

Urgent Field Safety Notice **Synergy™ Cranial (9733763) and StealthStation™ Cranial (9735585)** **Biopsy Depth Gauge Cycle View Inaccuracy** Notification

November 2021

Medtronic reference: FA1204

Dear Healthcare Professional,

The purpose of this letter is to provide information related to potential inaccuracy during biopsy procedures using the StealthStation™ S7 and i7 Biopsy Depth Gauge feature. This correction applies to all StealthStation™ S7 and i7 systems running Synergy Cranial Version 2.2.8 and StealthStation™ Cranial Versions 3.1.1-3.1.3 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.

PRODUCT DETAILS

Navigation System	Software Name	Model#/CFN	Version
StealthStation S7/i7	Synergy Cranial S7	9733763	2.2.8
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

Issue:

On June 9, 2021, a complaint was reported to Medtronic that during navigation in a Cranial Biopsy Procedure, the user may encounter an anomaly with the Biopsy Depth Gauge graphical display in the software. The software can enter a state where the Biopsy Depth Gauge is no longer synchronized with the rest of the navigational information on the screen and displays an inaccurate position of the biopsy needle.

Figure 1 Biopsy Depth Gauge Inaccuracy seen in Navigate Task



In order for this software anomaly to occur, ALL of the following must happen:

- The biopsy trajectory is locked, AND
- Guidance View is turned off or turned to a different view, AND
- The crosshairs are repositioned by clicking the 2D or 3D image, AND
- Guidance View is returned as an active view

OR

- The biopsy trajectory is locked, AND
- The crosshairs are repositioned by clicking the 2D or 3D image, AND
- Guidance View is turned off or turned to a different view, AND
- Guidance View is returned as an active view

If performed, these actions may cause the Biopsy Depth Gauge graphical display to incorrectly depict the tip of the biopsy needle. The graphical depiction of the biopsy needle may appear in a position relative to the plan target that does not represent the actual physical position of the biopsy needle, which may result in potential biopsy of healthy tissue or damage to critical structures.

Potential Health Hazard:

If the user encounters the software anomaly where the graphical Biopsy Depth Gauge is no longer synchronized with other navigation views, there is the potential to navigate the biopsy needle too shallow or deep to target. This issue can potentially lead to resection of normal brain tissue or eloquent anatomical regions of the brain. When this software anomaly is encountered, it may result in a prolonged procedure, the need for an additional surgical procedure, tissue injury, including potential for life-threatening injury (hemorrhage, unintended tissue damage, permanent neurological injury), which could lead to death. Between 01-Jan-2019 through 10-Sep-2021, Medtronic has received four (4) complaints, with one confirmed to be directly related to this software anomaly. The remaining complaints indicate an inaccuracy occurred during a cranial biopsy procedure; however, the provided information is insufficient to confirm whether those were directly related to this software anomaly. None of the complaints reported patient injury.

Mitigation Steps

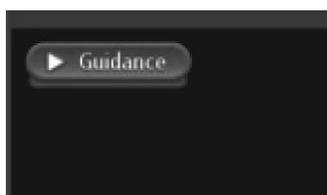
Medtronic will provide a warning and instructional placard to be applied to impacted systems to maintain visibility to the mitigations until a software fix is available.

The following steps should be utilized to prevent this software anomaly from occurring and to restore normal function if this anomaly is observed.

AVOID:

- Medtronic recommends **NOT** turning off **Guidance View** after locking the biopsy trajectory in the Cranial software.
- After locking trajectory for biopsy needle navigation, always ensure **Guidance View** remains an active view in at least one screen layout quadrant.

Figure 2 Guidance View Label on Screen Layout Quadrant



RECOVER:

If a discrepancy is detected between the biopsy depth gauge graphic and the other 2D information:

- **Step 1:** Obstruct the camera field of view of the biopsy needle or reference frame to **cause red status**.
- **Step 2: Return to green status** by no longer obstructing camera field of view of the biopsy needle and reference frame.
- **Step 3:** Use the **Cycle Views** icon to refresh guidance view and confirm that the biopsy depth gauge graphic matches the distance to target values and the position to target information provided by the 2D crosshairs.
- **Step 4: Visually confirm accuracy** before proceeding with navigation.

ALWAYS:

Visually confirm navigational accuracy and confirm that the biopsy depth gauge graphic matches the distance to target values and matches the position to target information provided by the 2D crosshairs, which represent the tip position of the navigated instrument.

Use the Biopsy Needle Mechanical Depth Stop.

If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.



Cycle Views icon that can be used to refresh the Guidance View if this anomaly is observed. Restoring accuracy to the Biopsy Depth Gauge.

Required Actions:

- Please review this information with all physician users. If you have any questions related to this issue, please contact your Medtronic representative.
- Please attach the warning and instructional placard to your impacted StealthStation systems. A Medtronic representative can assist you with placing the placards. 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.
- 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 Field Representative at <XXXX>.

Sincerely,

Local / BU Manager