

Preliminary Report

Wearable Glucose Alerting System

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BME 200/300

Abstract

The Wearable Glucose Alerting System is a device used to notify caregivers of blood glucose fluctuations in children with Type 1 Diabetes. The clients have requested the device to be compatible with a Continuous Glucose Monitor (CGM) and suited for patients with diabetes. Episodes of hyperglycemia (high blood sugar), hypoglycemia (low blood sugar), or anticipated changes in blood sugar levels need to be readable by the wearable system. Current devices to alert caregivers of changes in children's glucose levels include devices such as *Glowco* and *Sugar Pixel*, which are immobile and need a plug-in wall connection. The team elected to create a device that will change colors based on these glucose levels and be worn on a child's wrist. It will be portable and not impede the activity demands of daily life. The bracelet consists of a silicone wristband, LED lights, a connection compatible with Nightscout API, and a rechargeable Lithium-ion battery. The alerting system will display 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 provide the correct color signal, the amount of visibility of that signal, and the range of connectivity from the bracelet to a mobile device. These aspects will be important for caregiver understanding and overall functionality of the device.

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Introduction

Type 1 Diabetes is an autoimmune disease that affects 1.2 million children in the United States [1]. Studies show that a diagnosis of diabetes can become 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 Type 1 [2]. The vast majority of Type 1 Diabetics utilize Continuous Glucose Monitors (CGM) to actively monitor their blood glucose levels. For this project, the team has decided to focus on compatibility with the Dexcom G7 CGM because it is the newest, most accurate CGM and can directly connect to multiple devices [3]. 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. Although, 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 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. This option is not fully portable and requires a strong WIFI connection for use [6]. These challenges are what lead the client to request a CGM Bracelet to make blood glucose status more clearly visible, understandable, and actionable for anyone supervising a young child with Type 1 Diabetes. This prototype should help relieve some of this stress by eliciting a visible and actionable signal to parents, which will convey whether treatment is needed or not.

Background

Within the body of a Type 1 Diabetic, 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 Type 1 Diabetics if left untreated [7]. While Type 1 Diabetes 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]. 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, Dr. Beth Martin, a PhD professor within the School of Pharmacy, Olive Carniglia, and Callie Berg, two students in the School of Pharmacy, 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. Additionally, the bracelet will be compatible with a Dexcom G7. The battery aspect of the bracelet will be rechargeable and replaceable. The team will also ensure to follow FDA Class II, known as the Integrated CGM Category, as well as IP54 for water resistance [10]. ISO 15197 and ISO 175119 will also be met, ensuring a 95% accuracy when compared to glucose results of a test strip [11, 12]. A comprehensive outline of product specifications can be found in Appendix A.

Preliminary Designs

Band and Materials

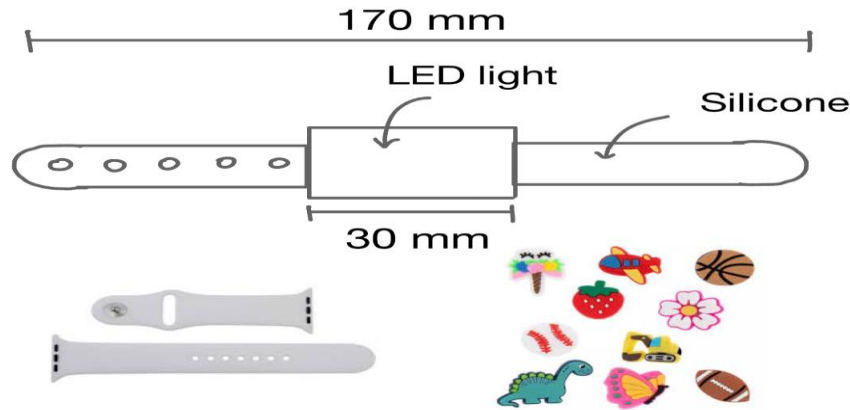


Figure 1: Initial Drawing of Bracelet Band and Light

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, able to be translucent to light, and a relatively cheap option. 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

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 have strict regulations for charging systems and 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 C for additional information.

