Validation of Home Blood Glucose Meters With Respect to Clinical and Analytical Approaches

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OBJECTIVE — To evaluate the clinical and analytical accuracy of home blood glucose meters.

RESEARCH DESIGN AND METHODS — Six blood glucose meters—Reflolux S (Boehringer Mannheim, Mannheim, Germany), One Touch II (LifeScan, Milpitas, CA), Glucocard Memory (Menarini, Florence, Italy), Precision QID (Medisense, Cambridge, U.K.), HaemoCue (HaemoCue, Ängelholm, Sweden), and Accutrend α (Boehringer Mannheim, Mannheim, Germany)—were compared with a reference method (Beckman Glucose Analyzer II) under controlled conditions (glucose clamp technique). Validation of the blood glucose meters was accomplished by clinically oriented approaches (error grid analysis), statistical approaches (variance components analysis), and by the criteria of the American Diabetes Association (ADA), which recommend a target variability of <5%.

RESULTS — A total of 1,794 blood glucose monitor readings and 299 reference values ranging from 2.2 to 18.2 mmol/l were analyzed (705 readings <3.89 mmol/l, 839 readings between 3.89 and 9.99 mmol/l, and 250 readings >9.99 mmol/l). According to error grid analysis, only Reflolux S and Glucocard M had 100% of estimations within the clinically acceptable zones A and B. Assessment of analytical accuracy revealed substantial differences between the glucose meters after separation of the data into defined glycemic ranges. None of the devices met the ADA criteria.

CONCLUSIONS — To evaluate accuracy of blood glucose meters, error grid analysis, as well as statistical models, are helpful means and should be performed together. Analytical performance of currently available home blood glucose meters differs substantially within defined glycemic ranges.

Accurate self-monitoring of blood glucose (SMBG) is one of the keystones in performing adequate intensified insulin therapy (1,2). Over the last decade, analytical and overall performance of home blood glucose meters has been studied in numerous investigations (3–9). However, there is an ongoing discussion about the appropriate way to validate devices for SMBG (10). In 1996, the American Diabetes Association (ADA) recommended a target variability of <5% for home blood glucose meters (11). Lately, Cox et al. (12) have proposed the use of error grid analysis to evaluate home blood glucose meters from a clinical point of view and the use of parametric statistical approaches to validate analytical accuracy of the devices. Trajanoski et al. (3) reported substantial differences in the accuracy of blood glucose meters in the lower range (<3.89 mmol/l) and recommended separation of the data into different subsets (low glycemic range <3.89 mmol/l, near-normoglycemic range 3.89–9.99 mmol/l, and high glycemic range >9.99 mmol/l) for further investigations. The objective of this study was, therefore, to validate six blood glucose meters *1*) after separation of the data into three different subsets from a clinical point of view, 2) by the use of the error grid analysis to evaluate clinical relevance of the estimations, 3) by using statistical models to evaluate analytical accuracy, and *4*) according to the stringent recommendations of the ADA (analytical error <5%).

RESEARCH DESIGN AND METHODS

Subjects and protocols

Informed written consent was obtained from five healthy volunteers and four IDDM patients after an explanation of the nature, purpose, and potential risks of the study. The study protocol was approved by the ethical committee of Karl Franzens University, Graz, Austria. IDDM patients were admitted the evening before the study and had their last long-acting insulin shot 12 h before admittance and their last regular insulin shot 4 h before admittance. They were fasting throughout the end of the study and were infused with regular insulin during the night to maintain euglycemia as previously described (13). Healthy subjects were admitted on the day of the study after an overnight fast. At 8:00 A.M., a dorsal hand vein was cannulated retrogradely and kept in a thermoregulated (55°C) box for the sampling of arterialized venous blood throughout the entire experiment. On the contralateral arm, an antecubital vein was cannulated for the infusion of glucose and insulin. All subjects and patients remained in a supine position during the experiment. After a 60-min period of calibration, intravenous glucose was started to achieve hyperglycemia according to a published protocol (14). Thereafter, plasma glucose

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Abbreviations: ADA, American Diabetes Association; SMBG, self-monitoring of blood glucose.

