

Urgent Field Safety Notice

O-arm™ 1000 Imaging System

September 2018

Medtronic reference: FA842

Dear customer,

The purpose of this letter is to inform you that Medtronic is voluntarily completing a field action of installing software ("SW") version 3.1.7 on all 2nd Edition O-arm™ 1000 Imaging Systems ("O-arm 1000"):

Issue Description:

In August 2018, Medtronic released SW version 3.1.7. This change is part of our commitment to Quality and continuous improvement and is in response to customer complaints and addresses several known software anomalies. The software anomalies were reported to affect the following system functionalities:

- Startup and shutdown
- System and network communication
- Motion control
- Image acquisition and output
- Dose reporting
- Logs generation

From the list of the complaints over the last six (6) years *five (5) complaints led to cancelled procedures after the patient was under anesthesia requiring additional surgery.* The field action is being initiated to address the issues relating to these 5 complaints.

Product Scope:

All 2nd Edition, O-arm 1000 Imaging Systems are in scope of this Field Corrective Action.

Actions:

No actions are required of you. Your local service representative will contact you to schedule completion of the SW install. You may choose to continue to use your 2nd Edition O-arm™ 1000 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, patient exposure to additional surgery 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

Appendix A: List of impacted model numbers: see below.

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Manufacturer's Product Number/Catalog Number
BI70000027
BI70000027R
BI70000027100
BI70000027100R
BI70000027120
BI70000027120R
BI70000027230
BI70000027230R
BI70000027GER
BI70000027GERR