

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: ExacTrac 6.0 Intra-Fraction Snap Verification: potentially incorrect software hint icon and result text for monoscopic X-ray Monitoring in combination with implanted markers.

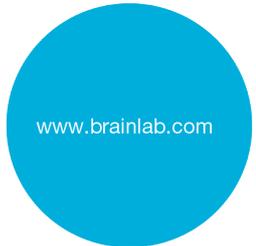
Product Reference: ExacTrac versions 6.0.1 and 6.0.2 only (Image Guided Radiation Therapy Patient Positioning System).

Date of Notification: February 22, 2013

Individual Notifying: Markus Hofmann, MDR & Vigilance Manager

Brainlab Identifier: **CAPA-20130221-000248**

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 the monoscopic Intra-Fraction X-ray Monitoring (Snap Verification) of the ExacTrac 6.0 patient positioning system (ExacTrac versions 6.0.1 and 6.0.2 only).

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:

After performing a Snap Verification, that is a monoscopic Intra-Fraction X-ray Monitoring using only one X-Ray tube, in combination with implanted markers, the ExacTrac 6.0 X-ray Monitoring tab might display an incorrect hint icon and result text (please refer to Figure 1): ExacTrac might incorrectly show the hint icon in green color with the result text “No Deviation detected”, despite the simultaneously displayed unaffected X-ray image showing the actual positions of the implanted markers (displayed as green crosses) potentially deviating from the user defined tolerance areas (displayed as red and white circles).

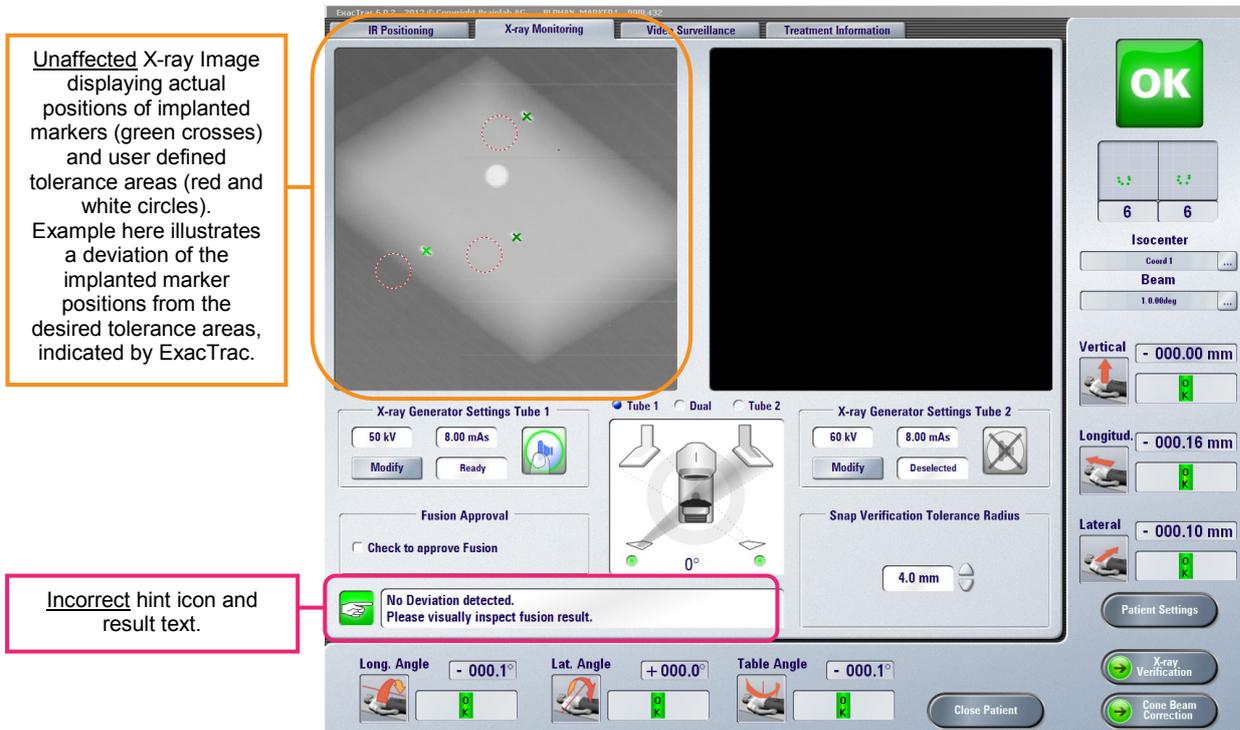


Figure 1: X-Ray Monitoring tab after Snap Verification - unaffected X-ray image displaying actual implanted marker positions deviating from the tolerance areas, but incorrect hint icon and result text.

