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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Brainlab Ultrasound Navigation Software: Changing the image width for a probe in the BK Medical Ultrasound System during surgery can add a deviation to the intraoperative ultrasound image displayed by the Brainlab navigation.
Product Reference:	Ultrasound Navigation Software 1.0.x Ultrasound Integration Software for Cranial/ENT Navigation 3.0.x and 3.1.x
Date of Notification:	August 31, 2020
Individual Notifying:	Markus Hofmann, Senior Vigilance Manager
Brainlab Identifier:	CAPA-20200825-002368
Type of action:	Advice regarding use of device; Device modification

We are writing to advise you that the intraoperative Brainlab Ultrasound Navigation Software does not support the modification of the probe's image width, an optional feature of the BK Medical Ultrasound System, resulting in an incorrect display of the depth of the ultrasound overlay by the navigation for non-linear ultrasound probes, with the deviation depending on the probe and the difference between the calibrated and used image width. Please refer to the second page of this notification for illustration and technical details for this effect.

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.

Background:
Ultrasound probes of the BK Medical Ultrasound System can be integrated into the Brainlab Navigation Software to display real-time or 3D-reconstructed ultrasound images. The navigation overlays these images onto other navigated patient image sets. These integrated probes are calibrated to the Brainlab navigation using a probe-specific adapter array, and calibration is performed and verified for each probe with a phantom, for and with the current (typically default) image width.

For specific, non-linear probes, changes of the optional image width setting inside the BK Medical Ultrasound System during surgery can add a deviation of several millimeters to the ultrasound overlay's position displayed in the navigation as compared to the other navigated patient image data sets.

If this deviation occurred and it was relevant for the surgery, it would become visible to the user when verifying and comparing anatomical landmarks to the ultrasound navigation display. The deviation occurs between the navigated patient data, such as a CT or MRI, and the overlaid ultrasound image – and can be seen during the acquisition and verification of a 3D ultrasound image set for navigation, as well as during intraoperative live ultrasound navigation.

To date, no occurrence, therefore also no negative effect on a surgery treatment or patient have been reported to Brainlab by any user site due to this issue. This potential navigation issue with this use option in the BK Medical Ultrasound System was detected internally by Brainlab during continued software integration testing.

Brainlab is not in a position to determine if and for which clinical visualization reasons this optional BK Medical Ultrasound System function – to change the ultrasound probe's image width while simultaneously using the Brainlab Ultrasound Navigation Software with specific, non-linear probes – might be used during surgery that would cause the described issue.

Effect:
The optional function to change the probe's ultrasound image width is available in the general image menu of the BK Medical Ultrasound System. The button is either labelled as "Width" (Flex Focus 800) or "Sector Width" (bk5000), and also shows the current value in percent.

Ultrasound probes that are integrated into the Brainlab navigation are calibrated and verified with a phantom, using the current (typically default) image width. As long as the same image width is used during surgery as was used during probe calibration to navigation, this potential issue does not come into effect; no deviation is added to the navigation display of real-time or 3D reconstructed ultrasound images overlaid to other CT or MRI navigated datasets. Further, this potential issue, even under the outlined specific circumstances, **does not occur for linear probes** for navigation, such as with the BK Medical X18L5s (9009) Transducer ("Hockey Stick").

However, if a non-linear (curved) probe's image width display was changed in the ultrasound system during a surgery from its value calibrated to navigation, this could **add a deviation of up to more than 3mm in a theoretical worst-case-scenario** to the navigation display of the ultrasound image.

The potential resulting allover deviation could exceed the clinically acceptable accuracy tolerances for the specific intended surgery. If such an unacceptable deviation of the navigation display occurred and remained undetected, despite being visible through landmark comparison during the required regular user accuracy verification of navigation throughout the surgery, the surgeon's clinical decisions might be influenced undesirably. Ultimately this could contribute to invasive surgical actions performed at other locations of the head or brain than intended.

Details
The described issue **affects only navigation with non-linear BK Medical probes**. The potential deviation depends on the probe type and the difference between the calibrated and used image width percentage. As a rule of thumb, the bigger the difference is between the calibrated and used image width, the larger the deviation becomes for a non-linear (curved) ultrasound probe.

If the added deviation occurs, it becomes visible in the depth of the probe's image in the direction of the ultrasound probe axis, as illustrated below.

