BRAINLAB

Brainlab AG
Olof-Palme-Straße 9
81829 Munich • Germany

phone: +49 89 99 15 68 0
fax: +49 89 99 15 68 5033
www.brainlab.com

URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	ExacTrac Dynamic Radiation Therapy Patient Positioning System: Deep Inspiration Breath Hold (DIBH) functionality may not work as specified when based on a standard-workflow Treatment Template
Product Reference:	ExacTrac Dynamic versions 1.1.0 and 1.1.1
Date of Notification:	January 25, 2023
Individual Notifying:	Andrea Miller, Vigilance Manager
Brainlab Identifier:	CAPA-20221221-002509
Type of action:	Advice regarding use of device; Device modification

We are writing to you to advise you of the following effect that has been identified for the Deep Inspiration Breath Hold (DIBH) workflow of Brainlab ExacTrac Dynamic (versions 1.1.0 and 1.1.1).

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 Deep Inspiration Breath Hold (DIBH) workflow requires ExacTrac Dynamic to be used as a Beam Hold Control device, to automatically gate the beam during treatment. Manual Beam Hold Control for DIBH treatments is not intended and must not be used.

Due to an error in the Template Editor, it is nevertheless, under special circumstances, possible to create and apply Treatment Templates for DIBH treatments that inconsistently require a manual beam hold. In this case, the software displays the Beam Hold Control setting as enabled and grayed out, however, the software fails to update the actual internal setting to Beam Hold Control enabled. Applying such a template for clinical treatment is technically possible, if ExacTrac Dynamic is actively disabled as a Beam Hold Control device on the Linac.

There have been no negative impacts on patient treatment reported by any user due to this issue, and it is not expected that full treatment would be performed in this configuration, as the information displayed on the Patient Monitoring page during treatment is correct, so that the missing automatic Beam Hold Control can be detected.

However, in the rare case in which a user is not aware of the consequences when a DIBH treatment is performed with Beam Hold Control disabled, unintended radiation may be applied to a patient. As a result, underdosage of the planned target volume and/or an overdosage of healthy tissue could occur.

Details:

ExacTrac Dynamic features Deep Inspiration Breath Hold (DIBH) functionality to correctly position the patient to a deep inspiration breath hold level to then monitor this position using surface tracking and X-ray positioning technology. The aim of the DIBH workflow is to treat the patient only during breath hold phases where the breast is at a defined position with a maximum distance to critical structures like the heart.

Unintended irradiation of a DIBH patient - with ExacTrac Dynamic Beam Hold Control disabled – occurs if all of the following steps are performed:

1) An inconsistent DIBH template is created in the Template Editor by the following steps:

    i)   A non-DIBH workflow **Treatment Template** is opened

    ii) **Beam Hold Control** is already **disabled** or manually set to **disabled** ("Off")

    iii) The workflow is changed from Standard to Breath Hold (see Figure 1).

*Figure 1 – Breath Hold Workflow selected in Preparation Application.*
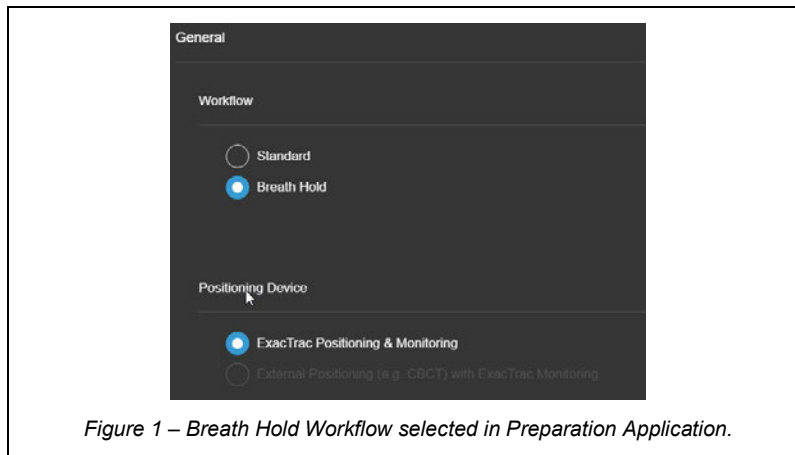
The software now **displays** the **Beam Hold Control enabled** and grayed out. However, due to an error, the software fails to update the actual internal setting (as it would be required for DIBH treatments).

