Cook Engineering Design Center at Dartmouth

Proposal

Submitted in partial fulfillment of the requirements for

Engineering Design Methodology and Project Initiation

Novel End-Tidal Carbon Dioxide Monitoring Device

November 26, 2024

Sponsored by

Christopher A. Yen, MD

Project Team 24

Achla Gandhi

Hayden Barry

Zihao Yuan

James Dodge

Faculty Advisor

Kimberley Samkoe

DARTMOUTH ENGINEERING

Table of Contents

Executive Summary

Significance

When breathing stops, people are intubated and given breaths manually by a healthcare provider. However, 25% of field intubations are misplaced, which can lead to hyperventilation or transient hypoxia [1]. Both of these complications put patients at risk for organ damage. End tidal CO_2 ($EtCO_2$), the air released at the end of the breath, effectively reflects a patient's respiratory and circulatory status so it is useful for ongoing monitoring of a patient's wellbeing. $EtCO_2$ is typically measured with expensive and delicate digital capnographs to ensure intubations are placed properly and the correct amount of air is being given. However, these devices cannot be used in austere military environments, in which noises and lights produced could alert an enemy, and where finding batteries and treating the device with the care required for it not to not break are not options; in developing countries, where hospitals do not have resources to buy expensive digital capnographs; and in emergency environments where a medic with less training is doing the intubation. While there are pH-based colorimetric $EtCO_2$ monitors in the market that aim to fill the gap, these devices fall short in providing critical life-saving information. Such devices use a chemical reaction to indicate the presence of $EtCO_2$ (thereby indicating if intubation has been placed correctly), but offer a limited indication of relative CO_2 levels and fail to communicate if the $EtCO_2$ is within a healthy range, rather than dangerous hypo- or hypoxic ranges.

Objective

Considering the accessibility of $EtCO_2$ monitors that provide critical life-saving information, there is a gap in the market for measuring $EtCO_2$ in a useful and easy way. This gap informs the problem that we intend to address in our project: ***There is no affordable, analog, and durable device to continuously monitor patient $EtCO_2$ levels and display them in medically relevant ranges to medical personnel working in various unstable and rural environments.***

Innovation

Our device will overcome the shortcoming of the binary CO_2-presence detecting devices by using two different chemical indicators with pKa's set to the upper and lower ends of the healthy range of $EtCO_2$. When used in tangent, they will not only indicate if a tube has been placed correctly, but also if medical personnel are ventilating at a healthy rate, which is not achievable by other analog devices on the market.

Approach

Using procedures described in literature, two CO_2 sensitive strips that change color at 35 and 45 mmHg partial pressure of CO_2 respectively will be made. Placing these two detectors beside each other creates a display with three outputs: over ventilation (no color change, CO_2 below 35 mmHg), correct ventilation (one deceive changes color, C_22 between 35-45 mmHg), and under ventilation (two devices change color, CO_2 above 45 mmHg). To test and validate our design, a breathing simulator that can simulate hyperventilation, correct ventilation, underventilation, and no ventilation will be constructed and used. To hold our CO_2-sensitive strips, a clear housing that joins with intubation tubing will be constructed.

Impact

This device would improve the quality of care for those in environments where highly technical devices, like digital capnographs, cannot be used. It would reduce the 25% of field intubations misplaced, 13.4% of patients who received hyperventilation, and 57% of patients who experienced transient hypoxia [1, 2].

Problem Definition and Value

Significance and Problem Statement:

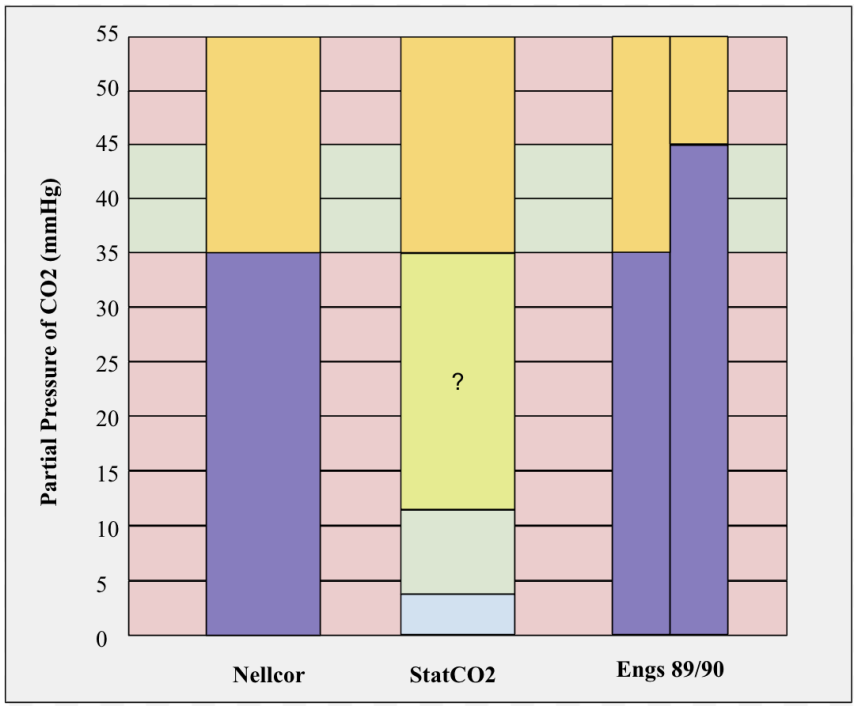
End-tidal carbon dioxide ($EtCO_2$) is the carbon dioxide released at the end of a breath. More specifically it is the amount of carbon dioxide carried by the blood to the lungs and then exhaled out of the body. As such, it is used to assess pulmonary blood flow and cardiac health. In fieldwork, it is also used to assess the success of airway and breathing intervention procedures such as endotracheal intubation. Since $EtCO_2$ effectively reflects a patient's respiratory and circulatory status it is also useful for the ongoing monitoring of a patient's wellbeing.

The healthy range for $EtCO_2$ is 35 to 45 mmHg [3]. A reading of 0 $EtCO_2$ indicates that the airway tube was put down the esophagus rather than the trachea. If the reading is below 35 mmHg, it indicates hyperventilation; conversely, an $EtCO_2$ above 45 mmHg indicates hypoventilation. In both cases, the patient is at risk of serious organ damage. Thus, when delivering air to a patient it is important to ensure that $EtCO_2$ remains within the healthy range.

The most common method of $EtCO_2$ measurement is a digital capnograph which displays a patient's $EtCO_2$ both quantitatively and as a wave. Due to its high sensitivity, accuracy, and ease of use it is considered the gold standard for measuring $EtCO_2$ in hospital settings. However, in rural or unstable environments such as military camps, digital capnography is inaccessible due to its price, size, and reliance on battery or electric power.

The lack of access to accurate $EtCO_2$ measuring methods is reflected in on-field statistics. 25% of intubations done by field EMTs are misplaced and 13% of the misplaced intubations go completely unrecognized until the hospital is reached[1,2]. In-field airway interventions are generally high-stress procedures. Medical personnel are fueled by adrenaline and may over-aggressively ventilate. As a result, of the intubations placed correctly, 13.4% of patients received hyperventilation [1]. This percentage decreased to 5.6% when providers were given digital capnography to monitor ventilation [1].

In light of this, it is clear that there is no affordable, analog, and durable device to continuously monitor patient $EtCO_2$ levels and display them in medically relevant ranges to medical personnel working in various unstable and rural environments. The lack of such a device presents a gap in the market that we intend on addressing in our project.



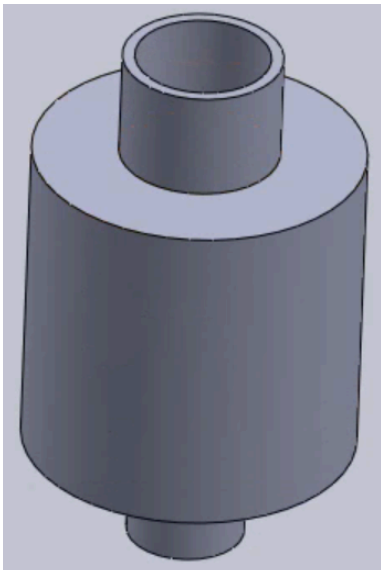


Figure 1. (Left) Color Response to partial pressure of CO_2 of State of the Art colorimetric detectors and our device. Nellcor and StatCO2 color change pressures were determined from the devices' label and cross-checked against the product manuals [4,5]. CO_2 levels outside of the healthy $EtCO_2$ levels are marked in red (0-35 mmHg, >45 mmHg) and within the healthy range in green (35-45 mmHg). The '?' labeled portion of the StatCO2 results from this range of CO_2 not appearing on the display. In the manual, this is labeled as 'yellow-green', marking the transition from ~12 mmHg to 35 mmHg.
Figure 2. (Right) Initial Computer-Aided Design for final "looks like" model of form factor case.

Value Proposition:

While there are already pH-based colorimetric $EtCO_2$ monitors that aim to fill the gap in the market left by digital capnography, these devices fall short of providing critical life-saving information. Such devices use a chemical reaction to indicate the presence of $EtCO_2$ (thereby indicating whether intubation has been placed correctly), but they offer a limited indication of relative CO_2 levels and fail to communicate if the patient's $EtCO_2$ level is within a healthy range. Given the prevalence of accidental hyperventilation in on-field intubations, this is a serious shortcoming.

Our device would overcome this shortcoming by using two different chemical indicators with pKa's set to the upper and lower ends of the healthy range of $EtCO_2$. When used in tangent to each other, they will not only indicate if a tube has been placed correctly but also if the medical personnel is ventilating at a healthy rate.

In defining the user of our device, it is important to consider both the medical personnel employing the device in fieldwork and the potential purchaser of our product. In terms of the device purchaser, our intended targets will be emergency response organizations, medical aid organizations, and military medical departments. The users in all of these cases will be certified medical professionals, specifically

front-line workers who are removed from the resources and power source that a hospital environment can provide. Our device will be much cheaper than the EMMA Capnograph, the only competitor that provides the same information our product will be providing. While EMMA does provide more information (ten markers), it is digital, and our device will provide a more quantitative measure of $EtCO_2$ (three markers) than the current analog options (one marker) when digital capnography is not possible. Furthermore, our group is dedicated to providing a device suitable for use in chaotic, suboptimal environments where respiratory therapy must be administered without the luxury of a controlled environment of a quiet, orderly operating room. Given these aims, our device's affordability and functionality will allow it to compete in the $EtCO_2$ monitor market.

Our product when completed will help medical personnel save more lives on-field. That being said, there are several risks we will have to mitigate prior to putting it into the hands of emergency responders. The main risk to mitigate would be ensuring that the chemicals we use in our product are biocompatible and would not interfere with the patient's airway system. Since this device would be FDA regulated there will be rigorous testing done down the line to ensure this is the case.

B. Technical Plan

Technical objectives

Table 1: Technical Objectives

Significance (in order)	Specification	Explanation	Metric of Success (ENGS 90)
1.	Safe	Must not cause an immune response or other adverse physiological reaction to the patient or caregiver	The product must have chemicals that are safe in the concentrations used, and/or completely separate toxic chemicals from inhalation with a filter. The user must not be able to touch the active chemical surface at any point in operation
2.	Non-binary Display	Must colorimetrically display the three levels of CO_2 presence	Sensitive, quick, and obvious indication of patient's $EtCO_2$ ranges of low (<35 mmHg), normal (35-45 mmHg), and high (>45 mmHg)
3.	Integratable	Must be able to be used seamlessly with existing endotracheal intubation equipment	Solution diameters match male-female joints in existing endotracheal intubation equipment without air leakage
4.	Intuitive	Must be easy to use in high-stress situations	Must be deployable in under ten minutes with minimal training required

5.	Continuous	Must continuously provide $EtCO_2$ measurements	Continuously provides patien ts $EtCO_2$ measurements for at least 2 hours
6.	Durable	Must be used in suboptimal environments	Material is resistant to dust, water, temperature, humidity, and the crushing force of a full military backpack (35lbs)
7.	Affordable	Must have competitive pricing with state-of-the-art technology	The solution is shown by economic analysis to be able to be under fifty dollars in full-scale production

Innovation

While creating a colorimetric CO_2-sensitive device using pH dyes is a well-understood and documented process, our innovation is specifically in applying the technology. Current state-of-the-art technology for pH-dependent CO_2-sensitive devices display a color change at one partial pressure of CO_2 (as in Nellcor), or attempt to display a range of CO_2 partial pressures by 'decoding' dye color transition (as in StatCO2). While both these devices successfully indicate correct intubation, information on correct ventilation is missing (for Nellcor) or difficult to interpret and missing information (for StatCO2).

Our device utilizes two CO_2-sensitive strips with color changes at 35 and 45mmHg CO_2, respectively. With the strip sensitive to 35 mmHg CO_2, our device will be able to determine correct intubation, as the color change will occur between the below 35mmHg CO_2 on inhalation and above 35mmHg CO_2 on exhalation. This matches the modality of the current devices on the market. With the addition of the second CO_2-sensitive strip, we expand the use of our device to two new uses. By observing the colors on the CO_2-sensitive strips, a user will be able to determine if the rate of ventilation is resulting in over-ventilation (CO_2 too low, no color change on either strip) or under ventilation (Too much CO_2 above 45 mmHg CO_2, both strips change color).

Our device will detect correct intubation and thus match the modality of the current colorimetric devices. At the same time, the ability to determine hyperventilation or hypoventilation expands our device's capability beyond those of the Nellcor and the StatCO2 monitors.

Approach and Methodology

1. Acquisition of Materials and Expertise (24F)

To begin our work, we prepared by acquiring reagents, training, and experimental spaces. To prepare for our chemical work, we have found an appropriate lab space with a fume hood, fire cabinets, pH meters, air supply, and traditional chemical laboratory safety equipment such as an emergency eye wash, shower, and fire extinguishers. Additionally, all members of the team have acquired the necessary Thayer safety training regarding chemical lab spaces. Lastly, our team treasurer, Zihao, has purchased or acquired from Thayer all chemical reagents as well as materials for the Airstream Simulation testbed. This phase prepared us for our work by ensuring that when our materials arrive, we will have all the necessary resources and training to begin working at the beginning of 24W.

2. Initial Chemical Design

Hayden and James' chemistry team will focus on creating initial $EtCO_2$-sensitive test strips. Using previous work from the 2023/24 $EtCO_2$ group, papers [6,7,8], and patents [9,10,11] , they will construct devices consisting of a poly(oxyethylene) based compound, a pH-sensitive indicator dye, an organic solvent, a cationic phase transfer agent, and an anionic base.

Table 2: Potential Reagents for the Initial Creation of Test Strips. For a list of literature reagents [9], see A.5

Poly(oxyethylene) based compound	**pH Dye**	**Organic Solvents**	**Cationic Phase Transfer Agent**	**Anionic Base**
Triton X-15 Octylphenol ethoxylate	M-cresol purple	Methanol	Methyltricaprylylammonium	Phenoxide trihydrate
TDA-15 polyoxyethylene	Thymol Blue	Ethanol	Tetrabutylammonium	Hydroxide
Polyethylene glycol	Phenol red	Propanol	Tetraoctylammonium	Tert-butoxide

The scheme for constructing a CO_2-sensitive marker is as follows: cationic phase transfer agent and anionic base are combined in a separatory funnel [9]. The aqueous phase is separated, and then the organic layer is washed an additional two times with water to ensure the isolation of the cationic phase transfer agent-anionic base isolation [9]. A pH dye is added to the solution, mixed, then a poly(oxyethylene) based compound is added and mixed well [9]. A desired test strip (such as a cotton ball) is dipped into the solution, then allowed to air dry. The concentration of reagents and procedure examples are found in "Rapid-response reversible dry surface CO2 detector", and example procedures can be found in A.6 [9].

