

URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: ExacTrac Dynamic Radiation Therapy Patient Positioning System:
 In case of a failed automatic detection of implanted markers, unexpected display behavior may allow the user to proceed to treatment without applying a shift exceeding predefined tolerances

Product Reference: ExacTrac Dynamic 1.0.0, 1.0.1, 1.0.2

Date of Notification: February 10, 2021

Individual Notifying: Andrea Miller, Vigilance Manager

Brainlab Identifier: CAPA-20210210-002387

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

We are writing to advise you of a safety issue with the Brainlab ExacTrac Dynamic software (versions 1.0.0, 1.0.1, 1.0.2) that might occur in a specific workflow that involves implanted markers. In case of a failed automatic marker detection, a software error causes parts of the display to incorrectly behave as if the current patient position is within predefined tolerances and may allow the user to proceed to treatment despite potentially exceeding shift values.

There has been no reported negative impact on patient treatment by any user site due to this issue. The purpose of this Product Notification letter is to provide you with the relevant user information on how this issue occurs and to inform you of the corrective actions Brainlab is taking to address this.

Effect:

ExacTrac Dynamic offers the possibility to perform X-ray-based verification of the patient position at different stages of the workflow. If at least one of the calculated translational or rotational shift values exceeds the predefined X-ray shift tolerances during the verification, the corresponding value shall be displayed in red by the software. Furthermore, highlighting the Send Shift button and hiding the Treatment button forces the user to apply the shift before proceeding to treatment.

Brainlab determined that the above described visual highlighting and guidance may not work as specified for the implanted marker workflow if the automatic marker detection failed. Please refer to Figure 1, which shows the intended display versus the actual display on the X-ray Verification / X-ray Repositioning page.

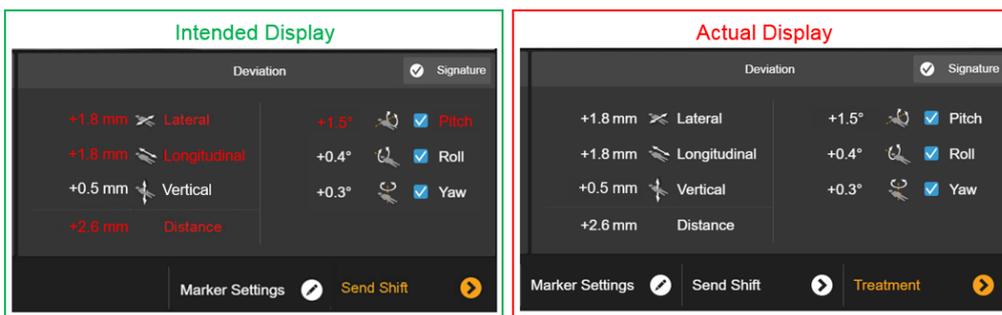


Figure 1: X-ray Verification / X-ray Repositioning page with shift values partly exceeding the predefined X-ray shift tolerances (in this example translation 1 mm, distance 1.7 mm, rotation 1°): Unlike in the intended display (left), the actual display (right) does not show the exceeding shift values in red, and the Treatment button may be displayed.

To clarify, the calculated numerical shift values are correct. Moreover, if the user proceeds to treatment, the patient monitoring based on surface tracking works as intended including the Automatic Beam Hold.

In the rare scenario in which a user relies solely on the graphical highlighting and guidance of the user interface display (e.g. if not aware of the tolerances), the user may fail to detect and apply a shift exceeding the predefined X-ray shift tolerances before proceeding to treatment.

If a deviation from the patient target position goes undetected, and the deviation exceeds clinically acceptable tolerances for the indication being treated, underdosage of the planned target volume and/or an overdosage of healthy tissue could occur.

The following details the specific conditions required for this error to occur, the affected workflows and the magnitude of potential deviation from the patient target position.

