WaveSense™ Whitepaper: Performance of the WaveSense Jazz™ Blood Glucose Monitoring System

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WaveSense™

www.wavesense.co.uk

Abstract

The WaveSense Jazz™ Blood Glucose Monitoring (BGM) system, manufactured by AgaMatrix, Inc., measures glucose concentration in a sample of fresh capillary whole blood. WaveSense™ 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 accurate and repeatable measurements. In addition, the Jazz Blood Glucose Monitoring system is a codeless system allowing our customers to use different lots of test strips without having to change calibration code. As such, the WaveSense Jazz BGM system is designed in a way so 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 WaveSense Jazz system.

All SMBG systems in major markets (US/Europe) must meet the performance requirements described in 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 4.16 mM) and within ± 0.83 mM (for results below 4.16 mM). WaveSense technology enables the Jazz meter to exceed this standard.

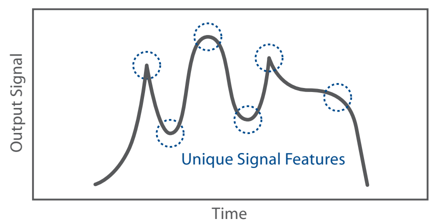
Some of the main sources of error in SMBG systems come from environmental and sample errors (temperature, hematocrit), and manufacturing errors. Many of these variations are "corrected" by WaveSense; thus the Jazz system powered by WaveSense has the ability to provide results that are accurate.

About WaveSense™

Jazz™ uses: *WaveSense Dynamic Electrochemistry™*

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

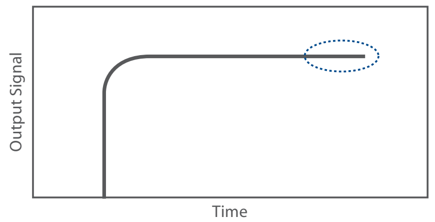
Output vs. Time



Many other leading SMBG systems use:
Static Electrochemistry

A fixed input signal (such as a fixed voltage for a fixed amount of time), from the blood glucose meter, results in an output signal that generally has few signal features.

Output vs. Time



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 extreme concentration requirements can be obtained in the laboratory utilizing venous blood that has been depleted or spiked. This study was conducted over 24 calendar days at Internal Medicine and Endocrinology located in Worcester, MA, USA. Capillary blood from 91 study participants was obtained to fill the glucose ranges. Once a glucose range was filled, subsequent samples that had a glucose concentration that would be in a filled range were excluded from the analysis. In order to meet the ISO sample requirements, an additional 9 glucose values were obtained in the lab with venous blood that was spiked or depleted for a total of 100 blood glucose samples.

Table 1

Percentage of samples (%)	Glucose Concentration (mM)
5	<2.8
15	2.8 to 4.3
20	4.3 to 6.7
30	6.7 to 11.1
15	11.1 to 16.6
10	16.7 to 22.2
5	>22.2

Procedure

A whole blood capillary sample was obtained by finger stick from each participant. The sample of blood obtained was collected into two capillary tubes and marked as the initial sample. Next, a whole blood capillary blood sample was introduced to two WaveSense Jazz Blood Glucose Monitor Systems and the glucose readings were recorded. Additional blood was obtained using a second finger stick, if necessary, 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 4% (for glucose concentrations >5.55 mM) or 0.22 mM (for glucose concentrations ≤5.55 mM), the results of that sample were omitted from the analysis as the results may have been affected by drift. 110 whole capillary blood samples were obtained with 5 samples excluded from the analysis due to drift and 14 samples excluded from the analysis due to previous fulfillment of a glucose range, resulting in analysis of 91 whole capillary blood samples. The remaining 9 samples were obtained by spiking or depleting venous, tonometered samples in the laboratory.

Accuracy Results

The individual results from the Jazz 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. Each 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 99.5% of the glucose readings obtained during the study are within the clinically accurate Zone A.

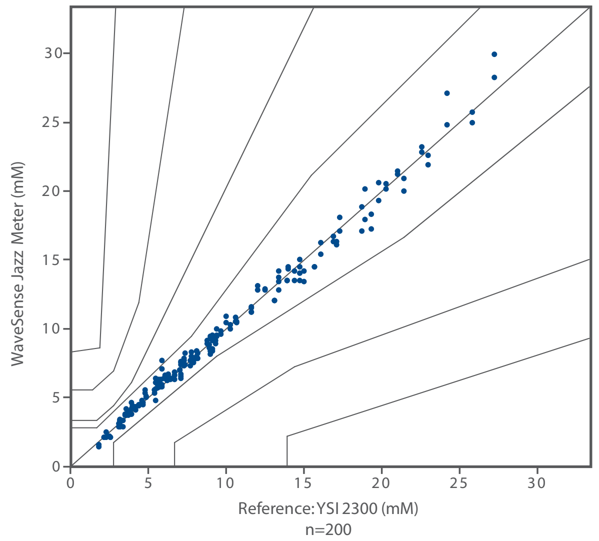


Table 2

Zone A	Zone B	Zone C	Zone D	Zone E
199/200 (99.50%)	1/200 (0.50%)	0/200 (0%)	0/200 (0%)	0/200 (0%)

Table 3

For reference concentrations <4.16 mM		
Within ±0.28 mM	**Within ±0.56 mM**	**Within ±0.83 mM**
22/36 (61.11%)	34/36 (94.44%)	36/36 (100%)

For reference concentrations ≥4.16 mM			
Within ±5%	**Within ±10%**	**Within ±15%**	**Within ±20%**
108/164 (65.85%)	151/164 (92.07%)	161/164 (98.17%)	162/164 (98.78%)

The ISO system accuracy data in Table 3 demonstrate that the WaveSense Jazz system exceeds the ISO minimum system accuracy requirements.

The data provided in this white paper establishes the WaveSense Jazz blood glucose monitor as a highly accurate system when evaluated according to the ISO 5197 system accuracy requirements.

[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.

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