

Ease of use of the OneTouch® UltraSmart™ Blood Glucose Monitoring System by patients with diabetes

Abstract

The OneTouch® UltraSmart™ Blood Glucose Monitoring System is intended for use by patients with diabetes for self-monitoring of blood glucose (SMBG) in fresh capillary whole blood. The OneTouch® UltraSmart™ System combines accurate quantitative measurement of blood glucose¹ with the FastFacts™ feature, which offers a variety of functions for data storage (insulin and oral medication doses, food intake, amount of exercise, illness) and data management (glucose averages and graphs). This report presents the results of a study designed to assess the OneTouch® UltraSmart™ System's ease of use, based on feedback from patients with diabetes who are experienced in SMBG but who have had no prior experience with the OneTouch® UltraSmart™ System. During a two-week familiarization period, 61 patients performed three daily self-tests with the OneTouch® UltraSmart™ System and recorded their monitoring activities on daily log sheets. At the end of this period, each patient completed two questionnaires, one to evaluate the ease of use of the OneTouch® UltraSmart™ System and the other to compare the OneTouch® UltraSmart™ System with the patient's current SMBG system. Analyses of patients' responses indicate that the OneTouch® UltraSmart™ System is a user-friendly, easy-to-learn, and easy-to-use system. A majority of patients gave favorable ratings to several FastFacts™ functions, including the electronic logbook and the blood glucose track/trend functions. In all comparisons with their current SMBG systems, patients expressed a significant preference for the OneTouch® UltraSmart™ System.

Objective

This study was designed to evaluate various aspects of the OneTouch® UltraSmart™ System (including overall ease of use, frequency of use of FastFacts™ data functions, and preference between OneTouch® UltraSmart™ and current SMBG systems) in the hands of patients with diabetes.

Methods

Overview of study design

Following a two-week familiarization period with the OneTouch® UltraSmart™ System, patients with diabetes provided critical feedback on their experiences with the system in the form of daily log sheets and end-of-study questionnaires.

Clinical sites

Three sites in different geographic areas of the United States were used for the study:

- Henry Ford Health System, Detroit, Michigan
- Atlanta Diabetes Associates, Atlanta, Georgia
- New England Diabetes and Endocrinology Center, Waltham, Massachusetts

Participants

Sixty-one (61) participants completed the study. Demographics for the study population are summarized in Table 1. Inclusion criteria included:

- Diagnosed with Type 1 or Type 2 diabetes
- Currently performing SMBG at least three times per day
- Currently recording medication or other information daily in a logbook, notebook, or meter memory

Procedure

At each site, the study was conducted in three parts:

Site visit 1

After completing informed consent and demographics forms, each patient received a OneTouch® UltraSmart™ System (meter, test strips, control solution, lancing device, lancets, and labeling) and was briefed on the home testing requirements. Patients were instructed to refer to the labeling to learn how to perform home testing tasks but received no training on use of the OneTouch® UltraSmart™ System.

Table 1. Demographic summary of study participants

	Site 1	Site 2	Site 3
N	19	20	22
Gender			
Females (%)	58	50	68
Males (%)	42	50	32
Age (%)			
≤ 10 years	21	0	0
11–20	53	15	0
21–30	21	20	9
31–40	5	25	41
41–50	0	15	31
51–60	0	10	9
61–70	0	15	5
71–80	0	0	5
Median (years)	15	35.5	40.5
Range (years)	8–36	13–66	29–74
Education level (%)			
≤ Elementary	48	5	0
Some high school	21	10	0
High school grad	5	15	23
Some college	16	10	23
College degree	5	45	31
Graduate degree	5	15	23
Diabetes (years)			
Median	7	15.5	21
Range	0.3–23	1.5–53	3–47
Type of diabetes (%)			
Type 1	100	90	73
Type 2	0	10	27
SMBG (years)			
Median	7	15	13
Range	0.3–20	1.5–20	3–22
Daily frequency SMBG (%)			
< 1 ×	0	0	5
1–2 ×	0	0	0
3–4 ×	16	50	45
5–6 ×	42	30	31
> 7 ×	37	20	14
Other	5	0	5
Diabetes management			
Insulin injection	68	15	27
Insulin pump	32	75	59
Oral hypoglycemic agents	0	10	14
Current SMBG system (n)			
LifeScan			
OneTouch® Ultra®	18	12	7
InDuo™	0	0	1
OneTouch® II	0	1	0
OneTouch® Profile®	0	2	1
OneTouch® FastTake®	0	0	1
MediSense® Precision™ Xtra™	1	0	0
Roche Accu-Check®	0	4	4
Bayer Glucometer Elite®	0	0	3
TheraSense FreeStyle™	0	1	5

