

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: ExacTrac 6.0 Patient Positioning System (Version 6.0.4 only): Potentially incorrect patient positioning when switching back to isocenters (radiation treatment targets), for which positioning steps were already applied within the same treatment session.

Product Reference: ExacTrac version 6.0.4

Date of Notification: June 24, 2014

Individual Notifying: [REDACTED], MDR & Vigilance Manager

Brainlab Identifier: **CAPA-20140610-000703**

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



We are writing to advise you of an anomaly internally detected by Brainlab in ExacTrac v.6.0.4, when using multiple isocenters (radiation treatment targets) within a single plan under unusual workflow circumstances. There has been no such occurrence of this anomaly reported to Brainlab by any user site.

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 multiple isocenters (multiple radiation treatment targets) within a single plan, for a specific unusual workflow involving switching back to isocenters, for which X-ray or Cone Beam CT positioning steps were already applied within the same treatment session, and if certain variables are met, ExacTrac v.6.0.4 might position the patient to an unintended isocenter position, despite displaying the green “OK” icon.

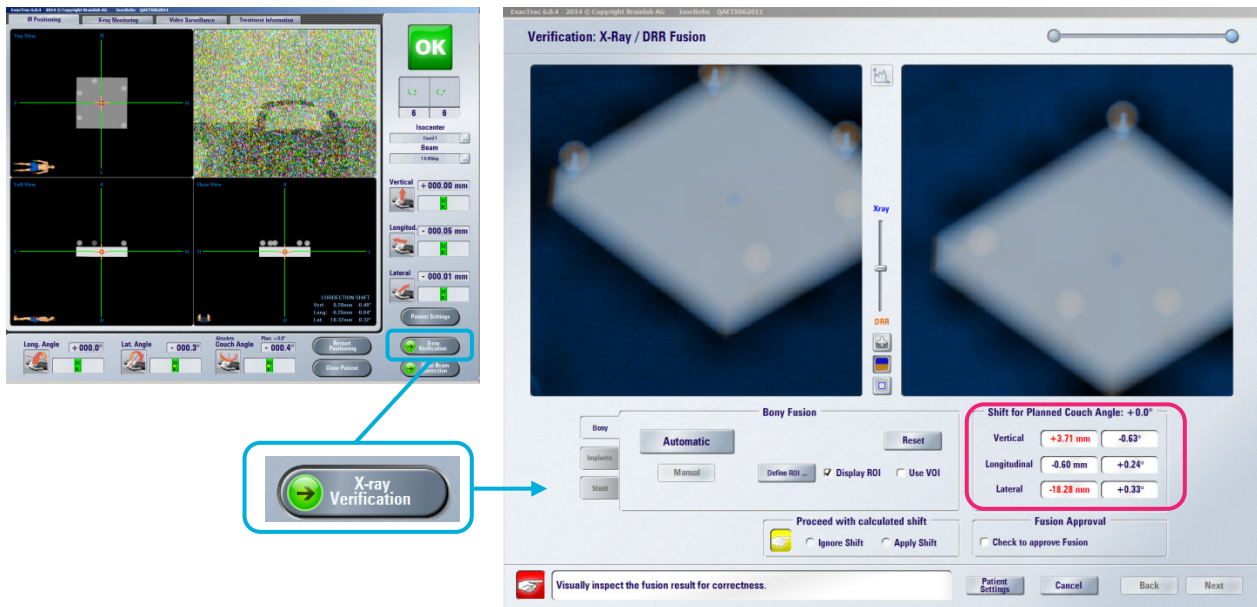


Figure 1: Illustration of effect: ExacTrac displays the green “OK” icon, but X-ray Verification still indicates a shift (marked pink)

If this anomaly occurs and is not detected by the user, there is a possibility that the radiation treatment dose at the linear accelerator may be delivered to the unintended target position. If the deviation exceeds clinically acceptable limits, **this could result in ineffective treatment, serious patient injury, or even death of the patient.**

This anomaly is only related to ExacTrac v.6.0.4.

Details:

The anomaly in ExacTrac v.6.0.4 only occurs if all of the following circumstances are met:

1. A patient is positioned using the ExacTrac “X-Ray Correction” or “Cone Beam CT Correction” module.
2. The plan contains two or more isocenters.
3. One of the following reference devices is used:
 - ET Positioning Star (Art. No. 49581)
 - ET Positioning Array (Art. No. 49583 or 49583A or 49583B)
 - ET Frameless SRS Radiosurgery Positioning Array (Art No. 49578 or 49578A) in a non-localized workflow

For the avoidance of doubt, not affected are any workflows applying

- ET Frameless SRS Radiosurgery Positioning Array when used with localized patient data.
- ET Infrared Body Markers.

4. When switching isocenters, the user at least once selects “No” in the below displayed dialog “Do you want to keep the previous correction shift?”.

