

## Results from a Real-Time Unblinded Study of a Short-Term Continuous Glucose Sensor in Subjects with Type 1 Diabetes.

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The accuracy and reproducibility of a transcutaneous glucose sensor (DexCom Inc.) was prospectively evaluated in 15 patients with Type 1 diabetes, at two clinical sites. The enzyme-electrode sensor was inserted under the skin and wirelessly transmitted data every 5 minutes to a hand-held display unit. Patients wore two sensors each for 72 hours. The patients themselves inserted all sensors. One sensor provided real-time continuous glucose data to the patient, including 1, 3, and 9 hour glucose trends, as well as high and low glucose alerts. Alerts were set at 200 mg/dL and 80 mg/dL and a non-changeable hypoglycemic alarm was set at 55 mg/dL. The other sensor was used for comparative purposes. An in-clinic tracking study was conducted during the first 12 hours and comparative blood glucose values collected every 20 minutes. Home-use data were collected from the subsequent 60 hours, during which patients were instructed to take 7 comparative values per day.

Of the 1139 matched blood/sensor glucose values prospectively analyzed over the study duration, 97.54 % fell in the Clarke Error Grid A+B zones, 1.76 % fell in the D zones, and no points were in the E zone. Mean Absolute Relative Difference (MARD) was 21.09%. Sensitivity / Specificity of high and low glucose alerts, at thresholds of 200 and 80 mg/dL (nominal settings), were 84.76 / 88.53 % and 83.96 / 83.14 %, respectively. Reproducibility of the 30 sensors was evaluated using Mean Relative Difference (MRD) and MARD between corresponding sensor values in each patient. The MRD was -1.65% and MARD was 16.20% for all 15 pairs.

There were no adverse events or incidents reported related to the sensors or the patient use of real-time continuous glucose data.

