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Urgent Field Safety Notice

O-arm™ O2 Imaging System

October 2018

Medtronic reference: FA846

Dear Customer,

The purpose of this letter is to inform you that Medtronic Navigation is initiating a field action to complete the following actions on O-arm™ O2 Imaging Systems ("O-arm O2"):

- Installing software ("SW") version 4.1.0
- Installing a new version of the user manual
- Installing component(s) of the new AC power input circuit for all serial numbers below C1434

Issue Description:

Medtronic released SW version 4.1.0, an updated user manual and a new design of the AC power input circuit within the Mobile View Station (MVS). These changes are part of our commitment to Quality and continuous improvement and includes changes made in response to customer complaints.

Software Version 4.1.0

This software update addresses several known software anomalies. The software anomalies were reported to affect the following system functionalities:

- Visual indicators
- Image acquisition/reconstruction
- Dose display/reporting
- Gantry motion
- Network and navigation system communication
- Navigational accuracy

Medtronic received complaints associated with these software anomalies that resulted in unused X-ray dose, delays in therapy (in all cases, of less than 1 hour), patient exposure to non-navigated surgery, and navigational inaccuracy. One (1) complaint resulted in injury that required medical intervention due to navigational inaccuracy.

SW version 4.1.0 was released in September 2018 and all O-arm O2 systems are impacted by the SW anomalies addressed by this change. In addition to anomalies, SW version 4.1.0 also includes expanded capabilities with angular annotation, improved visualization of metal, streamlined image transfer between systems and enhanced cybersecurity.

User Manual

The user manual was updated to include instructions on enhancements and new features associated with SW version 4.1.0, clarifications and updates in caution statements and warnings, including changes to address labeling requirements for the alignment and mouse lasers.

The update to the user manual was released with SW version 4.1.0 and all O-arm O2 systems are impacted by the changes made to the user manual.

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Mobile View Station Fuses

Medtronic received complaints associated with the MVS fuses within the AC power input circuit. Blown fuses can occur due to surges from being plugged in or due to line surges caused by other equipment on the same power line. Over the last three (3) years, sixteen (16) complaints resulted in delays in therapy and four (4) complaints resulted in patient exposure to non-navigated surgery. None of the reported complaints required medical intervention.

Until the system is equipped with the new design of the AC power input circuit, it is susceptible to blown fuses. O-arm O2 systems with serial numbers up to C1433 may be affected. O-arm O2 systems with serial numbers from C1434 already include the new design of the AC power input circuit.

Product Scope:
The scope of this FSCA includes the products listed below.

Product Names	**Manufacturer's Product Number/Catalog Number**
OARM BI70002000 SYS IMAGING O2 OARM BI70002000R SYS IMAGING O2 REFURB	BI70002000 BI70002000R

Actions:

No actions are required by you. Your local service representative will contact you to schedule completion of the SW install, user manual update, and, if your system is affected, installation of component(s) for the new AC power input circuit. You may choose to continue to use your O-arm™ O2 Imaging System at your clinical discretion in the meantime, but you need to be aware of the issues described above, which may result in a delayed surgery, patient exposure to non-navigated surgery, navigational inaccuracy or unused X-ray dose.

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 Directly or via Tel. No: 01 511 1400.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland