Calibration Schemes of a Truly Non-Invasive Glucose Monitor for Variety of Diabetics

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Background

Calibration is an essential process in Non-Invasive (NI) glucose monitors. This process minimizes the impact of individual tissue quasi-stable factors and sets a baseline for individual detection of physiological change. It is only valid as-long-as the quasi-stable factors remain unaltered; therefore, re-calibration is required periodically. Complexity, duration, special requirements and settings, as well as calibration validity period play major role in NI devices eligibility and acceptance for home use utilization.

GlucoTrack® is a CE-mark approved NI glucose monitoring device designed for home and home-alike environment. It combines utilization of three independent NI technologies: Ultrasound, Electromagnetic and Thermal, which enables performing frequent, real-time spot measurements in a convenient and easy way. ***GlucoTrack*** comprises a Main Unit (MU), which drives different sensors, located in a Personal Ear Clip (PEC) (Figure 1).

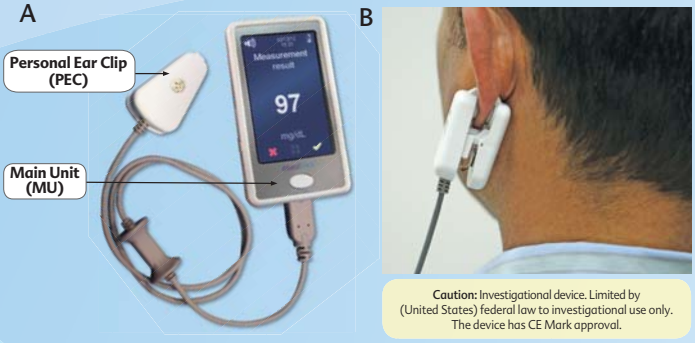

Figure 1: [A] GlucoTrack Glucose Monitor; [B] Performing a Spot Measurement

The device requires individual calibration process to be performed prior to conducting measurements. Calibration concept is described in Figure 2. The calibration is valid for the entire life span of the PEC (6 months). Calibration is preferably performed at the clinic by proficient personnel, against invasive reference device with high accuracy (HemoCue® 201+ Analyzer).

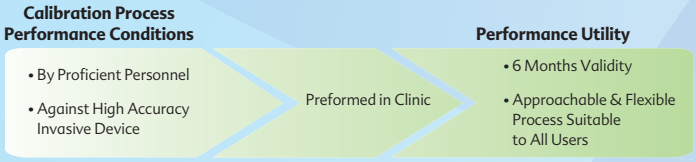

Figure 2: Calibration Process Performance Conditions and Utility

Objective

In order to have approachable and flexible calibration process suitable to all users, two supplementary calibration schemes are proposed.

Method

Calibration of ***GlucoTrack*** requires coverage of most of the user's regular dynamic range of his/her blood glucose (BG). During calibration, BG is changed in order to reach user's upper and lower BG levels (with some degree of flexibility). An overnight fasting (nominally 12 hours) is required prior to calibration, in order to increase the possibility of having a stable low glucose level. However, in some cases fasting values do not represent the user's regular BG levels. Therefore, two schemes for calibration are applied (Table 1; Figure 3). The calibration scheme choice is set by the device automatically.

Table 1: Calibration Schemes Description

Calibration Scheme	Approximate Duration	Performance Conditions	Number of Measurements (Invasive Measurements)
BG Elevation Scheme	1.5 to 2 hours	Fasting glucose values represent regular user's low BG levels	3 (1) pre-prandial + 5 (5) post prandial
BG Reduction Scheme	2 to 3.5 hours	Fasting glucose values don't represent regular user's low BG levels	3 (1) pre-prandial + up to 13 (13) post prandial (calibration ends once the BG reaches user's low BG level)

The efficacy of the calibration schemes was evaluated in clinical trials, conducted on 139 participants with demographic distribution (Figure 4) and results' accuracy level in each calibration scheme (Table 2). The measurements taken throughout the trial were based on individual calibration, which was performed at the beginning of each subject's trial.

