

Usability of a Hybrid Closed Loop Insulin Delivery System:

A Tandem t:slim X2™ Insulin Pump Formative Study



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Introduction

Hybrid Closed Loop (HCL) insulin delivery systems are being developed and used to minimize fluctuations in blood glucose levels associated with insulin therapy in people with diabetes. Usability of these systems is critical for their effectiveness.

The aim of this formative study was to assess the usability of a touchscreen, wearable insulin pump with an operating system that automatically adjusts insulin delivery (Control-IQ™ algorithm) based on a) continuous glucose monitoring (CGM) readings and b) user inputs that inform the algorithm of food intake and activity levels.



Methods

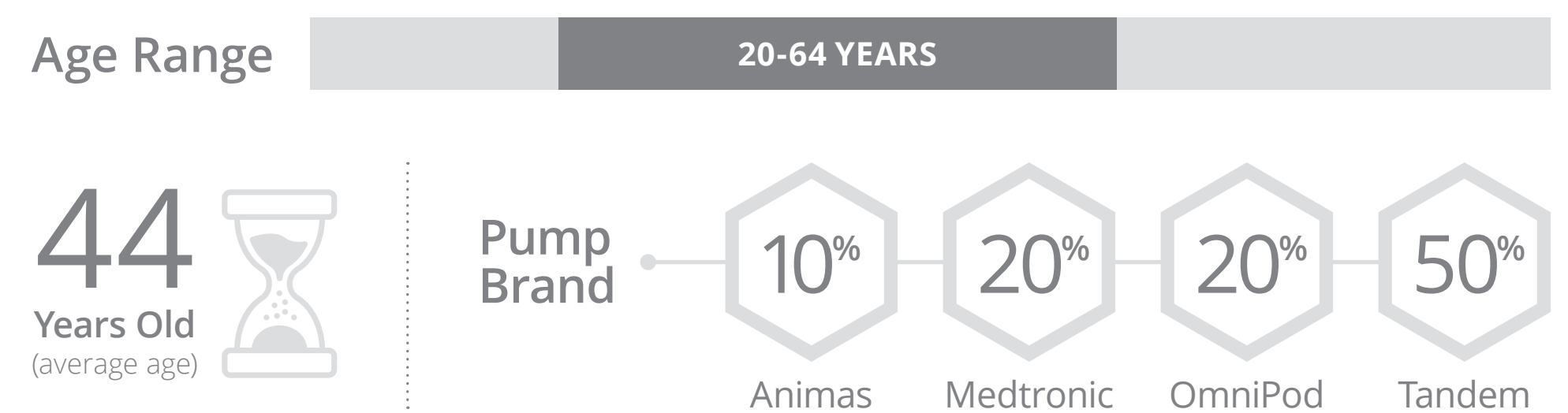
The study was conducted over the course of 3 days at an external research facility located in San Diego, CA. Test stimuli used in this study included static, electronically-displayed screen shots on an Android phone, and a functional prototype Graphical User Interface running on the Tandem t:slim X2™ Insulin Pump. 10 adult participants with experience using CGM and insulin pumps completed the study. After a 10-minute orientation to the t:slim X2 Insulin Pump, and HCL theory of operation, the participants were given real-life scenarios as context for 10 simulated use tasks and 8 knowledge tests. The study protocol was designed to assess the ease of use of a t:slim X2 Pump designed with a prototype HCL algorithm. Simulated use tasks had the users interact with the pump operating with a prototype of the HCL software, and knowledge tests utilized a smartphone to display

static images of prototype HCL pump screens. Task completion scores and ease of use scores were collected after simulated use tasks, and a System Usability Scale (SUS) questionnaire was administered at the end of each 1:1 session.

EVERYDAY TASKS

Participants were provided with real-world scenarios as context for tasks that asked them to enable and disable the HCL feature on the pump, input carbs into the pump and deliver a meal bolus, inform the pump of their current activity level (sleeping or exercising) and also assess if the pump was managing their current insulin needs based on the information provided to them on the different prototype screens.

▼ FIGURE 1: Demographics of Study Participants. All participants used an insulin pump and a CGM prior to enrolling in the study and have type 1 diabetes.

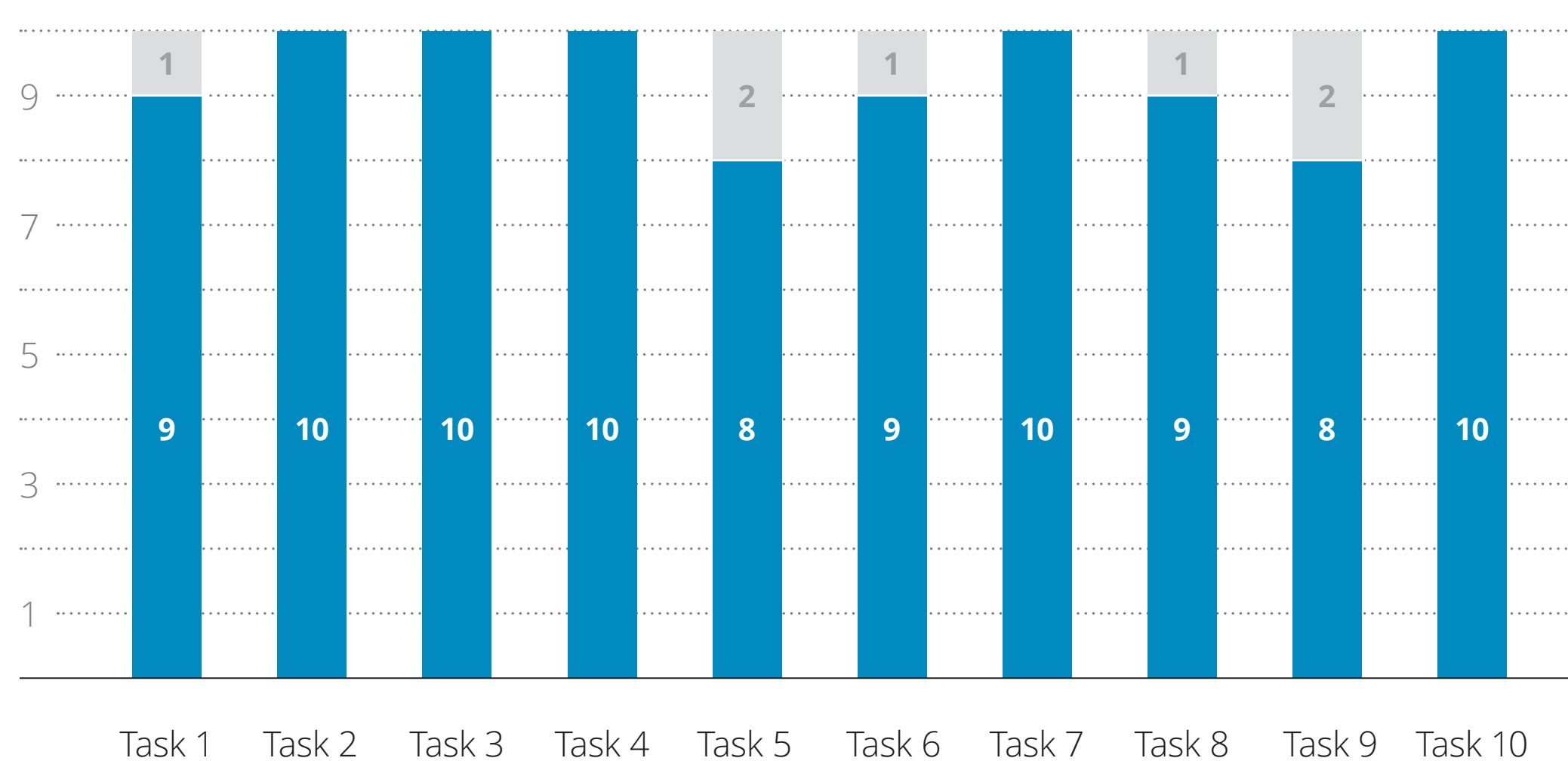


Results

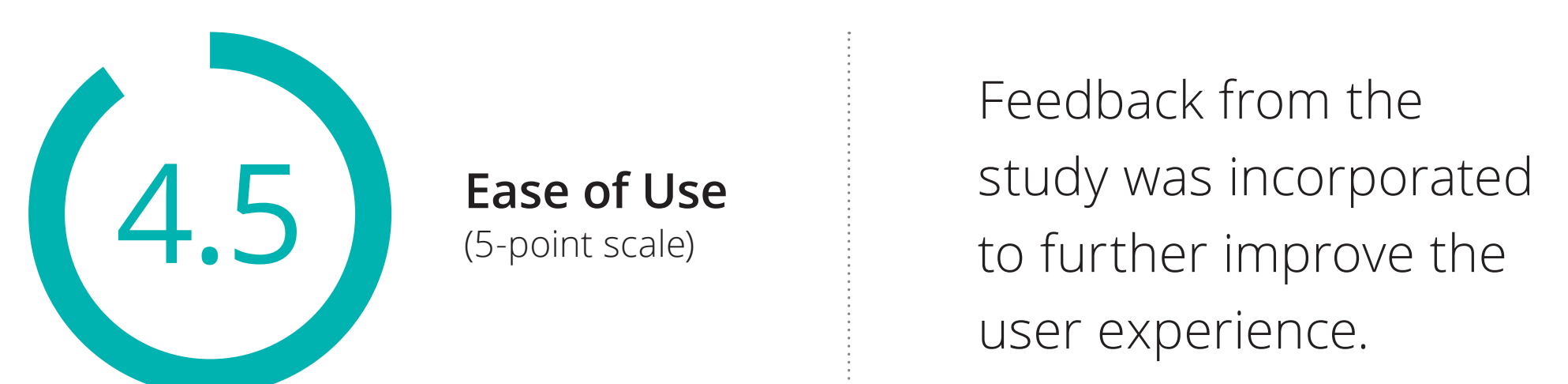
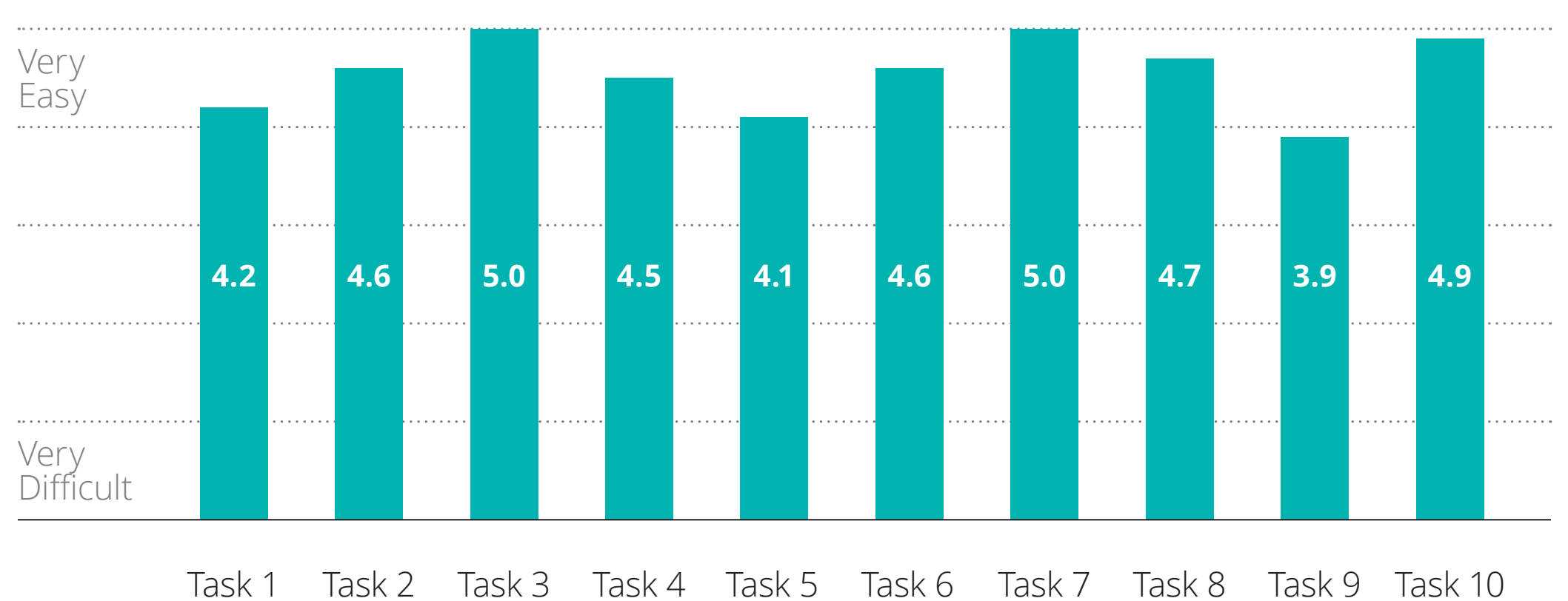
In simulated use, the average task completion rates range from 80%-100% for all measured tasks, with an overall 93% completion rate.

In simulated use, the average ease of use scores range between 3.9-5.0 for all measured tasks, with an overall average of 4.5 (5-Very Easy) with insignificant differences between the Tandem and non-Tandem pump users.

▼ FIGURE 2: Task Completion. Simulated use pass (■) and fail (■) scores of participants.



▼ FIGURE 3: Average Subjective Ease of Use Ratings. Ranges from Very Difficult (1) to Very Easy (5).



▲ FIGURE 4: Observed Metrics. The average System Usability Scale (SUS) score of 84 indicates high user satisfaction. Based on research, a SUS score above a 68 would be considered above average.

CONCLUSION: The Tandem t:slim X2 Insulin Pump with a Hybrid Closed Loop (HCL) insulin delivery system is intuitive and easy to use after minimal training.