Performance and Accuracy Capability of a New, Wireless-enabled Blood Glucose Monitoring System That Links to a Smart Mobile Device: Laboratory and Clinical Sample Reapplication Studies

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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 syncs with the Contour™ Diabetes app on a smartphone or tablet
- The accuracy of the Contour®Next ONE BGMS has been assessed in the laboratory according to International Organization for Standardization (ISO) 15197:2013 guidelines and in clinical settings based on ISO 15197:2013 guidelines and US Food and Drug Administration 2016 criteria[1-3]
- The blood glucose calculation algorithm used with Contour®Next test strips has been revised to further improve accuracy and mitigate risks from user errors
  - The meter logic can recognize an insufficient sample and prompt the user to apply more blood
  - The new algorithm includes an improved method for calculating the blood glucose result when a second sample is applied after an initial insufficient sample (Second-Chance® sampling)
- Two types of studies were conducted to demonstrate the accuracy of Second-Chance® sampling with the Contour®Next ONE BGMS
  - In a laboratory study, testing was conducted in controlled environments and with contrived specimens to achieve a wide range of temperature, method, and sample conditions
  - In a clinical study, subjects with diabetes performed self-tests using their own capillary fingertip blood

OBJECTIVE

- To evaluate the performance and accuracy of the Contour®Next ONE BGMS during Second-Chance® sampling

METHODS

Study Design

- In the laboratory study, samples were tested in 3 temperature environments (16°C, 22°C, and 34°C) with blood adjusted to 3 blood glucose levels (70, 300, and 500 mg/dL) at 3 hematocrit levels (20%, 42%, and 55%)
  - Two sample reapplication methods were used (initial volumes: 0.28 µL and 0.46 µL), and each sample was tested with 3 delay times between initial and second inoculation (5, 30, and 55 seconds)
  - For each sample and test condition, 10 replicate BGMS readings were obtained with each of the 3 test strip lots
- In the clinical study, 52 subjects with diabetes performed self-tests with an intentionally insufficient initial blood sample application in order to produce a number of Second-Chance® sampling opportunities
  - With each subject, study staff initially used a lancing device to obtain capillary fingertip blood for comparison glucose measurements on the YSI 2300 Stat Plus analyzer (YSI; YSI Life Sciences, Inc., Yellow Springs, OH, USA)
  - Subjects then lanced their own fingertips and performed 2 tests, 1 with each of 2 test strip lots
  - After subjects completed their testing, study staff performed another fingerstick and collected blood for a second YSI measurement

Assessments and Analyses

- In the laboratory study, the acceptance criterion was that all process capability statistics (Cpk) were ≥0.65
- In the clinical study, results were compared with the average of the YSI measurements taken before and after subject testing and assessed based on the following acceptance criterion: ≥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
  - Using proportionally weighted least squares regression, the slope and intercept of the regression line were calculated
  - Parkes-Consensus Error Grid analysis[4] was used to determine the effect of BGMS-obtained blood glucose reapplication results on clinical action

RESULTS

Laboratory Study

- In the laboratory study, all results met the protocol-specified acceptance criterion, demonstrating that the BGMS provides accurate sample reapplication results with hematocrit levels between 20% and 55% and test temperatures between 16°C and 34°C
- Summary statistics of Cpk for each initial sample application volume are summarized in **Table 1**

Table 1. Sample Reapplication Summary Statistics of Cpk With the BGMS From the Laboratory Study

	Initial sample volume of 0.28 µL								
Glucose	70 mg/dL			300 mg/dL			500 mg/dL		
Temp/ Hct	20%	42%	55%	20%	42%	55%	20%	42%	55%
16°C	2.13	1.88	1.47	1.49	1.66	1.66	1.30	1.33	2.05
22°C	1.63	1.41	1.77	0.95	1.31	1.41	1.14	1.54	1.34
34°C	1.72	1.39	1.76	1.10	1.44	1.50	1.00	1.01	1.18
	Initial sample volume of 0.46 µL								
Glucose	70 mg/dL			300 mg/dL			500 mg/dL		
Temp/ Hct	20%	42%	55%	20%	42%	55%	20%	42%	55%
16°C	1.90	1.92	1.74	1.90	1.67	1.40	1.42	1.70	1.19
22°C	1.49	1.66	1.55	0.76	1.13	1.64	0.80	0.97	1.16
34°C	0.66	1.19	1.46	0.81	1.08	0.72	0.92	1.50	1.96

Cpk, process capability statistics at ±15 mg/dL or ±15%; BGMS, blood glucose monitoring system; Temp, temperature; Hct, hematocrit.

