

February 4, 2010

Urgent: Medical Device Correction
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 and your patients can rely on. For that reason, we're also committed to communicating with you when we learn of product that does not meet our expected standards.

We have recently determined that up to 900 packages of OneTouch® Ultra® Test Strips contain vials of the wrong test strip. These incorrect test strips can be easily identified because they are dark blue and don't have a brand name printed on the strip (see picture). As a safety feature, these strips will not turn on a OneTouch Ultra® Brand meter or provide a test result.



Correct Incorrect

These mislabeled test strips are found only in 100-count packages (4 vials of 25 test strips each) of OneTouch Ultra Test Strips with Lot # **2964512**.

Please Help Us Reach Patients With This Important Information

Our priority is to make sure patients have only OneTouch Ultra Test Strips so that they can test their blood glucose with confidence.

Please share this information with your patients that use OneTouch Ultra Brand meters and refer any patients with questions directly to LifeScan for assistance. To help you, enclosed is a copy of our Patient Notification letter.

We take this issue very seriously and are conducting a broad-based communications program to alert patients, healthcare professionals, pharmacists and distributors. As part of this program, we are sending notices to our data base of registered OneTouch Ultra Brand meter users as well as an alert to all retail pharmacies in the U.S. 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. For more information please visit www.OneTouchProductID.com. If you still have any questions about this issue, please call our Customer Service line at **800 611-5337**. Thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service

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