Assessment of five portable blood glucose meters for use in cats

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Objective—To evaluate the clinical and analytic accuracy of 5 portable blood glucose meters (PBGM) in cats, with emphasis on the detection of potential sources of error.

Animals—200 cats.

Procedure—Venous blood glucose readings from 5 PBGM were compared with the results of a hexokinase reference method. Agreement among methods was determined by error grid analysis and statistical methods.

Results—A total of 2,975 PBGM readings and 513 reference values were analyzed. The accuracy of the PBGM varied in different glycemic ranges. The largest differences between PBGM readings and reference values were in the high glycemic range; 4 PBGM underestimated and 1 PBGM overestimated the reference values in most instances. In the low and reference glycemic ranges, the absolute differences between PBGM readings and reference values were small. Despite the analytic differences in accuracy, 4 PBGM had 100% and 1 PBGM had 98.7% of readings in the clinically acceptable values of the error grid analysis. Within- and between-day precisions were good for all PBGM. Significant differences were not detected between readings of EDTA and lithium-heparinized blood and fresh blood without anticoagulant. Compared with these blood types, 1 PBGM had significantly different readings with fluoride anticoagulated blood. In blood samples with a low Hct, all PBGM overestimated glucose concentrations. Sample volumes < 3 µl resulted in inaccurate measurements in 3 PBGM.

Conclusions and Clinical Relevance—Performance varied among the 5 PBGM analyzed; however, all PBGM were deemed acceptable for clinical use in cats. (*Am J Vet Res* 2000;61:1587–1592)

Blood glucose concentration is one of the most commonly determined biochemical variables in human and small animal medicine. Serial blood glucose determinations are often necessary for monitoring hypoglycemia as well as hyperglycemia. Thus, a simple, inexpensive, and accurate method of measuring blood glucose concentration, using minute amounts of blood, is desirable. **Portable blood glucose meters (PBGM)** are small devices that are used by humans with diabetes mellitus for self-monitoring of blood glucose concentrations.[1,2] Compared with laboratory methods, determination of blood glucose concentration by use of PBGM is less expensive, faster, and requires less blood.[3-6] In small animal medicine, PBGM are used to generate blood glucose curves or single glucose measurements.[3,5,6] In recent years, many new and improved PBGM from various manufacturers have appeared on the market; some improvements include greater precision, faster measurements, decreased blood volume requirements, and decreased dependence on the operator's technique. A number of different PBGM have been evaluated in human medicine[7-12]; however, to our knowledge, only 1 has been assessed for use in cats.[6] In that study, significant differences were not detected between reference values and those obtained with the PBGM, but only 10 cats were used, and only the results from the normo- and hyperglycemic ranges were evaluated. In studies in humans, large variations in the accuracy of PBGM, which changed with different glycemic ranges, have been reported.[7,8,12] In addition, several factors such as low Hct or inadequate sample volume can affect the accuracy of PBGM readings.[9,13,14] To date, those factors of error of PBGM have not been evaluated in cats. The purposes of the study reported here were to evaluate the clinical and analytic accuracy of 5 PBGM for use in cats and to determine potential sources of error.

Received May 14, 1999.
Accepted Dec 30, 1999.
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Materials and Methods

Cats—The study was performed at the Clinic for Small Animal Medicine, University of Zurich, Switzerland. Blood samples were collected from the jugular vein of 200 client-owned cats of various breeds that were evaluated for various medical reasons.

Instruments—The following 5 PBGM were evaluated: **Glucometer Elite**[a] **(Elite)**, **Glucometer DEX**[a] **(DEX)**, SureStep,[c] Precision QID,[d] and Accu-Chek Simplicity[e] (**Appendix**). If the blood glucose value is outside the range detectable by the PBGM, results will be displayed as LO or HI on these meters. For Elite and DEX, the blood sample is drawn into the reaction chamber of the test strip by capillary action (sip-in technique), whereas a drop of blood must be applied to the application zones of the test strips of the other 3 PBGM.

For comparison, blood glucose concentrations were measured by a hexokinase reference method,[f] using heparinized plasma, within 30 minutes after testing with the PBGM. For some samples, the reference method was performed simultaneously, using serum and EDTA and fluoridated plasma.

