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Biomedical Engineering

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GlycoBreath

Empowering Diabetes Care One Breath at a Time

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College of Engineering and Computing

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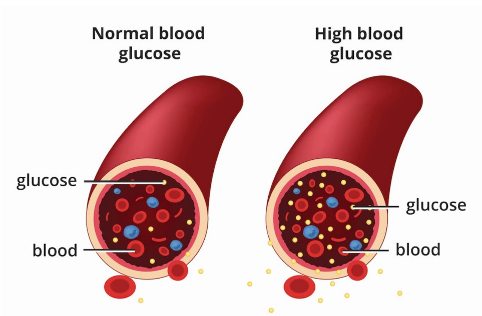
July 31, 2025

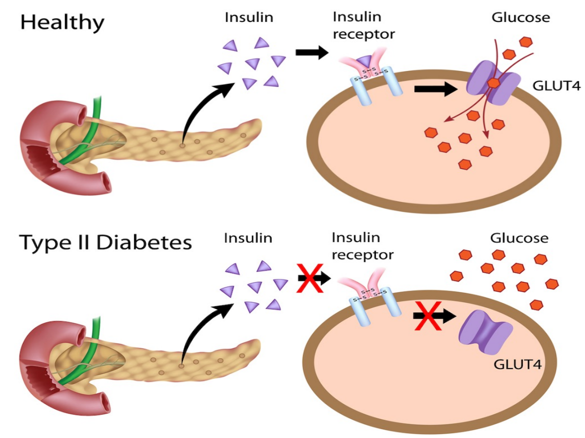
Pathology of Type 2 Diabetes



https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes

Uncontrolled blood sugar

Increased insulin resistance

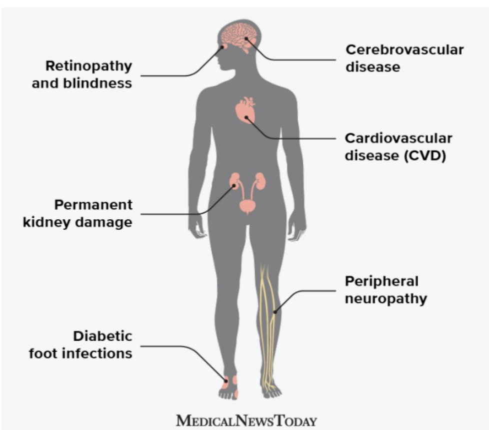


https://synergynutrition.info/2019/09/23/manage-diabetes-whole-foods-meal-plan/

Invasive methods to monitor blood sugar


https://www.nm.org/healthbeat/healthy-tips/nutrition/diabetes-in-the-black-community

Poor compliance with treatment



https://www.medicalnewstoday.com/articles/diabetes-mellitus-type-2-complications

Clinical Need

Population:
- Overall: 36 million
- At-risk (hyperglycemia): 24 million
- Projected at-risk (2050): 52 million

Occurrence & Severity:
- Hospitalizations: 25,000+ / yr
- 7th leading cause of death in U.S.

Definitions:
- Glucose: blood sugar / body's main energy source
- Hyperglycemia: high blood glucose

*"Up to **67%** of people with Type 2 Diabetes **fail** to monitor their blood glucose regularly."*

—CDC, 2024

https://www.reddit.com/media?url=https%3A%2F%2Fpreview.redd.it%2Fn0qpxf2jf3671.jpg%3Fwidth%3D640%26crop%3Dsmart%26auto%3Dwebp%26s%3D1cf9082f0952b9f2f20de52181892bdaccf9312d

Current Modalities

Drawing Blood

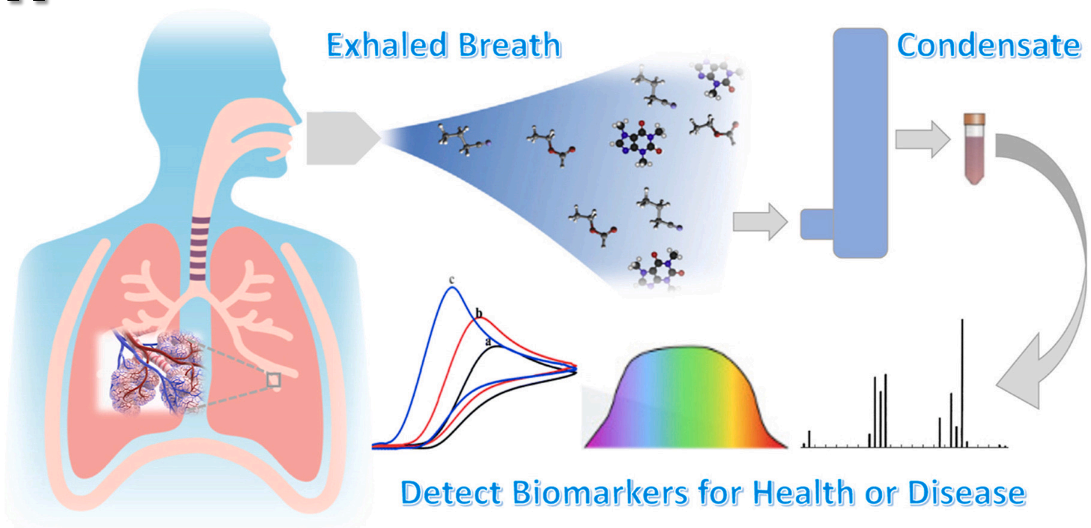
Finger Pricking

Ketone Monitor

Proposed Solution:

Breath Based Biosensor

- Detects 2 biomarkers via alveolar air
- Minimizes reliance on traditional invasive monitoring methods
- Noninvasive and portable



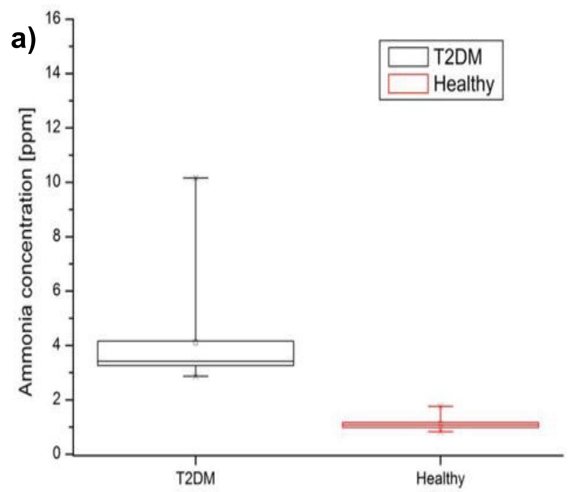
https://www.sciencedirect.com/science/article/pii/S095656632100230X

Breath as a Window into Hyperglycemia:

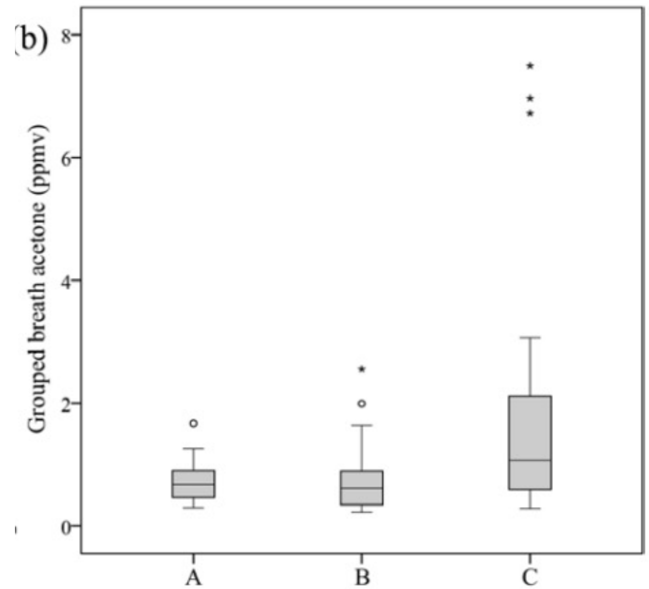
The Role of Biomarkers

Exhaled Biomarkers:
- Ammonia
- Acetone

Metabolic shifts:
- Oxidative stress
- Ketosis (fatty acid metabolism)



