Enabling Frequent Blood Glucose Monitoring at Home Using a Truly Non-Invasive Device

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Background

Conventional invasive Blood Glucose (BG) monitoring approach suffers from under-utilization, mainly due to its painful, costly and complex manner of use. BG monitors, that are painless, easy and simple to use, with acceptable accuracy, are likely to overcome these limitations and thus promote frequent self-monitoring of BG (SMBG).

GlucoTrack® Model DF-F is a CE Mark approved non-invasive glucose monitoring device for home use. It allows frequent real-time spot measurements of glucose, conducted on earlobe via a Personal Ear Clip (PEC). The PEC is attached to the earlobe for the duration of a measurement (~1 minute) and is removed afterwards (Figure 1A). Prior to conducting measurements, an individual calibration is required. This calibration is valid for 6 months.

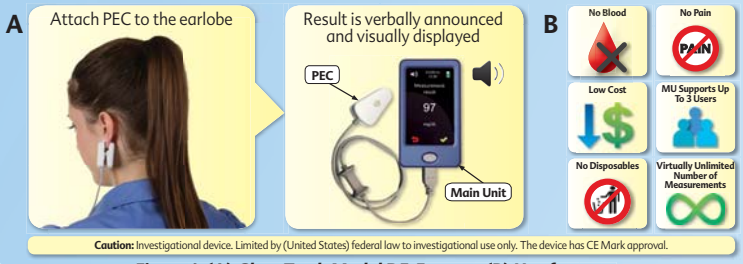

Figure 1: (A) GlucoTrack Model DF-F usage; (B) Key features

Method

GlucoTrack eligibility for frequent home use was evaluated in two groups (Table 1):

- **Performance group:**
  - Following individual calibration, 202 subjects participated in 2-19 non-consecutive full-day sessions (4.2 session days on average per subject) throughout up to 6 months.
  - Consistency in accuracy among inter-sessions' performances for up to 6 months was analyzed across all subjects.
- **Usability group:**
  - Following individual calibration, 89 subjects underwent brief training and performed measurements by themselves, at home or home-alike environment, for up to 7 days.
  - Usability, as a function of age and education level, as well as user satisfaction were assessed based on users' feedback.

Table 1: Population characteristics

	Consistency in accuracy	Usability and user satisfaction
Group	Performance group	Usability group
Number of subjects	202	89
Education (years)	–	40 subjects ≤ 12 ; 49 subjects > 12
Age (years)	Range: 18-88	Range: 18-88 35 subjects < 60 ; 54 subjects ≥ 60
Gender	110 M ; 92 F	47 M ; 42 F
BMI (kg/m²)	18.4 – 47.3	18.4 – 39.9
Diabetes type	33 type 1 ; 169 type 2	18 type 1 ; 71 type 2

Results

GlucoTrack inter-sessions performances, throughout the entire calibration validity period, were analyzed using Clarke Error Grid (CEG) and Mean Absolute Relative Differences (MARD) (Figure 2). Throughout all trial sessions results remain similar: 95.3% (±1.6% SD) of the points within the clinically acceptable A+B CEG zones with MARD values of 30.8% (±2.2% SD).

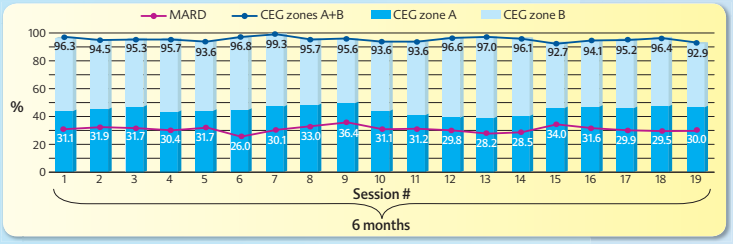

Figure 2: CEG analysis and MARD values throughout all trial sessions.

Figure 3 shows general impression and satisfaction from the device, based on users' feedback.

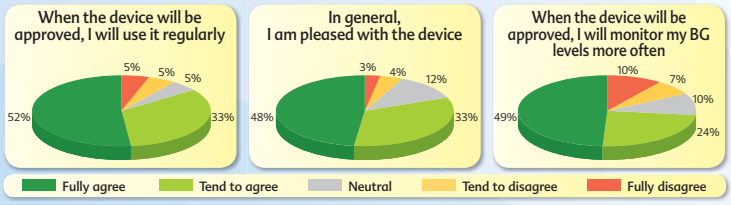

Figure 3: General impression and satisfaction from GlucoTrack Model DF-F

Figure 4 shows usability analysis based on users' feedback in accordance to education level.

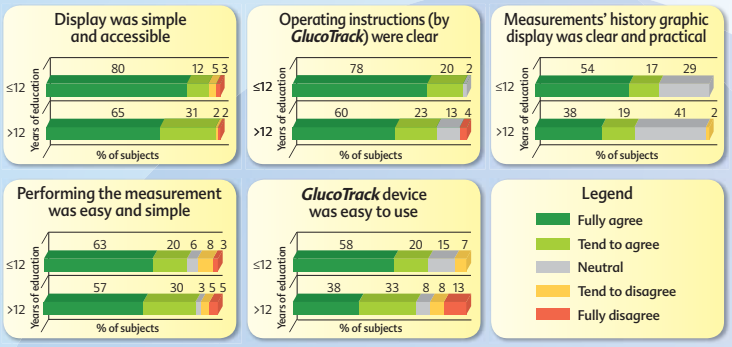

Figure 4: Usability analysis according to education level

Figure 5 shows usability analysis based on users' feedback in accordance to age.

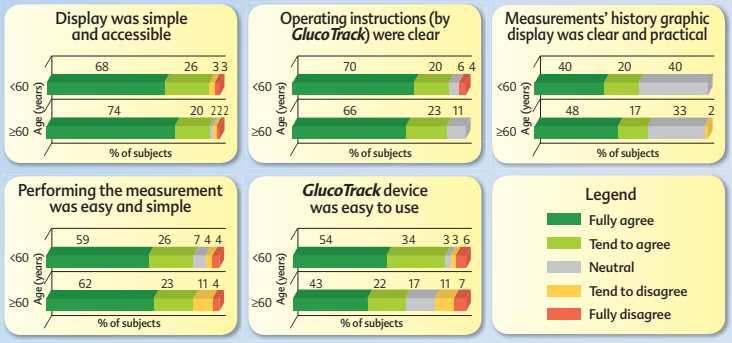

Figure 5: Usability analysis according to age

Feedback analyses demonstrate that most of the users find ***GlucoTrack*** to be simple and easy to use, regardless of education level or age category. Nevertheless, a higher percentage of users below 60 years old found ***GlucoTrack*** easy to use compared to users above 60 years old. Therefore, it is possible that additional training should be considered for older users.

Conclusions

- ***GlucoTrack*** Model DF-F performances are fairly maintained over its entire calibration validity period;
- Results demonstrate positive user feedback, high satisfaction of use and willingness to increase frequency of self-monitoring.

These findings, combined with painless and cost-effective nature of measurement, support ***GlucoTrack*** model DF-F utilization for frequent SMBG.

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