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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	ExacTrac Patient Positioning System: Additional instructions and warnings for beam authorization by ExacTrac via ADI
Product Reference:	ExacTrac version 6.0 - 6.5
Date of Notification:	January 25, 2018
Individual Notifying:	Julia Mehltretter, Manager MDR & Vigilance
Brainlab Identifier:	CAPA-20180124-002060
Type of action:	Advice regarding use of device

We are writing to advise you regarding the usage of workflows that deviate from the recommended specifications in the User manual for ExacTrac Patient Positioning System (versions 6.0, 6.1, 6.2, 6.5) with Auxiliary Device Interface (ADI) and Varian Clinac or Varian TrueBeam, which may result in misinterpretation of beam authorization via ADI.

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:

When using ExacTrac (version 6.0-6.5) on a Varian Clinac or Varian TrueBeam system equipped with the Auxiliary Device Interface (ADI), beam requests of the treatment application have to be authorized by ExacTrac to enable treatment. As is described in the corresponding Brainlab User Guides if no patient data is loaded in ExacTrac, ExacTrac always authorizes every beam request from the Varian side. This authorization is required and intended for clinical treatments for which ExacTrac is not used for patient positioning (e.g. Cone beam-based). When a patient has been loaded in ExacTrac, ExacTrac verifies the position of the patient and authorizes beam requests if the patient is correctly positioned (i.e. OK icon visible on ExacTrac screen).

With this Product Notification letter, Brainlab intends to clarify that the beam authorization by ExacTrac via ADI is not a safety feature to ensure correct patient positioning before treatment.

- Verification of patient positioning by ExacTrac before beam authorization is only performed if the **patient data has been fully loaded in ExacTrac <u>before</u> the beam is prepared** on the Varian Treatment Application / Console.
- If you have started the ExacTrac software, but did not yet login, no patient data is loaded yet and ExacTrac authorizes every beam request from the Varian side.
- If only the message box (see Figure 2), requesting if the patient data should be opened, is visible, no patient data is loaded yet and ExacTrac authorizes every beam request from the Varian side.
- If the beam has been authorized by ExacTrac, due to technical reasons this authorization cannot be withdrawn again for the specific beam. Therefore, **if the patient data is opened in ExacTrac <u>after the beam has been prepared</u> on the Varian Treatment Application / Console, the beam <u>remains authorized</u> after the patient data has been opened in ExacTrac** and treatment is possible, despite whether or not patient has been correctly positioned.
- **If the patient moves during treatment the beam <u>remains authorized</u>.**

For any treatments performed with ExacTrac always verify that ExacTrac confirms the target position by displaying the OK icon. Do not treat the patient if the OK icon is not displayed.

If a deviation of the patient position from the planned treatment position remains undetected by the user and the actual treatment beam that has been previously authorized by ExacTrac via ADI is initialized by the user, **underdose of the planned target volume and/or overdose of healthy tissue could occur if the deviation exceeds clinically acceptable tolerances for the indication being treated.**

Retrospective review:

For treatments that have already been performed, the actual patient position during treatment can be reviewed in the treatment report of ExacTrac, and by using the Review function in the ExacTrac software.

User Corrective Action:

Always follow the instructions below during use of ExacTrac Patient Positioning System (versions 6.0, 6.1, 6.2, 6.5) with Auxiliary Device Interface (ADI) and Varian Clinac or Varian TrueBeam:

Do not use beam authorization by ExacTrac via ADI as a safety feature to ensure correct patient positioning before treatment.

Figure 1: OK icon

For any treatments performed with ExacTrac always verify that ExacTrac confirms the target position by displaying the OK icon. Do not treat the patient if the OK icon is not displayed.

This indicates that the isocenter is in the planned treatment position. The treatment beam should not be activated unless the **OK** icon is shown.

If using ExacTrac on a Varian Clinac or Varian TrueBeam system equipped with the Auxiliary Device Interface (ADI) always perform treatment in the following sequence:

1. Start the ExacTrac Software and login using your user name and password
2. Load the Plan / Patient on the Varian Treatment Application / Console
3. **Open the Plan / Patient on ExacTrac by clicking "Open" in the message box (refer to Figure 2)**
4. Prepare the beam on the Varian Treatment Application / Console

If you intend to perform treatments for which ExacTrac is not used for patient positioning, please click "Cancel" in the message box to confirm not opening the patient and to continue the treatment without ExacTrac.

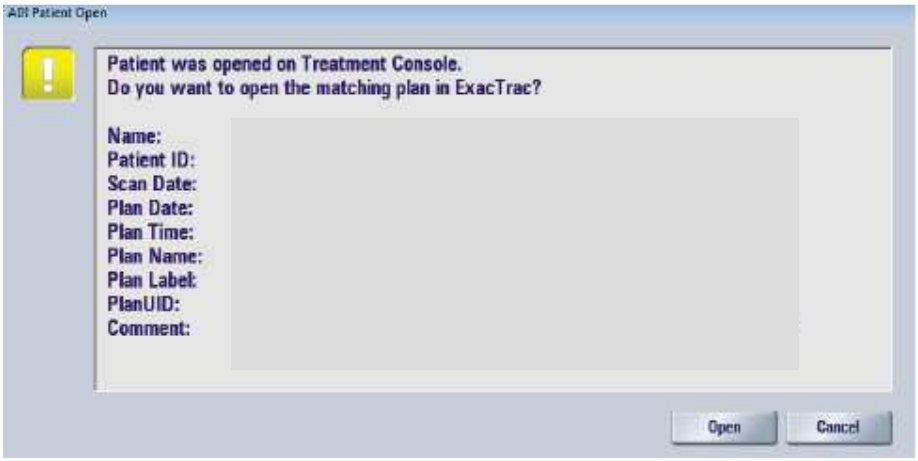

Figure 2: Message box in ExacTrac

ExacTrac can be configured to directly load the patient automatically in ExacTrac if it is opened on the Varian Treatment Application / Console - meaning that the message box (refer to Figure 2) is deactivated. However, this may not be the preferred solution for each user, as automatic loading causes delays in treatment preparation if no positioning via ExacTrac is to be used, since in these cases the patient data has to be closed manually. Please contact your local Brainlab Customer Support Representative to configure your preferred solution.

Additionally, review the attached update to the Instructions for Use BL-IL-60960-84_Rev1.0 regarding Beam Authorization by ExacTrac via ADI and always follow the contained instructions.

Please ensure to print the update to the Instructions for Use BL-IL-60960-84_Rev1.0 and file it with your relevant Brainlab User Guides.

Brainlab Corrective Action:

1. Existing potentially affected customers receive this product notification information.
2. These customers receive the attached update to the Instructions for Use BL-IL-60960-84_Rev1.0 regarding Beam Authorization by ExacTrac via ADI.

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.

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January 25, 2018

Kind Regards,

[redacted]

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