User Performance Evaluation of a New Wireless-enabled Blood Glucose Monitoring System That Links to a Smart Mobile Device in Subjects With and Without Diabetes

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INTRODUCTION

- The new Contour®Next ONE blood glucose monitoring system (BGMS) has been developed for use with currently available Contour®Next test strips (Ascensia Diabetes Care, Parsippany, NJ, USA)
- The new BGMS features an easy to use, wireless-enabled blood glucose meter that links to a smart mobile device via Bluetooth® technology and can sync with the Contour™ Diabetes App on a smartphone or tablet
- The International Organization for Standardization (ISO) provides guidelines that are used to assess the accuracy of blood glucose monitoring devices,[1] and the US Food and Drug Administration (FDA) has also provided guidance for BGMS accuracy[2]
- The accuracy of the Contour®Next ONE BGMS was assessed in the laboratory and exceeded ISO 15197:2013 Section 6.3 accuracy criteria, as previously presented[3]
- The accuracy of the new BGMS was also assessed in clinical settings based on both the ISO 15197:2013 accuracy criteria[1] and FDA Self-Monitoring of Blood Glucose (SMBG) Guidance 2016 Section C criteria[2]
  - The clinical study also evaluated the ease-of-use of the BGMS in subjects with and without diabetes
  - Accuracy data from subjects with diabetes based on ISO 15197:2013 accuracy criteria (primary objective) have been previously presented[3]; here, we report results from the total study population, including subjects with and without diabetes, based on FDA 2016 criteria

OBJECTIVE

- To evaluate the accuracy and ease-of-use of the Contour®Next ONE BGMS in clinical settings when used by subjects with and without diabetes

METHODS

Study Design

- In a 2-center clinical study, subjects with and without diabetes who were aged ≥18 years and had never used this BGMS previously were enrolled
  - In accordance with the FDA 2016 criteria, approximately 10% of enrolled subjects did not have diabetes
- Each subject's participation consisted of 1 study visit and, for ≥2 hours prior to capillary blood testing, subjects were not permitted to eat or drink liquids; take bolus insulin, rapid-acting insulin, or oral diabetes medications; or vigorously exercise
- Subjects learned to use the BGMS by reading instructional materials (User Guide and Quick Reference Guide)
  - Study staff observed that tests were conducted as instructed in the instructional guides
- Three test strip lots were used in the study, with each subject randomized to 1 lot
- Each subject used a lancing device to perform a fingerstick and tested his/her fingertip blood using the BGMS
- Within 5 minutes of each subject's fingertip test, the study staff collected blood from the subject's fingertip (using another lancing device) for the reference assay
- Immediately thereafter, subjects performed an alternate site (palm) test using the BGMS, followed by study staff lancing the subject's fingertip to perform a meter test
- After blood testing, each subject completed a questionnaire to assess the subjects' understanding of the instructions for use and the messages displayed on the meter
  - The questionnaire included 6 statements that the subjects responded to using a 5-point Likert scale: 1, strongly disagree; 2, disagree; 3, neutral; 4, agree; and 5, strongly agree
- Adverse events were monitored throughout the study

Assessments and Analyses

- BGMS results were compared with results from the reference assay, which was performed on a YSI analyzer (YSI; YSI Life Sciences, Inc., Yellow Springs, OH, USA)
- The primary objective was to assess the accuracy of the BGMS using fingertip self-test results in subjects with diabetes, based on ISO 15197:2013 accuracy criteria (ie, ≥95% of results within ±15 mg/dL of the reference result for samples with blood glucose concentrations <100 mg/dL or ±15% for samples with blood glucose concentrations ≥100 mg/dL)[1]
  - Secondary objectives included assessment of accuracy using results from all subjects per FDA 2016 criteria (ie, 95% of results within ±15% and 99% within ±20% of the laboratory method across the entire tested range)[2]
- Regression analysis was performed to compare BGMS results with YSI reference results
- Parkes-Consensus Error Grid analyses[4] were used to evaluate the clinical accuracy of the BGMS