Figure 2 – Beam Hold Control status is incorrectly displayed as enabled (and grayed out).
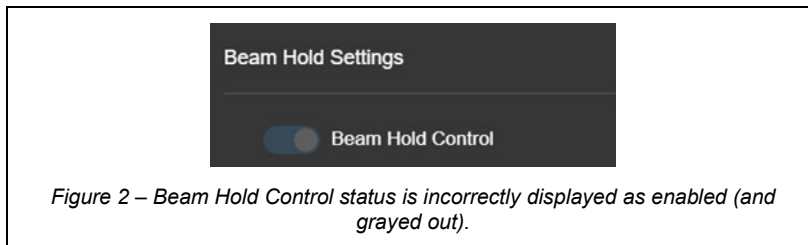
iv)   The file is **saved** as a new DIBH Treatment Template.

2)   This DIBH Treatment Template is used to **prepare a DIBH patient** in the Patient Preparation App.

3)   The user **proceeds to treatment** in the ETD Treatment Application, despite the Patient Confirmation Dialog (correctly) displaying a **warning message** indicating that the **Beam Hold Control is disabled** ("Off"). (see Figure 3).

Figure 3 – The Patient Confirmation Dialog (correctly) displays a warning message if the Beam Hold Control is disabled for a DIBH Treatment.
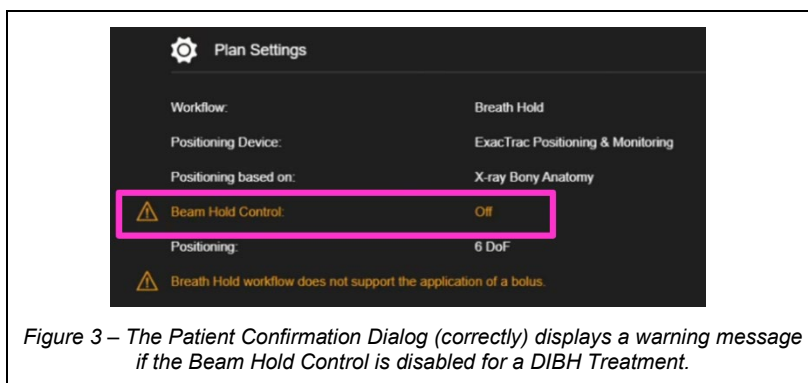
4)   The user follows the instructions subsequently displayed in the ETD Treatment Application and **actively disables ExacTrac Dynamic as Beam Hold device** on the Linac.


Figure 4 – ExacTrac Dynamic instructs the user to disable ExacTrac Dynamic as a beam holding device.
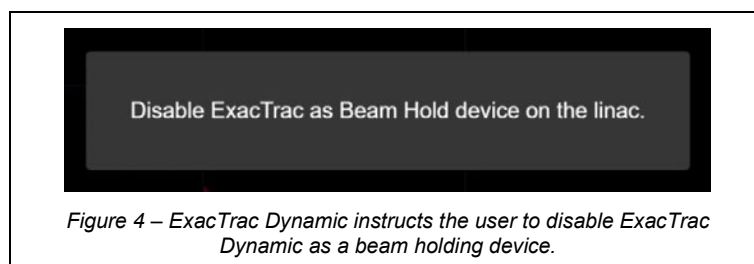
5) The monitoring workflow is entered in the ETD Treatment Application.
Note: The information displayed on the Patient Monitoring page is correct, i.e., the displayed feedback about the respiratory status of the patient, as well as the surface tracking result is correct.

6) The user enables the beam on the Linac, not considering if the patient's respiratory signal is within the breath-hold window and the surface tracking area is within tolerance.

This means that:
- The beam starts immediately (instead of waiting for the patient to inhale to the defined deep inspiration breath hold level)
- AND it is not held automatically if the patient exhales or the patient position is outside the predefined tolerances.