Organic Volatile Compounds Used in Type 2 Diabetes | IntechOpen



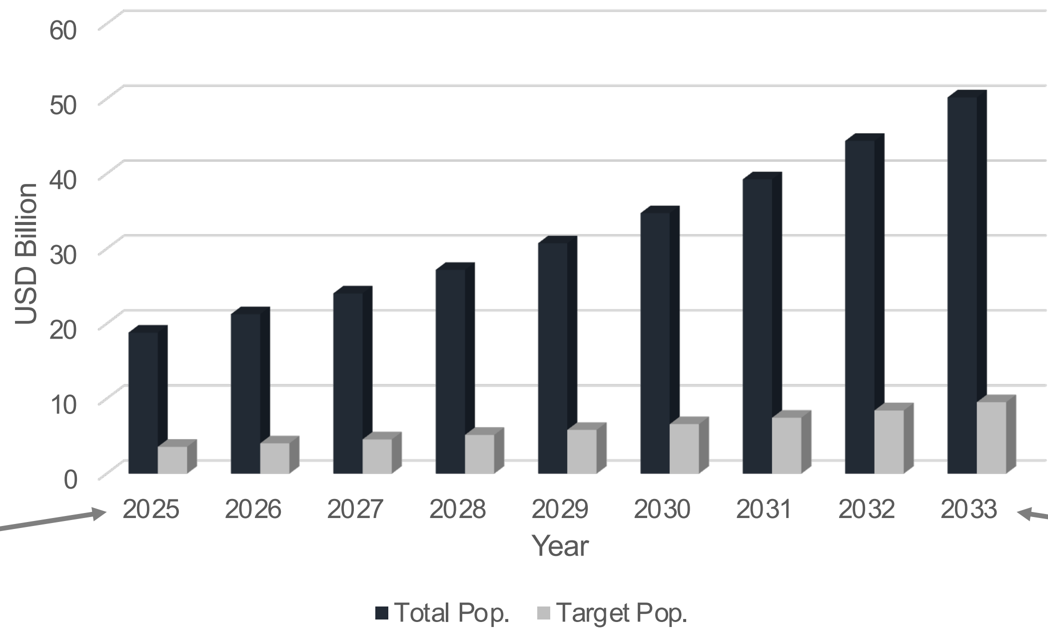
Group A: 74-250 mg/dL
Group B: 251-300 mg/dL
Group C: 301-495 mg/dL

https://iopscience.iop.org/article/10.1088/1752-7155/9/1/016005/pdf

Business Outlook

Global Glucose Biosensors Market Size

Healthcare burden:
USD 413 billion / yr



CAGR 13.05%

$3.6B

$9.5B

https://www.precedenceresearch.com/glucose-biosensors-market#:~:text=The%20global%20glucose%20biosensors%20market%20size%20was%20valued%20at%20USD,13.05%25%20from%202024%20to%202033

Project Scope

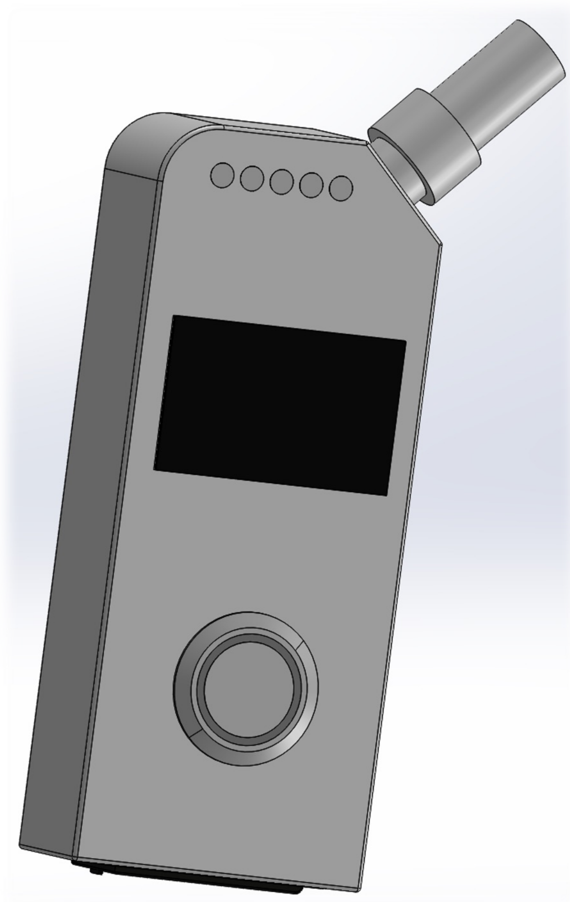
To design a noninvasive, portable breath analysis device that measures acetone and ammonia levels in exhaled breath, assesses glycemic state, and supports Type 2 Diabetes management without the need for invasive monitoring methods.

Budget for project: $2,000
January 6, 2025 – July 31, 2025

Market Requirements & Design Inputs

	Market Requirement	Design Input
1	Detect hyperglycemia accurately via breath.	Detect acetone (0.5–10 ppm) and ammonia (1–20 ppm) with LOD/LOQ of 0.2/0.5 ppm and 0.8/1.0 ppm, respectively. ±0.1 ppm resolution, $R^2 \geq 0.95$.
5	Comfortable to use.	0.05–0.851 psi to exhale.
7	Support sampling throughout the day.	10-15 full operational cycles per day.
10	Resistant to contaminants.	Functions in 95% humidity. ≤ 5 µm pore size.
13	Withstand hand-grip forces.	Compressive load ≥ 183 N for ≥ 190 s.

Breathalyzer
V.1



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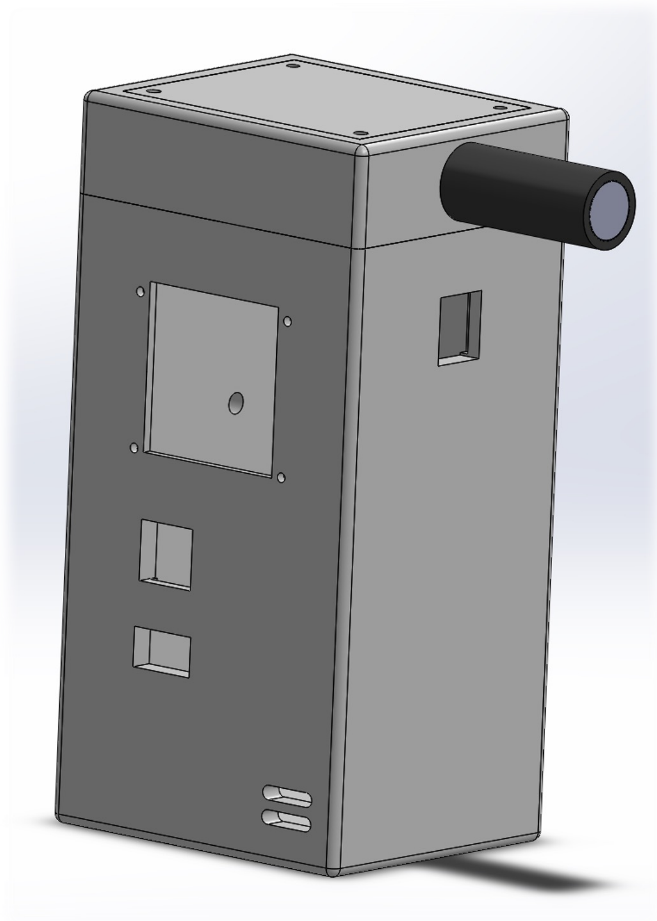

Breathalyzer V.2

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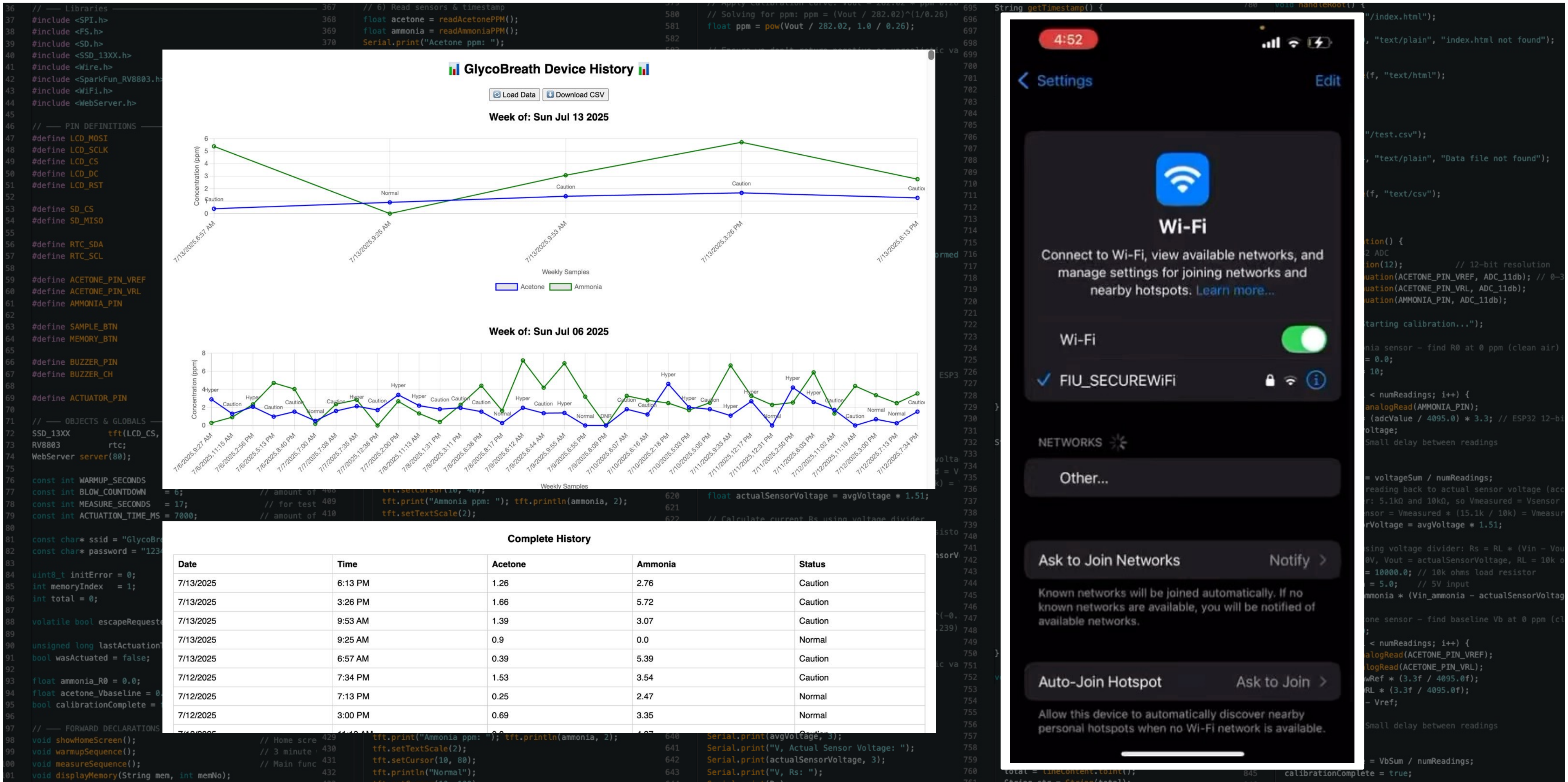
GlycoBreath