Details:

The described effect occurs only if ALL of the following conditions are fulfilled:

- The implanted marker positioning technique is used
- The automatic marker detection fails (markers can be defined manually by the user on the X-ray images)
- The patient moves outside the predefined X-ray shift tolerances

The issue might occur during any X-ray Verification / X-ray Repositioning step in the workflow (i.e., after initial X-ray Correction, after couch rotations, after an automatic beam hold, or if X-ray Verification is accessed manually during treatment).

The unintended behavior of the display is caused by inconsistent internal software states that consider the calculated shift to be within the predefined tolerances (independent of the actual values). This leads typically to two unintended display states:

- A. Calculated shift values exceeding predefined tolerances are shown in white (instead of red as intended)
- B. The Treatment button is displayed (instead of hidden as intended)

However, please note that there are also cases where only display state “A.” without display state “B.” occurs.

If the effect occurs, and the user proceeds to treatment without applying a shift exceeding the predefined X-ray shift tolerances, the maximum potential deviation from the patient target position is limited by the surface tracking tolerances as defined during patient preparation (5 mm / 5° is the maximum value allowed by the system). Since monitoring based on surface tracking works as intended, larger deviations are not expected, unless the Automatic Beam Hold is not used and the information displayed on the Patient Monitoring page is disregarded.

To clarify, if the user proceeds to Monitoring without applying the calculated X-ray Verification / X-ray Repositioning shift, the deviation from the patient target position is also visible on the Patient Monitoring page in the Surface Tracking view. The displayed shift values incorporate the preceding X-ray based shift, and are updated during monitoring in real time based on acquired surface tracking data.

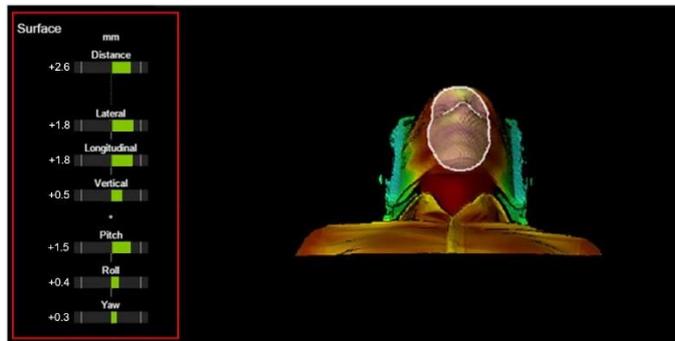


Figure 2: Patient Monitoring page with shift values displayed in the Surface Tracking view: The values incorporate the preceding X-ray based shift and are updated in real time during patient monitoring.

Retrospective review:

You can review the ExacTrac Dynamic treatment report for treatments that have already been performed. The report contains the X-ray based shift values, corresponding X-ray shift tolerances, information on whether a shift has been applied, and the surface-based patient position deviation recorded over the course of the treatment. The data documented in the treatment report is correct.

User Corrective Action:

1. During X-ray Verification / X-ray Repositioning when using the implanted marker workflow, closely review the calculated shift to verify if the shift is within the predefined tolerances.
2. If the shift is larger than the predefined X-ray tolerances, apply the shift before proceeding to treatment.
3. Always keep the Beam Hold Control functionality enabled. If the system holds the beam automatically, do not select “Ignore” and instead verify the patient position, taking into account all of the above.

Brainlab Corrective Action:

1. Existing customers that are potentially affected receive this product notification information.
2. Brainlab will provide a software revision of ExacTrac Dynamic to all affected customers with the described issue corrected. Brainlab will actively contact you to schedule the update, starting July 2021.

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 cooperation. If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

Customer Hotline:

+49 89 99 15 68 1044 or +1 800 597 5911 (for US customers)

E-mail: support@brainlab.com (for US customers: us.support@brainlab.com)

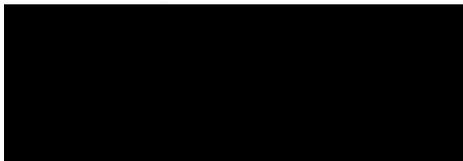
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February 10, 2021

Kind Regards,



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