Software Requirements Specification

for

Insulin Pump

//Version 1.0 approved

Prepared by Aşkın Gündüz

Esen System Integration

09.08.2023

Table of Contents

Revision History's

Name	Date	Reason For Changes	Version

1. Introduction

1.1 Purpose

The primary objective of this Software Requirements Specification (SRS) is to meticulously outline the intricate prerequisites of an insulin pump. Positioned as a pivotal component within the domain of medical technology, insulin pumps play a vital role in managing diabetes, a chronic medical condition.

The main purpose of this document is to introduce the concept of a leading insulin pump in the sector. Firstly, it introduces Type-1 and Type-2 Diabetes and the forms of solutions and all about insulin pumps. Then, it goes on to introduce the new device; the newest insulin pump, complete blood pressure tracking capabilities, a user-friendly interface with closed-loop technology to minimize user effort, outperforming its sector counterparts with an extended battery life and increased memory capacity. This document underlines its multifaceted benefits and properties, outlining a transformative approach to diabetes management and showing all the requirements to build it.

1.2 Document Conventions

Must: Be obliged to, something that should not be overlooked or missed.
Shall: used to express what is inevitable or seems likely to happen in the future, used to express determination
Will: Expressing the future tense
Verification: Agreement between the developer and tester about what will be tested to verify that the product meets the requirement.
Priority:

- High: critical, required for next release
- Medium: necessary, but can wait until next release
- Low: can wait until resources permit

1.3 Intended Audience and Reading Suggestions

This document caters to both vested stakeholders and diligent developers entrusted with its realization. Furthermore, it seeks to serve as a proposal to medical professionals, including doctors and pharmacies, interested in extending its application to patients affected by Type-1 Diabetes. The document will cover the system's purpose, features, interfaces, operational constraints, and requirements necessary for FDA approval.
Software developers can skip to 3.3 (6) for their field, and hardware developers can skip to 3.2 (5) for their field. But the language used in this document is easy to understand, and it is recommended for the readers of it to read the whole document.

1.4 Product Scope

The insulin pump is a safety-critical embedded medical device used for treatment of type 1 diabetes. In type 1 diabetes, insulin-producing pancreatic beta cells are destroyed by an immune-mediated process. So, the pancreas can’t produce insulin. The treatment for type 1 diabetes is intensive insulin therapy, either as multiple daily injections or with an insulin pump.

Intensive insulin therapy aims to mimic physiological insulin release by doing insulin injections each day for 3-4 times. However, most people who prefer this treatment are unable to achieve the recommended insulin levels. In addition, these people always have to do everyday diabetes tasks, such as managing blood glucose levels, taking insulin injections, planning meals, calculating calorie and carbohydrate intake, and staying active. All that work can take a toll on their mental health. Among these people, 1 in 4 will have symptoms of depression in their lifetime.
So, insulin pumps are getting more common each day and the technology of it keeps developing to make the users lives even more easier.

Insulin pumps can be open loop, closed loop, or hybrid. This document covers a closed-loop pump. The closed-loop systems are also called AID systems, Automated Insulin Delivery system. An AID System does not need user input for insulin dosing. This is a mostly hands-off system, culminating in an even more user-friendly experience. The user only needs to enter their weight when they first buy the device. Then, when they're eating, they just have to tell the pump if they're eating a small, medium, or a large meal. This is a welcome relief to constant diabetes decision-making. And it means no more carb counting or math for insulin dosing.

This insulin pump that the document is covering is a small, rechargeable battery-operated, portable device about the size of a cellphone. It is worn externally either in the patient's pocket or on a special belt, or it can be concealed under the clothing. Its rechargeable battery makes it environment-friendly, and long durable. Closed-loop systems – also referred to as the "artificial pancreas" – have been likened to the solution of diabetes management as they have the potential to improve glycemic outcomes and reduce disease burden.

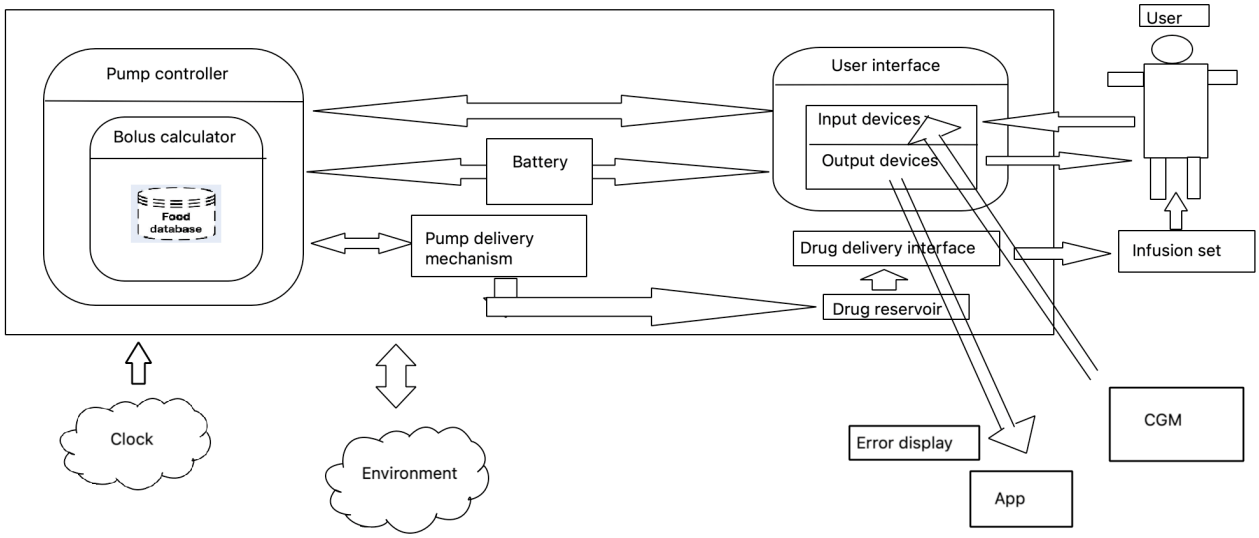
1.5 References

- Sommerville, Ian Software Engineering 7 th Edition, Addison Wesley, ISBN 0-321- 21026-3, 2004
- https://bms2021.ugent.be/BMS21_0069_FI.pdf
- https://pubs.rsc.org/en/content/articlelanding/2020/tb/d0tb00385a
- https://www.frontiersin.org/articles/10.3389/fendo.2022.919942/full
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3262707/pdf/dst-05-1403.pdf
- https://agentek.co.il/media/wysiwyg/Microtech/Manual_Eng.pdf
- https://www.mathworks.com/videos/modeling-an-insulin-infusion-pump-87684.html
- https://pubs.rsc.org/en/content/articlelanding/2020/tb/d0tb00385a
- https://higherlogicdownload.s3.amazonaws.com/THEACADEMY/bc90d439-1a0b-4d10-8426-0d0ccc40f516/UploadedImages/DCE/Documents/Insulin_Pump_Comparison_Table_3-2018.pdf
- https://bms2021.ugent.be/BMS21_0069_FI.pdf
- https://www.healthline.com/health/diabetes/best-glucose-monitors#A-quick-look-at-the-best-home-glucose-meters

2. Overall Description

2.1 Product Perspective

After a wide research of already existing insulin pumps, this product exceeds their capabilities and presents an even more accurate insulin pump. In addition, it's even more user-friendly and its battery lasts longer, as well as its nature friendly. Very simple menu layout, intuitive user interface, and fast navigation.



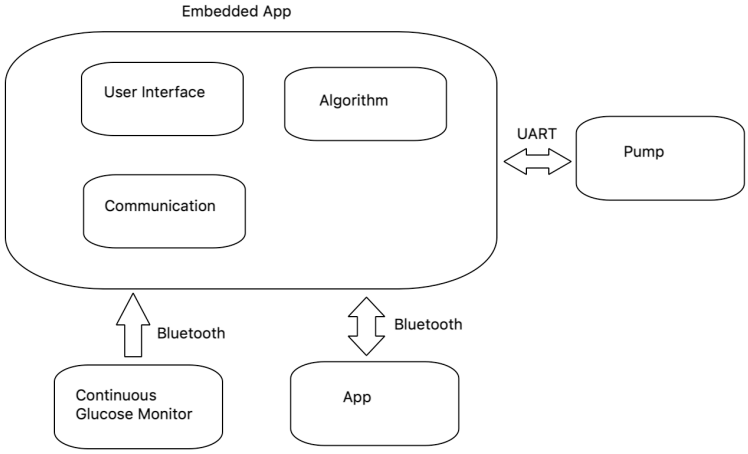
PUMPS	Medtronic 770G/780G	Tandem T:Slim x2	Omnipod DASH	Insulin Pump
Approved For	All Ages	>6 yo	All Ages	Suitable for all ages, but the design is for children.
Weight	95.7 g	112 g	26 g	105 g
Tubing	45-110 cm	60-110 cm	Tube-free	40-120 cm
Cannula	6-17 mm	6-13 mm	9mm with 6.5mm under the skin at 50 degree angle	6-12 mm
Reservoir	1.8 and 3 ml	0.95-3.0 ml	2.0 ml	3.0 ml
Battery	AA lithium/Alkaline	Rechargeable	Rechargeable	Rechargeable
Waterproof	3.6m, 24hrs (IPX8)	1m, 30mins (IPX7)	7.6m, 60mins (IP28)	3.6m, 24hrs (IPX8)
Glucose Meter	Accu-Chek Guide Link Meter	Verio Meter provided – Not Linke	None	Dexcom G6
Bolus Calculator	In-built in pump	In-built in pump	In-built in PDM	In-built in pump
Basal Range	0.0-35 units/hr	0.1-15 units/hr	0.0-40 units/hr	0.0-35 units/hr
Bolus Range	0.0 – 25 units	0.05 – 25 units	0.05 – 30 units	0.0 – 30 units
Basal Increment	0.025, 0.05, 1.0	0.001	0.05	0.01, 0.025, 0.05,1.0
Uploading	Automatic uploads via MiniMed Mobile App	Tandem USB cable	USB cable	Automatic uploads via Mobile App
Software	Carelink Web based	Diasend	Diasend	Carelink Web Based
CGM Integration	Yes	Yes	No	Yes
Loop Type	Hybrid-Closed	Hybrid-Closed	Hybrid-Closed	Closed

2.2 Product Functions

- Closed loop insulin delivery system: A system that regulates blood glucose automatically without a person with diabetes needing to enter date such as glucose or carbohydrate values.
- Zero fingersticks: You won't need to stick a needle to your thumb anymore, CGM takes care of it. Fingersticks are a method used to test blood glucose by using a puncturing device to take a small sample of blood from the user.
- The pump uses rechargeable batteries, and it offers convenience, saves cost over time, and reduces waste compared to disposable batteries.
- The pump displays the insulin and battery percentage.
- Bolus calculator: the device calculates the bolus and basal values so that you won't have to.

Connection:

- Custom Settings: create up to 8 personal profiles to monitor your loved one's insulin levels.
- CGM measures blood pressure every 5 minutes and sends the data simultaneously.
- Connects to its app and sends all the data every 24 hours.
- Reporting made simple: with just a few taps, you can view your insulin delivery and glucose history.
- Upload your data to the app easily, and the device does it for you every 24 hours.



2.3 User Classes and Characteristics

<Identify the various user classes that you anticipate will use this product. User classes may be differentiated based on frequency of use, subset of product functions used, technical expertise, security or privilege levels, educational level, or experience. Describe the pertinent characteristics of each user class. Certain requirements may pertain only to certain user classes. Distinguish the most important user classes for this product from those who are less important to satisfy.>

This pump is designed for individuals of all ages from 6, with type-1 diabetes. Its user-friendly interface and accompanying data monitoring app, which permits up to eight users to access all the data makes it suitable for all the age groups. The frequency of use is the same for all users, but the amount of insulin pumped will change for each patient, the software is capable of calculating the amounts.

The pump's design may seem childish, but its design was made like that on purpose, in order to maintain full understandability from all over the world. Ease of use is the pump's key, so the pump's screen was designed as simple as possible.

2.4 Operating Environment

The app must be compatible with IOS 13 and Android 10 (basically all types of phones), both the device and the phones that will download and use this app should be able to use Bluetooth. The pump should have a USB-input for it to be rechargeable and the pump should come with its own charging cable.
Durable housing: Shatter-resistant glass and an ultra-strong water case, waterproof device
The glucose monitor is Dexcom G6, which is known to be the one that has the most accurate measurements. The software is Carelink Web Based.

CPU: The CPU of this pump uses Texas Instruments, as its microcontrollers and processors are used in various medical devices, due to their low power consumption, real-time capabilities and safety features.
Operating System: The operating system of this pump is FreeRTOS, it has real-time control to accurately deliver the insulin doses, which is vital.

2.5 Design and Implementation Constraints

- Limited insulin storage (reservoir) because it will be too heavy.
- Customer's organization will be responsible for maintaining the delivered software up to 7 years. Insurance will cover everything for 3 years (dropping the device, errors, etc.)
- Memory requirement: the pump will have 2 days memory capacity with SD card and the app will have memory capacity up to 60 days of data. The device will send its data every 24 hours to the app.
- The app's data will be easily sharable through any sharing platforms. (WhatsApp, E-Mail, etc.)
- Bluetooth connection – Both the pump and the phone that uses the app will use Bluetooth connection to send and get the data.
- Battery requirement- biodegradable? And goes seven days with one charging.
- Language requirements- the device will be in English, but there will be almost no written texts, only icons. The app will have 25 languages for users to understand everything easily.
- The pumps screen should be strong and protected, shouldn't break unless it's thrown from very high places.
- The pump should be waterproof – but necessarily for the use underwater, but necessarily for showering.
- The software will be written according to the standard IEC 62304 software classification.
- The insulin will be pumped into the body in 5 seconds after the command is given.
- The CGM will check the blood glucose level every 5 minutes, the duration it takes is 10 seconds.
- Memory allocated for the device is 2GB.
- The algorithm will decide how much insulin the pump in 3 milliseconds.
- The device is fit to do up to1 million measurements.

2.6 User Documentation

User manual will both be in the package of the pump and on the website, available in 25 languages, online 7/24 help through call-lines and chatting online. Video tutorials about how to setup the device and how to use it, screen protector will already be attached to the device.
User manual shall include information about the device's capabilities and about what the user is responsible for (for instance, the user should always give information to the device about the size of their meal.)

2.7 Assumptions and Dependencies

Insulin pumps are portable medical equipment whose design and manufacture is regulated by the Food and Drug Administration (FDA). Without an FDA approval, this device won't be allowed to sell in anywhere. This means that their design and construction must follow precisely documented processes, and their performance must meet

stringent documentation, development testing, production testing, and field maintenance requirements. The equipment also must contain comprehensive self-test and fault-indication capabilities, which require additional circuitry and the use of components that include self-test features. Given the time and expense required to achieve FDA approval, manufacturers must select a supplier with a customer-oriented discontinuance policy to ensure that system components will be available for many years.

3. External Interface Requirements

3.1 User Interfaces

Pump has a touch screen and very simple GUI for ease of use. Most of the information is on the app rather than the pump so that the pump only has the most vital information (battery and insulin percentage, bolus and basal amounts, errors), so that the user can easily check them. Both the pump and app stores info about the battery percentage and insulin percentage and has many alarms if one of them starts to decrease.

If the user presses “Alarm” or if the pumps alarm is activated, the pump sends alarm to the app and the app sends messages to every user of the app (for example, if one person’s pump is connected to 7 people’s apps, all of them get notified.). This way, in case of an emergency, everybody is notified.

In the pump’s GUI:

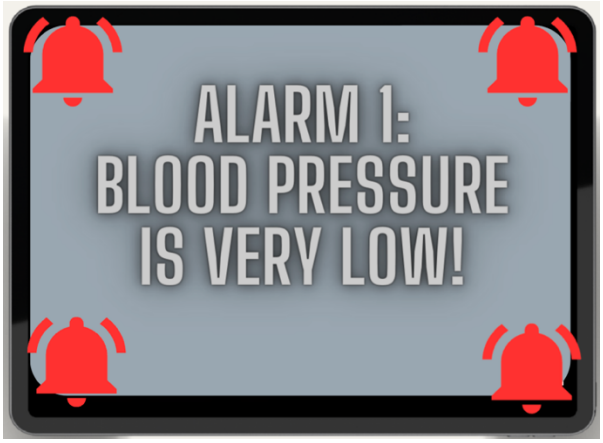
- A power on/off switch shall be displayed.
- If the pump is in a state in which user input is required, e.g., setting time and date, setting drug type, and concentration after reloading the drug reservoir, the pump shall issue periodic alerts/indications every 3 minutes until the required input is provided.
- Clearing, changing or resetting the pump settings shall require the user’s confirmation.
- A current blood sugar level and at least two previous levels shall be displayed. Implementing a graphical representation (with numerical values) to a current sugar level and previous sugar levels is required.
- Current real-time shall be displayed.
- The status of battery shall be displayed with a progress bar.
- The status of insulin reservoir shall be displayed with a progress bar.
- The amount of total calories taken, total carbohydrates taken, and given insulin will be displayed.
- Warning and error messages shall be displayed in the single line text box. If there is one message,
- keep displaying that message. When there is more than one message, each message is displayed.
- for 3 seconds until all messages have been displayed. The display sequence then restarts with the
- first message unless warnings and errors are clear. Also, an audio alarm for each message shall be
- given.
- If users decide that they require insulin immediately they can manually override the
- automatically delivering system. Users specify how much insulin to be injected by pressing the “manual.”
- button. The number of button presses within 5 second period specifies the number of units of
- insulin to be injected. The system must be in manual mode for this to be operational and you.
- may assume that after the first press is detected, the number of presses is counted automatically.

In the app’s GUI:

- The amount of the last dose of insulin to be administered shall be displayed.
- The amount of the cumulative of insulin injected shall be displayed.
- The status of battery shall be displayed with a numeric value and progress bar.
- The status of the insulin reservoir shall be displayed.
- Warning and error messages shall be displayed in the single line text box. If there is one message,

- keep displaying that message. When there is more than one message, each message is displayed.
- for 3 seconds until all messages have been displayed. The display sequence then restarts with the
- first message unless warnings and errors are clear. Also, an audio alarm for each message shall be
- given.
- If users decide that they require insulin immediately they can manually override the
- automatically delivering system. Users specify how much insulin to be injected by pressing the "manual."
- button. The number of button presses within 5 second period specifies the number of units of
- insulin to be injected. The system must be in manual mode for this to be operational and you.
- may assume that after the first press is detected, the number of presses is counted automatically.

The pump's GUI:



- The pump shall provide a locking option that, once selected, shall allow only the user and authorized personnel to unlock and access the pump status and user records and statistics.
- If the pump is in a state in which user input is required, e.g., setting time and date, setting drug type, and concentration after reloading the drug reservoir, the pump shall issue periodic alerts/indications every x minutes until the required input is provided.
- Clearing, changing or resetting the pump settings shall require the user's confirmation.
- Setting and changing the concentration and activity duration of the currently loaded insulin shall require the user's confirmation.
- If the user has not interacted with the pump for x minutes while programming a basal profile, a temporary basal, or a normal/extended bolus, the pump shall signal a notification and discard all parameters the user has entered.
- The pump shall generate a stuck key alarm whenever a key is held down for a minimum of x minutes.
- The pump and its accessories shall be designed to maintain a failsafe state in the presence of a single fault condition that results in the inability of the pump to ensure the integrity of the pump's operation. When in a failsafe state, the pump shall neither deliver insulin nor generate energy or substances that could affect the user's safety.
- Audible alarm signals shall be in the range of x dBA to y dBA. !
- The pump shall signal audible reminders when no food bolus has been requested by the user within 2 hours after normal meal hours.
- The pump shall issue a warning whenever there is a failure in event logging or log retrieving.
- A system failure alarm shall be issued if any of the safety checks fail

Requirements on Interacting with External Environment

- The pump shall be able to operate as intended within a temperature range of x °C to y °C.
- If the pump becomes overheated to more than x °C, the pump shall signal a pump overheated alarm.

- The pump shall be able to withstand and operate as intended under atmospheric pressure ranging from x to y mm Hg.
- The pump shall be able to operate as intended at relative humidity ranging from x% to y% (noncondensing).

3.2 Hardware Interfaces

Supported device types: Every mobile phone that has Bluetooth connectivity and ability to download an app. Communication between the pump device and app will go through Bluetooth. The device will send its data every 24 hours.

Pump Mechanism
Insulin is measured in "units" where there are 100 units per cc (or mL), assuming the standard U-100 concentration. This means that one unit is 10μL. Basal rates are on the order of one unit/hour administered every three to ten minutes, while bolus doses are several units. Typical cartridge volumes are 200 to 300 units. Due to these ultra-low flow rates, the motor is geared down, and a screw drive is used to advance the cartridge piston very slowly with many revolutions of the motor. Consequently, only coarse angular measurements of the motor are needed. Most major insulin pump manufacturers use optical encoders and DC motors, although stepper motors can also be used.

Flow Sensing
Pressure sensors are used to ensure normal operation and detect occlusions. Based on silicon strain gauges, these sensors provide signals in the millivolt range, rather than the microvolt level provided by bonded-wire strain gauges. The strain gauges use a typical bridge configuration, which provides a differential signal at a common-mode voltage that is roughly half of the supply voltage. Designs will use either analog-to-digital converters (ADCs) with a differential programmable gain amplifier (PGA) input, or ADCs internal to the microcontroller with external differential or instrumentation amplifiers for signal conditioning. Precision pressure measurements are not needed since pressure readings are used for indicating normal operation and not for calculating drug delivery.

Displays/Keyboards
The screen is touchscreen, minimal writings are used, mostly consisting of icons or images. Visible and audible response to user touch inputs is also usually needed.

Timekeeping
Due to the criticality of proper insulin dosing, the pump will keep track of time and time stamp all activity. A real-time clock (RTC) is required for this.

Interfaces
Data ports are provided on most insulin pumps to allow data transfer to a computer and to download firmware upgrades. This allows history files to be pulled into application programs and sent to caregivers to aid in insulin therapy. USB interfaces are commonly used. These interfaces shall include features such as ESD protection, current limiting, and logic-level translation for memory cards.

3.3 Software Interfaces

Modern insulin pumps depend increasingly on software for new features. Software is increasingly responsible for safety functions such as dosage control, interpreting user input and providing display output, and mitigating certain hazards through alarms and alerts.

Database – The app will have a database of the users info, such as their name, birth date, weight, height,the users who are connected to the same pump, their names and communication information.

- Controller and App: Controller checks the Bluetooth connection to the app, if there is a connection, it notifies the database
- Controller and CGM: Controller checks the Bluetooth connection to the CGM, if there is a problem, notifies the alarm system.
- Controller and Pump: Controller checks the UART connection to the Pump, if there is a problem, notifies the alarm system.
- Database and App: If the database is notified, it sends all the data it has to the app and updates the app's info.
- User Interface and Alarm System: If the userAlarm() is notified, the alarm system's userAlarmPressed() method is notified.
- User Interface and Pump: getTime() && getBLandIR()
- Algorithm and CGM: isCGMconnected()
- Algorithm and Pump: sendAvgBP() && getBP() && isBLorIRlow()

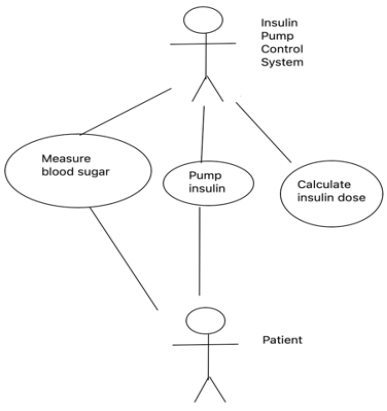
3.4 Communications Interfaces

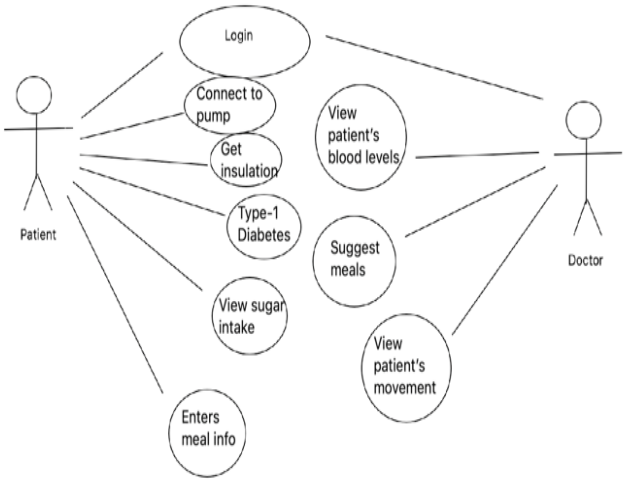
This pump will use Bluetooth to obtain data from the continuous glucose monitors.
Security or encryption issues
Data transfer will occur between the pump and app, each day (24h)/synchronization will occur.
When the user presses alarm or the pump device sends out an alarm, it firstly sends all the alarm signals to all the app users that are connected to the same pump. Then, after 3 minutes if the alarm is not deactivated, the app holds the data of the users' phone numbers, so it sends out messages about the alarm.
The app holds data of 60 days of all the inputs the pump has, thus, the meal and calorie intakes. The users can download that data to their phone as a PDF whenever they want.

Data ports are provided on most insulin pumps to allow data transfer to a computer and to download firmware upgrades. This allows history files to be pulled into application programs and sent to caregivers to aid in insulin therapy. USB interfaces are commonly used.

4. System Features

Use-Case Diagram:





4.1 System Feature 1 - Continuous Glucose Manager (CGM)

4.1.1 Description and Priority

With the emergence of continuous glucose monitoring (CGM) devices in the early 2000s, the possibility of creating a feedback loop came within reach. CGM systems consist of a disposable sensor placed subcutaneously that measures glucose concentration in the interstitial fluid approximately every 5 minutes and a transmitter that sends values to a receiver, providing near real-time glucose measurements. Some systems display glucose concentration only on demand, referred to as intermittently viewed or intermittently scanned CGM. Sensor accuracy is measured through the mean absolute relative difference, which is the average of the absolute error between CGM and matched reference values. Current best performing CGMs have a mean absolute relative difference of just below 10%, an accuracy broadly comparable to most blood glucose meters, making them safe for insulin dosing decisions. The first interoperable CGM system, the Dexcom G6, was licensed by the FDA in 2018 and is factory-calibrated obviating the need for finger-stick calibrations. High priority. The CGM connected with the pump makes it an artificial pancreas. While the development of it may cost much, the profit made will be much bigger.

4.1.2 Stimulus/Response Sequences

The user must put this device onto their bodies, preferably on their upper stomach and check if it is turned on or not.

4.1.3 Functional Requirements

After turning the CGM on, it shall work flawlessly and measure the user's blood pressure every 5 minutes and send the data to the pump immediately. If any error occurs (problem with sending the data, connection issue with the pump, low battery, problem with the measurements), the CGM' s alarm turns on and doesn't stop unless the problem is solved, or the device is removed or shut off.

REQ-1: CGM-A: ability to measure the blood pressure every 5 minutes
REQ-2: CGM-B: ability to send the read data to the pump
REQ-3: CGM-C: If anything goes wrong, send alarm to the embedded app for the pump and app to be alarmed.
REQ-4: CGM-D: being shut off if the device is disconnected from the user's body
REQ-5: CGM-E: re-chargeable
REQ-6: CGM-F: easy connection with the pump

4.2 System Feature 2 - Insulin Pump

4.2.1 Description and Priority

The insulin pump is the number 1 necessity of this device, as can be understood from the devices name: “Insulin Pump”. It has the highest priority and every aspect of it should be flawless, as any error may be fatal. The cost of it might be high but its value in the health market is very high and will bring a lot of profit.
Insulin pumps are programmable, battery-operated devices that deliver short- or rapid acting insulin into the subcutaneous tissue via Teflon or steel catheters at pre-programmed rates with user-initiated meal-time boluses.

4.2.2 Stimulus/Response Sequences

The user can press the “alarm” button in case of an emergency (such has feeling lightheaded or about to faint, generally if there are any symptoms about low or high blood pressure)
The user should almost always have this device on themselves. Only, not when they’re swimming or doing an activity that requires a lot of water (showering is not included, the user can have the device on when they are showering.)

4.2.3 Functional Requirements

REQ-1: IP-A: According to the blood pressure level information gotten from the CGM, basal insulin delivery is adjusted, and/or a bolus is recommended or given automatically.
REQ-2: IP-B: The alarm system shall be activated in the event of an error occurring in the insulin pump device, and it shall remain active until the error is resolved.
REQ-3: IP-C: The pump shall suspend all active basal delivery and stop any active bolus during a pump prime or refill.
REQ-4: IP-D: The average flow rate in any continuous x-minute period shall remain accurate within ±y% of the programmed rate.
REQ-6: IP-E: If the pump allows administering multiple types of insulin, changing drug types and concentrations shall stop any active infusion, remind the user to validate the basal profiles and related parameters.
REQ-7: IP-F: An air-in-line alarm shall be triggered within a maximum delay time of x seconds if air bubbles larger than y µL are detected, and all insulin administrations shall be stopped.
REQ-8: IP-G: Clearing, changing or resetting the pump settings shall require the user’s confirmation.
REQ-9: IP-H: Upon being powered on, the pump shall undergo a power-on self-test (POST), which shall include tests.
REQ-10: IP-I: Information logged shall be retained for at least 3 days.
REQ-11: IP-J: The pump shall be designed to use rechargeable batteries as its only power source.
REQ-12: IP-K: The pump shall be able to operate as intended within a temperature range of x °C to y °C. If the pump becomes overheated to more than x °C, the pump shall signal a pump overheated alarm.
REQ-12: IP-L: The pump shall suspend all active basal delivery and stop any active bolus during a pump prime or refill. It shall prohibit any insulin administration during the priming process and resume the suspended basal delivery, either a basal profile or a temporary basal, after the prime or refill is successfully completed.
REQ-12: IP-M: If the pump allows administering multiple types of insulin, changing drug types and concentrations shall stop any active infusion, remind the user to validate the basal profiles and related parameters, and force the reservoir time and volume to be recomputed.
REQ-12: IP-N: The pump shall allow the user to set at least two basal profiles at the same time, and require the user to activate no more than one profile at any single point in time.
REQ-12: IP-O: The pump shall notify the user when a basal profile is activated, and shall administer basal insulin according to the profile immediately after activation.

REQ-12: IP-P: The pump shall allow the user to stop a temporary basal while it is being administered. When the user chooses to stop a temporary basal, the pump shall either resume the active basal profile prior to the temporary basal or require the user to activate a predefined basal profile.
REQ-12: IP-R: The pump shall allow the user to set the maximum dosage limit for every normal or extended bolus. For each bolus whose dosage exceeds the limit, the pump shall prompt the user to either confirm this bolus or cancel it.
REQ-12: IP-S: The pump shall use the correction factor currently in effect to calculate a correction bolus. At the same time, it shall display the factor to the user through its user interface.
REQ-12: IP-T: The pump shall allow the user to program either a single or a set of insulin-to-carbohydrate ratios (food factors) in the range from x to y g/unit in increments of z g/unit. If the pump allows the user to define a set of food factors, it shall prompt the user to define a time segment with u-minute increments for each food factor. Time segments of all food factors shall not overlap each other and shall cover 24 hours of the day.
REQ-12: IP-U: When the option to suspend the pump is selected, the current pump stroke shall be completed prior to suspending the pump.
REQ-12: IP-V: When the pump is in suspension mode, insulin deliveries shall be prohibited. Any incomplete bolus delivery shall be stopped and shall not be resumed after the suspension.
REQ-12: IP-Y: When the pump resumes from suspension, calculations shall be performed to synchronize insulin used and remaining reservoir volume.

