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Integrated Self-Monitoring of Blood Glucose System: Handling Step Analysis

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Abstract

Self-monitoring of blood glucose (SMBG) implicates a number of handling steps with the meter and the lancing device. Numerous user errors can occur during SMBG, and each step adds to the complexity of use. This report compares the required steps to perform SMBG of one fully integrated (the second generation of the Accu-Chek® Mobile), three partly integrated (Accu-Chek Compact Plus, Ascensia® Breeze®2, and Accu-Chek Aviva), and six conventional (Bayer Contour®, Bayer Contour USB, BGStar™, FreeStyle Lite®, OneTouch® Ultra® 2, and OneTouch Verio™Pro) systems. The results show that the fully integrated system reduces the number of steps to perform SMBG. The mean decrease is approximately 70% compared with the other systems. We assume that a reduction of handling steps also reduces the risk of potential user errors and improves the user-friendliness of the system.

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Introduction

Self-monitoring of blood glucose (SMBG) is an integral part of diabetes self-management. The reliability of the SMBG value depends heavily on if and how well the user prepares and performs the measurement.[1,2]

Innovative technologies have led to high-quality SMBG systems that provide a wide range of user-friendly features such as short measurement times, small blood samples, or less painful lancing devices.[3–6]

However, nonadherence to recommended test frequencies is still a common issue.[7] User-friendliness of a system can help overcome barriers to testing that are closely linked to the SMBG adherence of patients.[8]

A number of user-errors can occur during SMBG, including miscoding of blood glucose (BG) meters, use of expired test strips, or inadequate storage conditions of test strips.[2,9,10] Current systems are often characterized by more integrative features. Some of the more integrated systems incorporate the tests (test fields or test strips) in cassettes, drums, or discs instead of using single test strips. Other integrative features concern the lancing technology, such as lancing devices that contain a drum with six sterile lancets instead of inserting single lancets for every measurement.

The aim of this study was to evaluate the required handling steps for performing a BG measurement with

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Abbreviations: (BG) blood glucose, (SMBG) self-monitoring of blood glucose

Keywords: handling steps, integrated blood glucose measurement system, potential user errors, self-monitoring of blood glucose, user-friendliness

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fully integrated, partly integrated, and conventional SMBG systems.

Methods

In this study, 10 SMBG systems (fully integrated, partly integrated, and conventional) were used (**Table 1** and **Figure 1**). Accu-Chek® Mobile, Accu-Chek Compact Plus, and Ascensia® Breeze®2 incorporate the tests in cassettes, drums, or discs (**Figure 1**, **Table 1**). The other systems are single-strip systems. Regarding the functional characteristics of the corresponding lancing devices, the Accu-Chek FastClix (Accu-Chek Mobile) and the Accu-Chek Multiclix (Accu-Chek Aviva) use a drum containing six sterile lancets. The lancing devices of the other systems require the insertion of a new lancet for each measurement (**Table 1**).

An important criterion is the coding technology of the systems (**Table 1**). Coding is a process for addressing batch-specific variations in the production of tests to ensure reliable SMBG values. Some systems require manual input of a batch-specific code number into the BG meter for every test strip batch. Other systems have an automatic coding feature by putting the test fields or test strips into the BG meter or do not require coding (**Table 1**).

Handling steps for each system were analyzed and counted for two different categories: routine

Table 1.
Features and Characteristics of the Investigated Self-Monitoring of Blood Glucose Measurement Systems

