

Validity of GlucoTrack®, a Non-Invasive Glucose Monitor, for a Variety of People with Diabetes

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Background

Inconvenience, cost, pain and complexity involved with Self-Monitoring of Blood Glucose (SMBG) lead to its underutilization. Availability of a monitoring device with acceptable accuracy, painless, inexpensive and easy to use would encourage more frequent glucose measurement, leading to tighter glucose control. **GlucoTrack** is such a Non-Invasive (NI) blood glucose (BG) monitor for indoor use (home and home-alike). It utilizes a combination of 3 NI technologies: Ultrasonic, Electromagnetic and Thermal, to allow diabetics a painless way to measure BG levels.

Objective

In order to achieve high efficacy, the device should be valid and applicable for the majority of people with diabetes. Series of clinical trials have been conducted, in order to check validity of the device for various demographic groups.

Method

GlucoTrack comprises a Main Unit (MU), smartphone sized device with color touch screen, and an individually calibrated Personal Ear Clip (PEC), where different sensors are placed (Figure 1-A). In order to perform a spot measurement, the PEC is clipped externally to user's earlobe for less than a minute, and is removed afterwards. A simple clip action commences a measurement (Figure 1-B), at the end of which a result is displayed on the MU screen, followed by a verbal result.



Figure 1: (A) GlucoTrack model DF-F; (B) Conducting a measurement

GlucoTrack Main Features:

- Easy to operate;
- User friendly;
- Large color touch screen, easy to read;
- Guided operations;
- Repeatable audio results;
- Memory: 1,000 readings per user;
- Graphic history results for easy analysis;
- Estimated HbA1c level;
- PEC life span: 6 months;
- Calibration validity: 6 months.

Prior to conducting glucose measurements, individual calibration process (Figure 2), which minimizes the effects of individually quasi-stable factors, such as tissue thickness and structure is performed, using an invasive device as a reference. This process adjusts the glucose behavior model to each user. In a device for home use, the duration of calibration procedure, number of pricking required and the interval between calibrations play a major role in the device efficacy and utilization.

To estimate the impact of individual quasi-stable factors and verify **GlucoTrack** suitability for different demographic categories, 126 subjects with diabetes were evaluated according to diabetes type, gender, age and body mass index (BMI). In this trial, HemoCue® was used as a reference device for calibration, as well as for evaluating measurements' accuracy.