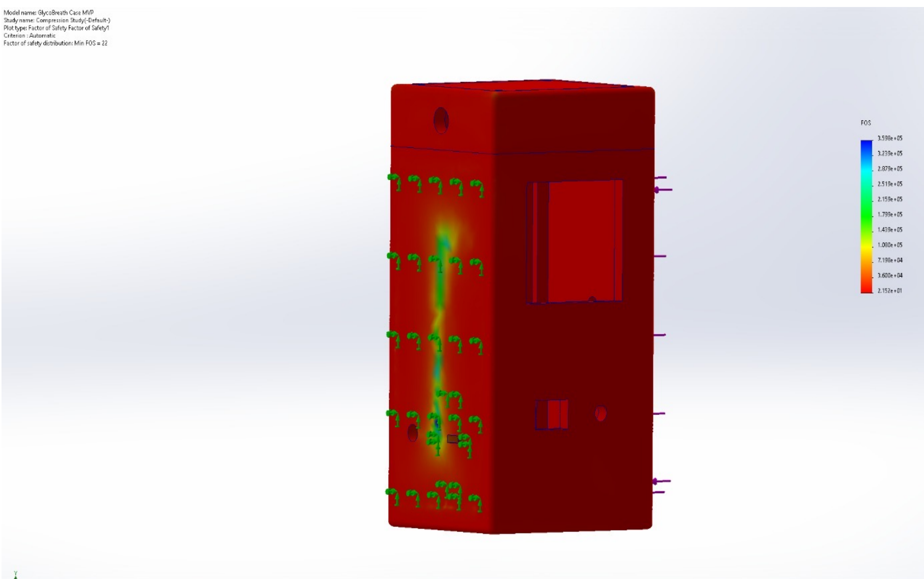
MVP



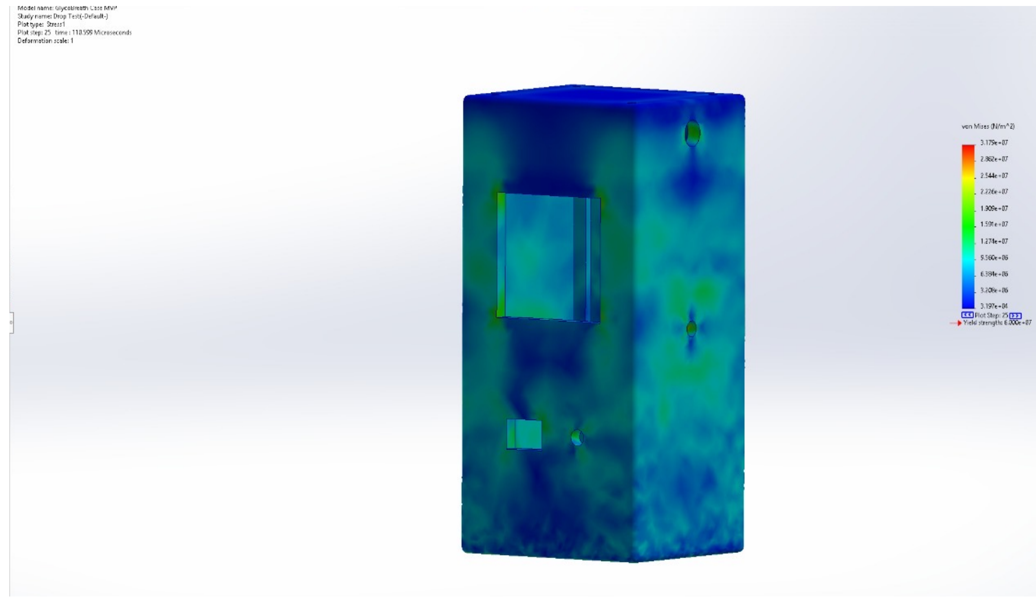
Date	Time	Acetone	Ammonia	Status
7/13/2025	6:13 PM	1.26	2.76	Caution
7/13/2025	3:26 PM	1.66	5.72	Caution
7/13/2025	9:53 AM	1.39	3.07	Caution
7/13/2025	9:25 AM	0.9	0.0	Normal
7/13/2025	6:57 AM	0.39	5.39	Caution
7/12/2025	7:34 PM	1.53	3.54	Caution
7/12/2025	7:13 PM	0.25	2.47	Normal
7/12/2025	3:00 PM	0.69	3.35	Normal

3D Model Simulations:

SolidWorks Simulation

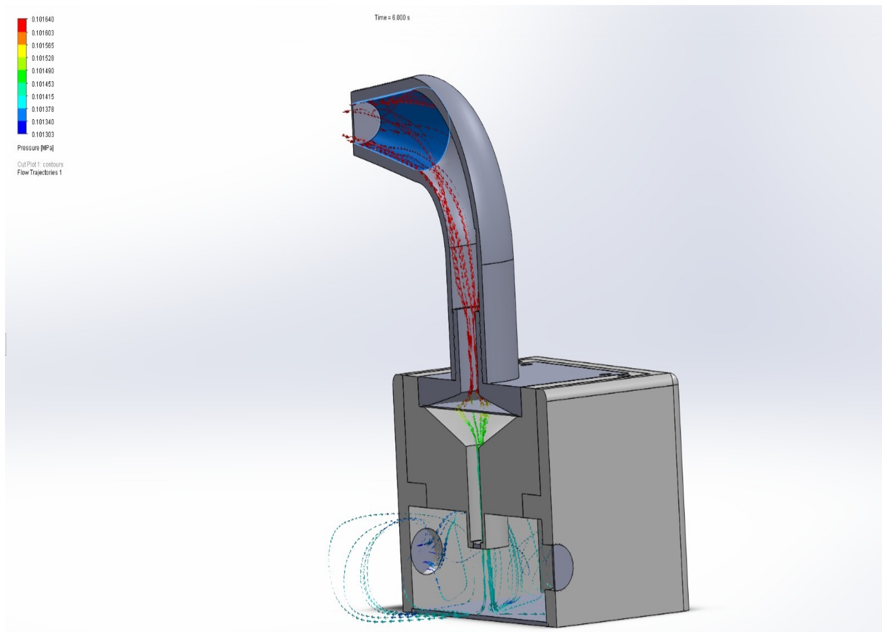


Compression Test: Factor of safety of 5.4



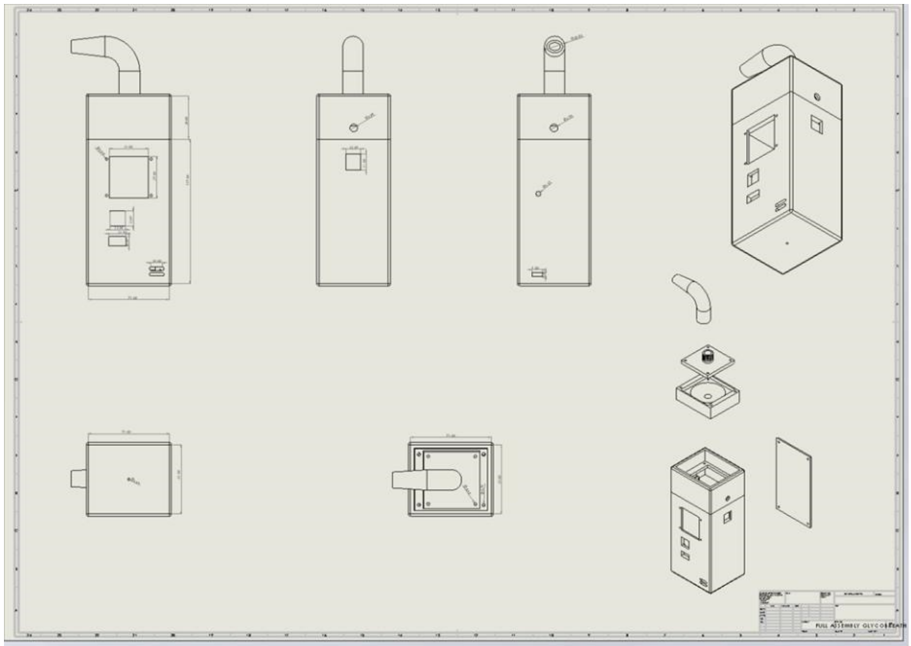
Drop Test: Peak von Mises stress of 3.17e+7 N/m² (or 31.7 MPa)