The Intra-Fraction X-Ray Monitoring is intended to instantly verify that the initial, correctly set up patient and target position in the treatment room did not change. Monoscopic X-Ray Monitoring (Snap Verification) is especially used if one of the two X-ray pathways is obstructed by e.g. the gantry position of the linear accelerator.

This issue only affects the monoscopic Snap Verification (using one-sided X-ray) of the ExacTrac versions 6.0.1 and 6.0.2, and only in combination with implanted markers.

This effect might contribute to failure to detect a deviation from the desired treatment target position, if all of the following conditions are met:

- A clinically relevant movement of the patient and/or target position after the initial patient positioning would have occurred, and
- a monoscopic Snap Verification would show the described behavior, and
- in this scenario the user would only rely on the incorrect hint icon and result text, without heeding the simultaneously displayed unaffected X-ray image indicating the actual positions of the implanted markers deviating from the user defined tolerance areas.

Such a radiation therapy continued with an undesirable treatment target position for the current treatment fraction **could result in serious patient injury and/or ineffective treatment.**

Details:

In situations where the positions of the implanted markers are displayed outside the defined tolerances, the following icon and message is intended:



Brainlab investigation has shown that only the first monoscopic Snap verification is affected, for example after a (stereoscopic) X-ray Verification was performed, or after entering and leaving the Patient Settings, or after re-opening the patient in ExacTrac. This first monoscopic Snap Verification always displays the hint item in green color and the result text "No Deviation detected". Subsequent Snap Verifications will display the correct and intended hint icon color and result text (=corresponding to the positions displayed in the X-ray image), until a different user action as mentioned in the above examples is performed.

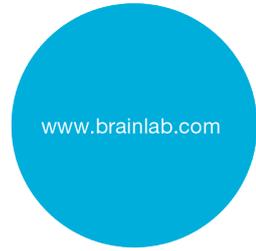
Not affected by this issue is:

- Snap Verification based on anatomical structure (bony fusion).
- Stereoscopic imaging (using two-sided X-ray).
- All other X-Ray Correction and X-ray Verification workflows and modalities.

User Corrective Action:

Always verify the result of a Snap verification within the simultaneously displayed X-ray image, as generally required. Never exclusively rely on the hint icon color and the result text only.

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

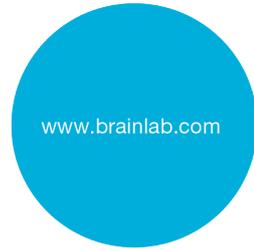


General Reminder:

Especially relevant for using Snap Verifications are the excerpts below (please refer to the Clinical user guide ExacTrac 6.0 Revision 1.2).

- How to Verify Accuracy: Steps
 1. Adjust the image contrast and windowing as required.
 2. Adjust the marker shift Tolerance to the required level in millimeters (mm). The displayed tolerance circles adjust accordingly.
 3. Verify that the red and white tolerance circles (indicate the marker position as defined in the patient settings) and the implanted markers are identically positioned.
 4. Verify that:
 - Long markers: a red and white tolerance circle correctly encloses each marker endpoint.
 - Short markers: the midpoint of each implanted marker is completely enclosed by a red and white tolerance circle.
 5. If the automatic marker detection implemented by the software was successful, green crosses are also displayed:
 - Long markers: **verify** that a green cross is positioned directly over each marker endpoint and **that each cross is also enclosed by a red and white tolerance circle.**
 - Short markers: **verify** that a green cross is positioned directly over each detected implanted marker and **that each cross is also enclosed by a red and white tolerance circle.**

- Procedure in the Case of Deviations: If automatic marker detection fails, and a significant accuracy deviation is observed, stop treatment and perform full X-ray verification in order to restore correct patient positioning.

**Brainlab Corrective Action:**

1. Existing potentially affected ExacTrac v. 6.0.1 and 6.0.2 customers with Intra-Fraction X-Ray Monitoring 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

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February 22, 2013

Kind Regards,



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