

Evaluation of the Non-Invasive Glucose Monitoring Device GlucoTrack in Patients with Type 2 Diabetes and Subjects with Prediabetes

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Introduction

GlucoTrack® (Integrity Applications, Ashdod, Israel) is a CE-approved non-invasive glucose monitoring device for use at home and in-door environment. The device measures three physiological conditions at the earlobe (see Fig. 1) that are known to be correlated with tissue glucose concentrations, employing ultrasound, electromagnetic and thermal measurement technologies. GlucoTrack is intended for use in adult type 2 diabetic patients and pre-diabetic patients. We performed this study to evaluate the performance of the device during a standardized meal test.

Methods

A total of 27 participants were enrolled into this prospective, open-label trial (20 type 2 patients, 4 female, 68±8 yrs (HbA1c: 7.2±1.0%, BMI: 32.1±4.7 kg/m²), 7 pre-diabetic subjects, 2 women, (HbA1c: 5.8±0.3%, BMI:30.4±5.9 kg/m²)). After calibration of the device on the day before by using comparator values from a Hemocue meter, the patients ingested a standardized breakfast at the site during the next visit. Blood glucose was measured every 30 min over 180 min with HemoCue, AccuChek Performa and YSI Stat 2300. Mean absolute relative difference and a consensus error grid analysis were performed against the YSI reference method.

Results

In the consensus error grid, 100 % of the GlucoTrack results were within the clinically accepted zones A and B (62.4 % and 37.6 %, respectively, see Fig. 2). The mean values of all patients shows the well established lag-time between blood glucosae and tissue glucose in case of descending blood glucose levels after the meal. Mean absolute relative difference of the Hemocue-calibrated GlucoTrack devices when compared to YSI Stat2300 was found to be 19.7 % (17.5 % vs. Hemocue). The performance was similar between patients and pre-diabetic subjects.

