

URGENT: MEDICAL DEVICE RECALL- LifeScan, Inc. One Touch, Sure Step Test Strips

Dear Valued Customer:

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 be performing to our expected standards.


This letter is to let you know that LifeScan is voluntarily removing and offering to replace free of charge two specific lots of OneTouch® SureStep® Blood Glucose Test Strips. We are replacing these two lots because we have learned that a very small number of vials in these lots may contain test strips that could produce inaccurately low or no blood glucose test results.

We have also informed the U.S. Food and Drug Administration of this action.

How To Tell If Your OneTouch SureStep Test Strips Are Affected

Please compare the lot numbers of any OneTouch SureStep Test Strips in your possession with the two affected lot numbers listed below. The lot number appears on the outside of the test strip box and on the test strip vial label. If you do not have any test strips from either of these two lots, then your OneTouch SureStep Test Strips are not affected and no further action is required. You can continue to use them to test your blood glucose.

<u>Affected Lot Number</u>	<u>Description</u>
2802961	100-count OneTouch SureStep Test Strips
2802962	50-count OneTouch SureStep Test Strips



(Example only)

Note: Replacement test strips will only be provided to those customers who have OneTouch SureStep Test Strips from either of the two lots identified in this letter. No other OneTouch® Brand products are included in this replacement program.

How To Receive Replacement OneTouch SureStep Test Strips

If you have any OneTouch SureStep Test Strips from either of the two lot numbers identified in this letter, please stop using them immediately and call LifeScan at **1 (866) 840-1758**. Tell the customer service representative that you have test strips that need to be replaced. You should also tell the representative if you have other test strips available to test with while you wait for your replacement test strips. The LifeScan representative will tell you how to return your affected test strips and will arrange to have replacement test strips sent to you at no charge. While you wait for your replacement test strips to arrive, please do not use the OneTouch SureStep Test Strips with the lot numbers identified in this letter.

Your Complete Satisfaction is Our Top Priority

Please know that, at LifeScan, we continually strive to ensure that we provide you with product of the highest quality. We apologize for any inconvenience this issue may cause, and we thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service

LIFESCAN: 1-866-840-1758