



DATE: March 17, 2014
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: *Kristin Gasper*
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Abbott - RECALL [Medical Device]

AFFECTED PRODUCT: FreeStyle® Blood Glucose Meter and the FreeStyle Flash® Blood Glucose Meter

SUMMARY: Unclassified Recall; When used with the Abbott FreeStyle test strips, the FreeStyle Blood Glucose Meter and the FreeStyle Flash Blood Glucose Meter may produce mistakenly low blood glucose results.

For users of the OmniPod® Insulin Management System with the built-in FreeStyle Blood Glucose Meter, please refer to the previously sent letter for Abbott recommended actions or visit <https://www.abbottdiabetescare.com/press-room/2014/2014-b.html>.

SUGGESTED ACTION: For consumer inquiry only. For more information, please visit www.abbottdiabetescare.com/press-room.

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 Issues Recall of Certain Blood Glucose Monitoring Systems

Contact:
Consumer:

1-888-345-5364

Media:

Jonathon Hamilton
847-935-8646

Jessica Sachariason
510-388-3013

FOR IMMEDIATE RELEASE - March 14, 2014 - *Abbott is voluntarily* conducting a recall for the FreeStyle® Blood Glucose Meter and the FreeStyle Flash® Blood Glucose Meter. These two meters have not been in production since 2010. Other Abbott Diabetes Care meters are not affected by the recall

When used with the Abbott FreeStyle test strips, the FreeStyle Blood Glucose Meter and the FreeStyle Flash Blood Glucose Meter may produce mistakenly low blood glucose results. Abbott began notifying users on Feb. 19, 2014, immediately after the issue was discovered.

Abbott recommends the following actions for people with meters affected by this recall:

- Immediately contact Abbott Diabetes Care at 1-888-345-5364 to obtain a replacement meter.
- If you have access to an alternative glucose meter, immediately discontinue use of the affected meter and take the necessary steps to continue to monitor your blood sugar with the alternative meter.
- If the only meter available to you is an affected meter, continue to test your blood glucose as recommend by your doctor while you wait for your replacement meter. When using an affected meter, take the following precautions to reduce the chance of a false reading:
 - As stated in the product insert, perform a quality control solution test to confirm that your meter is working correctly. Do not use a test strip vial if control solution results are not within the expected range.
 - Contact your health care provider immediately if your blood glucose result(s) are not consistent with your diabetes history, how you feel, or if you think your results are not accurate (higher or lower than expected). Symptoms of high blood sugar include excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting and abdominal pain. If you are experiencing any of these symptoms or are not feeling well, contact your health care professional immediately.

This voluntary recall does not apply to any other Freestyle brand blood glucose monitoring systems – Freestyle Lite®, Freestyle Freedom Lite® or Freestyle InsuLinx® systems can continue to be used with the Freestyle test strips.

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For more information, please visit www.abbottdiabetescare.com/press-room.

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.

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 69,000 people.

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