

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: ExacTrac 6.0 Patient Positioning System:
 Display of potentially incorrect Digitally Reconstructed Radiograph (DRR) for x-ray correction and verification.

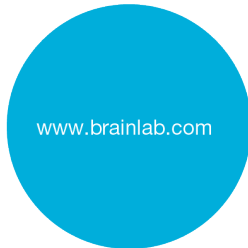
Product Reference: ExacTrac versions 6.0.0 through 6.0.5
 (Versions 6.0.0; 6.0.1; 6.0.2; 6.0.3; 6.0.4; 6.0.5)

Date of Notification: July 20, 2015

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

Brainlab Identifier: **CAPA-20150713-001446**

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



We are writing to advise you of the following potential effect that has been identified when using ExacTrac version 6.0.x for x-ray correction or verification of the patient position based on bony fusion. The phenomenon occurs under specific circumstances when using the ExacTrac x-ray module after a graphics memory error occurred at a previous patient positioning and the ExacTrac software has not been restarted since. There has been no negative effect on a patient treatment due to this issue reported to Brainlab by any user site.

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

Effect:

Loading and processing of large treatment plans, e.g. with a large image scan range and with a high number of outlined contours, may lead to an error in the ExacTrac internal graphic memory. After such a memory error has occurred, this might, under specific conditions, cause ExacTrac to display the Digitally Reconstructed Radiograph (DRR) of the previously loaded patient data set instead of the correct DRR during the positioning workflow of any subsequently opened patient treatment plan until the ExacTrac application is restarted.

For clarity, potentially affected are only the ExacTrac versions 6.0.0 through 6.0.5.

This issue affects X-ray correction and verification based on bony fusion to the DRR. The X-ray images acquired for current patient positions are not affected and still correct even if this issue occurs. Due to the unique signature of the patient anatomy in an X-ray image to distinguish an individual patient, a mismatch between the actual patient X-ray and an incorrect DRR simultaneously displayed at the fusion should be visible to the user. Only if the mismatch of displayed patient image data in ExacTrac is not discovered by the operator, the incorrect DRR might be used for image fusion to the acquired x-ray images, potentially resulting in the calculation of an incorrect shift.

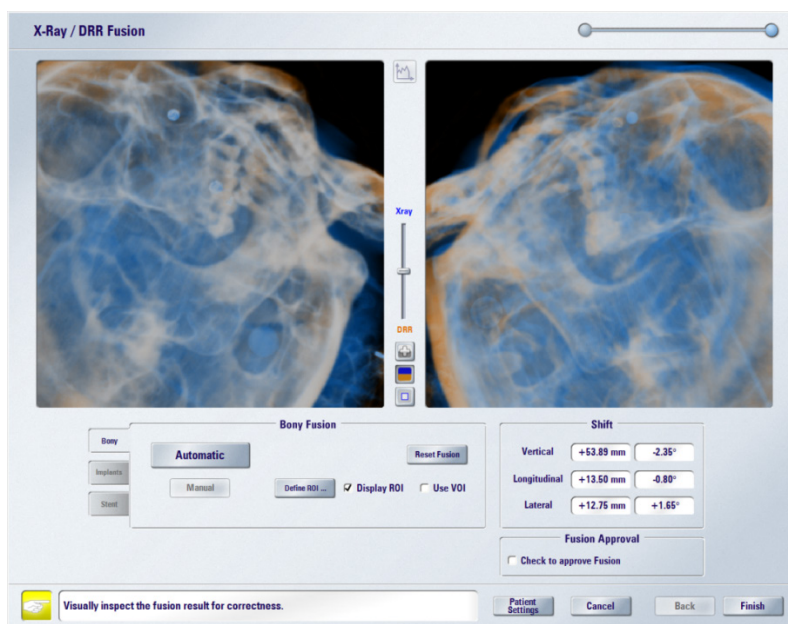


Figure 1: X-Ray Fusion – bony fusion to DRR to determine the shift to desired patient position.

Applying such an incorrect shift 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 exceeds 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 anomaly in ExacTrac are the functions:

- X-ray correction and verification based on implanted markers.
- Cone beam CT correction and verification.