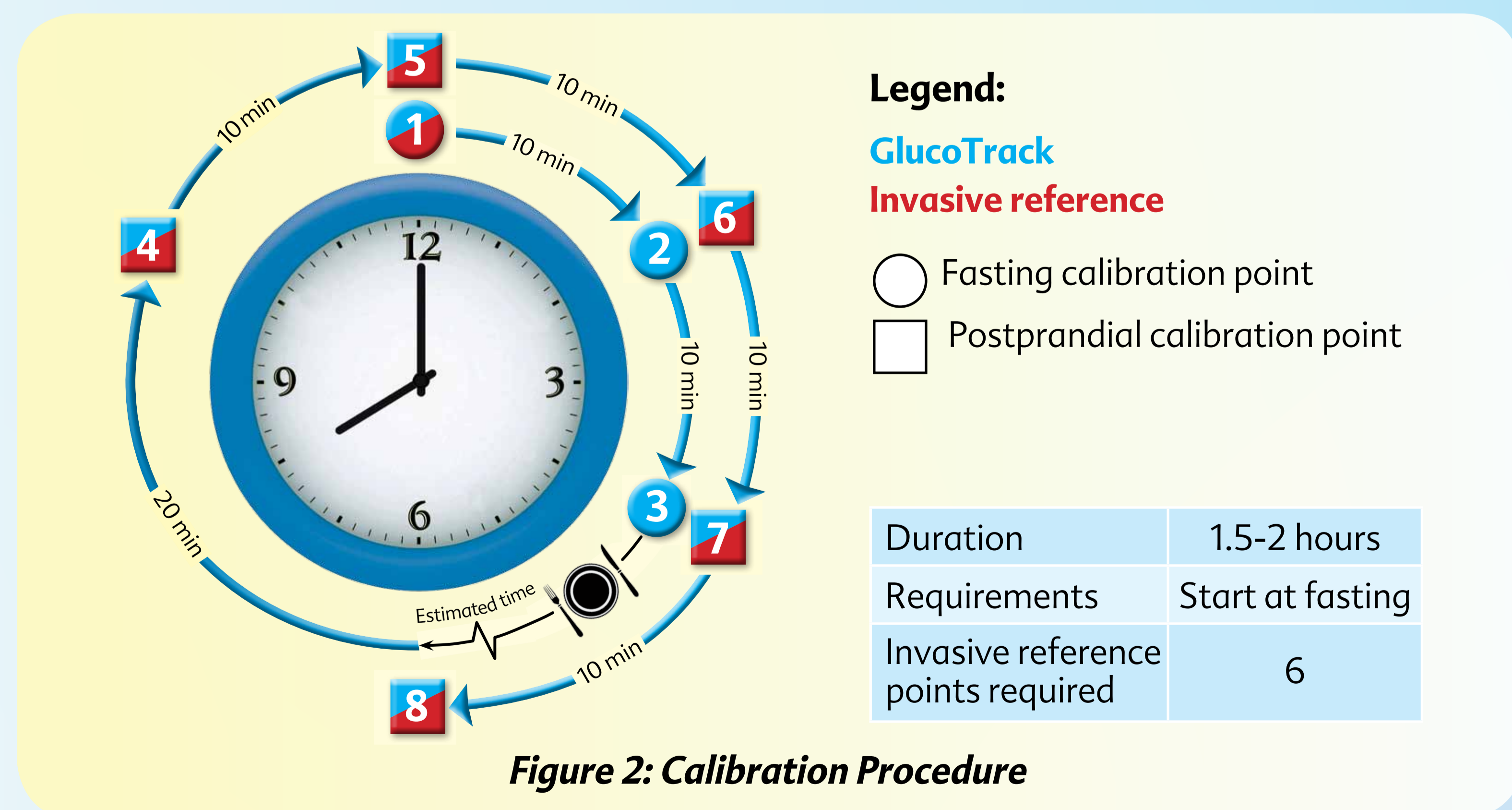


Figure 2: Calibration Procedure

Results

The Mean Absolute Relative Difference (MARD) for all subjects was 30.4%. The MARD values calculated for the different categories across all subsets are shown in Figure 3.