Fig.1: The GlucoTrack device

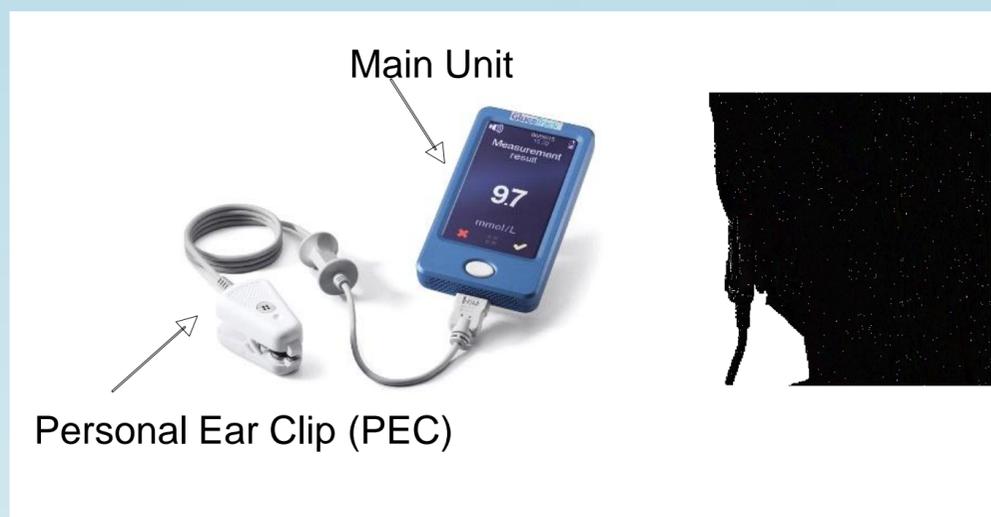
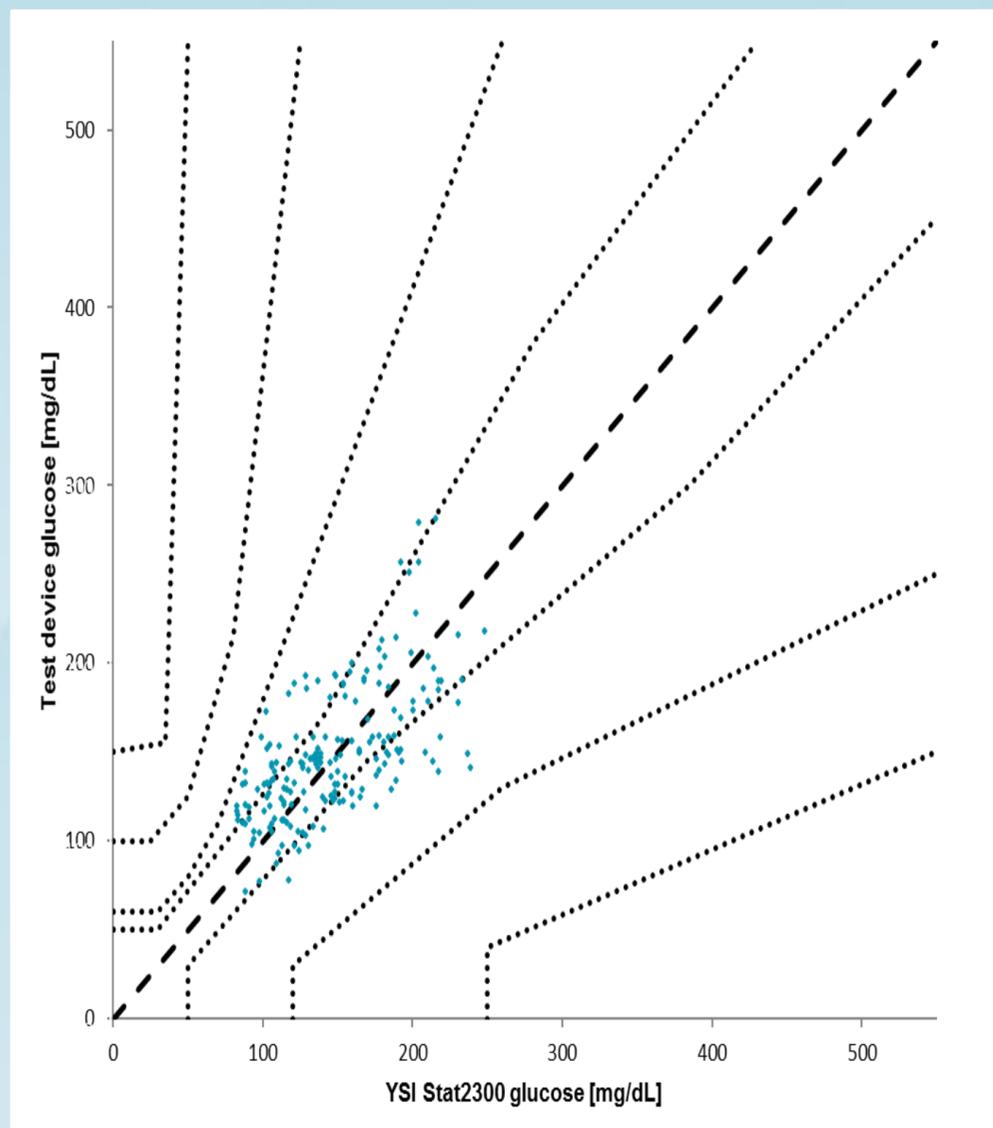
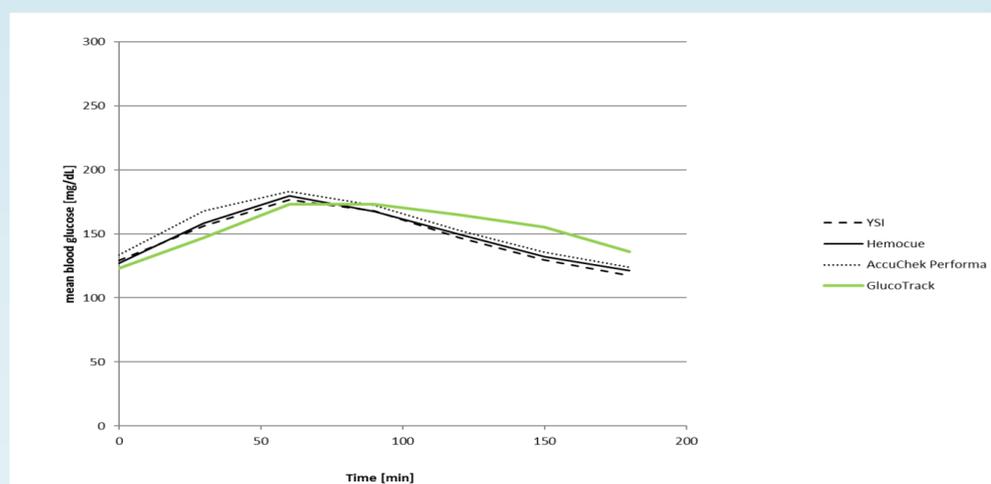


Fig.2: Consensus Error Grid of GlucoTrack tissue glucose vs. YSI capillary blood glucose



**Fig.3: Mean glucose values during the meal experiment
STD was left out for better readability**



Conclusions

The current data confirms the GlucoTrack device performance among its intended users, including pre-diabetic patients, for pain-free non-invasive monitoring of glucose levels.

Further product information: www.integrity-app.com