

## Evaluation of the Analytical Performance of the Coulometry-Based Optium Omega Blood Glucose Meter

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### Abstract

#### **Background:**

The goal of diabetes treatment is maintaining near normoglycemia based on self-monitoring of blood glucose (SMBG). In this study, an evaluation of the analytical performance of the coulometry-based Optium Omega™ glucose meter designed for SMBG has been carried out.

#### **Methods:**

The assessment of precision and between-lot variability was based on glucose measurements in ethylenediaminetetraacetic acid venous blood samples. Glucose concentrations measured in 289 fresh capillary blood samples using the Omega glucose meter and the Biosen C\_line analyzer were compared.

#### **Results:**

Within-run imprecision coefficient of variation for the lower and higher glucose concentrations amounted to 5.09 and 2.1%, respectively. The relative lot-dependent differences found for the lower and higher glucose concentrations were equal to 6.8 and 2.6%, respectively. The glucose meter error calculated for various concentration ranges amounted from 2.22 to 4.48%. The glucose meter error met the accuracy criteria recommended by the International Organization for Standardization and the American Diabetes Association. The Passing-Bablok agreement test and error grid analysis with 96% of results in zone A indicated good concordance of results, including glucose concentrations below 100 mg/dl.

#### **Conclusions:**

The evaluated Optium Omega glucose meter fits the analytical requirements for its use in blood glucose monitoring in diabetes patients.

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**Abbreviations:** (ADA) American Diabetes Associations, (CI) confidence interval, (CV) coefficient of variation, (EDTA) ethylenediaminetetraacetic acid, (ISO) International Organization for Standardization, (SD) standard deviation, (SMBG) self-monitoring of blood glucose

**Keywords:** diabetes mellitus, glucose meter, glucose meter error, self-monitoring of blood glucose

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