BME 4908 SENIOR DESIGN PROJECT
EXECUTIVE SUMMARY

GlycoBreath

BIOMEDICAL ENGINEERING EXPO

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1. Recognition of Need/Opportunity

Type 2 diabetes mellitus (T2DM) affects over 37 million people in the U.S. and is often diagnosed late due to the asymptomatic nature of early-stage hyperglycemia and the inconvenience of routine blood-based glucose testing. There is a critical need for a noninvasive, rapid, and accessible alternative to traditional glucose monitoring that can support early detection and encourage long-term adherence to screening protocols. Breath analysis represents a novel opportunity for metabolic disease detection, offering a painless, low-risk method for screening patients at risk of hyperglycemia without requiring specialized personnel or laboratory infrastructure. GlycoBreath addresses this need by enabling users to assess hyperglycemia through breath-based detection of volatile biomarkers linked to underlying metabolic dysregulation.

2. Problem Formulation

a. Project Objectives:

The objective of this project was to design and prototype a portable, user-friendly device capable of screening for hyperglycemia by analyzing breath samples for two validated biomarkers: acetone and ammonia. The device aims to deliver binary output (e.g., hyperglycemic vs. not) based on physiologically relevant thresholds, using real-time sensor data acquisition, filtration, and onboard processing. The broader goal is to lay the groundwork for a clinically useful and scalable system for noninvasive glycemic monitoring in at-risk populations.

b. Design Specifications:

The GlycoBreath device was designed to meet a comprehensive set of performance, usability, and safety requirements to ensure clinical relevance, user comfort, and engineering feasibility. To address Market Requirement 1 (MR1), the device must provide accurate and reliable detection of hyperglycemia using breath analysis. This is achieved by integrating sensors capable of detecting acetone at a limit of detection (LOD) of 0.2 ppm and a limit of quantification (LOQ) of 0.5 ppm, and ammonia at an LOD of 0.8 ppm and LOQ of 1.0 ppm. The system must detect concentration shifts as small as 0.1 ppm and maintain linearity with an $R^2 \geq 0.95$ across a range of 0.5–10 ppm for acetone and 1–20 ppm for ammonia. To satisfy MR2, the device incorporates intuitive multi-sensory feedback to guide users and indicate glycemic status. This includes auditory alerts in the 300–625 Hz frequency range at sound levels between 51 and 85 dB, as well as visual cues with a minimum 14-point font and a contrast ratio of at least 3:1. For MR3, portability is prioritized by limiting the total device weight to 2.3 kg (5 lbs) and overall dimensions to 5 × 10 × 4 inches. MR4 ensures the device is comfortable to hold, accommodating hand sizes ranging from 6.10 to 8.66 inches in length and 2.68 to 3.95 inches in width.

Comfort in use, addressed in MR5, is achieved by requiring no more than 0.05–0.851 psi of exhalation pressure to initiate airflow. MR6 emphasizes simplicity, specifying that users must be able to complete the full operation in just 3–5 steps. To support MR7, the device is powered by a rechargeable battery capable of supporting at least 10–15 full sampling cycles per day. MR8 focuses on efficiency, requiring the entire breath collection and result display process to be completed in 30 seconds or less. For long-term usability, MR9 specifies the device must store at least 900 readings to support data tracking over time. MR10 ensures environmental resilience by requiring the device to resist up to 95% relative humidity and incorporate filters with pore sizes no larger than 5 μm to block airborne contaminants. MR11 mandates that the mouthpiece be universally biocompatible, with a diameter between ¼ and ½ inch and a cytotoxicity viability score of at least 70%, in accordance with ISO 10993-5. MR12 addresses mechanical durability, requiring the device to withstand at least one drop from 1.66 meters on all faces, edges, and corners. Finally, MR13 ensures the structural integrity of the casing by requiring it to resist compressive loads of at least 183 N for 190 seconds without failure.

c. Constraints and other considerations

The GlycoBreath project was designed within a strict budget limitation of $2000, which covered all development and testing phases. To remain within this financial scope, the sensor system was limited to detecting only acetone and ammonia—biomarkers strongly associated with hyperglycemia—while other compounds like ethylene and isopropanol were reserved for future validation due to the additional cost and integration complexity. Material selection was guided by both biocompatibility requirements for components that come into contact with the oral cavity and the mechanical strength needed for structural integrity. Manufacturability was constrained by access to in-house tools and the EDGE Lab, necessitating a design that could be fabricated using 3D printing and assembled manually. Finally, due to the absence of human subject data, the device output was simplified to a binary classification system (yes/no for hyperglycemia), using fixed biomarker thresholds instead of more complex machine learning algorithms.

