## Comparison of the Freestyle Lite<sup>™</sup> Blood Glucose Monitoring System to the Yellow Springs Instruments Glucose Oxidase Analyzer for Use during Glucose Clamp Studies in Nondiabetic Subjects Undergoing Magnetic Resonance Imaging

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Lyperinsulinemic-euglycemic clamp studies are considered the gold standard for quantifying insulin resistance in humans. These procedures involve maintaining glucose at a target level during infusion of a fixed dose of insulin by measuring glucose every 2 to 5 minutes and varying the rate of a dextrose infusion. Thus a rapid and accurate real-time method for glucose determination is needed. A bedside reference-quality automated glucose-oxidase-based analyzer such as the YSI 2300 STAT (YSI; Yellow Springs Instruments Incorporated, Yellow Springs, OH) is usually used for this purpose. However, measurements by these instruments are typically delayed several minutes from the time of blood sampling and may be delayed further during required periodic instrument calibrations.

We needed to obtain glucose measurements in nondiabetic subjects undergoing glucose clamp studies during functional magnetic resonance imaging (fMRI), which generates a strong magnetic field. We noted that Cohen and colleagues<sup>1</sup> found excellent agreement between the FreeStyle Mini<sup>TM</sup> glucometer and the YSI during hyperglycemic clamps in patients with type 2 diabetes. However, the average glucose levels in these studies were high (mean YSI and FreeStyle glucose levels 246.0  $\pm$  59.6 and 254.6  $\pm$  65.5 mg/dl, respectively) and included very few measurements at levels desired when performing clamps in nondiabetic subjects.

Six healthy nondiabetic subjects (aged  $25 \pm 3$  years, body mass index  $21.6 \pm 1.7$  kg/m<sup>2</sup>) were therefore studied during hyperinsulinemic conditions with glucose levels modulated between euglycemic and hyperglycemic levels<sup>2</sup> while undergoing fMRI (Siemens Magnetom Trio 3-Tesla whole body system, Siemens Medical Solutions, Malvern, PA, and Erlangen, Germany). Arterialization of venous blood was achieved using a warming pad on the hand and forearm, and blood drawn every 5-minutes through a 20g catheter inserted into an antecubital vein. Whole venous blood was used to immediately obtain FreeStyle Lite<sup>TM</sup> glucose measurements (meter fastened 14 ft. from the scanner opening to avoid magnetic interference) then centrifuged and plasma analyzed for glucose level by YSI. A total of 217 samples were obtained, with glucose levels ranging from 52 to 183 mg/dl (mean 95 ± 28 mg/dl) as measured by the FreeStyle Lite and from 51 to 169 mg/dl (mean 92 ± 27 mg/dl) as measured by the YSI. Glucose values measured by the two methods were highly correlated (r = 0.97, p < .0001) and followed the line of identity. A total of 62.2%, 85.3%, and 94% of FreeStyle glucose measurements were within 5%, 10%, and 15% of YSI measured values, respectively,

Abbreviations: (fMRI) functional magnetic resonance imaging

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and Clarke error grid analysis<sup>3</sup> (**Figure 1**) showed that 98.2% of the readings were in zone A. Additionally, bias analysis revealed a difference of 3.1% between the two methods (data not shown), similar to that reported by Cohen and colleagues.<sup>1</sup>

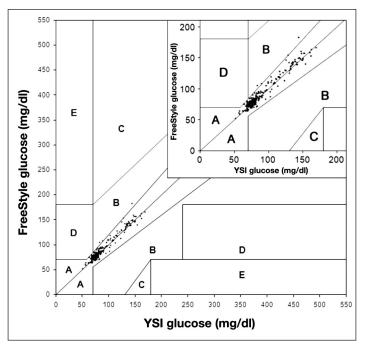


Figure 1. Clarke error grid. Inset shows enlargement of the lower end of the axes (0-200 mg/dl) to better illustrate the relationships between the two methods.

This study further demonstrates and extends the accuracy of using the FreeStyle glucometer during glucose clamp studies to nondiabetic subjects where glucose measurements are in the normoglycemic range and obtained during functional imaging in a 3T magnet. In a procedure where frequent real-time blood sampling for glucose level is required, the small sample volume (0.3  $\mu$ l) and rapid results (5 seconds) provided by the FreeStyle glucometer are advantageous over the YSI.

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