BrainLAB

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# URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

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|---|---|
| **Subject:** | Incorrect AC/PC offset for the Target Point on the treatment plan printout of the Brainlab Planning Software iPlan Stereotaxy 3.0 |
| **Product Reference:** | 21210E Planning Software iPlan Stereotaxy versions 3.0.0 and 3.0.1 in combination with 21242 iPlan AC/PC planning. |
| **Date of Notification:** | September 21, 2010 |
| **Individual Notifying:** | [redacted] MDR & Vigilance Manager |
| **Brainlab Identifier:** | 10-09-06.BAG.1 |
| **Type of action:** | Advice regarding use of device; device modification |

We are writing to advise you of the following effect that has been identified within the Brainlab Planning Software iPlan Stereotaxy versions 3.0.0 and 3.0.1 when using the AC/PC Planning functionality.

This Notification letter is to provide you with corrective action information, and to advise you of the actions Brainlab is taking to address this issue.

**Effect:**
When additionally referencing Target Points relative to the AC or the PC point, the offset relative to those points is correctly calculated and displayed on the screen. However, it is incorrectly printed within the iPlan Stereotaxy Planning software versions 3.0.0 or 3.0.1 (refer to Figure 1).

The software calculates, displays and prints the stereotactic arc settings correctly on the screen, as well as on the printout. These settings are used to align the planned trajectory.

However, when using the AC/PC planning functionality, the Target Point offset relative to the AC or PC point might be incorrect on the treatment plan printout due to a software error.

This offset is only provided as additional information and is not used for aligning the stereotactic arc. Nevertheless, it may be used for making clinical decisions, which due to the erroneous printout could be incorrect and **potentially resulting in ineffective treatment or in a serious injury to the patient.**

**Details:**
Affected is only the Target Point offset (the Lateral, Anterior and Inferior values) indicated relative to the AC point or the PC point within
- the treatment plan printout in the "AC/PC Coordinates" section
- the point measurement functionality in the planning software.

The Target Point offset referenced to the MC point is not affected. All other coordinates and/or angles entered and/or printed for trajectory planning are not affected as well.

The deviation of the incorrect Target Point offset relative to the AC or the PC point depends on the patient's head position in the used image set, and can reach more than 1mm for each value.

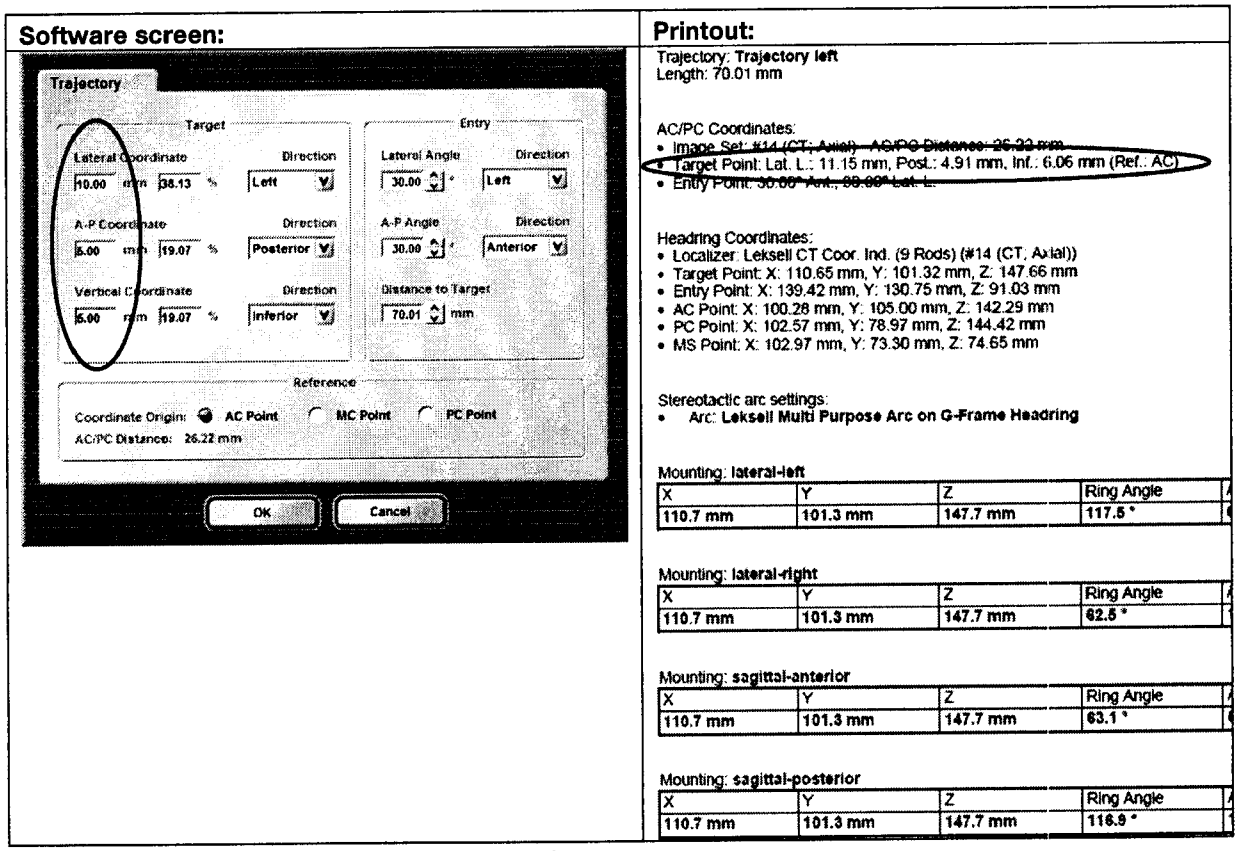


**Figure 1: Example of incorrect Target Point offset on printout**

**User Corrective Action:**
**Do not use the Target Point offset relative to the AC point or the PC point within the treatment plan printout for subsequent clinical decisions or manual plan adjustments.**

**Brainlab Corrective Action:**
1. Existing potentially affected iPlan Stereotaxy (versions 3.0.0 and 3.0.1) customers receive this product notification information.
2. Potentially affected customers will receive a software update to correct for this software error. Tentatively planned availability: end of October 2010
3. Brainlab will actively contact the potentially affected customers to implement the software update upon availability.

**Please advise the appropriate personnel working in your department of the content of this letter.**

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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. Fax Brainlab AG: + 49 89 99 15 68 33
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unlocking possibilities

Thank you for paying attention to this information.

September 21, 2010
Kind Regards,

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