

FDA NEWS RELEASE

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FDA Announces Recall Of Abbott Glucose Test Strips

Strips sold in retail stores, online and used in health care facilities

The U.S. Food and Drug Administration today announced the agency is working with Abbott Diabetes Care to recall 359 different lots of glucose test strips marketed under the following brand names:

- Precision Xceed Pro;
- Precision Xtra;
- Medisense Optium;
- Optium;
- OptiumEZ; and
- ReliOn Ultima

These strips are used with Abbott's Precision Xtra, Precision Xceed Pro, MediSense Optium, Optium, Optium EZ and ReliOn Ultima blood glucose monitoring systems. As many as 359 million strips may be affected by the recall. The blood glucose monitoring systems are not affected by this recall.

The recall pertains to certain lots of these test strips distributed in the United States and Puerto Rico. Other Abbott Diabetes Care products are not affected by the recall.

The test strips being recalled may give falsely low blood glucose results. False results may lead patients to try to raise their blood glucose unnecessarily, or they may fail to treat elevated blood glucose because of a false, low reading. Both scenarios pose risks to a patient's health.

The recall is related to the test strips' inability to absorb enough blood for monitoring. Strips exposed to warm weather or prolonged storage may be more likely to provide a false result.

The test strips were manufactured between January and September 2010 and are sold both in retail and online settings directly to consumers, but are also used in health care facilities.

The FDA has provided recommendations for consumers and health care professionals below that explain how to determine whether a particular lot is affected, how to order free replacement strips and how to use recalled strips to reduce the likelihood a false result.

"Patients with diabetes should be aware of the recalled glucose test strips and take steps to prevent them from affecting their health," said Alberto Gutierrez, Ph.D., director for the Office of In Vitro

Diagnostics in FDA's Center for Devices and Radiological Health. "FDA and Abbott are reviewing the cause of the manufacturing defect to avoid this problem in the future."

To determine if you have product being recalled:

Call Abbott Diabetes Care customer service at 1-800-448-5234 (English) and 1-800-709-7010 (Spanish) to speak with a customer service representative.

Visit www.precisionoptiuminfo.com to look up test strip lot numbers.

Consumers should report serious adverse events (side effects) with the device to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax, or phone.

Online

Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.

Fax: 800-FDA-0178

Phone: 800-332-1088

Recommendations for Consumers Who Purchased the Precision Xtra, Optium, OptiumEZ, and ReliOn Ultima Blood Glucose Blood Glucose Test Strips

For consumers who purchased test strips in retail stores or online, FDA recommends:

Calling Abbott for a replacement of the affected strips. Abbott will send you unaffected Precision Xtra, Optium, OptiumEZ, and ReliOn Ultima Blood Glucose Test Strips at no charge.

While waiting for the replacement strips to arrive, use an alternate method to measure blood glucose (such as a different test system) or purchase at least two weeks worth of new, unaffected strips while waiting for replacement strips.

If you purchase Precision Xtra, Optium, OptiumEZ, and ReliOn Ultima Blood Glucose Test Strips in a store or online, check to be sure these are from unaffected lots. Ask a pharmacist to help you.

If the only test strips available to you are from affected lots, do not stop testing your blood glucose. But do take the following two precautions to reduce the chance of erroneous reading:

Precaution 1: Check the amount of time it takes for your blood glucose meter to start the "countdown" after you first apply blood to the test strip. Start timing immediately after blood first makes contact with the test strip. If your meter takes longer than five (5) seconds to start the countdown that test strip is defective and the result should not be used.

Check the time for each test strip you use because all of the strips in a package may not be affected to the same degree.

Precaution 2: If any reading from a strip appears lower than you would expect or does not seem to match the way you are feeling, you should contact your health care provider.

Pay special attention to signs and symptoms of high blood sugar (hyperglycemia) and low blood sugar (hypoglycemia).

Symptoms of high blood sugar include excessive thirst, excessive urination, blurred vision, weakness, nausea, vomiting and abdominal pain. If you are experiencing any of these symptoms or are not feeling well, contact your health care professional immediately.

Symptoms of low blood sugar may include trembling, excessive sweating, weakness, hunger, confusion, and headache. Some individuals may have no symptoms at all before they develop unconsciousness or seizures. It is important to treat low blood sugars promptly to avoid loss of consciousness or a seizure. If you are unable to obtain unaffected strips, you should contact your health care provider for advice on how to treat these symptoms before they occur.

Recommendations for Health care Professionals using Precision Xceed Pro Blood Glucose System

If you have affected strips, FDA recommends the following:

If available, immediately switch to using test strips from unaffected lots.

If your facility does not have any test strips from unaffected lots, and you have immediate access to an alternate Point of Care blood glucose testing system within your healthcare facility, discontinue use of the Precision Xceed Pro Blood Glucose Test System and use the alternate method until you can obtain unaffected Precision Xceed Pro Blood Glucose Test Strip lots.

If your facility does not have test strips from unaffected lots, and you do NOT have immediate access to an alternate Point of Care blood glucose testing system, FDA recommends the following procedures:

1. Verify any critical glucose test results (e.g., test results that may be used to adjust insulin therapy in vulnerable patient populations) generated on the Precision Xceed Pro Blood Glucose Test System using a central laboratory blood glucose method. Medical judgment should be applied when deciding whether to act on results prior to verification.
2. Verify any Precision Xceed Pro Blood Glucose Test System results that do not match a patient's symptoms, or seem unexpected for the patient's clinical status, using a central laboratory blood glucose method.
3. When using the Precision Xceed Pro Blood Glucose Test System, take precautions to reduce the chance of an erroneous reading. Limited evidence suggests that results may be accurate using strips from affected lots if fill time does not exceed five seconds. Monitor the amount of time it takes for the Precision Xceed Blood Glucose Meter to start the "countdown" after blood is first applied to the test strip. If the amount of time exceeds five (5) seconds, discard that test strip immediately because the blood glucose result may be erroneously low. In addition, if this occurs:

- i. Note the specific lot number of that test strip;
- ii. Notify Abbott Diabetes Care to report the observed problem with that lot by calling 1-877-529-7185;
- iii. Make sure to check fill time on each individual strip during use and do not assume if one strip in a package/lot appears to be unaffected, that all strips in that package/lot are unaffected.