



Medtronic Ireland Limited

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Tel: 01 511 1400

Fax: 01 807 7220

www.medtronic.ie

URGENT FIELD SAFETY NOTICE

O-arm™ O2 Imaging System (O2)

Service notification

July 2023

Medtronic Reference: FA1351

EU Manufacturer Single Registration Number (SRN): US-MF-000023106

Dear Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is issuing a voluntary Correction for the O-arm™ O2 Imaging System (O2) serial numbers listed below.

Issue Description:

Medtronic has identified through internal manufacturing record review that your system may have an internal ground cable that was installed incorrectly. This issue with the ground cable does **not** impact the functionality, performance, or safety of the system. However, if the cable was installed incorrectly, it may present a hazard to Medtronic engineers when servicing the system due to potential of electric shock.

Risk to patient, operator or service personnel:

Medtronic has received zero (0) complaints associated with this issue. The impacted cable is located inside of the O-arm system and is not accessible to customers. There is no risk to patients or operators. This nonconformance does not have any impact on the functionality of the system. However, when the cable is installed inverted, there is a potential safety risk for any personnel attempting to service the O-arm or accessing the area where the cable is encased and stored. Medtronic is the Sole Source Service provider for the O2. Accordingly, only Medtronic authorized, and trained personnel should be servicing or repairing the O2.

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Additionally, this notification has no impact on patients who have previously undergone a procedure using the O-arm™ O2 Imaging System (O2). These patients should continue to be monitored per your practice's normal follow-up procedures.

Actions for Customer:

- Please continue to use the device as per your facility protocol. There is no risk to patient or other users when the system panels remain on the system.
- Immediately notify all personnel in all care environments in which the O-arm™ O2 Imaging System (O2) is used about this Medical Device Correction notice.
- Please post this notification in a prominent location and maintain awareness of this matter until the issue is resolved by your Medtronic Field Service Engineer.
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Complete and return the customer confirmation form.

Actions for Medtronic:

- Medtronic will contact customers to schedule servicing of your O-arm™ O2 Imaging System (O2) to correct this issue. In the interim, if you have questions regarding this issue, contact your Medtronic representative / Technical Services directly or via tel no: 01 511 1400
- Medtronic is the Sole Source provider for the O2. Accordingly, only Medtronic authorized, and trained personnel should be servicing or repairing the O2.

Product Scope:

Product Name	Model#	GTIN/Material #	Serial #
O-arm™ O2 Imaging System (O2)	BASE SYS BI70002000 O-ARM SYS O2	00763000074128	C2841, C2786
		00763000081041	C2781
		00763000496784	C2918
		00763000542801	C2968
		00763000616434	C3290
		00763000616526	C3363
		00763000616564	C3418, C3404, C3387, C3322, C3188
		00763000355555	C2624, C2659, C2660, C2665, C2672, C2708, C2723, C2735, C2760, C2774, C2775, C2779, C2873, C2823, C2798, C2814

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Additional Information:

Medtronic has notified the Competent Authority of your country 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.

Sincerely,



Keith Taverner

Principal Regulatory Affairs Specialist UK & Ireland

FA1351: Customer Acknowledgement Form Below



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FA1351: Customer Acknowledgement Form - Response is required
O-arm™ (O2) Incorrect Assembly

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name:

Country: IRELAND

I have read and understand the instructions provided and acknowledge receipt of the **notification** regarding the use of the O-arm (O2) by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed O-arm (O2) as required.

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

Keith.c.taverner@medtronic.com