

Medical Device Alert

Ref: MDA/2011/044 Issued: 12 May 2011 at 15:00

Device

Blood glucose meters for professional use only:
StatStrip Glucose manufactured by Nova Biomedical.



Problem	Action
<p>The meter may generate consecutive error codes for multiple samples from the same patient, which may mask abnormal glucose levels.</p>	<p>If the meter gives two or more error codes for the same patient, use an alternative point of care device or a laboratory based method.</p>
<h3 data-bbox="124 1247 304 1294">Action by</h3> <p data-bbox="124 1323 655 1384">Healthcare professionals who use these devices.</p>	
CAS deadlines	Contact
<p data-bbox="124 1514 539 1547">Action underway: 26 May 2011</p> <p data-bbox="124 1581 549 1615">Action complete: 09 June 2011</p>	<p data-bbox="810 1514 1318 1693"> Manufacturer Mr Andy O'Toole Nova Biomedical Tel: 01244 287087 Email: europa@novabiomedical.co.uk </p>

Problem

The MHRA received an incident report in which samples from a renal transplant patient gave recurrent sample flow error codes on the StatStrip Glucose meter, masking the patient's abnormal glucose level.

The manufacturer's investigation has been unable to confirm the root cause for this issue, and indicate that the device performs as intended. The manufacturer issued a [Field Safety Notice on 02 May 2011](#).

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (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 and clinical departments
- Anaesthetists
- Biochemists
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Intensive care units
- Medical directors
- Neonatology departments
- Nursing executive directors
- Outpatient clinics
- Point of care testing co-ordinators
- Purchasing managers
- Renal medicine, directors of
- Risk managers
- Theatres

Primary care trusts

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

- Community diabetes specialist nurses
- Community hospitals
- NHS walk-in centres
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

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 Andy O'Toole
Nova Biomedical
C3-5 Evans Business Centre
Deeside Industrial Park
Deeside
Flintshire CH5 2JZ

Tel: 01244 287 087

Email: europe@novabiomedical.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/044** or **2011/001/015/401/001**.

Technical aspects

Bina Mackenzie/Guido Fumagalli
Medicines & Healthcare products Regulatory Agency
Floor 4
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London SW1W 9SZ

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Clinical aspects

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London SW1W 9SZ

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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