



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

CONTOUR NEXT test strips are intended for use with the following approved systems:

- CONTOUR<sup>®</sup>NEXT GEN, CONTOUR<sup>®</sup>NEXT, CONTOUR<sup>®</sup>NEXT EZ, CONTOUR<sup>®</sup>NEXT USB, CONTOUR<sup>®</sup>NEXT ONE, and CONTOUR<sup>®</sup>NEXT LINK as an aid in monitoring the effectiveness of a diabetes control program.
- CONTOUR<sup>®</sup>NEXT LINK 2.4 for transmission of information with Medtronic MiniMed<sup>™</sup>630G and 670G pump systems.

**Warning**

- **This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.**
- **Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.**



**Storage and Handling**

- Store the test 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 be used until the expiration date printed on the bottle and 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. Your user guide will identify the appropriate operating temperature range for the CONTOUR<sup>®</sup>NEXT meter you are using.
- The test strips are for single-use only. **Do not reuse test strips.**
- After opening the test strip carton, ensure the test 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 meter user guide and additional instructions included with this carton for details on test strip handling and testing.

**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 (after a meal).<sup>1</sup> **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 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 Ascensia Diabetes Care Customer Service.



**Warning**

- **Always consult your health care professional before changing your medication based on test results or if your test results are not consistent with the way you feel.**
- **If your blood sugar reading is under the critical level you have established with your health care professional, follow their advice immediately.**
- **If your blood sugar reading is over the recommended limit set by your health care professional:**
  1. **Wash and dry your hands well.**
  2. **Retest with a new strip.****If you get a similar result, follow your health care professional's advice immediately.**

**CAUTION**

- If your meter does not display a value and displays the **LO** screen, **contact your health care professional immediately.**
- If your meter does not display a value and displays the **HI** screen, wash your hands or the test site, repeat the test with a new strip. If the meter again displays the **HI** screen, **follow medical advice immediately.**

Your Ascensia Diabetes Care meter result may vary slightly from your actual blood glucose value due to slight differences in testing technique and the natural variation in test technology. The tables below show the results of studies where typical users used Ascensia Diabetes Care meters to measure their blood glucose levels. For example, in the CONTOUR NEXT EZ study, the CONTOUR<sup>®</sup>NEXT EZ meter displayed results within 10 mg/dL or 10% of the actual blood glucose level in 181 out of 184 measurements.

<b>Fingerstick Accuracy</b>				
Results < 75 mg/dL calculated in mg/dL; results ≥ 75 mg/dL calculated in %				
	Within ±5 mg/dL or 5%	Within ±10 mg/dL or 10%	Within ±15 mg/dL or 15%	Within ±15 mg/dL or 20%
CONTOUR NEXT EZ	75.5% (139/184)	98.4% (181/184)	100% (184/184)	100% (184/184)
CONTOUR NEXT USB	78.4% (160/204)	96.1% (196/204)	98.5% (201/204)	99.5% (203/204)
CONTOUR NEXT LINK	81.8% (90/110)	99.1% (109/110)	99.1% (109/110)	100% (110/110)
CONTOUR NEXT ONE	81.2% (302/372)	96.2% (358/372)	99.5% (370/372)	100% (372/372)
Results < 100 mg/dL calculated in mg/dL; results ≥ 100 mg/dL calculated in %				
	Within ±5 mg/dL or 5%	Within ±10 mg/dL or 10%	Within ±15 mg/dL or 15%	Within ±15 mg/dL or 20%
CONTOUR NEXT	78.3% (173/221)	96.4% (213/221)	99.1% (219/221)	99.5% (220/221)
CONTOUR NEXT LINK 2.4	69.3% (151/218)	94.5% (206/218)	98.6% (215/218)	100% (218/218)
Percent (and number) of meter samples that match true blood glucose level within specified range				
	Within 5%	Within 10%	Within 15%	Within 20%
CONTOUR NEXT GEN	64.96% (241/371)	93.53% (347/371)	98.65% (366/371)	99.19% (368/371)

