Prior Authorization Therapeutic Justification Form
CONTOUR®NEXT LINK Meter for use with MiniMed® Paradigm® REAL-Time Revel™ insulin pumps

PLEASE COMPLETE ALL INFORMATION IN FIELDS ON PAGES 1 AND 3.
HEALTHCARE PROVIDER: PLEASE SEND PAGES 1-5 TO THE PLAN. SENDING PAGES 6-15 IS OPTIONAL BUT HIGHLY RECOMMENDED.

Date (mm/dd/yyyy):	
Patient Information	
Patient Full Name:	
DOB (mm/dd/yyyy):	
Age:	
Diabetes Type:	◯ **Type 1** ◯ **Type 2** ◯ **Gestational**
Years With Diabetes:	
Testing per Day:	
BGM System Used:	**CONTOUR®NEXT LINK Blood Glucose Monitoring (BGM) System**
Insurance Name:	
Insurance ID Number:	

Re: **CONTOUR®NEXT Test Strips for the CONTOUR®NEXT LINK BGM System**

ATTN: Medical Director

I am writing to seek your approval in prescribing CONTOUR®NEXT Test Strips. Below please find the prior authorization therapeutic justification language for the CONTOUR®NEXT LINK meter to be used with MiniMed® Paradigm® REAL-Time Revel™ insulin pumps.

The CONTOUR®NEXT LINK meter is the only linking meter provided with Medtronic Insulin Pumps*, and CONTOUR®NEXT test strips are the only test strips that work with the CONTOUR®NEXT LINK meter.

CONTOUR®NEXT LINK wirelessly transmits blood glucose (BG) results to the patient's Medtronic insulin pump, which eliminates manual BG data entry mistakes to the pump. This is important because a **manual BG entry mistake may result in an incorrect insulin bolus calculation by the pump.** Therefore, wireless transmission of BG data to the insulin pump is not only more convenient for the patient, but also ensures accurate BG data capture by the insulin pump.

Additionally, every BG test that the patient conducts using the automatic wirelessly transmitting CONTOUR®NEXT LINK meter is stored in the pump and can be viewed using the Medtronic MiniMed® CareLink® therapy management software. This means that low BG values that the patient can self-correct by ingesting carbohydrates (but may choose not to manually input into a pump since insulin dosing is not required) are captured by the pump and viewable in the software. In other words, automatic wireless transmission† of BG values does not allow

* MiniMed®530G with SmartGuard™ technology and MiniMed® Paradigm® REAL-Time Revel™ insulin pumps.
† CONTOUR®NEXT LINK Wireless Blood Glucose Monitoring System User Guide. See Page IV, "Talks to Your Compatible Medtronic MiniMed® Device". Automatic wireless transmission of BG values requires "Send Option" set to "Always".

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for discrimination during data collection, which provides the health care provider with a more comprehensive assessment of the patient's glycemic control, including information on hypoglycemia that may warrant insulin basal rate adjustments.

The Importance of Accuracy for Self-Monitoring of Blood Glucose (SMBG):

Self-monitoring of blood glucose (SMBG) plays a significant role in diabetes management. Obtaining accurate results is critical, as people with diabetes rely on glucose meter readings to detect and properly manage hypoglycemia and hyperglycemia, titrate insulin doses, calibrate continuous glucose monitoring (CGM) devices, adjust their diet and exercise, and improve their overall decision making in the management of their disease.[1]

In addition, clinical studies have demonstrated that accurate BGM readings are important for insulin pump systems to help avoid hypo-, hyperglycemia, and insulin dosing errors.[2]

As such, the performance and accuracy of blood glucose monitoring (BGM) systems require careful consideration for better diabetes management decision-making.

