

14 November 2013

**URGENT FIELD SAFETY NOTICE**

**Product:** FreeStyle Lite® Test Strips  
**Reference:** FA1054-2013  
**Type of Action:** Field Safety Notice

Dear Valued Customer,

Recently, it has come to our attention that certain lots of FreeStyle Lite® Blood Glucose Test Strips may produce erroneously low blood glucose results and may produce out of range control solution results when using FreeStyle® Blood Glucose Meters, FreeStyle Mini® Blood Glucose Meters and the FreeStyle® meter built into the Omnipod® System. Erroneously low results that are not recognised may pose significant risks to your health.

**If you do not use the meters in the photographs below, your blood glucose test results are not affected and you do not need to read any further.**

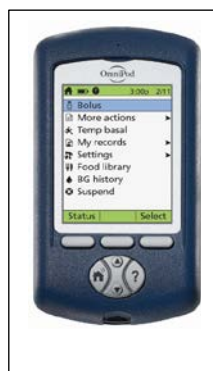
FreeStyle Mini®  
Blood Glucose Meter



FreeStyle®  
Blood Glucose Meter



Omnipod®



The FreeStyle Lite® Blood Glucose Test Strips lots listed below may produce erroneously low blood glucose results and out of range control solution results when using the Blood Glucose Meters illustrated in the photographs above.

**The affected FreeStyle Lite® Blood Glucose Test Strips lots are found in the table below:**

| Lot Numbers |         |
|-------------|---------|
| 1284962     | 1372611 |

A test strip insert is included with every carton of test strips, and provides very important product information. **Please read your test strip insert carefully to ensure that you are using the correct Blood Glucose Meter for your test strip type.**

**If you have affected product, we recommend you take the following steps:**

1. Call Abbott Diabetes Care Customer Service immediately at 008000 2255 232 for a replacement of the affected test strips. When you call, Abbott will send you unaffected FreeStyle Lite® Blood Glucose Test Strips at no charge.
2. While waiting for your replacement strips to arrive, either use an alternate method to measure your blood glucose (such as test strips from an unaffected lot number or a different blood glucose monitoring system). This issue only affects the lot numbers which are detailed in the table above



when using FreeStyle<sup>®</sup> Blood Glucose Meters, FreeStyle Mini<sup>®</sup> Blood Glucose Meters and the FreeStyle<sup>®</sup> meter built into the Omnipod<sup>®</sup> System.

If the only test strips available to you are from affected lots, do not stop testing your blood glucose. However, if any reading from a strip appears lower than you would expect or does not seem to match the way you are feeling, you should contact your health care provider. Pay special attention to signs and symptoms of high blood sugar (hyperglycemia).

**Symptoms of high blood sugar 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 health care professional immediately.

3. Please dispose of the test strips in accordance with your local and state disposal regulations.

**If the lot number of the test strips you are using is NOT in the table on this letter, you may continue to test your blood glucose as directed by your health care provider with your FreeStyle<sup>®</sup> Blood Glucose Test Strips. There are no other Abbott Diabetes Care products impacted by this issue.**

If you have any further questions, please call Abbott Diabetes Care Customer Service at 008000 2255 232.

Abbott Diabetes Care can confirm that this notice has been communicated to the Irish Medicines Board (IMB).

We recognise the importance of blood glucose testing and are committed to responding quickly to customers' requests for replacement test strips.

We want to assure you that our first priority is you, our customer. We sincerely regret any inconvenience this situation may cause. We thank you for your continued support of the FreeStyle Blood Glucose Monitoring System and Abbott Diabetes Care.

Sincerely,

Joe Bugler  
Director Global Clinical & EMEA Regulatory Affairs  
Abbott Diabetes Care