Preliminary 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 levels 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. Statuses of hyperglycemia (high blood sugar), hypoglycemia (low blood sugar), and healthy ranges must all be physically displayed by the wearable system. Current devices to alert caregivers of a child's blood glucose level include the *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 representing a blood glucose reading following the same color scheme as devices already on market: 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; therefore, 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 transmission to an iOS smart phone application. The device receives blood glucose data from a compatible programed mobile application, pulling directly from the user's Dexcom app. The alerting system displays a color intuitively corresponding to blood glucose levels, ensuring caregivers can respond confidently and appropriately. Testing will be focused on the bracelet's ability to display the correct color signal, provide sufficient visibility and color differentiation, and maintain an adequate range of connection. These metrics are vital for device reliability.

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Introduction

Type 1 Diabetes (T1D) is an autoimmune disease affecting the production of insulin-producing beta cells in the pancreas, leading to the inability to self-regulate blood sugar levels. Currently, there are 1.2 million Americans living with T1D [1]. Studies show that a diagnosis can be equally as stressful for parents as the child themselves, with an average of 33.5% of parents reporting distress following a diagnosis of T1D [2]. Currently, continuous glucose monitors (CGMs) are the most widely adopted device for active and constant observation of blood glucose. For this project, compatibility with Dexcom-branded CGMs will be prioritized, specifically the Dexcom G7 because it is the newest and most accurate model on the market [3].

There are a few third-party devices that help visually represent CGM readings, including the *Glowcose* light. The *Glowcose* works by mapping CGM data to a color-coded light source: red to yellow for hypoglycemia, green for numbers in range, and blue to purple for hyperglycemia. While this product is celebrated for its simplicity and ability to offer peace of mind, it relies on a steady Wi-Fi connection and wall plug power source [4]. Another similar product is the *Sugar Pixel,* which also relies on Wi-Fi to pull CGM data and displays blood glucose levels on a clock-like display [5]. For a portable solution, many T1Ds choose to use an *Apple Watch* or *Fitbit* to display CGM readings on their wrist for easy and frequent monitoring [6]. While using a smart watch display is convenient for the wearer, it provides no visible signal to others, and the high cost of smart watches can be a barrier to many families. The lack of a portable device that can visibly display blood glucose statuses led to the client's request for a wearable glucose alerting system to make status updates more clearly visible, understandable, and actionable for anyone supervising a child with T1D. The device should alleviate the stress associated with interpreting blood glucose numbers by eliciting a visible signal to parents and caregivers, which will convey whether treatment is needed or not.

Background

Type 1 Diabetes is an autoimmune disorder that affects the body's ability to produce insulin. Insulin regulates the concentration of glucose in the blood, commonly referred to as blood sugar levels. A lack of naturally produced insulin can lead to chronic high blood sugar, or hyperglycemia

[7]. When untreated, hyperglycemia can result in serious long-term health complications, including coma, nerve damage, vision impairment and blindness, heart disease, and impaired wound healing that may lead to amputation [8]. Currently, most individuals with diabetes manage their condition by routinely monitoring blood glucose levels using a CGM, counting ingested carbohydrates that raise blood sugar, and calculating insulin doses based on these factors [9].

While T1D can affect individuals of all ages, the Wearable Glucose Alerting System focuses on pediatric patients, who make up approximately 20% of diabetes diagnoses [1]. Children are often less able to fully understand and independently manage their treatment plans, especially at ages when they frequently spend time in school, daycare, or sports practices under supervision of caregivers who may not be trained in diabetes management. [10]. Diabetic treatment plans can vary significantly between individuals, depending on a range of factors such as exercise, gender, weight, height, and types of food consumed [11]. These variations, along with differences in how each child physically presents symptoms of dangerous blood sugar levels, make standardized training in these settings extremely difficult and often overwhelming for caregivers [12].

The clients, Dr. Beth Martin, PhD, a professor in the School of Pharmacy, along with Olive Carniglia and Callie Berg, students in the School of Pharmacy, have requested a device to help reduce this burden. The goal is to develop a wearable system that provides a universal signal that is visual, intuitive, and actionable for a wide range of caregivers.

The proposed device will display this signal, as well as indicate system failures, through a changeable LED interface. It will be rechargeable, wireless, comfortable for prolonged wear on a child's wrist, and adjustable to accommodate growth (12.5–17.5 cm) [13]. The device will be compatible with the Dexcom G7, one of the most widely used CGMs, to maximize potential usability and market reach. It will align with FDA Class II requirements under the Integrated CGM category and meet IP54 standards for water and dust resistance [14][15]. Additionally, ISO 15197 and ISO 17511 standards will be considered to ensure high accuracy relative to blood glucose measurements [16]. A comprehensive outline of product specifications can be found in Appendix A.

