

Medical Device Alert

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

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

Problem	Action
<p>This device may give falsely high readings. As a consequence, patients might take an inappropriately high dose of insulin.</p> <p>The meter uses strip-free technology so users need to follow a specific testing procedure that is different to standard meter and strip systems.</p> <p>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</p> <p>This meter has been distributed in the UK since 2010.</p>	<ul style="list-style-type: none"> • 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	
<p>Healthcare personnel managing patients who use these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 17 June 2014</p> <p>Action complete: 10 July 2014</p> <p>These deadlines are for staff and patients to be aware of the problem and the advice recommended by the manufacturer in the FSN.</p>	<p>Manufacturer</p> <p>Roche Diagnostics GmbH</p> <p>Tel: Accu-Chek Careline: 0800 701 000</p> <p>Email: rdc.vigilance_eea@roche.com</p>

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

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Clinical aspects

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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

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