

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/77

Issued: 18 December 2006

For:

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|-------------------------|---|
| IMMEDIATE ACTION | ✓ |
| ACTION | |
| UPDATE | ✓ |
| INFORMATION | |



HEALTH ESTATES

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| This alert replaces the guidance issued on 04 March 2005 in MDEA(NI)2005/31, which has now been withdrawn and updates the information given on 16 September 2006 in MDEA(NI)2006/56 | Section | | | | | | | | |
| Medical Device/Equipment: LifeScan OneTouch [®] Ultra [®] , LifeScan InDuo [®] and LifeScan PocketScan [®] blood glucose meters. | ▶ ① | | | | | | | | |
| Problem: The units of measurement displayed may change from mmol/L to mg/dL, resulting in the user thinking that the blood glucose level is too high and thus altering the treatment regime inappropriately. | ▶ ② | | | | | | | | |
| Action by: <ul style="list-style-type: none"> • Pharmacists supplying the OneTouch[®] Ultra[®] or PocketScan[®] blood glucose test strips. • Healthcare professionals managing patients who use these devices. • Healthcare professionals who use these devices. | ▶ ③ | | | | | | | | |
| Action: See page 32 for detailed description of action required by Pharmists and Healthcare Professionals. | ▶ ④ | | | | | | | | |
| Distributed by NIAIC to: <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> For onward distribution see Section 5 | 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 |
| 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 | | | | | | | | | |
| Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects. | ▶ ⑥ | | | | | | | | |
| Feedback Requirements to NIAIC See section 7 for further details on feedback requirements for HPSS Trusts | ▶ ⑦ | | | | | | | | |

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

1. DEVICE/EQUIPMENT:

Blood glucose meter

OneTouch[®] Ultra[®], InDuo[®] and PocketScan[®] **Affected meters. Replacement meter required.**

OneTouch[®] UltraEasy

OneTouch[®] Ultra[®]2

OneTouch[®] UltraSmart

Not affected by this issue. No further action required.

These blood glucose meters are used with OneTouch[®] Ultra[®] or PocketScan[®] test strips.

2. PROBLEM:

This alert supersedes MDEA(NI)2005/31.

The MHRA has continued to receive reports of incidents where the units of measurement displayed on affected blood glucose meters have changed from mmol/L to mg/dL. The units of measure may change if the meter is dropped, or if the battery is changed when the meter is switched on. There may also be some meters for which the units of measurement displayed can inadvertently be changed by the user.

Test results expressed in mg/dL are 18 times higher than those expressed in mmol/L. For example a result of 6 mmol/L would display as 108 mg/dL. This change in unit of measurement could lead the user to think that the blood glucose result is high and thus alter the treatment regime.

LifeScan is planning a comprehensive meter replacement programme for all affected meters. Users can expect to be contacted by Lifescan regarding this issue in early 2007.

3. ACTION BY:

The units of measurement displayed may change from mmol/L to mg/dL, resulting in the user thinking that the blood glucose level is too high and thus altering the treatment regime inappropriately.

4. ACTION:

Pharmacists supplying LifeScan OneTouch Ultra and PocketScan test strips:

- When you dispense OneTouch Ultra or PocketScan test strips advise the user to check whether they have an affected meter and if so to check the units of measurement displayed.
- Advise users to be extra vigilant at checking the units of measurement displayed every time they test, especially if the meter is dropped or the battery has been changed.
- Advise the user that if their meter is reading in mg/dL they should contact the LifeScan customer care line immediately for a replacement meter (see contact details section).
- If their meter is reading in mmol/L they can continue to use their meter as long as they ensure that the meter is reading in mmol/L every time they test. For instructions on how to do this the user should read the owner's booklet or contact the customer care line. These users should be advised that LifeScan will be contacting them in early 2007 regarding replacement meters.
- See Appendix for a safety information sheet, which you can photocopy for users.

