Medtronic
6135 Gunbarrel Avenue
Boulder, CO 80301
303-530-2300 [T]

URGENT: Medical Device Correction

Nellcor™ N-65 Handheld Pulse Oximeter with OxiMax™ Technology
Nellcor™ N-560 Pulse Oximeter with OxiMax™ Technology

July 10, 2015

Dear Valued Customer:

The purpose of this letter is to advise you that Covidien, now a part of Medtronic, is issuing a safety notification for all Nellcor™ N-65 Handheld Pulse Oximeters and Nellcor™ N-560 Pulse Oximeters with OxiMax™ Technology. Customers have reported that Nellcor™ N-65 Handheld Pulse Oximeters and N-560 Pulse Oximeters do not fully display segments of numeric data (see example below), which may lead to an end user's misinterpretation of the numeric data being displayed.

Example of missing segment

Covidien has had no reports of serious patient injury or death associated with this issue. The complaint rate for reports of missing and/or broken segments is 0.031%.

The safety notification is limited to the product codes and associated serial numbers listed in the table below.

Product Description Name	Product code	Serial Numbers
Nellcor™ N-560 Pulse Oximeter	N560	All
Nellcor™ N-65 Handheld Pulse Oximeter	N65	All
Nellcor™ N-65 Handheld Pulse Oximeter	N65P	All

Required Actions

- **Conduct the automated Power-On-Self-Test (POST) to confirm the full functionality of the display and audio alarm.**

  It is important to perform the Power-On-Self-Test (POST) prior to patient use. The procedure for performing the POST is described in the operator's manuals and home-use guides for the Nellcor™ N-65 Handheld Pulse Oximeters and N-560 Pulse Oximeters. If you observe during POST or during use that there is a missing segment in the numeric display, or if the speaker does not sound, discontinue use of the device and contact our Service Department at 800.635.5267 option 1, option 1, and again option 1.

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The Nellcor™ N-65 and N-560 Oximeter Operator's Manuals and Home Use Guides can be found on the websites below, or by contacting your Medtronic sales representative.

- **Nellcor™ N-560 Pulse Oximeter** http://www.covidien.com/rms/products/pulse-oximetry/nellcor-n560-pulse-oximetry-monitor#resources
- **Nellcor™ N-65 Handheld Pulse Oximeters** http://www.covidien.com/rms/products/pulse-oximetry/nellcor-n65-pulse-oximetry-monitor#resources

- **Please complete the attached Acknowledgement and Receipt Form on page 3.**

We ask that all customers reply to Covidien, now a part of Medtronic, by completing the Acknowledgement and Receipt Form and returning the form to Medtronic via the instructions provided. Your response is vital to our monitoring of the effectiveness of this safety notification.

This notification is being issued with the knowledge of the U.S. FDA and other regulatory authorities. Please communicate this important information within your facility as required. If you have any questions or concerns, please do not hesitate to contact your Medtronic sales representative.

If your facility has distributed the Nellcor™ N-65 Handheld Pulse Oximeters and Nellcor™ N-560 Pulse Oximeters with OxiMax™ Technology to other persons or facilities, please promptly forward a copy of this notification to those recipients. Please maintain awareness on this safety notification 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 Nellcor™ N-65 Handheld Pulse Oximeters and Nellcor™ N-560 Pulse Oximeters with OxiMax™ Technology, contact your local Medtronic sales representative.

Adverse reactions or quality problems experienced with the use of this product should be reported to Medtronic and the FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA 1-800-FDA-1088
- Email Medtronic Post Market Vigilance at: HQTSWEB@COVIDIEN.COM
- Call Medtronic Post Market Vigilance at: 800.635.5267 option 1, option 1, and again option 1

We apologize for this inconvenience and thank you for your business and continued support. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative.

Sincerely,

Subu Mangipudi
Vice President, Quality Assurance
Patient Monitoring and Recovery
Medtronic

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Medical Device Correction
Acknowledgement and Receipt Form—Response is Required

Nellcor™ N-65 Handheld Pulse Oximeter with OxiMax™ Technology
Nellcor™ N-560 Pulse Oximeter with OxiMax™ Technology

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone#: _____

Email: _____

Account Name: _____

Covidien Account Number: _____

Account Address: _____

City: _____ State: _____ Zip Code: _____

I have read and understand the instructions provided and acknowledge receipt of the Medical Device Correction regarding the Nellcor™ N-65 Handheld Pulse Oximeter Nellcor™ N-560 Pulse Oximeter by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

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

If you have any questions regarding this Medical Device Correction, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT (Page 3) TO:

Quality Compliance N65N560FSN@Covidien.com or (203)492-7719