3D Model Simulations:
SolidWorks Flow

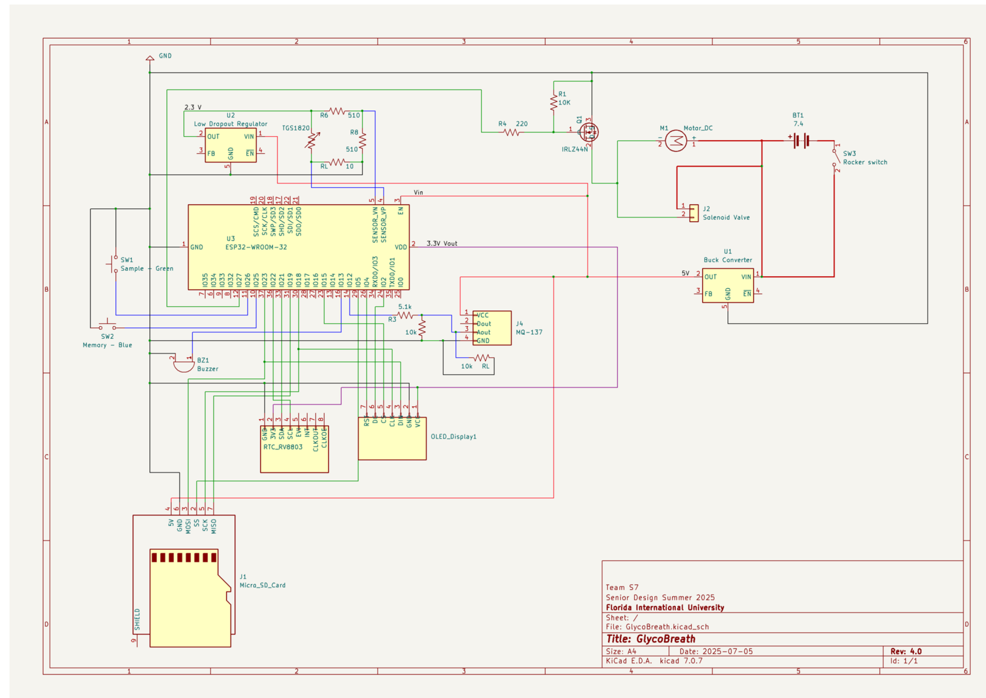


Flow Test: Maximum pressure of 0.10164 MPa

Engineering Drawings



SolidWorks Drawing



KiCad Schematic

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Manufacturing

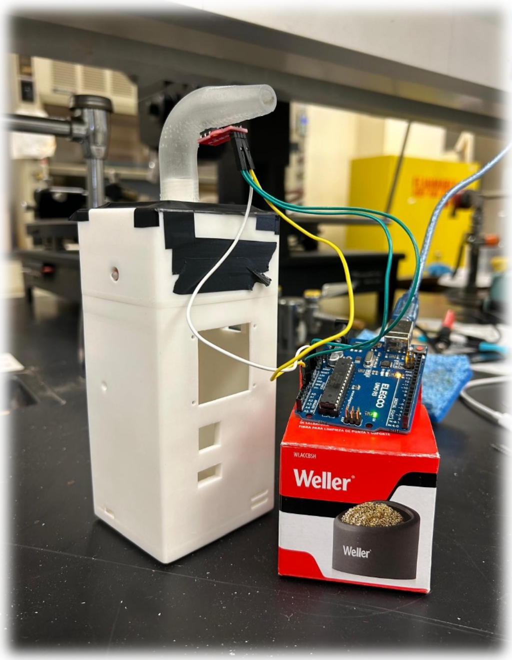
3D Printing

Soldering

Programming

Verification Testing:

Flow Test

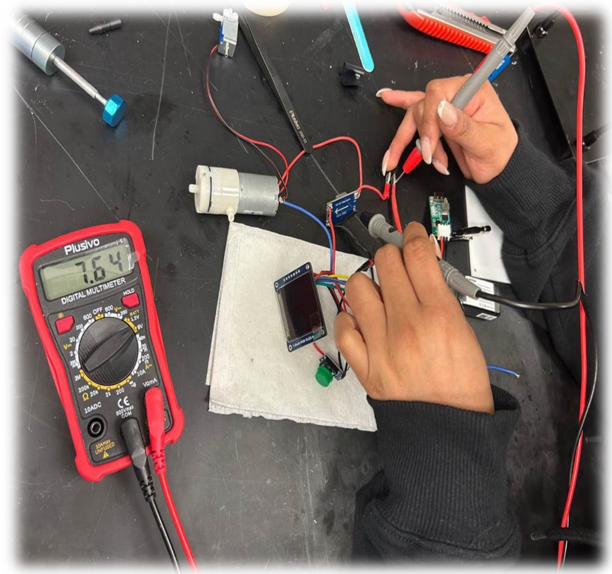


One-sample *t*-test & Binomial test
(Pressure Range & Pass Rate Evaluation) PASS

Squeeze Test

Pass/Fail Visual Inspection
(183 N Grip Load, 190 s)
PASS

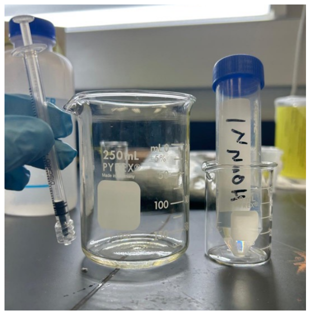
Battery Voltage Stability Test



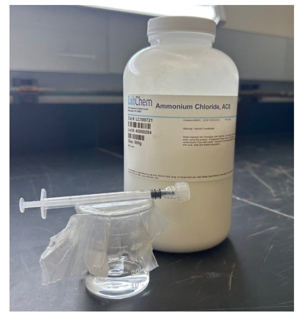
One-sample t-test
(Static Voltage Analysis)
PASS

Verification Testing:
Sensors

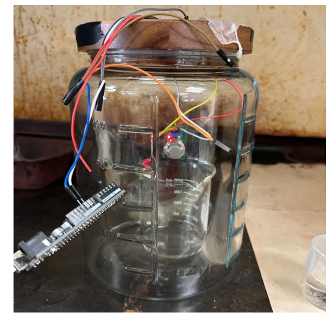
MQ137 (Ammonia)



NaOH (aq)

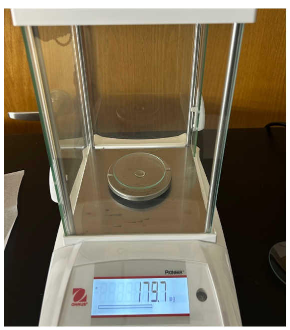


NH_4Cl (s)



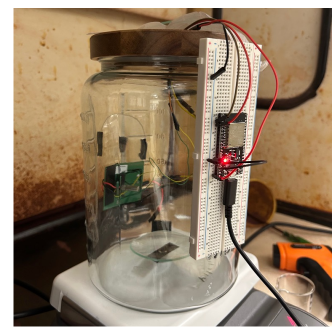
NH_3 (g)↑ + H_2O (l) + NaCl (aq)

TGS1820 (Acetone)



$(CH_3)_2CO$ (l)

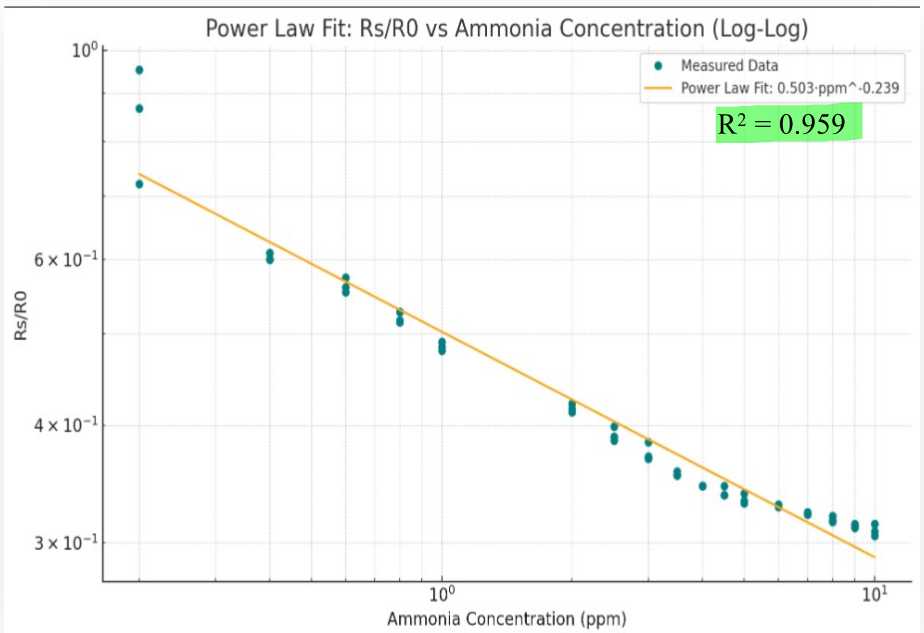
Heat (Δ)

