ECEN 403
Electrical Design Laboratory I
GlycoTrem: Project Proposal

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"An Aggie does not lie, cheat or steal or tolerate those who do."

Abstract

Diabetic patients suffer from poorly regulated glycemia levels. If left untreated, the change in glycemia levels presents severe, and possibly life threatening consequences. In spite of the availability of many sophisticated products that continuously monitor glycemia levels, these solutions are costly. The less expensive solutions are invasive and cumbersome for the patients, especially for hypoglycemia (low blood sugar) detection. The reasons behind this characterisation is the need to repeatedly prick the finger (test strips) or the arms (sensors).

Current research has shown a possible correlation between hypoglycemia and extremity tremors, for which reason this document proposes a solution for detection of hypoglycemic events by exploiting those tremors. The solution is based on developing applications for wearables that can be connected to a second application for smartphones. The proposed solution, GlycoTrem, provides a non invasive and cost effective solution to this issue. By providing a long term overview of hypoglycemic events along with a higher sampling rate, trends can be easily established and corrective action taken to reduce their frequency.

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1 Introduction and Project Statement

Diabetic patients are unable to naturally regulate glycemia levels. Glycemia is defined as the glucose level present in the blood. These patients rely on invasive and costly methods to cope with this disease. Poor blood sugar regulation can manifest itself in two ways; high blood sugar causes a condition called hyperglycemia, whereas low blood sugar causes hypoglycemia. Neglecting either of these conditions has severe and often debilitating and life-threatening consequences.

Hypoglycemia in particular is more difficult to predict in its early stages [1]. As such, it requires more frequent testing either through Continuous Glucose Monitors (CGMs) or Blood Sugar Test Strips.

Recent research shows a correlation between extremity tremors and hypoglycemic events. Upon drastic decrease of blood glucose, the body releases hormones (epinephrine and norepinephrine) that attempt to increase the blood sugar. Side effects of these hormones include anxiety, palpitations, and most importantly tremors [2].

Thus, our proposed solution GlycoTrem aims to exploit these tremors providing a secondary monitoring system for hypoglycemia that is non-invasive and cost-effective. This would be achieved through integrating our software solution into mainstream wearable devices with conventional accelerometers. Moreover, GlycoTrem would provide a platform for healthcare professionals and guardians to collect and analyze hypoglycemic event data.

This document will go in-depth about the methodology and proposed functionality of GlycoTrem. The proposed design, infrastructure, components, costs, challenges, and timelines will be outlined and discussed. A brief yet comprehensive literature review backing the main foundation of the product's principle and claims in this proposal was undertaken to provide references.

2 Proposed Design

2.1 System Outline

The GlycoTrem system would be composed of four integrated layers: (1) Smartwatch Application, (2) Smartphone Application, (3) Database, and (4) Data Analysis Server.

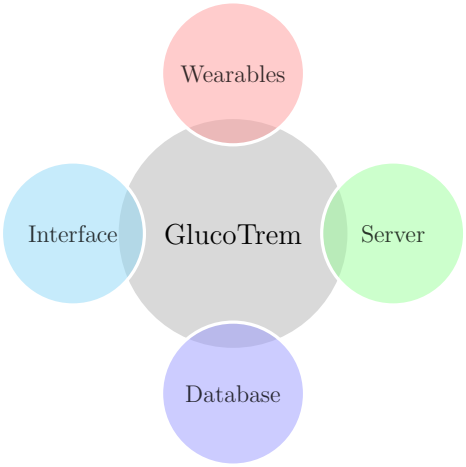

Figure 1: System Outline

The first layer consists of the data collection device. The patients would be required to wear a smartwatch equipped with a three-axis accelerometer and Bluetooth Low Energy support. This watch would then continuously record and transmit coordinate data back to the smartphone app at the second layer.

The second layer consists of the companion app on a smartphone that handles user roles and management. A web interface can also be developed to display this data. Depending on the nature of the user (patient, guardian, or healthcare provider) the application would adapt the visualized data to better fit their needs. Moreover, the app would be responsible for transmitting collected data from layer 1 to layers 3 and 4.

The third layer and fourth layers are the database and data analysis servers. The database simply stores collected data and distributes it to any layer that requests it. Due to the low power nature of the other layers, the data analysis server handles the computationally intensive workloads that are required to identify hypoglycemic events. The results are then transmitted back to layer 2 for long term visualization and potentially alerting.

Figure 2: Data Collection Mechanism

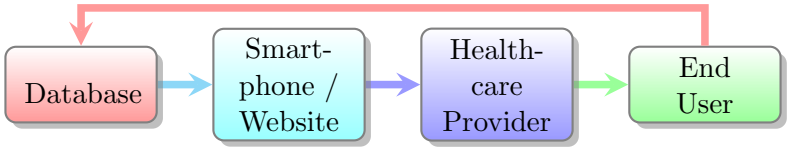

Figure 3: Longterm Trends and Feedback Data

2.2 Design Constraints

2.2.1 Isolating Noise

Many conditions manifest in physiological tremors. Age, physical fitness, and the overall health condition all influence their frequency [3]. Isolating the specific frequency range of tremors that are a result of hypoglycemic events might be a challenge. Further real world testing in this area is required to determine the effectiveness of filtering the noise out.

2.2.2 Quality of Accelerometers

There exists in the market a wide variety of smartwatches equipped with accelerometers. Testing which watch records more accurate data is crucial. For instance, the Android operating system (and Wear OS) limits the sampling rate of accelerometers from 7Hz to 200Hz [4]. iOS on the other hand, limits it to 100Hz.
Certain sensors also have different sensitivities to certain frequency ranges. The frequency range of interest for GlycoTrem is around[1] 10Hz to 14Hz [5]. This will need further testing and validation.

2.2.3 Power Consumption

Wearables have inherently small batteries. The battery life of the solution also needs to be long enough as to not inconvenience the user with frequent charging. For this reason, analyzing the data in the watch or the smartphone app is not feasible.
Offloading the computationally intensive workloads to a remote server is a possible solution. This might introduce further challenges due to latency, internet access, and synchronizing the data in as close as possible to real-time if an alerting system is to be considered.

2.2.4 User Experience & Privacy

One of GlycoTrem's objectives is to provide diabetic patients with a non-invasive product by being integrated within devices that they already use (watch, phone). The product needs to display information in a format that is accessible by the target audience.
For instance, healthcare providers might be interested in more raw data than the end users. A user interface that adapts to the role of the current user will need multiple revisions and surveys to determine their effectiveness. This process is time consuming and very iterative.
Ethical considerations also come into play when it comes to protecting user data and privacy. The user experience should reinforce that privacy is taken seriously. This would be achieved through specific application features as well as end-to-end encryption in the server.

2.2.5 Cost and Budget

Due to the aforementioned necessity of testing the different accelerometers, further research must be conducted to limit our options. The reason behind this limitation is the fact that it is financially inefficient to purchase and test all available products. Additionally, there exists a significant percentage of the population that opts for three main software and product ecosystems. This limits our options to WearOS, Tizen, and iOS.
In terms of final product cost, the current invasive healthcare products on sale are often

[1] Some studies suggest a tighter 8Hz to 12Hz range, this will need to be independently validated.

expensive. Since GlycoTrem is mainly a software based solution, the cost of the smartwatch and smartphone may be excluded. The only "running costs" of the product are the server and infrastructure costs discussed later in this proposal. If a licensing model is adopted, the software can be monetized to offset these costs[2]. Ethical considerations also come into play here, as the product shouldn't be prohibitively expensive leaving out a vulnerable portion of the user base.

2.3 Standards and Anticipated Results

The healthcare field is tightly regulated. Data collected and transmitted to remote servers will need to be encrypted and protected. For this reason, all of GlycoTrem's layers are to be developed in-house. No third party services for databases will be used. Potential compliance with HIPAA standards[3] is to be considered.
In terms of the expected results, GlycoTrem should be able to profile the hypoglycemic events trends as data is continuously collected. It should be able to highlight trends of hypoglycemic events that are harder to pinpoint in the short-term. For instance, if a user's blood sugar frequently decreases markedly at 3PM, GlycoTrem should be able to identify this through the occurance of tremors. Corrective action by the user or healthcare provider can then be taken to reduce these instances.

2.3.1 Potential for Realtime Alerts

GlycoTrem's primary purpose is providing a clear view of hypoglycemic event trends. This is primarily useful for healthcare providers and users in order to readjust their behavior to eliminate these windows.
However, if the data analysis and identification of hypoglycemic events is fast enough, GlycoTrem could potentially send the user realtime notifications in the event of hypoglycemic events. This would open up a plethora of other features, but would require further testing.

3 Components

3.1 Smartwatch

The smartwatch is one of the primary components of GlycoTrem. The reliability and accuracy of the collected data heavily depends on the quality of the watch's sensors. The smartwatch should simply collect raw accelerometer data and forward it to the smartphone app unchanged. Several smartwatches with varying price brackets and sensor capabilities exist in the market.
It is important that a wide range of these solutions is tested with GlycoTrem to establish the eventual cost to the user and to set a baseline of the expected accuracy. Most likely, a selection of three smartwatches (one for each platform) that work well with the system would be recommended and officially supported.

