

Tighter Accuracy Standards within Point-of-Care Blood Glucose Monitoring: How Six Commonly Used Systems Compare

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Abstract

Introduction:

Blood glucose monitoring systems (BGMS) are used in the hospital environment to manage blood glucose levels in patients at the bedside. The International Organization for Standardization (ISO) 15197:2003 standard is currently used by regulatory bodies as a minimum requirement for the performance of BGMS, specific to self-testing. There are calls for the tightening of accuracy requirements and implementation of a standard specifically for point-of-care (POC) BGMS.

Methods:

The accuracy of six commonly used BGMS was assessed in a clinical setting, with 108 patients' finger stick capillary samples. Using the accuracy criteria from the existing standard and a range of tightened accuracy criteria, system performance was compared. Other contributors to system performance have been measured, including hematocrit sensitivity and meter error rates encountered in the clinical setting.

Results and Discussion:

Five of the six BGMS evaluated met current accuracy criteria within the ISO 15197 standard. Only the Optium Xceed system had >95% of all readings within a tightened criteria of $\pm 12.5\%$ from the reference at glucose levels ≥ 72 mg/dl (4 mmol/liter) and ± 9 mg/dl (0.5 mmol/liter) at glucose levels <72 mg/dl (4 mmol/liter). The Nova StatStrip Xpress had the greatest number of error messages observed; Optium Xceed the least. OneTouch Ultra2, Nova StatStrip Xpress, Accu-Chek Performa, and Contour TS products were all significantly influenced by blood hematocrit levels.

Conclusions:

From evidence obtained during this clinical evaluation, the Optium Xceed system is most likely to meet future anticipated accuracy standards for POC BGMS. In this clinical study, the results demonstrated the Optium Xceed product to have the highest level of accuracy, to have the lowest occurrence of error messages, and to be least influenced by blood hematocrit levels.

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Abbreviations: (BGMS) blood glucose monitoring systems, (CLSI) Clinical Laboratory Standards Institute, (HCP) health care professional, (ISO) International Organization for Standardization, (MAPB) mean absolute percent bias, (MAPR) mean absolute percent residual, (POC) point-of-care

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