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URGENT: MEDICAL DEVICE CORRECTION
O-arm™ 1000 Imaging System
BI-700-00027-XXX and BI-700-00028-XXX

22nd May 2019

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

Dear Healthcare Professional,

The purpose of this letter is to inform you that Medtronic Navigation is voluntarily performing the following actions on affected O-arm™ 1000 Imaging Systems:

- Installing a new version of the user manual
- Installing a component (Mobile View Station ("MVS") heatsink) as part of the new design of the AC power input circuit
- Providing a Visual Mitigation Card for you to attach to the Image Acquisition System ("IAS") of your O-arm™ 1000 Imaging System to serve as a visual reminder

Our records indicate that you have one or more of the affected systems: O-arm™ 1000 Imaging Systems labeled with part numbers BI-700-00027-XXX or BI-700-00028-XXX, where XXX indicates the system voltage. Please reference *Attachment A* for further details on products in scope of this correction and how you may identify if your product is affected.

O-arm™ O2 Imaging Systems are not in scope of this correction and are not affected by the issues described below.

ISSUE DESCRIPTION

Charger Boards (User Manual Update)

The O-arm™ 1000 Imaging System uses energy from the batteries to generate X-rays and move the system. If a charger board is not functioning properly, the batteries will not receive a full recharge of the potential capacity. This can result in the inability of the system to take X-rays, open the gantry, and move the system from one place to another, which may affect the ability to continue use within the operating room until the charger board and/or the batteries are replaced. If the system is around a patient at the time the power is lost, the gantry can still be manually opened, and the system can be moved away from the patient; however, X-ray images cannot be taken. The surgeon will then need to decide whether to abort the procedure or continue the procedure without use of the system.

We have received complaints associated with failures of the charger boards. In one reported event, the charger board failed to charge all the batteries, and the system stopped working during the surgery after the patient had been placed under anesthesia. The surgery was aborted and rescheduled, and no additional patient impact was reported. The operator was not aware that the battery capacity was low before starting the procedure, and the system stopped functioning while the surgery was in progress. Medtronic Navigation considers subjecting patients to additional procedures due to the system not working properly to be a harm. In another reported event, a failure of the charger board led to an extended delay in therapy of greater than an hour, which Medtronic Navigation considers to be a minor harm due to extended exposure to anesthesia. The surgeon opted to discontinue use of the O-arm™ 1000 Imaging System, and there was no indication of long-term impact on the patient. Other reported failures of the charger boards have also resulted in other hazardous situations, although none resulted in injuries.

As part of this correction, the user manual is being updated to include additional cautions and instructions affecting the system charger boards, and hence, the system batteries.

<u>MVS Fuses</u>

The O-arm™ 1000 Imaging System is largely prevented from being susceptible to inrush current surges when being plugged in. However, when a component in the system used for inrush current surge limiting times out, and there is no longer any protection, an inrush current surge from any other source could cause a current surge in the system. This may result in the MVS fuse to open (i.e. blow), as has been reported in the field. Until an O-arm™ 1000 Imaging System is equipped with the new design of the AC power input circuit, there is a potential for blown fuses resulting from surges from being plugged in or to line surges caused by other equipment on the same power line. Once both or either fuse blows, the device becomes inoperable until the fuse is replaced by a trained technician.

We have received complaints associated with the MVS fuses within the AC power input circuit. In three instances reported by the customer, blown fuses resulted in the inability to use the systems after the surgery began when patients were already under anesthesia, and the surgeries had to be rescheduled to later dates; however, there was no additional patient impact reported. Medtronic Navigation considers subjecting patients to additional procedures due to the system not working properly to be a harm. Three other reported instances led to what Medtronic Navigation considers minor harm. In one event reported by the customer, a blown fuse led to an extended delay in therapy of greater than an hour, leading to prolonged exposure to anesthesia. In another reported event, the inability to use the O-arm™ 1000 Imaging System resulted in patient exposure to a non-navigated procedure when navigation was planned; however, there was no reported impact on patient outcome. In the third reported event, a user received an electrical shock while changing the fuses; however, this event did not require medical intervention. Other reported instances of blown fuses have also resulted in other hazardous situations, although none resulted in injuries.

