

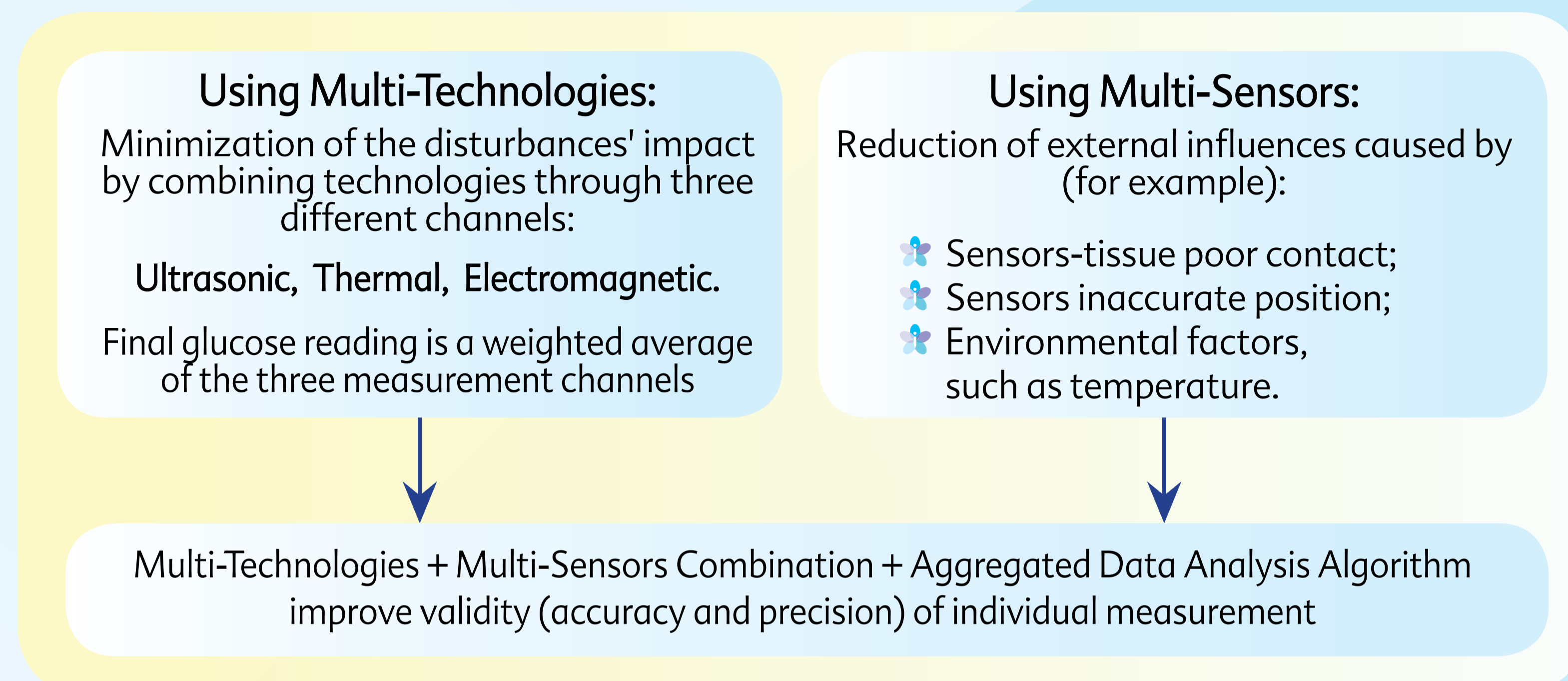
Non-Invasive Glucose Monitoring: Increasing Accuracy by Overcoming Environmental and External Influences by Using Multi-Sensors

Authors: A. Gal¹, I. Harman-Boehm², A. Raykhman³, E. Naidis¹, Y. Mayzel¹, L. Trieman¹

1) Integrity Applications Ltd., Ashkelon, Israel; 2) Internal Medicine and the Diabetes Unit, Soroka University Medical Center, Beer-Sheva, Israel; 3) InESA Inc., East Greenwich, Rhode Island, USA

Background:

Glucose readings obtained from Non-Invasive (NI) glucose methodologies often differ from the actual blood glucose value, since external and internal factors, other than glucose, influence the measured tissue parameters as well, causing inaccuracies in the reading. Thus, measurement contains information derived from glucose and accompanying disturbances.



Temperature change is one of the major external disturbances, which causes suboptimal measurement performance. Temperature change may be caused by:

- Air condition fan flowing directly toward the sensing site (ear lobe);
- Rubbing the sensing site;
- Warming the sensor, by holding it in the hand prior to conducting a measurement.

