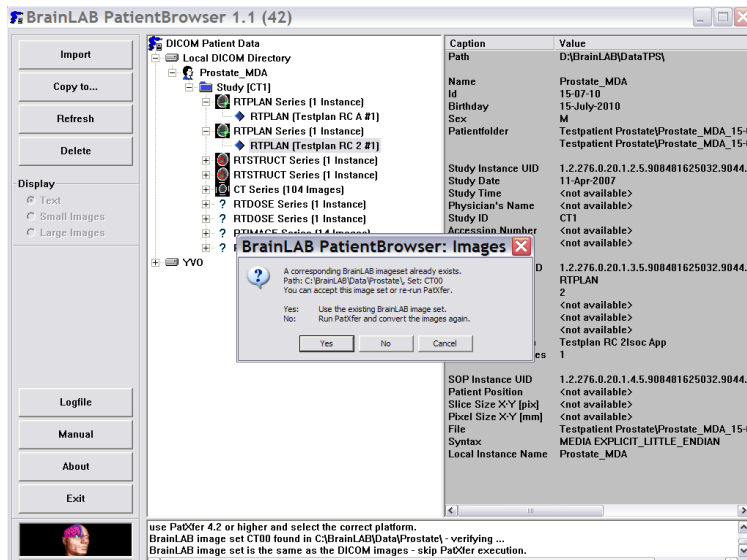


Figure 2 Patient Browser with “BrainLAB Patient Browser: Images” dialog during import to ExacTrac

- or, inside the PatXfer page “Store Options”, user actively selects the non-default option “Add image set to existing patient folder”:

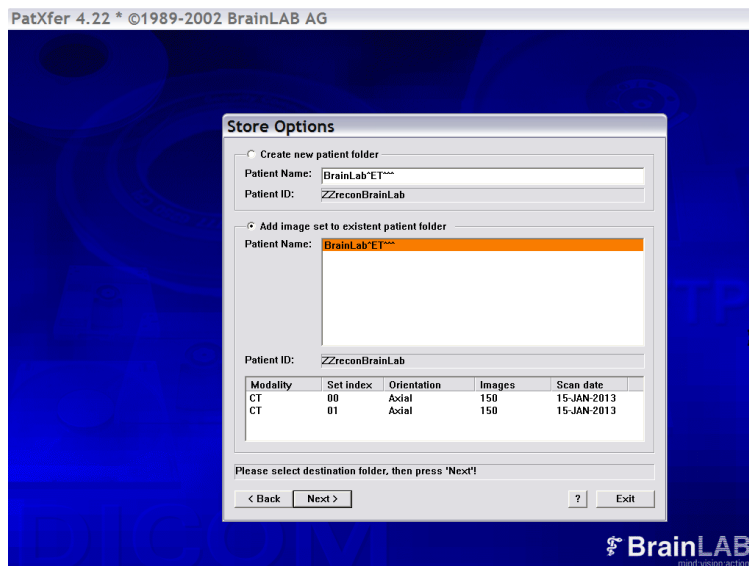


Figure 3 PatXfer with “Store Options” dialog during import to ExacTrac

User Corrective Action:

When using the Brainlab ExacTrac 5.x patient positioning system in combination with a non-Brainlab treatment planning system, always select the following options during a plan import into ExacTrac:

1. If the “BrainLAB Patient Browser: Images” dialog appears during import, always select “No” to “Run PatXfer and convert the images again”:

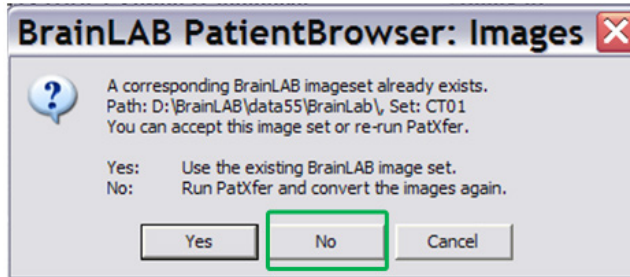


Figure 4 Always select “No” in the “BrainLAB Patient Browser: Images” dialog of Patient Browser