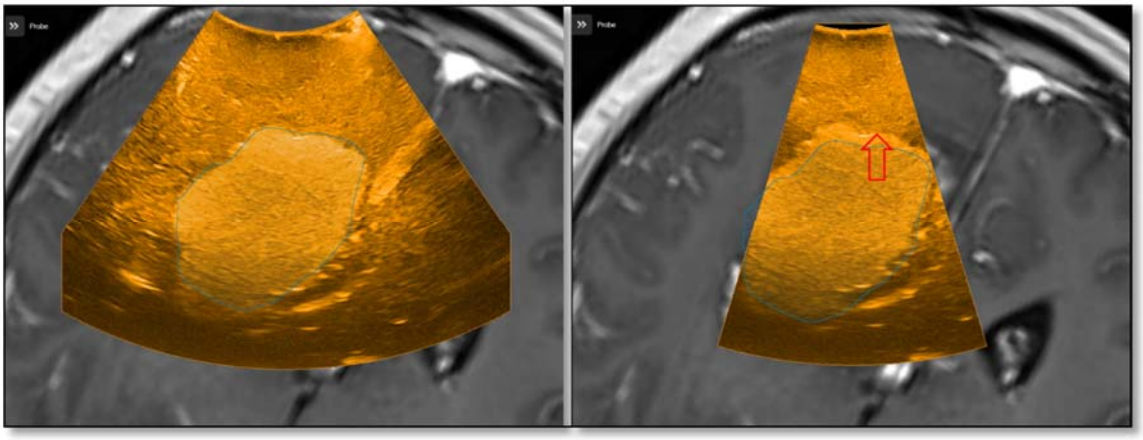

Figure 1: Illustration of the potential added vertical deviation to the intraoperative ultrasound navigation overlay display from a non-linear probe.
Left: Width = 100%; calibrated (default) value was used for navigation: the blue tumor object outlined in the navigation correctly coincides at the same height with the hyperechoic tumor (brighter portion).
Right: Width = 50%; image width was changed from its calibrated value during navigation: the hyperechoic tumor (brighter portion) in the ultrasound image appears incorrectly shifted higher compared to its actual location in the MR scan.

The user must regularly verify accuracy of the ultrasound probe's calibration to navigation with the corresponding phantom. The Ultrasound Navigation Software reminds the user to do this at regular intervals. Using the same image width during surgeries with navigation integration, with no changes as to how it was set for probe calibration, avoids the described issue. If you are unsure of the image width calibrated to navigation, use the same image width as was set for successful accuracy verification with the phantom.

The following table shows a deviation calculation of worst-case-scenarios for different non-linear probes (transducers).

The theoretical worst-case assumption made for this calculation is: image width at minimum value (50%) at calibration of the probe, and changed to its maximum value (140%) during surgery, or vice versa. This would result in the maximum difference possible.

Name of Ultrasound Probe	Ultrasound System	Theoretical Maximum Deviation
8862 Craniotomy Transducer	Flex Focus 800	ca. **3.2 mm**
8863 Burr-Hole Transducer	Flex Focus 800	Only in sub-millimeter range (ca. 0.6 mm)
N13C5 Transducer (Craniotomy)	bk5000	ca. **3.2 mm**
N11C5s Transducer (Burr Hole)	bk5000	Only in sub-millimeter range (ca. 0.6 mm)

User Corrective Action:

1. The Ultrasound Navigation Software does not support changing the image width of a non-linear BK Medical probe; therefore, **do not change this width value in the ultrasound system during a surgery, to avoid an incorrect overlay visualization in the navigation.** Keep the same (default) value as when the probe was calibrated to navigation.

Continue to verify the accuracy of the ultrasound probe's calibration to navigation with the corresponding phantom at regular intervals, as recommended and reminded by the Ultrasound Navigation Software. Calibration can be verified at any time. To avoid an occurrence of the described issue and if you are unsure of the image width calibrated to navigation, use the same image width during surgeries with navigation integration, with no changes as to how it was set for successful accuracy verification with the phantom.

2. Continue to follow the instructions and warnings as described in the user guide. Especially relevant is the following warning:

Frequency of Verification

⚠ **Warning**

Each time you perform ultrasound-guided navigation, verify the accuracy throughout the session.

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3. In general, do not use Ultrasound Navigation Software if you detect any unacceptable deviation in the navigation of the ultrasound image overlay during the necessary accuracy verification with anatomical landmarks and if you determine the accuracy to be outside of clinically acceptable limits for the surgery. At any time, you can use ultrasound imaging with the display of the BK Medical Ultrasound System independent of navigation, while navigating only on the other available patient image data (such as CT or MRI) in parallel.

Brainlab Corrective Action:

1. Existing affected customers receive this Field Safety Notice / Product Notification information.

2. Brainlab will provide an Ultrasound Navigation Software revision with this issue corrected and resolved to affected customers. Brainlab will actively contact you, starting in December 2020 to schedule the software revision installation.

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.

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August 31, 2020

Kind Regards,

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