Simplifying Calibration Practice for Home Use Non-Invasive Glucose Monitoring Device: Shortening Procedure Duration

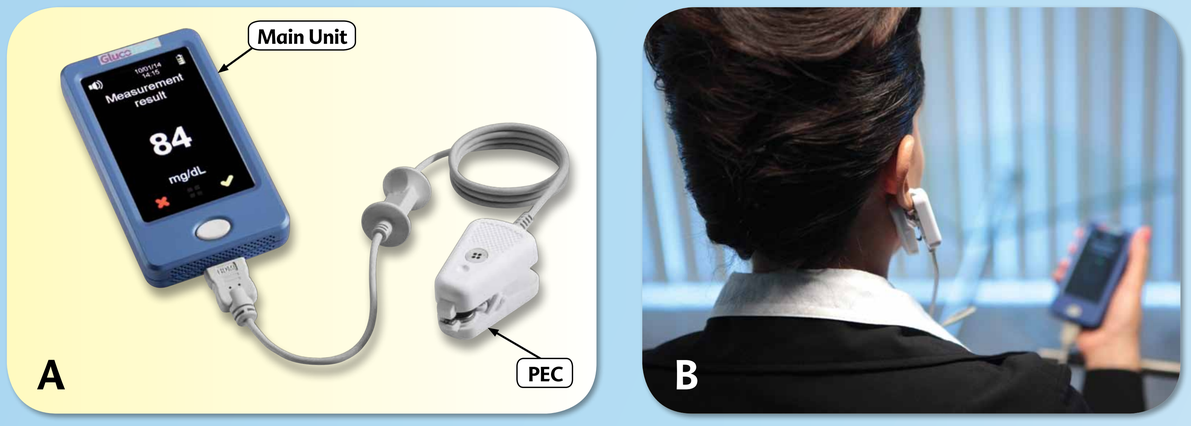
A. Gal[1], Y. Krasilshchikov[1], I. Harman-Boehm[2], A. Drexler[3], Y. Mayzel[1], K. Horman[1], N. Goldstein[1]

1) Integrity Applications Ltd., Ashkelon, Israel; 2) Internal Medicine and the Diabetes Unit, Soroka University Medical Center, Beer-Sheva, Israel;
3) Division of Endocrinology, Diabetes and Hypertension, David Geffen School of Medicine, University of California, Los Angeles, CA, USA

Background

Device calibration using invasive blood glucose values is an essential procedure for Non-Invasive (NI) glucose monitors. It establishes an individual baseline for physiological change detection. Calibration duration, complexity and settings play a major role in NI devices eligibility and acceptance for home use utilization.

GlucoTrack® is a NI device designed for spot measurement of glucose at home and home-alike environment. ***GlucoTrack*** comprises a Main Unit and a Personal Ear Clip (PEC) (Figure 1A). Spot measurements are performed by clipping the PEC to the earlobe and removing it afterwards (Figure 1B). The PEC is for individual use and requires user calibration to be performed once every 6 months.



Caution: Investigational device. Limited by (United States) federal law to investigational use only. The device has a CE certificate.

Figure 1: [A] GlucoTrack Glucose Monitor; [B] Performing a Spot Measurement

Thus far, calibration procedure involved a minimum of 6 invasive measurements and took about 2 hours. Moreover, the calibration procedure required inducing a glucose change by consuming a meal (Figure 2A). In order to simplify the calibration practice, a new shorter calibration scheme (supported by an upgraded algorithm) was evaluated for type 2 (currently) diabetic subjects.

Methods

The developed short calibration requires only 3 paired measurements (simultaneous ***GlucoTrack*** and invasive readings) with ten minutes intervals. Thus, the whole calibration process duration is about 30 minutes (Figure 2B).

Table 1 summarizes the differences between the Original and the Short calibration schemes.

Table 1: Calibration Schemes Comparison

Calibration Scheme	Original Calibration	Short Calibration
Invasive measurements	6 - 7	3
GlucoTrack measurements	8	3
Duration	~2 hours	~30 minutes
Performance conditions	Meal during calibration	No meal during calibration