RESULTS

Subjects

- A total of 376 subjects were enrolled (333 subjects with diabetes and 43 without diabetes; **Table 1**)
  - 375 subjects completed the study; 1 subject met enrollment criteria but did not meet day of study criteria

Table 1. Subject Demographic and Baseline Characteristics

Characteristic	All subjects N = 376	Characteristic	All subjects N = 376
Gender, n (%)		Duration of diabetes, n (%)[b,c]	
Female	202 (54)	<1 mo	1 (0.3)
Male	174 (46)	1-3 mo	2 (1)
Type of diabetes, n (%)		4-6 mo	1 (0.3)
Type 1	116 (31)	7-12 mo	2 (1)
Type 2	215 (57)	13 mo-2 y	14 (4)
Type unknown	2 (1)	3-5 y	35 (11)
No diabetes	43 (11)	6-10 y	55 (17)
Age, y		>10 y	223 (67)
Mean (range)	52 (18-81)	Frequency of daily SMBG, n (%)[c]	
Race, n (%)[a]		>4	84 (25)
White	292 (78)	4	39 (12)
African American	52 (14)	3	50 (15)
Asian	23 (6)	2	51 (15)
American Indian/Alaskan Native	7 (2)	1	65 (20)
Native Hawaiian/Pacific Islander	2 (1)	<1	27 (8)
No response	9 (2)	Does not test	17 (5)
Education, n (%)[b]			
Less than high school	9 (2)		
High school	68 (18)		
Some college	170 (45)		
College graduate	128 (34)		
No response	1 (0.3)		

SMBG, self-monitoring of blood glucose.
[a]More than 1 choice for race was allowed; therefore, the apparent frequency total was larger than the number of subjects in each category.
[b]Percentages may not total 100% due to rounding.
[c]Only for subjects with diabetes, n = 333.

Blood Glucose Measurements and Accuracy

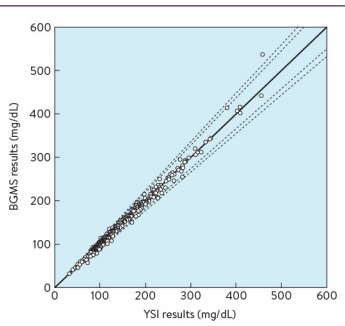
- For all subjects with and without diabetes, the range of plasma blood glucose concentrations was 32 mg/dL to 458 mg/dL for capillary blood samples; the hematocrit range was 33% to 59%
- The evaluation of subject-obtained capillary fingertip results based on FDA 2016 criteria showed that 99.5% (370/372) of results were within ±15% and 99.7% (371/372) of results were within ±20% of YSI reference results (**Table 2**)
  - Of study staff–obtained fingertip results, 99.7% (374/375) were within ±15% and 100% (375/375) were within ±20% of YSI reference results (**Table 2**)
  - Of subject palm results, 96.7% (349/361) were within ±15% and 98.6% (356/361) were within ±20% of YSI reference results (**Table 2**)
  - The results for capillary fingertip testing satisfied FDA 2016 criteria (ie, 95% of results within ±15% and 99% of results within ±20% of the laboratory method across the entire tested range)

Table 2. Summary of Accuracy for All Subjects With and Without Diabetes

		Number of results within specified error limits				
Test	N	±5%	±7%	±10%	±15%[a]	±20%[a]
Subject fingertip	372	298 (80.1%)	329 (88.4%)	358 (96.2%)	370 (99.5%)	371 (99.7%)
Study staff fingertip	375	300 (80.0%)	329 (87.7%)	363 (96.8%)	374 (99.7%)	375 (100%)
Subject palm	361	253 (70.1%)	300 (83.1%)	323 (89.5%)	349 (96.7%)	356 (98.6%)

FDA, US Food and Drug Administration.
[a]FDA 2016 criteria (ie, 95% of results within ±15% and 99% of results within ±20% of the laboratory method across the entire tested range).

