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Aeris: The Future of Breath-Based Diagnostics

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***Abstract*—We developed *Aeris*, a non-invasive diagnostic platform that analyzes exhaled breath to detect diabetes through acetone quantification. The system integrates breath sampling, chemical separation, high-sensitivity VOC detection, machine learning–based classification, and a clinician-facing web interface. Each test is completed in under five minutes and uses low-cost consumables suitable for deployment in resource-limited settings. Validation confirmed accurate detection of breath acetone at clinically relevant concentrations and consistent diagnostic classification using benchmark datasets. The integrated workflow enables rapid, low-barrier diabetes screening and establishes a scalable framework for future breath-based diagnostics.**

***Index Terms*—Acetone, Breath analysis, Diabetes, Diagnostic systems, Gas chromatography, Machine learning, Noninvasive detection, Photoionization detectors, Volatile organic compounds.**

I. Introduction

A. Motivation & Previous Work

Nearly 47% of people worldwide lack access to essential diagnostic services for major diseases such as diabetes, hypertension, HIV, tuberculosis, hepatitis B in pregnant women, and syphilis in pregnant women [1,2]. This diagnostic gap represents a major barrier to early detection, effective treatment, and disease management, particularly in low- and middle-income countries. Current diagnostic methods, including blood testing, imaging, and biopsies, are invasive, time-intensive, and require significant expertise and infrastructure to administer [3,4]. For example, the Oral Glucose Tolerance Test (OGTT), the gold standard for diagnosing diabetes, requires overnight fasting, ingestion of a controlled glucose solution, and multiple blood draws over several hours [5]. These procedures are not only uncomfortable for patients but also place heavy logistical demands on healthcare systems due to off-site lab processing, making them difficult to implement in under-resourced settings.

In response to these challenges, researchers have explored breath-based diagnostics as a non-invasive alternative, with studies demonstrating that volatile organic compounds (VOCs) in exhaled breath can serve as biomarkers for diseases such as diabetes, lung cancer, and infectious diseases. However, existing breath analysis technologies, such as gas chromatography-mass spectrometry (GC-MS) and electronic nose systems, have often been prohibitively expensive, limiting their clinical adoption outside of research settings. There is therefore a pressing need for new diagnostic technologies to bridge this critical gap and improve global health equity.

B. Problem Statement

Existing diagnostic standards are too invasive, slow, expensive, and infrastructure-dependent to meet the needs of nearly half the world's population. Without alternative approaches, timely disease detection remains inaccessible for millions, leading to preventable morbidity and mortality worldwide.

C. Proposed Solution

We developed Aeris, a breath-based diagnostic platform, to address the limitations of current diagnostics. Aeris analyzes exhaled breath for biomarkers whose concentrations shift in the presence of specific diseases, designed to provide rapid, non-invasive, and affordable disease detection. As a proof of concept, Aeris targets the diagnosis of diabetes by detecting acetone, a well-established biomarker that increases in the breath of individuals with elevated blood glucose levels. Breath samples are collected through a disposable mouthpiece and analyzed using a photo-ionization detector sensor to quantify acetone concentrations with high accuracy. Aeris then relies on a machine learning model to classify patient samples based on acetone levels and other features, and provides diagnostic results to clinicians through a clear interface. In addition to improving patient comfort and expanding accessibility, the system is designed with scalability in mind, enabling future adaptation for the detection of other diseases based on different breath-borne biomarkers.

II. Design and Methodology

A. Specifications and Constraints

The breath-based diagnostic system was developed to meet specific performance specifications that enable reliable, rapid, and non-invasive diabetes screening. The system is capable of detecting diabetes-associated volatile organic compounds (VOCs) at concentrations in the low parts-per-billion (ppb) range. Each test is designed to process a single 1-liter breath sample, and the entire diagnostic process is completed in under five minutes. Output data is formatted as a CSV file for downstream analysis, and the system is compatible with a machine learning–based classification model. Additionally, the cost of the disposable mouthpiece used per test is $0.33, meeting the affordability target for scalable, single-use deployment.

The design was also shaped by several key constraints. The device needed to be non-invasive and quick to administer, eliminating the need for blood samples and

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transmitting samples to other laboratories in uncontrolled environments. It had to be simple enough for use by healthcare professionals with minimal training, particularly in low-resource settings. Finally, cost was a critical constraint: all consumable components had to remain inexpensive to support widespread use in underserved or high-volume clinical environments.

B. Design Procedure

The project began with an analysis of diabetes biomarkers detectable in human breath, due to our emphasis on non-invasive testing. While breath contains hundreds of volatile organic compounds in concentrations ranging from parts-per-trillion to parts-per-million, acetone appears at a relatively high concentration of 300-900 parts-per-billion in healthy people. More notably, acetone significantly increases in concentration (>1800 parts-per-billion) in people with diabetes [6].

Once acetone was identified as the target biomarker, we evaluated several chemical separation methods to isolate it from the rest of the breath sample. Although molecularly imprinted polymers—synthetic materials engineered for high selectivity toward specific analytes—offered strong potential for acetone separation, their high cost and complex employment made them impractical for use in under-resourced healthcare settings. As a result, we used gas chromatography (see Gas Chromatography) to find the mole fraction of acetone rather than separating the acetone prior to the sensor.

We also considered several gas sensors, initially utilizing a metal oxide semiconductor gas sensor with MEMS detection principle. However, this sensor gave large fluctuations in voltage readings which lead to more varied measurements when testing known concentrations in the chemical engineering lab. This sensor is also cross sensitive to common atmospheric gases. Given that our device needs to detect concentrations in the range of breath-borne markers (PPB), we switched to ION Science's MiniPID 2 HS (high sensitivity) sensor, which is a photoionization detector, to measure the biomarker.

Finally, we considered various ways for communicating the results to patients and/or medical professionals, and ultimately decided that our UI should be geared toward the professional administering the test. We aimed to make the site easy to use with limited knowledge of the underlying machine learning algorithm and/or diabetes expertise.

C. System Architecture

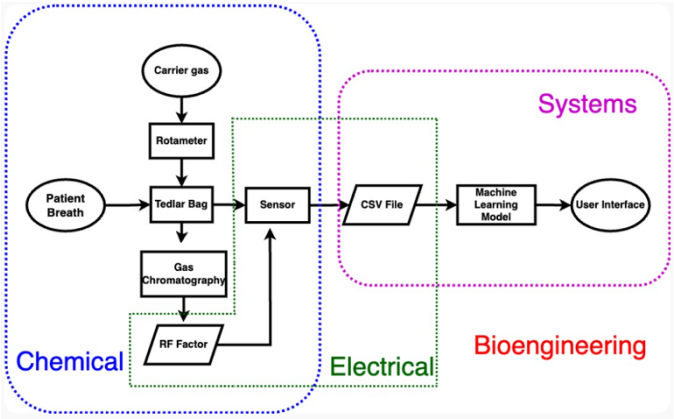


Figure 1. Block diagram showing the chemical, electrical, and systems components of the system, as well as the interface between them.

The system architecture (Fig 1) follows a modular pipeline that processes a patient's breath sample from collection to diagnosis. The process begins with the patient exhaling into a disposable mouthpiece, which directs the breath into a Tedlar bag for temporary storage. From the Tedlar bag, a portion of the sample is passed through a gas chromatography (GC) column to separate volatile compounds and determine the response factor (RF) of the target biomarker. This RF value is then manually entered into the sensor software to calibrate the detection process.

Following GC analysis, the carrier gas is routed through a rotameter into the Tedlar bag, propelling the sample out of the bag and into the sensor. The sensor, a photoionization detector (PID), detects the concentration of the aggregate VOCs in the breath at parts-per-billion and outputs this value. These concentrations are logged in the software and extracted as a CSV file, which is then processed by a machine learning model trained to classify diagnostic outcomes. The final result is presented on a user interface designed for use by healthcare professionals.

All physical components in the system are connected using silicone tubing and airtight tube connectors to maintain sample integrity and prevent contamination or leakage. This modular and sealed architecture ensures consistency across tests and enables straightforward assembly and maintenance in both laboratory and clinical settings.

D. Design Details

1. Gas Chromatography

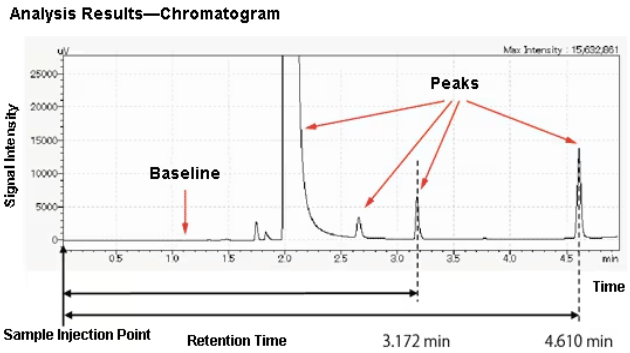


Figure 2. Sample output of a gas chromatogram. The sample is injected at time = 0, and then each gas is eluted from the column at a unique retention time. The higher the percentage of the gas in the sample, the larger the area under its unique peak will be. The area under the peak can then be used to determine the exact % of a gas within the overall sample.

Gas chromatography (GC) is a powerful separation technique that is used to isolate volatile components (e.g., VOCs) of a gas mixture into its component parts based on differences in the mode of partitioning between a flowing mobile phase and a stationary phase [7]. In the provided application, a Hydrocarbons and Sulfur Gases - HayeSep Q, 80/100 mesh GC column was employed, which utilizes a porous divinylbenzene-based polymer packing material as the stationary phase. This packed GC column is ideal for separating light hydrocarbons, alcohols, ketones, and sulfur gases [8]. Generally, smaller, more volatile compounds such as methane will elute (pass through and exit the column) more rapidly than less volatile, more interacting compounds such as acetone. This provides each molecule a unique retention time (Fig. 2). As each molecule is eluted, the GC outputs a peak for which the height reflects the instantaneous detector response (signal strength) as the compound elutes, and the width reflects how long it takes for all the molecules of that compound to pass the detector. The area under the peak is proportional to the total number of molecules detected.

GC involves using an inert carrier gas to deliver the inputted sample through the packed column. Helium was selected as the carrier gas as, in addition to being inert, helium also is safe to use, provides good separation efficiency, and is cheaper than alternatives [9]. To calibrate the column to be best equipped to measure acetone, helium was bubbled through liquid acetone to generate a calibration gas at 5℃. To determine the percentage of acetone within the calibration gas, the saturation pressure of acetone was calculated using Antoine's equation:

$$\log(P^{SAT}) = A - \frac{B}{T+C} \quad [1.a]$$

P^{SAT} = Saturation pressure of species at temperature of the bubbler (Bar)
A, B, C = Antoine constants for Acetone for temperature ∈ [259.16 K, 507.60 K]
T = Temperature of bubbler in Kelvin (K)

Solving Antoine's equation for the saturation pressure of Acetone in the given setup:

$$\log(P^{SAT}_{Acetone}) = 104.42448 - \frac{1312.253}{(5+273.15-32.445)} \quad [1.b]$$

Assuming the setup is at atmospheric pressure (i.e., 1 atm = 1.01325 bar), the mole fraction of acetone in the calibration gas was calculated using a modified Raoult's law assuming the liquid was purely acetone:

$$Y_{Acetone} = P^{SAT}_{Acetone}/P \quad [2]$$

$Y_{Acetone}$ = Mole fraction of acetone in calibration gas
$P^{SAT}_{Acetone}$ = Saturation pressure of acetone at temperature of the bubbler (Bar)
P = Total system pressure (Bar)

This calibration gas was used to generate a peak response curve for pure acetone (Fig. 2). The area under the acetone curve was numerically determined as 2805.14. After the GC was calibrated to measure acetone, breath samples were able to be injected into the GC column. Using this calibration, the final relationship to determine the percentage of acetone in a gas-mixture (i.e., breath) sample was derived as:

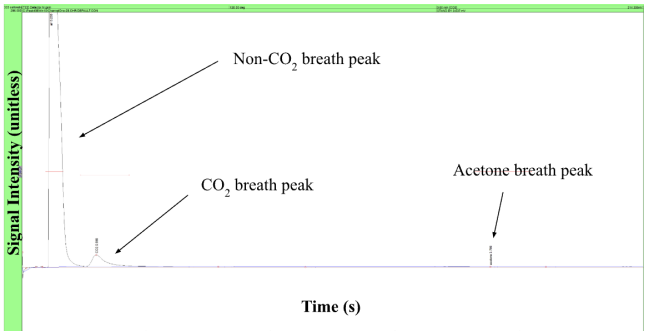
$$y_{Acetone} = Y_{acetone}\left(\frac{A_{Sample}}{A_{Calibration}}\right) \quad [3]$$

$y_{Acetone}$ = Mole fraction of Acetone in inputted gas sample (breath)
$Y_{Acetone}$ = Mole fraction of Acetone in calibration gas
A_{Sample} = Area under acetone peak of gas-mixture sample
$A_{Calibration}$ = Area under acetone peak of pure-acetone sample

Then, assuming the breath / acetone behave as ideal gasses which is reasonable at a relatively low system pressure of 1 atm, system temperature far from condensation points, and trace levels of acetone resulting in negligible interactions, the mole fraction ($y_{acetone}$) is set approximately equal to the volume fraction. This assumption holds because 1 mole of any ideal gas occupies the same volume at the same temperature and pressure. At that point, the % acetone by volume concentration of acetone in the breath sample can be determined by multiplying the mole fraction by 10^6:

$$\%\ Acetone\ by\ Volume = y_{Acetone} * 10^6 \quad [4]$$

An example output was created by measuring a breath sample on the calibrated GC column (Fig. 3). The area under the acetone peak was numerically determined as 0.1832. which, when utilizing equation [5], corresponded to an acetone mole fraction of 7.8 ppm.



Results

Component	Retention	Area	Internal	Units	Norm area %
air	0.230	7819.5312	0.0000		N/D
CO2	0.596	89.1880	0.0000		N/D
acetone	3.766	0.1832	0.0000		N/D
		7908.9024	0.0000		100.0000

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Figure 3. a) GC output of signal measurement upon elution of breath-borne air, carbon dioxide, and acetone. b) Numerical integration values of area under signal curve of respective species.

However, it was noted that the breath-borne acetone concentration, particularly for a healthy control, would be in the low ppm to ppb range which would not alone be accurately enough measured by the GC to validate a diagnosis [10]. It can, however, be used to calibrate a PID sensor specific with capabilities of measuring to the ppb range which in turn can output a higher-certainty secondary result on which to compare the diagnosis. The acetone concentration in the breath sample as measured by the GC was then corrected to the fraction using Procedure X (see *PID Sensor*). This corrected fraction is used to calculate the RF mix for the PID sensor and in turn output a more accurate concentration reading for acetone.

2. Mini PID HS Sensor for Volatile Organic Compound (VOC) Detection

The Mini PID HS Sensor is designed to detect volatile organic compounds (VOCs) at ppb concentrations. Each VOC has a unique ionization energy (IE), which represents the minimum energy required to ionize the molecule. The HS sensor uses an unfiltered krypton light source with a photon energy of 10.6 eV.

The sensor operates based on photoionization, where a gas sample diffuses through a porous membrane into the sensor. After passing through, the sample is exposed to an ultraviolet (UV) lamp through a crystal lamp window. The lamp emits photons that excite electrons within the gas molecules. When a photon collides with a photoionizable molecule, it provides sufficient energy to ionize the molecule, generating positive and negative ions. When the ions separate towards oppositely charged electrodes, a current is generated. This current is amplified and allows for the sensor to produce a voltage output, which can then be converted to a concentration.

The Sensor Development Kit (SDK) includes:

- An integration board for signal processing and communication,
- A sensor board housing the Mini PID HS Sensor,
- A gas delivery hood for the sensor to ensure controlled exposure to test gases, and
- A PC application that collects and displays real-time sensor measurements.

This setup enables precise VOC detection and quantification, making it suitable for applications requiring high sensitivity and accuracy.

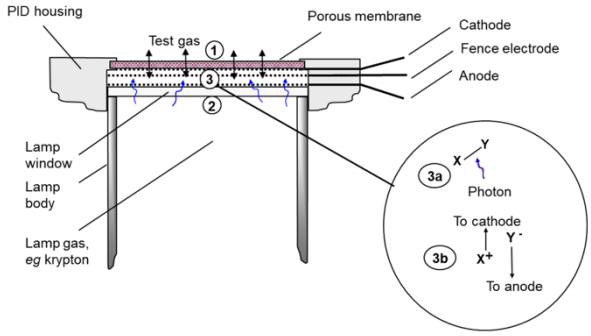

Figure 4: MiniPID 2 Sensor Operating Principle.

The diagram illustrates the working mechanism of the MiniPID 2 sensor for detecting volatile organic compounds (VOCs) using photoionization detection (PID). Test gas diffuses through a porous membrane into the sensor chamber, where an ultraviolet (UV) lamp emits photons. These photons ionize VOC molecules, generating positively charged ions (X^+) and negatively charged electrons (Y^-). The ions are collected at oppositely charged electrodes (anode and cathode), producing a small electric current proportional to the VOC concentration. A fence electrode prevents interference from external charge sources, ensuring measurement accuracy.

The sensor system consists of two Printed Circuit Boards (PCBs)—one for the development kit and another for the PID sensor. The development kit PCB is powered by a 12V DC supply, while the sensor PCB operates at 3.3V to support the PID sensor.

The development kit PCB incorporates essential signal conditioning circuits, including:

- Amplifiers for signal enhancement,

- Filters to reduce noise and interference,
- Voltage regulators for stable power delivery, and
- An Analog-to-Digital Converter (ADC) to digitize the sensor output.

