



# The Usability of a Hybrid Closed-Loop Insulin Delivery System: Simulated Use Studies of the t:slim X2 Insulin Pump With Control-IQ Technology

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## Introduction

Advanced hybrid closed-loop (AHCL) 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 objective of these studies was to assess the usability and safety of a touchscreen, wearable insulin pump with an operating system that automatically adjusts insulin delivery based on a) predicted continuous glucose monitoring (CGM) readings and b) user input that informs the insulin pump of food intake and activity levels.



## Methods

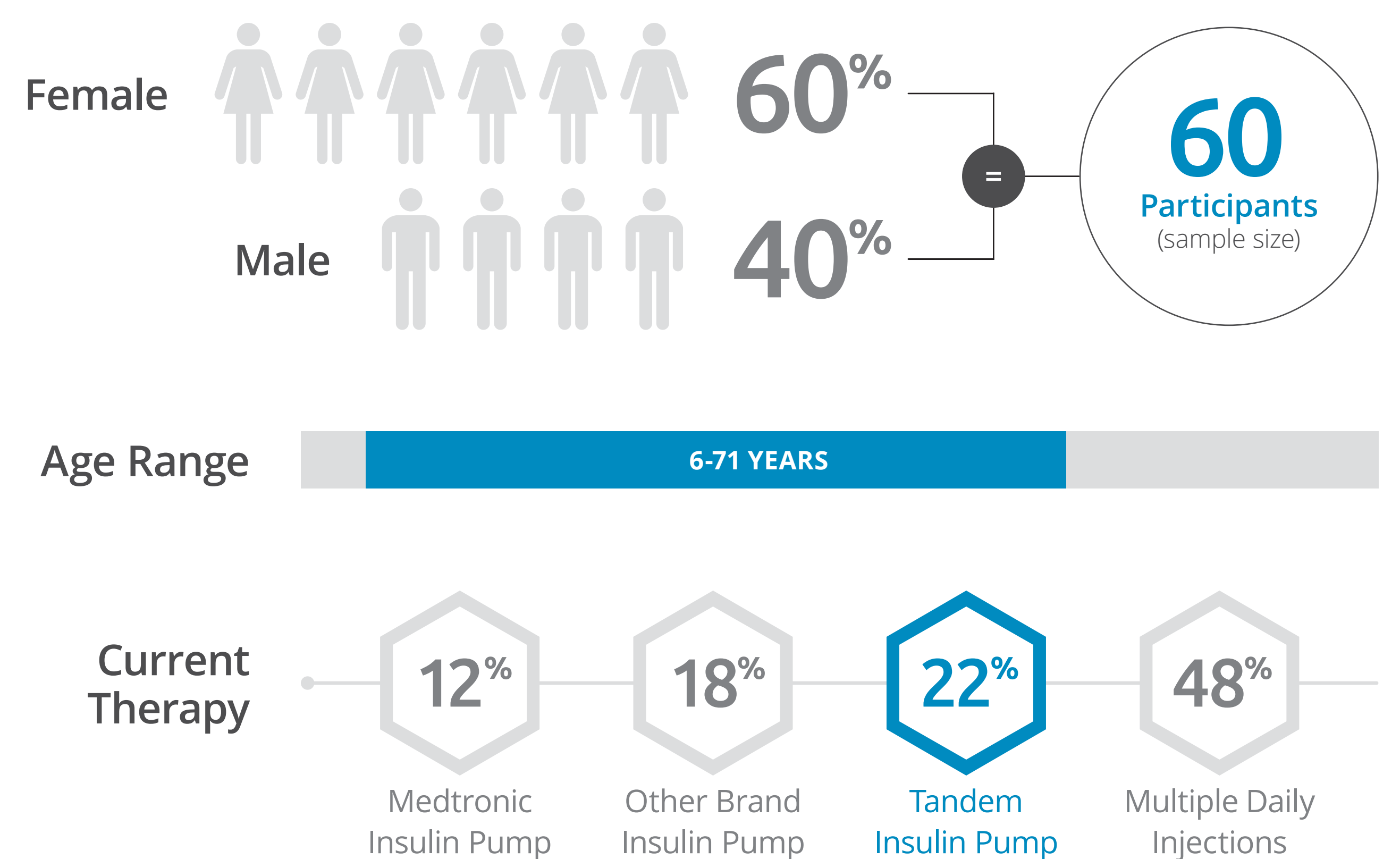
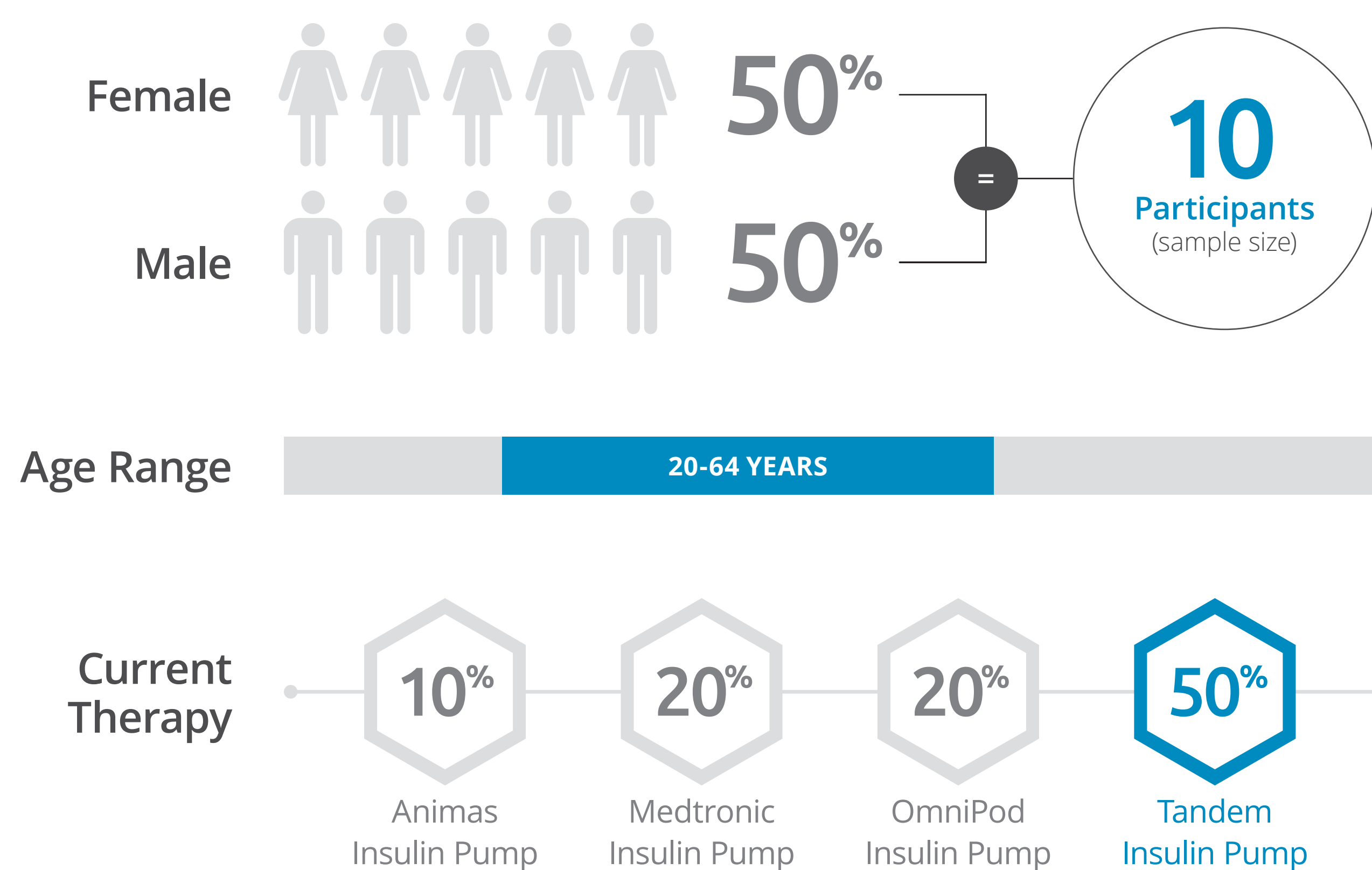
70 participants, composed of insulin pump users and multiple daily injection (MDI) users, completed the usability studies. The participants were given real-life scenarios as context for simulated use tasks and knowledge tests. Tasks and tests were designed to assess the safety and ease of use of the t:slim X2™ insulin pump designed with an AHCL insulin delivery system (Control-IQ™ technology). Task success rates

were collected, and a Systems Usability Scale (SUS) questionnaire was administered at the end of each session.

The formative study gave its 10 adult insulin pump users a 10-minute orientation to the system. The summative study gave its 60 pump and MDI users real-world training, with a memory decay period before testing.

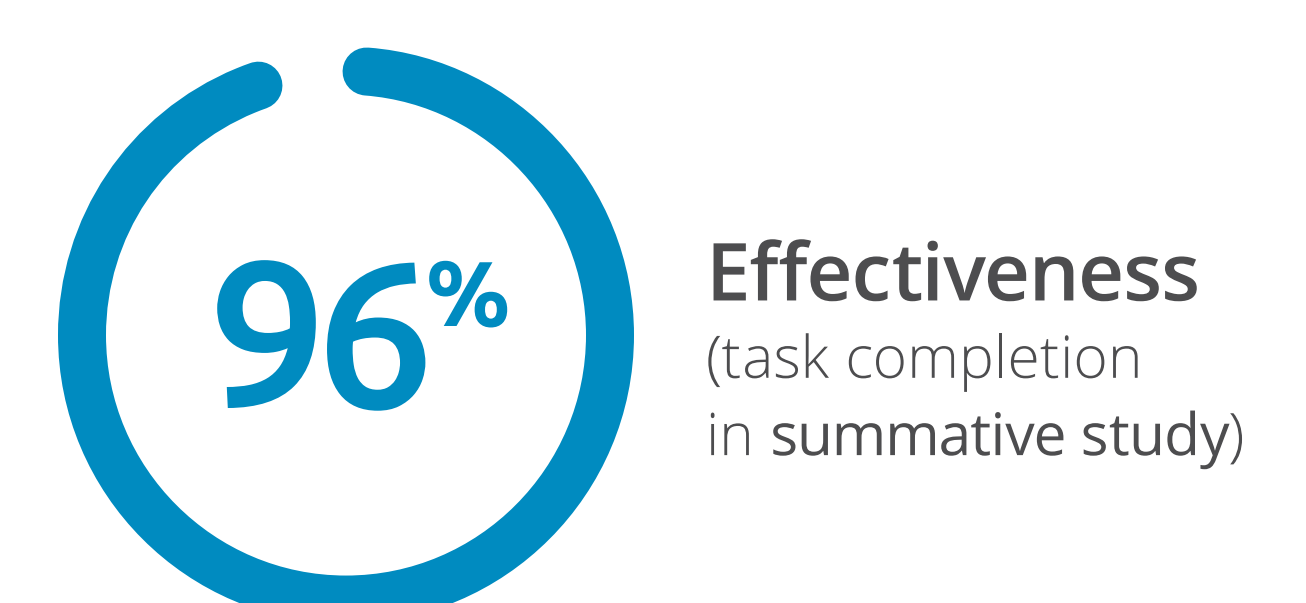
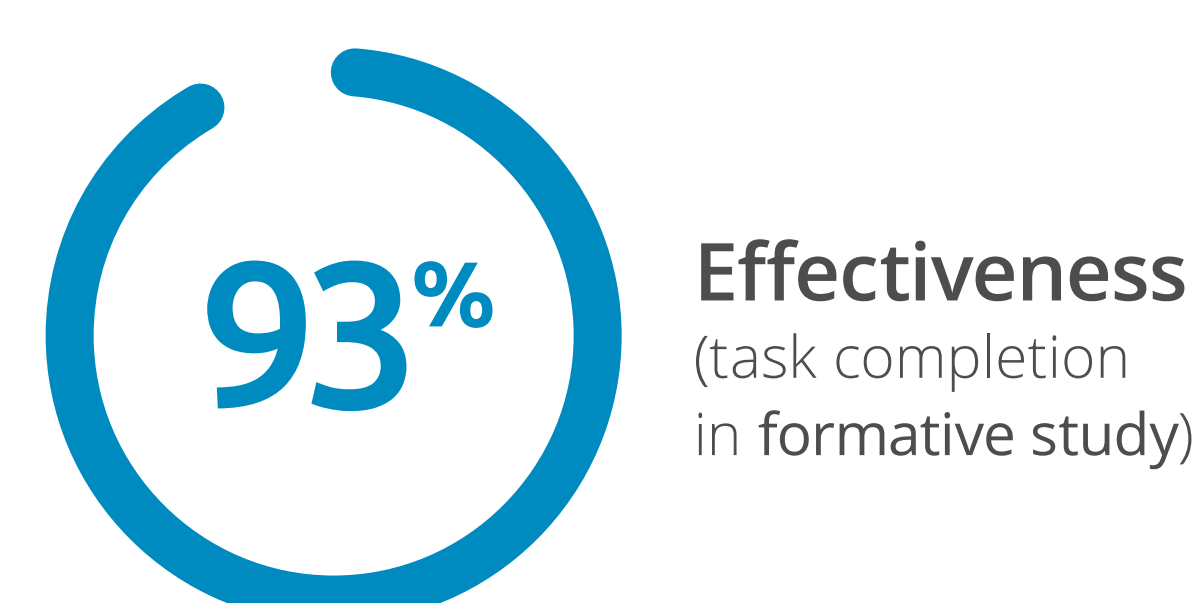
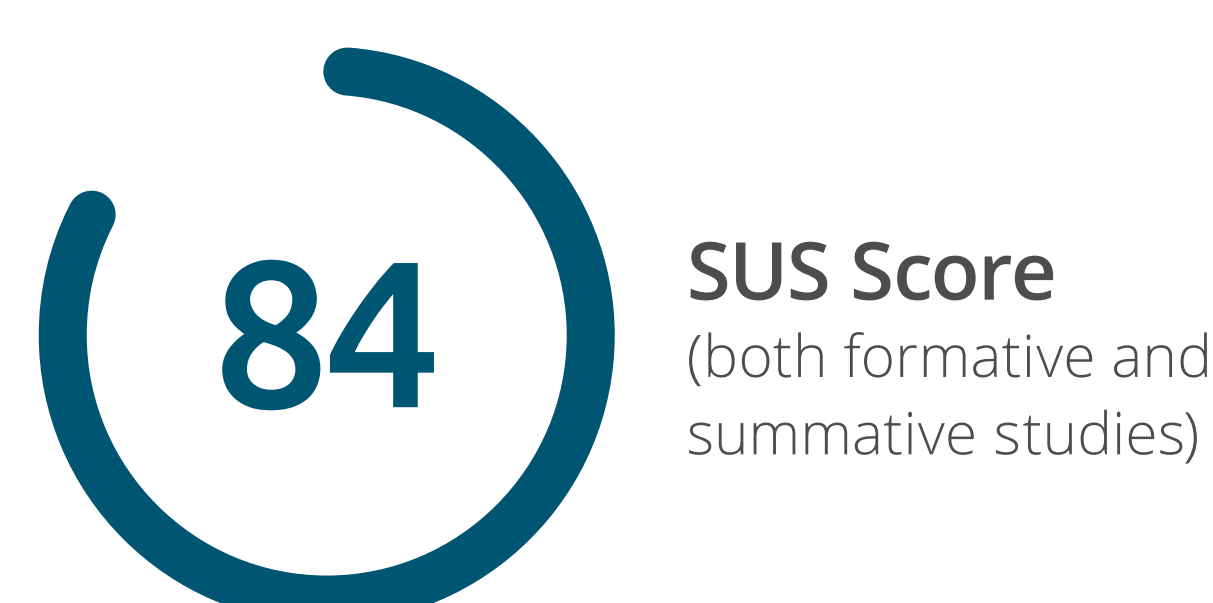
▼ **FIGURE 1: Demographics of Formative Study Participants.** All participants have type 1 diabetes and used an insulin pump and CGM prior to enrolling in the study.

▼ **FIGURE 2: Demographics of Summative Study Participants.** All participants have type 1 diabetes and used either an insulin pump or MDI prior to enrolling in the study.



## Results

The average SUS scores for the formative and summative tests were identical at 84, indicating a high user satisfaction (typical scores 65-75). Task completion rates of 93% and 96% were observed, respectively.



## CONCLUSIONS

The findings indicate that the t:slim X2 insulin pump with an advanced hybrid closed-loop insulin delivery system from Tandem Diabetes Care, in simulated use, was both intuitive and safe to use.