

# Patient and Health-care Professional Satisfaction with a New, Simple, High Accuracy Blood Glucose Meter with Color Range Indicator

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## Abstract

**Background:** Accurate self-monitoring of blood glucose (BG) is a key component of effective self-management of glycemic control. **Methods:** The OneTouch Select Plus Simple™ (OTSPS) BG monitoring system (BGMS) was evaluated for accuracy in a clinical setting. **Results:** OTSPS was accurate over a wide glucose range and met lay user and system accuracy BG standards described in ISO 15197:2013. Patients also used OTSPS for a 1-week trial period and reported their level of satisfaction with meter features. In a separate study, health-care professionals (HCPs) in India naïve to OTSPS experienced OTSPS online using a variety of interactive demonstrations of the BGMS and answered questions about its potential utility to their patients. **Summary:** Patients and HCPs felt the features of OTSPS, including a color range indicator, could provide significant benefits to them and their patients.

**Keywords:** Accuracy, blood glucose, blood glucose meter, blood glucose strips, self-monitoring of blood glucose

## INTRODUCTION

Self-monitoring of blood glucose (SMBG) is recognized as an integral part of diabetes care management in people with Type 1 diabetes (T1D) and Type 2 diabetes (T2D) and provides valuable information for helping them achieve and maintain glycemic control.<sup>[1-4]</sup> In addition, accurate SMBG results are required for optimal insulin dosing and detection of hypoglycemia.<sup>[5-7]</sup>

The current study evaluated the accuracy of a new BG monitoring system (BGMS) in patients with diabetes according to the International Organization for Standardization SMBG standard, ISO 15197:2013(E).<sup>[8]</sup> Patients also used the BGMS in a home setting to evaluate their satisfaction with the meter. In a separate study, health-care professionals (HCPs) in India used the online methodology, including interactive product simulators, video clips of the device, and multiple web pages with descriptive content to gain experience with the system before answering satisfaction questions.

## MATERIALS AND METHODS

### OneTouch Select Plus Simple™ blood glucose monitoring system

The simple-to-use meter has a small and slim design and a large visual display with big, easy-to-read numbers [Figure 1]. The meter automatically lets a patient know if their result is below, above, or within a target glucose range by displaying the current result with a range indicator arrow (ColorSure™ Technology) pointing to a corresponding color bar below the meter display [Figure 1]. The meter also emits a fast audible beep when the BG result is low and a slow audible beep when the BG result is high for an added level of safety. The system comes with a reference card that the doctor can fill out with reminders of the steps a patient may take based on their BG results.

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OneTouch Select Plus Simple™ (OTSPS) is intended for self-testing by people with diabetes as an aid to monitor the effectiveness of diabetes control. It provides glucose results over the range of 20–600 mg/dl within a hematocrit range of 30%–55% and an operating temperature range of 10°C–44°C without the need for user calibration coding. The meter uses OneTouch Select Plus® test strips, which use an electrochemical assay method based on the enzyme glucose oxidase.<sup>[9]</sup>

## Materials

Sponsor provided OTSPS meters (LifeScan Inc., Wayne, PA, USA), Owner's Guides, and auto-disabling BD Microtainer® lancing devices and lancets. In addition, sponsor provided 3 lots of production-equivalent select plus test strips randomly sourced and sequestered from the supply chain. Yellow Springs Instruments (YSI) 2300 Stat Plus Select Biochemistry Analyzers (YSI Inc., Yellow Springs, OH, USA) were used as the reference BG measuring device.

## Clinical accuracy study design and methodology

This was a multicenter, single-arm, nonrandomized study in 173 subjects aged ≥12 years with a current diagnosis of T1D or T2D currently performing unassisted SMBG. Clinical evaluations were conducted at 3 UK National Health Service clinical sites: Royal Infirmary of Edinburgh, Birmingham Heartlands Hospital and Highlands Diabetes Institute, Inverness, and one contracted clinic (BioKinetic Europe, Belfast, Northern Ireland). Of the 173 subjects, 160 participated in lay user accuracy testing; 100 participated in system accuracy testing; and 59 completed a user acceptance evaluation survey after completing home use.