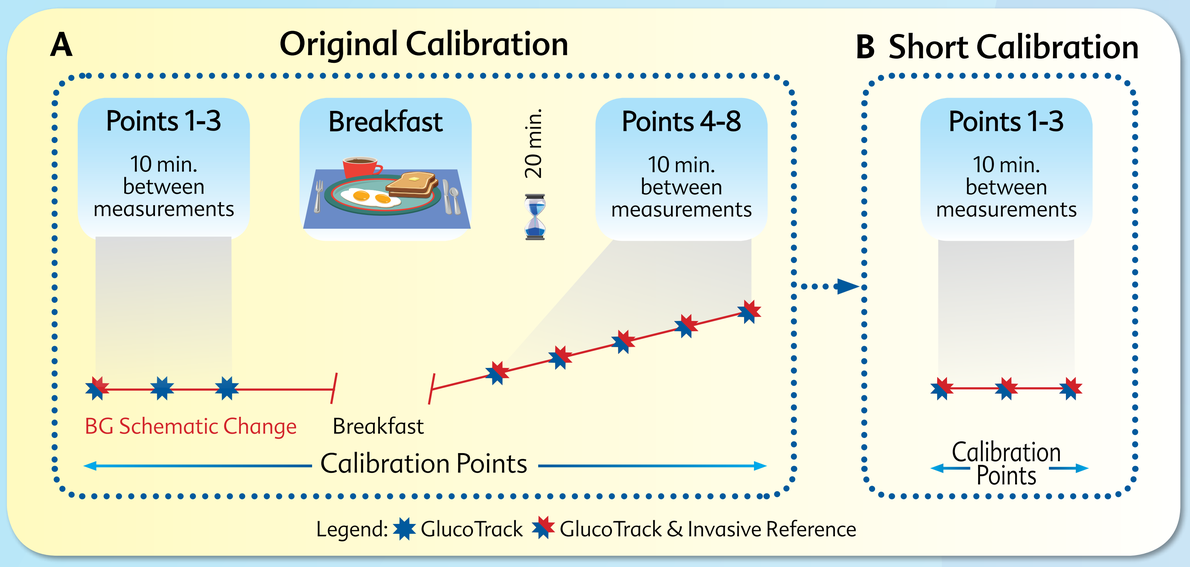


Figure 2: Calibration Schemes: [A] Original Calibration; [B] Short Calibration

Short Calibration — Algorithm Development

Calibration design and testing was based on data collected from a variety of clinical trials. The clinical trials were performed with original calibration, followed by regular measurements. Data from 53 type 2 subjects were used to develop an algorithm that supports the short calibration scheme. This dataset included over 4,300 paired ***GlucoTrack*** and invasive measurements.

Short Calibration — Algorithm Validation

The short calibration algorithm validity was evaluated off-line on an independent dataset of 117 type 2 subjects (over 8,200 paired readings), who performed the original calibration procedure in real-time. The dataset included both raw data as well as glucose predictions based on the original calibration model.

The short calibration model parameters were set individually, per subject, based on three points from the original calibration. These parameters were then applied on the raw data to form the new glucose predictions.

The short algorithm was validated by comparing ***GlucoTrack*** performances when applying the short calibration model parameters vs original calibration model parameters. The performances were evaluated based on Clarke Error Grid (CEG) and Absolute Relative Differences (ARD).

Results

CEG and ARD results in the validation set, for both the original (real-time) and the short calibration (off-line) are shown in Table 2 and Figure 3.

Table 2: Comparison of Results Obtained from the Two Calibration Schemes

		Original Calibration		Short Calibration	
Number of Points*		8,100		8,224	
CEG	Zones A+B	94.7%	(7,670)	95.7%	(7,874)
	Zone A	41.1%	(3,328)	48.5%	(3,990)
	Zone B	53.6%	(4,342)	47.2%	(3,884)
	Zone C	2.2%	(178)	0.2%	(20)
	Zone D	3.1%	(252)	4.0%	(329)
	Zone E	0.0%	(0)	0.1%	(1)
ARD	Mean	31.2%		24.2%	
	Median	24.8%		20.7%	

* Each calibration model yields a different number of points outside the device measurement range (70-500 mg/dL; 3.9-27.8 mmol/L). Such points were excluded. Hence the difference in the number of points.

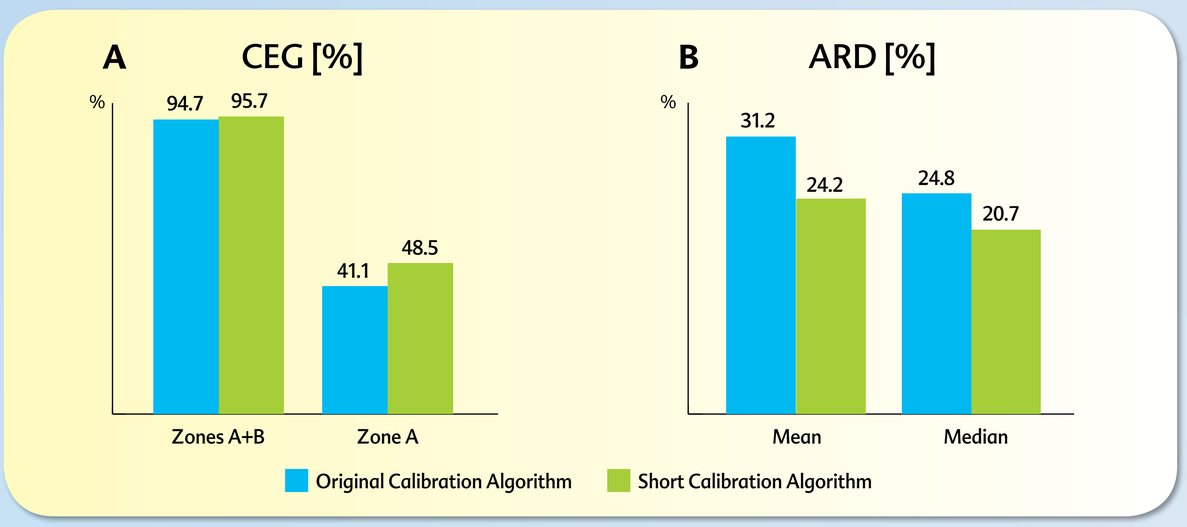


Figure 3: Comparison of Device Performances According to Each Calibration Scheme: [A] CEG percentages in A and A+B Zones; [B] Mean and Median ARD

Conclusions

- The demonstrated short calibration for type 2 diabetic patients:
  - ✔ Increases calibration simplicity and reduces calibration duration;
  - ✔ Improves device performances.
- Practicing a shorter and less-painful procedure is expected to positively affect device usability and user satisfaction.

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102 Ha'Avoda St., P.O. Box 432 Ashkelon 7810301 Israel
Phone: +972 (8) 675-7878 | Fax: +972 (8) 675-7850
e-mail: info@integrity-app.com | www.integrity-app.com

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