



December 22, 2010

URGENT PRODUCT RECALL – DISCONTINUE USE AND RETURN
Precision Xtra® Blood Glucose Test Strips

Dear Health Care Provider,

Abbott Diabetes Care is recalling certain lots of Precision Xtra Blood Glucose Test Strips because the strips may generate erroneously low blood glucose results. Erroneously low results that are not recognized may pose significant risks to your health.

If you have Precision Xtra Sample kits or Sample Blood Glucose Test Strips from affected lots, you are advised to immediately discontinue sampling of these products to your patients.

To determine if you have affected product and to arrange for product return:

- Please call Abbott Diabetes Care customer service at 1-800-448-5234
- Customers may also visit www.precisionoptiuminfo.com for more information.
- Abbott Diabetes Care will provide FreeStyle or FreeStyle Lite samples – which are unaffected by this recall - to replace affected Precision Xtra samples, should your office require immediate product for patients.

If you have Precision Xtra patients using test strips from affected lots, please:

- Advise patients to immediately discontinue use of affected Precision Xtra Blood Glucose Test Strips. Our letter to customers is attached for your review and information.
- If you or your patients have any questions, please call Abbott Diabetes Care customer service at 1-800-448-5234.

Abbott Diabetes Care will replace affected Precision Xtra Blood Glucose Test Strips at no charge. We recognize the importance of blood glucose testing and are committed to responding quickly to customers' requests for replacement test strips. We are working to make the necessary corrective actions to prevent this situation from recurring.

We sincerely regret any inconvenience this situation may cause and we thank you for your continued support of Abbott Diabetes Care.

Sincerely,

A handwritten signature in blue ink, appearing to read 'J. Scott House', with a long horizontal flourish extending to the right.

J. Scott House
Division Vice President, Quality Assurance and Compliance
Abbott Diabetes Care

Enclosure: US Consumer Letter



December 2010

**URGENT PRODUCT RECALL – DISCONTINUE USE AND RETURN
AFFECTED PRODUCT LOTS**

MediSense® Optium™ Blood Glucose Electrodes
45001A133, 45001A137, 45001A226, 45001A252, 45001A257, 45001A277, 45001A285, 45001A817, 45001A835, 45001A921, 45001C001
OptiumEZ Blood Glucose Test Strips
45358, 45369, 45377, 45504, 45677, 45678, 45681, 45789, 45841, 45848, 45849, 45999, 46000, 46008, 46061, 46067, 46102, 46104, 46117, 46159, 46179, 46201, 46202, 46211, 46230, 46247, 46311, 46312, 46341, 46368, 46369, 46371, 46395, 46399, 46401, 46436
Precision G3b Smartblue Blood Glucose Test Strips
45001A710
ReliOn® Ultima Blood Glucose Test Strips
45358, 45369, 45377, 45379, 45466, 45504, 45511, 45608, 45613, 45641, 45642, 45644, 45672, 45674, 45675, 45676, 45677, 45721, 45734, 45736, 45739, 45742, 45743, 45789, 45790, 45800, 45801, 45840, 45841, 45849, 45850, 46008, 46009, 46061, 46067, 46069, 46072, 46103, 46105, 46148, 46201, 46202, 46214, 46215, 46232, 46313, 46332, 46336, 46338, 46341, 46368
MediSense® Optium™ Blood Glucose Test Strips
45001A159, 45001A195, 45001A228, 45001A233, 45001A236, 45001A243, 45001A247, 45001A249, 45001A250, 45001A255, 45001A279, 45001A285, 45001A295, 45001A298, 45001A306, 45001A317, 45001A318, 45001A327, 45001A346, 45001A398, 45001A449, 45001A469, 45001A578, 45001A693, 45001A697, 45001A747, 45001A790, 45001A795, 45001A839, 45001A917
Optium™ Blood Glucose Test Strips
45001A484, 45001A486, 45001A512, 45001A514, 45001A517, 45001A519, 45001A527, 45001A541, 45001A544, 45001A552, 45001A558, 45001A564, 45001A572, 45001A598, 45001A665, 45001A677, 45001A709, 45001A713, 45001A732, 45001A771, 45001A819, 45001A852, 45455, 45516, 45708, 45709, 45737, 45738, 45777, 45778, 45783
Precision Xceed Pro® Blood Glucose Test Strips
44535H, 44545H, 44565H, 445A5H, 44645H, 44665H, 446E5H, 44725H, 44755H, 44925H, 44945H, 44945H, 44975H, 44995H, 449A5H, 44A15H, 44A35H, 44A75H, 44A85H, 44C65H, 44C75H, 44CE5H, 44CH5H, 44CP5H, 44CR5H, 45025H, 45035H, 450A5H, 450C5H
Precision® Point of Care Blood Glucose Test Strips
45515, 45517, 45701, 45791, 45963, 45964, 46367