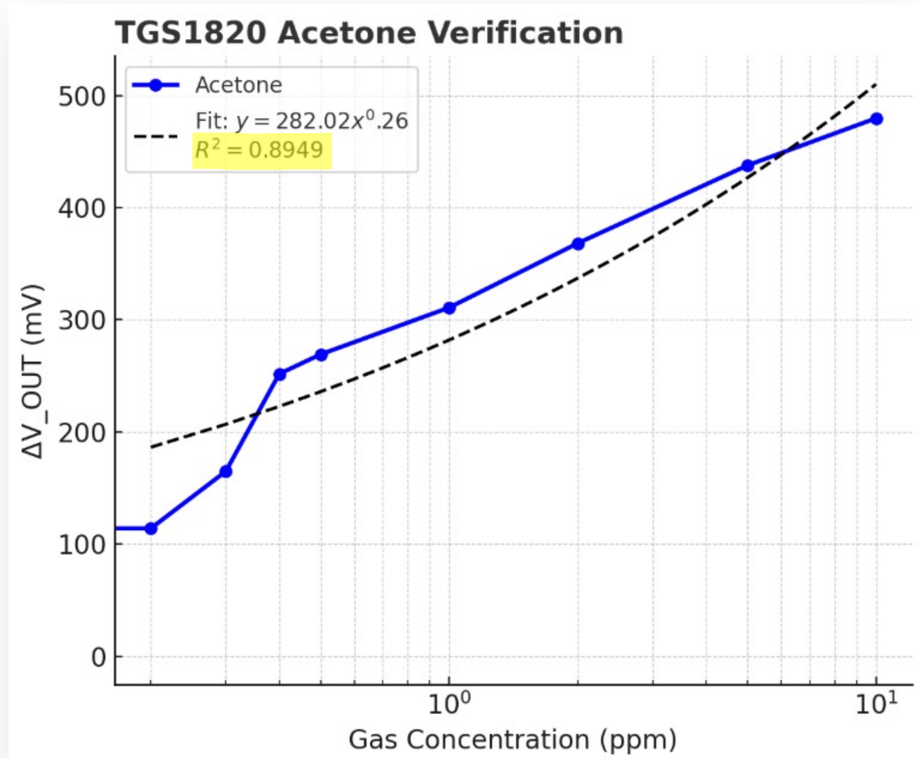


$(CH_3)_2CO$ (g)

Verification Testing:

Results





Engineering Standards

Standard	Purpose
IEC 60601-1	General Safety and Performance of Medical Electrical Equipment
ASB 118	Defines minimum capabilities for evidential breath alcohol instruments
ISO 9241-210	Ensures systems are intuitive and meet user needs
ISO 10993-1	Biological evaluation of medical devices
ISO 13485	Medical Devices Quality Management

Regulatory Assessment

FDA Classification:

- Class II Device: Clinical Chemistry and Clinical Toxicology Devices
- Regulation number: 21 CFR 862.1435

Regulatory Path:

- De Novo
- PMA not applicable

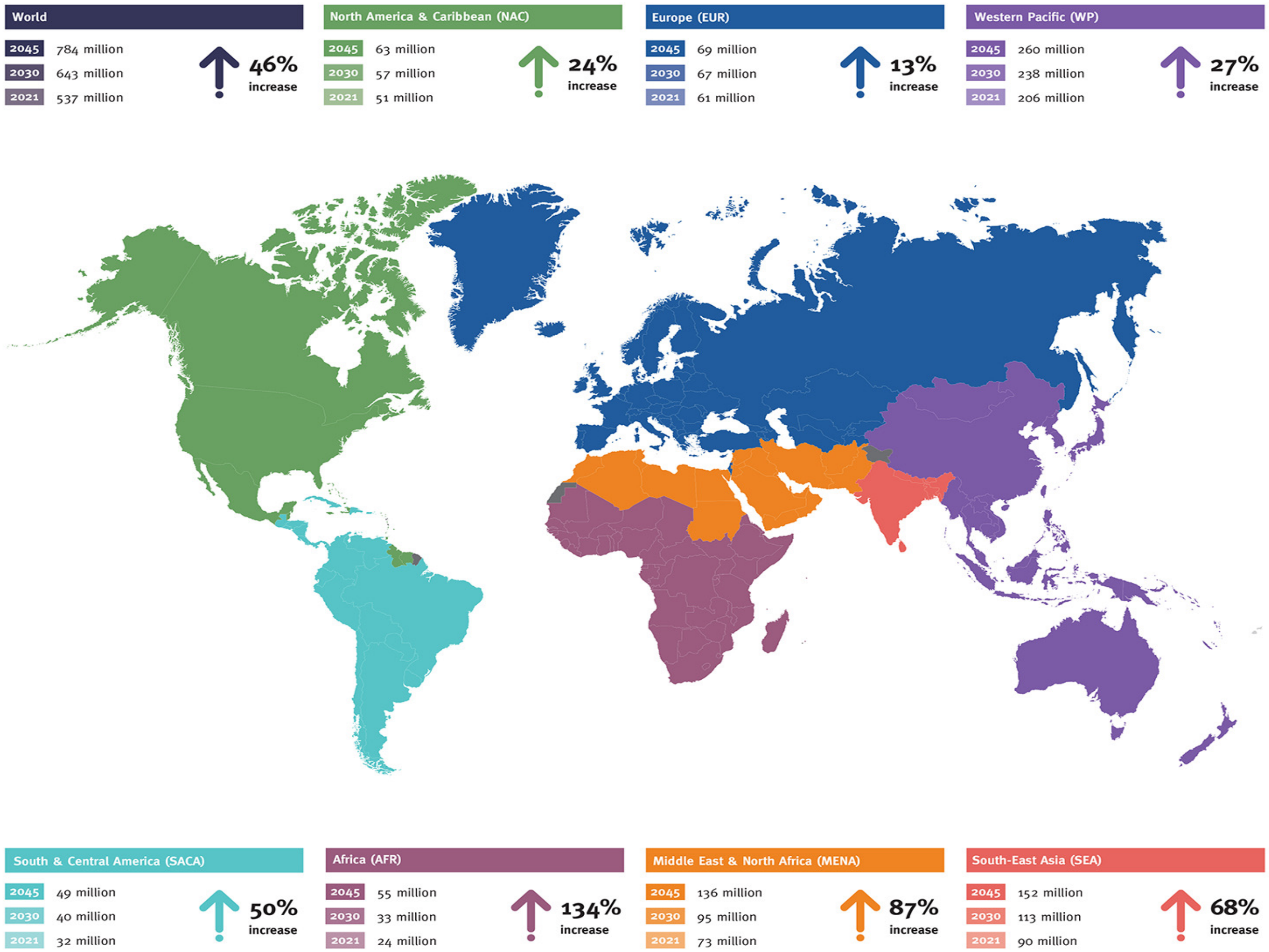
Cost Assessment:

Product

Category	Cost
Sensors & Electronics	$220
Interface & Housing	$100
Feedback System	$50
Material Total	**$370**
Labor (0.5 unit/hr @ $18/hr)	$40
Overhead (10% labor + 14% material)	$60
Unit Cost	**$470**

Global Awareness

- Racial and ethnic minorities
- Underinsured individuals
- Patients with limited access to care



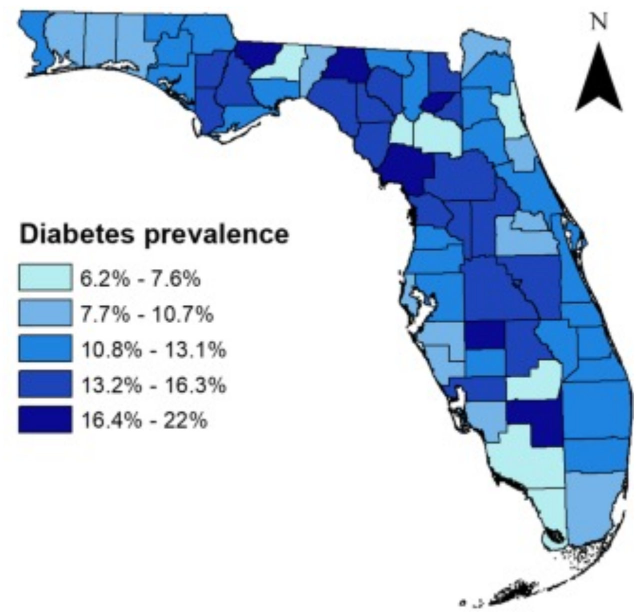
https://www.fic.nih.gov/News/GlobalHealthMatters/may-june-2023/Pages/facing-challenge-undiagnosed-diabetes--africa.aspx