	BG meter	Lancing device		Test strip system	Coding[a]	Weight (g)[b]	Required blood volume (µl)	Manufacturer
Fully Integrated system	Accu-Chek Mobile	Accu-Chek FastClix	Drum (6 lancets)	Cassette (50 test elements)	Aut	149	0.3	Roche Diagnostics GmbH, Mannheim, Germany
Partly integrated systems	Accu-Chek Compact Plus	Accu-Chek Softclix Plus	Single lancets	Drum (17 test elements)	Aut	267.5	1.5	Roche Diagnostics GmbH, Mannheim, Germany
	Ascensia Breeze2	Ascensia Microlet®	Single lancets	Disc (10 test elements)	Aut	170	1	Bayer Consumer Care AG, Basel, Switzerland
	Accu-Chek Aviva	Accu-Chek Multiclix	Drum (6 lancets)	Single test strips	Man	160	0.6	Roche Diagnostics GmbH, Mannheim, Germany
Conventional systems	Bayer Contour®	Bayer Microlet 2	Single lancets	Single test strips	Aut	119	0.6	Bayer Consumer Care AG, Basel, Switzerland
	Bayer Contour USB	Bayer Microlet 2	Single lancets	Single test strips	Aut	104.7	0.6	Bayer Consumer Care AG, Basel, Switzerland
	BGStar™	BGStar	Single lancets	Single test strips	No	102.4	0.5	AgaMatrix Inc. Salem, NH
	FreeStyle Lite®	FreeStyle™	Single lancets	Single test strips	No	100.5	0.3	Abbott Diabetes Care Inc., Alameda, CA
	OneTouch Ultra2	OneTouch Ultra Soft®	Single lancets	Single test strips	Man	145.5	1	LifeScan Inc., Milpitas, CA
	OneTouch Verio™Pro	OneTouch Comfort™	Single lancets	Single test strips	No	185.3	0.4	LifeScan Europe, Zug, Switzerland

[a] Coding technologies of the SMBG systems used are differentiated into manual coding, automatic coding, and no coding according to the manual's description. Man, manual coding; Aut, automatic coding; No, no coding.
[b] The calculated weight (g) includes meter + test strips/test strip drum(s)/test strip disc(s)/tape cassette(s) for 50 (51) measurements; lancing device (including lancet) + 5 lancets or lancing device, including drum with 6 lancets; and carrying case (if provided by manufacturer).

