Date: Feb 10, 2015

WHITE PAPER:

DARIO™ BLOOD GLUCOSE MONITORING SYSTEM – USER PERFORMANCE EVALUATION

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1.0 PURPOSE

Self-monitoring of blood glucose is a valuable tool for helping patients achieve and maintain target blood glucose levels in order to reduce the risk of diabetes-related complications. Particularly, frequent self-monitoring of blood glucose is an essential pre-requirement to adequately manage diabetes mellitus type 1 or type 2 treated with insulin. When performed and utilized properly, blood glucose meters for self-measurement of blood glucose allow diabetic patients to determine their blood glucose level and to use the information as part of their treatment program.

The analytical performance of blood glucose monitoring systems is defined by the term 'system accuracy' and there are currently no international standards for accuracy assessment that are generally accepted by all regulatory agencies, however, widely accepted method for accuracy determination is set forth in ISO 15197:2003 and its latest revision ISO 15197:2013.

The DARIO™ BGMS has already been cleared for marketing in several countries including EU, New Zealand and Australia based on demonstrating compliance with the requirements of ISO 15197:2003.

The aim of this study is to evaluate the accuracy of the DARIO™ BGMS compared to a 'reference method' (YSI 2300 STAT PLUS). This paper summarizes the results obtained during the first 4 weeks of a user performance study that was initiated on the 2nd week of December 2014.

2.0 THE DARIO™ BLOOD GLUCOSE MONITORING SYSTEM (BGMS)

The Dario™ Blood Glucose Monitoring System (BGMS) by LabStyle Innovations Ltd. is used for measuring blood glucose levels from fresh capillary whole blood samples taken from the fingertip. It consists of a blood glucose meter (dongle), which is attached to a smart mobile device via the audio jack to a dedicated application, disposable test strips, a strip cartridge, a lancing device and lancets.
The Dario™ BGMS has a unique all-in-one feature allowing the holding of all relevant items for glucose self-testing in one small, easy to carry, simple to use lancing device enclosure, while enabling blood glucose measurement as is customary in other smart and non-smart device-based products on the market.

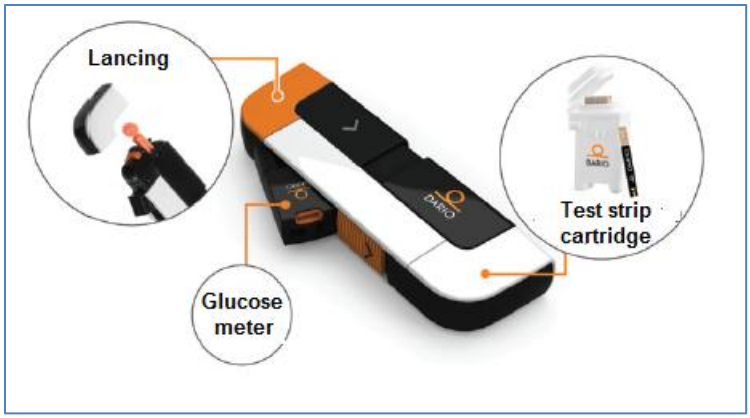

Figure 1: Dario™ Device

3.0 STUDY STRUCTURE

3.1 Enrollment Criteria

The study population included diabetic male and female subjects that were otherwise in general good health according to the following criteria:

Inclusion Criteria

1. Subject has Type I or Type II diabetes
2. Subject speaks and reads English proficiently
3. Subject owns and uses Android and iOS based smart mobile device for at least 1 year
4. Subject is able and agrees to sign the informed consent form (minor subjects must be accompanied by a parent or legal guardian to provide consent for their participation in the study)

Exclusion Criteria

1. Subject has medical training or works in the field of BGMS
2. Subject is critically ill
3. Subject has an impairment that prevents him/her from following the study procedures
4. Subject has any condition that the Principal Investigator believes may interfere in the subject's participation in the study

The recruitment was performed through advertisement, outpatient clinics, physician offices, and similar sources.

3.2 Sample Size

According to ISO 15197:2013 guidance; a user performance evaluation study includes 193 subjects.

