

## **URGENT: MEDICAL DEVICE CORRECTION**

### **O-arm™ O2 Imaging System**

1 October 2018

**Attention: Risk management Director and O.R Materials Management**

**CC: The Chairman Medical Board and relevant Head of Departments**

Dear Valued Customers:

The purpose of this letter is to inform you that Medtronic Navigation is voluntarily completing the following actions on affected O-arm™ O2 Imaging Systems ("O-arm O2"):

- Installing software ("SW") version 4.1.0
- Installing a new version of the user manual and an Image Acquisition System ("IAS") product label
- Installing component(s) of the new AC power input circuit

#### **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 and regulatory findings.

#### 4.1.0 SW

SW version 4.1.0 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

We've 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 & IAS Product Label

The user manual was updated to include instructions on enhancements and new features associated with SW version 4.1.0, corrections to typographical errors and grammar, clarifications, and updates in caution statements and warnings, including changes to address labeling requirements for the alignment and mouse lasers. In addition to the user manual update, a new IAS product label was released to reflect laser compliance to 21 CFR 1040.10 and 1040.11.

No information in the user manual or the IAS label has resulted in harm to our patients or users.

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. All O-arm O2 systems in the USA are impacted by the updated IAS product label.

### MVS Fuses

We've 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 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 below C1433 may be affected. O-arm O2 systems with serial numbers C1434 already include the new design of the AC power input circuit.

### **Product Scope:**

The scope of this FCA includes the products listed below. Of this group, systems in the USA are in scope of this FCA associated with the IAS Product Label.

<b>Product Names</b>	<b>Manufacturer's Product Number/Catalog Number</b>
OARM BI70002000 SYS IMAGING O2 OARM BI70002000R SYS IMAGING O2 REFURB	BI70002000 BI70002000R

### **Actions:**

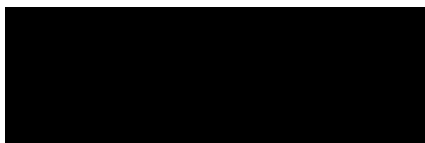
No actions are required of you. Your local service representative will contact you to schedule completion of the SW install, user manual update, and, if your system is affected, installation of component(s) for the new AC power input circuit and IAS product label application. You may choose to continue 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. 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.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



Diana Teo  
Quality Management System Manager  
South East Asia  
Medtronic

# Medtronic

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**Recall Customer Confirmation Form**  
**FCA-2018-08-30**

**O-arm™ O2 Imaging System**

**BI70002000, BI70002000R**

**ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY**

Customer Contact Details	Medtronic Contact Details
	<b>Name:</b>
<b>Hospital :</b>	<b>Contact:</b>
<b>Address:</b>	<b>Email:</b>
<b>Phone no:</b>	
<b>E-mail:</b>	

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 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 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 1 October 2018**, from Medtronic regarding the and taken appropriate action.

Name: \_\_\_\_\_ (print) Signature: \_\_\_\_\_ Stamp: \_\_\_\_\_ Date: \_\_\_\_\_