

URGENT: MEDICAL DEVICE CORRECTION

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

26 September 2023 | 20:27 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

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.

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 local 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.Hand or scan then send back the completed Customer Confirmation Form to your local Medtronic field representative.
4. 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 is communicating this information to the appropriate regulatory agencies. Adverse reactions 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. 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: 26 September 2023 | 20:27 SGT
90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director
Mainland and Island Southeast Asia



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.

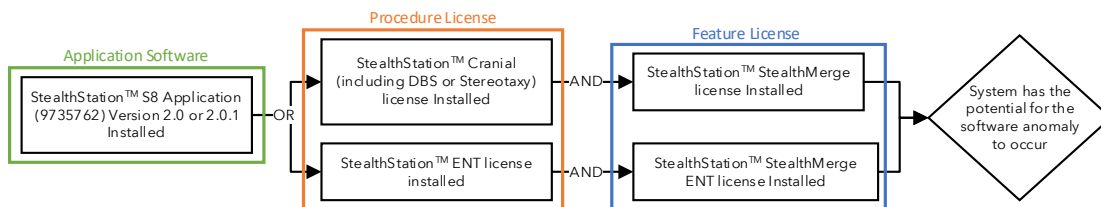


Figure 1. Software version and licenses

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.

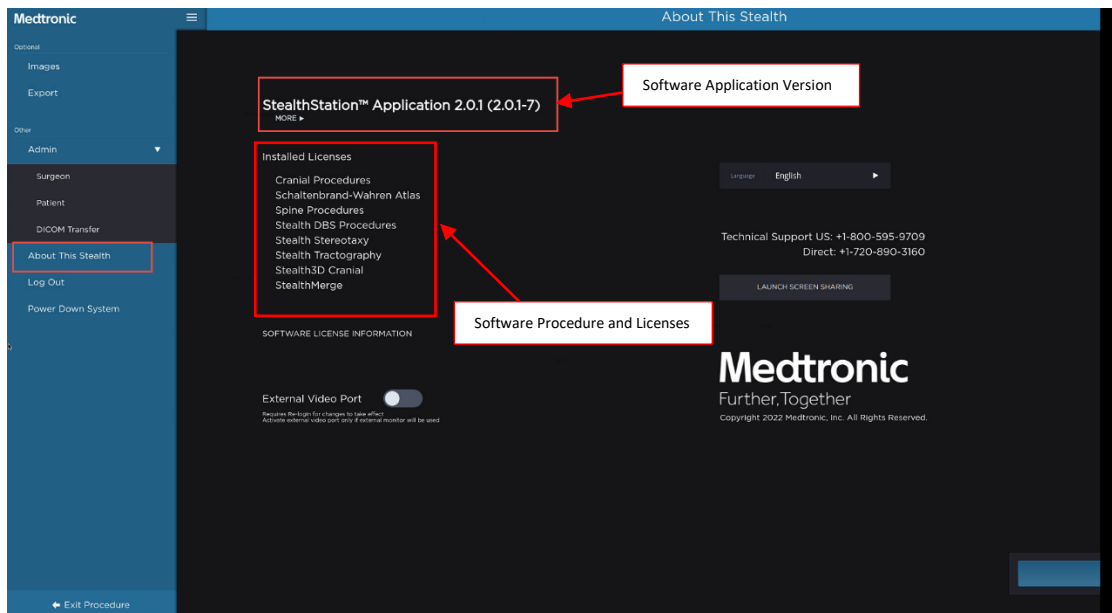


Figure 2. System page for Software Version and License

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.

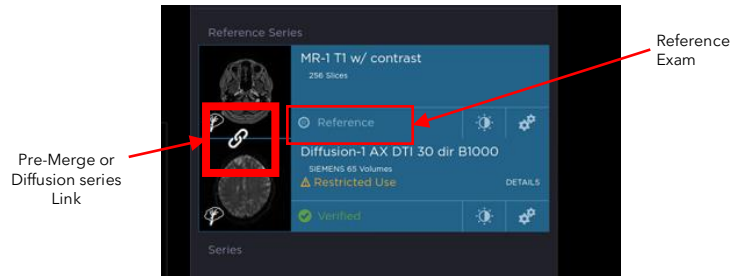


Figure 3. Pre-Merge/Diffusion Merge with Reference

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.

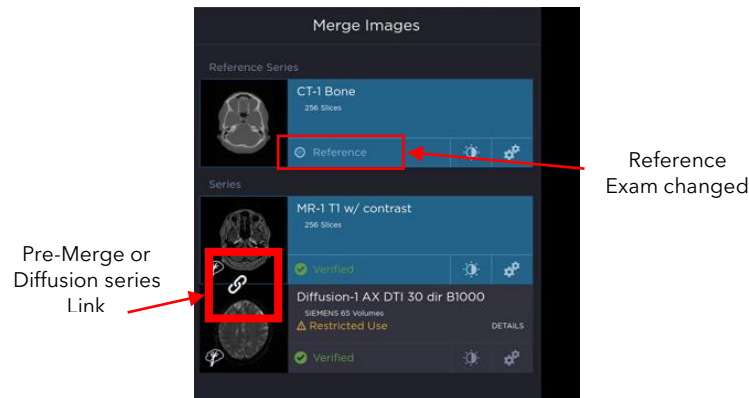


Figure 4. Pre-Merge/Diffusion Merge with changed Reference

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.

Customer Confirmation Form

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

Affected Product

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

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/Patient name:		Name:	
		Contact:	
Address:		Email:	
Phone no:	Email:		

Select the applicable box(es) below and complete and sign the area at the bottom of this form.

By signing this form, I confirm that:

- I have reviewed the information included in this notification and have informed all users of the StealthStation™ S8 and FlexENT™ system, including all physician users.
- The Warning and Instructional Placard was placed on affected StealthStation™ S8 and FlexENT™ systems with software version 2.0 or 2.0.1 according to the provided Installation Instructions.

Please populate the table below to indicate the software version for each StealthStation™ S8 and FlexENT™ system. Identify which system(s) have a laminated Warning and Instructional Placard attached.

System Serial Number	Software Version	Warning and Instructional Placard Attached (To be completed if your system has software version 2.0 or higher)
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic representative.

For any questions or assistance, please contact your local Medtronic Field Representative.

Name (print): _____ Signature: _____ Stamp: _____ Date:

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yyyy			

Note: The addressee may continue to receive reminders of this notice until a response is received.

Use this page *****ONLY IF***** the space in the previous page is not enough.

Fill out the previous table first and list the remaining in this page.

This page must also be signed and dated.

System Serial Number	Software Version	Warning and Instructional Placard Attached (To be completed if your system has software version 2.0 or higher)
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:
	<input type="checkbox"/> 1.3.2 or lower	n/a
	<input type="checkbox"/> 2.0 or higher	<input type="checkbox"/> YES <input type="checkbox"/> NO, Rationale:

Name (print): _____ Signature: _____ Stamp: _____ Date:

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