Medtronic
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**URGENT: Medical Device Correction Update**

**Follow up to November 2021 Notification (Phase 2)**

**Synergy™ Cranial (9733763) and StealthStation™ Cranial (9735585)**

**Biopsy Depth Gauge Cycle View Inaccuracy**

16 August 2022

**Attention: Risk Management Director and O.R Materials Management**

**CC: The Chairman Medical Board and relevant Head of Departments**

Dear Healthcare Professional:

The purpose of this letter is to notify you that the Software update to address the Biopsy Depth Gauge Cycle View Inaccuracy issue is now available. 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.

Issue Background: In 19 November 2021 Medtronic issued a notification detailing this issue and provided mitigation steps if the user were to encounter this issue. 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 and 05-Jul-2022, Medtronic has received four (4) complaints, with two 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. There has been one report of patient injury. A copy of the original notification letter has been attached for your convenience and includes the issue description, risks, and previously

communicated mitigations. The mitigations remain applicable until the software has been updated. 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.

**Required Actions:**

1. Please review this information with all physician users. If you have any questions related to this issue, please contact your local Medtronic field representative.
2. Please confirm via the enclosed confirmation form that you understand Medtronic will be performing a software update on your impacted StealthStation system(s) and removing the warning and instructional placard and that this notification has been communicated within your facility with all physician users. Hand or scan then email back the accomplished form to your local Medtronic field representative or service engineer.
3. Please maintain a copy of all records associated with this action.

**Regulatory Notification:**

Medtronic is communicating this information to the appropriate regulatory agencies. Adverse events or quality problems experienced with this product should be reported to your local Medtronic field representative.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. Please use the contact information provided if you have any questions regarding this communication.

Sincerely,

DocuSigned by:

Signer Name: Diana Teo
Signing Reason: I approve this document
Signing Time: 16 August 2022 | 06:02 SGT
05FB18D83D7745D787A6E905DEAE1FD1

Medtronic QRA Lead
Singapore & Malaysia

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 16 August 2022 | 07:00 SGT
90D0724C9B1C402A99B286449A1644B8

Medtronic QRA Lead
Indochina & Frontier Markets Plus

DocuSigned by:

Parichart

Signer Name: Parichart Bunjobchokchai
Signing Reason: I approve this document
Signing Time: 16 สิงหาคม 2022 | 20:35 SEAST
1EE8203B3B0D401EAAC8FA853EBB987A

Medtronic QRA Lead

Thailand

Enclosures:

- November 2021 Notification
- Customer Confirmation Form

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# Customer Confirmation Form
## Follow up to November 2021 Notification (Phase 2)
## URGENT: Medical Device Correction
## Synergy™ Cranial (9733763) and StealthStation™ Cranial (9735585)
## Biopsy Depth Gauge Cycle View Inaccuracy

***For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately***

| Customer Contact Details | Medtronic Contact Details |
|---|---|
| **Distributor/HCP/Patient name:** | **Name:** |
| | **Contact:** |
| **Address:** | **Email:** |
| **Phone no:** | |
| **E-mail:** | |

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. 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.

Please indicate in the table below the serial number of each of the unit/s in your facility:

| | | | |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

By signing this form, I confirm that:

- I have received and read the medical device correction notification, dated **16 August 2022**, from Medtronic regarding the Synergy™ Cranial (9733763) and StealthStation™ Cranial (9735585) software updates are available and took appropriate action.
- I have reviewed this information with all physician users.
- I acknowledge that Medtronic will be performing a software update on the impacted StealthStation systems and will be removing the warning and instructional placard.
- I have discarded any Synergy Cranial Version 2.2.8 and StealthStation™ Cranial Versions 3.1.1-3.1.3 software discs in my possession.

Name (print): _____ Signature: _____ Stamp: _____ Date: DD MMM YYYY

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# URGENT: Medical Device Correction

## Synergy™ Cranial (9733763) and StealthStation™ Cranial (9735585) Biopsy Depth Gauge Cycle View Inaccuracy

19 November 2021

**Attention: Risk Management Director and O.R Materials Management**
**CC: The Chairman Medical Board and relevant Head of Departments**

Dear Healthcare Professional:

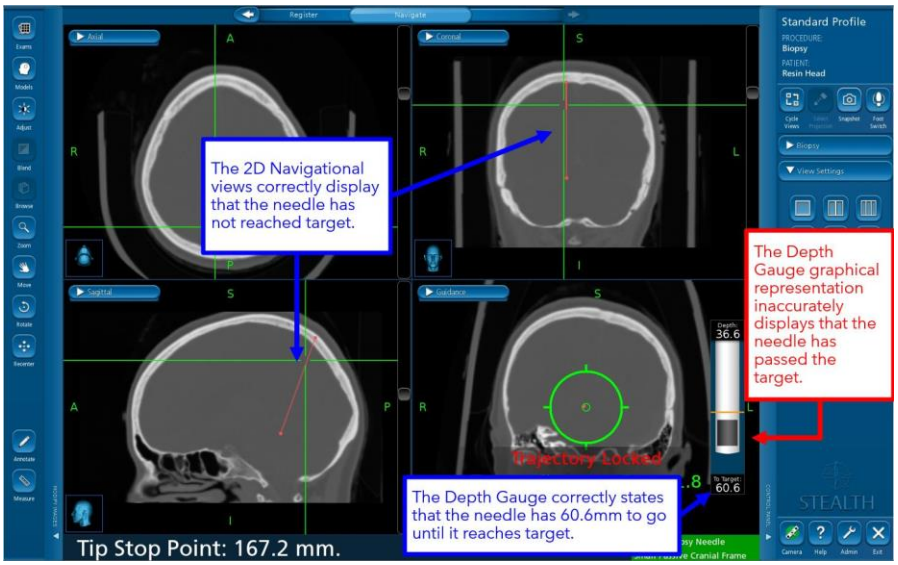
The purpose of this letter is to provide information related to potential inaccuracy during biopsy procedures using the StealthStation™ S7 and i7 Biopsy Depth Gauge feature. This correction applies to all StealthStation™ S7 and i7 systems running Synergy Cranial Version 2.2.8 and StealthStation™ Cranial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

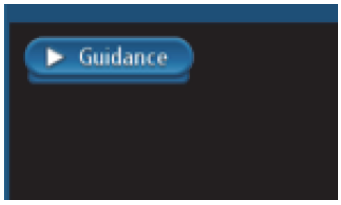
Medtronic will provide a warning and instructional placard to be applied to impacted systems to maintain visibility to the mitigations until a software fix is available.

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:**

1) Please review this information with all physician users. If you have any questions related to this issue, please contact your local Medtronic representative.
2) 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 or hand the completed Customer Confirmation Form to your local Medtronic representative.
3) Please maintain a copy of this notice in your records

**Additional Information:**

Medtronic is communicating this information to the appropriate regulatory agencies. Adverse events or quality problems experienced with this product should be reported to your local Medtronic representative.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. Please use contact information provided if you have any questions regarding this communication.

Sincerely,

**Diana Teo**
Medtronic QRA Lead
Singapore and Malaysia

**Chloe Tan**
Medtronic QRA Lead
Indochina and Frontier Market Plus

**Parichart Bunjobchokchai**
Medtronic QRA Lead
Thailand