



**EL DORADO COUNTY
HEALTH AND HUMAN SERVICES AGENCY**

Emergency Medical Services

Daniel Nielson, M.P.A.
Director

Richard Todd
EMS Agency Administrator



EMS Safety Bulletin 2013-02

DATE: March 13th, 2013

TO: All Personnel

FROM: EDCEMS

SUBJECT: Product Recall

Please refer to the attached documents for additional information regarding a recall of LifeScan One Touch Ultra.

MESSAGE CONFIRMATION:

NOT REQUIRED

REQUIRED

ACKNOWLEDGEMENT BY ALL PERSONNEL REQUIRED



February 25, 2013

Urgent Medical Device Recall
OneTouch® Ultra® Control Solution

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 of any issue requiring correction.

This letter is to inform you that LifeScan is voluntarily removing and replacing five lots of OneTouch® Ultra® Control Solution distributed in the United States. The purpose of Control Solution Testing is to confirm that the meter and test strips are working together correctly as a system. The five lots of control solution are being replaced because they may not provide an “in range” control test result when used with OneTouch® Ultra® Test Strips, even though your system is working correctly. As your meter’s User Guide and Control Solution instructions for use state, an out of range Control Solution test result may mean the meter system is not working properly. This may lead to a delay in further blood sugar testing until the issue is resolved.

This Issue Applies To Control Solution Test Results Only. The accuracy of patient blood sugar test results is not affected.

What you Should Do

1. Please check your OneTouch® Ultra® Control Solution to find out if it is from any of the five lots listed below that are subject to replacement. The lot number can be found on the outside of the Control Solution Carton and on the Control Solution Bottle Label.



Impacted OneTouch® Ultra® Control Solution Lot Numbers*

2AA2G01	2AA2G02	2AA2G03	3AA2G04	3AA2G05
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**These products were distributed only in the United States.*

2. If you have any OneTouch® Ultra® Control Solution from these lots, you should discontinue its use immediately and call OneTouch® Customer Service at **866-461-0043** to request replacement product free of charge.
3. If you have control solution from the lots listed in this letter, you may continue to use your blood glucose system while waiting for your replacement control solution. However, you should discontinue using your system and call LifeScan for assistance if you: suspect that the meter and strips are not working properly; have repeated unexpected glucose results; or drop or damage the meter.

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.

If you have any questions about this notice, please call our OneTouch® Customer Service Line at **866-461-0043**. We remain committed to providing you with the highest quality products and services and apologize for any inconvenience this issue may cause. Thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service

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