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 300 ml of fruit juice (containing nearly 2 BE = 24 g 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 forearm. To really capture the truest performance of the TRUEtrack ®, the final analysis consisted of data generated by the healthcare professional only. This procedure was applied to compare datasets 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 of 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.

REFERENCES
2. Kuschinsky, T., and Loughren, F. Role of hypoglycemia detection by glucose monitoring at the arm. Diabetics Care 24: 1093-1094, 2001
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 multicenter, 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 for 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/m²; mean duration of diabetes for 23 type 1 diabetic patients: 17.7 ± 10.6 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® (Theranes, Abbott), Ascensia® ConTour® (Roche), OneTouch® Ultra (LifeScan), and Accu-Chek® Comfort (Roche). A high quality standard of all study devices was shown on the error grid analysis according to Parkes. All brand names and models were used for conventional fingertip testing.

OBJECTIVE:
The main objective of the study was to evaluate the accuracy and precision of the TRUEtrack® in comparison to the laboratory reference instrument.

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/m². The mean duration of diabetes was 17.7 ± 10.3 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 glucose oxidase reference method.

RESULTS:

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.

Table 1: Parkes Error Grid Analysis – Fingertip Testing

<table>
<thead>
<tr>
<th>Test Device</th>
<th>n</th>
<th>Error Zone A (%)</th>
<th>Error Zone B (%)</th>
<th>Error Zone C (%)</th>
<th>Error Zone D (%)</th>
<th>Error Zone E (%)</th>
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<tbody>
<tr>
<td>TRUEtrack</td>
<td>196</td>
<td>93.2%</td>
<td>6.3%</td>
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</tr>
<tr>
<td>OneTouch</td>
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<td>93.7%</td>
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Table 2: Parkes Error Grid Analysis – Forearm Testing

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<th>Error Zone D (%)</th>
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