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NOTICE**

# FreeStyle Mini® and FreeStyle® Blood Glucose Monitoring Systems

**IMB Safety Notice: SN2014(06)**  
**Circulation Date: 21<sup>st</sup> February 2014**

**MANUFACTURER/SUPPLIER**  
Abbott Diabetes Care

**TARGET GROUPS**

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

**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.

**BACKGROUND**

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.

# S A F E T Y NOTICE

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 4<sup>th</sup> 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.

## **ACTION OR RECOMMENDATIONS**

### **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.

## **ENQUIRIES**

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](mailto:ADChelpuk@abbott.com)

# S A F E T Y

## NOTICE

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)