Final Report

Wearable Glucose Alerting System

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Abstract

The Wearable Glucose Alerting System is a device used to notify caregivers of blood glucose fluctuations in children with Type 1 Diabetes (T1D). The clients have requested the device to be compatible with a Continuous Glucose Monitor (CGM) and suited for patients with T1D. Episodes of hyperglycemia (high blood sugar), hypoglycemia (low blood sugar), or anticipated changes in blood sugar levels need to be displayed by the wearable system. Current devices to alert caregivers of changes in children's glucose levels include devices such as *Glowcose* and *Sugar Pixel*, which lack portability due to a required outlet power source. The team elected to create a device that will display a color signal consistent with active glucose readings: red for levels <55 mg/dL, orange for 56-65 mg/dL, yellow for 66-80 mg/dL, green for 81-139 mg/dL, blue for 140-200 mg/dL, and purple for levels >201 mg/dL. The device is intended to be worn on a child's wrist. It must be portable and not impede the activity demands of daily life. The bracelet consists of a resin watch face, silicone wristband, LED light, and XIAO Microcontroller with BLE capabilities. The device receives blood glucose data from a compatible programed mobile application. The alerting system displays a color intuitively corresponding to blood glucose levels, ensuring caregivers can respond confidently and appropriately. Testing was focused on the bracelet's ability to display the correct color signal, provide sufficient visibility and color differentiation, and the durability of the watch face. These metrics are vital for device functionality and proper usage.

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I. Introduction

Type 1 Diabetes (T1D) is an autoimmune disease that affects 1.2 million children in the United States [1]. Studies show that a diagnosis of diabetes can be just as stressful for parents to monitor and understand as it is for the kids, with an average of 33.5% of parents reporting distress at a diagnosis of T1D [2]. This lack of understanding and confidence extends to other caregivers, teachers, and guardians caring for children with T1D, as blood glucose levels can be difficult to interpret for an adult with no previous diabetic knowledge. The vast majority of T1Ds utilize Continuous Glucose Monitors (CGM) to actively monitor their blood glucose levels. For this project, compatibility with the Dexcom G7 CGM was prioritized because it is the newest, most accurate CGM and can directly connect to multiple devices [3]. One example of an existing device that uses CGM data mapped to a color-coded light source is the *Glowcose* light. This device connects to a CGM and displays a color associated with blood glucose readings: red to yellow for hypoglycemia, green for numbers in range, and blue to purple for hyperglycemia. However, it requires a wall connection and is not portable or wearable [4]. Another similar product that exists is the *Apple Watch*, which can be used by diabetics to display their blood glucose directly to their wrists via CGM readings [5]. However, it does not provide a signal visible to others and is an expensive option. A third product called *Sugar Pixel* receives data from a CGM to show real-time glucose readings and trends via a clock-like display. It also provides alerting systems that are useful for nighttime alerts. This option is not fully portable and requires a strong Wi-Fi connection for use [6]. These challenges led the client to request a CGM-compatible bracelet that would allow parents and caregivers of children with T1D the ability to quickly see and interpret glucose readings, mitigating stress and delayed decisions. The Wearable Glucose Alerting System aims to solve this problem by providing a clear, visible signal that instantly shows when a child's blood sugar needs attention.

II. Background

Within the body of a T1D, the immune system mistakenly attacks and destroys a hormone that regulates blood sugar levels called insulin. The loss of these insulin-producing beta cells in the pancreas leads to chronic hyperglycemia (high blood glucose) in T1Ds if left untreated [7]. While T1D can affect individuals of any age, the Wearable Glucose Alerting System focuses on juvenile diabetes, seeing as 1.2 million children in the United States are diagnosed [1]. This project also focuses on juvenile diabetes because children are less likely to be carrying a phone or other device capable of displaying blood glucose levels. Current treatment for this autoimmune disease consists of routinely checking blood glucose readings via CGM, counting carbohydrates ingested, and calculating doses of insulin based on basal and bolus calculations [8].

The clients are Dr. Beth Martin, a PhD professor within the School of Pharmacy, Olive Carniglia, and Callie Berg, two students in the School of Pharmacy. They are interested in a device compatible with a CGM that visibly alerts caregivers if a child with diabetes is hyperglycemic (high blood glucose), hypoglycemic (low blood glucose), or if a dramatic change in blood sugar levels is anticipated.

The proposed device will have the goal of displaying the glucose level status of a child with T1D, and the signal will be clearly visible, understandable, and actionable. The bracelet will be comfortable to wear around the wrist and will have a visual indication to signal when readings are unavailable or malfunctioning. The bracelet band will be adjustable to accommodate a wrist size ranging from 12.5-17.5 cm [9]. The band should fit securely around the wrist of the child, limiting opportunities for self-removal, but not impeding daily activity. Additionally, the bracelet will be compatible with a Dexcom G7. The bracelet's battery will be easily rechargeable, allowing for continuous use. The team will also ensure to follow FDA Class II, known as the Integrated CGM Category, as well as IP54 for water resistance [10][11]. ISO 15197 and ISO 175119 will also be met, ensuring a 95% accuracy when compared to glucose results of a test strip [12]. A comprehensive outline of product specifications can be found in Appendix A.

III. Preliminary Designs

Band and Materials

The band of the device will be made of silicone, a highly stable synthetic polymer that is both flexible and durable. It is resistant against sweat, water, and UV damage, and is a relatively cheap material. This design would include a silicone band and an LED encased in plastic, making up the face of the watch as shown in Figure 1. Croslite and plastic bands were also considered. See Appendix B for a more comprehensive analysis of material selection.

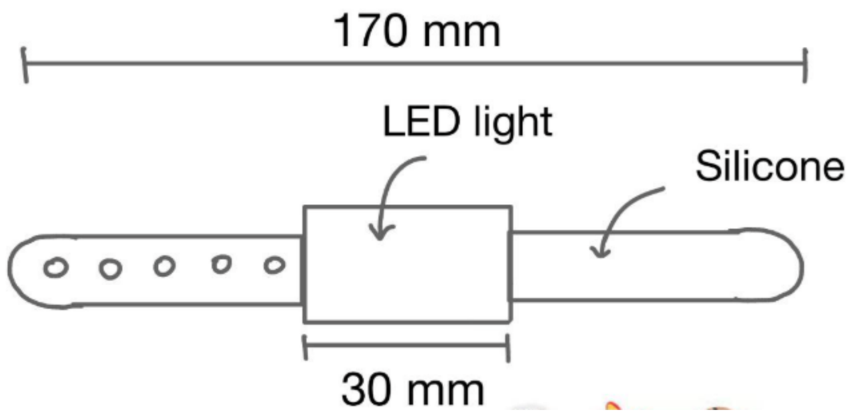

Figure [1]: Initial Drawing of Bracelet Band and Light

Battery and Charging

The battery and associated charging system to be used is a Lithium-ion battery permanently installed within the device, and a charging cord inserted directly into the watch. Lithium-ion batteries are known for their long lifespan and high voltage per cell ratio. Since the battery is permanently installed, it will easily integrate with other internal electrical components. Additionally, the secure connection in the watch will limit opportunities for children to have access to small components and dangerous chemicals inside a battery [13]. This said, Lithium-ion batteries require both constant current and constant voltage regulations during the charging process [14]. Disposable and removable batteries were also considered for power supply. See Appendix B for additional information.

Connectivity

For the connection between the CGM and the bracelet, the team considered three options. The first option involves accessing data directly from Dexcom. The Dexcom Developer Program is used by 3rd party devices, such as Omnipod, to extract CGM data and transmit it to their device. This program uses the existing Dexcom login credentials, providing a private and secure option for data transmission [15]. However, for the level of authorization, the delay time for data transmission can be up to 3 hours from CGM to 3rd party device [16]. As consistent with the Product Design Specifications (PDS), the delay time should be kept below 5 minutes [Appendix A]. The described process flow is depicted in Figure 2.

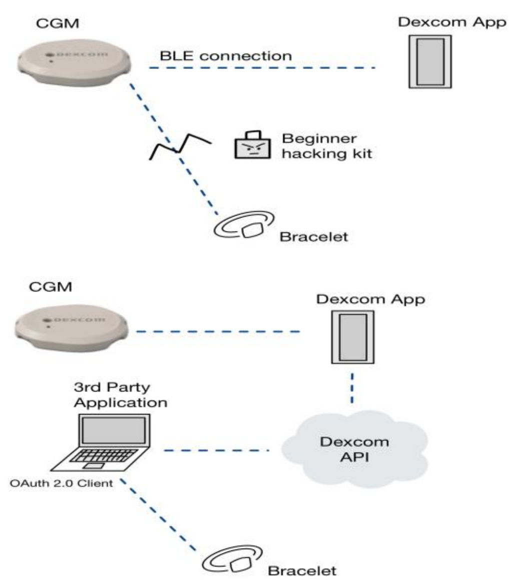

Figure [2]: Dexcom Developer Program Flow Chart

The Nightscout Application Programming Interface (API), also known as "CGM in the Cloud", is an open source "do it yourself" project led by a community of individuals who have reverse engineered their CGM's to optimize the use of their CGM data. The API is developed using a cloud storage database capable of pulling information from the Dexcom app and manipulating data to correspond to a color scale. The information will then be transmitted in real time to the bracelet via Bluetooth connection, as shown in Figure 3. Developing an API allows for a high degree of customization and flexibility. While this requires a high degree of initial development, the opportunity for replication is promising after the initial framework is established. Additionally, this API ensures the microcontroller receives current data, eliminating the need for a delay period.

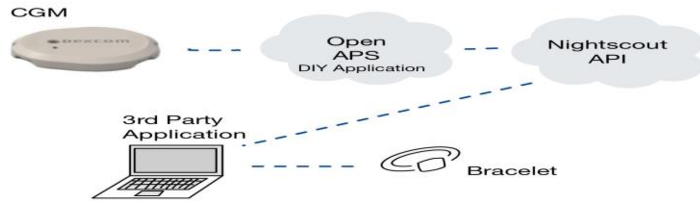

Figure [3]: Nightscout API Flow Chart

The third connectivity concept, shown in Figure 4, uses a direct Bluetooth Low Energy connection. BLE is the connection that comes from the CGM and can connect to three devices via direct Bluetooth. Reaching this secure connection would require the use of an intermediate hacking kit. This hacking kit would take up a large portion of the allotted budget and has the potential to raise ethical concerns regarding security. Additionally, the connection would need to be re-established for each CGM replacement, around once every two weeks. [17].