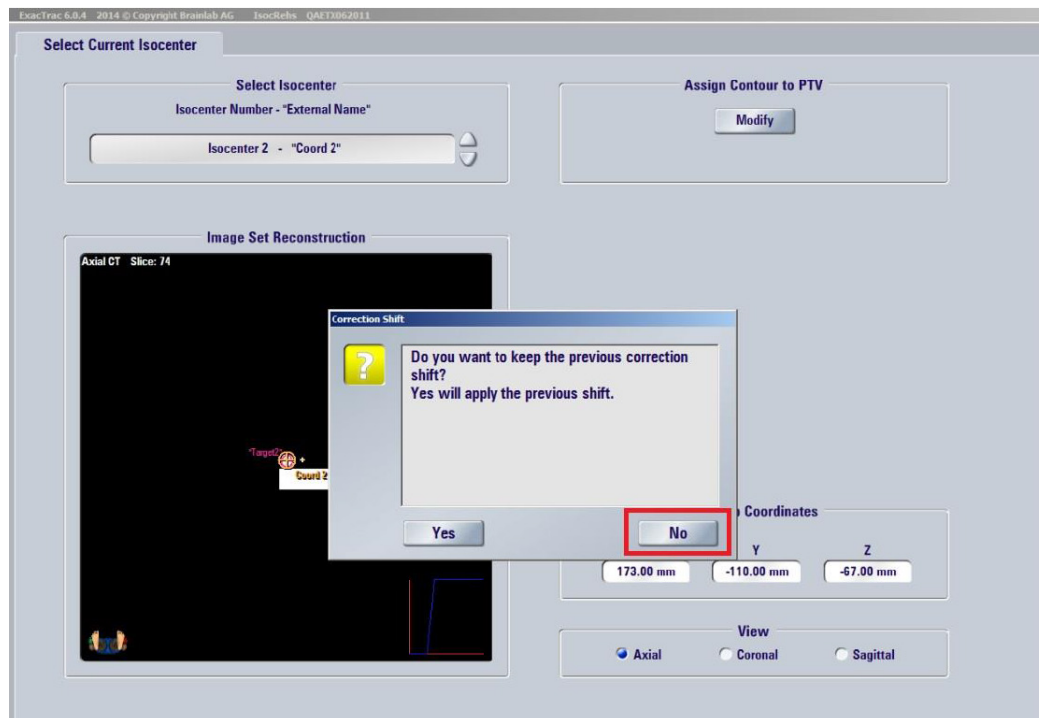


Figure 2: Dialog box shown when switching between isocenters

5. At least one correction was performed or partly performed (the “Finish” button was pressed on the X-ray / DRR Fusion or the Cone-Beam-CT / CT Fusion wizard page) after switching isocenters and selecting “No” in this dialog as shown above (Figure 2).

6. The user returns to an isocenter where a correction was already performed or partly performed in the same treatment session before the “No” button (Figure 2) was selected. For example, “No” was pressed for the first time when switching from isocenter #2 to isocenter #3. In this case the error could occur if the user returns to isocenter #1 or isocenter #2.

7. The recommended X-ray Verification of the final treatment position is not performed by the user or the result of this verification is not carefully evaluated after re-positioning the patient to an isocenter meeting the conditions described above.

Magnitude of potential error: If the error occurs, the magnitude is the difference of the distances and directions of the calculated correction shifts for the corresponding pre-positions between isocenters where “No” (Figure 2) has been selected during the switch.



Treatment verification and (retrospective) review:

Even if the anomaly occurs for a patient treatment which switches back to an isocenter, the recommended X-ray Verification still works as intended and reveals a positioning error caused by this issue, at the same time offering the possibility to correct it (refer also to Figure 1).

The performed X-ray Verification can retrospectively at any time be reviewed by the user with the "Review" function of ExacTrac.

In case you desire Brainlab support in detailed investigation of a specific case regarding this issue, please feel free to contact your local Brainlab Customer Support Representative to organize it.



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User Corrective Action:

- 1) Avoid using plans with multiple isocenters in ExacTrac 6.0.4 wherever possible. Treatment plans with only one isocenter are not affected by this anomaly.
- 2) If a plan with multiple isocenters cannot be avoided and such a plan is used in ExacTrac v.6.0.4, then
 - Always select "Yes" in the dialog displayed to "keep the previous correction shift" when switching between isocenters (refer also to Figure 2).
 - Always verify all final treatment positions.

Brainlab Corrective Action:

1. Existing potentially affected ExacTrac v.6.0.4 customers receive this product notification information.
 2. Brainlab will provide a software update with this issue solved to affected customers.
- Brainlab will actively contact you to schedule the update within the next 6 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.

Customer Hotline: +49 89 99 15 68 44 or +1 800 597 5911 (for US customers) or by

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June 24, 2014

Kind Regards,



MDR & Vigilance Manager

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