



**S
A
F
E
T
Y
NOTICE**

OneTouch Verio Pro and OneTouch Verio IQ Blood Glucose Meters

IMB Safety Notice: SN201304

Circulation Date: 15 April 2013

MANUFACTURER/SUPPLIER

LifeScan

TARGET GROUPS

Pharmacists supplying these devices
General Practitioners
Healthcare professionals who use these devices
Healthcare professionals managing patients who use these devices
General public
Risk Managers
Procurement Managers
Carers
Diabetic Clinics
Diabetic Nurse Specialists

ISSUE

LifeScan has identified that the OneTouch Verio Pro and OneTouch Verio IQ Blood Glucose Meters will not perform as expected at blood glucose levels of 56.8 mmol/L and above. LifeScan is recalling and replacing all OneTouch Verio Pro and Verio IQ blood glucose meters.

BACKGROUND

OneTouch Verio Pro

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.”. However 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.

The likelihood of experiencing extremely high blood glucose levels of 56.8 mmol/L and above is remote, however 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.

S A F E T Y NOTICE

As a result, LifeScan has decided to remove and replace all OneTouch Verio Pro Meters.

OneTouch Verio IQ

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.

The likelihood of experiencing extremely high blood glucose levels of 56.8 mmol/L and above is remote, however 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, LifeScan has decided to replace all OneTouch Verio IQ Meters.

LifeScan have advised that 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.

ACTION OR RECOMMENDATIONS

Immediate actions users should take:

Users of OneTouch Verio Pro

1. Discontinue use of these meters and use another method for testing their blood glucose.
2. Contact LifeScan Customer Service at +44 800 279 9118 (UK) or 1800 535 676 (Ireland) to make arrangements to receive a replacement meter at no charge and to speak with a LifeScan representative.
3. Never ignore symptoms or make significant changes to your diabetes management program without speaking to your health care professional.

Users of OneTouch Verio IQ

1. Contact LifeScan Customer Service at +44 800 279 9118 (UK) or 1800 535 676 (Ireland) to make arrangements to receive a replacement meter at no charge and to speak with a LifeScan representative
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.**
3. Never ignore symptoms or make significant changes to your diabetes management program without speaking to your health care professional.

SAFETY NOTICE

Actions for Pharmacists:

1. Identify and hold all OneTouch Verio Pro and Verio IQ Meters you have in inventory.
2. Return all OneTouch Verio Pro and Verio IQ Meters to the manufacturer.
3. Please share this information with patients who use the OneTouch Verio Pro and Verio IQ Meter.
4. Please refer any patients with OneTouch Verio Pro and Verio IQ Meters to LifeScan Customer Service at +44 800 279 9118 (UK) or 1800 535 676 (Ireland) to arrange to receive a replacement meter at no charge.

Actions for Healthcare Professionals:

1. Discontinue distributing OneTouch Verio Pro and Verio IQ Meters to patients and collect and hold all OneTouch Verio Pro and Verio IQ Meters 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 +44 800 279 9118 (UK) or 1800 535 676 (Ireland) for assistance.
2. Please share this information with your patients who use the OneTouch Verio Pro and Verio IQ Meters. Please refer any patients with OneTouch Verio Pro and Verio IQ Meters to LifeScan Customer Service at +44 800 279 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.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

LifeScan UK/Ireland, Johnson & Johnson,
50-100 Holmers Farm Way,
High Wycombe, Bucks,
HP12 4DP, United Kingdom

Customer Care Freephone: +44 800 279 9118 (UK) or 1800 535 676 (Ireland)

Telephone: + 44 (0)1494 658 750
Fax: + 44 (0)1494 658 751

All incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-676 4971
Fax: +353-1-634 4033
E-mail: vigilance@imb.ie
Website: www.imb.ie