

## Use Case 1: View Home Screen

- Primary Actors:
  - User
- Stakeholders:
  - Healthcare providers
  - Developers
- Preconditions:
  - Pump is powered on and initialized
  - User is authenticated basal ator (upper-left, percentage/recharge status)
    - Insulin fill gauge (upper-right, 300-unit cartridge level)
    - Insulin on Board (IOB) (active insulin duration)
    - CGM Glucose Value (central display with trend arrow)
    - Control IQ status icons
    - Navigation buttons (Bolus, Options, Tandem logo to return home)
- Main Success Scenario:
  - User taps the Tandem logo to return to the home screen
  - System navigates to the home screen, displaying:
    - Current insulin delivery details (basal rate, bolus activity).
    - CGM trend with arrows indicating glucose rise or drop.
    - Battery & insulin fill levels for quick monitoring.
- Extensions:
  - Low Battery: The battery indicator shows a warning icon or percentage when charge is low, prompting the user to recharge. System logs the low battery warning event.

- Low Insulin: The insulin gauge shows a warning when the cartridge level is low, advising the user to replace it soon. System logs the low insulin warning event.
- CGM Disconnects: If the CGM signal is lost, the glucose value area displays dashes or a message indicating unavailability. System logs the CGM disconnection event.
- Control IQ Status: Icons might change color or show alerts if Control IQ encounters issues or adjusts insulin delivery significantly. System logs significant status changes or alerts.

## Use Case 2: Power on the Pump

- Primary Actors:
  - User
- Stakeholders:
  - Regulatory Team
- Preconditions:
  - Pump is charged enough
  - Power is functional
- Success Guarantee:
  - Pump boots to home screen in minimal time
  - Control IQ initializes with last used-profile
- Main Success Scenario:
  - User presses and holds to power button
  - System performs self check initialization sequence
  - Pump displays startup animation and loads home screen
  - The pump retrieves the last used personal profile

- Control IQ initializes and resumes glucose monitoring
  - CGM connection is restored, and trend data is displayed
  - For security, a PIN-based lock screen can be set up to prevent accidental inputs
- Extensions:
  - Dead battery: The pump does not turn on at all. Requires charging first.
  - Startup error: The pump shows an error message during the self-check (e.g., memory issue, sensor failure) and may not reach the home screen. Requires troubleshooting or support. System logs the specific startup error.
  - PIN Required: If a security PIN is set, the user must enter it correctly after startup to unlock the pump interface.
  - Profile Issue: The last used profile might be corrupted or missing, requiring the user to select or create a profile. System logs the profile loading issue.
  - CGM Connection Failure: The pump might fail to connect to the CGM sensor during initialization. System logs the CGM connection failure event.

## Use Case 3: Power off or Sleep mode

- Primary Actors:
  - User
- Stakeholders:
  - Regulatory Team
- Preconditions:
  - Pump is idle
- Success Guarantee:

- Screen dims or powers off, based on user choice.
- If in Sleep Mode, insulin delivery continues normally.
- Main Success Scenario:
  - User navigates to the power settings
  - Selects power off or sleep
  - For Power off
    - User confirms shutdown
    - Pump safely terminates processes and shuts down
  - For Sleep mode:
    - Screen dims after inactivity
    - Pump continues insulin delivery
- Extensions:
  - Active bolus: The system may prevent shutdown or sleep if a bolus delivery is currently in progress, asking the user to wait or cancel the bolus. (System would log the prevented action).
  - Control IQ adjustments: If Control IQ is actively adjusting insulin (e.g., giving an automatic bolus), shutdown might be delayed. (System would log the delay reason).
  - Critical Alerts: If a critical alert occurs (like occlusion or very low glucose), the screen will turn on automatically, overriding sleep mode, and the pump may prevent shutdown until the alert is addressed. The critical alert itself is logged.
  - Low Battery during Sleep: If the battery becomes critically low while the screen is off, the pump might wake up to alert the user or shut down completely. System logs the critical low battery event and subsequent action (alert or shutdown).

