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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 TrueBeam-specific optional subvolume-CBCT.
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 TrueBeam system only.
Date of Notification:	February 16, 2015
Individual Notifying:	[redacted] Senior MDR & Vigilance Manager
Brainlab Identifier:	**CAPA-20150209-001309**
Type of action:	Advice regarding use of device; Device modification.

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We are writing to advise you of an unexpected phenomenon Brainlab has internally detected for ExacTrac v.6.x that could occur within an unusual workflow when using the ExacTrac Cone Beam CT (CBCT) module in combination with actively re-reconstructed CBCT images of a subvolume from the original CBCT volume. There has been no such occurrence of this phenomenon for any patient treatment reported to Brainlab by any user site.

Subvolume re-reconstruction of an acquired CBCT volume is an optional feature of the Varian CBCT system that is only available with the Varian TrueBeam system.

For a re-reconstructed CBCT subvolume, the acquisition position of the original CBCT is not regarded by the Brainlab ExacTrac CBCT module. Therefore, the position of such a CBCT subvolume may not be correctly imported by ExacTrac.

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 user-defined actively re-reconstructed CBCT subvolume is imported into ExacTrac, ExacTrac cannot regard the position of this CBCT subvolume correctly. If the center of this subvolume differs from the center of the original CBCT volume, this leads to an erroneous calculation of patient shifts needed to move the patient to the planned treatment position.

If the corresponding calculated shifts and rotations 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 <u>all</u> of the following circumstances are met:

1. The CBCT was acquired with a Varian TrueBeam system.
2. A CBCT subvolume was actively re-reconstructed by the user from the original CBCT in the TrueBeam CBCT system (by using the *"Re-Reconstr"* button in the Varian SW).
3. The center of this re-reconstructed CBCT subvolume is not identical to the center of the original CBCT volume.
4. The ExacTrac CBCT Import & Alignment Software module was used to import the re-reconstructed CBCT subvolume and to position the patient.

<u>Magnitude of potential error:</u> The magnitude of error equals the 3-dimensional distance (Euclidian distance) between the center of the original CBCT and the center of the re-reconstructed CBCT subvolume.

<u>Treatment verification and (retrospective) review:</u>

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.

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.

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.

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User Corrective Action:

With immediate effect, do not use any actively re-reconstructed CBCT subvolumes from the Varian TrueBeam system with the Brainlab ExacTrac 6.x CBCT Import & Alignment Software module.

Import exclusively original, not modified, CBCT volumes into ExacTrac to use for patient positioning.

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 TrueBeam system) 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)

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February 16, 2015

Kind Regards,

[redacted]

Senior MDR & Vigilance Manager

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