Details:

Conditions for the occurrence of the anomaly

The root cause for this anomaly is an error in the ExacTrac internal graphic memory, which may occur, if large treatment plans, e.g. with a large image scan range and with a high number of outlined contours, are loaded and processed. Brainlab was only able to reproduce this anomaly if the large treatment plan is the first plan loaded after start of the ExacTrac application. The ExacTrac graphical user interface does not present an error message for the internal graphic memory error.

For the large patient data being loaded and causing the first occurrence of this graphic memory error, the DRRs displayed are still correct.

Nevertheless, for following patients loaded, if the ExacTrac application has not been exited and restarted in between, this error might prevent corresponding new DRRs to be rendered and displayed, causing the anomaly for these following patient data loaded. After termination and restart of the ExacTrac application, the graphic memory error is cleared and the correct DRRs are displayed.

Phenomena correlated to the anomaly and effect on patient treatment

If the described anomaly occurs, the DRR of the same patient data set is continually displayed by ExacTrac for any following loaded patient plan throughout the application until the ExacTrac application is terminated and restarted.

The incorrect DRR might then be displayed during operation of the following functions:

1) X-Ray fusion

The DRR is displayed overlaid with X-ray images, the latter representing the current patient position. By image fusion of X-ray and DRR a shift is calculated, which has to be applied by movement of the couch and, if applicable, the Robotics Tilt Module in order to position the patient correctly under the treatment beam (please refer to Figure 1). Fusion of a DRR belonging to a different patient with the X-ray of the patient on the treatment couch may result in an incorrect shift.

The fusion has to be carefully inspected by the operator. Nevertheless, it cannot be excluded that due to similar treatment indications of subsequent patients, the incorrect DRR not matching the still correct current X-ray might not be immediately discovered by the operator.

2) Review of patient treatment (retrospective)

The DRR is displayed for the retrospective verification of image fusion that was applied during treatment. If the anomaly had occurred, the same incorrect DRR is displayed during review as it was displayed during patient positioning for treatment. If in doubt for a specific treatment, careful review of the DRR and the fusion result should enable the user to determine if this issue had occurred at the treatment.

If the fusion accuracy of the correct DRR and x-ray during review is clinically acceptable, correct patient positioning can be inferred.

3) For the further functions below the display of the DRR does not have any impact on patient positioning and does not affect patient treatment.

- Patient setting - DRR settings adjustment: A preview of the DRR with current settings is displayed.
- Pre-Positioning/Positioning view: The DRR is displayed for animation of patient movement and as design element.

User Corrective Action:

As generally required, always verify that the correct DRRs for the current patient are displayed in ExacTrac and an accurate fusion to the X-Ray images is possible for patient positioning.

In case incorrect DRRs would be displayed, exit and re-start the ExacTrac software.

To minimize the probability of this issue to occur for the affected ExacTrac versions:

- Reduce the amount of contours exported to ExacTrac as far as possible (export only contours needed for positioning to ExacTrac).
- Avoid exporting large contours, such as couch top models, to ExacTrac.
- After every (re-)start of the ExacTrac application on any workstation, always first load a phantom plan not containing contours. Generate DRRs of that phantom plan once by selecting the *Define DRR Settings* tab, before loading any other patient treatment plans.

General Reminder:

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

In the context of this notification please specifically consider the safety notes relevant for X-ray correction and verification:

- The image overlay functions must be used to verify fusion accuracy in both image views, especially if the images contain a series of similar structures such as vertebrae.
- Do not perform patient treatment unless accurate image fusion is possible.
- Large correction shifts (e.g. greater than 10 mm) may indicate incorrect automatic fusion. In such cases, verify the correction shift a second time.

Brainlab Corrective Action:

1. Existing potentially affected ExacTrac 6.0.x customers receive this product notification information.
2. Brainlab will provide a software revision (ExacTrac v. 6.0.6) with this issue solved to affected customers.

Brainlab will actively contact you starting December 2015 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) or by

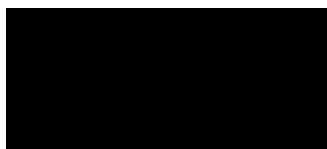
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July 20, 2015

Kind Regards,



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



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