The accuracy and performance of the CONTOUR®NEXT LINK BGM system has been assessed in multiple studies looking at:

(1) ***Analytical Performance*** by *Trained Operators* and ***User Performance Evaluations*** in the *Hands of Patients* using the ISO 15197:2013 accuracy criteria[3-7]

(2) The clinical relevance of BGM system readings using Error Grid Analysis (e.g., ***Parkes Error Grid***),[4-8] and

(3) Accuracy assessments versus leading BGM systems using *Mean Absolute Relative Difference* (**MARD**) and *Mean Absolute Difference* (**MAD**) from the laboratory reference values.[9]

Please note that **MARD** and **MAD** were used to assess accuracy in the Linking Meter Comparator Trial (LMCT).[9]

While currently available BGM systems have met guidelines (e.g., ISO 15197 accuracy standard) for sufficient accuracy and precision to be used by people with diabetes, these studies argue that MARD and MAD analysis may be better suited to evaluate differences in accuracy of multiple BGM systems in a single study.

For example, discrete values such as those described by ISO 15197, provide less information per observation than continuous measure and require much larger sample sizes to detect differences between systems. MARD is a continuous measure that accounts for percentage bias of each observation.[10] In addition, MARD correlates with ISO accuracy measurements and has been used in comparative studies of BGM systems[11]. It has been utilized in accuracy studies of CGM systems as well.[12,13]

As you will read in the following pages, the CONTOUR®NEXT LINK BGM system has demonstrated **highly accurate** results within **10%** of laboratory reference values.*

I am writing to seek your approval in prescribing the following items:

Patient Full Name: _____

Item: CONTOUR®NEXT Test Strips

Quantity: ____/30 Days – OR – ____/90 Days

Diagnosis code: E10.9 Type 1 diabetes mellitus without complications

(Select from menu)

Thank you for your consideration of this matter and for doing everything possible to approve insurance coverage for the CONTOUR®NEXT Test Strips.

If you have any questions or require more information, please feel free to contact me.

Sincerely,

Prescriber Information

Prescriber Name: _____

Prescriber Title: _____

Prescriber ID (Select One): ◯ NPI ◯ UPIN ◯ ME

Number: _____

Phone: _____

* 10% applies to glucose levels ≥ 100 mg/dL. In multiple clinical trials examined in an article by Bernstein et al., the CONTOUR®NEXT meter portfolio delivered at least 95% of results within 10% of the laboratory reference value for blood glucose concentrations ≥100 mg/dL and within ±10 mg/dL of the laboratory reference value for blood glucose concentrations <100 mg.[4]

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References:

1 American Diabetes Association. Standards of Medical Care in Diabetes—2015.Diabetes Care. 2014; 37 (suppl 1):S14-S80.

2 Walsh, et al. New Criteria for Assessing the Accuracy of Blood Glucose Monitors Meeting. Diabetes Science & Technology, 2012 6(2): 466-474.

3 International Organization for Standardization. In vitro diagnostic test systems—Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus. Geneva, Switzerland: International Organization for Standardization; 2013.

4 Harrison B. et al Accuracy Evaluation of a New Platform of Blood-Glucose Monitoring Systems with the CONTOUR®NEXT test strip. Poster presented at: 12th Annual Meeting of the Diabetes Technology Society (DTS); November 8-12, 2012; Bethesda, Maryland.

5 Bernstein R, et al. A New Test Strip Technology Platform for Self-Monitoring of Blood Glucose. J Diabetes Sci Technol, 2013, 7 (5): 1386-1399

6 Brown D, Plug B. Accuracy and Precision Evaluation of the CONTOUR®NEXT LINK Blood Glucose Monitoring System. Poster presented at: 16th Annual Meeting of the Canadian Diabetes Association (CDA)/Canadian Society and Metabolism (CSEM); October 17 – 20, 2013, Montreal, Quebec, Canada.

7 Wallace JF, et al. Accuracy of the CONTOUR®NEXT LINK Blood Glucose Monitoring (BGM) system in the Hands of Users. Poster presented at: 12th Annual Meeting of the Diabetes Technology Society (DTS); November 8 – 12, 2012. Bethesda, Maryland.

8 Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A New Consensus Error Grid to Evaluate the Clinical Significance of Inaccuracies in the Measurement of Blood Glucose. Diabetes Care. 2000;23(8):1143-1148.

9 Greene L, et al. Comparative Accuracy of Three Blood Glucose Monitoring Systems that Communicate with an Insulin Pump, Endocr Pract, 2014; 1:1-29.

