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ORIGINAL ARTICLE

Performance Evaluation and Labeling Comprehension of a New Blood Glucose Monitoring System with Integrated Information Management

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Abstract

Background:

This study evaluated performance and product labeling of CONTOUR® USB, a new blood glucose monitoring system (BGMS) with integrated diabetes management software and a universal serial bus (USB) port, in the hands of untrained lay users and health care professionals (HCPs).

Method:

Subjects and HCPs tested subject's finger stick capillary blood in parallel using CONTOUR USB meters; deep finger stick blood was tested on a Yellow Springs Instruments (YSI) glucose analyzer for reference. Duplicate results by both subjects and HCPs were obtained to assess system precision. System accuracy was assessed according to International Organization for Standardization (ISO) 15197:2003 guidelines [within ±15 mg/dl of mean YSI results (samples <75 mg/dl) and ±20% (samples ≥75 mg/dl)]. Clinical accuracy was determined by Parkes error grid analysis. Subject labeling comprehension was assessed by HCP ratings of subject proficiency. Key system features and ease-of-use were evaluated by subject questionnaires.

Results:

All subjects who completed the study (N = 74) successfully performed blood glucose measurements, connected the meter to a laptop computer, and used key features of the system. The system was accurate; 98.6% (146/148) of subject results and 96.6% (143/148) of HCP results exceeded ISO 15197:2003 criteria. All subject and HCP results were clinically accurate (97.3%; zone A) or associated with benign errors (2.7%; zone B). The majority of subjects rated features of the BGMS as "very good" or "excellent."

Conclusions:

CONTOUR USB exceeded ISO 15197:2003 system performance criteria in the hands of untrained lay users. Subjects understood the product labeling, found the system easy to use, and successfully performed blood glucose testing.

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Abbreviations: (BGMS) blood glucose monitoring system, (CLSI) Clinical and Laboratory Standards Institute, (CV) coefficient of variation, (HCP) health care professional, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose, (USB) universal serial bus, (YSI) Yellow Springs Instruments

Keywords: blood glucose monitoring, CONTOUR USB, diabetes, diabetes management, diabetes management software

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Introduction

Diabetes affects an estimated 285 million people worldwide, with global incidence expected to rise by more than 50% by 2030.[1] Chronic hyperglycemia can lead to serious clinical complications, including blindness, kidney failure, severe damage of the nervous system, heart disease, and stroke[2] and represents a significant burden to the health care system.[3] Microvascular and macrovascular complications associated with elevated blood glucose levels can be reduced with proper glycemic control.[4]

The role of self-monitoring of blood glucose (SMBG) in improving glycemic control and reducing the risks for clinical complications associated with diabetes is well established, particularly in patients with type 1 diabetes.[5,6] Increased frequency of SMBG has been correlated with improved glycemic control,[5] and the American Diabetes Association recommends SMBG testing three to four times daily, depending on the patient.[7] This practice can lead to accumulation of large data sets, and for this information to be appropriately translated into clinical benefit, the data must be organized, interpreted, and incorporated into ongoing diabetes management strategies. Thus, attaining glycemic goals through SMBG requires that health care professionals (HCPs) readily obtain glucose monitoring data from patients to help individualize disease management recommendations and that patients are able to access and interpret their blood glucose data to self-assess their response to treatment.[7]

Use of the proper data management system can enhance the clinical utility of blood glucose readings collected over time.[8,9] Diabetes management software not only allows for collection of data, but provides standard statistical and graphical tools to facilitate review of these data by patients and their HCPs. By offering HCPs a more complete picture of a patient's blood glucose profile over the past weeks or months, data management systems may allow the development of a more efficacious treatment regimen.[10] Ideally, an integrated meter and data management system should allow patients to easily upload and review their data at home prior to an in-clinic visit.

The objective of the current study was to evaluate product performance, labeling comprehension, and usability of key system features of the new CONTOUR® USB integrated blood glucose monitoring system (BGMS; Bayer HealthCare LLC, Diabetes Care, Tarrytown, NY). This BGMS couples the CONTOUR blood glucose meter with expanded information management through universal serial bus (USB) computer connectivity and integrated GLUCOFACTS® software.

Methods

Study Population

This study was open to male and nonpregnant female subjects between 18 and 76 years of age with type 1 or type 2 diabetes. The protocol and subject informed consent forms were approved by an institutional review board, and all subjects completed the informed consent process. Subjects were required to have routinely performed SMBG at home and to have experience using a computer for more than simply email communication prior to enrollment in the study. Subjects were excluded if they had hemophilia or any other bleeding disorder, were taking prescription anticoagulants (excluding 81–325 mg aspirin daily) or had clotting problems that could prolong bleeding, had an acute or chronic infection, or had disorders in the fingertip lancing areas or other physical, visual, or neurological impairment that would make the subject unable to perform testing with the BGMS.

Study Design

The study was conducted at a single clinical site in the United States (International Diabetes Center, Park Nicollet Institute, Minneapolis, MN) from December 8, 2008, through January 8, 2009. Subjects were scheduled to arrive at the clinic within a 2 hour minimum elapse time after eating, exercising, or taking insulin to ensure a steady state for glucose at the time of the test procedures.

