Simplifying Calibration Practice for Home Use Non-Invasive Glucose Monitoring Device: Reference Device Aspects

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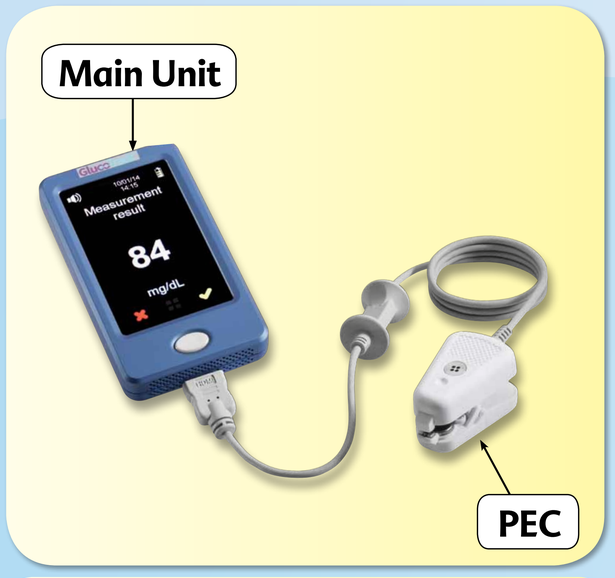
Background

GlucoTrack® is a CE Mark certified Non-Invasive (NI) glucose monitor for home use. It allows frequent real-time spot measurements of glucose, conducted on earlobe via a Personal Ear Clip (PEC) connected to Main Unit (Figure 1).
Like any other NI device, ***GlucoTrack*** requires calibration by an invasive glucose meter prior to conducting measurements. This calibration remains valid for the entire PEC lifespan (6 months).
The calibration establishes an individual baseline for physiological change detection. Thus, the accuracy of the invasive device used for calibration can directly impact the NI device's performance. Up to now HemoCue® Glucose 201 RT system was recommended as the only reference device used for calibration of ***GlucoTrack***, as it is a reliable Point-Of-Care (POC) clinical use device. However, the choice of invasive reference device and the related required logistics may strongly affect NI device eligibility and acceptance for home use utilization. Characteristics of ***GlucoTrack*** calibration using POC vs home use glucose meter are summarized in Table 1:



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

Figure 1: GlucoTrack Glucose Monitor

Table 1: Considerations When Choosing the Invasive Reference Device

Device Type	POC meter	Home use meter
Device accessibility	Low	High
Procedure location options	Clinic	Clinic/Home *
Calibration can be performed by	Trained medical personnel	Trained medical personnel/User*

* A potential future option. Currently, calibration is available only in clinic by trained medical personnel.

Objective

In order to simplify calibration practice and improve the acceptability of the reference meter, the possibility of using users' own invasive device as a calibration reference was evaluated.

Methods

Clinical trials on 187 type 2 subjects (Table 2) evaluated the employment of two invasive reference devices for calibration of ***GlucoTrack***:

- POC (in-clinic use) device - HemoCue Glucose 201 RT System;
- Home use device - FreeStyle Freedom Lite® (complies with ISO 15197) - a common blood glucose monitoring device for home use.

Table 2: Population Characteristics

Number of Subjects	187
Age (years)	Range: 21-88 ; 61 ± 9 (mean ± SD)
Gender	97 M ; 90 F
BMI (Kg/m²)	Range: 18.9 - 47.3; 30.0 ± 5.0 (mean ± SD)

Throughout the clinical trials, simultaneous POC, home use meter and ***GlucoTrack*** readings were collected at all times. At the beginning of the trial, each subject was calibrated. Since ***GlucoTrack*** can be calibrated with only one invasive device per person, during the trials real-time calibration was done using HemoCue readings. For the purpose of this analysis, ***GlucoTrack*** was calibrated off-line with FreeStyle readings using the same ***GlucoTrack***'s raw data signals.
GlucoTrack performances following both calibrations were evaluated against HemoCue using Clarke Error Grid (CEG), mean and median Absolute Relative Differences (ARD) and Mean Absolute Differences (MAD).

Results

CEG, ARD and MAD values, following calibration using POC vs home use device, are shown in Table 3 and Figure 2.

