

URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: ExacTrac Dynamic - Patient Positioning System:
For CBCT positioning workflows using setup beams with Varian LINACS, yaw angle may be incorrect

Product Reference: ExacTrac Dynamic 1.0.0, 1.0.1, 1.0.2, 1.0.3

Date of Notification: February 07, 2022

Individual Notifying: Maura Boyle, Vigilance Manager

Brainlab Identifier: CAPA-20220204-002455

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 (ETD) software (versions 1.0.0, 1.0.1, 1.0.2, and 1.0.3), which may occur under specific conditions, when used with non-Brainlab Cone Beam Computed Tomography (CBCT) positioning on a Varian LINAC. The issue may result in an inaccurate handling of the yaw (couch) angle.

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:

The X-ray module of ETD detects the patient's position by comparing X-ray images to Digitally Reconstructed Radiographs (DRRs). When ETD is used to monitor and potentially reposition a patient who was positioned based on CBCT, ETD internally calculates a CBCT offset indicating the difference between the position determined by CBCT and the position detected by ETD.

Brainlab determined that calculation of the yaw angle of the CBCT offset may be wrong under the following conditions:

- A setup beam is loaded on the Varian LINAC during the calculation of the CBCT offset at the CBCT X-ray Reference Acquisition step of the ETD workflow.
- The internal parameters *original planned Patient Support Angle (PSA)* and *updated planned Patient Support Angle (PSA)* have different values at this CBCT X-ray Reference Acquisition step (this will be explained in more detail in the subsequent sections).

As a consequence, for all subsequent patient repositioning(s) performed using ETD, there will be a deviation from the patient's intended position for the yaw value. Additionally, the offset error might be propagated to the ETD surface tracking, and therefore may adversely affect the surface monitoring (indicators, related warnings, and beam hold functionality).

The error only affects the yaw angle. All other angles and directions are handled as intended. The isocenter is always positioned correctly. Typically the angular yaw error will be less than 3°.

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 the potential error.

Details:

Background of Patient Support Angle (PSA)

For the ETD X-ray module to determine a patient's position, or more specifically the deviation of the current position from planned target position, the ETD algorithm needs multiple input parameters, including the PSA. The correct functioning of the algorithm specifically requires the *original planned PSA* (typically defined during treatment planning).

There is a second PSA value referred to as the *updated planned PSA*. The *updated planned PSA* is used at the LINAC to position the couch and considers changes in the PSA angle resulting from already performed positioning processes during the current treatment session. *Updated planned PSAs* are indicated on the Varian treatment screen by a bracket preceding the value, e.g. “)-359.5°”. Initially the *updated planned PSAs* are identical to the *original planned PSAs*, but may be later modified by multiple processes, including ETD prepositioning, CBCT positioning, and ETD positioning.

Error root cause

For treatment beams the algorithm reads the *original planned PSA* correctly from the DICOM RT treatment plan. For setup beams, the PSA value is imported “on the fly” from data broadcasted by the Varian ADI (Auxiliary Device Interface); during this “on the fly” process, ETD erroneously imports the *updated planned PSA* instead of the required *original planned PSA*.

Background of CBCT offset calculation

The CBCT offset is determined on the X-ray Reference Acquisition page, after reference X-ray images have been acquired, as seen in Figure 1.

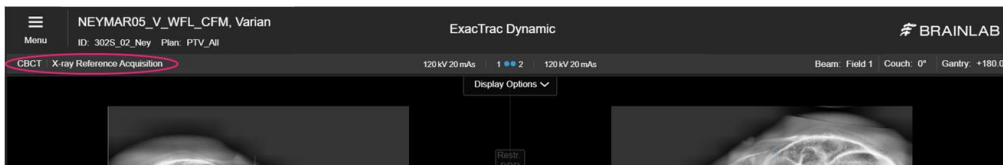


Figure 1: CBCT X-ray Reference Acquisition step as shown on the ETD software.

