

MEDICAL DEVICE ALERT

Issued: 12 February 2008 at 12:00

Ref: MDA/2008/006

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|-------------------------------------|---------------------|
| <input type="checkbox"/> | Immediate action |
| <input checked="" type="checkbox"/> | Action |
| <input type="checkbox"/> | Update |
| <input type="checkbox"/> | Information request |

Device:

Blood glucose meters and test strips:

- MediSense Optium, Optium Xceed meters manufactured by Abbott Diabetes Care;
- Boots brand meters;
- OneTouch Ultra test strips manufactured by LifeScan.

Problem:

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

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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.

Action:

Ensure that OneTouch Ultra test strips are not used with MediSense Optium, Optium Xceed or Boots brand meters.

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Distributed to:

| | |
|--|------------------------------------|
| NHS trusts in England | – Chief Executives* |
| OFSTED | – Directors of Children's Services |
| Commission for Social Care Inspection (CSCI) | – Headquarters |
| Healthcare Commission (CHAI) | – Headquarters |
| Primary care trusts in England | – Chief Executives* |
| Social services in England | – Directors* |

* via CE Bulletin

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Contacts:

Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.

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Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 12 March 2008

Deadline (action complete): 12 May 2008

This notice is also on our website: <http://www.mhra.gov.uk>

Problem:

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.

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 | 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.

Distribution:

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

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- 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

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- 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

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults) and FECs registered as care homes
- Domiciliary care providers
- Nursing agencies

Contacts:

Enquiries to the 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

[Medicines and Healthcare products Regulatory Agency](#)

OFSTED to:

Directors of children's services for onward distribution to:

- Children's services
- Educational establishments with beds for children
- Residential special schools

Primary care trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- Directors of public health
- District nurses
- General practitioners
- Health visitors
- NHS walk-in centres
- Occupational health departments
- Pharmaceutical advisors
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Children's hospices
- Clinics
- Directors of pathology
- Hospices
- Hospitals in the independent sector
- Laboratories in the independent sector
- Occupational health departments
- Private medical practitioners
- Private midwives
- Treatment centres

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

Contacts (Continued):

Enquiries to the MHRA should quote reference number **2007/010/030/291/002** and be addressed to:

Technical aspects:

Bina Mackenzie or Susan Mclellan
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3229 / 3215

Fax: 020 7084 3106

E-mail: bina.mackenzie@mhra.gsi.gov.uk
susan.mclellan@mhra.gsi.gov.uk

Clinical aspects:

Dr Christopher Brittain
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3126

Fax: 020 7084 3111

E-mail: christopher.brittain@mhra.gsi.gov.uk

Change of address or removal from address list for CSCI and Healthcare Commission:

CSCI Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

Further information about **SABS** can be found at www.info.doh.gov.uk/sar2/cmopatie.nsf

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