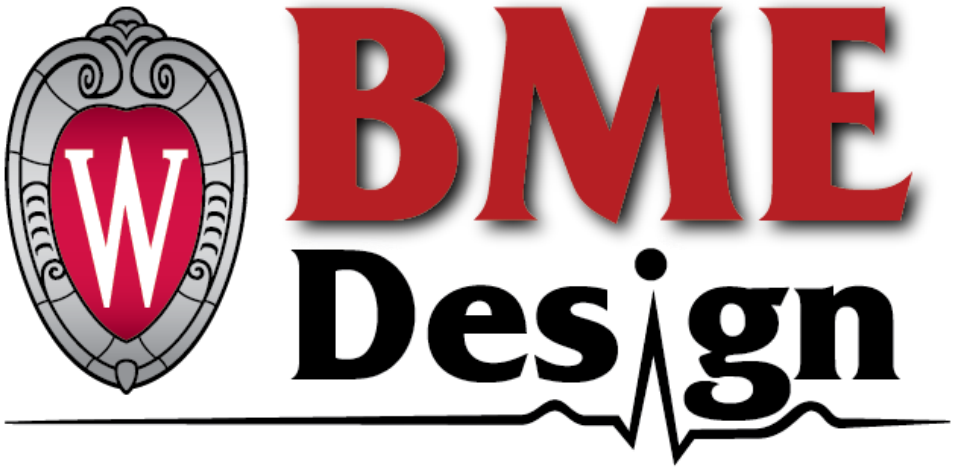

Product Design Specifications

Wearable Glucose Alerting System

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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.
- 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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