

# A Novel Non-Invasive Glucose Monitor for Home Use: Assessing the Learning Curve of Use

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## Background

The required time for a naïve user to learn how to properly use and operate a new device, i.e. the learning curve length (Figure 1), is an important factor in the device utilization acceptance.

**GlucoTrack**<sup>®</sup> model DF-F is a Non-Invasive, CE Mark approved real-time spot glucose monitoring device for home use. Measurements are conducted by attaching a Personal Ear Clip (PEC) to the earlobe for the measurement duration (~1 minute) and removing it afterwards (Figure 2A). Prior to measurements' conductance, an individual calibration is required (valid for 6 months). Post calibration measurements are to be performed the same earlobe's location, as during calibration. Once PEC is attached to the earlobe, position is automatically verified; if wrongly positioned, the device instructs about location adjustment and disables a measurement until the PEC is appropriately located (see Figure 2B).

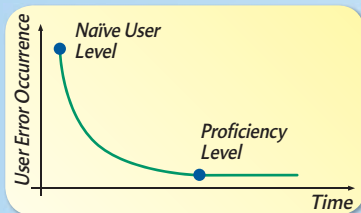


Figure 1: Example of a typical learning curve - from naïve user level to proficiency

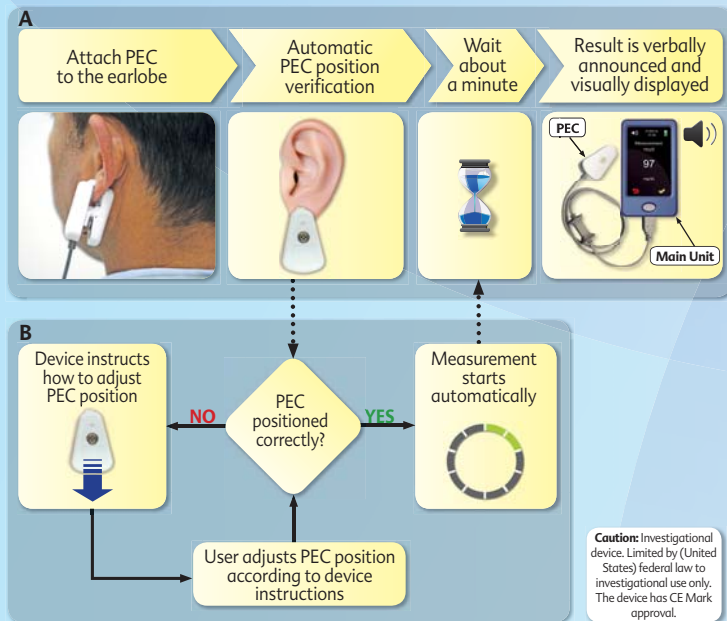


Figure 2: (A) Performing a measurement using GlucoTrack; (B) PEC position verification prior to measurement initiation

## Objective

Different factors, such as motor coordination level and ability to follow instructions, may affect the time needed to acquire skills in attaching the PEC to its correct position. Thus, as part of assessing **GlucoTrack** for home use, device's learning curve length was evaluated in clinical trials in terms of education level, gender and age.

## Method

41 **GlucoTrack**-naïve subjects (Table 1) participated in the study. At the beginning of the study each subject underwent a calibration process by a proficient team.

Following calibration, subjects participated in a short training session, where they received guidance about **GlucoTrack** operation. Afterwards, subjects conducted all measurements by themselves for 3 non-sequential days within a month.

Table 1: Characteristics of the tested population

Gender	22 males	19 females
Education Level	16 high-school educated	25 higher educated
Age	19 aged ≤ 55 years	22 aged >55 years

The time required for naïve users to learn how to position the PEC successfully, was assessed as the Mean number of Times to Successful PEC Positioning per Measurement (MSPM) at each day. Data was analyzed according to users' age, education level and gender.

## Results

In naïve users, MSPM is 1.63 on the 1<sup>st</sup> day of use, while on the 2<sup>nd</sup> day of use, MSPM reduces to 1.30 and on the 3<sup>rd</sup> day to 1.25 (Figure 3A). The same trend was found among all naïve users in different demographic categories, as shown in figure 3 (B, C, D).

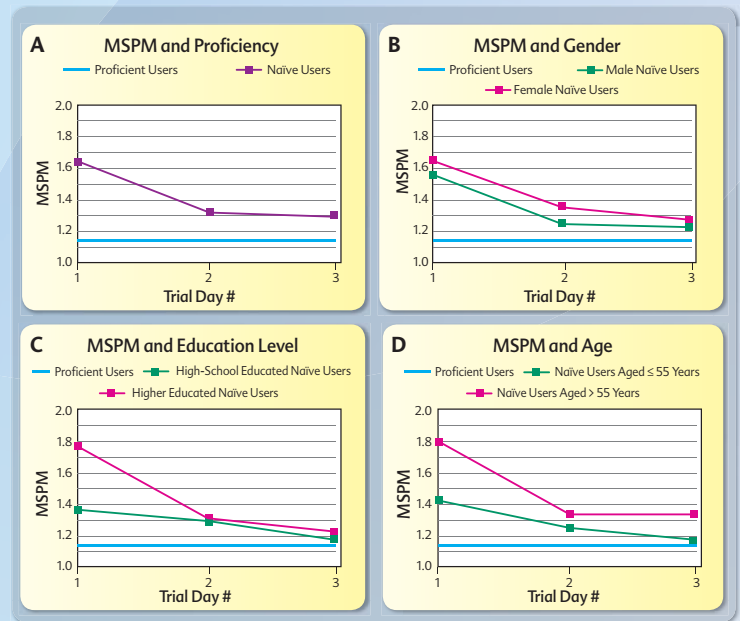


Figure 3: MSPM as a function of trial day

## Conclusions

- The results suggest that near-proficiency level in conducting measurements for majority of users is gained after ~3 days of use;
- The most significant increase in PEC positioning skill level is obtained after only one day regardless of user's age, gender or education level;
- MSPM was noted to be higher in users aged over 55 years, suggesting some users may require more adaptation time than others;
- Achieving high proficiency level after such short experience is expected to encourage **GlucoTrack** acceptance among new users.