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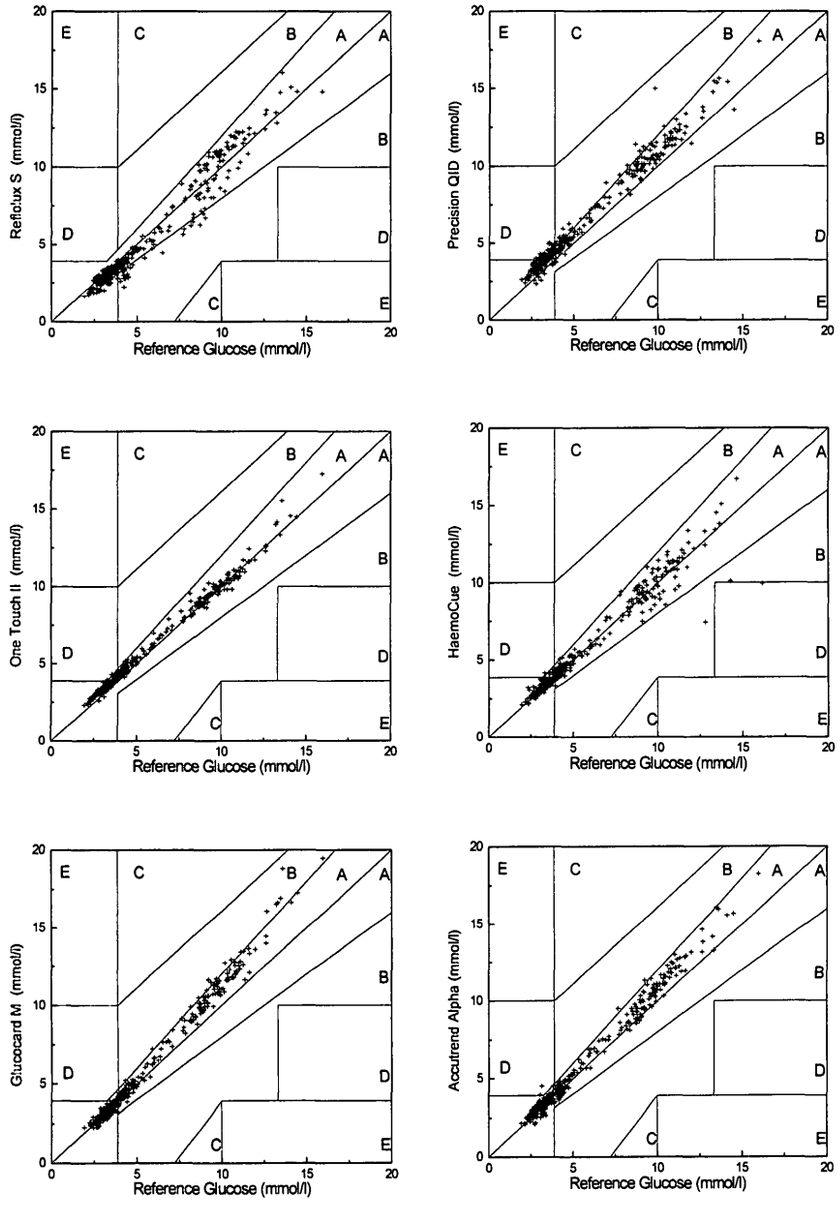

Figure 1—*Error grid analysis (4,12) for each single blood glucose meter. Single readings of the glucose meters are plotted against the mean of duplicate measurements from the reference method. Values in zone A (clinically accurate) or zone B (benign estimate errors) are accurate or acceptable. Values in zone C (unnecessary corrections), D (dangerous failure to detect and treat), or E (erroneous treatment) are potentially dangerous and therefore not acceptable from a clinical point of view.*

was modified by constant insulin infusion (1 mU · kg^{-1} · min^{-1}) and by variable glucose infusion using the stepwise hypoglycemic-hyperinsulinemic clamp method (15). Steady-state levels of plasma glucose were 11.1, 7.8, 5.0, 4.3, 3.7, and 3.0 mmol/l. Every 10 min during the experiment, whole blood glucose concentrations were immediately measured from the same arterialized venous blood sample using each of the glucose meters in a random fashion. To avoid user errors, measurements with the blood glucose devices were done by the same person (M.E.). The reference was plasma glucose from the same blood sample measured in duplicate using a Beckman Glucose Analyzer II (Beckman Instruments, Fullerton, CA). The intra- and interassay variability for the reference method is 2% (4.7 and 9.9 mmol/l). Arterialized venous blood samples were chosen for the convenience of the subjects, as it has been shown previously that capillary glucose is very similar to arterialized venous glucose (3,16). To compare plasma glucose measurements (Beckman Glucose Analyzer II) with whole blood estimations (devices for SMBG), adjustment of the data was performed by conversion factors as recommended by the selected manufacturers.

