

1) Initialize Pump System

Primary Actor(s): User (patient)

Stakeholders:

- User: wants to begin using the pump for insulin management
- Pump System: load essential data and prepare for safe operation

Preconditions: pump is powered on and battery level is sufficient to operate

Postconditions: user is presented with home screen and user profiles and system data (insulin + glucose levels) are successfully loaded

Main Success Scenario:

1. The user powers on the pump.
2. The system performs a hardware and software check.
3. The system retrieves and loads user profile data.
4. The system reads the current insulin reserve and CGM data.
5. The home screen is displayed, showing battery level, insulin remaining, IOB, and glucose readings.
6. The system is ready for interaction (bolus input, profile management).

Extensions:

2a. If a hardware/software error is detected, the system enters safety mode and displays an error.

3a. If no user profiles are found, the system prompts the user to create a new profile.

4a. If CGM is disconnected, an alert is shown and the system waits for reconnection or manual input.

2) Create or Modify personal profile

Primary Actor(s): User

Stakeholders:

- User: wants custom insulin delivery settings based on lifestyle & routines
- Pump System: uses profile data for calculations

Preconditions: Pump is initialized & unlocked and user is active on profile or settings screen

Postconditions: a new/updated profile is saved in the system and available for insulin delivery logic

Main Success Scenario:

1. The user navigates to the Profile Settings screen.
2. The user selects "Create New Profile" or "Edit Existing Profile."
3. The system prompts for inputs: name, basal rate, carb ratio, correction factor, target glucose.
4. The user enters the required data.
5. The system validates inputs and saves the profile.
6. Confirmation is shown and the profile is now active or stored for selection.

Extensions:

3a. If an existing profile is selected, pre-filled data is shown for editing.

5a. If validation fails (missing or invalid values), an error message is displayed.

6a. If the user cancels before saving, changes are discarded.

3) Deliver Manual Bolus

Primary Actor(s): User

Stakeholders:

- User: needs to administer insulin based on meal or glucose level
- Pump System: delivers insulin accurately and logs the event

Preconditions: pump is unlocked and user has active profile and sufficient insulin is available

Postconditions: Insulin in as a bolus and action is logged and IOB updated

Main Success Scenario:

1. The user navigates to the Manual Bolus screen.
2. The system prompts for carbohydrate intake and/or current glucose level.
3. The user inputs values or imports from CGM.
4. The system calculates the suggested insulin dose based on profile settings.
5. The user reviews the suggestion.
6. The user confirms and initiates bolus delivery.
7. The pump delivers the insulin.
8. The event is logged in history, and IOB is updated.

Extensions:

- 3a. If CGM data is unavailable, user inputs values manually.
- 5a. If the user overrides the suggested dose, the override is recorded.
- 6a. If the user cancels before delivery, no insulin is delivered.
- 7a. If an error occurs (occlusion), an alert is shown and delivery is aborted.

4) Calculate Bolus Dose

Primary Actor(s): User, Bolus Calculator

Stakeholders:

- User: wants accurate insulin dosing suggestions for safe glucose management
- Bolus Calculator Module: performs dose computation based on personalized factors

Preconditions: Pump is active and user has an active profile and carbohydrate intake or glucose level is provided.

Postconditions: A suggested insulin dose is calculated and displayed to the user

Main Success Scenario:

1. The user accesses the Bolus Calculator.
2. The system prompts for carbohydrate intake and current glucose level.
3. The user inputs values manually or imports from CGM.
4. The Bolus Calculator uses the user's basal rate, insulin sensitivity, carb ratio, and target glucose to compute the dose.
5. The calculated dose is displayed to the user for confirmation.

Extensions:

- 3a. If CGM data is missing or unavailable, user must provide manual input.
- 4a. If inputs are out of acceptable range, validation prompts user to correct them.
- 5a. If the user disagrees with the calculated dose, they can override it from case 3.

5) Monitor and Adjust Insulin Delivery

Primary Actor(s): Control IQ technology - algorithm?

Stakeholders:

- User: relies on safe, automated glucose regulation
- Control IQ: ensures stable glucose levels through dynamic insulin adjustments

Preconditions: CGM connected and transmitting data, pump = active & delivering insulin and user profile loaded

Postconditions: insulin delivery is adjusted based on glucose and adjustments are logged for future review

Main Success Scenario:

1. Control IQ receives real-time CGM readings.
2. It predicts the glucose level 30 minutes into the future.
3. Based on predictions:

- If glucose is within 6.25–8.9 mmol/L, maintain current delivery.
- If glucose is rising above 8.9, increase insulin delivery.
- If glucose is falling below 6.25, reduce insulin delivery.
- If glucose is predicted to fall below 3.9, suspend insulin delivery.
- 4. If glucose is predicted to reach or exceed 10 mmol/L, deliver automatic correction bolus.
- 5. Status and adjustments are visually reflected on the home screen.
- 6. All actions are logged by the system.

Extensions:

- 1a. If CGM connection is lost, Control IQ pauses adjustments and triggers an alert.
- 3d. If basal insulin is suspended, it automatically resumes once safe glucose levels are predicted.
- 4a. Correction bolus is only delivered if allowed by user settings and timing of prior doses.

6) Suspend and resume insulin delivery

Primary Actor(s): User, ControlIQAlgorithm

Stakeholders:

- User: wants to avoid insulin overdose during low glucose episodes
- Pump System: must ensure safe management of insulin delivery

Preconditions: Pump is powered and running, insulin delivery is active and CGM is functioning or manual readings are available

Postconditions: insulin delivery is either suspended or resumed, and actions are logged in the system

Main Success Scenario:

1. Glucose levels drop below the safety threshold (3.9 mmol/L).
2. Control IQ Algorithm predicts continued drop and triggers suspension of basal insulin.
3. The system halts basal delivery and displays a red icon on the status screen.
4. Once glucose levels recover (predicted above 3.9 mmol/L), Control IQ resumes insulin delivery.
5. The previous basal rate or updated profile settings are restored.
6. All events are recorded in the history log.

Extensions:

- 2a. The user manually suspends insulin delivery via the options menu.
- 4a. The user manually resumes delivery at their discretion.
- 3a. If suspension continues beyond a critical time window, an alert is triggered.
- 5a. If a profile change occurred during suspension, resumed delivery uses new settings.

7) Handling Pump Malfunction or Alert

Primary Actor(s): Pump System, ErrorHandling

Stakeholders:

- User: wants to stay informed about system errors to take corrective action
- Pump System: must detect, report, and respond to faults or critical events

Preconditions: Pump is powered on and in active use and system monitoring functions are operational

Postconditions: User is notified of the issue, action is taken (automatic or manual) to handle or resolve the problem and critical errors may result in insulin delivery suspension and safety mode activation

Main Success Scenario:

1. The system detects an error (low battery, insulin low, occlusion, CGM disconnection).
2. Error Handling module identifies the error type and severity.
3. A visual and/or audio alert is triggered.
4. A message is displayed explaining the issue and suggesting corrective action.
5. The user acknowledges and addresses the alert (charges battery, refills insulin).

6. If necessary, the system suspends insulin delivery and enters safety mode.
7. Once resolved, the system resumes normal operation and logs the incident.

Extensions:

- 2a. For critical errors (pump failure), system shuts down non-essential functions and preserves logs.
- 3a. Alerts repeat periodically if unresolved.
- 5a. If user takes no action in a critical situation, emergency protocols are escalated (emergency stop).

8) View History and DataLogs

Primary Actor(s): User

Stakeholders:

- User: wants to monitor past insulin usage and system behavior for better diabetes management
- Healthcare Provider (indirect): may use the data for treatment decisions

Preconditions: Pump is powered on and accessible and historical data has been logged from previous usage

Postconditions: User successfully views past insulin deliveries, alerts, and system activity and data may be exported or shared

Main Success Scenario:

1. The user navigates to the History screen from the home or options menu.
2. The system displays a list or graph of logged events (bolus, basal adjustments, alerts).
3. The user filters the data by date, event type, or glucose levels.
4. The user selects a specific entry to view detailed information (time, dose, glucose reading).
5. (Optional) the user exports the data log for external review or backup.

Extensions:

- 2a. If no history is available, the system displays a message: "No records to show."
- 3a. If data logs are corrupted, a recovery or error message is shown.
- 5a. Export may be restricted based on pump settings or file system availability.

9) Unlocking pump w/ PIN

Primary Actor(s): User

Stakeholders:

- User: wants to prevent unauthorized access while maintaining ease of use
- Pump System: ensures security of sensitive functions and data

Preconditions: Pump is powered on and lock screen is active and PIN protection is enabled

Postconditions: User gains access to the home screen and pump functionality and system logs successful or failed unlock attempts

Main Success Scenario:

1. The user activates the screen and is presented with the PIN entry interface.
2. The user enters their PIN code.
3. The system validates the PIN against stored credentials.
4. If correct, the lock screen disappears and the user is taken to the home screen.

Extensions:

- 2a. If the entered PIN is incorrect, an error message is displayed.
- 2b. After multiple failed attempts, a timeout period is enforced.
- 4a. A forgotten PIN option prompts the user to follow a recovery or reset procedure (if needed).

10) Navigating between screens

Primary Actor(s): User

Stakeholders:

- User: needs intuitive access to all pump functions for efficient diabetes management
- Pump System: must ensure smooth, responsive UI transitions

Preconditions: Pump is unlocked and responsive and user is interacting with the touchscreen interface

Postconditions: Target screen is displayed and ready for interaction and navigation state is updated in the UI

Main Success Scenario:

1. The user taps a navigation button (Bolus, Settings, History).
2. The system registers the tap input.
3. The corresponding screen (Bolus Calculator, Profile Settings) is loaded and displayed.
4. UI elements are refreshed based on the context of the new screen.
5. The user can perform actions or return to the home screen using the Tandem logo or navigation options.

Extensions:

2a. If input is delayed or misregistered, the system prompts the user to retry.

3a. If navigation fails due to a system issue, an error message is shown and the user is redirected to the home screen.

4a. Contextual data (like current glucose or IOB) is retained and displayed across screens.