

Medical Device Alert

Ref: MDA/2013/043 Issued: 20 June 2013 at 14:00

Device
<p>Rad-8 Pulse Oximeter with 20-pin patient cable connector.</p> <p>Manufactured by Masimo.</p> <p>Manufactured from 27 March 2009 to 24 January 2013 inclusive.</p> <p>Specific serial numbers are affected.</p>

Problem	Action
<p>Risk of delay in treatment.</p> <p>Some Rad-8 pulse oximeters turn off when they are moved, without the operator pressing the power button.</p> <p>The manufacturer has issued a Field Safety Notice (dated 08 March 2013) to each customer listing specific affected serial numbers.</p>	<p>Stop using and quarantine these pulse oximeters.</p> <p>If no alternatives are available, check that the pulse oximeter is still turned on whenever it is moved.</p> <p>Contact the manufacturer to arrange for the repair of affected devices and return the completed tracking/verification form to the manufacturer.</p>
Action by	
<p>Clinical and nursing staff who use these devices and those responsible for maintenance.</p>	
CAS deadlines	Contact
<p>Action underway: 22 July 2013</p> <p>Action complete: 20 September 2013</p> <p>Note: These deadlines are for systems to be in place to identify and arrange for replacements of affected devices.</p>	<p>Manufacturer Mr Ben Franklin Masimo UK Tel: 01256 479 988 Email: TechsupportEU@masimo.com</p>

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS England area teams for information
- NHS 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:

- All wards and clinical departments
- Directors of nursing
- EBME departments
- Equipment stores
- Medical directors

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults and paediatric)
- Domiciliary care providers
- Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can 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 Ben Franklin, UK Country Manager, Masimo UK, Unit Q, Loddon Business Centre, Roentgen Road Basingstoke, RG24 8NG

Tel: 01256 479 988

Fax: 01256 473 684

Email: TechsupportEU@masimo.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/043** or **2013/004/004/081/001**

Technical aspects

Andy Marsden or Paul Sandhu
Medicines & Healthcare products Regulatory Agency
Floor 4, 151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7205 / 7266

Fax: 020 8754 3965

Email: andy.marsden@mhra.gsi.gov.uk
paul.sandhu@mhra.gsi.gov.uk

Clinical aspects

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Floor 4, 151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 6648
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:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ
Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk

MHRA is an executive agency of the Department of Health
© Crown Copyright 2013

Addressees may take copies for distribution within their own organisations