Initially, the chemistry team will focus on using Triton X-15 octylphenol ethoxylate, M-cresol purple, methanol, Methyltricaprylylammonium, and Phenoxide trihydrate. These compounds have been selected for their demonstrated color changes faster than the rate of breathing, highly humidity resistance, and long active life (>24hrs) [9]. As a quick qualitative test, the chemistry team will exhale over the resultant $EtCO_2$ strips (through a straw to keep the head out of the fume hood) to see if a color change occurs. If the initial construction succeeds, we will continue with the reagents used. If unsuccessful, we will troubleshoot our reagents in the following order:

1. Vary the anionic base concentration.
    a. It is possible to create a false negative in our initial design, where the device does detect CO_2, but at a higher concentration than human breath reaches. If this is the case, then decreasing the amount of anionic base in our device will decrease the concentration of CO_2 at which color change is observed. This works because our base competes with our dye for available protons. When the dye receives a proton, it changes its color. For our purposes, when the base receives a proton, it hoards it from the dye preventing color

change. By decreasing the amount of base, we increase concentration of protons available to our dye at the same CO_2 concentration, lowering the color change concentration. In this we take advantage of Le Chatelier's principle.

b. It is also possible that we create a test strip stuck in the protonated form of the dye, which is the color of the dye corresponding to a high concentration of CO_2 in a working device. If we observe our device in the 'high concentration' color at ambient CO_2 pressures, we will increase the amount of anionic base to raise the CO_2 concentration at which color change occurs.

2. Vary the concentration of Dye
    a. It is possible to create a device that appears insensitive to CO_2 due to the concentration of Dye being too low. If this is the case, we can expect our device to be colorless. If we observe this result, we will double the concentration of dye used.
3. Vary Reagents
    a. We expect one of the two solutions above to work, as our procedure is well documented [9]. If the above solutions do not work, however, we will begin by changing one reagent at a time. We will begin with changing the anionic base used, keeping all other reagents fixed. First, a device with hydroxide will be produced and evaluated. The above two troubleshooting principles will be addressed. If no result, Tert-butoxide will be used instead of hydroxide and troubleshooted. If changing the base does not work, we will return to using Phenoxide trihydrate as the anionic base and vary the cationic phase transfer agents. The procedure will mirror that for the anionic base. In sum, We troubleshoot these reagents first, as they are responsible for the swift color change we expect. If we do not experience swift color change, the cationic phase transfer agent and anionic base are the best places to examine. If changing the anionic base or cationic phase transfer agent does not work, we will change our Poly(oxyethylene) based compound and experiment in the same manner as described.
4. We anticipate that a successful CO_2 sensitive composition will be found. However, in the unlikely case where no composition is found to change color at the relevant CO_2 ranges, we will meet with our sponsor to convey our experimental results and next steps to scope our work appropriately. Since we anticipate procedural errors to be an important impediment to finding the desired composition, we will thoroughly document the amount of components used in each experimental trial and the corresponding result to minimize or eliminate procedural errors. In any case, we will keep our experimental data organized for analysis and potential adjustments to our chemistry design.

When a successful CO_2 sensitive composition is shown, the dye reagent will be varied across the three described in table 2. We do this to test which dye will have, qualitatively, the most visible color change. The result of this work will be a CO_2 sensitive device that changes color at an unspecified partial pressure of CO_2 within normal human breathing range. To tune this color change to correspond to the low and high thresholds of healthy CO_2 pressures, the chemistry team will work with the Airway Simulation Testbed (described in 3. Airway Simulation testbed). The Airway simulation testbed will indicate to the chemistry team what exact pressure of CO_2 induces a color change on the prototype device. From this, the chemistry team can increase the amount of anionic base to increase the partial pressure of CO_2 required to induce color change, or decrease the amount of anionic base to decrease the partial pressure of CO_2 required for

color change. The amount of anionic base will be iterated over until two strips are produced that induce color change at 35 mmHg and 45 mmHg partial pressure of CO_2 respectively.

3. Airway Simulation Testbed

Engs 89 Progress

Over the course of the engs89, we remodeled the Airway Simulation System that was inherited from Team 09-675. Figure 3 below displays both the previous model and our redesigned version of it.

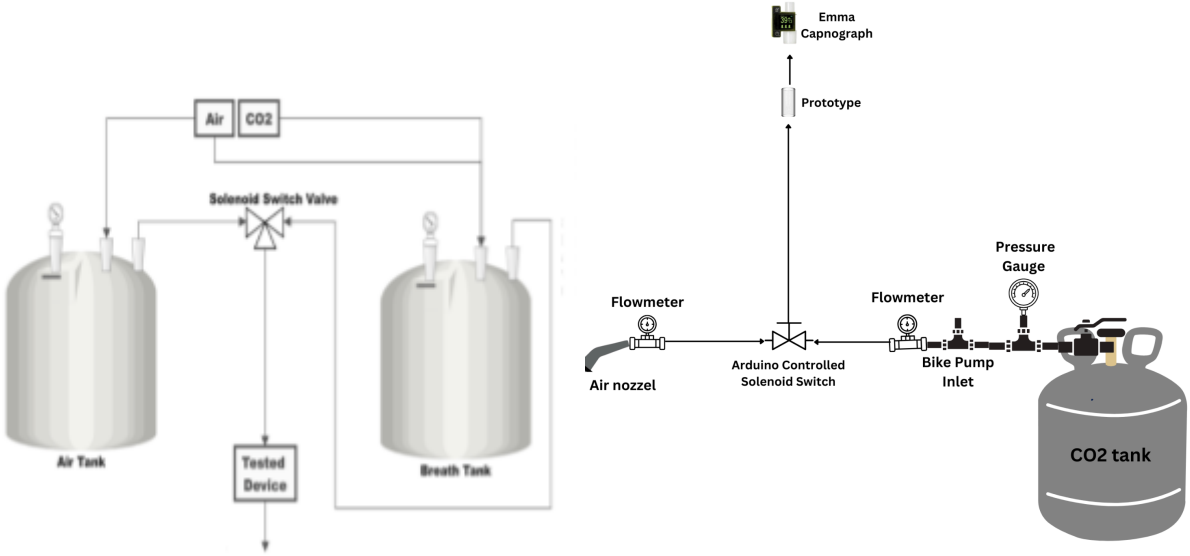


Figure 3. Color Response to partial pressure of CO_2 of State of the Art colorimetric detectors and our device.

