

March XX, 2013

**Urgent Field Safety Notice**  
**OneTouch® Verio® Pro Blood**  
**Glucose Meter**

Dear Valued Customer:

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 your 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.

**You should discontinue use of this meter immediately and use another meter for testing your blood glucose.**

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

1. Please call LifeScan Customer Service at XXX-XXX-XXXX to verify your OneTouch® Verio® Pro Meter Serial Number and confirm your mailing address so that we may ship you a replacement meter.
2. Our representatives will also be happy to answer any questions you may have and discuss your replacement meter options so that you can continue to test your blood glucose per your healthcare professionals' recommendation with minimal disruption.
3. Included with your replacement meter will be instructions for the return of your original meter.

Extreme hyperglycemia requires immediate medical attention. If you ever experience symptoms that are not consistent with your blood glucose results, call your health care professional. Never ignore symptoms or make significant changes to your diabetes management program without speaking to your health care professional.

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+

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blood glucose meter. All other OneTouch<sup>®</sup> brand products, including OneTouch<sup>®</sup> Ultra<sup>®</sup> blood glucose meters, OneTouch<sup>®</sup> Vita<sup>®</sup> blood glucose monitors and OneTouch<sup>®</sup> Verio<sup>®</sup> test strips, are not affected and can continue to be used with confidence.

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