

URGENT FIELD SAFETY NOTICE

FreeStyle InsuLinx Blood Glucose Monitoring System
ADC FA1023-2013
Software Update

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 issuing a Field Safety Notice for **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 56.8 mmol/L and above, the FreeStyle InsuLinx meter will display and store in memory an inaccurate low result. If this occurs there may be a delay in identification and treatment of high blood glucose levels, or incorrect treatment may be recommended by the insulin calculator, if this feature is enabled on the meter.

The likelihood of experiencing extremely high blood glucose levels is rare however this could lead to serious injury. 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 software update to the FreeStyle InsuLinx meter to quickly address this issue.

Action to be taken:

- There is a step-by-step process that you should follow immediately to update the software on your meter. This is available on our website www.freestyleinsulin.com/swupdate.

This software update will enable you to maintain your settings and historical data in your meter, including insulin calculator settings.

- Alternatively, please contact your local Abbott Diabetes Care Customer Service at 0800-088-5521.

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

Abbott Diabetes Care confirms that this notice has been provided to all relevant National Competent Authorities.

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 0800-088-5521. 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 0800-088-5521. 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 0800-088-5521.

Abbott Diabetes Care