

Performance Evaluation and Labeling Comprehension of a New Blood Glucose Monitoring System with Integrated Information Management

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Abstract

Background:

This study evaluated performance and product labeling of CONTOUR® USB, a new blood glucose monitoring system (BGMS) with integrated diabetes management software and a universal serial bus (USB) port, in the hands of untrained lay users and health care professionals (HCPs).

Method:

Subjects and HCPs tested subject's finger stick capillary blood in parallel using CONTOUR USB meters; deep finger stick blood was tested on a Yellow Springs Instruments (YSI) glucose analyzer for reference. Duplicate results by both subjects and HCPs were obtained to assess system precision. System accuracy was assessed according to International Organization for Standardization (ISO) 15197:2003 guidelines [within ± 15 mg/dl of mean YSI results (samples < 75 mg/dl) and $\pm 20\%$ (samples ≥ 75 mg/dl)]. Clinical accuracy was determined by Parkes error grid analysis. Subject labeling comprehension was assessed by HCP ratings of subject proficiency. Key system features and ease-of-use were evaluated by subject questionnaires.

Results:

All subjects who completed the study ($N = 74$) successfully performed blood glucose measurements, connected the meter to a laptop computer, and used key features of the system. The system was accurate; 98.6% (146/148) of subject results and 96.6% (143/148) of HCP results exceeded ISO 15197:2003 criteria. All subject and HCP results were clinically accurate (97.3%; zone A) or associated with benign errors (2.7%; zone B). The majority of subjects rated features of the BGMS as "very good" or "excellent."

Conclusions:

CONTOUR USB exceeded ISO 15197:2003 system performance criteria in the hands of untrained lay users. Subjects understood the product labeling, found the system easy to use, and successfully performed blood glucose testing.

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Abbreviations: (BGMS) blood glucose monitoring system, (CLSI) Clinical and Laboratory Standards Institute, (CV) coefficient of variation, (HCP) health care professional, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose, (USB) universal serial bus, (YSI) Yellow Springs Instruments

Keywords: blood glucose monitoring, CONTOUR USB, diabetes, diabetes management, diabetes management software

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