

# **AgaMatrix White Paper**

WaveSense JAZZ™ System Accuracy Study:

EN ISO 15197:2015

An Independent UK Study

## System Accuracy

### EN ISO 15197:2015

Updated system accuracy requirements for blood glucose monitoring systems (BGMS) have been published in EN ISO 15197:2015 standard.<sup>1</sup>

### Requirement

The minimum acceptable accuracy performance criteria are specified in EN ISO 15197:2015, section 6.3.3.

**The BGMS shall meet both of the following minimum criteria for acceptable system accuracy:**

- A.** 95% of the measured glucose values shall fall within either  $\pm 0.83$  mmol/l ( $\pm 15$  mg/dl) of the average measured values of the reference measurement at glucose concentrations  $< 5.55$  mmol/l ( $< 100$  mg/dl) or within  $\pm 15\%$  at glucose concentrations  $\geq 5.55$  mmol/l ( $\geq 100$  mg/dl).
- B.** 99% of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid (CEG) for type 1 diabetes.

Criterion A shall be applied to each reagent lot individually. The measured values from each lot shall be analyzed and reported separately.

Criterion B shall be applied to the 3 reagent lots taken together. All measured values from the 3 lots shall be combined before analysis and reporting.

### Objective

The objective of this study is to investigate the accuracy of the blood glucose readings provided by the WaveSense JAZZ™ BGMS, when compared to the laboratory reference method, Yellow Springs Instruments 2300 STAT Plus.

### Method

The study was performed in UK by the Diabetes Research Group at Swansea University according to EN ISO 15197:2015, section 6.3. The Principal Investigator was Professor Stephen Bain.

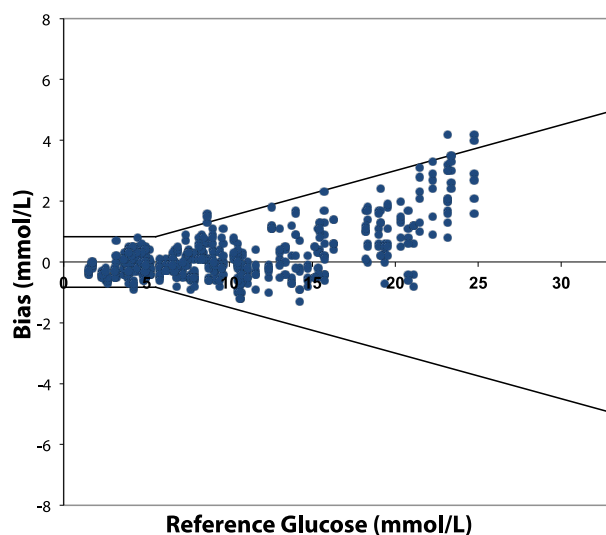
System accuracy was evaluated using fresh blood samples from study participants with diabetes, and was conducted in conditions reflecting actual conditions of use. Three lots of test strips were used in the study. The blood glucose concentrations of the samples were targeted to be distributed as in the below table, per EN ISO 15197:2015. Also, if the study population does not provide sufficient samples in the lowest and highest categories shown in the table below, these may be supplemented with modified blood samples in which the glucose concentration may be raised or lowered. In this study, modified samples were used to supplement bin 1 (4 samples), bin 2 (7 samples) and bin 7 (2 samples).

Bin #	Percentage of Samples (%)	Glucose Concentration mmol/l (mg/dl)
1	5	$\leq 2.77$ ( $\leq 50$ )
2	15	$> 2.77$ to $4.44$ ( $> 50 - 80$ )
3	20	$> 4.44$ to $6.66$ ( $> 80 - 120$ )
4	30	$> 6.66$ to $11.10$ ( $> 120 - 200$ )
5	15	$> 11.10$ to $16.65$ ( $> 200 - 300$ )
6	10	$> 16.65$ to $22.20$ ( $> 300 - 400$ )
7	5	$> 22.20$ ( $> 400$ )

## Results

### Accuracy Criterion A

The difference between each individual BGM reading and its corresponding YSI 2300 STAT Plus plasma glucose reference concentration for all the three lots of test strips is shown in the system accuracy difference plot, Figure 1. All the three lots have passed system accuracy Criterion A. Overall, 99% of readings met accuracy criterion A.



