

**FIELD SAFETY NOTICE / PRODUCT NOTIFICATION**

**Subject:** Potentially incorrect positioning when using implanted marker detection in combination with a mix of 6D and 3D fusion

**Product Reference:** ExacTrac Vero 3.5.0 - 3.5.3

**Date of Notification:** February 8, 2017

**Individual Notifying:** Paul Neil, Quality Manager

**Brainlab Identifier:** CAPA-20170130-001869

**Type of action:** Advice regarding use of device

We are writing to advise you of the following effect which may potentially influence the positioning accuracy of the Brainlab ExacTrac Vero software, version 3.5.0 - 3.5.3 when using implanted markers.

There has been no negative effect on patient treatment due to this specific issue reported to Brainlab by any user site. The purpose of this Product Notification letter is to provide you with the relevant user information and to inform you of the actions Brainlab is taking to address the issue.

**Effect:**

In ExacTrac Vero software 3.5.0 - 3.5.3, if Patient positioning is done with the 6D isometric match and rotational correction of the vertical axis, but verification or tracking is done using the 3D Center of gravity match; then an incorrect treatment target may result. Ultimately this may lead to an under-dose of the Planned Target Volume (PTV) and an over-dose of healthy tissue.

This effect can only occur under the following circumstances:

For static treatments:

1. Patient positioning/correction is done with the 6D isometric match and rotational correction of the vertical axis.
2. Verification is done using the fallback 3D Center of Gravity match instead of 6D isometric match because not all requirements for a 6D isometric match are fulfilled, e.g.: not more than two short markers are defined.

For dynamic treatments:

1. Patient positioning/correction is done with the 6D isometric match and rotational correction of the vertical axis.
2. Tracking is done using the 3D Center of gravity algorithm (which means 2 short markers or one long marker).

Details regarding the conditions for this error to occur and affected workflows are described below.

### Affected workflows:

The following two workflows described below may result in incorrect targeting if all of the conditions listed below are fulfilled, unless a step is marked by “OR”.

#### Workflow I: Static treatments without Dynamic tracking

- Patient is initially positioned with ExacTrac Vero based on stereo x-ray (“Bony” or “Implants”) or CBCT.
  - The positioning procedure includes the correction of the ring angle, which is 6D positioning (rotational error around the vertical axis).
- Verification is performed.
  - X-ray is acquired.
  - During the verification step, only two short markers or one long-marker are used. In this case the software automatically switches to the “center of gravity match” method (3D verification).

OR

- ExacTrac Vero suggests switching to the “center of gravity match” (3D verification) by displaying the message box depicted below. For example, this may occur in cases where the actual x-ray detected pattern is significantly distorted compared to the pattern defined in the CT scan.
  - The operator accepts this proposal by pressing the “Retry” button (see Figure 1).

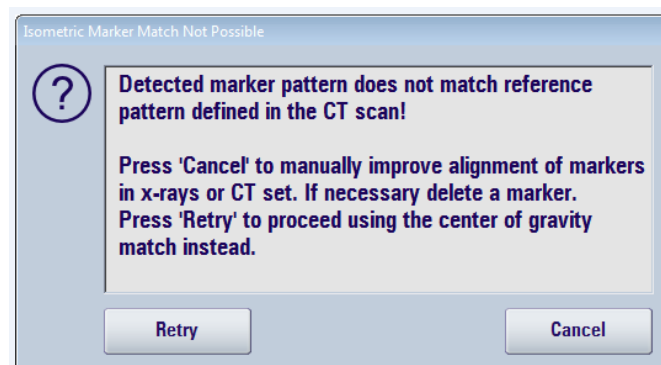


Figure 1: Message box indicating that ExacTrac Vero suggests switching to a “center of gravity match”

- Before pressing “Fuse Marker”, the planned marker positions (green) and the detected marker positions (blue) appear to match within usual tolerances.
- After pressing “Fuse Marker”, a deviation above the usual tolerances between the planned marker positions (green) and the detected marker positions (blue) is displayed by ExacTrac Vero. Corresponding correction “shifts” and possibly correction angles are indicated (see Figure 2).

- In such cases, the deviation, shifts and angles are caused by the described software malfunction and do not indicate a real patient misalignment.

