

Acceptance of a Truly Non-Invasive Glucose Monitoring Device for Home Use

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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. A non-invasive (NI) glucose monitoring approach, which is also cost-effective and suitable for home use, is expected to overcome these limitations and encourage frequent self-monitoring of BG (SMBG) (Figure 1).

GlucoTrack® is a CE Mark approved NI glucose monitoring device intended for home and home-like environment use. **GlucoTrack** unique approach is based on combining three NI independent technologies: Ultrasonic, Electromagnetic and Thermal. It allows frequent real-time spot measurements of glucose, conducted on an earlobe through a Personal Ear Clip (PEC). The PEC is attached to the earlobe for the duration of a measurement (~1 minute) and is removed afterwards. The glucose reading is then heard and displayed on a color touch-screen of the device's Main Unit (MU) (Figure 2A).

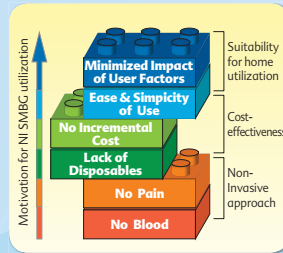


Figure 1: Motivators for SMBG utilization

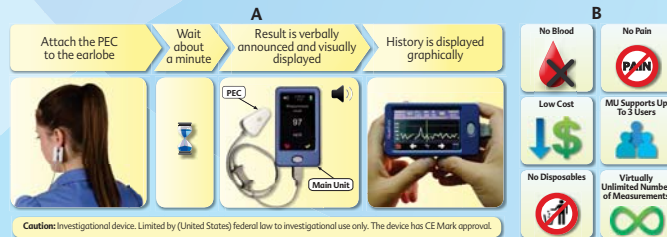


Figure 2: (A) GlucoTrack Model DF-F usage; (B) Key features

The PEC lifespan is 6 month; therefore bi-annual replacement of the PEC is necessary. Prior to conducting measurements with a new PEC, an individual calibration is required. The calibration is valid for the entire PEC lifespan, offering virtually unlimited number of measurements (Figure 2B).

Objective

GlucoTrack suitability for home utilization was evaluated in regards to the impact of a newly-introduced user upon the device accuracy, ease and simplicity of use and general user satisfaction.

Methods

Clinical trials were conducted to assess usability, user satisfaction and possible user impact upon the device performance (e.g. accuracy). The trial population was divided into 3 groups:

- Home Environment (HE):** Measurements were conducted by the subjects themselves at home;
- Home Simulated (HS):** Measurements were conducted by the subjects themselves at a clinic facility;
- Clinic (CL):** Measurements were conducted by a professional team at a clinic facility.

- All trials began with individual calibration. Following calibration, HS and HE subjects underwent brief training on device operation;
- HemoCue® Glucose 201+ served as the reference device for calibration in all groups and for performance evaluation in HS and CL groups;
- Possible user impact upon the measurements' accuracy was evaluated by comparing performances of the CL and the HS groups (Table 1);
- GlucoTrack** usability and user satisfaction were assessed based on feedback received from HE and HS groups in general population and as a function of age and education (Table 1).

Table 1: Population characteristics and trial details

Groups included	Usability and user satisfaction		User impact on measurements' accuracy	
	HE	HS	CL	HS
# of subjects	89	162	42	
Trial duration	3 days during up to 1 month		3 days during up to 1 month	
Education	40 subjects ≤ 12 years 49 subjects > 12 years		-	-
Age (years)	Range: 18-88 35 subjects < 60; 54 subjects ≥ 60		Range: 19-88	Range: 18-70
Gender	47 M ; 42F		87 M ; 75 F	23 M ; 19 F
BMI range (kg/m ²)	18.4 – 39.9		18.4 – 47.3	23.5 – 39.9
Diabetes type	18 type 1 71 type 2		26 type 1 136 type 2	7 type 1 35 type 2

Results

User impact was assessed by comparing **GlucoTrack** performances in the CL and HS groups. Results were analyzed using Clarke Error Grid (CEG) and Absolute Relative Differences (ARD). The results show negligible dependence upon user skills, based on similar accuracy when used by proficient personnel and by new users (Table 2). General impression and satisfaction analysis from the device for HS and HE groups, based on users' feedback in general population is presented in Figure 3.

Table 2: GlucoTrack performances in the CL and HS groups

	CL	HS
# of data points	8,069	1,854
CEG A+B Zones (%)	95.7	96.2
CEG A Zone (%)	41.9	40.3
Mean ARD (%)	30.9	30.7
Median ARD (%)	24.3	25.5

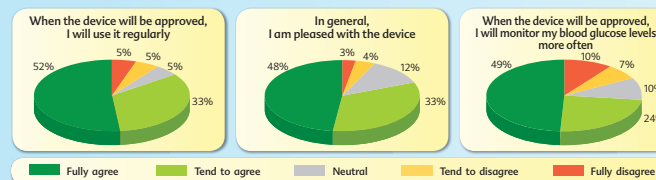


Figure 3: General impression and satisfaction analysis from the device for HS and HE groups in general population

Usability analysis according to education level is presented in Figure 4. This analysis was based on users' feedback in HS and HE groups.

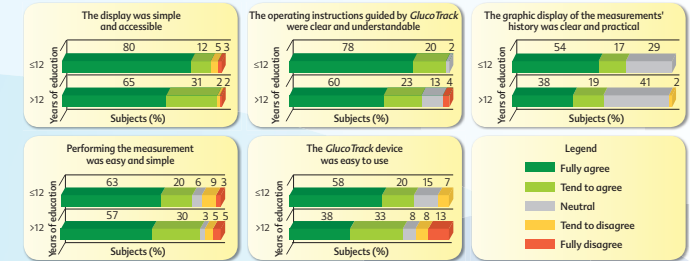


Figure 4: Usability analysis according to education level

Usability analysis based on users' feedback in HS and HE groups in accordance to age is presented in Figure 5.

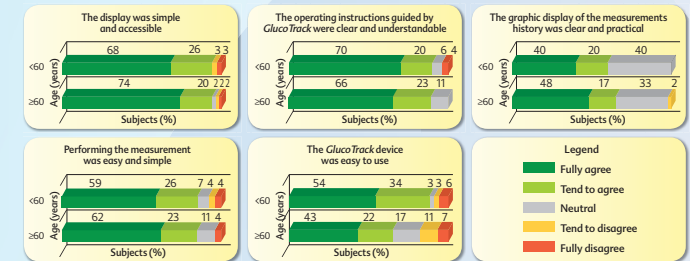


Figure 5: Usability analysis according to age

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

Conclusions

- GlucoTrack** uses a truly NI methodology
- GlucoTrack** requires no disposables, can be used by up to 3 users and offers virtually unlimited number of measurements
- GlucoTrack** maintenance of performances in home use regardless of user skills shows device suitability for layperson use. The vast majority of feedback demonstrates:
 - Willingness to use **GlucoTrack** more frequently than invasive devices;
 - High level of general satisfaction;
 - Ease of use and measurement simplicity regardless of education level or age.
- Painless
- Cost-effective
- Suitable for home utilization
- GlucoTrack** can be considered as a useful home-use solution for SMBG