CONTOUR USB meters and three lots of commercially available CONTOUR blood glucose test strips (Bayer HealthCare, LLC, Diabetes Care) were evenly distributed among subjects and HCPs for blood glucose testing. Fifteen meters were used in conjunction with GLUCOFACTS diabetes management software (version 1.05.11). The meter's User Guide and Quick Reference Guide and selected pages from the GLUCOFACTS User Guide were provided to subjects in written form, along with a version of the User Guide uploaded onto the meter.

Testing Procedure

Using the instructional material, subjects were asked to perform an initial setup of the meter, connect the meter to a provided laptop computer, and access the uploaded User Guide and the TRENDS, LOGBOOK, and setup menus on the meter. Subjects and HCPs each performed duplicate blood glucose tests in parallel using a subject- or HCP-dedicated meter, test strips from the same lot, and subject finger stick capillary blood samples. Finger punctures were performed using commercially available Microlet®2 lancing devices and Microlet®2 silicone-coated lancets (Bayer HealthCare LLC, Diabetes Care). For hematocrit determination, a sample for a spun micro-hematocrit (StatSpin, Inc., Norwood, MA) was collected from one of the finger punctures used for blood glucose determinations. Capillary blood samples (400 µl) for a reference laboratory glucose test were obtained by deep finger puncture using Tenderlett® lancing devices (ITC, Edison, NJ) and blood was collected in Microtainer® blood collection tubes (Becton Dickinson, Franklin Lakes, NJ) containing heparin and a gel separator for centrifugation prior to analysis. Laboratory glucose results were obtained in duplicate using a Yellow Springs Instruments (YSI) glucose analyzer (YSI Life Sciences, Inc., Yellow Springs, OH). A set of six control sera, assayed by a method traceable to the National Institute of Standards and Testing and the Centers for Disease Control and Prevention reference method,[11] was used to document accuracy and precision of the laboratory glucose method.

System accuracy was assessed as the percentage of subject results that met minimum acceptable performance criteria given in International Organization for Standardization (ISO) 15197:2003 standard guidelines[12] (i.e., within ±15 mg/dl of the mean YSI reference result for samples with glucose concentrations <75 mg/dl and ±20% for samples ≥75 mg/dl); data were graphically represented as bias plots. The effect of hematocrit on meter bias was determined from regression analysis using all blood samples with glucose concentrations ≥75 mg/dl; biases within ±7% were calculated from subject results. Parkes error grid analysis[13] was used to determine clinical accuracy. Precision was evaluated based on duplicate glucose measurements of finger stick capillary blood samples obtained by both subjects and HCPs.

Approximately half of the subjects (n = 39) used the system at home for 7 to 10 days to determine if there were any issues with longer-term use of the system. Subjects were required to perform a single assay of the normal control solution each day and to measure their blood glucose using self-finger-stick capillary blood a minimum of two times per day. These tests did not replace the normal testing routine of subjects, and subjects were required to continue testing their blood glucose using their usual meter. Because the meter was considered investigational, results of these at-home tests were not used for any diabetes self-management.

Labeling Comprehension

Subject comprehension of instructional material was assessed by HCPs during initial setup and subsequent use of the BGMS. Health care professionals observed subject performance and recorded an overall proficiency rating of 1 through 4 for basic tasks related to blood glucose testing [1 = performed all tests correctly without assistance; 2 = performed all tests correctly when directed to a specific part of the User Guide/Quick Reference Guide by the HCP because of a question; 3 = performed all tests correctly but required HCP verbal assistance or review of a part of the User Guide/Quick Reference Guide; or 4 = incorrectly performed part of the testing regimen and was unaware of the error (required intervention by the HCP)]. Successful completion of a task was defined as a score of 1 through 3. The HCP recorded whether subjects successfully completed specific tasks related to the operation of other system features and the number of attempts that were required. At the conclusion of the initial visit, subjects completed a questionnaire rating the ease-of-use of the system, clarity of the instructional material, and meter features on a scale of 1 (unacceptable) to 5 (excellent), with a rating of 0 indicating no opinion.

Statistical Analyses

A sample size of 75 was chosen in accordance with published recommendations.[14] Regression analyses (including 95% confidence intervals of the slopes and y-intercepts of scatter plots) were used to evaluate the relationship between subject and HCP finger stick results and the YSI laboratory glucose method. For precision measurements, mean, standard deviation, and coefficient of variation (CV) were calculated according to Clinical and Laboratory Standards Institute (CLSI) EP5-A2 guidelines.[15] Average CV was calculated from groups of samples with glucose concentrations less than 126 mg/dl and greater than or equal to 126 mg/dl; the appropriate group was determined by the glucose concentration of the first replicate for each subject. Outliers (determined according to CLSI EP09-A2 guidelines[16]) were included in the calculation for determining the percentage of results within the acceptable limits for accuracy but were not included in statistics calculations for precision.