10 Halldorsdottir S, et al. Accuracy Evaluation of Five Blood Glucose Monitoring Systems: The North American Comparator Trial. J Diabetes Sci Technol, 2013, 7 (5): 1294-1304.

11 Tack C, Pohlmeier H, Behnke T, Schmid V, Grenningloh M, Forst T, Pfützner A. Accuracy Evaluation of Five Blood Glucose Monitoring Systems Obtained from the Pharmacy: a European Multicenter Study with 453 Subjects. Diabetes Technol Ther. 2012;14(4):330–7.

12 Luijf YM, Mader JK, Doll W, Pieber T, Farret A, Place J, Renard E, Bruttomesso D, Filippi A, Avogaro A, Arnolds S, Benesch C, Heinemann L, Devries H. On Behalf Of The Ap Home Consortium JH. Accuracy and Reliability of Continuos Glucose Monitoring Systems: a Head-to-Head Comparison. Diabetes Technol Ther. 2013. Epub ahead of print.

13 Damiano ER, El-Khatib FH, Zheng H, Nathan DM, Russell SJ. A Comparative Effectiveness Analysis of Three Continuous Glucose Monitors. Diabetes Care. 2013;36(2):251–9.

14 International Organization for Standardization. In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva, Switzerland: International Organization for Standardization; 2003.

15 Breton MD, Kovatchev BP. Impact of blood glucose self-monitoring errors on glucose variability, risk of hypoglycemia, and average glucose control in type 1 diabetes: an in silico study. J Diabetes Sci Technol. 2010; 4(3):562-570.

16 US Department of Health and Human Services, Food and Drug Administration. Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use: Draft Guidance for Industry and Food and Drug Administration Staff. Draft Guidance: Center for Devices and Radiological Health (CDRH) January 7, 2014: 1 – 40.

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Important Safety Information

Insulin infusion pumps, continuous glucose monitoring (CGM) systems and associated components are limited to sale by or on the order of a physician and should only be used under the direction of a healthcare professional familiar with the risks of insulin pump therapy. Insulin pump therapy is not recommended for individuals who are unable or unwilling to perform a minimum of four blood glucose tests per day. Insulin pump users should have sufficient visual and audio acuity to recognize the alerts and alarms provided by the pump. Insulin pumps use rapid-acting insulin. If your insulin delivery is interrupted for any reason, you must be prepared to replace the missed insulin immediately. The information provided by CGM systems is intended to supplement, not replace, blood glucose information obtained using a home glucose meter. A confirmatory fingerstick is required prior to making adjustments to diabetes therapy. Insertion of a glucose sensor may cause bleeding or irritation at the insertion site. Consult a physician immediately if you experience significant pain or if you suspect that the site is infected. A version of the CGM product specially designed for children is indicated for patients age 7-17. Please visit **http://www.medtronicdiabetes.com/important-safety-information** for additional details.

Patients should read the CONTOUR®NEXT LINK User Guide, the MICROLET®2 lancing device package insert, and all instructional materials provided in your meter kit before testing. Patients should follow all instructions for use and care exactly as described to help avoid inaccurate results. Used test strips and lancets are possible biohazards and must be disposed of as medical waste.

Warning:

- 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 kit are considered bio hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Always wash your hands well with soap and water before and after testing, handling the meter, lancing device or test strips.

Examine product for missing, damaged, or broken parts. If test strip bottle is open inside the new box of strips, do not use those strips. Contact Ascensia Diabetes Care Customer Service at **1-800-348-8100** (available 24 hours a day, 7 days a week) for replacement part.

- Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip.
- Wash and dry your hands well before and after testing.
- Test strips are for single use only. Do not use a test strip that appears damaged or has been used.
- Your test strip is designed to easily “sip” the blood into the sample tip.
- Do not press the test strip against your finger when testing.
- Use a new MICROLET® lancet each time you test because it is no longer sterile after use.
- Use only the CONTOUR®NEXT test strip with your CONTOUR®NEXT LINK meter.
- Use only the CONTOUR®NEXT control solution with your CONTOUR®NEXT LINK meter.

