Project Proposal – Canine Insulin Pump

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1 Introduction

1.1 Objective

While technology for managing diabetes in humans has improved significantly in the last few decades, the same is not true for most pets and animals including dogs. Owners of dogs that suffer from diabetes typically do not have options to purchase the same kind of insulin delivery and blood-glucose monitoring systems that are available for humans. Instead, owners must manually give their diabetic dogs insulin shots every time they have a meal, which is recommended to be twice a day [1]. That process requires measuring insulin into a syringe, injecting the insulin into the dog, and disposing of used sharps. This is a wasteful process that is also very time intensive for the owner and potentially stressful for the dog. Additionally, unlike for a human, most dog owners do not measure blood glucose on a regular basis or at all and simply deliver a fixed amount of insulin when the dog has a meal. This ignores medical research showing that insulin requirements change over time [2].

Our solution is a system comprised of a wearable, miniaturized insulin pump for the dog that can connect to an owner's smartphone app via Bluetooth Low Energy (BLE). The app allows the owner to dispense insulin doses as necessary with a button press. The amount of insulin dispensed can also be adjusted from the app, saving the owner the difficulty of measuring out slightly more or less insulin into a syringe. The wearable pump will be battery powered and will be charged whenever the insulin reservoir is refilled. The app will track general pump status information, time of feedings, time and amount of insulin infusions, and optional discrete blood glucose measurements performed by the owner with separate tools. If these glucose measurements are provided, the insulin dose can be adjusted over time. The goal is to prove that such a device can be made in a small enough form factor and for a low enough cost that it would be beneficial as a real product. We believe the proposed system provides utility to both the dog, the owner, and the veterinary doctor. The dog will no longer have to deal with a lengthy and invasive injection, the owner gets an easy way to administer and track infusions, and the doctor can get useful data on how well the feeding and insulin infusion schedule is being followed. The occasional blood glucose measurements can be used to adjust dosages [1].

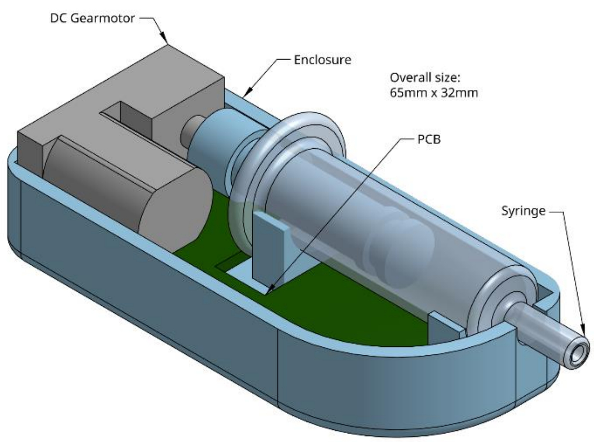
1.2 Background

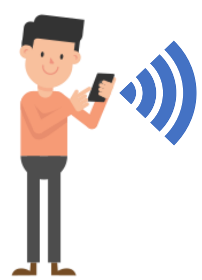
In the typical case of treating a diabetic dog, the doctor only can adjust dosages every time the dog is taken in which is typically every few months [1]. Insulin resistance in dogs varies with many factors so more frequent measurements can keep glycemic control on track since insulin resistance can vary among dogs and within one dog over time [2]. There are models that provide a method of estimating insulin dose based on infrequent discrete blood sugar measurements [3] and with this device and app, it becomes easier for the owner to track these measurements. This paper was strongly recommended to us by Jeremy DeJournett, a UIUC ECE alumni whose company is developing a human rated artificial pancreas [4].

In addition to personal use, many studies involving diabetes use canines instead of humans. Researchers usually use off the shelf disposable subcutaneous insulin catheters meant for humans on dogs [5]. An insulin pump scaled down and designed for dogs would be useful to researches, and the accompanying app would assist in data collection and tracking.

1.3 Physical Design

The physical design of the insulin pump must be small enough to fit on a dog's collar. The reservoir and pump consist of a small 1mL glass syringe. A custom syringe plunger will slide linearly as the motor spins an M4 threaded shaft. A 3d printed clamshell will hold the insulin syringe, motor, battery, and PCB. Mounting clips built into the clamshell will allow the pump to be attached to a dog collar. The end of the syringe will have a Luer-Lok [6] connector to attach to a small hose that leads to the subcutaneous catheter. The catheter and hose are beyond the scope of this project.





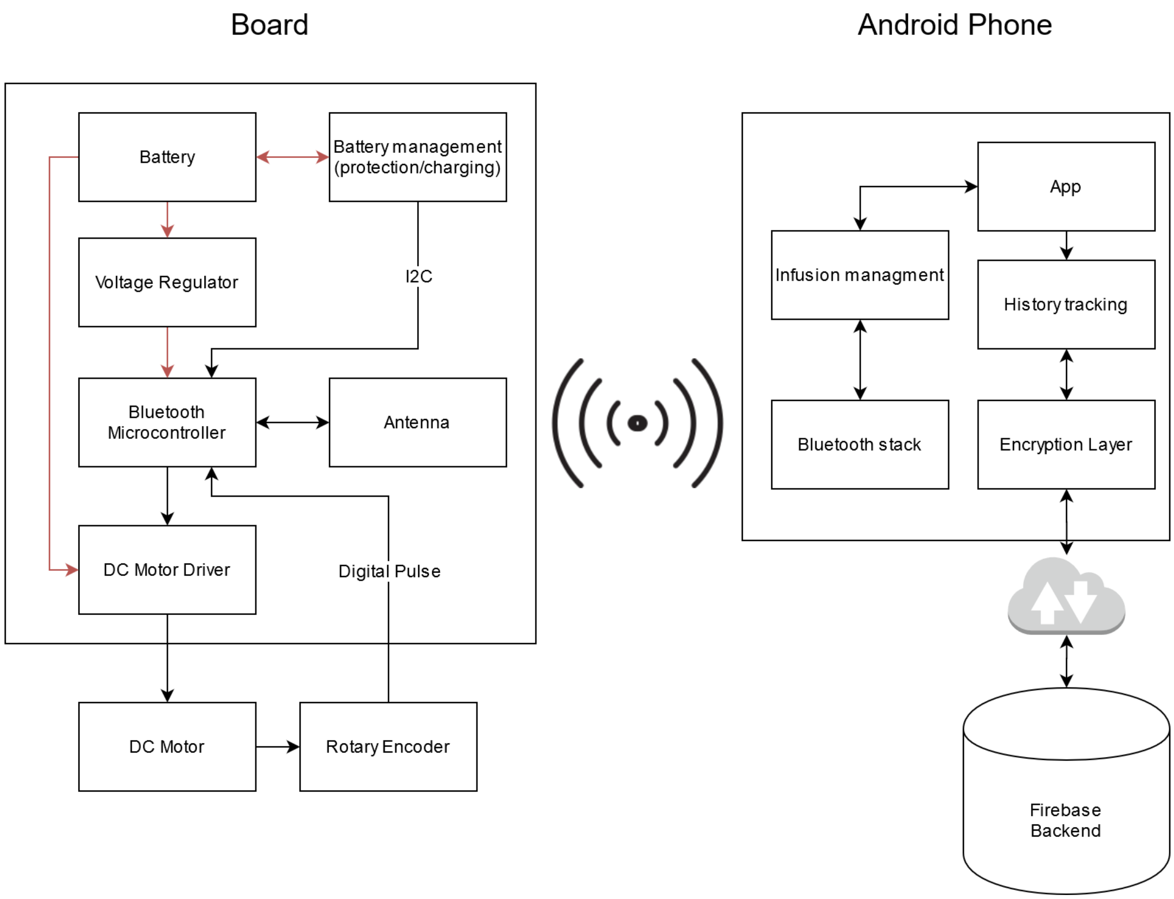
1.4 High Level Requirements

- The device must be able to deliver accurate (+/- 5%) bolus infusions of insulin twice a day for at least 3 days before refilling or charging.
- The device must be controllable via a Bluetooth Low Energy enabled Android phone loaded with a custom app.
- The app must be able to control the device via Bluetooth Low Energy and log the data including time of infusion, time of meal, infusion amount, and optional glucose level monitoring.

2 Design

2.1 Block Diagram

The pump circuit board contains the necessary hardware and software to precisely drive a brushed DC gearmotor from a single cell lithium ion battery. Encoder feedback is used to stop the motor when a full infusion has been delivered. Over a wireless Bluetooth Low Energy connection, the pump communicates with an Android phone that tracks all infusion management data. Date is stored in a Google Firebase backend in an encrypted form. The Android app can pull down previous data from this backend to display to the user.



2.2 Functional Overview and Block-level Requirements

2.2.1 Battery

The battery is responsible for powering the microcontroller, pump and other devices over the three days of continuous operation. The must be enough energy storage to deliver two infusions each day.

Requirement: The battery shall provide at least 100mAh of stored energy with a nominal voltage of 3.7v.

2.2.2 Rotary Encoder

The rotary encoder is connected to the output shaft of the DC gearmotor and provides a digital pulse to the microcontroller for each step. With 64 pulses per revolution, we can measure fluid quantities in discrete steps of 547 nL. A typical infusion is 100uL, so this corresponds to an accuracy of +/- 0.5%. This is well below the +/-5% we guarantee. This allows for some amount of mechanical backlash to be present in the system.

Requirement: The encoder shall have at least 64 pulses per revolution.

2.2.3 Voltage Regulator

The voltage regulator is responsible for converting the voltage from the battery to a stable supply voltage for the microcontroller. This allows the microcontroller to function over a variety of battery voltages.

Requirement: The voltage regulator shall provide 1.8v (+/- 5%) at up to 100mA from a 3.0v-4.2v supply.
Requirement: The voltage regulator shall have a quiescent current of less than 10uA.

2.2.4 Motor

The motor must have a geared output that spins slow enough that we do not overshoot the required dose. Assuming a typical dose of 100uL, we should be able to dispense this amount in 5 seconds. This corresponds to a rotational speed of 35 RPM.

Requirement: The gearmotor output shall spin at less than 35 RPM at 3.7V.

2.2.5 Motor Driver

The motor driver is responsible for controlling the brushed DC motor that drives the syringe pump. The motor driver connects to the microcontroller with simple digital pins to specify direction and enable/sleep.

Requirement: The motor driver shall be able to drive a brushed DC motor in both directions.
Requirement: The motor driver shall be able to drive the motor with up to 100mA of current.
Requirement: The motor driver shall have a shutdown/sleep current of less than 10uA.

2.2.6 Antenna

A simple 2.4GHz surface mount chip antenna provides enough gain for a stable BLE connection in almost all conditions.

Requirement: The BLE connection shall be reliable at a distance of at least 25 feet.

2.2.7 Microcontroller

The microcontroller on the board must be able to receive Bluetooth commands and drive the motor driver with a digital signal. It must be able to count encoder ticks and stop the motor once the correct infusion amount has been delivered. The microcontroller must also communicate with the battery management IC using I^2C to track the battery state of charge, and charger status.

Requirement: The microcontroller shall have an average sleep current of less than 50uA while advertising every 10 seconds.
Requirement: The microcontroller shall be able to communicate with the battery management IC over I^2C at 400KHz.

2.2.8 Battery Management

The battery management block is made up of two parts, a discrete lithium ion battery charger IC and a battery gas gauge. The charger IC has a single digital output that indicates charge status which connects directly to a microcontroller general purpose input/output pin. The battery gas gauge connects to the microcontroller over a standard I2C interface and can provide useful metrics about the state of the battery.

Requirement: The battery charger shall charge a single cell lithium polymer battery from 3.0v to 4.2v from a 5.0v power source with a maximum charge current of 100mA.
Requirement: The battery gas gauge circuit shall provide the battery state of charge (SoC), voltage, temperature, and current to the microcontroller.
Requirement: The battery gas gauge shall have a quiescent current of less than 50uA.

2.2.9 Bluetooth Stack

This is the built-in Bluetooth stack available in modern Android phones. We will specifically test on a Google Pixel 3A. However, any Android phone that supports Bluetooth Low Energy could be used.

Requirement: The Bluetooth Low Energy radio must be capable of communicating with the receiving antenna within a range of at least 25 feet.

2.2.10 Infusion Management

The Infusion Management System is a layer of the Android application code. It is responsible for managing communication with the microcontroller on the board. The packets it generates are then passed to the Bluetooth Stack to be sent to the board. Data related to infusion times, amounts, and other sensor data will come back from the board and be delivered to the Main Application.

Requirement: The Infusion Management System must allow the Main Application to control the board's operation

Requirement: The Infusion Management System must allow the Main Application to collect data from the board

Requirement: The Infusion Management System shall instantiate an encrypted link over Bluetooth Low Energy between itself and the board.

Requirement: The Infusion Management System shall use the established encrypted link over Bluetooth Low Energy for all further communication with the board.

2.2.11 History Tracking

The History Tracking System is responsible for handling data related to manual blood-glucose level measurements, as well as other sensors present on the board. It also manages data transfers between the Android Phone and the Encryption Layer/Firebase Backend.

Requirement: The History Tracking System must allow the Main Application to transfer data between itself and the History Tracking System.

Requirement: The History Tracking System must utilize the Encryption Layer to communicate with the Firebase Backend.

2.2.12 Encryption Layer

The Encryption Layer is a responsible for ensuring that all data leaving the Android Phone for the Firebase Backend is properly encrypted and that data coming from the Firebase Backed to the Android Phone has been properly decrypted upon arrival.

Requirement: The Encryption Layer must allow the History Tracking System a way to transfer data in both directions with the Firebase Backend

Requirement: The Encryption Layer must properly encrypt all outgoing data to the Firebase Backend

Requirement: The Encryption Layer must properly decrypt all incoming data from the Firebase Backend

2.2.13 Firebase Backend

The Firebase Backend is a cloud storage service provided by Google. To satisfy our legal and ethical obligations to keep the data collected by this project secure, all of the data stored in the Firebase Backend will be encrypted before it is sent to Google's servers, as described in the Encryption Layer requirements.

Requirement: The Firebase Backend will serve and store encrypted data transmitted to it via the Encryption Layer

2.3 Risk Analysis

The Bluetooth Low Energy communication used in this system adds serious risk to the successful completion of this project. The reliable operation of Bluetooth communication on the 2.4GHz ISM band is critically important to the successful operation of the device. The antenna, matching network, and software stack that make up the communication link is complex and easy to get wrong. We require only 25 feet of range which is on the low end of how far BLE typically goes. This allows for some amount of antenna mismatch.

The software side of using Bluetooth Low Energy will also be complicated and prone to failure. On the microcontroller side, not only do we have to conform to the BLE specifications, but we will also need to implement encryption and likely error correction for reliable communication. Algorithms like these tend to not be particularly difficult on a computing environment like a phone, but on a microcontroller debugging an incorrect encryption or error correction algorithm can be extremely tedious and time consuming. There may also be concerns around processing the data quickly enough. The Android side is likely to be easier, however particular features of the phone and the specific operating system that we test with occasionally introduces undocumented complexities that can turn into serious time sinks.

3 Safety and Ethics

There are several possible safety and security hazards present in our project. A threat to physical safety that must be managed in accordance with the IEEE Code of Ethics sections 7.8.1 “to hold paramount the safety (…) of the pubic…” [7], 7.8.9 “to avoid injuring others…” [7], and the ACM Code of Ethics section 1.2 “avoid harm” [8] is the risk from using a small Lithium Ion Polymer battery. Such batteries can be extremely dangerous if allowed to overcharge, over discharge, or if they are brought to extreme temperatures [9]. To meet the requirements of preventing harm, a battery was chosen that provides automated discharge cutoff at under and over voltage as well as protection against output shorts [10]. Additionally, the board will provide temperature protection and the charging circuitry will prevent over charging of the cell. The battery is small enough that runaway discharge is not a concern, in addition to the mentioned mechanisms to prevent that. Charging the battery while the device is in use or attached to any living creature is dangerous and will be expressly prohibited.

Another concern for electronic devices, especially ones using battery power, is protection against water. However, since this project is focused on the design of the pump, we would consider protecting significantly against dust and water to be outside the scope of the design. Therefore, our device will conform to IP31 [11].

The Bluetooth Low Energy communication between the board and the Android app is a serious concern ethically. Theoretically, a malicious actor could abuse such a connection to either prevent the dispensing at the appropriate time or cause too much liquid to be dispensed. To address this concern and meet the requirements of the previously mentioned IEEE Code of Ethics sections 7.8.1 [7], 7.8.9 [7] and the ACM Code of Ethics section 1.2 [8] as well as 2.9 “design and implement systems that are (…) secure” [8], the communication between the Android app and the board will be encrypted.

A final concern to address is that our app and Firebase Backend will be storing protected personal medical data for the dog and possibly the owner. To act in accordance with ACM Code of Ethics section 1.6 “respect privacy” [8] and in accordance with the basic principle of HIPAA laws [12], any data stored on the phone, transmitted between the phone and the Firebase backend, and/or stored in the Firebase backend will be encrypted so that only the user of the app will have access.

Normally a medical device like this one would fall under strict regulations from the Food and Drug Administration and other related organizations, but using this device in anyway except to demonstrate the capability to dispense accurate amounts of liquid into a container is outside of the scope of this project. No human, animal, or actual insulin will be utilized due to the legal and ethical requirements, cost constraints, and time constraints.

4 References

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