Clinical studies were performed in compliance with all legal and ethical requirements and standards. Protocols were approved by the responsible ethical review committees and all participants gave written informed consent before study

procedures. BG samples were collected by finger stick and were conducted by technicians qualified to perform capillary draws and laboratory testing.

Study protocol consisted of two site visits with up to a 1-week home use period between visits. During the first site visit, lay user and system accuracy testing were performed. A subset of subjects was issued a home testing kit and was asked to conduct regular SMBG at home for up to 1 week. On returning to the clinic, subjects completed a user acceptance survey consisting of statements about the ease of use of the meter and its potential benefits. Answers were given on a 5-point scale (5 = strongly agree; 4 = agree; 3 = neither agree nor disagree; 2 = disagree; 1 = strongly disagree).

## Lay user accuracy testing

Self-testing was performed by subjects with SMBG experience; however, no previous experience with OTSPS was permitted. Subjects lanced a fingertip and performed a self-test using the BGMS and a test strip from the assigned lot. Study staff collected blood from the same finger puncture for hematocrit and reference plasma glucose testing.

## System accuracy testing

System accuracy evaluation of the BGMS was conducted immediately following lay user testing to avoid influencing subject performance in the latter. Study staff lanced a different subject fingertip; collected blood for YSI reference plasma glucose testing; and applied blood onto strips in 6 OTSPS meters and two control meters. Finally, study staff collected blood from the same lancing for a second YSI reference plasma glucose testing.

Blood samples were collected to meet glucose distribution bins described in ISO 15197:2013(E) [Table 1].<sup>[10]</sup> When necessary to obtain samples with very high or very low glucose concentrations, samples were adjusted upward by adding a small volume of concentrated glucose solution (bins 6–7) or downward by allowing endogenous glycolysis to occur at room temperature (bins 1–2).

## Acceptance criteria

To determine bias, fingertip test results were compared to the reference method (YSI) and assessed according to the ISO 15197:2013(E) criteria.<sup>[8]</sup>



**Figure 1:** OneTouch Select Plus Simple™ blood glucose monitoring system components. An arrow pointing to the color bar on the meter casing indicates if the current blood glucose result is below (blue bar), in-range (green bar), or above (red bar) a target blood glucose range. The system uses OneTouch Select Plus blood glucose test strips and Delica lancing devices and contains a Reference Information Card in the system kit that has space for health-care professionals to write instructions and advice to their patients

**Table 1: Distribution of blood glucose concentrations obtained for system accuracy evaluation**

Bin number	Glucose range (mg/dl)	n	Percentage
1	≤50	5	5
2	>50-80	15	15
3	>80-120	20	20
4	>120-200	30	30
5	>200-300	15	15
6	>300-400	10	10
7	>400	5	5
Total		100	100

Ninety-five percent of the measured glucose values shall fall within either  $\pm 15$  mg/dl of the average measured values of the reference measurement procedure at glucose concentrations  $< 100$  mg/dl or within  $\pm 15\%$  at glucose concentrations  $\geq 100$  mg/dl.

Ninety-nine percent of individual glucose measured values shall fall within zones A and B of the consensus error grid for T1D.

**Health-care professional study**

In total, 50 HCPs in India (30 endocrinologists, 8 primary care physicians [PCPs], 7 certified diabetes educators [CDEs], and 5 pharmacists) were asked to evaluate the OTSPS BGMS using an online experience that included a meter simulation that provided identical functionality in terms of capability, functions, and navigation to the intended product. The OTSPS BGMS simulator was preloaded with representative low, in-range, and high BG results or information to ensure that meter screens could accurately provide an illustration of what these screens would show when HCPs (or patients) review information on this BGMS in actual use. HCPs interacted online digitally with a series of 19 web pages displaying both text and visual images of the new meter, with embedded links at certain points automatically transporting the HCP to a hands-on (via mouse) interaction with an OTSPS simulator. In addition, HCPs viewed two product videos showing real-time meter setup and routine glucose testing [Figure 2]. Clinical practice questions were completed before the online experience section and 25 survey questions were presented during the experience to determine HCP opinion of the potential value of various functions and features of the BGMS to them and their patients. An external vendor (Ipsos InnoQuest, Parsippany, NJ, USA) managed the study in terms of recruitment of HCPs and study execution.

