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Urgent Field Safety Notice

StealthStation™ S7/i7 Cranial Software v3.1.1, 3.1.2, and 3.1.3 Biopsy Depth Gauge Cycle View Inaccuracy & Incorrect Distance to Target Text

Notification and instructional placard placement

April 2023

Medtronic Reference: FA1204

EU Manufacturer Single Registration Number (SRN): US-MF-000023263

Dear Healthcare Professional,

This notification is a follow-up to Medtronic's previous communication which informed you that the software correction to address the Biopsy Depth Gauge Cycle View Inaccuracy was available. The previous communication notified you that the Synergy™ Cranial model 9733763 software is being updated to version 2.2.9, and the StealthStation™ Cranial model 9735585 software is being updated to version 3.1.4.

Medtronic has identified a new software anomaly in StealthStation Cranial model 9735585 version 3.1.4 and therefore is ceasing installation of this version pending an updated software version. Synergy™ Cranial model 9733763 version 2.2.9 is unaffected and installation of this software version will continue.

In addition to the above change in software version installation, this notification is also intended to inform you of actions being taken to address an additional anomaly impacting the StealthStation™ S7 and i7 systems running StealthStation™ Cranial Version 3.1.1, 3.1.2, and 3.1.3 software. Under specific conditions, this anomaly can result in the potential for inaccurate/conflicting information to be displayed during Tumor Resection, Shunt Placement, and Nexframe™ DBS procedures. Information

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within this correction notification applies to all StealthStation™ S7 and i7 systems running StealthStation™ Cranial Version 3.1.1, 3.1.2, and 3.1.3 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 a software anomaly in StealthStation™ Cranial Version 3.1.1, 3.1.2, and 3.1.3 software that can occur under specific workflow scenarios:

- 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 A** 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 this anomaly it 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 01-JAN-2016 through 15-MAR-2023, Medtronic has received no customer complaints related to the anomaly.

Product Scope:

Product Information			
Navigation System	Software Name	Model#/CFN	Version
StealthStation™ S7/i7	StealthStation™ Cranial	9735585	3.1.1
StealthStation™ S7/i7	StealthStation™ Cranial	9735585	3.1.2
StealthStation™ S7/i7	StealthStation™ Cranial	9735585	3.1.3

Required Actions:

1. Follow below instructions and refer to Appendix A for full detail on issues and mitigations:

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- a. 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 Appendix A, with all physician users. If you have any questions related to this issue, please contact your Medtronic field representative.
3. A Medtronic Representative will apply a warning and instructional placard to your impacted StealthStation System.
4. This notice needs to be passed on to all those who need to be aware of 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 has notified the Competent Authority of your country of this action.

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 directly or via Tel. No: 01 511 1400.

Sincerely,



Natasha Mthethwa (Senior Regulatory Affairs Specialist)

Enclosures:

- Appendix A

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Appendix A

StealthStation™ S7 Cranial Software v3.1.1, 3.1.2, and 3.1.3: Inaccurate Distance to Target Text

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

Medtronic identified an anomaly during internal testing impacting 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.

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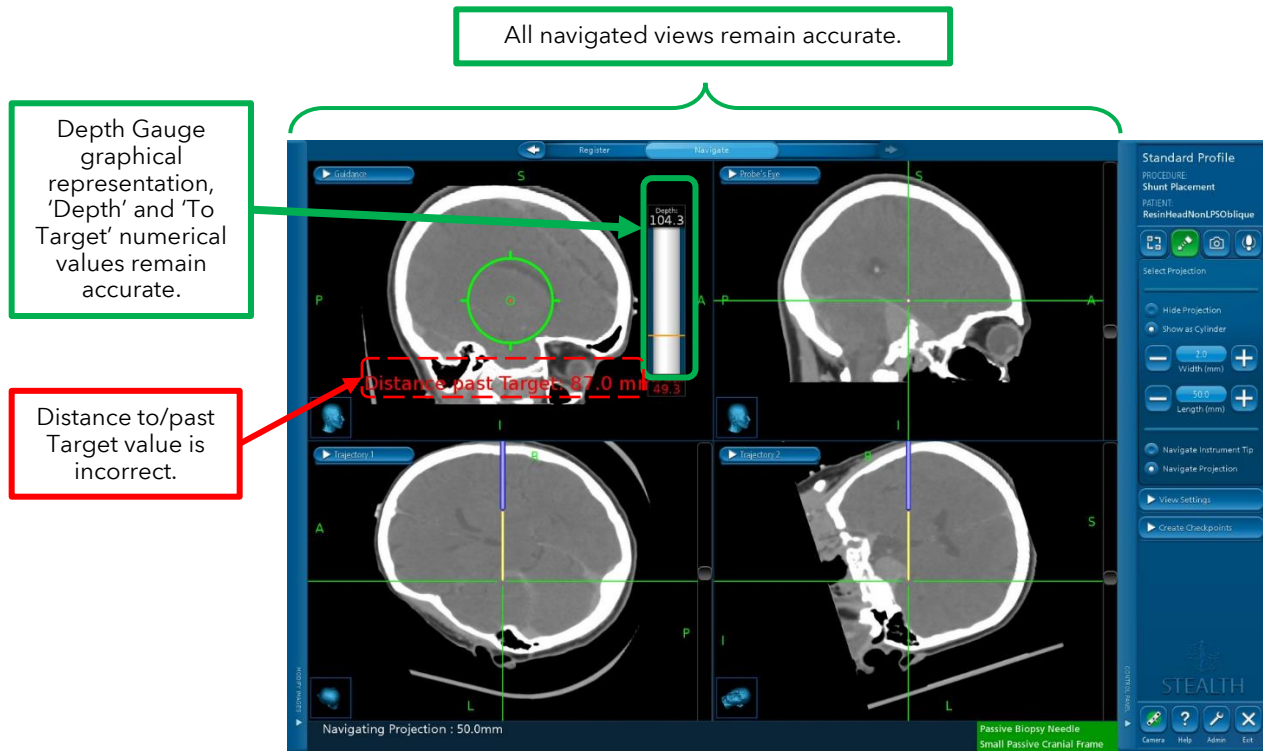


