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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	ExacTrac Vero 3.x Patient Positioning System: Display of potentially incorrect Digitally Reconstructed Radiograph (DRR) for x-ray correction and verification.
Product Reference:	ExacTrac Vero versions 3.0 and higher (Versions 3.0.0; 3.1.0; 3.1.1; 3.2.0; 3.2.1)
Date of Notification:	May 15, 2014
Individual Notifying:	[redacted], MDR & Vigilance Manager
Brainlab Identifier:	**CAPA-20140507-000686**
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 Vero version 3.0 or higher for x-ray correction or verification of the patient position based on bony fusion.

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 treatment plans containing multiple contours with ExacTrac Vero may block the internal graphic memory. Under specific conditions this might cause ExacTrac Vero to display the Digitally Reconstructed Radiograph (DRR) of a previously loaded patient data set instead of the correct DRR during the positioning workflow of any subsequently opened patient treatment plan until the ExacTrac Vero application is restarted.

This issue affects X-ray correction and verification based on bony fusion. If the anomaly occurs and the mismatch of patient image data in ExacTrac Vero is not discovered by the operator, the incorrect DRR might be used for image fusion to the acquired stereo x-ray image, potentially resulting in the calculation of an incorrect shift.

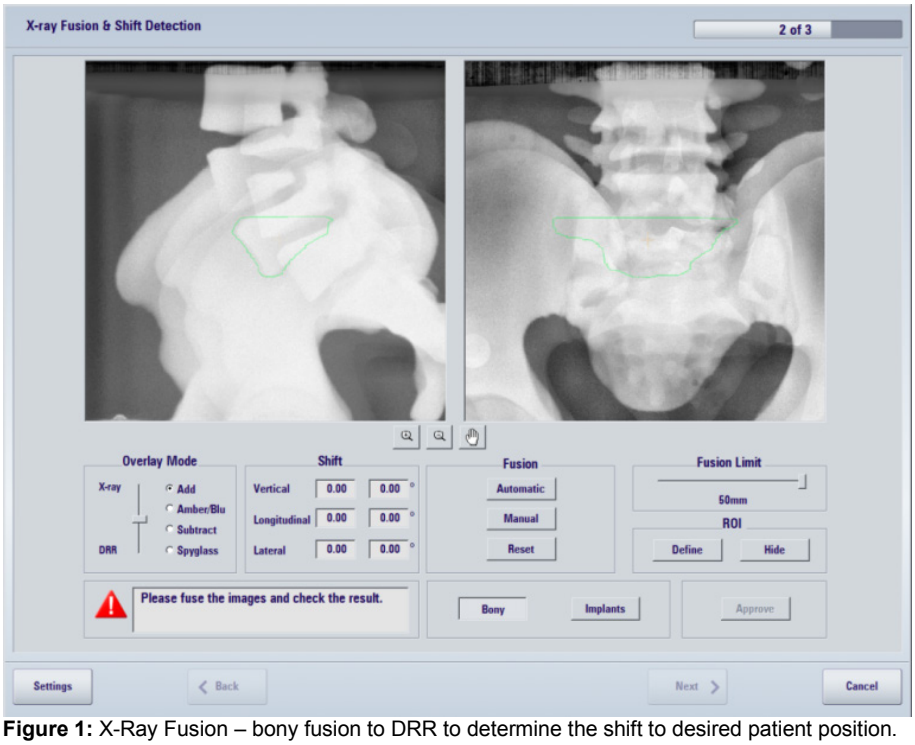

Figure 1: X-Ray Fusion – bony fusion to DRR to determine the shift to desired patient position.

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 Vero are the functions:

- X-ray correction and verification based on implanted markers.
- Cone beam CT correction and verification.
- Dynamic Tracking performance including re-positioning to the center of motion.

Details:

Conditions for the occurrence of the anomaly

The root cause for this anomaly is an overflow of the graphic memory, which may occur, if multiple contours are rendered without closing the software application intermittently. Typically such an overflow results in a forced termination of the software application, which immediately clears the graphic memory. In this case the anomaly does not occur.

Nevertheless, a “near” overflow can occur in a way that the application does not terminate forcefully, but prevents new DRRs to be rendered and displayed, causing the anomaly. Also in these exceptional cases the graphic memory is cleared after termination and restart of the ExacTrac Vero application.

Phenomena correlated to the anomaly and effect on patient treatment

If the described anomaly occurs, the DRR of always the same patient data set is displayed by ExacTrac Vero for any following loaded patient plan throughout the application until the ExacTrac Vero 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 a stereo X-ray, 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 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 the similarity of the DRRs for different patients the DRR mismatch is not discovered by the operator.

2) Review of patient treatment

   The DRR is displayed for the retrospective verification of image fusion that was applied during treatment. If the anomaly occurs and the same incorrect DRR is displayed during review as it was displayed during patient positioning for treatment, the user may falsely conclude at review that the fusion during treatment was correct. Although the use of the Review function does not directly affect the patient positioning during treatment, undesirable fusion results might not be discovered retrospectively in these specific circumstances.

   The occurrence of the anomaly during review can be excluded by restarting ExacTrac Vero prior to the review session. If the fusion accuracy of the correct DRR and x-ray during review is clinically acceptable, correct patient positioning can be inferred independent of a potential occurrence of the anomaly during treatment.

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 / Static Treatment view: The DRR is displayed for animation of patient movement and as design element.
   - Dynamic Tracking: Imager settings dialog: A preview of the DRR at the selected Ring/Gantry angle is displayed.
   - Dynamic Tracking: Re-Positioning view: The DRR is displayed for animation of patient movement and as design element.
   - Replay of Patient treatment: The DRR is displayed for demonstration of image fusion.

User Corrective Action:

With immediate effect, exit and restart the ExacTrac Vero application after each patient treatment.

In detail, the following procedure shall be applied after each patient treatment:

- MHI-TM2000 Operator Console: Disable ExacTrac.
- ExacTrac Workstation: 'Exit' the ExacTrac Vero application.
- ExacTrac Workstation: Restart the ExacTrac Vero application.
- MHI-TM2000 Operator Console: Enable ExacTrac.

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For patient treatment review, always restart ExacTrac Vero prior to the review session.

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.

Brainlab Corrective Action:

1. Existing potentially affected ExacTrac Vero customers receive this product notification information.
2. Brainlab will provide a software revision with this issue solved to affected customers. Tentative planned timeline for availability: End of June 2014.

   Brainlab will actively contact you to schedule the update within the next six months.

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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May 15, 2014

Kind Regards,

[redacted]
MDR & Vigilance Manager
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Europe: The undersign confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.