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Section 1

CONTOUR®NEXT LINK BGM System Features:

The CONTOUR®NEXT LINK BGM system has the following features which meet many of the needs of patients using a compatible *Medtronic Insulin pump*.†

- Wirelessly sends results proven to be **highly accurate**[5] to compatible Medtronic devices for fast and easy bolus dosing and CGM calibration
- USB connector allows for easy downloading to CareLink® software and battery recharging
- **Second-Chance™ sampling,** which allows patients to apply more blood to help prevent wasted test strips and save money
- **No Coding™ technology,** which eliminates errors due to user miscoding and reduces the number of tests in the testing and training process

†MiniMed®530G with SmartGuard™ technology and MiniMed® Paradigm® REAL-Time Revel™ insulin pumps.

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CONTOUR®NEXT LINK BGM System Performance and Accuracy results:

- **Table 1** [ISO 15197:2013 Performance Table] shows that the CONTOUR®NEXT LINK BGM system has demonstrated highly accurate results in the hands of trained operators and in the hands of patients.

- **Graph 1.1** [CONTOUR®NEXT LINK Parkes Error Grid] The Parkes-Consensus Error Grid analysis was used to evaluate the clinical accuracy of the CONTOUR®NEXT LINK BGM system

- **Graph 1.2** [LMCT] summarizes the results of the Linking Meter Comparator Trial (LMCT)[8] which evaluated differences in accuracy between the CONTOUR®NEXT LINK BGM system and linking BGM systems from other companies included in the LMCT.

- **Graph 1.3** [LMCT] shows the Modified Bland-Altman plots of the difference of BGM system results from the laboratory reference values for the CONTOUR®NEXT LINK BGM system and linking BGM systems from other companies included in the LMCT.

- **Graph 1.4** [LMCT – Natural Sample Analysis] shows that the CONTOUR®NEXT LINK BGM System was proven highly accurate by demonstrating results close to lab reference values (YSI).

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Table 1

CONTOUR®NEXT LINK BGM System ISO 15917:2013 Performance Results[3-7]

Results:

The CONTOUR®NEXT LINK BGM system has demonstrated **highly accurate results** within **10%** of lab reference values* and has been **proven highly accurate** by meeting the ISO 15197:2013 accuracy standard.§

Percentage of highly accurate results				
Glucose concentration	In the hands of	Within ±10%	Within ±15%	Within ±20%
≥100 mg/dL	Trained operators	**99.5%** (412/414)	**100%** (414/414)	**100%** (414/414)
	Patients†	**98.9%** (93/94)	**98.9%** (93/94)	**100%** (94/94)
Glucose concentration	In the hands of	Within ±10 mg/dL	Within ±15 mg/dL	Within ±20 mg/dL
<100 mg/dL	Trained operators	**99.5%** (185/186)	**100%** (186/186)	**100%** (186/186)
	Patients†	**100%** (16/16)	**100%** (16/16)	**100%** (16/16)

†Data based on routine finger sticks vs. lab method

Note on accuracy standards:

Until January 30, 2014, the US FDA recognized the ISO 15197:2003 standard, which required the following minimal accuracy acceptability criteria:

- 95% of results to fall within ±20% of a laboratory reference value for blood glucose concentrations ≥75 mg/dL and
- 95% of results to fall within ±15 mg/dL of a laboratory reference value for blood glucose concentrations <75 mg/dL.[14]

* 10% applies to glucose levels ≥ 100 mg/dL. In multiple clinical trials examined in an article by Bernstein et al., the CONTOUR®NEXT meter portfolio delivered at least 95% of results within 10% of the laboratory reference value for blood glucose concentrations ≥100 mg/dL and within ±10 mg/dL of the laboratory reference value for blood glucose concentrations <100 mg.[4]
§ International Organization for Standardization. The ISO 15197:2013 standard requires 95% of results to fall within ±15 mg/dL of a laboratory reference value for blood glucose concentrations <100 mg/dL and within ±15% of a laboratory reference value for blood glucose concentrations ≥100 mg/dL, and 99% of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid.[2]

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Therefore, the allowable margin of error of BGM systems today can be up to ±20% for glucose levels ≥ 75 mg/dL. Please note that a ± 20% margin of error could lead patients to take the wrong course of action to correct their blood sugar.[15]

Regulatory agencies and other stakeholders pushed for a tighter accuracy standard.

