

Performance of the DIDGET Blood Glucose Monitoring System in Children, Teens, and Young Adults

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Abstract

Background:

This study evaluated the performance of the DIDGET® blood glucose monitoring system (BGMS) in the hands of its intended users: children, teens, and young adults with diabetes.

Methods:

Finger stick capillary blood samples were tested in duplicate by subjects (with parent/guardian assistance, if needed) and health care professionals using the DIDGET BGMS, and results were compared with those obtained using a Yellow Springs Instruments (YSI) glucose analyzer. Modified venous blood samples (i.e., glycolyzed or spiked with glucose) were used to analyze meter performance under extreme glucose concentrations. Accuracy was assessed using International Organization for Standardization (ISO) 15197:2003 guidelines (i.e., 95% of meter results within ± 15 mg/dl or $\pm 20\%$ of reference values).

Results:

A total of 123 subjects aged 4 to 24 years with type 1 or type 2 diabetes were enrolled. The DIDGET meter achieved accuracy according to ISO 15197:2003 criteria: $>97\%$ of meter results were within ± 15 mg/dl or $\pm 20\%$ of reference values. Regression analyses showed a high degree of correlation between meter and YSI results: coefficient of determination (R^2) = 98.2% for all samples combined and 97.2% for capillary samples only. Clinical accuracy for combined samples was demonstrated by Parkes consensus error grid analyses; 100% of meter results were in zone A (98.5%) or zone B (1.5%). There was no difference in performance or accuracy across age subsets. Hematocrit values did not affect meter blood glucose results.

Conclusion:

The DIDGET BGMS provided accurate test results across all age ranges in children, teens, and young adults with diabetes.

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Abbreviations: (BGMS) blood glucose monitoring system, (HCP) health care professional, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose, (YSI) Yellow Springs Instruments

Keywords: blood glucose monitoring, children with diabetes, diabetes management, health-related video game technology, motivational tools for self-monitoring of blood glucose, self-monitoring of blood glucose

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