Safeguarding public health

# MEDICAL DEVICE ALERT

Issued: **19 July 2007 at 15:00** Ref: **MDA/2007/058**

| | |
|---|---|
| ☐ | **Immediate action** |
| ☑ | **Action** |
| ☑ | **Update** |
| ☐ | **Information request** |

| | |
|---|---|
| **Device:**<br>Point of care and home-use blood glucose meters: Roche Accu-Chek and Glucotrend; Abbott Diabetes Care FreeStyle. | ►Page 2 |
| **Problem:**<br>Risk of overestimation of blood glucose results when these meters are used on samples from patients on treatments that contain (or are metabolised to) maltose, xylose or galactose.<br>This problem does not apply to treatments taken orally.<br>This alert updates and supersedes MDA/2003/011. | ►Page 2 |
| **Action by:**<br>• Healthcare professionals managing patients that monitor their blood glucose using these meters.<br>• Healthcare professionals who use these meters. | |
| **Action:**<br>Do not use affected meters to measure blood glucose in patients receiving treatments that contain (or are metabolised to) maltose, xylose or galactose.<br>If you are unsure if a particular patient treatment contains (or is metabolised to) maltose, xylose or galactose consult the medicines information department of your local hospital pharmacy. Telephone numbers for other medicines information services are listed in the British National Formulary (BNF). | ►Page 2 |
| **Distributed to:**<br>NHS trusts in England – Chief Executives*<br>Commission for Social Care Inspection (CSCI) – Headquarters<br>Healthcare Commission (CHAI) – Headquarters<br>Primary care trusts in England – Chief Executives*<br>Social services in England – Directors*<br>* via CE Bulletin | ►Page 3 |
| **Contacts:**<br>Details of manufacturer contacts and MHRA contacts for technical and clinical aspects.<br>Change of address or removal from address list for CSCI and Healthcare Commission. | ►Page 3- 4 |

| Action deadlines for the Safety Alert Broadcast System (SABS) | |
|---|---|
| **Deadline (action underway): 16 August 2007** | **Deadline (action complete): 11 October 2007** |

This notice is also on our website: **http://www.mhra.gov.uk**

## Device:

| Manufacturer | Meter | Test strips |
|---|---|---|
| Roche | Accu-Chek Active | Active |
| | Accu-Chek Advantage | Advantage Plus |
| | Accu-Chek Inform | Advantage Plus |
| | Accu-Chek Aviva | Aviva |
| | Accu-Chek Compact Plus | Compact |
| | Glucotrend<br>(No longer distributed in the UK) | Active |
| | Glucotrend 2<br>(No longer distributed in the UK) | Active |
| | Glucotrend Premium<br>(No longer distributed in the UK) | Active |
| Abbott Diabetes Care | FreeStyle Mini | FreeStyle |
| | FreeStyle Freedom | FreeStyle |
| | FreeStyle Lite | FreeStyle Lite |

Currently all Roche blood glucose meters and all Abbott Diabetes Care FreeStyle blood glucose meters use test strips that are affected by this problem.

Note: The above meters use test strips that use the glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) technology. The MHRA is not aware of any problems with other meters and test strips.

## Problem:

Since issuing MDA/2003/011 in April 2003, the MHRA has become aware of further incidents involving Roche Accu-Chek and Abbott Freestyle blood glucose meters, where patient treatments that contain (or are metabolised to) maltose, xylose or galactose have caused overestimation of glucose levels. Overestimation of blood glucose levels can mask hypoglycaemia and may result in the inappropriate administration of insulin.

Treatments that are known to contain (or that are metabolised to) maltose, xylose or galactose include (Extraneal) icodextrin (used in peritoneal dialysis, PD), and certain immunoglobulin preparations (used in treating pre- and post-surgery patients). Orally administered treatments that contain (or are metabolised to) maltose, xylose or galactose are not affected by this problem.

## Action:

Read the instructions for use of **ALL** point of care blood glucose measuring systems to ensure that you are familiar with their limitations and criteria for use.

When writing Standard Operating Procedures or training staff, include information on the limitations associated with the use of point of care blood glucose measuring systems.

Consult your local hospital's clinical chemistry department if you are in any doubt about the use of a particular system or the validity of the test results

# Distribution:

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

### Trusts to:

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

- A&E departments
- All wards
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Diabetes clinics/outpatients
- Diabetes, directors of
- Diabetes nurse specialists
- Health and safety managers
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff (adult/paediatrics)
- Intensive care nursing staff (adult/paediatrics)
- IV nurse specialists
- Medical directors
- Medical information services
- Neonatal nurse specialists
- Nursing executive directors
- Peritoneal dialysis units
- Pharmacists
- Point of care testing co-ordinators
- Purchasing managers
- Renal physicians
- Special care baby units
- Supplies managers
- Theatre managers

### Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes (with nursing and personal care)
- Domiciliary care agencies

### Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house domiciliary care providers (personal care services in the home)
- in-house residential care homes

### Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Children's hospices
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Laboratories in the independent sector
- Private medical practitioners
- Treatment centres

### Primary care trusts to:

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

- Community diabetes specialist nurses
- Community hospitals
- Community pharmacists
- District nurses
- General practitioners
- Health visitors
- NHS walk-in centres
- Pharmaceutical advisors
- Practice managers
- Practice nurses
- Walk-in centres

# Contacts:

Enquiries to the manufacturer should be addressed to:

Roche Diagnostics Limited
Charles Avenue
Burgess Hill
RH15 9RY
United Kingdom

Customer care line(freephone): 0800 701 000
Professional Services care line: 0808 100 1920

Abbott Diabetes Care
Abbott Laboratories
Customer Services
Abbott House
Vanwall Business Park
Maidenhead
SL6 4UD

Customer care line: Freephone 0500 467 466
Pharmacy care line: 0800 316 8884

## Contacts continued:

Enquiries to the MHRA should quote reference number **2006/009/021/291/017** and be addressed to:

**Technical aspects:**
Bina Mackenzie or Stephen Lee
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3229 / 3309
Fax: 020 7084 3106

E-mail: bina.mackenzie@mhra.gsi.gov.uk
stephen.lee @mhra.gsi.gov.uk

**Clinical aspects:**
Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3123
Fax: 020 7084 3111

E-mail: susanne.ludgate@mhra.gsi.gov.uk

**Change of address or removal from address list for CSCI and Healthcare Commission:**

CSCI Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

## How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (http://www.mhra.gov.uk).

Alternatively, further information and printed incident report forms are available from:
MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk
(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the MHRA website:** http://www.mhra.gov.uk

Further information about **SABS** can be found at www.info.doh.gov.uk/sar2/cmopatie.nsf