Quality control—For quality control and determination of the precision between days, the manufacturers' respective aqueous control solutions were used: 2 for Elite,[f] 3 for DEX,[g] 1 for SureStep,[h] 2 for QID,[i] and 2 for Accu-Chek Simplicity.[j] Quality control tests were performed once a week and whenever a new test strip box was used. The PBGM were calibrated for each new box of test strips according to manufacturers' recommendations.

Effect of anticoagulants—Blood samples from 10 euglycemic (70 to 140 mg/dl) cats and from 10 hyperglycemic

(> 140 mg/dl) cats were used to assess the effect of anticoagulation and type of anticoagulant on the measurements. From each blood sample, the following aliquots were prepared: fresh blood without anticoagulant; blood anticoagulated with EDTA, fluoride, or lithium-heparin; and serum. Each PBGM was tested, using all aliquots except serum. Results obtained from fresh blood without anticoagulant were then compared with those of anticoagulated blood.

Samples of EDTA, fluoride, and lithium-heparin anticoagulated blood were centrifuged, and the plasma was used to determine glucose concentrations, using the hexokinase reference method. Results of plasma were compared with those of serum.

Because fresh blood without anticoagulant and heparinized blood samples are most often used in clinical practice, another 120 blood samples of these 2 blood types were analyzed, using the 5 PBGM. Glucose concentrations of these cats were also measured in serum and lithium-heparinized plasma, using the hexokinase reference method. Of the 120 samples, 60 were in the reference range for glycemia, and 60 were in the high reference range for glycemia.

Effect of blood volume—To determine effect of blood volume on the accuracy of the measurements, test strips were covered with 1, 2, 3, 5, 8, 10, and 15 µl of lithium-heparinized blood from 1 sample in the euglycemic range and from 1 in the hyperglycemic range, respectively. Samples of each volume were tested 3 consecutive times.

Effect of Hct—Lithium-heparinized blood samples from 13 euglycemic cats with low Hct (12 to 26%) were used to evaluate the effect of low Hct on glucose measurements. Differences between PBGM readings and reference values were calculated, and their means were compared with means of the differences between PBGM readings and reference values of 60 euglycemic cats with Hct within reference range.

Within-day precision and between-day precision—To evaluate within-day precision, the glucose concentration of lithium-heparinized blood samples from 15 cats was analyzed 10 times each within 15 minutes, using all PBGM and the hexokinase reference method. Of the 15 samples, 5 each were in the hypoglycemic, euglycemic, and hyperglycemic ranges. Between-day precision was assessed by testing each manufacturers' respective aqueous glucose control solution in duplicate on 10 consecutive days.

Agreement among methods—Of 150 blood samples, 30 were in the low glycemic range (< 70 mg/dl), 60 were in the euglycemic range (70 to 140 mg/dl), and 60 were in the high glycemic range (> 140 mg/dl). Anaerobic glycolysis was used to induce the 30 low glycemic range samples in lithium-heparinized blood samples that were left at room temperature. For technical reasons, lithium-heparinized blood was used for the PBGM and lithium-heparinized plasma for the reference method in all 3 glycemic ranges.

Statistical analyses—Data were analyzed by use of commercially available software.[1] For testing the effect of anticoagulant, means, SD, and SEM of the differences (mg/dl) between results of PBGM and reference method were calculated for the different specimens. One-way ANOVA (paired sample test) was then used to compare means of the blood specimens. One-way ANOVA was also used to test the significance of differences between the various blood drop volumes. Readings from cats with low Hct and those with Hct within reference range were compared by use of the *t*-test; differences were considered significant when $P < 0.05$. Mean (± SD) and coefficients of variation were calculated for each PBGM to assess within-day and between-day precision.

