

A Novel Non-invasive Glucose Monitoring Device

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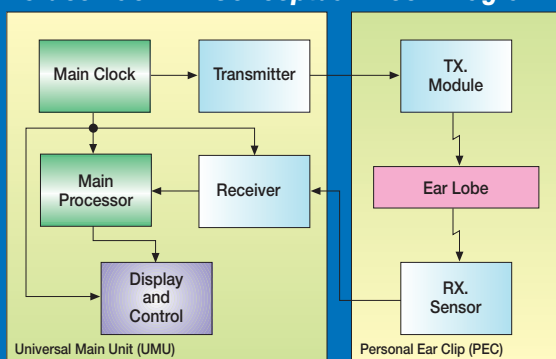
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Background

The use of currently available glucose monitoring devices is limited by their invasive nature, thus decreasing adherence to monitoring recommendations necessary to achieve target glucose levels. Attempts to develop an accurate non-invasive glucose monitoring device have been only partially successful. Non-invasive methods measure physiological processes in the human body and correlate them with blood glucose levels. The actual glucose value derived from such correlations is different than the absolute blood glucose value. In order to overcome the inherent discrepancy and attain accuracy of measurement, we developed a device based on the integration of three simultaneous independent modalities: ultrasound, conductivity and heat capacity. In essence, the measurement is repeated sequentially three times using each of the technologies and the independent results are analyzed, compared and integrated using a unique algorithm to give a final reading displayed on a LCD screen and recorded in the memory. The device is calibrated by entering a basal and a post-feeding finger-stick glucose value. The attained results are combined to give an accurate measure of blood glucose.

GlucoTrack™ - Conceptual Block Diagram



Objective

To assess the accuracy and reliability of the GlucoTrack device.

Methods

Glucose determinations using GlucoTrack were performed on volunteers in the fasting and postprandial state and compared to blood values measured by glucometer (Ascensia Elite®). A small, light weight Personal Ear Clip (PEC), containing the different sensors, is attached externally to the user's ear lobe. Individual calibration assures precise reading for each user. Up to three different users can use a single device, where only personal, individually calibrated PEC is required for each user.

Results

Clinical tests were performed on 69 healthy and diabetic patients.

Table 1: Distribution of Examinees

	Examinees	Points		
Healthy	23	33%	85	49%
IGT	1	1%	26	15%
Type 1	10	14%	15	9%
Type 2	35	51%	48	28%
Total	69	100%	174	100%

Table 2: Patients' Characteristics

	Range	Average
Age (years):	26-76	51.5
BMI (Kg/m ²):	16.9-43.3	27.3
HbA1C (%):	5.3-12.0	7.5
Glucose level: Min: 67 mg/dL		Max: 507 mg/dL
Gender:	50 Males	19 Females

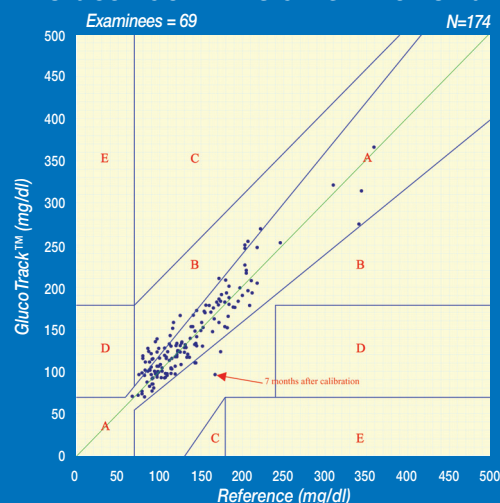
Analysis of the accuracy of the determinations was performed using a Clarke Error Grid. The pair of glucose determinations was located on the grid, where the horizontal (x) axis represents the reference value and the vertical (y) axis the GlucoTrack value.

GlucoTrack™ (Model DF-F)
US Patent 6,954,662

Caution:
Investigational device.
Limited by federal law to
investigational use only.
Not available for sale.



GlucoTrack™ - Clarke Error Grid



Zone A	Zone B	Zone C	Zone D	Zone E	Intercept Point (mG/dL):	9.5
83.3%	16.7%	0%	0%	0%	Slope:	0.950
					Correlation Coefficient:	0.940
					R ² :	0.883

GlucoTrack™ - Specifications (Model DF-F)

Feature	Specifications	Remarks
Operation Modes	Spot (Continuous mode in Next generation)	By user choice
Users	Up to 3 users	Individual Ear Clip Unit for each user
Range	40-500 mg/dL (2.2-27.8 mmol/Liter)	
Ear Clip Unit	Ergonomic, Externally plugged, Each individual Ear Clip Unit Automatically recognized by the device and display user's name	Color grip for easy handling and identification
Indications / Operation	'On' LED indicator, 'Alarm' LED indicator, Buzzer, Alphanumeric Keypad, Navigator	
Display	Time, Date, Glucose Level (mG/dL or mmol/Liter - by User choice), Glucose High/ Low/ Normal indication, Battery Level, Low Battery indication, Replacement of Ear Clip Unit request, Re-Calibration request, last measurement reading upon device turn on, User name, Memory use status	Dot Matrix Display Light blue Backlight
Controls	Turn On/Off Push button, Navigator, "Select" Push button, Fast menu enter, Key pad	Auto turn off after 3 minutes Backlight turns off after 30 seconds
Memory	Up to 300 last points per user (including level, date, time)	
Warnings	Glucose High / Low level, Low battery, Replace Ear Clip Unit, Re-Calibration Request, Ear Clip Unit not in place	LED + Audible, Levels are preset by each user
Interface	IR, USB for Data Downloading	
Calibration	Automatic process user's instructions	
General	Auto turn off after 3 minutes of non operation. Latency compensation algorithm in Continuous Mode	In Spot Mode only
Battery	Li-Ion Built in, Rechargeable	Operation inhibited during recharge period
Working temperature		+5°C to +45°C
Storage temperature		-5°C to +55°C
Relative humidity		95%
Dimensions	Universal Main Unit: 116 X 55 X 26 mm Personal Ear Clip: 41 X 24 X 19 mm	
Weight	Universal Main Unit: 190 gm Personal Ear Clip: 35 gm (including cable)	

Conclusions

The GlucoTrack non-invasive glucose measuring device is safe and easy to operate, and provides results comparable to those obtained with a conventional invasive home-used glucose monitors.



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