The sensor PCB contains positive voltage, negative voltage, signal(+) which is non-inverting output, and signal(-) which is inverting output. The non-inverting output is the positive output voltage generated by the sensor in response to ionized VOCs. It carries the amplified signal corresponding to the detected gas concentration. It is connected to an Analog to Digital Converter on the development PCB board to process the sensor output. The inverting output is the negative or reference signal in the differential output. It reduces noise and improves signal integrity. These differential signals lead to higher accuracy, better noise reduction, and improved signal integrity, ensuring that low level signals are processed.

The sensor outputs a voltage which is transmitted via USB to a computer running the Sensor Development Kit (SDK) software. To obtain accurate measurements, the appropriate Response Factor (RF) must be entered into the software to convert the sensor's readings. The response factor relates the sensitivity of PID to a specific VOC to the sensitivity of the calibration gas, which in this case is isobutylene. The software then converts the voltage output to a concentration of parts per million (ppm) or parts per billion (ppb).

This integrated system ensures precise VOC measurement and enables real-time data acquisition for analytical applications.

3. Machine Learning Model for Diagnosis

The machine learning (ML) model is designed to process the CSV outputs generated from the sensor's signal. The model's primary function is to classify breath samples as indicating a healthy state or a potential case of GDM. In designing the model, we have taken cues from recent research on sensor data analysis and machine learning in medical diagnostics.

The machine learning pipeline leverages a random forest classifier as its core model to integrate sensor-derived features with traditional biometric data for diabetes diagnosis. Initially, we validated this model on a benchmark diabetes dataset that used conventional biomarkers (such as glucose levels, age, weight, and height). This established a baseline model performance.

Data Preprocessing and Feature Extraction

1. Sensor Data Integration: The raw output from the PID sensor is processed and stored in CSV format. This data will be loaded into the model, with its features being normalized using standard scaling techniques to mitigate sensor noise and inter-test variability.
2. Additional Biometric Data: In addition to sensor derived features, patient-specific data including age, weight, and other relevant parameters are incorporated into the model. BMI is calculated based on these inputs. This multi-dimensional feature set will allow for enhanced diagnostic accuracy by providing a comprehensive view of the patient's metabolic profile.
3. Feature Validation: Given that our sensor measures acetone—a biomarker correlated with diabetes—and prior studies have demonstrated the utility of such biomarkers in non-invasive diagnostics, rigorous validation will be performed to ensure that the extracted features contribute meaningfully to classification accuracy.

Model Training and Evaluation

1. Algorithm Rationale: A random forest classifier was selected for its ability to model nonlinear interactions between features, robustness to overfitting, and strong empirical performance on medical datasets. Random forests also provide feature importance rankings, offering some level of interpretability while maintaining high classification accuracy.
2. Training Protocol: The model was trained using k-fold cross-validation to ensure robustness and generalizability to unseen data. Performance is evaluated based on metrics such as accuracy, sensitivity, specificity, and the area under the ROC curve (AUC). These evaluation metrics are in line with methodologies reported in similar sensor-based diagnostic studies.

Comparative Analysis: Preliminary experiments on the benchmark diabetes dataset showed that the random forest model achieved strong baseline performance, balancing predictive power with interpretability. Future work will involve optimizing the model and potentially exploring ensemble approaches to improve sensitivity and specificity when incorporating larger, more diverse acetone datasets.

4. User Interface for Diagnostic Website

The website serves as the central integration hub for the project, allowing healthcare professionals to input data from the GC and PID sensor into the ML model and receive an immediate diagnostic outcome. The UI is tailored specifically for clinicians who manage the test process from start to finish, ensuring that every diagnostic result is communicated in a clear, concise, and actionable manner.

The website's design is grounded in two key principles: simplicity and actionable data presentation. Its minimalistic layout reduces cognitive load by avoiding unnecessary technical jargon and emphasizing only the critical diagnostic metrics—such as acetone concentration, ML prediction confidence, and recommended follow-up actions.

Workflow and Functionality

Test Initiation and Patient Data: Upon logging in, users can register each test administration. The system prompts clinicians to enter essential patient data—such as name, age, height, and

weight—at the start of each new test.

Input and Calibration: When an acetone concentration reading is obtained from the GC, the user inputs this value on the website. This step provides the necessary response factor for the PID sensor.

Sensor Data Integration: After the breath sample is processed by the sensor, the resulting CSV file is uploaded to the website. This action automatically triggers the ML model, which analyzes both the patient data and sensor readings.

Diagnostic Output: The ML model returns a final classification, indicating whether the patient has diabetes. This result is displayed clearly on the dashboard, with accompanying data that supports clinical decision-making.

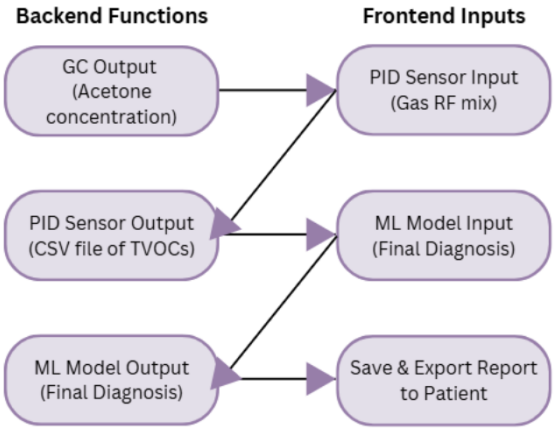

Figure 5. This workflow depicts the relationship between the frontend and backend interactions occurring as a user administers a test on the website.

$$RF_{MIX} = \frac{y_{Acetone}}{RF_{Acetone}} + \frac{(1-y_{Acetone})}{N-1}\left(\sum_{i=2}^{N} \frac{1}{RF(i)}\right) \qquad [5]$$

The equation above depicts the logic behind the conversion of the GC input (Xacetone) to RF Mix. The RF mix value is then fed into the PID sensor.

Ultimately, the streamlined UI on the website not only facilitates a smooth end-to-end process for healthcare professionals, but it also ensures that every step (from data entry to diagnostic output) is optimized for clarity and efficiency.