[2]Should the cost of the smartwatch be accounted for, a target of 150$ upfront cost (wearable) with a minimal recurring monthly license (5$ per user) would easily cover the costs of running the service with only four users. The server would be able to handle a much higher user count, further reducing the costs as the number of users scale.

[3]HIPAA stands for the "Health Insurance Portability and Accountability Act". The security and privacy relevant sections of the act are such that it is often alternatively called the Health Information Privacy and Portability Act (HIPPA). HIPAA compliance requires strict healthcare data privacy and security practices.

The current preliminary candidates are: The Polar Smartwatch (Highend, Android); The Ticwatch E (Lowend, Android); The Galaxy Gear (Highend, Tizen); and the Apple Watch (Highend, iOS).

3.1.1 Contingency Plan

Should the smartwatches prove to be ineffective due to low accelerometer accuracy, a purpose built ring/watch wearable device could be designed with good quality validated accelerometers.
This would significantly increase complexity, but would provide greater control over component selection. Until validation of existing smartwatches, the development of this solution in parallel would allow for a smooth contingency plan. This could still be used as a supplementary device even if the smartwatch sensors are validated.

3.2 Phone Application

The end user's only direct interaction with GlycoTrem is through the smartphone application. This OS agnostic application's duty is to provide the users with a medium on which they can access their data. The application would have different interfaces depending on the role of the user. This role would be determined by the user as they log into the application.
The patients themselves should be able to input their own personally identifiable information, i.e. age, gender, etc. This patient's guardians (if they're a minor) or healthcare provider would be able to access their data by requesting permission and establishing their relation to the patient in the app. Therefore, the information is kept private and only accessible to those the patient allows. In addition, a minor's application access would have parental controls.

3.3 Database and Server

The database will serve as both an intermediary and long term storage space for collected data. To make data security and compliance with HIPAA easier and more straightforward, the database will be self-hosted. Depending on further testing and validation, MariaDB and PostgreSQL are potential solutions that require no licensing. The data analysis server should be capable of handling the computationally intensive workloads that are needed to identify hypoglycemic events.
It is possible to combine the database and data analysis server in one physical (docker[4] containerized) dedicated server. This would eliminate the latency concerns between the database and the data analysis server. Several dedicated server providers with good specifications are available at reasonable costs. Ideally, the dedicated server should be able to analyze the collected data at minimal delay to avoid backlogs during continuous monitoring.

[4]docker is a free, open source container solution that can help isolate services running on the same dedicated server.

4 Estimated Budget

4.1 Overview

The development cost of GlycoTrem will be largely attributed to the cost of acquiring a variety of wearables for assessment. Some costs are attributed to the exploration of implementing and developing a custom ring design to replace or complement the smartwatches if their accelerometers prove to be inadequate for GlycoTrem.
The dedicated server's monthly running costs are comparatively minimal.

4.2 Breakdown

The following table provides a preliminary part list for GlucoTrem's components and associated costs. All figures below are approximate and predicted to the best of our ability at this early stage of the project.

Item	**Quantity**	**Unit Price**	**Total Price**
Polar M600 Smartwatch	1	298$	298$
Ticwatch E2	1	159.99$	159.99$
Apple Watch	1	384$	384$
Galaxy Gear	1	198$	198$
Dedicated Server Monthly	10	22.3$	223$
Domain Yearly	1	8.69$	8.69$
HC-06 MPU6050	2	15.71$	31.42$
Lithium Batteries 1/2 AA - 1200mAh	4	10$	40$
Apple iPhone 7	1	440$	440$
		TOTAL:	**1743.1$**

Table 1: Part List and Costs

Since the project still needs to undertake a few milestone tests, other costs can easily crop up. As a result, an optional contingency "buffer" amount of 500$ is proposed to cover any unexpected costs. This should also be able to cover any shipping charges. This would raise the total to **2243.1$**.

Links to parts are available in the Appendix - some products may require custom quotes or direct communication with the manufacturer.

4.3 Reasoning and Justification

To validate the quality of the accelerometers in commercially available smartwatches, we need to order at least one model from each platform. In the case of Android, the Polar smartwatch was previously used in research and validated, but it carries a hefty price. As a result, a cheaper WearOS model is also selected.
Team members are already in possession of Android devices, and the only required purchase is an iOS device for testing purposes with the Apple Watch.