**RESULTS**

**Lay user accuracy**

Totally, 160 subjects participated in the lay user accuracy evaluation, including 66 (41%) females and 94 (59%)

males. The mean and median age was 51.0 and 54.6 years, respectively, with a range of 14–79 years; 46% of subjects had T1D, and 54% had T2D; 81% were taking insulin either by bolus or by insulin pump. The mean time since diabetes diagnosis was 17.1 years with a range of 0.2–60 years. Patients were experienced SMBG users with a median frequency of 3 tests/day (range 0.03–10 tests/day).

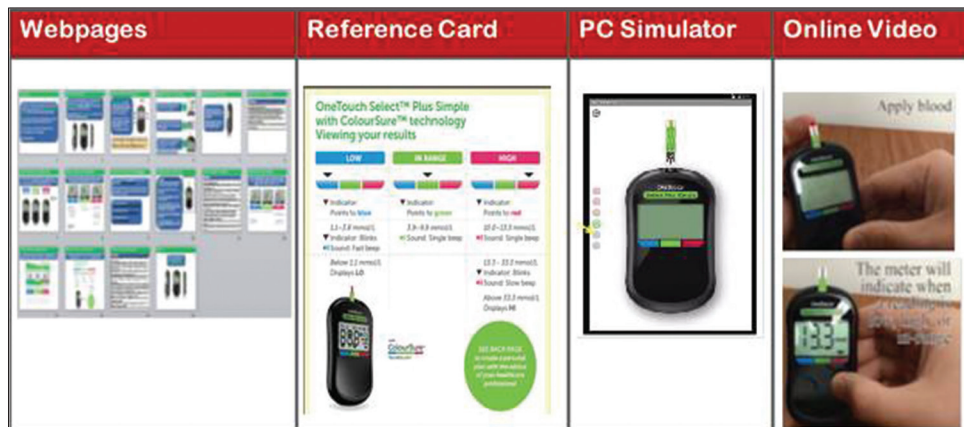
Table 2 summarizes lay user accuracy results across all 3 lots tested. ISO 15197:2013(E) accuracy criteria were met when all glucose values were taken together with 95.0% (152/160) of results within the acceptance criteria. Although not required to meet ISO 15197:2013(E) accuracy specifications, the guideline stipulates that results  $\geq 100$  mg/dl and  $< 100$  mg/dl be described. 96.6% (28/29) of BG results  $< 100$  mg/dl had a bias within the  $\pm 15$  mg/dl limit, and 94.7% (124/131) of BG results  $\geq 100$  mg/dl had a bias within the  $\pm 15\%$  limit.

Table 3 shows the favorable response rates to the statements presented to the 59 subjects who took the user acceptance

**Table 2: Clinical accuracy of OneTouch Select Plus Simple blood glucose monitoring system**

	$< 100$ mg/dl ( $\pm 15$ mg/dl)	$\geq 100$ mg/dl ( $\pm 15\%$ )	All glucose values ( $\pm 15$ mg/dl or $\pm 15\%$ )
Lay user accuracy			
3 lots	96.6% (28/29)	94.7% (124/131)	95.0% (152/160)
System accuracy			
Lot A	100% (56/56)	99.3% (143/144)	99.5% (199/200)
Lot B	98.2% (55/56)	99.3% (143/144)	99.0% (198/200)
Lot C	100% (56/56)	98.6% (142/144)	99.0% (198/200)
3 Lots	99.4% (167/168)	99.1% (428/432)	99.2% (595/600)

Data shown for system accuracy are from duplicate samples in 3 batches in 100 subjects in all lots tested using 100 mg/dl as cutoff point (ISO 15197:2013 criteria). Data shown for lay user accuracy are from patient administered finger sticks in 160 subjects using 100 mg/dl as cutoff point (ISO 15197:2013 criteria)



**Figure 2:** Methodology for health-care professional study. Health-care professionals interacted online with web pages describing features of the OneTouch Select Plus Simple meter; a reference card which is contained in the meter kit; an interactive simulation of use of the meter; and an online video demonstrating the proper use and features of the meter

