GlucoTrack® - a Truly Non-Invasive SMBG Device for Home Use

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Background:

For over a decade, the medical and industrial communities have struggled to provide an answer for people with diabetes and replace painful finger-prick glucose monitoring with a Non-Invasive (NI) methodology. Generally, NI devices measure physiological phenomena of the body, which are reflected in tissue parameter changes that are correlated with blood glucose (BG). These devices (in developmental stages) produce either trend analysis or continuous glucose values. However, the actual glucose level derived from such correlation is different than the real glucose value, since factors - other than glucose - influence tissue parameters as well and cause inaccuracies in the reading. Previous publications suggest a unique way to minimize the impact of such disturbances through an approach of combining technologies.

GlucoTrack utilizes three independent NI methods: **Ultrasound**, **Electromagnetic** and **Thermal**. The weighted average of the readings reflects the blood glucose value with minor impact of interferences, leading to more accurate, ***real-time***, ***spot*** glucose readings.

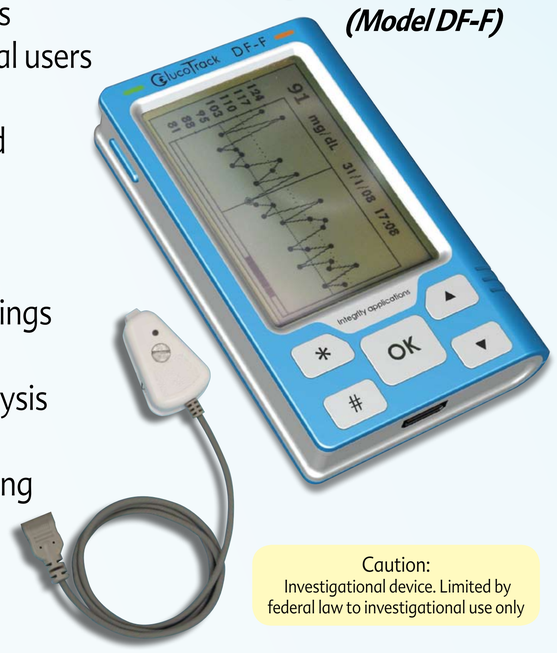
Figure 1: GlucoTrack - performing a measurement

GlucoTrack comprises a Main Unit, which drives three different sensor pairs (one per technology), located at the tip of a Personal Ear Clip (PEC) (Fig. 1 & 2). In order to perform a spot measurement, the PEC is clipped externally to the user's earlobe for the duration of the measurement (less than a minute) and is removed afterwards. The earlobe has a large blood supply and is also a convenient site that doesn't interfere with daily activities.

GlucoTrack (Model DF-F) Main Features:

- PEC Operational life span : 6 months
- Main Unit supports up to 3 individual users
- Individual preset alerts
- Large screen and digits, easy to read
- Repeatable audio results as well as audio instructions
- Easy to navigate; User friendly
- Memory storage of up to 1000 readings (330 readings per user)
- Graphic history results for easy analysis
- Estimated HbA1c level
- USB connection for data downloading
- Rechargeable built in battery

Figure 2: GlucoTrack (Model DF-F)