Blood glucose meters

The following six blood glucose meters were studied: Reflolux S (Boehringer Mannheim, Mannheim, Germany), One Touch II (LifeScan, Milpitas, CA), Glucocard Memory (Menarini, Florence, Italy), Precision QID (Medisense, Cambridge, U.K.), HaemoCue (HaemoCue, Ängelholm, Sweden), and Accutrend α (Boehringer Mannheim, Mannheim, Germany). Reflolux S, OneTouch II, Accutrend α, and HaemoCue were the latest models in photometric detection technology available from the selected manufacturers, whereas Glucocard Memory and Precision QID measurements were based on electrochemical detection. HaemoCue was a larger device, designed mainly for general practitioners, whereas the other devices were small and handheld and were frequently used by a large outpatient IDDM group (1). HaemoCue was included in this study because of enhanced performance in previous investigations (3,17).

Statistical analysis

Glycemic ranges were divided into three zones (all in millimoles per liter): low glycemic range (<3.89), near-normoglycemic range (3.89–9.99), and high glycemic range (>9.99). The clinical relevance of the glucose meter readings was examined using the error grid analysis (4) (Fig. 1). In short, zones A and B represent accurate and acceptable glucose estimations, respectively. Values in zones C, D, or E are not acceptable. Values in zone C might result in overcorrection of the true glucose level, values in zone D represent a "dangerous failure to detect and treat," and values in zone E represent "erroneous treatment." Although error grid analysis may favor glucose meters that measure falsely low in the low range (3), it seems to be the most useful approach to evaluate glucose meters from a clinical point of view (3,10,12).

However, error grid analysis gives no detailed information about agreement of home blood glucose meter estimations in comparison to a reference method. Therefore, analytical accuracy of the tested

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Table 1—*Percentage of measurements within the zones A–E (error grid analysis) for each blood glucose meter according to different glycemic ranges*

	Low glycemic range (<3.89 mmol/l)						Near-normoglycemic range (3.89–9.99 mmol/l)						High glycemic range (>9.99 mmol/l)					
Monitor	A	B	C	D	E	*n*	A	B	C	D	E	*n*	A	B	C	D	E	*n*
Reflolux S	100	0	0	0	0	118	83.1	16.9	0	0	0	136	100	0	0	0	0	39
One Touch II	96.6	0	0	3.4	0	118	100	0	0	0	0	140	100	0	0	0	0	41
Glucocard Memory	100	0	0	0	0	115	94.3	5.7	0	0	0	140	78.0	22.0	0	0	0	41
Precision QID	79.7	0	0	20.3	0	118	82.9	17.1	0	0	0	140	97.5	2.5	0	0	0	40
HaemoCue	99.1	0	0	0.9	0	115	98.6	1.4	0	0	0	139	93.3	4.5	0	2.2	0	45
Accutrend α	97.5	0	0	2.5	0	118	98.6	1.4	0	0	0	139	100	0	0	0	0	41

Data are % or *n*. Values in zone A (clinically accurate) or zone B (benign estimate errors) are accurate or acceptable. Values in zone C (unnecessary corrections), D (dangerous failure to detect and treat), or E (erroneous treatment) are potentially dangerous and therefore not acceptable from a clinical point of view (4,12).

devices was evaluated by variance components analysis (18): the differences between each single determination of the blood glucose monitor readings and the reference method were calculated and assumed to consist of a random measurement error and a systematic bias. Systematic bias was estimated by the mean difference. This mean difference and its standard error were calculated as the least squares estimate of a general linear model with patient as a random effect. The random measurement error was quantified by the variance and its square root, the standard deviation. Because we performed repeated measurements with one subject, this error was split into an error within subjects and an error between subjects. The corresponding variances add up to the total measurement error. The *F* test for one-way analysis of variance was used to test whether there was a between-subject variance component. A *P* value <0.05 was considered to be significant for the one-way analysis of variance. Furthermore, accuracy of home blood glucose meters was assessed according to the recommendations of the ADA (analytical error <5%) (11).

