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Urgent Field Safety Notice

StealthStation™ S8 App version 2.0 and 2.0.1 (Model # 9735762)

StealthStation™ S8 and StealthStation FlexENT™ Software Plan Data Shift
with New Reference Exam

Software Update

January 2024

Medtronic Reference: FA1361
EU Manufacturer Single Registration Number (SRN): US-MF-000023263

Dear Healthcare Professional:

The purpose of this letter is to notify you that the Software update to address the Software Plan Data Shift with New Reference Exam issue is now available. Your Medtronic representative will be performing this software update on your impacted StealthStation™ S8 and StealthStation FlexENT™ system(s) in the coming months. If a warning and instructional placard was placed on your system, your Medtronic representative will remove the placard once the software update is complete. As a reference, the below information was previously shared with you, refer to the September 2023 Field Safety Notice for additional details.

The details contained in this communication pertain to all StealthStation™ S8 and FlexENT™ systems utilizing the StealthStation™ S8 App software version 2.0 and 2.0.1 (please consult the table below for more details on affected products). In certain situations, this anomaly could lead to incorrect planning data displayed during surgical procedures. Our records indicate that you might have one or more systems installed with a version of the software that is impacted by this issue.

Issue Description:

Medtronic has identified a software anomaly in StealthStation™ S8 Software App versions 2.0 and 2.0.1 that can occur within a Cranial (including DBS and Stereotaxy) or ENT procedure type, while merging exams with StealthMerge™ or StealthMerge™ ENT software, under the following specific clinical workflow scenarios:

1. The navigation reference exam is merged with either a diffusion series (for tractography processing) or a pre-merge type series (an exam that does not contain anatomical information that must already be aligned or pre-merged to the anatomy in the reference exam - examples are a functional MRI activation map overlay or a PET exam).
2. Surgical planning data (surgical plans, annotations, or AC-PC data) are defined on the reference exam merged with Pre-Merge type or Diffusion exams.
3. The reference exam is changed to a different exam at a later point after initial planning is completed.

If all three of the scenarios above occur, the surgical planning data may shift to an unintended location.

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Note: This anomaly only impacts situations where the surgical planning data is displayed, there is no impact on the accuracy of the anatomical navigation information. There is no impact on tractography data (fiber tracts). Additionally, if diffusion merge or pre-merge is not utilized, "Auto-merge" is not impacted.

As of 03-Jan-2024, Medtronic has received five (5) complaints confirmed to be directly related to the plan moving or shifting after changing the reference exam. None of the complaints reported serious patient injury.

Product Scope:

Navigation System	Software Name	Model#/CFN	Version
StealthStation™ S8 and FlexENT™	SW APP 9735762 STEALTH S8 APP	9735762	2.0 and 2.0.1

Required Actions:

1. Please review this information, with all physician users. Refer to the September 2023 Field Safety Notice for additional details if needed. If you have any questions related to this issue, please contact your Medtronic representative.
    a. Do not remove the warning and instructional placard. A Medtronic Representative will remove the warning and instructional placard when the software is updated.
2. Please complete and return the customer acknowledgment form enclosed with this letter acknowledging receipt of this information.
3. This notice needs to be passed on to those who need to be aware 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 or via Tel. No: 01 511 1400.

Sincerely,

N Mthethwa

Natasha Mthethwa

Senior Regulatory Affairs Specialist

Enclosed:
- September 2023 Field Safety Notice