

## URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

**Subject:** Specific NDI Polaris Spectra Cameras installed on Brainlab Curve and Kick Navigation Systems were delivered with an incorrect manufacturer calibration, affecting the use of active marker registration instruments with the navigation system, especially relevant for the Z-touch Laser Pointer patient registration with Cranial or ENT navigation software.

**Product Reference:** Specific Curve and Kick Navigation systems.

**Date of Notification:** July 1, 2020

**Individual Notifying:** [REDACTED]

**Brainlab Identifier:** CAPA-20200624-002355

**Type of action:** Advice regarding use of device; Device modification

We are writing to advise you that some navigation cameras installed on specific Brainlab Curve and Kick Navigation systems were delivered with an incorrect manufacturer calibration, **resulting in combination with the Z-touch Laser Pointer in a registration shift of about 6mm that becomes obvious during the necessary adequate registration validation.**

As another side effect of the same camera manufacturing defect, the communication with the Softouch Pointer and with the optional Disposable Clip-On Remote Control does not work.

The navigation camera calibration error affects specific camera serial numbers only. A navigation system delivered to you has been identified as having one of these cameras. Passive marker detection, for e.g. with the Disposable Reflective Marker Spheres, is not affected.

There has been no negative effect on a patient reported to Brainlab by any user site due to this issue.

The purpose of this notice is to provide you with the relevant user information, and to inform you of the corrective actions Brainlab is taking, to address this issue. Please also refer to the appendix for the list of Brainlab Curve and Kick Navigation Systems with an erroneously calibrated camera installed to confirm which of your systems is affected.

### Effects:

#### A) For Cranial and ENT navigation software used with an affected navigation system camera:

The Softouch Pointer and the Z-touch Laser Pointer are the only active marker instruments available for Brainlab Cranial and ENT navigation software. These are designed for patient registration on the patient's skin to match the current patient anatomy to the patient scan imported to and displayed by the navigation, in order to show instrument positions relative to the 3D reconstruction of the scan image set.



Picture 1: Z-touch Laser Pointer



Picture 2: Softouch Pointer

#### ○ Effects on the use with the Z-touch Laser Pointer:

The locations of the acquired laser registration points are misinterpreted by an affected camera and deviate by ca. 6 mm from the actual position. The points are consistently shifted in left / right direction of the camera. That means, that with an affected camera, the registration accuracy achieved with a Z-touch Laser Pointer for Cranial or ENT navigation, deviates visibly by about 6mm.

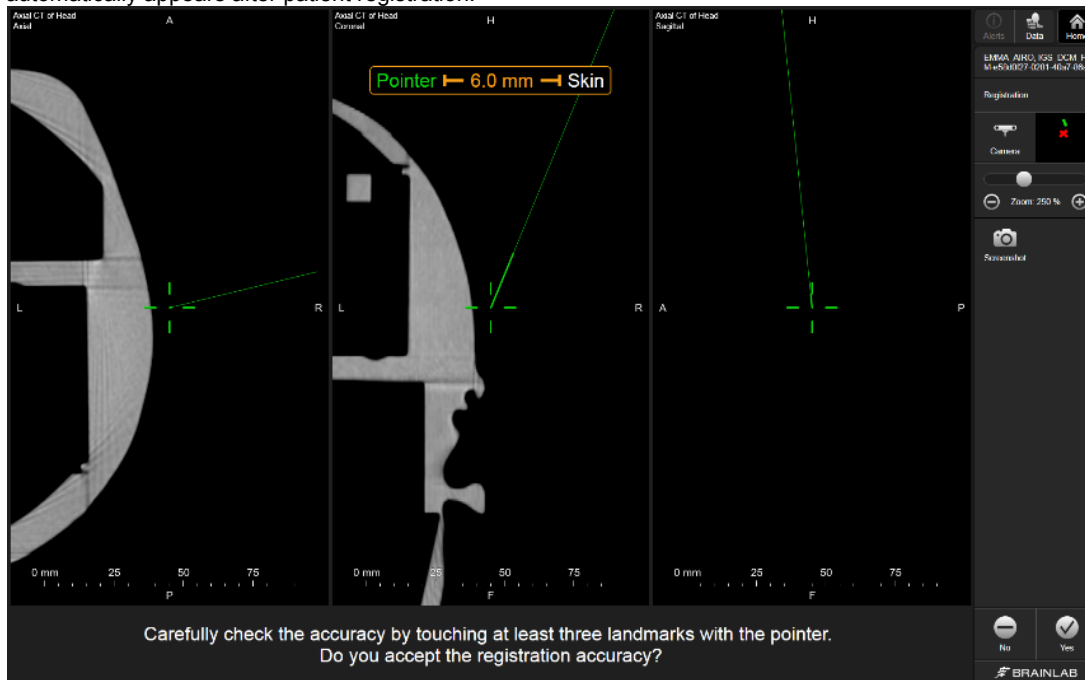
**However, if this shift of about 6mm occurred at patient registration with the Z-touch Laser Pointer and was not detected by the user, despite being obvious at the required adequate registration accuracy verification with necessary active acceptance by the user, and if this deviation exceeded the clinically acceptable accuracy tolerances for the specific intended surgery, and continued to remain undetected during the further required regular user accuracy verification throughout the surgery, the resulting instrument positions displayed by the navigation might ultimately contribute to invasive surgical actions performed at locations of the head or brain other than intended.**

Registrations performed using a combination of Z-touch points with points collected with a pointer will also be affected. As all of the Z-touch laser points will be shifted, while the other points are collected correctly, the resulting registration will be inaccurate, but perhaps to a lesser degree.

