Combination of Multi Technologies and Multi Sensors for Non-Invasive Spot Glucose Measurement

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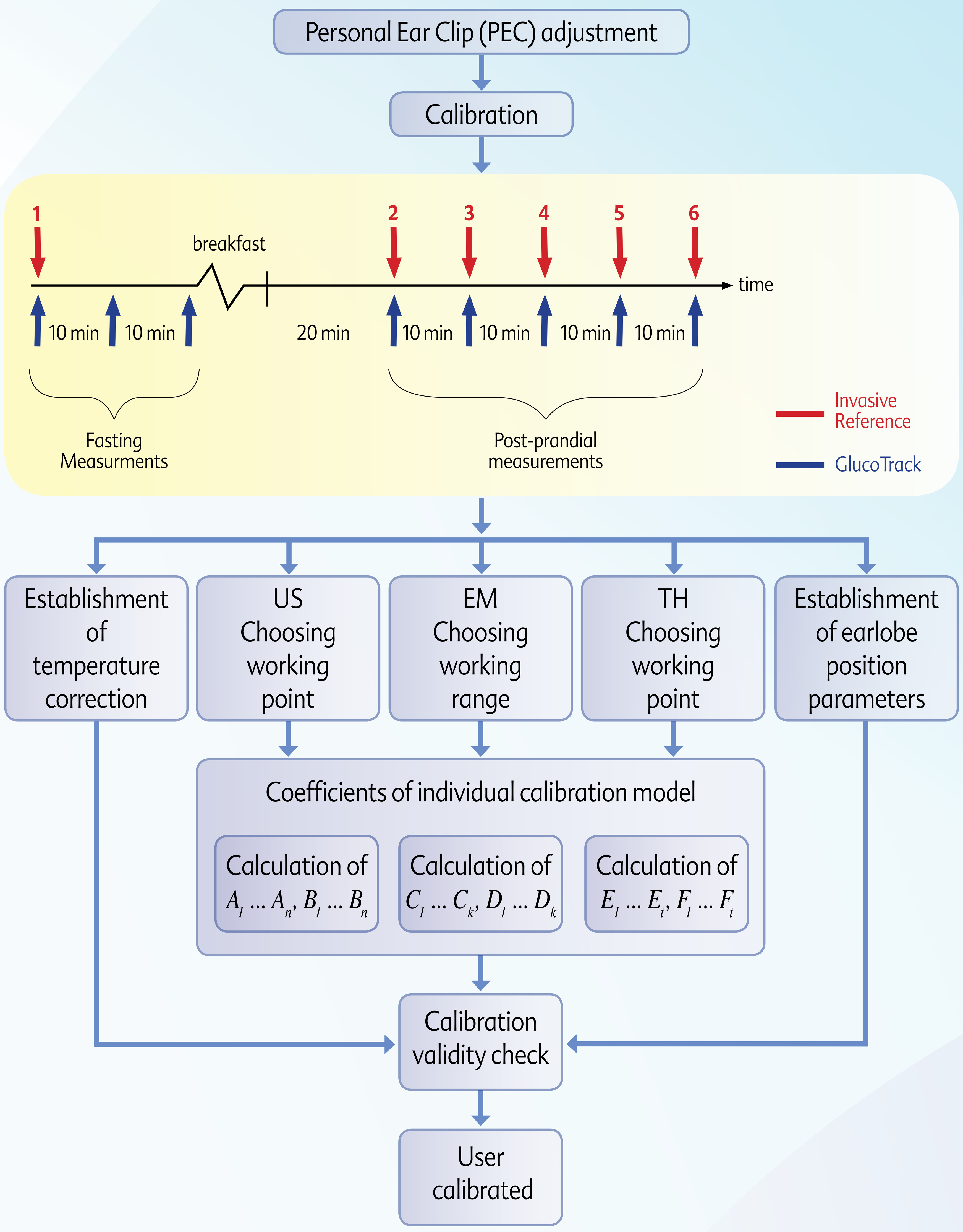
Objective:

Previous publications reported a unique method for non-invasive glucose measurement, combining three independent technologies: Ultrasonic (US), Electromagnetic (EM) and Thermal (TH). Each channel contains information derived from glucose and accompanying disturbances. A multi-dimensional signal processing algorithm produces a glucose value with smaller impact of interferences, leading to more accurate, real-time, spot readings.

