

Approaching a Truly Non-Invasive Glucose Monitor – Calibration Validity

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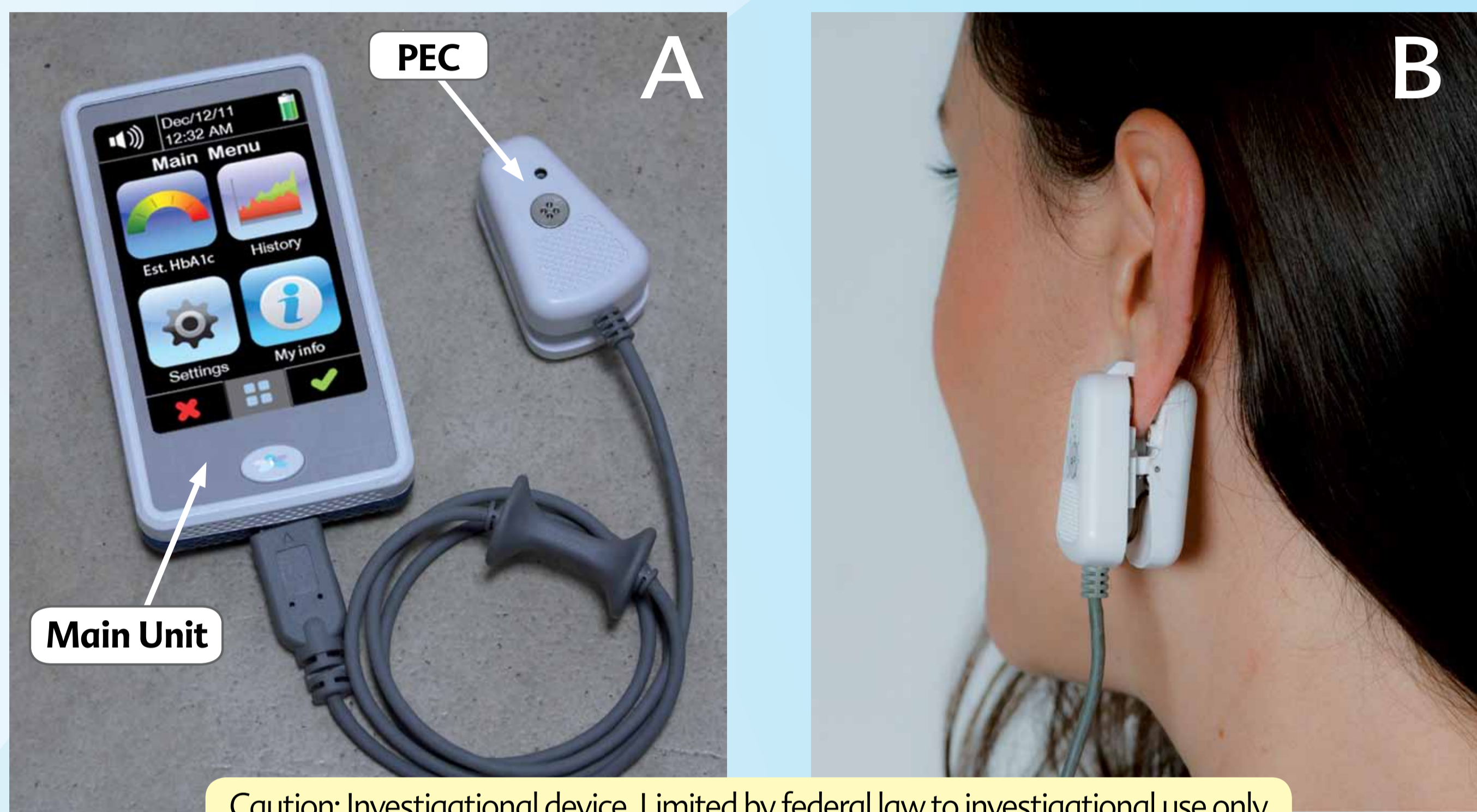
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Background

In general, non-invasive (NI) glucose monitors require calibration with invasive reference, prior to conducting measurements. Calibration minimizes the effect of individual quasi-stable factors and sets a baseline for physiological change detection. It is only valid as long as the quasi-stable factors remain unaltered; therefore, re-calibration is required periodically. Intervals' length between re-calibrations play major role in home-use NI devices usability and utilization.

GlucoTrack® is a NI glucose level monitoring device for home and home-alike environment, which enables performing frequent, real-time spot measurements. It combines utilization of three independent NI methods: Ultrasound, Electromagnetic and Thermal.