Precision Xtra® Blood Glucose Test Strips

45001A330, 45001A467, 45001A481, 45001A482, 45001A483, 45001A487, 45001A488, 45001A496, 45001A497, 45001A499, 45001A500, 45001A503, 45001A505, 45001A506, 45001A510, 45001A511, 45001A513, 45001A519, 45001A520, 45001A521, 45001A530, 45001A532, 45001A534, 45001A536, 45001A537, 45001A545, 45001A556, 45001A565, 45001A566, 45001A568, 45001A573, 45001A577, 45001A584, 45001A594, 45001A595, 45001A597, 45001A605, 45001A607, 45001A608, 45001A609, 45001A613, 45001A614, 45001A626, 45001A634, 45001A637, 45001A641, 45001A644, 45001A645, 45001A656, 45001A660, 45001A664, 45001A669, 45001A670, 45001A671, 45001A677, 45001A678, 45001A682, 45001A685, 45001A694, 45001A700, 45001A705, 45001A706, 45001A707, 45001A709, 45001A712, 45001A730, 45001A732, 45001A739, 45001A742, 45001A744, 45001A751, 45001A753, 45001A757, 45001A762, 45001A777, 45001A778, 45001A786, 45001A788, 45001A790, 45001A798, 45001A806, 45001A814, 45001A815, 45001A816, 45001A820, 45001A840, 45001A842, 45001A847, 45001A852, 45001A856, 45001A860, 45001A861, 45001A872, 45001A876, 45001A882, 45001A910, 45001A912, 45001A914, 45001A918, 45001A920, 45001A921, 45001A940, 45001A947, 45001A948, 45001A949, 45001A971, 45001A976, 45001A979, 45001A982, 45001A983, 45001C008, 45001C011, 45001C012

45384, 45388, 45396, 45407, 45418, 45455, 45456, 45463, 45464, 45512, 45514, 45516, 45521, 45611, 45612, 45614, 45619, 45627, 45632, 45639, 45645, 45646, 45653, 45670, 45679, 45680, 45682, 45707, 45708, 45724, 45729, 45731, 45732, 45733, 45735, 45737, 45738, 45755, 45777, 45782, 45783, 45784

Precision Xtra® Blood Glucose & Ketone Monitoring System

01P107D, 01P128D, 01P139D, 02P140D, 01P153D, 02P201D, 02P223D, 02P229D, 03P107D, 03P155D, 03P158D, 03P194D, 03P209D, 03P222D, 03P223D, 03P242D, 04P154D, 04P194D, 04P201D, 04P315D, 05P106D, 05P107D, 05P127D, 05P130D, 05P138D, 05P139D, 05P140D, 05P152D, 05P201D, 06P180D, 06P322D, 07P141D, 08P106D, 08P138D, 08P279D, 09P106D, 09P140D



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**Precision Xtra® Blood Glucose Test Strips
Optium™ Blood Glucose Test Strips
OptiumEZ Blood Glucose Test Strips
ReliOn® Ultima Blood Glucose Test Strips**

Dear Valued Customer,

Abbott Diabetes Care is recalling certain lots of Precision Xtra, Optium, OptiumEZ and ReliOn Ultima Blood Glucose Test Strips because the strips may generate erroneously low blood glucose results. Erroneously low results that are not recognized may pose significant risks to your health.

To determine if you have affected product and to arrange for product return:

- Call Abbott Diabetes Care customer service at 1-800-448-5234 to speak with a customer service representative. This customer service phone number is available 24 hours a day, 7 days a week with support available in English and Spanish, or
- Visit www.precisionoptiuminfo.com to look up test strip lot numbers. See the attached page for additional information on locating your test strip lot number, or
- Refer to the attached listing of lots that are affected by this recall.

If you have affected product, we recommend you take the following steps:

1. Call now for a replacement of the affected strips. When you call 1-800-448-5234, Abbott will send you unaffected Precision Xtra, Optium, OptiumEZ, and ReliOn Ultima Blood Glucose Test Strips at no charge.
2. While waiting for the replacement strips to arrive, either use an alternate method to measure blood glucose (such as a different test system) or purchase at least two week's worth of new strips to use while waiting for your replacement strips. If you purchase Precision Xtra, Optium, OptiumEZ, and ReliOn Ultima Blood Glucose Test Strips in a store or through your mail order provider, check to be sure these are from unaffected lots. You can ask pharmacy staff to assist you or contact Abbott Diabetes Care by calling 1-800-448-5234.



3. 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 results:

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 affected and the result should not be used.

You should 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).

- a. 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.
- b. 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.

We recognize the importance of blood glucose testing and are committed to responding quickly to customers' requests for replacement test strips.

You may continue to test your blood glucose as directed by your health care provider with unaffected Precision Xtra, Optium, OptiumEZ, or ReliOn Ultima Blood Glucose Test Strips.

We sincerely regret any inconvenience this situation may cause and we thank you for your continued support of Abbott Diabetes Care.

Sincerely,

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J. Scott House
Division Vice President, Quality Assurance and Compliance
Abbott Diabetes Care



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Precision Xtra® Blood Glucose Test Strips
Optium™ Blood Glucose Test Strips
OptiumEZ Blood Glucose Test Strips
ReliOn® Ultima Blood Glucose Test Strips

How to Locate the Lot Number of Precision Xtra, Optium, OptiumEZ, and ReliOn Ultima Blood Glucose Test Strips.

The lot number appears on the bottom of the test strip box and on each individually foil-wrapped test strip packet. Examples are included below.



To determine if you have affected product, call Abbott Diabetes Care customer service at 1-800-448-5234. You can also visit www.precisionoptiuminfo.com to look up your test strip lot number.

Both the customer service phone number and the website are available 24 hours a day, 7 days a week, with support available in English and Spanish for customers seeking information about Precision Xtra, Optium, OptiumEZ, or ReliOn Ultima Blood Glucose Test Strips.



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Precision Xtra® Blood Glucose & Ketone Monitoring System

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