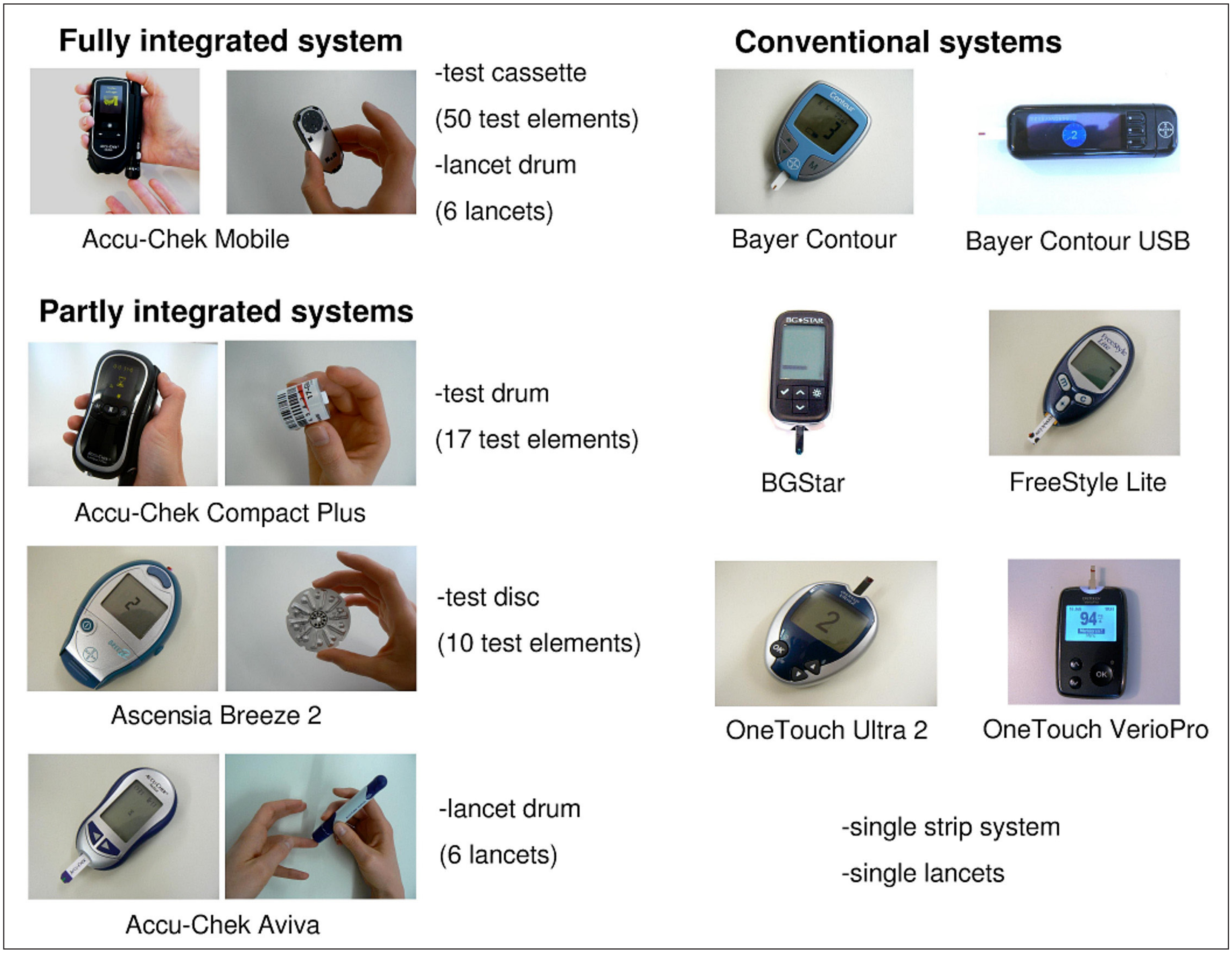

Figure 1. Self-monitoring of blood glucose measurement systems. Fully integrated system: the BG meter incorporates the tests in cassettes *and* the corresponding lancing device uses a drum containing six sterile lancets. Partly integrated systems: the BG meter incorporates the tests in discs or drums *or* the corresponding lancing device uses a drum containing six sterile lancets. Conventional systems: the systems are single-strip systems *and* the corresponding lancing devices require the insertion of a new lancet for each measurement.

measurement and routine measurement with additional tasks (**Tables 2** and **3**). Additional tasks are not required for each measurement but repeat regularly in a series of 100 routine measurements.

Table 2 gives an overview on handling step categories to perform a routine BG measurement. **Table 3** shows possible additional tasks with the used systems. System-independent steps that are required to perform SMBG correctly (e.g., washing hands before the measurement) were not counted.

Each handling step with each system was performed and documented several times by two investigators. Only steps mentioned in the manual were counted, including associated steps, e.g., if the manual mentioned "put the strip into BG meter," we also counted the steps "open the test strip vial" and "take the test strip out of the vial." Handling steps required for 100 measurements were calculated by combining the number of steps performed for 100 measurements as well as the number of steps of additional tasks.

Additionally, the relative decreases of handling steps required for the fully integrated system (Accu-Chek Mobile) compared with each partly integrated and conventional system and the respective mean values were calculated.

Table 2.
Analyzed Handling Step Categories and Corresponding Handling Steps within a Routine Blood Glucose Measurement