Agreement among results of PBGM and the reference method was evaluated, using statistical and clinically oriented approaches. Using the method of residuals, the differences between results of PBGM and the reference method were plotted against the reference values.[15] Relationships between variables were examined by use of Pearson correlation coefficients. The clinical significance of PBGM readings was examined by use of the error grid analysis.[16] The grid system assigns predicted glucose values (PBGM, y-axis) versus actual glucose values (reference method, x-axis) to 5 zones (A through E) and is based on the assumption that the clinical goal is to maintain blood glucose concentrations between 70 and 180 mg/dl. Measurements in zones A and B are clinically accurate in that they lead to clinically correct treatment decisions. The PBGM readings in zone A deviate from the reference value by no more than 20%, or both are < 70 mg/dl. The PBGM readings in zone B represent benign errors and deviate from reference values by > 20%; however, they either would not lead to a change in treatment, or treatment would not have any harmful effects. Values in zones C, D, and E would lead to treatment errors or failure to initiate treatment. Values in zone C would lead to unnecessary correction or overcorrection of the acceptable glucose concentration and would cause the actual blood glucose concentration to fall below 70 mg/dl or to increase above 180 mg/dl. Zone D represents potentially dangerous errors of failing to detect and treat actual glucose values that are outside the target range, because PBGM readings are within this range. The PBGM readings in zone E are opposite to the actual glucose values, and therapeutic actions would be opposite to those indicated.

Results

A total of 2,975 PBGM readings and 513 reference values were analyzed. The minimum volume of blood required for all PBGM was 3 to 5 :µl.

Effect of anticoagulant—Significant differences were not detected among glucose concentrations of fresh blood without anticoagulant, EDTA-anticoagulated blood, and lithium-heparinized blood in all PBGM. In 4 PBGM, fluoride anticoagulated blood yielded readings that did not differ from those of the other types of blood. However, SureStep was the exception; in both glycemic ranges, significantly larger mean underestimations of the actual glucose concentration were detected with fluoride anticoagulated blood samples, compared with the other types of blood. The differences between reference values and SureStep readings for fluoride anticoagulated blood, fresh blood without anticoagulant, EDTA anticoagulated blood, and lithium-heparinized blood were –31, –9, –12, and –10 mg/dl for euglycemic samples and –147, –23, –32, and –32 mg/dl for hyperglycemic samples, respectively.

With the hexokinase reference method, results for serum were not significantly different from results for any of the anticoagulated blood samples. Subsequently, after this preliminary experiment, plasma obtained from heparinized blood samples was used for the reference method.

Effect of blood volume—To determine the influence of blood volume on the accuracy of measurements, 210 blood glucose measurements were performed. The minimum volume of blood required to consistently initiate the measuring process differed among the 5 PBGM. For Elite, values were obtained with 1 or 2 µl of blood; in only 1 instance was LO (< 20

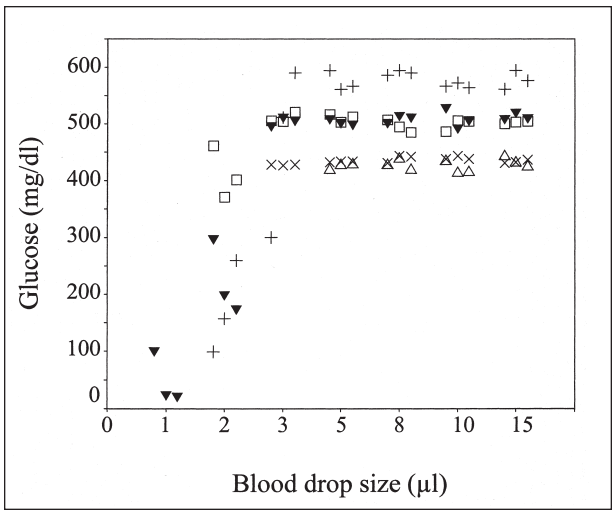


Figure 1—Effect of blood drop size on results of 5 portable blood glucose meters (PBGM; ▼= Glucometer Elite, += Glucometer DEX, ×= SureStep, △= Precision QID, □= Accu-Check Simplicity) used to measure glucose concentrations in cats.