4.3 System Feature 3 –Embedded App

The embedded app is the interface that connects the pump, CGM and app altogether. It has an algorithm to calculate the needed insulin amounts, it is responsible for sending out information to the pump and the app, and it handles errors.

4.3.1 Algorithm

- The algorithm is a computer program integrated into the insulin pump.
- It reads blood sugar data and calculates necessary insulin dosage.
- Modern closed-loop therapy relies on advanced pumps and CGM systems.
- Three main types of closed-loop control algorithms exist:
- Proportional, Integral, Derivative (PID) controllers
- Model Predictive Control (MPC) controllers
- Fuzzy Logic controllers
- The chosen algorithm is Model Predictive Control (MPC):
- Uses a mathematical model linking insulin delivery to glucose levels.
- Dynamic and multi-compartmental model predicts glucose levels.
- Simultaneously adjusts insulin to treat-to-target.
- Accommodates delays in insulin absorption and glucose-affecting events.
- MPC is commonly used for closed-loop systems, modeling diurnal variations and exercise.
- Proportional, Integral, Derivative (PID) controllers:
- Direct insulin doses based on target glucose difference (proportional).
- Consider rate of change in measured glucose (derivative).
- Account for area under the curve between measured and target glucose (integral).
- System prioritization:
- Pump and CGM are higher priority than the algorithm.
- Algorithm failure affects the entire system, making it still a high priority.
- User involvement:
- Algorithm operates automatically with its own triggers.
- Algorithm is pre-connected to the pump upon device purchase.
- In case of algorithm error, pump and app alarms activate.

Input-Output:

- Checks the CGM connection and gives a Boolean output.
- Gets the time from the Pump's embedded clock.
- Gets the blood pressure info from the pump.
- Calculates the average of the last 3 blood pressure levels, and sends this info to the pump.
- Calculates the needed insulin amount accordingly, and sends it to the pump.
- Gets the Battery Level and Insulin Reservoir info from the pump.
- Checks if these levels are low or not, outputs a Boolean.

4.3.2 Connection

- Crucial for device functionality; lack of proper connection leads to failure.
- Connects algorithm and its output to app, pump, and CGM.
- CGM sends measurements to embedded app via Bluetooth every 5 minutes.
- Algorithm triggered every 10 minutes after CGM data provided twice.
- Algorithm calculates needed insulin and checks reservoir levels.
- Algorithm output (insulin amount) sent to pump via UART.

Meal Information and Insulin Calculation:

- User enters meal info in app; app calculates insulin needed (μL).
- Calculated insulin amount sent to embedded app via Bluetooth.
- Embedded app triggers algorithm with received amount; sends amount to pump.

Battery and Insulin Level Monitoring:

- Pump sends battery and insulin level to embedded app every 12 hours.
- Embedded app stores this data for calculations and alerts.
- Low battery/insulin triggers error system; user alerted.
- Low battery alarms start at 15%; continuous alarms below 5%.
- Algorithm sends alarm signals to pump; pump's alarm screen activates.
- Low battery (10%) forces hourly data transmission and user alerts.

Data Exchange and Storage:

- Pump sends all data to embedded app via UART every 24 hours.
- App receives data via Bluetooth if user's phone Bluetooth is open.
- Up to 60 days' worth of data stored in app.

Error Handling and Alarms:

- Monitor/pump inform errors to embedded app.
- App and pump display error info and alarms.
- User alarm press prompts algorithm to check last sent blood levels.
- Algorithm sends blood level info to app users connected to device.

Connectivity Checking:

- Embedded app checks monitor and pump connectivity every hour.
- Issues trigger alarms in pump and app.

CGM Errors and Disconnection:

- CGM informs embedded app of errors/problems.
- App and pump receive error alarms from embedded app.
- CGM disconnection alerts embedded app; info sent to app and pump.

Connection Method:

- CGM and phone app connected via Bluetooth to Embedded App.
- Pump connected to Embedded App via UART.

4.4 System Feature 4 – App

4.4.1 Description and Priority

The app is for controlling the pump and keeping all the data. It is also open to use for the close people of the pump's user. For example, the pump user's family and a few close friends, up to 7 people, are allowed to be connected to the same pump. Therefore, if an emergency occurs, they will also be notified. In addition, whenever they want, they can see all the data of the insulin pump user. This app has a medium priority. It should be done, but after the insulin pump and all its features are finished. It will require 1-2 people to build and publish the app, so the cost shouldn't be high, but the use of the app will be remarkable. In addition, the app will feature a "food" section, including up to 10,000 different foods the user can choose from. This function will take the burden of the user to always calculate calories and carbohydrate amounts. Instead, the user will just choose the meal that they will be eating, and the size of it, and the rest will be done with the app. The app will send out the information about the food and how much insulin should be pumped to the pump. The user's job will become much easier.

4.4.2 Stimulus/Response Sequences

The main user of this app, is the diabetes patient, the one who's using the app. They will have all the control over the app and will be able to see all the values of their blood pressure and more.
They will have the responsibility to always notify the app about what they are about to eat.
Furthermore, the user can download the blood pressure, insulin levels and more as a PDF with just one click. All that info is kept for 60 days and renewed after 60 days.

4.4.3 Functional Requirements

REQ-1: AppA: The apps connection with the device shall be flawless. If the user must do something to ensure that connection, this must be written in the user manual, highlighted.
REQ-2: AppB: The app shall be fit for the use of at most 7 people for the same pump device. They will all have the same login info but will be able to login from their own phones, and therefore monitor the same person all in the comfort of their phones.
REQ-3: AppC: The app shall be compatible with all the smartphones in the sector. In addition, it shall always be ready for any updates, as phones develop each day.
REQ-4: AppD: The app shall not take much space off the phone as phone storage may be a problem for the users.

