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Clinical Trial Report

Evaluation of GlucoTrack® Model DF-F Non-Invasive Glucose Monitoring Device in Patients with Type 2 Diabetes and Subjects with Prediabetes

prepared by

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Issued: October 25th , 2016

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Signature Page:

This final study report was prepared and approved by the principal study investigator Prof. Andreas Pfützner, MD, PhD. With the signatures below, it is confirmed that the report correctly displays the results of the study performed in accordance with protocol CL-RE-04-0-027 (Study code: IAP-NGM-001).

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1. Introduction

1.1. General

GlucoTrack is a CE-mark approved non-invasive glucose monitoring device for individuals, to be used at home and in-door environment. The device is battery operated and includes 2 subunits: Main Unit (MU), containing a color touch screen display and control, transmitter, receiver and processor, and a Personal Ear Clip (PEC), containing sensors and calibration electronics, that is attached (externally clipped) to the earlobe, to perform a non-invasive monitoring. Figure 1 shows the device and illustrates how a measurement is performed.

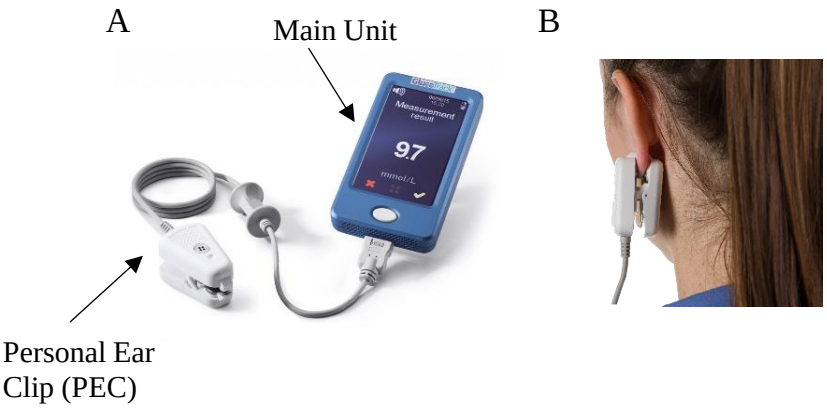

Figure 1: GlucoTrack non-invasive glucose monitoring device. A. GlucoTrack Model DF-F. The device includes a main unit and three different sensor pairs, one per each of the three technologies, all located at the tip of a personal ear clip (PEC) . **B.** . Illustration of glucose measurement performance using GlucoTrack. The PEC is clipped to the earlobe for spot measurement.

1.2. Device Technology -Principle of Operation

GlucoTrack principle of operation is based on measuring physiological phenomena which are correlated with glucose levels in the body. The “translation” of the measured signals into glucose reading is done by individual calibration, which also reduces the impact of quasi-stable components in the earlobe tissue. The measurement is conducted by three independent technologies, which act sequentially, in order to not interfere with each other. Since the whole process takes about a minute, from the user's point of view the measurement is considered as simultaneous. The three independent readings are combined together by a proprietary algorithm, which calculates their weighted average.

GlucoTrack combines the following technologies:

- Ultrasound (phase shift as a function of speed of sound change within the tissue);
- Electromagnetic (conductivity of the tissue);
- Thermal (heat capacity of the tissue).

The combined end-result (reading) is displayed to the user on a large color screen, as well as announced verbally. Extreme values, pre-determined by the user, evoke visual and audible alerts.

The device does not require sterilization and does not have any disposable components. The Ear Clip life span is 6 months from first use; after which it must be replaced.

1.3. Device Intended Use

GlucoTrack Model DF-F is intended for use in non-invasive quantitative spot measurement of glucose, for home-use. The GlucoTrack Model DF-F is intended for adult (over age 18) type 2 diabetic patients and pre-diabetic patients.

Medications intake / treatment decisions should not be based only on measurements by GlucoTrack model DF-F.

The GlucoTrack Model DF-F is a monitoring device and should not be used for diagnosis.

1.4. Device Specifications

Feature	**Specifications**
Operation Modes	Spot
Users	Up to 3 users. Personal Ear Clip (PEC) for each user
Range	70-500 mg/dL (3.9-27.8 mmol/Liter)
Display	Color-Touch Screen. Time, Date, Glucose Level (mg/dL or mmol/Liter – by User choice), Glucose High/ Low/ Normal indication (preset by user), Battery Level, Low Battery indication, Replacement of PEC Unit request, Re-Calibration request, User name, Memory use status
Controls	Turn On/Off Push button, “Home” Push button, Touch Screen

Feature	Specifications
	control
Memory	Up to 1000 last readings per user (including level, date, time)
Interface	USB for Data Downloading and charging
Battery	Li–Ion Rechargeable
Working temp.	+15ºC to +35ºC
Storage temp.	-5ºC to +55ºC
Relative humidity	Up to 95%
Accessories	Adjusting/ Pointing Tool (ATL) , USB Cable, Charger, Case, Self-Test Aid (STA)

More details can be found in "RD-SP-04-0-002 GlucoTrack Technical Specs - DF-F model"

2. Study Objectives

The purpose of this post marketing clinical study was to demonstrate the performance of the GlucoTrack® Model DF-F in measuring glucose levels in Type 2 diabetics and prediabetic subjects (impaired fasting glucose >110 mg/dL or impaired glucose tolerance 2 hours postprandial >140-200 mg/dL), when operated according to its instructions for use.

This clinical study was conducted pursuant to previous clinical trials that were successfully performed in Israel and used to obtain a CE certificate for the EU market.

2.1. Primary Endpoints

- Demonstrate GlucoTrack Model DF-F performance and accuracy in monitoring glucose levels using the proportion of GlucoTrack measurements that fall within ±15 mg/dL of the measured values of the YSI device at glucose concentrations <100 mg/dL and within ±15% of the YSI measurements at glucose concentrations ≥100 mg/dL.
- Demonstrate Device Clinical Performance using Consensus Error Grid Analysis

2.2. Secondary Endpoints

- Demonstrate GlucoTrack Model DF-F precision
- Demonstrate GlucoTrack Model DF-F performance and accuracy in monitoring glucose levels using the proportion of GlucoTrack measurements that fall within ± 15 mg/dL of the measured values of HemoCue® Glucose 201 RT system and of the AccuChek® Performa (by Roche) devices ("Secondary References") and at glucose concentrations <100 mg/dL and within ±15% of the Secondary References measurements at glucose concentrations ≥100 mg/dL.

3. Study Measures

3.1. Performance measures

- GlucoTrack's clinical accuracy was evaluated by Consensus Error Grid Analysis (described in appendix A) of data points measured during a standardized meal experiment. Performance was further assessed by calculating the mean and median absolute relative differences (ARD) between GlucoTrack readings and paired capillary blood glucose readings. Demonstrating an accuracy level that leads to similar clinical treatment decisions as the gold standard reference is an indication of the GlucoTrack's sufficient performance.

3.2. Precision measures

- GlucoTrack's precision was assessed by computing the mean precision absolute relative differences (PARD) between two simultaneous GlucoTrack readings.

4. Study Design

4.1. Overview of Study Design

The current study was performed according to a clinical protocol: CL-PL-04-0-001 VER. 1. This report was prepared to summarize the results obtained during this study.

This study was conducted as a combined, open label, prospective, comparative, single-center trial. Participants were recruited and enrolled by the study site. The study was conducted in order to collect more data for further performance evaluation of the product. After signing informed consent, a GlucoTrack device was individually calibrated with the participant during a first "calibration visit". The same device and ear clip were used in a follow-up visit to track the glucose values occurring before and after uptake of a standardized breakfast consisting of two pieces of white bread with cream cheese and water (total carbohydrate content: 24 g).

