

# Accuracy of a Blood Glucose Meter System (BGMS) as it relates to the ISO 15197:2013 Requirements in the Monitoring of Diabetes Mellitus

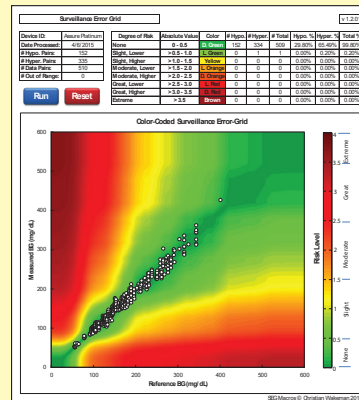


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## BACKGROUND

Blood Glucose Monitoring Systems (BGMS) are a critical tool used in the management of diabetes. The gold standard in measuring the accuracy of BGMS in the testing of diabetes mellitus is known as the ISO 15197:2013. The level of accuracy of the BGMS results in the ability to regulate an individual's blood glucose levels. According to the ISO 15197:2013, system accuracy performance criteria is defined as 95% of the BGMS results falling within  $\pm 15$ mg/dL of the reference analyzer results with glucose concentrations less than 100 mg/dL.

For samples with glucose concentrations  $\geq 100$  mg/dL, 95% of the BGMS results need to be within 15% of the reference analyzer results. Furthermore 99% of all results are required to be in the A and B zones of the Consensus Error Grid.

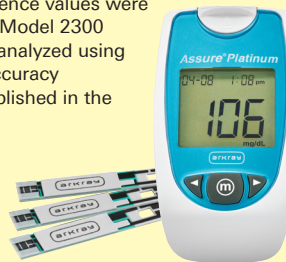


## PURPOSE

The objective of this study is to demonstrate whether the Assure® Platinum aligns with the ISO 15197:2013 BGMS accuracy performance requirements.

## METHOD

Seventeen lots of Assure® Platinum blood glucose test strips were evaluated for performance and bias comparison (n=510 data points). The samples were collected from the fingertip of confirmed diabetics by trained personnel at the ARKRAY Factory, Inc. in Minneapolis, MN. Reference values were obtained using the YSI Model 2300 Analyzer. The data was analyzed using the minimum system accuracy performance criteria published in the ISO 15197:2013.



## RESULTS

The results showed that 100% of the <100 mg/dL samples (48/48) were within  $\pm 15$  mg/dL thus meeting the 95% accuracy criteria. 98.3% of the  $\geq 100$ mg/dL samples (n=454/462) fell within the pre-determined 15% which met the 95% performance criteria. All data were within the A and B zones of the Consensus Error Grid. The overall bias was -2.7% demonstrating strong agreement between the Assure Platinum and YSI reference analyzer results, which is considered the gold standard glucose assay for BGMS studies. The correlation coefficient (r) = 0.97 demonstrates a strong linear relationship between the YSI reference method and the meter results.

**Table 1:**  
**Assure® Platinum Results**  
**ISO 15197:2013 guidelines**

<100 mg/dL	Within $\pm 15$ mg/dL
n = 48	48
	100.0%
$\geq 100$ mg/dL	Within $\pm 15\%$
n = 462	454
	98.3%

## CONCLUSION

The data acquired on the Assure® Platinum met the ISO 15197:2013 system accuracy performance criteria, the most stringent BGMS requirement in the monitoring of diabetes mellitus.