Two-week home testing phase

In addition to his or her current SMBG regimen, each patient a) performed three daily self-tests with the OneTouch® UltraSmart™ System at normal test times, and b) completed a log sheet of testing activities performed and FastFacts™ functions used that day. Patients also conducted control solution tests on days 1, 5, and 10 of the two-week home testing phase.

Site visit 2

Each patient completed two questionnaires based on the experience of the home testing phase. Questionnaire 1 asked patients to rate the ease of use of the OneTouch® UltraSmart™ System from several perspectives, using a rating scale of 1 (Very Difficult) to 5 (Very Easy). Questionnaire 2 allowed the patients to provide feedback about the basics of the OneTouch® UltraSmart™ System, including their preferences between using the OneTouch® UltraSmart™ System and continuing their current SMBG practices.

Analysis

- Questionnaire 1 (ease of use) results were evaluated by calculating the mean response to each item for all patients; mean values greater than 3.0 indicate favorable responses to the OneTouch® UltraSmart™ System.
- Questionnaire 2 (user preference) results were evaluated by determining the proportion of favorable responses to the OneTouch® UltraSmart™ System. Preferences for each of several aspects of the OneTouch® UltraSmart™ System are statistically significant if at least 60% of patients a) prefer the OneTouch® UltraSmart™ System over their current system or b) “somewhat agree” or “strongly agree” with statements of preference for the OneTouch® UltraSmart™ System.
- Use of FastFacts™ functions was assessed by tabulating the number and percentage of patients who used the functions, as recorded on the daily log sheets during the two-week home testing phase.

Results

Ease of use

Figure 1 summarizes patients’ responses to Questionnaire 1. Mean responses ranged from 3.8 to 4.6 on a scale of 1 (Very Difficult) to 5 (Very Easy). Most patients found the OneTouch® UltraSmart™ System to be “Easy” or “Very Easy” to use.

User preference

Figure 2 (back page) summarizes patients' responses to Questionnaire 2. The proportions of favorable responses to the OneTouch® UltraSmart™ System ranged from 67%–85%, in all cases exceeding the statistical significance criterion. The majority of patients stated that they would probably or definitely buy the OneTouch® UltraSmart™ System, without (75%) or with (81%) a recommendation from a healthcare professional. Most patients agreed that a) the OneTouch® UltraSmart™ System offers an easier way to see trends than anything they had seen before (74%) and b) the OneTouch® UltraSmart™ logbook function is easier to use than written logbooks (72%). On all questions of preference, a significant majority of patients preferred the OneTouch® UltraSmart™ System to their current SMBG system or practice.

Use of FastFacts™ functions

Figure 3 summarizes patients' log sheet records of their use of FastFacts™. All functions were used to some extent. The most commonly used were the electronic logbook and the average and graph of all blood glucose results; least commonly used were health checks and food averages.