3.3 Accuracy Data Analysis

The accuracy analysis focuses on comparing the BGL results obtained by the subject using the Dario™ BGMS vs. the BGL results by the YSI.

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3.4 Demographics and Baseline Characteristics

A total of 193 subjects (Table 1) participated in the study. The gender distribution is 76 (39.4%) females and 117 (60.6%) males between the ages of 13 and 81 (mean age 52.6 ± 13.51). Thirty-seven (19.3%) subjects have type I diabetes and 155 (80.7%) subjects have type II diabetes.

The demographic and baseline characteristics are provided in Table 2.

Table 1: Patient Disposition

Summary	***All Subjects***
Enrolled Subjects	193
Usability Subjects	193
Efficacy Subjects	193
Completion Status	
Yes	193 (100.0%)
No	0 (0.0%)
Reason for Not Completing	
Failure to perform self-test	0
Technical problem	0
Consent withdrawn	0
Non-compliant participant	0
Protocol violation	0
Adverse Event	0
Other	0

Table 2: Demographics and Baseline Characteristics

Summary	***All Subjects***
Number of Subjects	193
Age	
N	193
Mean (SD)	52.6 (13.51)
Median	53.0
Min, Max	13, 81
Gender	
Female	76 (39.4%)
Male	117 (60.6%)
Total	193

Table 2: Demographics and Baseline Characteristics

Summary	*All Subjects*
Diabetes Type	
I	37 (19.3%)
II	155 (80.7%)
Unknown	0
Total	192
Time Elapsed Since Diabetes Diagnosis	
1 to 5 years ago	59 (31.4%)
6 to 10 years ago	53 (28.2%)
More than 10 years ago	73 (38.8%)
Unknown	3 (1.6%)
Total	188

3.5 Blood Glucose Results

All 193 subjects successfully performed the self-test with the Dario™ BGMS using only its labeling material and the medical staff successfully obtained blood glucose results with the YSI 2300 STAT PLUS reference method for all 193 subjects. The results are provided in Table 3.

Table 3: Blood Glucose Results

Summary	*All Subjects*	
Number of Subjects	193	
Subject Dario Self-Test Blood Glucose[1] [N=193]	**(mg/dL)**	**(mmol/l)**
Mean (SD)	155.41 (72.976)	8.63 (4.05)
Coefficient of Variation	46.96	2.61
Median	136.00	7.55
Min, Max	58.0, 477.0	3.22, 26.47
Average YSI Reference Test Blood Glucose[2] [N=193]	**(mg/dL)**	**(mmol/l)**
Mean (SD)	151.89 (70.787)	8.43(3.93)
Coefficient of Variation	46.60	2.59
Median	133.00	7.38
Min, Max	51.9, 435.5	2.88, 24.17

The range of the blood glucose levels was from 58mg/dL (3.2mmol/l) to 477mg/dL (25.5mmol/l) as measured by the Dario™ BGMS or from 52mg/dL (2.9mmol/l) to 436mg/dL (24.2mmol/l) as measured by the YSI.
As presented in Table 4 below, the mean difference between the blood glucose results obtained by the Dario™ BGMS and these obtained by the YSI reference method on the

[1] Table summary captures the results from the first successful attempt
[2] The average of two tests per patient

entire blood glucose range was 3.5mg/dL (0.2mmol/l). The results of the Regression Analysis are summarized in Table 5 and the system accuracy is illustrated in Figure 2.