Global Engagement

- Reusable for low resource communities
- No medical training required
- Empowers self management

Global Perspective

- 270,000 adults in Miami-Dade County
- 36 million Americans
- 483 million people globally



https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09311-2

Existing Patents:

US 20040134637A1

- Optical Light Breath Gas Analyzer
- Only analyzes acetone
- Nonportable

US 20250160677A1

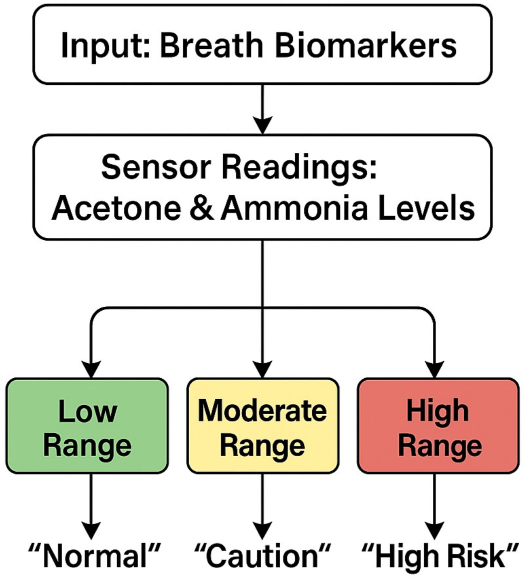
- Electrochemical Breath Diagnostic Tool
- Focus on ammonia
- Liver and kidney diseases

https://depenning.com/blog/the-ultimate-guide-to-provisional-patents-and-their-public-disclosure/

https://ppubs.uspto.gov/pubwebapp/ US20040134637A1 and US20250160677A1

Intellectual Property Opportunities

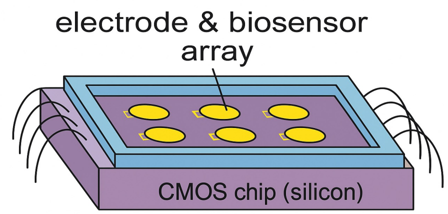
- Dual-biomarker detection
- Three-Level decision Logic
- Embedded system



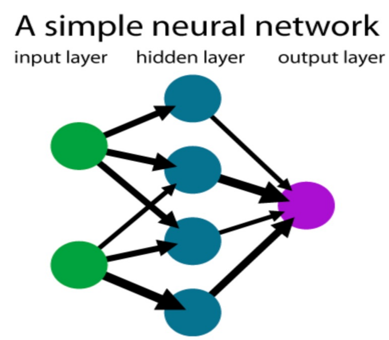
Three-Level decision

Future Work

- Sensor array
- More durable material
- Injection molding manufacturing
- Miniaturized circuit
- Machine learning implementation



https://www.researchgate.net/figure/Conceptual-illustration-of-a-CMOS-circuit-with-on-chip-electrode-array-and-packaging-for_fig2_254013753



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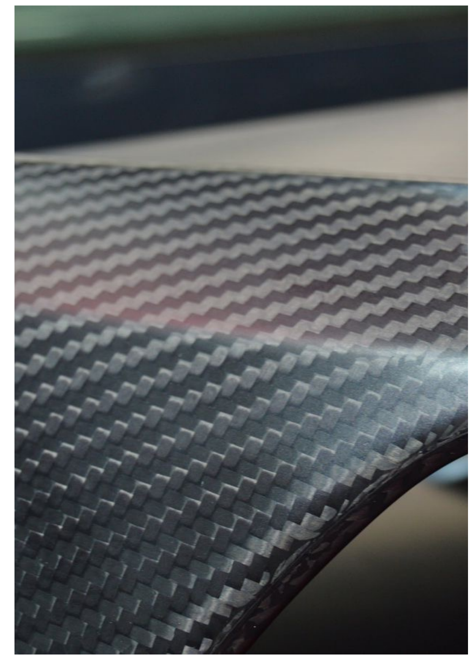

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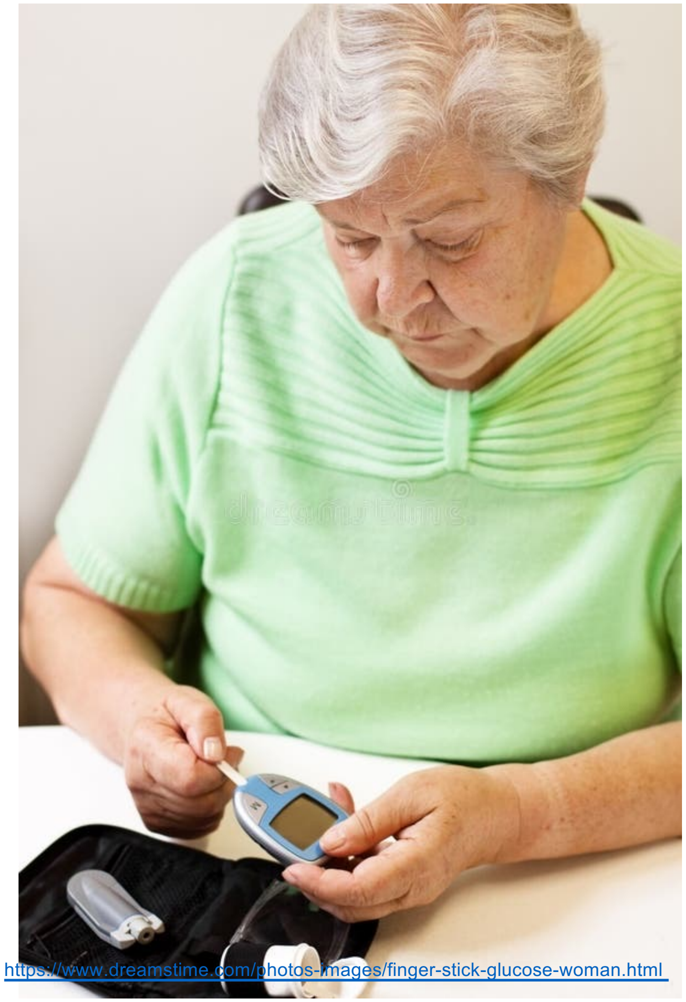

https://www.dreamstime.com/photos-images/finger-stick-glucose-woman.html

Acknowledgements


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FIU Biomedical Engineering

FIU HONORS COLLEGE EDGE LAB


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Friends and Family

Department of Chemistry and Biochemistry

Analytical Chemistry Lab

Questions?

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Appendix

Full MRs and DIs

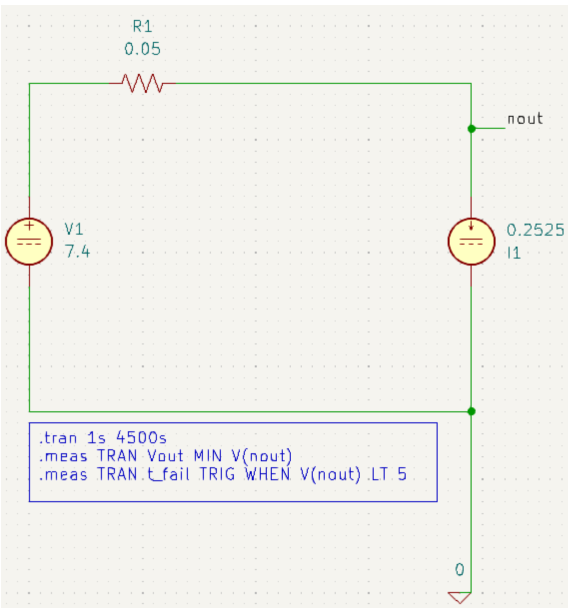
	Market Requirements	Design Inputs
1	Detect hyperglycemia accurately via breath	Detect acetone (0.5–10 ppm) and ammonia (1–20 ppm) with LOD/LOQ of 0.2/0.5 ppm and 0.8/1.0 ppm, respectively. ±0.1 ppm resolution, $R^2 \geq 0.95$.
2	Provide visual and auditory feedback	Auditory cues: 300–625 Hz at 51–85 dB. Visual cues: ≥14 pt font with ≥3:1 contrast.
3	Lightweight and portable	Total device weight shall not exceed 2.3 kg (5 lbs) and dimensions less than 5 × 10 × 4 inches.
4	Comfortable to hold	The device should fit hand sizes from 6.10–8.66" long and 2.68–3.95" wide.
5	Comfortable to use	Device shall allow one-way airflow at 0.05–0.851 psi for ease of use.
6	Minimal use steps	Device use will involve only 3-5 steps.
7	Support sampling throughout the day	Battery must support 10-15 full operational cycles per day without voltage collapse .

