Medtronic

49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

tel +65 6436 5000
fax +65 6776 6355

URGENT MEDICAL DEVICE CORRECTION
O-arm™ 1000 Imaging System (3rd Edition)

25 January 2018

Dear Valued Customer:

The purpose of this letter is to inform you that Medtronic Navigation is in the process of installing software maintenance update 3.2.1 ("SW Update 3.2.1") on all 3rd Edition, O-arm 1000 Imaging Systems.

Issue Description:

In July 2017, Medtronic Navigation rolled out routine SW Update 3.2.1. 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 system behavior that include the following issues:

- Inability to power the system after shutdown
- System stays in standalone mode
- Image reconstruction
- System/Pendant bootup
- Dose display/report
- Gantry motion
- Network communication
- System shutdown
- Early termination of 3D spin

We've received complaints associated with these software anomalies. In 3 instances the use of the O-arm was aborted and the surgeries rescheduled after incision.

Product Scope:

All 3rd Edition, O-arm 1000 Imaging Systems are in scope of this Field Corrective Action.

Product Names	Manufacturer's Product Number/Catalog Number	Quantity
O-arm 1000 Imaging System, 3rd Edition	BI70000028100 BI70000028120 BI70000028120R BI70000028230 BI70000028230R	249

Required 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 the SW update or to inform you if you have already received the SW update. You may choose to continue to use your O-arm 1000 Imaging System but need to be aware of the software anomaly system behaviors which may result in a delayed or aborted 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. If you have any questions regarding this communication, please contact your local Medtronic Representative.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

Sincerely,

[redacted]

Diana Teo
QA Supervisor
Medtronic

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Corrective Action Confirmation Form
O-arm™ 1000 Imaging System (3rd Edition)
BI70000028100, BI70000028120, BI70000028120R, BI70000028230, BI70000028230R

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**E-mail Address:**
Address:	**Phone:**
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 (3rd 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 (3rd 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 **URGENT MEDICAL DEVICE CORRECTION O-arm™ 1000 Imaging System (3rd Edition)** Notification Letter, dated **25 January 2018** from Medtronic. I also agree to further distribute and communicate this import information within my facility as required.

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