

Accuracy of the CONTOUR[®] Blood Glucose Monitoring System

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Abstract

Objective:

The aim of the study was to assess the accuracy of the CONTOUR[®] blood glucose monitoring system (BGMS) according to the International Organization for Standardization's International Standard 15197 (ISO 15197:2003) guidelines and to more stringent criteria.

Method:

Finger stick blood samples from 105 subjects with diabetes (25 with type 1, 77 with type 2, and 3 with type unknown) were tested using the CONTOUR BGMS and YSI glucose analyzer.

Results:

99.3% of results were within ISO 15197:2003 criteria (± 15 mg/dl of YSI results at glucose concentrations < 75 mg/dl and $\pm 20\%$ at glucose concentrations ≥ 75 mg/dl). Additionally, 96.7% of results were accurate according to more stringent criteria (± 15 mg/dl of YSI results for glucose concentrations < 100 mg/dl and $\pm 15\%$ for glucose concentrations ≥ 100 mg/dl). Error grid analysis showed that 99.3% and 0.7% of results were within zones A and B, respectively.

Conclusion:

The CONTOUR BGMS exceeded both the minimum acceptable accuracy based on ISO 15197:2003 and the more stringent accuracy criteria.

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Abbreviations: (CDC) Centers for Disease Control and Prevention, (CI) confidence interval, (FDA) U.S. Food and Drug Administration, (ISO) International Organization for Standardization

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