Connectivity

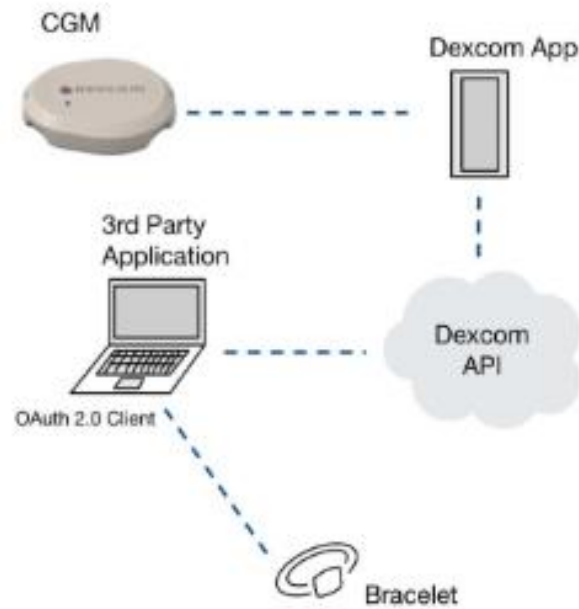


Figure 2: Dexcom Developer Program Flow Chart

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 [1]. However, for the level of authorization, the delay time for data transmission can be up to 3 hours from CGM to 3rd party device [1].

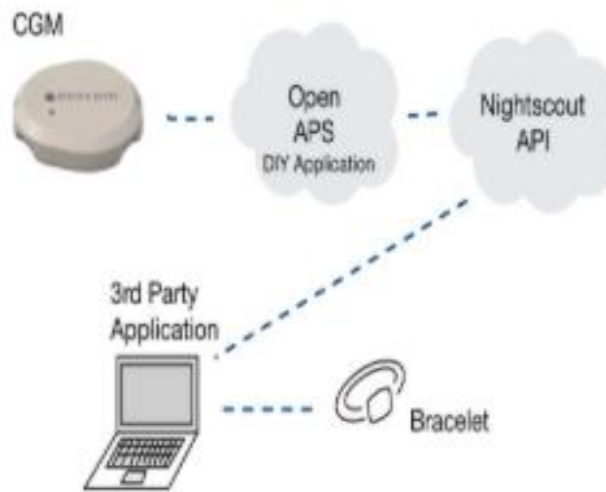


Figure 3: Nightscout API Flow Chart

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 to the bracelet via Bluetooth connection. Developing an API allows for a high degree of customization. While this requires a high degree of initial development, the opportunity for replication is promising once the framework is established.

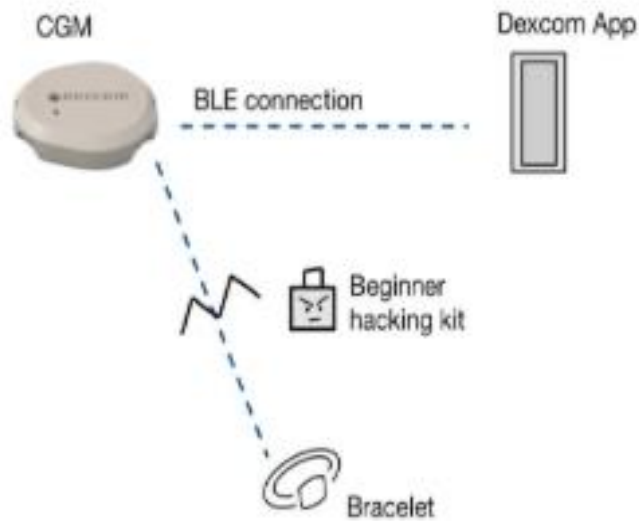
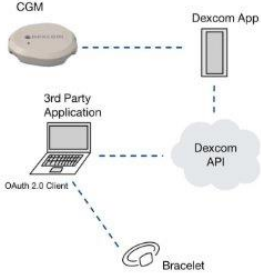

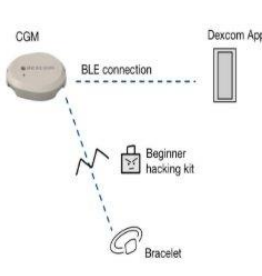


Figure 4: Bluetooth Low Energy Connection Flow Chart

The third connectivity concept 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. Since we would need to reach this secure connection, it 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 newly connected CGM: around once every two weeks. [17].

