System Accuracy of Blood Glucose Monitoring Devices According to the Current and Proposed ISO 15197 Standards

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Daily diabetes management requires blood glucose monitoring systems (BGMS), which provide accurate readings, such as OneTouch® Verio™ meter devices and test strips (LifeScan, Inc., Milpitas, CA). Two recent studies[1,2] that evaluated several BGMSs reported that these systems did not, in all cases, meet the current and the draft revision International Organization for Standardization (ISO) 15197 standards.[3,4] This contrasts with previous LifeScan-sponsored studies evaluating the accuracy of our three BGMSs (A, B, and C), which reported that these systems met the current ISO 15197 criteria,[5] and were particularly accurate at low blood glucose levels.[6] A reanalysis of the same data,[5,6] presented here, further shows that the aforementioned three BGMSs meet the current and proposed ISO 15197 criteria for system accuracy (refer to **Table 1**).

In the LifeScan-sponsored studies, blood glucose testing was performed by trained clinical staff on capillary blood samples from individuals with diabetes (100 per system). Blood samples were centrifuged immediately after collection, to avoid glycolysis, and plasma glucose was measured directly on the YSI 2300 STAT PLUS™ blood glucose analyzer (Yellow Springs Instrument Co., Inc., Yellow Springs, OH).

In comparison, Freckmann and coauthors[1] and Baumstark and coauthors[2] used two different reference methods, comparing some BGMSs to a hexokinase reference and others to a glucose oxidase (GOx) reference method, depending on the manufacturers' specifications. In the Freckmann study, 12 out of 13 BGMSs (92.3%) compared to hexokinase reference method met proposed ISO criteria, whereas only 9 of 30 systems (30%) compared to GOx method met proposed ISO criteria. Approximately two-thirds (19/30, 63.3%) of the systems compared to GOx reference method showed a systematic positive bias. Although not conclusive, this suggests the presence of a systematic negative error in their GOx reference measurements.

The accuracy of the reference methods in the Freckmann study was verified using different standards (National Institute of Standards and Technology Standard Reference Material for hexokinase method, and New England Reagent Laboratory glucose standards for GOx method), making it difficult to directly compare the two methods and identify if either had a systematic bias.

In addition, the two reference methods used different samples: plasma from hemolyzed and deproteinated whole blood for the hexokinase method and whole blood for the GOx method. The authors did not specify how the whole blood

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Table 1.
Percentage of Results within the Defined Accuracy Criteria for the Three LifeScan Blood Glucose Monitoring Systems

System	Strip lot	Current ISO criteria (15197:2003)			Proposed ISO criteria		
		< 75 mg/dl	≥ 75 mg/dl	All	< 100 mg/dl	≥ 100 mg/dl	All
		Within ±15 mg/dl, n/N (%)	Within ±20%, n/N (%)	Within ±15 mg/dl or 20%, n/N (%)	Within ±15 mg/dl, n/N (%)	Within ±15%, n/N (%)	Within ±15 mg/dl or 15%, n/N (%)
A	1	32/32 (100)	168/168 (100)	200/200 (100)	58/58 (100)	141/142 (99.3)	199/200 (99.5)
	2	32/32 (100)	168/168 (100)	200/200 (100)	58/58 (100)	142/142 (100)	200/200 (100)
	3	32/32 (100)	167/168 (99.4)	199/200 (99.5)	56/58 (96.6)	141/142 (99.3)	197/200 (98.5)
	All	96/96 (100)	503/504 (99.8)	599/600 (99.8)	172/174 (98.9)	424/426 (99.5)	596/600 (99.3)
B	1	38/38 (100)	161/162 (99.4)	199/200 (99.5)	46/46 (100)	152/154 (98.7)	198/200 (99)
	2	38/38 (100)	162/162 (100)	200/200 (100)	45/46 (97.8)	153/154 (99.4)	198/200 (99)
	3	38/38 (100)	162/162 (100)	200/200 (100)	46/46 (100)	153/154 (99.4)	199/200 (99.5)
	All	114/114 (100)	485/486 (99.8)	599/600 (99.8)	137/138 (99.3)	458/462 (99.1)	595/600 (99.2)
C	1	34/34 (100)	166/166 (100)	200/200 (100)	56/56 (100)	139/144 (96.5)	195/200 (97.5)
	2	34/34 (100)	166/166 (100)	200/200 (100)	56/56 (100)	140/144 (97.2)	196/200 (98)
	3	34/34 (100)	166/166 (100)	200/200 (100)	56/56 (100)	142/144 (98.6)	198/200 (99)
	All	102/102 (100)	298/498 (100)	600/600 (100)	168/168 (100)	421/432 (97.5)	589/600 (98.2)

samples were protected from glycolysis from the draw time to the reference measurement, possibly allowing for glycolysis to take place. Changes in sample glucose concentrations and/or systematic bias in the reference method could be mistaken for inaccuracy in the investigated BGMSs.

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Disclosures:

All authors were employees of LifeScan, Inc., when the studies were executed. At present, Jan Stegmann and Maria Teodorczyk are no longer with LifeScan, Inc.

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