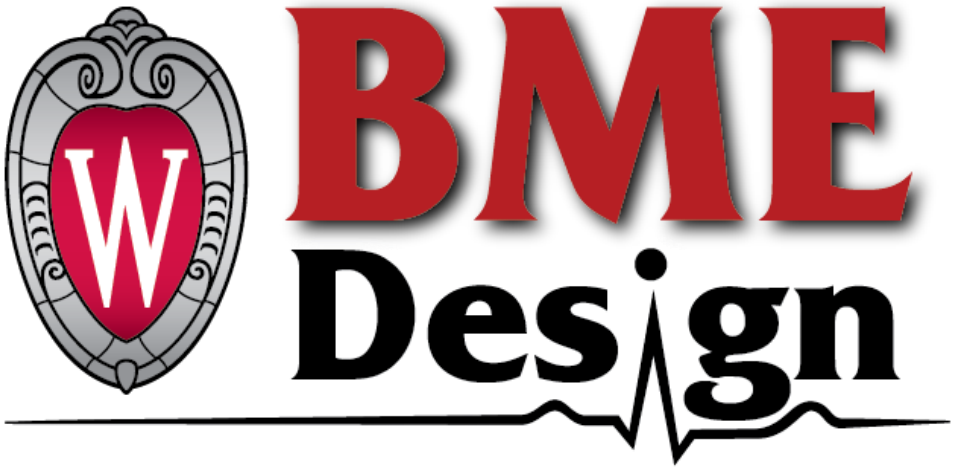

Product Design Specifications

Wearable Glucose Alerting System

Team Members:

Isabel Ploessl

Claudia Beckwith

Lauren Klein

Ella Prose

Audrey Zeller

Kiera Klemm

Clients: Olive Cerniglia and Callie Berg

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 to make blood glucose statistics clearly visible, understandable, and actionable to anyone supervising a child with diabetes.
- 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 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. 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. 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 equally as reliable as Continuous Glucose Monitoring (CGM) devices currently on the market. 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, 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 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 [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 such as latex. 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.

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.

2. Production Characteristics:

a. Quantity:

Only one functioning device is necessary per diabetic child.

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.

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 [10]. This class of medical devices must abide by the necessary guidelines to achieve 510(k) approval [10]. A mandatory shutoff is a requirement for these devices after the approved time-in-range (TIR) [10]. 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 [10].

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 [11]. The current version is ISO 15197:2013 and contains requirements directed at both health care professionals and patient users [11]. 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 [11]. According to 15197, each glucose test strip must achieve 95% accuracy when tested by the user without prior training or assistance [12]. 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 [13].

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, but requires a wall connection and is not portable or wearable [14]. 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 [15]. However, it does not provide a signal visible to others.

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. Kurtoğlu, "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] 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] 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.

[12] 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.

[13] KOMPAN, "Playground Sizes and Dimensions," *KOMPAN*, 2025. [Online]. Available: https://www.kompan.com/en/us/planning/playground-sizes-and-dimensions. [Accessed: Sep. 17, 2025].

[14] “Glowcose,” *Glowcose*, 2024. https://glowcose.com/ [Accessed: Sep. 17, 2025].

[15] 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.