Medtronic

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URGENT: MEDICAL DEVICE CORRECTION

O-arm™ 1000 Imaging System

4 Sep 2018

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

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.

Product Names	**Manufacturer's Product Number/Catalog Number**
OARM ASSY BI70000027 SYSTEM PRODUCT	BI70000027
OARM ASSY BI70000027R SYS PRODUCT RWK	BI70000027R
BASE OARM BI70000027100 SYSTEM 100V	BI70000027100
BASE OARM BI70000027100R SYSTEM 100V RWK	BI70000027100R
BASE OARM BI70000027120 SYSTEM 120V	BI70000027120
BASE OARM BI70000027120R SYSTEM 120V RWK	BI70000027120R
BASE OARM BI70000027230 SYSTEM 230V	BI70000027230

Product Names	Manufacturer's Product Number/Catalog Number
BASE OARM BI70000027230R SYSTEM 230V RWK OARM ASSY BI70000027GER SYS PRODUCT GER OARM ASSY BI70000027GERR SYS PRODUCT REFURB	BI70000027230R BI70000027GER BI70000027GERR

Actions:

Please complete the attached Confirmation Form in its entirety and return it as directed to confirm your receipt and understanding of this information.

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.

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

Sincerely,

[redacted]

Diana Teo
Quality System Manager SEA
Medtronic

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Customer Confirmation Form
URGENT MEDICAL DEVICE RECALL

Corrective Action Confirmation Form

FCA-2018-08-22

O-arm™ 1000 Imaging System

BI70000027, BI70000027R, BI70000027100, BI70000027100R, BI70000027120, BI70000027120R, BI70000027230, BI70000027230R, BI70000027GER, BI70000027GERR

Customer Contact Details	Medtronic Contact Details
Hospital / HCP/Patient:	**Name/Tel:**
	By E-mail:
Address:	**By Post:**
Telephone no:	
Fax no:	
E-mail:	

Tick ☐ here: If the unit (s) have been obsoleted, and fill up the serial # of the affected unit(s) in below table

Indicate in the columns below all serial numbers you have in your facility. If you have forwarded affected O arm™ 1000 Imaging System (2nd Edition) to other persons or facilities, provide the serial numbers and the recipient's name and address, if known. Forward the Field Safety Notice notification to these facilities:

O-arm™ 1000 Imaging System 2nd Edition) Serial Number	Sent to another facility Yes/No	Facility name and address (if different than above)

By signing this form, I confirm that I have read the **Medical Device Correction O-arm™ 1000 Imaging System Letter, dated 4 September 2018, from Medtronic regarding the and taken appropriate action.** I also agree to further distribute and communicate this important information within my facility as required.

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