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

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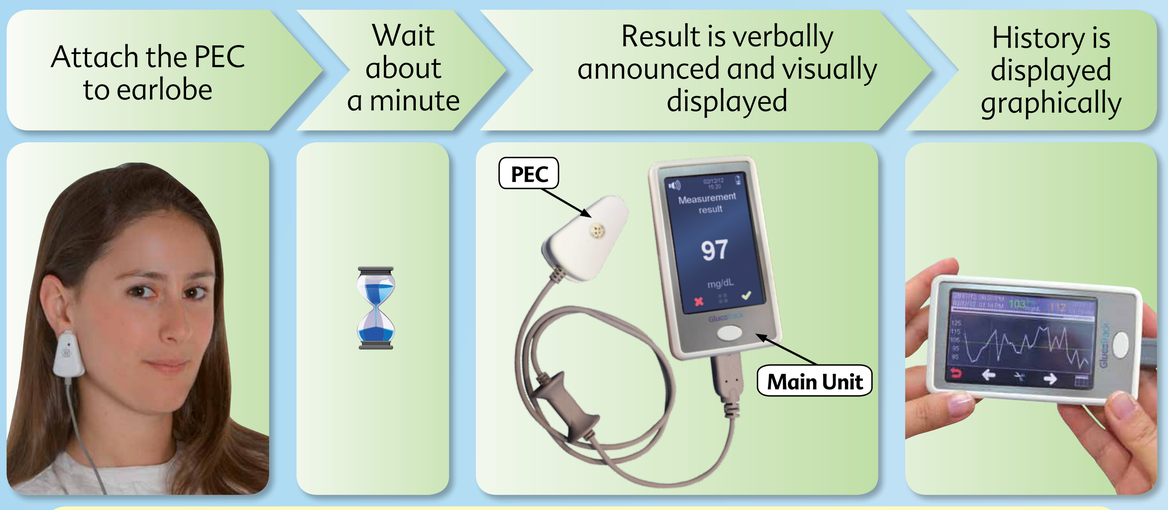
Background

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:

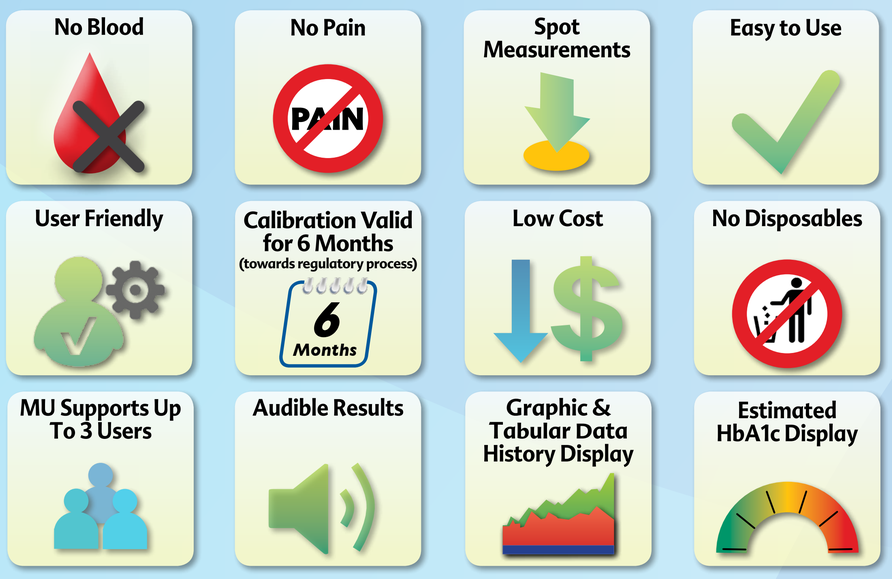
- User friendly Main Unit (MU) with color touch screen;
- Personal Ear Clip (PEC) with 6 months life span.



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:



Method

GlucoTrack performances were evaluated in various clinical trials, including simulating home-alike 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).

