

19 February 2014

**URGENT FIELD SAFETY NOTICE**

**Product:** FreeStyle Navigator® Continuous 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 Navigator® Continuous Glucose Monitoring System (1.0 and 1.5 generation) 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.

FreeStyle Navigator® (Version 1.0 and 1.5)



**If you are currently using the receiver pictured above, please take the following steps:**

1. Please dispose of all test strips that are currently in your possession in accordance with your local and state disposal regulations.
2. **Call Abbott Diabetes Care Customer Service immediately at 0500 467 466.** When you call, Abbott will send you replacement FreeStyle® Blood Glucose Test Strips at no charge.
3. It is very important that you use strips only sent to you by Abbott Diabetes Care for use with your Navigator receiver when performing calibrations or testing your blood glucose levels.

Control solution should be used to check the performance of your receiver and test strips prior to calibration or blood testing. If any reading from a strip with control solution is outside the range printed on the test strip vial do not use the strips to calibrate your system.

When performing a blood glucose test with your receiver and any reading 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.

4. While waiting for your replacement strips to arrive, use an alternative meter such as the FreeStyle® Freedom blood glucose meter that you may have. FreeStyle® and FreeStyle® Lite test strips when used the FreeStyle® Freedom blood glucose meter will produce accurate blood glucose results.

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



Navigator<sup>®</sup> Continuous Glucose Monitoring System and Abbott Diabetes Care. If you have any further questions, please call Abbott Diabetes Care Customer Service.

Sincerely,

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