Preliminary Designs

Band and Materials

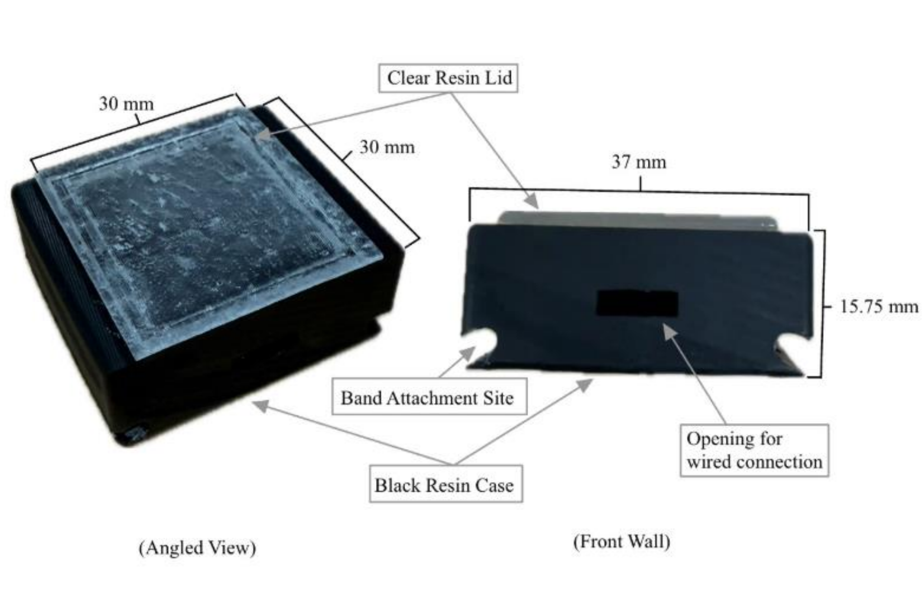

Figure 1: Resin Case and Lid

The enclosure is designed as a 3D-printed black resin box paired with a clear, snap-fit resin lid. Resin was selected for its high print resolution, durability, and overall strength. The box includes two band attachment points on opposite sides, compatible with commercially available Apple Watch bands [17]. To accommodate the geometry of these connectors, the side walls are extruded to a thickness of 5.41 mm, while the front and back walls are thinner at 1.905 mm.

A 9 × 3 mm opening is incorporated into the front wall to allow USB-C access for charging the internal microcontroller and battery. The internal cavity measures 26.2 × 26.2 mm, providing sufficient space for all electronic components. The lid measures 30 × 30 mm and attaches using snap-fit features along both side walls. All external edges of the case and lid are filleted with a radius of 1.27 mm for a smoother, more ergonomic finish. Detailed CAD drawings of the enclosure are provided in Appendix D.

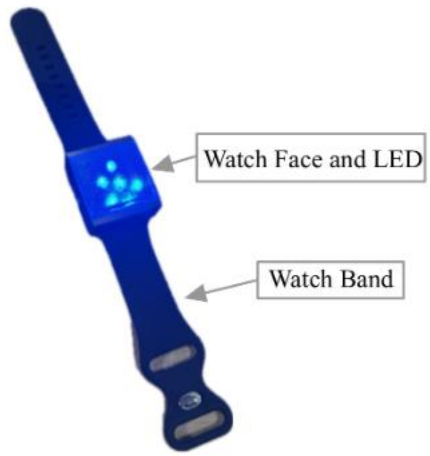

Figure 2: Current Band and Box Design

The Polyjoy Kids Apple Watch Strap, designed for compatibility with Series 10/11 Apple Watches, is made from silicone, providing waterproof, heat-resistant, and easily sanitizable, while remaining safe for most skin types. It features an adjustable loop with a peg-style closure and a double buckle mechanism, offering added security and making it difficult for a child to remove independently [17].

Hardware

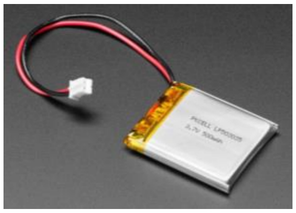

Figure 3: Battery

Figure 4: LED

Figure 5: Microcontroller

The device will use a 3.7 V, 500 mAh lithium-ion battery that is permanently soldered in place and charged directly through the microcontroller via USB-C forward charging [18]. The selected LED component is a NeoPixel 7-ring Jewel, with each LED drawing up to 18 mA at maximum brightness; this represents the primary load of the system. Based on this, the expected runtime is approximately 6 hours per charge. The XIAO ESP32-C6 microcontroller supports very low power consumption along with Wi-Fi 6 and Bluetooth Low Energy (BLE) 5.0 connectivity, while also remaining a cost-effective option within the project budget.

Data Transmission

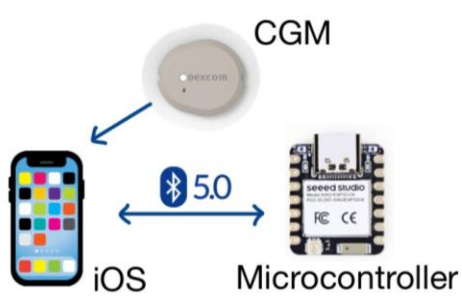

Figure 6: BLE 5.0 Only Connection

The first transmission method considered for communication between the application and the microcontroller was BLE 5.0 only. This method uses a minimal amount of current to maintain a connection, typically under 10 mW [19]. Its connection range is approximately 50 m indoors and up to 100 m outdoors, which satisfies the PDS requirement of 50 m [20]. A BLE connection is generally straightforward to set up, involving a single pairing process similar to connecting headphones or a speaker to an application. BLE is also widely accessible both nationally and globally, which would help expand the device's potential market. Because it only requires a single connection, this transmission method is easily replicable and feasible for the team to implement.

Figure 7: Wi-Fi 6 Only Connection

The second transmission method considered was using Wi-Fi 6 only. Wi-Fi connections require significantly more power than BLE and generally have slightly shorter effective ranges: 41 m indoors, and 90 m outdoors [19][20]. When used with the microcontroller, a Wi-Fi connection would also require access to a specific network, along with password and router configuration, making it a much less user-friendly option.

Figure 8: Both Wi-Fi 6 and BLE Connection

The third connectivity option is to enable transmission through both BLE and Wi-Fi. The main drawback of this approach is the significantly higher overall power consumption when both systems are used simultaneously. Additionally, both Wi-Fi and BLE operate on the 2.4 GHz frequency band [18], which can lead to potential interference or crossover in data transmission. While this hybrid model would be beneficial in terms of range and accessibility, it lacks the user-friendliness and replicability of the other options.

Preliminary Design Evaluation

Table 1: Design Matrix of Connection Mode Options

Designs	BLE 5.0 	Wi-Fi 6 	Both Wi-Fi 6 and BLE 5.0 
Power Consumption (25)	5/5 (25 pts)	3/5 (15 pts)	2/5 (10 pts)
Connectivity (25)	3/5 (15 pts)	4/5 (20 pts)	5/5 (25 pts)
Ease of Use (20)	4/5 (16 pts)	2/5 (8 pts)	3/5 (12 pts)
Accessibility (15)	3/5 (9 pts)	4/5 (12 pts)	5/5 (15 pts)
Feasibility (10)	5/5 (10 pts)	3/5 (6 pts)	2/5 (4 pts)
Replicability (5)	4/5 (4 pts)	3/5 (3 pts)	1/5 (1 pt)
Total (100)	79 pts	64 pts	67 pts

The BLE 5.0, Wi-Fi 6 (2.4 GHz), and a combination of BLE and Wi-Fi designs all have distinct tradeoffs across power consumption, connectivity, ease of use, accessibility, feasibility, and replicability. BLE 5.0 is the most efficient power option by a significant margin, typically consuming less than 0.01 W [19]. Wi-Fi however draws substantially more power, 0.5 to 2 W, and the combined BLE and Wi-Fi design utilizes additional power due to shared frequency operation [18][19]. From a connectivity standpoint, the combination offers the most reliable and consistent coverage since it can theoretically switch to the method with a stronger connection. BLE is more susceptible to interference from the environment but meets the 50 m range requirement as outlined in Appendix A. Wi-Fi on its own receives less interference with a similar range to BLE [19][21]. Ease of use favors BLE due to its simple device pairing and minimal configuration. Wi-Fi requires network credentials and router setup and could run into issues if there is a firewall or proxy in place, a common occurrence in schools [22]. The combination increases the complexity of user set up since it requires both routes to be configured correctly. Wi-Fi and BLE see similar accessibility globally and domestically. The United States (US) sees about 90% access to Wi-Fi and 70% globally while BLE is available in 82% of the US and 63% worldwide [23][24]. The hybrid option naturally takes the combination of both accessibility percentages and allows for flexible pairing, hence its high scoring. In terms of feasibility, BLE is the winning option due to its standardized iOS support and lack of network requirements or a backend API. Wi-Fi and the combination design have additional complexity with network policies and extra logins [22][25]. Each device can operate independently with the BLE model, giving it the highest replicability score. Significant configuration and maintenance would be required to adapt to multiple devices with the Wi-Fi and combination designs [26]. The BLE option is the most straightforward, power efficient, and overall well-suited model for the final design.

Proposed Final Design

The proposed final design consists of an adjustable silicone band attached to a 3D resin box with a detachable lid. The light will be a NeoPixel ring LED which will display a color corresponding to the glucose status. The LED will display a pulsing white light in the event of a malfunction or dropped connection. The Lithium-ion battery will be permanently installed and charged using a USB-C cable through the microcontroller. The battery will also be soldered to the XIAO ESP32-C6 Microcontroller and LED to minimize hardware dimensions. See Appendix D for a detailed CAD representation. The data retrieval system will be adapted for compatibility with an iOS application and updated to initiate a BLE transmission to the device. A user's CGM will connect to the Dexcom app, and their individual login information will be used to access the custom-created app. The app will pull the most recent blood glucose value, auto-refreshing every 5 minutes, to communicate with the microcontroller via BLE. The microcontroller then categorizes the new value to a color that matches the set ranges. The LED will then be updated to display the corresponding color.

Fabrication

The chosen final design will focus on the microcontroller's BLE capabilities for data transfer from iOS application to the device. Deployment of the mobile app will be implemented using Flutter, Google's open-source user interface (UI) programming platform. The program is an advancement of the previously developed UI running locally on a Windows computer. The codebase will be transferred into an Apple toolchain, so it can be built and deployed on iOS. The existing project directory was version-controlled and pushed to a GitHub repository from the Windows machine, then cloned onto a Mac to create a consistent, reproducible development environment. On the Mac, Flutter and Xcode are used to generate and maintain the iOS build artifacts, manage CocoaPods dependencies, and compile the application into an iOS application bundle compatible with the iPhone. Once installed on iPhone, the app operates as the wireless gateway for the system, retrieving glucose data from the backend application programming interface (API) and transmitting values over BLE. The microcontroller is configured as the BLE peripheral device, displaying a unique identifier for paring. The iPhone connects to the device and is routinely prompted to send a small packet of data to a specific memory location, called a characteristic, on the microcontroller. Upon receiving the packet, the microcontroller will initialize the intended behavior of updating the LED.

The process of pulling data from the CGM to the mobile app utilizes the same backend logic for data retrieval as with the Windows environment. The backend API 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 [27]. 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 system consists of three primary hardware components: a 3.7V Lithium-ion battery for power supply, a microcontroller for signal processing and control logic, and an LED for visual output. The LED will be electrically connected to a designated DIO (Digital Input/Output) pin on the microcontroller to enable software-controlled signaling. The Lithium-ion battery will be connected to the microcontroller's power input through appropriate voltage regulation circuitry to provide stable operating voltage. Once assembled, the microcontroller firmware will control the LED behavior based on programmed logic, completing the integrated hardware–software system.

Circuit components will be encased in a 3D printed box made of black resin filament. The box will initially be created with internal dimension of 26.2 x 26.2 mm, but is subject to adjustment based upon the measured size of assembled software components. The box will feature one rectangular cutout measuring 9 mm x 3 mm, for the USB-C cable insertion necessary for battery charging and microcontroller programing. The top of the box will be open with a sunken lip along the top, where a 30 mm x 30 mm lid printed of clear resin will securely snap into place. This will allow for the colored light from the internal LED to display brightly out of the top. Resin was selected for both the box and lid components due to its widespread availability, existing prevalence is medical devices, and low cost at $0.24/mL [28][29]. All edges of the watch face and lid are filleted with a radius of 1.27 mm to remove any sharp edges. Along opposite bottom edges will be two cylindrical grooves designed according to the specifications of an Apple Watch band insertion slit. This will enable compatibility with third party Apple Watch bands, notably the PolyJoy children's band. This band is made of silicone, a material chosen due to its durable and hypoallergenic nature, meeting the client's requirement for a water resistance rate of IP 54 [30][18]. Additionally, this band features a double-slit securing system, making it more difficult for children to remove themselves. It also is adjustable to the desired wrist sizes of 127-178 mm.

Testing and Results

In evaluating the accuracy of the Glucose Alerting System, a series of tests will be performed to measure the device's ability to provide accurate, visible, and timely signals. For the tests to be considered successful, they will need to be consistent with ISO 15197:2013, which focuses on the standard of a CGM device to achieve 95% accuracy compared to the glucose test strip reading [13]. The first test will consist of measuring the bracelet's ability to provide the correct color signal with 95% accuracy over the course of 5 hours at intervals of 15 minutes. At each time interval, the color of the bracelet will be recorded along with the data provided by the Dexcom app to determine the expected color of the bracelet. The actual and anticipated colors of the bracelet will be compared, and a t-test will be performed to determine the presence of statistical significance between the Dexcom and the Wearable Glucose Alerting System. A successful test will produce results showing no statistical significance between monitoring from the Dexcom app and the Wearable Glucose Alerting System.

The second test will evaluate the visibility of the bracelet's LED light from a distance of 50 m away in a variety of conditions, including sunny, cloudy, and indoor settings. The team will test with 10 individuals observing the bracelet at lengths of 25 and 50 m away. Their color interpretation will be compared to the actual color of the bracelet. The team will test both the hyperglycemic and hypoglycemic color ranges to simulate a variety of statuses. A successful test will demonstrate 95% or greater success in subjects' ability to distinguish different color settings at distances of both 25 m and 50 m in all tested environments.

The third test will focus on the range of connectivity between the wearable device and the iOS application through which blood glucose data is transmitted, per the clients' requirement of having a connection range of 50 m. The device will be placed at a location 50 m away from the iPhone running the application. The microcontroller will be manually manipulated to circulate through each of the 6 colors, simulating changes in glucose statuses, at 5-minute intervals. The microcontroller will be prompted to cycle through each color 5 times to ensure accuracy over a sustained period. The ability of the bracelet to update color status within the 5-minute interval will be recorded as a pass or failure. A successful test will demonstrate 95% accuracy with color updates, proving that the bracelet is effective at the desired transmission ranges.

A fourth test will be conducted to test the responsiveness of the malfunction alert. The device and the iPhone will start in-range and paired, then the iPhone will forcefully drop the BLE connection to the device. A successful test will observe the device switching to a pulsing white light within an interval of 5 minutes, signaling a connection drop. The test will be performed 10 times at different distances, measuring 5 m to 50 m from the device at intervals of 5 m. A 100% success rate is required for a passed test.

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. Last semester's accuracy, visibility, and Materials Testing System (MTS) 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 blood sugar as presented by the Dexcom app vs received by the microcontroller 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 last semester due to the inability to establish a Bluetooth connection between the microcontroller and mobile device, but it is currently the main improvement focus of the project. Before the ShaRx presentation, new accuracy, visibility, connectivity range, and malfunction tests will be used to further support the client specifications and improve the device.

In previous 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. Current modifications have begun scaling down the circuitry to fit within the box capacity. 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. Altering the box dimensions or improving the release mechanism of the commercially available watch band will be implemented to alleviate the wear on the band. The primary problem, the BLE connection between the XIAO and the Flutter app will be aimed to model the proposed final design using the C6 XIAO, BLE 5.0 and a future iOS app. All soldering issues encountered in the first prototype have been addressed in subsequent models. The Soldered Electronics LED that had issues maintaining complete functionality because of cheap manufacturing has been replaced with the NeoPixel Jewel Ring LED which offers increased durability and simplifies soldering. The original circuit included a 330 kΩ resistor and a 1000 F capacitor, both of which were removed from the final design due to redundancy. The 3.7V battery that was incompatible with the XIAO nRF last semester will now be fully functioning in conjunction with the XIAO ESP and a longer mAh version has been purchased. A release latch is also going to be added to the watch face sides to prevent shredding of the band upon installation and removal. The current planned changes aim to accommodate remaining client specifications, streamline process flow, and improve appearance and useability of the device.

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 [14]. 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 [31][32]. The main device implications are data transfer accuracy between the bracelet and user CGM data, malfunction detection, 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 device also raises several ethical considerations centered on safety, privacy, and user well-being. Since 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 [33]. 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 should be avoided to the best of the team's ability. Overall, many changes based off last semester's progress 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.

Conclusion

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 blood glucose values.

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 ring LED offers a highly visible method for conveying glucose status efficiently.

Despite demonstrating functionality in initial fabrication and testing, several challenges came to light. Achieving a stable and reliable BLE connection between the Flutter-based mobile application and the microcontroller was not accomplished previously and will be the main goal for the revamped connection mode. Addressing this issue is critical for ensuring seamless communication and dependable alerts. The device will be optimized to be completely wireless using the iOS app, BLE connection, and microcontroller. Extensive testing will be conducted before the April 2026 ShaRx Competition to eliminate any issues that arise during upcoming fabrication.

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Appendix

Appendix A: Product Design Specifications

Product Design Specifications

Wearable Glucose Alerting System

Team Members:

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February 5, 2026

BME 301

Function:

Understanding the needs of a child with Type 1 Diabetes (T1D) can be stressful and confusing for caregivers. The goal of the Wearable Glucose Alerting System is to provide a visible, actionable, and intuitive signal to help streamline the process of maintaining a healthy blood glucose level in a child with T1D. Pulling from the child's existing Dexcom-brand Continuous Glucose Monitor (CGM), the device will display a unique range of colors to indicate statuses of hyperglycemia (high blood sugar), hypoglycemia (low blood sugar), or normal levels [1]. The alerting system must be unambiguous, ensuring caregivers can respond confidently and appropriately. Additionally, the device will be worn on the child's wrist and must not impede the activity demands of daily life.

Client Requirements:

- Develop a device capable of displaying the status of blood glucose to anyone supervising a child with diabetes.
- Device should display up-to-date readings with a time delay no greater than 5 minutes.
- The signal must be clearly visible and distinguishable from 50 m.

- The device should be designed for a secure and comfortable fit 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 alerting system must be compatible with a Dexcom CGM device.
- A rechargeable or replaceable battery system must power the device.
- Wireless connection to the device will be controlled through an associated mobile app.
- The device must maintain a Wi-Fi connection within 50 m of a connected cellular device.

Design Requirements:

1. Physical and Operational Characteristics:

a. Performance requirements:

The prototype will display a visible color signal corresponding to predetermined blood glucose ranges received from the child's Dexcom CGM. While specific ranges are adjustable, default settings are programmed as follows:

- <55: Red
- 56-65: Orange
- 66-80: Yellow
- 81-139: Green
- 140-200: Blue
- >201: Purple

The light will be powered by an internal rechargeable battery, allowing for continuous use over the course of 10 hours.

b. Safety:

The device must maintain a continuous visual signal at all times during operation. In the event of a system failure or loss of connectivity, the device will emit a distinct signal, preventing the display of outdated information. The internal circuitry will be encased in a water-resistant, durable enclosure to protect components from external elements. This layer will also make the device easy to sanitize, promoting better hygiene for regular daily use.

c. Accuracy and Reliability:

The bracelet's live color signals should mirror readings from the child's CGM with a delay of no longer than 5 minutes. Received data as shown by the app must not differ from industry expectations of a CGM, having a mean absolute relative difference (MARD) of approximately 8.5% between blood glucose readings and CGM measurements [3]. The bracelet must also contain a visual indication in the event of a connectivity error.

d. Life in Service:

The final product should last between 3 to 5 years of regular use. This is consistent with the lifespan of marketed commercial fitness watches [4]. Operationality will be determined by the device's ability to accurately display CGM readings for the duration of at least 10 hours of device use.

e. Shelf Life:

When not in use or during charging, the device should be stored in a cool, dry environment. This will mitigate opportunity for internal condensation, battery corrosion, or circuitry component malfunction due to elemental factors. Wear and tear from daily use must be minimal and not impede with the device's function.

f. Operating Environment:

The device should be designed to operate across a range of environmental conditions, including outdoor temperatures from –20 °C to 43 °C [5]. It should feature an IP54 water-resistance rating and be sufficiently durable to withstand routine wear by an active child, including accidental drops from heights of up to 2.5 meters, comparable to typical playground equipment height [6][7].

g. Ergonomics:

The device must be designed to ensure user safety and comfort during prolonged use. All materials in contact with the skin should be biocompatible and suitable for continuous wear, with no risk of irritation or adverse skin reactions. Electronic components and the battery must be fully enclosed to prevent exposure to chemical or physical hazards. Additionally, the device should maintain a safe operating temperature, not exceeding 35 °C, to prevent discomfort or potential skin injury [8].

h. Size:

The device should fit comfortably around a child's wrist and be easily adjustable to accommodate growth over time. The device should be suitable for children aged 5 to 17, with wrist circumferences ranging from 12.5 to 17.5 cm [2][9]. The watch face should measure less than 35 mm in both length and width and less than 20 mm in height to ensure a comfortable fit on a child's wrist [2][9]. Additionally, the device should sit as flush to the skin as possible to minimize snagging on clothing or other materials and to avoid interfering with daily activities.

i. Weight:

The weight of the device should not interfere with normal use of the wearer's hand or arm. The device should weigh less than 58 g, in line with commercially available fitness watches, with consideration given to the fact that many watches designed for women and children weigh approximately 32 g [10].

j. Materials:

The device should be comfortable for extended wear. The wristband should be constructed from a durable, flexible, and water-resistant material that avoids common skin allergens. Many commercially available fitness watch bands use materials such as silicone, polyester, or nylon [4]. The enclosure for the alerting system should be made from material that protects internal electronic components from human exposure while providing water resistance. All materials should be easy to clean and sanitize after prolonged usage by a child.

k. Aesthetics, Appearance, and Finish:

The device should use light-based color cues to indicate different blood glucose states, including hypoglycemia, hyperglycemia, and anticipated rapid changes in blood glucose levels [1]. The device should have a smooth, finished surface with no sharp edges that could pose a safety risk.