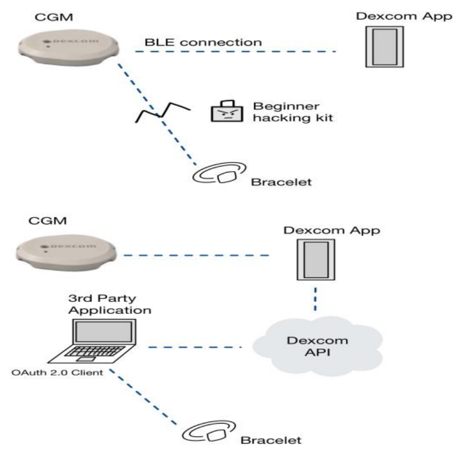

Figure [4]: Bluetooth Low Energy Connection Flow Chart

IV. Preliminary Design Evaluation

Table [1]: Design Matrix of Connectivity Options

Designs Criteria	Design 1: Dexcom Developer Program 		Design 2: Nightscout API 		Design 3: BLE Connection 	
Delay Time (25)	1/5	5	4/5	20	4/5	20
Feasibility (20)	3/5	12	4/5	16	2/5	8
Reliability (20)	5/5	20	3/5	12	2/5	8
Privacy (15)	4/5	12	3/5	9	4/5	12
Cost (10)	5/5	10	5/5	10	1/5	2
Replication (10)	2/5	4	4/5	8	1/5	2
Total (100)	63		75		52	

The Dexcom Developer program provides the most reliability with its direct connection to the G7 CGM. Additionally, the data transmitted through this is guaranteed to be both secure and private and does not incur any additional cost for data storage. However, the delay time associated with this level of authorization can take up to three hours to update, which does not meet PDS requirements [Appendix A]. The Nightscout API reduces this delay time to around 5 minutes while providing a high degree of customization for the user Additionally, this API has the potential to be designed completely free of charge and the connection is secure as it relies on private Dexcom data. The BLE connection model ensures a short time delay from data retrieval to bracelet updates. However, it involves the use of hacking toolset to override the CGM connection. This raises ethical concerns with data breaches as hacking into the transmitter for the bracelet may open additional avenues for malicious activity. Additionally, the replication of this design is significantly more challenging as each individual transmitter requires individual hacking to access data. This model also involves a large amount of data, potentially incurring additional costs of cloud storage. Overall, the Nightscout API is the most feasible and well-suited model for the final design.

Proposed Final Design

The proposed final design consists of an adjustable silicone band attached to a silicone face. The light will be an LED which will show the glucose status. Additionally, a light on the side of the bracelet will illuminate blue during charging and green when the device is functioning properly, and glucose is within range. The light will be off when the battery is dead. The battery will be a permanently installed lithium-ion battery that will be charged using a generic USB-C cable. The data retrieval system will use the Nightscout API which will transmit CGM data to the cloud, back to a computer application, and ultimately the bracelet. See Appendix D for detailed CAD representation.

V. Fabrication

Software

The software flow of the project works in three main stages. The first stage is the backend application programming interface (API) that serves as the initial point of communication from the Dexcom app on the user's mobile device. The API is processed through PyDexcom, a Python package designed to interact with the built-in Dexcom Share service, allowing users to retrieve real-time data from their CGM in the same manner that they can share blood glucose levels with friends and family [18]. This is a common package for users looking to integrate Dexcom data into individual projects due to its flexibility, customizability, and access to real-time data. For the purposes of this project, PyDexcom is running on a BME SharedLab webpage managed by Dr. John Puccinelli, PhD. The website displays a user interface displaying current readings, although the rest of the software flow is not dependent on this interface.

The second stage is the Flutter application. Flutter is an open source, fully customizable user interface (UI) operated by Google [19]. This application format was chosen due to its promising scalability from a localized desktop application to an accessible mobile application. The Flutter application is coded with 4 main blocks. The main block controls the UI including the login screen prompting users to log in with Dexcom credentials, as seen in Figure 5, as well as the home page that displays data, shown in Figure 6. The service handler uses provided Dexcom login credentials to pull the most recent blood glucose levels from the backend API through a series of HTTP requests and webpage scraping. Once retrieved, a separate block oversees collecting the glucose value, attaching the correct timestamp, and sending it back to the main page in a clean package. The main block then formats the package in a color-coded box that is then displayed onto the home page of the screen. The fourth and final block controls the auto-refresh, pulling an updated value every 5 minutes and subsequently pushing it to the microcontroller via a USB-C serial connection.

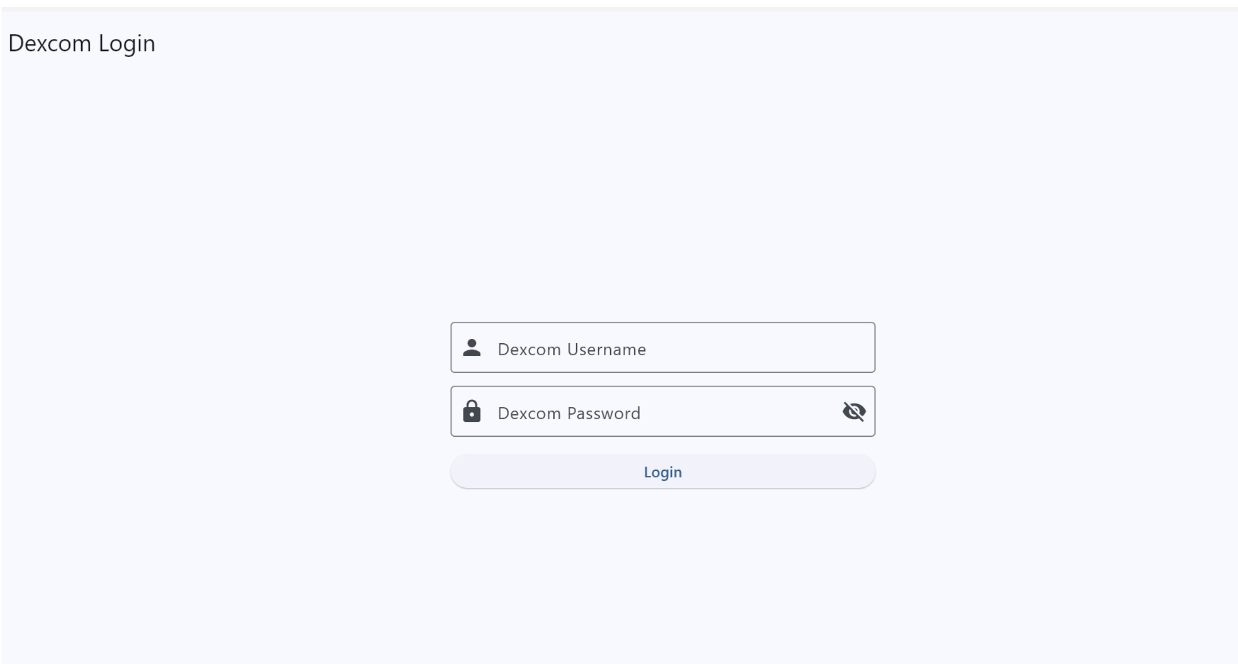

Figure [5]: Flutter Application Login Screen

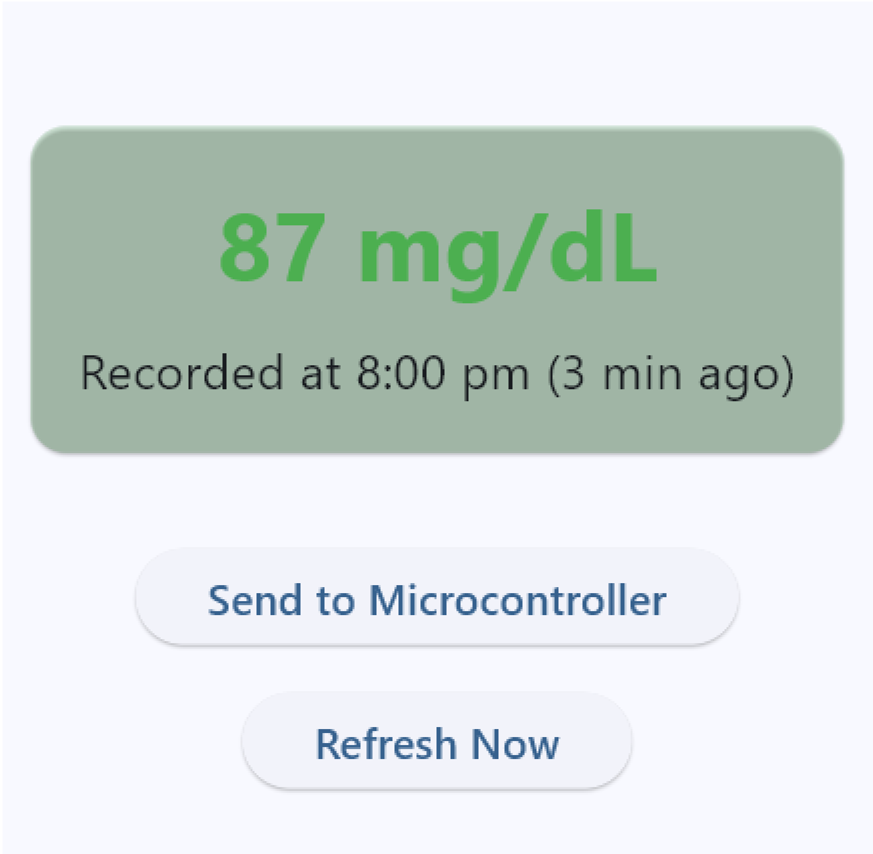

Figure [6]: Flutter Home Page Displayed Upon Successful Login

Stage three involves the programmed microcontroller and visual LED display. Upon receiving an updated glucose value, the microcontroller has the ability to interpret the correct glucose status range based upon PDS specifications [Appendix A]. It then assigns the corresponding RGB color code to the connected LED, ensuring the device displays the correct color for the blood glucose range. The color of the LED matches the color of the app display, as demonstrated in Figure 7.

