

Medical Device Alert

Action

Ref: MDA/2011/004 Issued: 18 January 2011 at 10:00

Device

Counterfeit Covidien Nellcor SpO₂ Durasensor® (DS-100A) sensors.



Problem

Counterfeit Nellcor SpO₂ Durasensor (DS-100A) may have been supplied to hospitals and clinics.

Covidien, the legitimate manufacturer, has found that sample counterfeit devices partially failed to provide SpO₂ readings when tested with OxiMax™/Nellcor monitors.

Action by

All those who use or maintain these devices.

Action

- Identify and quarantine any suspect devices using the information in the manufacturer's [Field Safety Notice](#).
- Contact your local Covidien representative to authenticate suspected devices.
- Return any confirmed counterfeit devices to your local Covidien representative and inform the MHRA.

CAS deadlines

Action underway: 01 February 2011

Action complete: 08 February 2011

Contact

Manufacturer

Mr B Cole
Covidien

Tel: 07710 597 649

Fax: 020 3027 1758

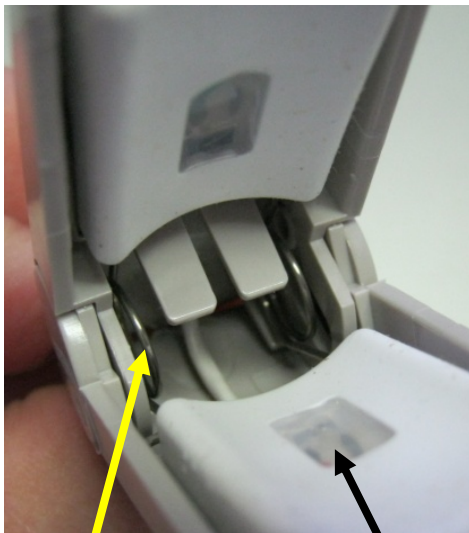
Email: ben.cole@covidien.com

Device

Nellcor SpO₂ Durasensor (DS-100A) sensors are used with pulse oximeters for non-invasive measurement of oxygen saturation of patients over 40kg.

The most noticeable differences between genuine and counterfeit sensors are shown below. See the manufacturer's [Field Safety Notice](#) for a full list of differences.

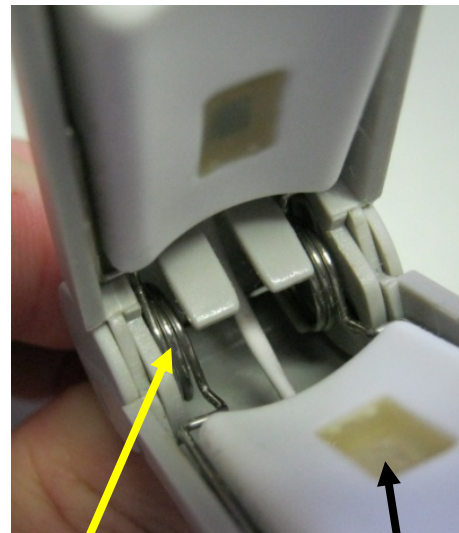
Original Nellcor Durasensor sensor



One winding on feather

Red and black cables visible

Counterfeit sensor



Three windings on feather

No visible cables

Problem

The Medicines and Healthcare products Regulatory Agency has been informed by Covidien that counterfeit Nellcor SpO₂ Durasensor (DS-100A) sensors have been found on the market in Germany and the Netherlands.

The accuracy and safety of the counterfeit devices cannot be determined as they have not gone through Covidien's validated conformity assessment.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- All wards
- Ambulance staff
- Anaesthetists
- Biomedical engineering staff
- Cardiac care units
- EBME departments
- Health and safety managers
- High dependency units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Medical directors
- Medical physics departments
- Nursing executive directors
- Operating theatre practitioners
- Risk managers
- Supplies manager
- Theatres

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- Equipment libraries and stores
- General practitioners
- Maintenance staff
- Palliative care team
- Walk-in centres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Establishments registered with OFSTED

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Mr B Cole
Covidien

Tel: 07710 597 649

Fax: 020 3027 1758

Email: ben.cole@covidien.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/004** or **2010/012/015/081/017**.

Technical aspects

Mr J Lefever or Mrs M King
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7262/7286
Fax: 020 8754 3965
Email: jim.lefever@mhra.gsi.gov.uk
mel.king@mhra.gsi.gov.uk

Clinical aspects

Mr J Plumb
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128
Fax: 020 8754 3965
Email: jonathan.plumb@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900
Email: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk