Use Cases

USE CASE 1: Getting to Know the t:slim X2 Insulin Pump

Primary Actor:

- Pump User

Stakeholders and Interests:

- <u>Pump User:</u> Wants to understand the layout and navigation features of the pump for efficient use.
- Pump Manufacturer: Aims to provide a user-friendly interface that supports insulin management

Preconditions:

- Pump is powered on
- User has completed the initial setup
- Pump interface is unlocked and functional

Success Guarantees:

- User can identify key components on the home screen (battery, insulin, IOB)
- User understands the function of the main navigation buttons
- User is able to navigate between screens and return to the home screen

Main Success Scenario:

- 1. User powers on the t:slim X2 pump
- 2. User observes the battery indicator, insulin fill gauge and the Insulin on Board (IOB).
- 3. User clicks the bolus button which opens the bolus calculator.
- 4. User clicks the options button to access Insulin delivery settings, alerts and system configurations
- 5. User navigates to different screens and taps the Tandem logo at any time to return to the home screen

Extensions:

3a. User clicks the bolus button accidentally

- 3a1. System shows bolus calculator with a cancel option
- 3a2. User cancels and returns to the home screen

5a. User explores the options menu without saving changes

5a1. System automatically saves previous settings unless user confirms a change

USE CASE 2: Getting Started

Primary Actor:

- Pump User

Stakeholders and Interests:

- <u>Pump User:</u> Wants to power on and set up the pump to begin using it for insulin delivery
- Pump Manufacturer: Ensures a smooth onboarding process that prepares users to operate the pump

Preconditions:

- User has the t:slim X2 insulin pump and the provided USB charging cable
- Pump is not yet fully set up or recently powered off

Success Guarantees:

- Pump is charged and powered on
- User understands how to turn the pump on/off and use the touchscreen interface

Main Success Scenario:

- 1. User connects the pump to a power source using the provided USB charging cable
- 2. Battery indicator displays the charging progress
- 3. Once charged, user holds the power button until the startup sequence completes
- 4. Home screen appears with access to pump functions
- 5. User navigates through screens using the touchscreen interface
- 6. User opens the Options menu to explore system settings
- 7. User learns how to turn off the pump screen or put it to sleep through the options menu
- 8. Pump is now ready for insulin delivery

Extensions:

2a. Battery is too low to power on

- 2a1. System displays low battery warning
- 2a2. User connects pump to a charger and waits until it reaches a minimum charge level

USE CASE 3: Manage Insulin Delivery Settings

Primary Actor:

- Pump User

Stakeholders and Interests:

- <u>Pump User:</u> Wants to create and manage insulin profiles for different daily routines (ex. morning, exercise, etc.) to better control glucose levels.
- Control IO System: Relies on accurate user settings to calculate insulin doses and adjust delivery.

Preconditions:

- Pump is powered on and charged.
- User has successfully logged into the pump interface.

Success Guarantees:

- Users can create, view, update, and delete personal profiles.
- Profile changes are stored and used by Control IQ for insulin delivery calculations.

- Profiles are accessible and labeled based on the user's routines

Main Success Scenario:

- 1. User navigates to the Personal Profiles section and selects "Create New Profile"
- 2. System prompts user to enter:
 - Profile name (e.g., "Morning Routine", "Exercise Mode").
 - Basal rates, carbohydrate ratios, correction factors, target glucose levels
- 3. User creates and save new profiles.
- 4. User selects a profile to update & system allows editing of any field.
- 5. User can delete profiles that are no longer needed
- 6. System updates the list of available profiles and reflects changes in insulin delivery behavior.

Extensions:

2a. User attempts to create a profile with missing or invalid data.

- 2a1. System displays error message indicating required fields.
- 2a2. User corrects input and resubmits.

3a. User tries to create a profile with a duplicate name.

3a1. System prompts user to choose a different name.

4a. User cancels midway through editing/updating a profile.

4a1. System discards unsaved changes and returns to the profile list.

USE CASE 4: Manual Bolus Delivery

Primary Actor:

- Pump User

Stakeholders and Interests:

- Pump User: Wants to deliver insulin bolus based on current glucose level & carbohydrate intake.
- <u>Control IQ System:</u> Provides suggested bolus recommendations based on CGM data and user settings to control glucose levels.

Preconditions:

- Pump is powered on and charged.
- User has successfully logged into the pump interface.
- Personal profile (with insulin-to-carb ratio, sensitivity, and target glucose) is set up.
- CGM is connected for automatic retrieval of current blood glucose level and carbohydrate intake.
- Insulin must be available in the cartridge.

Success Guarantees:

- User delivers a bolus based on calculator recommendations or manual adjustment.
- Bolus data is logged, including insulin dose, time, and any CGM-related information.

- The Insulin on Board (IOB) display updates to show the current amount of active insulin remaining in the body.

Main Success Scenario:

- 1. User presses on the bolus button or accesses the bolus calculator via the home screen.
- 2. User enters blood glucose level & carbohydrate intake (manually or autofilled).
- 3. Bolus calculator uses the user's profile settings (insulin sensitivity, carb ratio, and target glucose) to suggest a dose.
- 4. User reviews the suggested bolus dose.
- 5. User accepts the suggested dose or manually adjusts (override) based on current needs.
- 6. User selects between standard (immediate) or extended delivery methods (delivered over time).
- 7. User confirms and initiates bolus delivery.
- 8. Pump delivers the bolus and logs the event.
- 9. IOB indicator is updated to reflect the active insulin from the new bolus.
- 10. User can cancel bolus mid-delivery if needed.

Extensions:

5a. User cancels bolus mid-delivery

- 5a1. Pump stops insulin delivery immediately.
- 5a2. Partial dose is recorded, and the system logs the cancellation with timestamp.

CASE 5: Start, Stop or Resume Insulin Delivery

Primary Actors:

- Pump user
- Control IQ System

Stakeholders and Interests:

- **Pump User:** Wants a safe, consistent insulin delivery that can be started, stopped or resumed based on personal and/or medical needs
- **Control IQ System:** Ensures insulin is delivered only when appropriate and adjusts automatically to CGM feedback to maintain user safety

Preconditions:

- Pump is powered and on
- User has selected a valid personal profile or configured a manual basal rate
- CGM is connected and providing valid glucose readings

Success Guarantees:

- Insulin delivery is active at the intended basal rate, paused appropriately, or resumed safely with updated system logging
- Any interruption due to low glucose is logged and acted on according to safety protocols

Main Success Scenario:

- 1. User navigates to the Basal Rate menu thru the touchscreen
- 2. User selects an active personal profile or manually enters a basal rate
- 3. System begins continuous basal insulin delivery at the configured rate
- 4. System, monitors CGM data using control IQ
- 5. If blood glucose drops below 3.9 mmol/L, the system automatically suspends delivery
- 6. Event gets logged with timestamp and glucose reading
- 7. When glucose stabilizes, the system:
 - a. Resumes previous basal rate
 - b. Prompts user to switch to a new profile
- 8. User can manually stop insulin delivery though the system menu at any moment
- 9. Manual resumption is possible through the Resume Basal option or by selecting a new profile

Extensions:

5a. CGM data temporarily unavailable

- 5a1. Control IQ pauses auto-adjustments and defaults to user-defined basal rate.
- 5a2. System displays warning

8a. User attempts to stop insulin delivery during an active Control IQ alert

- 8a1. System confirms with an alert and requires user acknowledgment
- 8a2. Delivery is paused, and the event is logged

7b. Glucose does not stabilize after 15 minutes

- 7b1. System keeps delivery suspended and displays a caution message
- 7b2. User is prompted to take corrective action

USE CASE 6: View Pump Information and History (Data Storage)

Primary Actors:

- Pump Users

Stakeholders and Interests:

- **Pump User:** wants to view insulin delivery history to monitor their treatment
- **Healthcare provider:** wants to utilize logged data to optimize treatment plans and assess insulin effectiveness

Preconditions:

- Pump is powered and on
- Insulin delivery events and alerts have been logged by the system

Success Guarantees:

- User is able to access accurate records of insulin delivery events and CGM triggered alerts

Main Success Scenario:

- 1. User selects Status or History menu through the touchscreen
- 2. System displays an overview of recent insulin activity (Time and dosage of last bolus, current basal rate and insulin duration, alerts triggered by CGM readings) all organized by timestamp
- 3. Each event displays its type, amount of insulin, and related CGM context
- 4. The user filters the view by event type or selects a specific date range
- 5. System retains historical data

Extensions:

5a. The user taps on a specific event entry.

5a1. The system expands the entry to show detailed data, including active profile settings and CGM readings at that time.

7a. The user chooses to export their history.

- 7a1. The system prompts the user to confirm the export.
- 7a2. The data is exported securely in a readable format to a connected device or platform.

USE CASE 7: Detect and Respond to Pump Malfunction (Error Handling)

Primary Actors:

- Pump User
- Error monitoring system

Stakeholders and Interests:

- **Pump User:** wants to be alerted immediately about any pump issues and receive instructions to fix them
- **Healthcare provider:** needs access to error logs to ensure patient well-being and safety
- **Error monitoring System:** detects malfunctions, suspends insulin delivery if required, and prevents unsafe operation.

Preconditions:

- Pump is powered and on
- Alerts and diagnostic features are functional

Success Guarantees:

- System detects malfunctions, alerts the user, safely suspend insulin delivery when required and logs the issue

Main Success Scenario:

- 1. Pump system continuously monitors internal and external components
- 2. A malfunction is detected such as: low battery, low insulin, blockage, CGM disconnection
- 3. System immediately triggers a warning
- 4. System provides guidance based on issue

- 5. If malfunction is considered critical, the pump's error handling system automatically suspends insulin delivery to prevent incorrect dosing, while keeping logs and malfunctions maintained
- 6. If the issue is severe, the system provides guidance on restarting or contacting support if necessary
- 7. User follows the provided instructions to resolve the issue
- 8. After successful resolution, the system will resume normal operation

Extensions:

4a. The user attempts to dismiss or ignore a critical error.

4a1. The system blocks the dismissal and prompts confirmation before proceeding

7a. System provides guidance on a specific issue.

- 7a1. A malfunction such as a CGM disconnection is detected.
- 7a2. The system displays a message describing the issue: "CGM disconnected. Please reconnect sensor".
- 7a3. Once resolved, the system confirms that the issue has been fixed.