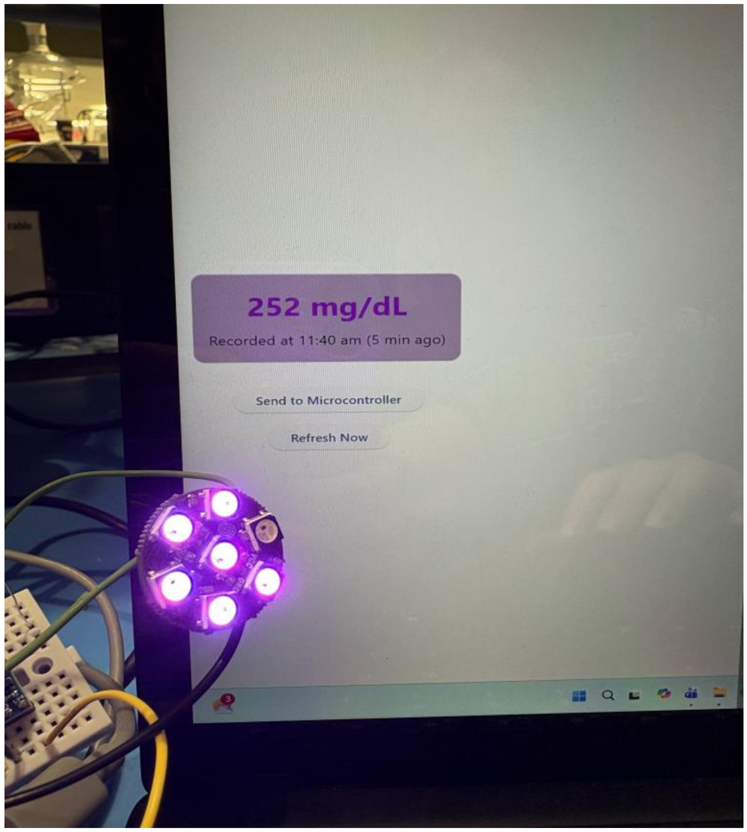

Figure [7]: Flutter homepage and LED display, both showing purple range

Hardware

For the hardware portion of the system, a Seeed Studio XIAO nRF52840 BLE microcontroller serves as the central control unit and is programmed through a USB-C connection. To establish robust electrical pathways, 24–28 AWG wires were used to interface key microcontroller pins: D8, GND, and 5VUSB- to a miniature breadboard that distributes power and signals to other components. Because the computer's USB-C power source delivers approximately 5.5 V, a level shifter was incorporated to safely step the voltage down to the microcontroller's 5 V maximum input, preventing potential overvoltage damage and ensuring long-term reliability.

The Soldered Electronics 4-Pin Rainbow Ring LED was integrated into the circuit through its VCC, GND, and Data In terminals. A 220 Ω resistor was added to the data line in series to maintain signal integrity, reduce noise, and ensure consistent, accurate LED color transitions. All wiring, including microcontroller leads, power rails, and LED connections, were carefully hand-soldered to produce durable, low-resistance electrical joints and minimize the risk of disconnection or intermittent faults during operation and use.

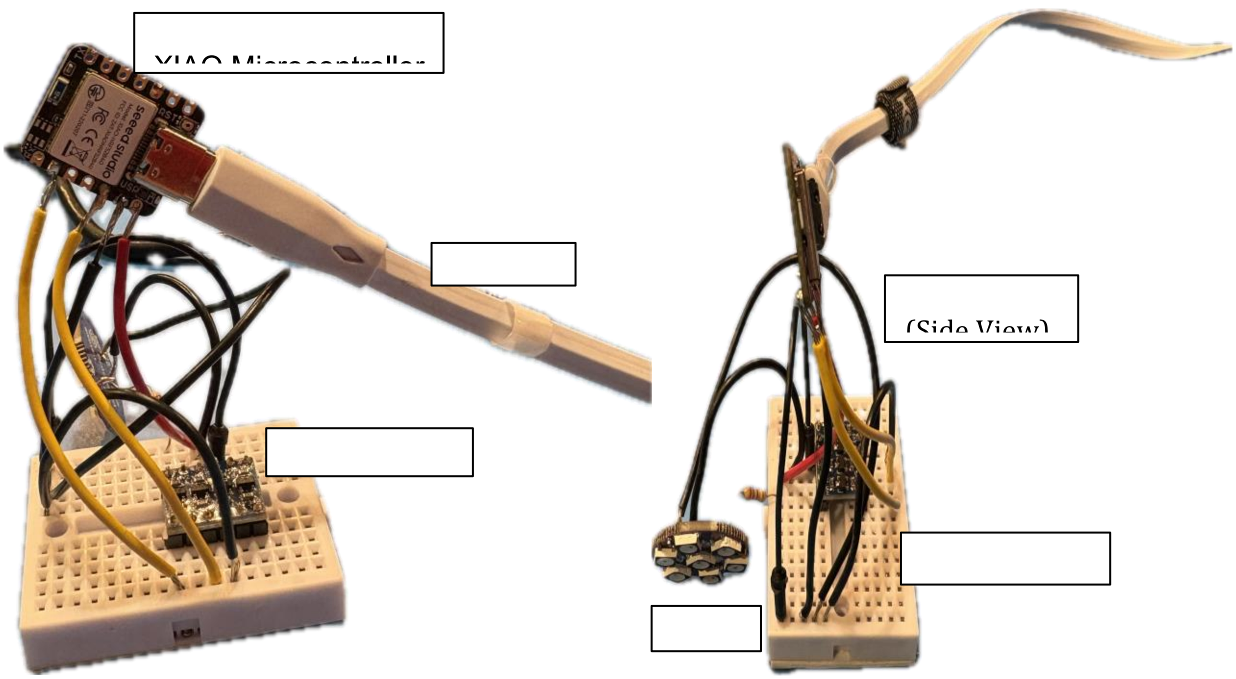

Figure [8]: Project Circuitry

Watch Face

The watch face portion of the design is a 3D Printed black resin case with a clear 3-D Printed snap-fit resin lid. Resin was used for the case due to its high printing accuracy, durability, and strength. There are two band connection sites on opposite sides of the watch face that are compatible with commercially available Apple Watch bands [20]. To accommodate the indentations of the band connection sites, the side walls of the watch face are extruded to a thickness of 5.41 mm. The front and back walls are thinner with a thickness of 1.905 mm. To allow connection of the internal LED to the external breadboard, there is an opening of 9 x 3 mm on the front wall of the watch face. The inside of the case is 26.2 x 26.2 mm in dimension, allowing for adequate space to house electrical components. The lid is 30 x 30 mm with snap-fit connections on both side walls. All edges of the watch face and lid are filleted to a radius of 1.27 mm. Detailed CAD Drawings of the case and lid can be found in Appendix D.

The band is a Polyjoy Kids Apple Watch Strap compatible with series 10/11 Apple Watches. The band is silicone, making it waterproof, heat heat-resistant, and safe for most skin types. It also features an adjustable loop and peg closure with a double buckle mechanism for additional strength.

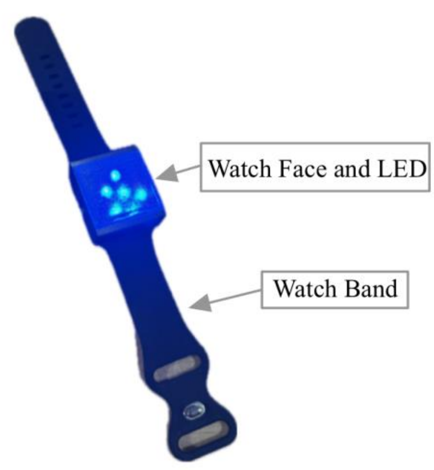

Figure [9]: Watch Face with Band and LED

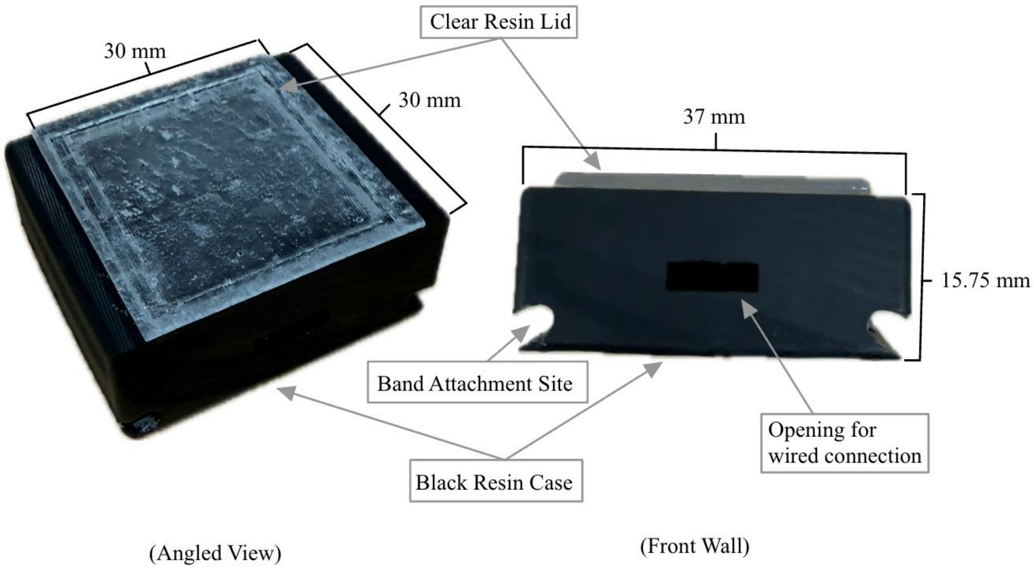

Figure [10]: Resin Case and Lid

VI. Testing and Results

Visibility Testing

Visibility testing was conducted to ensure the LED color was clearly visible and distinguishable from a distance of 50 m. The LED was programmed randomly through each of the six possible display colors and participants at 50 m away were asked to state the observed color of the LED. Results found that at this distance, the LED color is both visible and distinguishable from other colors in the rainbow 100% of the time. This confirms that the signal will be actionable and visible to caregivers.