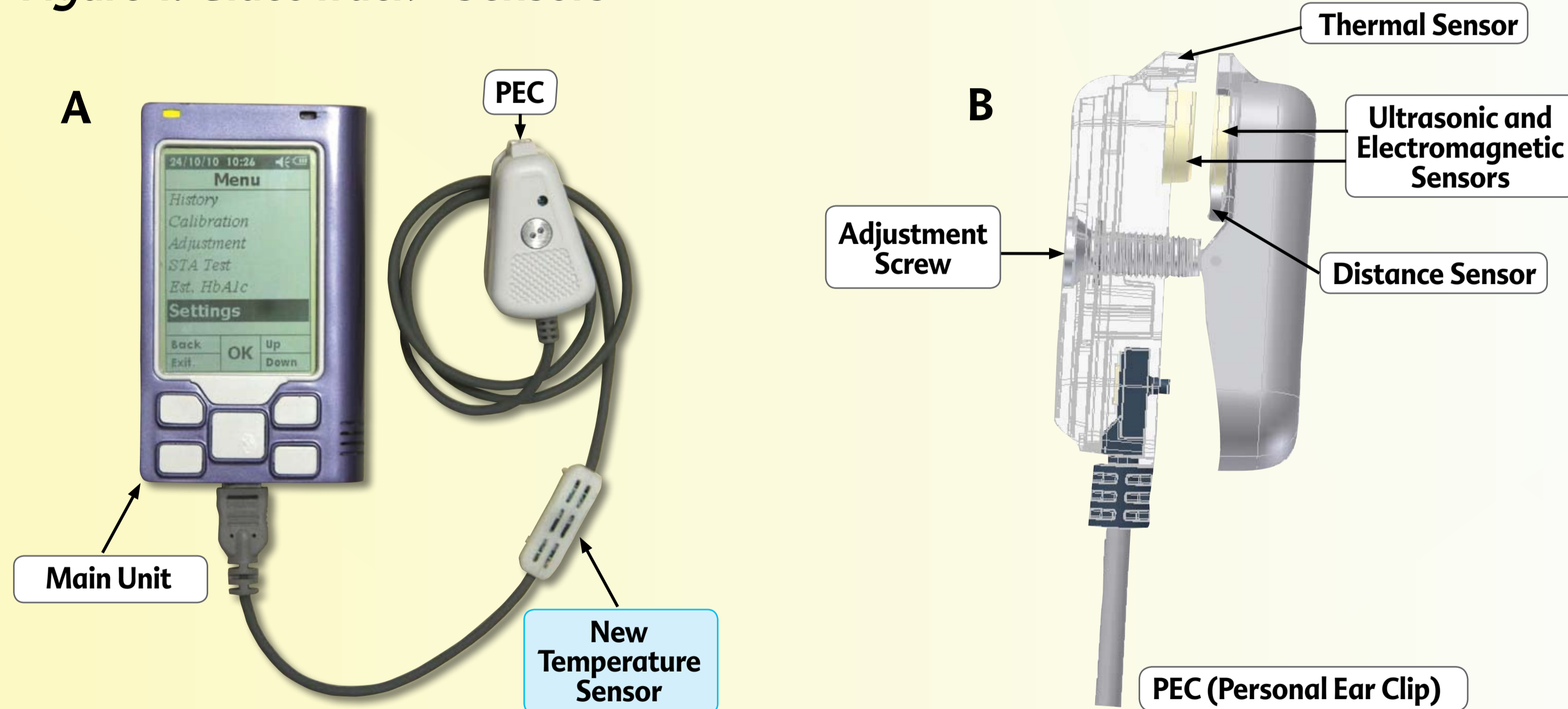
Since the measured signal in each technology channel is influenced by both tissue and ambient temperatures, an incorrect measurement of these temperatures will lead to subsequent inaccuracy in the translation of the signal into glucose level.

Therefore, in order to achieve a correct measurement of the ambient temperature and attain more reliable glucose reading, an external temperature sensor has been added.

Method:

A new temperature sensor has been added to the device, in a more inert location. This place is less accessible by the user, unlike the original one, located in the Personal Ear Clip (PEC) itself. The thermal sensor location takes into consideration a possible influence by the heat dissipation of the device as well. Figure 1A shows the location of the new temperature sensor.

Figure 1: GlucoTrack® Sensors



The new temperature sensor engages several functions:

- Confirms that the ambient temperature is within the designated working conditions of the device. Out of range environmental conditions inhibit conducting a measurement.
- Allows comparing temperature data from PEC and external temperature sensors to reveal the occurrence of interferences in the measured temperature as well as their source; then, if needed, the measured temperatures are corrected, to reflect true ambient and tissue temperatures.

Each channel's reading, i.e. ultrasonic, electromagnetic and thermal, is compensated, using the correct ambient and tissue temperatures.