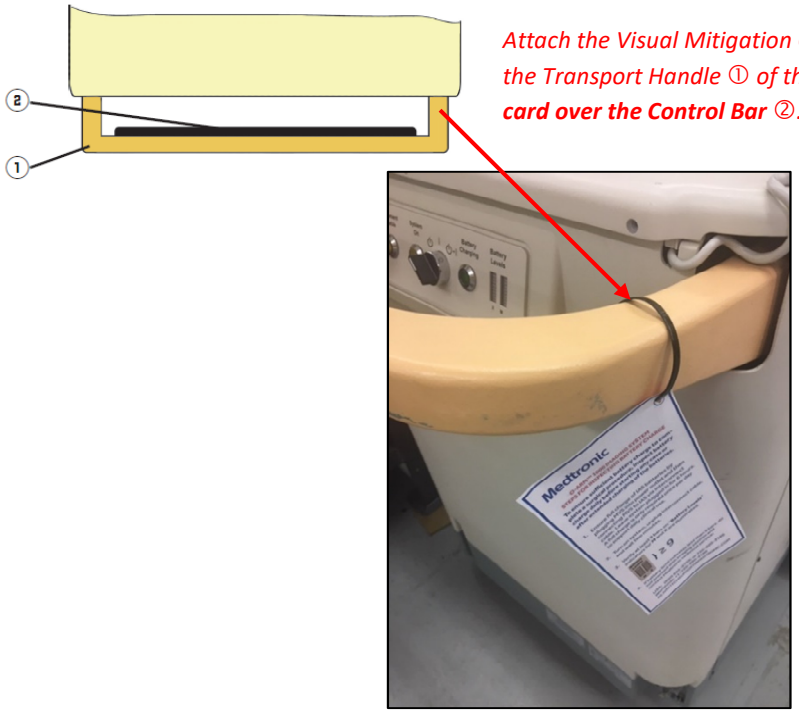
Until the system is equipped with the new design of the AC power input circuit (MVS heatsink)*, it is susceptible to blown fuses.*

REQUESTED ACTIONS

Your local service representative will contact you to schedule installation of the MVS heatsink and installation of the new user manual.

In the meantime, you are requested to:

1) *Attach the **Visual Mitigation Card** to the IAS of your O-arm™ 1000 Imaging System, as illustrated in the image below, and follow the directions as noted.*



*Attach the Visual Mitigation Card to the rightmost part of the Transport Handle ① of the IAS. **DO NOT ATTACH the card over the Control Bar** ②.*

2) ***Review and retain Attachment B** for further guidance on using your system to prevent the risk of having to delay or to abort a surgery due to a failure of the charger boards, prior to receiving the new version of the user manual. Attachment B provides instructions* for inspecting the battery and chargers. Additionally, please be sure to follow the "Performance Checks and Maintenance" section of your user manual, in addition to the information in Attachment B, to ensure your system is available for surgical procedures.

3) ***Sign and date the bottom of Attachment C, Consignee Confirmation Form**, and return the form to your local Medtronic representative within 30 days of receipt.*

You may choose to continue to use your O-arm™ 1000 Imaging System at your clinical discretion, with attention to the instructions provided in Attachment B and your user manual. Please be aware of the issues described above, which may result in patient exposure to additional surgery, delays in therapy, patient exposure to non-navigated surgery, and user exposure to electrical hazard.

Sincerely,

[redacted]

Diana Teo

QRA Lead Cluster 1

Enclosures: Attachment A
Attachment B
Attachment C

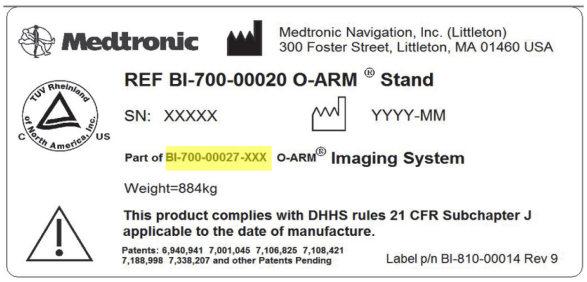
ATTACHMENT A: PRODUCT SCOPE

The scope of this correction includes the products listed below.

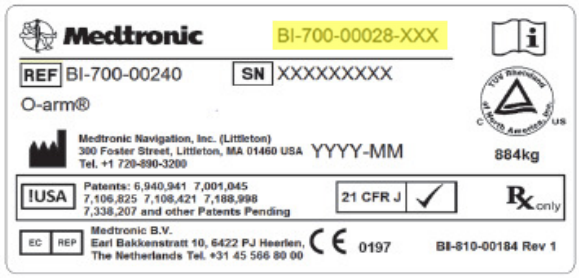
Product Names	Manufacturer's Product Number/Catalog Number
OARM ASSY BI70000027 SYSTEM PRODUCT	BI-700-00027
OARM ASSY BI70000027R SYS PRODUCT RWK	BI-700-00027R
BASE OARM BI70000027100 SYSTEM 100V	BI-700-00027-100
BASE OARM BI70000027100R SYSTEM 100V RWK	BI-700-00027-100R
BASE OARM BI70000027120 SYSTEM 120V	BI-700-00027-120
BASE OARM BI70000027120R SYSTEM 120V RWK	BI-700-00027-120R
BASE OARM BI70000027230 SYSTEM 230V	BI-700-00027-230
BASE OARM BI70000027230R SYSTEM 230V RWK	BI-700-00027-230R
OARM ASSY BI70000027GER SYS PRODUCT GER	BI-700-00027GER
OARM ASSY BI70000027GERR SYS PRODUCT REFURB	BI-700-00027GERR
BASE OARM BI70000028100 SYS 100V	BI-700-00028-100
BASE OARM BI70000028120 SYS 120V	BI-700-00028-120
BASE OARM BI70000028120R 3RD EDIT REFURB	BI-700-00028-120R
BASE OARM BI70000028230 SYS 230V	BI-700-00028-230
BASE OARM BI70000028230R 3RD EDIT REFURB	BI-700-00028-230R

You may view the product labels on the Image Acquisition System (IAS) or the Mobile View Station (MVS), as indicated in the locations noted below, to confirm if the product is labeled with the product numbers BI-700-00027 or BI-700-00028 (highlighted in yellow) and is in scope of this correction.

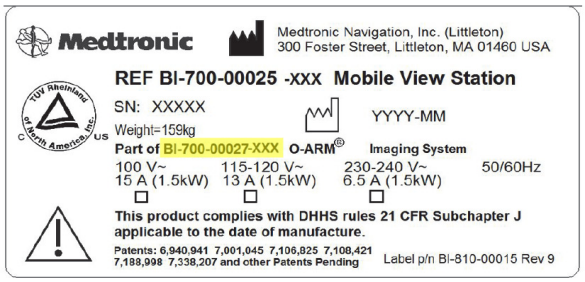
IAS Label
Located on rear cabinet of IAS



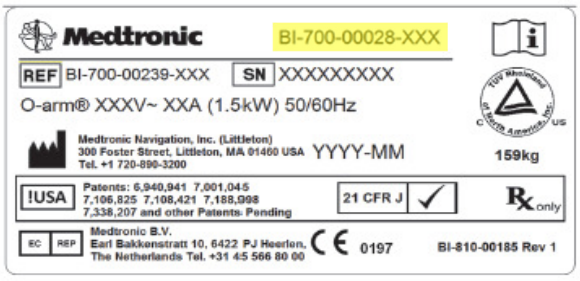
or



MVS Label
Located on bottom of panel on rear of MVS



or



ATTACHMENT B: BATTERY & CHARGER CHECK

Please retain and review this attachment for inspecting the battery and chargers to ensure your O-arm™ 1000 Imaging System is available for surgical procedures until your local service representative has installed the updated user manual. These inspection procedures assume yearly preventive maintenance (PM) has been performed.

Battery Level Indicators: On the IAS Power Control Panel shown in Figure 1, the two columns of yellow LED lights (①) indicate the battery levels for the motion batteries (**M**) and the X-ray batteries (**X**). See "Battery Charge Level Indicators" in the user manual for more information about battery charge levels represented by the scrolling LEDS. See "User Performance Checks" in the user manual to ensure proper operation of the machine.

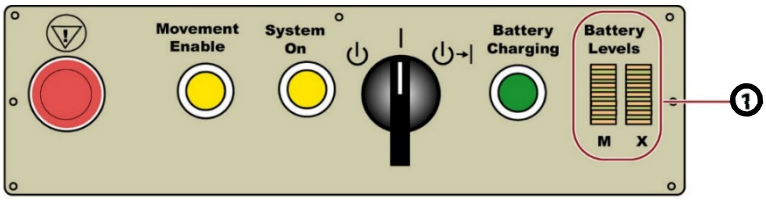


FIGURE 1

To ensure sufficient battery charge to complete a surgical procedure, inspect battery charge daily before starting any case or after extended charging of the batteries. Ensure full charge of IAS batteries by plugging MVS into power outlet and then connecting MVS to IAS via interconnect cable. Leave system plugged in for 6 hours. A full charge is only required once per day to support daily clinical use.

Battery Charge Inspection

After performing all "Before Case" checks listed in the IFU (see Chapter 9, Table 9-3):

- While the Image Acquisition System (IAS) is turned on, unplug the interconnect cable and wait two minutes.
- Check the battery charge indicators on the power control panel.
- Verify that the **X** and **M** battery level indicators have at least 9 out of 10 bars illuminated to ensure sufficient battery charge to accomplish the procedure.
- If battery level indicates less than 9 bars, do not proceed with imaging session and contact Medtronic technical service: (800) 595-9709 or 720-890-3160 for US; +1-720-890-3160 for worldwide; or via email to RS.NAVTECHSUPPORT@MEDTRONIC.COM.

Battery and Charger Check

After charging the system and prior to any operation of the system:

- While the Image Acquisition System (IAS) is turned on, unplug the interconnect cable and wait two minutes.
- Check the battery charge indicators on the power control panel.
- Verify that the **X** and **M** battery level indicators have at least 9 out of 10 bars illuminated to ensure that the battery chargers and batteries are recharging properly.
- If battery level indicates less than 9 bars, do not proceed with imaging session and contact Medtronic technical service: (800) 595-9709 or 720-890-3160 for US; +1-720-890-3160 for worldwide; or via email to RS.NAVTECHSUPPORT@MEDTRONIC.COM.

CAUTION: Failure to follow the instructions for inspecting the battery and charger may result in insufficient battery charge to complete a surgical procedure.

CAUTION: Do not leave the machine for extended periods of time with the interconnect cable disconnected or MVS main power not plugged in. Being in standalone mode drains the motor batteries.

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Attachment C

Customer Confirmation Form

URGENT: MEDICAL DEVICE CORRECTION

O-arm™ 1000 Imaging System
BI-700-00027-XXX and BI-700-00028-XXX

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
	Name:
Physician / HCP/Hospital :	**Contact:**
Address:	**Email:**
Phone no:	
E-mail:	

Indicate in the columns below on all Product code and serial number in your facility.
Should the system has been moved to other facility, please also indicate the information in below and facility information under remarks

□ Please check here if your system has been obsoleted and fill up the below table.

Product code	System Serial #	Remarks

Note: The addressee may continue to receive reminders of this notice until a response is received.

By signing this form, I confirm that I have received and understand information attached and that the Visual Mitigation Card (VMC) has been attached on the Image Acquisition System (IAS) of the affected system(s).

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