Results

Subject Disposition

Of 79 subjects who were enrolled, 74 met inclusion/exclusion criteria and completed the study. Subject demographic and clinical characteristics are presented in **Table 1**. Subject ages ranged from 24 to 73 years (median, 55 years). The majority of subjects were female (54%), had type 2 diabetes (72%), and had not used diabetes management software prior to study entry (92%). All subjects had prior experience using a computer for more than email communication.

Labeling Comprehension

All subjects (100%; 74/74) were able to perform a finger stick and blood glucose measurement successfully without intervention by the HCP to demonstrate the procedure. The majority of subjects (96%; 71/74) were successful in obtaining blood glucose results independently, using only the printed instructional materials (ratings of 1 or 2); the remaining 4% (3/74) of subjects required verbal assistance (rating of 3). No subject received a proficiency rating of 4. All subjects were able to successfully connect the meter to and remove it from a laptop computer using the USB port, synchronize the meter date and time with that of the computer, and access data presentations of results stored in the meter memory (**Figure 1**). All subjects successfully utilized additional test mode functions, such as charging via the USB port, turning on the strip port light, navigating meter setup procedures, accessing and viewing the LOGBOOK, and comprehending the data presentation in the TRENDS features. In addition, all subjects were successful in understanding the elements of the data presentation as well as understanding it on their first attempt.

Accuracy

Assessment of system accuracy (**Figure 2**) showed a significant correlation between both subject- and HCP-obtained blood glucose results and the YSI laboratory method [n = 148, coefficient of determination (R^2) = 0.96 for both]. A total of 98.6% of subject and 96.6% of HCP blood glucose results met ISO 15197:2003 system accuracy criteria (**Figure 3**). For samples with glucose concentrations <75 mg/dl, 100% of both subject and HCP results (n = 8 for each) were within 15 mg/dl of the YSI laboratory method; for samples with glucose concentrations ≥75 mg/dl, 90.7% of subject results and 88.6% of HCP results (n = 140 for each) were within 15% of the YSI laboratory method. Meter results by glucose concentration and test strip lot are shown in **Table 2**.

Table 1.
Subject Demographic and Clinical Characteristics

Characteristic	*N* = 74
Median age (range), years	55 (24–73)
Gender, *n* (%)	
Female	40 (54)
Male	34 (46)
Race, *n* (%)	
Caucasian	67 (91)
Black or African American	6 (8)
Asian	1 (1)
Type of diabetes, *n* (%)	
Type 1	21 (28)
Type 2	53 (72)
Education, *n* (%)[a]	
Less than high school	1 (1)
High school	9 (12)
Associate's degree	32 (43)
Bachelor's degree or higher	32 (43)
Length of time testing blood glucose, *n* (%)	
1 to 12 months	4 (5)
1 to 5 years	19 (26)
6 to 10 years	18 (24)
>10 years	33 (45)
Use of diabetes management software, *n* (%)	
Yes	6 (8)
No	68 (92)
Use of electronic devices, *n* (%)	
Cellular phone, iPhone	71 (96)
iPod, other MP3 player	28 (38)
Blackberry/Palm	7 (9)
Gaming devices (Xbox)	15 (20)
USB thumb drive/flash drive	41 (55)
Other	11 (15)

[a] Percentages may not total 100% because of rounding.

Meter bias from the YSI laboratory method was similar across test strip lots and ranged from –2.6% to –0.6% among subjects and from –1.1% to 0.4% among HCPs.

The effect of hematocrit on meter results was assessed using results obtained by subjects using the three test strip lots (**Figure 4**). Regression analysis of the relationship between hematocrit (x axis) and the percentage difference

of the meter result compared with the mean YSI value (y axis, n = 140) was used to calculate the effect of hematocrit on the BGMS result. At hematocrit extremes of 20% and 70%, the effect on the glucose result was –7.1% and +5.4%, respectively, from a mean hematocrit of 42%.

Clinical accuracy results based on the Parkes error grid analyses (**Figure 5**) showed that, compared with the YSI results, 97.3% of both subject and HCP results were within zone A (measurement error classification of no effect on clinical action); less than 3% were within zone B (altered clinical action with little or no effect on clinical outcome). There were no results in zones C, D, or E for either analysis.

Precision

Duplicate glucose readings obtained by subjects and HCPs were used to estimate system precision with subjects' capillary finger stick blood. The CVs ranged from 4.9% to 8.7%, with subject results having less overall variation than HCP results (**Table 3**).

