

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/006

Issued: 13th Feb 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section								
<p>Medical Device/Equipment: Blood glucose meters and test strips: MediSense Optium, Optium Xceed meters manufactured by Abbott Diabetes Care; Boots brand meters; and OneTouch Ultra test strips manufactured by LifeScan.</p>	▶ ①								
<p>Problem: The OneTouch Ultra test strips may generate incorrect results when used in conjunction with the MediSense Optium, Optium Xceed or Boots brand meters.</p>	▶ ②								
<p>Action by:</p> <ul style="list-style-type: none"> • Pharmacists supplying these devices. • GPs who prescribe test strips. • Healthcare professionals, including diabetes specialist nurses, managing patients who use these devices. • Healthcare professionals who use these devices. 	▶ ③								
<p>Action: Ensure that OneTouch Ultra test strips are not used with MediSense Optium, Optium Xceed or Boots brand meters.</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 and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>									
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; color: magenta;"> Acknowledge Receipt of Alert: 15th Feb 2008 </td> <td style="width: 33%; color: magenta;"> Action Under Way: 14th Mar 2008 </td> <td style="width: 33%; color: magenta;"> Action Complete: 14th May 2008 </td> </tr> </table>	Acknowledge Receipt of Alert: 15 th Feb 2008	Action Under Way: 14 th Mar 2008	Action Complete: 14 th May 2008	▶ ⑦					
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

The MHRA is aware of cases in the UK where incorrect results were obtained from OneTouch Ultra test strips used in conjunction with Optium Xceed meters.

OneTouch Ultra test strips are not intended for use with MediSense Optium, Optium Xceed or Boots brand meters, doing so may lead to lower than expected blood glucose results.

2. PROBLEM:

The OneTouch Ultra test strips may generate incorrect results when used in conjunction with the MediSense Optium, Optium Xceed or Boots brand meters.

3. ACTION BY:

- Pharmacists supplying these devices.
- GPs who prescribe test strips.
- Healthcare professionals, including diabetes specialist nurses, managing patients who use these devices.
- Healthcare professionals who use these devices.

4. ACTION:

Table showing compatible meters and test strips

Manufacturer	Meter	Compatible test strip
Abbott Diabetes Care	MediSense Optium	Optium Plus test strips (Foil wrapped)
	Optium Xceed	
	Boots Brand	
Boots	Boots Brand	
LifeScan	OneTouch Ultra	OneTouch Ultra test strips
	OneTouch Ultra2	
	OneTouch UltraEasy	
	OneTouch UltraSmart	

Pharmacists supplying OneTouch Ultra test strips and MediSense Optium, Optium Xceed or Boots brand meters:

- When you dispense OneTouch Ultra test strips you should advise the user that these test strips are only intended for use with the OneTouch Ultra brand meters.
- If you supply MediSense Optium, Optium Xceed or Boots brand meters advise the user to only use Optium Plus test strips.

GPs prescribing blood glucose meter test strips:

- Only prescribe OneTouch Ultra test strips for use with OneTouch Ultra brand meters.
- Only prescribe Optium Plus test strips for use with MediSense Optium, Optium Xceed or Boots brand meters.

Healthcare professionals managing patients who use affected devices:

- Advise patients who use the MediSense Optium, Optium Xceed or Boots brand meters to ensure that they are using the Optium Plus test strips, as specified in the instructions.
- Advise patients who use the OneTouch Ultra brand meters to ensure that they are using the OneTouch Ultra test strips, as specified in the instructions.

Healthcare professionals who use these devices:

- Ensure that OneTouch Ultra test strips are only used with the OneTouch Ultra brand meters.
- Ensure that Optium Plus test strips are only used with the MediSense Optium, Optium Xceed or Boots brand 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:

- A&E departments
- All wards
- Ambulance services directors
- Ambulance staff
- Biochemists
- Chief pharmacists
- Clinical pathologists
- Clinical pathology directors
- Day surgery units
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Hospital pharmacists
- Medical directors
- Nursing executive directors
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Pharmacists
- Point of care testing co-ordinators
- Risk managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics, Residential and Nursing Homes through RQIA
- 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
- Community children's nurses
- Community diabetes specialist nurses
- Community nurses
- Community pharmacists
- Directors of public health
- District nurses
- General practitioners
- Health visitors
- Occupational health departments
- Pharmaceutical advisors
- Practice managers
- Practice nurses
- School nurses

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Abbott Diabetes Care

Customer Services
Abbott House
Vanwall Business Park
Maidenhead
Berkshire
SL6 4UD

Healthcare professional care line 0800 032 1016
Customer care line: Freephone 0500 467 466
Pharmacy care line: 0800 316 8884
Email: ADChelp@abbott.com

Kevin Linthwaite
Boots NPI Healthcare
D90 West First 17
Thane Road
Nottingham NG90 1BS

Boots helpline 0800 072 1230
E-mail: kevin.linthwaite@boots.co.uk

LifeScan Customer Care

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

Enquiries to NIAIC should quote reference number MDEA(NI)2008/006 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

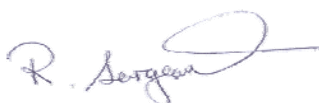
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
15th Feb 2008

Action Under Way:
14th Mar 2008

Action Complete:
14th May 2008



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)2007/01. 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