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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

Software Update

December 2023

Medtronic Reference: FA1204

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

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.

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.

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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 Medtronic field representative.
2. Please confirm via the enclosed Customer Acknowledgment 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. Send the completed Customer Acknowledgment Form to Medtronic via **rs.duregulatory@medtronic.com**.
3. 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 Field Representative.

Sincerely,
Medtronic GmbH