Restorative Therapies Group
Medtronic Navigation
300 Foster Street
Littleton, MA 01460

September 22, 2016

Customer Name
Number, Street,
City, State, Zipcode

URGENT Medical Device Safety Notice

O-arm™ O2 Surgical Imaging System navigation accuracy - Spatial calibration may be erroneous in StealthStation™ navigated images

Problem Description:

It has come to our attention that your O-arm™ O2 surgical imaging system (model number BI-700-02000) has an issue that can affect navigation accuracy when used with Medtronic's StealthStation™ surgical navigation systems. Specifically, navigation calibration data that is stored on the O-arm™ O2 imaging system is incorrect in systems that have had either software upgrades or software re-installs. Because of this, images that are acquired with the O-arm™ O2 and used for surgical navigation with Medtronic StealthStation™ may erroneously indicate the position of surgical instruments and/or implant devices with respect to patient anatomy. This issue only affects the use of the O-arm™ O2when used as part of a navigation solution to automatically register the anatomy.

Manual or image-based registration techniques are not affected. The O-arm™ O2 may still be used with these techniques as well as for general intraoperative imaging.

Required Actions:

Because of the potential for patient harm due to inaccurate placement of surgical tools and/or implanted devices, *Medtronic requests that you immediately discontinue the use of the O-arm™ O2 Surgical Imaging system for automatic registration in StealthStation™ navigated surgical procedures until further notice. Medtronic Service Personnel will contact you to inspect your device and perform any necessary required spatial calibration procedures before it can be returned to use for automatic registration with StealthStation™*. Your system can still be used for general imaging as well as manual or image-based registration.

Medtronic Response:

Your Service Representative will be contacting you shortly with further instructions. Until such time, please discontinue use of the system for automatic registration in navigated surgical procedures using StealthStation™.

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Your device will be inspected to insure that the proper spatial calibration data are in place in the system. Once the inspection and any necessary spatial calibrations have been performed, your system may be fully returned to use, including use of the system for automatic registration with StealthStation™ surgical navigation systems.

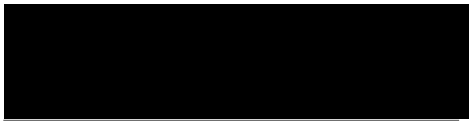
Additional Information:

We became aware of this issue via a complaint regarding a surgical complication. It was addressed during the procedure, which was reported as completed without further impact on the patient. Our investigation has determined that inspection and restoration of the calibration data addresses the issue. Systems that have not had software upgrades or re-installs are not affected.

O-arm 1000 surgical imaging systems are not affected by this issue.

Medtronic Navigation regrets this disruption and thanks you for your cooperation. We believe that patient safety is of the utmost importance and we are committed to addressing this issue quickly. Please do not hesitate to contact Medtronic Navigation Technical Support at 1-800-595-9709 if you have any questions or concerns regarding this matter.

Sincerely,



Paul Smolenski
Senior Regulatory Affairs Manager