GlucoTrack comprises a Main Unit (MU), which drives different sensors, located at a Personal Ear Clip (PEC) (Figure 1A), attached to the earlobe. Performing a measurement (Figure 1B) is convenient, easy, and takes less than a minute.



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

Figure 1: (A) GlucoTrack Monitor; (B) Performing a Spot Measurement

Calibration

Prior to implementing measurements, a calibration procedure (1.5-2 hours) is required. Calibration is performed individually, using invasive fasting and postprandial capillary fingertip blood glucose (BG) references. Calibration purpose is to adjust the glucose behavior model for each user and to minimize the individual's tissue quasi-stable factors influence, such as tissue thickness and structure.

One fasting and five postprandial invasive measurements generate individual calibration (Figure 2).

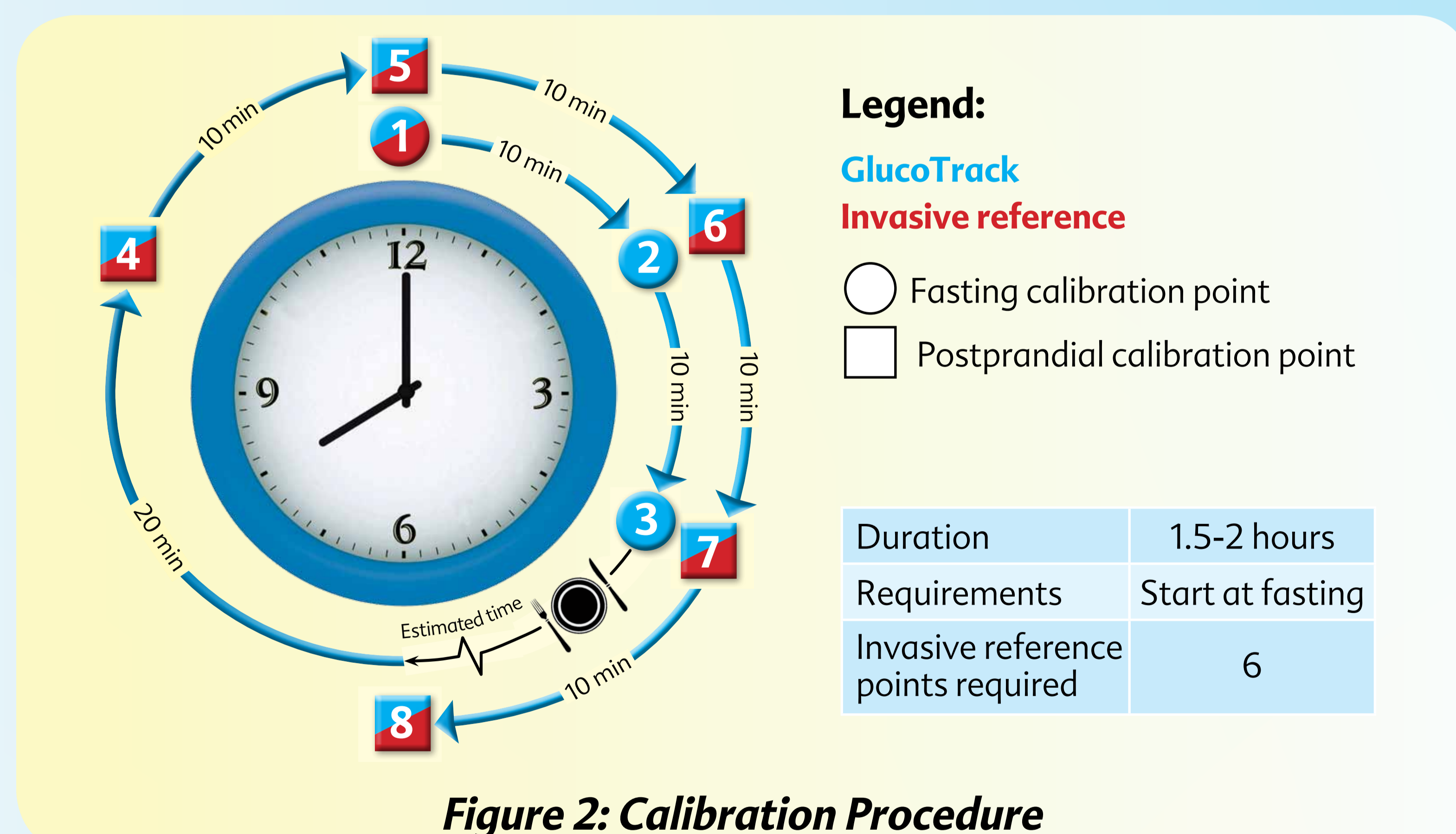


Figure 2: Calibration Procedure

Method

Clinical trials were conducted to evaluate calibration validity period. Each trial was performed in 4 to 16 days, evenly spread over 1 to 5 months, accordingly: individual calibration took place in the first day (day 1); on days 2-16, full-day measurements sessions were conducted. To this end, the clinical trials are ongoing, aimed to collect data up to six months.