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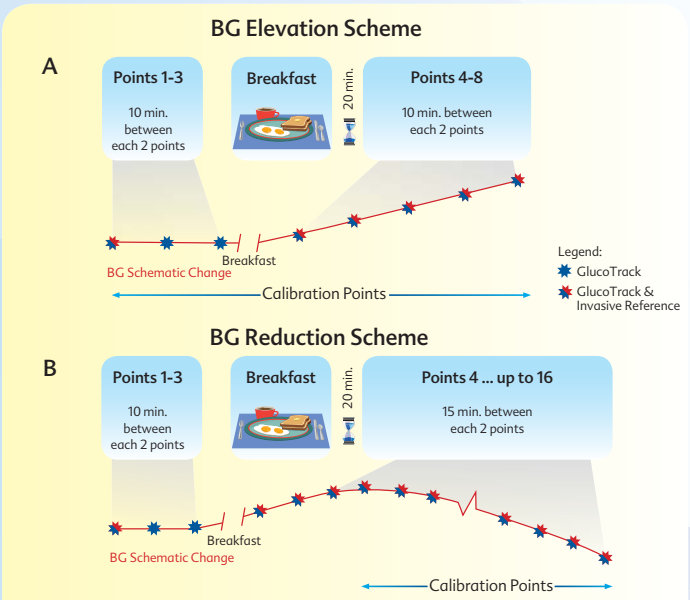

Figure 3: Calibration Scheme Procedures: [A] Calibration During Elevation in BG; [B] Calibration During Reduction in BG

Results

The characteristics of subjects who were calibrated in each scheme are described in Figure 4.

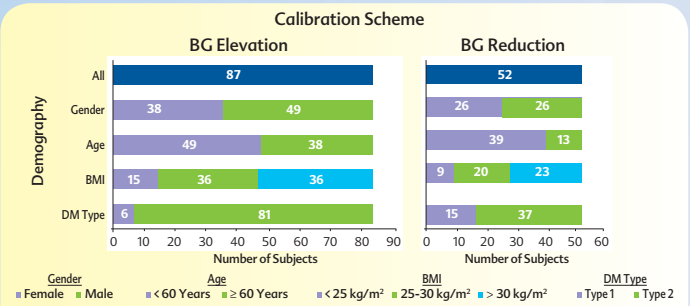

Figure 4: Characteristics of Subjects Calibrated in Elevation Scheme vs. Reduction Scheme

Clarke Error Grid (CEG) and Absolute Relative Difference (ARD) results for both calibration schemes are shown in Table 2.

Table 2: Comparison of Results Obtained from the Two Calibration Schemes

		BG Elevation Calibration Scheme	BG Reduction Calibration Scheme
Number of Subjects		**87 (63%)**	**52 (37%)**
Number of Points		**6,213**	**2,320**
CEG	Zones A+B	97% (6,021)	95% (2,200)
	Zone A	42% (2,627)	40% (934)
	Zone B	55% (3,394)	55% (1,266)
	Zone C	2% (107)	3% (68)
	Zone D	1% (79)	2% (48)
	Zone E	0% (6)	0% (4)
ARD	Mean	30.0%	31.6%
	Median	24.2%	25.3%

Conclusions

- The two calibration schemes yield similar ***GlucoTrack*** accuracy, with a slight advantage to the elevation scheme;
- Both calibration schemes show relevance to all demographic categories. Nevertheless, majority of subjects (63%) undergo calibration in BG elevation scheme, resulting in a shorter calibration process;
- Application of joined calibration schemes enables more flexible and approachable calibration process, suitable to all users;
- Combined calibration process is valid for variety of potential users and validates ***GlucoTrack*** to be eligible as a useful NI home-use solution for self monitoring of blood glucose.