Figure [11]: Brightness Testing

Accuracy Testing

Accuracy testing was performed to verify that the blood glucose values received by the microcontroller were equal to values received in the Dexcom app. Per client specifications, the delay time on result updates must not exceed 5 minutes. For this test, the microcontroller was connected to the computer running the Flutter application. At intervals of approximately 5 minutes over a total of 3 hours, blood glucose levels from the Dexcom app and the received levels on the microcontroller displayed on the serial monitor were both recorded. The expected and observed colors were also recorded. Note that testing was not done for three consecutive hours to ensure values were spanned across the spectrum of ranges, both low and high. Results demonstrated that the microcontroller received the correct, updated blood glucose values with 100% accuracy. Plotting expected values against observed shows a near perfect linear slope with an R^2 of 1, as demonstrated in Figure 11. This meets our PDS requirements of maintaining a MARD of 8.5%, effectively maintaining the accuracy of the user's CGM. Additionally, our expected color matched the observed display for each time interval, proving the Flutter app was successful in providing up to date glucose levels at intervals of 5 minutes. It should be noted that no observed data point corresponded to the "dangerously low" range of a blood glucose level less than 55 mg/dL, although due to ethical considerations, this status was not induced in the induvial whose Dexcom account was logged into the app. Successful display of the other 5 ranges led to the inferred conclusion that in the event of a dangerously low blood glucose level, the device would update accordingly. See Appendix E for full data report.

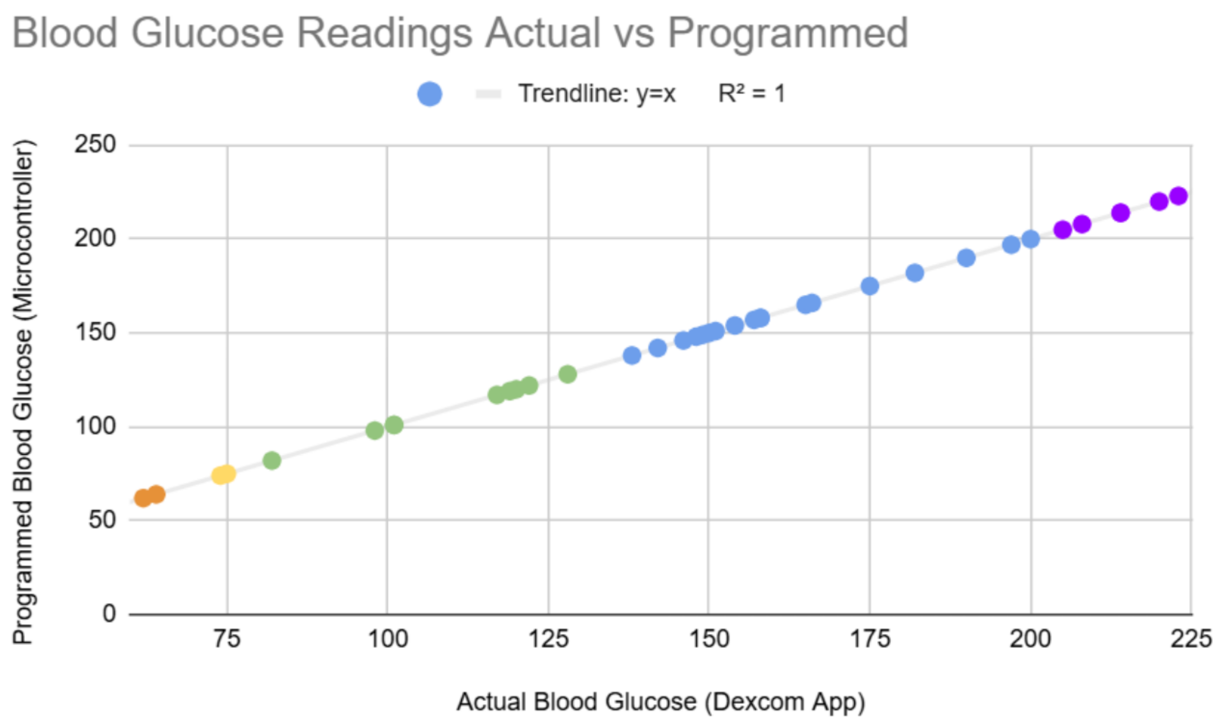

Figure [12]: Plotted Graph Showing Actual vs Programmed Blood Glucose Levels (LED colors denoted by plot points)

Material Strength Testing of the Device Container/Box

Compression testing was conducted using a Material Test System (MTS) testing machine to evaluate the structural performance of the resin and PETG watch face. All watch faces were 3D printed with identical wall thicknesses and infill to ensure direct comparison between materials.

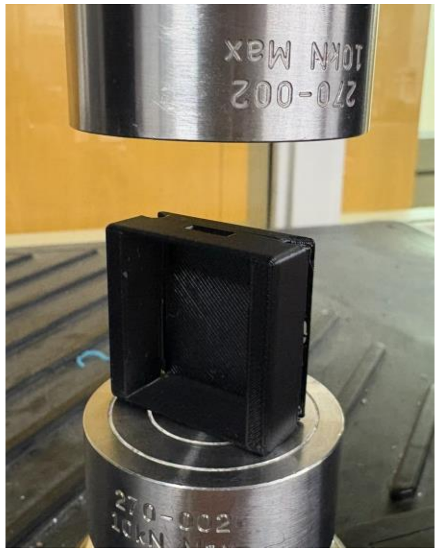

Figure [13]: MTS Testing Orientation of Device Watch Face with PETG Material

Figure [14]: MTS Testing Orientation of Device Watch Face with Resin Material

Each watch face was tested at the same orientation to maintain uniformity: the side with a thicker amount of material of structural support/material was compressed. See Figures 13 and 14 for watch face orientation. Theoretical compressive capacity for each material was estimated using published average compressive strengths of 68 MPa for resin and 35.03 MPa for PETG for comparison and for verifying compliance with PDS requirements [21][22]. Calculated compressive stresses based on experimental failure loads and areas of each were 20.3 MPa for the resin samples and 9.1 MPa for the PETG samples. Although these values are lower than the theoretical material strengths, this outcome is expected because the test watch faces were hollow, rather than solid blocks. Both materials exceeded the minimum load and compressive stress required by the PDS.

The MTS testing showed clear differences between the materials. The resin watch face reached a maximum load of 6.380 kN, while the PETG watch face failed at 2.850 kN. Resin therefore carried higher loads in both orientations. PETG exhibited earlier deformation, while resin-maintained load capacity until higher forces were applied. Figures 15 and 16 present the corresponding load vs extension curves for each material.