mg/dl) displayed, which was designated as 18 mg/dl. For DEX, the minimum volume required was 3 µl. When the blood volume was smaller, the measuring process was initiated in only 9 of 12 instances; ERROR was displayed in 5, and LO (< 10 mg/dl) was displayed in 1 of those 9 readings. The latter reading was designated as 9 mg/dl. The minimum blood volume required for SureStep and QID was 3 and 5 µl, respectively. A minimum volume of 3 µl was required by Accu-Chek Simplicity to obtain an accurate reading; 9 of 12 samples with less than this volume initiated the measuring process, but ERROR was displayed 2 times. When a minimum of 3 µl (5 µl for QID) was used, glucose measurements did not differ among the 5 PBGM. For Elite and DEX, values obtained from volumes < 3 µl were significantly lower than those from larger volumes. The same was true for Accu-Chek Simplicity, although the discrepancy was less pronounced. Results for the blood glucose samples within reference range were similar: Elite, DEX, and Accu-Chek Simplicity had much lower results for blood volumes < 3 µl than with larger blood volumes (**Fig 1**). On the basis of these findings, in all subsequent experiments, blood samples were extruded with a 2-ml syringe and a 22-gauge needle, which delivered a blood volume of 10 to 15 µl.

Effect of Hct—Four PBGM yielded glucose concentrations that were significantly higher for blood samples with a low Hct (mean difference compared with reference method: Elite, –11; DEX, 0; SureStep, 4; QID, 11 mg/dl) than for those within reference range (mean difference compared with reference method: Elite, –20; DEX, –18; SureStep, 14; QID, 2 mg/dl). Values obtained with Accu-Chek Simplicity were not significantly different between the 2 groups.

Within-day and between-day precision—All coefficients of variation were < 8%; for all PBGM except SureStep, they were lower in the high glycemic range than in the reference and low ranges. SureStep yielded lower coefficients of variation in the low and reference glycemic ranges than in the high glycemic range. Only Accu-Chek Simplicity yielded coefficients of variation < 5% in all 3 glycemic ranges. The coefficient of variation was < 5% in 2 glycemic ranges for SureStep, DEX, and Elite and in only the high glycemic range for QID. For between-day precision, the coefficient of variation was < 8% (**Table 1**).

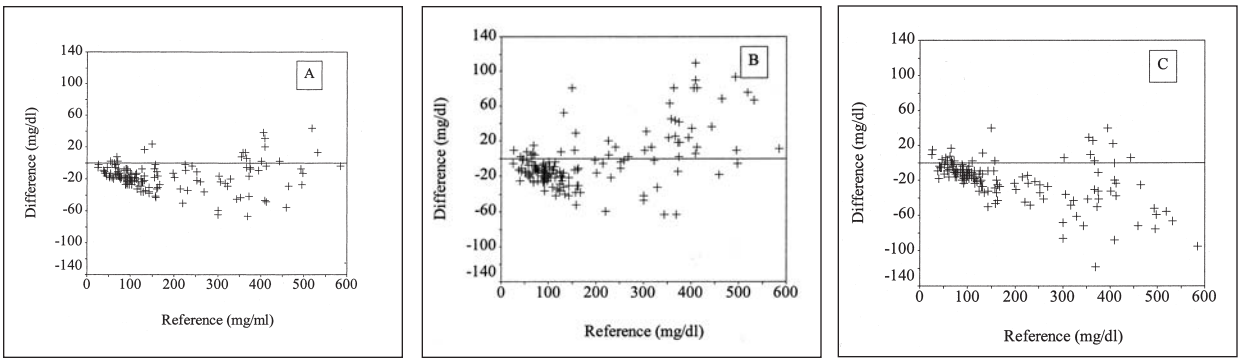
Agreement among methods—A total of 750 and 150 blood glucose measurements were performed with PBGM and the reference method, respectively, using lithium-heparinized blood in the 3 glycemic ranges. Reference values ranged from 25 to 585 mg/dl.

