

URGENT: MEDICAL DEVICE CORRECTION
StealthStation™ S7 Cranial Software v3.1.4
Biopsy Depth Gauge Inaccuracy & Incorrect Distance to Target Text

April 2023

Dear Healthcare Professional:

This Urgent Medical Device Correction notification is to inform you of actions being taken to address two software anomalies impacting the StealthStation™ S7 and i7 systems. Under specific conditions, these anomalies can result in the potential for inaccurate/conflicting information to be displayed during Cranial Biopsy, Tumor Resection, Shunt Placement, and Nexframe™ DBS procedures. Information within this correction notification applies to all StealthStation™ S7 and i7 systems running StealthStation™ Cranial Version 3.1.4 software (reference the table below for additional impacted product information). Our records indicate that you may have one or more systems installed with an affected version of the software.

Issue Description:

Medtronic has 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. Refer to **Appendix A** for a complete description of the issue and associated mitigations.
- 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. Refer to **Appendix B** for a complete description of the issue and associated mitigations.

Medtronic is currently working on a StealthStation™ Cranial software update that will resolve the issues above and will communicate additional information when it becomes available.

Potential Health Hazard:

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. Between 16-JUN-2022 through 15-MAR-2023, Medtronic has received three (3) complaints confirmed to be directly related to

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the Inaccurate Biopsy Depth Gauge Graphic and no complaints related to the Distance to Target anomaly. None of the complaints reported patient injury.

Product Scope:

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

Required Actions:

1. Follow below instructions and refer to Appendices A & B for full detail on issues and mitigations:
 - a. Do not utilize the Biopsy Depth Gauge Graphic in Cranial Biopsy procedures.
 - b. Do not utilize the Distance to/past Target value for Tumor Resection, Shunt Placement, and Nexframe™ DBS procedures.
2. Please review this information, including the additional details in Appendices A and B, 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
3. Please confirm via the enclosed confirmation form that you understand Medtronic will provide a warning and instructional placard to be applied to impacted StealthStation™ Systems and that this notification has been communicated within your facility with all physician users. Send the completed Customer Confirmation Form to Medtronic via email at neuro.quality@medtronic.com within 30 days of receipt.
4. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please maintain a copy of this notice in your records.

Additional Information:

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

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

Appendix B

StealthStation™ S7 Cranial Software v3.1.4: Inaccurate Distance to Target Text

Impacting Tumor Resection, Shunt Placement, and Nexframe™ DBS procedures

Medtronic identified an anomaly during our own internal testing that impacts Tumor Resection, Shunt Placement, (Refer to Figure 2) and Nexframe™ DBS procedures (Refer to Figure 3) with the Distance to/past Target text. This anomaly does not impact Cranial Biopsy procedures. When certain settings are used, the software can enter a state where the Distance to/past Target text is no longer synchronized with the rest of the navigational information on the screen and displays an inaccurate numerical value. All other information on the screen, including the Depth Gauge Graphic (Shunt Placement, Tumor Resection), remains accurate. The steps required to encounter this anomaly are as follows:

- Non-Axial exams (sagittal, coronal) and a small subset of non-standard Axial exams are used
- A surgical plan has been created and must be utilized.
- The Target Guidance option must be selected within the guidance view options.
- A tip projection must be utilized.
- The 'Navigate Projection' must be enabled.

Figure 2 Distance to/past Target Text Inaccuracy seen in Navigate Task of Shunt Placement and Tumor Resection

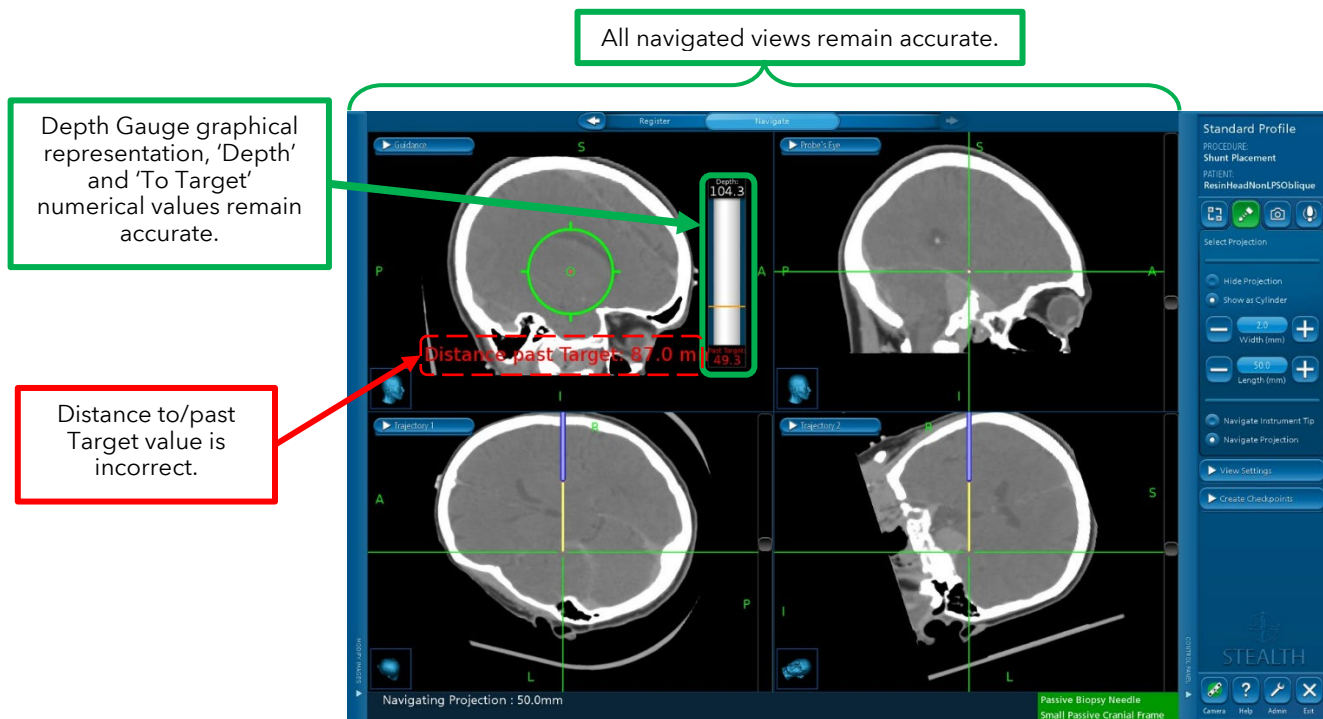


Figure 3 Distance to/past Target Text Inaccuracy seen in Navigate Task of NexFrame™ DBS



Mitigations:

Medtronic recommends that users do not utilize the Distance to/past Target value (outlined in Red in Figure 2) in Tumor Resection, Shunt Placement, of Nexframe™ DBS procedures due to the potential for the presence of this software anomaly. All other navigation information is unaffected and can be utilized to complete the desired procedure. Per the IFU: "Warning: Frequently confirm navigation accuracy and system responsiveness during live navigation. Use the navigation instrument to touch several bony anatomical landmarks and confirm that the locations identified on the images match the locations touched on the patient. If accuracy degrades, re-register the patient." and "If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system."