III. Implementation

The Aeris diagnostic platform was implemented by assembling modular subsystems designed during the prototyping phase. System integration involved combining hardware, firmware, and software components to create a cohesive diagnostic tool.

Hardware Assembly

Physical assembly began with the fabrication of the breath sampling system. A disposable mouthpiece was connected via airtight silicone tubing to a Tedlar bag, which served as a temporary breath reservoir. The Tedlar bag was then connected to the GC column via a flow control valve and rotameter. After separation, the carrier gas pushed the sample through the MiniPID 2 HS sensor for VOC detection. Silicone seals and airtight connectors were used at every junction to maintain system integrity and minimize sample loss.

Sensor Integration

The MiniPID 2 HS sensor was connected to the Sensor Development Kit (SDK), which provided power, signal conditioning, and real-time data acquisition capabilities. Calibration was performed by introducing known concentrations of acetone in helium carrier gas, and corresponding response factors were programmed into the SDK software. A USB interface enabled the transmission of sensor data to a dedicated computer.

Software Development

The CSV files generated by the SDK were processed using a machine learning pipeline implemented in Python. The Random Forest Classifier was trained and validated on benchmark datasets before being adapted for use with the breath sensor outputs. A lightweight web application was developed to enable healthcare professionals to input calibration data, upload test results, and receive diagnostic outputs. The web backend processed uploaded CSVs, passed the data through the ML model, and displayed a classification result alongside sensor metrics.

Deployment

1. A simple startup protocol was defined:
2. Insert a new disposable mouthpiece.
3. Collect a 1-liter breath sample in the Tedlar bag.
4. Open flow control valves to allow GC separation.
5. Calibrate and initialize the PID sensor with updated RF values.
6. Record PID sensor outputs and download CSVs.
7. Upload CSVs and patient metadata to the diagnostic website.
8. View and interpret diagnostic results.

This structured deployment protocol ensures minimal training requirements for healthcare providers in diverse clinical environments.

IV. Testing and Verification

A. *Testing Procedure*

To verify the functionality and accuracy of the Aeris system, we conducted a series of tests using both spiked and control breath samples. Control samples consisted of real breath samples from healthy individuals. Spiked samples were prepared by bubbling healthy breath samples through an acetone-water solution to simulate the breath acetone concentrations typically observed in diabetic patients. Each sample was collected in a Tedlar bag and processed through the full system workflow.

Verification against standard testing procedures were designed to align with relevant ISO (ISO 14971 risk management, ISO 18113 labeling) and IEC (IEC 60601 device safety) standards. Sensor calibration methods followed traceability practices outlined in ISO 17511, and the diagnostic reporting adhered to STARD guidelines for clarity and accuracy.

B. *Results & Analysis*

As shown, acetone levels in healthy breath samples were consistent with literature-reported ranges of 0.3–0.9 ppm.

Spiked samples produced acetone readings well above 5 ppm, aligning with diabetic thresholds (>1.8 ppm). PID sensor readings closely matched the expected trend, validating the calibration protocol. The near-zero values for ambient air confirmed minimal baseline contamination and high selectivity of the PID.

These results support the system's ability to accurately quantify acetone and classify samples, confirming feasibility for diagnostic use. The PID sensor displayed good linearity in output across the target range, supporting its integration into real-time diagnostic workflows.

C. *Future Improvement*

To validate diagnostic performance in real-world conditions, future testing should include breath samples from actual diabetic and non-diabetic individuals. Additional improvements may include automating RF calibration input and improved methods of ensuring consistent flow through the system.

VI. Applicable Standards

Our project is designed to comply with several critical industry standards, ensuring it meets the highest standards for ethical management, effectiveness, and safety of patient data. These standards have influenced the development and implementation of our diagnostic tool.

The physical device component of the project adheres to regulations for FDA Class II devices, which requires 510(k) premarket approval to confirm safety and effectiveness in clinical settings. This classification ensures that our device can be safely introduced into healthcare environments. Furthermore, compliance with 21 CFR 890 regulations emphasizes the importance of performance and safety, specifically tailored to physical therapy and diagnostic devices. To address potential risks, we have incorporated ISO 14971 standards for risk management, enabling systematic identification, evaluation, and mitigation of any hazards associated with the device. Additionally, our design follows the IEC 60601 Series standards, which govern the safety and essential performance of medical electrical equipment, ensuring both electrical reliability and user safety.

On the systems side, the project integrates IEEE 11073 standards for health informatics, facilitating secure and interoperable communication between point-of-care medical devices. This is crucial for ensuring that data collected by our device can be effectively integrated into healthcare systems. Our design also adheres to ISO 17511 requirements, ensuring metrological traceability of calibrators and samples used in in-vitro-diagnostic medical devices. Compliance with IEC 62304 standards has guided the software development lifecycle, ensuring that the software we are utilizing for our final website and model are tested and reliable. Additionally, the methods used to report diagnostic test results align with the STARD guidelines, which ensure accurate and transparent reporting of diagnostic test performance.

From the patient's perspective (regarding patient data), we prioritize the secure handling of sensitive information by adhering to HIPAA regulations (45 CFR 160). This ensures robust data protection and privacy throughout the diagnostic process. Moreover, compliance with ISO 18113 standards has informed the development of clear and user-friendly labeling and instructions for the device, promoting safe and effective use by healthcare providers.

VII. Ethical Considerations

Our project aims to expand access to non-invasive, affordable, and accurate diagnostic tools, particularly in underserved and low-resource settings. Ethically, we prioritize patient safety, data privacy, and diagnostic reliability. Compliance with HIPAA regulations ensures that patient data is securely handled, while adherence to ISO 14971 and IEC 60601 standards supports safe device operation.

Socially, the project addresses disparities in diabetes screening by offering a painless alternative to traditional blood-based diagnostics. By simplifying the workflow for healthcare providers and reducing barriers to testing, we aim to promote early detection of diabetes. Therefore, we prioritize ensuring that diagnostic outputs are communicated clearly and used appropriately, minimizing the risk of misinterpretation or over-reliance on a single test result without appropriate medical consultation.