More specifically, it is calculated from the values displayed in the ETD software as shown in Figure 2a “Deviation to ExacTrac Position”, by inverting the signs. After the user selects “Accept CBCT Positioning”, the CBCT offset is added, such that the final ETD position results in 0mm/0° in all dimensions, indicating that from now on the CBCT position is accepted as the reference position (shown in Figure 2b).

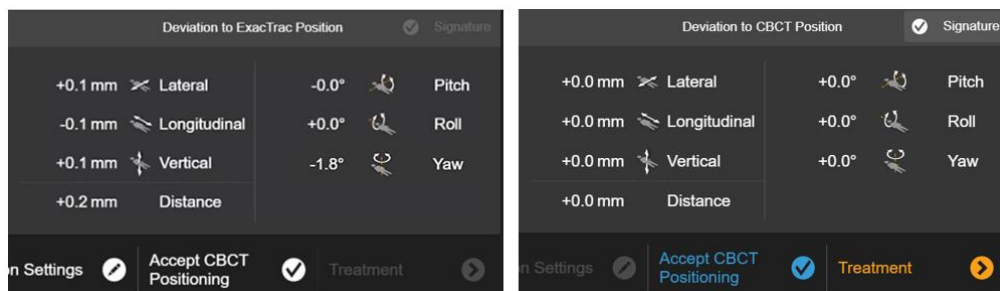


Figure 2a (left): The deviation between the current patient position and the planned ExacTrac internal position. **Figure 2b (right):** The CBCT offset has been added to the ExacTrac internal position, resulting in 0mm/0° in all dimensions.

Impact of error

If a setup beam is loaded during this step, any difference in the *original planned PSA* and the *updated planned PSA* will result in an incorrect ETD X-ray detection of the patient position (incorrect yaw value). Consequently, this wrong position results in an incorrectly calculated CBCT offset (yaw value).

Once the user selects “Accept CBCT Positioning”, the displayed yaw value changes to 0 as displayed in Figure 2b. Thus the wrong ETD internal position and wrong CBCT offset initially compensate each other and lead to expected 0 result in all directions.

For all additional X-ray pairs acquired while a treatment beam is active on the LINAC, the ETD algorithm correctly uses the *original planned PSA* read from the treatment plan, but since the incorrect CBCT offset is added to this internal position, all subsequent ETD X-ray positioning information for the yaw value will be incorrect. At the same time, the error will be propagated to the ETD surface detection, as the surface values are re-initialized every time an X-ray pair is successfully acquired. Therefore the surface monitoring for the yaw angle (indicators, related warnings, and beam hold functionality) will also thereafter be incorrect.

Detailed conditions for effect to occur

All of the following conditions must be fulfilled:

- The use of the CBCT module of ETD 1.0.x with an ETD system installed on a Varian LINAC
- The user starts the CBCT offset detection by acquiring X-ray images on the CBCT X-ray Reference Acquisition page while a setup beam is active on the LINAC, as shown in Figure 3
- The values for *original planned PSAs* and *updated planned PSAs* are different, when the CBCT offset detection is started
- After determining the CBCT offset, at least one additional X-ray pair is successfully acquired and evaluated while a treatment beam is selected at the LINAC.

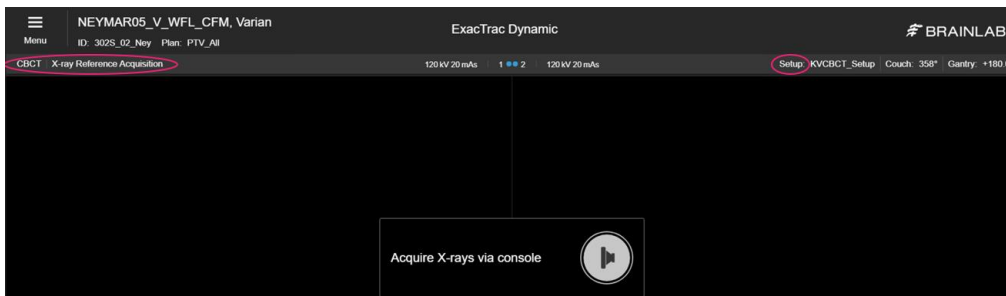


Figure 3: The display of the CBCT X-ray Reference Acquisition page with a setup beam selected.