4.2. Accuracy Assessment (AA) Group

The AA group was designed for further performance evaluation of the device. In the AA group, GlucoTrack (GT) results were compared with the readings from YSI 2300 STAT Plus™ glucose and lactate analyzer by Yellow Springs Instrument Co., Inc., which served as the gold standard reference instrument. In addition, a HemoCue® Glucose 201 RT system, which is widely used as point-of-care glucose monitoring device served as a secondary reference device as well as an AccuChek® Performa device (Roche Diagnostics), which is a widely used home glucose monitoring device.

All subjects in the performance verification underwent individual calibration during the first visit followed by an experimental measurement day (visit 2) with consumption of a standardized meal. All measurements and calibration related actions were performed by the investigators.

Since the results of the YSI are not immediately available, in order to complete the calibration stage, during the study, HemoCue results were entered into the GlucoTrack when calibrating the device.

4.3. Precision Assessment (PA) Group

The PA group was designed for the evaluation of device precision. 5 subjects out of the AA group participated in the PA as well. Each subject was simultaneously calibrated with two GlucoTrack devices at visit 1, each device applied to a different earlobe, using the same invasive reference glucose values. At visit 2, the investigators conducted 7 measurements with 30 minutes intervals with both GlucoTrack devices applied in parallel. Reference glucose values were taken using the same three reference devices as in the AA group.

4.4. Regulatory Approvals

The study was approved by the local Institutional Review Board/Ethics Committee for Human Research of the State of Rheinland-Pfalz and by the National German Medical Agency (BfARM, Bundesinstitut für Arzneimittel und Medizinprodukte), and was conducted in accordance with all applicable local regulations and standards.

During the clinical study, the GlucoTrack Model DF-F readings had no influence of the participant's glucose control in any way. Only the information obtained by the standard invasive measurements was used by the participants, if applicable. Therefore, the study presented no additional risk to the participants.

4.5. Subjects Selection

All participants were men and women older than 18 years, who were known to suffer from type 2 diabetes or pre-diabetes. Patients were excluded if they had any anatomical abnormalities at the earlobe or carried major metal items in the earlobe, as determined by the investigator.

4.6. Statistical Analysis

Clinical accuracy was determined using Consensus Error Grid Analysis (as described in Appendix A). Statistical accuracy was demonstrated by the mean and median Absolute Relative Differences (MARD) values. Precision was demonstrated from the Precision Absolute Relative Difference (PARD). These analyses were done based on data gathered from the AA and PA groups with 20 patients with type 2 diabetes and 7 pre-diabetic subjects.

4.7. Dropouts

One subject did not complete the trial, because the anatomical situation at both earlobes did not allow for proper placement and replacement of the ear clip because it was too thick. This condition was detected after he had signed informed consent. The patient was considered a drop-out and an additional patient was enrolled to replace this subject.

5. Performance Evaluation Study Results

The patient characteristics are provided in Appendix B and the raw data collected during the meal experiments are provided in Appendix C together with the individual patients glucose curves.

5.1. Safety Results

In total, 224 measurements from 20 type 2 diabetes patients and 7 pre-diabetic patients were performed and evaluated in this study. In the accuracy study, 189 measurements were collected. An additional 35 data points were obtained in the precision part of the protocol.

- No adverse event which is related to GlucoTrack was observed following the use of the GlucoTrack DF-F.
- No injury or appearance of complications such as skin irritation, burning or discomfort were observed.

5.2. GlucoTrack DF-F Performance Results – AA Group

The following results were obtained from 20 patients with type 2 diabetes and 7 pre-diabetic subjects. GlucoTrack was calibrated with the HemoCue device, which served as the home use reference device. GlucoTrack was compared with YSI Stat2300 as a gold standard reference method and with AccuChek Performa. The results of the overall data gathered from all participants and according to all calibrations are presented in Appendix C with their corresponding reference values.

Table 1 summarizes the Consensus Error Grid statistics of the HemoCue-calibrated GlucoTrack performance according to the 3 reference devices. The Consensus Error Grids are also presented in Figure 2.

Table 1 - Consensus Error Grid analysis of all subjects

Reference Method	YSI 2300 STAT Plus		HemoCue		Accu Chek Performa	
Consensus EG Zone	**Number of Points**	**%**	**Number of Points**	**%**	**Number of Points**	**%**
A+B	189	100 %	189	100 %	189	100 %
A	165	87.3 %	168	88.9 %	161	85.2 %
B	24	12.7 %	21	11.1 %	28	14.8 %
C	0	0	0	0	0	0
D	0	0	0	0	0	0
E	0	0	0	0	0	0
Total	189	100%	189	100%	189	100%

Figure 2: Consensus Error Grid of the HemoCue-calibrated GlucoTrack vs. the different reference methods

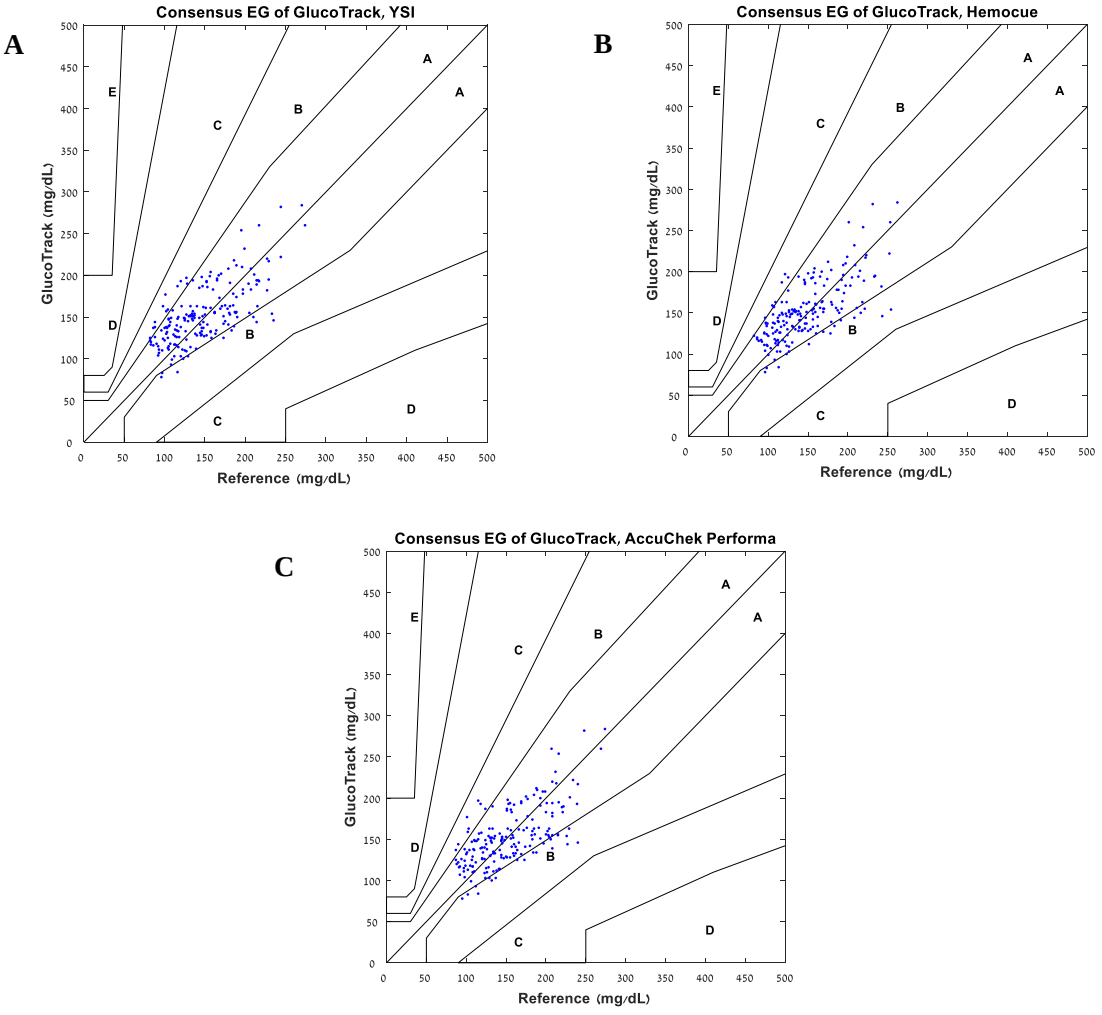

Table 2 describes the mean and median ARD of GlucoTrack according to each of the reference methods.