VIII. Environmental, Social, or Economic impact

Environmental considerations were incorporated into the system's design by minimizing the use of non-recyclable materials and ensuring that disposable components (i.e. the mouthpiece) are made from cost-effective and lightweight plastics. The system operates using a carrier gas, which, while inert and safe, requires conscious sourcing when implemented in healthcare clinics in underserved communities. In future iterations of our system, we hope to explore alternative mechanisms to flush each patient's breath to the sensor.

Economically, the breath-based diagnostic system was designed with affordability and scalability in mind. Each test costs approximately $0.33 in consumables, making it a viable option for deployment in high-volume or under-resourced clinical environments. The modular nature of the device also reduces maintenance and replacement costs, supporting long term sustainability. By reducing the need for lab processing and blood draws, the system may lower overall healthcare costs associated with diabetes screening, particularly in community health programs. In future iterations of the project, we aim to incorporate an alternative GC machine that is specifically designed to separate breath biomarkers, which would help reduce overall system cost.

IX. Conclusions and Reflections

This project demonstrated the feasibility of a low-cost, non-invasive diagnostic platform for diabetes detection using breath acetone analysis. By integrating gas chromatography, a photoionization detector, and a machine learning model into a streamlined workflow, we successfully developed a modular system capable of delivering rapid diagnostic results through a clinician-friendly interface. Testing with spiked acetone samples confirmed that the system could detect volatile organic

compounds at clinically relevant concentrations and produce consistent outputs.

However, further development is needed to validate Aeris in real-world clinical contexts. Specifically, the system must be tested on breath samples from diagnosed diabetic and non-diabetic patients to ensure the model's reliability, account for inter-individual variability, and confirm diagnostic sensitivity and specificity. Expanding the sample pool will also allow for more robust training and validation of the machine learning model. Regulatory compliance and long-term calibration stability are additional challenges we anticipate as we move toward potential clinical deployment.

Future improvements include redesigning the gas chromatography setup to reduce cost and optimize separation for acetone, automating the response factor calibration process to improve consistency, and enhancing the website interface to support longitudinal patient tracking and diagnostic history. These refinements would support broader adoption and help position Aeris as a scalable, accessible solution for breath-based disease screening.

X. Business Writeup

A. Value Proposition

Aeris offers a non-invasive, scalable solution to a critical global diagnostic gap with nearly 47% of the world's population lacking access to essential diagnostic services, including diabetes testing, largely due to limited laboratory infrastructure. Traditional blood-based tests can be uncomfortable, carry risks such as infection, and require complex logistics for sample processing. Aeris replaces this with a simple breath test that detects acetone, a biomarker for diabetes, eliminating the need for needles, lab equipment, or specialized training. This not only improves patient comfort, but also accelerates turnaround times and expands access in underserved regions. With growing demand for accessible chronic disease diagnostics, Aeris represents a high-impact, high-need investment opportunity positioned to transform early diabetes detection. Its underlying platform also holds long-term potential to be adapted for breath-based screening of other conditions, enabling broader clinical utility and market reach.

B. Stakeholders

The primary stakeholders for the diabetes diagnostic test are global communities with underserved healthcare infrastructure. These populations often face significant barriers to early detection due to the lack of affordable, accessible diagnostic tools. The test is designed to directly address their needs by providing a portable, low-cost solution that promotes health equity and improves outcomes in resource-limited settings. Secondary stakeholders include medical professionals, who will use the diagnostic tool in clinical and community settings to enhance their ability to identify and treat diabetes at an early stage to reduce the risk of consequential conditions. In addition, patients, as end-users, benefit directly from improved access to diagnostics, reduced financial burden, and better health outcomes. Governments also have an interest in the device as it has the potential to alleviate the financial burden on national healthcare systems as well as improve population health. They could also work to ensure the device is integrated into public healthcare systems. Finally, insurance companies are key stakeholders as the diagnostic tool reduces healthcare costs by enabling early detection and minimizing unnecessary procedures, aligning with their goal of managing expenditures while improving care outcomes.

C. Competition

Competition for this device comes from two primary sources: alternative breath-based diabetes diagnostics and non-breath-based diagnostics. While research has explored the use of breath-borne VOCs for detecting diabetes in recent years, no commercial device currently exists due to challenges with standardizing breath sample collection and ensuring repeatability. This gap in the market presents a significant opportunity for Aeris to establish itself as a pioneering solution. Non-breath-based diagnostics, such as saliva-based tests, are another potential competitor. However, like breath-based technologies, these alternatives are still in development and not yet commercially available.

Other potential competition comes from traditional diagnostic methods such as Oral Glucose Tolerance Tests. While these methods are well-established, they are often costly, less accessible in underserved areas, and associated with risks like bruising and infection. Additionally, advancements in machine learning and AI-based predictive models could emerge as competition by analyzing existing patient data to predict diabetes risk. However, these methods still rely on robust healthcare infrastructure and large data sets, which limits their applicability in underserved communities. These distinctions position Aeris as a unique and highly competitive option in the landscape of diabetes diagnostics.

A principal current competitor in the breath-based diagnostics market is Owlstone Medical. Owlstone Medical is currently leading the breath-based diagnostic market with early disease detection in cancer, liver disease, and respiratory illnesses. Owlstone's Breath Biopsy platform focuses on scalability and is currently in clinical testing for LC diagnostics, which indirectly proves a threat to Aeris's diabetes value proposition. Breath Diagnostics is another company focused on breath-based diagnostics that is leveraging its patented OneBreath technology. We believe that as there is not yet a viable breath-based diagnostic device for diabetes, Aeris is competing to get to market as we believe the first mover advantage will prove highly influential in market share dynamics given friction in switching costs for consumers.