Subject Assessment of the Blood Glucose Monitoring System

All 74 subjects completed a questionnaire that rated features of the BGMS (**Table 4**). The majority (>79%) of subjects rated meter features as "very good" or "excellent," including marking meal results using the AutoLog feature (95.9%), accessing results in memory and blood glucose averages (TRENDS menu; 95.9%), size of the memory (96.0%), and TRENDS data presentation (89.2%). The majority of subjects rated the clarity of the instructional material as "very good" or "excellent" (89.2% and 81.1% for the User Guide and Quick Reference Guide, respectively), and their overall testing experience as "very good" or "excellent" (96.0%). Three subjects

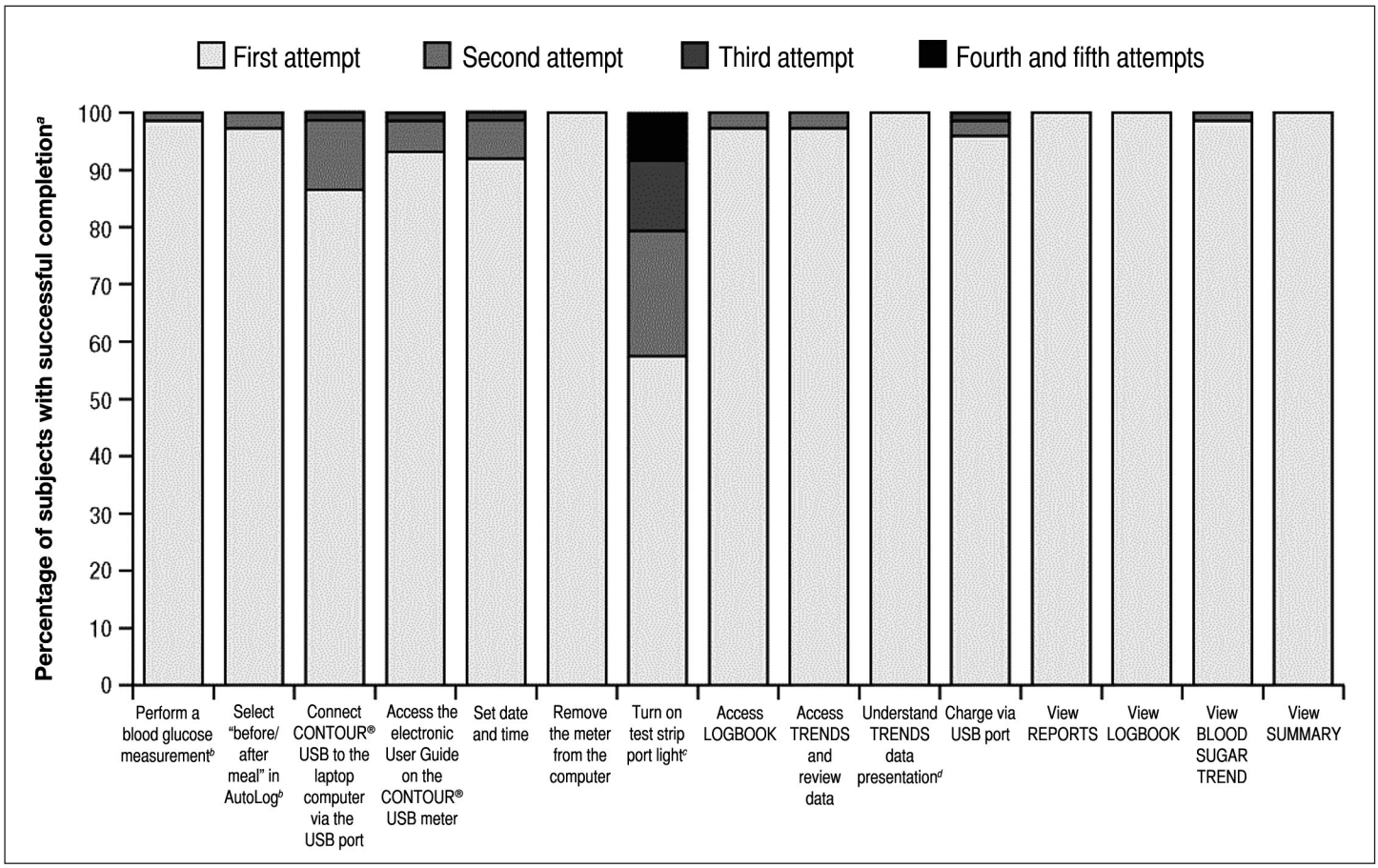

Figure 1. Number of attempts for successful completion of key system operations and features (N = 74). [a]Success was determined by a proficiency rating of 1 through 3 (1 = performed all tests correctly without assistance; 2 = performed all tests correctly but was directed to a specific part of the User Guide/Quick Reference Guide by the HCP because of a subject's question; 3 = performed all tests correctly but required verbal assistance or review of part of the User Guide/Quick Reference Guide with the HCP). [b]n = 72. [c]n = 73. [d]Includes before meal, after meal, and 14-day results with respect to the average glucose value, the number above range setting, the number within range setting, and the number below range setting.

indicated that the system would not meet their testing needs. Their reasons were no autolink for an insulin pump, the meter was too small, and difficulty in using the lancing device (n = 1 for each).

Discussion

In order to maximize the benefit of regular SMBG, patients must not only obtain accurate measurement of their blood glucose levels, but be able to access, interpret, and act upon their daily glucose measurements, as well as their overall glycemic patterns as part of a larger trend over time. Further, SMBG data should be organized and presented in a way that easily allows individuals to interpret their glycemic patterns in a manner that is able to elicit a response from patients if their glucose levels are not consistently within the target range.

