

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/56

Issued: 19 September 2006



HEALTH ESTATES

creating healing environments

For:

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

| | Section | | | | | | | | |
|--|-----------------------------------|------------------------------|-----------------------------------|-----------------------|--------------------------------|--|------------------------|--|-----|
| Medical Device/Equipment: Blood glucose meters: LifeScan OneTouch [®] Ultra [®] 2. | ▶ ① | | | | | | | | |
| Problem: Recall because of potential to misread results. | ▶ ② | | | | | | | | |
| Action by: <ul style="list-style-type: none"> Pharmacists supplying these devices or OneTouch[®] Ultra[®] test strips. Healthcare professionals managing patients who use these devices. Healthcare professionals who use these devices. | ▶ ③ | | | | | | | | |
| Action: <ul style="list-style-type: none"> Users of these meters need to obtain a replacement meter from the manufacturer. Users can continue to use these meters prior to replacement as long as they take note of the decimal point each time they read a result. | ▶ 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 Dental 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></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> | Chief Executive of each HSS Board | General Dental Practitioners | Chief Executive of each HSS Trust | Community Pharmacists | Chief Executive of each Agency | | NIAIC Liaison Officers | | ▶ ⑤ |
| Chief Executive of each HSS Board | General Dental Practitioners | | | | | | | | |
| Chief Executive of each HSS Trust | Community Pharmacists | | | | | | | | |
| Chief Executive of each Agency | | | | | | | | | |
| NIAIC Liaison Officers | | | | | | | | | |
| Contacts Details of supplier contacts and NIAIC contacts for clinical 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:

All LifeScan - OneTouch® Ultra®2 blood glucose meters with the last two digits of the nine character serial number ending in 'AY' .

2. PROBLEM:

LifeScan has received three reports involving UK users of OneTouch® Ultra®2 blood glucose meters who have misread results. The decimal point on the display for these meters is too close to the digits either side and is therefore hard to distinguish. In the UK incidents, users misread results as being ten times higher than they actually were e.g. 2.4mmol/L was misread as 24mmol/L. One patient went on to treat themselves on the basis of a misread result.

LifeScan has recalled all OneTouch® Ultra®2 blood glucose meters manufactured to date and has written to patients and relevant healthcare professionals i.e. diabetes specialist nurses, GPs, practice nurses and pharmacists. These field safety notices are available via the MHRA website (www.mhra.gov.uk).

OneTouch® Ultra®2 blood glucose meters have been available in the UK since June 2006 and about 49,000 devices have been distributed.

This issue does not affect any other blood glucose meter supplied by LifeScan.

3. ACTION BY:

- Pharmacists supplying these devices or OneTouch® Ultra® test strips.
- Healthcare professionals managing patients who use these devices.
- Healthcare professionals who use these devices.

4. ACTION:

Pharmacists supplying OneTouch® Ultra®2 meters or OneTouch® Ultra® test strips:

- Do not supply any affected OneTouch® Ultra®2 meters.
- If you have any affected OneTouch® Ultra®2 meters in your current stock contact LifeScan customer care for replacements.
- When you dispense OneTouch® Ultra® test strips advise users with affected meters to contact LifeScan customer care for a replacement meter.
- Advise the user that they can continue to use their meter prior to contacting LifeScan as long as they take note of the decimal point each time they read a result.
- Advise users to return their affected meters to LifeScan once they have a replacement.
- See Appendix for a safety information sheet, which you can photocopy for users.

Healthcare professionals managing patients who use OneTouch® Ultra®2 meters:

- Identify patients who are using affected meters.
- Advise users of affected meters to contact LifeScan customer care for a free replacement.
- Advise the patient that affected meters can continue to be used prior to receiving a replacement as long as the user takes note of the decimal point each time they read a result.
- Advise users to return their affected meters to LifeScan once they have a replacement.
- See Appendix for a safety information sheet, which you can photocopy for users.

Healthcare professionals who use OneTouch® Ultra®2 meters:

- Identify all affected OneTouch® Ultra®2 meters.
- Contact LifeScan customer care for free replacements.
- Affected meters can continue to be used prior to receiving the replacement as long as you take note of the decimal point each time you read a result.
- Return all affected meters to LifeScan once you have been sent replacements.

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: Customer care: 0800 028 8039
Fax: 0800 001220
E-mail: CustomerCare@LifeScan.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2006/56 and be addressed to:

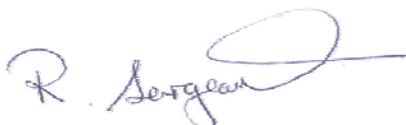
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

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 September 2006**
- 2. Deadline (action underway) : 26 September 2006**
- 3. Deadline (action complete): 18 December 2006**



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

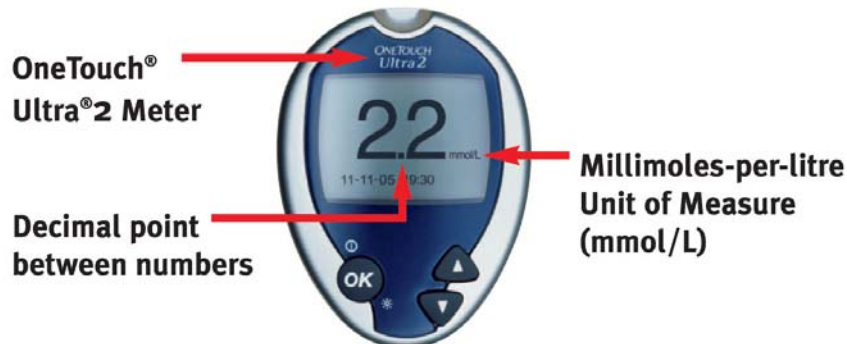
Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using 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

Diabetes: Important Information

Recall of OneTouch® Ultra® 2

blood glucose monitoring system



- Some users of OneTouch® Ultra®2 have not noticed the decimal point between the numbers in their blood glucose reading (e.g. 5.0 mmol/L). If you use the new OneTouch® Ultra®2 meter to test your blood glucose you may misread the result, particularly when your blood glucose readings are very low.
- Our primary concern is for your safety and so we are voluntarily recalling all OneTouch® Ultra®2 meters and will replace them with an alternative meter free of charge.
- Until your replacement meter arrives, it is important that you keep testing your blood glucose as directed by your doctor or nurse. You can continue to use OneTouch® Ultra®2 because the results are accurate but you should carefully note the position of the decimal point in any reading. You should also check particularly carefully if you feel that you are having a 'hypo' (hypoglycaemia or very low blood glucose).
- It is very important that you call LifeScan without delay on the following number so that we can arrange for a free-of-charge replacement meter and the return of your OneTouch® Ultra®2 meter.

If you are in the UK call **Freephone 0800 028 8039**

If you are in the Republic of Ireland call **Freephone 1800 535 676**

Monday - Friday **8:30am - 6:00pm**

Saturday - Sunday **9:00am - 5:00pm**

or visit www.lifescan.co.uk

This recall notice does not affect any other LifeScan meter which you can continue to use.