Medical Device Alert

Ref: MDA/2014/021    Issued: 10 June 2014 at 15:00

Device
Home use blood glucose meters.
Accu-Chek Mobile meter and Accu-Chek Mobile test cassette manufactured by Roche.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Action</th>
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| This device may give falsely high readings. As a consequence, patients might take an inappropriately high dose of insulin. The meter uses strip-free technology so users need to follow a specific testing procedure that is different to standard meter and strip systems. Roche has sent its Field Safety Notice (FSN), with updated instructions, to registered patients, healthcare professionals, distributors and retailers. The instructions are also online: www.accu-chek.co.uk/mobilepropertesting | - Identify patients who use these meters and advise them to follow the correct testing procedure, details of which have been provided in the FSN.  

- Ensure that patients can continue to monitor their blood glucose.

- If patients are concerned about their blood glucose readings when using this meter, advise them to contact their healthcare professional. |

Action by
Healthcare personnel managing patients who use these devices.

CAS deadlines
Action underway: 17 June 2014
Action complete: 10 July 2014

These deadlines are for staff and patients to be aware of the problem and the advice recommended by the manufacturer in the FSN.

Contact
Manufacturer
Roche Diagnostics GmbH
Tel: Accu-Chek Careline: 0800 701 000
Email: rdc.vigilance_eea@roche.com
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:
- 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
- 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

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
Roche
Tel:  Accu-Chek Careline: 0800 701 000
Email:  rdc.vigilance_eea@roche.com

England
If you are in England, please send enquiries about this notice to the MHRA, quoting reference number MDA/2014/021 or 2014/005/023/081/008.

Technical aspects
Bina Mackenzie or Sonal Vara
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7229 / 7710
Fax: 020 8754 3965
Email:  bina.mackenzie@mhra.gsi.gov.uk
sonal.vara@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.iric@nhs.net

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

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