

**Urgent Field Safety Notice**  
**StealthStation™ Cranial and Synergy™ Cranial**  
Depth Gauge Inaccuracy

March 2019

Medtronic reference: FA848 Phase II

Dear Healthcare Professional,

In October 2018, Medtronic notified customers of a software error present in the StealthStation™ S7 and StealthStation™ i7 Synergy™ Cranial Software which could lead to inaccurate placement of a biopsy needle. As a follow up, this letter is intended to provide further information on the issue including additional actions that Medtronic is taking.

**Additional Actions and Information**

Medtronic has committed to the following two (2) additional actions:

- Update the software to correct this error. Your local Medtronic representative will inform you when this software release is available to install on your system.
- Attach a laminated card to the handle of your StealthStation™ S7 until the updated software is installed to ensure you have the information you need to safely use your system and avoid this potential risk. You may continue to use your device at your clinical discretion, but please be aware of this issue, risks, and the mitigations listed below to eliminate the risks.

**Scope and Likelihood of Issue**

In order for this software error to occur, ALL of the following must happen:

- The biopsy needle mechanical depth stop on any manufacturers needle is not used,
- The projection is set longer than the plan,
- The projection is navigated when locking the trajectory, AND
- The graphical representation in the Biopsy Depth Gauge feature is only viewed without viewing the navigated views and the overlay of the biopsy needle.

If performed, these actions will cause the Biopsy Depth Gauge graphical display inaccurately depicting the tip of the instrument. The instrument will appear to not have reached the plan target and could cause the biopsy needle to be inserted too deeply, resulting in potential biopsy of healthy tissue or damage to critical structures.

This error is present in StealthStation™ S7 Synergy™ Cranial Software versions 2.2.0, 2.2.5, 2.2.6, and 2.2.7, and in StealthStation™ Cranial Software versions 3.0.0, 3.0.1, 3.0.2 and 3.1.0. The likelihood of occurrence is low, and the confirmed occurrence rate is 0.018% worldwide. Since 2011, Medtronic has received 32 potential complaints (total potential occurrence rate is 0.074%),

including eight (8) confirmed complaints related to this software error, one (1) in which healthy tissue was biopsied. 19 additional harms which are likely not related, but could not be excluded based upon available information, involved the sampling of healthy tissue, additional passes of the biopsy needle, additional surgery or a transition to open biopsy. There have been no reported patient deaths.

## Mitigations to Eliminate this Risk

- Per the Cranial Software Pocket Guide, always use the Biopsy Needle Mechanical Depth Stop.
- Do not set a projection longer than the length of the surgical plan.
- Ensure Navigate Instrument Tip setting is selected prior to locking the trajectory and subsequently navigating the instrument (see graphic on right).



## Regulatory Reporting

The Competent Authority of your country has been notified 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 at <XXXXXX>.

Sincerely,

## **Urgent Field Safety Notice**

### **StealthStation™ Cranial and Synergy™ Cranial**

#### **Depth Gauge Inaccuracy**

October 2018

Medtronic reference: FA848

Dear Healthcare Professional,

The purpose of this letter is to provide information related to potential inaccuracy during biopsy procedures using the StealthStation™ S7 Depth Gauge feature. This information is intended to supplement the StealthStation™ S7 and StealthStation™ i7 Cranial Software Guides. This correction applies to all StealthStation™ S7 and i7 systems running Synergy™ Cranial and StealthStation™ Cranial software. Our records indicate that you may have one or more systems installed with an affected version of the software.