D. FDA Approval Process

As a novel medical device, one of the primary risks Aeris faces is navigating the complex approval process by regulatory agencies. This memorandum will focus specifically on the FDA's approval process for medical devices in the US, since many international regulatory bodies have followed the FDA's structure for medical device approval. The FDA regulates the sale of medical devices in the US to ensure devices' safety and accuracy, and medical devices cannot be sold or marketed in the US without first receiving FDA approval or clearance [11]. The FDA approval process is rigorous, reflecting the agency's commitment to ensuring that all medical devices meet high standards of safety and effectiveness before they are introduced to the market. The

potential of failure to receive FDA approval represents a significant risk to Aeris' success.

There are two pathways that Aeris could follow to pursue FDA approval. The first pathway would be to pursue approval as a Class II medical device with Exalenz Bioscience's BreathID System as a predicate device. Class II medical devices, which make up 43% of all medical devices in the US are devices that pose a medium-level of risk to patients, including pregnancy tests, electrified wheelchairs, and syringes [12]. Aeris's non-invasive nature means its risks to patients are consistent with those of other Class II devices, suggesting that it would not be subject to as rigorous an approval process as higher-risk Class III devices. However, to pursue approval as a Class II medical device, an appropriate predicate device would have to be selected to match Aeris' technology and indication. A predicate device is a legally-marketed device that has already been approved or cleared by the FDA and can serve as a point of comparison for a new medical device seeking approval ("Predicate Device"). Exalenz Bioscience's BreathID System, an FDA-approved breath-based diagnostic test for H. pylori, serves as a potential predicate device for Aeris, given its similar use for breath-based diagnostics [13,14] Summary for K130524). However, since the indication for the BreathID System is not for diabetes diagnostics, it is possible that Aeris could fail to secure FDA approval through this pathway if it is deemed that BreathID would not serve as a suitable predicate device for comparison. Given the novelty of breath-based diagnostics for diabetes, Aeris could pursue a second pathway for FDA approval, which involves classification as a De Novo device instead of Class II classification. De Novo classification allows novel technologies and devices to be introduced in the US without the prior existence of a comparable predicate device (U.S. Food and Drug Administration, "Step 3: Pathway to Approval"). However, devices approved through the De Novo pathway are subject to lengthy review times. Additionally, user fees for De Novo submissions increased in 2017, making the approval process more expensive for devices seeking clearance through the De Novo pathway [15].

In summary, the FDA approval process poses many challenges for Aeris. The ambiguity of an existing Class II predicate device for Aeris may mean that Aeris must pursue a lengthier review process under De Novo classification. Even if Aeris is able to use the BreathID System as a predicate device, approval rates of Class II submissions with predicate devices have been trending down in recent years, suggesting that even Class II classification for Aeris could subject Aeris to a lower likelihood of FDA approval [16]. Ultimately, proactive risk mitigation strategies – such as early engagement with the FDA through pre-submissions, strong clinical testing plan development, and hiring talent with regulatory expertise – can help Aeris overcome the challenges associated with the FDA approval process. For other international regulatory bodies, many streamline their approval processes for products already approved by the FDA. Therefore, FDA approval provides, in many ways, an all encompassing approach to global approval.

E. IP

As we continue to develop the diagnostic tool, we are exploring intellectual property opportunities to protect the unique aspects of our design. Potential patents include the GC-PID separation mechanism, which represents a novel approach to combining multiple technologies. The portable device design, which integrates sensor technology with machine learning capabilities, is another candidate for IP protection. Additionally, the proprietary software pipeline, including algorithms for real-time data preprocessing and SVM-based classification, offers further opportunities for securing intellectual property. While the device leverages open-source frameworks for development, our innovations in sensor design, biomarker separation, and data analysis represent significant contributions to the field and merit IP protection. Securing patents will not only safeguard our work but also position the device for commercialization and competitive differentiation in the market.

F. Market Assumptions Methodology

Our financial projections are built on a comprehensive market analysis model that accounts for both global trends and regional variations in healthcare access. We began with foundational market drivers:

- Global population growth rate of 0.8% annually
- 40% of global population without access to diagnostic healthcare
- Baseline 1.0% improvement in diagnostic access due to non-Aeris solutions

We then developed region-specific adoption models based on demographic and healthcare infrastructure data (Appendix B):

- Africa: Represents 18% of world population with 45% lacking diagnostic access. Our model targets 5% of needed facilities with 1 device per facility and 8% annual growth in patients served. We project delivery of 20% of needed devices initially as we establish presence in this high-need market [17].
- Asia: Comprises 59% of world population with 45% lacking diagnostic access [18]. We target 8% of needed facilities with 1 device per facility and 8% annual growth in service capacity. Our projections include 15% of needed devices delivered due to infrastructure constraints.
- North America: Contains 8% of world population with 20% lacking diagnostic access [19]. We target 15% of needed facilities, reflecting better existing infrastructure, with 10% annual growth in patients served and 50% of needed devices delivered due to stronger adoption capacity.
- Europe: Represents 9% of world population with only 4% lacking diagnostic access. We target 15% of needed facilities with 5% annual growth in service capacity and 50% of needed devices delivered.
- South America and Oceania: Account for 5% and 1% of world population respectively, with targeted device delivery rates of 20% and 50% reflecting the different infrastructure capabilities.

These regional parameters drive our year-by-year projections of facility growth, patient access, and device sales, with a 2-year timeline for regulatory approval across markets.

G. Market Penetration Strategy

Our regional growth strategy accounts for varying market conditions:

- North America and EU/Oceania: Higher revenue potential with premium pricing and developed healthcare systems
- Asia: Priced with slight premium, accounting for regional differences within Asia for healthcare accessibility
- Africa and South America: Slower market entry due to less developed healthcare system, priced without premium to maximize accessibility.

H. Revenue Projections

Aeris operates with a dual revenue stream business model based on upfront device sales and recurring cartridge usage. Our devices cost $21,500 (inclusive of cost per sensor, cost per GC, and cost for delivery and installation) and are priced differently based on the region of sale.

- In North America, we predict a 100% revenue premium to initial cost.
- In the EU/Oceania, we predict a 100% revenue premium to initial cost.
- In Asia, we predict a 75% revenue premium to initial cost.
- In South America, we predict a 0% revenue premium to initial cost.
- In Africa, we predict a 0% revenue premium to initial cost.