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. Currently, $100.11 has been used from the budget in the first semester. Market prices for the device will be determined by the pharmacy representatives upon presentation in the spring of 2026. This price should be comparable to competing glucose alerting systems like *Glowcose* at $60 [11].

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 [12]. This class of medical devices must abide by the necessary guidelines to achieve 510(k) approval [12]. A mandatory shutoff is a requirement for these devices after the approved time-in-range (TIR) [12]. 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 [13].

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 [6].

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 in specifications of 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 to reflect typical playground environments [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 device aims to reduce stress and should not be a burden to wear or adjust. 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. It requires a wall connection and is not portable or wearable, decreasing patient ease of use [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 more expensive than many alternatives. A third product, the Sugar Pixel, receives data from a CGM to show real-time glucose readings and trends using a clock-like display. It also provides alerting systems that are useful for nighttime alerts. This device is also not fully portable and requires a strong Wi-Fi connection for use [17].

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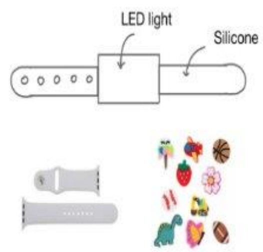
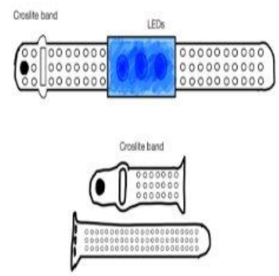
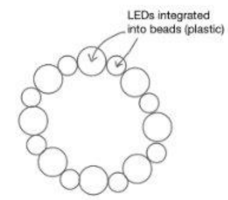
Appendix B: Material Design Considerations and Design Matrix

Table 1: Design Matrix of Band Materials

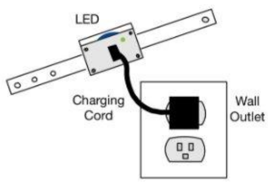
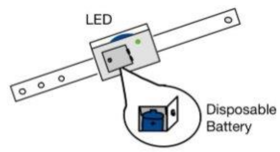
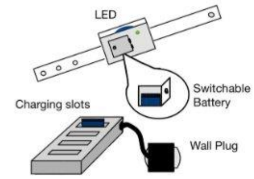
Designs / Criteria	Design 1: Silicone band with LED light 		Design 2: Croslite band with LEDs 		Design 3: LED light with plastic beaded bracelet 	
Safety & Ergonomics (25)	5/5	25	4/5	20	3/5	15
Adjustability (20)	5/5	20	4/5	16	3/5	12
Durability (20)	5/5	20	3/5	12	2/5	8
Accuracy (15)	5/5	15	4/5	12	3/5	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.

Appendix C: Battery and Charging Design Considerations and Design Matrix

Table 1: 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 D: Proposed Final Design Drawings