The resulting registration accuracy is visible in the verification page that appears automatically after the registration is calculated, with the verification page instructing for adequate accuracy check and active acceptance by the user before being able to proceed with the navigation.

The required adequate verification process makes the shift obvious, and therefore demonstrates the effectiveness of the design measures for accuracy verification.

Illustration: the deviation due to this issue is visible in the registration accuracy verification page that automatically appears after patient registration:



**Picture 3: Registration accuracy verification page example, illustrating the resulting deviation on a phantom.**

#### ○ Effects on the use with the **Softouch Pointer**:

When used with an affected camera system, the communication with the Softouch Pointer does not work. Therefore the Cranial or ENT navigation software is largely unable to actively acquire Softouch registration points at skin contact.

Registration points can still be acquired by pivoting the Softouch Pointer at the desired position on the patient, allowing the user to perform the necessary patient registration for navigation. The accuracy of the acquired registration points is not affected by this issue, whether collected actively, or by pivoting, since the location of the points registered is solely dependent on the instrument position tracked with the passive, reflective marker spheres on this instrument.

Correspondingly, in regard to patient registrations using the Softouch Pointer, there is no risk of inaccurate navigation added to the patient by this issue. This also demonstrates the effectiveness of the design measures, i.e., of the navigation software only accepting active registration points that fit to the simultaneous tracking of passive markers available on the instrument.

**B) For Spine & Trauma 3D and Orthopedic (Hip or Knee) Navigation software** used with an affected navigation system camera:

The only active marker tool available for Brainlab Spine & Trauma 3D and Orthopedic navigation software is the optional Disposable Clip-On Remote Control, designed to trigger the acquisition of patient registration points instead of the standard method of pivoting the registration instrument.



**Picture 4: Disposable Clip-On Remote Control**

- Effects on the optional use of the **Disposable Clip-On Remote Control** with an affected camera:  
The communication with the Clip-On Remote Control does not work. The Spine & Trauma 3D or Orthopedic navigation software is largely unable to recognize the acquisition triggered with the Clip-On Remote Control when attempted. The desired registration points can still be acquired with the standard method of pivoting the registration instrument on the patient, allowing the user to perform the necessary patient registration to navigation.

The accuracy of the acquired registration points is not affected by this issue, neither actively, if remote triggering was possible, nor by pivoting, since the location of the points registered is solely dependent on the instrument position tracked with the passive, reflective marker spheres on the instrument.

Correspondingly, in regard to patient registrations using the Disposable Clip-On Remote Control, there is no risk of inaccurate navigation added to the patient by this issue. This also demonstrates the effectiveness of the design measures, i.e., of the navigation software only accepting active registration points that fit to the simultaneous tracking of the passive markers available on the instrument.

For the Spine & Trauma 3D Navigation software, instrument pivoting for registration point acquisition remains always available, independent of the optional use of Clip-On Remote Control.

For Orthopedic – Hip or Knee – Navigation software, the optional Clip-On Remote Control for registration point acquisition, if intended for the specific surgery, must first be actively enabled in the settings of the navigation software. In this circumstance, to be able to return to using instrument pivoting instead, the Clip-On Remote Control function must be disabled again, at the same software settings location it was formerly actively switched on.

**User Corrective Action:**

1. Refer to the appendix for the list of Brainlab Curve or Kick Navigation Systems with an affected camera installed to determine if your navigation system is affected.
2. **For Cranial or ENT navigation software in combination with an affected system camera installed: Do not use the Z-touch Laser Pointer for patient registration.** Use other instruments with the standard instrument pivoting method for Surface Matching or Landmark Registration, or Automatic Image Registration (AIR) if available.
3. Please continue to follow the instructions and warnings as described in the user guide. Especially relevant is the following warning, in addition to the instructions on the registration verification page appearing in the Cranial or ENT software:



**Verify accuracy at multiple anatomical landmarks, especially in the region of interest, as it may differ from the accuracy verified on the skin surface. If the region of interest is not accessible, verify in areas as close as possible to the region of interest.**

4. In order to avoid nuisance with Spine & Trauma 3D or Orthopedic Navigation software in combination with an affected system camera installed: Do not attempt to use the optional Disposable Clip-On Remote Control. For patient registration, acquire registration points with the standard instrument pivoting method; or for Spine & Trauma 3D use Automatic Image Registration (AIR) if available.

