

Tandem t:slim X2 Insulin Pump Use Cases

Use case 1

Name: Start device

Primary Actor: Patient

Stakeholders:

Patient - Needs to use device to practise monitoring and management of their blood sugar

Tandem Diabetes - Needs the product's features to fully understood by clients to best tend to their needs

Precondition: Insulin pump simulation is functional and has sufficient battery to operate

Success Guarantee: Patient can interface with the simulation

Main Success Scenario:

1. Patient holds the power button until startup sequence is complete
2. The program displays an interface to the user where they can use the simulation to learn about the t:slim insulin pump's features

Extensions:

- 1a. The device is broken/otherwise unable to turn on
- 1b. The device does not have sufficient battery to turn on
 - 1b1. The device will display a message/symbol requesting the user to charge the device
- 2a. The device turns on but is otherwise unresponsive or non-functional

Use case 2

Name: Setup Personal Profiles

Primary Actor: Patient

Stakeholders:

Patient - Needs to know how to cater their insulin pump to their specific lifestyle and needs

Tandem Diabetes - Needs clients to understand the product is configurable and works for everyone

Precondition: Device is started and the user can navigate the options interface to manage profiles

Success Guarantee: Patient can set up personal profiles to precisely adjust critical settings

Main Success Scenario:

1. Patient navigates to the profiles menu as follows: Options > My Pump > Personal Profiles
2. Patient taps an existing profile to read/update/delete, or the plus icon to create a new profile
3. Patient sets the name of the profile and presses the green checkmark icon to continue
4. Patient edits the insulin delivery settings for a time segment beginning at 12:00 a.m and presses the blue checkmark icon to confirm each
5. When all settings are complete, patient taps the green checkmark icon to proceed to next step
6. Patient is prompted to review the new settings and confirm (✓) or continue editing (X)
7. Patient repeats step 4-7 for each time segment they wish to add the the profile
8. When all time segments are complete, the user taps the bolus settings to manage their dose
9. Patient is prompted to review the new settings and confirm (✓) or continue editing (X)

Extensions:

- 1-9a. The patient wishes to exit the profiles menu
 - 1-9a1. The patient can press the tandem logo to return to the main menu. All unsaved changes will be lost.
- 1-9b. The program encounters a failure while attempting to manage user profiles

Use case 3

Name: Monitor Glucose Level (Continuous Glucose Monitoring or CGM)

Stakeholders:

Patient - Needs to know how to view glucose level if they wish to manage their insulin manually

Tandem Diabetes - Needs clients to understand how blood sugar is monitored and insulin administered

Precondition: Device is started and can display the blood sugar graph correctly

Success Guarantee: Patient can view their glucose levels which updates

Main Success Scenario:

1. The program provides simulated glucose levels to display on the home screen
3. The glucose levels are displayed and adjust based on the administration of insulin

Extensions:

- 2a. Glucose levels cannot be updated or displayed

Use case 4

Name: Manual Insulin Bolus Delivery

Stakeholders:

Patient - Needs to know how to administer insulin manually to handle certain situations

Tandem Diabetes - Needs clients to handle situations that cannot be automatically dealt with by software

Precondition: Device is started and the bolus calculator is accessible

Success Guarantee: Patient can prepare a manual insulin delivery with the dosage of their choosing

Main Success Scenario:

1. The patient navigates to the bolus calculator from the home screen using the Bolus button
2. Patient enters the their carbohydrate intake and glucose level, or uses the values provided by the CGM
3. Patient edits the bolus amount, or uses the calculated value and continues by pressing the blue check
4. Patient is prompted to confirm the dose
5. Patient chooses whether to administer the dose immediately or extend the dose over time
 - a. If the patient wishes to extend the dose, they must choose what portion of the dose to deliver now and what portion to deliver over time, along with the duration of the extended dose.
6. Patient is prompted to review the manual bolus and start the bolus (✓) or continue editing (X)
7. A confirmation that the bolus is being delivered is displayed and can be seen on the home screen

Extensions:

- 1-6a. The patient wishes to exit the bolus calculator

1-6a1. The patient can press the tandem logo to return to the main menu. All unsaved changes will be lost.

- 1-6b. The program encounters a failure while setting or administering the bolus

- 3a. The patient selects a value that will leave them below a healthy blood sugar level (below 3.9 mmol/L)

3a1. The program will not allow this dose to be administered

- 3b. The patient selects a value that will leave them above or below their target blood sugar level but still above 3.9 mmol/L

3b1. The program will offer the patient a reduced dose which can be accepted or rejected

- 7a. The patient wishes to cancel their bolus mid-delivery

7a1. Manual bolus delivery can be cancelled from the home screen

Use case 5

Name: Automated Basal Insulin Delivery

Stakeholders:

Patient - Needs to know and be able to observe how insulin is administered throughout the day

Tandem Diabetes - Needs clients to know how insulin is delivered and edit their profiles accordingly

Precondition: The device is receiving CGM data and can administer basal insulin accordingly

Success Guarantee: The effect of the patient's basal insulin rate can be observed from the CGM data

Main Success Scenario:

1. The patient sets a basal rate from their active personal profile, or configures it from the options menu
2. The system will administer basal insulin at that rate continuously unless interrupted

Extensions:

- 2a. The device detects that insulin levels will drop or rise outside of target range
 - 2a1. Basal insulin delivery will be adjusted accordingly
- 2b. The device detects that insulin levels will drop or rise outside of a healthy range
 - 2b1. If too high, a correction bolus will be administered
 - 2b2. If too low, basal insulin delivery will be stopped until glucose levels stabilize. Such an event will be logged into the system for future reference.

