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NOTICE**

Blood Glucose Meters and Test Strips

**Optium Xceed meters manufactured by Abbott Diabetes Care;
Boots brand meters;
OneTouch Ultra test strips manufactured by LifeScan**

**IMB Safety Notice: SN2009(08)
Circulation Date: 23rd October 2009**

MANUFACTURER/SUPPLIER

Abbott Diabetes Care
LifeScan
Boots

TARGET GROUPS

- 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.
- General public.

ISSUE

The Optium Xceed blood glucose meter (manufactured by Abbott Diabetes Care) or Boots brand blood glucose meters, may generate incorrect results when used in conjunction with the OneTouch Ultra test strips, manufactured by LifeScan.

BACKGROUND

In February 2008 the Medicines and Healthcare products Regulatory Agency (MHRA) circulated a Medical Devices Alert (MDA) advising of cases where incorrect results were obtained from Optium Xceed meters when used in combination with One Touch Ultra test strips. The Irish Medicines Board (IMB) circulated this MDA alert (MDA/2008/006) to all Irish hospitals in February 2008.

Since February 2008 the IMB has been informed of two further incidents in Ireland where incorrect results were obtained from Optium Xceed meters used in conjunction with OneTouch Ultra test strips. In one incident a patient adjusted their insulin treatment based on the readings generated by the Optium Xceed meter with the OneTouch Ultra test strips. The patient was admitted to hospital and diagnosed with Diabetic Ketoacidosis (DKA).

The IMB wish to reiterate that OneTouch Ultra test strips are not intended for use with Optium Xceed or Boots brand meters. The labelling (outer carton and instructions for use) for OneTouch Ultra test strips states that OneTouch Ultra test strips should only be used with OneTouch brand meters. The User Guide for the Optium Xceed meter

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also restricts users to use only Abbott Diabetes Care Optium Plus test strips. In some instances an error code is not generated when OneTouch Ultra test strips are used in combination with the Optium Xceed or Boots brand meters and a lower than expected blood glucose reading may be obtained. However, on insertion of the incorrect strip, the meter will display the incorrect calibration “Lot” number.

ACTION OR RECOMMENDATIONS

The IMB recommends that users follow the manufacturer’s instructions for use and User’s Guide to determine which blood glucose meters and test strips are compatible.

Table showing compatible meters and test strips

Manufacturer	Meter	Compatible test strip
Abbott Diabetes Care	Optium Xceed	Optium Plus test strips (foil wrapped)
Boots	Boots Brand	Optium Plus test strips (foil wrapped)
LifeScan	OneTouch Ultra	OneTouch Ultra test strips
	OneTouch Ultra 2	
	OneTouch UltraEasy	
	OneTouch UltraSmart	

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

- If you supply Optium Xceed or Boots brand meters you should advise the user to only use Optium Plus test strips.
- 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.

GPs prescribing blood glucose meter test strips:

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

Healthcare professionals managing patients who use the affected devices:

- Advise patients to ensure that they are using the correct test strips for their meter as described in the meter’s user manual.

Healthcare professionals who use these devices:

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

General public:

- Only use Optium Plus test strips with the Optium Xceed or Boots brand meters.
- Only use OneTouch Ultra test strips with OneTouch Ultra brand meters.

S A F E T Y NOTICE

Please bring this safety notice to the attention of all who need to be aware of it. This will include further distribution to:

Accident & Emergency 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
Outpatients theatre nurses
Pharmacists
Point of care testing co-ordinators
Risk managers

The IMB has also published an Information leaflet on safety tips for blood glucose meters. Please see the Information leaflets section on the Publications page of the IMB website.

<http://www.imb.ie/EN/Publications/Publications/Medical-Devices-Information-leaflet-Safety-tips-for-blood-glucose-meters.aspx?page=5&year=0&categoryid=&letter=&q=>

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Abbott Diabetes Care
4051 Kingswood Drive
Citywest Business Campus
Tallaght
Dublin 24
Ireland

Telephone: +1-4691570 (press 2)
Fax: +1 4691565

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

Tel: 1800 535676 (Ireland)
0800 121200 (UK)