March 25, 2013

LifeScan Announces Voluntary Recall of All OneTouch® Verio®IQ Blood Glucose Meters

At extremely high blood glucose levels (1024 mg/dL and above), the OneTouch® Verio®IQ Meter will not provide a warning and will shut off

Milpitas, CA - March 25, 2013 - LifeScan, Inc. is initiating a voluntary recall and replacement for all of its OneTouch® Verio®IQ blood glucose meters in the United States, effective immediately.

LifeScan is recalling and replacing all OneTouch® Verio®IQ Meters because at extremely high blood glucose levels of 1024 mg/dL and above, the meter will not provide a warning that the blood glucose is extremely high and will shut off, thereby potentially leading to incorrect treatment and delaying proper treatment.

The likelihood of experiencing an extremely high blood glucose level of 1024 mg/dL or higher is remote; however, when such a blood glucose level occurs, it is a serious health risk requiring immediate medical attention. Because these products do not provide an appropriate warning at glucose levels of 1024 mg/dL or higher, diagnosis and treatment of extreme hyperglycemia may be delayed or incorrect treatment may be given resulting in potentially serious health risk or fatality.

Patients who are using the OneTouch® Verio®IQ Meter should:

- Contact LifeScan Customer Service at (800) 717-0276 to make arrangements to receive a replacement meter at no charge and to speak with a LifeScan representative. Representatives are available 8 a.m. to 10 p.m. EDT Monday through Sunday (LifeScan U.S. Customer Service).
- Seek additional information about this recall on www.onetouch.com.
- Please note that patients may continue to test with their OneTouch® Verio®IQ Meters while they wait for their replacement meter to arrive as long as they are aware of this issue. However, LifeScan advises that if the meter unexpectedly turns itself off during testing, this could be a sign of extreme hyperglycemia requiring immediate medical attention and the patient should call a healthcare professional.

"Our patients' safety is our number one priority," said Dr. Michael Pfeifer, LifeScan's Chief Medical Officer. "When we learn that a product does not fully meet our expected standards, we will voluntarily notify our customers and patients and take corrective action. We regret the inconvenience these actions may cause. However, we will always err on the side of caution and make a decision that is in the best interest of our patients."

Notifications are being sent to all registered users, healthcare professionals, pharmacies and distributors wherever these products are sold. LifeScan estimates that there are approximately 90,000 active OneTouch® Verio®IQ Meter users in the U.S. The company is in the process of implementing an update to the meter to address the issue, however, the timing to resume shipments of OneTouch® Verio®IQ Meters has not yet been determined.

In the U.S., this recall affects the Verio®IQ blood glucose meter from OneTouch®

To date, no adverse events or patient injuries related to this specific issue have been reported for the OneTouch® Verio®IQ Meter. All other OneTouch® blood glucose brands sold in the U.S., including OneTouch® Ultra® Meters, OneTouch® Select Meters and OneTouch® Verio® Test Strips, are not affected and can continue to be used with confidence.

Outside the U.S., this recall affects three Verio® blood glucose meters from OneTouch®

Three OneTouch® Verio® Brand Meters are being recalled outside the U.S. because of incorrect glucose value display or record storage at extremely high glucose levels. These meters include the OneTouch® Verio®IQ, OneTouch® Verio®Pro and OneTouch® Verio®Pro+ Brands. To date, no adverse events or patient injuries related to this issue have been reported globally for the OneTouch® Verio®IQ and OneTouch® Verio®Pro+ Meters. For the OneTouch® Verio®Pro Meter, LifeScan has received one report of a serious adverse event, which occurred outside the United States. The company has not determined whether the OneTouch® Verio®Pro Meter was a causal factor.

LifeScan has notified the U.S. Food and Drug Administration (FDA) and healthcare authorities around the world of this voluntary action. LifeScan is working with the individual regulatory agencies around the world where the affected products have been sold.

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LifeScan, Inc. is a leading maker of blood glucose monitoring systems for people with diabetes. For information about diabetes care and LifeScan products and services, visit http://www.onetouch.com.