Figure 1. Summary of Questionnaire 1 results

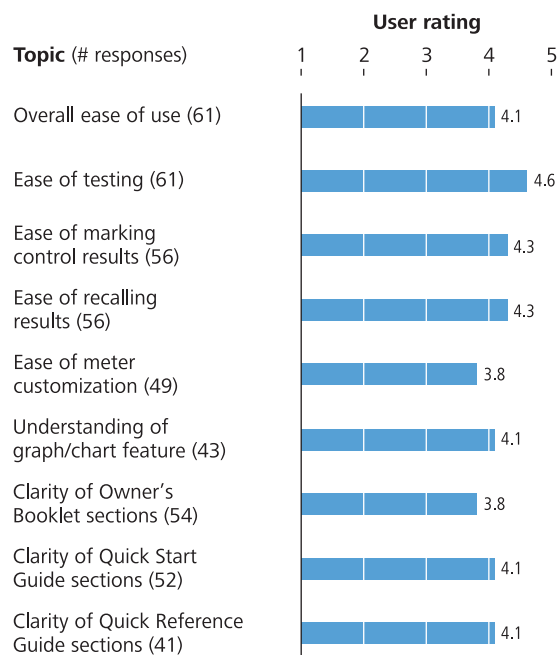
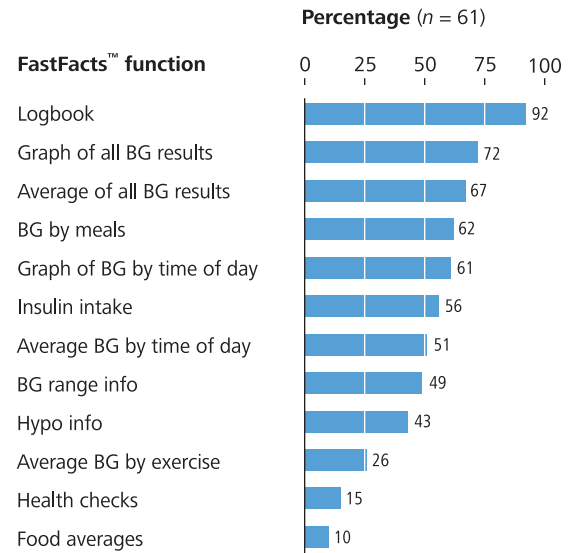


Figure 3. Reported use of FastFacts™ functions



Conclusions

- The OneTouch® UltraSmart™ System with its FastFacts™ feature is a user-friendly system for patient self-monitoring.
- Most patients in the current study found the OneTouch® UltraSmart™ System easy to learn and easy to use.
- Most patients indicated that they probably or definitely would buy the OneTouch® UltraSmart™ System.
- Most patients agreed that the OneTouch® UltraSmart™ System offers an easier way to see trends than anything they had seen before.
- Most patients agreed that the OneTouch® UltraSmart™ logbook function is easier to use than written logbooks.

Reference

1. LifeScan report AW058-874A, 2003. *Clinical accuracy and user acceptance of the OneTouch® UltraSmart™ Blood Glucose Monitoring System*. LifeScan, Inc.

