

## **Urgent Medical Device Voluntary Recall** **OneTouch® Verio®IQ Blood Glucose Meter**

March 25, 2013

Dear Valued Customers:

If you use, recommend or sell the OneTouch® Verio®IQ Blood Glucose Meter, we want to make you aware that **LifeScan is voluntarily replacing all OneTouch® Verio®IQ Blood Glucose Meters.**

### **Failure To Provide A Warning At Extremely High Blood Glucose Levels**

We have recently determined that 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 1024 mg/dL or above when testing, the meter will shut down again.

The likelihood of experiencing extremely high blood glucose levels of 1024 mg/dL and above is remote. However, when they occur, they are a serious health risk and require immediate medical attention. Because the OneTouch® Verio®IQ Meter does not provide the “EXTREME HIGH GLUCOSE above 600 mg/dL” message at glucose levels of 1024 mg/dL and above, there may be a delay in the diagnosis and treatment of extreme hyperglycemia or incorrect treatment may be given. This could lead to serious injury. As a result, we have decided to replace all OneTouch® Verio®IQ Meters at no charge.

### **In Order To Receive Replacement Meters At No Charge, Please Follow The Steps Below:**

**People with Diabetes:** Please call LifeScan Customer Service at **1-800-717-0276** to verify your OneTouch® Verio®IQ Meter Serial Number and confirm your mailing address so that we may ship you a replacement meter. You can continue to test 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.

**Healthcare 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 Healthcare Professional Line at 1-800-717-0285. While LifeScan will be notifying patients directly, we also 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 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 inventory for a credit following your normal return procedures.

**UPC No. 353885007702 LifeScan Part No. 022267 NDC No. 53885026701**

While LifeScan will be notifying patients directly, we also 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.

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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.

We remain committed to providing you with the highest quality products and services, and apologize for any inconvenience this issue may cause. Thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service