

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Camera unit potentially not reliably fixated on the Kolibri Mobile Camera Stand
Product Reference: 19506C KOLIBRI NAVIGATION STATION 2.0 (WITH MOBILE CAMERA STAND 2.0)
Date of Notification: July 13, 2010
Individual Notifying: ██████████ MDR & Vigilance Manager
Brainlab Identifier: 10-06-02.SEL.3 (II)
Type of action: Device component exchange; advice regarding use of device.

We are writing to advise you of the following potential effect that has been identified for specific batches of the 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 specific batches of the 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 exchanged, 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:

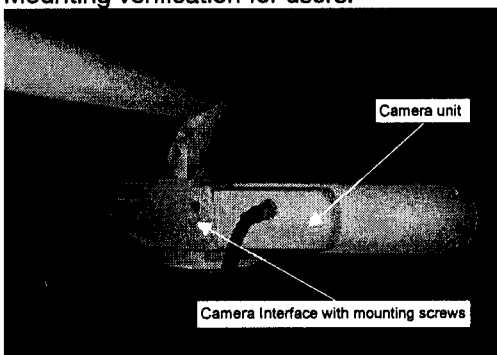


Figure 1

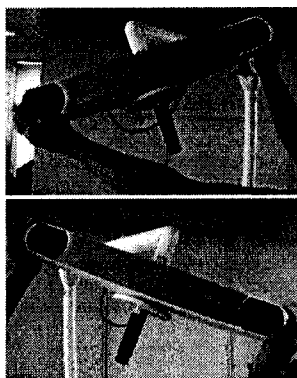


Figure 2

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 specific batches of the Camera Interface receive this product notification information.
2. Brainlab will exchange the according device component at no cost for these customers within the next 6 months.

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 [REDACTED]

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.

July 13, 2010
Kind Regards,

[REDACTED]

[REDACTED]

MDR & Vigilance Manager
brainlab.vigilance@brainlab.com

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