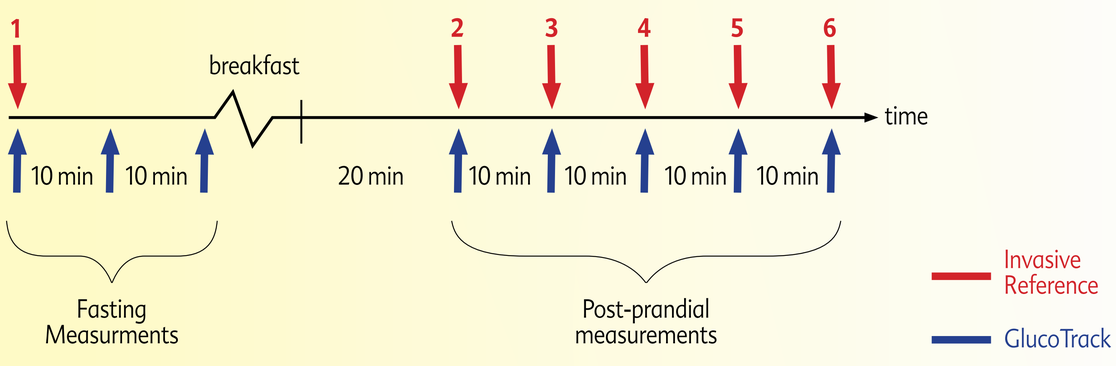


Caution:
Investigational device. Limited by federal law to investigational use only

Calibration:

Calibration is performed individually against invasive basal and post-prandial capillary fingertip BG references. Six invasive pre and post-prandial measurements generate individual calibration (Fig. 3). The first measurement pair is taken in the fasting state. The calibration procedure is easy, lasts about 1.5 hours and more importantly, is valid for a month (a longer period is forecast in the future).

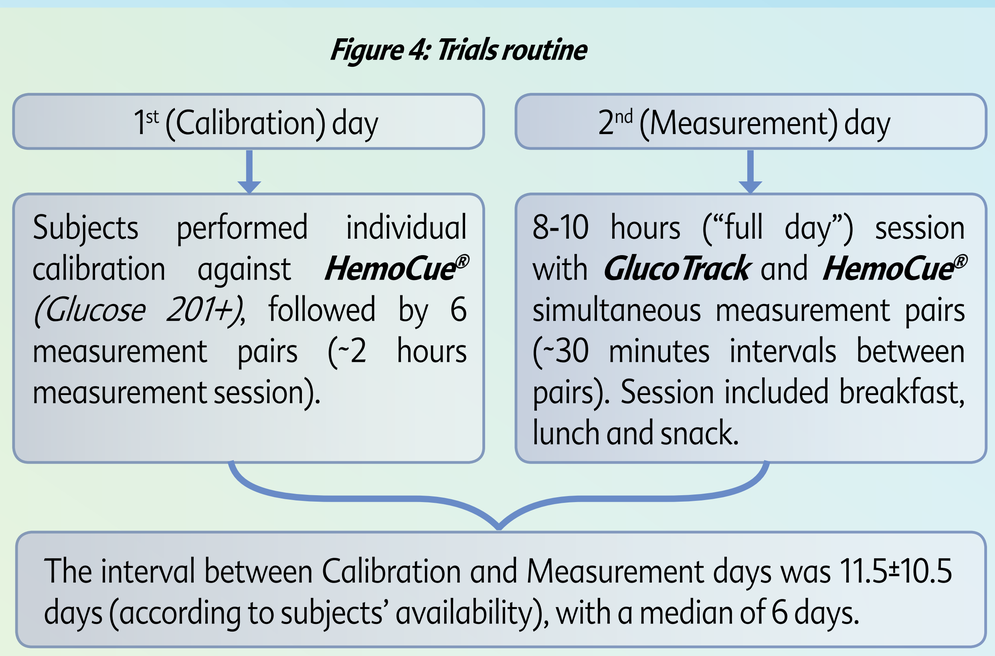
Figure 3: Calibration procedure



Method:

Clinical trials were performed at the Diabetes Unit, Soroka University Medical Center, Beer-Sheva, Israel. 68 subjects were evaluated (1318 measurement pairs): 7 T1DM (4F, 3M), 61 T2DM (27F, 34M), age 52 ± 29 years, BMI of 30.5 ± 9.5 Kg/m^2. In order to ensure realistic conditions, measurements were performed in the pre-prandial and post-prandial states as well as in various ambient environments. Each subject arrived at the clinic on two different days (Fig 4):

