6 Months Analysis of Intra and Inter-Daily Performances of a Truly Non-Invasive Glucose Monitoring Device for Home Use

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Background

GlucoTrack® is a CE Mark approved Non-Invasive (NI) glucose monitoring device designed for home and home-alike environment. It combines utilization of three independent NI methods: Ultra-sound, Electromagnetic and Thermal. As a NI glucose monitor (with no disposables), ***GlucoTrack*** represents a utilizable alternative to the complex, costly and painful nature of conventional (invasive) glucose monitoring. Figure 1 describes the device (A) and its way of use (B).

Figure 1: [A] GlucoTrack Glucose Monitor; [B] Conducting a Spot Measurement

Caution: Investigational device. Limited by (United States) federal law to investigational use only. The device has CE Mark approval.

Individual calibration is required to be performed prior to conducting measurements. The calibration minimizes the impact of individual tissue quasi-stable factors and sets a baseline for physiological change detection. The calibration is valid for 6 months. To allow virtually unlimited use of the device at any time, its accuracy level should be kept throughout the entire calibration validity period, regardless of user physiological state and environmental factors.

Objective

To demonstrate ***GlucoTrack*** consistency in accuracy, by evaluating the device performances across all subjects inter-daily, among clinical trials session days, as well as intra-daily, with pre- and post-prandial states.

Method

GlucoTrack performances were evaluated in 198 subjects. Each subject performed between 2 to 19 full-day non-consecutive sessions (4.2 days on average per subject) throughout up to 6 months. Each session consisted of ~16 measurements during over 8 hours and included 2 meals, to allow variability in the glucose profile. ***GlucoTrack*** performances were analyzed among all subjects, inter- and intra-daily. Figure 2 shows graphical representation of the two analyses.

The intra-daily analysis compared between pre- and post-prandial states. Pre-prandial readings were defined as 0—60 min before mealtimes, while post-prandial readings were defined as 30—90 min after mealtimes.

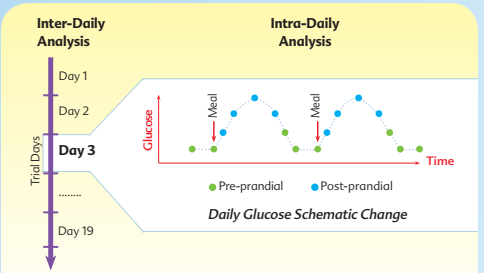

Figure 2: Graphical representation of the intra- and inter-daily analyses

Results

For this analysis, Clarke Error Grid (CEG) and Mean Absolute Relative Difference (MARD) were used to assess the ***GlucoTrack*** performances on 12,956 data points collected from 198 subjects (Table 1).

Table 1: Subjects' Demography

Age (Years)	18 - 80
Gender	107 male; 91 female
BMI (Kg/m^2)	18.4 - 39.9
Diabetes type	31 Type 1; 167 Type 2
Trial duration	Up to 6 months
Total subjects	**198**
Total data points	**12,956**

Results demonstrate that 95.0% and 95.4% of the points are in the clinically acceptable A+B zones, for pre- and post-prandial data, respectively. MARD values are 34.3% and 29.7%, accordingly (Figure 3).

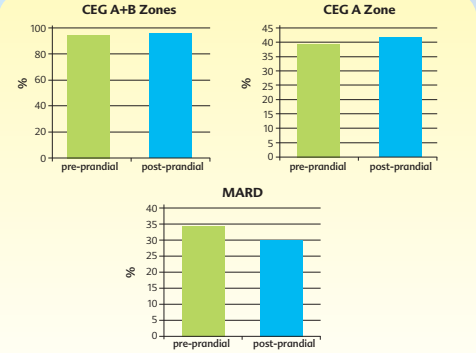

Figure 3: Intra-daily analysis - pre- and post-prandial performances presented as CEG percentage in A and A+B zones, and MARD

Throughout all days of the trial, up to 6 months from calibration, results remain similar: 95.9 ± 3.1% of the points within CEG A+B zones and MARD of 32.9 ± 4.2% (Figure 4).

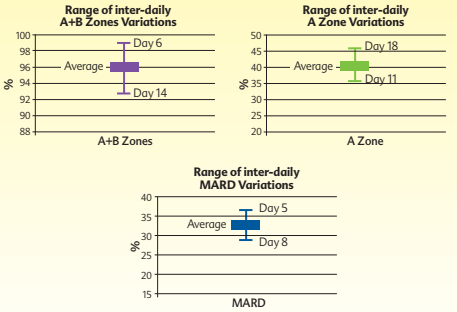

Figure 4: Range of inter-daily variations of CEG percentage of A, A+B Zones and of MARD

Conclusions

GlucoTrack performances are fairly maintained inter-daily over its entire calibration validity period

GlucoTrack performances are fairly maintained at both pre- and post-prandial states

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Painless and cost-effective nature of measurement

GlucoTrack can be considered useful for frequent home-use SMBG

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