When all samples were considered, the correlation

Table 1—Within-day and between-day precision in 3 glycemic ranges for 5 commercially available portable blood glucose meters (PBGM). Manufacturers' control solutions were not available in all glycemic ranges for all PBGM to determine between-day precision

		Within-run precision*			Between-day precision†		
PBGM	**Glycemic range**	**Mean (mg/L)**	**SD**	**CV (%)**	**Mean (mg/L)**	**SD**	**CV (%)**
Elite	Low	45	4	135	ND	ND	ND
	Normal	99	4	83	94	5	101
	High	419	9	41	290	86	81
DEX	Low	47	4	121	68	4	103
	Normal	94	4	86	137	5	61
	High	446	18	76	308	9	52
SureStep	Low	58	2	54	ND	ND	ND
	Normal	103	2	52	113	4	59
	High	398	23	108	ND	ND	ND
QID	Low	65	4	119	50	4	106
	Normal	119	5	95	ND	ND	ND
	High	376	13	54	292	22	133
Simplicity	Low	58	2	74	ND	ND	ND
	Normal	106	4	59	83	2	56
	High	416	18	77	194	5	58
Reference	Low	63	0	22	ND	ND	ND
	Normal	121	2	43	ND	ND	ND
	High	437	5	25	ND	ND	ND

*Calculated by measuring glucose concentrations in 15 blood samples (5 with low concentrations, 5 with concentrations within reference range, and 5 with high concentrations) 10 times within 15 minutes. †Calculated by measuring glucose concentrations, using manufacturers' specific calibration solution, in duplicate on 10 consecutive days. CV = Coefficient of variation. ND = Not determined, because manufacturer did not provide a calibration solution in the specified range.



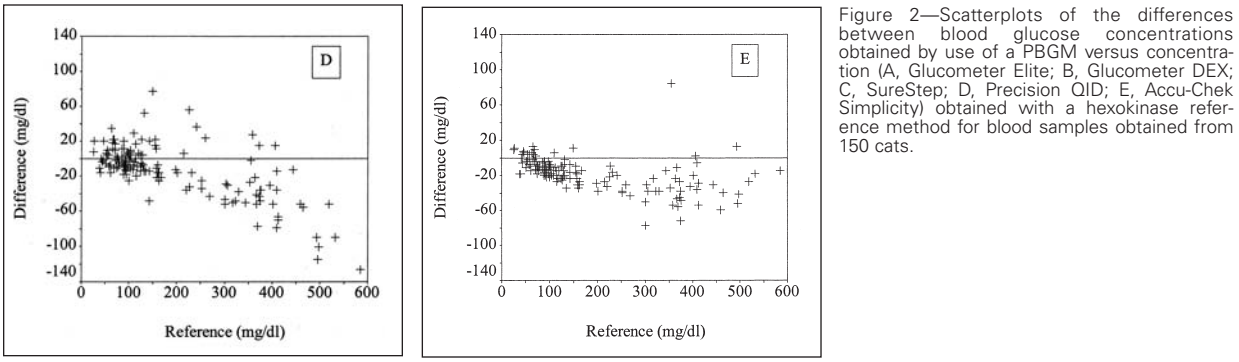
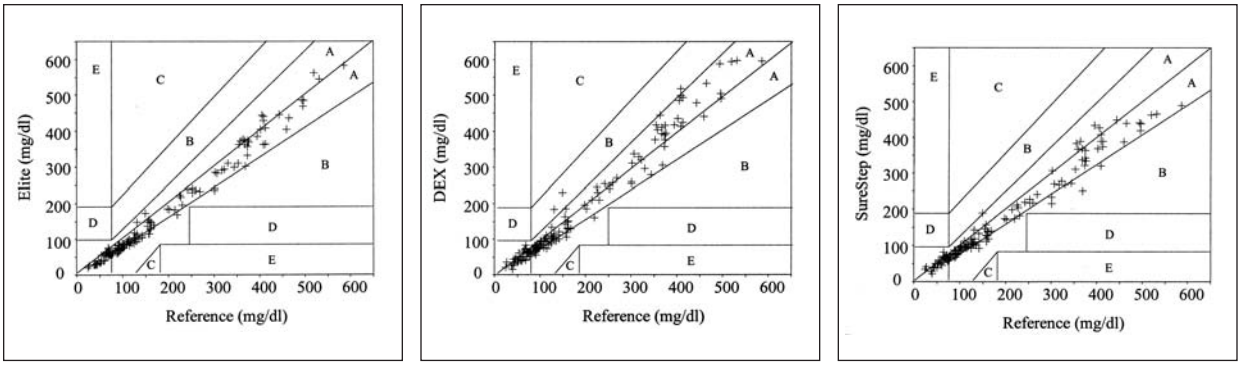