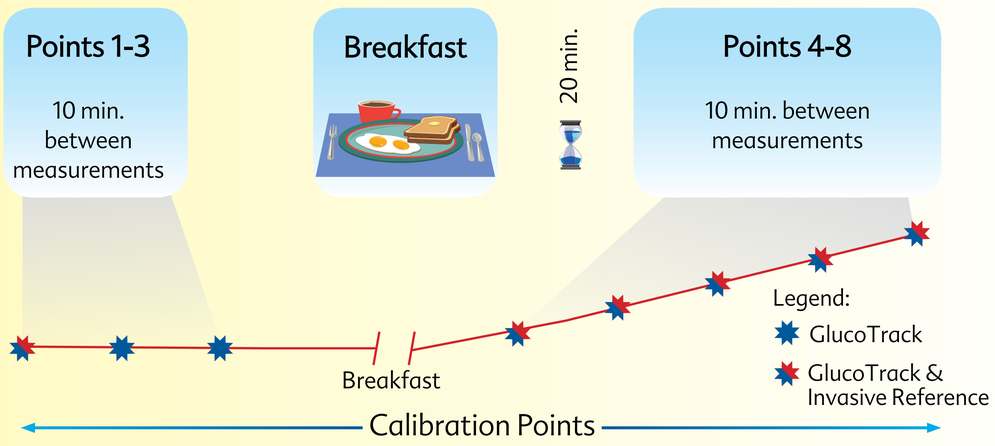


Figure 2: Calibration Procedure

- 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 (%)
1st month	172	8,023	95.7	41.2	31.7	24.8
2nd month	22	728	97.5	42.6	30.4	23.6
3rd month	14	571	96.8	39.1	33.0	26.1
4th month	12	545	96.5	43.9	29.4	23.6
5th month	9	429	95.1	43.1	28.4	23.7
6th month	9	414	95.7	38.6	30.2	26.7
Accumulated	**172**	**10,710**	**95.9**	**41.3**	**31.4**	**24.8**

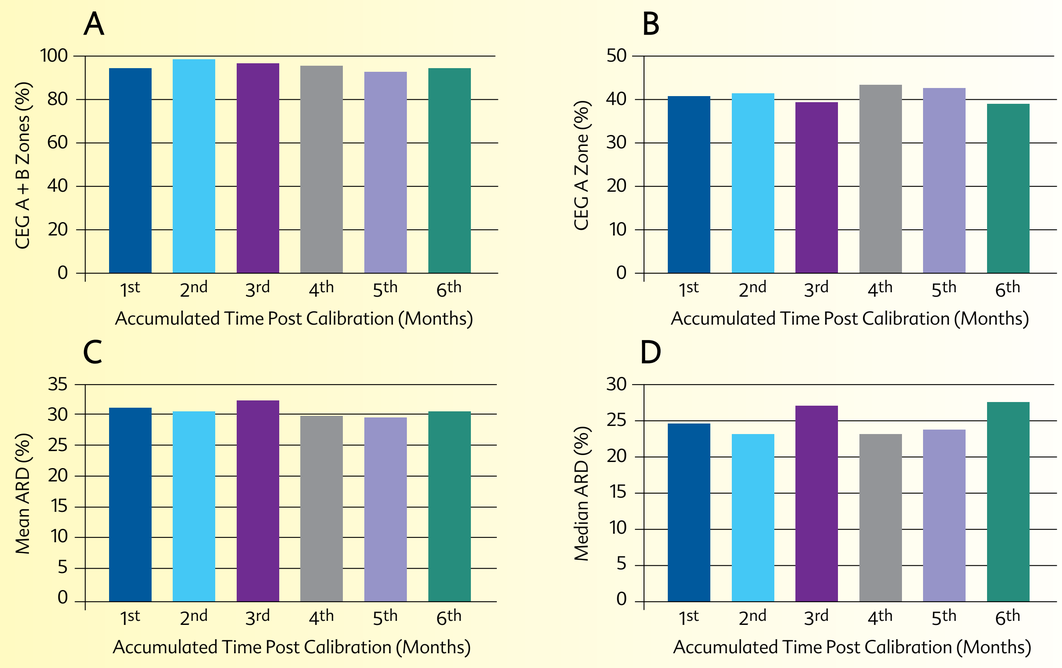


Figure 3: Device Accuracy Throughout Six Months From Calibration Assessed by: [A] CEG A+B Zones; [B] CEG A Zone; [C] Mean ARD; [D] Median ARD

Users feedback analysis is presented in Figure 4.