Method:

Measurements are performed externally on the earlobe. The sensor is individually adjusted (directed by the device, according to the user's earlobe) for optimal fit, prior to calibration. The calibration is individually performed against invasive basal and post-prandial blood glucose references, producing an individual calibration model for each measurement channel (Figure 1). The procedure is easy, takes about 1.5 hours and more importantly, is valid for over a month.

Figure 1: Building a Calibration Model

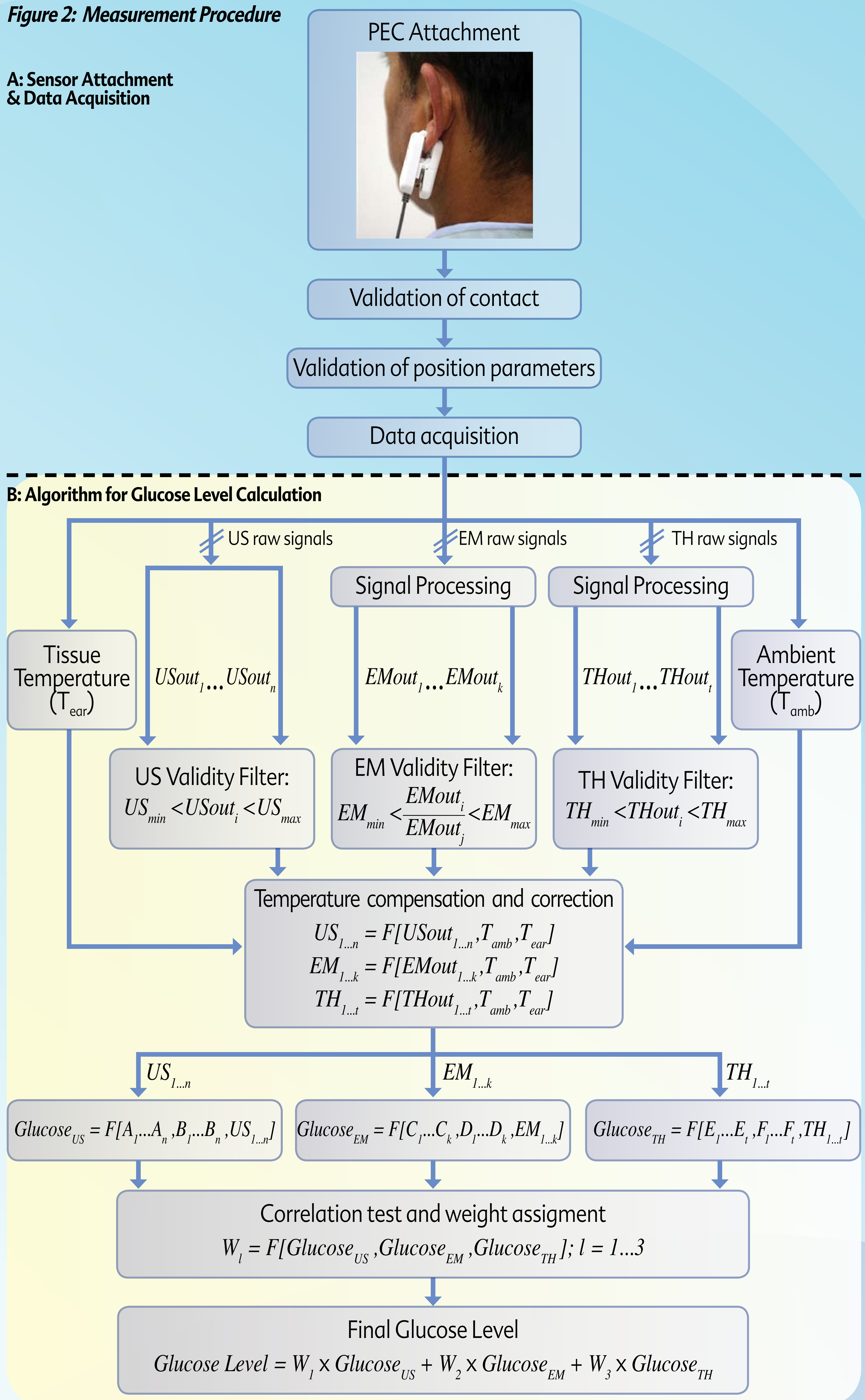


After calibration, glucose spot measurements can be performed by clipping the sensor to the earlobe (Figure 2A). Following Sensor's positioning verification (by the device), each channel produces several outputs, upon which 3 stage signal processing is applied: Signal validation and recognition of outliers; temperature compensation and temperature correction. By using the data from the different sensors, the algorithm also accounts for parameters including contact quality, ambient and skin temperatures. A weighted combination of the 3 technologies' multiple outputs produces a more sensitive and accurate glucose reading (Figure 2B).

