

# Safety Notice

## Medical Devices

### OxiMax N-65 and N560 Pulse Oximeters

#### Priority 2 – Warning

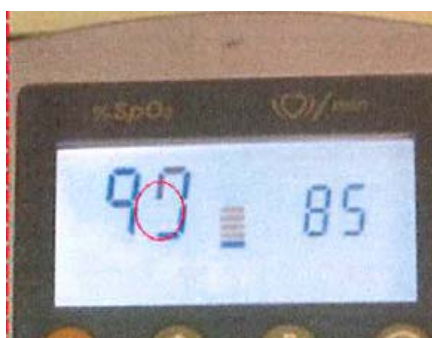
HPRA Safety Notice: SN2015(11)

Issue Date: 26 May 2015

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Covidien	V24011

#### ISSUE

Covidien has received reports related to the above devices not fully displaying segments of data, which may result in misinterpretation of data being displayed. This was highlighted in a Field Safety Notice issued by Covidien in May 2015. An example of a missing data segment is shown in the image below.



Example of a missing data segment

Please refer to the attached Field Safety Notice for additional details on the issues affecting the devices, the list of affected devices and the actions proposed by the manufacturer.

## ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Ensure that you have read and following the instructions that were provided in the manufacturers Field Safety Notice that was circulated in May 2015
- 2 Complete and return the Acknowledgement Form included with the FSN if you have not already done so.
- 3 If your device is displaying this issue, contact Covidien's Technical Service Department so that they may schedule a repair or replacement of the device.
- 4 Forward this HPRA Safety Notice to all those that need to be made aware within your organisation or to any organisation/person where the device has been transferred.
- 5 Ensure that relevant personnel receive a copy of the attached Customer Advisory Notice.

## TARGET GROUPS

HSE Hospital Staff Private Hospital Staff Clinical Engineering/Medical Physics Public Health Nurse Home Users	Risk Managers Purchasing Managers Supplies Managers Nursing Homes Carers
---	--

## BACKGROUND

In addition to communicating the possibility of devices not fully displaying segments of data, Covidien is also reminding customers in the FSN of the importance of conducting the automated Power-On-Self-Test (POST) prior to use with a patient. This is described in the N-65 & 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 Covidien's Technical Service Department at [TechServices.cslreland@covidien.com](mailto:TechServices.cslreland@covidien.com). They will instruct you on how to return the device for service. If the device is under warranty and cannot be repaired, a replacement unit will be provided.

#### MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Audrey Doyle  
Regulatory Affairs Specialist (Ireland)

**Medtronic**

Block G, Ground Floor,  
Cherrywood Technology Park,  
Loughlinstown,  
Dublin 18

Telephone: +353 14381609  
E-mail: [audrey.doyle@medtronic.com](mailto:audrey.doyle@medtronic.com)  
Website: [www.covidien.com](http://www.covidien.com)

Enquiries to the **distributor** should be addressed to:

Edel O' Sullivan  
Business Manager Medical Care Solution  
Healthcare 21  
HQ: Unit 5, Westpoint Buildings,  
Westpoint Business Park, Ballincollig,  
Cork,

Telephone: +353214860528  
E-mail: [Edel.OSullivan@hc21.ie](mailto:Edel.OSullivan@hc21.ie)  
Website: [www.healthcare21.eu](http://www.healthcare21.eu)

#### HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2

Telephone: +353-1-6764971  
Fax: +353-1-6344033  
E-mail: [devicesafety@hpra.ie](mailto:devicesafety@hpra.ie)  
Website: [www.hpra.ie](http://www.hpra.ie)