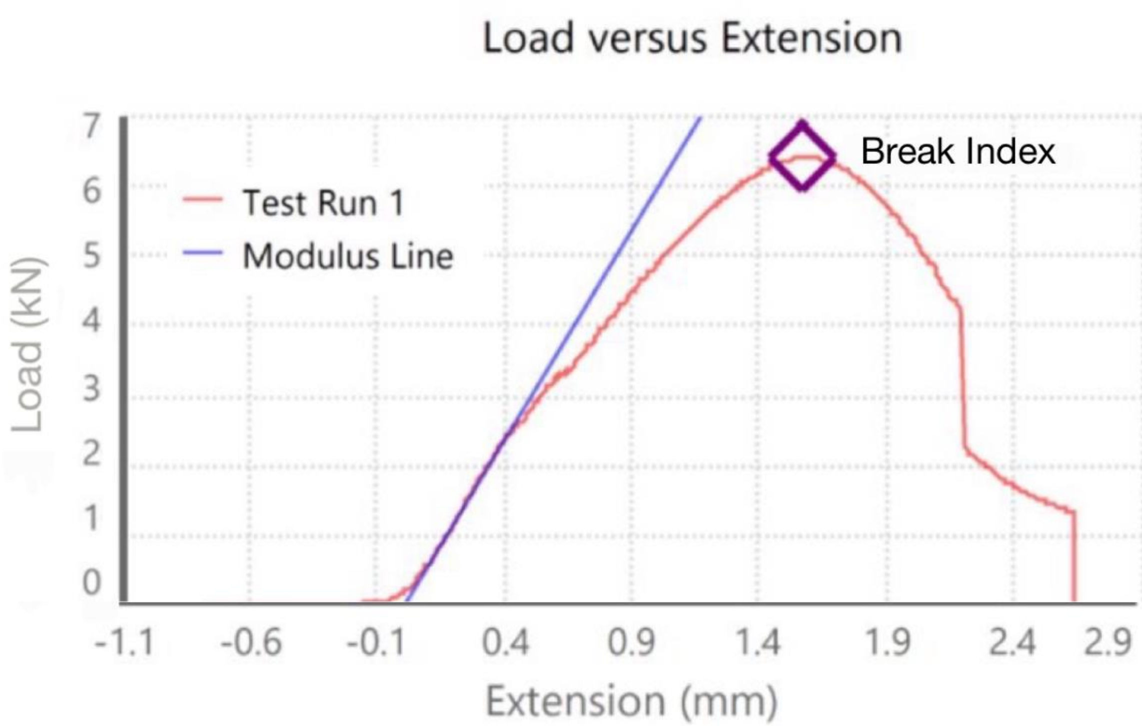

Figure [15]: Curve Showing Load (kN) vs Extension (mm) of Resin Material

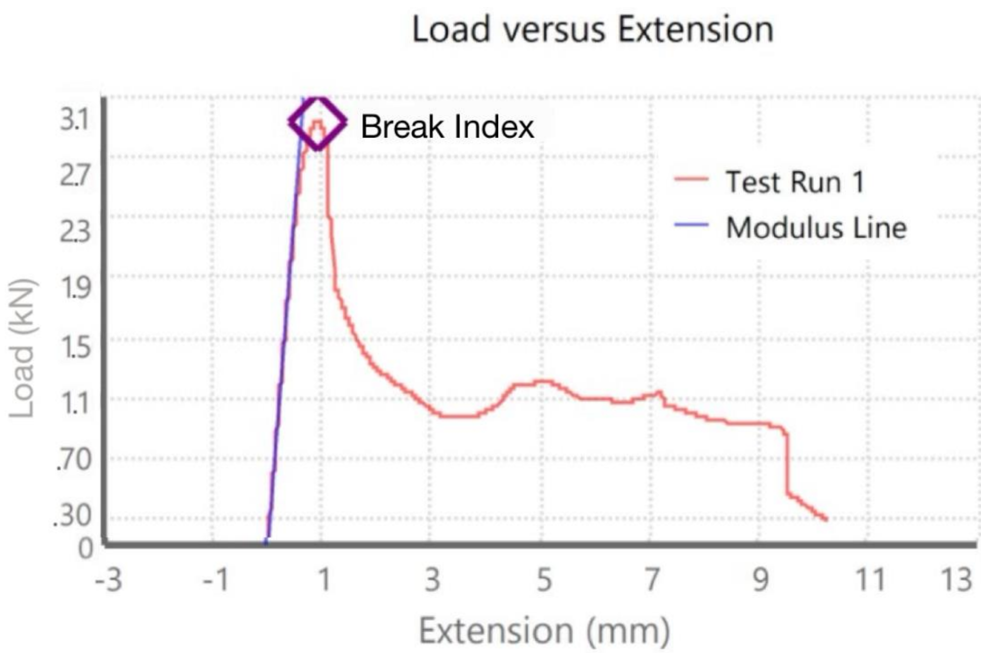

Figure [16]: Curve Showing Load (kN) vs Extension (mm) of PETG Material

In addition to compression testing, a drop test from 2.5 meters was performed, as specified in the PDS based on the average height of a playground. Both the resin and PETG watch faces passed this requirement with no breakage and no visible damage.

All experiments confirmed that both resin and PETG exceeded the minimum load requirements specified in the PDS. However, resin provided a significantly larger compression margin, outperforming PETG across all test conditions, and demonstrating better compressive strength and deformation resistance. These results indicate that resin is the material of choice for our device.

VII. Discussion

The Wearable Glucose Alerting System attempts to correct the communication barrier between parents of T1D children and any approved supervisor without access to the Dexcom users' current levels. The accuracy, MTS, and visibility tests all proved to be successful and provided data to meet the outlined client specifications [Appendix A]. The accuracy test produced a linear slope of actual vs transmitted levels and proved the functionality of the color-updating system.

Visibility was tested from 50 m, a distance comparable to the average length of a playground. This range was determined to account for the anticipated distance a caregiver may be from the child. The final design resin watch face was able to withstand an MTS max compression load of 6380 N and passed the drop height test from 2.5 m, and the band is adjustable 12.5-17.5 cm [Appendix A]. The connectivity test had to be deferred due to the inability to establish a Bluetooth connection between the microcontroller and mobile phone or computer, but it will be a primary focus for future improvements.

Throughout the fabrication and testing of this device, each section had varying sources of error. Due to setbacks with the proposed circuit configuration, the final resin watch face was unable to house all electrical components. Future modifications will focus primarily on scaling down the circuitry to fit within the box capacity. Specifically, transitioning to a Printed Circuit Board (PCB) will help meet size constraints. The tight-fitting slide in slots on the sides of the box used for the watch band connection were abrasive and caused mild shredding on the band with repeated use. Capitalizing on the release mechanism of the commercially available watch band will help alleviate the wear on the band. Additionally, the BLE connection between the XIAO and the Flutter app was not independently established, leading to a lack of testing on connectivity distance. The hardware development experienced the bulk of the device's setbacks, due to size considerations as well as the team's familiarity with such components. During the soldering process, unintentional component contact, small size constraint, and team soldering capabilities all proved to be incredibly challenging obstacles. The Soldered Electronics LED also had issues maintaining complete functionality as a result of cheap manufacturing; future work points to exploring more sustainable alternatives. The original circuit included a 330 kΩ resistor, a 1000 F capacitor, and a 3.7 V battery, all of which had to be removed from the final design due to either incompatibility or redundancy. The potential PCB in Figure 17 should fix many sources of error in the circuit. There are still many changes needed to accommodate client specifications, streamline process flow, and improve appearance and useability of the device.

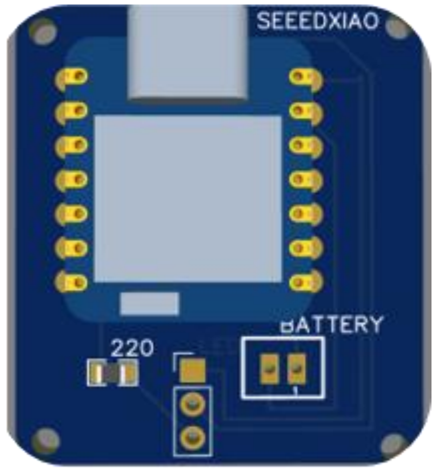

Figure [17]: Potential Future PCB

Ethical considerations in the ultimate use of this device will be regulated under FDA Class II Medical Devices, as the necessary market specifications address safety concerns for a wearable data-using device [10]. ISO 15197:2013 outlines the required test strip accuracy needed for user safety, and IP54 enforces water and dust resistance to prevent electronic short-circuiting [11][12]. The main device implications are data transfer accuracy between the bracelet and user CGM data, visibility of the LED from specified distances, and the connectivity range of the operating phone receiving Dexcom data with the bracelet [Appendix A]. These key sources of error are currently being examined and will be addressed following the testing protocols explained above.

Beyond these mechanical and regulatory requirements, the prototype also raises several ethical considerations centered on safety, privacy, and user well-being. Because the bracelet handles sensitive health information, strong data protection and clear control over who can access glucose readings are essential to safeguard patient privacy. Ensuring device accuracy is equally critical, as false alerts or missed warnings could result in inappropriate treatment decisions and potential medical harm. Additionally, since this device is intended for children, both informed consent from caregivers and age-appropriate assent from users must be prioritized [23]. Finally, considerations of accessibility and cost are important to prevent technology from widening health disparities, ensuring that the benefits of safer, more visible glucose monitoring are available to all families who need them.

During fabrication of the device, environmental concerns such as waste of materials, frequent malfunction and replacement, or incompatibility of parts were avoided to the best of the team's ability. Minor wire waste and part replacement were required due to the difficulty of soldering 20 x 20 mm components. As a result of the weaknesses revealed through fabrication and testing, there are many anticipated changes to implement before the device's participation in the SHARx competition. The current XIAO nRF52840 BLE does not have charging capabilities or on-board Wi-Fi, making full portability entirely impossible. Other XIAO series with the necessary capabilities will need to be explored and implemented in the new circuit. After taking out redundant components and replacing the microcontroller, the circuit schematic will be revamped and used to create and order a custom PCB such as the potential option in Figure 16. The PCB will aid in the downsizing of the circuit and require a new watch face with updated dimensions. The primary challenge that needs to be accomplished before next semester's presentation is the BLE connection between the Flutter app and the microcontroller. Without proper BLE connection, the blood glucose levels will not update correctly, resulting in time delays or incorrect LED coloring. Currently, the device requires constant computer connection to connect to the Flutter app and receive updates. The app will be made mobile for iOS and Android devices using the updated XIAO. Once the circuit components and app are functioning, the resin lid of the watch face will be replaced with a screen to increase LED visibility. The device's malfunction and unavailable reading visual indication on the side of the watch face was cut out this semester due to the unexpected size of the circuit but will be restored upon downsizing. A release latch must also be added to the watch face sides to prevent shredding of the band due upon installation and removal of the band.

The device's initial functionality has proven to be successful and provides a highly promising outlook. Overall, many changes still must be made prior to the SHARx presentation in April of 2026, ensuring that the final design meets the technical, clinical, and ethical standards required for real-world development.

VIII. Conclusions

The Wearable Glucose Alerting System aims to improve how caregivers monitor the blood glucose status of young children with T1D by providing a clear, intuitive, and actionable visual indicator. Research and preliminary prototyping efforts identified a wrist-worn device as the most effective solution. The resulting design integrates a resin watch face, a silicone wristband, an LED-based alert mechanism, and a Seeed Studio XIAO microcontroller with Bluetooth Low Energy (BLE) capabilities. This microcontroller interfaces with a custom-developed mobile application to display and communicate real-time glucose information.

Component selection was guided by performance, durability, and user-centered considerations. The resin casing provides suitable protection for internal electronics; the silicone band ensures comfort and secure placement, and the LEDs offer a highly visible method for conveying glucose status at a glance.

Despite demonstrated functionality, challenges remain, particularly in achieving a stable and reliable BLE connection between the Flutter-based mobile application and the microcontroller. Addressing this issue is critical for ensuring seamless communication and dependable alerts. Future development will focus on optimizing wireless performance, extending battery life to improve wearability and reduce maintenance, and preparing the device for potential large-scale deployment and user testing.

IX. References

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X. Appendix

Appendix A: Product Design Specifications

Product Design Specifications

Wearable Glucose Alerting System

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Advisor: Dr. John Puccinelli

September 18, 2025

BME 200/300

Function:

The overall goal of the Wearable Glucose Alerting System is to create a device compatible with a market-available Continuous Glucose Monitor (CGM) that visibly alerts caregivers if a child with diabetes is hyperglycemic (high blood sugar), hypoglycemic (low blood sugar), or a dramatic change in blood sugar levels is anticipated [1]. The device will be worn on the child's wrist and must not impede the activity demands of daily life. The alerting system should be intuitive, unambiguous, and able to differentiate statuses, ensuring caregivers can respond confidently and appropriately.

