

## **URGENT: Field Safety Notice**

**OxiMax™ N-65 Handheld Pulse Oximeter**

**OxiMax™ N-560 Pulse Oximeter**

13<sup>th</sup> May 2015

### **FSCA Reference: Oximeter 05/15**

Dear Valued Customer,

The purpose of this letter is to advise you that Covidien, now a part of Medtronic, is issuing a Field Safety Corrective Action (FSCA) for all OxiMax™ N-65 Handheld Pulse Oximeters (Product code: N65, N65-1, N65P & N65P-1) and OxiMax™ N-560 Pulse Oximeters (Product code: N560) related to an issue identified from customer complaints. If you have any OxiMax™ N-65 Handheld Pulse Oximeters or OxiMax™ N-560 Pulse Oximeters at your facility, please read this notice carefully.

The issue is related to the oximeters not fully displaying segments of data (see example below), which may result in misinterpretation of the data being displayed.



*Example of missing segment*

Covidien has had no reports of serious patient injury or death associated with this issue.

### **Actions to be taken by the customer/user**

The purpose of this communication is to remind you of the importance of conducting the automated Power-On-Self-Test (POST) prior to patient use, as described in the N65 & N560 Operator's Manual and Home-Use guide. If you observe during POST or during device use, any missing display segment or if the speaker does not sound, discontinue use and contact our Service Department as explained below.

The N-65 Operator's Manual and Home Use Guide, and the N-560 Operator's Manual may be obtained from your local Covidien representative.

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Please complete the attached acknowledgement form in full and fax it to 01 439 3039 for the attention of Audrey Doyle or e-mail it to [audrey.doyle@medtronic.com](mailto:audrey.doyle@medtronic.com).

This notification is being issued with the knowledge of the Irish Competent Authority, The Health Products Regulatory Authority (HPRA). Please communicate this important information within your facility as required.

If your facility has distributed the OxiMax™ N-65 Handheld Pulse Oximeters and/or the OxiMax™ N-560 Pulse Oximeters to other persons or facilities, please promptly forward a copy of this letter to those recipients. Please maintain awareness on this notice for an appropriate time period to ensure effectiveness of this information.

Should you have any questions regarding this letter or to report any issues with the OxiMax™ N-65 Handheld Pulse Oximeters and OxiMax™ N-560 Pulse Oximeters contact your local Representative Edel O'Sullivan by telephone 087 0620475 or by e-mail at [Edel.OSullivan@hc21.ie](mailto:Edel.OSullivan@hc21.ie) to ensure proper device reporting procedures are followed.

Sincerely,

  
Audrey Doyle

RA Specialist, Email: [audrey.doyle@covidien.com](mailto:audrey.doyle@covidien.com) Tel: 01 4381609

Attachment: Acknowledgement Form