As seen in the images, we have forgone the air tank in favor of simply using the air nozzles available in the fluid's lab and a flowmeter to control the flow. By removing the air tank we are decreasing the room for error and increasing the efficiency of the testing process as there will be one less tank to fill. In addition to removing the air tank, we have opted to put our inlets and outlets in series rather than in parallel as it was in the previous model. This is beneficial because instead of drilling three holes into our tank we will only need to drill one. By doing this we will maintain more of the structural integrity of the tank, thus allowing us to fill the tank to a higher pressure.

Once we modeled our system we began building it with the help of Raina White and Daniel DeNauw. We have fully assembled our CO_2 tank and it was able to hold 60 psi of pressure. Below is a figure of the assembly.

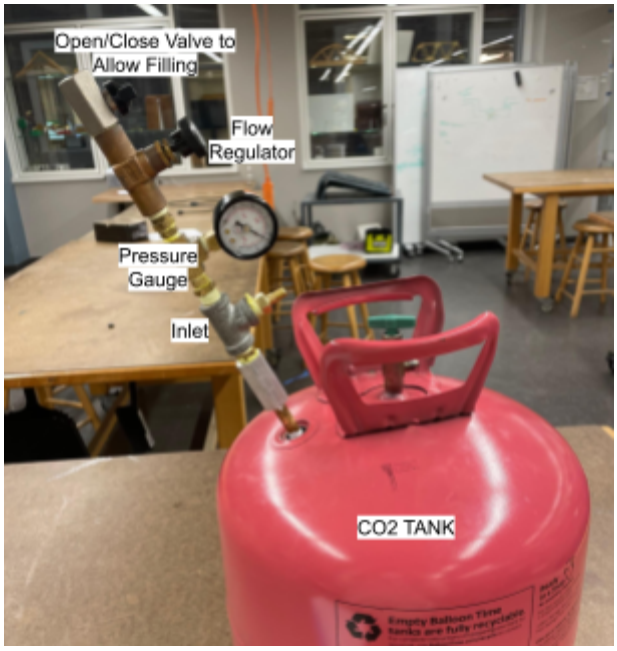


Figure 4: Current Assembly of CO_2 Tank. In this image, it is holding 45 psi of Air.

Engs 90 Plan

In the first two weeks of the winter, we will continue to focus on assembling the fully functional testing device. The actual assembly of the rest of the rig is expected to be fairly low risk. It involves adding tubing and a solenoid switch controlled by an Arduino. We are already in possession of most of the materials needed for this including the code for the Arduino used by the previous group.

Our plan to vary the level of CO_2 in the breathing simulator is to fill the CO_2 tank to different partial pressures of CO_2 for each cycle. The equations we will be referring to are seen below.

CO_2 Input Equation:

$$\frac{(0.0004*T+C)}{(T+C)} = \frac{ETCO2}{A}$$

Equation 1: *CO_2 Input Equation where T is the pressure of air added to the tank, C is the pressure of pure CO_2 added to the tank, $EtCO_2$ is the desired partial pressure of CO_2, and A is atmospheric pressure (0.0004*T indicates CO_2 in atmospheric air)*

Once we have fully assembled the testing rig we will test the accuracy of our CO_2 levels by attaching an EMMA capnograph to the end of our assembly and seeing if the output of the capnograph matches the intended partial pressure of CO_2. Specifically, we will test CO2 partial pressures from the range of 0 to 50 mmHg. In our testing we will move up in increments of 10 mmHg. We will test each partial pressure three times and then record the mean and standard deviation of the output.

After rigorously confirming that the testing rig is giving accurate and consistent outputs of CO_2 and air we can begin using it to test initial prototypes. Simultaneously we will be working on ways to modulate the humidity of the testing environment so that in later prototyping we can test various humidity levels on our device.

4. Testing our Design and Iteration

With the Airway simulation testbed and the initial CO_2 detecting prototype completed, we integrate both projects together and test our device to bring it within our technical objectives. We will use digital color analysis to determine the pH range of color change with MATLAB code. This code will compare photos of solution at various pHs to a standard color chart to give quantitative data on color change. With these results, the chemistry team will tune the amount of anionic base to create accurate color changes at 35 and 45 mmHg CO_2, respectively. With the information on specificity gained, the chemistry team will be able to widen the color change window (the range of CO_2 pressure between all pH sensitive dye being in the unprotonated form to being in the protonated form) by increasing the concentration of dye, cationic phase transfer agent, and anionic base equally. Conversely, the chemistry team will be able to narrow the color change window by decreasing the concentration of dye, cationic phase transfer agent, and anionic base equally. By raising or lowering the concentration of these reagents in comparison to a constant concentration of CO_2, we take advantage of Le Chatelier's principle to obtain the results described above. Additionally, the chemistry team will tune the CO_2 concentration that induces color change on our device by modifying the concentration of anionic base, As described above in section 2. At this point, we will also iterate over the casing, ensuring the results of the test strips are visible and easy to read.