Microcal Origin (Microcal Software, Northhampton, MA) was used for descriptive analysis and diagrams. All other analyses were performed with SAS software (SAS Institute, Cary, NC).

RESULTS — A total of 1,794 blood glucose monitor readings and 299 reference values ranging from 2.2 to 18.2 mmol/l were analyzed (705 readings <3.89 mmol/l, 839 readings 3.89–9.99 mmol/l, and 250 readings >9.99 mmol/l). Results of the error grid analysis for each blood glucose monitor are shown in Fig. 1. Single readings of the home blood glucose meters are plotted against the mean of duplicate measurements of the reference method from all experiments. Table 1 shows the percentage of measurements within the different zones of the error grid analysis according to the different glycemic ranges. In the low glycemic range (<3.89 mmol/l), Reflolux S and Glucocard Memory had 100% of estimations in the clinically accept-

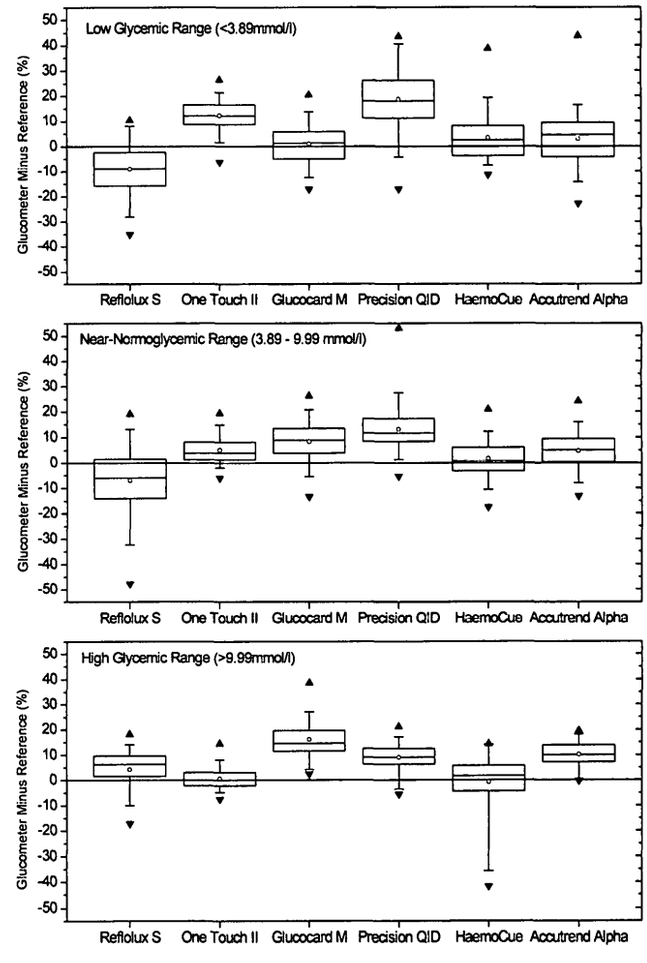

Figure 2—*Data are expressed as box plots. The difference between the measurements of the devices and the reference method is expressed as percentage deviation from the reference method. ▲, maximum valeue; ▼, minimum value. The top and the bottom of the vertical lines mark the 5th and 95th percentiles, respectively. The box shows the 25th (bottom), the 50th (horizontal line), and the 75th (top) percentiles. ○, the mean.*

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Table 2—*Variance components analysis of the difference in glucose meter readings versus the reference method*

