

## Appendix – LifeScan customer letters



LifeScan UK/Ireland, Johnson & Johnson, 50-100 Holmers Farm Way, High Wycombe, Bucks, HP12 4DP  
 Tel: 01494 658 750 Fax: 01494 658 751 www.LifeScan.co.uk  
**Customer Care Freephone: UK 0800 121200 IRELAND 1800 535676**

March 25<sup>th</sup> 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 33.3 mmol/L and above, the OneTouch®Verio®Pro Meter should display a warning that says "EXTREME HIGH BG above 33.3 mmol/L." We have recently determined that at extremely high blood glucose levels of 56.8 mmol/L and above, the OneTouch®Verio®Pro Meter will display and store in memory an incorrect test result that is 56.8 mmol/L below the measured result.

**Example:** a blood glucose value of 59.1 mmol/L would result in the following: 59.1 mmol/L – 56.8 mmol/L = 2.3 mmol/L. The meter would display 2.3 mmol/L and store 2.3 mmol/L in the log.

The likelihood of experiencing extremely high blood glucose levels of 56.8 mmol/L and above is rare. However, when they occur, they are a serious health risk and require immediate medical attention. As the OneTouch®Verio®Pro Meter does not provide a warning at blood glucose levels of 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 **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to verify your OneTouch®Verio®Pro Meter Serial Number and confirm your address so that we may send 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.



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The OneTouch products included in this Field Safety Corrective Action are the OneTouch<sup>®</sup> Verio<sup>®</sup> Pro blood glucose meter, the OneTouch<sup>®</sup> Verio<sup>®</sup> IQ blood glucose meter, and the OneTouch<sup>®</sup> Verio<sup>®</sup> Pro+ 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 apologise for any inconvenience this issue may cause. Thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service



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### Urgent Field Safety Notice

### OneTouch® Verio®IQ 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®IQ Blood Glucose Meter.

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

We have recently determined that at extremely high blood glucose levels of 56.8 mmol/L and above, the OneTouch® Verio®IQ Meter will turn off instead of displaying the message "EXTREME HIGH GLUCOSE above 33.3 mmol/L" 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 your glucose level is still 56.8 mmol/L or above when testing, the meter will shut down again.

The likelihood of experiencing extremely high blood glucose levels of 56.8 mmol/L and above is rare. However, when they occur, they are a serious health risk and require immediate medical attention. As the OneTouch® Verio®IQ Meter does not provide the "EXTREME HIGH GLUCOSE above 33.3 mmol/L" message at glucose levels of 56.8 mmol/L 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 A Replacement Meter At No Charge, Please Follow The Steps Below:

1. Please call LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to verify your OneTouch® Verio®IQ Meter Serial Number and confirm your address so that we may send you a replacement meter. Our representatives will also be happy to answer any questions you may have.
2. You can continue to test with your current OneTouch® Verio®IQ Meter while you wait for your replacement meter to arrive. However, if the meter unexpectedly turns itself off during testing, this could be a sign of extreme hyperglycemia requiring immediate medical attention. **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 keep this letter with your Owner's Booklet.
3. Included with your replacement meter will be instructions for the return of your original meter.

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,



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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.

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

Sincerely,

LifeScan Customer Service