Preliminary Design Evaluation

Table 1: Design Matrix of Connectivity Options

Designs	Design 1: Dexcom Developer Program		Design 2: Nightscout API		Design 3: BLE Connection	
Criteria						
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 Continuous Glucose Monitor. 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 that would result from the level of authorization to use this system would be up to 3 hours, which does not meet the requirements of the client, as outlined in Appendix A. The Nightscout API reduces this delay time to around 5 minutes and provides a high degree of customization for the user. The security connection is also relatively secure as it relies on private Dexcom data. Also, this API has the potential to be designed completely free of charge. The BLE connection model is efficient in terms of providing 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 changed using a generic USB-C cable. The data retrieval system will use Nightscout API which will transmit data from the CGM up into the cloud then to a computer and ultimately to our bracelet. See Appendix D for detailed CAD representation.

Fabrication

The final prototype will feature a bracelet and its corresponding charging cord. The bracelet's appearance will consist of a silicon adjustable band, a plastic hardware containment system with a transparent face, multiple LEDs, and a Lithium-ion rechargeable battery. Of the silicone bracelet brands on the market, the children's band from PolyJoy was the top contender. The band has a double-slit securing system, which is more difficult for children to remove themselves, is adjustable to the desired wrist sizes, 127-178 mm, and is hard to rip or break, water and sweat-proof [18]. The watch face itself will be initially modeled using SolidWorks. This will allow for a more comprehensive dimensioning of the face and will allow for ease of fabrication of the base itself, which will be made of Black PLA. The top of the bracelet will be fabricated out of Clear PLA, to achieve maximum visibility of the LED affixed inside. PLA was chosen for fabrication of these components due to its ready availability on campus, it is low cost at \$0.05/g, and it is proven for safe use on the skin as it is a common component in many medical tools such as prosthetics [19][20]. The main component of the bracelet will need to be small enough to fit comfortably on a child's wrist, about 30 by 30 mm by 15 mm; the edges will be filleted and smooth to the skin. The electrical components of the bracelet will be manufactured around a Seeed Studio XIAO nRF52840 microcontroller, which is used commonly with similar wearable devices [21]. It is quite small, measuring 21 by 17.8 mm, and it has an

operating voltage of 3.3 V, which is in the range of what the Polymer Lithium-Ion rechargeable battery will supply. These two key components coupled with the necessary circuit components will be mounted and fit into the base of the bracelet along with the help of a Printed Circuit Board (PCB).

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. 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 Glucose Alerting System. A successful test will produce results showing no statistical significance between monitoring from the Dexcom app and the Glucose Alerting System. This is 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 [12].

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 bracelet and the phone device from which CGM data is passed. Per the requirement of having connectivity from 50 m away. The bracelet will be placed at a location 50 m away from the phone device containing the API. The API will be manually manipulated to change colors, simulating changes in glucose statuses, at 10-minute intervals. Each color will be programmed 5 times, cycling through at

random. The ability of the bracelet to update color status within the 10-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.

Discussion

The Continuous Glucose Monitoring Bracelet attempts to correct the communication barrier between parents of Type 1 Diabetic children and any approved supervisor without access to the Dexcom users' current levels. Successful results of the accuracy, visibility, and connectivity range tests will be used to support the client specifications and improve the device further prior to presentation in the Spring of 2026. During fabrication of the device, environmental concerns such as waste of materials, frequent malfunction and replacement, or incompatibility of parts should be avoided when possible. Further environmental preservation can be focused on in future semesters. Ethical considerations in the ultimate use of this device will be regulated by the FDA Class II for Medical Devices as the necessary market specifications cover 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 three testing protocols explained above.

Conclusion

The overall goal of the Wearable Glucose Alerting System is to make blood glucose status more clearly visible, understandable, and actionable for anyone supervising a young child with Type 1 Diabetes. The final device determined to be the most effective through research and preliminary design work consists of a bracelet with a silicone wristband, LED lights, a connection compatible with Nightscout API, and a rechargeable Lithium-ion battery. The silicone wristband, LEDs, and the Lithium-ion battery were all selected due to relative success in their respective uses. The challenges the team has to now overcome revolve primarily around the

connection aspect of the project. The Nightscout API connection could be improved to optimize the interface for ease of use in setup. Future work includes extending the device's battery life to improve usability and user satisfaction, and eventually large-scale distribution.

References

- [1] American Diabetes Association, "Statistics about diabetes," diabetes.org, 2023.
<https://diabetes.org/about-diabetes/statistics/about-diabetes>
- [2] R. Whittemore, S. Jaser, A. Chao, M. Jang, and M. Grey, "Psychological Experience of Parents of Children With Type 1 Diabetes," *The Diabetes Educator*, vol. 38, no. 4, pp. 562–579, May 2012, doi: <https://doi.org/10.1177/0145721712445216>.
- [3] G. Freckmann, "Basics and use of continuous glucose monitoring (CGM) in diabetes therapy," *Journal of Laboratory Medicine*, vol. 0, no. 0, Feb. 2020, doi: <https://doi.org/10.1515/labmed-2019-0189>.
- [4] "Glowcose," *Glowcose*, 2024. <https://glowcose.com/> [Accessed: Sep. 17, 2025].
- [5] S. G. James, M. Elaine, Z. S. Abdallah, H. Emerson, and Aisling Ann O'Kane, "Integrating Technology into Self-Management Ecosystems: Young Adults with Type 1 Diabetes in the UK using Smartwatches," pp. 1–20, Apr. 2025, doi: <https://doi.org/10.1145/3706598.3713247>.
- [6] "SugarPixel blood glucose pixel clock Review - Integrated Diabetes Services," *Integrateddiabetes.com*, 2022. <https://integrateddiabetes.com/sugarpixel-blood-glucose-pixel-clock-review/?print=print> (accessed Oct. 01, 2025).
- [7] M. Campbell-Thompson, T. Rodriguez-Calvo, and M. Battaglia, "Abnormalities of the Exocrine Pancreas in Type 1 Diabetes," *Current Diabetes Reports*, vol. 15, no. 10, Aug. 2015, doi: <https://doi.org/10.1007/s11892-015-0653-y>.

- [8] Centers for Disease Control and Prevention, “Type 1 Diabetes,” *CDC*, May 15, 2024. <https://www.cdc.gov/diabetes/about/about-type-1-diabetes.html>
- [9] The Jewelry Vine, “Child bracelet size Chart by Age & length| Bangle Size Chart,” The Jewelry Vine, Oct. 27, 2024. <https://www.thejewelryvine.com/bracelet-size-chart/>
- [10] S. K. Garg and H. K. Akturk, “A New Era in Continuous Glucose Monitoring: Food and Drug Administration Creates a New Category of Factory-Calibrated Nonadjunctive, Interoperable Class II Medical Devices,” *Diabetes Technology & Therapeutics*, vol. 20, no. 6, pp. 391–394, Jun. 2018, doi: <https://doi.org/10.1089/dia.2018.0142>.
- [11] D. Greaney, “Exploring Waterproof Ratings: IP54, IP64, IP65, and IP67,” *Ledlightexpert.com*, Jun. 20, 2023. <https://www.ledlightexpert.com/waterproof-ip-rating?srsltid=AfmBOoqlF9uPNfmQMAFAKaD1VpC3POvxlHFofQorsXY1-xBURPGT08Cm> (accessed Oct. 02, 2025).
- [12] Guido Freckmann, A. Baumstark, and S. Pleus, “Do the New FDA Guidance Documents Help Improving Performance of Blood Glucose Monitoring Systems Compared With ISO 15197?,” *Journal of Diabetes Science and Technology*, vol. 11, no. 6, pp. 1240–1246, Jun. 2017, doi: <https://doi.org/10.1177/1932296817713220>.
- [13] “What to Do If Your Child Swallows or Ingests a Button Battery,” *Connecticut Children’s*, Dec. 15, 2023. <https://www.connecticutchildrens.org/growing-healthy/what-to-do-if-your-child-swallows-or-ingests-a-button-battery>
- [14] “Elevate Your Wearables With Advanced Wearable Device Battery,” *Ufine Battery [Official]*, 2025. <https://www.ufinebattery.com/applications/wearable-device-battery/> (accessed Oct. 06, 2025).
- [15] “Dexcom API | Overview,” *Dexcom Developer*. <https://developer.dexcom.com/docs/>
- [16] P. Randine, M. K. Wolff, M. Pocs, I. R. O. Connell, J. A. Cafazzo, and E. Årsand, “Unlocking Real-Time Data Access in Diabetes Management: Toward an interoperability

model,” *Journal of Diabetes Science and Technology*, Mar. 2025, doi: 10.1177/19322968251327602.