Figure 5 shows the unintended "Beam On" status despite patient being outside the DIBH gating window.

Figure 5 – DIBH treatment with Beam Hold Control disabled allows for beam on despite patient being outside DIBH Gating Window.
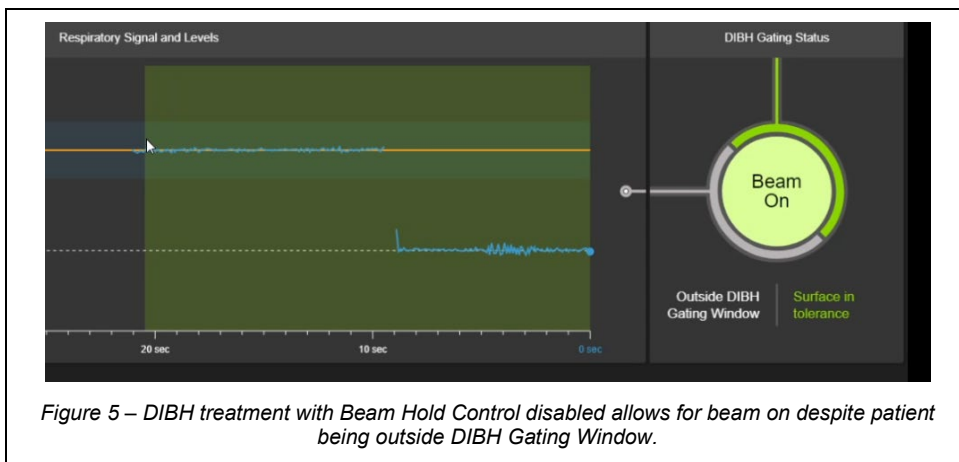
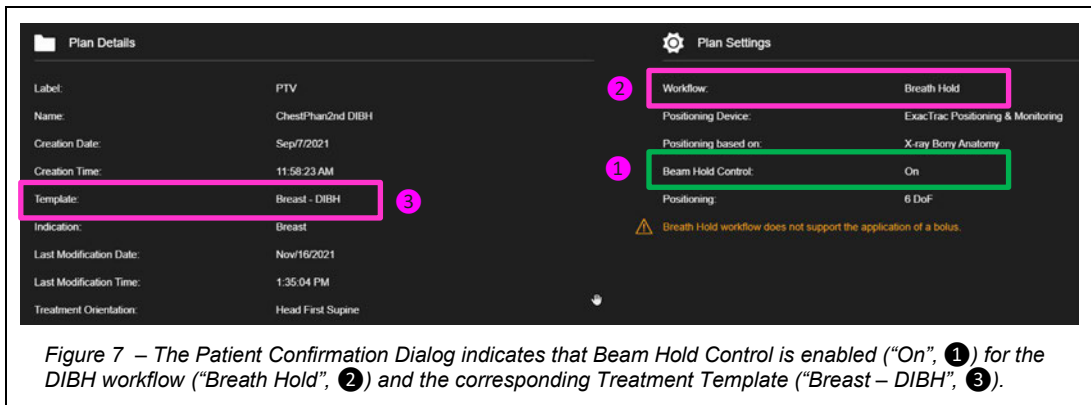Note: The user can hold the beam manually at any time on the Linac console

Retrospective review:

To confirm that no DIBH Treatment Template is affected by the above described issue, each available DIBH Treatment Template needs to be verified.

This can be done by opening the **Preparation Application** and selecting the corresponding DIBH Treatment Template. In the Plan Settings Preview, the template settings are displayed and the Beam Hold Control status can be reviewed. **The Beam Hold Control status must be displayed as "On".** If the Beam Hold Control status shows "Off" as shown in Figure 6, this template must not be used and needs to be deleted.