	Low glycemic range (<3.89 mmol/l)						Near-normoglycemic range (3.89–9.99 mmol/l)						High glycemic range (>9.99 mmol/l)					
Monitor	Mean difference	SE	SD within	SD between	SD total	*n*	Mean difference	SE	SD within	SD between	SD total	*n*	Mean difference	SE	SD within	SD between	SD total	*n*
Reflolux S	−0.30	0.09	0.20	0.25	0.32	118	−0.33	0.21	0.72	0.57	0.92	136	0.32	0.38	0.48	0.80	0.93	39
One Touch II	0.39	0.04	0.14	0.10	0.17	118	0.27	0.05	0.26	0.12	0.29	140	0.18	0.17	0.42	0.32	0.53	41
Glucocard Memory	−0.01	0.05	0.20	0.12	0.23	115	0.63	0.09	0.58	0.22	0.62	140	2.04	0.30	0.84	0.53	0.99	41
Precision QID	0.61	0.08	0.30	0.21	0.37	118	0.85	0.10	0.59	0.26	0.64	140	0.95	0.25	0.45	0.53	0.69	40
HaemoCue	0.11	0.05	0.23	0.12	0.26	115	0.11	0.10	0.45	0.26	0.52	139	0.22	0.37	1.52	0.60	1.64	45
Accutrend α	0.02	0.08	0.22	0.23	0.32	118	0.38	0.12	0.40	0.32	0.52	139	1.02	0.19	0.49	0.36	0.61	41

Data are given in millimoles per liter. The variance components analysis was adapted from Hocking (18). Mean difference is between glucose meter readings and the reference method. SD between, standard deviation of interindividual error; SD total, square root of the sum of square of SD within and square of SD between; SD within, standard deviation of the difference of the results within the subjects; SE, standard error of the mean.

able zones (zones A and B). One Touch II, Precision QID, HaemoCue, and Accutrend α had measurements in zone D in this range. In the near-normoglycemic range (3.89–9.99 mmol/l), all devices provided 100% of the estimations in acceptable zones A and B. In the high glycemic range (>9.99 mmol/l), Reflolux S, One Touch II, and Accutrend α had 100% of the estimations in zone A, only HaemoCue had measurements in zone D, and none of the devices showed estimations in zones C or E.

The differences in the estimations of the glucose meters from the reference method are shown as box plots in Fig. 2. The results of variance components analysis are given in Table 2. In the low glycemic range, Accutrend α and Glucocard Memory were the most accurate devices. In the near-normoglycemic range, Reflolux S underestimated, whereas the other devices overestimated, the true glucose levels. HaemoCue and One Touch II showed the best analytical performance in this range. In the high glycemic range, all devices overestimated the true glucose values. One Touch II was the most accurate device in this range. Comparing the analytical accuracy of the devices, One Touch II showed better performance with increasing glycemic range, whereas all the other devices showed best performance in the low glycemic range and tended to be less accurate in the high glycemic range. One-way analysis of variance showed a significant between-subject variance component. However, the standard deviation of the difference in the results within the subjects exceeded the standard deviation of interindividual error in most cases (Table 2).

The percentage of blood glucose monitor readings that were within the ±5, ±20, and out of 20% deviation from the reference values according to the different glycemic ranges is shown in Table 3. None of the devices had 100% of estimations within a 5% deviation limit as recommended by the ADA (11).

CONCLUSIONS — In this study, six devices for SMBG were evaluated by clinically oriented nonparametric approaches (error grid analysis) and statistical models (variance components analysis) after separation of the data into different glycemic ranges. Error grid analysis provides no definite information about analytical accuracy of the devices, but it categorizes individual glucose meter readings with respect to inadequate therapeutic consequences on the reported values (zones C, D, and E). According to error grid analysis, only Reflolux S and Glucocard M had 100% of estimations in the clinically acceptable zones A and B. One Touch II, Precision QID, HaemoCue, and Accutrend α had estimations in zone D in the low glycemic range (<3.89 mmol/l), and HaemoCue showed values in zone D in the high glycemic range (>9.99 mmol/l). In the near-normoglycemic range (3.89–9.99 mmo/l), estimations of all devices were in the clinically acceptable zones A and B. One might argue that separation of the data into different glycemic ranges is arbitrary. However, performance of home blood glucose meters showed substantial differences in the low glycemic range in a previous investigation (3). In our study, we found varying performance of the devices not only in the low glycemic range but also in the near-normoglycemic and hyperglycemic ranges. Furthermore, this separation into different ranges seems to be useful from a clinical

Table 3—*Percentage of measurements within a defined range of the reference values for each blood glucose meter according to different glycemic ranges according to the recommendations of the ADA*