Routine BG measurement	Handling steps
Unpacking the carrying case	• Unzip the carrying case/detach the elastic tape, open the case, and lay it on the desk
Preparation of the lancing device	• Open the inside pocket of carrying case • Take out a lancet • Close the inside pocket • Take lancing device/meter, including lancing device • Twist the lancing device to choose a new lancet • Detach the cup of the lancing device and lay it on the desk • Loosen cap of lancet • Put the lancet into the lancing device • Take off the cap of the lancet • Lay the lancet cap on the desk • Take cup and close the lancing device • Check/adjust lancing depth • Stress the lancing device • Lay the lancing device on the desk
Preparation of the BG meter	• Take (out) the BG meter/meter, including lancing device • Lay the BG meter on the desk • Take the test strip vial out • Open the vial • Take a test strip out of the vial • Close the vial • Put the test strip into the BG meter • Put the vial back into the carrying case • Check/adjust test strip code/change code chip • Open the tip cover • Push the start or test strip release button • Stress the BG meter to release a BG test strip • Lay BG meter on the desk
Measurement	• Put the lancing device onto the fingertip • Push the release button • Apply blood onto the test strip/field • Choose before/after meal/skip • Wait for the result
Cleaning up BG meter	• Take BG meter • Take the test strip out of the BG meter • (Release and) throw the test strip away • Push the start button to switch off the BG meter • Close the tip cover to switch the meter off
Cleaning up lancing device	• Detach the cup of the lancing device • Take the lancet cap • Put the lancing cap on the lancet • Take the used lancet out • Throw the used lancet away • Close the lancing device • Put the lancing device into the carrying case
Packing in	• Put the BG meter/meter, including lancing device, into the carrying case • Fold up and zip/attach the elastic tape of the carrying case

Table 3.
Analyzed Additional Tasks and the Corresponding Handling Steps

Additional tasks	Handling steps
Change code chip/code number	• Take out the old/used code chip • Throw the old code chip away • Take the new code chip out of the package • Put the code chip into the meter • Start the meter/insert test strip • Check code on display • Adjust code manually
Change tape cassette/drum/strip disc	• Open tip cover • Stress cassette box open button • Open tape cassette/drum/strip disc box • Push the drum release button • Take out the used cassette/drum/strip disc • Throw it away • Open tape cassette/drum/strip disc package • Take the new cassette/drum/strip disc • Put in the new cassette/drum/strip disc • Close the cassette/drum box/strip disc • Close the tip cover
Change test strip vial	• Take old test strip vial out of the carrying case • Throw old test strip away • Take new test strip vial out of package • Note expiry date on vial • Put new test strip vial into the carrying case
Perform control measurement	• Lay the BG meter on the desk • Take the test strip vial out • Open the vial • Take a test strip out of the vial • Close the vial • Put the test strip into the BG meter • Put the vial back into the carrying case • Check/adjust test strip code • Push the start or test strip release button • Stress the BG meter to release a BG test strip • Open the tip cover • Lay the BG meter on the desk • Shake control solution vial • Open control solution vial • Discard first drop/wipe tip of vial • Put drop of control solution on clean surface • Take BG meter • Apply control solution onto the test strip/field • Wait for the result • Discard/close control solution vial • Manually mark measurement as control • Check result with target value • Take the test strip out of the BG meter • (Release and) throw the test strip away • Push the start button to switch off the BG meter • Close the tip cover to switch the meter off
Change lancet drum	• Detach the lancing device cup • Take out the used lancet drum • Throw the used lancet drum away • Open inside pocket • Take out lancet drum • Close inside pocket • Take a new lancet drum out of the package • Put in the new lancet drum • Close the lancing device cup

Results

The smallest number of handling steps was found for the Accu-Chek Mobile system (9 steps) to perform a single routine BG measurement. The other systems needed between 25 and 38 steps (**Table 4**).