[17] M. Cäsar, P. D. Le, and M. Hollick, “A survey on Bluetooth Low Energy security and privacy,” *Computer Networks*, vol. 192, p. 108712, Jul. 2021, doi: 10.1016/j.comnet.2021.108712

[18] “Polyjoy Silicone Replacement Watch Band,” Amazon, accessed Oct. 8, 2025. [Online]. Available: <https://www.amazon.com/Polyjoy-Silicone-Replacement-Compatible-Suitable/dp/B0B28PBHY9>

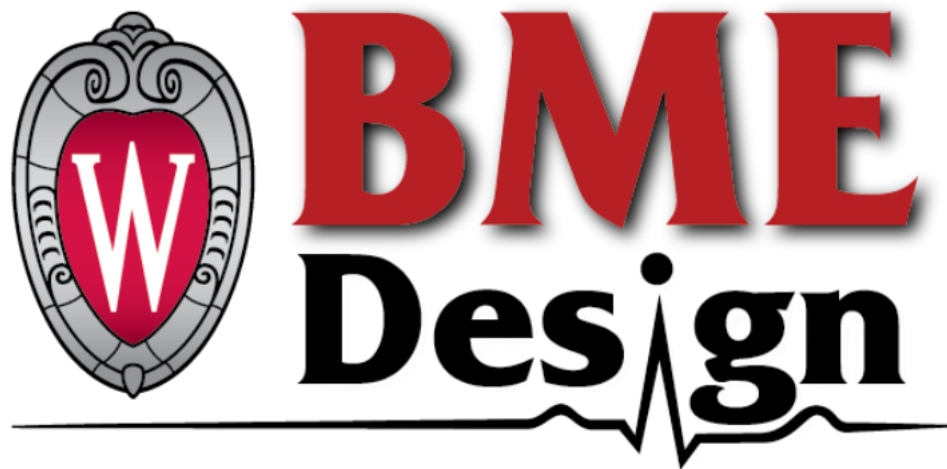
[19] P. Tan, A. Mohamed, L. M. H. Yusof, and M. N. Ahmad, “Emerging Biomedical and Clinical Applications of 3D-Printed Poly(lactic acid) (PLA),” *Frontiers in Bioengineering and Biotechnology*, vol. 11, p. 1133551, 2023. [Online]. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11273440>

[20] “3D printers,” Design Innovation Lab, <https://making.engr.wisc.edu/equipment/3d-printers/> (accessed Oct. 9, 2024)

[21] “Seeed XIAO BLE nRF52840,” Seeed Studio. [Online]. Available: <https://www.seeedstudio.com/Seeed-XIAO-BLE-nRF52840-p-5201.html>. [Accessed: Oct. 8, 2025].

Appendix

Appendix A: Product Design Specifications



Product Design Specifications

Wearable Glucose Alerting System

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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.

- o 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 Glowcase 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].

References:

- [1] Mayo Clinic, “Type 1 diabetes in children - Diagnosis and treatment - Mayo Clinic,” *Mayoclinic.org*, 2023. <https://www.mayoclinic.org/diseases-conditions/type-1-diabetes-in-children/diagnosis-treatment/drc-20355312>
- [2] The Jewelry Vine, “Child bracelet size Chart by Age & length| Bangle Size Chart,” *The Jewelry Vine*, Oct. 27, 2024. <https://www.thejewelryvine.com/bracelet-size-chart/>
- [3] “Most accurate glucose monitor for diabetes,” Dexcom, <https://www.dexcom.com/accuracy> (accessed Sep. 14, 2025).
- [4] “Apple Watch Lifespan: How Many Years Will Your Device Last? - SimplyMac,” *SimplyMac*, Jul. 10, 2024. [Online]. Available: <https://www.simplymac.com/apple-watch/apple-watch-lifespan>. [Accessed: Sep. 17, 2025].
- [5] “United States Climate, Weather By Month, Average Temperature - Weather Spark,” *Weather Spark*. [Online]. Available: https://weatherspark.com/countries/US#google_vignette. [Accessed: Sep. 15, 2025].
- [6] “What Is Critical Fall Height? - Zeager,” *Zeager*, Jun. 21, 2021. <https://zeager.com/what-is-critical-fall-height/> (accessed Sep. 18, 2025).

