



County of Erie

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COUNTY EXECUTIVE

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COMMISSIONER OF HEALTH

TO: All E.M.S. Providers

FROM: John Adolf, Deputy Commissioner / E.M.S.
Erie County Division of Emergency Medical Services

DATE: April 23, 2013

SUBJECT: Recall of LifeScan, Inc., OneTouch Verio IQ Blood Glucose Meter

Date Recall Initiated: March 11, 2013

Product: LifeScan, Inc., OneTouch Verio IQ Blood Glucose Meter

All OneTouch Verio IQ Blood Glucose Meters are being recalled.

These blood glucose meters were distributed from December 14, 2011 through March 7, 2013.

Use: The OneTouch Verio IQ Blood Glucose Meter measures sugar (glucose) in blood drawn from the fingertips of people with diabetes or people with high levels of blood sugar. The OneTouch Verio IQ Blood Glucose Meter is an Over-the Counter single-use device intended to be used by a patient outside of a health care facility as an aid to monitor the effectiveness of diabetes control.

Recalling Firm:

LifeScan Inc.
1000 Gibraltar Drive
Milpitas, California 95035-6301

Reason for Recall: Failure to provide a warning at extremely high blood glucose levels.

The One-Touch Verio IQ meter will shut off and revert to “set up mode” at glucose values above 1023 mg/dL instead of displaying EXTREME HIGH GLUCOSE.

At extremely high blood glucose levels of 1024 mg/dL and above, the OneTouch Verio IQ Meter will turn off instead of displaying the message “EXTREME HIGH GLUCOSE above 600 mg/dL” as intended. When turned back on, the meter enters the “Set-Up” mode and requires the user to confirm the date and time settings before being able to test again. However, if the glucose level is still measuring 1024 mg/dL or above when testing, the meter will shut down again.

Because diagnosis and treatment of extreme hyperglycemia may be delayed or incorrect treatment may be given, serious adverse health consequences, including death may occur.

Public Contact:

Consumers, Health Care Professionals, Pharmacists, Distributors, please see contact and other information below.

FDA Comments:**Consumers:**

To receive replacement glucose meters at no charge, follow these steps. Call LifeScan Customer Service at 1-800-717-0276 to verify your OneTouch Verio IQ Meter Serial Number and confirm your mailing address to send you a replacement meter. You can continue testing with your current OneTouch Verio IQ Meter while you wait for your replacement meter to arrive.

However, **if your OneTouch Verio IQ Meter unexpectedly turns off and enters set-up mode after turning it back on, your blood glucose may be extremely high, and you should call your health care professional.** Never ignore symptoms or make significant changes to your diabetes management program without speaking to your health care professional. Please **print and keep this notice with your Owner's Booklet.**

Health Care Professionals:

Discontinue distributing OneTouch Verio IQ Meters to patients and collect all OneTouch Verio IQ Meter samples that are in your possession. Call 1-877-644-0004 to arrange for pick-up of the sample meters. If you have any additional questions, please contact your local LifeScan sales representative or the LifeScan Health Care Professional Line at 1-800-717-0285.

While LifeScan will notify patients directly, they are requesting Health Care Professionals to share this information with their patients who use the OneTouch Verio IQ Meter. Patients can continue to test with their OneTouch Verio IQ Meter while they wait for their replacement meter to arrive as long as they are aware of this issue and know how to respond.

Please refer any patients with OneTouch Verio IQ Meter to LifeScan Customer Service at 1-800-717-0276 to arrange to receive a replacement meter at no charge.

Pharmacists:

Identify and return all OneTouch Verio IQ Meters you have in your inventory for a credit following your normal return procedures.

While LifeScan will be notifying patients directly, we request your assistance in sharing this information with your patients who use the OneTouch Verio IQ Meter. Patients can continue to test with their OneTouch Verio IQ Meter while they wait for their replacement meter to arrive as long as they are aware of this issue and know how to respond. Please refer any patients with OneTouch Verio IQ Meters to LifeScan Customer Service at 1-800-717-0276 to arrange to receive a replacement meter at no charge.

Please call LifeScan Customer Service at 1-800-717-0291 if you have questions about this action.

Distributors:

Identify and hold all OneTouch Verio IQ Meters you have in inventory.

Communicate this replacement program to your customers that purchased OneTouch Verio IQ Meters from you. Request that they return only OneTouch Verio IQ Meters per your normal return procedures. Once you have received all OneTouch Verio IQ Meters to be returned, call Inmar Corp. at 1-877-644-0004 Option 2 for a returned goods authorization (RGA) and product return instructions.

More about this Class I Recall:

On March 25, 2013, the firm started sending recall notification letters by mail and/or email to: Consumers, Pharmacies and Retailers, Health Care Professionals, Distributors and Wholesalers, and Mail Order Distributors.

See the firm's Press Release and Urgent Medical Device Voluntary Recall letter under **Additional Links** below. Customer Service and Sales Account Managers will be provided with information to respond to questions regarding the recall.

The firm sent recall letters to Health Care Professionals, Distributors, and Wholesalers on March 25, to Retail/Pharmacies on March 26, and to Users on March 27. The firm will continue to send letters to users in the U.S. during March and April. The firm is using a combination of the U.S. Postal Service, email, and fax. Standard mail and email were used for Consumers.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) either online, by regular mail or by FAX.

Cc Commissioner Burstein
Commissioner Neaverth