The error may have a negative effect on the patient if repositioning is then performed using ETD and/or the user relies on information from the surface tracking, specifically the yaw indicator, warnings, or beam hold.

Magnitude of error

The extent of the angular error in the yaw angle of ETD detected positions equals the difference between the *original planned PSA* and the *updated planned PSA*. The maximum deviation between these angles is by default limited to 3° at Varian LINACs. However a user can increase this number to 10° after approval, requiring the corresponding user rights. This is the maximum angular error that can occur.

For repositioning by ETD, the effect of a rotational error is greatest in cases where the target is distant from the isocenter. A typical example for such a scenario would be a single-isocenter Multi Metastasis treatment, with a metastasis close to the skull and the isocenter in the middle of the brain.

For surface tracking, all yaw values are shifted by the angular error.

Retrospective review:

In order to retrospectively analyze whether the problem has occurred during patient treatment, please review the ETD treatment report, with the steps outlined below and displayed in Figure 4:

1. Search for the beam which includes the information “Deviation to CBCT Reference”
2. If the beam name contains the word “Setup”, the error might have occurred: continue to step 3; if not, the error did not occur.
3. Compare the *updated planned PSA* as shown in the ETD treatment report to the *original planned PSA* (typically 0° for CBCT setup beams).

The example displayed in Figure 4 indicates a yaw error of 3°, assuming the *original planned* PSA was 0°.

1 Beam 4 2 3 = updated planned PSA

KVCBCT (Setup) (Gantry Position: 180°, Table 3°, 0MU)
Correction Shifts

	Shift [mm]			Angle [°]			Applied	Reviewed
	Lat	Long	Vert	Pitch	Roll	Yaw		
1 Deviation To CBCT Reference Reference Acquisition 0	0.17 (0.00)	0.04 (0.00)	-0.36 (0.00)	0.06 (0.00)	0.01 (0.00)	-2.95 (0.00)	No	

* If sent shift and calculated shift deviates, the calculated shift is shown in brackets.

Figure 4: Excerpt of an example ETD treatment report.

User Corrective Action:

When using the ETD CBCT module, always ensure that during the “CBCT X-ray Reference Acquisition” step (CBCT offset detection), a treatment beam and not a setup beam is loaded on the Varian treatment console. If a setup beam is loaded, the word “Setup” will display in the ETD software, and it is **not** safe to continue; see Figure 5. In this case make sure you first switch to a treatment beam on the Varian treatment console and confirm the change in the Brainlab ETD software before continuing.

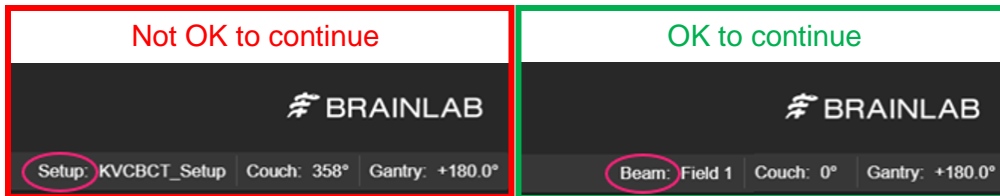


Figure 5: (left) A setup beam is active and it is not safe to continue; (right) A treatment beam is active and it is safe to continue.

Brainlab Corrective Action:

- Existing customers that are potentially affected receive this product notification information.
- Brainlab will provide a software revision of ExacTrac Dynamic with the described issue corrected to all affected customers. Brainlab will actively contact you to schedule the update, starting in May 2022.

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:

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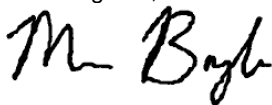
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Kind Regards,



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