



Performance of a non-invasive glucose monitoring device: accuracy and precision

integrity
applications

Sror M¹, Bahartan K¹, Rozner A¹, Gimmon M¹, Naidis E¹ and Lin T¹

¹Integrity Applications Ltd., Ashdod, Israel

Background

Self-monitoring of glucose has an integral role in diabetes management. However, patient compliance to glucose self-monitoring is limited. Non-invasive glucose monitoring aim to overcome the barriers of current glucose monitoring methods by offering a simple, painless and convenient mean to measure glucose levels.

Objective

To evaluate the accuracy and precision of GlucoTrack®, a non-invasive glucose monitoring device



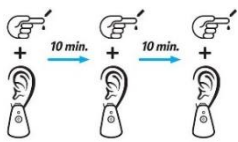
GlucoTrack is a Conformité Européene (CE) certified non-invasive glucose monitoring device for people with type 2 diabetes or prediabetes. The device tracks physiological changes which are correlated with glucose excursions by measuring acoustic impedance, electromagnetic impedance and heat capacity of the earlobe tissue.

Methods

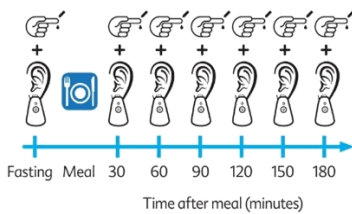
Device accuracy

- 37 people with type 2 diabetes
- Consensus error grid analysis for type 2 diabetes
- Median absolute relative difference (ARD)

First day: Calibration



Second day: Trial day



Sensor to sensor precision

- 20 people with type 2 diabetes
- ~19 simultaneous measurements using two GlucoTrack devices on each earlobe



- Precision absolute difference (PARD):

$$PARD = \frac{|glucose_{GlucoTrack1} - glucose_{GlucoTrack2}|}{\text{mean}(glucose_{GlucoTrack1}, glucose_{GlucoTrack2})} \cdot 100[\%]$$

Methods (cont.)

Test-retest precision

- 20 people with type 2 diabetes
- 86 sequences of ~6 measurements performed with 10-minutes intervals under stable glycemic conditions (~3 hours postprandial)

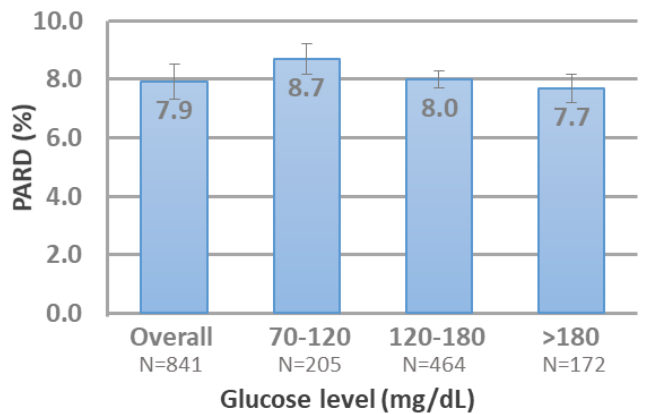


- coefficient of variation (CV):

$$CV = \frac{\sigma}{\mu} \cdot 100\%$$

Results

- **99.6%** of 257 measurements were in zones A and B of the Consensus error grid, with **90.3%** of the measurements in zone A
- Mean and median ARD were **17.2%** and **12.9%**, respectively.
- In various glucose levels, mean PARD ranged from **7.7%-8.7%**



- Mean CV was **7.83±1.03%**

Conclusions

- GlucoTrack is highly accurate
- Sensor-to-sensor precision is comparable to that of CGMs

| Device | GlucoTrack® | Dexcom G4™ | FreeStyle Navigator™ |
|-------------------|-------------|------------|----------------------|
| Overall mean PARD | 8.1% | 7.3% | 9.6% |

- GlucoTrack measurements are reliable under stable conditions



19 Ha'Yahalomim St., P.O. Box 12163 Ashdod 7760049 Israel
Phone: +972 (8) 675-7878 Fax: +972 (8) 675-7850
e-mail: info@integrity-app.com
www.integrity-app.com

www.glucoTrack.com

