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 starts the power on pin pad
- 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 button*
 - 2a1. Pump alerts the user via home screen and speaker that the power on button 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 BUTTON

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 button

3a1. Pump alerts users to recharge, reconnect CGM, or contact support.

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).

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)

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.

SUB-USE CASE 5: CONFIGURING USER PROFILE FOR DIABETIC PATIENT

Actors: Diabetic patient, Insulin pump

Preconditions:

- Pump passes the *Power On Button*

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.

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:

- 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.