**Table 3: Subject user acceptance responses to survey statements regarding use of the OneTouch Select Plus Simple™ Meter**

Statement	Favorable response percentage
This meter is so straightforward; I could use it right out of the box	97
This meter is a simple first step to understand my blood sugar results	97
This easy-to-understand ColorSure Technology could support me to know when to act on my BG results	97
This meter helps tell me when I may need to act and when I may be good to go	95
This easy-to-understand ColorSure Technology helps me to know when I may need to act on my BG results	93
Small, slim design with large, easy-to-read numbers helps OneTouch Select Plus Simple fit into my life	93
With this meter, I can feel reassured because I can see and hear if I may need to act	93
With ColorSure Technology to help me understand my numbers, a beep to tell me when I need to take action, and reference card guide, I feel reassured with this meter	92
I feel reassured using this meter because of the ColorSure Technology and audio signals, and it is so simple and easy to use right out of the box	90
The audio signal makes it clear when my results are high or low so that I can consider when to take action	90
With this meter, I can feel secure because I can see and hear when I may need to act	90
ColorSure Technology shows me when I am in range (green) and gives positive feedback which helps to keep me on track	88
This meter brings clear understanding of results with sight and sound	88
I feel a sense of security using this meter because of the ColorSure Technology, the audio signals, and it is so simple and easy to use right out of the box	86
This meter provides me with the added reassurance of understanding my BG numbers and confidence about managing my diabetes	86
The fast beep makes me aware that I may need to take action for low glucose levels	86
This meter provides me with the added security of understanding my BG numbers and reassurance about managing my diabetes	85
The slow beep makes me aware that I may need to take action for high glucose levels	85
Reassurance from understanding, confidence in managing my diabetes	85
I feel secure about managing my diabetes when using this meter because it has ColorSure Technology and audio signals	83
Security from understanding, confidence in managing my diabetes	83
Using a meter with ColorSure Technology helps me feel more secure about managing my blood sugar levels than a meter without ColorSure Technology	83
This meter with ColorSure Technology helps me feel more confident about managing my diabetes than numbers alone	83
In less than a week, this meter helped me feel confident about managing my diabetes	81
I would recommend this meter to others	81
Recommendations from my HCP written in my reference card guide could help me make the right decisions about my BG results	78
Recommendations from my HCP written in my reference card guide could help me know what to do next	78

Favorable responses are defined as a response of “strongly agree” or “agree” on a 5-point scale (5=strongly agree; 4=agree; 3=neither agree nor disagree; 2=disagree; and 1=strongly disagree). All favorable responses are statistically significant (95% CL >50%), ( $n=59$ ). HCP: Health-care professional, CL: Confidence limits, BG: Blood glucose

evaluation survey after the OTSPS home use. Key findings include 97% of subjects strongly agreeing or agreeing that “the meter is so straight forward, I could use it right out of the box,” and “the easy to understand ColorSure Technology could support me to know when to act on by BG results.” Ninety-two percent of subjects strongly agreed or agreed that “with ColorSure Technology to help me understand my numbers, a beep to tell me when I need to take action, and Reference Card guide, I feel reassured with this meter.”

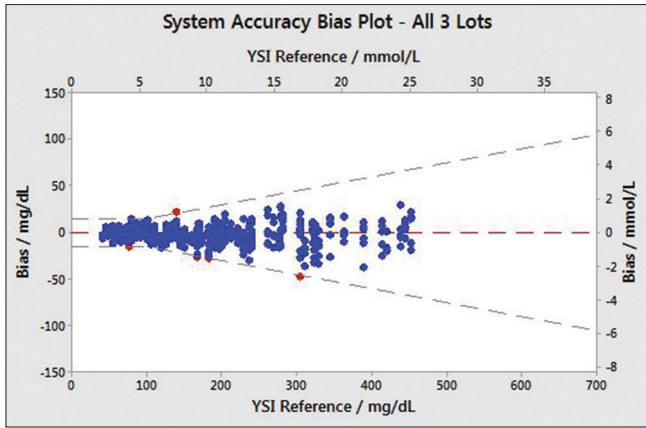
### System accuracy

Table 2 summarizes system accuracy results across all 3 lots tested. ISO 15197:2013(E) accuracy criteria were met with 99.2% of results within the acceptance criteria (all lots) and when each lot was analyzed individually. Using a cutoff point of 100 mg/dl, 99.4% of BG results <100 mg/dl were within a

