

## Performance of the CONTOUR<sup>®</sup> TS Blood Glucose Monitoring System

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### Abstract

#### *Background:*

Self-monitoring of blood glucose (SMBG) remains an important component of diabetes management, engendering a need for affordable blood glucose (BG) meters that are accurate, precise, and convenient. The CONTOUR<sup>®</sup> TS is a BG meter that endeavors to meet this need. It uses glucose dehydrogenase/flavin dinucleotide chemistry, automatic test strip calibration, and autocompensation for hematocrit along with the ease of use that has come to be expected of a modern meter. The objective of this clinical trial was to determine whether the CONTOUR TS system met these criteria.

#### *Methods:*

The system was evaluated at a single clinical site with 106 subjects with type 1 or type 2 diabetes. Blood glucose values ranged from 60 to 333 mg/dl over all subjects. Both lay users and health care professionals (HCPs) tested the meters, with test strips from three different lots. Results were compared to a reference analyzer of verified precision and accuracy. Forty-nine of the subjects also participated in a home study of the meter. Lay users learned to use the system without assistance and were surveyed on its use at the end of the study.

#### *Results:*

When used with capillary blood, both subjects and HCPs obtained results that exceeded the International Organization for Standardization 15197:2003 criteria, (i.e.,  $\geq 95\%$  of values fell within 20% or 15 mg/dl of the laboratory value for BG levels greater than or less than 75 mg/dl, respectively). Specifically, lay users achieved 97.9% and HCPs 98.6%. When used with venous blood, 99.8% of measurements were within the criteria. All measurements for both capillary and venous blood fell into zones A or B of the Parkes error grid, deemed clinically accurate. Hematocrit was found to have no influence on BG measurements. A large majority of the subjects found the system easy to learn and to use.

#### *Conclusions:*

The CONTOUR TS BG meter system gave accurate and reproducible results with both capillary and venous blood; subjects learned to use the meter system by following the user guide and quick reference guide.

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**Abbreviations:** (BG) blood glucose, (CV) coefficient of variation, (FAD) flavin dinucleotide, (GDH) glucose dehydrogenase, (HCP) health care professional, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose

**Keywords:** accuracy of blood glucose meters, blood glucose meter, CONTOUR TS, diabetes, hematocrit, no coding, self-monitoring of blood glucose

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