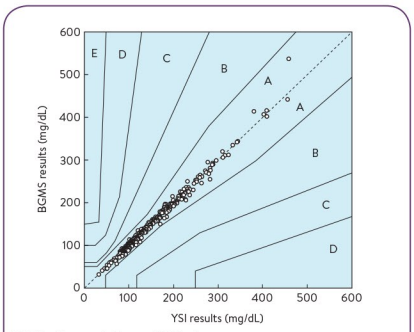
- 95% error range: An ad hoc analysis was conducted to determine the smallest error range within which ≥95% of meter inaccuracies (ie, differences between meter results and YSI reference results) fell; ≥95% of meter results for all subjects were within the following:
  - 9.5% of the YSI reference result for subject fingertip tests
  - 8.9% of the YSI reference result for study staff tests of subject fingertip blood
  - 11.8% of the YSI reference result for subject palm tests
- Regression analysis of clinical results for all subjects demonstrated a strong correlation between BGMS and YSI reference results (adjusted R^2 >0.96 for all regressions)
  - The R^2 value was 0.9876 for subject-obtained capillary fingertip results (**Figure 1**)
  - The R^2 values for study staff–obtained fingertip and subject palm results were 0.9886 and 0.9684, respectively



BGMS, blood glucose monitoring system; YSI, YSI analyzer.

Figure 1. Regression plot of subject-obtained capillary fingertip results for all subjects with and without diabetes.

- By Parkes-Consensus Error Grid analysis, 100% (372/372) of all subject-obtained capillary fingertip results were within Zone A (**Figure 2**)
  - All (100%; 375/375) results were also within Zone A for study staff–obtained fingertip testing; 98.9% (357/361) of results were within Zone A for subject palm testing, with the remainder (1.1%; 4/361) in Zone B



BGMS, blood glucose monitoring system; YSI, YSI analyzer.

Figure 2. Parkes-Consensus Error Grid analysis of subject-obtained capillary fingertip results for all subjects with and without diabetes.

Questionnaire Results

- Among all subjects (N = 375), ≥97% responded "strongly agree," "agree," or "neutral" on all 6 statements of the ease-of-use questionnaire (**Figure 3**)

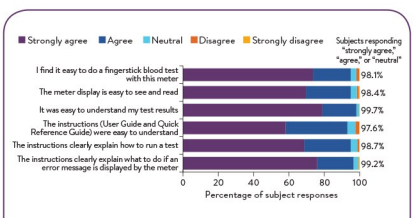


Figure 3. Ease-of-use questionnaire results for all subjects with and without diabetes (N = 375).

Safety

- There were 8 mild, anticipated, non–device-related adverse events, all classified as hypoglycemia and all occurring in subjects with diabetes
  - Hypoglycemia was defined as a blood glucose level <70 mg/dL at the clinical site where these events occurred
- All adverse events resolved prior to the subjects leaving the testing site

CONCLUSIONS

- **Results of this clinical study demonstrated the accuracy of the Contour®Next ONE BGMS in subjects with and without diabetes**
  - **The new BGMS features a wireless-enabled blood glucose meter that links to a smart mobile device via Bluetooth® technology and can sync with the Contour™ Diabetes App on a smartphone or tablet**
- **For subjects with and without diabetes in a clinical setting, the BGMS exceeded FDA 2016 criteria when used for capillary fingertip testing**
- **Accuracy was achieved regardless of whether testing was performed by study staff or by subjects who never used this BGMS previously and had no training other than access to the product instruction manual**
- **The BGMS also demonstrated ease-of-use in the hands of subjects with and without diabetes**

References

1. ISO 15197:2013(E): In vitro diagnostic test systems—Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. May 2013.
2. US Food and Drug Administration. http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm380327.pdf. Accessed December 8, 2016. (Document issued on October 11, 2016)
3. Christiansen M, et al. A new, wireless-enabled blood glucose meter in development that links to a smart mobile device via Bluetooth® connectivity: accuracy and user performance evaluation. Poster presented at: 9th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD); February 3-6, 2016; Milan, Italy.
4. Parkes JL, et al. *Diabetes Care.* 2000;23(8):1143-1148.

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