## Use Case 4: Create a personal profile

- Primary Actors:
  - User
- Stakeholders:
  - Developers
  - Clinics
- Preconditions:
  - User navigates to profile creation menu
- Success Guarantee:
  - Profile saved with the following information:
    - Basal rates
    - Carbohydrate Ratio
    - Correction Factor
    - Target Glucose levels
  - Profile appears in the list of saved profiles.
- Main Success Scenario:
  - Users navigate to profile creation menu
  - Enter Profile name
  - Configure settings by inputting various mandatory values:
    - Basal rates
    - Carbohydrate Ratio
    - Correction Factor
    - Target Glucose Levels
  - Click save
    - System validates inputs and creates new profile
  - System validates inputs:
    - Checks for missing values.
    - Ensures values are within a safe range.
    - Verifies profile name is unique.

- System creates the new profile and confirms success
- Profile is stored and can now be used for insulin delivery.
- Extensions:
  - Invalid Entry: If the user enters a value outside the safe or allowed range (e.g., negative basal rate, unrealistic carb ratio), the system shows an error and prevents saving until corrected. System may log the validation error attempt.
  - Duplicate Profile names: The system prevents saving if the chosen profile name already exists, asking the user to pick a unique name. System may log the duplicate name attempt.
  - Missing Information: If mandatory fields (like basal rates) are left empty, the system prompts the user to complete them before saving.
  - Cancel Creation: The user can choose to discard the new profile settings before saving.

## Use Case 5: Edit personal profile

- List of Actors:
  - User
- Stakeholders:
  - Developers.
- Preconditions:
  - User selects Edit Profile from the active profile screen.
- Success Guarantee:
  - Updated profile impacts Control IQ adjustments immediately.

- Main Success Scenario:
  - User selects the profile edit menu
  - Modifies/ updates a field value
  - Clicks save
  - System validates new inputs:
    - Checks for conflicting settings.
    - Ensures values are within a safe range.
  - System applies changes and confirms the update.
  - Control IQ adjusts insulin delivery immediately.
- Extensions:
  - Active Delivery: Editing the currently active profile might be restricted or require confirmation, as changes impact ongoing insulin delivery. (System would log the restriction/confirmation event).
  - Conflicting settings: The system checks if new values conflict with other settings or safety limits (e.g., total daily insulin dose) and prompts for correction. System may log the conflicting settings attempt.
  - Invalid Input: Similar to creation, entering values outside safe ranges during editing triggers an error. System may log the validation error attempt during edit.

## Use Case 6: View Personal Profiles

- Primary Actors:
  - Users
- Stakeholders:
  - Clinics (may review user settings remotely)

- Preconditions:
  - At least one profile exists.
- Success Guarantee:
  - The user can see all saved profiles and settings.
- Main Success Scenario:
  - User navigates to the Profile List.
  - System displays a list of saved profiles.
  - User selects a profile to view.
  - System shows:
    - Profile name
    - Basal rates
    - Carbohydrate Ratio
    - Correction Factor
    - Target Glucose Levels
- Extensions:
  - No Profiles Available: If no profiles have been created yet, the system displays a message like “No profiles found” and might guide the user to the creation screen.
  - Corrupted Profile Data: In a rare case, if a profile's data is unreadable, it might be shown differently or with an error indicator. System logs the corrupted profile data error upon access attempt.

## Use Case 7: Delete a Personal Profile

- Primary Actors:
  - User
- Stakeholders:



- Developers (ensuring proper deletion logic)
- Preconditions:
  - At least one profile exists.
- Success Guarantee:
  - The selected profile is permanently removed.
- Main Success Scenario:
  - User selects a profile to delete.
  - System prompts for confirmation:
    - "Are you sure you want to delete this profile?"
  - User confirms deletion.
  - System removes the profile from storage.
  - Profile no longer appears in the list.
- Extensions:
  - Deleting an Active Profile: The system prevents deleting the profile currently being used for insulin delivery. It prompts the user to switch to a different profile first. System logs the prevented deletion attempt.
  - Deleting the Only Profile: The system might prevent deletion if it's the only profile available, ensuring there's always at least one profile for operation. System logs the prevented deletion attempt.

## Use Case 8: Deliver a Manual Bolus

- Primary Actors
  - Users
  - Control IQ system
- Stakeholders:
  - Clinicians & Healthcare Providers
  - Developers

- Technical Support
- Preconditions:
  - The pump is unlocked and available for use.
  - The cartridge has enough insulin for the bolus dose.
  - User has an active personal profile with configured carb ratio, correction factor, and target glucose levels.
  - If using CGM, the Dexcom G6 sensor is transmitting valid glucose readings. (from the video)
- Success Guarantee:
  - The bolus is successfully delivered, and the system provides:
    - A confirmation animation (progress bar showing delivery).
    - An update to the Insulin on Board (IOB) value.
    - A change in the CGM trend reflecting the bolus effect.
- Main Success Scenario:
  - User presses Bolus button on the home screen
  - User enters current blood glucose (manual entry or auto-import from CGM).
  - User inputs the number of carbs consumed (if applicable).
  - The system calculates the recommended bolus dose based on:
    - Carb ratio (units of insulin per gram of carbohydrate).
    - Correction factor (how much 1 unit of insulin lowers glucose).
    - Active Insulin on Board (IOB) (to avoid insulin stacking).
  - The suggested dose is displayed, along with the breakdown of the calculation.
  - User reviews the suggested dose and:

- Accepts the recommendation.
  - Manually overrides the suggested dose (if needed).
- The bolus delivery begins, and the user sees:
  - A progress bar animation showing insulin being delivered.
  - A delivery confirmation message once completed.
- IOB is updated to reflect the new insulin dose.
- CGM trend graph updates, displaying the expected effect on glucose levels.
- The bolus event is logged in insulin delivery history for future reference.
- Extensions:
  - Extended Bolus: The user can choose to deliver the bolus over a specified duration (e.g., for high-fat meals) instead of all at once. The log entry indicates it was an extended bolus with duration.
  - Quick Bolus: A pre-set or simplified bolus option might be available for quick corrections without full calculation steps (requires configuration). The log entry indicates it was a quick bolus.
  - Insufficient Insulin: If the calculated or entered bolus amount exceeds the insulin remaining in the cartridge, the system delivers only the available amount and alerts the user. System logs the partial bolus delivery due to insufficient insulin.
  - IOB Impact: The calculation explicitly shows how existing Insulin on Board reduces the suggested bolus to prevent over-correction (stacking). The log entry for the bolus includes the IOB considered.

- Maximum Bolus Limit: The system enforces a maximum limit for a single bolus dose for safety. If the user attempts to exceed it, the system prevents it and logs the attempt.
- Alert During Bolus: If an alert occurs during delivery (e.g., occlusion, low battery), the bolus is paused, and the user must resolve the issue before resuming. System logs the alert and the bolus pause/resume actions.

## Use Case 9: Start Insulin Delivery

- List of Actors:
  - User
  - Control IQ
- Stakeholders:
  - Developers
  - Clinics & Healthcare Providers
- Preconditions:
  - User has a selected active personal profile.
  - Infusion set is properly connected.
  - Pump battery is sufficiently charged.
- Success Guarantee:
  - Basal insulin delivery starts according to the selected profile.
  - Control IQ begins monitoring glucose levels and adjusts insulin delivery accordingly.
- Main Success Scenario:
  - User navigates to the "Basal" menu.
  - User selects "Start Delivery" from the active profile.

- System validates preconditions:
  - Ensures the infusion set is primed and connected.
  - Checks if a personal profile is selected.
  - Ensures the battery level is sufficient.
- Pump starts delivering basal insulin at the defined rate.
- Home screen updates basal delivery status.
- Control IQ actively monitors glucose levels and may adjust the rate accordingly.
- System logs the "Start Basal Delivery" event.
- Extensions:
  - Infusion Set Not Primed/Connected: The system may require the user to confirm the infusion set tubing is filled with insulin (primed) and properly attached to the body before starting. If start is prevented due to this, system logs the reason.
  - No Active Profile Selected: If no profile is active, the system prompts the user to select or create one before starting basal delivery. System logs the prevented start due to no active profile.
  - Battery Too Low: If the battery is below a minimum level required for safe operation, the system prevents starting delivery. System logs the prevented start due to low battery.
  - Control IQ/CGM Issues: If Control IQ relies on CGM data, delivery might start, but alerts may appear if CGM is not connected or providing readings. System logs these related alerts.

## Use Case 10: Stop Insulin Delivery

- List of Actors:
  - User
  - Control IQ
- Stakeholders:
  - Developers
  - Clinics & Healthcare Providers
- Preconditions:
  - Basal insulin is actively being delivered.
- Success Guarantee:
  - Basal insulin delivery stops as requested (manually or automatically).
  - System logs the event for future reference.
- Main Success Scenario:
  - Manual Stop
    - User navigates to the "Basal" menu.
    - User selects "Stop Delivery."
    - System prompts the user to confirm the stop action.
    - User confirms stop request.
    - Basal insulin delivery pauses.
    - Home screen updates to reflect insulin delivery suspension.
    - System logs the stop event with a timestamp.
  - Automatic Stop
    - Control IQ detects glucose dropping below 3.9 mmol/L (via CGM readings).
    - System automatically stops basal insulin delivery.
    - Pump displays alert: "Basal insulin suspended due to low glucose."

- Red warning icon appears on the home screen.
  - System logs the automatic stop event.
  - Users are notified via visual and audio alerts.
- Extensions:
  - Stop Duration Confirmation: When stopping manually, the user might be asked to set a duration after which delivery should automatically resume, or if it should remain stopped indefinitely until manually resumed. The log entry for the manual stop includes the duration set, if any.
  - User Tries to Resume During Low Glucose Suspension: If the system stops insulin due to low glucose, it prevents the user from manually resuming until CGM readings show glucose has risen to a safe level (e.g., above 3.9 mmol/L). System logs the prevented resume attempt.
  - CGM Signal Loss During Suspension: If CGM signal is lost while insulin is suspended due to low glucose, the suspension might continue until the signal returns or the user manually intervenes. System logs the CGM signal loss during the suspension event.

## Use Case 11: Resume Insulin Delivery

- List of Actors:
  - User
  - Control IQ
- Stakeholders:
  - Developers
  - Clinics & Healthcare Providers

- Preconditions:
  - Basal insulin delivery is currently paused
  - If insulin was suspended due to low glucose, glucose must now be above 3.9 mmol/L.
- Success Guarantee:
  - Basal insulin resumes at the previous rate or profile setting
  - System logs the resumption event.
- Main Success Scenario:
  - Manual Resume:
    - User navigates to the "Basal" menu
    - User selects "Resume Delivery."
    - System validates preconditions:
      - Ensures a personal profile is still active.
      - If insulin was manually stopped, checks if pause duration has elapsed
    - Basal insulin resumes at the previous rate
    - Home screen updates to reflect resumed delivery
    - System logs the event with a timestamp
  - Automatic Resume:
    - Control IQ detects glucose rising above 3.9 mmol/L.
    - Basal insulin resumes automatically at the previous rate
    - Pump displays message: "Basal insulin resumed."
    - System logs the automatic resumption event
- Extensions:
  - User Tries to Resume Insulin Too Soon: If insulin was stopped due to low glucose, the system prevents manual resume until CGM confirms glucose is safely above the



threshold (e.g., 3.9 mmol/L). System logs the prevented resume attempt due to low glucose.

- No Active Profile Found: If the previously active profile was deleted or became unavailable while delivery was stopped, the user must select a valid profile before resuming. System logs the prevented resume due to no active profile.
- Battery Too Low for Safe Operation: If the battery level dropped significantly while paused, the system may prevent resuming until charged. System logs the prevented resume due to low battery.
- Infusion Set Check: The system might recommend checking the infusion site/set connection before resuming after a prolonged pause. (Recommendation, not typically logged as an event).
- CGM Data Unavailable: If automatic resume depends on CGM confirming glucose rise, and the signal is lost, manual intervention might be required. System logs the CGM unavailability preventing automatic resume.

## Use Case 12: View Insulin Delivery History

- List of Actors
  - User
  - Clinician
- Stakeholders:
  - Developers
  - Clinics & Healthcare Providers
- Preconditions

- User has active insulin delivery logs stored in the system.
  - User successfully navigates to the "Log History" menu.
- Success Guarantee
  - Logs Display:
    - basal rates,
    - bolus injections,
    - insulin duration, and
    - Correction factors
  - User can filter and sort data to analyze trends
  - Event details are accessible for in-depth review
- Main Success Scenario
  - User navigates to the "Log History" menu.
  - System retrieves stored insulin delivery logs.
  - System displays a timeline-based view of insulin events, including:
    - Basal insulin delivery trends.
    - Bolus injections (manual & automatic).
    - Correction factors applied.
    - CGM-related insulin adjustments.
  - User interacts with the timeline:
    - Scrolls through past events.
    - Selects a specific day or time range.
    - Applies filters to refine the data view.
  - User taps a specific bolus event to view details.
  - System displays:
    - Date & time of bolus injection.
    - Bolus amount (units of insulin delivered).
    - Blood glucose level at the time of injection.
    - Carbohydrate intake logged (if applicable).
    - Correction factor used.

- Any Control IQ auto-adjustments.
- User exits the history menu or continues filtering.
- Extensions:
  - Filtering and sorting: Users can filter logs by event type (bolus, basal, alerts) or date range, and sort by time.
  - No Insulin Delivery History Available: If the pump is new or logs have been cleared, a message indicates no history exists.
  - Data Storage Limit: If the pump has limited memory, very old data might be automatically purged. The history view might indicate the oldest available record date. System logs data purge events.

## Use Case 13: Graph Insulin Delivery and CGM Data

- Primary Actors:
  - Users
- Stakeholders
  - Developers
  - Data engineers
- Preconditions
  - User navigates to the Reports menu.
  - The pump has recorded insulin delivery data and CGM readings.
  - Control IQ system has logged automatic insulin adjustments and events.
- Success Guarantee
  - Interactive graph displays
    - CGM Trend line

- Basal Bars
  - Bolus markers
  - Control IQ events
- Main Success Scenario:
  - User selects the report menu
    - System retrieves insulin delivery history and CGM data.
  - System plots the appropriate data values
    - The graph displays:
      1. CGM trend line showing glucose levels over time.
      2. Basal insulin bars corresponding to the user's active profile.
      3. Bolus markers at injection times.
      4. Control IQ events such as insulin suspensions, automatic boluses, and profile adjustments.
  - User pinches to zoom in, swipes, taps for finer detail
  - User exports report
- Extensions:
  - Zoom/pan adjustments: Allow users to pinch-to-zoom and swipe to pan the graph horizontally (time) to examine specific periods closely.
  - Time Range Selection: Users can select predefined time ranges (e.g., 3 hours, 6 hours, 12 hours, 24 hours, 7 days) or custom ranges for the graph display.
  - Missing Data Handling: The graph should visually indicate gaps where CGM data was unavailable (e.g., dotted line, break in the line). System logs the periods of missing CGM data when generating the report/graph.

- Tap for Details: Tapping on specific points (like bolus markers or CGM readings) could show exact values and timestamps.