5. Other Nonfunctional Requirements

5.1 Performance Requirements

The insulin pump shall be a Real Time Operating System. Because it will get the glucose level in the blood from the CGM and shall act as fast as possible to normalize the blood pressure. The algorithm in it should work very fast to calculate the needed insulin amount, and as soon as that information gets to the pump, that amount of insulin shall be pumped.
The battery life of the pump shall be long, minimum 3 weeks with full charge. The battery will be rechargeable, but still, the user shouldn't have to always charge it. In addition, the charging time shouldn't be long, as the user will be without a pump for that time, this is fatal. The best time would be, that when the user is taking a shower, the almost empty battery should be charged almost to full. Somewhat a similar time would mean the best insulin pump in the sector and would be sold without any effort.
To keep batteries as small as possible, designers must reduce power consumption and improve efficiency wherever possible. If possible, any circuitry that is not in use at any given time is shut down until needed.

The storage of the pump shouldn't take much. It stores only the data of 3 days, and all the data shall be kept in a SD Card inside the pump device. The storage shall be 2GB?

This insulin pump is a wearable device, so, it must be very small and lightweight. It will measure about 5cm x 7.7cm x 2cm, and weigh 105gr.
Size, weight, and power consumption are higher priorities of a product.

5.2 Safety Requirements

Insulin pumps require audible and visible alarms to alert users when a fault is detected, a specific time arrives, or a warning condition is triggered. Individual LEDs can be used as visual indicators in glucose monitor remotes and insulin pumps. A flashing green LED usually indicates normal operation, while a red LED signals an alarm or warning.

- The device is waterproof but still not advised to wear underwater, wearing it while showering is no problem.
- The pump shall suspend all active basal delivery and stop any active bolus during a pump prime or refill. It shall prohibit any insulin administration during the priming process and resume the suspended basal delivery, either a basal profile or a temporary basal, after the prime or refill is successfully completed.
- If the pump allows administering multiple types of insulin, changing drug types and concentrations shall stop any active infusion, remind the user to validate the basal profiles and related parameters, and force the reservoir time and volume to be recomputed.
- The pump shall allow the user to set seven basal profiles at the same time and require the user to activate no more than one profile at any single point in time.
- The pump shall notify the user when a basal profile is activated and shall administer basal insulin according to the profile immediately after activation.
- The pump shall allow the user to set the maximum dosage limit for every normal or extended bolus. For each bolus whose dosage exceeds the limit, the pump shall prompt the user to either confirm this bolus or cancel it.
- The reservoir volume remaining shall be updated after each pump stroke by subtracting the amount of insulin delivered during the stroke.
- When the option to suspend the pump is selected, the current pump stroke shall be completed prior to suspending the pump.
- If the suspension occurs due to a fault condition, the pump shall be stopped immediately without completing the current pump stroke.
- The pump and its accessories shall be designed to maintain a failsafe state in the presence of a single fault condition that results in the inability of the pump to ensure the integrity of the pump’s operation. When in a failsafe state, the pump shall neither deliver insulin nor generate energy or substances that could affect the user’s safety.
- The meal information given to the app should be precise and accurate. Otherwise, wrong amounts of insulin may be pumped.
- These devices shouldn’t be dropped. Even though they won’t break, any little calibration that may change due to the effect of the crash could result in bigger and dangerous ways.

5.3 Security Requirements

The pumps security involves cybersecurity. It refers to the tools and practices that prevent attackers from gaining access to the devices and their data, or even worse, control them. The cybersecurity of this pump is one our highest priorities, as any mistakes could become even fatal. We give you these for protection from getting hacked:

Protect firmware: Firmware is the software that is built into physical devices. Because firmware security flaws can lead to unauthorized access, device managers must be aware of which firmware runs on all devices in their network and upgrade it if device manufacturers announce a security flaw in their firmware.

Secure data stored in device: Data that remains on medical devices (as opposed to data that is forwarded to another device or server immediately after it is collected) should be secured via encryption and access controls.

Secure communication among devices: Whenever data leaves a device, it shall be encrypted to prevent access by network eavesdroppers. In addition, networking protocols used by IoMT devices must be secure to prevent attackers from exploiting protocol flaws to gain unauthorized access.

The FDA provides guidance to help manufacturers design and maintain products that are cyber secure. And on behalf of patients, the FDA urges manufacturers to monitor and assess cybersecurity vulnerability risks, and to be proactive about disclosing vulnerabilities and solutions to address them.

5.4 Software Quality Attributes

Availability: available for all ages, for many environments such as high-pressured places, high places, pools, or seas although it's not really recommended.
Correctness: we are 100% sure that our measurements are correct, and the algorithm works flawlessly so the insulin pump is working for the best of the user.
Maintainability: with our insurance for such long years (5 I guess), we are certain that this product will go on working flawlessly for long years and will be maintainable for at least 5 years.
Reliability: the calculations are correct for sure, so the pump is reliable for the patient's health.
Testability: before putting this device on production, we will be testing it on… for…
Usability: It's usable for all ages starting from 6. (6+)
Ease of use is the key, no complicated interfaces, everything is certain.

5.5 Business Rules

<List any operating principles about the product, such as which individuals or roles can perform which functions under specific circumstances. These are not functional requirements in themselves, but they may imply certain functional requirements to enforce the rules.>

Up to 7 people can monitor the blood pressure data when they also install the app and connect it to your device. These users have full control over the pump, just like the user of the pump.

6. Other Requirements

<Define any other requirements not covered elsewhere in the SRS. This might include database requirements, internationalization requirements, legal requirements, reuse objectives for the project, and so on. Add any new sections that are pertinent to the project.>.

Maybe database for calories of foods for the app.
https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices
https://www.emergobyul.com/news/new-revised-qa-resource-regulation-eu-2023607#:~:text=The%20new%20regulation%20allows%20legacy,2017%2F745%20(MDR).

