

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

**Summary:** The CONTOUR NEXT test strip is designed for use with the CONTOUR®XT and all CONTOUR®NEXT blood glucose meters. The test provides a quantitative measurement of glucose for CONTOUR XT and all CONTOUR NEXT meters.

**Storage and Handling:**

- Store the strips at temperatures between 0°C and 30°C.
- **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 handling the test strips.**
- Do not use the test strips after the expiry date. The expiry 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. Your user guide will identify the appropriate operating temperature range for the CONTOUR XT or CONTOUR NEXT meter you are using.
- 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 1-800-289-312 for replacement parts and assistance.

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

**Test Results:**

Your meter has been preset to display results in mmol/L (millimoles of glucose per liter) or mg/dL (milligrams of glucose per deciliter). Results in mmol/L will **always** have a decimal point (e.g., 5.3 <sup>mmol</sup>/<sub>L</sub>); results in mg/dL will **never** have a decimal point (e.g., 96 <sup>mg</sup>/<sub>dL</sub>). If your test results are not displayed correctly in mmol/L or mg/dL, contact Customer Service at 1-800-289-312.

- **If your blood glucose reading is under 2.8 mmol/L on the meter display, follow medical advice immediately.**
- **If your blood glucose reading is above 13.9 mmol/L 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 XT or CONTOUR NEXT test results.**

**Questionable or Inconsistent Results:** See the CONTOUR XT or CONTOUR NEXT user guide for problem solving. If attempts to correct a problem fail, contact Customer Service at 1-800-289-312.

**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 the CONTOUR XT and 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.



**Information For Safety**

- For **IVD** *in vitro* diagnostic use only. External use, do not swallow.
- Potential Biohazard: Health care professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting infectious diseases. The user should follow the recommendations for the prevention of blood-borne transmissible diseases in health care settings as recommended for potentially infectious human specimens.<sup>1</sup>
- Dispose of the test strips as medical waste or as advised by your health care professional.

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

**Comparison Options:** The CONTOUR XT and all CONTOUR NEXT systems are designed for use with venous and 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).<sup>2</sup>

**Limitations:**

1. **Preservatives:** Blood may be collected by health care professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.
2. **Altitude:** Up to 6301 meters does not significantly affect results.
3. **Alternative Site Testing:** Please see your meter user guide for Alternative Site Testing instructions.
4. **Peritoneal dialysis solutions:** Icodextrin does not interfere with CONTOUR NEXT test strips.
5. **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.<sup>3</sup>
6. **Interference:** The CONTOUR NEXT system was tested against the following potentially interfering substances occurring naturally in the blood: bilirubin, cholesterol, creatinine, galactose, glutathione, hemoglobin, triglycerides, and uric acid. No interfering effect was observed for any substance at the highest concentration<sup>4</sup> of either the common pathological level or three times the upper reference value.<sup>5</sup>
7. **Interference:** The CONTOUR NEXT system was tested against the following potentially interfering substances occurring from therapeutic treatments: ascorbic acid, paracetamol (acetaminophen), dopamine, sodium gentisate, ibuprofen, icodextrin, L-dopa, maltose, methyl dopa, pralidoxime iodide, sodium salicylate, tolazamide, tolbutamide. No interfering effect was observed for any substance at the highest concentration<sup>4</sup> of either the toxic concentration or three times the maximum therapeutic concentration.<sup>5</sup>
8. **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.
9. **Hematocrit:** CONTOUR NEXT test strip results are not significantly affected by hematocrit levels in the range of 0% to 70%.<sup>5</sup>

See your meter user guide for intended use with neonates.

**References:**

1. Sewell DL. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline, 3rd Edition.* Clinical and Laboratory Standards Institute. CLSI document M29-A3; ISBN 156238-567-4. March 2005.
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. Fingerstick glucose determination in shock. *Annals of Internal Medicine.* 1991;114(12):1020-1024.
4. McEnroe RJ, et al. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition.* EP7-A2, vol 25, no 27. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.
5. Bernstein R, Parkes JL, Goldy A, et al. A new test strip technology platform for self-monitoring of blood glucose. *Journal of Diabetes Science and Technology.* 2013;7(5):1386-1399.

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Number of test strips included.

90003654

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<b>FILE NAME:</b> 90003654_CntrNXT_RgtIns_EN.indd	<b>SKU:</b> MULTI	<b>NEW COMP. BAN:</b> 90003654	<b>VO 05/08/19 Initial Build</b> <b>V1 05/30/19 Blue Annotations</b>
<b>DESCRIPTION:</b> Contour Next Reagent Insert	<b>REV DATE:</b> 05/19	<b>PREVIOUS BAN:</b> 85498142	
<b>CLIENT:</b> Ascensia Diabetes Care	<b>DATE:</b> 05/30/19	<b>MARKET:</b> AU	<b>PARENT BAN:</b> N/A
<b>TRIM SIZE:</b> 6.614" (H) x 11.654" (W)	<b>LANGUAGES:</b> EN	<b>SPEC:</b> 10000758428 REV -	
<b>SOFTWARE:</b> Indesign CC 2014	<b>MASTER REF:</b> CntrNEXT_M_INSR_RGT_0057_R0008	<b>BARCODE(S):</b> 90003654 (Code 128)	

<b>LASER PROOF</b>	<b>EPSON PROOF</b>	<b>SIGNATURE</b>	<b>VERSION: V1</b>
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