

14 November 2013

URGENT FIELD SAFETY NOTICE

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

Dear Distribution Partner,

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, FreeStyle Navigator® and the FreeStyle® meter built into the OmniPod® System. Erroneously low results that are not recognised may pose significant risks to a user's health.

If patients do not use the meters in the photographs below, their blood glucose test results are not affected.

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. We recommend that patients read their test strip insert carefully to ensure that they are using the correct Blood Glucose Monitoring System for their test strip type.

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

1. Do not continue to distribute the affected test strips lots. Please immediately dispose of the lots in accordance with your local and state disposal regulations. **If the lot numbers of the test strips you currently have are NOT in the table above, you may continue to distribute them. There are no other Abbott Diabetes Care products impacted by this issue.**
2. Call Abbott Diabetes Care Customer Service immediately at 1800 776633 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.



We are notifying patients directly of the issue. We request your assistance in sharing this information with your customers. Our letter to patients is attached for your information.

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 for your patients, and are committed to responding quickly to requests for replacement test strips.

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 1800 776633.

Sincerely,

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