

Evaluation of the Effects of Insufficient Blood Volume Samples on the Performance of Blood Glucose Self-Test Meters

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Abstract

Background:

Accuracy of blood glucose readings is (among other things) dependent on the test strip being completely filled with sufficient sample volume. The devices are supposed to display an error message in case of incomplete filling. This laboratory study was performed to test the performance of 31 commercially available devices in case of incomplete strip filling.

Methods:

Samples with two different glucose levels (60–90 and 300–350 mg/dl) were used to generate three different sample volumes: 0.20 μ l (too low volume for any device), 0.32 μ l (borderline volume), and 1.20 μ l (low but supposedly sufficient volume for all devices). After a point-of-care capillary reference measurement (StatStrip, NovaBiomedical), the meter strip was filled (6x) with the respective volume, and the response of the meters (two devices) was documented (72 determinations/meter type). Correct response was defined as either an error message indicating incomplete filling or a correct reading ($\pm 20\%$ compared with reference reading).

Results:

Only five meters showed 100% correct responses [BGStar and iBGStar (both Sanofi), ACCU-CHEK Compact+ and ACCU-CHEK Mobile (both Roche Diagnostics), OneTouch Verio (LifeScan)]. The majority of the meters (17) had up to 10% incorrect reactions [predominantly incorrect readings with sufficient volume; Precision Xceed and Xtra, FreeStyle Lite, and Freedom Lite (all Abbott); GlucoCard+ and GlucoMen GM (both Menarini); Contour, Contour USB, and Breeze2 (all Bayer); OneTouch Ultra Easy, Ultra 2, and Ultra Smart (all LifeScan); Wellion Dialog and Premium (both MedTrust); FineTouch (Terumo); ACCU-CHEK Aviva (Roche); and GlucoTalk (Axis-Shield)]. Ten percent to 20% incorrect reactions were seen with OneTouch Vita (LifeScan), ACCU-CHEK Aviva Nano (Roche), OmniTest+ (BBraun), and AlphaChek+ (Berger Med). More than 20% incorrect reactions were obtained with Pura (Ypsomed), GlucoCard Meter and GlucoMen LX (both Menarini), Elite (Bayer), and MediTouch (Medisana).

Conclusions:

In summary, partial and incomplete blood filling of glucose meter strips is often associated with inaccurate reading. These findings underline the importance of appropriate patient education on this aspect of blood glucose self-monitoring.

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Abbreviations: (BGM) blood glucose meter

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