Figure 2—Scatterplots of the differences between blood glucose concentrations obtained by use of a PBGM versus concentration (A, Glucometer Elite; B, Glucometer DEX; C, SureStep; D, Precision QID; E, Accu-Chek Simplicity) obtained with a hexokinase reference method for blood samples obtained from 150 cats.



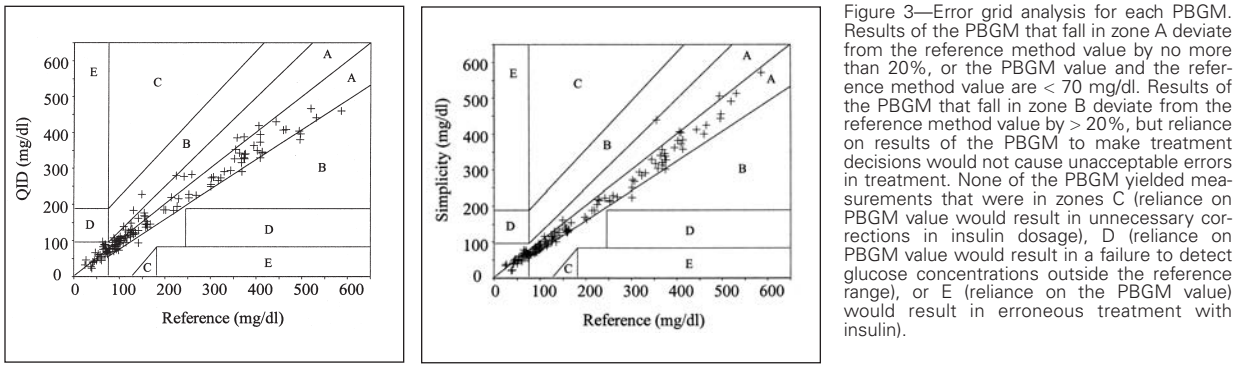


Figure 3—Error grid analysis for each PBGM. Results of the PBGM that fall in zone A deviate from the reference method value by no more than 20%, or the PBGM value and the reference method value are < 70 mg/dl. Results of the PBGM that fall in zone B deviate from the reference method value by > 20%, but reliance on results of the PBGM to make treatment decisions would not cause unacceptable errors in treatment. None of the PBGM yielded measurements that were in zones C (reliance on PBGM value would result in unnecessary corrections in insulin dosage), D (reliance on PBGM value would result in a failure to detect glucose concentrations outside the reference range), or E (reliance on the PBGM value) would result in erroneous treatment with insulin).

coefficients were 0.98 for QID and 0.99 for the other 4 PBGM. For hyperglycemic samples, correlation coefficients ranged from 0.95 to 0.98 for the 5 meters, whereas for the euglycemic samples, the correlation coefficient was 0.93 for Accu-Chek Simplicity and ranged from 0.79 to 0.89 for the other 4 meters; for the hypoglycemic samples, correlation coefficients ranged from 0.74 to 0.88.

The Bland and Altmann difference plots (**Fig 2**) indicated that different deviations from the reference values developed in the 3 glycemic ranges. In the low glycemic range, mean deviations from reference values were small for all PBGM and measured –10, –8, –2, +4, and –1 mg/dl for Elite, DEX, SureStep, QID, and Accu-Chek, respectively. The Elite meter consistently underestimated glucose concentrations in the low glycemic range, whereas the other PBGM had some readings that overestimated the reference values.

Mean deviation from reference ranges varied from

–3 mg/dl (QID) to –20 mg/dl (Elite). Most PBGM readings in the reference glycemic range underestimated glucose concentrations. However, in that glycemic range, 40% of the samples tested with QID yielded overestimations of glucose concentration, whereas the other 4 PBGM yielded only isolated overestimations.