Figure 6: Corrupt Template "DIBH_BHOFF" (❶) showing unintended Beam Hold Control Status "Off" (❷).
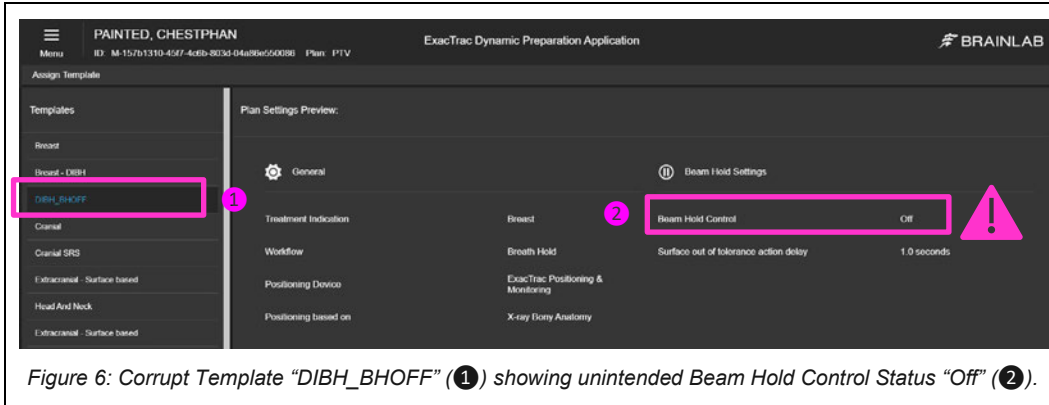
Additionally, it can be verified within the ExacTrac Dynamic Patient Confirmation Dialog that Beam Hold Control is enabled for the specific patient (as shown in Figure 7 below).

Figure 7 – The Patient Confirmation Dialog indicates that Beam Hold Control is enabled ("On", ❶) for the DIBH workflow ("Breath Hold", ❷) and the corresponding Treatment Template ("Breast – DIBH", ❸).

If you have any questions or require further assistance for retrospective review, please contact your local Brainlab Customer Support Representative.

User Corrective Action:

1. Always create DIBH Treatment Templates from the Brainlab provided DIBH Master Templates.

2. Always ensure that Beam Hold Control is enabled ("On") before proceeding to DIBH treatment, as shown in Figure 9 below.
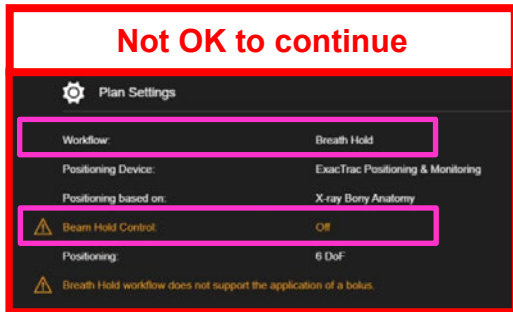

Figure 8 – The Patient Confirmation Dialog (correctly) displays a warning message if the Beam Hold Control is disabled for a DIBH Treatment. Don't proceed to DIBH Treatment if a warning message indicates Beam Hold Control is disabled ("Off").
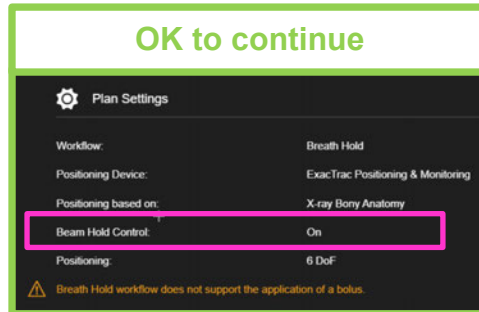

Figure 9 – Ok to proceed to DIBH Treatment if Beam Hold Control is enabled ("On").

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 April 2023.

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:
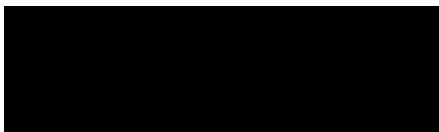+49 89 99 15 68 1044 or +1 800 597 5911 (for US customers)
E-mail: support@brainlab.com (for US customers: us.support@brainlab.com)
Fax: Brainlab AG: + 49 89 99 15 68 5033
Address: Brainlab AG (headquarters):
Olof-Palme-Strasse 9, 81829 München, Germany

January 25, 2023

Kind Regards,

brainlab.vigilance@brainlab.com

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