Performance of the CONTOUR® TS Blood Glucose Monitoring System

Joy Frank, R.N.,¹ Jane F. Wallace, C.C.R.A.,² Scott Pardo, Ph.D.,² and Joan Lee Parkes, Ph.D., C.C.R.A.²

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® 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., ≥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.


Author Affiliations: ¹Consumer Product Testing Co., Fairfield, New Jersey; and ²Bayer Healthcare LLC, Diabetes Care, Elkhart, Indiana

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

Corresponding Author: Joan Lee Parkes, Ph.D., C.C.R.A., Bayer Healthcare LLC, Diabetes Care, 1884 Miles Ave., P.O. Box 70, Elkhart, IN 46515-0070; email address joan.parkes@bayer.com