Table 2 - ARD depiction of all subjects

Reference Method	Mean ARD [%]	Median ARD [%]
YSI 2300 STAT Plus	19.7 %	15.9 %
HemoCue	17.5 %	14.7 %
Accu Chek Performa	18.1 %	16.1 %

Table 3 depicts the characteristics of the tested data.

Table 3 - Characteristics of study's data

Number of Points	189
Number of Subjects	27
Minimal Reference Glucose (according to YSI)	82 mg/dL
Maximal Reference Glucose (according to YSI)	274 mg/dL

GlucoTrack results show that in the Consensus error grid analysis 100 % of all data points are within the clinically accepted zones A and B. These results indicate that a clinical decision based on GlucoTrack readings would lead to an appropriate treatment, which would not have caused any safety concerns in all cases.

Cumulative percentage of GlucoTrack readings within 5%, 10%, 15%, 20%, 30% and 40% deviation of capillary blood glucose readings that are equal or above 100 mg/dL are presented in Table 4.

Table 4 - Cumulative percentage of GlucoTrack readings within 5%, 10%, 15%, 20%, 30% and 40% deviation of capillary blood glucose readings

	Percentage of GlucoTrack readings within a certain accumulated error range for invasive reverence values ≥ 100 mg/dL		
Reference Method	**YSI 2300 STAT Plus**	**HemoCue**	**Accu Chek Performa**
±5%	11.8 %	19.5 %	17.3 %
≤±10%	32.0 %	39.1 %	31.2 %
≤±15%	50.3 %	55.0 %	49.7 %
≤±20%	68.6 %	69.2 %	68.2 %
≤±30%	85.8 %	88.8 %	87.3 %
≤±40%	94.1 %	94.7 %	96.0 %
>±40%	5.9 %	5.3 %	4.0 %
Total # of points	169	169	173
Total # of subjects	27	27	27

Cumulative percentage of GlucoTrack readings within 5 mg/dL, 10 mg/dL, 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL deviation of capillary blood glucose readings below 100 mg/dL are presented in Table 5.

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Table 5 - Cumulative percentage of GlucoTrack readings within 5 mg/dL, 10 mg/dL, 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL deviation of capillary blood glucose readings

	Percentage of GlucoTrack readings within a certain accumulated error range for invasive reverence values < 100 mg/dL		
Reference Method	**YSI 2300 STAT Plus**	**HemoCue**	**Accu Chek Performa**
±5 mg/dL	0.0 %	0.0 %	0.0 %
≤±10 mg/dL	0.0 %	5.0 %	6.3 %
≤±15 mg/dL	20.0 %	20.0 %	18.8 %
≤±20 mg/dL	30.0 %	30.0 %	37.5 %
≤±30 mg/dL	50.0 %	55.0 %	56.3 %
≤±40 mg/dL	75.0 %	90.0 %	87.5 %
>±40 mg/dL	25.0 %	10.0 %	12.5 %
Total # of points	20	20	16
Total # of subjects	10	7	8

5.3. GlucoTrack DF-F Precision Evaluation Results – PA Group

The raw data (in mg/dL) collected for the precision analysis is provided below. These results (35 data pairs) were obtained from 5 patients with type 2 diabetes**.**

	time [min]						
	0	30	60	90	120	150	180
Patient No. 1							
1	193	217	260	284	282	260	212
2	214	237	309	289	304	259	243
Patient No. 2							
1	117	130	152	154	151	138	129
2	118	127	144	180	181	155	138
Patient No. 7							
1	99	137	153	154	148	137	107
2	83	113	129	135	130	120	112
Patient No. 8							
1	127	151	178	160	147	137	162
2	144	161	196	173	155	149	151
Patient No. 24							
1	111	143	153	133	123	113	125
2	114	156	163	146	144	134	125

The mean PARD as calculated from these values is 9.49±5.48 %.

5.4 GlucoTrack DF-F Performance Results according to offline simulations – AA Group

In addition to the online HemoCue calibration additional offline calibrations were performed simulating the respective online calibrations with YSI and AccuCheck Performa. YSI is considered to be the gold standard reference, as it is an accepted regulatory reference method for glucose measurement. The following Table 6 summarizes the Consensus Error Grid result for each of the three comparator methods, when the analysis is performed with the results of the respective calibration. This means CGA was done with the simulated YSI calibration-derived GlucoTrack results vs. YSI, the HemoCue calibration-derived GlucoTrack results vs. HemoCue, and with the simulated AccuChek calibration-derived GlucoTrack results vs. AccuCheck. The full data are presented in Appendix D.

Table 6 - Consensus Error Grid analyses of all subjects with the GlucoTrack results derived from the online or offline calibrations with the respective reference device

Reference Method	**YSI 2300 STAT Plus**		**HemoCue**		**Accu Chek Performa**	
Consensus EG Zone	**Number of Points**	**%**	**Number of Points**	**%**	**Number of Points**	**%**
A+B	189	100.0 %	189	100.0 %	189	100.0 %
A	161	85.2 %	169	88.9 %	165	87.3 %
B	28	14.8 %	20	11.1 %	24	12.7 %
C	0	0.0	0	0.0	0	0.0
D	0	0.0	0	0.0	0	0.0
E	0	0.0	0	0.0	0	0.0
Total	189	100.0%	189	100.0%	189	100.0%

Table 7 describes the mean and median ARD of GlucoTrack according to each of the reference methods.

Table 7 - ARD depiction of all subjects with the GlucoTrack results derived from the online (HemoCue) or offline (YSI and AccuCheck) calibrations with the respective reference device

Reference Method	**Mean ARD [%]**	**Median ARD [%]**
YSI 2300 STAT Plus	18.6	15.9
HemoCue	17.5	14.7
Accu Chek Performa	18.4	15.0

5.5 GlucoTrack DF-F Performance Results according to most recent software – AA Group

Integrity Applications constantly works on GlucoTrack DF-F's algorithm improvements, in order to increase the performance of the device. Prior to the trial in Germany, an updated software version was developed and in implementation stages. The main modification in the updated software is signals' correction according to the ambient temperature sensor reading. Offline calibrations were performed simulating the respective online calibrations with YSI and AccuCheck Performa. The following Table 8 summarizes the Consensus Error Grid result for each of the three comparator methods, when the analysis is performed with the results of the respective calibration, similar to section 5.4. The full data are presented in Appendix E.