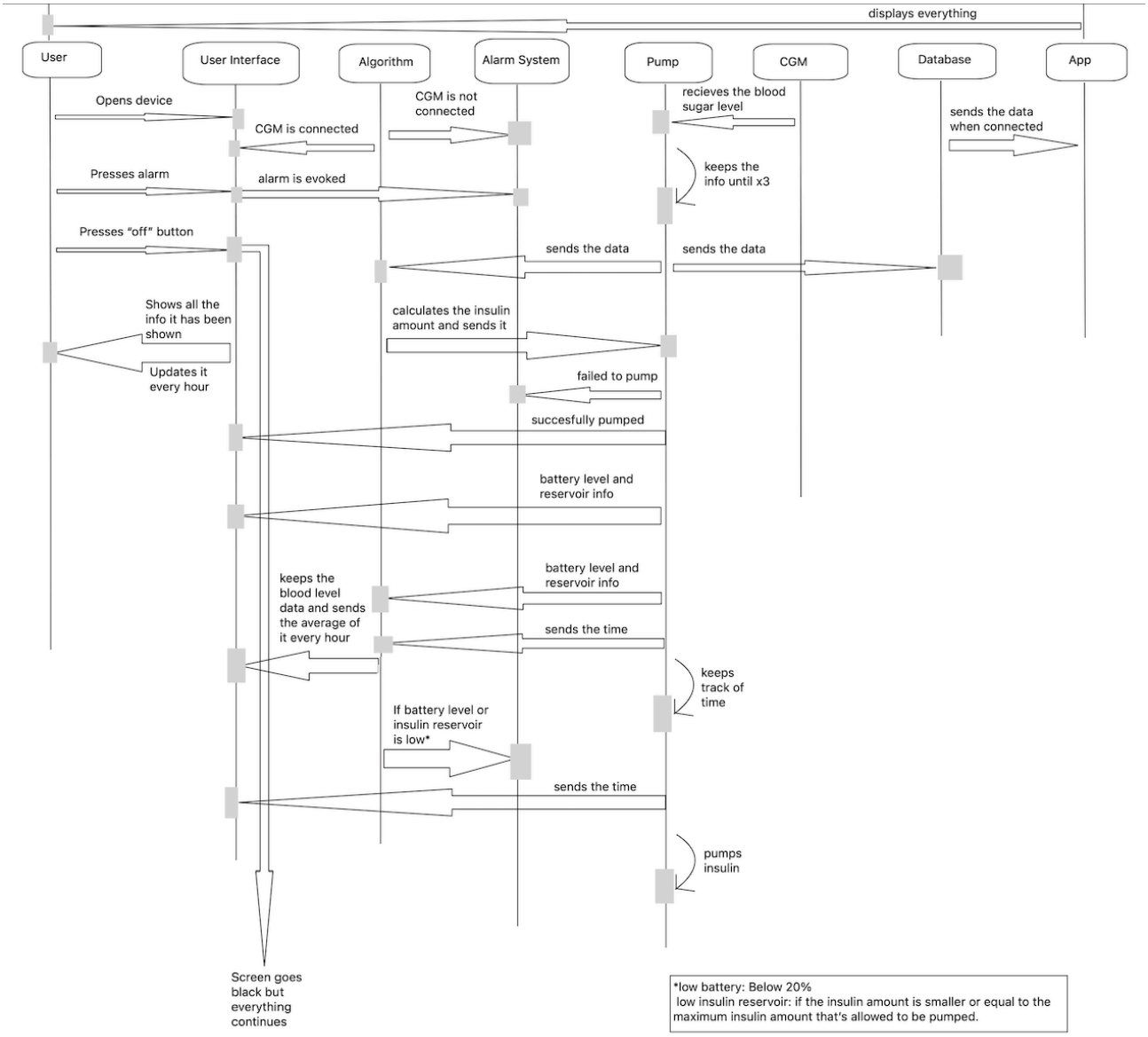
Appendix A: Glossary

- Basal: Insulin infusion given as low regular flow throughout the day. This is done in AUTORUN.
- mode of the insulin pump.
- Reservoir: Cartridge of insulin housed in the pump.
- Tubing (delivery line): Plastic tubing that connects cannula to reservoir.
- Cannula: A cannula is a thin tube that doctors insert into a person's body cavity, such as their nose or into a vein.
- Infusion set: Includes cannula and tubing.
- Continuous Glucose Monitor (CGM): Subcutaneous glucose sensor that measures glucose levels in the subcutaneous fluid every few minutes. May be integrated with a pump.
- Bolus: Insulin infusion given as a one-time delivery in addition to any basal delivery. A bolus is
- given, for example, when eating a high carbohydrate meal. This is done in MANUAL mode of the
- insulin pump.
- Insulin: A hormone produced in the pancreas that regulates the level of glucose in the blood.
- Pancreas: A large elongated glandular organ lying near the stomach. It secrets juices into the
- small intestine and the hormones insulin, glucagons and somatostatin into the bloodstream.
- Glucose: A simple sugar which is an important energy source in living organisms and is a component of many carbohydrates.
- Artificial Pancreas: An investigational device designed to mimic a human pancreas by combining an insulin pump with a continuous glucose sensor.
- Cannula: The tiny, flexible section of the infusion set that is inserted under the skin through which insulin is delivered.
- Closed Loop: A system that regulates blood glucose automatically without a person with diabetes needing to enter date such as glucose or carbohydrate values.
- Fingerstick: A method used to test blood glucose by using a puncturing device (like a lancet) to take a small sample of blood from the finger.

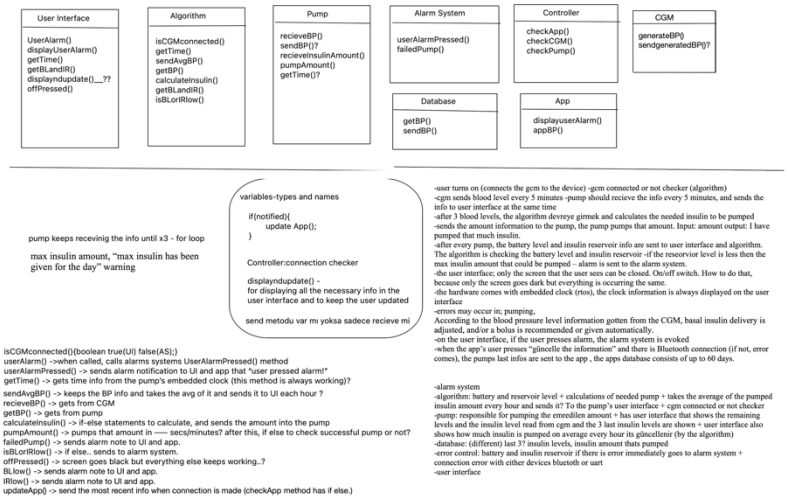
Appendix B: Analysis Models

<Optionally, include any pertinent analysis models, such as **data flow diagrams, class diagrams, state-transition diagrams, or entity-relationship diagrams**.>

UML SEQUENCE DIAGRAM



UML CLASS DIAGRAM



Appendix C: To Be Determined List

Wi-Fi: Should we make a pump that has a WIFI connection? Or is it not worth the risk of cyberattacks?
Remote software updates?
Instead of user inputting what they ate to the app, how about visual recognition and the user just takes the photo of what they're about to eat?
The age restriction of the pump?