

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/64

Issued: 23rd July 2007



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION	

This alert updates and supersedes MDEA(NI)2003/07.

	Section								
<p>Medical Device/Equipment: Point of care and home-use blood glucose meters: Roche Accu-Chek and Glucotrend; Abbott Diabetes Care FreeStyle.</p>	▶ ①								
<p>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. This problem does not apply to treatments taken orally.</p>	▶ ②								
<p>Action by:</p> <ul style="list-style-type: none"> Healthcare professionals managing patients that monitor their blood glucose using these meters. Healthcare professionals who use these meters. 	▶ ③								
<p>Action: Do not use affected meters to measure blood glucose in patients receiving treatments that contain (or are metabolised to) maltose, xylose or galactose. 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).</p>	▶ ④								
<p>Distributed by NIAIC to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Community Pharmacists	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
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<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥								
<p>Feedback Requirements to NIAIC None required.</p>	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

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 (No longer distributed in the UK)	Active
	Glucotrend 2 (No longer distributed in the UK)	Active
	Glucotrend Premium (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. We are not aware of any problems with other meters and test strips.

2. PROBLEM:

Since issuing MDEA(NI)2003/07 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.

3. ACTION BY:

- Healthcare professionals managing patients that monitor their blood glucose using these meters.
- Healthcare professionals who use these meters.

4. 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

5. ONWARD DISTRIBUTION TO:

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

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Trust Pharmacy Managers
- Medical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Intensive Care
- Renal Units
- All Wards
- Point of Care testing Co-ordinators
- Clinical Chemistry Departments
- Diabetic Nurse Specialists
- Laboratories
- Accident & Emergency Departments
- Theatre Managers
- Directors of Public Health
- Clinical Governance Lead Health and Social Care Groups
- Social Care Staff
- Community Care Staff
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Practice Nurses
- District Nurses

6. CONTACTS:

Enquires to manufacturer should be addressed to:

David Owolabi
Roche Diagnostics Limited
Charles Avenue
Burgess Hill
RH15 9RY

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

Direct dial: 01444 256 561 (Office ext: 6561)

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

Enquires to NIAIC should quote reference number MDEA(NI)2007/64 and be addressed to:

Northern Ireland Adverse Incident Centre
(NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

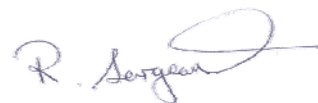
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety