


Medical Device Alert

Ref: MDA/2013/025 Issued: 01 May 2013 at 12:00

Device	
<p>Home use blood glucose meter:</p> <p>FreeStyle InsuLinx manufactured by Abbott Diabetes Care</p>	

Problem	Action
<p>At extremely high blood glucose levels of 56.8 mmol/l and above, the meter will display and store in its memory an incorrect low test result.</p> <p>An incorrect low result may delay a diagnosis of diabetic ketoacidosis and suggest an incorrect insulin dose.</p> <p>The manufacturer has published a Field Safety Notice on this problem dated 15 April 2013.</p>	<p>Healthcare professionals to immediately discontinue supplying these meters and return any unused meters to your supplier.</p> <p>Healthcare professionals and pharmacists to advise users to either:</p> <ul style="list-style-type: none"> download new software through the Auto-Assist computer application supplied with the meter <p style="text-align: center;">or</p> <ul style="list-style-type: none"> obtain a replacement meter by contacting Abbott Diabetes Care Customer Service (0800-088-5521).
Action by	
<p>Healthcare professionals who manage patients who use this device.</p> <p>Pharmacists supplying FreeStyle Lite blood glucose test strips.</p>	
CAS deadlines	Contact
<p>Action underway: 08 May 2013</p> <p>Action complete: 31 May 2013</p>	<p>Manufacturer Mike Clayton Abbott Diabetes Care Tel: 0500 467 466 Email: adchelpuk@abbott.com</p>

Problem

There are no other Abbott Diabetes Care products affected by this issue.

The performance of the test strips is not affected by this problem.

The meter is capable of reporting results in the range 1.11 to 27.78 mmol/l.

A communication has been sent out by the manufacturer to customers, healthcare professionals and pharmacists detailing the issue.

Action

Pharmacists supplying FreeStyle Lite blood glucose test strips advise users with FreeStyle InsuLinx meters to either:

upgrade their meters by downloading and installing new meter software through the Auto-Assist personal computer application supplied with the meter. When connected, users will be prompted to upgrade where required. A link to the website www.freestyleinsulin.com/swupdate is provided in the communication to customers, healthcare professionals and pharmacists

or

contact Abbott Diabetes Care Customer Service to obtain a replacement meter (0800-088-5521).

Meters with the updated software are marked with a yellow circle on the carton near the lot number.

Healthcare professionals who manage patients who use FreeStyle InsuLinx meters:

- Identify patients who are using these meters.
- If you have FreeStyle InsuLinx meters in your current stock contact Abbott Diabetes Care customer care for replacements.
- Advise users of FreeStyle InsuLinx meters to either:
upgrade their meters by downloading and installing new meter software through the Auto-Assist personal computer application supplied with the meter. When connected, users will be prompted to upgrade where required. A link to the website www.freestyleinsulin.com/swupdate is provided in the communication to customers, healthcare professionals and pharmacists
or
contact Abbott Diabetes Care Customer Service to obtain a replacement meter (0800-088-5521).
Meters with the updated software are marked with a yellow circle on the carton near the lot number.

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
- NHS England area teams (chief executives)
- NHS England regional teams
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- Social services in England (directors)

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:

- Ambulance services directors
- Ambulance staff
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- District nurses
- Endocrinology units
- Endocrinology, directors of
- Health and safety managers
- Health visitors
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- NHS walk-in centres
- Nursing executive directors
- Outpatient clinics
- Paramedics
- Pharmaceutical advisors
- Pharmacists
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- School nurses
- Vascular units
- Walk-in centres

NHS England: local area teams

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

- Community pharmacists
- Directors of public health
- General practitioners
- Practice managers
- Practice nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Directors of public health
- In-house residential care homes

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
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector

- Independent treatment centres
- Nursing agencies
- 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. 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

Mike Clayton
Abbott Diabetes Care

Tel: 0500 467 466

Email: adchelpuk@abbott.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/025** or **2013/004/011/081/007**

Technical aspects

Guido Fumagalli and Bina Mackenzie
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7144 and 020 3080 7229

Fax: 020 8754 3965

Email: guido.fumagalli@mhra.gsi.gov.uk
bina.mackenzie@mhra.gsi.gov.uk

Clinical aspects

Nicola Lennard
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7126

Fax: 020 8754 3965

Email: nicola.lennard@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.iric@nhs.net

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

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