

URGENT FIELD SAFETY NOTICE

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

April 15, 2013

Dear Distribution Partner,

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 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 mmol/L – 56.8 mmol/L = 2.3 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, or incorrect treatment may be given. This could lead to serious injury. As a result, we have decided to remove and replace all FreeStyle InsuLinx meters.

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. While we will be notifying our patients directly, we also request your assistance in sharing this information with your customers who use the FreeStyle InsuLinx products. The letter to our patients is attached for your information.

To arrange for product return, please call Abbott Diabetes Care customer service at 0800-088-5521.

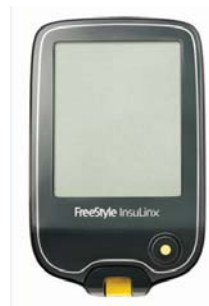
There are no other Abbott Diabetes Care products impacted by this issue.

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

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 0800-088-5521.

Sincerely,

Kelly E. Duffy
Division Vice President, Quality Assurance and Compliance
Abbott Diabetes Care



URGENT FIELD SAFETY NOTICE



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

April 15, 2013

Dear Health Care Provider,

Abbott Diabetes Care is issuing a Field Safety Notice for **FreeStyle InsuLinx Blood Glucose Meters**. Our records indicate that you may have received FreeStyle InsuLinx Blood Glucose Monitoring Kits. 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 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 mmol/L – 56.8 mmol/L = 2.3 mmol/L).

The likelihood of experiencing extremely high blood glucose levels of 56.8 mmol/L and above is rare. However, as you are aware, they are a serious health risk and when they occur, 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, or incorrect treatment may be given. This could lead to serious injury.

We are notifying patients directly of an **immediate** software update that they can use to resolve the issue. We request your assistance in sharing this information with your patients. Our letter to patients is attached for your information.

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.

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.

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 0800-088-5521.

Sincerely,

Kelly E. Duffy
Division Vice President, Quality Assurance and Compliance
Abbott Diabetes Care

URGENT FIELD SAFETY NOTICE



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

April 15, 2013

Dear Valued Customer,

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.

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 0800-088-5521.

Sincerely,

Kelly E. Duffy
Division Vice President, Quality Assurance and Compliance
Abbott Diabetes Care