

Medical Device Alert

Ref: MDA/2014/009 Issued: 13 March 2014 at 10:00

Device

FreeStyle Mini[®] and FreeStyle[®] blood glucose monitoring systems manufactured by Abbott Diabetes Care.

Problem

These blood glucose meters may give incorrect low blood glucose results when they are used with FreeStyle Lite and FreeStyle blood glucose test strips.

Abbott Diabetes Care is therefore asking people to stop using these affected meters and to contact them to get a replacement.

The manufacturer has sent [Field Safety Notices](#), dated 19 February 2014, to customers.

To deal with this problem when using FreeStyle Navigator continuous glucose monitoring system (1.0 and 1.5 generation) and the FreeStyle blood glucose meter built into the OmniPod insulin management system, follow the advice in the manufacturer's Field Safety Notice.

Action by

Healthcare professionals who manage patients who use these devices.

Pharmacists supplying FreeStyle Lite and FreeStyle blood glucose test strips to patients who use the affected devices.

CAS deadlines

Action underway: 20 March 2014

Action complete: 14 April 2014

Action

Advise users to contact Abbott Diabetes Care customer services on 0500 467 466.

Pharmacists supplying FreeStyle Lite and FreeStyle blood glucose test strips:

When dispensing test strips advise users to contact Abbott Diabetes Care customer services for a replacement meter.

Healthcare professionals managing patients:

Advise users to contact Abbott Diabetes Care customer services for a replacement meter.

This Medical Device Alert replaces MDA/2013/082R.

Contact

Manufacturer

Mike Clayton
Abbott Diabetes Care

Tel: 0500 467 466

Email: ADChelpuk@abbott.com

Device



Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- 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 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:

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|---|---|
| <ul style="list-style-type: none"> • All wards • Ambulance services directors • Ambulance staff • Biomedical science departments • Chief pharmacists • Clinical governance leads • Community diabetes specialist nurses • Community hospitals • Community midwives • Community nurses • Diabetes clinics/outpatients • Diabetes nurse specialists • Diabetes, directors of • Dietetics departments • District nurses • Health and safety managers | <ul style="list-style-type: none"> • Health visitors • Hospital at home units • Hospital pharmacies • Hospital pharmacists • NHS walk-in centres • Outpatient clinics • Paediatricians • Paediatrics departments • Paramedics • Pharmaceutical advisors • Pharmacists • Point of care testing co-ordinators • Purchasing managers • Risk managers • School nurses • Walk-in centres |
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NHS England area teams

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

- Community pharmacists
- 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)
- 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, Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, SL6 4XE

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/2014/009** or **2014/002/018/291/022**.

Technical aspects

Guido Fumagalli or Bina Mackenzie

Medicines & Healthcare Products Regulatory Agency

Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7144 or 7229

Fax: 020 8754 3965

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

Clinical aspects

Dr Camilla Fleetcroft
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ
Tel: 020 3080 6097
Email: camilla.fleetcroft@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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 5801 Email: Haz-Aic@wales.gsi.gov.uk