Verio Pro Distributor Letter – V.3

March XX, 2013

Urgent Field Safety Notice

OneTouch® Verio®Pro Blood Glucose Meter

Dear Distribution Partner:

At LifeScan, we hold our products to the highest standards of quality and are committed to communicating with you when we learn that a product does not fully meet expectations. Please read the following important information about the operation of the OneTouch®Verio®Pro Blood Glucose Meter.

Incorrect Test Results At Extremely High Blood Glucose Levels

At blood glucose levels of [600 mg/dL / 33.3 mmol/L] and above, the OneTouch®Verio®Pro Meter should display a warning that says "EXTREME HIGH BG above [600 mg/dL / 33.3 mmol/L]." We have recently determined that at extremely high blood glucose levels of [1024 mg/dL / 56.8 mmol/L] and above, the OneTouch®Verio®Pro Meter will display and store in memory an incorrect test result that is [1024 mg/dL / 56.8 mmol/L] below the measured result

> **Example**: a blood glucose value of [1064 mg/dL / 59.1 mmol/L] would result in the following: [1064 mg/dL / 59.1 mmol/L] – [1024 mg/dL / 56.8 mmol/L] = [40 mg/dL / 2.3 mmol/L]. The meter would display [40 mg/dL / 2.3 mmol/L] and store [40 mg/dL / 2.3 mmol/L] in the log.

The likelihood of experiencing extremely high blood glucose levels of [1024 mg/dL / 56.8 mmol/L] and above is remote. However, when they occur, they are a serious health risk and require immediate medical attention. Because the OneTouch®Verio®Pro Meter does not provide a warning at blood glucose levels of [1024 mg/dL / 56.8 mmol/L] and above and displays an inaccurate low result, there may be a delay in the diagnosis and treatment of severe hyperglycemia, or incorrect treatment may be given. This could lead to serious injury. As a result, we have decided to remove and replace all OneTouch®Verio®Pro Meters at no charge.

Patients should discontinue use of this meter immediately and use another meter for testing their blood glucose.

Please Check Your Inventory And Return All OneTouch®Verio®Pro Meters

1. Identify and hold all OneTouch®Verio®Pro Meters you have in inventory.
   UPC No. xxxxxxxx LifeScan Part No. xxxxxx NDC No. xxxxxx

2. Communicate this replacement program to your customers that received OneTouch®Verio®Pro Meters from you. Request that they return only OneTouch®Verio®Pro Meters per your normal return procedures. To assist you, we have enclosed a notification letter as a template to use in communicating with your customers.

3. Once you have received all OneTouch®Verio®Pro Meters to be returned, call **XXX XXX-XXXX** for a returned goods authorization (RGA) and product return instructions.

4. When we receive your returned product, we will issue a credit memo for an amount equivalent to your invoiced price of the returned product. No deductions will be allowed.

The OneTouch products included in this Field Safety Corrective Action are the OneTouch®Verio®Pro blood glucose meter, the OneTouch® Verio®IQ blood glucose meter, and the OneTouch®Verio®Pro+ blood glucose meter. All other OneTouch® brand products, including OneTouch® Ultra® blood

glucose meters, OneTouch® Vita® blood glucose monitors and OneTouch® Verio® test strips, are not affected and can continue to be used with confidence.

If you have any questions about this notice, please call **XXX XXX-XXXX.** We remain committed to providing patients and healthcare professionals 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

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