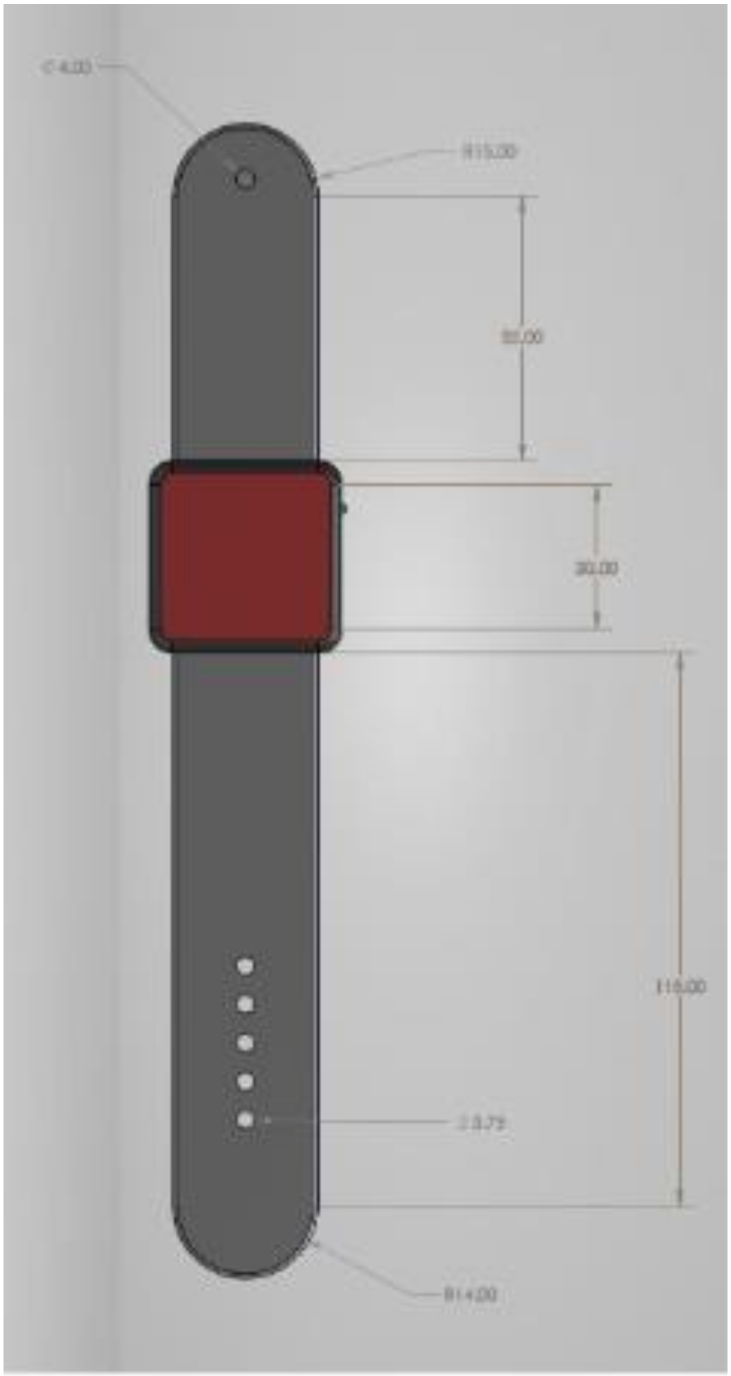

Figure 1: Top View of Proposed Final Design Drawings (All measurements in mm)

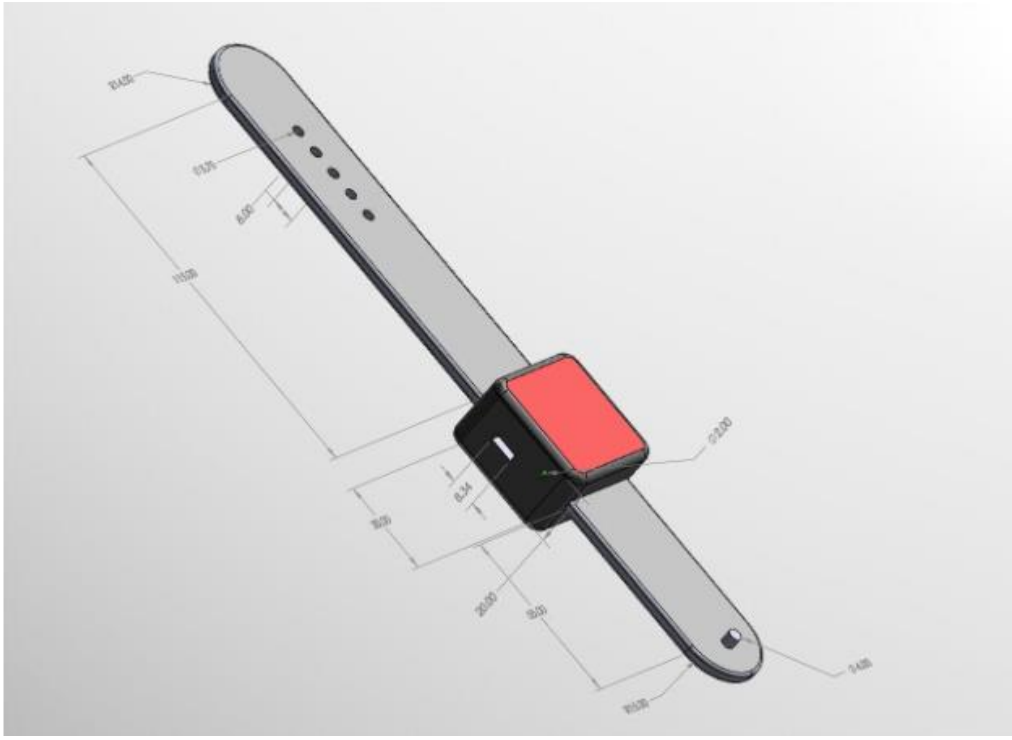

Figure 2: Isometric View of Proposed Final Design Drawing (all measurements in mm)