

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/034

Issued: 20<sup>th</sup> May 2008

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section
<b>Medical Device/Equipment:</b> Masimo Rainbow Rad-57 Pulse CO-Oximeter.	▶ ①
<b>Problem:</b> <ul style="list-style-type: none"> <li>Elevated levels of methaemoglobin (MetHb) will lead to inaccurate carboxyhaemoglobin (COHb) readings (SpCO).</li> <li>Elevated levels of either MetHb or COHb will lead to inaccurate oxygen saturation readings (SpO<sub>2</sub>).</li> </ul>	▶ ②
<b>Action by:</b> Anaesthetists, operating theatre practitioners, intensive care specialists, A&E specialists and ambulance staff.	▶ ③
<b>Action:</b> <ul style="list-style-type: none"> <li>If both COHb and MetHb readings (SpCO and SpMet) are raised users should check blood gases using a blood gas analyser.</li> </ul>	▶ ④
<b>Distributed by NIAIC to:</b> <ul style="list-style-type: none"> <li>Chief Executive of each HSS Board</li> <li>Chief Executive of each HSS Trust</li> <li>Chief Executive of each Agency</li> <li>NIAIC Liaison Officers</li> </ul>	▶ ⑤
<b>Contacts</b> Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥
<b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b>	
<b>Acknowledge Receipt of Alert:</b> 23 <sup>rd</sup> May 2008	▶ ⑦
<b>Action Under Way:</b> 20 <sup>th</sup> June 2008	
<b>Action Complete:</b> 20 <sup>th</sup> Aug 2008	

This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

## 1. DEVICE/EQUIPMENT:

Masimo Rainbow Rad-57 Pulse CO-Oximeter.

## 2. PROBLEM:

MetHb levels above 3% affect the accuracy of COHb measurement in these monitors. This is due to the overlap of the absorbance spectra of MetHb and COHb used to calculate their values. An increase in MetHb will cause the COHb (SpCO) reading to be high.

Similarly increases in either MetHb or COHb will affect the accuracy of the oxygen saturation measurement (SpO<sub>2</sub>) due to the overlap of the absorbance spectra of MetHb and COHb with those of reduced haemoglobin (RHb) and oxyhaemoglobin (O<sub>2</sub>Hb).

Increased levels of COHb will increase the oxygen saturation reading (SpO<sub>2</sub>) by a similar amount. Increases in MetHb will decrease the oxygen saturation readings (SpO<sub>2</sub>) by 10 to 15%. At high levels of MetHb the oxygen saturation (SpO<sub>2</sub>) reading may read in the region of 80 to 85%.

## 3. ACTION BY:

Anaesthetists, operating theatre practitioners, intensive care specialists, A&E specialists and ambulance staff.

## 4. ACTION:

- If both COHb and MetHb readings (SpCO and SpMet) are raised users should check blood gases using a blood gas analyser.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- A&E consultants
- Ambulance staff
- Anaesthetists
- Intensive care, directors of
- Medical directors
- Operating theatre practitioners
- Risk managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

## 6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Mr K Ashover  
UK Country Manager  
Masimo UK  
Unit Q  
Loddon Business Centre  
Roentgen Road  
Basingstoke  
Hants RG24 8NG

Tel: 01256 479 988  
Fax: 01256 473 684  
E-mail: [TechsupportEU@masimo.com](mailto:TechsupportEU@masimo.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/034 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868  
Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

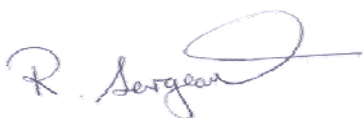
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:  
23<sup>rd</sup> May 2008

Action Under Way:  
20<sup>th</sup> June 2008

Action Complete:  
20<sup>th</sup> Aug 2008



Robert Sergeant  
NIAIC Operational Manager

#### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*