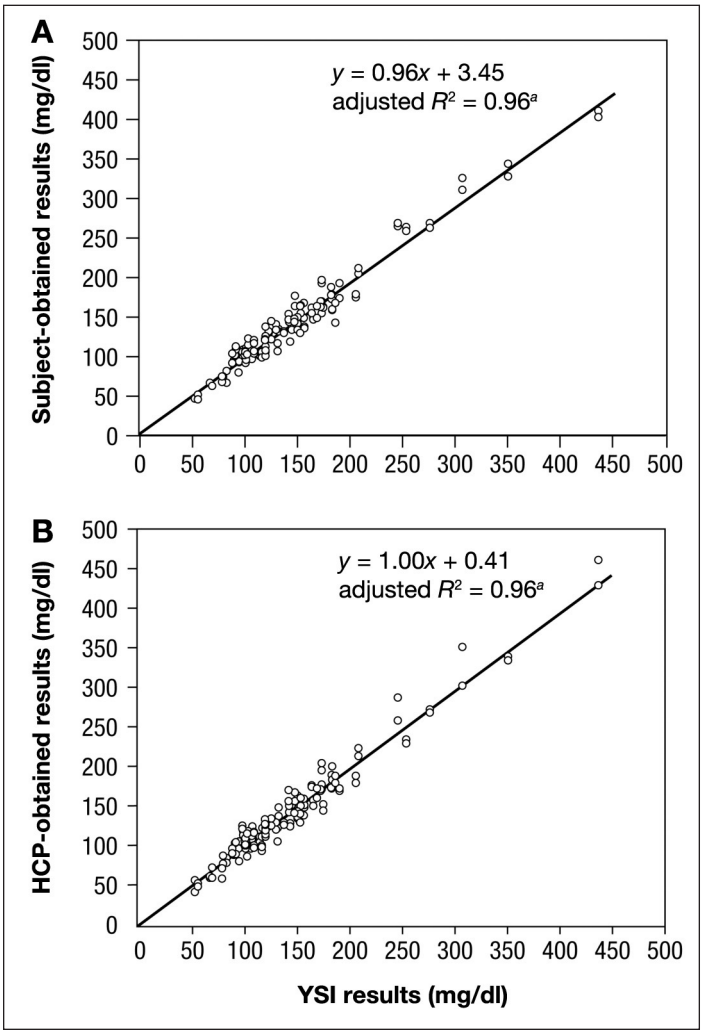

Figure 2. System accuracy. Regression analysis of **(A)** subject- and **(B)** HCP-obtained blood glucose results versus the YSI laboratory method. The regression line derived from the corresponding equation is shown in each panel. [a]Coefficient of determination (R^2) adjusted for sample size.

Improvements in BGMS technology that allow for easy data review and sharing may also help facilitate discussions of SMBG data among patients with diabetes and their HCPs and families, an important component of optimal diabetes management decision making.[17] Use of the proper diabetes management system can enhance the clinical utility of SMBG readings collected over time.[8,9] Despite the advantages, less than one quarter of HCPs routinely upload data from their patients' devices.[9] Two of the major barriers to effective use of SMBG devices in clinical practice have been the use of different proprietary software and connecting cables for each separate meter.[9]

