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Urgent Field Safety Notice
StealthStation™ S8 App versions 1.0.1, 1.0.2, 1.0.3, 1.1.0, 1.2.0 (Model # 9735762)
StealthStation™ S8 Application – Missing Character in Banner Text
Software Update

April 2024

Medtronic Reference: FA1414

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

Dear Healthcare Professional:

This notice alerts you to an issue associated with the StealthStation™ S8 Application, and specifically the display that shows the "distance to target" or "tip stop point" measurements. There is the potential for a missing digit, letter, or decimal in either the "distance to target" or "tip stop point" display during navigation. In certain situations, this anomaly could lead to incorrect data being displayed during surgical procedures. StealthStation™ S8 Application software versions 1.0.1, 1.0.2, 1.0.3, 1.1.0, 1.2.0 are affected. Customers with software version 1.3.0 or later are not impacted by this issue.   Medtronic has a software update that corrects this issue, and we will be working to deploy that update to any impacted StealthStation S8 systems.

Issue Description:

The StealthStation S8 Application is used to help guide surgeons in surgically navigated procedures. A software anomaly present in certain software versions can cause a digit or letter to be replaced by a blank space. The symptoms of the missing character anomaly can appear in two different large text fields (sometimes referred to as 'banners') in the software and could occur in cranial procedure types. Reference Appendix A for images that illustrate the missing character.

<u>Distance to Target</u>:
- o   This anomaly can affect the "Distance to Target" messaging in the "1-up Guidance View". In this instance, the anomaly is expected to be transient, as the messaging updates as the instrument moves during live navigation.

<u>Tip Stop Point</u>:
- o   The "Tip Stop Point" number is seen by the surgeon following the completion of the plan. This number tells the surgeon how far to measure the mechanical depth stop on the biopsy needle. If a surgeon did not notice the error and the biopsy needle depth stop was set incorrectly, it could potentially result in a biopsy outside of the intended target location.   However, live navigation to the target is accurately displayed by the system even in cases where this anomaly presents.

If this anomaly occurs, the user should log out of the software and log back in to display the accurate "**Distance to Target"** or "**Tip Stop Point"** value. A software update is available and resolves the issue so that this error will not occur. Your Medtronic representative will be contacting your facility to schedule time to perform a software update to your StealthStation S8 system and install an updated software version that resolves this anomaly.

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Potential Health Hazard:

Medtronic has not received any report of patient injury as a result of these software anomalies but has received confirmed complaints as outlined below. Medtronic is alerting customers of the potential risk that, if a clinician encounters the software anomaly and proceeds based on the incorrect, displayed information, there is the potential of setting the biopsy depth stop to an incorrect distance which could result in a permanent impairment (e.g. nerve damage, neurological deficit, paralysis).

As of March 25, 2024, Medtronic has received twenty-seven (27) complaints confirmed to be related to this anomaly. In these complaints, the anomaly was identified and resulted in a brief delay of procedure without report of serious patient injury.

Product Scope:

Navigation System	Software Name	Model#/CFN	Version
StealthStation™ S8 Application	SW APP 9735762 STEALTH S8 APP	9735762	1.0.1, 1.0.2, 1.0.3, 1.1.0, 1.2.0

Required Actions:

1. Please review this information with all physician users. If you have any questions related to this issue, please contact your Medtronic Representative.
2. 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.

Medtronic Actions:

Medtronic will contact your facility to schedule time to perform a software update that will resolve this anomaly.

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 Representative.

Sincerely,

Local / BU Manager

Enclosed:
Appendix A – Images that illustrate the missing character

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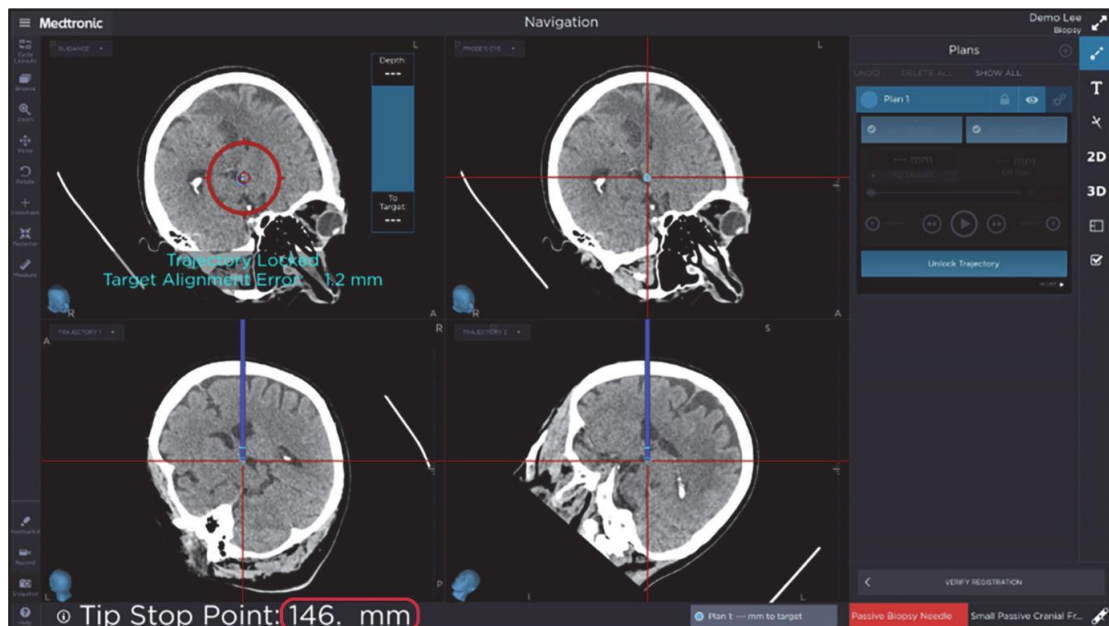**Appendix A – Images that illustrate the missing character**

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Example Images of Anomaly

Distance to Target value with missing character

Tip Stop Point value with missing character