

URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Verification of pre-fused image sets with identical frame-of-reference ID within the Brainlab Digital Lightbox 2.0 software

Product Reference: Brainlab Digital Lightbox 2.0 with data export

Date of Notification: May 6, 2010

Individual Notifying: Markus Hofmann, MDR & Vigilance Manager

Brainlab Identifier: 10-04-09.DWI.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 Digital Lightbox 2.0 when using one treatment plan containing two or more image sets with the identical frame-of-reference ID assigned by the imaging device.

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

Effect:

Inaccurate navigation could occur if all of the following conditions are met:

- Different image sets with the same coordinate system (= same frame-of-reference ID) assigned by the imaging device are acquired
and
- Two or more of those image sets are used for treatment planning with the Brainlab Digital Lightbox 2.0
and
- The treatment plan is exported to a Brainlab navigation system
and
- The user does not review those pre-fused image sets.

The possibly resulting inaccuracy of the navigation, if not recognized by the user, could **potentially result in a serious injury of the patient.**

Details:

When two or more different image sets for one patient are created by an imaging device (e.g. an MRI scanner) using identical coordinates at the scanner, the imaging device purposefully assigns the same frame-of-reference ID to those image sets.

Nevertheless, the same frame-of-reference ID does not always ensure that the patient position in the acquired images is identical. For example, a movement of the patient in between the acquisition of the image sets could have occurred.

The Brainlab Digital Lightbox 2.0 presumes these image sets to be pre-fused by the scanner, but does not require the user to actively review and confirm or adjust the correct correlation of the image sets using the 'Image Fusion' functions.

User Corrective Action:

Always verify the correct fusion of all image sets that are used for treatment planning and/or are to be used for navigation with the 'Image Fusion' function before exporting from the Digital Lightbox 2.0.

Brainlab Corrective Action:

1. Existing potentially affected Digital Lightbox 2.0 customers receive this product notification information
2. Potentially affected customers will receive a software update that will require the user to actively review and confirm the correct image fusion for all image sets. Tentatively planned availability: July 2010
3. Brainlab will actively contact 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.

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 or MDR & Vigilance Manager Markus Hofmann.

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

Address: Brainlab AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

Thank you for paying attention to this information.

May 6, 2010
Kind Regards,



Markus Hofmann
MDR & Vigilance Manager
brainlab.vigilance@brainlab.com

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