

Medical Device Alert

Immediate action

Ref: MDA/2011/011 Issued: 07 February 2011 at 11:30

Device

Blood glucose meters for professional use only:
Accu-Chek Inform and Inform II
manufactured by Roche
Diagnostics Limited.



Inform



Inform II

Problem

Units of measure may change from mmol/L to mg/dL, which could result in the meter user thinking that the blood glucose level is higher than it actually is.

Action by

Healthcare professionals who use these devices.

Action

Inform

If the meter battery is low, charge as soon as possible. Every time you use the meter, check the units of measure to ensure that it is reading in the correct units - mmol/L.

Inform II

Every time you use the meter, check the units of measure to ensure that it is reading in the correct units - mmol/L.

CAS deadlines

Action underway: 21 February 2011

Action complete: 07 March 2011

Contact

Manufacturer

Mr John Burling
Roche Diagnostics Limited

Tel: 0144 425 6484

Email: john.burling@roche.com

Device

All Accu-Chek Inform meters including the Inform (also known as Inform I) and Inform II. These meters are not intended for self/home use.

Problem

Accu-Chek Inform

Roche Diagnostics has received nine reports worldwide for Accu-Chek Inform meters where the units of measure switched from mmol/L to mg/dL. Meters with a nearly depleted battery were not docked in the charging unit for sufficient time to allow the meter to synchronise with the data management system and the units of measure reverted to mg/dL.

Roche Diagnostics has found the cause of this problem to be premature disruption of the charging, loading and synchronising process of Accu-Chek Inform meters with nearly depleted batteries.

Accu-Chek Inform II

The MHRA has been notified of two incidents involving Accu-Chek Inform II meters where the user reported a change to the units of measure from mmol/L to mg/dL. Roche Diagnostics has been unable to establish the root cause of this problem to date.

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 (Chief Executives)
- 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

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

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Roche Diagnostics Limited
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Burgess Hill
West Sussex RH15 9RY

Tel: 0144 425 6484

Email: john.burling@roche.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/011** or **2008/012/001/401/014**.

Technical aspects

Bina Mackenzie or Guido Fumagalli
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7229/7144

Fax: 020 8754 3965

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

Clinical aspects

Jonathan Plumb
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London SW1W 9SZ

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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

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:

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