Appendix

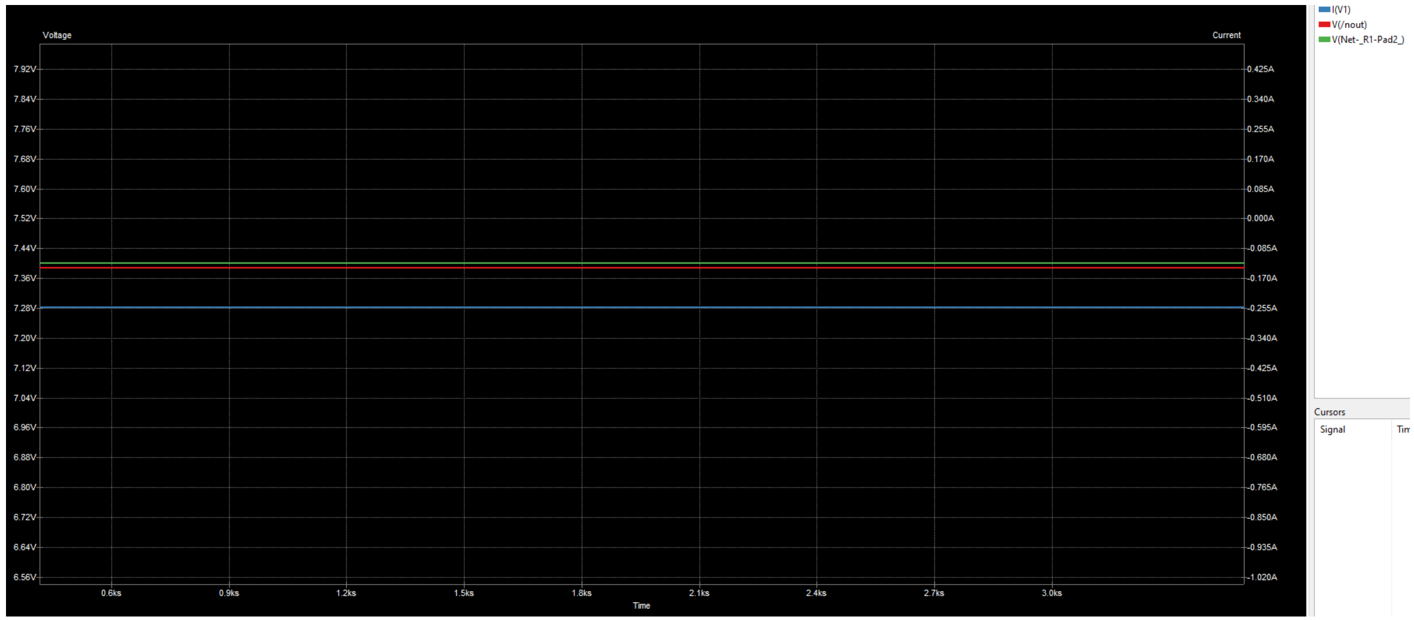
Full MRs and DIs

	Market Requirements	Design Inputs
8	Device shall provide fast sampling, rapid results, and timely feedback.	Device shall collect breath in 5–10 s and display results within 180 s, for total latency of 5–180 s.
9	Device shall allow data storage and retrieval	Storage shall hold ≥ 900 readings for reliable, long-term tracking and data retrieval.
10	Device shall resist contaminants to ensure safety and accuracy	Device shall resist up to 95% humidity, use ≤ 5 µm breath inlet, and have a nonporous enclosure.
11	Device mouthpiece shall be universally biocompatible	Mouthpiece shall show ≥70% cell viability (ISO 10993-5) and measure 20–30 mm^2 for comfort.
12	Device shall withstand drops without damage or loss of function	Device shall withstand ≥ 1 drop from ≥ 1.66 m onto concrete on faces, edges, and corners.
13	Device shall withstand hand-grip forces during use	Casing shall withstand a sustained compressive load ≥ 183 N for ≥ 190 s.

Electronics Simulations:
KiCad – SPICE simulation



Simplified Power Model



Transient analysis

Appendix

Slide 16 Explanation

This simulation was focused on verifying average current delivery over a 5-minute cycle using a simplified model. We intentionally averaged the current to validate power integrity at the battery input, checking for sustained voltage above critical thresholds like 5 V. However, we acknowledge that this model does not capture transient events like inrush current from the pump or solenoid.

In real applications, these brief surges could cause the battery voltage to dip more than expected due to dynamic internal impedance and recovery time. To account for this, future simulation or testing should model time-domain spikes explicitly using pulsed current profiles.

Q1: Why did you choose to simulate using only one current source instead of modeling each component individually?

A:

We chose to abstract the downstream components into a single current source representing the system's total average load over a 5-minute session. This includes both the high-current spike from devices like the pump, solenoid, sensors, and SD card, and the baseline draw from components like the ESP32 and OLED. Since most components lack accurate SPICE models—especially for digital and mixed-signal behavior—we simplified the simulation to focus on the worst-case current delivery. This approach isolates the power integrity question without introducing unnecessary model uncertainty or convergence issues.

Two Rails feed by a 7.4V lipo battery

- 5V rail for 12 sec (for purging)
- 3.3V rail for the total 5 min sample ~~minus~~ the 12 seconds

Power of each rail

5V rail: 1150mA load

3.3V rail: 480mA load

$$P_{5V} = 5V \times 1150mA = 5.75\,W$$

$$P_{3.3V} = 3.3 \times 480mA = 1.584\,W$$

- Since the 5V rail is for the 12 sec of purging our breath collection chamber, out of the whole 5 min of sample collection, we are going to do a weighted average to get a total current draw per 5 min.
- First we calculate total average power:

$$P_{Total} = \frac{300s}{300s} \times P_{3.3V} + P_{5V} \times \frac{12s}{300s}$$

$$= 1.814\,W$$

Next, we account for buck converter so we use P_{Total} and divide by its efficiency.

$$P_{Total\_new} = \frac{P_{Total}}{Efficiency} = \frac{1.8140}{0.97} = 1.8701\,W$$

Average Current

$$I_{Av} = \frac{P_{Total\_new}}{V_{battery}} = \frac{1.8701\,W}{7.4V} = 0.2525\,A$$

Avg current in 1 use of 5 minutes.

Appendix

Verification test for battery

10.1 Data Type and Test Selection Rationale

The data collected in this verification test consists of **continuous numerical** values; specifically, the final battery voltage recorded after each full sampling cycle. Because this dataset represents repeated measurements from a single battery under identical conditions, a one-sample statistical test is appropriate. The objective is to determine whether the average final voltage remains statistically above the predefined collapse threshold of 6.0 V. A parametric test was chosen because the sample size ($n = 10$) is sufficient for basic inferential analysis, and the values show no outliers or extreme variation.

10.2 Normality Check

To justify the use of a parametric test, a normality assessment was conducted using the Lilliefors test. The resulting p-value was ≥ 0.5, indicating no significant deviation from normality. Therefore, the assumption of normal distribution was considered valid for this dataset.

10.3 One-Sample t-Test Results

- **Null Hypothesis (H_0):** Mean final voltage ≤ 6.0 V
- **Alternative Hypothesis (H_1):** Mean final voltage > 6.0 V
- **Significance Level (α):** 0.05
- **p-value:** 1.51×10^{-18}
- **Interpretation:** The p-value is far below the significance threshold, indicating strong evidence that the battery maintains a voltage above 6.0 V during repeated use.

11.0 DISCUSSION

- Ten sampling cycles were selected to reflect the lower bound of expected daily use, as defined by the device's design input. This number was sufficient to evaluate system performance across repeated operations and to conduct meaningful statistical analysis. Final voltage values decreased gradually over the course of the test, but remained well above the collapse threshold of 6.0 V.

- To validate the use of a parametric test, a Lilliefors normality check was performed on the final voltage data. The test returned to a p-value of ≥ 0.5, indicating that the data were normally distributed. This justified the use of a one-sample t-test to assess whether the battery's mean voltage remains statistically above 6.0 V. The test produced a p-value of 1.51×10^{-18}, strongly rejecting the null hypothesis and confirming that the battery can reliably support full operation across multiple cycles without voltage collapse.

Appendix

Slide 21

MQ137

ppm	Mean_V	Std_V	SE_V	SNR_V
0	2.155	0	0	Inf
0.2	2.3687	0.17654	0.10193	13.417
0.4	2.7843	0.011547	0.0066667	241.13
0.6	2.8693	0.022368	0.012914	128.28
0.8	2.9653	0.016073	0.0092796	184.49
1	3.0483	0.012583	0.0072648	242.26
2	3.2243	0.012583	0.0072648	256.24
2.5	3.2977	0.020257	0.011695	162.79
3	3.3467	0.02409	0.013908	138.92
3.5	3.4037	0.0057735	0.0033333	589.53
4	3.436	0	0	Inf
4.5	3.452	0.013856	0.008	249.13
5	3.4703	0.012662	0.0073106	274.07
6	3.4867	0.0028868	0.0016667	1207.8
7	3.5073	0.0028868	0.0016667	1215
8	3.5223	0.0076376	0.0044096	461.18
9	3.5387	0.0045092	0.0026034	784.76
10	3.5436	0.013612	0.0060877	260.32

Summary Statistics:

Avg_SNR	Max_SNR	Min_SNR	Median_SNR	Avg_SE
400.58	1215	13.417	252.69	0.012875

The MQ 137 sensor delivers highly consistent and precise readings across most concentrations, with especially strong performance from 0.4 to 10 ppm.