It must be noted the color change window may be too large to clearly display the desired 35-45 mmHg CO_2 partial pressure range. In effect, both CO_2 strips are too ‘muddied’ in a state between one color and the other in our range. To solve this, the chemistry team may decrease the color change point of the 35 mmHg CO_2 partial pressure and increase the color change point of the 45 mmHg CO_2 partial pressure, to move the ‘muddied’ color region outside of the critical 35-45 mmHg CO_2 partial pressure region. This will be accomplished by the same method described in 2 to change the CO_2 partial pressure response point of a device.

5. Final Design and Testing

In the final part of our project, we want to take our best prototype and characterize it. We will use the Airstream Simulation testbed to test our test device. Key experiments will be observing the response of test strips to CO_2 partial pressure, humidity, and user experience. To find the response to CO_2, the partial pressure of CO_2 will be varied, and the colorimetric response will be filmed. This film will be analyzed with digital color software to find the sensitivity of our dye and the speed of color change. Similarly, the humidity will be varied, and the device's response will be filmed and analyzed using digital color software to understand the effect of moisture on the sensitivity and speed of color change. Lastly, a user experience test will be performed by giving our device to people not involved in the project and observing their interactions. Using a survey response, we will better understand if our device is intuitive, easy to use, and easy to understand.

Key personnel

To address each concern and constraint identified in the previous sections, our group has compartmentalized ownership of certain aspects of this multidisciplinary project to different key personnel which align with the breadth of our experiences and previous coursework. James has a background in biochemistry as well as biomedical engineering, and previous research on bioelectronic neuroimplants, biomaterials, and biochemistry. Hayden has a background in chemical engineering and

materials science with knowledge in fluid mechanics and research in material characteristic modification via crystalline matrix impurity additions. Achla has a background in biomedical engineering with a concentration in protein engineering, has worked in a protein engineering lab, and has expertise in drug discovery and vaccine development. Zihao has a background in biomedical engineering with a concentration in mechanical engineering. As a whole, our group has vast chemical experience in organic, physical, inorganic, and general chemistry, which will play a significant role in identifying and creating pH-tuned dyes for our project. James' strong background in biochemistry allows him to take charge of the chemistry aspect of the project and identify the pH-tuned dyes, with support from Hayden's materials science background to create a durable paper to host the dyes in the form factor case. Because of his mechanical experience, Zihao will head the design of the form factor case, with support from Hayden's fluid mechanical experience. Achla will be primarily responsible for creating our Airstream Simulation testbed so we can systematically test and ensure the effectiveness of our device and dyes.

Consultants and supporting staff

We acknowledge that we do not have all the expertise necessary, and are actively working with Daniel DeNauw at the Thayer MShop, Raina White, and Tad Truex for help constructing our Airstream Simulation testbed. We will eventually also work with Daniel DeNauw to create the form factor device so it is airtight and unaffected by outside humidity. Furthermore, we have worked with Prof. Colin Meyer for fluidic analysis expertise regarding airflow through the device and will continue to do so to tune the form factor to the specifications of the device. Prof. Kimberley Samkoe has been working with us regarding chemistry-, colorimetric-, and pH-specific inquiries. Our sponsor, Dr. Christopher Yen, MD, is available for frequent feedback regarding medical devices and critical-care medicine. We are also working with Molly Carpenter regarding our lab space (ECSC 143) and acquisition of chemicals, as well as Mary Kay Brown for ordering chemicals. Other key personnel include various stakeholders, such as Brooke Judd, M.D. (Sleep Medicine Physician, DHMC), Matt Fulton and Allison Pitman (Dartmouth Ski Patrol), Sigrid Tantillo (VT National Guard Captain), and Juli Hobbs, M.D. (Anesthesiologist, Touching Hands).

Management plan

To ensure we achieve the deliverables we have outlined and make sure we are on track, there will be a strict organizational structure for making decisions on project direction and resolving conflicts. At the very beginning of the term, we will fill in the weekly schedule for the entire term with rough completion dates for each deliverable. Every week on Tuesday during our registered 10A period, we will have a weekly action meeting to discuss what was completed the week prior and what must be completed in the upcoming week(s), as well as if we are on track to complete the deliverables. By consistently reviewing what is to be done in the future, deliverables will not sneak up on us, and we will be able to adjust timelines if necessary. During this time, risks will also be discussed to ensure we have a solution for mitigating them. In the sure event that important decisions must be made, discussion will be had until we reach a consensus. If a consensus cannot be reached within the 10A time period, we will schedule a meeting with Prof. Samkoe to get her expert opinion and then take a majority-rules vote, with Prof. Samkoe as a tie-breaker if necessary. The same process will be followed for resolving conflicts. As project manager, Hayden will be responsible for booking meeting spaces and scheduling meetings outside of the 10A time period. Similarly, she will lead the weekly action meeting to ensure the deliverables for each forthcoming week, as well as risks, are addressed. Hayden also plans to read "Risk Up Front:

Managing Projects in a Complex World" by Adam Josephs and Brad Rubenstein over the break to gain further insight into management techniques that may be incorporated in the winter term. As treasurer, Zihao will be in charge of ordering components for any testing, including chemicals for the pH indicators and parts for the Airstream Simulation testbed. Achla, as Sponsor Liaison, is taking the lead on communications with our sponsor and certain other consultants and supporting staff. Technical and scientific roles will follow the form as outlined in "Key Personnel".

