COVIDIEN

URGENT: Field Safety Alert

Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter
Nellcor™ OxiMax® N-560 Pulse Oximeter

21 May 2015

Dear Valued Customer,

The purpose of this letter is to advise you that Covidien (a Medtronic company) is issuing a Medical Device Safety Alert for all Nellcor™ OxiMax® N-65 Handheld Pulse Oximeters and OxiMax® N-560 Pulse Oximeters. Customers have reported that Nellcor™ OxiMax™ N-65 Handheld Pulse Oximeters and OxiMax™ 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 Medical Device Safety Alert is limited to the product codes and associated serial numbers listed in the table below.

Product Description Name	Product code	Serial Numbers
Nellcor™ OxiMax® N-560 Pulse Oximeter	N560	All
Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter	N65	All
Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter	N65-1	All
Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter	N65P	All
Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter	N65P-1	All

COVIDIEN PRIVATE LIMITED
CO. REGISTRATION NO: 199800515M

103 PENANG ROAD
VISIONCREST COMMERCIAL
#10-01
SINGAPORE 238467

65-6482-0100[T]
65-6482-0300 [F]

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Required Actions

1. **Conduct the automated Power-On-Self-Test (POST)**

   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 Nellcor™ OxiMax® N-65 Handheld Pulse Oximeters and OxiMax® N-560 Pulse Oximeters Operator's Manual and Home-Use guide. 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 as explained below. The Nellcor™ OxiMax® N-65 and N-560 Operator's Manuals and Home Use Guides can be found on the websites below, or by contacting your local Covidien representative

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

2. **Please complete the attached acknowledgement form**

   We ask that all customers reply to Covidien by completing the Acknowledgement Form and returning the form to your local Covidien representative. Your response is vital to our monitoring of the effectiveness of this Medical Device Safety Alert.

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.

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

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

Sincerely,

[redacted]

Alec Chow
Director, Asia Pacific
Quality Regulatory Affairs-Operations & PMV

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Acknowledgement Form

Field Safety Alert Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter
Nellcor™ OxiMax® N-560 Pulse Oximeter

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Name of Person completing this form:
Hospital / HCP:
Address:
Telephone no:
Fax no:
E-mail:

Product Description Name	Product code	Serial Numbers
Nellcor™ OxiMax® N-560 Pulse Oximeter	N560	All
Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter	N65	All
Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter	N65-1	All
Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter	N65P	All
Nellcor™ OxiMax® N-65 Handheld Pulse Oximeter	N65P-1	All

Required Actions

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

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3. **Indicate in the columns below all serial numbers you have in your facility**.
   If you have forwarded affected Nellcor™ OxiMax® N-65 & N560 to other persons or facilities, provide the serial numbers and the recipient's name and address, if known. Forward the Field Safety Alert notification to these facilities.

Item code	Serial Number	Sent to another facility Yes/No	Facility name and address (if different than above)

I have read and understand the instructions provided and acknowledge receipt of the Field Safety Alert regarding Nellcor™ OxiMax® N-65 & N560 by signing below. I also agree to further distribute and communicate this important information within my facility as required.

Name: _____ (Print) Signature: _____ Date: _____

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