AgaMatrix® White Paper:
Performance of the AgaMatrix Presto® Advanced Blood Glucose Monitoring System

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Abstract

The AgaMatrix Presto® Blood Glucose Monitoring (BGM) system, manufactured by AgaMatrix, Inc., measures glucose concentration in a sample of fresh capillary whole blood. WaveSense™ Technology uses Dynamic Electrochemistry® coupled with specific signal processing algorithms to correct for a number of errors that are common in self-monitoring blood glucose (SMBG) systems, resulting in more accurate measurements. In addition, the AgaMatrix Presto Blood Glucose Monitoring system will allow our customers to use different lots of test strips without having to change calibration code. As such, the AgaMatrix Presto BGM system is designed in a way that users will not be able to, nor need to, change calibration code. This white paper presents the clinical data to highlight the system accuracy of the AgaMatrix Presto system.

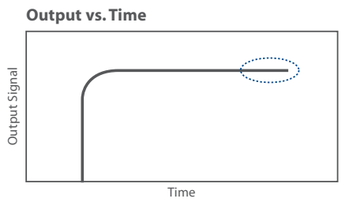
All SMBG systems in major markets (US/Europe) must meet the International Organization for Standardization (ISO) 15197:2003-1, specifying that 95% of glucose results must be within ± 20% of a reference standard (for results at or above 75 mg/dL) and within ± 15 mg/dL (for results below 75 mg/dL). WaveSense Technology enables the Presto meter to exceed this standard.

Some of the main sources of error in SMBG systems come from environmental and sample errors (temperature, hematocrit), and manufacturing errors. Many of these variations are "corrected" by WaveSense Technology; thus the Presto system powered by WaveSense Technology has the ability to provide results that are accurate.

About WaveSense Technology

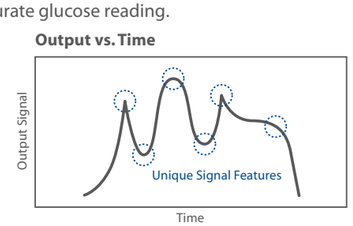
Other leading SMBG systems use: *Static Electrochemistry*

A fixed input signal (such as an applied voltage) from the blood glucose meter results in an output signal that correlates to the glucose concentration in the sample.



AgaMatrix Presto uses: *WaveSense Dynamic Electrochemistry™*

A time-varying input signal from the AgaMatrix Presto meter induces an output signal that is much more information rich, which can then be exploited by sophisticated digital signal processing algorithms to give an accurate glucose reading.



Study Method

This study was conducted according to the requirements in the ISO 15197 standards for accuracy assessment. The ISO standard requires an accuracy study to be conducted at a single site for at least 10 days with at least 100 different capillary blood samples at varying glucose concentrations as shown in Table 1. The <50 mg/dL and the >400 mg/dL requirements can be obtained in the laboratory utilizing venous blood that has been depleted or spiked. This study was conducted over 15 calendar days at Internal Medicine and Endocrinology located in Worcester, MA, USA. Capillary blood from 96 study participants was obtained to fill the glucose ranges. In order to meet the ISO sample requirements, an additional 4 glucose values were obtained in the lab with venous blood that was depleted and 3 glucose values were obtained in the lab with venous blood that was spiked for a total of 103 blood glucose samples.

Table 1

Percentage of samples (%)	Glucose Concentration (mg/dL)
5	<50
15	50 to 80
20	80 to 120
30	120 to 200
15	201 to 300
10	301 to 400
5	>400

Procedure

A whole blood capillary sample was obtained from the finger of each participant. First, blood was collected into two capillary tubes and marked as the initial sample. Next, a whole blood capillary blood sample was introduced to two AgaMatrix Presto Blood Glucose Monitor Systems and the glucose reading was recorded. Blood was further expressed from the lanced site and collected into two more capillary tubes marked as the final sample. The two initial and two final capillary tubes were then centrifuged and the plasma was extracted to be presented to the YSI 2300 STAT Plus Glucose Analyzer. The plasma glucose concentration for the initial capillary tubes was then measured using the YSI. Next, the plasma glucose concentration for the final capillary tubes was measured on the YSI. If the glucose concentration (as determined by the YSI) between the plasma from the initial pair of capillary tubes and the final pair differed by more than 5% (for glucose concentrations >100 mg/dL) or 5 mg/dL (for glucose concentrations ≤100 mg/dL), the sample was affected by drift and the results for that sample were omitted from the analysis. 97 whole capillary blood samples were obtained with one sample excluded from the analysis due to drift resulting in analysis of 96 whole capillary blood samples.

Accuracy Results

The individual results from the AgaMatrix Presto meter were plotted on the Parkes Error Grid[2] against the mean of the YSI (reference) value. The Parkes Error Grid is divided into 5 zones. A zone represents the significance of the error in a glucose reading as it relates to making a clinical decision based on the glucose reading.

Zone A: No effect on clinical outcome.
Zone B: Altered clinical action with little or no effect on clinical outcome.
Zone C: Altered clinical action likely to affect clinical outcome.
Zone D: Altered clinical action could have significant medical risk.
Zone E: Altered clinical action could have dangerous consequences.

The data presented in the Parkes Error Grid and Table 2 indicates that all of the glucose readings obtained during the study are within the clinically accurate Zone A.

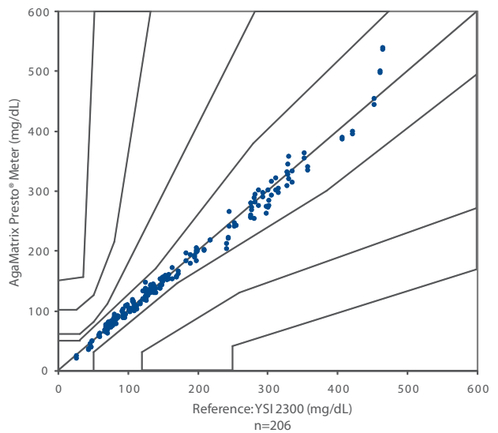


Table 2

Zone A	Zone B	Zone C	Zone D	Zone E
206/206 (100%)	0/206 (0%)	0/206 (0%)	0/206 (0%)	0/206 (0%)

Table 3

For reference concentrations <75 mg/dL			
Within ±5 mg/dL	**Within ±10 mg/dL**	**Within ±15 mg/dL**	
18/28 (64.3%)	27/28 (96.4%)	28/28 (100%)	
For reference concentrations ≥75 mg/dL			
Within ±5%	**Within ±10%**	**Within ±15%**	**Within ±20%**
102/178 (57.3%)	166/178 (93.3%)	173/178 (97.2%)	178/178 (100%)

The clinical accuracy of the AgaMatrix Presto system was evaluated as required in ISO 15197. The ISO system accuracy data in Table 3 demonstrate that the AgaMatrix Presto system exceeds the ISO minimum system accuracy requirements.

The data provided in this white paper illustrates that the AgaMatrix Presto blood glucose monitor is a highly accurate system.

[1]ISO 15197:2003. *In vitro* diagnostic test systems —Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
[2]Parkes, J.L., Pardo S., Slatin S.L., Ginsberg G.H.: A new consensus Error Grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care; 23:1143-1148, 2000.