Despite negligible revenue premiums in several key markets, Aeris's long-term recurring revenue from disposable cartridges priced at $0.50 each provides an efficient razor-and-blade approach to maximize accessibility while building sustainable revenue growth over time.

I. . *Cost Structure*

Our cost analysis reveals the following breakdown per device:

- Sensor components: $1,200
- Gas chromatography unit: $20,000
- Delivery and installation: $300
- **Total Cost: $21,500**

The significant investment in the gas chromatography technology is essential to maintain clinical-grade accuracy. However, with in-house manufacturing, there is significant potential to reduce costs in coming years while maintaining diagnostic accuracy, ultimately facilitating an even more accessible technology.

K. Operational Expenses

Staffing projections include [20]:

- 10 marketing employees ($60k/year each)
- 2 management personnel ($150k/year each)
- 10 technicians ($85k/year each)
- 4 business development specialists ($60/year each)

These staffing levels were calibrated to support our initial market penetration while maintaining a lean operational structure and enabling rapid scalability of our business. We allocate 15% of revenue to ongoing R&D, 12% to working capital, and 10% to capital expenditures, with 3% annual depreciation of CapEx [21, 22, 23]. These assumptions were made by examining previously performed holistic industry analyses of MedTech, Biotech, and Pharmaceutical companies and utilizing the assumptions that best aligns with Aeris' business model. Together, these analyses were used to construct a projected Income Statement for Aeris (Appendix C).

J. Cost of Capital

The cost of equity was determined by collecting financial information on 5 Aeris comps: Delcath Systems, Inc., Sensus Healthcare, Inc., Pro-Dex, AngioDynamics, and KORU Medical Systems, Inc. The median beta was determined as 0.85 (the Beta for Delcath) and was subsequently unlevered with Delcath's financial structure and relevered with the proposed Aeris structure of 100% equity. The 100% equity assumption, though limiting some Aeris value through debt financing for projects and additional interest tax shields, was employed to provide a fundamental valuation of the company's operations. Given that the NPV of the project was still positive over a range of discount rates excluding the cost of debt which often lowers the WACC, choosing to make the 100% equity assumption provided a reasonable valuation for investors and reaffirmed our confidence in Aeris. Ultimately, the cost of equity for Aeris, which was equivalent to WACC, came to 9.34% (Appendix D).

K. Valuation Output

Our DCF (Appendix E) yields an NPV of $$66,380,764.32 using a WACC of 9.34%. The valuation output is driven primarily on the following assumptions:

- Comparable company analysis using medical device firms including Delcath Systems, Sensus Healthcare, Pro-Dex, AngioDynamics, and KORU Medical Systems (median Beta of 0.85)
- 30-year risk-free rate of 4.74%
- Market risk premium of 5.5%
- Industry-appropriate D/V ratio of 0% with 100% equity financing
- Marginal tax rate of 21%

The substantially positive NPV demonstrates the compelling return potential on the proposed $7M investment, with positive cash flows expected as early as year 4. The valuation was sensitized on a range of WACC values to account for the potential variation in a debt-financing scenario, or in case the cost of equity was higher or lower than anticipated:

WACC				
6.00%	8.00%	10.00%	12.00%	14.00%
$100,790,772	$78,445,926	$61,171,041	$47,672,239	$37,018,783

Additional sensitivities on market sizing were performed on the valuation to reaffirm confidence in Aeris' ability to blend profit and purpose by delivering an NPV positive project that greatly increases global diagnostic access.

Sensitivity - Revenue Premium in NA vs. Revenue Premium in EU/Oceania and Implied Valuation from DCF

Revenue Premium in EU/Oceania	Revenue Premium in NA: 80%	90%	100%	110%	120%
80%	$ 58,493,706	$ 60,066,449	$ 61,639,192	$ 63,211,935	$ 64,784,678
90%	$ 60,864,492	$ 62,437,235	$ 64,009,978	$ 65,582,721	$ 67,155,464
100%	$ 63,235,278	$ 64,808,021	$ 66,380,764	$ 67,953,507	$ 69,526,250
110%	$ 65,606,064	$ 67,178,807	$ 68,751,550	$ 70,324,293	$ 71,897,036
120%	$ 67,976,850	$ 69,549,593	$ 71,122,336	$ 72,695,079	$ 74,267,822

Sensitivity - % of Needed Devices Delivered in Asia vs. % of Needed Devices Delivered in Africa and Implied Valuation from DCF

% of Needed Devices Delivered in Asia	% of Needed Devices Delivered in Africa: 16%	18%	20%	22%	24%
11%	$ 51,282,634	$ 50,952,720	$ 50,668,496	$ 50,421,472	$ 50,205,001
13%	$ 59,799,694	$ 59,469,780	$ 59,185,556	$ 58,938,531	$ 58,722,061
15%	$ 66,994,902	$ 66,664,988	$ 66,380,764	$ 66,133,740	$ 65,917,269
17%	$ 73,125,653	$ 72,795,739	$ 72,511,515	$ 72,264,491	$ 72,048,020
19%	$ 78,393,819	$ 78,063,905	$ 77,779,682	$ 77,532,657	$ 77,316,186

Sensitivity - Growth in % Served Per Facility in NA vs. % of Needed Devices Delivered in NA and Implied Valuation from DCF

% of Needed Devices Delivered in NA	Growth in % Served Per Facility in NA: 0%	5%	10%	15%	20%
40%	$ 70,968,696	$ 67,882,441	$ 65,998,971	$ 64,770,706	$ 63,923,327
45%	$ 71,339,681	$ 68,148,862	$ 66,207,808	$ 64,945,106	$ 64,075,557
50%	$ 71,648,375	$ 68,369,783	$ 66,380,764	$ 65,089,532	$ 64,201,678
55%	$ 71,909,245	$ 68,555,976	$ 66,526,409	$ 65,211,161	$ 64,307,936
60%	$ 72,132,603	$ 68,715,052	$ 66,650,766	$ 65,315,029	$ 64,398,711

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