Table 8 - Consensus Error Grid analyses of all subjects with the GlucoTrack results derived from the most updated software with the respective reference device

Reference Method	**YSI 2300 STAT Plus**		**HemoCue**		**Accu Chek Performa**	
Consensus EG Zone	**Number of Points**	**%**	**Number of Points**	**%**	**Number of Points**	**%**
A+B	189	100 %	189	100 %	188	99.5 %
A	173	91.5 %	178	94.2 %	173	91.5 %
B	16	8.5 %	11	5.8 %	15	7.9 %
C	0	0.0 %	0	0.0 %	1	0.5 %
D	0	0.0	0	0.0	0	0.0
E	0	0.0	0	0.0	0	0.0
Total	189	100.0%	189	100.0%	189	100.0%

Table 9 describes the mean and median ARD of GlucoTrack's most updated software version according to each of the reference methods.

Table 9 - ARD depiction of all subjects with the GlucoTrack results derived from the most updated software with the respective reference device

Reference Method	**Mean ARD [%]**	**Median ARD [%]**
YSI 2300 STAT Plus	18.1 %	14.8 %
HemoCue	17.3 %	14.3 %
Accu Chek Performa	17.7 %	14.2 %

6. Summary and Conclusions

The current results from the clinical study show substantial evidence of GlucoTrack safety and acceptable performance.

Following are the main outcomes from the study:

1. No device-related complications or adverse events were observed with the use of the device during this study.

2. GlucoTrack results show that 100% of the performance evaluation group's data points are within the clinically accepted zones of the Consensus Error Grid (A + B: 87.3 % + 12.7 %), respectively, when compared to the YSI Stat2300. 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). Therefore, it can be concluded that the overall accuracy is comparable or better as compared to the trials performed in Israel : MARD of 22.9 %, for further information please refer to Integrity Applications' report number CL-RE-04-0-002).

3. The mean PARD was 9.5±5.5 %. These results are similar to the results obtained in the previous clinical trials performed in Israel (mean PARD in previous trials was 9.1±7.5 %). For further information, please refer to Integrity Applications' report number CL-RE-04-0-023.

It is of note that the different reference methods showed results which were very close to each other in this study. However, the results and all analyses presented above in this performance evaluation were made with the HemoCue-calibrated GlucoTrack device.

A calculation of the GlucoTrack results simulating that the device would have been calibrated with the YSI reference or the AccuChek self-monitoring device can be found in Appendix D. As can be seen in section 5.4, the analyses with the offline calibration derived GlucoTrack data resulted in very similar results.

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The GlucoTrack results in these simulations are so close to the HemoCue-calibrated results that the analyses based on these simulated results only vary by minor decimal changes, while the overall results remain the same. This finding has the practical implication that GlucoTrack calibration may be performed with sufficiently accurate point-of-care devices for patient self-testing without losing major performance quality in comparison to calibration by means of accepted gold standard reference methods.

Most recent GlucoTrack software version demonstrates that 94.2 % of the data points are within the clinically accurate A zone of the Consensus Error Grid, and 100 % are in the clinically accepted zones A+B, when calibrated and compared to the HemoCue device. Both YSI Stat2300 and AccuChek show similar results. Mean and Median ARD are 17.3% and 14.3 %, respectively, for the HemoCue-calibrated results.

In conclusion, the current data suggests that the GlucoTrack device performance as evaluated in this recent trial in Germany is better or at least equal as compared to the previous trials performed in Israel. This data confirms the performance of GlucoTrack among its intended users, including pre-diabetic patients and independent from the reference method used for calibration.

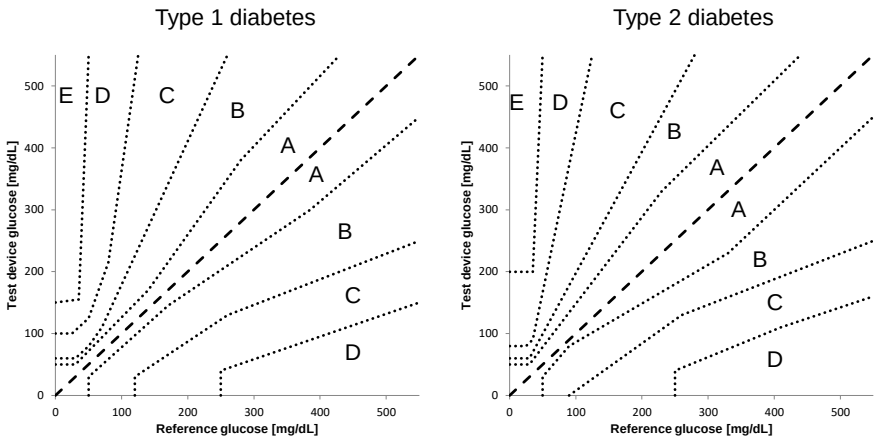
Appendix A - Consensus Error Grid Analysis

The Consensus error grid was suggested by Parkes et al (Diabetes Care, 2000), who along with a team of 100 physicians constructed an error grid alternative to Clarke's. The definitions of the risk zones in the Consensus error grid correspond to the definitions of risk zones in CEG. The consensus error grid has no discontinuities of risk at the boundaries (i.e., all boundaries separate regions that are adjacent in both proximity on the graph and severity of risk) as further elucidated by Pfützner et al (J. Diabetes Sci. Technol 2013). This stands in contrast with the CEG, which has several boundaries separating nonadjacent categories.
Parkes et al presented two grids, one per each diabetes type. In this evaluation only patients with type 2 diabetes were included and the corresponding grid version was used for the analysis. The following table and figure describes the properties of the Consensus error grid.

Description of Consensus Error Grid Zones

Description	Zone
No effect on clinical action	A
Altered clinical action or little or no effect on clinical outcome	B
Altered clinical action - likely to affect clinical outcome	C
Altered clinical action - could have significant medical risk	D
Altered clinical action - could have dangerous consequences	E

A- Consensus error grid for people with type 1 diabetes, B- Consensus error grid for people with type 2 diabetes.



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Appendix B - Patient Characteristics

Subject #	Trial group	Diabetes	HbA1c [%]	Gender	Age [year]	Weight [kg]	BMI [kg/m^2]	DM duration [years]
1	A+P	Type 2	9,4%	male	67	96	30,29	7
2	A+P	Type 2	7,2%	male	69	108	34,86	12
3	A	Type 2	6,9%	male	73	96	32,44	16
4	A	pre diabetes	5,2%	male	51	122	34,88	n.a.
5	A	pre diabetes	6,1%	male	71	85	26,82	n.a.
6	A	Type 2	7,2%	male	55	88	29,06	12
7	A+P	Type 2	6,1%	male	70	98	34,31	7
8	A+P	Type 2	6,3%	male	60	115	38,42	1
9	A	Type 2	5,8%	female	74	80	30,11	6
10	A	pre diabetes	6%	female	67	75,5	27,5	n.a.
11	A	pre diabetes	6,0%	male	65	105	30,35	n.a.
12	A	Type 2	6,8%	male	67	76	24,53	11
13	A	pre diabetes	5,7%	male	64	90	27,77	n.a.
14	A	Type 2	7,9%	male	56	148,6	42,04	2
15	A	pre diabetes	5,8%	male	51	148	41,43	n.a.
16	A	Type 2	6,6%	female	77	92	36,85	11
17	A	pre diabetes	6%	female	77	52	24,39	n.a.
18	A	Type 2	6,5%	female	58	86	31,58	12
19	A	Type 2	6,8%	male	67	116	37,44	2
20	A	Type 2	6,4%	male	60	88	29,74	8
21	A	Type 2	9,6%	male	59	110	36,3	17
22	A	Type 2	8,1%	male	79	111	35	11
23	A	Type 2	8,1%	male	70	85	27,7	11
24	A+P	Type 2	7,6%	male	76	70	25,4	26
25	A	Type 2	7%	male	66	90,7	31,38	9
26	A	Type 2	7,6%	female	76	69	28	13
27	A	Type 2	6,8%	male	75	88	26,3	12

Appendix C – Raw Data and Individual Graphs

YSI Stat 2300 results from the standard meal experiments

Blood glucose results are provided in mg/dL.

