
CLASS I RECALL
Abbott Diabetes Care Blood Glucose Test Strips
Questions and Answers

On February 15, 2011, the U.S. Food and Drug Administration (FDA) upgraded the recent Abbott Diabetes Care blood glucose test strip recall from a voluntary to a Class I medical device recall. A Class I recall is the most serious type of recall and is issued when there is a high probability that product use will cause serious adverse effects or death.

The initial recall was announced on December 22, 2010 as a voluntary recall of 359 lots of MediSense Optium, Optium, OptiumEZ, Precision Xceed Pro, Precision Xtra and ReliOn Ultima blood glucose test strips in the U.S. and Puerto Rico. Test strips displaying the recalled lot numbers were manufactured between January and May 2010 and sold either directly to patients or distributed for use in health care facilities. The blood glucose monitors used with these test strips are not being recalled and can continue to be used by patients.

Q. Why did Abbott Diabetes Care recall specific lots of its blood glucose test strips?

- A.** The affected test strips may report low blood glucose results due to a defect that inhibits sufficient absorption of blood into the test strip. Exposure to warm weather or prolonged storage may increase the likelihood of the test strips providing a false blood glucose reading. These false low readings may lead patients to try to raise their blood glucose when it is unnecessary to do so, or cause patients to fail to treat elevated blood glucose.

Q. Which products are affected by this recall?

- A.** This recall includes specific lots of the following Abbott Diabetes Care blood glucose test strips:
- MediSense Optium
 - Optium
 - OptiumEZ
 - Precision Xceed Pro
 - Precision Xtra
 - ReliOn Ultima

Patients can determine if they are in possession of a recalled test strip by visiting Abbott's website at www.precisionoptiuminfo.com/ and checking their product lot number. The lot number is located on the bottom of the test strip carton and on the back of the test strip foil package.

Q. Should I immediately stop using Abbott Diabetes Care blood glucose test strips?

- A.** If you have recently purchased Abbott Diabetes Care blood glucose test strips, you are advised to:
1. Check the product's label to determine if it is affected by this recall.
 - If you are in possession of a recalled product, immediately discontinue use and contact Abbott Diabetes Care Customer Service at 1-800-448-5234 (English) or 1-800-709-7010 (Español) for product replacement instructions.
 2. Contact your health care professional to discuss any concerns related to the use of these products.

3. Report adverse events or side effects related to the use of these products. Adverse events related to a recalled product should be reported to the FDA's *MedWatch* program by either:
 - Completing and submitting the voluntary report online at:
www.fda.gov/MedWatch/report.htm.
 - Downloading the voluntary reporting form at:
www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm or calling 1-800-332-1088 to request a copy. After completion, it should be returned to the address provided on the form, or submitted by fax to 1-800-FDA-0178 (1-800-332-0178).

For more information, please visit:

www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm243421.htm

www.precisionoptiuminfo.com/EN/faq.php