Facilities and Equipment

To prepare for our chemical work, we have found an appropriate lab space in ECSC 143 with a fume hood, fire cabinets, pH meters, and traditional chemical laboratory safety equipment such as an emergency eye wash, shower, and fire extinguishers. This space is available to us through the end of 25W. To achieve the construction of our Airstream Simulation testbed, we are using the M-Shop and its equipment for mechanical prototyping as well as the Fluids Lab for airstream testing. Both of these spaces are available for use throughout 25W with communication with their advisor, Daniel DeNauw and Raina White, respectively. All spaces are in the Thayer cluster, giving good proximity for movement between lab spaces during testing.

Budget

The $1500 budget will be used on components for the Airstream Simulator testbed and on the chemicals for the dye-solvent identification. For the testbed, we plan to purchase pressure vessels, flowmeters, tubings, tube joint connectors, and electronic components including Arduino, solenoid valves, and relays. For the chemicals, we purchased dyes including phenol red, thymol blue, m-cresol purple; anionic bases including potassium hydroxide and sodium hydroxide; organic solvents including propanol, methanol, and ethanol; and plasticizers including triton x-100. To ensure we have enough budget for needed materials, we plan to borrow resources from Thayer such as pressure gauges in the fluid lab and left over materials from the previous group including Fluval CO_2 canisters. If we end up needing more than what our budget allows in the spring, we will apply for supplemental funding through our sponsor.

Timeline

Week	F8	F9	F10	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10
Team members obtain chemical safety training													
Purchase chemical reagents and components of breathing simulator													
Prototype casing for pH-dye strip													
Construct Airstream Simulation Test Bed													
Construct MATLAB color analysis code and set up													
Test Airstream Simulation Test Bed against technical requirments													
Construct Working CO2 sensitive test strips													
Construct first full prototype and test on the Airway Simulation Testbed													
Tune color change to 35 and 45 mmHg CO2 by varying amount of base													
Tune sensitivity of pH-sensor with transfer agents													
Test pH-sensor interaction with humidity													
Test ease of use for medical professtionals													
Construct the best prototype possible using our gained knowledge													
Test our prototype against our benchmarks from our preproposal													

Table 3: Timeline of project.

Desirability Plan and Consideration of the Broader Context

Stakeholder Engagement Process

Since our device is used in conjunction with the endotracheal tube, we consulted the 2023 endotracheal tube market report and decided on contacting the following professionals: emergency medical technicians, doctors, military medics, and hospital purchasers [12]. These professionals work in segments that hold a large share of the endotracheal tube market, and their works involve using or purchasing/distributing endotracheal tubes and related monitoring devices [12]. Our sponsor and advisors, through their connections, helped us to get in contact with these professionals. Specifically, we reached out to Brooke Judd, Physician, on hospital purchasing in DHMC; Matt Fulton and Allison Pitman, Dartmouth Ski Patrol, on wilderness medicine; Sigrid Tantillo, VT National Guard Captain, on combat related medicine; Larry Yost, Medical Technology Consultant, on business plans. To better understand regulatory requirements of our device, we talked with Sally Mansur and Kathy Phipps, clinical research managers at Dartmouth, on FDA regulations and processes. Talking to medical professionals helps us to validate our device's usefulness and inform design choices. On the other hand, talking to medical consultants and research managers help us to make better regulatory and marketing and partnership choices.

Societal Context Considerations

During our device prototyping process, it is important to consider the economic, environmental, and healthcare impact of our device, which provides continuous $EtCO_2$ measurements in rural areas, austere settings, and military environments, in place of a digital capnograph. While digital capnography is the gold standard for continuous $EtCO_2$ monitoring, in austere settings where access to medical infrastructure resources like electricity is limited, digital capnography is unsuitable because of its size and power requirements. Furthermore, many medical emergency responders and workers simply cannot afford digital capnography. As an Army Special Forces Medic puts it (Appendix A1), "it would be awesome to be able to track End Tidal CO_2 but the Army won't buy us EMMAs, we don't have enough money." As medical personnel in the military and in other forward medical settings often don't get to use digital capnographs because of their high expenses, our device provides a cost-effective solution, providing continuous monitoring capabilities at a cost comparable to that of state-of-the-art binary CO_2 detectors (ex. Nellcor).

Besides military and rural settings, our device contributes to improving the success rate of intubation treatments in low and middle income countries. Many countries in South Asia, South East Asia, and Sub-Saharan Africa lack essential medical resources, equipment, and skilled personnel for intubation, resulting in higher complication, morbidity, and mortality rates for patients with illnesses that require intubation in those regions [13]. Since intubation is placed in incidents of cardiac arrest, trauma, respiratory failure, and loss of consciousness, chronic respiratory diseases (CRDs) such as asthma, pneumonia and chronic obstructive pulmonary disease (COPD) often require intubation, for example when those diseases cause acute respiratory failure or respiratory distress. Significantly, the death rate of chronic respiratory diseases in 2021 estimated by the Institute of Health Metrics and Evaluation (IHME), a Lancet data collection and analysis program, is high in middle and low income countries located in South Asia, Southeast Asia, and Africa. The death rate of chronic respiratory diseases in India, for

example, is 133 per 100,000 individuals, 259% higher than that in the US, which is 37 per 100,000 individuals [14]. This difference in mortality rate between developed and low/middle income countries can be attributed to scarcity in critical and emergency care facilities and resources, but the social determinants of health (SDH), a term coined by sociologists and public health scientists, is another contributing factor. Since intubations are often placed for chronic illnesses, the demand for intubation and related medical operations is linked to broader socio-economic factors [15]. Social determinants of health such as income, education, working life conditions, job insecurity, housing, basic amenities and the environment, conditions in which people are born, grow, work, and live, contribute to the cases of chronic illnesses and thus the demand for intubation in low and middle income countries.