GlucoTrack® (Model DF-F)

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

Figure 2: Measurement Procedure

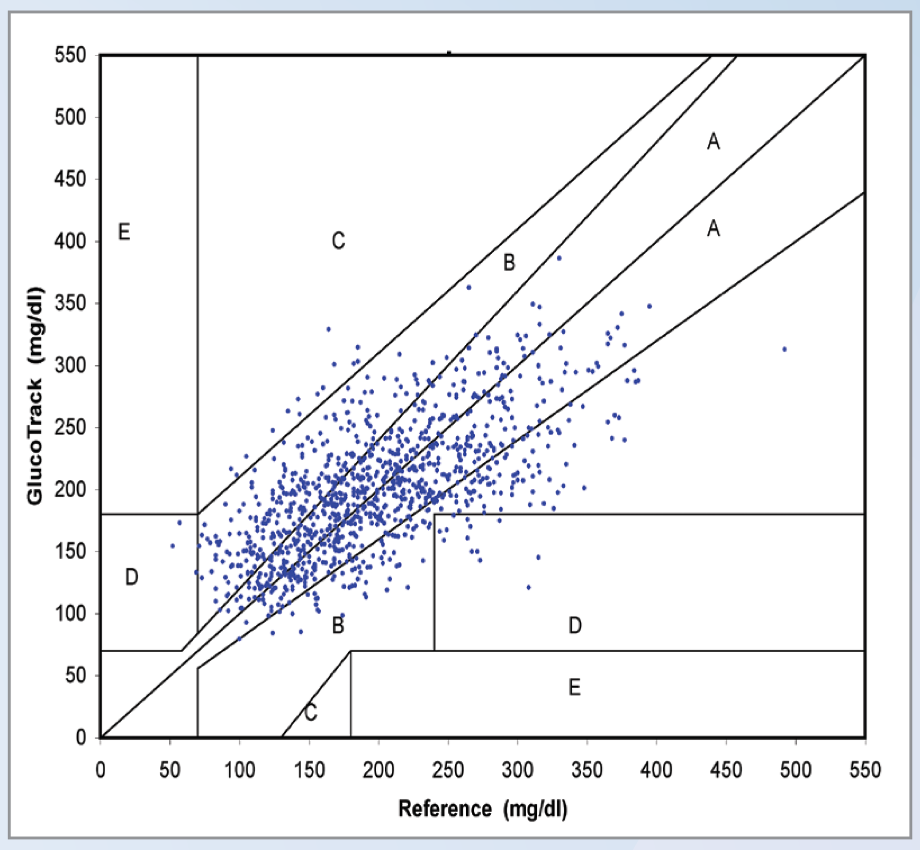


Results:

Clarke Error Grid analysis of 1501 points from 77 patients [9 T1DM (5F, 4M) and 68 T2DM (29F, 39M)] shows 97% of the points within the clinically accepted A+B zones, of which 61% in zone A. $MARD_{mean}$ is 21.7 % and $MARD_{median}$ is 16.5 %.

Figure 3: Clarke Error Grid of GlucoTrack Readings

Zone	Number	Percent	A+B zones
A	907	61%	97%
B	542	36%	
C	19	1%	
D	33	2%	
E	0	0%	
Total	1501	100%	
Mean ARD	21.7%		
Median ARD	16.5%		



Conclusions: Combining several (non-invasive) technologies and multi-sensor data collection improves validity of glucose measurement. The suggested approach provides a method to increase the accuracy of non-invasive glucose measurements and encourages more frequent testing, thus improving control of the diabetes and quality of life.

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