

Tandem t:slim Insulin Pump Use Cases

MAIN USE CASE: INSULIN PUMP FOR GLUCOSE MANAGEMENT

Actors: Diabetic patient, Insulin Pump, CGM (Continuous Glucose Monitor)

Preconditions:

- Insulin pump is sufficiently charged for proper use.
- 300-unit cartridge is filled with insulin
- CGM is connected and correctly transmitting real-time glucose readings to the insulin pump
- Diabetic patient's information is configured for their user profile

Postcondition: Insulin is pumped into the patient accordingly (different based on glucose levels) and/or the CGM provides alerts as to how to manage glucose levels.

Main success scenario:

1. User powers on the insulin pump
2. Insulin conducts the *Power On Self Test*
3. Insulin pump home screen displays battery level, IOB (Insulin on board) and CGM data
4. Control IQ receives messages from CGM regarding real-time glucose readings (continuous)
5. Control IQ predicts glucose level 30 mins ahead and adjusts amount of insulin pumped into patient
 - If glucose level is within range 6.25mmol/L - 8.90mmol/L, then basal rate is to be maintained. Pump displays a gray diamond icon on the home screen and status icon is a black "B" in a light blue square.
 - If glucose level is above 8.9mmol/L, increase basal insulin amount. Pump displays the upper half of the diamond icon as blue. Pump status icon is a white "B" in a dark blue square.
 - If glucose level is below 6.25mmol/L, decrease basal rate. Pump displays the lower half of the diamond icon as orange. Pump status icon becomes orange.
 - If glucose level is above 10 mmol/L, bolus correction should be issued to the patient. Pump displays white droplet icon in a blue square. Pump screen indicates "Control IQ Bolus."
 - If glucose level is below 3.9mmol/L, suspend basal insulin. Pump displays the lower half of the diamond icon as red. Pump status icon is a red zero.
6. User is alerted via insulin pump home screen and speaker about low/high glucose levels, amount of bolus delivered, any errors that occurred.
7. Pump continues monitoring and adjusting insulin indefinitely unless manually powered off or an error occurs.

Extensions:

2a. Insulin pump fails the *Power On Self Test*

2a1. Pump alerts the user via home screen and speaker that the self test failed.

2a2. Pump alerts users to recharge, reconnect CGM, or contact support.

5a. User manually selects bolus option from insulin pump home screen

5a1. User inputs desired insulin amount

5a2. Insulin pump checks if amount is available and delivers manual bolus insulin. Logs events are displayed depending on success or not.

SUB-USE CASE 1: POWER ON SELF TEST

Actors: Diabetic patient, Insulin pump

Preconditions:

- User is present to turn on insulin pump
- State of insulin pump is turned off to begin with

Postcondition: Pump is ready for use.

Main Success Scenario:

1. User presses and holds the power button to turn on the pump.
2. Pump performs diagnostic checks including battery, amount of insulin, CGM connectivity, and correct deployment of software.
3. Home screen loads successfully displaying battery level, insulin reservoir status, and CGM connectivity.

Extensions:

- 3a. Insulin pump fails power on self test.
 - 3a1. Pump alerts users to recharge, reconnect CGM, or contact support.
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SUB-USE CASE 2: AUTOMATIC INSULIN DELIVERY ADJUSTMENT

Actors: Diabetic patient, Insulin Pump, CGM

Preconditions:

- Pump is operating as expected connected to the diabetic patient
- CGM is transmitting real-time glucose data

Postcondition: Insulin pump adjusts insulin delivery automatically based on glucose prediction.

Main Success Scenario:

1. Pump receives glucose data from CGM. (Continuous delivery)
 2. Pump predicts glucose 30 minutes ahead.
 3. Pump adjusts insulin delivery as specified in main use case scenario step 5.
 4. Pump updates home screen icons accordingly (gray, orange, red, blue, droplet icons).
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SUB-USE CASE 3: AUTOMATIC BOLUS DELIVERY (GLUCOSE > 10mmol/L)

Actors: Diabetic patient, Insulin Pump

Preconditions:

- Control IQ predicts glucose will be ≥ 10 mmol/L
- Insulin basal is at maximum amount and/or insulin basal was already added prior to prediction

Postcondition: Automatic correction bolus delivered.

Main Success Scenario:

1. Control IQ predicts glucose levels will be ≥ 10 mmol/L in 30 minutes

2. Pump automatically calculates correction bolus.
 3. Pump delivers correction bolus automatically.
 4. Pump home screen visually indicates bolus delivery ("Control IQ Bolus," droplet icon)
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SUB-USE CASE 4: USER VIEWS INSULIN DELIVERY HISTORY

Actors: Diabetic patient, Insulin pump

Preconditions:

- Previous insulin injections have been correctly logged and stored in backend system

Postcondition: User is able to clearly view the insulin history of their previous alerts/events

Main Success Scenario:

1. User navigates to *History* tab on insulin pump home screen
 2. Screen displays past bolus and basal insulin injection delivery with relevant information.
 3. User can review past CGM-triggered alerts and/or readings.
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SUB-USE CASE 5: CONFIGURING USER PROFILE FOR DIABETIC PATIENT

Actors: Diabetic patient, Insulin pump

Preconditions:

- Pump passes the *Power On Self Test*

Postcondition: User profile is successfully created, modified and/or deleted.

Main Success Scenario:

1. User accesses the *User Profile* tab via the Insulin pump home screen
 2. User creates a new profile by clicking *Add* and edits a profile by clicking on the profile
 3. If users decides to edit a profile, they can modify insulin delivery settings (basal rate, carb ratios, correction factors, glucose targets).
 4. If user decides to delete the profile, the click on the *Delete* button when editing a profile
 5. User saves and activates the profile, or deletes if no longer needed.
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SUB-USE CASE 6: INSULIN PUMP MALFUNCTION & ERROR HANDLING

Actors: Diabetic patient, Insulin Pump

Preconditions:

- Pump receives a malfunction and an error occurs with functionality

Postcondition: Pump provides alerts and instructions to resolve the error

Main Success Scenario:

1. Insulin pump detects an error due to a hardware/software error (low battery, insulin occlusion, CGM disconnected)
2. Insulin pump alerts the user via home screen and insulin pump speaker that a malfunction has occurred.

3. Pump provides explicit instructions to resolve malfunction. This includes, recharging the battery, reconnecting the CGM, checking insulin cartridge and infusion set for proper insulin amount and/or contacting support.
4. Malfunction of insulin pump will result in suspension in functionality until precautions have been taken.