Objective
Blood glucose levels were manipulated in a predefined manner to evaluate accuracy and precision of a continuous glucose monitor (CGM).

Methods
Twelve diabetic subjects (6 subjects diagnosed with T1DM) were consented and studied. Each study was divided into several periods: (1) blood glucose levels of 150 mg/dL were achieved and maintained for 30 min, (2) blood glucose levels were decreased from 150 mg/dL to 50 mg/dL at a rate of 1 mg/dL/min, (3) blood glucose levels were maintained at 50 mg/dL for 30 min, (4) blood glucose levels were increased from 50 mg/dL to 150 mg/dL and maintained for 30 min, (5) glucose levels were decreased from 150 mg/dL to 50 mg/dL at a rate of 2 mg/dL/min, (6) same as period 3, and (7) blood glucose levels were normalized. The target glucose levels were achieved by infusing insulin and glucose intravenously. Frequent venous blood samples (collected in alternating intervals of 2 and 5 minutes) were assayed for glucose using the Accu-Chek Inform and YSI 2300 STAT Plus. The blood glucose values were analyzed jointly in a linear mixed effects model which is suitable to accommodate repeated measures per subject.

Results
The fitted mixed effect model for periods 2 and 5 indicated significant random subject effects in both slopes and intercepts as well as significant serial correlation among consecutive repeated over time blood glucose values. The average slopes during periods 2 and 5 were -0.91 mg/dL/min (95% CI: -1.07 to -0.75, p<0.05) and -1.17 mg/dL/min (95% CI: -1.37 to -0.97, p<0.05), respectively. During periods 3 and 6, the intercepts were 48.3 mg/dL (95% CI: 44.8 to 51.8) and 50.6 mg/dL (95% CI: 45.8 to 55.4), respectively, and average slopes were not significantly different from 0. The average slope in period 5 was significantly steeper than the average slope for 2. However, the goal of -2 mg/dL/min for period 5 was not achieved. Two stable periods of hypoglycemia were achieved without any serious adverse effects.

Conclusions
A standardized test such as the one presented here should become an integral part of CGM evaluation in order to compare one CGM device to another.

Insulin/Dextrose Titration
Initial rates of intravenous insulin and dextrose were based on the subject’s type and duration of diabetes, basal and total daily insulin requirements, doses of anti-diabetic agents, age, and body weight. Whereas the dextrose (D20W) rate was adjusted whenever new blood glucose information was available, the insulin rate was adjusted on an hourly basis only if the desired glucose target could not be achieved solely by manipulating the dextrose infusion. Meals were served at the end of periods 3 and 6. Insulin and D20W infusions were stopped after eating the second meal. The study ended when the stable euglycemia was reached.