Non-Invasive Glucose Monitoring Device: Reducing Impact of Post-prandial Lagging Effect During Measurement

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Introduction

GlucoTrack® is a non-invasive (NI) home-use device for self-monitoring of glucose level. The device tracks physiological changes which are correlated with glucose excursions by measuring ultrasonic, electromagnetic and thermal parameters of the earlobe tissue. The measured parameters are translated into a glucose value based on patented algorithm and individual calibration. ***GlucoTrack*** comprises of a Main Unit and a Personal Ear Clip (PEC) (Figure 1A). Spot measurement is performed by clipping the PEC to the earlobe for the measurement duration (~1 min.) (Figure 1B).

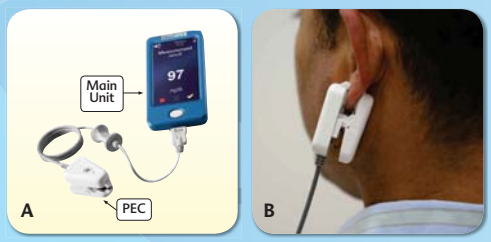

Figure 1: [A] GlucoTrack glucose monitoring device; [B] Conducting a measurement.

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

GlucoTrack device reads glucose levels in the earlobe tissue rather than in the blood alone. Notably, the tissue interstitial fluid (ISF) volume is 15-20 times greater than the blood volume in tissue capillaries [1,2]. Thus, a NI sensor is likely to track glucose excursions (or the correlative changes) in the ISF rather than in the blood plasma [2] (Figure 2A). Post-prandial glucose lagging effect in the tissue is expected, since ISF glucose level tends to lag behind the blood post-prandial glucose level, both in time and in magnitude [3] (Figure 2B).

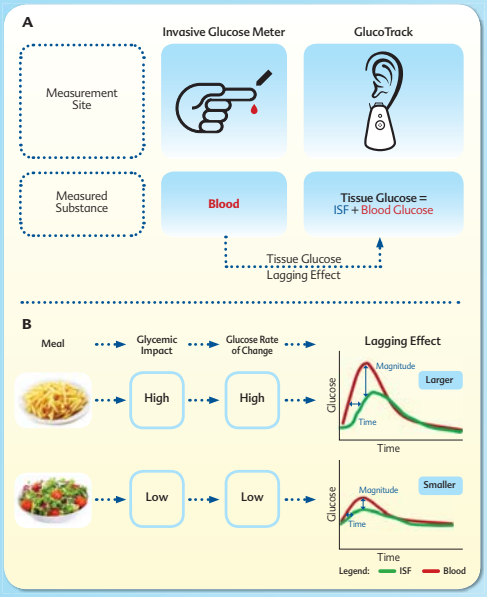

Figure 2: Lagging effect demonstration

Objective

In order to improve postprandial tracking, a new algorithm was developed and evaluated, to compensate tissue glucose lagging effect relative to blood-glucose changes, by accounting for meals intake.

Method

A new algorithm, based on post-prandial correction of the lagging effect between the tissue and blood glucose is proposed. The correction is done based on qualitative input on meal time and glycemic load. In the new algorithm only post-prandial ***GlucoTrack*** glucose readings, where lagging effect is mostly pronounced, are adjusted with regard to the most recent meal. Furthermore, pre-prandial readings, where lagging effect is minimal, remain unadjusted.

- Device performances are evaluated using new versus original algorithm, in pre-prandial and 30 to 90 minutes post-prandial states.
- Both algorithms are applied on the same dataset of 35 Type 2 subjects (1,131 invasive and non-invasive reading pairs) who consumed various meals with different glycemic loads throughout the day. The differences between the algorithms are demonstrated in post-prandial readings only, since the pre-prandial readings remain the same when using both algorithms.
- Results are analyzed at pre- and post-prandial states, using Surveillance Error Grid (SEG) [4], Clarke Error Grid (CEG), Mean and Median Absolute Relative Difference (ARD) and Mean Absolute Difference (MAD).

Results

Using original algorithm leads to lower accuracy of post-prandial measurements, where lagging effect is mostly expressed, compared to pre-prandial measurements, where lagging effect is minimal. Using the new algorithm improves the accuracy of post-prandial readings, showing analogous performances compared to pre-prandial readings, as presented in Table 1, Table 2, Figure 3 and Figure 4. The pre-prandial and post-prandial groups contain 190 points and 941 points, respectively.

Table 1: GlucoTrack clinical accuracy in pre- and post-prandial states

	Pre-prandial	Post-prandial	
		Original algorithm	New algorithm
SEG: Risk Level - "None" (0 - 0.5)	62.3%	54.9%	63.4%
SEG: Risk Level - "None + Slight Lower" (0 - 1)	93.2%	87.3%	88.1%
CEG: A Zone	55.8%	46.0%	58.9%
CEG: A+B Zones	100%	95.6%	98.2%

Table 2: GlucoTrack statistical accuracy in pre- and post-prandial states

		Pre-prandial	Post-prandial	
			Original algorithm	New algorithm
MAD		30.6 mg/dL	40.0 mg/dL	33.1 mg/dL
Mean ARD		22.2%	24.6%	23.1%
Median ARD		16.9%	21.7%	16.5%
Accumulated % of Readings within Error Margins	≤±5%	17.4%	11.1%	16.2%
	≤±10%	27.4%	21.6%	30.5%
	≤±15%	43.7%	35.3%	45.9%
	≤±20%	55.8%	46.0%	58.9%
	≤±30%	73.2%	68.2%	74.7%
	≤±40%	84.7%	84.7%	84.6%

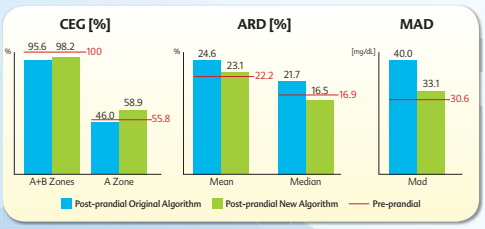

Figure 3: Device performances according to each algorithm

Figure 4 shows that the measurements obtained with the new algorithm are mostly within the deep green zone (risk level - "None": 0-0.5; 63.4%) or within the light green zone (risk level - "Slight, lower": 0.5-1; 24.7%).

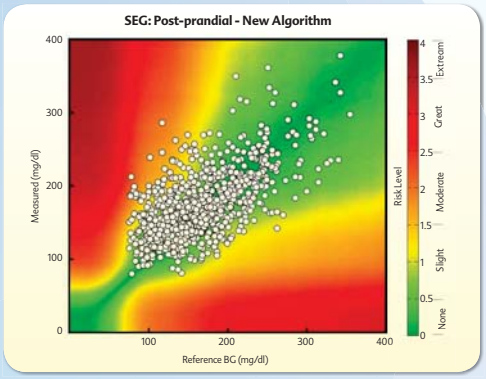

Figure 4: Surveillance error grid analysis of post-prandial points: Using new algorithm

Note: Further improvement of the algorithm (next version) is under evaluation, demonstrating more accurate results.

Conclusions

- Incorporating information regarding recent meal significantly improves ***GlucoTrack*** accuracy at different post-prandial states.
- Lagging effect correction equalizes accuracy for pre- and post-prandial readings.
- Given the overall performances using the new algorithm, it seems that ***GlucoTrack*** may be a valuable tool for tracking glucose levels and better understanding of individual glucose profiles.

References

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