



Contour[®]
BLOOD GLUCOSE TEST STRIPS

For use with **CONTOUR**[®],
CONTOUR[®] USB AND **DIDGET**[™].



Intended Use: **CONTOUR**[®] test strips are intended for self-testing by people with diabetes and by healthcare professionals to monitor glucose concentrations in whole blood.

Summary: The **CONTOUR** test strip is designed for use with the **CONTOUR**[®], **CONTOUR**[®] USB and **DIDGET**[™] blood glucose meters. When used with the **DIDGET** meter, **CONTOUR** test strips are for fingertip use only. The test provides a quantitative measurement of glucose in blood from 10 to 600 mg/dL for **CONTOUR** meters and 20 to 600 mg/dL for **CONTOUR** USB and **DIDGET** meters.

Storage and Handling:

- ▲ **Store test strips in their original vial only. Always close the lid immediately and tightly after removing a test strip.**
- ▲ **Wash, rinse and dry hands thoroughly before handling the test strips.**
- ▲ Do not use the test strips after the expiration date. The expiration date is printed on the vial label and on the outside carton.
- ▲ Store the strips at temperatures between 48°F and 86°F.
- ▲ If the meter and test strips are moved from one temperature to another, allow 20 minutes for them to adjust to the new temperature before performing a blood glucose test. Your user guide will identify the appropriate operating temperature range for the **CONTOUR** or **DIDGET** model you are using.
- ▲ The test strips are for single use only. **Do not reuse test strips.**

Test Procedure: See your meter's User Guide and accompanying inserts for detailed instructions for all test procedures, including information on Alternative Site Testing.

Test Results:

- ▶ Your meter has been preset to display results in mg/dL (milligrams of glucose per deciliter). Results in mg/dL will **never** have a decimal point (e.g., 96 ^{mg}/_{dL}); results in mmol/L will **always** have a decimal point (e.g., 5.3 ^{mmol}/_L). If your test result is displayed in mmol/L, contact Bayer Diabetes Care Customer Service (1-800-348-8100).
- ▶ **Glucose levels below 50 mg/dL or above 250 mg/dL may indicate a potentially serious medical condition. Consult a healthcare professional immediately if your test result is below 50 mg/dL or above 250 mg/dL. Some healthcare providers may recommend 60 mg/dL as a lower limit.**



Always consult a healthcare professional before changing medications based on your CONTOUR or DIDGET blood glucose results.

Questionable or Inconsistent Results: See the Help section in the meter user guide for problem solving. High, low or questionable test results that are not correct may cause adverse medical consequences. If attempts to correct a problem fail, contact your healthcare professional about your condition or call Bayer Diabetes Care Customer Service (1-800-348-8100).

Quality Control: You should perform a control test when using your meter for the first time, or to check if you are testing correctly, or when you open a new vial of test strips, or if you leave the test strip vial open for an extended period of time, or if you think your meter may not be working properly, or if your test results do not match how you feel. Only use **CONTOUR**[®] control solutions. These control solutions are designed specifically for use with the **CONTOUR** and **DIDGET** systems. The control results should fall within the control range(s) printed on the test strip vial and the test strip carton. If they don't, do not use your meter for blood glucose testing until you resolve the issue.



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CAUTION

- For *in vitro* diagnostic use only. External use, do not swallow.
- Potential Biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.¹

Chemical Composition: FAD glucose dehydrogenase (*Aspergillus sp.*, 2.0 U/test strip), 6%; potassium ferricyanide 56%; Non-reactive ingredients 38%.

Principles of the Procedure: The **CONTOUR** blood glucose test is based on measurement of electrical current caused by the reaction of glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and potassium ferricyanide. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.

Comparison Options: The **CONTOUR** and **DIDGET** systems are designed for use with capillary whole blood. Comparison to a laboratory method must be done simultaneously with aliquots of the same sample. Note: Glucose concentrations drop rapidly due to glycolysis (approximately 5–7% per hour).²

Limitations:

1. **Alternative Site Testing** is not intended for use with the **DIDGET** meter.
2. **Preservatives:** Blood may be collected by healthcare professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.
3. **Altitude:** Up to 10,000 feet does not significantly affect results.
4. **Lipemic Specimen:** Cholesterol concentrations >500 mg/dL or triglyceride concentrations >3000 mg/dL may produce elevated readings.
5. **Peritoneal dialysis solutions:** Icodextrin does not interfere with **CONTOUR** test strips.
6. **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
7. **Contraindications:** Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension, hyperosmolar hyperglycemia and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.³
8. **Interference:** Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect results. Interference might occur when the values of the limiting concentrations of these compounds are greater than those listed below.

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| | <p>Bilirubin >20 mg/dL Uric Acid >13 mg/dL Ascorbic Acid >5 mg/dL Acetaminophen >15 mg/dL Maltose no interference Galactose no interference</p> | <p>Hematocrit: At normal glucose levels, CONTOUR test strip results are not significantly affected by hematocrit levels in the range of 20% to 60%. At glucose ranges above 200 mg/dL, hematocrit levels above 55% will cause lowered results. <i>Neonatal use:</i> At glucose levels between 10 mg/dL and 120 mg/dL, CONTOUR test strip results are not significantly affected by hematocrit levels in the range of 20% to 70%.</p> |
| | <p>Bilirubin >20 mg/dL Uric Acid >32 mg/dL Ascorbic Acid >36 mg/dL Acetaminophen >22 mg/dL Maltose no interference Galactose no interference</p> | <p>Hematocrit: CONTOUR test strip results are not significantly affected by hematocrit levels in the range of 0% to 70%.</p> |

This row includes data for the **CONTOUR**[®] USB and **DIDGET** meter.

The **CONTOUR** USB and **DIDGET** systems are not indicated for Neonatal Use. The **CONTOUR** System may be used by Healthcare professionals to monitor hypoglycemia in neonates diagnosed with laboratory glucose levels. The **CONTOUR** System should not be used with high risk or pre-term infants or for screening for Neonatal hypoglycemia. Diagnosis of Neonatal hypoglycemia should be performed using a laboratory blood glucose method. Monitoring with this product should be done only with neonates that are more than one day old. For neonates exhibiting hypoglycemic symptoms, provide appropriate medical care to treat symptoms and monitor patient. If symptoms are inconsistent with meter results, obtain a laboratory blood glucose test.

References:

1. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Third Edition.* Clinical and Laboratory Standards Institute (CLSI), document M29-A3, (ISBN 1-56238-567-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2005.
2. *Tietz Fundamentals of Clinical Chemistry, 5th Edition,* Edited by Burtis CA and Ashwood ER, W. B. Saunders Co., Philadelphia, PA, 2001, p. 444.
3. Atkin S., Jaker M.A., Chorost M.J., Reddy S.: Fingerstick Glucose Determination in Shock. *Annals of Internal Medicine*, 1991, 114: 1020–24.



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