

# Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/061

Issued: 31<sup>st</sup> July 2008

For:

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



**HEALTH ESTATES**

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	Section			
<p><b>Medical Device/Equipment:</b> Blood glucose meters – Ascensia Contour (5-second) manufactured by Bayer Diabetes Care.</p>	▶ ①			
<p><b>Problem:</b> Affected devices may show falsely high readings when testing samples from neonates less than 24 hours old. This may mask hypoglycaemia.</p>	▶ ②			
<p><b>Action by:</b> Healthcare personnel who procure, use or manage these devices</p>	▶ ③			
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>Do not use affected devices for monitoring blood glucose levels in neonates less than 24 hours old.</li> <li>Use an alternative method, and if necessary seek advice from the local hospital laboratory.</li> </ul>	▶ ④			
<p><b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b></p>	▶ ⑤			
<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥			
<p style="text-align: center;"><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p> <table border="1" style="width: 100%;"> <tr> <td><b>Acknowledge Receipt of Alert:</b> 1<sup>st</sup> Aug 2008</td> <td><b>Action Under Way:</b> 7<sup>th</sup> Aug 2008</td> <td><b>Action Complete:</b> 28<sup>th</sup> Aug 2008</td> </tr> </table>	<b>Acknowledge Receipt of Alert:</b> 1 <sup>st</sup> Aug 2008	<b>Action Under Way:</b> 7 <sup>th</sup> Aug 2008	<b>Action Complete:</b> 28 <sup>th</sup> Aug 2008	▶ ⑦
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This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

The Bayer Ascensia Contour blood glucose meters use Ascensia MICROFILL strips and are available in two versions – 5-second and 15-second devices – distinguishable by the length of time it takes to perform a blood glucose test.

***This Medical Device Alert covers the newer 5-second devices only.*** We are not aware of any evidence to suggest that the 15-second device is affected.



## 2. PROBLEM:

Bayer Diabetes Care has reported that in eight non-UK hospitals, samples from neonates less than 24 hours old have shown falsely high readings with affected devices, particularly for blood glucose levels under 2.8 mmol/L. This may mask neonatal hypoglycaemia. For neonates less than 24 hours old, the manufacturer has observed a bias of 12-13%.

The manufacturer is currently investigating the root cause of this problem. There have been no adverse incidents associated with the use of the affected devices. There is no change to the intended use of affected devices in monitoring hypoglycaemia in neonates diagnosed with laboratory glucose methods, and who are more than 24 hours old.

## 3. ACTION BY:

Healthcare personnel who procure, use or manage these devices.

## 4. ACTION:

- Do not use affected devices for monitoring blood glucose levels in neonates less than 24 hours old.
- Use an alternative method, and if necessary seek advice from the local hospital laboratory.

## 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:

- Biochemists
- Clinical biochemistry departments
- Clinical governance leads
- Clinical pathologists
- Clinical pathology departments
- Clinical pathology directors
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maternity units
- Medical directors
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Nutrition nurses
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Phlebotomists
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics who care for Neonates through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Melanie Thorp  
Bayer Diabetes Care  
Bayer House  
Strawberry Hill  
Newbury Berks  
RG14 1JA

Tel: 0845 600 6030 (Bayer Diabetes Support)

Fax: 01635 566 275

E-mail: [diabetesUKsupport@bayer.co.uk](mailto:diabetesUKsupport@bayer.co.uk)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/061 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)

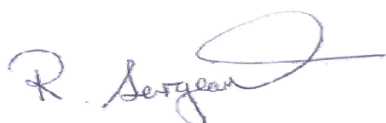
## 7. FEEDBACK:

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

**Acknowledge Receipt of Alert:**  
1<sup>st</sup> Aug 2008

**Action Under Way:**  
7<sup>th</sup> Aug 2008

**Action Complete:**  
28<sup>th</sup> Aug 2008



Robert Sergeant  
NIAIC Operational Manager