Use case 6

Name: Generate Insulin Data/History

Stakeholders:

Patient - Needs to be able to view CGM history and insulin administration to tailor their personal profile

Tandem Diabetes - Needs clients to have pump data and alerts as a service to understand how insulin is administered in different situations and to assist healthcare providers with improving treatment

Precondition: The device is logging CGM and insulin delivery data where it can be accessed later

Success Guarantee: The patient is able to view a history of their blood sugar, insulin delivery and alerts

Main Success Scenario:

1. Patient navigates to their desired pump data from the home screen
 - a. The patient accesses information about their pump as follows: Options > My Pump > Pump Info
 - b. The patient accesses their pump history as follows: Options > History > Pump History
2. Patient searches for their desired data using the up and down arrows

Extensions:

- 1-2a. The patient wishes to exit the pump data menu
 - 1-2a1. The patient can press the tandem logo to return to the main menu. All unsaved changes will be lost.
 - 1-2b. The data cannot be accessed or the menu interface is broken

Use case 7

Name: Simulate Low Battery

Stakeholders:

Patient - Needs to know how to use the pump's mechanisms to handle malfunctions

Tandem Diabetes - Needs clients to be able to handle malfunctions independently to reliably use the pump

Precondition: The device can detect its battery level and notify the user when it is too low

Success Guarantee: The device notifies the user and suspends insulin delivery during critical issues

Main Success Scenario:

1. The device detects that its battery level is below a certain threshold
2. The patient is notified of the low battery and prompted to charge the device
3. If situation becomes critical, Malfunction is logged for future reference

Extensions:

- 1a. The device is unable to correctly read the battery level
- 2a. The patient ignores or misses the notification
 - 2a1. In this situation, the battery may deplete until it is empty. If this happens, the system will suspend insulin delivery and shut down, providing a symbol indicating to charge and restart the device

Use case 8

Name: Simulate Low Insulin

Stakeholders:

Patient - Needs to know how to use the pump's mechanisms to handle malfunctions

Tandem Diabetes - Needs clients to be able to handle malfunctions independently to reliably use the pump

Precondition: The device can detect insulin level and notify the user when it is too low

Success Guarantee: The device notifies the user and suspends insulin delivery during critical issues

Main Success Scenario:

1. The device detects that its insulin level is below a certain threshold
2. The patient is notified of the low insulin and prompted to refill the insulin cartridge
3. If situation becomes critical, Malfunction is logged for future reference

Extensions:

- 1a. The device is unable to correctly keep track of the remaining insulin
- 2a. The patient ignores or misses the notification
 - 2a1. In this situation, the insulin cartridge may deplete until it is empty. If this happens, the systems will suspend insulin delivery and notify the user until the cartridge is refilled

Use case 9

Name: Simulate CGM Disconnection

Stakeholders:

Patient - Needs to know how to use the pump's mechanisms to handle malfunctions

Tandem Diabetes - Needs clients to be able to handle malfunctions independently to reliably use the pump

Precondition: The device can interface with the CGM and detect when it is unable to read data from it

Success Guarantee: The device notifies the user and suspends basal insulin delivery during critical issues

Main Success Scenario:

1. The device detects that it is not receiving data from the CGM
2. Patient is notified of the CGM disconnection and the graph is no longer displayed on the home screen
3. Malfunction is logged for future reference

Extensions:

- 1a. The device is unable to detect loss of signal from the CGM
- 2a. The patient ignores or misses the notification
 - 2a1. The device will continue to operate based on the patient's active profile for 15 minutes. Afterwards, the device will stop basal insulin delivery until connection is restored

Use case 10

Name: Simulate Detected Occlusion

Stakeholders:

Patient - Needs to know how to use the pump's mechanisms to handle malfunctions

Tandem Diabetes - Needs clients to be able to handle malfunctions independently to reliably use the pump

Precondition: The device can detect a blockage in the insulin cartridge or tubing and notify the user

Success Guarantee: The device notifies the user and suspends basal insulin delivery during critical issues

Main Success Scenario:

1. The device detects that insulin is not properly being pumped into the patient
2. Patient is notified of the occlusion and prompted to check the insulin delivery site
3. Insulin delivery is suspended until the occlusion is resolved
4. Malfunction is logged for future reference

Extensions:

- 1a. The device is unable to detect the occlusion
- 2a. The patient ignores or misses the notification