

URGENT PRODUCT RECALL

FreeStyle InsuLinx Blood Glucose Meter

April 15, 2013

Dear Valued Customer,



If you use, recommend or sell the FreeStyle InsuLinx Blood Glucose Meter, we want to make you aware that Abbott Diabetes Care is recalling **FreeStyle InsuLinx Blood Glucose Meters**. Our records indicate that you may have received a FreeStyle InsuLinx meter. Please read the following information carefully.

Incorrect Test Results At Extremely High Blood Glucose Levels

We have determined that at extremely high blood glucose levels of 1024 mg/dL and above, the FreeStyle InsuLinx meter will display and store in memory an incorrect test result that is 1024 mg/dL below the measured result.

Example: For a blood glucose value of 1066 mg/dL, the meter will display and store a value of 42 mg/dL (1066 mg/dL – 1024 mg/dL = 42 mg/dL).

The likelihood of experiencing extremely high blood glucose levels 1024 mg/dL and above is rare. However, when they occur, they are a serious health risk and require immediate medical attention. If the FreeStyle InsuLinx meter displays an inaccurate low result, there may be a delay in identification and treatment of severe hyperglycemia (high blood glucose levels). This could lead to serious injury or death.

If you are using the FreeStyle InsuLinx Meter, you should immediately take one of the following actions to address this issue with the meter:

- You can access a software update to resolve the issue at www.freestyleinsulinx.com/swupdate. The software update will allow you to maintain settings and historical data on your meter.
- You can contact Abbott Diabetes Care Customer Service at 1-866-723-2697 to expedite return and replacement of your FreeStyle InsuLinx meter at no charge. Replacements are available, and Abbott will send a meter to you immediately upon request.

Until you are able to update the meter software or until your requested replacement meter arrives, the current FreeStyle InsuLinx meter may be used; however, if you experience symptoms that are not consistent with your readings, you should contact your healthcare professional and follow his or her treatment advice.

Extremely high blood glucose levels require immediate medical attention. If you experience symptoms which are not consistent with your readings you should contact your healthcare professional and follow his or her treatment advice.

There are no other Abbott Diabetes Care products impacted by this issue.

Healthcare Professionals: If you have FreeStyle InsuLinx Blood Glucose Monitoring Kits, you are advised to immediately discontinue dispensing them to your patients. To arrange for product return and replacement, please call Abbott Diabetes Care customer service at 1-866-723-2697. While we are notifying patients directly, we also request your assistance in sharing this information with your patients who use the FreeStyle InsuLinx Meters.

Retailers/Distributors: If you have FreeStyle InsuLinx Blood Glucose Monitoring Kits in your current stock, you are advised to immediately discontinue distributing this product. Abbott Diabetes Care will be replacing your FreeStyle InsuLinx Blood Glucose Monitoring Kits with product that does not have this issue. To arrange for product return and replacement, please call Abbott Diabetes Care customer service at 1-866-723-2697. While we are notifying our patients directly, we also request your assistance in sharing this information with your customers who use the FreeStyle InsuLinx products.

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 InsuLinx Blood Glucose Monitoring System and Abbott Diabetes Care. If you have any further questions, please call Abbott Diabetes Care Customer Service at 1-866-723-2697.

Additional information about this recall can be found at www.abbottdiabetescare.com.

Abbott Diabetes Care