Contour plus
Blood Glucose Test Strips

For use with the CONTOUR®PLUS BLUE meter

NO CODING®

Intended Use: The CONTOUR®PLUS BLUE blood glucose monitoring system consists of the CONTOUR PLUS BLUE meter, the CONTOUR PLUS blood glucose test strips, and the CONTOUR®DIABETES app.

The CONTOUR PLUS BLUE blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The CONTOUR PLUS BLUE blood glucose monitoring system is intended to be used by a single person and should not be shared. The CONTOUR PLUS BLUE blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program.

The CONTOUR PLUS BLUE blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. The CONTOUR PLUS blood glucose test strips are for use with the CONTOUR PLUS BLUE meter to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips.

The system is intended for in vitro diagnostic use only.

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.**
- **The CONTOUR PLUS blood glucose test strips and CONTOUR PLUS BLUE meter are not intended for use with Alternative Site Testing (AST).**

Storage and Handling

- The test strips when either stored closed or after opening can be used until the expiration date printed on the test strip bottle or carton. **Always store the test strips at temperatures between 41°F–86°F and 10%–80% Relative Humidity (RH).**
- ***Store the 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.**
- 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 PLUS BLUE 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).[1] **You should consult with your health care professional for glucose values specific to your needs.**

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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 table below shows the result of a study where typical users used the CONTOUR PLUS BLUE meter to measure their blood glucose levels. For example, in this study, the CONTOUR PLUS BLUE meter displayed results within 10% of the actual blood glucose level in 362 out of 381 measurements.

Fingerstick Accuracy				
Percent (and number) of meter samples that match true blood glucose level within specified range				
	Within 5%	Within 10%	Within 15%	Within 20%
CONTOUR PLUS BLUE	70.87% (270/381)	95.01% (362/381)	97.90% (373/381)	100% (381/381)

A measurement repeatability study was conducted with the CONTOUR PLUS BLUE blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 39 mg/dL to 348 mg/dL. With each blood specimen, each of 3 lots of CONTOUR PLUS blood glucose test strips was tested 10 times on each of 10 meters for a total of 300 readings. The following precision results were obtained.

Precision: Repeatability			
System repeatability results for CONTOUR PLUS BLUE meter using CONTOUR PLUS blood glucose test strips			
Mean, mg/dL	Pooled Standard Deviation, mg/dL	95% CI of SD, mg/dL	Coefficient of Variation, %
37.9	1.3	1.11–1.50	3.4
76.7	1.2	1.05–1.40	1.6
132.6	1.9	1.64–2.19	1.4
200.9	3.6	3.11–4.17	1.8
334.2	6.7	5.84–7.83	2.0

Intermediate measurement precision (which includes variability across multiple days) was evaluated using control solutions at 5 glucose levels. With each control solution, each of 3 lots of CONTOUR PLUS blood glucose test strips was tested once on each of 10 meters on 10 separate days for a total of 300 readings. The following precision results were obtained.

Precision: Intermediate				
System intermediate precision results for CONTOUR PLUS BLUE meter using CONTOUR PLUS blood glucose test strips				
Control Level	Mean, mg/dL	Pooled Standard Deviation, mg/dL	95% CI of SD, mg/dL	Coefficient of Variation, %
1	42.7	0.6	0.53–0.71	1.4
2	84.1	1.0	0.91–1.22	1.2
3	127.7	1.6	1.37–1.84	1.2
4	221.9	2.9	2.55–3.42	1.3
5	379.0	6.4	5.58–7.49	1.7

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 if you think your test strip may be damaged, or if you think your meter may not be working properly, or if you have repeated, unexpected blood glucose results. **Use only CONTOUR®PLUS control solutions. These control solutions are designed specifically for use with the CONTOUR PLUS BLUE blood glucose monitoring system.** The control results should fall within the control range(s) printed on each test strip bottle. 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 PLUS BLUE 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 PLUS BLUE blood glucose monitoring system is designed for use with capillary whole blood. Capillary samples should be applied directly to the CONTOUR PLUS blood glucose 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

- **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, those dehydrated or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoxia state, or a hyperglycemic-hyperosmolar state, with or without ketosis.[3,4]
- **System Operating Conditions:** 41°F–113°F, 10%–93% RH.
- **Meter Storage Temperature Range:** -4°F–149°F.
- **Control Testing Temperature Range:** 59°F–95°F.
- **Test Strip Storage Conditions:** 41°F–86°F, 10%–80% Relative Humidity (RH).
- **Second-Chance® sampling conditions:** Temperature Range 59°F–95°F.
- **Sample Volume:** 0.6 µL.
- **Measuring Range:** 20 mg/dL–600 mg/dL of glucose in blood.
- **Altitude:** This system has not been tested at altitudes higher than 20,674 feet (6301 meters).
- **Hematocrit:** CONTOUR PLUS blood glucose test strip results are not significantly affected by hematocrit levels in the range of 20% to 55%.
- **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
- **Neonatal Use:** The CONTOUR PLUS BLUE meter is **not indicated** for neonatal use.
- **Alternative Site Testing:** The CONTOUR PLUS BLUE meter is not intended for use with Alternative Site Testing (AST).

ISO Symbols

Symbol	Title	Description	ISO 15223-1:2021 Reference Number[5]
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	5.4.4
	Do not reuse	Indicates a medical device that is intended for one single use only.	5.4.2
UDI	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.	5.7.10

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. Fingerstick 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 information to be supplied by the manufacturer—Part 1: General requirements.* ISO 15223-1:2021.

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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