

**UPDATE TO**  
**FIELD SAFETY NOTICE / PRODUCT NOTIFICATION**

**Subject:** Brainlab Cranial Navigation System:  
Effect of setup on overall navigation accuracy

**Product Reference:** Brainlab Cranial Navigation System  
(all versions before Cranial 3.0)

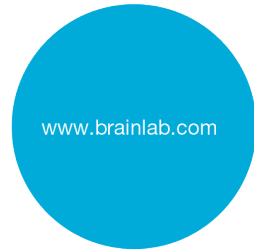
**Date of original Notification:** April 22, 2013

**Date of this Notification:** May 29, 2015

**Individual Notifying:** Julia Mehlretter, Manager MDR & Vigilance

**Brainlab Identifier:** CAPA-20130417-000315

**Type of action:** Device modification



We are writing as a follow up to the Brainlab Field Safety Notice / Product Notification Letter CAPA-20130417-000315 "Brainlab Cranial Navigation System: Effect of setup on overall navigation accuracy" you have received in 2013.

This Notification letter is to provide you with updated information regarding corrective actions Brainlab is taking to address this issue.

**Original Effect:**

Brainlab has detected that, when using the Brainlab Cranial Navigation System, the following may have a significant effect on the overall navigation accuracy:

- Large distance between reference array and region of interest
- Major changes of the camera position relative to the reference array during the procedure

Those instances could potentially intensify small inaccuracies arising from individual steps of the complex navigation procedure. In the worst case scenario, these inaccuracies may cause an inaccurate display of instruments by the navigation system, compared to the actual patient anatomy. If these inaccuracies are not detected by user verification of navigation accuracy as described in the user manual, this could ultimately **lead to ineffective treatment, serious injury or even death of the patient.**

**Updated: Brainlab Corrective Action Information**

Based on the detected effects described in the original Field Safety Notice / Product Notification Letter CAPA-20130417-000315, Brainlab has performed a comprehensive investigation and researched possibilities to further improve the inherent safe design of the Brainlab Cranial Navigation System. As a result Brainlab has released the new software version Brainlab Cranial 2.1.2 which integrates the following improvement related to the Field Safety Notice:

*Reference Array Software Positioning Guide:*

Cranial/ENT Version 2.1 features a setup guide that opens if the distance between the reference array and the region of interest is greater than recommended.

**Brainlab will provide customers with an updated software version to ensure the inherent safe design of the Brainlab Cranial Navigation System.**

**Brainlab will actively contact you starting September 2015 to schedule the update installation.**

Despite this additional improvement, please continue to follow the measures described in the leaflet "Measures to Improve Cranial Navigation Accuracy" when using the Brainlab Cranial Navigation System.

**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.

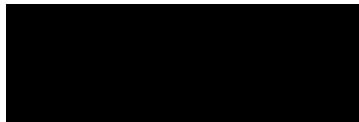
**Customer Hotline:** +49 89 99 15 68 44 or +1 800 597 5911 (for US customers) or by

**E-mail:** [support@brainlab.com](mailto:support@brainlab.com). Fax Brainlab AG: + 49 89 99 15 68 33

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May 29, 2015

Kind Regards,



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