In addition, users filled out questionnaires regarding usability, satisfaction and general impression from **GlucoTrack**.

Results

Performance

GlucoTrack accuracy level, as a function of elapsed time from calibration was maintained and analyzed, using Clarke Error Grid (CEG) and Absolute Relative Difference (ARD). The performance analysis was performed on 4,014 data points from 80 subjects (40 F, 40 M; 3 type 1, 77 type 2; Age: 63±18 years; BMI: 32.1±10.4). Table 1 summarizes the results of the trials.

Table 1: Device Accuracy as a Function of Time Elapsed from Calibration

Time Elapsed from Calibration	Data Points	CEG A Zone (%)	CEG A+B Zones (%)	Mean ARD (%)	Median ARD (%)
1 month	3,065	45	97	29.2	22.5
2 months	244	40	100	30.4	24.7
3 months	272	35	96	35.6	29.5
4 months	256	35	96	33.8	30.1
5 months	177	38	98	31.7	26.8

Efficacy

Questionnaires were completed at the end of the trials by all participants, in order to provide feedback regarding:

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

Users' feedback analysis is presented in Figure 3.

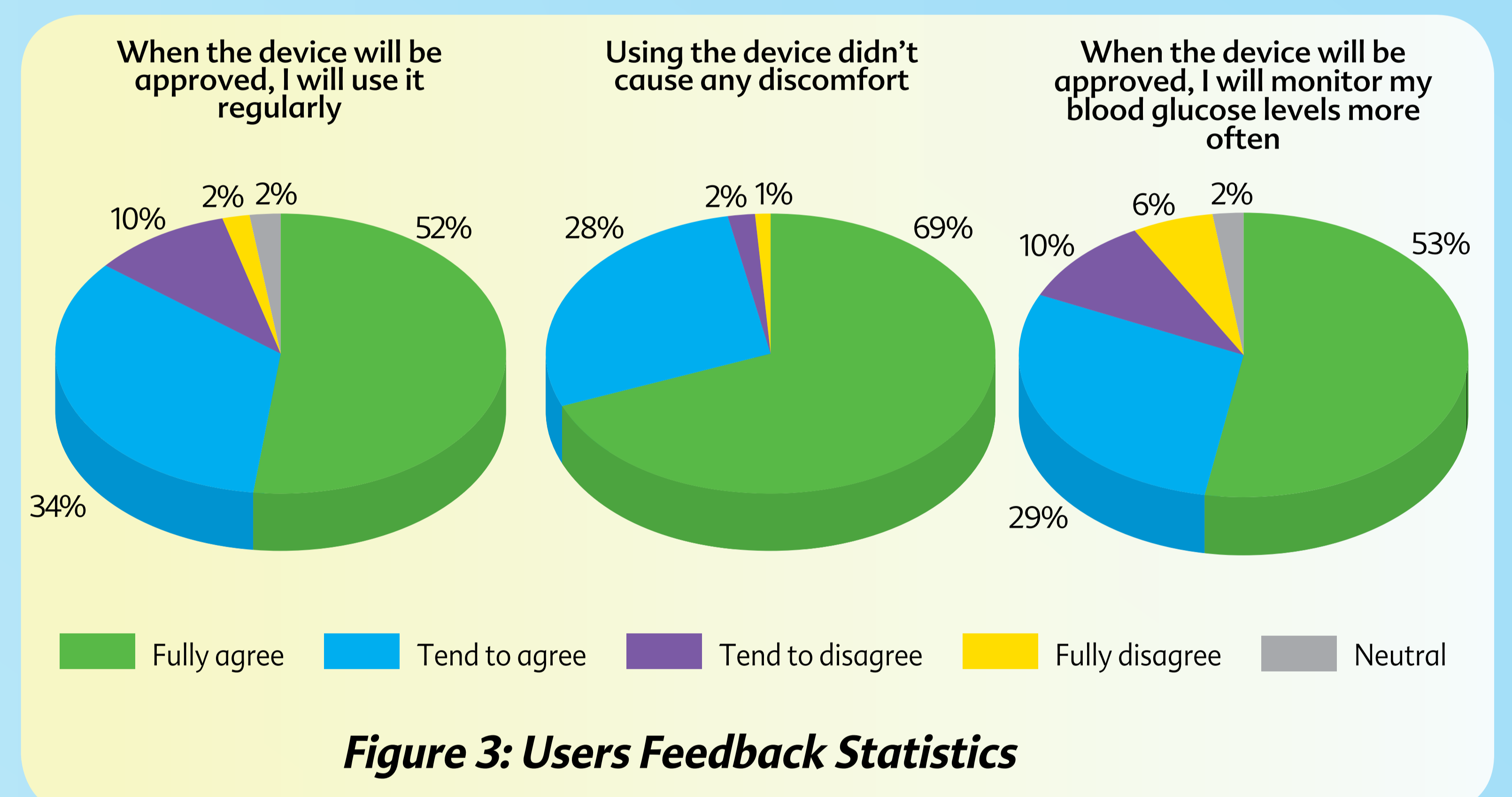
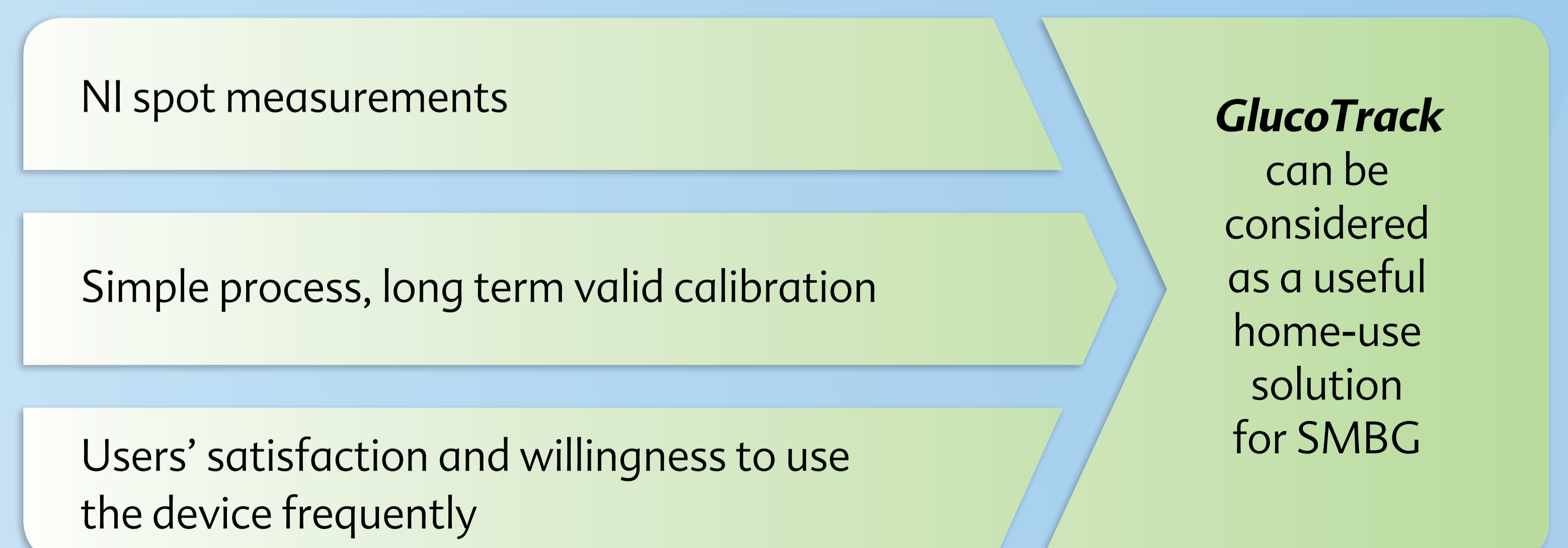


Figure 3: Users Feedback Statistics

Conclusions

- Clinical trials demonstrate no degradation in performance of **GlucoTrack** as a function of elapsed time from calibration;
- Validity of long intervals between re-calibrations (so far, up to 5 months) was clearly observed;
- Further trials to justify our goal for extended re-calibrations intervals of up to 6 months are in process. Based on the results gained thus far, it can be fairly estimated that such a period is indeed feasible;
- Users' feedback indicate:
 - 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 self-monitoring of blood glucose, thus enhancing a tighter glucose control.