**Brainlab Corrective Action:**

1. Existing affected customers receive this Field Safety Notice / Product Notification information.
2. Brainlab will exchange the affected specific cameras installed on a Brainlab Curve or Kick Navigation System, to a camera functioning as specified. Brainlab will actively contact you, starting mid of September 2020 to schedule the exchange.

**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.

**Customer Hotline:**

+49 89 99 15 68 1044 or +1 800 597 5911 (for US customers)

**E-mail:** [support@brainlab.com](mailto:support@brainlab.com) (for US customers: [us.support@brainlab.com](mailto:us.support@brainlab.com))

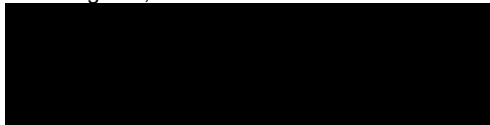
**Fax:** Brainlab AG: + 49 89 99 15 68 5033

**Address:** Brainlab AG (headquarters):

Olof-Palme-Strasse 9, 81829 München, Germany

July 1, 2020

Kind Regards,



[brainlab.vigilance@brainlab.com](mailto:brainlab.vigilance@brainlab.com)

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

**Attachment:** Refer to the appendix for the list of Brainlab Curve or Kick Navigation Systems with an erroneously calibrated camera installed, to determine if your system is affected.

**Appendix: List of Brainlab Curve and Kick Navigation Systems with an affected camera installed.**

You can determine if your system is affected by comparing the Serial Number in the last column of the listed Curve or Kick Navigation System with the label on your Navigation Station.

S/N of affected NDI camera installed	Installed on Brainlab Navigation system – Platform name	Serial Number of affected Navigation System (label on Navigation Station)
P7-21527	CURVE 1.1 DUAL NAVIGATION STATION	3911619001-19901
P7-21173	CURVE 1.2 DUAL NAVIGATION STATION	1173019001-19901B
P7-21183	CURVE 1.2 DUAL NAVIGATION STATION	1444519001-19901B
P7-21325	CURVE 1.2 DUAL NAVIGATION STATION	1937319001-19901B
P7-21324	CURVE 1.2 DUAL NAVIGATION STATION	2201419001-19901B
P7-21382	CURVE 1.2 DUAL NAVIGATION STATION	2456219001-19901B
P7-21414	CURVE 1.2 DUAL NAVIGATION STATION	3524219001-19901B
P7-21830	CURVE 1.2 DUAL NAVIGATION STATION	5379420001-19901B
P7-21892	CURVE 1.2 DUAL NAVIGATION STATION	5609520001-19901B
P7-20390	CURVE 1.2 DUAL NAVIGATION STATION	6968320001-19901B
P7-21890	CURVE DUAL DISPLAY NAVIGATION STATION	0824912001-19900
P7-21780	CURVE DUAL DISPLAY NAVIGATION STATION	3894613001-19900
P7-07290	CURVE DUAL DISPLAY NAVIGATION STATION	4387415001-19900
P7-10719	CURVE SINGLE DISPLAY NAVIGATION STATION	5762713001-19905
P7-12520	KICK 2 NAVIGATION STATION	0164217001-18170
P7-20938	KICK 2 NAVIGATION STATION	2703119001-18170
P7-21378	KICK 2 NAVIGATION STATION	2933119001-18170
P7-18830	KICK 2 NAVIGATION STATION	6171619001-18170
P7-15162	KICK 2 NAVIGATION STATION	8745417001-18170
P7-16025	KICK 2 NAVIGATION STATION	9178819001-18170
P7-13227	KICK 2 NAVIGATION STATION	9607118001-18170
P7-06110	KICK NAVIGATION STATION	1190017001-18070



System: Curve 1.2 Dual  
Navigation Station

SN REF 1234567890 -19901B  
2018-06-05

UDI (01)04056481140809  
(11)180605  
(21)1234567890

Brainlab AG  
Olof-Palme Str. 9  
81829 Munich  
Germany

RxOnly



BRAINLAB  
Kick 2 Navigation Station

SN REF 1234567890 -18170  
2020-01-22

26kg CE 0123

IP 20 RxOnly

Kick 2 Monitor Cart

REF 18171

Voltage (US): 100 - 240 VAC~ (100 - 120V~)

Frequency: 50 / 60 Hz

Power consumption: 3A@100VAC / 1.5A@240VAC

Brainlab AG  
Olof-Palme Str. 9  
81829 Munich  
Germany

UDI (01)04056481006655  
(11)200122  
(21)1234567890

Conform to ANSI/AAMI ES60601-1  
Certified to CSA C22.2#60601 -1

Sample Label Curve 1.2 with Navigation System Serial No.

Sample Label Kick 2 with Navigation System Serial No.