First, the ISO 15197:2013 standard was published, which requires:

- 95% of results to fall within ±15 mg/dL of a laboratory reference value for blood glucose concentrations <100 mg/dL,
- 95% of results to fall within ±15% of a laboratory reference value for blood glucose concentrations ≥100 mg/dL, and

99% of individual glucose measured values shall fall within Zones A and B of the Consensus Error Grid.[3]

Second, the Food and Drug Administration (FDA) proposed, but has not yet adopted, tighter accuracy criteria in its draft guidance entitled: "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" issued on January 7, 2014.[16]

As shown on Table 1, the CONTOUR®NEXT LINK BGM system has demonstrated **highly accurate results** within **10%** of lab values.*

Ascensia Diabetes Care places the highest priority on accuracy you can trust, so you, as well as your patients, can make better diabetes management decisions.

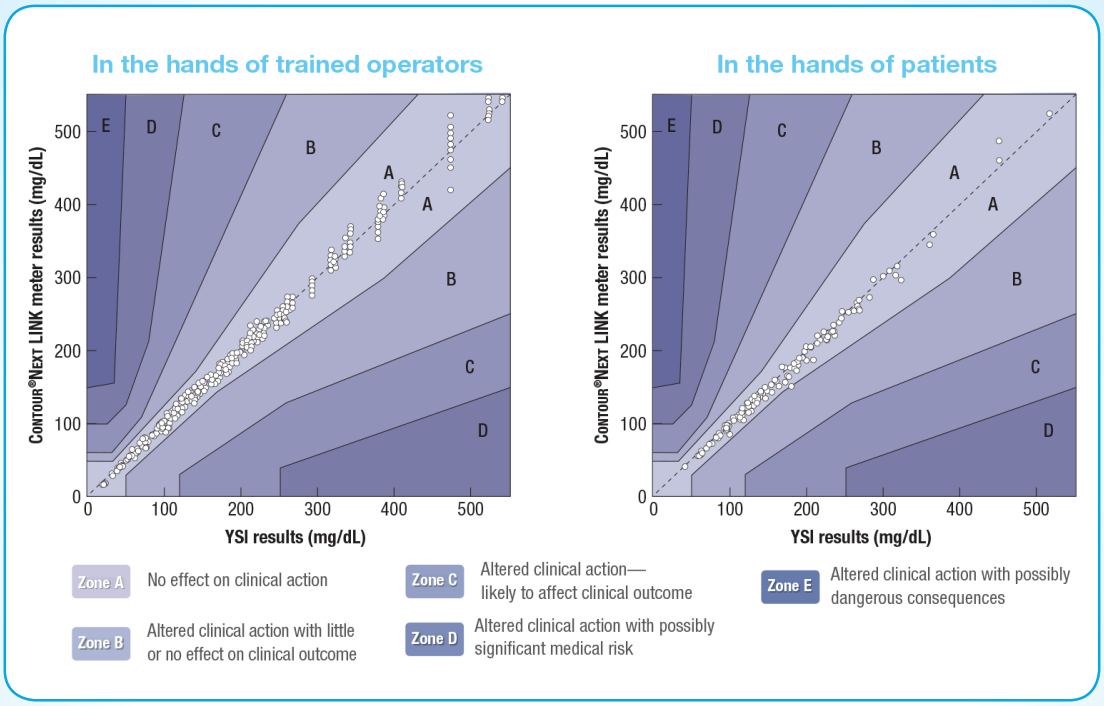
* 10% applies to glucose levels ≥ 100 mg/dL. In multiple clinical trials examined in an article by Bernstein et al., the CONTOUR®NEXT meter portfolio delivered at least 95% of results within 10% of the laboratory reference value for blood glucose concentrations ≥100 mg/dL and within ±10 mg/dL of the laboratory reference value for blood glucose concentrations <100 mg.[4]

Graph 1.1

CONTOUR®NEXT LINK BGM System Parkes Error Grid Results[4-8]

Results:

100% of the CONTOUR®NEXT LINK meter results were within **Zone A** in the Parkes-Consensus Error Grid Analysis.