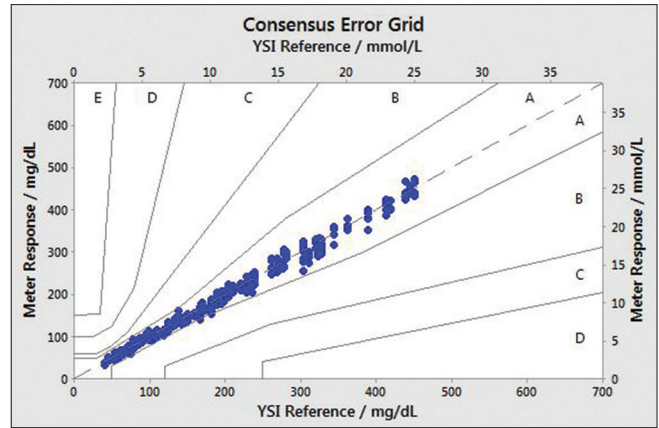
bias of  $\pm 15$  mg/dl and 99.1% of results  $\geq 100$  mg/dl had a bias within the  $\pm 15\%$  limit. Similar results were seen when each lot was analyzed individually, and in all cases, ISO 15197:2013(E) accuracy criteria were met. Seven total samples in bins 1, 6, and 7 were adjusted to meet glucose frequency distributions.

Figure 3 shows the system accuracy glucose bias plot obtained with OTSPS and the corresponding YSI reference glucose concentration results. 99.2% of the values fell within the accuracy threshold limits of  $\pm 15$  mg/dl at glucose concentrations <100 mg/dl and  $\pm 15\%$  at glucose concentrations  $\geq 100$  mg/dl.

Linear regression analysis for each individual lot and all 3 lots taken together showed a highly significant correlation between the BG observed with OTSPS and the reference standard (YSI) values. Slope for all 3 lots was 1.00 (0.99–1.00; 95% confidence interval) with a correlation coefficient ( $R^2$ ) of 0.99.



**Figure 3:** System accuracy blood glucose bias plot. Accuracy limit lines are  $\pm 15$  mg/dl ( $< 100$  mg/dl) or  $\pm 15\%$  ( $\geq 100$  mg/dl). 99.2% (595/600) of glucose results (200 per test lot  $\times$  3 lots) (blue dots) fell within the accuracy limit lines. Red dots (5/600) represent results outside the accuracy limit lines. YSI: Yellow Springs Instruments



**Figure 4:** Consensus error grid plot glucose plot.  $n = 600$  data points (200 per test lot  $\times$  3 lots). 599 data points (99.8%) in zone A (blue dots). 1 data point (0.2%) in zone B (red dot). YSI: Yellow Springs Instruments

The consensus error grid is a plot of BGMS results (y-axis) versus the corresponding reference results (x-axis) that is overlaid with a grid that divides the plot into zones.<sup>[10,11]</sup> Each zone signifies the degree of clinical risk posed to a T1D user obtaining an incorrect measurement on their BG meter. For system accuracy testing, 99.8% of individual glucose values for OTSPS fell within zone A (no effect on the clinical action) and 0.2% fell within zone B (little or no effect on clinical outcomes) of the consensus error grid [Figure 4]. For lay user performance testing, the corresponding values were 95.6% (153/160) in zone A and 4.4% (7/160) in zone B.

### Safety and tolerability

No adverse events were observed. Anticipated, some subjects experienced transient mild pain at the site of lancing during the lancing procedure.

### Health-care professional study

Fifty HCPs practicing in India participated in the study. HCPs had been in clinical practice with a median of 11 (endocrinologists), 14 (PCPs), 9 (CDEs), and 11 (pharmacists) years and saw a median of 45–60 patients with diabetes per week. These include a mean of between 21% and 32% of patients with T1D with a mean of 55% of all their patients with diabetes taking insulin either alone or in conjunction with oral medication.

