

Intended Use: CONTOUR[®]NEXT test strips are an over the counter (OTC) product and are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples. The CONTOUR[®]NEXT blood glucose monitoring systems are not intended for the diagnosis of or screening for diabetes mellitus.

Storage and Handling:

- Store the strips at temperatures between 41°F–86°F and 10%–80% Relative Humidity (RH).
- **Store test strips in their original bottle only. Always close the lid immediately and tightly after removing a test strip.**
- **Wash and dry your hands well before and after handling the test strips.**
- The test strips can continue to be used after first use through the expiration date printed on the bottle and carton.
- Do not use the test strips after the expiration date. The expiration date is printed on the bottle label and on the test strip carton.
- If the meter and/or 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. The operating temperature range for all CONTOUR NEXT meters is 41°F to 113°F and the humidity range is 10% to 93% RH.
- The test strips are for single use only. **Do not reuse test strips.**
- Upon opening the test strip carton ensure the strip bottle cap is securely closed. If the cap is not closed, do not use the test strips for testing. Examine the product for missing, damaged, or broken parts. Contact Customer Service at 1-800-348-8100 (available Monday through Sunday, from 8:00 am through 12:00 Midnight, Eastern Time) for replacement parts and assistance.



Test Procedure: See your CONTOUR NEXT user guide and accompanying inserts for detailed testing instructions.

Test Results:

Expected values: Blood sugar values will vary depending on food intake, medication dosages, health, stress, or activity. Non-diabetic plasma glucose concentrations should be <100 mg/dL in the fasting state and <140 mg/dL in the post prandial state.¹ **You should consult with your health care professional for glucose values specific to your needs.**

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 $\frac{mg}{dL}$); results in mmol/L will **always** have a decimal point (e.g., 5.3 $\frac{mmol}{L}$). If your test result is displayed in mmol/L, contact Customer Service at 1-800-348-8100 (available Monday through Sunday, from 8:00 am through 12:00 Midnight, Eastern Time).

- If your blood glucose reading is under 50 mg/dL on the meter display, follow medical advice immediately.
- If your blood glucose reading is above 250 mg/dL on the meter display, call your health care professional as soon as possible.
- Always consult your health care professional before changing your medication based on CONTOUR NEXT test results.

Questionable or Inconsistent Results: See the meter user guide for problem solving. If attempts to correct a problem fail, contact Customer Service at 1-800-348-8100 (available Monday through Sunday, from 8:00 am through 12:00 Midnight, Eastern Time).

Quality Control: You should perform a control test when using your meter for the first time, or when you open a new bottle or package of test strips, or if you think your meter may not be working properly, or if you have repeated unexpected blood glucose results. **Only use CONTOUR[®]NEXT control solutions. These control solutions are designed specifically for use with all CONTOUR NEXT systems.** The control results should fall within the control range(s) printed on the test strip bottle label and the test strip carton. If they don't, do not use your meter for blood glucose testing until you resolve the issue.

CAUTION

- For [IVD] in vitro diagnostic use only. External use, do not swallow.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the system are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- For more information and complete instructions regarding cleaning and disinfecting your meter and lancing devices see your user guide.
- Dispose of the test strips as medical waste.
- Always wash your hands well with soap and water before and after testing, handling the meter, lancing device, or test strip.



Chemical Composition: FAD glucose dehydrogenase (*Aspergillus sp.*, 4.0 U/test strip) 21%; mediator 54%; nonreactive ingredients 25%.

Principles of the Procedure: The CONTOUR NEXT blood glucose test is based on measurement of electrical current caused by the reaction of glucose in the blood 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 the mediator. 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 by the user.

Comparison Options: The CONTOUR NEXT system is designed for use with capillary whole blood. Capillary samples should be applied directly to the CONTOUR NEXT test strip. 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. **Altitude:** This system has not been tested at altitudes higher than 20,674 feet (6,301 meters).
2. **Alternative Site Testing:** See your meter user guide for Alternative Site Testing instructions.
3. **Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.**
4. **Contraindications:** The system should not be used to test critically ill patients and should not be used by persons with reduced peripheral blood flow. Shock, severe hypotension, and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.³

The CONTOUR NEXT meters are not indicated for neonatal use.

References:

1. American Diabetes Association. Standards of medical care in diabetes—2015. *Diabetes Care*. 2015;38(supplement 1):S10.
2. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*, 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.
3. Atkin SH, et al. Fingertick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12):1020-1024.