Note on the Parkes Error Grid

Error grid analysis (EGA), such as the Parkes Error Grid, was developed to assess the clinical significance of inaccurate BGM system readings compared with reference laboratory readings. EGA classifies BGM system readings into 5 zones based on their impact on the clinical decision to either treat or not treat.[8]

When the clinical relevance of accurate results was assessed using the Parkes Error Grid, the CONTOUR®NEXT LINK BGM system demonstrated highly accurate results **as 100%** of results in the hands of trained operators and in the hands of patients fell **within Zone A**.

Recall that a result in Zone A signifies that such a result would have no effect on clinical action. Zone B signifies that it is one that may alter the clinical action, though with little to no effect on clinical outcome. Zones C, D & E signifies that results may alter clinical action, and are likely to affect the clinical outcome, could have significant medical risk, and could have dangerous consequences, respectively.[8]

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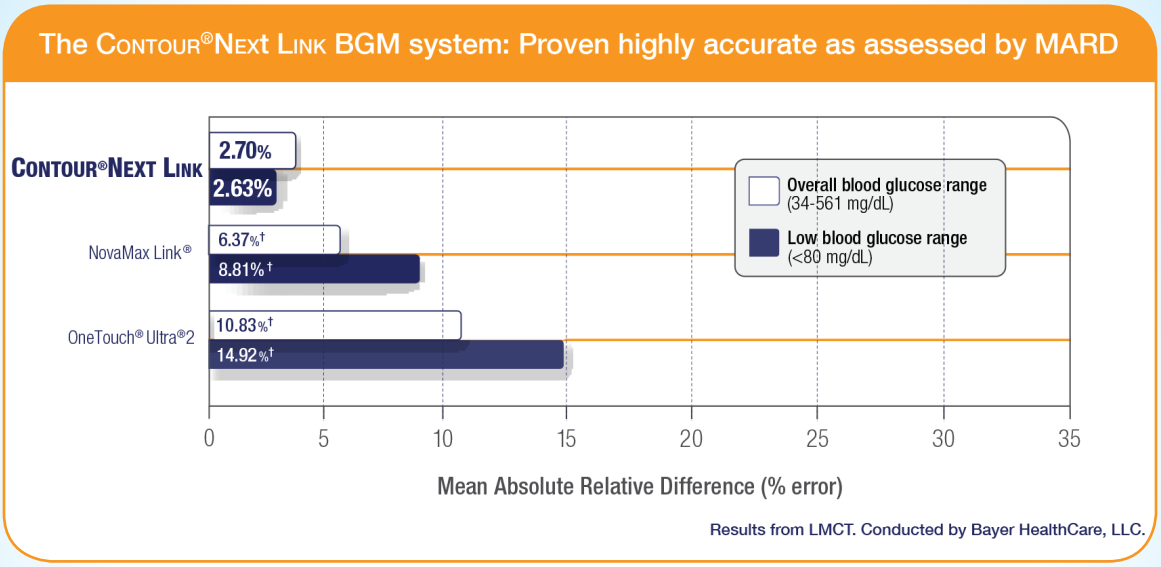
Graph 1.2

CONTOUR®NEXT LINK BGM System – Linking Meter Comparator Trial (LMCT)[9]

Results:

In the Linking Meter Comparator Trial (LMCT), the CONTOUR®NEXT LINK BGM system **delivered highly accurate results close to lab reference values** (YSI)[§]



Accuracy assessed by Mean Absolute Relative Difference (MARD)* from lab reference values (YSI).[§]

Assessing BGM system accuracy using Mean Absolute Relative Difference (MARD)

Please note that while currently available BGM systems have met guidelines (e.g., International Organization for Standardization [ISO 15197:2003 accuracy criteria])[14] for sufficient accuracy and precision to be marketed and used by people with diabetes, other types of analyses such as Mean Absolute Difference (MAD) and Mean Absolute Relative Difference (MARD) may be better suited for comparing accuracy of multiple meters.[10]

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§ YSI Life Sciences, Inc., Yellow Springs, OH, USA.
† P<0.00001 vs. the CONTOUR®NEXT LINK BGM system.
* MARD is calculated by taking the average for the set of individual absolute errors relative to its reference value.