Acknowledgments

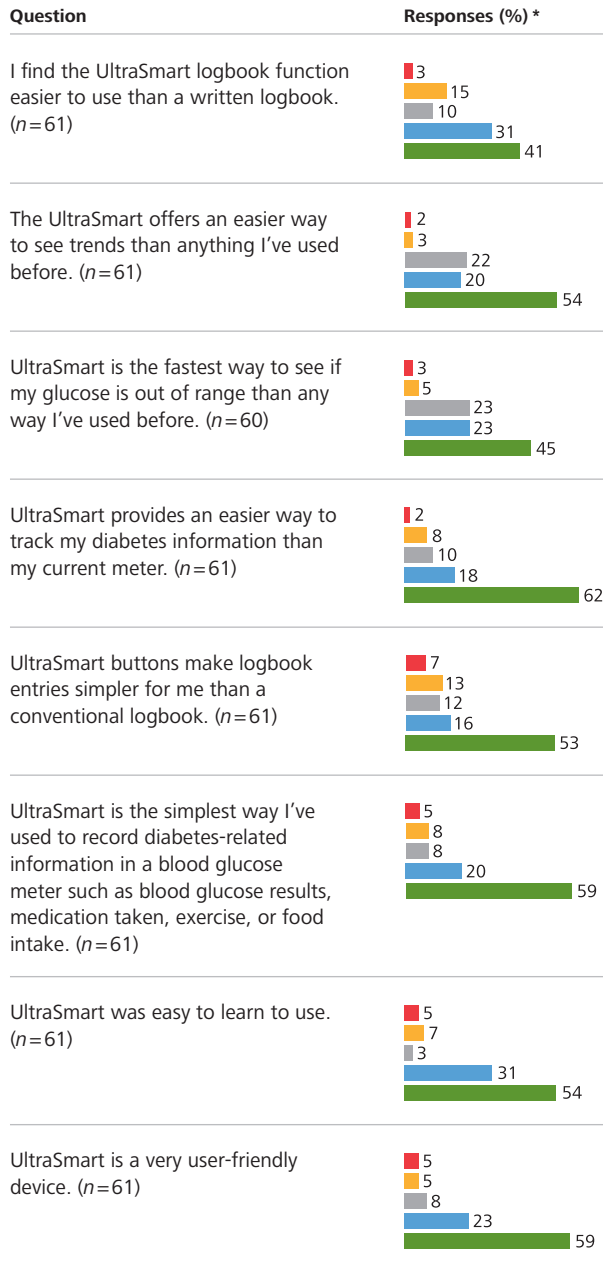
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 - Stuart Brink, MD (Principal Investigator), at the New England Diabetes and Endocrinology Center, Waltham, Massachusetts.

Figure 2. Summary of Questionnaire 2 results

A. Usability

User rating

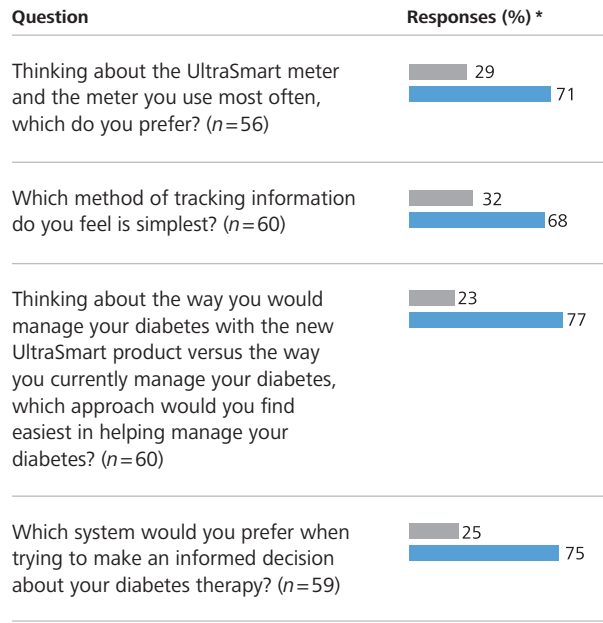
- Strongly disagree
- Somewhat disagree
- Neither agree nor disagree
- Somewhat agree
- Strongly agree



B. User preference

Preferred meter/method

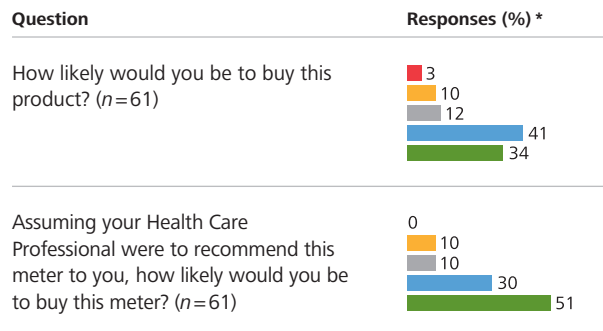
- Current meter/method
- OneTouch® UltraSmart™



C. Purchase of OneTouch® UltraSmart™ System

Likelihood to buy

- Definitely not
- Probably not
- Maybe or maybe not
- Probably buy
- Definitely buy



* Response percentages were rounded off to the nearest whole number and therefore may not total 100.

