**Schedule of Observations**

After giving informed consent, each patient entered the study clinic for two visits. At test visit 1, inclusion and exclusion criteria were checked. A physical examination was carried out to assess each participant's eligibility. Medical history and concomitant medication were recorded.

Thereafter, a test cycle was performed, containing blood glucose measurements at the fingertip and forearm with each device. Two blood glucose reference measurements were performed, one at the beginning and one at the end of the test cycle. The statistical mean of both values was used as reference value for the analysis.

After the first glucose measurement series, the patients were each asked to consume 300ml of fruit juice (containing nearly 2 BE = 24g glucose) to moderately increase the blood glucose level. Approximately one hour after consumption of the juice, a second blood glucose measurement series was performed.

Test visit 2 was performed 14 ± 7 days after test visit 1 and consisted of 2 blood glucose test series identical to the series in test visit 1. At test visit 2, the patients were asked to perform the blood glucose measurements using the investigational device TRUEtrack® at the fingertip and the forearm. To really capture the truest performance of the TRUEtrack®, the final analysis consisted of data generated by the healthcare professionals only. This procedure was applied to compare data sets obtained by identical sources..

## RESULTS AND DISCUSSION:

The evaluation demonstrated an acceptable accuracy for all trial devices with a significant correlation to the reference method ($p < 0.01$). Glucose measurements at the fingertip showed a considerably better performance in comparison to AST at the forearm, for all study devices. These observed differences between the results obtained from the fingertip and alternate testing site have been well documented in the literature.[1,2]

The clinical significance was assessed with error grid analysis by Parkes et al.[3] Parkes and colleagues developed a tool to analyze the clinical significance of the blood glucose results obtained by the handheld device in comparison to the laboratory reference. All results were plotted on an error grid which consists of five zones. Each zone represents the significance of the error as it relates to clinical decision making.

Zone A: No effect on clinical outcome.

Zone B: Altered clinical action with little or no effect on clinical outcome.

Zone C: Altered clinical action likely to affect clinical outcome.

Zone D: Altered clinical action could have significant medical risk.

Zone E: Altered clinical action could have dangerous consequences.

All study devices performed very well. For the TRUEtrack® all blood glucose values were observed in the clinically acceptable zones A and B at the fingertip (Figure 1) and the forearm (Figure 2). These results were consistent with the comparative systems (Table 1 and Table 2).

## CONCLUSIONS:

In this study, the TRUEtrack® was compared to state-of-the-art blood glucose monitoring systems with known, high levels of technical performance and market acceptance. During the entire statistical analysis, the TRUEtrack® showed comparable performance with regard to precision and accuracy at the fingertip and the forearm in comparison to a standard laboratory reference method and competitive blood glucose monitoring systems. In summary, the TRUEtrack® has demonstrated clinical equivalence to current state-of-the-art devices and, thus, can be recommended for use by patients performing blood glucose testing at the fingertip and the forearm.

*ikfe is an independent, clinical laboratory and research institute located in Mainz, Germany, established in 1998. ikfe specializes in conducting clinical research trials for pharmaceutical companies and device manufacturers throughout Europe and the United States, in the area of diabetes mellitus and endocrinology. The institute works on the basis of worldwide quality standards (ISO, CAP) and has gained high international scientific recognition; in particular for research on blood glucose measurement, insulin resistance and microcirculation.*

*sciema was founded in 2003 to supply scientific marketing services for pharmaceutical companies and device manufacturers throughout Europe and the United States. Designing, organizing and supporting scientific marketing projects – like clinical studies – is one of sciema's primary scope of duties.*

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# Accuracy Evaluation of the TRUEtrack®: Results of a New Blood Glucose Monitoring Device Suitable for Fingertip and Forearm Testing


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## ABSTRACT:

The TRUEtrack® is a newly developed, blood glucose self-monitoring device that allows for measurement at the fingertip and at the forearm (alternate site testing). The goal of this multi center, clinical trial was to evaluate the accuracy of this device in comparison to a laboratory reference method and 4 commercially available, state-of-the-art blood glucose meters. Blood glucose measurements were performed both at the fingertip and the forearm by diabetes healthcare professionals at 3 study centers. Data sets were collected from 102 diabetic patients (34 women, 68 men, age: 54.7 ± 13.2 years; BMI: 29.2 ± 5.4 kg/m$^2$; mean duration of diabetes for 23 Type 1 diabetic patients: 17.7 ± 10.5 years, and for 79 Type 2 diabetic patients: 10.1 ± 7.5 years; up to 4 test series per patient). The comparative devices were FreeStyle™ (TheraSense/Abbott), Ascensia® Contour™ (Bayer), OneTouch® Ultra (LifeScan), and Accu-Chek® Comfort (Roche; fingertip only). During each test series, investigational and comparative devices were used in randomized order. For each study site 3 study devices of each brand and 3 lots of test strips were utilized. A laboratory reference measurement was performed at the beginning and the end of each test series by means of a whole blood calibrated glucoseoxidase reference method. For each test series, the mean of both laboratory readings was used as the reference value for analysis. All devices correlated well with the laboratory reference method: TRUEtrack® (fingertip: r = 0.946/forearm: r = 0.929), FreeStyle (0.961/0.933), Ascensia Contour (0.934/0.895), OneTouch Ultra (0.943/0.898), and Accu-Chek Comfort (0.949/-). A high quality standard of all study devices was shown on the error grid analysis according to Parkes. All blood glucose measurements were within the clinically acceptable zones A and B. In conclusion, for both fingertip testing and alternate site testing at the forearm, TRUEtrack® shows comparable accuracy and reliability to competitive state-of-the-art blood glucose monitoring systems.


## OBJECTIVE:

The main objective of the study was to evaluate the accuracy and precision of the TRUEtrack® in comparison to the laboratory reference instrument. A second objective was to compare the results obtained at the fingertip and forearm using the TRUEtrack® to the results obtained with four competitive blood glucose monitoring systems. The laboratory reference result would be the standard for all glucose measurements.

## SUBJECTS AND METHODS:

### Demographic Data

The study was performed in accordance with Good Clinical Practices and the Declaration of Helsinki. The patients were recruited from the inpatient and outpatient groups of the investigative sites. In total, 102 patients of Caucasian origin were enrolled in the study and signed informed consent. There were 34 female and 68 male participants with a mean age of 54.7 ± 13.2 years and a mean Body Mass Index of 29.2 ± 5.4 kg/m$^2$. The mean duration of diabetes was 17.7 ± 10.5 years for 23 Type 1 diabetic patients and 10.1 ± 7.5 years for 79 Type 2 diabetic patients.

### Blood Glucose Monitoring Systems

In this study, the accuracy of the investigational device – the TRUEtrack® by Home Diagnostics, Inc.– was compared to a laboratory reference based on whole blood calibrated glucoseoxidase method (Super GL, Dr. Müller Gerätebau, Möhnesee) and the 4 competitive devices: FreeStyle (TheraSense/Abbott), Ascensia Contour (Bayer), OneTouch Ultra (LifeScan) and Accu-Chek Comfort (Roche). Accu-Chek Comfort was only used for conventional fingertip testing. All 5 blood glucose monitoring systems used in this study are based on biosensor technology. Only fresh, capillary, whole blood samples drawn directly from the fingertip and forearm were used for this evaluation.

During the entire study, 3 lots of test strips and 3 meters of each brand were used for monitoring at the 3 study sites. It was intended to use approximately the same amount of test strips for each lot per monitoring device. All devices were used by trained healthcare professionals according to the instruction manuals of the manufacturers.

Figure 1: Parkes Error Grid Analysis for Fingertip Testing

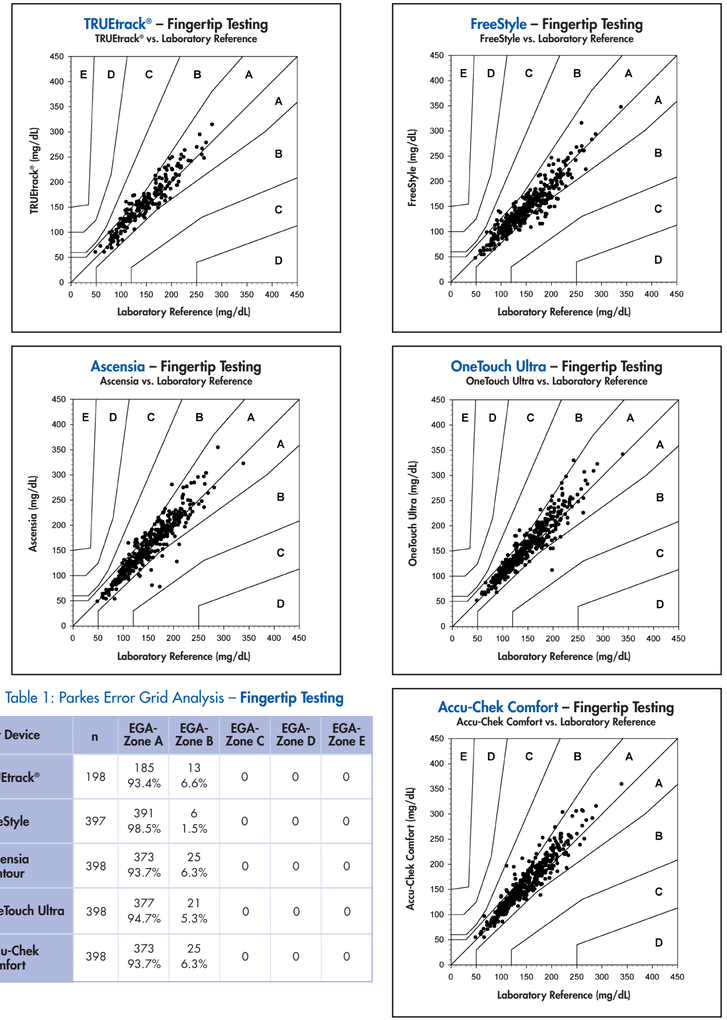


Table 1: Parkes Error Grid Analysis – **Fingertip Testing**

| Test Device | n | EGA-Zone A | EGA-Zone B | EGA-Zone C | EGA-Zone D | EGA-Zone E |
|---|---|---|---|---|---|---|
| TRUEtrack® | 198 | 185<br>93.4% | 13<br>6.6% | 0 | 0 | 0 |
| FreeStyle | 397 | 391<br>98.5% | 6<br>1.5% | 0 | 0 | 0 |
| Ascensia Contour | 398 | 373<br>93.7% | 25<br>6.3% | 0 | 0 | 0 |
| OneTouch Ultra | 398 | 377<br>94.7% | 21<br>5.3% | 0 | 0 | 0 |
| Accu-Chek Comfort | 398 | 373<br>93.7% | 25<br>6.3% | 0 | 0 | 0 |

Figure 2: Parkes Error Grid Analysis for Forearm Testing

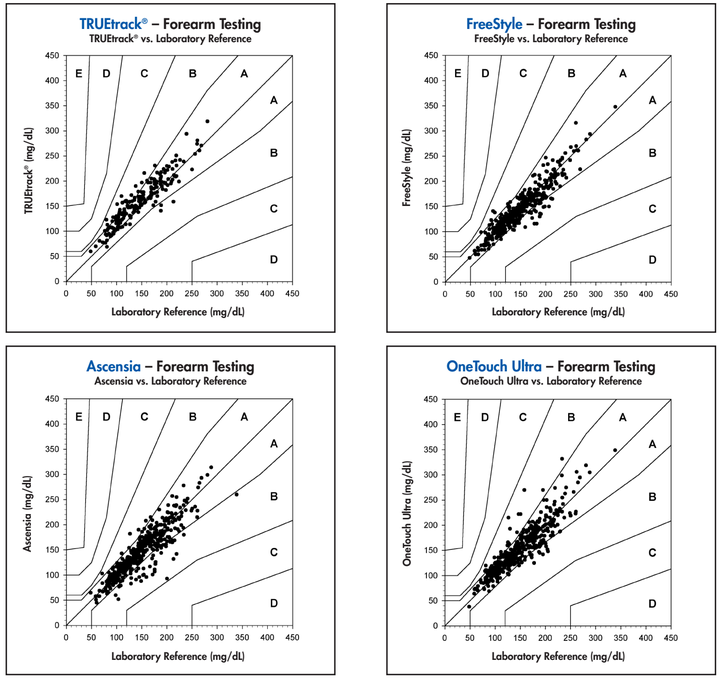


Table 2: Parkes Error Grid Analysis – **Forearm Testing**

| Test Device | n | EGA-Zone A | EGA-Zone B | EGA-Zone C | EGA-Zone D | EGA-Zone E |
|---|---|---|---|---|---|---|
| TRUEtrack® | 199 | 166<br>83.4% | 33<br>16.6% | 0 | 0 | 0 |
| FreeStyle | 398 | 361<br>90.7% | 37<br>9.3% | 0 | 0 | 0 |
| Ascensia Contour | 398 | 351<br>88.2% | 47<br>11.8% | 0 | 0 | 0 |
| OneTouch Ultra | 398 | 362<br>91.0% | 36<br>9.0% | 0 | 0 | 0 |