MEDTRONIC NAVIGATION, INC.
200 Medtronic Drive
Lafayette, CO 80026
www.medtronic.com

URGENT: MEDICAL DEVICE CORRECTION

StealthStation™ S7 Cranial Software v3.1.4

Biopsy Depth Gauge Inaccuracy & Incorrect Distance to Target Text

Software Update Fix Availability - Follow-up Communication

December 2023

Dear Healthcare Professional:

The purpose of this letter is to notify you that the Software update to address the Biopsy Depth Gauge Inaccuracy & Incorrect Distance to Target Text issue is now available. As a reference, below is information that was previously shared. Your Medtronic representative will be performing this software update on your impacted StealthStation™ S7 and i7 system(s) in the coming months. Your Medtronic representative will remove the warning and instructional placard currently attached to your system when the update is complete and provide the updated Instructions for Use (IFUs).

Issue Background:

In April 2023, Medtronic identified two software anomalies in StealthStation™ Cranial Version 3.1.4 software that can occur under specific workflow scenarios:

- Under certain situations, the Biopsy Depth Gauge Graphic on the screen may not display accurately. This can impact **Cranial Biopsy** procedures.
- Under certain situations, the "Distance to Target" text that displays on the screen may not display accurately. This can impact **Tumor Resection, Shunt Placement, and Nexframe™ DBS** procedures.

As previously communicated, if the user encounters either software anomaly and proceeds based on the inaccurate information, there is the potential to navigate too shallow or deep to the intended target. During a **cranial biopsy procedure**, this issue can potentially lead to biopsy of normal brain tissue, a non-diagnostic biopsy, or unintended tissue damage including the potential for life-threatening injury (hemorrhage or permanent neurological injury) which could lead to death.

In addition to potential serious injury during cranial biopsy, either anomaly may result in the potential for a prolonged procedure, the need for an additional surgical procedure, or tissue injury from unintended additional pass of a device (biopsy needle, shunt catheter, electrode) during all procedure

types listed above. As of November 2023, Medtronic has received three (3) customer complaints confirmed to be directly related to the Inaccurate Biopsy Depth Gauge Graphic and no customer complaints related to the Distance to Target anomaly. None of the complaints reported patient injury.

As of the date of this letter, Medtronic developed a new software version (3.1.5) for the StealthStation™ S7 and i7 systems utilizing the software versions 3.1.4, indicated in the below table, to address this issue. The new software version, StealthStation™ Cranial Version 3.1.5 removed the biopsy depth gauge graphical representation of the needle cutting window but maintains the numerical values of Depth and To Target. StealthStation™ Cranial Version 3.1.5 corrected the "Distance to Target" text directly within the software and remains available for use.

Product Scope:

Product Information			
Navigation System	**Software Name**	**Model#/CFN**	**Version**
StealthStation™ S7/i7	StealthStation™ Cranial	9735585, 9735586, 9735587	3.1.4

Required Customer Actions:

1. Please review this information with all physician users. If you have any questions related to this issue, please contact Medtronic Technical Services for help at 1-888-826-5603 or email at rs.navtechsupport@medtronic.com
2. Please confirm via the enclosed confirmation form that you understand Medtronic will be performing a software update on your impacted StealthStation™ system(s), providing the updated IFU(s) upon software update completion, and removing the warning and instructional placard and that this notification has been communicated within your facility with all physician users.
3. Please complete and return the customer confirmation form enclosed with this letter acknowledging receipt of this information via email to neuro.quality@medtronic.com within 30 days of receipt.
4. Please maintain a copy of all records associated with this action.

Additional Information:

[For U.S. use only] Medtronic is communicating this information to the appropriate regulatory agencies. Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA (800) FDA-1088
- Call Medtronic Technical Services at 1-888-826-5603

Medtronic

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Sales Representative or Technical Services at 1-888-826-5603.

Sincerely,

Alison Webster
VP Quality
Medtronic Cranial and Spinal Technologies