Presenting a Truly Non-Invasive Glucose Monitor for Home Use

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Background

One of the keys to achieve tight glycemic control in people with diabetes is through a routine, frequent monitoring of blood glucose (BG). However, invasive BG monitoring is underutilized, mostly since it involves painful, inconvenient and costly process. Non-Invasive (NI) device for home use is expected to overcome these barriers and thus increase BG monitoring adherence. ***GlucoTrack®***, a CE Mark approved truly NI device for self-monitoring of BG at home and home-alike environments, is suggested as an available solution.

GlucoTrack comprises a Main Unit (MU), which drives different sensors, located at a Personal Ear Clip (PEC) (Figure 1-A). The PEC is clipped externally to the earlobe, to commence a real-time spot measurement. Prior to conducting measurements with a new PEC, an individual calibration procedure (~2 hours) is required. Calibration is performed by using invasive capillary fingertip BG as a reference. PEC life span is 6 months; therefore Bi-annual replacement of the PEC is necessary.

Performing a measurement (Figure 1-B) is convenient, easy, and takes less than a minute. Glucose readings are heard and displayed on a color touch-screen of a smartphone sized MU.

A

B

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

Figure 1: (A) GlucoTrack Model DF-F; (B) Conducting a Measurement

Key features of ***GlucoTrack*** model DF-F:

Method

GlucoTrack eligibility for home use was assessed according to:

- Calibration validity period: evaluated by clinical trials conducted for up to 6 months (towards regulatory process);
- Evaluation of user impact, based on comparison between the performance analysis of two groups:
  - ✔ Clinic group, where measurements were performed by a skilled medical team;
  - ✔ Home Simulated group, where measurements were conducted by the subjects themselves, after a brief training.
- Feedback analysis regarding user satisfaction: questionnaires were completed at the end of the trials by all participants.

Results

GlucoTrack accuracy level as a function of elapsed time from calibration was analyzed using Clarke Error Grid (CEG) and Absolute Relative Difference (ARD). The performance analysis was performed on 8,749 data points from 138 subjects (64 F, 74 M; 20 type 1, 118 type 2; Age: 18-81 years; BMI: 18.3-47.3 kg/m^2). No degradation in performance was noticed as a function of time elapsed from calibration (Table 1).

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

Months Post Calibration	# of Subjects	# of Data Points	CEG A+B Zones (%)	CEG A Zone (%)	Mean ARD (%)	Median ARD (%)
1st month	138	6,507	96.3	41.8	30.7	24.5
2nd month	14	480	98.5	42.1	28.7	23.3
3rd month	10	429	96.5	38.7	30.6	26.6
4th month	10	481	96.0	43.7	29.5	24.0
5th month	10	438	95.2	43.6	28.2	23.2
6th month	9	414	95.7	38.6	30.2	26.7
Accumulated	**138**	**8,749**	**96.3**	**41.7**	**30.4**	**24.6**

GlucoTrack performances were maintained across Clinic and Home Simulated groups, as presented in Table 2.

Table 2: Device Accuracy in Clinic and Home Simulated Groups

	Clinic Group	Home Simulated Group
# of Subjects	96	42
# of Data Points	6,895	1,854
CEG A+B Zones (%)	96.3	96.2
CEG A Zone (%)	42.0	40.3
Mean ARD (%)	30.3	30.7
Median ARD (%)	24.3	25.5

Users feedback statistics is presented in Figure 2.

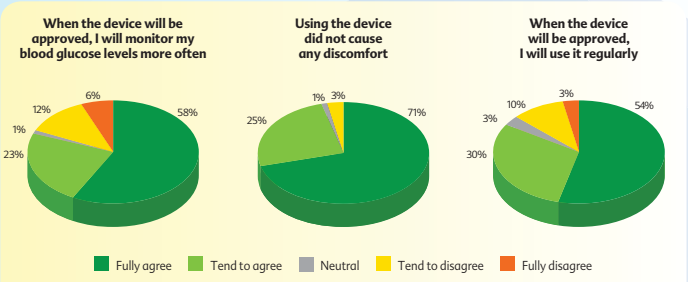

Figure 2: Users Feedback Statistics

Conclusions

- The clinical trial results demonstrate acceptable accuracy in both Clinic and Home Simulated groups, indicating low user impact. This implies that users quickly overcome device learning curve;
- The results suggest validity of ***GlucoTrack*** calibration for the entire life span of the PEC (6 months) without a need for re-calibration;
- Users' feedback show:
  - ✔ High satisfaction from ***GlucoTrack***;
  - ✔ Willingness to use the device more frequently than the invasive devices.

GlucoTrack is a user friendly device, which provides pain-free and inexpensive use, without the need to be continuously worn, and is technically available for use.

GlucoTrack advantages emphasize its suitability for home use, which consequentially lead to better BG monitoring adherence and tighter glucose control.

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