YSI	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	217	229	274	270	244	217	189
2	113	138	134	137	135	120	111
3	124	135	153	176	146	120	98
4	93	103	106	117	88	86	92
5	113	164	189	171	147	129	112
6	153	173	211	197	180	148	127
7	109	146	150	134	116	103	93
8	148	151	165	168	162	143	130
9	125	157	127	104	105	108	105
10	107	162	175	132	102	88	82
11	105	115	140	125	102	96	97
12	105	152	169	102	83	83	86
13	116	129	144	137	137	115	104
14	118	181	185	156	135	116	105
15	112	122	144	132	110	100	90
16	139	188	185	179	149	126	115
17	104	140	160	152	128	101	88
18	97	108	123	113	90	88	88
19	117	143	157	157	132	113	107
20	163	190	227	244	227	207	189
21	127	173	233	229	216	214	210
22	197	179	195	199	186	167	152
23	120	135	178	181	148	121	100
24	132	162	215	235	214	183	158
25	157	175	204	205	173	146	125
26	127	187	207	186	146	117	82
27	145	181	214	196	165	147	134

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Hemocue results from the standard meal experiments

Blood glucose results are provided in mg/dL.

Hemocue	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	205	222	253	262	231	201	175
2	112	134	138	133	134	123	111
3	140	141	159	179	150	125	117
4	95	105	112	117	96	97	96
5	109	162	185	167	159	127	115
6	139	169	215	188	170	146	126
7	100	148	155	130	128	108	103
8	147	148	194	159	169	156	148
9	123	156	121	105	114	122	113
10	108	157	168	123	107	95	95
11	98	110	142	123	97	98	99
12	121	150	160	124	86	91	88
13	113	126	146	130	135	119	109
14	114	179	186	157	138	117	106
15	115	112	140	126	107	99	86
16	151	221	193	191	169	139	130
17	106	151	170	156	145	125	106
18	98	108	123	115	98	92	96
19	116	146	158	159	132	120	112
20	153	189	242	252	223	209	183
21	126	178	254	234	233	213	216
22	197	194	219	208	199	167	154
23	111	141	180	174	144	109	100
24	130	165	218	243	208	183	160
25	139	162	192	192	156	131	118
26	124	211	203	179	143	113	82
27	138	187	220	197	165	146	137

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AccuChek Performa results from the standard meal experiments

Blood glucose results are provided in mg/dL.

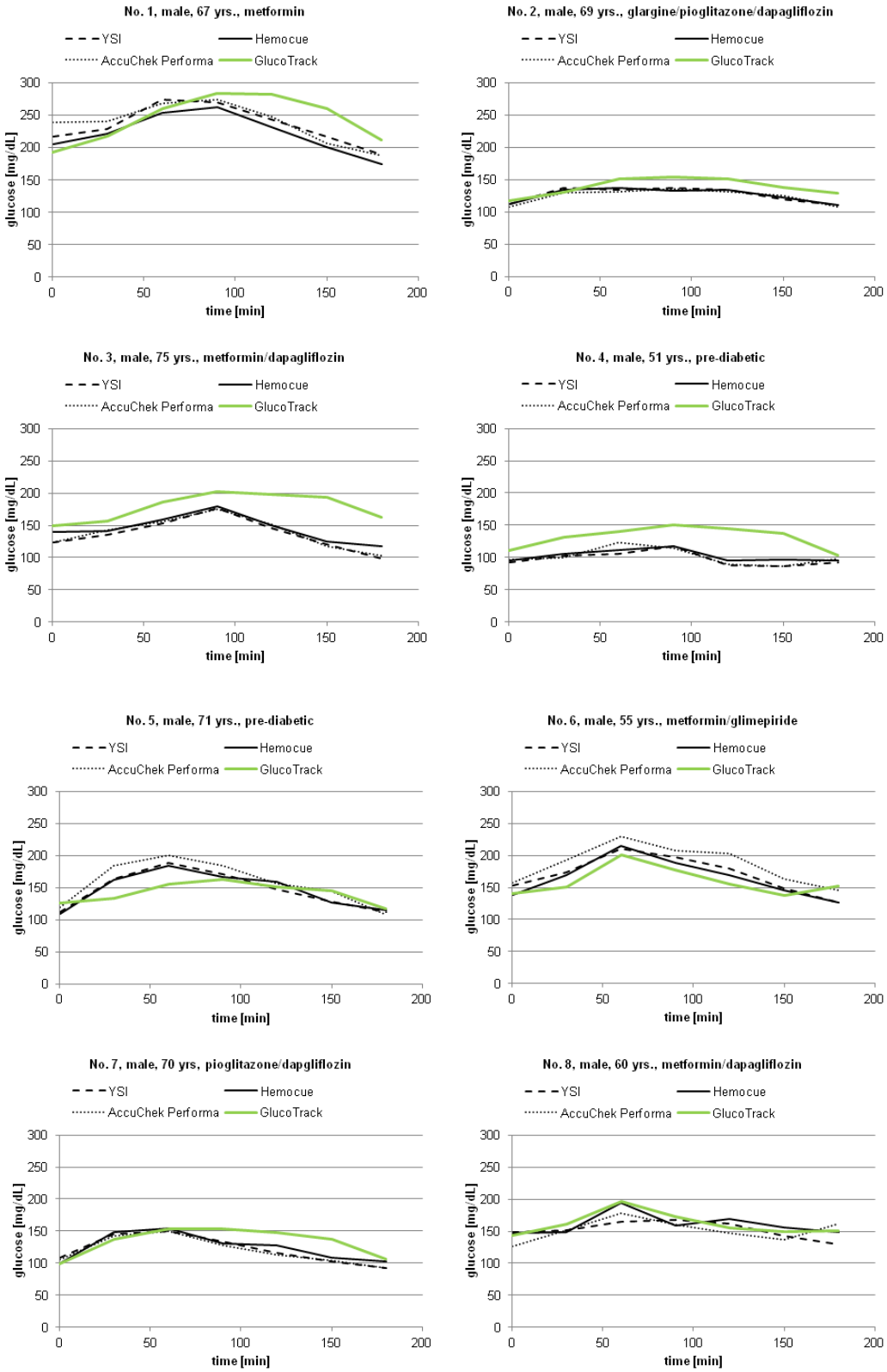
AccuChek	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	239	240	269	274	248	207	188
2	108	130	132	136	131	126	108
3	124	142	156	175	152	118	103
4	97	100	123	115	90	87	98
5	120	184	200	185	156	145	108
6	157	193	230	208	203	164	145
7	106	142	150	128	113	104	92
8	160	172	169	163	158	148	135
9	126	162	115	102	107	110	118
10	105	182	176	133	116	94	87
11	110	128	144	132	109	101	108
12	125	151	183	130	88	92	91
13	115	137	144	144	130	120	102
14	123	204	177	177	155	124	111
15	124	134	162	145	119	110	99
16	138	215	191	174	147	134	121
17	107	152	157	153	133	101	98
18	102	112	132	120	98	97	95
19	136	151	185	156	159	134	125
20	160	183	208	234	208	196	183
21	123	173	226	216	208	201	206
22	200	199	216	212	213	193	160
23	129	166	202	193	166	129	112
24	142	186	229	240	227	188	164
25	169	197	222	208	180	159	131
26	135	215	221	208	150	141	90
27	155	204	220	189	169	151	144

GlucoTrack results, calibrated according to HemoCue, from the standard meal experiments. In patients participating in the precision evaluation, the data from one device was randomly assigned to be taken for the analysis.