	Low glycemic range (<3.89 mmol/l)				Near-normoglycemic range (3.89–9.99 mmol/l)				High glycemic range (>9.99 mmol/l)			
Monitor	±5%	±20%	>20%	*n*	±5%	±20%	>20%	*n*	±5%	±20%	>20%	*n*
Reflolux S	22.9	87.3	12.7	118	25.7	83.1	16.9	136	23.0	100.0	0.0	39
One Touch II	5.9	92.4	7.6	118	56.4	100.0	0.0	140	85.4	100.0	0.0	41
Glucocard Memory	46.1	99.1	0.9	115	25.0	94.3	5.7	140	4.9	78.0	22.0	41
Precision QID	5.1	55.1	44.9	118	11.4	82.9	17.1	140	20.0	97.5	2.5	40
HaemoCue	48.7	95.7	4.3	115	55.4	98.6	1.4	139	46.7	93.3	6.7	45
Accutrend α	30.5	94.9	5.1	118	39.6	98.6	1.4	139	14.6	100.0	0.0	41

Data are % or *n*. Recommendations were taken from a 1996 ADA Consensus Statement (11).

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point of view as well: to perform adequate intensive insulin therapy, patients have learned to change actual insulin dosage according to the current SMBG data (1). To achieve satisfactory long-term metabolic control by avoidance of hypoglycemic episodes, patients are instructed to raise blood glucose levels <3.89 mmol/l (low glycemic range) immediately by carbohydrate intake and to lower blood glucose levels >9.99 mmol/l (high glycemic range) by adjusting the dose of insulin.

To assess the analytical accuracy of the devices, the frequently applied analysis of correlation coefficients was not used in this study. This statistical approach is not appropriate to compare blood glucose monitor readings with a reference method, since the correlation coefficient may be enlarged by augmentation of the measurement range (19). In our study, analytical accuracy was evaluated by variance components analysis. Because we performed repeated measurements in each single subject (range: 20–42 measurements), this analysis allowed the assessment of a possible systematic bias and a random measurement error. Table 2 gives information about agreement between the glucose meter estimations and the measurements of the reference method. Glucocard M had the best analytical performance in the low glycemic range, whereas this device showed the largest deviation from the reference values in the high glycemic range. In contrast, One Touch II revealed optimal analytical performance in the high glycemic range, whereas this device was less accurate in the low glycemic range.

We found a significant difference between patient variance components, which indicates an interaction between the measuring device and the individual subject. A consequence of this finding might be that one needs to calibrate the devices for each individual subject to minimize this bias. However, this finding may also be caused by a day-to-day variability in the measurement error of the devices. In addition, in everyday practice of SMBG, analytical accuracy of the devices may not only be influenced by this interindividual error but also by altitude, environmental temperature, humidity, and other causes (20). Controlled conditions in our study excluded these environmental factors to a larger extent. Moreover, variations in the day-to-day sampling technique of capillary blood by the patients may enlarge the analytical error in comparison to the standardized arterialized venous blood samples in our study. Nevertheless, it is important to point out that not all analytical errors are clinically significant such that they will result in a change of insulin dosage (11).

It should be emphasized that overall accuracy of home blood glucose meters depends not only on the analytical performance of the instrument (potential analytic error) but also on the proficiency of the operator (potential user error). To avoid user errors in our study, all measurements were done by the same person (M.E.). Hence, in everyday SMBG by the patients themselves, total error (analytical plus user error) might influence the results to a larger extent than shown in our study. Thus, appropriate SMBG training for the patients by professional health care providers seems to be one of the keystones of performing adequate SMBG (20). Manufacturers are not only encouraged to develop future devices with optimal analytical accuracy but also with a minimum of dependence on the operator's skill (11).

In 1996, the ADA recommended a target variability for blood glucose meters of <5% (11). Because of this method of analysis, none of the glucose meters gives satisfactory results and meets these stringent criteria. Most of the glucose meters had readings that were even beyond the 20% deviation limit, as shown in Table 3.

In summary, validation of devices for SMBG requires complementary approaches. From a clinical point of view, error grid analysis gives good information about clinical impact and potential therapeutic consequences on blood glucose estimations by home blood glucose meters. To assess analytical accuracy of the devices, appropriate statistical models should be used. Moreover, analytical accuracy of devices for SMBG shows substantial differences in performance in different glycemic ranges.

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