

## CORRIGENDA

## Corrigenda to Volume XXXVII, Number 3, September 2000: Abstracts of the 20th Workshop of the Study Group on Artificial Insulin Delivery, Pancreas and Islet Transplantation (AIDPIT), Igls, Austria, January 28-30, 2001

**Interim results from multi-center study into the use of near-infrared spectroscopy for the non-invasive measurement of blood glucose** S.L. Monfre, T.L. Ruchti, T.B. Blank, A.D. Lorenz; Instrumentation Metrics, Inc., Chandler, AZ, U.S.A.

The non-invasive measurement of blood glucose levels in people with diabetes using near-infrared (NIR) diffuse reflectance spectroscopy is a challenging and complex task that has attracted investigators from a broad range of scientific and engineering backgrounds. The measurement requires a solid understanding of the living sample from such diverse perspectives as tissue optics, spectroscopy, multivariate statistics, signal processing, and analytical chemistry. The non-linear effect of variable tissue scattering on the near-infrared measurement complicates the detection of the blood glucose signal. The dynamic nature and heterogeneous composition of skin will lead to variations in the effective tissue sample causing changes in the relative photon flux delivered to individual skin layers. It is likely that the sampling protocol governing the preparation of the measurement site and the coupling of the instrument to the skin is of critical importance. Furthermore, advanced signal processing and multivariate analysis are necessary for the extraction of the small spectral contribution due to glucose amid the complex and varying background signals. Variations between subjects make it necessary to develop calibration models based on the individual rather than the entire population or a group of subjects.

Currently, we are conducting a multi-center study involving 129 enrolled subjects with diabetes to evaluate the calibration requirements and performance of our non-invasive blood glucose monitor based on NIR spectroscopy. The study includes a two-week calibration phase for developing patient specific calibrations on the basis of 64-96 paired Hemocue capillary glucose measurements and NIR scans. An eight week period of bi-weekly measurement visits follows and is used to evaluate the device performance over manipulated glycemic profiles. Thirty-two patients have terminated early for personal reasons or mechanical failure and nine subjects were dropped due to the insufficiency of their

calibration data. Interim near-infrared glucose measurements from the first twelve subjects that were calibrated are clinically acceptable over the eight-week measurement phase. Evaluation of these measurement values based on the Clark Error Grid is shown in Figure 1 and yields 55% of the data in the A region, 38.9% of the data in the B region, 2.9% of the data in the C region, and 3.2% of the data in the D region. The average absolute error is approximately 25%.

These interim results indicate that robust measurements of blood glucose levels can be achieved using near-infrared spectroscopy, and that this robustness can last at least 8 weeks in duration. The goal of the current study is to demonstrate with certainty that a NIR-based instrument and calibration protocol can be incorporated into a methodology that allows for the measurement blood glucose values non-invasively, with performance that is clinically acceptable.