Clinical Study

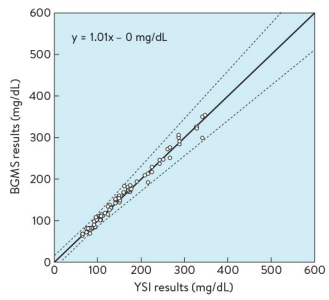
- A total of 52 subjects with diabetes participated in the clinical study; each subject performed 2 tests, 1 test with each of 2 lots of test strips
- A total of 104 tests were performed
  - 85 tests provided a reading after the second sample application (elapsed time between applications ranged from 6-52 seconds). Most subjects were able to obtain the additional blood for the second application from the original lancing site; however, for 1 test, the subject had to perform a separate fingerstick to obtain the additional blood
  - 18 tests filled the sensor with the initial drop of blood and did not require sample reapplication
  - One reading produced an underfill error when the subject did not successfully apply a second drop of blood
- Plasma glucose levels ranged from 65 mg/dL to 347 mg/dL, and hematocrit levels ranged from 35% to 55%
- Evaluation of capillary fingertip results showed that 100% (85/85) of subject fingertip self-test results were within ±15 mg/dL or ±15% of the YSI reference result (**Table 2**)
  - Moreover, 92.9% (79/85) of self-test results were within ±10 mg/dL or ±10% of the YSI reference result

Table 2. Summary of BGMS Sample Reapplication Results From the Clinical Study

	Number of results within the specified error limits		
Test strip lot	±5 mg/dL[a] or ±5%[b]	±10 mg/dL[a] or ±10%[b]	±15 mg/dL[a] or ±15%[b]
Lot 1	27 of 42 (64.3%)	40 of 42 (95.2%)	42 of 42 (100%)
Lot 2	32 of 43 (74.4%)	39 of 43 (90.7%)	43 of 43 (100%)
Combined	59 of 85 (69.4%)	79 of 85 (92.9%)	85 of 85 (100%)

BGMS, blood glucose monitoring system.
[a]For blood glucose values <100 mg/dL.
[b]For blood glucose values ≥100 mg/dL.

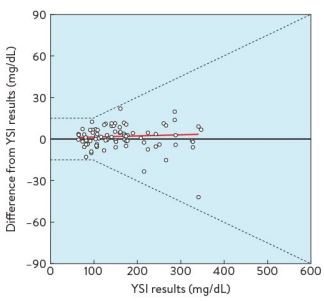
- The proportionally weighted least squares regression statistics indicated a good correlation of BGMS results with YSI plasma glucose values (**Figure 1**)



BGMS, blood glucose monitoring system; YSI, YSI glucose analyzer.
[a]Proportionally weighted least squares model.
[b]Test strip lot 1: n = 42; test strip lot 2: n = 43. Total = 85 data pairs.

Figure 1. Regression analysis of BGMS sample reapplication results versus YSI reference results in the clinical study.[a,b]

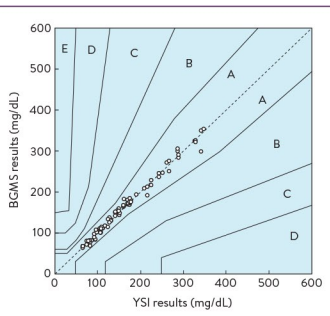
- A plot of the difference of BGMS results from YSI reference results is shown in **Figure 2**



BGMS, blood glucose monitoring system; YSI, YSI glucose analyzer.
[a]Test strip lot 1: n = 42; test strip lot 2: n = 43. Total = 85 data pairs.

Figure 2. Difference of BGMS sample reapplication results from YSI reference results in the clinical study.[a]

- Parkes-Consensus Error Grid analysis demonstrated that 100% (85/85) of subject-obtained sample reapplication results were within Zone A, indicating no effect on clinical action (**Figure 3**)
  - There were no results within Zones B, C, D, or E (ie, no results indicated altered clinical action with increasingly severe effects on clinical outcome)



BGMS, blood glucose monitoring system; YSI, YSI glucose analyzer.
[a]Test strip lot 1: n = 42; test strip lot 2: n = 43. Total = 85 data pairs.

Figure 3. Parkes-Consensus Error Grid analysis of BGMS sample reapplication results in the clinical study.[a]

CONCLUSIONS

- **The Contour®Next ONE BGMS sample reapplication results met the acceptance criteria in the laboratory and in a clinical setting when used by subjects with diabetes**
- **In the laboratory study, the BGMS provided accurate sample reapplication results for hematocrit levels between 20% and 55% and ambient temperatures between 16°C and 34°C**
- **In the clinical study, all subject fingertip self-test results were within ±15 mg/dL or ±15% of the YSI reference result**

References

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