

Automated Optical Glucose Measurement Comparison with Point of Care Blood Gas Device

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ABSTRACT

Introduction

Management of blood glucose intraoperatively and perioperatively has been studied extensively over the past decade. Hyperglycemia and hypoglycemia negatively effect patient mortality and morbidity, and the ability to maintain blood glucose at optimum concentration requires frequent and reliable measurements. As companies recognize this inherent financial opportunity, there have been increasing attempts to introduce adaptations of measurement technologies from consumer blood glucose monitors as patient monitoring solutions in perioperative and critical care settings. A currently utilized point of care blood gas analyzer was compared in blind studies against the automated optical measurement technology in TecMed, Inc.'s Surgical Suite Unit (the "SSU") in a limited number of studies utilizing human blood components.

Methods

Glucose measurements were completed utilizing human serum ultrafiltrate samples from hemoconcentrator effluent. Glucose measurements were made utilizing a point of care blood gas analyzer and the SSU. Glucose measurements made with the SSU were statistically compared with the results from blood gas device.

Results

All SSU measurements were within the FDA-preferred "A" area of the Clarke Error Grid, showed strong linear regression and correlation coefficients, and were within mean average deviation agreement limits in Bland-Altman analysis.

Conclusions

The automated optical measurement system in the SSU provided blood glucose measurements that demonstrate improved accuracy over hospital blood gas determinations. Measurements from the SSU meet and/or exceed all current and proposed future regulatory specifications for human blood glucose measurement.