

November 23, 2009

Urgent: Field Safety Notice
Affecting 2 Lots of
OneTouch® Ultra® Test Strips

Dear Healthcare Professional:

At LifeScan we hold our products to the highest standards of quality; constantly working to ensure they provide glucose results you can rely on. For that reason, we're also committed to communicating with you when we learn of product that may not meet our expected standards.

The Issue: Very Small Number of Damaged Test Strip Vials

We have recently determined that two lots of 100-count OneTouch® Ultra® Test Strips may contain a very small number of damaged test strip containers (also called "vials"). These test strips were sold in 100-count packages containing 4 vials of 25 test strips each.

The defect in the bottom of the vial (Figure 1) does not penetrate the inner portion of the vial which contains the test strips. Due to the fact that the test strips are not exposed, performance of the test strips is not impacted when vials are stored and used as instructed.



Figure 1

We estimate that less than 25 damaged vials are among all the test strips in the two lots that have been identified as having this issue in the U.S.

Patients Should Not Use Test Strips From Damaged Vials

Please share this information with your patients that use OneTouch Ultra Brand meters and test strips. To assist you, enclosed is a copy of the patient notification.

1. As described in the instructions included with each package of test strips, users are advised: "**Do not** use your OneTouch Ultra Brand Test Strips if your vial is open or damaged in any way as this could lead to error messages or inaccurate blood glucose values." We are encouraging patients to follow this instruction and be aware of the possibility of a defect in the bottom of a limited number of vials (Figure 1).

Note: Only 100-count OneTouch Ultra Test Strips (sold as 4 vials of 25 test strips each) with lot numbers **#2960566** or **#2960878** are included in this notice. The lot number can be found on both the vial label and the outer carton.

2. Patients should not use any test strips from vials that are damaged. For more information or to report damaged vials, patients should visit

www.OneTouchProductID.com for further instructions. Patients may also contact LifeScan Customer Service by calling **866 621-6156**, Monday through Friday between the hours of 8:00 am and 5:00 pm PST.

3. If their OneTouch Ultra Test Strip vials are not damaged, patients can continue to use the strips with confidence to test their blood glucose as directed by their healthcare professional.

We take this issue very seriously and are conducting a broad-based notification program to alert patients, healthcare professionals, pharmacists and distributors. In addition, the U.S. Food & Drug Administration is aware of this issue and the steps we are taking to address it.

We apologize for any inconvenience this may cause. If you have any questions about OneTouch Ultra Test Strips, please call our Healthcare Professional line at the **800 218-1863**. Thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service

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