

CONTOUR[®]NEXT LINK 2.4 Blood Glucose Monitoring System - Media Factsheet

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The CONTOUR[®]NEXT LINK 2.4 Blood Glucose Monitoring System and the MiniMed[®] 670G system



The MiniMed[®] 670G system is the first Hybrid Closed Loop (HCL) insulin delivery system to be approved anywhere in the world, and includes an insulin pump, a continuous glucose monitoring (CGM) system and a blood glucose meter, the CONTOUR[®]NEXT LINK 2.4 Blood Glucose Monitoring System (BGMS) from Ascensia Diabetes Care. The CONTOUR[®]NEXT LINK 2.4 is the only BGMS FDA-approved for use with the MiniMed[®]670G system, and provides highly accurate results for CGM calibration and insulin dosing. Both the highly accurate CONTOUR[®]NEXT LINK 2.4 BGMS and the CONTOUR[®]NEXT Test Strips have been approved through the Premarket Approval (PMA) process; the most stringent medical device marketing application pathway required by the FDA.

CONTOUR[®]NEXT LINK 2.4 BGMS Features:

- Communicates wirelessly with Medtronic's MiniMed[®] 670G system to form the world's first commercialized hybrid closed loop system, that delivers a variable rate of insulin 24 hours a day based on the personalized needs of the individual with diabetes.
- The CONTOUR[®]NEXT LINK 2.4 BGMS was designed to wirelessly transmit highly accurate results for CGM calibration and insulin dosing as part of the MiniMed[®] 670G system.
- The CONTOUR[®]NEXT LINK 2.4 BGMS automatically sends blood glucose results into the Bolus Wizard[®] calculator, allowing patients to discreetly deliver a bolus of insulin remotely from the meter, providing added convenience for patients, and eliminating manual blood glucose entry mistakes to the pump.
- Easy-to-use, manual or preset remote bolusing from the meter allowing patients to discreetly give themselves a bolus of insulin and providing added convenience.
- Uses the highly accurate CONTOUR[®]NEXT Test Strips which offer No Coding[™] technology and Second-Chance[®] sampling:
 - Second-Chance[®] sampling allows people with diabetes to apply more blood to the same test strip if the first sample is insufficient, helping to avoid wasting test strips and providing the potential to save money
 - No Coding[™] technology means one less step in the testing process and eliminates errors due to user miscoding
- Connects directly to patient's computer via USB connector for download of blood glucose and insulin data from the meter to Medtronic's CareLink[®] Personal and CareLink[®] Professional Therapy Management Software for instant access to test results and trends.



According to the FDA, the accuracy of a BGMS is an essential part of any Artificial Pancreas Device Systems (APDS) as it has a major impact on the quality of the calibration and the performance of the APDS. In a laboratory study, the CONTOUR[®]NEXT LINK 2.4 Meter has been demonstrated as highly accurate with 99% of results within $\pm 10\%^*$ of lab reference values (YSI reference) helping patients to optimize their insulin pump therapy.¹

1. Bailey J WJGC. Accuracy and User Performance Evaluation of the CONTOUR[®]NEXT LINK 2.4 blood glucose monitoring system. *Clinica Chimica Acta*. 2015(448):139 -145.
* 10% applies to blood glucose values ≥ 100 mg/dl per Section 6.3 of the ISO 15197:2013 accuracy standard. The CONTOUR[®]NEXT LINK 2.4 BGM system has been demonstrated to deliver at least 95% of results within $\pm 10\%$ of the laboratory reference values at blood glucose levels ≥ 100 mg/dL and within ± 10 mg/dL at blood glucose values < 100 mg/dL. See the product user guide for additional information on system and user performance.