Healthcare professionals managing patients who use affected devices:

- Identify patients who are using these meters and advise them to check the units of measurement displayed on their meter.
- Advise users to be extra vigilant at checking the units of measurement displayed every time they test, especially if the meter is dropped or the battery has been changed.
- Advise the user that if their meter is reading in mg/dL they should contact the LifeScan customer care line immediately for a replacement meter (see contact details section).
- If their meter is reading in mmol/L they can continue to use their meter as long as they ensure that the meter is reading in mmol/L every time they test. For instructions on how to do this the user should read the owner's booklet or contact the customer care line. These users should be advised that LifeScan

will be contacting them in early 2007 regarding replacement meters.

- See Appendix for a safety information sheet, which you can photocopy for users.

Healthcare professionals who use these devices:

- Identify any affected meters and check the units of measurement displayed.
- If the meter is reading in mg/dL contact the LifeScan customer care line immediately for a replacement.
- If the meter is reading in mmol/L you can continue to use the meter as long as you ensure that the meter is reading in mmol/L every time you test. For instructions on how to do this you should read the owner's booklet or contact the customer care line (see contact details section). LifeScan will be contacting you in early 2007 regarding replacement meters.

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:

- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- A&E Departments
- All Wards
- Ambulance Services Directors
- Anaesthetists
- Biochemists
- Biomedical Engineering Staff
- Biomedical Science Departments
- Chief Pharmacists
- Clinical Governance Leads
- Clinical Pathologists
- Clinical Pathology Directors
- Consultant Physicians
- Day Surgery Units
- Diabetes, Directors Of
- Diabetic Clinics/Outpatients
- Diabetes Nurse Specialists
- Dieticians
- Directors Of Endocrinology
- Hospital Pharmacists
- Intensive Care Units
- Maternity Units
- Medical Directors
- Medical Libraries
- Nursing Executive Directors
- Outpatient Clinics
- Paediatric Intensive Care Units
- Paramedics
- Point Of Care Testing Co-Ordinators
- Purchasing Managers
- Risk Managers
- Supplies Managers
- Theatre Managers
- Paediatric Intensive Care Units
- Paramedics
- Point of Care Testing Co-Ordinators
- Purchasing Managers
- Renal Medicine Departments (Renal Units)
- Risk Managers
- Supplies Managers
- Theatre Managers
- Residential Special Schools
- Staff Undertaking Care Home Inspection
- Children's Homes
- Domiciliary Care Providers
- Pharmaceutical Advisors
- Practice Managers
- Practice Nurses
- Directors of Public Health
- School Nurses
- Walk-In Centres
- Community Children's Nurses
- Community Diabetes Specialist Nurses
- Community Midwives
- Community Nurses
- District Nurses

6. CONTACTS:

Enquiries to the supplier should be addressed to:

LifeScan Customer Care
LifeScan
Johnson & Johnson
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire HP12 4DP

Tel: 0800 028 8039
Fax: 0800 001 220
E-mail: CustomerCare@LifeScan.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2006/77 and be addressed to:

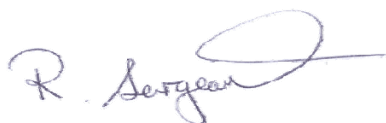
Northern Ireland Adverse Incident Centre
(NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given by HPSS Trusts **ONLY**:-

- 1. Deadline (Email received) : 21 December 2006**
- 2. Deadline (action underway) : 5 January 2007**
- 3. Deadline (action complete): 30 March 2007**



Robert Sergeant
NIAIC Operational Manager

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

Safety Information Sheet

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| OneTouch [®] Ultra [®] | Blood glucose meters manufactured by LifeScan |
| InDuo [®] | |
| PocketScan [®] | |

Some of these meters might give results that could be confusing. LifeScan plan to contact all users of these meters to arrange for a replacement in early 2007.

In the meantime you can continue to use your blood glucose meter as long as you check that your meter displays **mmol/L** every time you use it.

If your meter displays **mg/dL** contact the LifeScan customer care line 0800 028 8039 immediately for a replacement meter.

The following LifeScan meters are NOT affected:

OneTouch[®] UltraEasy, OneTouch[®] Ultra[®] 2, OneTouch[®] UltraSmart