

**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 has determined that at extremely high blood glucose levels of 56.8 mmol/L and above, the FreeStyle InsuLinx meter will display and store in memory an incorrect test result that is 56.8 mmol/L below the measured result.

**Example:** For a blood glucose value of 59.1 mmol/L, the meter will display and store a value of 2.3 mmol/L ( $59.1 \text{ mmol/L} - 56.8 \text{ mmol/L} = 2.3 \text{ mmol/L}$ ).

The likelihood of experiencing extremely high blood glucose levels of 56.8 mmol/L 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), or incorrect treatment may be recommended by the insulin calculator if you use the calculator. This could lead to serious injury.

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.

Abbott Diabetes Care has a meter software update to the FreeStyle InsuLinx meter to quickly address this issue. **The software update will enable you to maintain your historical data in your meter and settings, including insulin calculator settings, if you use this option.** A step-by-step process that you should follow to update the software on your meter is available on our website [www.freestyleinsulin.com/swupdate](http://www.freestyleinsulin.com/swupdate). Alternatively, please contact your local Abbott Diabetes Care Customer Service at 1-866-723-2697.

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 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 Care at 1-866-723-2697.