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URGENT: Medical Device Correction

StealthStation™ S7/i7 Cranial Software v3.1.1, 3.1.2, and 3.1.3

Biopsy Depth Gauge Cycle View Inaccuracy

Software Update Fix Availability - Follow-up Communication

18 December 2023 | 19:24 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Healthcare Professional:

This letter is to inform you that Medtronic has made available the new Cranial Software (9735585), Version 3.1.5 to correct the potential for inaccuracy during biopsy procedures using the StealthStation™ S7 and i7 Biopsy Depth Gauge feature. Information within this correction follow-up communication applies to all StealthStation™ Cranial Versions 3.1.1-3.1.3 software versions. 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 November 2021, Medtronic initially notified customers of a complaint 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.

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In April 2023, Medtronic sent a follow up letter informing customers of a new software anomaly identified in the StealthStation Cranial model 9735585 version 3.1.4 software correction. This software version 3.1.4 was intended to address the Biopsy Depth Gauge Cycle View Inaccuracy impacting the StealthStation™ Cranial Version 3.1.1, 3.1.2, and 3.1.3 software. Synergy™ Cranial model 9733763 version 2.2.9 was unaffected, and installation of this software version 2.2.9. continued. Installation StealthStation Cranial model 9735585 version 3.1.4 was discontinued.

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 3.1.1, 3.1.2, and 3.1.3, 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 maintained the numerical values of Depth and To Target.

As of November 2023, Medtronic has received 4 customer complaints worldwide. To date, Medtronic has not received any reports of patient harm attributed to this issue.

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 Customer 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), 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. To acknowledge the receipt of this information, please complete and return the customer confirmation form enclosed with this letter within 30 days of receipt. Hand or scan then email back the completed form to your local Medtronic Field Representatives.
4. Please maintain a copy of all records associated with this action.

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Additional Information:

Medtronic is communicating this information to the appropriate regulatory agencies.

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 local Medtronic Field Representative.

Sincerely,

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 18 December 2023 | 19:23 SGT
90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director
Mainland and Island Southeast Asia

Medtronic

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Customer Confirmation Form

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

Customer Contact Details		Medtronic Contact Details
Distributor / Hospital / Clinic / Physician / Patient name:		**Name:**
		Contact:
Address:		**Email:**
Phone no:	**Email:**	

This correction applies to all StealthStation™ S7 and i7 systems running the StealthStation™ Cranial Versions 3.1.1-3.1.3 software. The StealthStation™ Cranial model 9735585 software is being updated to version 3.1.5.

By signing this form, I confirm that:

- I have received and read the medical device correction notification, dated 18 December 2023 | 19:24 SGT, from Medtronic regarding the 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 StealthStation™ Cranial Versions 3.1.1-3.1.3 software discs in my possession.

Please complete and sign the form as indicated below and submit to your local Medtronic Field Representative within 30 days of receipt. For questions, contact your local Medtronic Sales Representative.

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Medtronic requests the signature below to be from **one** of the following roles:

Requested role for customer signature (**One signature required)**					
Head or Director of Neurosurgery	Operating Room Director or Manager	Neurosurgical Coordinator	Medical Director	Perioperative Manager	Department manager responsible for communicating recall information to physicians

Customer Name (Print): _____ Date: _____
(First Name, Last Name)

Customer Title (Print): _____

Customer Signature (ink): _____

Telephone: _____

Email: _____

Comments: _____

Note: Reminders of this notice may continue to be sent until a response is received