

Abstract

Background:

The main concern in Non-Invasive (NI) glucose monitoring methods is to achieve high accuracy results, despite the fact that no direct blood or interstitial fluid glucose measurement is performed. An alternative approach to increase the accuracy of NI glucose measurement was previously suggested through a combination of three NI methods: ultrasonic, electromagnetic and thermal. This paper provides further explanation about the nature of the implemented technologies and multi-sensors are presented, as well as a detailed elaboration on the novel algorithm for data analysis.

Methods:

Clinical trials were performed in two different days. During the first day calibration and subsequent 6 measurements were performed. During the second day a “full day” session of about 10 hours took place. During the trial, type 1 and 2 diabetics were calibrated and evaluated with *GlucoTrack*[®] glucose monitor against *HemoCue*[®] (Glucose 201+).

Results:

A total of 89 subjects were tested during the trial period. Clarke Error Grid analysis (CEG) shows 96 % of the readings (on both days 1 and 2) fall in the clinically accepted A and B zones, of which 60% are within zone A. The Absolute Relative Differences yield Mean and Median values of 21.9% and 15.9%, respectively. The CEG for day 2 of the trial shows 96% of the points in the A and B zones, with 57% of the values in the A zone. Mean and Median ARD values for the readings on day 2 are 23.6% and 16.9%, respectively. The intervals between Day 1 (calibration and measurements) and Day 2 (measurements only) were 11.5 ± 10.5 days, with a median of 6 days.

Conclusions:

The presented methodology shows that increased accuracy was indeed achieved by combining multi-technology and multi-sensors. The approach of integration contributes increasing of the signal to noise ratio (glucose to other contributors). A combination of several technologies allows compensation of a possible aberration in one modality by the others, while multi-sensors' implementation enables corrections for interferences' contributions.

Furthermore, clinical trials indicate the ability of using the device for a wide range of demography, showing clearly that the calibration is valid for long term.