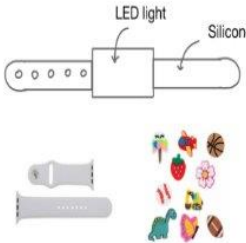
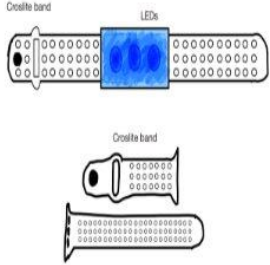
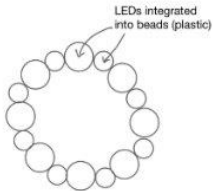
- [7] “Keep Apple Watch within acceptable operating temperatures - Apple Support,” *Apple Support*, Mar. 18, 2025. <https://support.apple.com/en-us/108766>
- [8] A. Öztürk, B. Çiçek, M. M. Mazıcıoğlu, G. Zararsız, and S. Kurtoglu, “Wrist Circumference and Frame Size Percentiles in 6-17-Year-Old Turkish Children and Adolescents in Kayseri,” *Journal of Clinical Research in Pediatric Endocrinology*, pp. 329–336, Dec. 2017, doi: <https://doi.org/10.4274/jcrpe.4265>
- [9] H. Zhu, M. Zhou, and B. Wu, “Comfort of smartwatch wearing: A comparative study of different hand types,” *Wearable Technology*, vol. 5, no. 1, p. 2963, Dec. 2024, doi: <https://doi.org/10.54517/wt2963>.
- [10] “Glowcose,” *Glowcose*, 2024. <https://glowcose.com/> [Accessed: Sep. 17, 2025].
- [11] S. K. Garg and H. K. Akturk, “A New Era in Continuous Glucose Monitoring: Food and Drug Administration Creates a New Category of Factory-Calibrated Nonadjunctive, Interoperable Class II Medical Devices,” *Diabetes Technology & Therapeutics*, vol. 20, no. 6, pp. 391–394, Jun. 2018, doi: <https://doi.org/10.1089/dia.2018.0142>.
- [12] D. Greaney, “Exploring Waterproof Ratings: IP54, IP64, IP65, and IP67,” *Ledlightexpert.com*, Jun. 20, 2023. <https://www.ledlightexpert.com/waterproof-ip-rating?srsId=AfmBOoqlF9uPNfmQMAFAKaD1VpC3POvxlHFofQorsXY1-xBURPGT08Cm> (accessed Oct. 02, 2025).
- [13] Guido Freckmann, A. Baumstark, and S. Pleus, “Do the New FDA Guidance Documents Help Improving Performance of Blood Glucose Monitoring Systems Compared With ISO 15197?,” *Journal of Diabetes Science and Technology*, vol. 11, no. 6, pp. 1240–1246, Jun. 2017, doi: <https://doi.org/10.1177/1932296817713220>.
- [14] G. Freckmann, C. Schmid, A. Baumstark, M. Rutschmann, C. Haug, and L. Heinemann, “Analytical Performance Requirements for Systems for Self-Monitoring of Blood Glucose With Focus on System Accuracy,” *Journal of Diabetes Science and Technology*, vol. 9, no. 4, pp. 885–894, Apr. 2015, doi: <https://doi.org/10.1177/1932296815580160>.
- [15] KOMPAN, “Playground Sizes and Dimensions,” *KOMPAN*, 2025. [Online]. Available: <https://www.kompan.com/en/us/planning/playground-sizes-and-dimensions>. [Accessed: Sep. 17, 2025].

[16] S. G. James, M. Elaine, Z. S. Abdallah, H. Emerson, and Aisling Ann O'Kane, "Integrating Technology into Self-Management Ecosystems: Young Adults with Type 1 Diabetes in the UK using Smartwatches," pp. 1–20, Apr. 2025, doi: <https://doi.org/10.1145/3706598.3713247>.

