

## Plasma-Generating Glucose Monitor Accuracy Demonstrated in an Animal Model

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### Abstract

#### **Introduction:**

Four randomized controlled trials have compared mortality and morbidity of tight glycemic control versus conventional glucose for intensive care unit (ICU) patients. Two trials showed a positive outcome. However, one single-center trial and a large multicenter trial had negative results. The positive trials used accurate portable lab analyzers. The negative trial allowed the use of meters. The portable analyzer measures in filtered plasma, minimizing the interference effects.

OptiScan Biomedical Corporation is developing a continuous glucose monitor using centrifuged plasma and mid-infrared spectroscopy for use in ICU medicine. The OptiScanner draws approximately 0.1 ml of blood every 15 min and creates a centrifuged plasma sample. Internal quality control minimizes sample preparation error. Interference adjustment using this technique has been presented at the Society of Critical Care Medicine in separate studies since 2006.

#### **Method:**

A good laboratory practice study was conducted on three Yorkshire pigs using a central venous catheter over 6 h while performing a glucose challenge. Matching Yellow Springs Instrument glucose readings were obtained.

#### **Results:**

Some 95.7% of the predicted values were in the Clarke Error Grid A zone and 4.3% in the B zone. Of those in the B zone, all were within 3.3% of the A zone boundaries. The coefficient of determination ( $R^2$ ) was 0.993. The coefficient of variance was 5.02%. Animal necropsy and blood panels demonstrated safety.

#### **Conclusion:**

The OptiScanner investigational device performed safely and accurately in an animal model. Human studies using the device will begin soon.

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**Abbreviations:** (APTT) activated partial thromboplastin time, (CBC) complete blood count, (CEG) Clarke Error Grid, (CV) coefficient of variance, (ICU) intensive care unit, (IR) infrared, (PT) prothrombin time, (RCT) randomized controlled trial, (SD) standard deviation, (TGC) tight glycemic control, (YSI) Yellow Springs Instrument

**Keywords:** accuracy, continuous monitor, critical care, glucose, interference, mid-infrared spectroscopy, tight glycemic control

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