**Figure 1:** System accuracy plot for BGMS glucose vs. YSI 2300 plasma glucose concentration. Data shown is from all the three test strip lots. Area inside the solid lines represents minimum acceptable accuracy from EN ISO 15197:2015.

**Table 1:** Summary of system accuracy results for each lot at all glucose concentrations

LOT #	System Accuracy Results for Glucose Concentrations		
	$< 5.55$ mmol/l ( $< 100$ mg/dl), Within $\pm 0.83$ mmol/l ( $\pm 15$ mg/dl)	$\geq 5.55$ mmol/l ( $\geq 100$ mg/dl), Within $\pm 15\%$	All glucose concentrations
KL19WN18M	68/70 (97%)	129/130 (99%)	197/200 (99%)
KL29WN55D	70/70 (100%)	128/130 (98%)	198/200 (99%)
KL24WN36H	70/70 (100%)	128/130 (98%)	198/200 (99%)

Table 2: Overall system accuracy results

System Accuracy Results for Glucose Concentrations < 5.55 mmol/l (< 100 mg/dl)		
Within $\pm 0.28$ mmol/l ( $\pm 5$ mg/dl)	Within $\pm 0.56$ mmol/l ( $\pm 10$ mg/dl)	Within $\pm 0.83$ mmol/l ( $\pm 15$ mg/dl)
111/210 (53%)	197/210 (94%)	208/210 (99%)
System Accuracy Results for Glucose Concentrations $\geq 5.55$ mmol/l ( $\geq 100$ mg/dl)		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
224/390 (57%)	349/390 (89%)	385/390 (99%)
System Accuracy Results for Glucose Concentrations Combined, Using EN ISO 15197:2015 Criteria		
Within $\pm 0.83$ mmol/l ( $\pm 15$ mg/dl) and $\pm 15\%$		
593/600 (99.0%)		

### Accuracy Criterion B

The consensus error grid in Figure 2, shows that 600/600 (100%) values fall within zone A, defined as “no effect on clinical action”.<sup>2</sup>

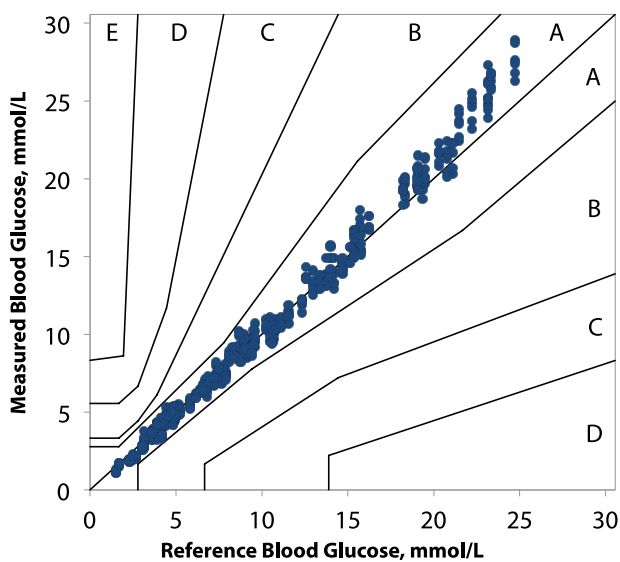


Figure 2: Plot of BGMS glucose concentrations vs. YSI 2300 plasma glucose concentrations.

Zone	A	B	C	D	E
Cases	600	0	0	0	0
Percentage	100.0%	0.0%	0.0%	0.0%	0.0%

### Conclusion

The WaveSense JAZZ™ blood glucose monitoring system meets and exceeds the minimum acceptable system accuracy criteria specified in EN ISO 15197:2015.

### References

1. International Organization for Standardization. *In vitro diagnostic test systems - requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus*. 2013. EN ISO 15197:2015.
2. Parkes, J.L., et al. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. 2000, *Diabetes Care*, Vol. 23, pp. 1143-1148.



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