Dedicated servers are usually billed on a monthly term. A server capable of performing FFTs at a reasonable rate can be acquired for around 25 Euro (27.83$) / month. A domain name for GlycoTrem costs 8.56$ / year. The website can be hosted on the same dedicated server that does data analysis and that houses the database.

In order to explore the possibility of developing a wearable in-house, two MPU6050 (validated in research) high precision accelerometers can be acquired. Small but high capacity batteries that operate in the desired 3.6V range for the HC-06 are also available. However, they are usually non-rechargeable. As such, an initial order of four batteries to account for discharge during testing is likely sufficient.

5 Estimated Timeline

The proposed timeline for the Fall 2019 semester is as shown in the Gantt Chart below.

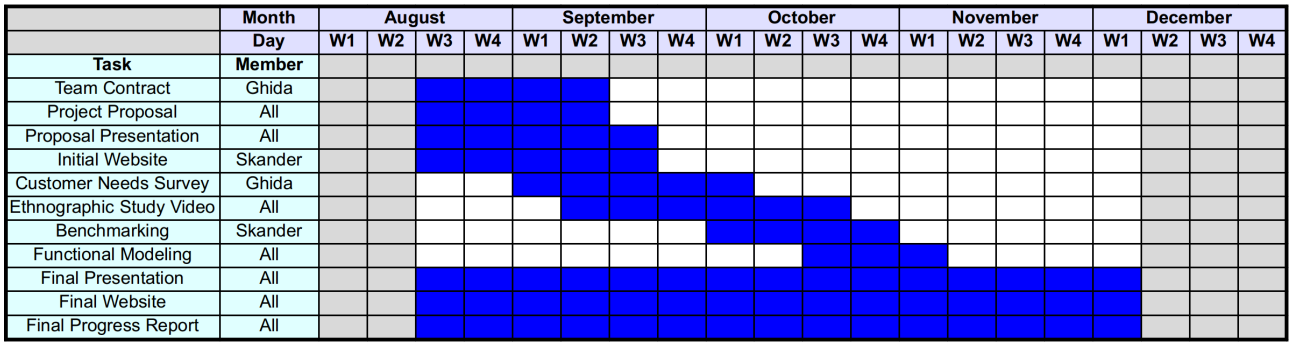

Figure 4: Project Gantt Chart

6 Conclusion

A significant market exists for non invasive, low cost solutions in the healthcare field. GlycoTrem aims to fill this niche for diabetic patients who suffer from hypoglycemia unawareness. Further research, surveys, and testing will need to be conducted throughout this semester. Depending on the results of the experiments, a final verdict will be taken in regards to GlycoTrem's monitoring device (ring, watch, or both).

By the end of the semester, a clear outline of the system's functionality, base design, and overall concept will be finalized with a functional prototype or proof of concept, thus paving the way for the continuation and conclusion of the project in the upcoming semester.

REFERENCES — NEXT PAGE

7 References

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[3] R. Bhidayasiri, "Differential diagnosis of common tremor syndromes", *Postgraduate Medical Journal*, vol. 81, no. 962, pp. 756–762, 2005, ISSN: 0032-5473. DOI: 10.1136/pgmj.2005.032979. eprint: https://pmj.bmj.com/content/81/962/756.full.pdf. [Online]. Available: https://pmj.bmj.com/content/81/962/756.

[4] E. Casilari, R. Luque, and M.-J. Morón, "Analysis of android device-based solutions for fall detection", *Sensors*, vol. 15, no. 8, pp. 17 827–17 894, 2015.

[5] H. Abbas, K. Zahed, L. Alic, Y. Zhu, F. Sasangohar, R. Mehta, M. Lawley, Q. Abbasi, and K. Qaraqe, "A wearable, low-cost hand tremor sensor for detecting hypoglycemic events in diabetic patients", 2018.

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8 APPENDIX A

Component links as of the time of proposal:

Polar Smartwatch: https://tinyurl.com/y28uj2v9

Ticwatch E2: https://tinyurl.com/y22qwfcc

Apple Watch: https://tinyurl.com/y3vnfygc

Galaxy Gear: https://tinyurl.com/y4r77kgk

Dedicated Server Monthly: https://alphavps.bg/

Domain Yearly: https://porkbun.com

Apple iPhone 7: https://tinyurl.com/y32xpkpq

HC-06 MPU6050: Direct from Manufacturer - Might be able to locally source.

Lithium Batteries 1/2 AA - 1200mAh: Direct from Manufacturer - Might be able to locally source.