Most values obtained with Elite and Accu-Chek in the high glycemic range were lower than reference values. The maximum (and mean) differences between PBGM and reference values were –67 (–16) mg/dl for Elite and –77 (–29) mg/dl for Accu-Chek. The largest differences were between 290 and 400 mg/dl of the reference values. With glucose concentrations > 400 mg/dl, the inaccuracies of Elite and Accu-Chek decreased; inaccuracies were quite small for the highest readings. In the high glycemic range, most readings obtained with SureStep were lower than the reference values, and only a few small overestimations were detected. The maximum and mean differences between SureStep readings and reference values were –119 and –32 mg/dl, respectively. The DEX monitor had over- and underestimations of the reference values in the high glycemic reference range of up to 380 mg/dl. Above 380 mg/dl, almost all DEX readings overestimated the glucose concentration by up to 110 mg/dl. However, because of over- and underestimations, the mean difference between DEX and the reference values was only 12 mg/dl. In contrast, QID over- and underestimated samples with reference values between 140 and 270 mg/dl. With concentrations > 270 mg/dl, the difference between QID readings and reference values increased. The amount of underestimation was highest in the high glycemic range, with a maximum and mean of -126 and -30 mg/dl, respectively. Overall, Elite and Accu-Chek yielded the most reliable results.

For Elite, DEX, SureStep, and Accu-Chek, 100% of the measurements were in the clinically acceptable zones A and B of the error grid analysis (**Fig 3**). The QID had 3 readings in zone D because of overestimations in the low glycemic range. All other QID readings were in zones A and B.

Discussion

In human medicine, numerous factors affecting the clinical accuracy of PBGM have been examined and include sample volume, Hct, blood incubation time, color stability of test strips, altitude, degree of hemolysis, blood temperature, humidity, oxygen tension of the sample, prandial state, and type of blood (venous, arterial, or capillary).[9,13,17-21] To our knowledge, there are no reports that addressed potential sources of error of PBGM in small animal medicine, and thus, we attempted to do so from a clinical standpoint. Although PBGM are designed to measure blood glucose concentration in humans using capillary blood, we found no significant differences among the glucose readings of fresh jugular blood without anticoagulant, lithium-heparinized blood, and EDTA-anticoagulated blood of cats. Fluoride-anticoagulated blood of cats can also be used in all the PBGM tested, except for SureStep. This is important in view of the manufacturers' instructions that only fresh blood without anticoagulant or lithium-heparinized blood should be used in QID and Accu-Chek, whereas all conventional anticoagulants except fluoride can be used in SureStep, DEX, and Elite. To obtain an adequate number of blood samples in the low glycemic range, lithium-heparinized blood samples were left at room temperature to allow for glycolysis. This anticoagulant was chosen because it can be used for PBGM as well as the hexokinase reference method.

The minimum volume of blood required for all PBGM was 3 to 5 µl, which is a minute amount and precludes iatrogenic anemia even after repeated sampling. It should be remembered that blood volumes lower than this may result in inaccurate readings, especially with Elite, and to a lesser extent with DEX and Accu-Chek. Those devices start the measuring process regardless of sample volume, and a warning message may be displayed in DEX and Accu-Chek but not in Elite. Thus, one must ensure that the test strip chamber is filled with blood up to the indicator mark when using Elite. This type of error was not encountered with SureStep and QID, because with inadequate sample volume, the measuring process was not initiated.

Another critical factor is Hct. In cats with low Hct, PBGM consistently overestimated glucose concentrations. The reason for this is believed to be an increased diffusion rate of plasma to the reagent pad when the number of erythrocytes is decreased.[9] The effect of Hct was evaluated in the normoglycemic range only because of an insufficient number of hyperglycemic cats with low Hct. In 2 studies performed in humans, an inverse relationship between PBGM readings and Hct was observed; the effect was more pronounced in the hyperglycemic than in the normoglycemic range.[9,13] Thus, the overestimation of the blood glucose concentration observed in normoglycemic anemic cats may be even more pronounced in hyperglycemic anemic cats. Therefore, a clinician experienced in correctly interpreting results from PBGM in the low and high glycemic ranges should use extra caution when evaluating results from anemic cats.

