Health Devices Alerts
WEEKLY ACTION ITEMS AND NEWS FOR HEALTH DEVICES MEMBERS
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April 12, 2013

A19853 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: April 12, 2013
UMDNS Terms:
- Monitors, Personal, Glucose [20184]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Home Care
- Nursing
- Diabetes Education/Coordination

Geographic Regions:
- Asia Pacific
- Australia
- Benelux
- Canada
- Central Eastern Europe
- France
- Germany
- Iberia
- Italy
- Japan
- Nordics
- Saudi Arabia
- Switzerland
- U.K.
- U.S.

LifeScan—OneTouch Blood Glucose Meters: May Not Provide Warning at Extremely High Blood Glucose Levels

Product Identifier:

OneTouch Verio Blood Glucose (BG) Meters:	UPC Nos.:	LifeScan Part Nos.:	NDC Nos.:
(1) IQ (U.S. only)	(1) 353885007702	(1) 022267	(1) 5388526701
(2) Pro	(2 and 3) Not listed	(2 and 3) Not listed	(2 and 3) Not listed
(3) Pro+			

[Capital Equipment]

Manufacturer:
- LifeScan Inc1000 Gibraltar Dr, Milpitas, CA 95035, United States

Problem:
In a March 25, 2013, Urgent Field Safety Notice letter posted by LifeScan and the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and a March 25, 2013, Urgent Medical Device Voluntary Recall letter, LifeScan states that the above meters may not operate as intended at extremely high BG levels, potentially leading to incorrect treatment and delayed diagnosis and treatment of extreme hyperglycemia.
For the above OneTouch VerioIQ meters, LifeScan states that, at extremely high BG levels ≥1,024 mg/dL/56.8 mmol/L, the meter may turn off instead of displaying the message "Extreme High Glucose above [600 mg/dL/33.3 mmol/L]" as intended. LifeScan also states that when turned back on, the above OneTouch Verio IQ meters will enter the setup mode and require the user to confirm the date and time settings before being able to test again; however, if the BG level is still ≥1,024 mg/dL, the meter may shut down again.
For the above OneTouch VerioPro meters, LifeScan states that, at BG levels ≥600 mg/dL/33.3 mmol/L, the system should display a warning that states "EXTREME HIGH GLUCOSE above [600 mg/dL/33.3 mmol/L];" however, LifeScan has determined that at BG levels ≥1,024 mg/dL/56.8 mmol/L, the above meters may not display a warning and may instead display and store in memory an incorrect test result that is 1,024 mg/dL below the measured result.
For the above OneTouch VerioPro+ meters, LifeScan states that, at BG levels ≥600 mg/dL/33.3 mmol/L, the meter should display and store in the results log an "Extreme High Glucose above [600 mg/dL/33/3 mmol/L]" message; however, LifeScan has determined that at BG levels ≥1,024 mg/dL/56.8 mmol/L, the above OneTouch VerioPro+ meters may display the correct message, but store an incorrect test result that is 1,024 mg/dL/56.9 mmol/L below the measured result in the results log.
LifeScan states that the likelihood of patients experiencing extremely high BG levels ≥1,024 mg/dL/56.8 mmol/L is remote; however, when they do, it is a serious health risk and this problem may lead to inappropriate or delayed treatment. LifeScan also states that no other OneTouch brand products are affected by this problem.

Action Needed:
Identify and isolate any affected product in your inventory. If you have affected product, verify that you have received the March 25, 2013, letter from LifeScan. Discontinue distributing affected product to your patients. To arrange to return affected product, U.S. customers should contact LifeScan by telephone at (877) 644-0004, or by using the information below. LifeScan states that, depending on your meter, the following actions should be taken:
OneTouch VerioIQ Meters:
- Until replacement product arrives, patients may continue to test with their OneTouch VerioIQ meters.
- LifeScan recommends that if the meter unexpectedly turns itself off during testing, patients should call a health care professional, because this could be a sign of extreme hyperglycemia requiring immediate medical attention.

OneTouch VerioPro Meters:

- Discontinue use of OneTouch VerioPro meters immediately and use another method for testing BG.

OneTouch VerioPro+ Meters:

- Until replacement product arrives, healthcare professionals may continue to use their OneTouch VerioPro+ meters because the test results and warning messages displayed at the time of the test are unaffected by this problem.
- Healthcare professionals should not rely on test results stored in the results log to make patient treatment decisions because they may be inaccurate.

Notify your patients of the information in the March 25, 2013, letter, and refer them to LifeScan customer service to arrange to receive replacement product.

For Further Information:

LifeScan customer service or LifeScan local representative

U.S.:

Tel.: (800) 717-0276

Ireland:

Tel.: (1800) 535676

U.K.:

Tel.: (0800) 2799118

Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. LifeScan. IVDs, self/home testing; blood glucose meters and/or strips. OneTouch Verio Pro/IQ/Pro+ system [online]. London: Department of Health; 2013 Mar 25 [cited 2013 Mar 26]. 1 p. (Field safety notice; reference no. 2013/003/015/081/011). Available from Internet: Click here.

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

Source(s):

- 2013 Mar 26. MHRA FSN. 2013/003/015/081/011
- 2013 Mar 26. MHRA FSN.
- 2013 Mar 26. Member Hospital. LifeScan letter submitted by an ECRI Institute member hospital
- 2013 Mar 26. Member Hospital. AmerisourceBergen letter submitted by an ECRI Institute member hospital
- 2013 Mar 26. Manufacturer. LifeScan letter posted on LifeScan website
- 2013 Mar 27. Manufacturer. LifeScan confirmed the information provided in the source material.
- 2013 Apr 11. Member Hospital. LifeScan Reply Form submitted by an ECRI Institute member hospital (includes reply form)
- 2013 Apr 12. Germany FIDMD. 1338/13
- 2013 Apr 12. Germany FIDMD.