

A New Test Strip Technology Platform for Self-Monitoring of Blood Glucose

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Abstract

In the management of diabetes, accuracy of devices used for self-monitoring of blood glucose (SMBG) is critical because SMBG results can affect patient diabetes-related health outcomes. A new blood glucose monitoring system (BGMS) platform has been developed that is based on the new CONTOUR[®] NEXT (CN) test strip. This BGMS platform uses a proprietary electron mediator and algorithm to minimize errors at different steps in the testing process, thus minimizing outliers and significantly improving accuracy from prior-generation blood glucose meter systems. As demonstrated by questionnaire results from clinical studies with the new BGMS platform, accuracy and ease of use are important considerations for people with diabetes and their health care professionals when selecting an SMBG device. This article provides an overview of laboratory studies and clinical trials in the hands of lay users involving the performance of the portfolio of blood glucose meters that uses the new test strip. Each BGMS in the platform, which includes the CONTOUR XT (CONTOUR NEXT EZ in the United States), CONTOUR NEXT LINK, CONTOUR NEXT USB, and CN systems, demonstrated advanced accuracy both in the laboratory and in the hands of subjects (people with diabetes) and trained health care professionals. All systems met and exceeded International Organization for Standardization accuracy criteria (both ISO 15197:2003 and ISO 15197:2013). Each system in the new BGMS platform delivers advanced accuracy, which is essential to people who utilize SMBG for improved management.

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Abbreviations: (ACA) ACCU-CHEK Aviva, (AST) alternate site testing, (BGMS) blood glucose monitoring system, (CN) CONTOUR NEXT, (CNEZ) CONTOUR NEXT EZ, (CNL) CONTOUR NEXT LINK, (CNUB) CONTOUR NEXT USB, (CXT) CONTOUR XT, (FFL) FreeStyle Freedom Lite, (HCP) health care professional, (ISO) International Organization for Standardization, (MARD) mean absolute relative difference, (OTU2) OneTouch Ultra2, (OTV) OneTouch Verio, (SMBG) self-monitoring of blood glucose, (TT) TRUEtrack, (YSI) Yellow Springs Instruments

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