

**Notice Information: - Advisory
21 January 2011**

Part 1. Product Information

- a) Title: Counterfeit Covidien Nellcor SpO2 Durasensor® (DS-100A) sensors
- b) Product Name/Type: Nellcor Durasensor® (DS-100A) sensors Product Code: DS-100A
- c) Reference: SN2011(01)
- d) Manufacturer/Supplier: Tyco Healthcare group LP
Nellcor Puritan Bennett Division
Pleasanton, CA USA

Part 2. Target Audience

- a) Target Audience:
- General Surgeons
 - Theatre and Nursing Staff
 - Purchasing Managers
 - Nursing Managers
 - Consultant General Surgeons
 - A&E Departments
 - Hospital Managers / CEOs
 - Clinical Directors
 - Risk Managers
 - Hospital personnel
 - Clinical Engineers
 - Patients

Part 3. Problem/Issue

a) Problem/Issue:

The supply and use of counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors that are not guaranteed to meet the required standards of safety and quality, as required by the medical devices legislation

Part 4. Background Information

a) Background Information:

In December 2010 the Irish Medicines Board (IMB) were informed that counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors had been found on the market in the Netherlands and Germany. Following distribution of the IMB Safety Notice SN2010(17) the IMB has received confirmation that the counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors have been supplied to a number of hospitals in Ireland.

The legal product is manufactured by Tyco Healthcare Group LP, Nellcor Puritan Bennett Division.

The IMB is distributing this updated Safety Notice to remind users of the Nellcor SpO2 Durasensor (DS-100A) sensors to carry out an inspection of all devices in stock, as per the instructions provided below by Covidien, to confirm their authenticity.

Covidien has highlighted the following differences between the counterfeit devices and the genuine devices:

1. Sensor- The authentic Covidien product has shiny finish on the device housing (figure 1- see pdf document) whereas the counterfeit product has an opaque finish (figure 2 - see pdf document)

2. Feather of the sensor (can be seen when sensor is opened) - The authentic Covidien product has one winding of the feather (figure 3 - see pdf document) whereas the counterfeit product has three windings of the feather (figure 4 - see pdf document)

3. Optical part of the sensor (can be seen if sensor is opened) - The authentic Covidien product has two visible cables in red and black (figure 5 - see pdf document) whereas the counterfeit product has no visible cables (figure 6- see pdf document)

4. Carton Top - The authentic Covidien product does not have the REF symbol printed in Bold on the carton top label (figure 7- see pdf document) whereas the counterfeit product has the REF symbol printed in Bold (figure 8 -see pdf document)

5. Carton bottom - The authentic Covidien

5. Carton bottom - The authentic Covidien product has a rounded press cut in the carton round (figure 9 - see pdf document) whereas the counterfeit product has an angular press cut in the carton (figure 10 - see pdf document)

6. Carton bottom - The counterfeit product has additional labels where "Handheld Pulse Oximeter-Oxygen Sensor" is printed on an additional bill of materials (figure 10 - see pdf document), as can be seen on picture 10 the additional labels indicate that the sensors were manufactured for use out of Europe and the European Union as there are none of the European languages on there.

7. Carton bottom - The counterfeit product has a darker background colour (figure 9 - see pdf document) than the authentic product (figure 10 - see pdf document).

The exact risks associated with the use of the counterfeit product are unknown. As the counterfeit product was not manufactured by Covidien they cannot confirm the performance, mechanical properties, biocompatibility or sterility of the product. Functional tests carried out by Covidien showed the counterfeit devices partially failed to provide SpO2 readings, when tested with OxiMax™/ Nellcor monitors. These sensors can be used with a range of monitors.

The manufacturer, Tyco Healthcare Group, Nellcor Puritan Bennett Division, recommends that all products are purchased directly from Covidien or an authorised distributor.

Covidien can be contacted by calling Deirdre O'Connor at 087 816 85 19 or Mark Gray at 087 653 8087 if you have medical questions regarding suspected counterfeit product.

Part 5. Action to be taken

a) Action to be taken:

The IMB advises that:

- All products in your possession should be checked using the details above to assess whether the product is genuine or counterfeit.
- If from your assessment you determine or suspect that you have product that is counterfeit identify, locate and quarantine all product to ensure it will not be used.
- If you identify that you have product that is counterfeit you should submit the information detailed in Appendix I to the IMB (enforcement@imb.ie and vigilance@imb.ie). On receipt of this information the IMB will contact you to advise what further course of action is required.

Part 6. Enquiries

a) All enquiries should be made to:

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

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Enquiries should be addressed to:

Local Covidien Office:

Deirdre O'Connor at: 087 8168519

Mark Gray at: 087 6538087

Covidien Ireland

Block G, 1st Floor

Loughlinstown

Dublin

APPENDIX I Counterfeit Nellcor SpO2 Durasensor (DS-100A) Sensors Information

Counterfeit Nellcor SpO2 Durasensor (DS-100A) Sensors Information

Where counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors have been identified at your facility the IMB request that you provide the following information to the IMB (enforcement@imb.ie or vigilance@imb.ie):

- Name, position and contact details of submitter.

- Name and contact details of your facility.

- Number of counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors supplied.

- Number of counterfeit Nellcor SpO2 Durasensor (DS-100A) identified and current location.

- Name and contact details of supplier of counterfeit Nellcor SpO2 Durasensor (DS-100A) sensors.

- Date of supply of counterfeit Nellcor SpO2 Durasensor (DS-100A).
 - Have any adverse incidents relating to counterfeit Nellcor SpO2 Dura

- Have any adverse incidents relating to counterfeit Nellcor SpO2 Durasensor (DS-100A) been reported? If so, please provide details.

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