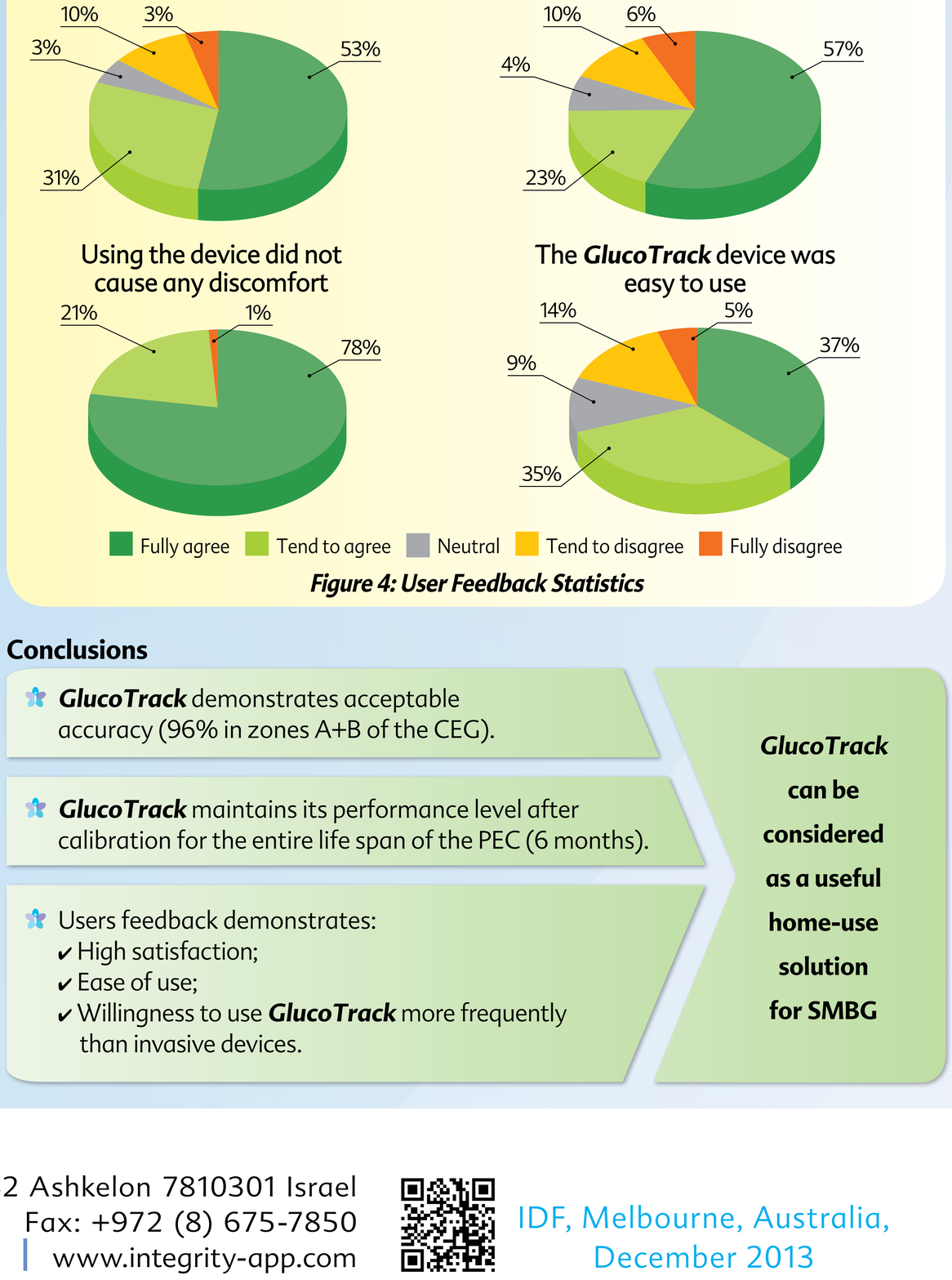


Figure 4: User Feedback Statistics

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

integrity applications

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