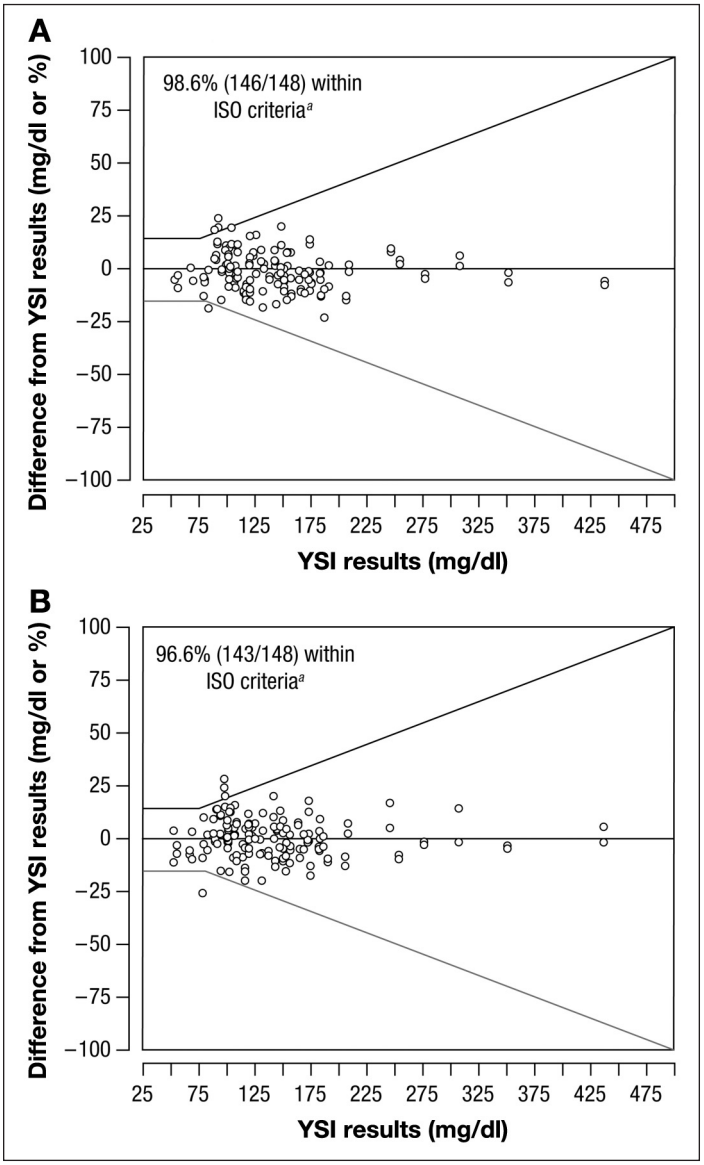

Figure 3. System accuracy. Bias plots for **(A)** subject- and **(B)** HCP-obtained blood glucose results versus the YSI laboratory method. [a]ISO 15197:2003 system accuracy criteria: ±15 mg/dl or ±20% of the mean laboratory-measured blood glucose result for samples with glucose concentrations <75 or ≥75 mg/dl, respectively. Upper and lower lines mark the upper and lower limits of these criteria, respectively.

CONTOUR USB is a new BGMS that couples the accuracy of the CONTOUR blood glucose meter with integrated data management software. This system enables connection of the meter to a computer via USB plug, and because software is contained directly on the meter, patients and HCPs can view SMBG data from any computer at home or in the office setting. This may be especially beneficial in practices that are not devoted specifically to patients with diabetes and that may not have the necessary compatible software or for those who find the installation cumbersome. The meter's software captures pre- and post-meal blood glucose readings and can display results over time, allowing patients to see the impact of treatment decisions and dietary choices on blood glucose levels, and may help them to better understand how their blood glucose levels can fluctuate relative to meals.

In the current study, all subjects were able to understand product labeling and were able to successfully perform blood glucose measurements using the system; 96% of subjects were able to do so using only the written instructional material. All subjects were able to connect

Table 2.
CONTOUR USB Meter Results by Glucose Concentration and Test Strip Lot

Test strip lot and parameter		Glucose concentration by YSI			
	Operator	<75 mg/dl	75–180 mg/dl	>180 mg/dl	All samples
Lot A					
n		2	38	10	50
Mean glucose, mg/dl	YSI	68.7	128.5	245.7	149.5
	Subject	63.0	126.7	233.4	145.5
	HCP	65.5	127.0	243.7	147.9
Difference of sample means (CONTOUR USB–YSI), mg/dl (%)	Subject	-5.7 (-8.3)	-1.8 (-1.4)	-12.3 (-5.0)	-4.0 (-2.7)
	HCP	-3.2 (-4.7)	-1.5 (-1.2)	-2.0 (-0.8)	-1.6 (-1.1)
Lot B					
n		4	36	8	48
Mean glucose, mg/dl	YSI	60.8	128.6	214.0	137.2
	Subject	58.0	124.9	210.3	133.6
	HCP	55.0	130.9	208.1	137.5
Difference of sample means (CONTOUR USB–YSI), mg/dl (%)	Subject	-2.8 (-4.6)	-3.7 (-2.9)	-3.7 (-1.7)	-3.6 (-2.6)
	HCP	-5.8 (-9.5)	2.3 (1.8)	-5.9 (-2.8)	0.3 (0.2)
Lot C					
n		2	40	8	50
Mean glucose, mg/dl	YSI	52.2	115.5	280.4	139.3
	Subject	47.0	116.3	272.8	138.5
	HCP	48.5	115.9	283.1	139.9
Difference of sample means (CONTOUR USB–YSI), mg/dl (%)	Subject	-5.2 (-10.0)	0.8 (0.7)	-7.6 (-2.7)	-0.8 (-0.6)
	HCP	-3.7 (-7.1)	0.4 (0.3)	2.7 (1.0)	0.6 (0.4)
Combined lots					
n		8	114	26	148
Mean glucose, mg/dl	YSI	60.6	124.0	246.6	142.1
	Subject	56.5	122.5	238.4	139.3
	HCP	56.0	124.4	244.9	141.8
Difference of sample means (CONTOUR USB–YSI), mg/dl (%)	Subject	-4.1 (-6.8)	-1.5 (-1.2)	-8.2 (-3.3)	-2.8 (-2.0)
	HCP	-4.6 (-7.6)	0.4 (0.3)	-1.7 (-0.7)	-0.3 (-0.2)

the meter to a laptop computer using the USB port, access the electronic user guide for the meter, and use key features of the integrated diabetes management software.

