

**Notice Information: - Warning  
23 October 2009**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

**Part 2. Target Audience**

- a) Target Audience:

**Part 3. Problem/Issue**

- a) Problem/Issue:

**Part 4. Background Information**

a) Background Information:

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 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.

## Part 5. Action to be taken

a) Action to be taken:

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)



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OneTouch UltraEasy
OneTouch UltraSmart
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OneTouch Ultra test strips
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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 dev

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.

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 director

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-Info>

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

## Part 6. Enquiries



a) All enquiries should be made to:

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](mailto:vigilance@imb.ie)

Website: [www.imb.ie](http://www.imb.ie)

Enquiries to the manufacturer should be addressed to:

Abbott Diabetes Care

4051 Kingswood Drive

Citywest Business

Tallaght Dublin 24

Ireland

Telephone: +1-4691570 (press 2)

Fax: +1 4691565

LifeScan Customer Care 50-100 Holmers Farm Way Campus High Wycombe

LifeScan Customer Care

50-100 Holmers Farm Way

Campus High Wycombe

Buckinghamshire HP12 4DP

UK

Tel: 1800 535676 (Ireland)

0800 121200 (UK)

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