



Michael R. Pence  
Governor

William C. VanNess II, MD  
State Health Commissioner

**DATE:** April 17, 2013  
**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer  
**FROM:** *DIG*  
A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program  
**SUBJECT:** Abbott Recall

**SUGGESTED ACTION:** Unclassified Recall; FreeStyle Insulinx® Blood Glucose Meters in the United States because it will display and store in memory an incorrect test result; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. The product was distributed across the United States. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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### Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

### Abbott Initiates Voluntary Recall of FreeStyle Insulinx® Blood Glucose Meters in the United States

*At rare, extremely high blood glucose levels (1024 mg/dL and above), the FreeStyle InsuLinx Blood Glucose Meter may provide an inaccurate reading*

**Contact:**  
Consumer:  
(866)723-2697

Media:  
Johnathan Hamilton  
(408)624-0314

Jeff Christensen  
(510)358-1686

**FOR IMMEDIATE RELEASE** - April 15, 2013 - Abbott today announced it is initiating a voluntary recall of FreeStyle Insulin<sup>®</sup> Blood Glucose Meters in the United States.

The company has determined that at extremely high blood glucose levels of 1024 mg/dL and above, the FreeStyle Insulin Meter will display and store in memory an incorrect test result that is 1024 mg/dL below the measured result. For example, at 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). No other Abbott blood glucose meters are impacted by this issue.

Blood glucose levels at 1024 mg/dL and above are very rare. However, if high blood glucose levels of 1024 mg/dL and above do occur, they are a serious health risk and require immediate medical attention. As the FreeStyle Insulin Meter can display an inaccurate low result at a blood glucose level above 1024 mg/dL, there may be a delay in the identification and treatment of severe hyperglycemia, or incorrect treatment may be given. This could lead to serious injury or death.

Customers who are using the FreeStyle Insulin Meter should immediately take one of the following actions to address this issue with their meter:

- Customers can access a software update to resolve the issue at [www.freestyleinsulin.com/swupdate](http://www.freestyleinsulin.com/swupdate)<sup>1</sup>. The software update will allow customers to maintain settings and historical data on their meter.
- Customers can contact Abbott Diabetes Care Customer Service at 1-866-723-2697 to expedite return and replacement of their FreeStyle Insulin meter at no charge. Replacements are available, and Abbott will send meters to customers immediately upon request.

Until customers are able to update the meter software or until a requested replacement meter arrives, the current FreeStyle Insulin 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.

"Our first priority is to safeguard the health and safety of patients," said Heather Mason, Senior Vice President, Diabetes Care, Abbott. "We are committed to ensuring that our customers are able to continue to test their blood glucose with confidence, and we initiated this voluntary recall to ensure our products continue to meet the highest standards of quality and safety. We regret any inconvenience this action may cause."

The company is notifying all registered users, healthcare professionals, pharmacies and distributors where the FreeStyle Insulin Meter is sold. Abbott estimates that there are approximately 50,000 active FreeStyle Insulin Meter users in the United States. Upon identifying the issue, Abbott promptly developed and implemented an update to the meter.

### **In the United States**

To date, there has been one reported patient incident in the United States that may be related to this specific issue. The patient sought medical treatment, was diagnosed with hyperglycemia, treated and released. It has not been determined that the FreeStyle Insulin Meter was the cause.

### **Outside the United States**

Outside the United States, there have been no patient incidents reported related to this specific issue. The FreeStyle Insulin meter is available in Australia, Belgium, Canada, France, Germany, Israel, Italy, Netherlands, Spain, Switzerland and United Kingdom. Customers in these countries can get more information about how to address this issue by visiting [www.freestyleinsulin.com/swupdate](http://www.freestyleinsulin.com/swupdate)<sup>2</sup>.

Abbott has notified the U.S. Food and Drug Administration and all relevant healthcare authorities in the other countries. Abbott is working with the individual regulatory agencies around the world where the affected products have been sold.

Additional information about this recall can be found at <https://www.abbottdiabetescare.com/press-room/2013/2013-c.html><sup>3</sup> or by calling 1-866-723-2697.

### **About Abbott Diabetes Care**

Abbott Diabetes Care, based in Alameda, Calif., is a leader in developing, manufacturing and marketing glucose monitoring systems designed to help people better manage their diabetes. Additional information about Abbott Diabetes Care may be found at [www.abbottdiabetescare.com](http://www.abbottdiabetescare.com)<sup>4</sup>.

### **About Abbott**

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 70,000 people.

Visit Abbott at [www.abbott.com](http://www.abbott.com)<sup>5</sup> and connect with us on Twitter at @AbbottNews.