3. Solution Formulation

GlycoBreath is a handheld, noninvasive breath analysis device that screens for hyperglycemia by detecting elevated levels of acetone and ammonia in exhaled breath. The device integrates two metal-oxide (MOX) gas sensors mounted within an airtight detection chamber. A check valve, mini air pump, and solenoid valve assembly ensure selective collection of alveolar breath, which contains the most representative concentrations of target biomarkers. Signals from the sensors are acquired using an ESP32 microcontroller, processed in real-time, and compared against literature-derived concentration thresholds. Based on this comparison, the device displays a binary result to the user and logs measurements for later analysis. This solution prioritizes speed, affordability, and usability, using commercially available components and accessible fabrication methods to ensure it can be prototyped and refined within an academic setting. Future iterations of the system

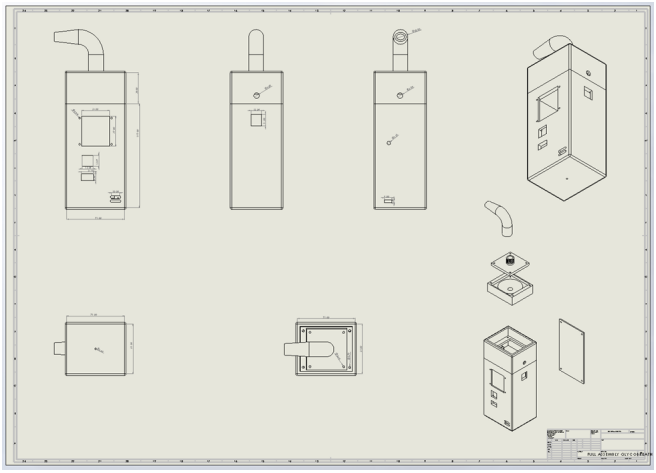
may incorporate additional sensors, validation analytes, and machine learning algorithms to increase diagnostic accuracy and enable personalized screening.

4. Engineering Analysis and Decision-Making

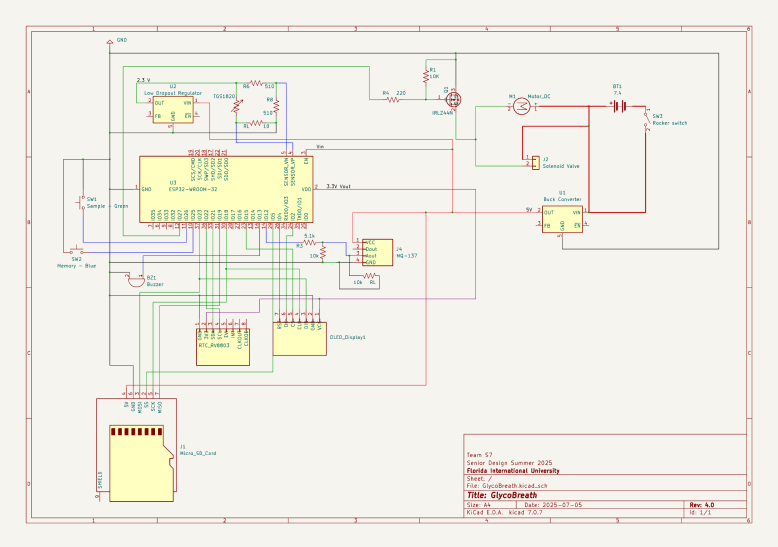
To support the design of GlycoBreath, engineering analysis focused on ensuring reliable biomarker detection, safe airflow control, and user comfort within strict budget and time constraints. MOX sensors were selected for their low cost, compact size, and ability to detect acetone and ammonia in the 0.1–20 ppm range—key biomarkers linked to fat metabolism and oxidative stress in hyperglycemia. Fluid dynamics and biotransport principles like Darcy's Law, Hagen-Poiseuille, and Ohm's Law for flow were used to model air resistance through filters and tubing, ensuring accurate alveolar breath sampling with minimal backpressure. Electrical analysis supported the integration of sensors, solenoid valve, and air pump within a low-power ESP32-based system, optimized for 15 daily uses on a single charge. Sensor performance was rigorously validated through metrics such as sensitivity, specificity, linearity, and detection limits (LOD and LOQ), for reliable classification of glycemic state based on biomarker concentrations. The interface was designed according to the Multimodal Redundancy Principle, using distinct visual and auditory cues for each critical step for proper use. The device's user interface and physical form were shaped by ergonomic standards, including one-handed operation, secure grip based on anthropometric data, and minimized wrist strain. An IP65-rated enclosure with an electrospun/pleated barrier was selected to shield sensitive electronics from high humidity and debris present in exhaled air, while still allowing vapor-phase analytes to reach the sensors. Data storage was configured to retain 3 months of readings, supporting trend analysis in parallel with HbA1c cycles. To ensure structural integrity under typical use conditions, the device was subjected to a 1.66 m drop simulation and compressive force testing equivalent to 30% of peak grip strength sustained for 190 seconds. These engineering choices were made to uphold safety, usability, and diagnostic reliability under long-term, real-world use.