Blood glucose results are provided in mg/dL.

GlucoTrack Calibrated by HemoCue	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	193	217	260	284	282	260	212
2	117	130	152	154	151	138	129
3	149	157	186	202	198	193	163
4	111	132	140	150	144	137	104
5	127	134	156	163	151	145	117
6	141	151	201	178	155	137	153
7	99	137	153	154	148	137	107
8	144	161	196	173	155	149	151
9	110	133	197	159	147	149	139
10	118	155	164	163	157	126	125
11	111	116	128	146	138	134	110
12	115	128	160	130	120	117	116
13	84	103	131	149	152	140	113
14	126	163	178	199	194	187	148
15	103	111	141	151	158	137	118
16	112	155	164	148	127	133	134
17	125	163	183	193	190	177	138
18	83	93	100	126	124	115	78
19	133	185	204	161	152	135	144
20	130	150	182	222	220	208	174
21	109	125	154	195	194	194	150
22	183	208	254	232	218	200	192
23	103	146	160	191	162	163	122
24	114	156	163	146	144	134	125
25	132	145	190	155	142	133	148
26	123	156	183	139	129	114	122
27	128	153	189	210	194	197	148

The individual patient glucose curves with GlucoTrack and the different reference devices are provided in the following Figures



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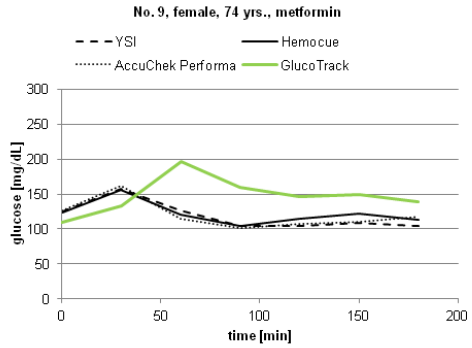

