

**Notice Information: - Advisory
21 February 2014**

Part 1. Product Information

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

Part 2. Target Audience

a) Target Audience:

All Hospital staff
All Nursing Home staff
Risk Managers
Nursing Managers
Hospital Pharmacists
Diabetic Clinics/ outpatients
Diabetic nurse specialists
Diabetic departments
Endocrinology units
Endocrinology Consultants
Paediatric wards
Laboratory Managers
Chief Medical Scientists
Purchasing / Procurement / Material Managers
Pharmacists supplying these devices
General Practitioners
Healthcare professionals who use these devices
Healthcare professionals managing patients who use these devices
Carers
General public

Part 3. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board (IMB) has been notified that FreeStyle Mini® Blood Glucose Meters and FreeStyle® Blood Glucose Meters may give erroneously low blood glucose results and may produce out of range control solution results when using FreeStyle Lite® and FreeStyle® Blood Glucose Test Strips.

Part 4. Background Information

a) Background Information:

Abbott Diabetes Care (UK) has advised that the affected blood glucose meters (FreeStyle Mini® and FreeStyle® Blood Glucose Meters) have been supplied to the Irish market.

The current issue affects all FreeStyle Mini® and FreeStyle® Blood Glucose Meters when used with any FreeStyle test strip lots (refer to attached FSN). Affected meters were placed on the Irish market between January 2004 and September 2007. Abbott Diabetes Care (UK) has confirmed that the above meters are the only affected meters supplied to the Irish market and no adverse incidents related to this issue have been reported for the Irish market.

A previous Safety Notice (SN2013(14)) issued by the IMB on 4th December 2013 advised that certain lots of FreeStyle Lite® Blood Glucose Test Strips may give erroneously low blood glucose results when using FreeStyle Mini® and FreeStyle® Blood Glucose Meters – see attached FSN.

Part 5. Action to be taken

a) Action to be taken:

Advice for End Users / Patients:

1. Follow the manufacturer's instructions outlined in the attached FSN and contact Abbott Diabetes Care Customer Service on 1800 776633 for a replacement meter.
2. Ensure that you can continue to monitor your blood glucose appropriately. This should be done in consultation with your healthcare professional.
3. Pay special attention to signs and symptoms of high blood sugar (hyperglycemia). Symptoms may include excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting and abdominal pain. If you are experiencing any of these symptoms or are not feeling well, contact your healthcare professional immediately.

Advice for Healthcare Professionals / Pharmacists / Distributors:

1. Follow the manufacturer's instructions outlined in the attached FSN and contact Abbott Diabetes Care Customer Service on 1800 776633 for replacement meters.
2. Ensure that end users who dispose of affected blood glucose meters can continue to appropriately monitor their blood glucose.
3. Ensure that the appropriate personnel are made aware of this notice and the attached FSN. Please also pass this notice and the attached FSN on to any end user or organisation where the potentially affected blood glucose meters have been transferred.

Part 6. Enquiries

- a) All enquiries should be made to:

Enquiries to the manufacturer should be addressed to:

Barbara Scott

Abbott Diabetes Care

4051 Kingswood Drive

Citywest Business Campus

Dublin 24

Telephone: 1800 776633

E-mail: ADChelpuk@abbott.com

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

[Please click here to view a copy of the 1st FSN](#)

[Please click here to view a copy of](#)

Please click here to view a copy of the 2nd FSN

Please click here to view a PDF version of this Safety Notice