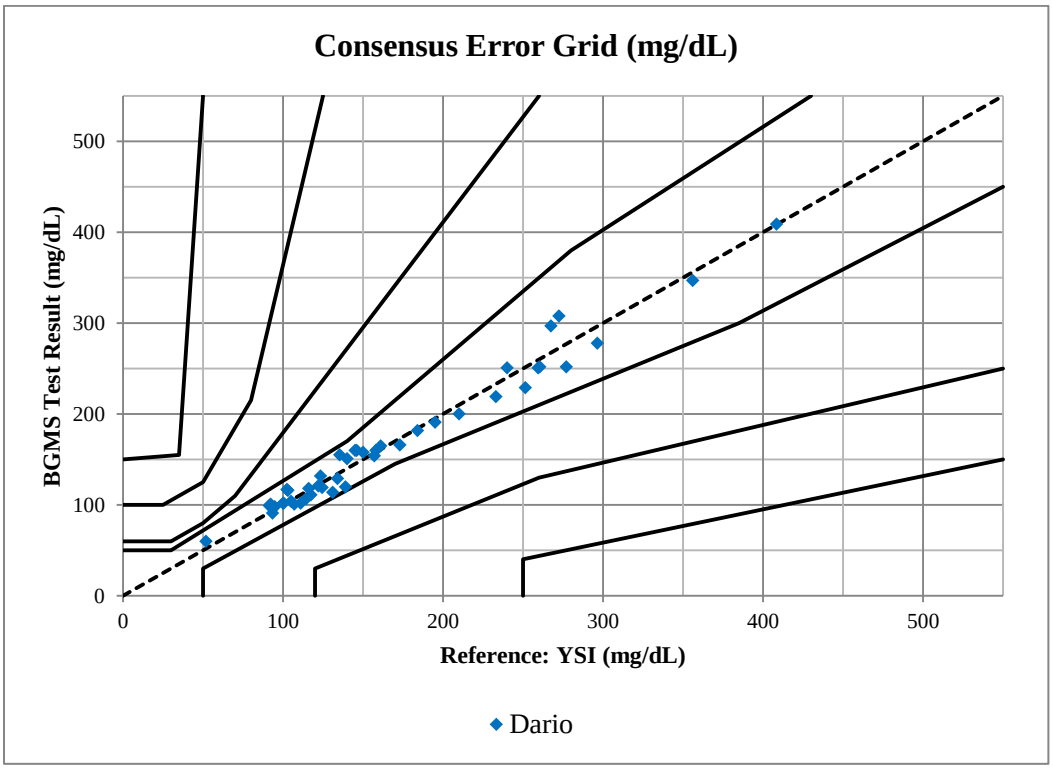
Table 4: Paired Difference Blood Glucose Results

Summary	***All Subjects***	
Number of Subjects	193	
Subject Self-Test - YSI Reference Test	**(mg/dL)**	**(mmol/l)**
Mean (SD)	3.52 (12.661)	0.20 (0.70)
Median	3.00	0.17
Min, Max	-32.0, 48.5	-0.18, 2.69

Table 5: Regression Analysis Results

Comparison	***Intercept***	***Slope***	***R-Value***
Subject Self-Test vs. YSI Reference Test	1.185	1.015	0.970

Figure 2: System Accuracy Plot



Presented below are the accuracy limits of the Dario™ BGMS per ISO 15197:2013 (Table 6)

Table 6: Accuracy Limits of Dario™ BGMS – ISO 15197:2013					
for glucose concentrations <100 mg/dL (5.5 mmol/l)			for glucose concentrations >=100 mg/dL (5.5 mmol/l)		
Within ± 5 mg/dL (0.28 mmol/l)	Within ± 10 mg/dL (0.56 mmol/l)	Within ± 15 mg/dL (0.83 mmol/l)	Within ± 5%	Within ± 10%	Within ± 15%
23 / 45 (51.1%)	39 / 45 (86.7%)	45 / 45 (100.0%)	65 / 148 (43.9%)	113 / 148 (76.4%)	142 / 148 (95.9%)

4.0 DISCUSSION AND CONCLUSIONS

The acceptance criteria for accuracy of BGMS per ISO 15197:2013 is "*95 % of the individual glucose measured values shall fall within ± 0,83 mmol/l (±15 mg/dl) of the measured values of the manufacturer's measurement procedure at glucose concentrations < 5,55 mmol/l (<100 mg/dl) and within ± 15% at glucose concentrations ≥ 5,55 mmol/l (≥100 mg/dl)*". According to table 7-2, 100% of the Dario glucose results within ± 0,83 mmol/l (15 mg/dl) at glucose concentrations < 5.5 mmol/l (< 100 mg/dl) and 95.9% of the Dario glucose results within± 15% at glucose concentrations ≥5.5 mmol/l (≥100 mg/dl). Therefore, the Dario™ BGMS meets the acceptance criteria of ISO 15197:2013.