Applicability of a Non-Invasive Glucose Monitor in Subjects with Various Demographic Profiles throughout 6 Months of Use

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Introduction

GlucoTrack® is a CE certified, non-invasive, home-use device for self-monitoring of glucose. The device tracks physiological changes which are correlated with glucose excursions by measuring ultrasonic, electromagnetic and thermal parameters of the earlobe tissue. The measured parameters are translated into a glucose value based on individual calibration. *GlucoTrack* comprises of a Main Unit (MU), and a Personal Ear Clip (PEC) (Figure 1B). Spot measurements are performed by clipping the PEC to the earlobe for the duration of the measurement (about 1 minute; Figure 1A). The PEC is intended for personal use and its lifespan is 6 months. Each PEC replacement requires user calibration. In order to achieve high efficacy and reliability, the device should maintain its performance in various diabetic populations for the whole 6 months of PEC lifespan.

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

Figure 1: [A] Conducting a glucose measurement; [B] *GlucoTrack* contains a Personal Ear Clip (PEC) and a Main Unit (MU).

Objective

This study demonstrates the applicability of the device for type 2 diabetes mellitus (DM) patients with different demographic parameters (gender, age, BMI, HbA1c level and DM duration).

Method

Clinical trials were conducted in a group of 187 type 2 DM subjects. In the beginning of the trial, each subject was individually calibrated. The calibration process takes up to 30 minutes and involves 3 paired measurements of *GlucoTrack* and invasive reference with 10 minutes intervals between each pair (Figure 2).

Following calibration, paired *GlucoTrack* and invasive reference measurements were conducted. HemoCue® Glucose 201 RT system was used both for calibration and subsequent performance evaluation.

Device performances were evaluated:

🔹 In different demographic categories (Table 1), based on data collected from 187 subjects who participated in 3 non-consecutive full-day sessions.

🔹 During the 6 months period — 17 subjects (out of the 187) performed additional 16 full-day measurement sessions along the entire 6 months period, based on single calibration at the beginning of the trial. Performances were analyzed on a monthly basis as a function of time elapsed from calibration.

Data were analyzed using Clarke Error Grid (CEG) analysis, and mean Absolute Relative Differences (ARD).

Figure 2: Calibration process scheme

**Table 1: Demographic distribution of 187 type 2 subjects.**

Tested categories		Number of subjects	Number of measurements
Gender	Male	97	5,533
	Female	90	5,028
Age (years)	< 60	88	4,999
	≥ 60	99	5,562
BMI (kg/m²)	< 25	24	1,411
	25-30	80	4,400
	> 30	83	4,750
HbA1c (%) *	< 7.5	50	2,844
	≥ 7.5	54	3,171
DM Duration (years)	< 1	72	3,914
	1-10	52	2,968
	> 10	63	3,679

* Data were available for 104 subjects only

Results

🔹 Figure 3 (A and B) summarizes *GlucoTrack* performances across the different demographic categories.

🔹 Figure 4 (A and B) summarizes *GlucoTrack* monthly performances as a function of time elapsed from a single calibration. Average number of measurements per month: 804 with a standard deviation of ±105.
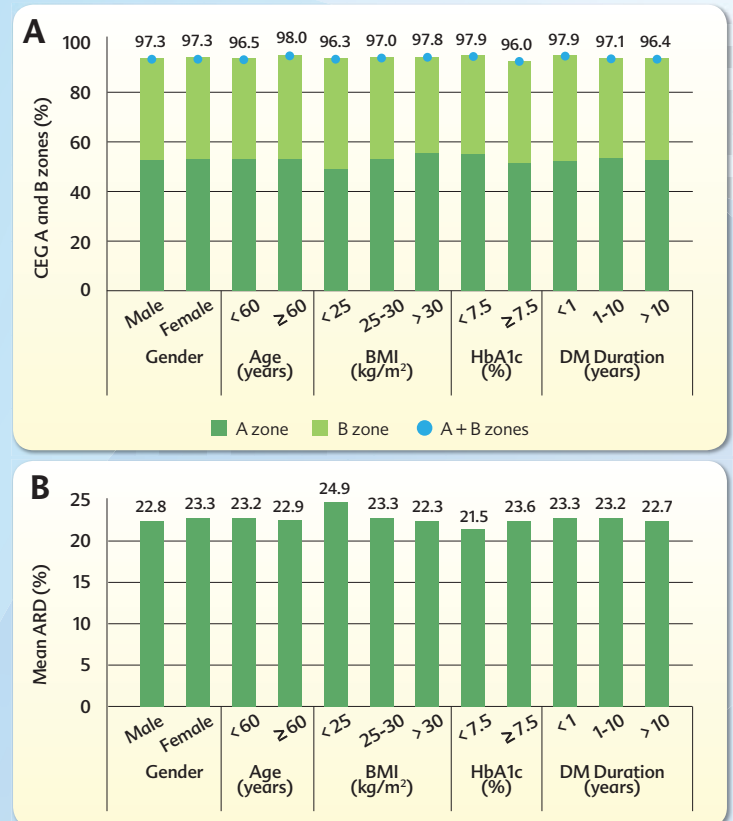
Figure 3: *GlucoTrack* performances according to the tested categories: Gender, Age, BMI, HbA1c and DM duration. A - CEG A and B zones (%); B - mean ARD (%).
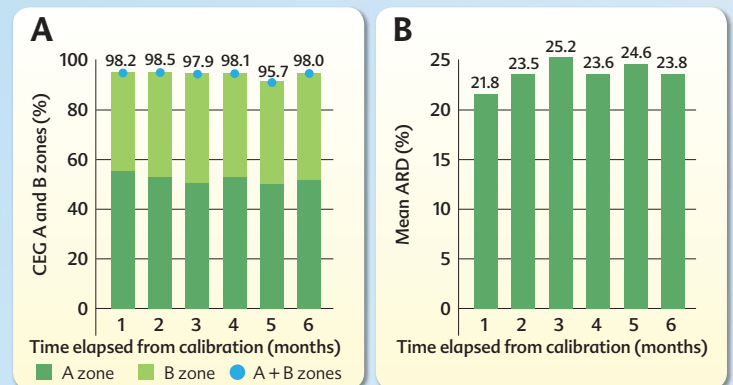
Figure 4: *GlucoTrack* performances as a function of time elapsed from single calibration. A - CEG A and B zones (%); B - mean ARD (%).

Conclusions

🔹 The device is equally suitable for various populations of type 2 diabetics;

🔹 Measurements' accuracy is stable for the entire 6 months of PEC lifespan;

🔹 These findings suggest that the cost-effective, painless device is suitable for various type 2 diabetes population, for the entire calibration validity period.