The new performances of *GlucoTrack* (after adding the new temperature sensor) were evaluated by 8 subjects in a wide range of ambient temperatures, as shown in Table 1:

Table 1: Subjects' Data of Home Use Trial

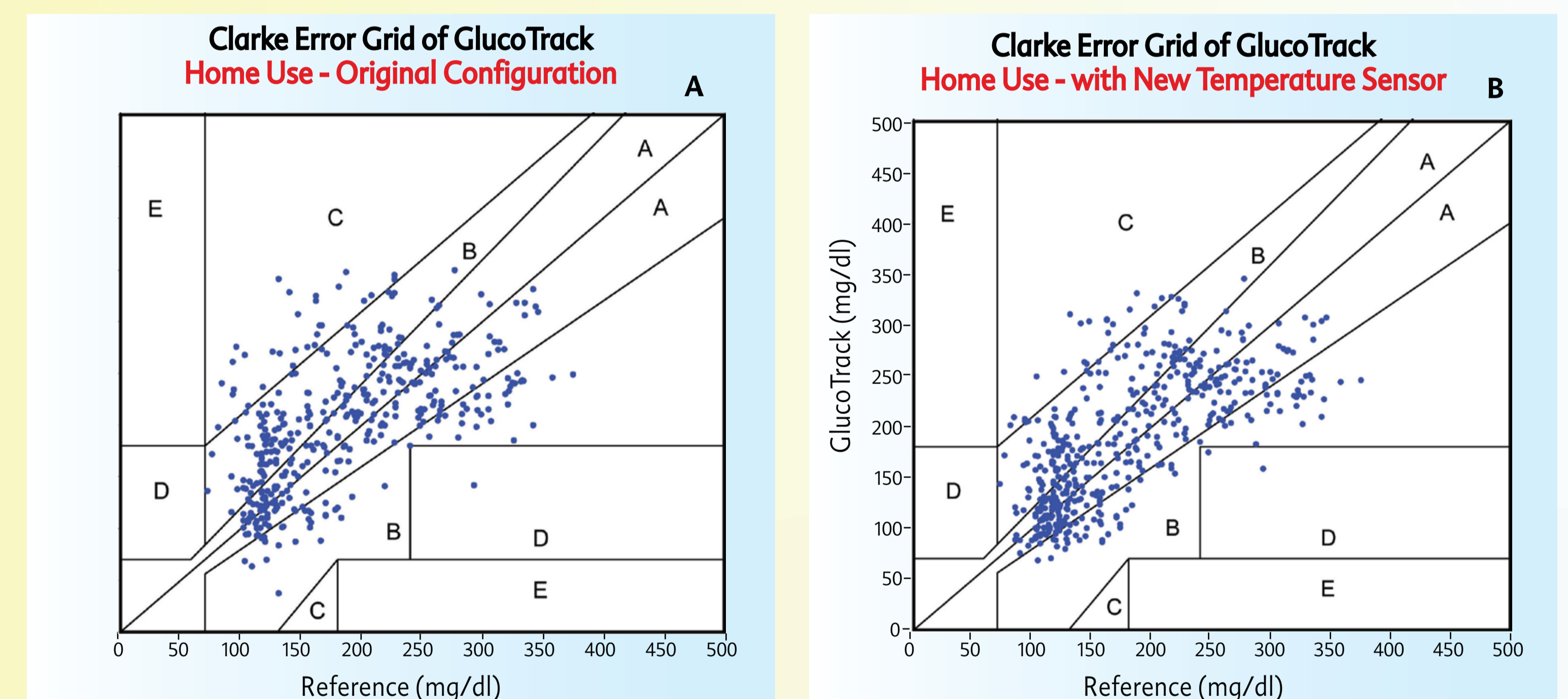
Diabetes Type	2 T1DM (1F, 1M) ; 6 T2DM (1F, 5M)
BMI	29.2 ± 7.5 Kg/m ²
Age	46.5 ± 24.5 years
Measured Glucose Dynamic Range	72 - 375 mg/dl
Earlobe Thickness	4.3 ± 1.7 mm
Ambient Temperature Range	15.5 - 31.9 °C Median of ambient temperature dynamic range: 6.3°C
Post-Calibration Measurements' span	2-37 days Median span of 16 days

In this trial, the calibration procedure was performed by the medical team. Each subject performed the measurement procedure by him/herself in their home/work (home alike) environment for several days. Data records were collected according to participants' own routine of glucose monitoring (timing and number of readings per day), but no less than 5 measurements per day. *GlucoTrack* readings were compared with the participants' own glucose monitoring devices, which served as the reference for calibration, as well as for comparison of measurements. Performances of *GlucoTrack* were then analyzed, using Clarke Error Grid.

Results:

Results of *GlucoTrack* performances in Home / Home alike conditions with and without using data from the new temperature sensor are shown in Figure 2.

Figure 2: Clarke Error Grid Analysis of GlucoTrack Home Use



Zone	Number	Percent	A+B Zones
A	244	50%	94%
B	213	44%	
C	30	6%	
D	1	0%	
E	0	0%	
Total	488	100%	
Mean ARD	28.1%		
Median ARD	20.0%		

Zone	Number	Percent	A+B Zones
A	266	55%	95%
B	197	40%	
C	23	5%	
D	2	0%	
E	0	0%	
Total	488	100%	
Mean ARD	25.7%		
Median ARD	18.1%		

Conclusions:

- Initial results in real home-alike conditions suggest that *GlucoTrack* provides good results;
- The new temperature sensor, in the given location, is a key solution in overcoming ambient temperature influences upon the measurement;
- Further efforts should be conducted, in order to reduce impacts of other external sources as well, such as variability in the epidermis condition (like the degree of oiliness and moisture).