The calculated numbers of handling steps to perform 100 routine BG measurements are shown in **Figure 2**. **Figure 3** shows the calculated numbers of lancing-device-specific and BG-meter/measurement-specific steps to perform 100 measurements (routine measurements, including additional tasks). Considering the required

Table 4.
Number of Required Handling Steps to Perform a Single Routine Measurement and Number of Required Handling Steps to Perform Additional Tasks for 100 Routine Blood Glucose Measurements

BG meter	Accu-Chek Mobile	Accu-Chek Compact Plus	Ascensia Breeze2	Accu-Chek Aviva	Bayer Contour	Bayer Contour USB	BGStar	FreeStyle Lite	OneTouch Ultra2	OneTouch VerioPro
Lancing device	Accu-Chek FastClix	Accu-Chek Softclix Plus	Ascensia Microlet	Accu-Chek Multiclix	Bayer Microlet 2	Bayer Microlet 2	BGStar	FreeStyle	OneTouch Ultra Soft	OneTouch Comfort
Routine Measurement										
Unpacking	0	2	2	2	2	2	2	2	2	2
Preparation of lancing device	3	11	13	5	12	12	12	12	12	12
Preparation of BG meter	1	1	3	9	8	8	8	8	9	8
Measurement	4	4	4	4	4	4	4	4	4	4
Cleaning up BG meter	1	2	3	2	2	2	2	2	2	2
Cleaning up lancing device	0	6	7	1	7	7	7	7	7	7
Packing in	0	2	2	2	2	2	2	2	2	2
Steps for a single routine measurement	9	28	34	25	37	37	37	37	38	37
Additional tasks										
Change code chip/code number	0	0	0	12[a]	0	0	0	0	12[b]	0
Change tape cassette/drum/ strip disc	20[a]	48[c]	80[d]	0	0	0	0	0	0	0
Change test strip vial	0	0	0	8[a]	8[a]	8[a]	10[a]	8[a]	20[b]	20[b]
Perform control measurement	18[a]	22[e]	0	34[a]	0	0	0	0	72[b]	68[b]
Change lancet drum	102[f]	0	0	153[f]	0	0	0	0	0	0
Additional steps/100 routine measurements	140	70	80	207	8	8	10	8	104	88

The required steps for the additional tasks are counted for 100 routine measurements, and the additional tasks are repeated every
[a] 50 measurements,
[b] 25 measurements,
[c] 17 measurements,
[d] 10 measurements,
[e] 51 measurements,
[f] 6 measurements.

