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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 Notification and warning & instructional placard placement

September 2023

Medtronic Reference: FA1361

<For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000023263>

Dear Healthcare Professional:

This notice communicates the steps Medtronic is taking to address a software anomaly affecting certain StealthStation™ S8 and StealthStation FlexENT™ systems. In certain situations, this anomaly could lead to incorrect planning data displayed during surgical procedures. 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 provided table for more details on affected products). 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.

Refer to **Appendix A** to determine if your StealthStation™ S8 or StealthStation™ FlexENT system is impacted and for further details into the impacted clinical workflow.

Medtronic is currently working on a StealthStation™ S8 Application software version 2.1 update that will resolve the issues above and we will communicate additional information when it becomes available.

Potential Health Hazard:

If the user encounters the software anomaly and proceeds with (navigation or electrode placement) based on the displayed shifted surgical planning data, there is the potential of proceeding to an incorrect location from the planned target. This could result in unintended tissue damage leading to permanent neurological injury, additional pass of device (biopsy needle or electrode), prolonged procedure or need for additional surgery.

As of 22-Aug-2023, Medtronic has received three (3) 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. Follow the below instructions and refer to **Appendix A** for full details on impacted systems, issues and mitigations:
    a. Do not change the reference exam in Cranial or ENT procedures, if the surgical planning data is defined on a reference exam merged with pre-merge type or diffusion series.
2. Please review this information, including the additional details in **Appendix A**, with all physician users. If you have any questions related to this issue, please contact your Medtronic field representative
3. <Please confirm via the enclosed confirmation form:
    a. Which software version (1.3.2 or lower, 2.0 or higher) you have,

   b. That you understand Medtronic will provide a warning and instructional placard, detailing the mitigations included in **Appendix A,** to be applied to impacted StealthStation™ S8 and FlexENT™ Systems (v2.0 or higher),
   c. That this notification has been communicated within your facility with all physician users.

   Send the completed Customer Confirmation Form to Medtronic via <rs.ranordic@medtronic.com>
4. <A Medtronic Representative will attach a warning and instructional placard to your impacted StealthStation System.>
5. 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.

Sincerely,

Local / BU Manager

Enclosures:

- Appendix A

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Appendix A

StealthStation™ S8 Software version 2.0 and 2.0.1

StealthStation™ S8 and StealthStation FlexENT™ Software Plan Shift with new Reference Exam

Cranial and ENT Procedures

Medtronic has received three complaints reporting that during a cranial procedure, the user encountered an anomaly with the surgical plan shifting in the software. Investigation of the complaints determined that in the Cranial or ENT procedure type, when the original reference exam includes a pre-merge or a diffusion-merge, and the reference exam is changed, the internal software calculations based on the new reference exam coordinate system are calculated incorrectly. This may cause specific surgical plan data (surgical plans, annotations, or AC-PC data) to be in an incorrect location. All other information on the screen remains accurate.

Applicable Clinical Software and Licenses:

This anomaly occurs within the StealthStation™ S8 Application version 2.0 or 2.0.1, however in order for this anomaly to occur clinically, the StealthStation™ S8 must also have specific procedures (Cranial or ENT) and feature licenses (StealthMerge) installed. **Figure 1** includes the details of these procedures and licenses.

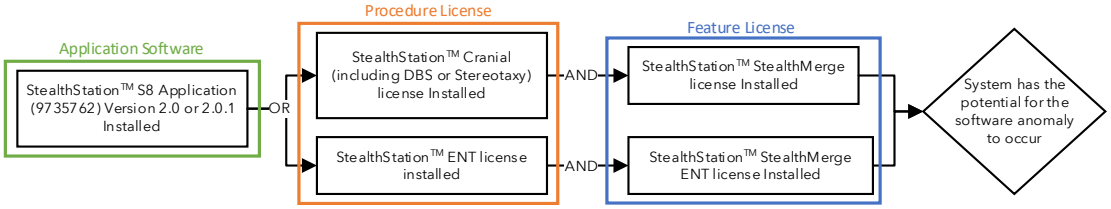

***Figure 1**. Software version and licenses*

Note: To check the application software version and license(s), open the "About this Stealth" page, see **Figure 2** for the location of this information.

