

Sample Workflows

Always:

- **Encrypt data at rest (inputted data that needs to be stored on a device) with AES-256**
- **Data in Transport (data communicated between devices) using TLS 1.3**

Step	Action	Cybersecurity Concerns
1	Create an Account: Sign up for the app by providing your information.	<ul style="list-style-type: none">• Cloud to App - Check to ensure app version is valid and updated• App to Cloud – Ensure connection, if receiving update information check via hashing or signatures that the update is valid• App to Device – Ensure the device is running valid firmware• Enforce Strong Password Policy (currently 15+ characters but no rules on symbols or capitals or numbers added)• Enforce Multi Factor Authentication (Checking what device supports then one time password with phone number, biometric/voice/face recognition)• Informing user of security concerns/tools they can use on their own app for cybersecurity (secure folders, their own)
2	Profile Setup: Fill in your personal details and your doctor's information.	<ul style="list-style-type: none">• Use Regex or other tools to verify inputs, this not only ensures data matches, but to ensure no data entered could be used for attempted SQL injection or other reasons• Ensure data kept and transported is encrypted
3	Prescription Dosage Entry: Enter the dosage prescribed by your doctor.	<ul style="list-style-type: none">• Use Regex or other tools to verify inputs, this not only ensures data matches, but to ensure no data entered could be used for attempted SQL injection or other reasons• Ensure data kept and transported is encrypted
4	Activate Bluetooth: Enable Bluetooth on your smartphone.	<ul style="list-style-type: none">• Ensure Bluetooth version 5.0+ with LE Secure Connections.• Monitor and Block unexpected Bluetooth activity or pairing requests. Pairing should only be enabled when required
5	Pair with Main Pod: Connect the app to the main pod device.	<ul style="list-style-type: none">• Ensure devices are not discoverable by default

		<ul style="list-style-type: none"> Utilizing NFC for secure key exchange (assuming phone supports NFC, other secure pairing methods could be used) Ensure Bluetooth version 5.0+ with LE Secure Connections. Monitor and Block unexpected Bluetooth activity or pairing requests.
6	Cartridge Connection Check: Verify if the drug cartridge is securely connected to the main pod.	<ul style="list-style-type: none"> Confirm pairing for scanning cartridges, ensure protection from QR code scanning (fake/wrong images used)
7	Cartridge Capacity Check: Determine the remaining drug capacity in the cartridge.	<ul style="list-style-type: none"> Ensure regular security (device at rest/transport encryption)
8	Prepare the Pump: Perform the initial setup to ensure the pump is ready.	
9	Needle Mechanism Release: Release the needle mechanism by pressing the release button.	<ul style="list-style-type: none"> Ensure secure, solid connection between smartphone and device before dosing process Depending on time since last verification, re-verify identity using MFA methods?
10	Start Dosing: Initiate the dosing process.	
11	Pre-Meal Data Input: Before a meal, input your carbohydrate intake and blood glucose levels.	<ul style="list-style-type: none"> Use Regex or other tools to verify inputs [Note for future: Security for integration process with glucose monitoring system]
12	Dosage Calculation: Allow the app to calculate your dosage based on your doctor's prescription.	<ul style="list-style-type: none"> Ensure regular security between device and cloud (or just device if prescription stays stored on device) (device at rest/transport encryption)
13	User Confirmation: Confirm the suggested dosage or make adjustments if needed.	
14	Injection Initiation: Press the button to start the injection.	<ul style="list-style-type: none"> Ensure secure, solid connection between smartphone and device before dosing process
15	Track Drug Volume: Keep an eye on the remaining drug volume in the cartridge.	
16	Cartridge Replacement Alert: Receive an alert to replace the cartridge when it's empty.	
17	Dosing Completion: Stop the pump when the dosing process is finished.	<ul style="list-style-type: none"> Log completed dosing to cloud

Special Cases

App Initialization when User has Existing Account (lost/inaccessible or new phone)

Step	Action	Cybersecurity Concerns
1	Request existing account information	<ul style="list-style-type: none">• Use existing credentials and MFA to verify login information• Ensure data is encrypted at rest and in transport• Sending e-mail or other record to log to user and cloud that a new device has logged into the account• Potential use of one time codes if regular MFA methods inaccessible, in which case only temporary use• Log all attempts, successful or not to cloud
2	Ask what the device will be used for and whether it should be trusted	<p>Temporary Use for Lost Device or Out of Battery (e.g. using a friend's phone)</p> <ul style="list-style-type: none">• Register user/device for limited access and restrict features (what information they can pull from cloud that can contain personal identifiable information, ect.)• Require more frequent verification and re-sign in procedures• Prompt on main device to remove or disable additional trusted devices when no longer being used <p>New Device</p> <ul style="list-style-type: none">• Register/record user as a patient and establish regular patient permissions
3	Pair with Main Pod: Connect the app to the main pod device.	<ul style="list-style-type: none">• Ensure devices are not discoverable by default• Utilizing NFC for secure key exchange (assuming phone supports NFC, other secure pairing methods could be used)• Ensure Bluetooth version 5.0+ with LE Secure Connections.• Monitor and Block unexpected Bluetooth activity or pairing requests.
	Continue regular process	