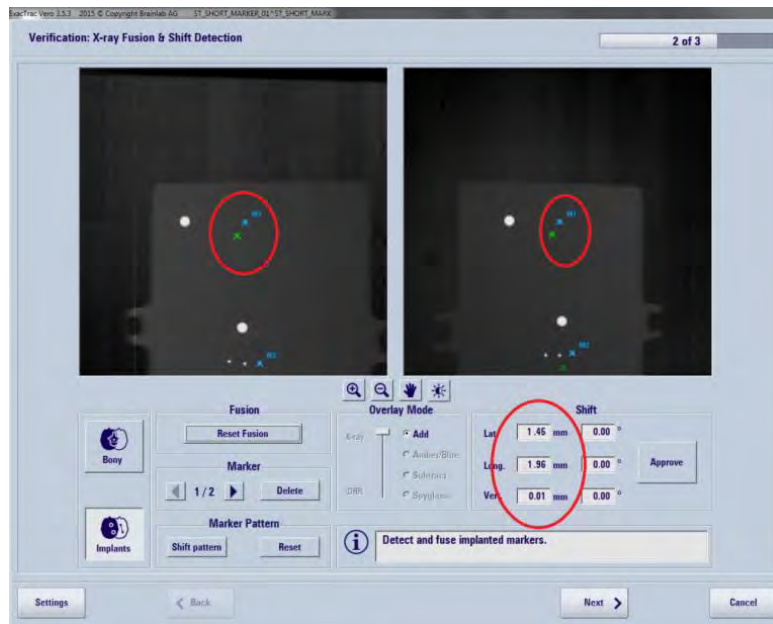


Figure 2:: Screen indicating the above described issue

- The user applies the (incorrectly) indicated shifts and angles by pressing “Next” and moves the couch and possibly the gantry-ring to the updated position.
- The treatment is started without an additional verification as required by the user guide. Any additional verification performed before and after fusion would again display a deviation between the position of the green planned marker positions and the blue detected marker positions, thus allowing the user to identify this issue.

## Workflow II: Dynamic tracking treatments

- Patient is initially positioned with ExacTrac Vero based on stereo x-ray (“Bony” or “Implants”) or CBCT.
  - The positioning procedure includes the correction of the ring angle, which is 6D positioning (rotational error around the vertical axis).
- The tracking is based on two short markers or one long marker (3D tracking).
- During treatment the user does not recognize that the calculated real-time target position (pink in Figure 3) and calculated marker positions (orange) deviate from the corresponding structures in the x-ray image(s) (see Figure 3).

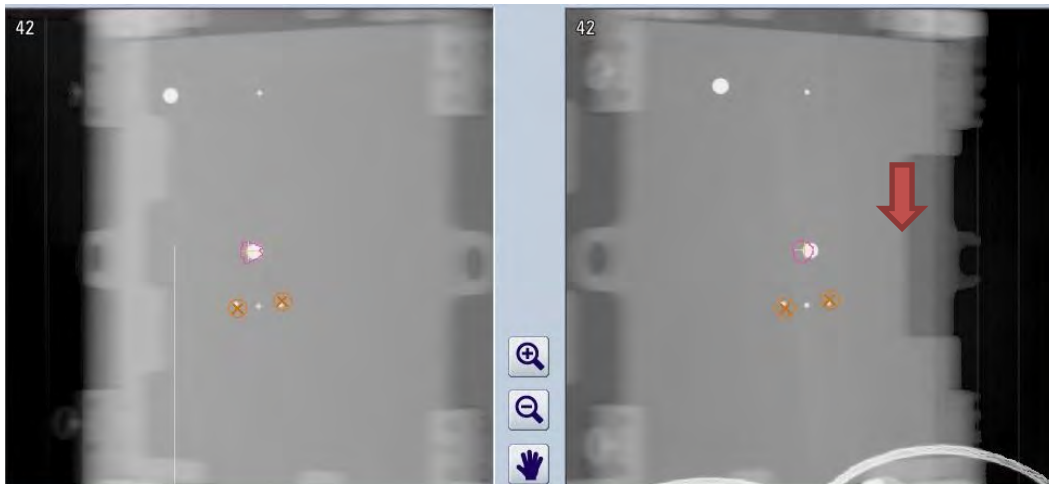


Figure 3: Phantom treatment- Dynamic Tracking Treatment view, the pink circle is the calculated real-time target position, which is not 100 % covering the corresponding structure in the image. Also the orange crosses do not match perfectly.

