

FreeStyle Lite—A Blood Glucose Meter That Requires No Coding

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Abstract

Background:

Abbott Diabetes Care introduced the FreeStyle® Lite blood glucose monitoring system, which simplifies the management of diabetes. The FreeStyle Lite system relies on FreeStyle technology but eliminates the need for coding the meter for individual strip lots. The meter is precoded for the FreeStyle Lite strips. FreeStyle systems use coulometry technology where the glucose signal is calculated from the total charge generated as a result of the glucose reaction in the sample. FreeStyle strip calibration parameters can be controlled by controlling the sample volume. Coulometry technology is less sensitive to measurement conditions such as temperature and hematocrit. FreeStyle chemistry is less sensitive to interference from electroactive compounds. The ability to control calibration parameters coupled to a robust measurement technology enabled the development of a blood glucose monitoring system that does not require coding by the user.

Methods:

Laboratory studies were performed to determine analytical performance, such as linearity, precision, and sensitivity to operating temperature. Clinical accuracy for finger tip capillary blood testing was assessed with five lots of FreeStyle Lite test strips. FreeStyle Lite results in these studies were compared to the plasma equivalent glucose values of finger tip blood samples measured by the Yellow Springs Instrument glucose analyzer.

Results:

In the analytical performance evaluation, repeatability (within-run precision) of the FreeStyle Lite system showed an average standard deviation of 3.4 mg/dl (0.19 mmol/liter) at glucose concentrations <100 mg/dl (<5.56 mmol/liter) and an average coefficient of variation of 4.3% at glucose concentrations ≥100 mg/dl (≥5.56 mmol/liter). Linearity demonstrated across the measuring range of the FreeStyle Lite system was 20–500 mg/dl (1.1–27.8 mmol/liter) with $r^2 > 0.99$. The FreeStyle Lite system was also shown to maintain accuracy across the operating temperature range of 4 to 40°C.

Conclusions:

The FreeStyle Lite system has good analytical performance and clinical accuracy. While simplifying the process of blood glucose monitoring, the FreeStyle Lite system continues to provide the performance that users have come to expect from FreeStyle products.

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Abbreviations: (CV) coefficient of variation, (ISO) International Organization for Standardization, (SD) standard deviation, (YSI) Yellow Springs Instrument

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