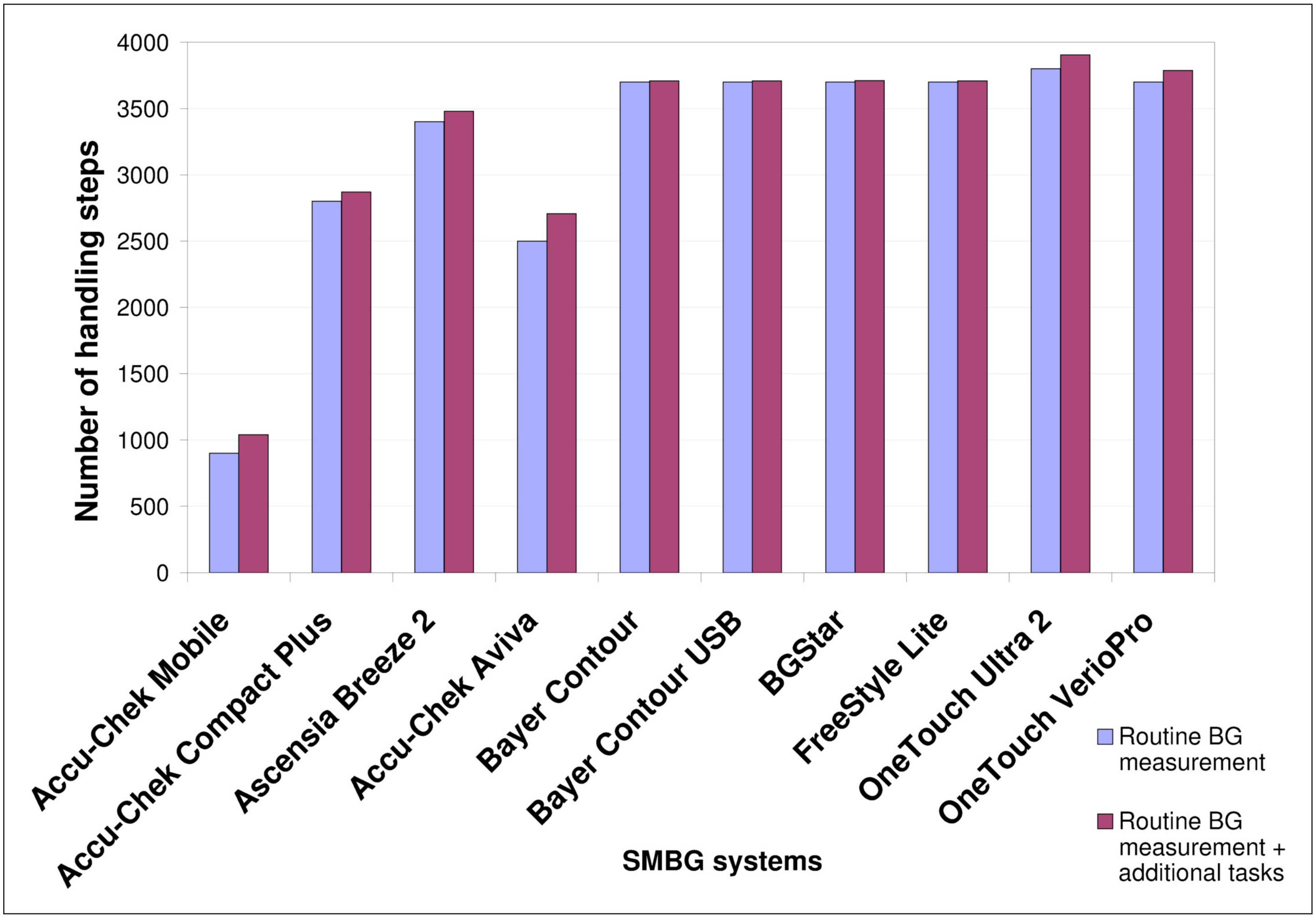

Figure 2. The calculated numbers of handling steps to perform 100 routine BG measurements and additionally the numbers of handling steps to perform 100 routine BG measurements and the required additional tasks within 100 measurements are shown. The minimum number of required handling steps is found for the fully integrated Accu-Chek Mobile system (100 routine measurements, 900; 100 routine measurements, including additional tasks, 1040) The partly integrated and conventional systems require between 2500 (Accu-Chek Aviva) and 3800 (OneTouch Ultra2) handling steps for 100 routine BG measurements and between 2707 (Accu-Chek Aviva) and 3904 (OneTouch Ultra2) when additional tasks are taking into account.

steps for 100 routine measurements and taking into account the additional tasks, the minimum number of required steps is found in the Accu-Chek Mobile system (1040; 402 lancing device specific, 638 BG meter/measurement-specific steps; **Figures 2** and **3**). The other systems require between 2707 (Accu-Chek Aviva meter with 753 lancing-device-specific and 1954 BG-meter/measurement-specific steps) and 3904 (OneTouch® Ultra®2 with 1900 lancing-device-specific and 2004 BG-meter/measurement-specific steps) steps (**Figures 2** and **3**).

The reduction of the required handling steps with the Accu-Chek Mobile system compared with partly integrated and conventional systems leads to a decrease in mean by 73% (ranges between 64% and 76%) for one single routine measurement and to a decrease in mean by 70% (ranges between 62% and 73%) for 100 measurements (routine measurements, including additional tasks; **Table 5**).

Discussion

Today, SMBG systems have to meet the challenge of providing improved features to maximize user-friendliness on one hand and to minimize errors on the other hand. User-friendliness may be improved by a reduction of handling steps.[8]

The results of this study show that the fully integrated system (Accu-Chek Mobile) requires the least number of handling steps to perform SMBG compared with partly integrated and conventional systems.