Table 3: GlucoTrack Performances When Calibrated with POC and Home Use Glucose Meters

		Calibration using HemoCue		Calibration using FreeStyle	
Number of Points		14,639		14,656	
CEG	Zones A+B	96.0%	(14,058)	96.2%	(14,098)
	Zone A	47.2%	(6,915)	47.2%	(6,914)
	Zone B	48.8%	(7,143)	49.0%	(7,184)
	Zone C	0.1%	(16)	0.2%	(35)
	Zone D	3.9%	(564)	3.6%	(522)
	Zone E	0.0%	(1)	0.0%	(1)
ARD	Mean	24.5%		25.1%	
	Median	21.2%		21.3%	
MAD		37.3 [mg/dL]		37.2 [mg/dL]	

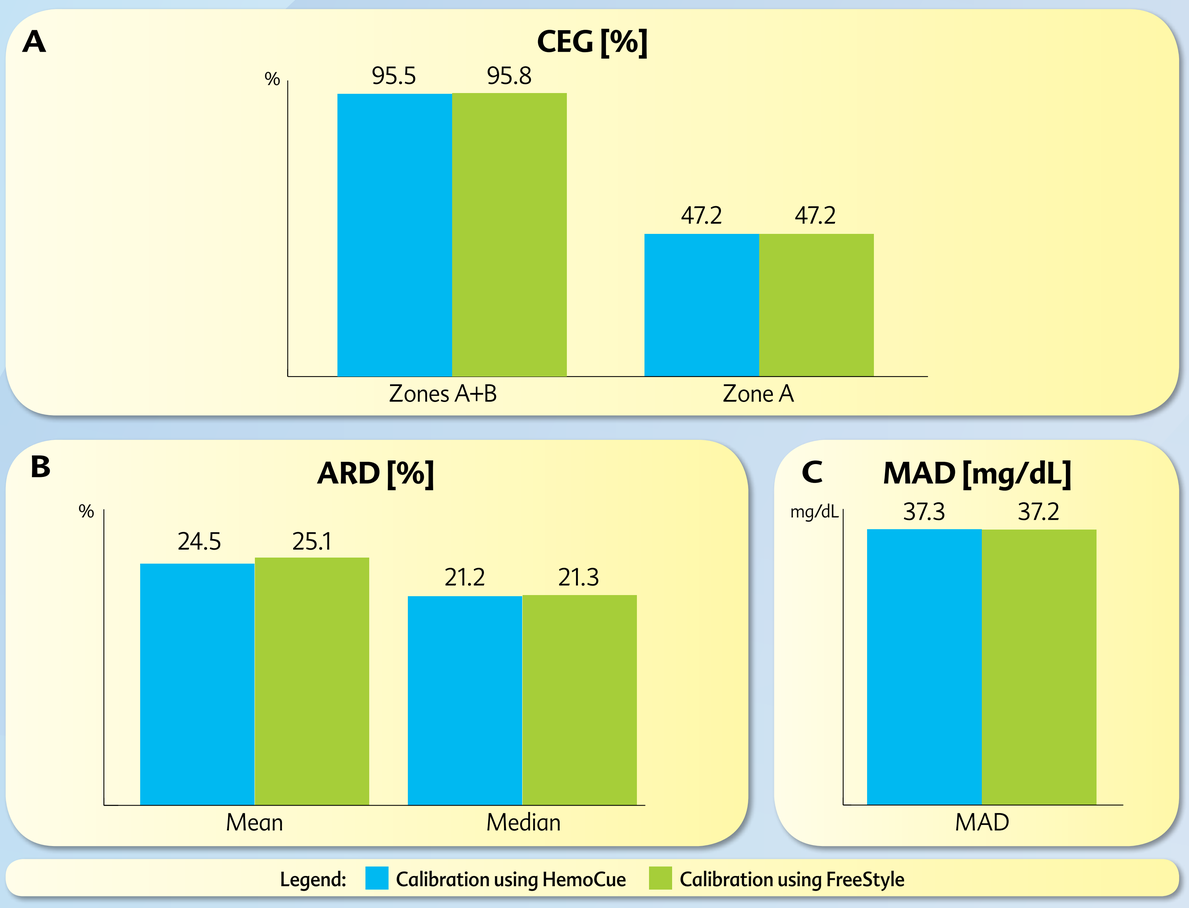


Figure 2: Device Performances According to Each Calibration Reference Device: [A] CEG percentages in A and A+B Zones; [B] Mean and Median ARD; [C] MAD

Conclusions

GlucoTrack performances remain similar when using either a home use or a POC glucose meter for calibration

Conventional home use device (complying with ISO 15197) can be used as a reference device for ***GlucoTrack*** calibration

More flexible, accessible and practicable calibration

Expected better ***GlucoTrack*** acceptability and utilization

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