#### **Issue Description:**

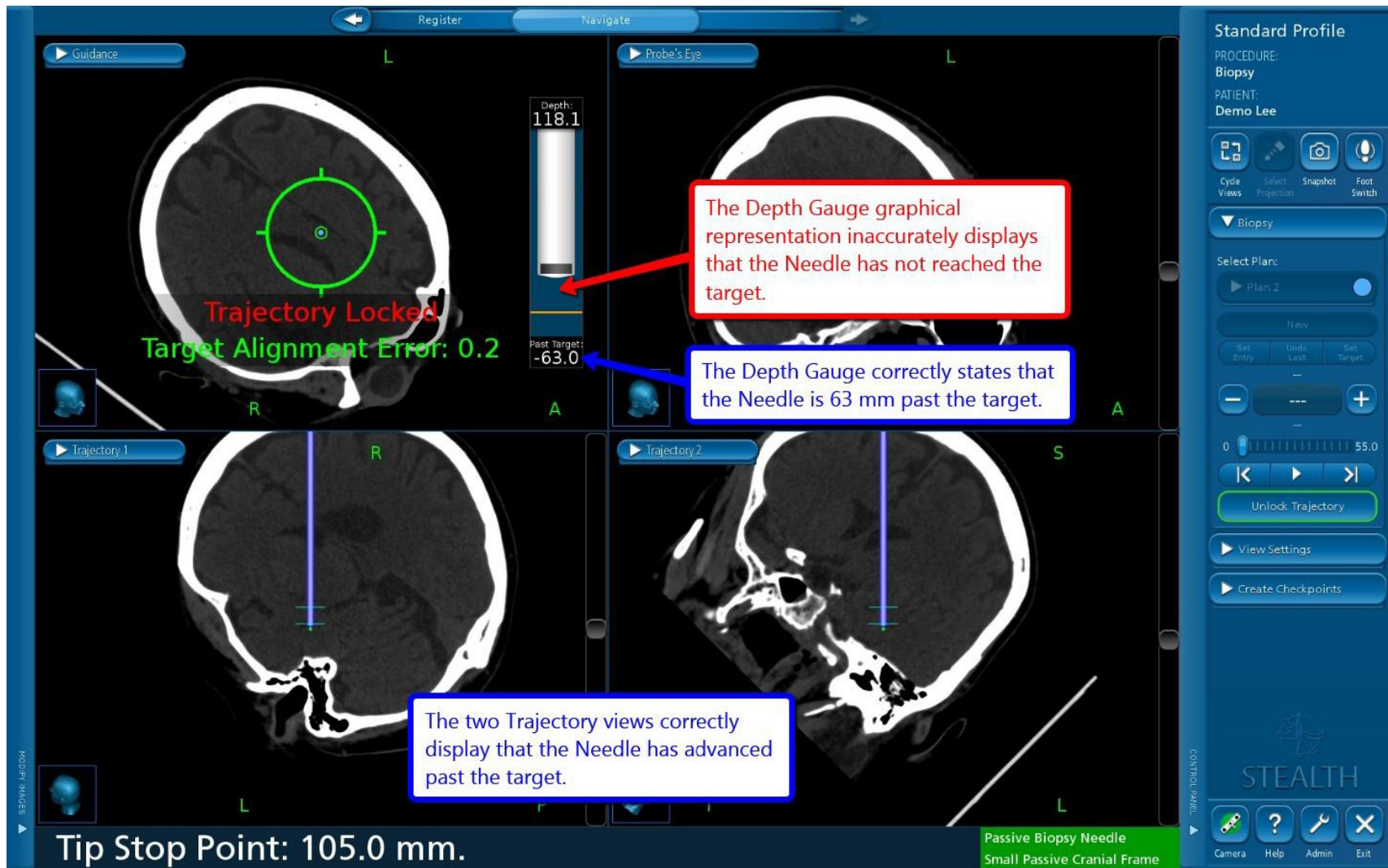
In navigated biopsy procedures, where the "Navigate Projection" feature is used and the projection is longer than the length of the plan, the graphical Biopsy Depth Gauge feature can display inaccurate information. The Biopsy Needle Depth Gauge is a numerical and graphical representation of the needle cutting window in the Guidance view quadrant to assist in visualization of the cutting window position.

During a biopsy procedure, the monitor shows four quadrants (Trajectory 1, Trajectory 2, Guidance, and Probe's Eye views) as well as the Biopsy Depth Gauge. The overlay of the Biopsy Needle within the anatomical views accurately indicates the correct tip location of the instrument. However, if "Navigate Projection" is selected, and the projection is longer than the length of the plan, then the Biopsy Depth Gauge graphical display inaccurately depicts that the tip of the instrument has not yet reached the plan target. Since 2011, Medtronic has received seven (7) complaints potentially related to this software anomaly, one in which healthy tissue was biopsied.

The image on page two contains an example of the error use case. All views correctly show that the instrument is past the target, and the Depth Gauge correctly displays the past-target measurement of -63, which indicates the instrument tip has advanced 63 mm beyond the intended target. However, the graphical Biopsy Needle cut window appears not to have advanced to the target position.

If the surgical team relies solely on the graphical representation in the Biopsy Depth Gauge feature and disregards other factors (such as setting the Mechanical Depth Stop on the Biopsy Needle to the indicated length, using the correct display within the Trajectory views, and using the 'distance to target' values within the anatomical views), the Biopsy Needle could be inserted too deeply, resulting in potential biopsy of healthy brain tissue or damage to critical structures.

Medtronic is working to ensure all impacted customers are fully aware of the risk and associated mitigations.



The Depth Gauge graphical representation inaccurately displays that the Needle has not reached the target.

The Depth Gauge correctly states that the Needle is 63 mm past the target.

The two Trajectory views correctly display that the Needle has advanced past the target.

**Mitigations to Eliminate this Risk:**

- Do not set a projection longer than the length of the surgical plan.
- Per the Cranial Software Pocket Guide, always use the Biopsy Needle Mechanical Depth Stop.
- Ensure *Navigate Instrument Tip* setting is selected prior to locking the trajectory and subsequently navigating the instrument (see image below).

**Requested Action:**

Please review this information with all physician users.

The Competent Authority of your country has been notified 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 at <XXXXX>.

Sincerely,