Figure 1 Distance to/past Target Text Inaccuracy seen in Navigate Task of Shunt Placement and Tumor Resection

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All navigated views remain accurate.

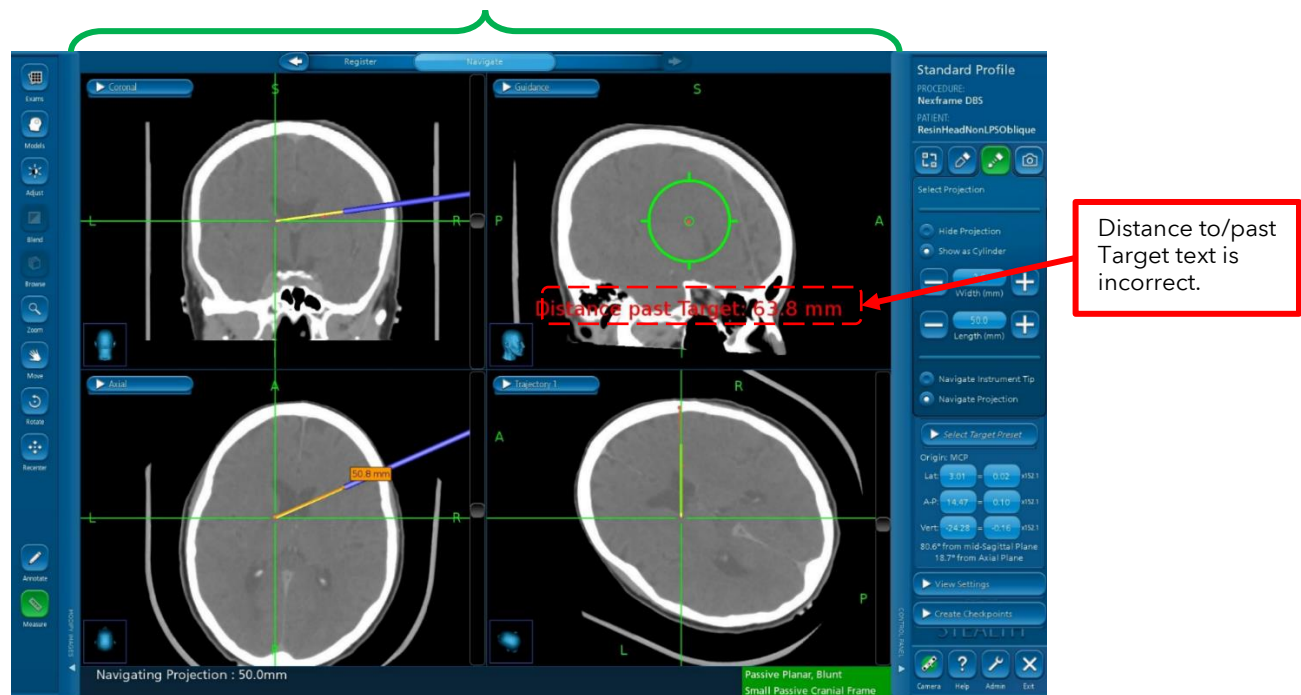


Figure 2 Distance to/past Target Text Inaccuracy seen in Navigate Task of NexFrame™ DBS

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."