The system was found to be accurate and precise in the hands of lay users and HCPs. The majority of results from both subjects and HCPs (97.3% for each) were determined to have had no effect on clinical outcome as measured by Parkes error grid analysis, and hematocrit did not significantly affect system performance. Overall, 98.6% of subject results and 96.6% of HCP results met ISO 15197:2003 system performance criteria. For samples with glucose concentrations <75 mg/dl, 100% of both subject and HCP results were within ±15 mg/dl of the YSI laboratory method; for samples with glucose concentrations ≥75 mg/dl, 90.7% of subject results and 88.6% of HCP results were within ±15% of the YSI laboratory method. As several organizations and regulatory agencies are considering tighter accuracy standards at various

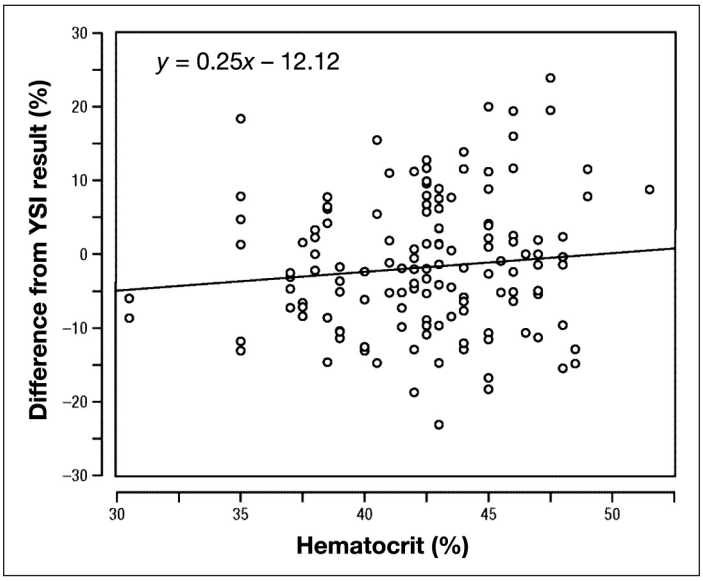

Figure 4. Effect of hematocrit on subject-obtained blood glucose results.

Table 3.
Precision of Subject and Health Care Professional Results[a]

	<126 mg/dl[b] (%CV)	³126 mg/dl[c] (%CV)	All[d] (%CV)
Subject	4.99	5.24	5.12
HCP	8.68	4.90	6.90

[a] Assessed by calculating CVs from duplicate blood glucose measurements. The first replicate result was used to determine whether the glucose concentration of the sample was <126 or ≥126 mg/dl.
[b] Subject, *n* = 36; HCP, *n* = 34.
[c] Subject, *n* = 38; HCP, *n* = 40.
[d] Subject, *n* = 74; HCP, *n* = 74.