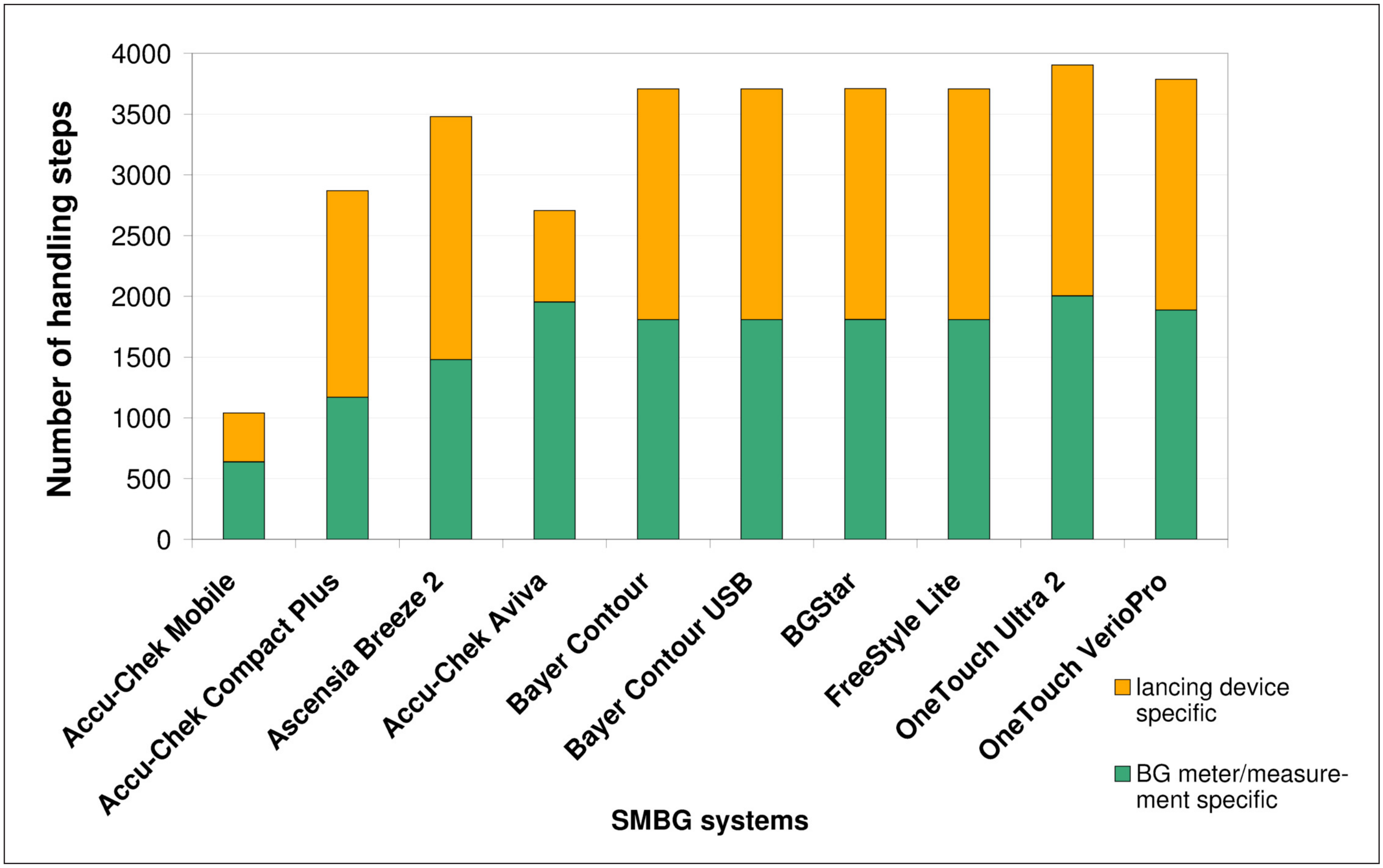

Figure 3. Calculated numbers of lancing-device-specific and BG-meter/measurement-specific handling steps to perform 100 measurements (routine measurements, including the additional tasks). Lancing device specific: preparation/cleaning up lancing device (routine measurement); change lancet drum (additional tasks). BG-meter/measurement specific: unpacking/packing in the carrying case, preparation/cleaning up BG meter, measurement (routine measurement); change code chip/code number, change tape/cassette/drum/strip disc, change test strip vial, perform control measurement (additional tasks).

