

Accuracy Evaluation of Five Blood Glucose Monitoring Systems: The North American Comparator Trial

Solveig Halldorsdottir, Ph.D., Mary Ellen Warchal-Windham, B.S., Jane F. Wallace, B.A., C.C.R.A.,
Scott Pardo, Ph.D., P.Stat., Joan Lee Parkes, Ph.D., C.C.R.A., and David A. Simmons, M.D.

Abstract

Background:

This study evaluated differences in accuracy between the CONTOUR[®] NEXT EZ (EZ) blood glucose monitoring system (BGMS) and four other BGMSs [ACCU-CHEK[®] Aviva (ACAP), FreeStyle Freedom Lite[®] (FFL), ONE TOUCH[®] Ultra[®]2 (OTU2), and TRUEtrack[®] (TT)].

Methods:

Up to three capillary blood samples ($N = 393$) were collected from 146 subjects with and without diabetes. One sample per subject was tested with fresh (natural) blood; the other samples were glycolyzed to lower blood glucose to <70 mg/dl. Meter results were compared with results from plasma from the same sample tested on a Yellow Springs Instruments (YSI) 2300 STAT Plus[™] glucose analyzer. Blood glucose monitoring system accuracy was compared using mean absolute relative difference (MARD; from laboratory reference method results) and other analyses. Separate analyses on fresh (natural) samples only were conducted to determine potential effects of glycolysis on MARD values of systems utilizing glucose-oxidase-based test strip chemistry.

Results:

Across the tested glucose range, the EZ had the lowest MARD of 4.7%; the ACAP, FFL, OTU2, and TT had MARD values of 6.3%, 18.3%, 23.4%, and 26.2%, respectively. For samples with glucose concentrations <70 mg/dl, the EZ had the lowest MARD (0.65%), compared with the ACAP (2.5%), FFL (18.3%), OTU2 (22.4%), and TT (33.2%) systems.

Conclusions:

The EZ had the lowest MARD across the tested glucose ranges when compared with four other BGMSs when all samples were analyzed as well as when natural samples only were analyzed.

J Diabetes Sci Technol 2013;7(5):1294–1304

Author Affiliation: Bayer HealthCare LLC, Diabetes Care, Tarrytown, New York

Abbreviations: (ACAP) ACCU-CHEK Aviva, (AE) adverse event, (ARD) absolute relative difference, (BGMS) blood glucose monitoring system, (EZ) CONTOUR NEXT EZ, (FFL) FreeStyle Freedom Lite, (GOx) glucose oxidase, (ISO) International Organization for Standardization, (MARD) mean absolute relative difference, (NIST) National Institute of Standards and Technology, (OTU2) ONE TOUCH Ultra2, (TT) TRUEtrack, (YSI) Yellow Springs Instruments

Keywords: accuracy, blood glucose monitoring system, diabetes, glucose meter

Corresponding Author: Solveig Halldorsdottir, Ph.D., Bayer HealthCare LLC, Diabetes Care, 555 White Plains Rd., Tarrytown, NY 10591; email address solveig.halldorsdottir@bayer.com