<b>Alternative Site Testing (Palm) Accuracy</b>				
Results < 75 mg/dL calculated in mg/dL; results ≥ 75 mg/dL calculated in %				
	Within ±5 mg/dL or 5%	Within ±10 mg/dL or 10%	Within ±15 mg/dL or 15%	Within ±15 mg/dL or 20%
CONTOUR NEXT USB	60.8% (124/204)	92.2% (188/204)	99.0% (202/204)	99.5% (203/204)
CONTOUR NEXT LINK	61.5% (67/109)	89.0% (97/109)	96.3% (105/109)	97.3% (106/109)
CONTOUR NEXT ONE	70.6% (255/361)	89.5% (323/361)	97.0% (350/361)	98.6% (356/361)
Results < 100 mg/dL calculated in mg/dL; results ≥ 100 mg/dL calculated in %				
	Within ±5 mg/dL or 5%	Within ±10 mg/dL or 10%	Within ±15 mg/dL or 15%	Within ±15 mg/dL or 20%
CONTOUR NEXT	65.2% (144/221)	90.1% (199/221)	96.8% (214/221)	99.1% (219/221)
CONTOUR NEXT LINK 2.4	54.0% (114/211)	88.6% (187/211)	97.2% (205/211)	99.1% (209/211)

**Questionable or Inconsistent Results:** See the meter user guide for problem solving. If attempts to correct a problem fail, contact Ascensia Diabetes Care 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, when you open a new container of test strips, if you think your meter may not be working properly, or if you have repeated, unexpected blood glucose results. **Use only 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 container. If they don't, do not use your meter for blood glucose testing until you resolve the issue.

#### Warning: Potential Biohazard

- For [IVD] in vitro diagnostic use only. For 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 meter 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%; non-reactive 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 test 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 on the meter. No calculation is required by the user.

**Comparison Options:** The CONTOUR NEXT systems are 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).<sup>2</sup>

#### 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.

#### IMPORTANT:

- Alternative Site Testing (AST) is NOT intended for use with the CONTOUR NEXT GEN or CONTOUR NEXT EZ meters.
- Although Alternative Site Testing (AST) is cleared for CONTOUR NEXT, CONTOUR NEXT USB, CONTOUR NEXT ONE, CONTOUR NEXT LINK, and CONTOUR NEXT LINK 2.4, do not use AST under the following conditions. Use fingertip testing in any of these cases:
  - When blood sugar is changing rapidly (after a meal, insulin dose, or exercise).
  - For calibration of a Continuous Glucose Monitoring (CGM) system.
  - AST should not be used with the Bolus Wizard™ (only available with CONTOUR NEXT LINK or CONTOUR NEXT LINK 2.4), or other insulin dose calculations, or to verify a low blood glucose level. Consult your health care professional to determine if AST is right for you.

3. **Hematocrit:**




- CONTOUR NEXT Test Strips are not significantly affected by hematocrit levels in the range of 20% to 55% when used with CONTOUR NEXT GEN meter.
- CONTOUR NEXT Test Strips are not significantly affected by hematocrit levels in the range of 15% to 65% when used with CONTOUR NEXT EZ, CONTOUR NEXT, CONTOUR NEXT USB, CONTOUR NEXT ONE, CONTOUR NEXT LINK, and CONTOUR NEXT LINK 2.4 meters.

4. **Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.**

5. **Contraindications:** Serious illness: The system should not be used to test critically ill patients and should not be used by persons with reduced peripheral blood flow. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoxia state, or a hyperglycemic-hyperosmolar state, with or without ketosis.<sup>3,4</sup>

6. The CONTOUR NEXT meters are not indicated for neonatal use.

#### Symbols Used

Symbol	Title	Description	ISO 15223-1:2016 Reference Number <sup>5</sup>
	Consult instructions for use	This symbol indicates the need for the user to consult the instructions for use.	5.4.3
	Caution	This symbol indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4
	Do not reuse	This symbol indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2

#### References

1. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes—2020. *Diabetes Care*. 2020;43(supplement 1):S14–S31.
2. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.
3. Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
4. Atkin SH, et al. Fingertick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12):1020-1024.
5. International Organization for Standardization / Technical Committee 210. *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements*. ISO 15223-1:2016.

#### Contact Information:

Ascensia Diabetes Care Customer Service is available at 1-800-348-8100 from Monday through Sunday 8:00 AM to 12:00 AM (ET).

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