

March 25th, 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 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.

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

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 **0800 279 9118 (UK) or 1800 535 676 (Ireland)**. We remain committed to providing patients and healthcare professionals 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
Enc.

March 25th, 2013

Urgent Field Safety Notice

OneTouch[®] Verio[®] Pro Blood Glucose Meter

Dear Valued Customer:

We have been notified by LifeScan, Inc. that they are voluntarily removing and replacing all **OneTouch[®] Verio[®] Pro Blood Glucose Meters ONLY**. **OneTouch[®] Verio[™] Test Strips are not impacted by this action**. Our records indicate that you may have received shipments of OneTouch[®] Verio[®] Pro Meters. Please read the following information to determine if you have any impacted product and how to return it.

Incorrect Test Results At Extremely High Blood Glucose Levels

As communicated by LifeScan, 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 [3 mmol/L]." LifeScan has 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, LifeScan has decided to remove and replace all OneTouch[®] Verio[®] Pro Meters at no charge.

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

LifeScan requests your assistance in notifying patients of this issue by sharing this information with your customers who have received OneTouch[®] Verio[®] Pro Meters. Please refer any patients with OneTouch[®] Verio[®] Pro Meters to LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)**. to arrange to receive a replacement 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, 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 action, please call the LifeScan Customer Service: **0800 279 9118 (UK) or 1800 535 676 (Ireland)**. Thank you for your cooperation.

Sincerely,

[Distributor Signature]

March 25th 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.



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.

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

March 25th, 2013

Urgent Field Safety Notice
OneTouch[®] Verio[®] Pro+
Blood Glucose Meter

Dear Healthcare Professional:

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.

Note: the OneTouch[®] Verio[®] Pro+ Meter is a professional blood glucose monitoring system used by healthcare professionals in multi-patient hospital and clinic settings. This product is not available to patients with diabetes for personal blood glucose testing.

Incorrect Test Results Stored In Results Log At Extremely High Blood Glucose Levels

At blood glucose levels of 33.3 mmol/L and above, the OneTouch[®] Verio[®] Pro+ Meter should display and store in the results log an "Extreme High Glucose above 33.3 mmol/L" message. However, 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 the correct message, but will store an incorrect test result that is 56.8 mmol/L below the measured result in the results log. Relying on the result stored in the log could lead to incorrect treatment or delay the diagnosis and treatment of severe hyperglycemia, which could result in serious adverse events.

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 this issue compromises the integrity of the data stored in the results log, we have decided to remove and replace all OneTouch[®] Verio[®] Pro+ Meters at no charge.

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

1. If you use the OneTouch[®] Verio[®] Pro+ Meter, please call LifeScan Customer Service at **0800 279 9118 (UK) / 1800 535 676 (Ireland)** to verify your OneTouch[®] Verio[®] Pro+ Meter Serial Number and confirm your address so that we may send you a corrected, replacement meter as soon as possible.
2. While you wait for your replacement meter to arrive, you can continue to use your current OneTouch[®] Verio[®] Pro+ Meter because the test results and warning messages displayed at the time of the test are unaffected by this issue. **However, it is important that you do not rely on test results stored in the results log to make patient treatment decisions as they may be inaccurate.**
3. Included with your replacement meter will be instructions for the return of your original meter.



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

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.

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

March 25th, 2013

Urgent Field Safety Notice

OneTouch[®] Verio[®]IQ Blood Glucose Meter

Dear Pharmacist:

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[®]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 the 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.

Please Check Your Inventory And Return OneTouch[®]Verio[®]IQ Meters

1. Identify and hold all OneTouch[®]Verio[®]IQ Meters you have in inventory.
2. Return all OneTouch[®]Verio[®]IQ Meters for a credit following your normal return procedures.
3. 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. To assist you, enclosed is a copy of our Patient Notification. 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 **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to arrange to receive a replacement meter at no charge.

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.



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

We remain committed to providing you and your patients 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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March 25th, 2013

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OneTouch[®] Verio[®]IQ 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[®]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 the 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.

Please Check Your Inventory And Return All OneTouch[®]Verio[®]IQ Meters

1. Please Identify and hold all OneTouch[®]Verio[®]IQ Meters you have in inventory.
2. Once you have gathered all OneTouch[®] Verio[®]IQ Meters to be returned, call **0800 279 9118 (UK) or 1800 535 676 (Ireland)** for a returned goods authorisation (RGA) and product return instructions.
3. 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.
4. Please share this information with your patients who use the OneTouch[®]Verio[®]IQ Meter. To assist you, enclosed is a copy of our Patient Notification. 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 **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to arrange to receive a replacement meter at no charge.

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



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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 **0800 279 9118 (UK) or 1800 535 676 (Ireland)**. We remain committed to providing patients and healthcare professionals 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

Enc.

March 25th, 2013

Urgent Field Safety Notice

OneTouch[®] Verio[®]IQ Blood Glucose Meter

Dear Healthcare Professional:

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[®]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 the 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.