**The magnitude of the error depends on two factors:**

- The magnitude of the applied 6D ring angle correction, which is introduced by the initial correction. Small ring angle corrections are less critical than large ones.
- Distance between targeted isocenter and center of gravity of the implanted marker(s). Short distances are less critical than large ones.

The below table displays the resulting potential maximum target deviation if the error were to occur.

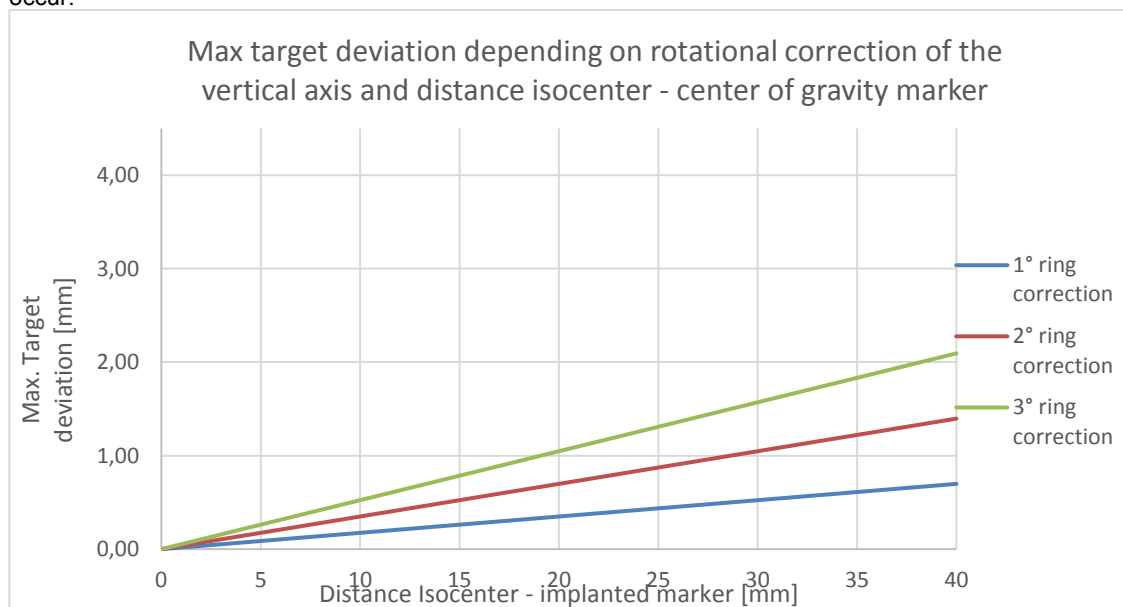


Figure 4: Max target deviation depends on the correction angle of the vertical axis and the distance between isocenter and center of gravity of the implanted markers

### User Corrective Action:

#### For static treatments without tracking:

1. Do not delete defined implanted markers between positioning and subsequent verifications.
2. Do not perform a verification based on 2 short or 1 long implant after a correction based on X-ray bony fusion or CBCT fusion has been performed.
3. If the software displays the message box depicted below, always select "Cancel" (see Figure 5).

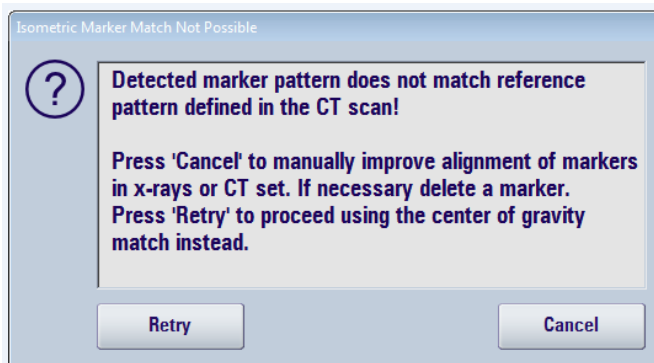


Figure 5: Message box indicating that ExacTrac Vero suggests switching to a "center of gravity match".

4. Remind operators to follow the user guide warnings and to always visually inspect the correct match between the planned marker positions (green) and the detected marker positions (blue) during the verification step after "Fuse Marker" was pressed. In case of a deviation above the usual level, restart the positioning process considering the points listed above.