5. Detailed Design

Engineering Drawing:



Circuit Diagram:



6. Testing

Verification testing was conducted to confirm that the device met its design requirements and could reliably detect glycemic trends through breath biomarkers. Testing focused on validating sensor performance and environmental durability to ensure the device functions as intended during regular use. Calibration testing was performed to evaluate the sensitivity and accuracy of the sensors to acetone and ammonia across a target range of 0.2 to 10 ppm and 0.2 to 20 ppm respectively. Known gas concentrations were generated inside separate sealed calibration chambers using controlled chemical reactions, and voltage outputs were recorded and mapped to ppm values. This allowed for the creation of calibration curves used in glycemic state classification. To assess environmental resistance, additional testing was performed using a phantom breathing model to simulate a full user exhalation into the device. The goal was to evaluate how much moisture entered the breath collection chamber and determine whether humidity interfered with sensor readings. The chamber was inspected post-exhalation to assess condensation buildup and airflow behavior. Tools used during testing included a controlled phantom breath model, microsyringes, hot plates, and the MQ-137 and TGS 1820 sensors wired to a microcontroller for live voltage tracking. Calibration and humidity tests were repeated to ensure reliability and to capture potential variability in performance. Data from these tests confirmed that the sensors remained responsive under moist conditions, and that the device maintained functionality across repeated uses. Although the verification tests allowed engineers to develop calibration curves for the sensors, the acetone verification did not have an R2 value > 0.95. Further experiments with increased accuracy and better equipment should be done to truly validate or invalidate the sensor's acceptability for use in GlycoBreath.

7. Evaluation of Verification Testing

Verification testing was evaluated statistically based on whether it was a quantitative or qualitative test. Since we only had one final prototype, verification tests for market requirements such as evaluation of dimensions and weight were considered qualitative pass/fail verifications, while other tests such as our sensor verification and device comfortability while blowing were validated through statistical analysis using mean, standard deviation, and t-test statistics. Out of 13 design inputs, 2 failed including the drop test and auditory user feedback, and 1 (the sensor verification) remains inconclusive. Although the MQ137 (ammonia) sensor passed with a calibration curve R2 of 0.95, the TGS 1820 reached R2 of 0.89, 0.06 away from its acceptance. The lack of precise equipment due to budget constraints reduced the test engineer's accuracy in measurements and dilutions, potentially skewing the results at concentrations less than 1.0 ppm. Successful verifications include weight and portability, comfortable to hold, maximum exhalation pressure (comfortable during use), number of steps to use, supports sampling all day, collection of an alveolar breath sample in minimal time, data storage and retrieval of at least 3 months worth of data, resistance to airborne particles and moisture, biocompatibility, and squeeze test.

8. Relevance to the BME Curriculum

The GlycoBreath project applied core biomedical engineering principles across physiology, electronics, fluid mechanics, biotransport, and biomaterials to design a functional, noninvasive biosensor. We used mathematical modeling and physical science concepts to estimate breath biomarker behavior and airflow dynamics. Experimental calibration and verification required us to design and conduct protocols, collect sensor data, and interpret results using statistical methods. These efforts reflect the integration of foundational coursework in transport phenomena, instrumentation, and data analysis. Our design met real-world constraints, including cost, size, power, and manufacturability. The project addressed an unmet biological need by enabling pain-free screening for hyperglycemia, offering an alternative to invasive glucose testing. We used modern engineering tools such as SolidWorks, Arduino IDE, and ESP32 firmware to develop an integrated system combining mechanical, electrical, and biological components. Our team collaborated across disciplines to align sensor performance with physiological targets, and to iterate on 3D-printed prototypes and embedded code. The project emphasized teamwork and communication through detailed design reports, regulatory documentation, and Q&A responses. Design control forms and verification protocols highlighted our ability to clearly justify engineering decisions. This experience deepened our awareness of responsible engineering practice and device safety. Ethical considerations were addressed through breath chamber design and sensor selection, ensuring user safety and data integrity. Faculty feedback and technical challenges required us to adapt our thinking, reinforcing the value of lifelong learning. The project reflected our growth in designing systems that interface with biology under real constraints. GlycoBreath ultimately demonstrated our readiness to transition into professional biomedical engineering roles.