Medtronic

49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

tel +65 6436 5000
fax +65 6776 6355

URGENT: MEDICAL DEVICE CORRECTION

StealthStation™ Cranial and Synergy™ Cranial Depth Gauge Inaccuracy

29 October 2018

Attention: Risk management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

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:

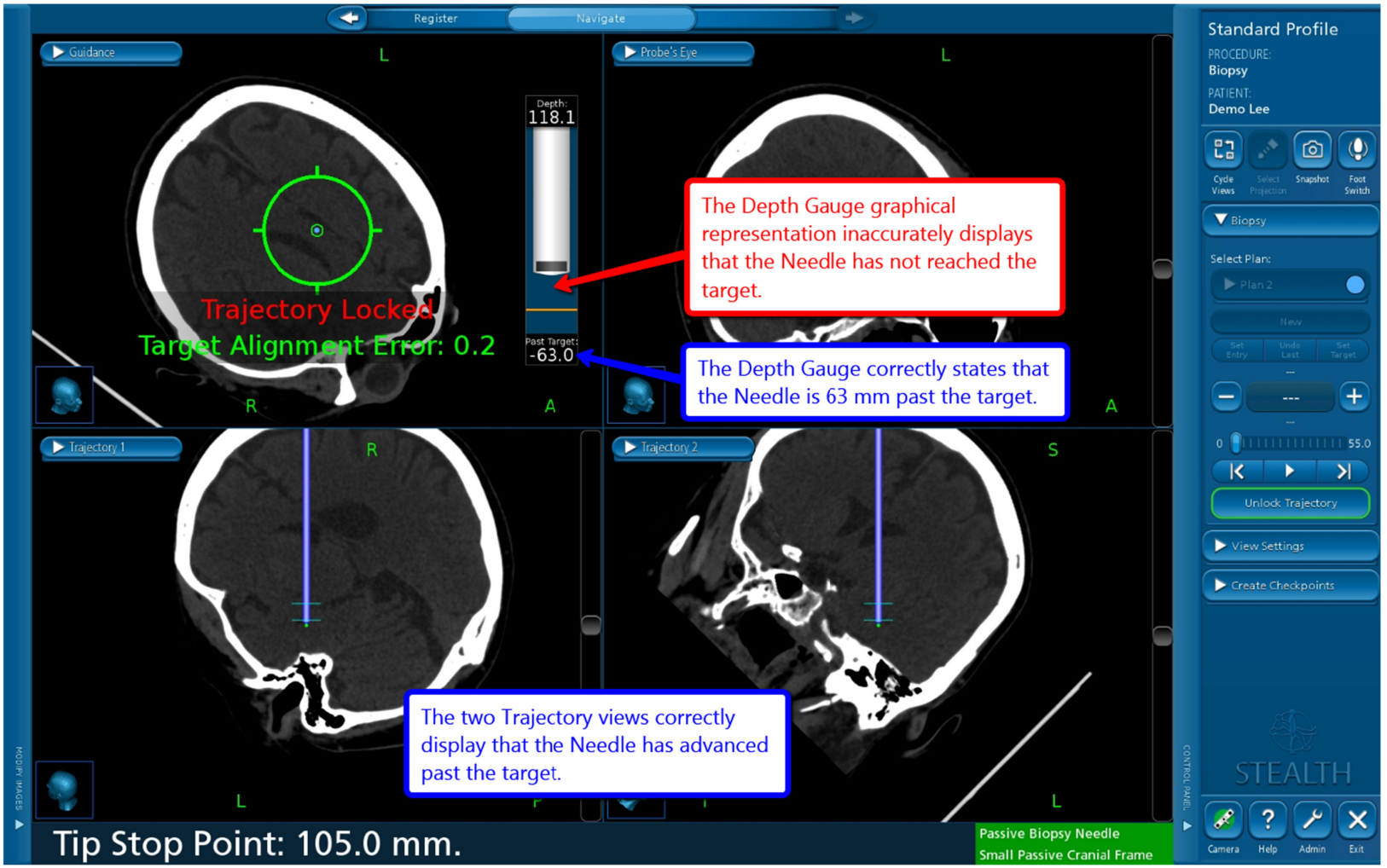
In navigated biopsy procedures, where the "Navigate Projection" feature is used and the projection is longer than the length of the plan, the graphical Biopsy Depth Gauge feature can display inaccurate information. The Biopsy Needle Depth Gauge is a numerical and graphical representation of the needle 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 theTrajectory 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 takes the potential risk seriously and is working to ensure all Medtronic customers are fully aware of the risk and associated mitigations.


Register
Navigate
Guidance
Probe's Eye
Depth:
118.1
Trajectory Locked
Target Alignment Error: 0.2
Past Target:
-63.0
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.
Trajectory 1
Trajectory 2
The two Trajectory views correctly display that the Needle has advanced past the target.
Tip Stop Point: 105.0 mm.
Passive Biopsy Needle
Small Passive Cranial Frame
Standard Profile
PROCEDURE:
Biopsy
PATIENT:
Demo Lee
Cycle Views
Select Projection
Snapshot
Foot Switch
Biopsy
Select Plan:
Plan 2
New
Set Entry
Undo Last
Set Target
55.0
Unlock Trajectory
View Settings
Create Checkpoints
STEALTH
Camera
Help
Admin
Exit
MODIFY IMAGES
CONTROL PANEL

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:

1) Please read and acknowledge the below customer confirmation form that is attached below.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this Field Action, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

[redacted]

Diana Teo
Quality Management System Manager
South East Asia
Medtronic

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Customer Corrective Action Confirmation Form
StealthStation™ Cranial and Synergy™ Cranial Depth Gauge Inaccuracy

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
	Name:
Hospital :	**Contact:**
Address:	**Email:**
Phone no:	
E-mail:	

Serial # of StealthStation S7 or i7 systems	Qty On-hand	Address of the facility if moved to another place

By signing this form, I confirm that I have read and understand the **URGENT: MEDICAL DEVICE CORRECTION StealthStation™ Cranial and Synergy™ Cranial Depth Gauge Inaccuracy**. I will also communicate this information with all users of the StealthStation™ S7 or i7 systems, including all physician users within the organization as required.

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