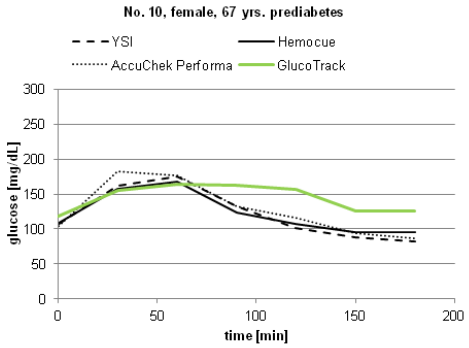

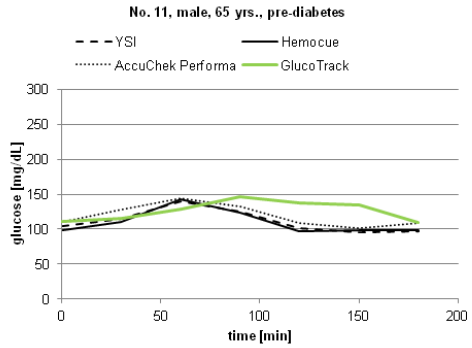

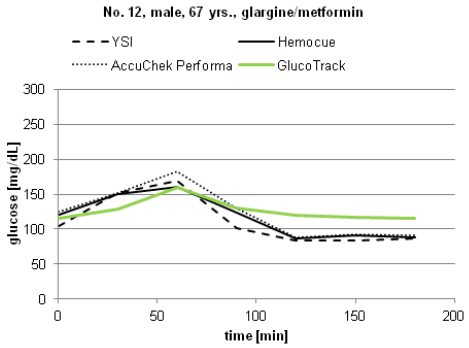

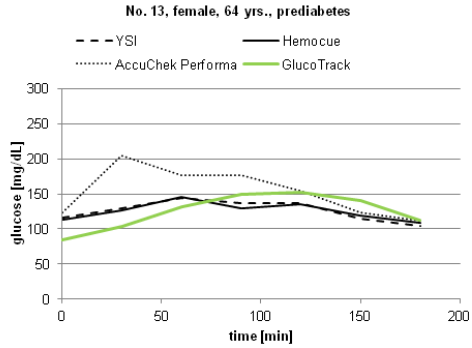

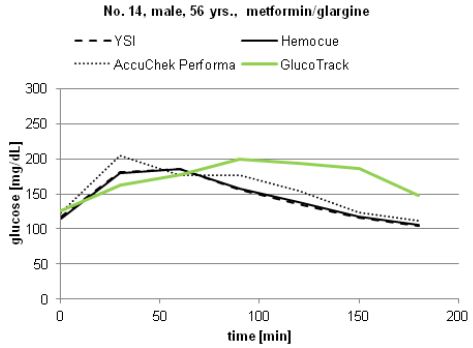

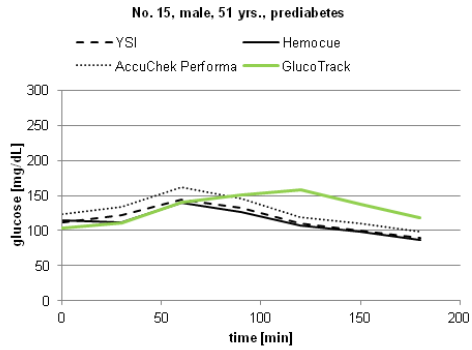

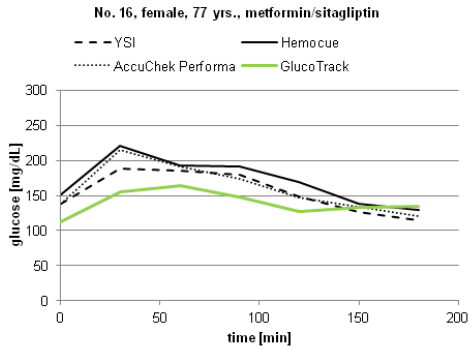

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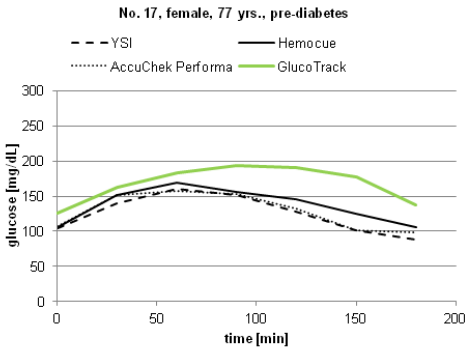
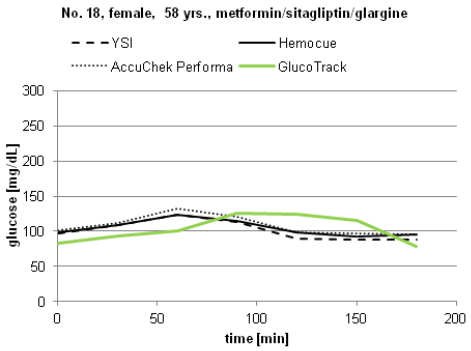
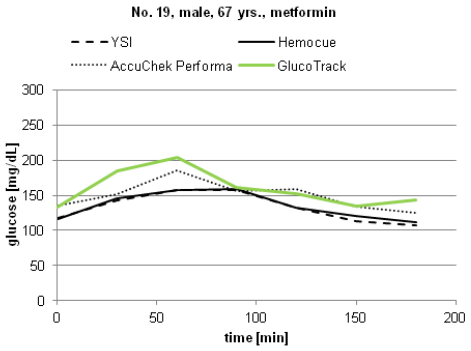
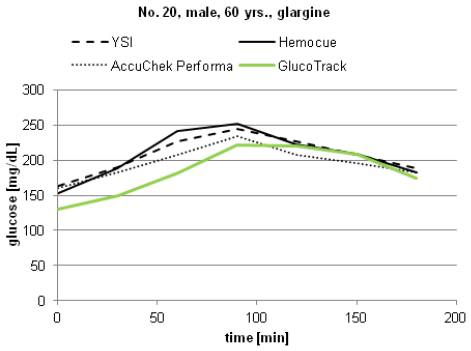
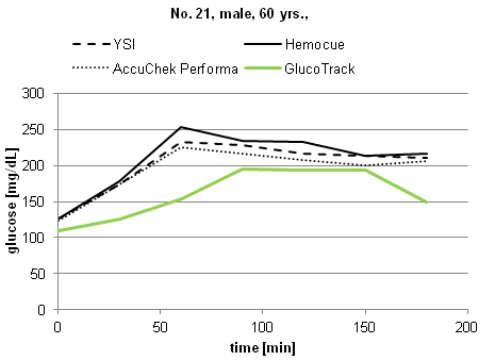
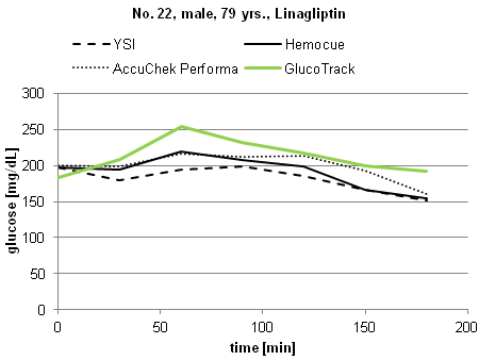


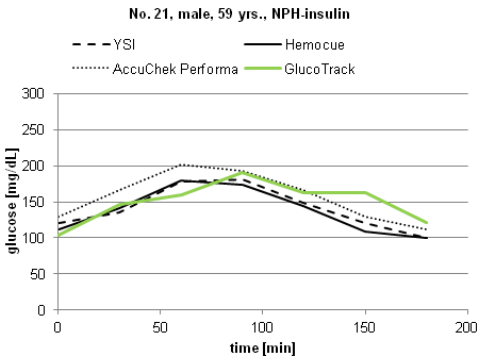


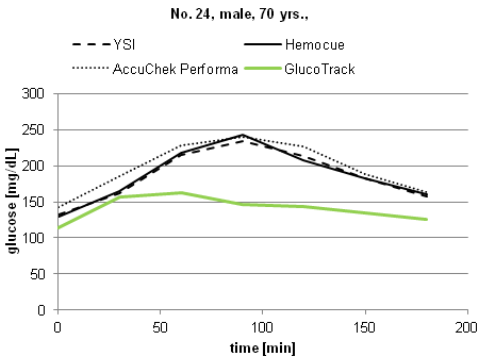


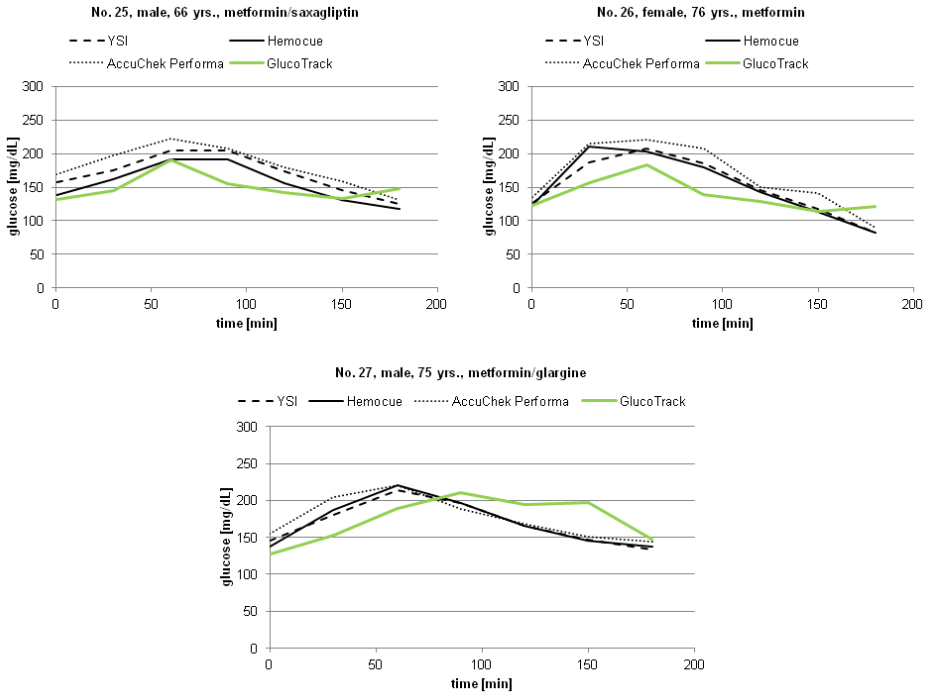




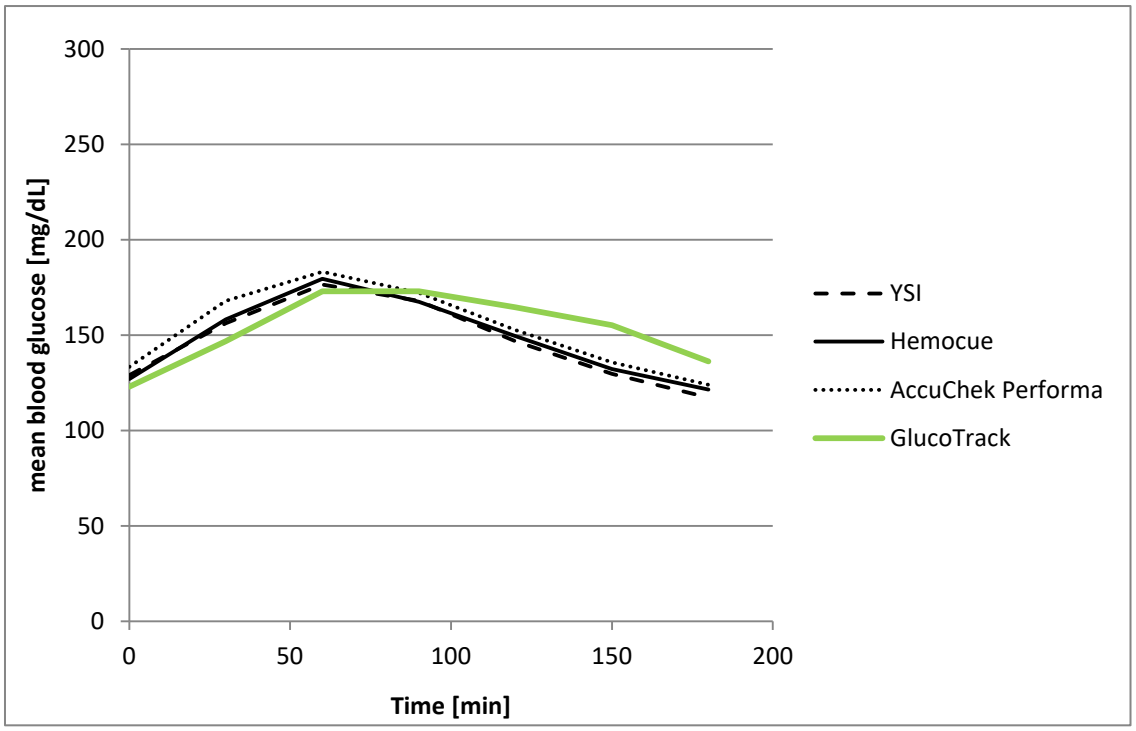








The mean curves over all patients indicating an existing lag-time in the tissue glucose as assessed by GlucoTrack is given below.