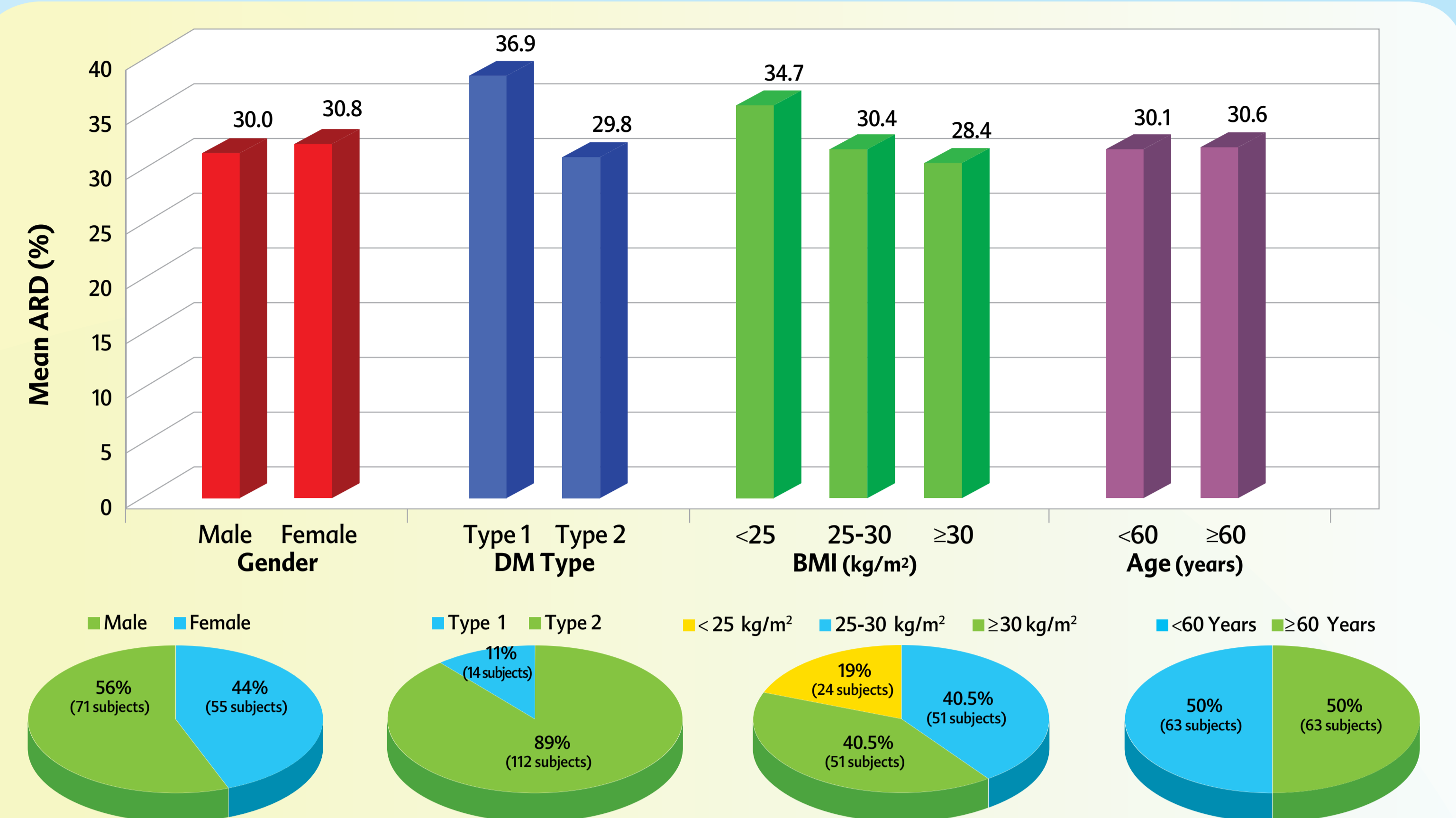


Figure 3: MARD Values, Calculated for Different Demographic Categories

Clarke Error Grid (CEG) analyses of all categories are shown in Table 1.

Table 1: CEG Analysis for GlucoTrack Performance with Different Demographic Categories

Category	# Points	A Zone	A+B Zones	
Gender	Female	3,179	41.7%	97.0%
	Male	3,758	43.6%	96.2%
DM Type	Type 1	513	39.2%	92.2%
	Type 2	6,424	43.0%	96.9%
BMI	< 25 kg/m ²	1,299	38.1%	94.8%
	25-30 kg/m ²	2,722	40.7%	96.5%
	≥ 30 kg/m ²	2,916	46.6%	97.4%
Age	< 60 y	3,548	44.1%	95.6%
	≥ 60 y	3,389	41.2%	97.6%
All subjects	6,937	42.7%	96.6%	

At the end of the trial, questionnaires were filled in by all participants, in order to provide feedback regarding:

- Willingness to use the device consistently, once available to the market;
- Convenience of use;
- Anticipated frequency of using the device.

Users' feedback analysis is presented in Figure 4.