While signal clarity is excellent overall (average SNR ~400), reliability drops at 0.2 ppm, suggesting limited sensitivity near the detection threshold.

Overall, the sensor is well-suited for applications requiring stable measurements in low-to-moderate concentration ranges.

TGS1820

ppm	Mean_V	Std_V	SE_V	SNR_V	Abs_SNR_V
0	-0.33117	0.016696	0.003408	-19.835	19.835
0.2	-0.21508	0.027835	0.0054589	-7.7268	7.7268
0.3	-0.16663	0.010555	0.0037318	-15.786	15.786
0.4	-0.074111	0.013932	0.0046441	-5.3193	5.3193
0.5	-0.0608	0.018016	0.0040286	-3.3747	3.3747
1	-0.022	0.037311	0.0090493	-0.58964	0.58964
2	0.0372	0.0099197	0.0031369	3.7501	3.7501
5	0.1115	0.011199	0.0039596	9.9558	9.9558
10	0.1652	0.020655	0.0065316	7.9981	7.9981

Summary Statistics (using absolute SNR):

Avg_Abs_SNR	Max_Abs_SNR	Min_Abs_SNR	Median_Abs_SNR	Avg_SE
8.2595	19.835	0.58964	7.7268	0.0048832

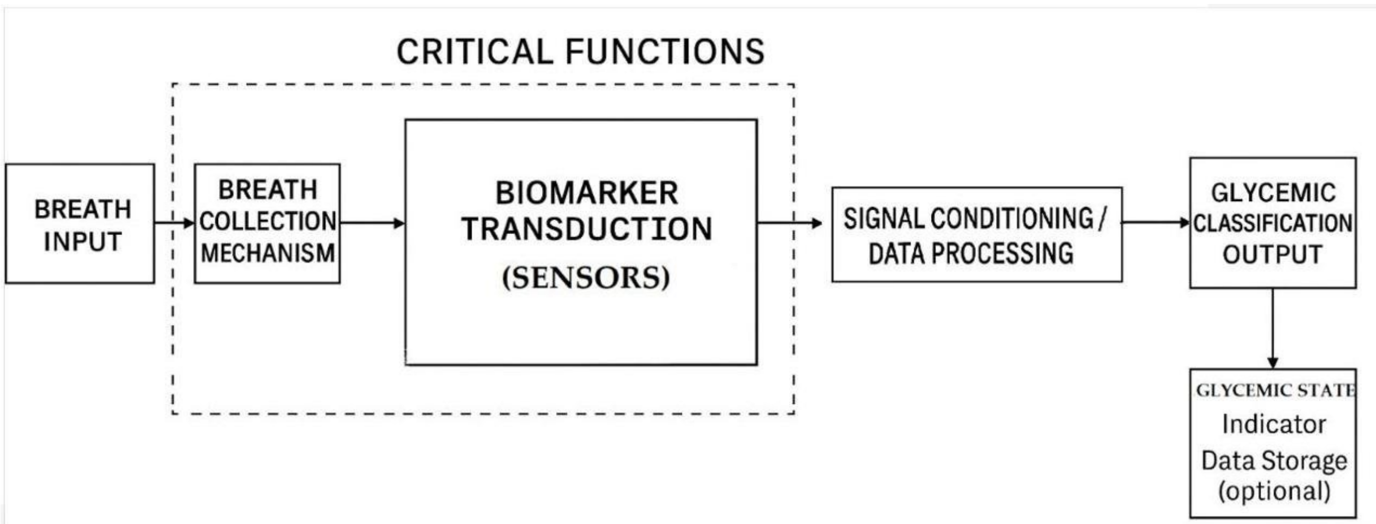
The TGS1820 sensor demonstrates consistent precision across all concentrations, with low standard error values throughout.

While signal strength is limited at very low concentrations (0–1 ppm), performance improves notably from 2 ppm and above, where signal clarity becomes more reliable.

With an average absolute SNR of ~8.3 and strong repeatability in the mid-to-high range, the sensor shows promise for applications focused on detecting moderate to elevated acetone levels.

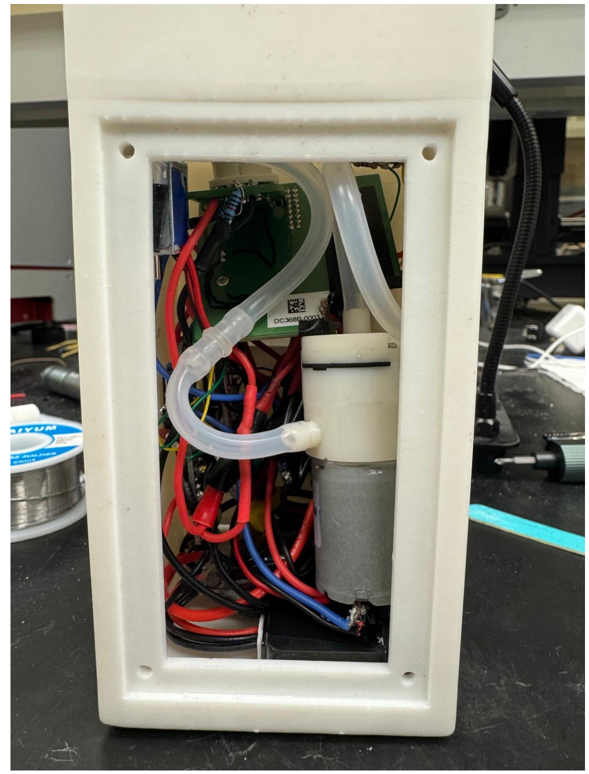
Appendix

GlycoBreath Flowchart



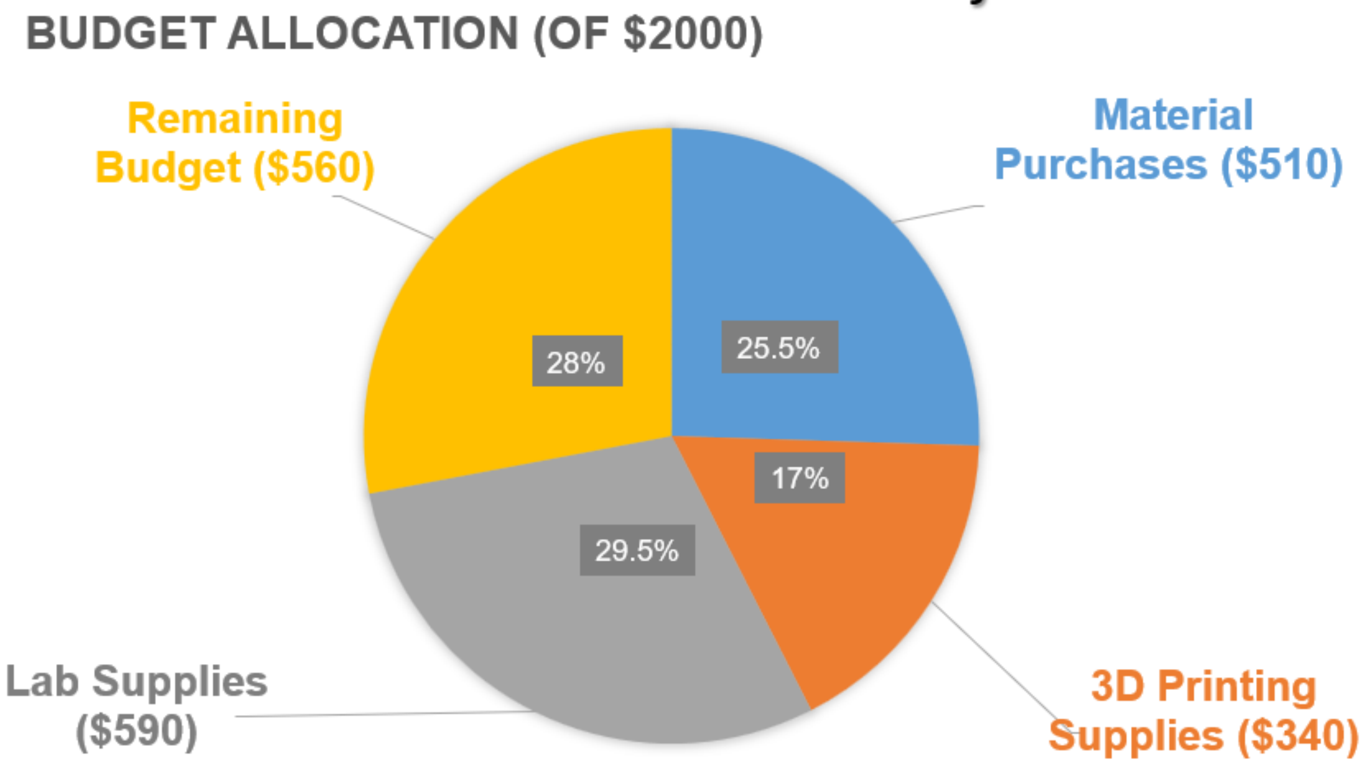
Appendix

Internal components



Cost Assessment:

Project



Material Purchases (incl. bulk/inventory)	$510.00
3D Printing Supplies	$340.00
Lab Supplies	$590.00
Total	$1,440.00