

Readiness of *GlucoTrack*[®] - a Truly Non-Invasive Glucose Monitor for Home Use

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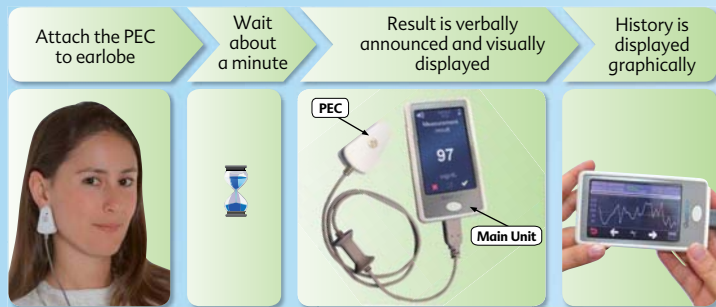
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Background

Invasive blood glucose (BG) monitoring lacks utilization due to its painful, costly and complex manner of use. Non-Invasive (NI) monitors can overcome these limitations and thus improve BG monitoring adherence. *GlucoTrack* model DF-F (Figure 1) is a CE Mark approved, truly NI device for self-monitoring of BG (SMBG) at home and home-alike environment, incorporating 3 technologies: Ultrasonic, Electromagnetic and Thermal.

The device comprises:

- User friendly Main Unit (MU) with color touch screen;
- Personal Ear Clip (PEC) with 6 months life span.



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

Figure 1: Device Usage

Key features of *GlucoTrack* model DF-F:

No Blood 	No Pain 	Spot Measurements 	Easy to Use
User Friendly 	Calibration Valid for 6 Months (towards regulatory process) 	Low Cost 	No Disposables
MU Supports Up To 3 Users 	Audible Results 	Graphic & Tabular Data History Display 	Estimated HbA1c Display

Method

GlucoTrack performances were evaluated in various clinical trials, including simulating home-like environment by subjects of both genders and diabetes types, as well as diverse BMI and ages (currently ≥18 years). At the beginning of the study each subject underwent individual calibration, which took about 2 hours (Figure 2).

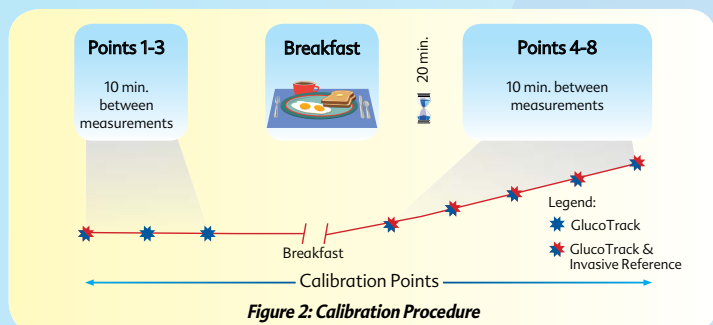


Figure 2: Calibration Procedure

- All measurements of a given subject were taken based on that individual calibration;
- Subjects participated in the trial for up to 6 months, in order to verify the calibration validity period;
- Feedback survey regarding device usability and users satisfaction was analyzed.

Results

Clarke Error Grid (CEG) analysis of 10,710 data points (172 subjects), over up to 6 months of operation shows that 95.9% of the points fall within the clinically accepted A+B zones. Mean and Median Absolute Relative Differences (ARD) of 31.4% and 24.8% were observed, accordingly.

No degradation in performance was noticed as a function of time elapsed from calibration (Table 1, Figure 3).

Table 1: Device Accuracy as a Function of Time Elapsed From Calibration

Acc. Time Post Calibration	# of Subjects	# of Data Points	CEG A+B Zones (%)	CEG A Zone (%)	Mean ARD (%)	Median ARD (%)
1 st month	172	8,023	95.7	41.2	31.7	24.8
2 nd month	22	728	97.5	42.6	30.4	23.6
3 rd month	14	571	96.8	39.1	33.0	26.1
4 th month	12	545	96.5	43.9	29.4	23.6
5 th month	9	429	95.1	43.1	28.4	23.7
6 th month	9	414	95.7	38.6	30.2	26.7
Accumulated	172	10,710	95.9	41.3	31.4	24.8

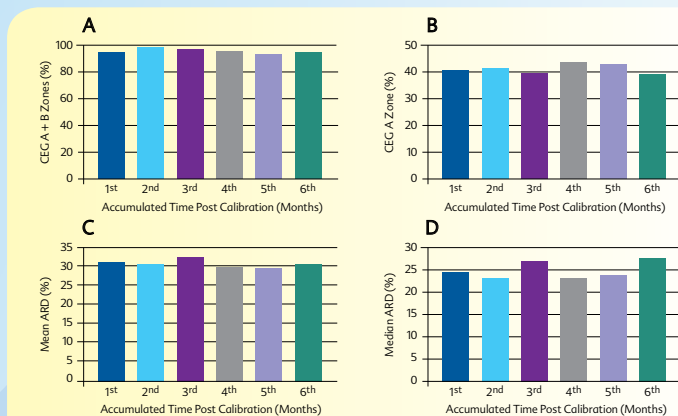


Figure 3: Device Accuracy Throughout Six Months From Calibration Assessed by: [A] CEG A+B Zones; [B] CEG A Zone; [C] Mean ARD; [D] Median ARD

Users feedback analysis is presented in Figure 4.

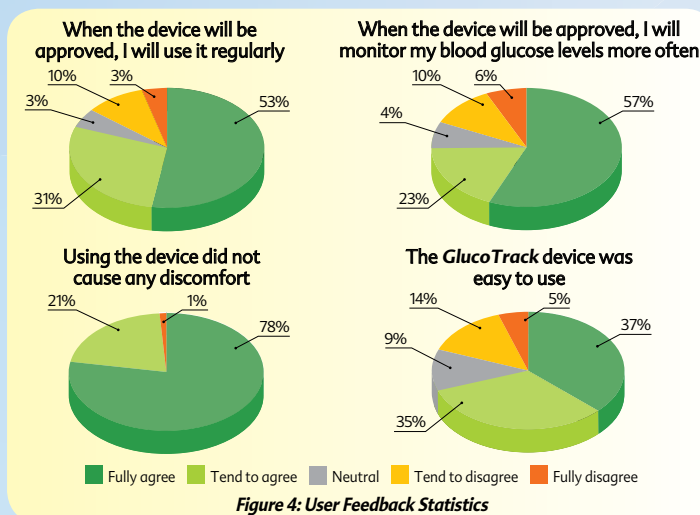


Figure 4: User Feedback Statistics

Conclusions

• *GlucoTrack* demonstrates acceptable accuracy (96% in zones A+B of the CEG).

• *GlucoTrack* maintains its performance level after calibration for the entire life span of the PEC (6 months).

• Users feedback demonstrates:
 ✓ High satisfaction;
 ✓ Ease of use;
 ✓ Willingness to use *GlucoTrack* more frequently than invasive devices.

***GlucoTrack* can be considered as a useful home-use solution for SMBG**