Each HCP spent approximately 30–60 min reading web content, experiencing the meter simulator, viewing the product demo video, and responding to survey questions. The results of 4 clinical practice questions completed before the online experience are shown in Table 4. Results from the additional 25 survey questions are shown in Table 5. Key favorable response findings included 94% strongly agreeing or agreeing that with security from understanding their BG results, patients will feel confident in managing their diabetes; 90% agreeing or strongly agreeing that patients will feel reassured using this meter because of the ColorSure Technology, audio signals, and

**Table 4: Health-care professional response to clinical practice questions**

Question	Responses	Percentage
How aware do you think most of your patients are about what represents a low, in-range, or high glucose result when testing at home with their current meter?	Very aware or aware	64
How would you describe the ability of most of your patients to immediately recognize when a result is either low, in-range or high when testing at home with their current meter?	Very easy or easy	42
In terms of keeping their BG results in-range, how often do you provide your patients with specific target levels for their glucose results?	Every time or most times	88
How confident are you that your patients always take action when they get a low or a high glucose result when testing at home?	Very confident or confident	40

HCPs included 30 endocrinologists, 8 primary care physicians, 7 certified diabetes educators, and 5 pharmacists. Responses shown were the top two responses on a 5-point scale in which response 3 was neutral (e.g., neither aware nor unaware) and responses 4 and 5 were negative (e.g., unaware or very unaware). HCPs: Health-care professionals, BG: Blood glucose

it is so simple and easy to use right out of the box; and 86% agreeing or strongly agreeing that with this meter, patients can feel secure because they can see and hear when they may need to act.

### DISCUSSION

A symposium on BG monitoring highlighted the importance of measurement accuracy and precision for all patients using SMBG.<sup>[12]</sup> In the current clinical evaluation, using finger stick capillary blood obtained from a patient by a trained medical assistant and finger stick capillary blood obtained by the patient themselves, OTSPS met ISO 15197:2013(E) accuracy criteria. The accuracy criteria specified in the ISO

**Table 5: Health-care professional responses to survey statements on OneTouch Select Plus Simple™ Meter following an interactive experience with a simulated meter**

Statement	Favorable response percentage
With security from understanding their BG results, patients will feel confident in managing their diabetes	94
CST shows patients when they are in range (green) and gives positive feedback which may help to keep them on track	90
Patients will feel reassured using this meter because of the CST, audio signals, and it is so simple and easy to use right out of the box	90
Recommendations from me, written in the reference card guide could help my patients know what to do next	88
This meter with CST helps patients feel more confident about managing their diabetes than numbers alone	86
With this meter, patients can feel secure because they can see and hear when they may need to act	86
With CST to help them understand their numbers, a beep to tell them when they may need to take action, and reference card guide, patients can feel reassured with this meter	86
This meter helps tell patients when they may need to act and when they may be good to go	86
The small and slim design with large, easy-to-read numbers will help this meter fit into my patient's life	84
Easy-to-understand CST could support patients to know when to act on their BG results	84
Patients would feel secure when using this meter because it has CST and audio signals	84
With this meter, patients can feel reassured because they can see and hear if they may need to act	84
This meter provides patients with the added security of understanding their BG numbers and reassurance about managing their diabetes	84
The meter is so straight forward, it could be used right out of the box without any additional instruction from me	82
This meter will help patients to feel confident about their BG result/about managing their diabetes, they just insert a test strip to get started	82
Easy-to-understand CST helps patients to know when they may need to act on their BG results	82
Patients will feel a sense of security using this meter because of the CST, audio signals, and it is so simple and easy to use right out of the box	82
The audio signal makes it clear when results are high or low so that patients can consider when to take action	82
Recommendations from me written in the reference card guide could help my patients make the right decisions about their BG results	82
This meter is so simple, the majority of my patients could start using it without additional training	80
Using a meter with CST helps patients feel more secure about managing their blood sugar levels than a meter without CST	80
This meter provides patients with the added reassurance of understanding their BG numbers and confidence about managing their diabetes	80
This meter brings clear understanding of results for my patients with sight and sound	78
With the reassurance from understanding their BG results, patients will feel confident in managing their diabetes	78
The meter is a simple first step to understand blood sugar results	74