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Study Design Information:

Linking Meter Comparator Trial (LMCT)[9]

Objectives

Primary end point:

Differences in accuracy between the CONTOUR®NEXT LINK BGM system and linking BGM systems from other companies across the overall tested glucose range, reported as MARD (Mean Absolute Relative Difference).*

Secondary end point:

Differences in accuracy between the CONTOUR®NEXT LINK BGM system and BGM systems from other companies in each of three glucose ranges: ≤ 80 mg/dL; 81 to 180 mg/dL; and > 180 mg/dL.

Methods

The LMCT included 111 subjects. The CONTOUR®NEXT LINK (NL) BGM system was compared with the OneTouch® UltraLink® (UL) and NovaMax Link™ (ML) BGM systems. All lancing and testing were performed by trained operators. Three blood samples were taken per subject with a total of 333 blood samples tested per meter. One natural sample per subject was tested, for a total of 111 natural samples. The two remaining samples from each subject were either spiked or glycolyzed to achieve the higher and lower blood glucose ranges, respectively. Analysis of variance (ANOVA) was performed on the absolute value of relative difference (ARD) between BGM and the laboratory reference method (YSI)§, p = 0.05.

Results:

Primary endpoint results (MARD %): NL 2.70%; ML 5.37%; UL 10.83%. Secondary endpoint results (MARD %): For ≤ 80 mg/dL, NL 2.63%; ML 8.81%; UL 14.92%; For 81 to 180 mg/dL, NL 2.80%; ML 5.78%; UL 8.82%; For > 180 mg/dL, NL 2.66%; ML 4.52%; UL 8.76%. A retrospective analysis of natural samples only was conducted, with the following results: NL 2.76%; ML 5.65%; UL 5.97%.

In the Linking Meter Comparator Trial (LMCT), the CONTOUR®NEXT LINK BGM system **delivered highly accurate results close to lab reference values** (YSI)§

* MARD is calculated by taking the average for the set of individual absolute errors relative to its reference value.
§ YSI Life Sciences, Inc., Yellow Springs, OH, USA.

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Graph 1.3

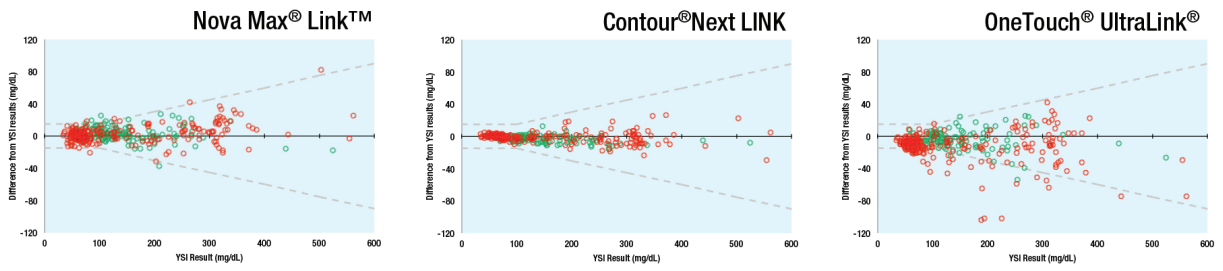
LMCT: Modified Bland-Altman Plots

Modified Bland-Altman plots can be used to compare the performance of a measurement method (BGM sytem) with a gold standard (laboratory method or YSI§) and provides another way to visualize performance, in this case, of a BGM system.

When looking at these plots, keep in mind that the closer the data points are to the center of the graph (solid black line), the ***more accurate*** the BGM system.

Results:

The CONTOUR®NEXT LINK BGM system has been **proven highly accurate by demonstrating results close to lab reference values** (YSI).§



Unmodified blood samples
Modified blood samples

YSI = Yellow Springs Instruments
*Dashed lines represent ±15 mg/dL or ±15% of the reference result for samples with YSI glucose concentrations <100mg/dL and ≥100 mg/dL, respectively.

§ YSI Life Sciences, Inc., Yellow Springs, OH, USA.

