Abbott
Diabetes Care

19 February 2014

URGENT FIELD SAFETY NOTICE

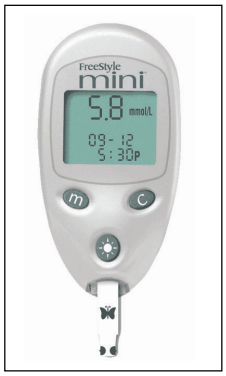
Product: **FreeStyle Mini® and FreeStyle® Blood Glucose Monitoring System**
Reference: **ADC FA1002-2014**
Type of Action: **Field Safety Notice**

Dear Valued Customer,

Recently, it has come to our attention that FreeStyle Mini® and FreeStyle® Blood Glucose Meters may produce erroneously low blood glucose results when using FreeStyle Lite® and FreeStyle® Blood Glucose Test Strips. Erroneously low results that are not recognized may pose significant risks to your health.

No action is required if you do not use the meters pictured below.

FreeStyle Mini®
Blood Glucose Meter



FreeStyle®
Blood Glucose Meter

If you are currently using either of the meters pictured above, please take the following steps:

1. **Discontinue use of your FreeStyle Mini® and FreeStyle® Blood Glucose Meter and call Abbott Diabetes Care Customer Service immediately at 0500 467 466.** When you call, Abbott will send you a new FreeStyle® branded meter at no charge.

   If the only meter you have available is a FreeStyle® or FreeStyle Mini® Blood Glucose Meter, do not stop testing your blood glucose. Control solution should be used to check the performance of your test strips and meter until you receive your replacement meter. 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.

2. Upon receiving your replacement meter, please be sure to dispose of your old meter in accordance with your local and state disposal regulations.

A test strip insert is included with every carton of FreeStyle® and FreeStyle Lite® Blood Glucose 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.

Abbott Diabetes Care

Abbott Diabetes Care can confirm that this notice has been communicated to the required Competent Authority.

We recognize the importance of blood glucose testing and are committed to responding quickly to our customers' needs.

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. If you have any further questions, please call Abbott Diabetes Care Customer Service at **0500 467 466**.

Sincerely,

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