

December 21, 2007

Test Strip Recall for CONTOUR TS

Bayer Diabetes Care has initiated a voluntary market recall of test strips (sensors) used exclusively with the Contour TS Blood Glucose Meter. In the course of its routine quality control monitoring processes the Company identified a manufacturing issue with test strips from specific lots that could result in blood glucose readings with a positive bias that is outside of our product specifications. Test results may demonstrate results 5 -17% higher.

This issue is unrelated in any way to the Contour TS meter itself and pertains only to certain test strips used with the meter. Additionally, this issue has no impact on the performance of strips used with other Bayer meters including Ascensia Contour and Ascensia Breeze2 systems.

The affected Contour TS strips were produced during the initial manufacturing process on new manufacturing equipment designed for the new Contour TS strips. The root cause of the problem has been identified, and corrective actions implemented including additional quality control measures to prevent recurrence. The quality of our products and the results our customers receive are very important to Bayer and, as such, we are notifying regulatory authorities, healthcare professionals and customers in the countries where Contour TS is marketed - France, Austria, Turkey, Korea, Mexico, India and predominantly through mail order channels in the United States.

Healthcare providers, retailers, patients and other customers who use Contour TS are advised to check the lot number on the bottles of Contour TS strips and to contact Bayer Diabetes Care for information regarding return and replacement of strips. The lot numbers can be found on the bottom of the box and on the side of the bottle containing the strips. The affected lots begin with WK followed by the characters 7D, 7E, 7F or 7G and then followed by a series of other numbers and letters (for example WK7ED3E52C).

Only bottles of test strips with the characters 7D, 7E, 7F, or 7G in the third and fourth position in the sequence are affected. Bottles with a lot number including 7J through 7M after WK are not affected and need not be returned. Additional information can be found at <http://www.bayerdiabetes.com>. Please call your Bayer customer service phone number (in the U.S., call 1-800-348-8100) to return any affected bottle of strips and to get a replacement.

TEST STRIP RECALL FOR CONTOUR TS

Affected Product Code Numbers by Country

Country	Product	Product Code	Article Number
U.S.	Meter kit with 10 strips	1802	06555364
U.S.	Bottle of 50 strips	1820	06548864
U.S.	Bottle of 10 strips	9578	06548880
France/Turkey/Austria	Meter kit with 10 strips	1803	06548724
France	Meter kit with 10 strips	1803V	06548732
France	Bottle of 50 strips	1826	06548929
France	Bottle of 50 strips	1826V	06548937
Austria/Turkey	Bottle of 50 strips	1827	06548945
Austria/Turkey	Bottle of 100 strips	1828	06548953
Austria/Turkey	Bottle of 25 strips	1829	06548961
Korea	Meter kit with 10 strips	1810	06548791
Korea	Bottle of 50 strips	1835	06549011
Korea	Bottle of 100 strips	1836	06549038
India	Meter kit with 10 strips	1811	06548805
India	Bottle of 25 strips	1832	06549194
India	Bottle of 50 strips	1833	06549216
India	Bottle of 10 strips	1837	0654946
Mexico	Meter kit with 10 strips	1813	06548821
Mexico	Bottle of 50 strips	1823	06548899
Mexico	Bottle of 25 strips	1825	06548910

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