Medical Device Alert

Ref: MDA/2013/022 Issued: 11 April 2013 at 12:00

Device

Home use blood glucose meters:

- Lifescan OneTouch Verio Pro
- Lifescan OneTouch Verio IQ

Pro **IQ**

Problem

Recall of One Touch Verio meters because of a software fault at glucose levels of 56.8mmol/l and above.

One Touch Verio Pro: At very high blood glucose concentrations a falsely low result will be displayed.

One Touch Verio IQ: At very high blood glucose concentrations no result will be displayed.

Action

Advise users of affected meters to contact Lifescan customer services on 0800 279 9118.

Action by

- Pharmacists supplying these devices or OneTouch Verio test strips.
- Healthcare professionals who manage patients who use these devices.

CAS deadlines

Action underway: 18 April 2013

Action complete: 13 May 2013

Contact

On behalf of the manufacturer
Joanne Bullen
Lexington Communications
Tel: 020 7025 2345
Email: verio@lexcomm.co.uk

Device

- Lifescan **OneTouch Verio Pro** meters with serial numbers beginning RA, RB, RC, RD and RE have been recalled. Replacement meters have serial numbers beginning RF. The serial number can be found on the back of the meter itself.

- Lifescan **OneTouch Verio IQ** meters with serial numbers beginning TA and TB have been recalled. Replacement meters have serial numbers beginning TC. The serial number can be found on the back of the meter itself.

Problem

LifeScan has notified the MHRA of a software problem affecting the **One Touch Verio Pro** and **One Touch Verio IQ** blood glucose meters.

OneTouch Verio Pro: displays an incorrect result and stores this incorrect result in the memory. At extremely high blood glucose levels (56.8mmol/l and above), the incorrect result will be 56.8mmol/l lower than the measured result.

OneTouch Verio IQ: no result will be displayed, and no result will be stored in the memory. At extremely high blood glucose levels (56.8mmol/l and above), the meter will countdown then turn off instead of displaying a result.

LifeScan is recalling all OneTouch Verio blood glucose meters manufactured up to the 07 March 2013 and has written to patients and relevant healthcare professionals i.e. diabetes specialist nurses, GPs, practice nurses and pharmacists.

One Touch Verio Pro and **One Touch Verio IQ** meters are capable of reporting results in the range 1.1 – 33.3mmol/l.

The performance of the test strips is not affected by this problem.

This problem also affects the **OneTouch Verio Pro+** device, which is used by health professionals only. LifeScan has issued a Field Safety Notice concerning this to all affected customers.

This problem does not affect any other blood glucose meter supplied by Lifescan.

Action

Pharmacists supplying OneTouch Verio meters or OneTouch Verio test strips:

- Do not supply any affected OneTouch Verio meters.
- If you have any affected OneTouch Verio meters in your current stock contact LifeScan customer care for replacements.
- When dispensing OneTouch Verio test strips advise users with affected meters to contact LifeScan customer care for a replacement meter, and provide a copy of the relevant customer letter (see appendix).

Healthcare professionals who manage patients who use OneTouch Verio meters:

- Identify patients who are using affected meters.
- Advise users of affected meters to contact LifeScan customer care for a free replacement.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS Commissioning Board area teams
- NHS Commissioning Board area teams (chief executives)
- NHS Commissioning Board regional teams
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- Social services in England (directors)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Ambulance services directors
- Ambulance staff
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Endocrinology units
- Endocrinology, directors of
- Health and safety managers
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- Nursing executive directors
- Outpatient clinics
- Paramedics
- Pharmacists
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- Vascular units

NHS Commissioning Board: local area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- Directors of public health
- District nurses
- General practitioners
- Health visitors
- NHS walk-in centres
- Pharmaceutical advisors
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Social services
Liaison officers for onward distribution to all relevant staff including:
- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house residential care homes

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
This alert should be read by:
- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED
This alert should be read by:
- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

On behalf of the manufacturer
Communication Office
Joanne Bullen
Lexington Communications
Tel: 020 7025 2345
Fax: 020 7025 2301
Email: verio@lexcomm.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/022** or **2013/003/015/081/011**

Technical aspects
Bina Mackenzie or Susan Mclellan
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7229/7215 Fax: 020 8754 3965

Email: bina.mackenzie@mhra.gsi.gov.uk
susan.mclellan@mhra.gsi.gov.uk

Clinical aspects
Nicola Lennard
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ
Tel: 020 3080 7126 Fax: 020 8754 3965
Email: nicola.lennard@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group, Room 17, Annex 6, Castle Buildings, Stormont Estate, Dundonald BT4 3SQ
Tel: 02890 523 704 Fax: 02890 523 900 Email: NIAIC@dhsspsni.gov.uk
http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland, NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Fax: 0131 314 0722 Email: nss.iric@nhs.net
http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ
Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk

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Addressees may take copies for distribution within their own organisations

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 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.

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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

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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.

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