Please Check Your Sample Inventory and Return All OneTouch[®] Verio[®]IQ Meters

1. Discontinue distributing OneTouch[®] Verio[®]IQ Meters to patients and collect and hold all OneTouch[®] Verio[®]IQ Meter samples. A LifeScan sales representative will contact you in the near future to arrange for pick up and replacement. You may also call LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)** for assistance.
2. 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. To assist you, enclosed is a copy of our Patient Notification. 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 **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to arrange to receive a replacement meter at no charge.
3. Please share this with other healthcare providers in your office who may be impacted by this notification.



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.

We remain committed to providing you and your patients 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

Enc.

March 25th, 2013

Urgent Field Safety Notice

OneTouch[®] Verio[®]IQ 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[®]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 the 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. 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.

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 **0800 279 9118 (UK) or 1800 535 676 (Ireland)**. We remain committed to providing patients and healthcare professionals 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

Enc.

March 25th, 2013

Urgent Field Safety Notice

OneTouch[®] Verio[®]IQ Blood Glucose Meter

Dear Valued Customer:

We have been notified by LifeScan, Inc. that they are voluntarily removing and replacing all **OneTouch[®] Verio[®]IQ Blood Glucose Meters ONLY**. **OneTouch[®] Verio[™] Test Strips are not impacted by this action**. Our records indicate that you may have received shipments of OneTouch[®] Verio[®]IQ Meters. Please read the following information to determine if you have any impacted product and how to return it.

Failure To Provide A Warning At Extremely High Blood Glucose Levels

LifeScan has 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 the glucose level is still 56.8 mmol/L or above when testing, the meter will shut down again.

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LifeScan requests your assistance in notifying patients of this issue by sharing this information with your customers who have received the OneTouch[®] Verio[®]IQ Meters. 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 **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to arrange to receive a replacement meter at no charge.

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 action, please call the LifeScan Customer Service: **0800 279 9118 (UK) or 1800 535 676 (Ireland)**. Thank you for your cooperation.

Sincerely,

[Distributor Signature]

March 25th, 2013

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

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

March 25th, 2013

Dear Valued Customers:

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

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 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.

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

Extreme hyperglycemia requires immediate medical attention. If patients ever experience symptoms that are not consistent with their blood glucose results, they should call their health care professional. They should never ignore symptoms or make significant changes to their diabetes management program without speaking to their health care professional.

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

People with Diabetes: Discontinue use of your OneTouch® Verio® Pro Meter immediately and use another method for testing your blood glucose. 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.

Healthcare Professionals: Discontinue distributing OneTouch® Verio® Pro Meters to patients and collect and hold all OneTouch® Verio® Pro Meter samples. A LifeScan sales representative will contact you in the near future to arrange for pick up and replacement.

You may also call LifeScan Customer Service at 0800 121 200 (UK) 1800 535 676 (Ireland) for assistance. While LifeScan will be notifying patients directly, we also request your assistance in sharing this information with your patients who use the OneTouch®Verio®Pro Meter. Please refer any patients with OneTouch®Verio®Pro Meter to LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to arrange to receive a replacement meter.

Pharmacists: While LifeScan will be notifying patients directly, we also request your assistance in sharing this information with your patients who use the OneTouch®Verio®Pro Meter. Please refer any patients with OneTouch®Verio®Pro Meters to LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to arrange to receive a replacement meter.

Please call LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)** if you have questions about this action.

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.

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

March 25th, 2013

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

Dear Pharmacist:

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 [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.

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

While LifeScan will be notifying patients directly, we also request your assistance in sharing this information with your patients who use the OneTouch® Verio® Pro Meter. To assist you, enclosed is a copy of our Patient Notification. Please refer any patients with OneTouch® Verio® Pro Meters to LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to arrange to receive a replacement 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, 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 and your patients 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
Enc.

March 25th, 2013

Urgent Field Safety Notice
OneTouch[®] Verio[®]Pro Blood
Glucose Meter

Dear Healthcare Professional:

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 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

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

Please Check Your Sample Inventory and Return All OneTouch[®]Verio[®]Pro Meters

1. Discontinue distributing OneTouch[®]Verio[®]Pro Meters to patients and collect and hold all OneTouch[®]Verio[®]Pro Meter samples. A LifeScan sales representative will contact you in the near future to arrange for pick up and replacement. You may also call LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)** for assistance.
2. While LifeScan will be notifying patients directly, we also request your assistance in sharing this information with your patients who use the OneTouch[®]Verio[®]Pro Meter. To assist you, enclosed is a copy of our Patient Notification. Please refer any patients with OneTouch[®]Verio[®]Pro Meter to LifeScan Customer Service at **0800 279 9118 (UK) or 1800 535 676 (Ireland)** to arrange to receive a replacement meter.
3. Please share this with other healthcare providers in your office who may be impacted by this notification.



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Tel: 01494 658 750 Fax: 01494 658 751 www.LifeScan.co.uk

Customer Care Freephone: UK 0800 121200 IRELAND 1800 535676

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.

We remain committed to providing you and your patients 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

Enc.