

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/38

Issued: 5 December 2003

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section		
<p><b>Medical Device/Equipment:</b> LifeScan OneTouch glucose test strips for use with: LifeScan OneTouch II, LifeScan OneTouch Profile or LifeScan OneTouch Basic blood glucose meters</p>	▶ ①		
<p><b>Problem:</b> Patients using plasma calibrated LifeScan OneTouch glucose test strips with the above blood glucose meters may be getting results that are 12% higher than the whole blood calibrated test strips. If Patients are unaware of this difference it may result in them inappropriately altering their treatment or being unaware that their blood glucose concentration is markedly low.</p>	▶ ②		
<p><b>Action by:</b></p> <ul style="list-style-type: none"> <li>Healthcare professionals managing patients using the LifeScan OneTouch II, LifeScan OneTouch Profile and OneTouch Basic blood glucose meters.</li> <li>Community Pharmacists supplying OneTouch test strips.</li> </ul>	▶ ③		
<p><b>Action:</b> Advise patients not to use plasma calibrated OneTouch test strips and to retest blood glucose levels using whole blood calibrated OneTouch test strips.</p>	▶ ④		
<p><b>Distributed by NIAIC to:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">                     Chief Executive of each HSS Board                      Chief Executive of each HSS Trust                      Chief Executive of each Agency                      NIAIC Liaison Officers                 </td> <td style="width: 50%; border: none;">                     General Medical Practitioners                      Community Pharmacists                      Hospices                 </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	General Medical Practitioners Community Pharmacists Hospices	▶ ⑤
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<p><b>Contacts</b> Detail of manufacturer details, NIAIC contacts for technical aspects</p>	▶ ⑥		
<p><b>Feedback Requirements to NIAIC</b> None Required</p>	▶ ⑦		

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

## 1. DEVICE/EQUIPMENT:

LifeScan OneTouch glucose test strips for use with: LifeScan OneTouch II, LifeScan OneTouch Profile or LifeScan OneTouch Basic blood glucose meters

## 2. PROBLEM:

LifeScan OneTouch II, LifeScan OneTouch Profile, and LifeScan OneTouch Basic blood glucose meters are used in combination with LifeScan OneTouch glucose test strips. These test strips are manufactured in two variants: whole blood calibrated and plasma calibrated.

In the UK, LifeScan only market whole blood calibrated OneTouch test strips.

Plasma calibrated LifeScan OneTouch glucose test strips have been imported into the UK. This may not be immediately apparent to the user, as it is not indicated on the external packaging.

Plasma calibrated test strips give results which are approximately 12% higher than the whole blood calibrated test strips. If users are unaware of this difference it may result in them inappropriately altering their treatment or being unaware that their blood glucose concentration is markedly low.

LifeScan intend to issue information to patients on their database, GP practices, wholesalers and independent pharmacies.

## 3. ACTION BY:

- Healthcare professionals managing patients using the LifeScan OneTouch II, LifeScan OneTouch Profile and OneTouch Basic blood glucose meters.
- Pharmacists supplying OneTouch test strips.

## 4. ACTION:

**Community Pharmacists supplying LifeScan OneTouch test strips for use with the LifeScan OneTouch II, LifeScan OneTouch Profile or LifeScan OneTouch Basic blood glucose meters:**

- Check your stock of these test strips to see if they are plasma or whole blood calibrated (see below).
- Do not dispense plasma calibrated OneTouch test strips.
- In relation to patients, please:
  - identify those who you have supplied with plasma calibrated OneTouch test strips.
  - replace any plasma calibrated strips with whole blood calibrated strips.
  - advise them to retest using whole blood calibrated OneTouch test strips.
  - advise them to contact their healthcare professional.

**Healthcare professionals managing patients using either the LifeScan OneTouch II, LifeScan OneTouch Profile or LifeScan OneTouch Basic blood glucose meters:**

Please could you:

- identify patients who are using any of these meters.
- contact them and ask them to check if their test strips are plasma or whole blood calibrated by examining the box, the package insert and test strip vial (see below).
- advise them to:
  - stop using plasma calibrated test strips.
  - obtain replacement whole blood calibrated test strips.
  - retest using whole blood calibrated test strips.
  - review glucose measurements of affected patients to ensure they are on the correct regime.

How to check whether OneTouch test strips are plasma or whole blood calibrated:

- The words 'whole blood calibrations' appear prominently on the front and back of the boxes of whole blood calibrated test strips.
- The words 'Genuine 25 OneTouch test strips Plasma Calibrated' appear on the vials of plasma calibrated test strips.

## 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
- Supplies Staff (RSS)
- Adult and Paediatric Intensive care Units
- All wards
- Maternity Units
- Anaesthetists
- Biochemistry Laboratories
- Consultants in Diabetology
- Diabetes Clinics
- Diabetes Specialist Nurses
- Directors of Pathology
- Accident & Emergency Departments
- Endocrinologists
- Point of Care Testing Co-ordinators
- Practice Nurses
- District Nurses
- District Midwives
- Health Visitors
- Day Care Centres
- Community Care Staff
- Directors of Public Health
- Independent Health and Social Care Providers – Residential and Nursing Homes and Private Clinics through R&I Units.
- Local Health and Social Care Groups

## 6. CONTACTS:

Enquiries to the supplier should be addressed to:

Customer Care Helpline

LifeScan UK

Enterprise House

Station Road

Loudwater

High Wycombe

HP10 9UF

Tel: 0800 121200

E-mail: [CustomerCare@LifeScan.co.uk](mailto:CustomerCare@LifeScan.co.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2003/38 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](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None Required



Brian Godfrey, NIAIC 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 Safety Notice SN (NI) 2003/01. 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](http://www.dhsspsni.gov.uk/niaic)

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