Performance Evaluation of the Dario Blood Glucose Monitoring System In Compliance With the ISO 15197:2013 Standard

Paul Rosman and Billy Pery; New York, New York, USA and Caesarea, Israel

Introduction

Self-monitoring of blood glucose (SMBG) is an integral component of successful diabetes mellitus management. International Standards Organization (ISO) 2003 performance requirements of glucose monitoring systems have been upgraded to ISO 15197:2013 rules. The Dario™ Blood Glucose Monitoring System (BGMS) meets ISO 15197:2013 precision and accuracy criteria for performance as shown here.

Objective:

To evaluate the Dario™ BGMS performance according to the upgraded ISO 15197:2013 standard.
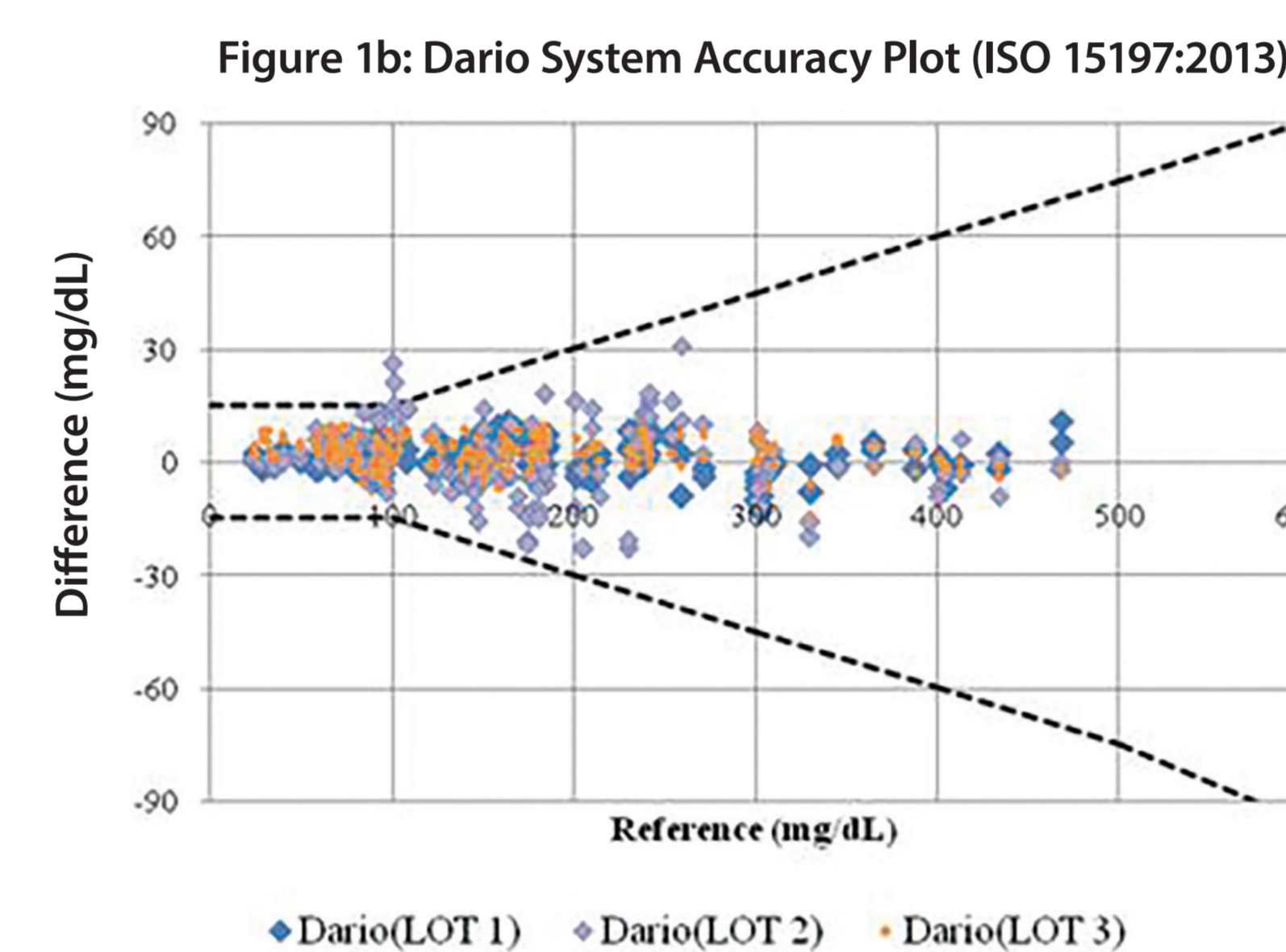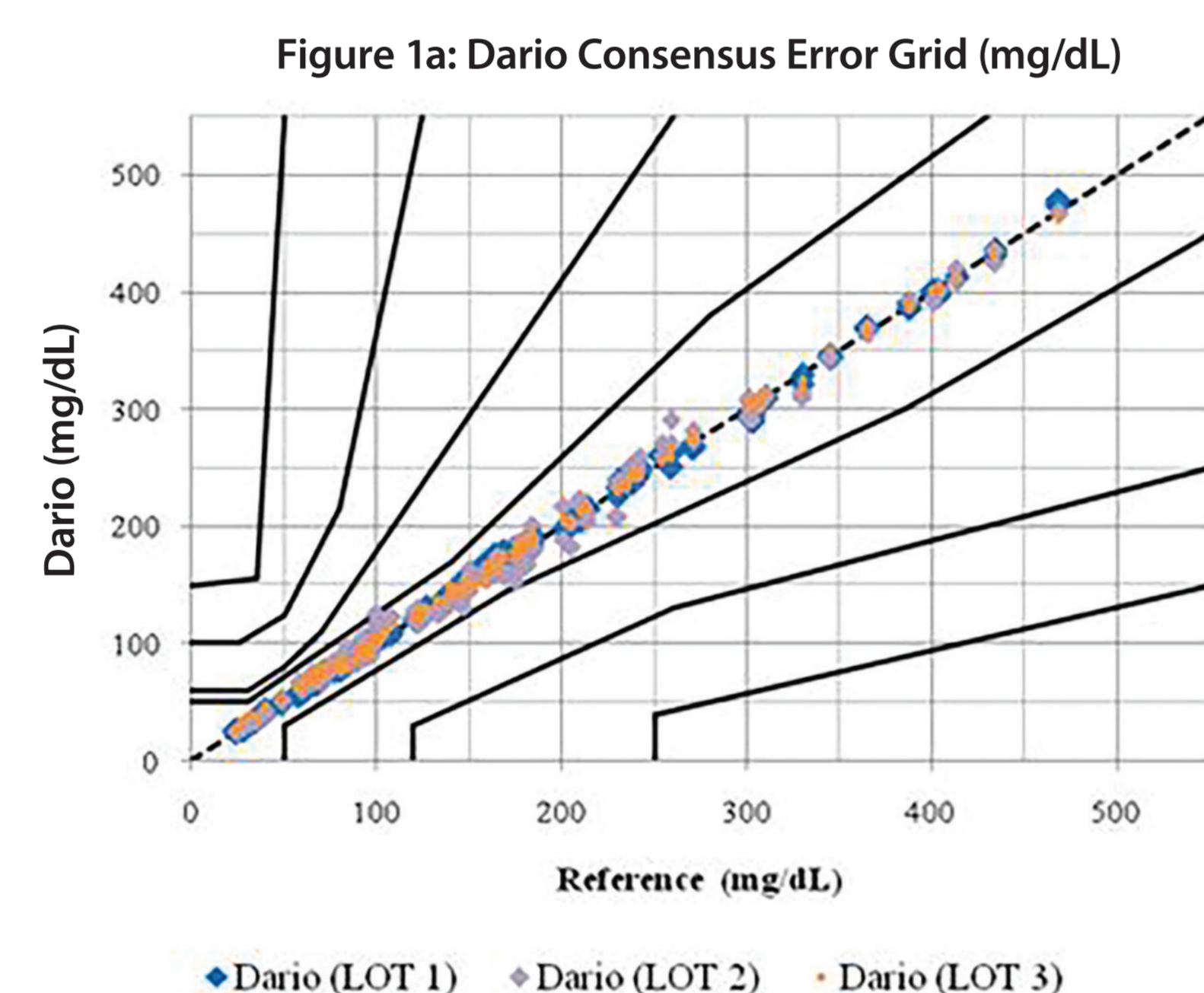
Method:

78 adult diabetes patients donated 100 fresh capillary whole blood samples. Glucose values were measured from the fresh blood samples using two different Dario™ meters, and three Dario™ test strips lots. Data from each of the 600 measured blood samples were compared with the results obtained from the same blood samples on a YSI (Yellow Springs Instruments, Yellow Springs, Ohio) glucose analyzer. These comparisons were assessed for accuracy. Analytical precision analysis used 3 test strip lots, 10 DBGMS meters and 5 glucose concentrations over 10 days: Hb and temperature were controlled.

Results:

Accuracy results

Below 100 mg/dL, 100% (216/216) of the values fell within ± 15 mg/dL. Above 100 mg/dL, 99.5% (382/384) of the values were within ± 15% of the reference value. Additionally, consensus error grid analysis showed 100% of the individual values fell within zones A and B. These results meet the ISO 15197:2013 accuracy requirements for the Dario™ BGMS.

Table 1: Dario System Accuracy Results					
System accuracy results for glucose concentrations <100 mg/dL			System accuracy results for glucose concentrations ≥100 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 5%	Within ± 10%	Within ± 15%
175/216 81%	213/216 98.6%	216/216 100%	330/384 85.9%	372/384 96.9%	382/384 99.5%

Figure 1a: Dario Consensus Error Grid (mg/dL)

Figure 1b: Dario System Accuracy Plot (ISO 15197:2013)

Precision results

The combined repeatability measurement precision had an SD of less than 1.789 mg/dL at glucose concentrations of less than 100 mg/dL and a CV of less than 2.5% at blood glucose concentrations ≥ 100 mg/dL. The combined intermediate measurement precision had a CV of less than 2.9% for blood glucose concentration of ≥ 100 mg/dL and an SD of under 2.324 mg/dL at blood glucose concentration of under 100 mg/dL. These results exceed the analytic precision acceptance criteria for ISO 15197:2013.

Table 2a: Analytical Precision Analysis: Repeatability Evaluation		
Acceptance Criteria	Glucose Concentration (mg/dL)	Combined Results (all lots)
< 100 (mg/dL)	< 100 (mg/dL)	STD (mg/dL)
Within standard deviation 3 mg/dL	30 - 50	1.257
	51 - 110	1.789
≥ 100 (mg/dL)	≥ 100 (mg/dL)	CV (%)
Within CV 4%	111 - 150	1.8
	151 - 250	2.5
	251 - 400	2.1

* For Concentrations under 100 mg/dL Standard Deviation (mg/dL) Was Calculated for Repeated Measurements.
 For Concentrations ≥ 100 mg/dL Coefficient of Variation (%) Was Calculated.

Table 2b: Analytical Precision Analysis: Intermediate Precision Evaluation		
Acceptance Criteria	Glucose Concentration (mg/dL)	Combined Results (all lots)
< 100 mg/dL	< 100 (mg/dL)	STD (mg/dL)
Within standard deviation 3 mg/dL	30 - 50	2.324
≥ 100 (mg/dL)	≥ 100 (mg/dL)	CV (%)
Within CV 4%	96 - 144	2.9
	280 - 420	2.4

* Calculations for Concentrations under 100 mg/dL Standard Deviation (mg/dL) for Repeated.
 Measurements over Multiple Days and for Concentrations ≥ 100 mg/dL Coefficient of Variation (%).

Conclusion:

Dario™ BGMS performance meets and exceeds the upgraded ISO15197: 2013 standard for glucose monitoring systems. By meeting these standards, the Dario BGMS demonstrates the technological proficiency required to deliver vital clinical data accurately and precisely to people with diabetes and their caregivers.