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TECHNOLOGY REPORT

Hematocrit Compensation in Electrochemical Blood Glucose Monitoring Systems

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Abstract

Background:

Hematocrit (Hct) is a common interferent in test strips used by diabetes patients to self-monitor blood glucose (BG), resulting in measurement bias. Described is an electrochemical BG monitoring system (OneTouch® Verio™) that uses a cofacial sensor design, soluble enzyme chemistry, and multiphasic waveform to effectively correct for patient Hct, delivering an accurate reading for whole BG.

Methods:

The test strip comprises thin-film gold and palladium electrodes arranged cofacially and spatially separated with a thin spacer. Soluble glucose-sensing reagents are located on the lower palladium electrode and are hydrated on sample application. Blood glucose is oxidized by flavoprotein glucose dehydrogenase, with electron transfer via (reduced) potassium ferrocyanide mediator at the palladium electrode. Hematocrit levels are estimated by measuring oxidation of mediator diffusion to the upper gold electrode during the first portion of the assay. The Hct-corrected glucose levels are determined by an on-meter algorithm.

Results:

In performance testing of blood samples at five glucose levels (30–560 mg/dl) and five Hct levels (19–61%), using 12 test meters and 3 test strip lots, 100% of results (N = 2700) met International Organization for Standardization accuracy criteria (within ± 15 mg/dl and ± 20% of reference results at glucose levels of <75 and ≥75 mg/dl, respectively). Furthermore, 99.9% (2698 of 2700) of results were within ±12 mg/dl and ± 15% of reference values at glucose levels <80 and ≥80 mg/dl, respectively.

Conclusions:

The technology used in this system provides accurate BG measurements that are insensitive to Hct levels across the range 20–60%.

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Abbreviations: (AC) alternating current, (BG) blood glucose, (Hct) hematocrit, (ISO) International Organization for Standardization, (RBC) red blood cell, (SMBG) self-monitoring of blood glucose

Keywords: hematocrit interference, potential-time waveform, self-monitoring of blood glucose, test strip design

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