



Urgent Recall for Product Correction
FreeStyle InsuLinx Blood Glucose Meter

16 April 2013

Dear Valued Customer,

Abbott Diabetes Care is issuing a Recall for Product Correction on the **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.

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

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. If you experience symptoms which are not consistent with your readings you should contact your healthcare professional and follow his or her treatment advice.

Until customers are able to update the meter software or until a requested replacement meter arrives, the current FreeStyle InsuLinx meter may be used; however, if patients experience symptoms that are not consistent with their readings, they should contact their 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.freestyleinsulinx.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 **on 1800 639 505 between the hours of 8am to 5pm Australian Eastern Standard Time (AEST) Monday to Friday.**

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

This Urgent Recall for Product Correction is being done after consultation with the Therapeutic Goods Administration.

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 **on 1800 639 505 between the hours of 8am to 5pm Australian Eastern Standard Time (AEST) Monday to Friday.**

Sincerely,



Sarah Haldon
Customer Service Manager
Abbott Diabetes Care