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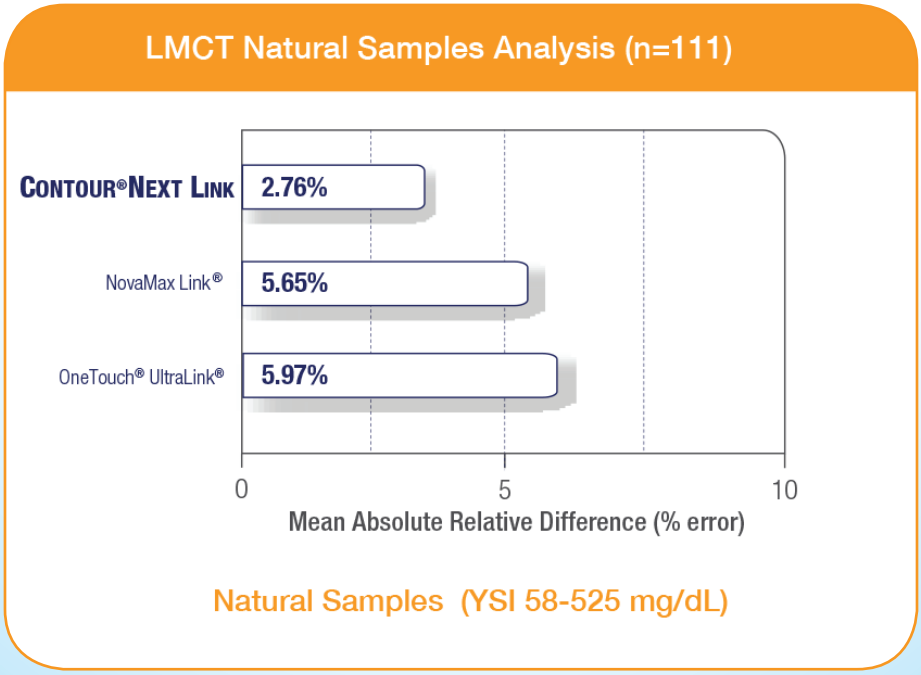
Graph 1.4:

LMCT Natural Samples Analysis (YSI 58 – 525 mg/dL, n = 111)

- In the LMCT, some samples were spiked with glucose to get enough samples in the high glucose range and some samples were glycolyzed to get enough samples in the low glucose range.
- It is possible that the process of modifying the blood samples altered their oxygen content.
- In the LMCT, a Natural Samples Analysis was conducted to control for potential oxygen interference with BGM systems which use Glucose Oxidase test strip technology: NovaMax Link™ and OneTouch® UltraLink®.
- In the LMCT Natural Sample analysis, the CONTOUR®NEXT LINK BGM System was proven highly accurate by demonstrating results close to lab reference values (YSI).§

Results:

The CONTOUR®NEXT LINK BGM system: **proven highly accurate** by demonstrating close to lab reference values even when using natural samples in the LMCT (n=111).



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Summary:

The Importance of Accuracy for Self-Monitoring of Blood Glucose (SMBG):

Self-monitoring of blood glucose (SMBG) plays a significant role in diabetes management. Obtaining accurate results is critical, as people with diabetes rely on glucose meter readings to detect and properly manage hypoglycemia and hyperglycemia, titrate insulin doses, calibrate continuous glucose monitoring (CGM) devices, adjust their diet and exercise, and improve their overall decision making in the management of their disease.[1]

As such, the performance and accuracy of blood glucose monitoring (BGM) systems require careful consideration for better diabetes management decision-making.

The accuracy and performance of the CONTOUR®NEXT LINK BGM system has been assessed in multiple studies looking at:

(1) ***Analytical Performance*** by *Trained Operators* and ***User Performance Evaluations*** in the *Hands of Patients* using the ISO 15197:2013 accuracy criteria[3-7]

(2) The clinical relevance of BGM system readings using Error Grid Analysis (e.g., ***Parkes Error Grid***),[4-8] and

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As you read in this document, the CONTOUR®NEXT LINK BGM system has demonstrated **highly accurate** blood glucose monitoring for people with diabetes in support of their diabetes management.