2. In the Store Options dialog of PatXfer, always select “Create new patient folder”:

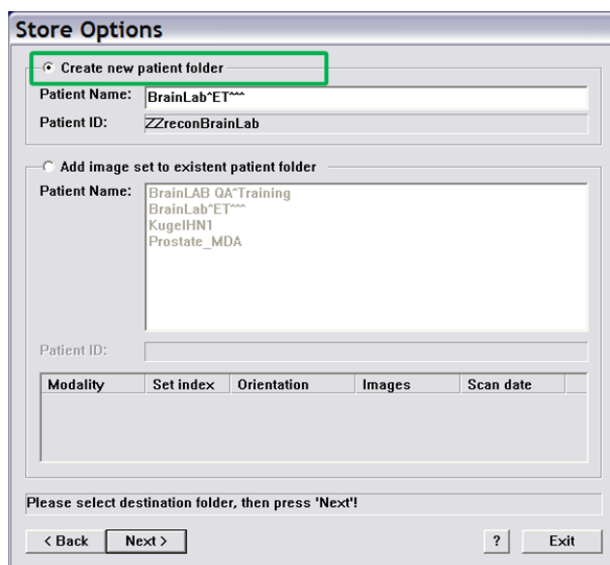





Figure 5 Always select “Create new patient folder” in the Store Options dialog of PatXfer

General Reminder:

Please continue to always follow the instructions and warnings as described in the user guide.

Especially relevant are the following warnings in the ExacTrac Clinical User Guide for reviewing isocenter information regarding plausibility and correctness, before patient positioning and treatment:

- 
Verify that the correct patient data (patient name and ID, and plan date) is shown in the open patient dialog.
- 
Verify that the treatment plan loaded in ExacTrac matches the treatment plan loaded on the linac, and ensure that the isocenter coordinates are correct by comparing them to the printout from the treatment planning system. This is especially important if the treatment plan has been updated in order to take possible gantry/table collision, tumor shrinkage, boost planning, etc. into account.
- 
Ensure that your clinic has established appropriate procedure in order to verify that the treatment plan loaded in ExacTrac matches the treatment plan loaded on the linac.

In order to support these requirements, Brainlab also recommends:

- To enter meaningful plan comments during treatment planning. When selecting a plan in ExacTrac, before proceeding with patient positioning, always review this comment within ExacTrac together with the plan date (please refer also to Figure 6).

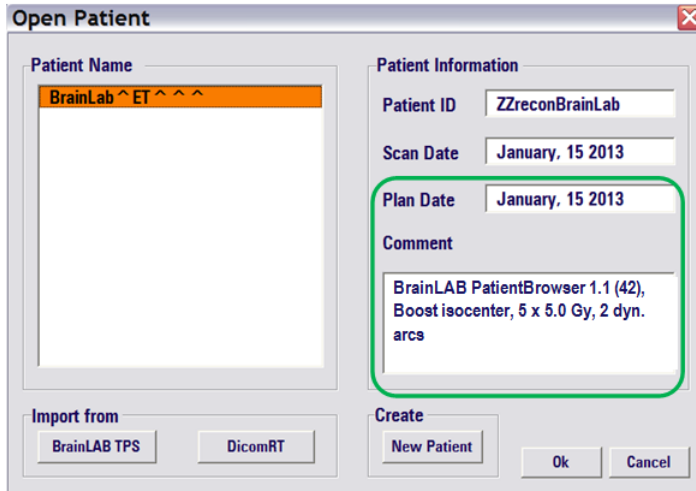


Figure 6 Review plan comments together with the plan date, displayed by ExacTrac.

- To always verify the correct isocenter position inside the “Image Set Reconstruction” picture (please refer to Figure 1) before proceeding with patient positioning.

Brainlab Corrective Action:

1. Existing potentially affected ExacTrac 5.x customers receive this product notification information.
2. Brainlab will provide a software update with this issue solved to affected customers. Tentative planned timeline for availability: end of August 2013.

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.

March 12, 2013

Kind Regards,



Markus Hofmann
MDR & Vigilance Manager

brainlab.vigilance@brainlab.com

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