Table 5.
Relative Difference in the Number of Required Handling Steps[a]

BG meter Lancing device		Steps decrease with the fully integrated Accu-Chek Mobile compared with partly integrated and conventional systems (%)									
		Accu-Chek Compact Plus Accu-Chek Softclix Plus	Ascensia Breeze2 Ascensia Microlet	Accu-Chek Aviva Accu-Chek Multiclix	Bayer Contour Bayer Microlet 2	Bayer Contour USB Bayer Microlet 2	BGStar BGStar	FreeStyle Lite FreeStyle	OneTouch Ultra 2 OneTouch Comfort	OneTouch VerioPro OneTouch Verio	Mean
Accu-Chek Mobile versus partly integrated and conventional systems	Steps decrease/ 1 test[b]	68	74	**64**	**76**	**76**	**76**	**76**	**76**	**76**	73
Accu-Chek Mobile versus partly integrated and conventional systems	Steps decrease/ 100 tests[c]	64	70	**62**	72	72	72	72	73	73	70

[a] Minimum and maximum values are given in bold font.
[b] 1 test = 1 routine BG measurement.
[c] 100 tests = 100 routine BG measurements + additional tasks necessary within this series.

One main reason for the reduction of handling steps with fully integrated systems is the elimination of single-test-strip insertion, which was achieved by integrating a test cassette with 50 tests. Handling with single test strips and test strip vials (opening, closing) and the expiration date of test strips is a commonly underestimated but frequent source of error that potentially impacts the reliability of SMBG values.[2,10] Integration of a test strip drum (Accu-Chek Compact Plus) or disc (Ascensia Breeze2) into the BG meter also eliminates the single insertion of test strips for every measurement.

Another important reason for the reduction of steps with fully integrated systems is the insertion of a lancet drum containing six sterile lancets instead of handling with single lancets. The insertion of lancets represents a frequent user-error source.[2] Insertion of single lancets for every measurement requires good handling skills, as the sharp lancets represent a potential risk of accidental sticks for the user. The development of lancing drums (Accu-Chek FastClix, Accu-Chek Multiclix) improves the user-friendliness because the insertion of the lancet drum is much easier and safer than the insertion of single lancets, as the user does not come into contact with the sharp lancets when inserting the drum into the BG meter. The reuse of lancets, which is done by many patients, has not been taken into consideration, as steps were counted strictly according to the manual. Another limitation of this study is the counting of handling steps under laboratory conditions by well-trained personnel, which does not represent the patient's measurement procedure. Additionally, for some patients, the complexity of steps to perform a measurement might be more important than the number.

Compared with partly integrated and fully integrated systems, most of the conventional systems are smaller and lighter. On the other hand, the conventional systems require separate carrying of all measurement components (lancing device, lancets, test strip vial), not to forget the disposal of waste, which can be reduced with more integrated systems.

Most of the systems used in this study provide a clear simplification for users—they do not require manual coding. Previous studies demonstrated that some miscoded meters resulted in readings of up to 30% median difference when compared with the results obtained with a laboratory glucose analyzer.[11–13] Miscoded meters can result in significant insulin dose errors.[11]

In summary, we demonstrated that fully integrated systems require the least number of handling steps to perform SMBG. It can be assumed that the reduction of handling steps is associated with an improved user-friendliness and a reduction of potential errors. It seems likely that, in the future, the trend will keep moving toward more integrated SMBG systems, as they have the potential to improve user-friendliness and SMBG adherence and concurrently avoid user errors.

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