In human medicine, substantial differences in the accuracy of PBGM in different glycemic ranges have been reported, and separation of the data into low, near-normal, and high glycemic ranges has been recommended.[7,12,14] In 2 studies in which PBGM was evaluated for use in dogs and cats, PBGM readings and reference values were highly correlated.[4,6] However, it has been reported that correlation is not an appropriate test for the evaluation of PBGM. Correlation measures association rather than agreement and may be inflated because of an increased measuring range.[15,22] Results of our study supported this, because the correlation coefficient was quite high when calculated for the entire glycemic range but was much lower for individual glycemic ranges. In our study, the accuracy of the PBGM varied in the 3 glycemic ranges. For the most part, the largest difference between PBGM readings and reference values was observed in the high glycemic range. Four PBGM predominantly yielded underestimations in that range, whereas many overestimations were observed with the remaining PBGM (DEX). In the low and reference glycemic ranges, differences between PBGM and reference values were small. It is interesting that all PBGM except QID underestimated the reference value by

approximately 8 mg/dl in the low glycemic range and 18 mg/dl in the reference glycemic range. A possible explanation for this is that PBGM are designed for self-monitoring of blood glucose concentration by humans with diabetes, who adjust their dosage of insulin according to the PBGM reading. With PBGM readings that are slightly less than true (actual) blood glucose values, the diabetic would avoid hypoglycemia by injecting less insulin or by treating potential hypoglycemia earlier.

Although error grid analysis may be biased toward PBGM that underestimate true glucose concentrations in the low range,[23] the technique is used widely and is recommended in studies in humans as the most useful method for the clinical evaluation of PBGM.[11,12,16,22] Although error grid analysis provides no definite information about analytic accuracy of an instrument, it categorizes individual measurements with respect to inadequate therapeutic consequences (zones C, D, and E). This analysis is based on the assumption that the clinical goal in human medicine is to maintain blood glucose concentration between 70 and 180 mg/dl. This range is narrower than that which is usually achieved in the clinical management of dogs and cats with diabetes.

Although there were some significant differences between PBGM readings and reference values in the high glycemic range, all PBGM were clinically accurate and suitable for use in cats. Accu-Chek and Elite appeared to be the most accurate PBGM.

[a]Bayer Diagnostics, Tarrytown, NY.
[b]SureStep (marketed under the name Gluco Touch in Europe), LifeScan Inc, Johnson & Johnson, Milpitas, Calif.
[c]MediSense Inc, Bedford, Mass.
[d]Accu-Chek Simplicity (marketed under the name Glucotrend in Europe), Roche Diagnostics, Indianapolis, Ind.
[e]Cobas Integra Analyser, Roche, Basel, Switzerland.
[f]Glucometer Elite Control Solutions (normal and high concentrations), Bayer Diagnostics, Tarrytown, NY.
[g]Glucometer DEX Control Solutions (low, normal, and high concentrations), Bayer Diagnostics, Tarrytown, NY.
[h]SureStep Normal Control Solution, LifeScan, Milpitas, Calif.
[i]Precision QID Control Solutions (low and high concentrations), MediSense Inc, Bedford, Mass.
[j]Simplicity Control Solutions (normal and high concentrations), Roche-Diagnostics, Indianapolis, Ind.
[k]SPSS for Windows, version 8.0, SPSS Inc, Chicago, Ill.

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Appendix

Characteristics of 5 commercially available portable blood glucose meters

Meter	Measurement range (mg/dl)	Reaction time(s)	Calibration method	Reaction principle	Minimum sample size (µl)
Glucometer Elite[a]	20–600	30	batch-specific calibration strip	electrochemical	3
Glucometer DEX[a]	10–600	30	no calibration	electrochemical	3–4
SureStep[c]	0–500	30	manual	photometric	3–4
Precision QID[d]	20–600	20	batch-specific calibration strip	electrochemical	5
Accu-Chek[e] Simplicity	10–600	30	Batch-specific code chip	photometric	3