Appendix D – GlucoTrack results based on different reference calibrations

In addition to the regular performance assessment as described in the protocol, additional calculations were made to simulate a calibration based on the YSI and AccuCheck Reference results from the calibration days. These simulated calibrations were performed using a designated MATLAB code and GlucoTrack measurements. The resulting simulated GlucoTrack results for the standardized meal experiments are displayed below.

GlucoTrack results, when calibrated according to YSI, from the standard meal experiments (Simulation based on raw signal data). Blood glucose results are provided in mg/dL.

GlucoTrack Calibrated by YSI	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	208	233	278	303	301	278	227
2	122	135	158	160	157	144	134
3	135	141	167	182	179	175	148
4	112	132	141	150	145	138	104
5	124	130	152	158	147	141	114
6	145	156	206	183	159	138	157
7	99	138	153	155	149	137	108
8	134	150	182	161	144	139	141
9	108	130	193	156	144	146	136
10	115	151	160	159	153	132	122
11	117	122	135	154	145	141	116
12	103	117	149	121	111	109	108
13	84	103	131	149	152	140	113
14	120	156	171	191	186	179	142
15	103	111	141	151	157	136	118
16	107	135	143	122	110	116	117
17	114	149	168	177	174	162	126
18	79	89	95	121	119	110	74
19	112	168	187	146	138	121	130
20	127	148	179	219	217	205	172
21	108	124	153	194	192	191	148
22	154	188	241	224	211	190	185
23	110	154	169	200	171	171	129
24	110	151	158	142	140	128	121
25	139	153	200	163	150	138	156
26	123	156	183	139	129	114	122
27	128	152	188	209	192	185	147

GlucoTrack results, when calibrated according to AccuChek Performa, from the standard meal experiments. (Simulation based on raw signal data). Blood glucose results are provided in mg/dL.

GlucoTrack Calibrated by AccuChek	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	214	240	286	312	309	286	234
2	120	133	156	157	154	141	132
3	142	149	175	191	188	183	155
4	113	135	143	152	147	140	106
5	137	144	167	175	163	157	126
6	153	164	216	192	167	145	165
7	95	133	149	150	144	133	104
8	135	152	184	163	145	140	142
9	120	144	209	170	157	159	149
10	117	132	168	137	126	124	123
11	85	104	132	150	152	140	114
12	129	167	183	204	198	190	151
13	111	119	151	162	167	145	126
14	109	152	161	138	124	130	132
15	121	158	178	187	184	172	133
16	82	91	99	124	122	113	77
17	135	188	208	164	155	138	147
18	124	144	174	214	213	200	168
19	107	123	152	193	190	190	147
20	180	205	250	228	214	194	188
21	116	162	177	208	179	178	136
22	115	148	157	137	126	114	129
23	144	158	205	168	155	142	160
24	118	160	168	150	148	135	129
25	129	154	190	211	194	187	149
26	123	161	170	169	163	131	130
27	121	127	141	160	151	146	120

It can be seen that the simulated results are very close to the HemoCue –calibrated device results and would not have resulted in an overall change of any of the conclusions.

Appendix E – GlucoTrack most recent algorithm results

GlucoTrack results using the most updated device software, when calibrated according to YSI, from the standard meal experiments (Simulation based on raw signal data). Blood glucose results are provided in mg/dL.

GlucoTrack Calibrated by YSI	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	211	247	283	302	299	262	226
2	125	144	164	168	162	138	127
3	135	141	166	172	170	158	141
4	114	129	142	150	144	128	108
5	129	136	156	160	150	140	117
6	149	163	208	209	194	162	158
7	111	132	152	155	151	135	114
8	141	163	195	190	176	149	141
9	114	150	198	188	165	149	138
10	120	144	158	160	153	136	125
11	123	132	149	163	153	136	118
12	112	126	150	148	129	122	111
13	112	122	138	150	152	132	120
14	124	153	173	189	183	156	139
15	107	117	145	155	156	126	109
16	116	134	146	155	135	127	121
17	121	142	167	176	171	150	128
18	79	92	96	118	117	96	74
19	126	160	185	175	167	129	116
20	127	162	194	221	221	195	175
21	114	139	167	195	192	179	148
22	185	221	254	269	259	223	192
23	113	150	168	197	168	155	129
24	116	147	161	172	176	153	123
25	144	165	210	202	192	168	156
26	129	156	190	169	155	141	122
27	131	166	196	210	191	171	146

GlucoTrack results using the most updated device software, when calibrated according to HemoCue, from the standard meal experiments. (Simulation based on raw signal data). Blood glucose results are provided in mg/dL.

GlucoTrack Calibrated by HemoCue	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	196	231	265	283	280	245	211
2	120	139	158	162	156	133	123
3	148	156	183	190	187	173	139
4	113	128	142	150	143	128	107
5	132	140	159	164	154	143	120
6	145	159	203	204	188	157	154
7	111	131	151	154	150	135	114
8	147	169	203	198	183	155	147
9	117	153	202	191	168	152	140
10	123	148	162	164	157	139	128
11	118	126	142	156	146	130	112
12	120	135	161	159	139	131	119
13	112	122	138	150	152	132	120
14	130	160	180	196	190	162	145
15	107	117	145	155	156	126	109
16	125	157	172	181	159	149	142
17	133	156	182	191	186	163	140
18	83	97	101	123	122	100	78
19	140	176	203	194	184	144	129
20	130	165	197	224	224	198	178
21	115	140	168	196	194	180	149
22	192	228	263	278	268	231	199
23	107	142	160	188	160	148	122
24	120	152	166	177	181	157	127
25	136	157	200	192	182	160	149
26	129	156	190	169	155	141	122
27	131	167	197	211	192	172	147

GlucoTrack results using the most updated device software, when calibrated according to AccuChek Performa, from the standard meal experiments. (Simulation based on raw signal data). Blood glucose results are provided in mg/dL.

GlucoTrack Calibrated by AccuChek	Time [min]						
Patient No.	*0*	*30*	*60*	*90*	*120*	*150*	*180*
1	211	247	283	302	299	262	226
2	125	144	164	168	162	138	127
3	135	141	166	172	170	158	141
4	114	129	142	150	144	128	108
5	129	136	156	160	150	140	117
6	149	163	208	209	194	162	158
7	111	132	152	155	151	135	114
8	141	163	195	190	176	149	141
9	114	150	198	188	165	149	138
10	120	144	158	160	153	136	125
11	123	132	149	163	153	136	118
12	112	126	150	148	129	122	111
13	112	122	138	150	152	132	120
14	124	153	173	189	183	156	139
15	107	117	145	155	156	126	109
16	116	134	146	155	135	127	121
17	121	142	167	176	171	150	128
18	79	92	96	118	117	96	74
19	126	160	185	175	167	129	116
20	127	162	194	221	221	195	175
21	114	139	167	195	192	179	148
22	185	221	254	269	259	223	192
23	113	150	168	197	168	155	129
24	116	147	161	172	176	153	123
25	144	165	210	202	192	168	156
26	129	156	190	169	155	141	122
27	131	166	196	210	191	171	146