[17] "SugarPixel blood glucose pixel clock Review - Integrated Diabetes Services," *Integrateddiabetes.com*, 2022. <https://integrateddiabetes.com/sugarpixel-blood-glucose-pixel-clock-review/?print=print> (accessed Oct. 01, 2025).

Appendix B: Material Design Considerations and Design Matrix

Table 1: Design Matrix of Band Materials

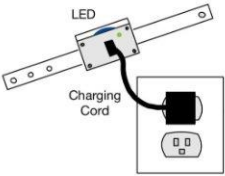
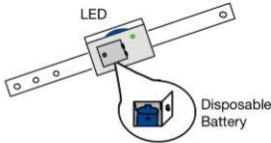
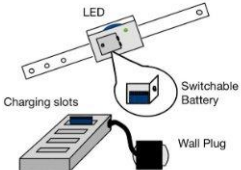
Designs	Design 1: Silicone band with LED light		Design 2: Croslite band with LEDs		Design 3: LED light with plastic beaded bracelet	
						
Criteria						
Safety & Ergonomics (25)	5/5	25	4/5	20	3/5	15
Adjustability (20)	5/5	20	4/5	16	3/5	12
Durability (20)	5/5	20	3/5	12	2/5	8
Accuracy (15)	5/5	15	4/5	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	Design 1: Lithium-Ion with Recharging Cord		Design 2: Disposable Battery		Design 3: Switching Battery with Wall Charger	
						
Criteria						
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].

References:

[1] “Elevate Your Wearables With Advanced Wearable Device Battery,” *Ufine Battery [Official]*, 2025. <https://www.ufinebattery.com/applications/wearable-device-battery/> (accessed Oct. 06, 2025).

[2] A. Kiran, “A Study on the Application of Alkaline Batteries,” *Journal Of Applied Physics (IOSR-JAP) e*, vol. 14, no. 6, pp. 45–51, 2022, doi: <https://doi.org/10.9790/4861-1406014551>.

[3] “What to Do If Your Child Swallows or Ingests a Button Battery,” *Connecticut Children’s*, Dec. 15, 2023. <https://www.connecticutchildrens.org/growing-healthy/what-to-do-if-your-child-swallows-or-ingests-a-button-battery>

[4] D. Parsons, “The environmental impact of disposable versus re-chargeable batteries for consumer use,” *The International Journal of Life Cycle Assessment*, vol. 12, no. 3, pp. 197–203, Aug. 2006, doi: <https://doi.org/10.1065/lca2006.08.270>.