Client Requirements:

- Develop a device capable of displaying the status of blood glucose to anyone supervising a child with diabetes.
    - The signal will be clearly visible, understandable, and actionable.
- The device should be designed for comfortable wear around a child's wrist, encouraging consistent use while minimizing interference with daily activities.
- A visual indicator must be included on the device to signal when glucose readings are unavailable or when a malfunction is detected.
- The bracelet should be adjustable to accommodate wrist sizes from 12.5-17.5 cm [2].
- The bracelet band should be secure around wrist of child, limiting opportunities for the child to take it off on their own.
- The alerting system must be compatible with a modern CGM device.
- A rechargeable or replaceable battery system must power the device.

Design Requirements:

1. Physical and Operational Characteristics:

a. Performance requirements:

The bracelet prototype will display an actionable signal, such as a color indicator, symbol, or physical display, which correlates directly to the wearer's blood glucose levels, with the default settings as follows:

- <55: Red
- 56-65: Orange
- 66-80: Yellow
- 81-139: LED off, side LED green
- 140-200: Blue
- >201: Purple

It will also include an internal rechargeable or replaceable battery, allowing it to be worn for most hours of the day and extend the device's longevity.

b. Safety:

The prototype will feature built-in sensors that alert users if the device becomes too hot, as well as grounded circuits to prevent short-circuiting. Additionally, there will be a signal to alert if the device is no longer connected to the CGM's readings, and no light present anywhere on the device when the device is dead. It will be designed to be water-resistant and encased in a thick, durable material that not only protects the internal wiring but also ensures a comfortable fit. This layer will also make the bracelet easy to sanitize and clean, promoting better hygiene for regular daily use.

c. Accuracy and Reliability:

The bracelet's live signals should be just as reliable as those from the Continuous Glucose Monitoring (CGM) device it receives data from, with minimal or no delay. These devices typically show a mean absolute relative difference (MARD) of approximately 8.5% between blood glucose readings and CGM measurements [3]. The bracelet should alert if an issue in connectivity occurs in order to maintain the most reliable responses possible.

d. Life in Service:

The final product should last 3-5 years or as long as the device's battery is operational. This is consistent with the lifespan of marketed commercial fitness watches [4]. The device will be tested on individuals with Type 1 Diabetes and should remain accurate, operational, and durable to achieve the longest possible device runtime.

e. Shelf Life:

The device should be capable of maintaining accuracy and full functionality for at 3-5 years once fabricated [4]. This requirement ensures that CGM readings are displayed accurately for the duration of device use. Wear and tear from daily use must be minimal and not impede with the device's function.

f. Operating Environment:

The device should be able to withstand a range of environmental conditions, such as outdoor temperatures from –20 °C to 43°C [5]. It should be water-resistant with an IP rating of 54, and durable enough to handle normal wear and tear associated with use by an active child, including accidental drops from 2.5 meters, the typical height of playground equipment [6].

g. Ergonomics:

The device should not cause harm to the user. All materials used in the device should be safe for prolonged skin contact and should not elicit any skin reactions. The electronic components and battery must not expose the user to chemical or physical hazards. The device must maintain a safe, normal operating temperature, not exceeding 35°C to avoid damage to the skin [7].

h. Size:

The Wearable Glucose Alerting System should comfortably fit around the wrist of a child and be easily adjustable to grow with the child. The device should fit children aged 6 to 17 with wrist sizes ranging from 12.5-17.5 cm in circumference [2, 8]. The face of the watch should be under 30mm in length and 30mm in width as well as under 15mm in height. to fit comfortably on a child's wrist [2,8]. The device should be as flush to the skin as possible to avoid catching on clothing, other materials, or inhibiting daily activities.

i. Weight:

The weight of the device should not impede the wearer's use of the hand or arm. The device should weigh under 58g, consistent with the weight of marketed commercial fitness watches, it should be considered that most watches marketed towards women and children are around 32g [9].

j. Materials:

The device should be comfortable to wear for prolonged periods of time. The band should be made of a tough, flexible, and water-resistant material, avoiding common skin allergens. Most comedically available fitness watch bands are made of silicone or polyester and nylon. The alerting system encasement should be made of a durable material that can protect internal electronic components from wear and tear and provide water resistance. The materials should be easily cleaned and sanitized.

k. Aesthetics, Appearance, and Finish:

The light in the device should display a range of colors associated with different blood glucose levels, including hypoglycemia, hyperglycemia, and anticipated dramatic changes in blood sugar level. The device should have a smooth finish, avoiding any potentially hazardous sharp edges. The band of the device should be customizable and colorful to pique the interest of many children.

2. Production Characteristics:

a. Quantity:

Only one functioning device is necessary per diabetic child. The team will produce one product for presentation at the SHARx tank competition.

b. Target Product Cost:

The target product cost for the device and all necessary materials should stay under a total of $400 per the client's budget. Market prices for the device will be determined by the pharmacy representatives upon presentation in the spring of 2026. This price should be close in value to that of a competing glucose alerting system like *Glowcose* at $60 [10].

3. Miscellaneous:

a. Standards and Specifications:

As a form of a self-monitoring blood-glucose device, the CGM bracelet falls into the Food and Drug Administration Class II integrated CGM (iCGM) category [11]. This class of medical devices must abide by the necessary guidelines to achieve 510(k) approval [11]. A mandatory shutoff is a requirement for these devices after the approved time-in-range (TIR) [11]. If devices in Class II do not achieve 510(k) approval, they will be forced to go through a longer process through pre-market approval submissions for Class III medical devices [11].

An IP water rating also must be enforced to cover the water-resistant aspect required by the client. IP54 will meet the needs of this product as this indicates any electrical exposure must be protected from water and dust[12].

Blood-glucose monitoring systems also have their own International Standard (ISO) that sets performance and quality criteria for the self-testing used by those with diabetes [13]. The current version is ISO 15197:2013 and contains requirements directed at both health care professionals and patient users [13]. The standard specifies glucose concentration categories and percentages to be used in testing for an accurate distribution of high to low values. ISO 15197:2013 references four standards that cover measurement procedure, stemming from ISO 175119 [13]. According to 15197, each glucose test strip must achieve 95% accuracy when tested by the user without prior training or assistance [14]. The 2013 version added extensive testing procedures for user performance evaluation, still including the previously stated accuracy percentage.

b. Customer:

The device will be worn by a child for prolonged periods of time and should not cause any discomfort. The light should be visible to a caregiver from 50 meters in clear conditions [15].

c. Patient-related concerns:

The Wearable Glucose Alerting System should provide visual alerts with an accuracy of MARD of 8.5% to measured blood glucose readings [3]. The team must ensure that the data taken from the CGM is safeguarded and maintains the same levels of confidentiality provided by CGM companies.

d. Competition:

An existing device that uses CGM data mapped to a color-coded light source is the Glowcose light. This device connects to a CGM and displays a color associated with blood glucose readings: red to yellow for hypoglycemia, green for numbers in range, and blue to purple for hyperglycemia. But it requires a wall connection and is not portable or wearable [10]. Another similar product that exists is the Apple Watch, which can be used by diabetics to display their blood glucose directly to their wrists via CGM readings [16]. However, it does not provide a signal visible to others and is too expensive. A third product called Sugar Pixel receives data from a CGM to show real-time glucose readings and trends via a clock-like display. It also provides alerting systems that are useful for nighttime alerts. However, it is not fully portable and requires a strong WIFI connection for use [17].

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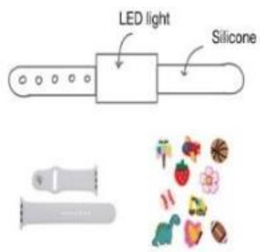
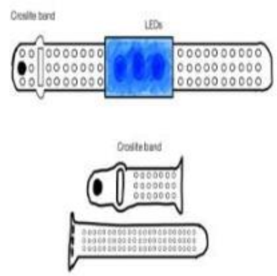
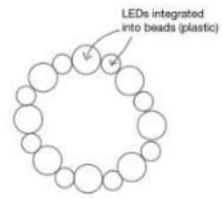
Appendix B: Material & Battery Design Considerations and Design Matrix

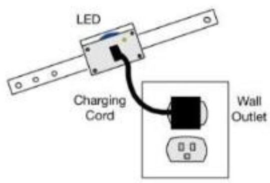
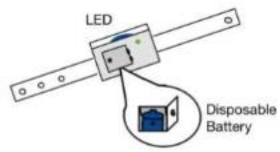
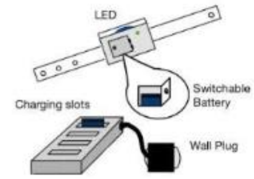
Table 1: Design Matrix of Band Materials

Designs / Criteria	Design 1: Silicone band with LED light 		Design 2: Croslite band with LEDs 		Design 3: LED light with plastic beaded bracelet 	
Safety & Ergonomics (25)	5/5	25	4/5	20	3/5	15
Adjustability (20)	5/5	20	4/5	16	3/5	12
Durability (20)	5/5	20	3/5	12	2/5	8
Accuracy (15)	5/5	15	4/5	12	3/5	9
Water Resistant (10)	4/5	8	3/5	6	2/5	4
Cost (10)	4/5	8	5/5	10	2/5	4
Total (100)	96		76		52	

For band of the device of silicone, Croslite, and plastic were considered as material options. Silicone is a highly stable synthetic polymer that is both flexible and durable. This design would include a silicone band and casing of the watch face. Croslite is a lightweight polymer material known for its use in Croc shoes, similar to silicone. This design would be a Croslite band and watch face casing. The plastic design has a bracelet made of light-up beads each in their own spherical clear plastic casing.

The silicone band significantly outperformed the other materials as it is flexible and chemically stable, durable against sweat, water, and UV damage, able to be translucent to light, and relatively cheap to buy and mold/fabricate.

Table 2: Design Matrix of Battery and Charging

Designs / Criteria	Design 1: Lithium-Ion with Recharging Cord 		Design 2: Disposable Battery 		Design 3: Switching Battery with Wall Charger 	
Compatibility (20)	5/5	20	3/5	12	4/5	16
Safety (15)	3/5	9	4/5	12	5/5	15
Security (25)	5/5	25	2/5	10	3/5	15
Lifespan (20)	5/5	20	3/5	12	4/5	16
Cost (10)	3/5	6	1/5	2	4/5	8
Size & Weight (10)	4/5	8	2/5	4	3/5	6
Total (100)	88		52		76	

The battery and associated charging system varied by both battery type and internal vs external charging. The first design is a Lithium-ion battery permanently installed within the device and a charging cord inserted directly into the watch. Lithium-ion batteries are known for their long lifespan and high voltage per cell ratio. They do, however, have strict regulations for charging systems and require both constant current and constant voltage regulations during the charging process [1]. The second design is a removable disposable alkaline battery that would be replaced with a new battery periodically. This design includes a panel secured by a screw and no changing system. Alkaline batteries are ideal for slow-drain devices such as watches and have a high charge density, they are not rechargeable [2]. The final battery and charging system is a removable lithium-ion battery with a removable charging system. This allows batteries to be easily swapped out with a panel secured by a screw. The battery would be bulkier to allow it to be externally table.

The permanently installed lithium-ion battery was the clear best option for the battery and charging system. Since the battery is permanently installed it is easily integrated with other internal electrical components and preventing children from having access to small parts and harmful chemicals that can cause harm [3]. Lithium-ion batteries also have a strong battery life, and the battery would be smaller than the alternatives as it does not need to be easily removable and externally stable. While this battery system risks overheating and can be more expensive to replace these effects can be mitigated with proper usage [1][4].

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Appendix C: Purchasing Logs

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Category 1 - Appearance										
Silicone Band	Silicone band for kids - 38/42 mm	Amazon	113-7232568-5800209	DQ-Tech	N/A	10/13/2025	2	$5.00	$9.99	Silicone Band
Black PLA Box	Preliminary box - 30x30x15 mm	Wendt DI Lab	N/A	N/A	N/A	10/24/2025	6	$0.25	$1.50	N/A

Clear Resin Lid	Box clear Lid	Wendt DI Lab	N/A	N/A	N/A	10/24/2025	2	$2.34	$4.68	N/A
Clear Resin Lid	Final Clear Lid	Wendt DI Lab	N/A	N/A	N/A	11/18/2025	2	$1.00	$2.00	N/A
Black Resin Box	Final Resin Box	Wendt DI Lab	N/A	N/A	N/A	11/18/2025	1	$2.77	$2.77	N/A
Black Resin Box	Final Resin Box	Wendt DI Lab	N/A	N/A	N/A	11/20/2025	1	$3.32	$3.32	N/A
Resin Box	Final Box	Wendt DI Lab	N/A	N/A	N/A	12/2/2025	1	$2.34	$2.34	N/A
Resin Lid	Final Lid	Wendt DI Lab	N/A	N/A	N/A	12/2/2025	1	$1.05	$1.05	N/A
Category 2 - Internal/Electronic Components										
Seeed Studio XIAO nRF52840 (XIAO BLE)	Microcontroller used for led light control	Seeed Studio	ORDER # 4000434924	Seeed Studio	N/A	10/25/2025	1	$17.59	$17.59	Microcontroller
LED Board	LED Opto/Lighting Evaluation Board	Soldered Electronics	333055	DigiKey	5032-333055-ND	10/30/2025	1	$8.40	$8.40	LED
Battery	3.7 V Lithium Polymer Battery	TinyCircuits	ASR00035	DigiKey	1832-1051-ND	10/30/2025	1	$11.31	$11.31	Battery

	Rechargeable (Secondary) 500mAh									
Perfboard	Printed circuit board	MakerSpace	N/A	N/A	N/A	11/14/2025	1	$1.00	$1.00	N/A
Header	Electrical connector	MakerSpace	N/A	N/A	N/A	11/14/2025	1	$0.02	$0.02	N/A
Seeed Studio XIAO nRF52840 (XIAO BLE)	Mcrocontroller used for led light control	Amazon	113-4450112-6245029	Seeed Studio	N/A	11/14/2025	1	$16.65	$16.65	Microcontroller
Seeed Studio XIAO nRF52840 (Pre-Soldered)	Mcrocontroller used for led light control	Seeed Studio	102010631	Seeed Studio	N/A	11/20/2025	1	$17.49	$17.49	Microcontroller
								TOTAL:	**$100.11**	

Appendix D: Watch Face Fabrication CAD Drawings

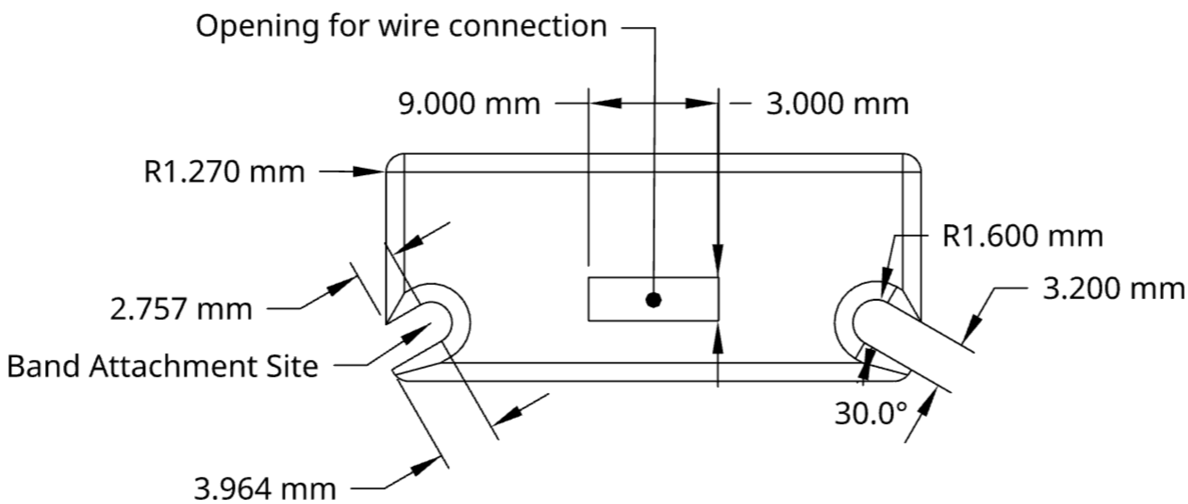

Figure [1]: CAD Drawing of Front wall of Case with Dimensions

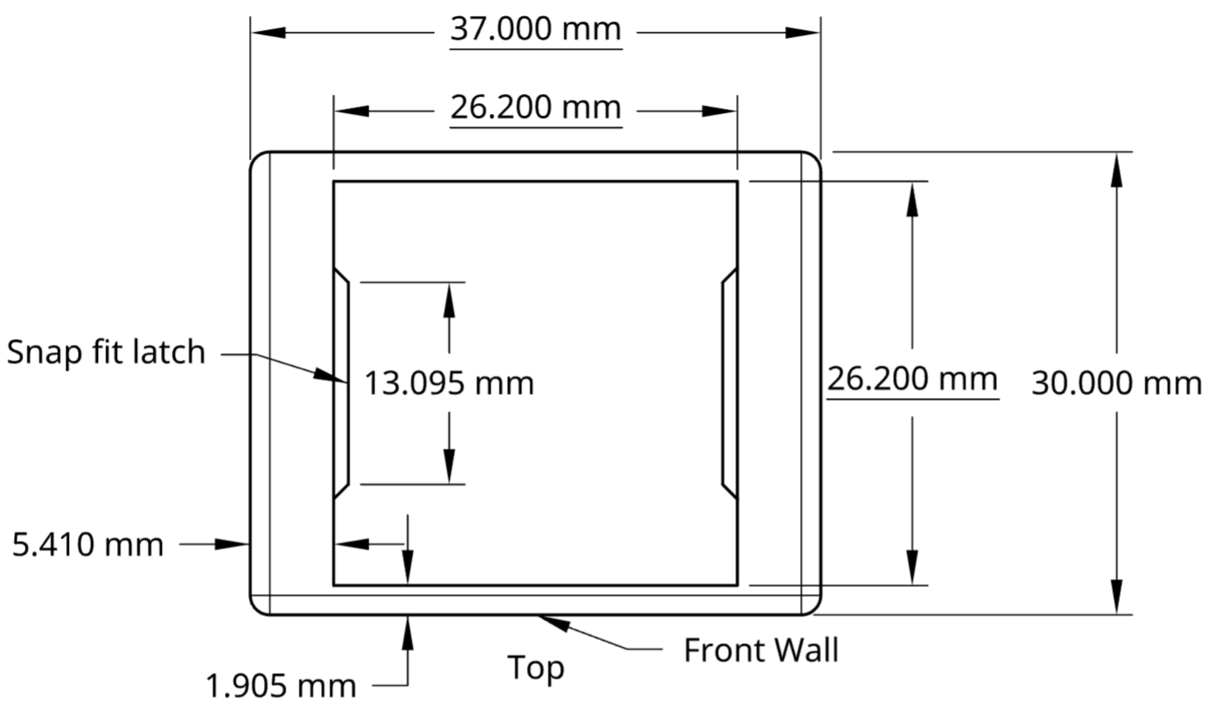

Figure [2]: CAD Drawing of Top View of Case with Dimensions

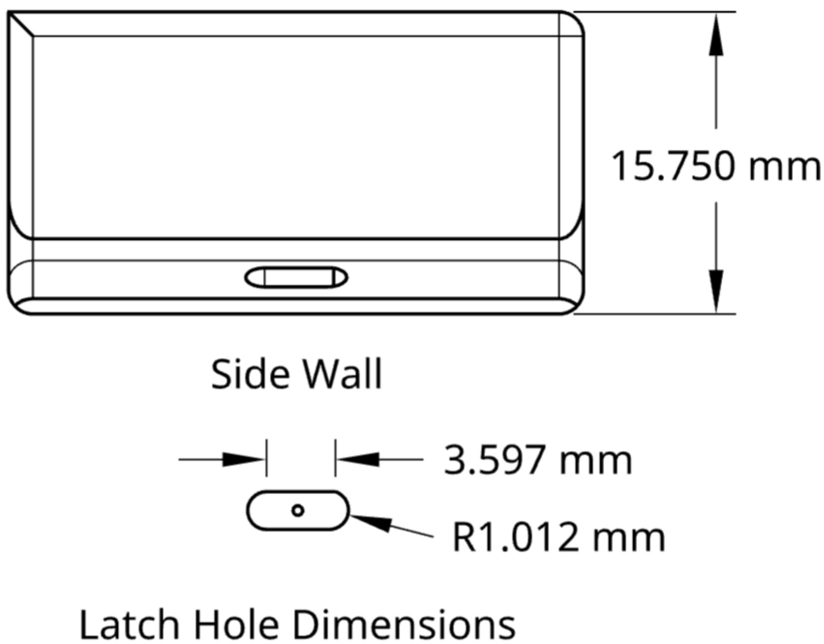

Figure [3]: CAD Drawing of Side Wall of Case with Dimensions

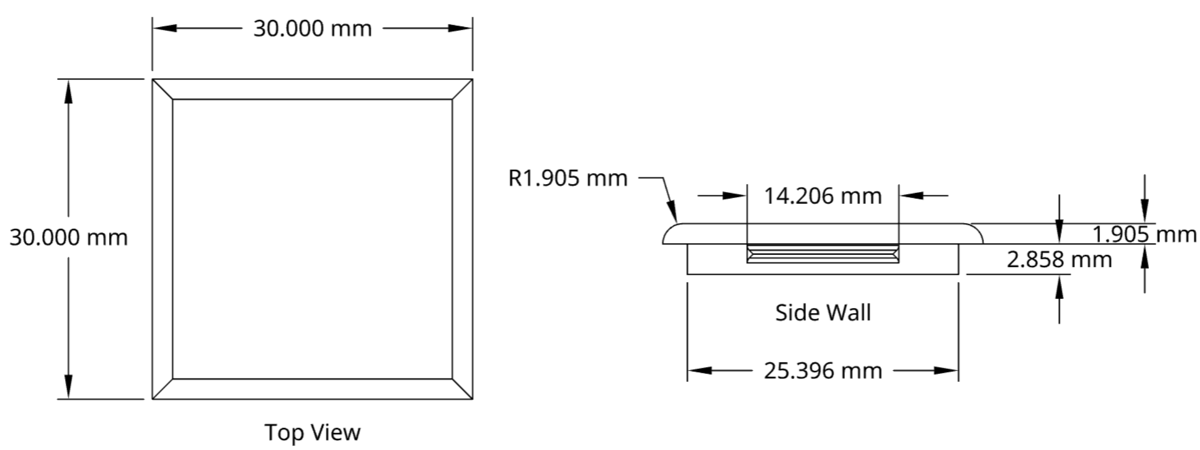

Figure [4]: CAD Drawing of Top Side Wall of Lid with Dimensions

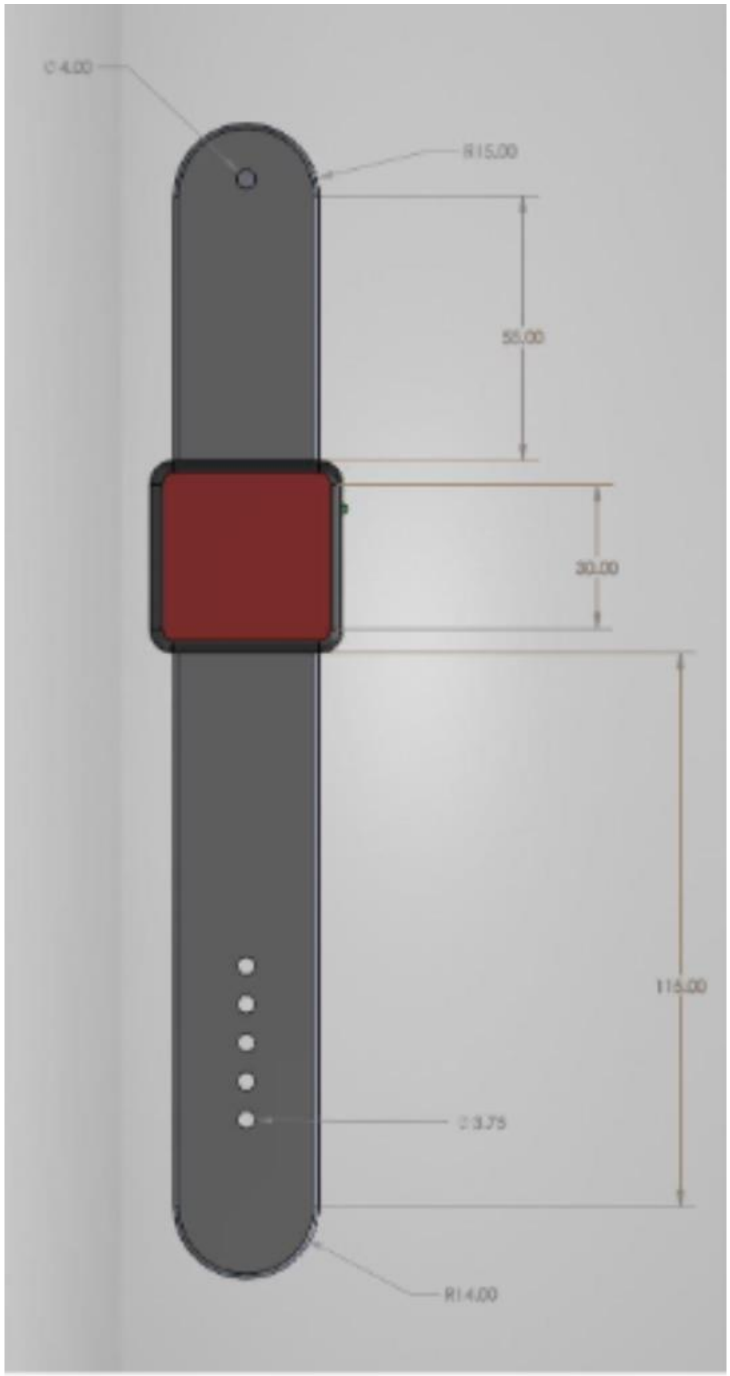

Figure [5]: Top View of Proposed Final Design Drawings (All measurements in mm)

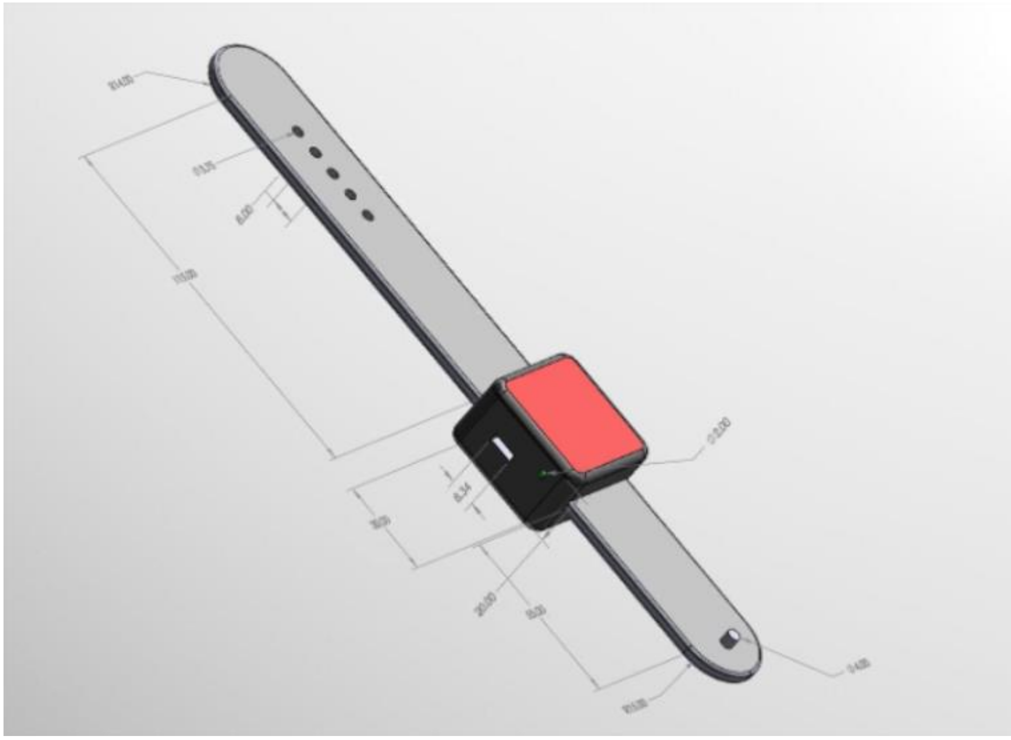

Figure [6]: Isometric View of Proposed Final Design Drawing (all measurements in mm)

Appendix E: Connectivity Testing Data

Table 1: Raw Data from Connectivity Testing

Time	Dexcom App Reading	Microcontroller reading	Expected color	Actual color
9:20	160	160	Blue	Blue
9:25	158	158	Blue	Blue
9:30	154	154	Blue	Blue
9:36	146	146	Blue	Blue
9:41	149	149	Blue	Blue
9:45	157	157	Blue	Blue
9:50	165	165	Blue	Blue
9:55	175	175	Blue	Blue
10:01	182	182	Blue	Blue
10:08	190	190	Blue	Blue
10:09	200	200	Purple	Purple
10:16	208	208	Purple	Purple

10:19	214	214	Purple	Purple
10:26	220	220	Purple	Purple
4:19	74	74	Yellow	Yellow
4:27	62	62	Orange	Orange
4:32	62	62	Orange	Orange
4:39	84		Green	Green
4:44	98		Green	Green
4:50	108	148	Green	Green
4:58	122	122	Green	Green
5:03	117	117	Green	Green
5:08	119	119	Green	Green
5:16	148	101	Blue	Blue
5:22	166	166	Blue	Blue
8:42	223	223	Purple	Purple
8:48	214	214	Purple	Purple
8:54	205	205	Purple	Purple
9:02	197	197	Blue	Blue
1:32	150	150	Blue	Blue
1:33	151	151	Blue	Blue
1:38	158	158	Blue	Blue
1:45	142	142	Blue	Blue
1:50	138	138	Green	Green