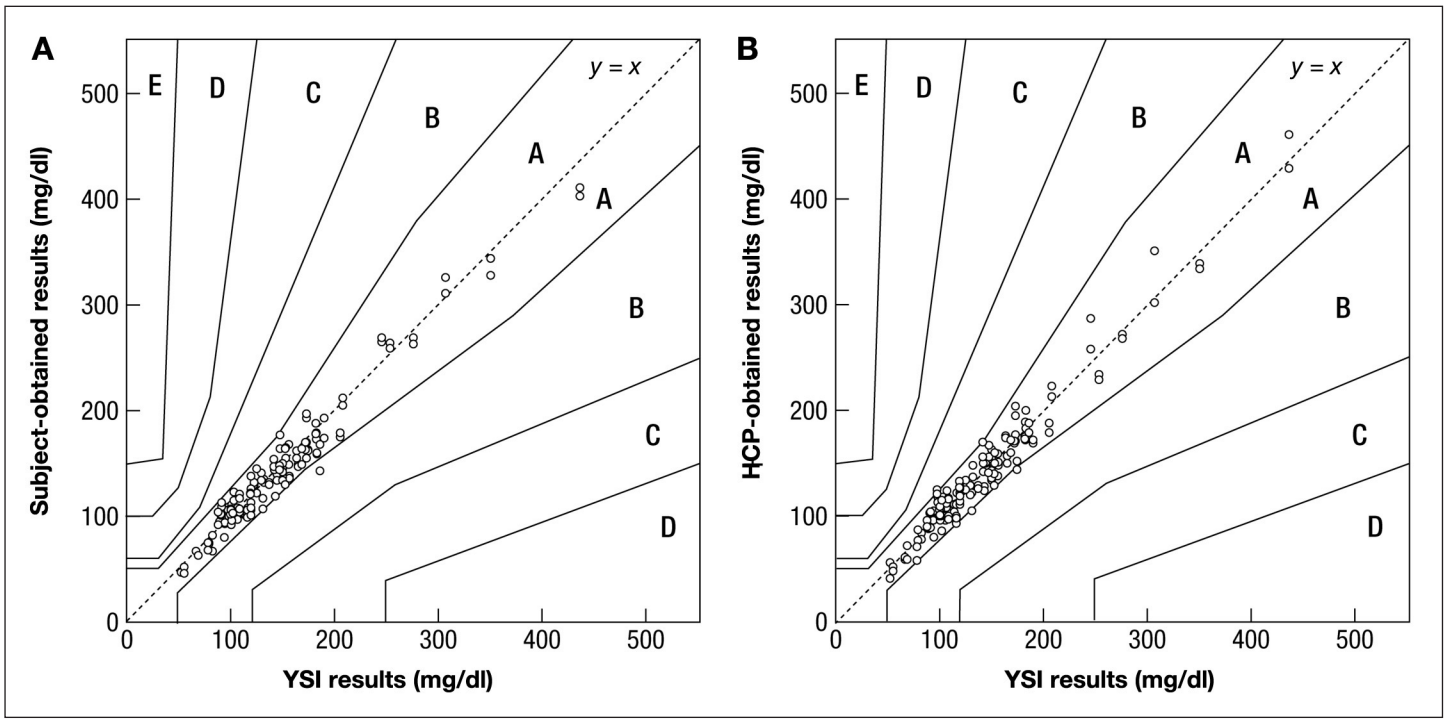

Figure 5. Clinical accuracy. Parkes error grid analyses of **(A)** subject- and **(B)** HCP-obtained blood glucose results versus the YSI laboratory method.

Table 4.
Percentage of Subject Ratings of Key System Features (N = 74)

Meter features, %	Unacceptable	Poor	Good	Very good	Excellent	No opinion
Visual alerts for low and high blood glucose outside target ranges	0	2.7	8.1	33.8	51.4	4.1
Test time (5 s)	0	0	8.1	23.0	68.9	0
Blood glucose range (20–600 mg/dl)	0	0	10.8	20.3	66.2	2.7
Sample size required (0.6 µl)	0	1.4	5.4	18.9	74.3	1.4
Autocoding (no coding required)[a]	0	0	4.1	11.0	83.6	1.4
Autodetection of control solution[a]	0	0	5.5	19.2	71.2	4.1
Ease of setting date and time	0	0	5.4	40.5	54.1	0
Ease of marking before meal and after meal results using AutoLog feature	0	0	4.1	32.4	63.5	0
Ease of accessing memory and blood glucose averages (TRENDS menu)	0	0	2.7	37.8	58.1	1.4
Usefulness of the TRENDS data presentation	0	0	8.1	39.2	50.0	2.7
Ability to adjust target ranges in setup menu	0	0	1.4	43.2	54.1	1.4
Lighted test strip port[a]	0	1.4	11.0	27.4	54.8	5.5
Benefit of the alarm icon for understanding a reminder was set	0	2.7	13.5	32.4	47.3	4.1
Size of memory (2000 results)	0	0	4.1	17.6	78.4	0

[a] n = 73.

glucose ranges for blood glucose monitoring devices than the current ISO 15197:2003 guidelines,[18–20] it will become increasingly important for technology to deliver accurate blood glucose meters in light of the more stringent criteria that may emerge and also to enable patients to readily use devices to obtain optimal results to help manage their diabetes.

Conclusion

The coupling of blood glucose meter accuracy and meter usability as well as data access is important in diabetes management for patients and their HCPs. Advances in BGMS accuracy and precision as well as technological innovation for data access will best be utilized when incorporated into a user-friendly device. Findings from this study showed that CONTOUR USB exceeded ISO 15197:2003 system performance criteria in the hands of untrained lay users. Subjects understood the product labeling, found the system easy to use, performed blood glucose testing successfully, and understood the glucose data presentation; the majority of subjects rated features of the system as "very good" or "excellent." These results suggest that technological features of the new CONTOUR USB system may facilitate collection, organization, and understanding of SMBG data and enable patients with diabetes to review results more easily with their HCP and actively manage their disease.

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John Baum, Scott Pardo, Carmine Greene, Joan Parkes, and Holly Schachner are full-time employees of Bayer HealthCare LLC, Diabetes Care, Tarrytown, NY. Susan M. List is a senior research clinician at the International Diabetes Center in Minneapolis, MN, and has stock ownership in Eli Lilly and Company, a primary manufacturer of insulin in the United States. Robert Cuddihy serves as principal investigator or co-investigator for sponsored clinical trials research for Amylin, Abbott, Bayer, Daiichi–Sankyo, DexCom, Edwards Lifesciences, Eli Lilly, Hygeia, Intarcia, Johnson & Johnson/Lifescan, Mannkind, Medtronic, Merck, Novo Nordisk, Quotient Diagnostics, ResMed, Roche, sanofi-aventis, Takeda, and Valeritas; he serves as an advisory board member for Abbott, Bayer, CeQur, Eli Lilly, Novo Nordisk, and Roche; he provides support for educational activities for Lifescan, Eli Lilly, Merck, Novartis, and sanofi-aventis. Robert Cuddihy receives no personal payments for any of these activities; all honoraria, speaking fees, consulting fees, and research and educational support were paid directly to the nonprofit International Diabetes Center, of which he was a salaried employee when the study was conducted. He has since left the institution. Nykole Starks was a full-time employee of the International Diabetes Center (Minneapolis, MN) when the study was conducted but has since left the institution.

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