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Urgent Field Safety Notice

StealthStation™ DBS Software Auto-Registration Potential Inaccuracy

Customer notification

August 2019

Medtronic reference: FA884

Dear Healthcare Professional,

Medtronic has received reports of entry point and lead placement inaccuracies during Deep Brain Stimulation (DBS) lead implantation procedures when using the Nexframe™ Stereotactic System (Nexframe) and the StealthStation™ autoregistration feature with the O-arm™ Imaging System. This letter is to inform you of the potential of this type of inaccuracy and to recommend actions that may prevent it from occurring.

Issue Background and Summary:
Medtronic has received reports of entry point and lead placement inaccuracies during Deep Brain Stimulation (DBS) lead implantation procedures using Nexframe and the StealthStation auto-registration feature with the O-arm Imaging System (also known as a "fiducial-less" procedure). Deep Brain Stimulation (DBS) lead implantation procedures using Nexframe and the auto-registration feature with the O-arm Imaging System are characterized as not having implanted bone fiducials and not having rigid head fixation (the patient's head is not pinned), which can lead to undetected patient motion during the O-arm registration scan.
Investigation has shown that minor patient movement may not be initially detected by the user or the software during the O-arm auto-registration scan and could have caused the observed inaccuracies. Potential sources of movement may include: respiration motion, tremor, or other voluntary/involuntary motion. The undetected movement could lead to risks for the patient, including: inaccurate lead placement, delay of surgery, aborted surgery, or additional intervention (including revision of the lead placement and subsequent imaging). Between January 2016 and May 2019, Medtronic is aware of twenty-eight (28) events potentially related to this issue. Seven (7) of these events resulted in an additional pass of the lead, and one (1) event required a subsequent surgery to resolve symptomatic dysarthria. There were no reports of long-term neurological impact in any of the events.

Scope:
The following Medtronic products must be used in combination during a DBS procedure for this issue to occur:

- Nexframe Stereotactic System AND
- StealthStation Cranial software version 3.0 or newer with StealthStation DBS License or StealthStation S8 Software with Stealth DBS License AND
- O-arm Imaging System utilizing the auto-registration (fiducial-less) workflow

The following procedures are NOT affected:

- Procedures using StealthStation with Stereotactic frames other than Nexframe
- Nexframe DBS procedures using manual registration (also known as a "fiducial-based" procedure)
- Other procedure types (Spinal Fusion, Cranial Resection) which utilize O-arm auto-registration

Recommended Actions:
Although there are benefits to the use of auto-registration (fiducial-less), as a healthcare professional, you must determine which registration method is appropriate at your clinical discretion, considering the information disclosed in this letter. When using auto-registration, Medtronic recommends minimizing the sources of patient motion during registration and considering the below methods that may aid in detecting and verifying registration accuracy.
Manual registration (fiducial-based) should be considered as an option, if clinically warranted, as an alternative patient registration method if the sources of patient motion (respiration motion, tremor, or other voluntary/involuntary motion) cannot be eliminated. Instructions for manual registration are found in the IFU[1].

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Recommended Tools for Confirming Registration Accuracy:

- Assess Navigational Accuracy
  - Verify the accuracy of the registration on several known anatomical landmarks, as described in the IFU[1], before using the registration for navigation.

Recommended Tools for Confirming Cannula or Lead Placement Accuracy:

- StealthMerge
  - Use the StealthMerge functionality in the software, as described in the IFU[1], to compare the actual location of the cannula or lead to the surgical plan.
- Surgical Plans
  - Use the planning functionality in the software, as described in the IFU[1], to compare the cannula to planned trajectory. This can be accomplished by making an additional plan along the axis of the cannula to evaluate cannula position.

Requested Actions:

- Neurosurgeon users: Medtronic is making training available to provide an overview of this issue. Please register for and complete training. A Medtronic representative will contact you shortly with available training dates.

The Competent Authority of your country has been notified of this action. Please share this notification with others in your organization as appropriate.

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, please contact your Medtronic Representative at 01923 212213.

Sincerely,

Samantha Baxter
Regulatory Affairs Manager
UK and Ireland