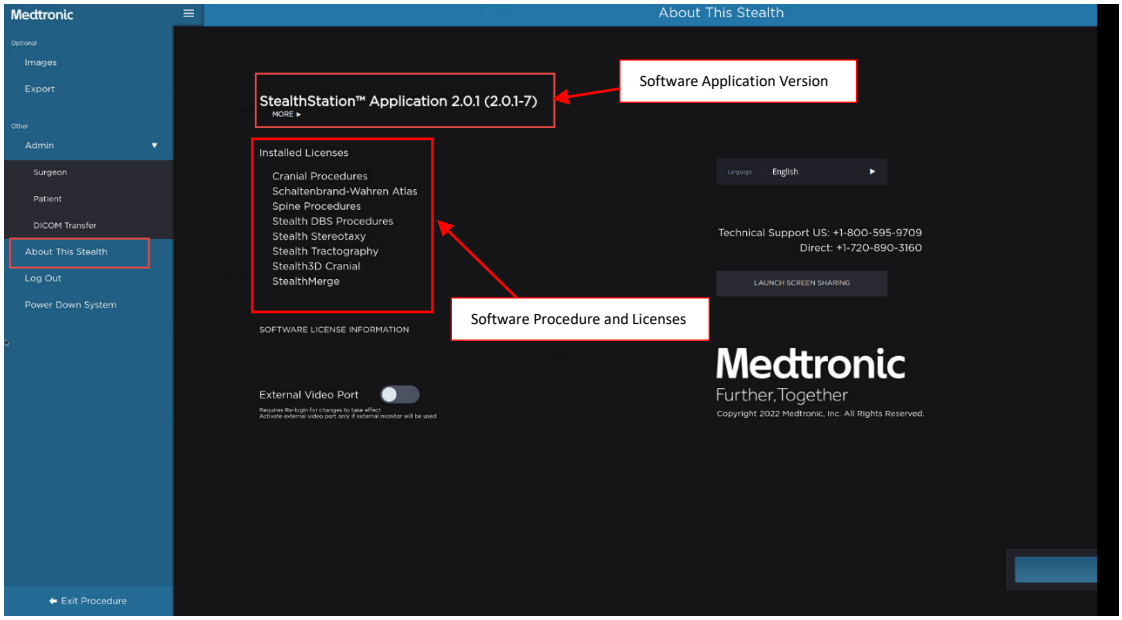

***Figure 2**. System page for Software Version and License*

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Clinical Workflow to create anomaly:

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).

   Note: The icon link in **Figure 3**, below indicates the use of pre-merge or diffusion merge. Merged images without this icon link is not impacted by this anomaly.

***Figure** 3. Pre-Merge/Diffusion Merge with Reference*

2. Surgical planning data (surgical plans, annotations, or AC-PC data) is established based on the reference exam with the Pre-Merge or Diffusion Merge exams.
3. The reference exam is changed to a different exam as seen in **Figure 4**, below.

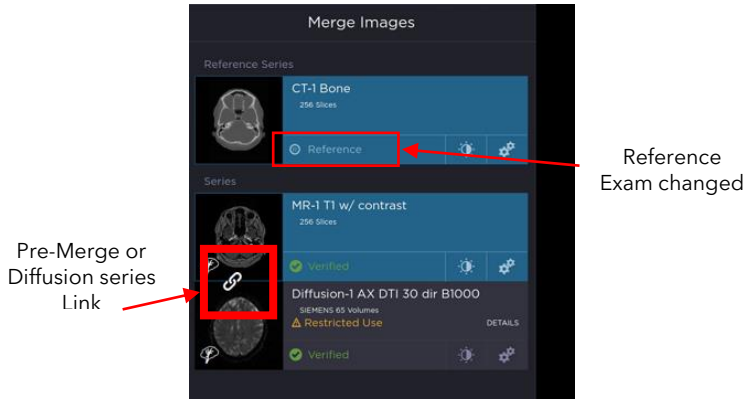

***Figure 4**. Pre-Merge/Diffusion Merge with changed Reference*

Mitigations:

Medtronic recommends that users do not change the reference exam after establishing a surgical plan if the original reference exam included pre-merge or diffusion merge exam. The incorrect surgical plan data **cannot** be recovered by reverting to the original reference exam. To resolve this issue, the user must manually update the existing plans to the original locations or make new plans.

In accordance with the IFU: Verify that a plan's target point, entry point, and trajectory are clinically valid before using it for a procedure. Traverse the surgical plan to check the entry, target, and trajectory after any edit.