

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: ExacTrac 6.x Patient Positioning System:
Potentially incorrect patient positioning when using the ExacTrac Cone Beam CT (CBCT) with a CBCT acquired at a couch angle other than 0.0°.

Product Reference: CBCT Import & Alignment Software module of ExacTrac v. 6.x (v. 6.0.0, 6.0.1, 6.0.2, 6.0.3, 6.0.4, 6.0.5; and v. 6.1.0), in combination with Varian C-Series linac only.

Date of Notification: March 6, 2015

Individual Notifying: Markus Hofmann, Senior MDR & Vigilance Manager

Brainlab Identifier: **CAPA-20150209-001308**

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



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We are writing to advise you of an anomaly detected in ExacTrac v.6.x during phantom based acceptance testing. The phenomenon occurs under specific circumstances when using the ExacTrac CBCT module with Varian CBCT images acquired with a Varian C-Series linear accelerator (linac) at a couch angle other than 0.0°. There has been no negative effect on a patient treatment due to this issue 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:

If a Cone Beam CT (CBCT), acquired with a Varian C-Series linac at a couch angle other than 0.0° (as displayed on the Varian monitor), is retrieved by ExacTrac, ExacTrac will not consider this angle correctly. This would lead to an erroneous calculation of patient shifts needed to move the patient to the planned treatment position.

If the corresponding calculated shifts are applied with ExacTrac, the patient will be positioned incorrectly at the linear accelerator (linac). If not detected by the user, the radiation treatment dose at the linac may be delivered to an 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.**

Details:

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

1. The CBCT was acquired with a Varian C-Series linac at a couch angle other than 0.0° (as displayed on the Varian monitor).
2. The CBCT Import & Alignment Software module of ExacTrac v. 6.x was used to retrieve the CBCT set and to position the patient.

For clarity, CBCT images acquired with a Varian TrueBeam linac are not affected by this issue, even under the above circumstances.

Magnitude of potential error: The magnitude of error depends on the couch angle and the field of view as defined by the Varian software. The largest effect of this error occurs in the longitudinal (head to feet) direction. An approximation of the specific error can be determined with the help of the table provided in the appendix of this notification.

Treatment verification and (retrospective) review:

When using the ExacTrac CBCT module in combination with the ExacTrac X-ray module, please note: after a CBCT-based correction, the mandatory X-ray verification still works as intended independent of this anomaly. If, for a specific treatment, the patient is finally positioned based on the shifts and rotations calculated during the X-ray verification, the described anomaly will not come into effect.

For clarity:

- The above mentioned couch angle refers only to the couch angle displayed on the Varian monitor; it does not refer to the couch angle displayed in the ExacTrac software.
- It does not matter if Brainlab Robotics is used for 6D positioning or not. Likewise, the Robotics tilt angle is irrelevant for the above described issue.

Possibilities for retrospective review:

1. The user can retrospectively identify the couch angle and the field of view within the "Offline Review" functionality of ARIA.
2. For angles other than 0.0°, an approximation of the specific error can be determined with the help of the table provided in the appendix of this notification.

The performed X-ray verification for patient treatment positioning can be reviewed retrospectively at any time by the user with the "Review" function of ExacTrac.

If the ExacTrac CBCT module is used with an ExacTrac system without an X-ray module, the user must verify the final treatment position by an independent external IGRT. The hospital's own IGRT verification would also reveal an unacceptable patient positioning error that would have occurred due to this anomaly. Non-Brainlab IGRT verifications of patient positioning are assumed to be available to the hospital and user for retrospective review.

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

User Corrective Action:

- 1) With immediate effect, always make sure the couch is at exactly 0.0° (displayed on the Varian monitor) when acquiring a CBCT set to import into the ExacTrac software.
- 2) For Varian systems providing an option to prevent a CBCT acquisition for couch angles other than 0.0°, Brainlab recommends selecting that option for use in combination with ExacTrac.
- 3) Continue to verify any ExacTrac CBCT based correction using the ExacTrac X-ray verification and/or an external IGRT procedure as mandatory.

Brainlab Corrective Action:

1. Brainlab provides existing potentially affected ExacTrac v.6.x CBCT Import & Alignment Software customers (with a Varian C-Series linac) with this product notification information.
2. Brainlab will provide a software update with this issue solved to affected customers. Brainlab will actively contact you starting August 2015 to schedule the update installation.

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

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

Fax Brainlab AG: + 49 89 99 15 68 33

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March 6, 2015

Kind Regards,



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

Appendix

Magnitude of systematic error in relation to field of view and couch angle (by LINAC type)

Treatment LINAC is a C-Series LINAC with OBI (e.g. Clinac iX, Trilogy, Novalis Tx, Clinac 2100 EX)

Field of View [mm] (Reconstruction Diameter)	Couch Angle [°] (Couch Rtn.)	Lateral Translational Error* [mm]	Longitudinal Translational Error* [mm]
250	0.5	0.00	1.09
250	1.0	-0.02	2.18
250	1.5	-0.04	3.27
250	2.0	-0.08	4.36
250	2.5	-0.11	5.45
460	0.5	-0.01	2.01
460	1.0	-0.04	4.01
460	1.5	-0.08	6.02
460	2.0	-0.14	8.03
460	2.5	-0.21	10.03

* According to IEC 61217 coordinate system