

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Camera unit potentially not reliably fixated on the Kolibri Mobile Camera Stand

Product Reference: 19506B, 19506C KOLIBRI NAVIGATION STATION 2.0 (WITH MOBILE CAMERA STAND 2.0); 19801A KOLIBRI MOBILE CAMERA STAND 2.0

Date of Notification: August 18, 2010

Individual Notifying: Markus Hofmann, MDR & Vigilance Manager

Brainlab Identifier: 10-06-02.SEL.3 (III)

Type of action: Device modification; advice regarding use of device.

We are writing to advise you of the following potential effect that has been identified for Spectra Camera Interfaces assembled within the Brainlab Kolibri Mobile Camera Stand. 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:
 For the Spectra Camera Interfaces assembled within the Kolibri Mobile Camera Stand, a long-term reliable fixation of the camera unit cannot be guaranteed due to a manufacturing error.

The camera unit with a weight of approximately 3 kg (approx. 6.6 lbs) could loosen and detach while moving the camera arm or stand of the Kolibri Navigation System, for example during use or transportation, which could **potentially result in a serious patient or user injury**.

User Corrective Action:

Until the device component is modified, Brainlab highly recommends that the specific users receiving this notice by Brainlab regularly verify before use or transportation that the camera unit is still mounted rigidly by both mounting screws.

Mounting verification for users:

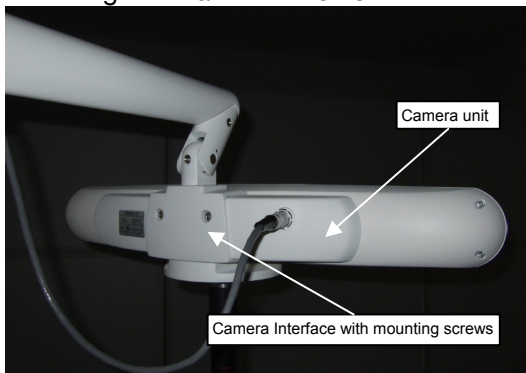


Figure 1

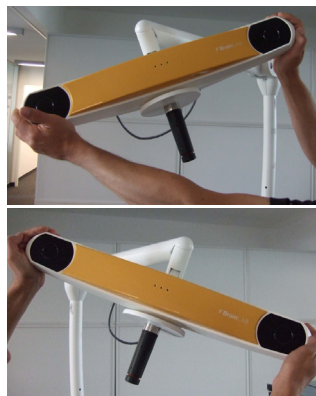


Figure 2

Figure 3

- Close all wheel brakes of the Mobile Camera Stand
- Bring the camera arm in 90° (horizontal) position until it snaps into place
- Hold the camera unit as shown and rotate it around its vertical axis until reaching the limit (refer to Figures 2 and 3)
- Apply a moderate force in horizontal and vertical direction to the camera unit: there shall be no movement between the camera unit and the Camera Interface (refer to Figure 1).

Brainlab Corrective Action:

1. Customers with a Kolibri Mobile Camera Stand assembled with the potentially affected Spectra Camera Interfaces receive this product notification information.
2. Brainlab will modify the according device component at no cost for these customers
3. Brainlab will actively contact potentially affected customers to implement the modification.

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.

August 18, 2010

Kind Regards,

A handwritten signature in black ink, appearing to read 'Markus Hofmann'.

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.