Appendix D: Proposed Final Design Drawings

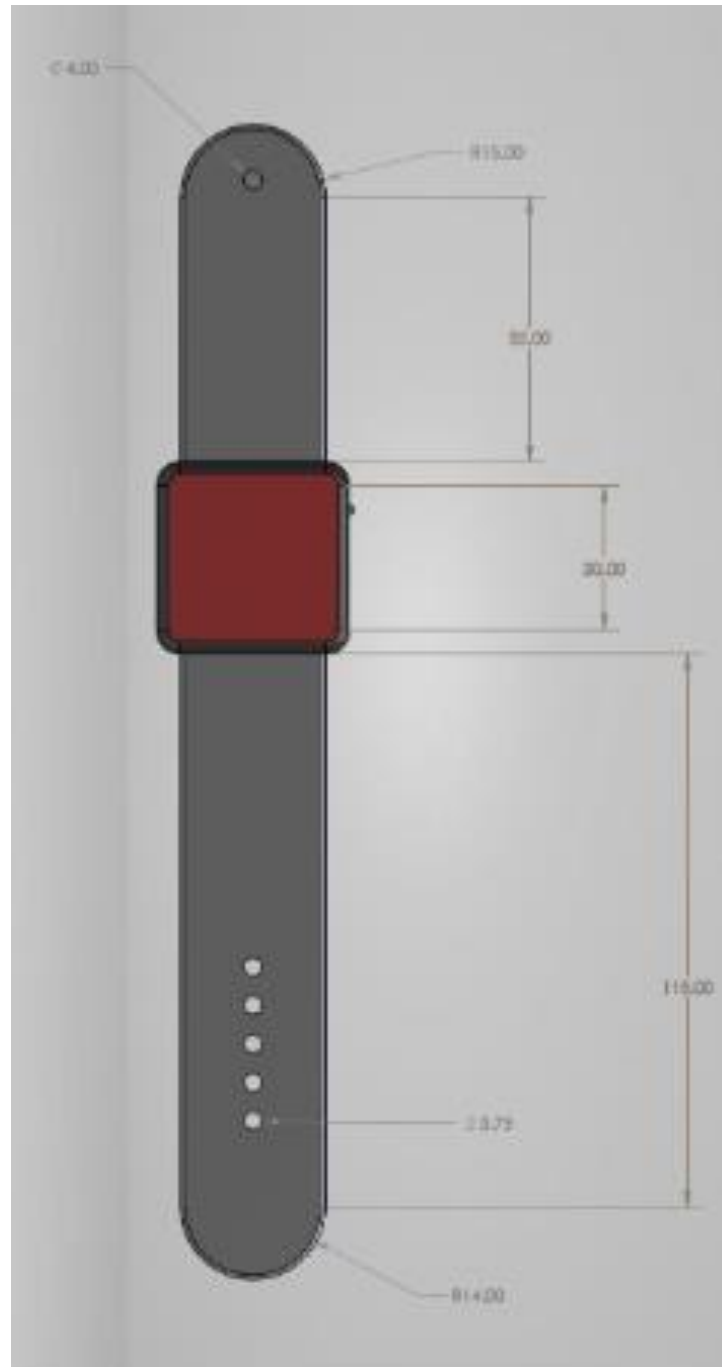


Figure 1: Top View of Proposed Final Design Drawings (All measurements in mm)

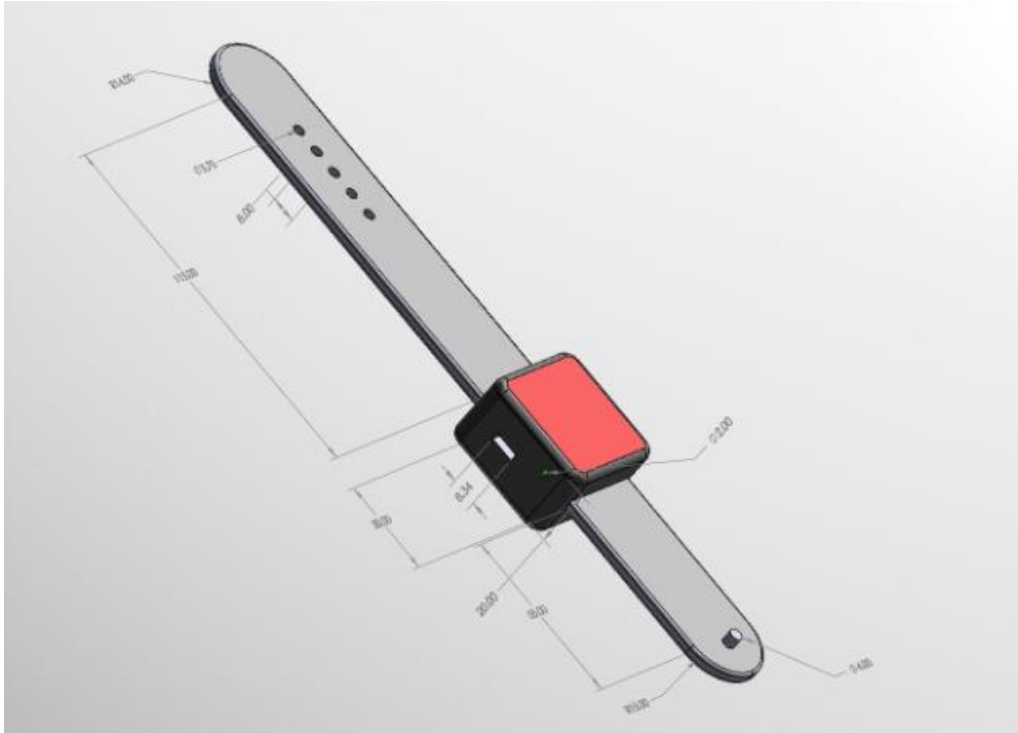


Figure 2: Isometric View of Proposed Final Design Drawing (all measurements in mm)