Journal of Diabetes Science and Technology
Volume 1, Issue 1, January 2007

ORIGINAL ARTICLES

Self-Monitoring of Blood Glucose Levels Requires Intensive Training for Use of Meters to Obtain Reliable and Clinically Relevant Measurements

Thomas A. Mohr, M.Sc.,[1] Andreas Pfützner, M.D., Ph.D.,[1,2] Senait Forst,[1]
Thomas Forst, M.D.,[1] and Thomas Schöndorf, Ph.D.[1,3]

Abstract

Background:

Anecdotal reports from pediatric sites have indicated that some blood glucose meters may display wrong and misleading numbers rather than error indications, when operated in deviation from the instructions for use (IFU), e.g., by manipulating the strip during the count-down phase.

Methods:

This study was performed with 60 patients with diabetes [32 female, 28 male, 21 type 1, 39 type 2, age (mean ± SD): 56 ± 11 years] who measured their blood glucose levels twice with five different blood glucose meters [Precision® Xceed™ (Abbott Medisense), Freestyle Mini™ (Abbott Medisense), Accu-Chek® Comfort (Roche Diagnostics), Accu-Chek® Aviva (Roche Diagnostics), and Ascensia Contour® (Bayer Vital)]. The first measurement was performed in accordance with the IFU, and the second by manipulating the test strip using a standardized inflexion/release procedure during the count-down phase. A standard glucose oxidase method (SuperGL) served as laboratory reference.

Results:

All meters worked in full compliance with current accuracy standards when operated according to the IFU. When manipulating the test strip, the results varied considerably: While changes in reliability were acceptable for two devices (Precision® Xceed®, Freestyle Mini™), the other devices produced an unacceptable number of errors and a series of entirely wrong values without error indication.

Conclusions:

The use of all devices is recommended when used according to the IFU. The use under the artificially induced impaired testing conditions is a major concern. This study underlines the importance of appropriate patient training regarding adherence to the IFU of glucose meters.

J Diabetes Sci Technol 2007;1(1):56-61

Author Affiliations: [1]Institute of Clinical Research and Development, Mainz, Germany; [2]University of Applied Science, Department of Applied Natural Sciences, Rheinbach, Germany; and [3]University of Cologne, Medical Center, Cologne, Germany

Abbreviations: (BGMS) blood glucose meters, (IFU) instructions for use, (MAPD) mean absolute percentage deviation, (SMBG) self-monitoring of glucose

Keywords: blood glucose meters, diabetes mellitus, self-monitoring BG, SMBG

Corresponding Author: Thomas Schöndorf, Ph.D., Associate Professor, ikfe GmbH Clinical Research Parcusstraße 8 55116, Mainz, Germany; email address thomass@ikfe.de