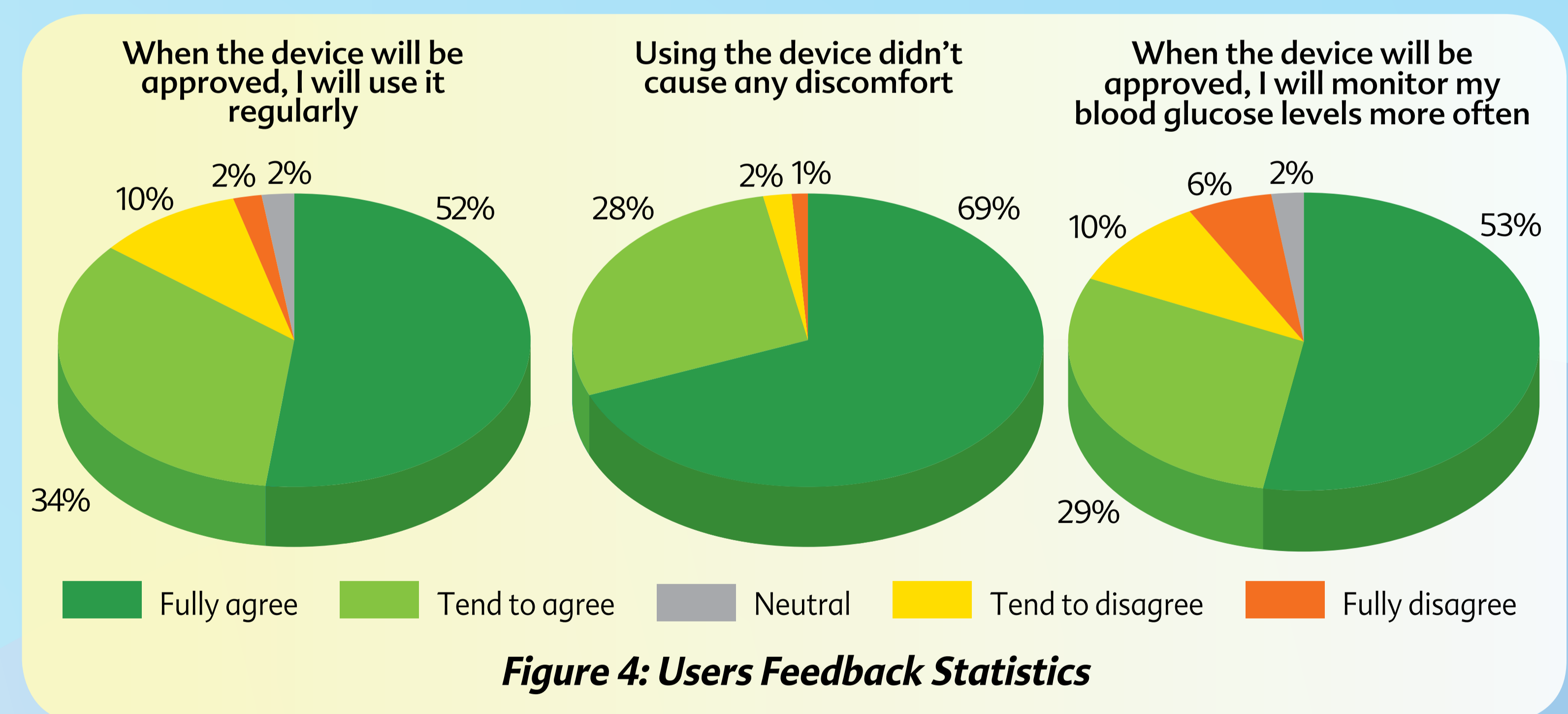


Figure 4: Users Feedback Statistics

Conclusions

- GlucoTrack** performances among various demographic categories suggest that the device is equally suitable for people with both types of diabetes, of different gender, age and BMI;
- Although there is some difference between the DM type groups in **GlucoTrack** performances, the relatively small group size of Type 1 is most likely the cause for this difference;
- Non-invasive painless monitoring, long intervals between calibrations, ability to perform (unlimited) frequent spot measurements, competitive cost and suitable accuracy suggest high likelihood of **GlucoTrack** as an appropriate solution to improve BG monitoring adherence;
- Users' feedback clearly indicates:
 - High satisfaction from **GlucoTrack**;
 - Willingness to use the device repeatedly and frequently.
- Due to more routine measurements, **GlucoTrack** may lead to a better adherence and compliance in SMBG, thus enhancing a tighter glucose control.