**Retrospective review:** For already performed static treatments, the patient position at the time of irradiation can also be reviewed retrospectively by the user using the Review/Replay mode as described in the clinical user guide. These modes show the verification screens including all deviations in the same way as displayed during treatment.

#### For Dynamic Tracking:

1. Ask the surgeon to implant the markers as close as possible to the target volume as indicated in the user guide.
2. Minimize rotational corrections of the vertical axis by precise alignment of the patient to the treatment couch. This can be achieved if the patient's vertical rotation is as close as possible to the patient's rotation during CT scan (see Figure 6-8).
3. Continuously verify the predicted target position in the acquired X-ray images, as described in the user guide. (see Figure 3).

Patient Orientation on  
Couch during CT Scan

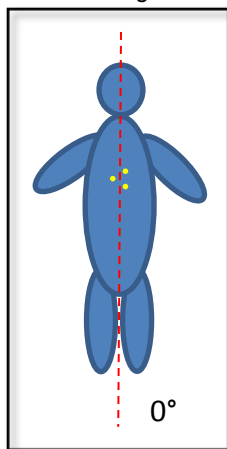
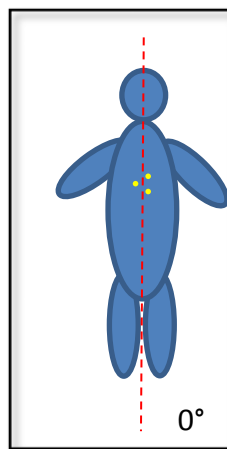


Figure 6

Patient Orientation on  
Treatment Couch



No target deviation, even  
when using the affected  
workflow.

Patient Orientation on  
Couch during CT Scan

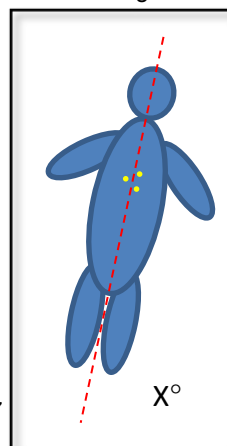
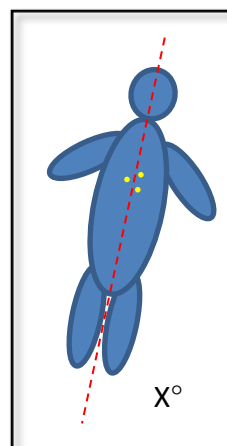


Figure 7

Patient Orientation on  
Treatment Couch



No target deviation, even  
when using the affected  
workflow.

Patient Orientation on  
Couch during CT Scan

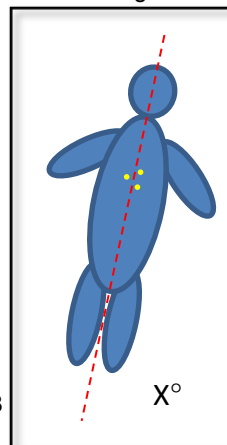
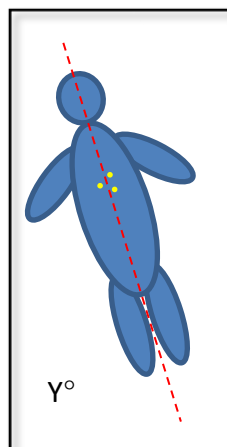


Figure 8

Patient Orientation on  
Treatment Couch



Potential target deviation,  
when using the affected  
workflow.

**Brainlab Corrective Action:**

1. Existing potentially affected customers receive this product notification information.
2. Brainlab will provide a software revision of ExacTrac Vero, where the described malfunction has been corrected, to all affected customers. Brainlab will actively contact you, starting in February 2017 to schedule the update.

**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 1044 or

+1 800 597 5911 (for US customers)

**E-mail:** [support@brainlab.com](mailto:support@brainlab.com) (for US customers: [us.support@brainlab.com](mailto:us.support@brainlab.com))

**Fax:** Brainlab AG:

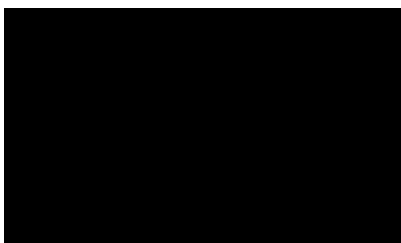
+ 49 89 99 15 68 5033

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February 8, 2017

Kind regards,



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