

77-LB — 2015

Performance of Dario Blood Glucose Monitoring System Evaluated in a Clinical Study in Compliance with the New ISO 15197:2013 Standard[View ePoster](#)*Clinical Therapeutics/New Technology - Glucose Monitoring and Sensing*

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Blood glucose monitoring systems (BGMS) are an in basic tool for diabetes patients. The innovative Dario™ BGMS enables convenient self-monitoring by adding a proprietary smart phone application. We evaluated accuracy and user performance in a clinical trial of 368 type 1 and type 2 diabetic patients, each of whom tested fresh capillary finger prick blood glucose levels while using this BGMS for the first time, as instructed only by the manufacturer's directions for using the device. Glucose value accuracy was determined in one sample obtained from each subject measured both on the BGMS by individual subjects and by a reference analysis of the identical sample. We documented sample collection or measurement errors. When needed, repeat sampling by each subject was limited to 3 per subject. The interval of glucose levels tested were BGMS range 43.0-477.0 mg/dL, and YSI range 42.3-435.5 mg/dL. There were no outliers. We used all 368 lay subjects' samples. Accuracy for this BGMS met ISO 15197:2013 criteria. Below 100 mg/dL, 97.8% of values were within ± 15 mg/d of YSI reference glucose values. For samples with glucose above or equal to 100 mg/dL, 96.4% of values were within $\pm 15\%$ of YSI glucose levels. Lay subject performance assessment of the Dario BGMS' instruction clarity and usefulness showed 97.1% of subjects found instructions easy to follow with 70.7% rating they were very satisfied (5/5) and 26.4% rating they were satisfied (4/5). Reading the result on the smart mobile device was rated easy to understand by 99.1% of lay subjects, with 86.1% rated it very easy (5/5) and 13% rated it easy (4/5). If an error message displayed on the report screen, 96.4% of lay subjects were clear about what to do, with 50% reporting it was very clear (5/5) and 46.4% reported it was clear (4/5). The Dario BGMS meets ISO 15197:2013 standards for clinical performance as determined by lay user accuracy and by satisfactory experience with the BGMS instructions clarity and system utility

Disclosure: **B. Pery:** *Employee; Author, LabStyle Innovations, Ltd.* **P.M. Rosman:** *Advisory Panel; Author, LabStyle Innovations Ltd. Consultant; Author, LabStyle Innovations Ltd. Research Support; Author, LabStuke Innovations Ltd. Speaker's Bureau; Author, LabStyle Innovations Ltd.*

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