

**PATIENT EVALUATION
ON SATISFACTION AND
EASE OF USE OF THE
TRUETRACK® SYSTEM**

NIPRO
DIAGNOSTICS™

PURPOSE:

The purpose of this study was to obtain feedback from patients with diabetes on satisfaction and ease of use of the TRUTrack® System. The study was a multi-center, randomized, clinical trial in which all subjects independently learned and used the TRUTrack® System.

DESIGN:

Diabetes healthcare professionals at four diabetes centers, nationwide, were contacted and asked to recruit patients to participate in the study. All patients that had a diagnosis of diabetes and were familiar with blood glucose monitoring could participate in the study. TRUTrack® System Meter Kits, Test Strips, Manufacturer Instructions For Use and a copy of the Study Procedure were distributed to study participants. Participants were asked to read the TRUTrack® System Owner's Manual and Instructions For Use, and to use the TRUTrack® System to perform several meter functions including setup, coding, and accessing data management options. Participants were also required to use the TRUTrack® System at home to perform blood glucose testing for a period of seven to ten days. After this period, participants completed a study questionnaire that asked them to rate their satisfaction with the TRUTrack® System features and to evaluate the ease of use of the TRUTrack® System blood glucose testing procedure. All questionnaires were returned to the study sponsor for analysis.

PARTICIPANTS:

Forty patients with diabetes agreed to participate in the study and were given the study kits by diabetes healthcare professionals, or the kits were sent to their homes. At the completion of the study only 34 of the 40 participants completed and returned the questionnaire within the stated timeframe. Participants ranged in age from 13-79 years. 29% of the participants had been

diagnosed with Type 1 diabetes and 59% with Type 2 diabetes. The remaining 12% failed to answer this question on the evaluation.

The reported time since diagnosis ranged from four weeks to 39 years, with 41% being diagnosed for less than five years. The most common meters used in the patient population were ACCU-CHEK® Advantage®, OneTouch® Ultra® and TheraSense FreeStyle. 59% of the population used their current systems, because they were recommended by their physicians, diabetes educators or dieticians. The most common payment method for testing supplies was managed care with a copayment (59%), followed by cash (23%), Medicare (12%), and then Medicaid (6%). The majority of the participants (88%) responded that they tested their blood glucose two to three times per day.

RESULTS AND DISCUSSION:

All participants rated their satisfaction and ease of use of the TRUTrack® System by completing a study questionnaire.

Evaluation Of Satisfaction With TRUTrack® System Features And Benefits

The first part of the questionnaire asked participants to evaluate five features and benefits of the TRUTrack® Blood Glucose Monitoring System. Participants were asked to rate their satisfaction of the system's features – from very unsatisfied to very satisfied (*Figure 1*).

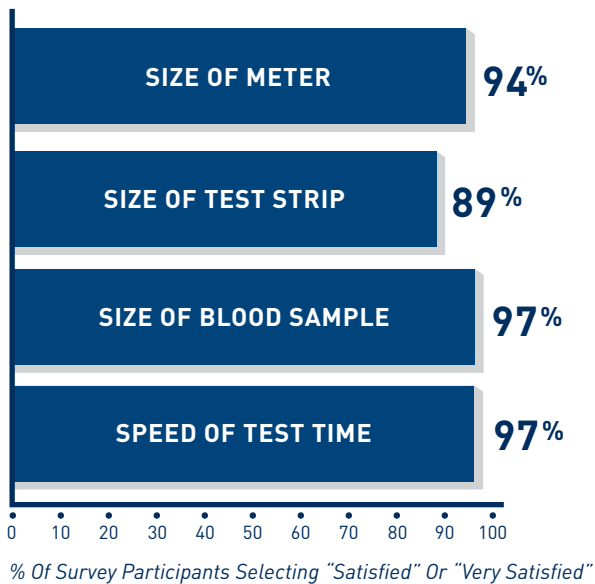


Figure 1

Responses to the questionnaire showed that participants were overwhelmingly satisfied with the key features of the TRUEtrack® System including the size of the meter and test strips, the amount of blood the test strips required and the fast, 10-second test time.

Evaluation Of Ease Of Use Of The TRUEtrack® System

The second part of the questionnaire asked the participants to rate, from very easy to very difficult, their experiences with setting up the meter options, coding the meters and performing blood glucose testing (Figure 2).

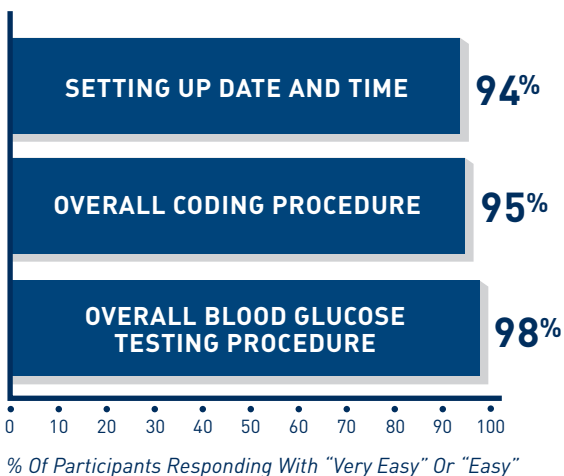


Figure 2

Participants positively rated setting up the meter and coding the meter as very easy or easy. The response to performing a blood glucose test was evaluated by the majority of participants as very easy/easy to perform. This rating included handling the test strips, locating the sample end of the test strip and applying the blood sample.

The final part of the questionnaire asked participants to evaluate the TRUEtrack® System in relation to daily self management of diabetes (Figure 3).

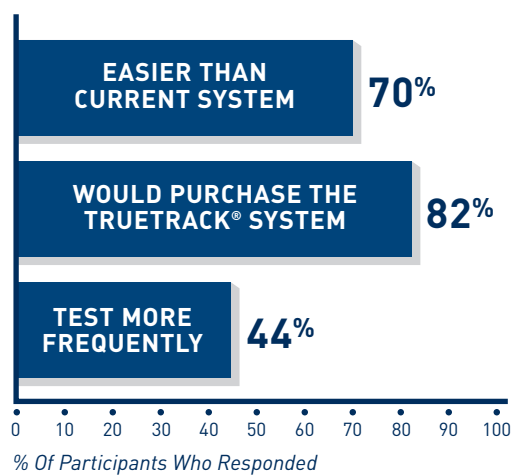


Figure 3

CONCLUSION :

Study participants gave high ratings to the TRUEtrack® System in terms of satisfaction with features and benefits, and overall ease of use of the system.

Participants were satisfied with the design of the meter including setup options, coding and blood glucose testing. Participants were also satisfied with the test strip design, and overwhelmingly agreed that it was easy to locate and apply blood to the test strip sample end. Further evaluation showed that 70% of the participants agreed that the TRUEtrack® System was easier to use than their current systems, and 82% said they would purchase a TRUEtrack® System to manage their diabetes. Almost half of all respondents (44%) agreed that they would test more often using the TRUEtrack® System.