HCPs included 30 endocrinologists, 8 primary care physicians, 7 certified diabetes educators, and 5 pharmacists. Favorable responses are defined as a response of "strongly agree" or "agree" on a 5-point scale (5=strongly agree; 4=agree; 3=neither agree nor disagree; 2=disagree; and 1=strongly disagree). All favorable responses are statistically significant (95% CL >50%), (n=50). CL: Confidence limits, HCPs: Health-care professional, BG: Blood glucose, CST: Color Sure™ Technology

15197:2013(E) guideline are used for regulatory clearance in India and countries in the EU. Regression analysis of OTSPS results against results using the YSI reference standard showed a strongly significant linear correlation for both system and lay user accuracy testing. In addition, nearly, all of the bias results fell within Zone A on a consensus error grid for (type 1 diabetes mellitus [T1DM]), meaning that the error associated with the use of this BGMS would be expected to have no effect on clinical outcomes.

Many people with diabetes are looking for quick, easy-to-understand information about their blood sugar results. The OTSPS BGMS offers a simple, accurate, and easy-to-use meter in a compact design with a large visual display. In addition, it has a simple color range indicator utilizing ColorSure™ Technology that informs patients at the time of testing whether their BG readings are low, in-range, or high. Patients using this meter felt strongly that these features

would be of potential benefit to them. They felt that the meter would bring a clear understanding of glucose results using sight (color) and sound (audible fast or slow beeps). In addition, most patients agreed that the use of color to identify where results fell in relationship to a target BG range would help them feel more confident and reassured about managing their diabetes. Although it is possible that patients might want to please the study staff and hence give a higher score, the study was conducted at independent clinic sites and facilitated by study staff who were not sponsor employees and were trained to be impartial. Patients were encouraged by study staff to offer their genuine feedback and were given sufficient time and space to complete the survey. In addition, the survey offered space to collect open feedback prefaced with the question, "Do you have an opinion to share? We'd really like to hear it. Your opinions and comments help us make improvements to future products and better meet your needs."

HCPs taking part in a simulated version of the BGMS felt that the features would be of benefit to their patients. Only 42% of the HCPs believed that most of their patients could easily or very easily recognize whether their results were within their target range when testing at home with their current meter. This is despite 88% of the HCPs stating that they provide their patients with specific target ranges every time or most times when they come into the office. Moreover, most of the HCPs were not confident that their patients took action when they got a low or a high glucose result when testing at home. The use of a color range indicator should increase the ability of patients to recognize whether their BG results are within a target range, and the audible beep, when their results are low or high, should increase the likelihood that they will take some action after receiving their glucose results.

HCPs who participated in the simulated version of the BGSM felt that it was so straightforward it could be used right out of the box without any additional instruction from them. The lack of any button or setup was seen as contributing to the ease of use. Nine out of ten HCPs felt that the positive feedback of showing patients when they are in range may help them keep on track in their diabetes management between doctor visits. The addition of a reference card was seen by the HCPs as a positive addition. They responded strongly that recommendations from them written in the reference card guide could help their patients make the right decisions about their BG results and know what to do next. In addition, with color to help them understand their numbers, a beep to tell them when they may need to take action and reference card guide instructions, patients could feel reassured with this meter.

Recently, Zikmund-Fisher *et al.*<sup>[13]</sup> reported that numeracy and literacy independently predict the ability of patients to identify out-of-range test results. In addition, poor numeracy skills have been associated with a worse glycemic control in patients with T1DM.<sup>[14]</sup> A high percentage of the HCPs experiencing the meter simulation agreed that the meter may provide an extra benefit for patients with low numeracy or low education who may struggle to interpret glucose results.

## CONCLUSION

The OTSPS meter is accurate over a wide range of BG levels in the laboratory and clinical settings. In all cases, results met ISO 15197:2013 criteria for acceptable BGMS performance. After home use in patients with diabetes and after a simulation experience by HCPs, both groups felt that the features of the system could help in the management of BG.

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## Conflicts of interest

Laurence B. Katz, Mike Grady, Lorna Stewart, Hilary Cameron and Pamela A. Anderson are employees of LifeScan Inc., a subsidiary of Johnson and Johnson. Anish Desai is an employee of Johnson & Johnson.

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