Figure 4: Trials routine

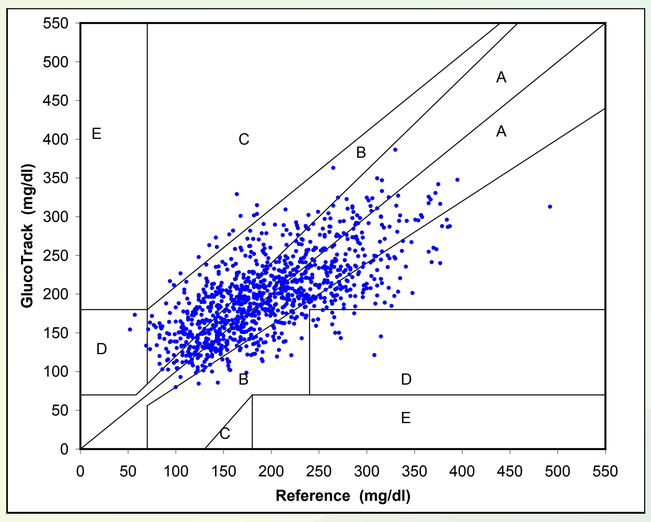


Results:

Clarke Error Grid shows all the measurements performed in the trials (Fig. 5A). The majority of the readings during the trials was measured on a different day than the calibration process (Fig. 5B).

Figure 5A

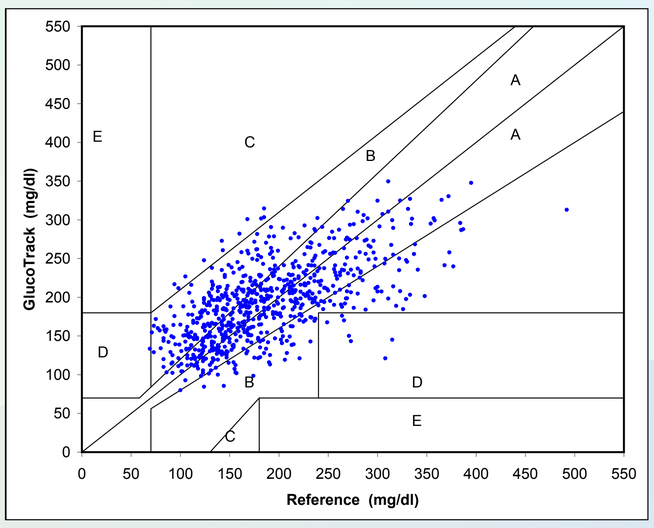
Clarke Error Grid of *GlucoTrack* readings all data pairs



Zone	Number	Percent	A+B zones
A	800	61%	97%
B	478	36%	
C	18	1%	
D	22	2%	
E	0	0%	
Total	1318	100%	
Mean ARD	21.5%		
Median ARD	15.9%		

Figure 5B

Clarke Error Grid of *GlucoTrack* readings on a different day than calibration (1-22 days)



Zone	Number	Percent	A+B zones
A	535	59%	97%
B	351	39%	
C	15	2%	
D	8	1%	
E	0	0%	
Total	909	100%	
Mean ARD	22.8%		
Median ARD	16.5%		

Conclusions:

- Current readings show that the present model of ***GlucoTrack*** gives promising results. Further work is currently being done to improve accuracy even further.
- The upgraded version of the device is in its final stage and new set of clinical trials is scheduled for November 2009, including measurements during controlled hypoglycemia.
- A key benefit of the device is the long interval between re-calibrations and the ability to perform frequent spot measurements without the need to continuously wear the device.
- This small, i-pod size, user friendly and easy to operate device is intended for home use and provides answers for the diabetic population (type 1 and 2, as well as IGT patients).
- The device is benficial primarily, but not only, for non-insulin dependent type 2 DM, since it doesn't need to be worn continuously and doesn't require disposables.
- ***GlucoTrack*** will improve monitoring adherence and will provide people with a painless way to track their BG, leading to tighter glucose control.

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