

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

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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 noninvasive 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



60 90 120 150 180
Time after meal (minutes)

Sensor to sensor precision

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



• Precision absolute difference (PARD):

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

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)

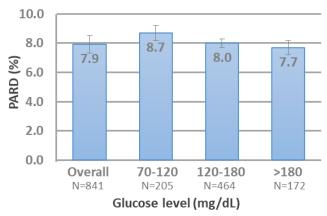


• coefficient of variation (CV):

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

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