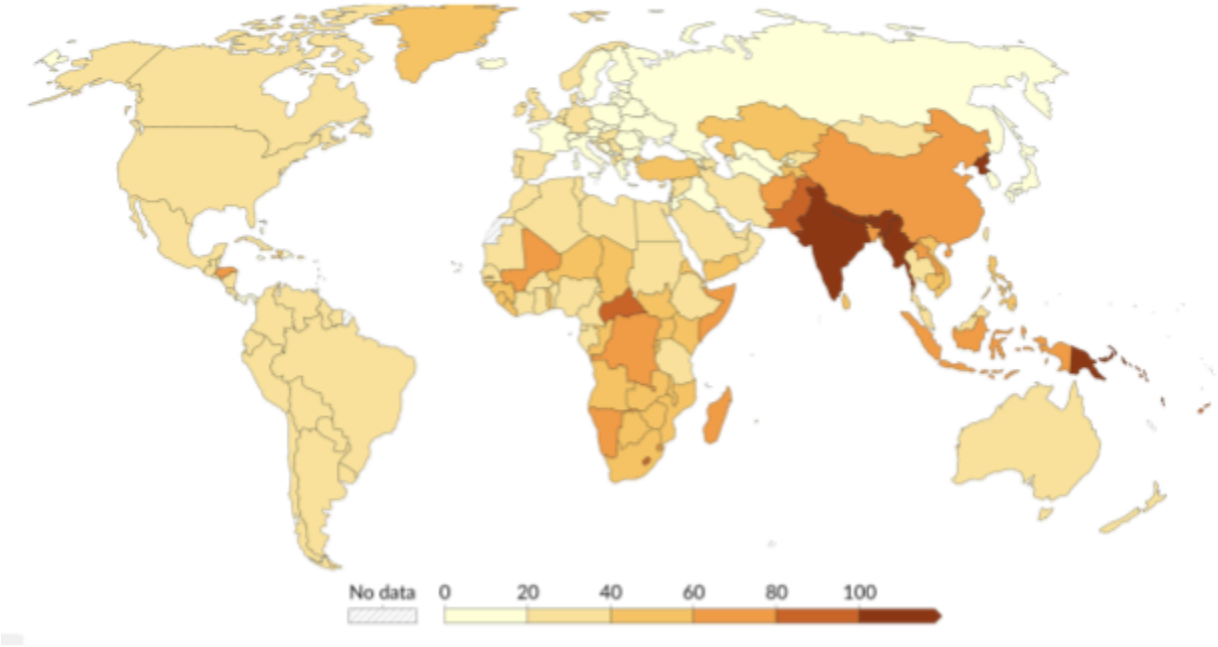


Figure 4. Chronic respiratory diseases death rate, 2021, IHME, Global Burden of Disease. Chronic respiratory diseases death rate is high in developing countries including India, Myanmar, and Papua New Guinea.

By designing and building an intuitive End Tidal CO_2 monitoring device that can continuously monitor the patient's status during intubation, our device will increase the success rate of intubation treatment, especially in low and middle income countries with limited intubation related medical supplies. Unlike operating rooms in developed countries, those in low and middle income countries lack digital capnographs that are the gold standard for monitoring a patient's ventilation status while intubated [16]. Our device alleviates these shortages of capnography compared to the high demand in these regions by achieving comparable monitoring capabilities of a patient's ventilation status, thereby improving perioperative and resuscitation outcomes. Furthermore, our device is cheap (aimed price of $40 compared to ~$1500 for a basic digital capnograph) and it has no electricity requirement, making it attractive to medical providers in resource limited regions [17]. Because of this, we believe our device will gain attention from medical providers, related government branches, and non-profit medical aid organizations working in developing countries. Unlike developed countries, many developing countries have lower investments on healthcare, resulting in the lack of funded health coverages and high out-of-pocket healthcare expenditures, placing health related financial burden on individuals [18]. Our device reduces

intubation-related financial burden for patients in these countries by partially meeting the unaddressed demands for digital capnography with a more affordable alternative. The World Federation of Societies of Anesthesiologists (WFSA) and the South African Society of Anesthesiologists (SASA) are relevant international medical aid organizations to contact regarding our product's value [19]. To expand usage of our device for delivering the demanded critical care in these countries, partnership with local grassroot medical aid organizations to facilitate allocation, distribution, and training for use of our device is needed. These international marketing activities will occur after gaining regulatory approval and demonstrating the device's safety and efficacy.

Finally, waste reduction is an important consideration during the design process. A 2018 Mayo Clinic survey reports that 20% or more of US medical waste consists of single-use plastic, illustrating the plastic's high contribution to environmental footprint [20]. When prototyping, we plan to identify opportunities for material reuse. Our product is likely single use as it comes into contact with the patient's bodily fluid, so we plan to abide by the US Environmental Protection Agency (EPA) disposal standards for medical wastes when disposing prototypes, and to state the proper disposal procedure in the user manual of the device [21].

Design for Inclusion:

Since our device detects End Tidal CO_2 levels via color changes, we anticipate no barrier for use of our device to people with different languages, cultural backgrounds, class, race, gender, and ethnicities. However, the colorimetric nature of our device means that we are excluding color-blind individuals from our user groups. One possible solution to address this issue is to design an accessory that is used in conjunction with our device that converts color output to visual, audio, or mechanical output indicative of the corresponding CO_2 levels.

To evaluate the intuitiveness of our product, we plan to recruit military medics, field EMTs, and wilderness medicine personnel to use our product on a medical training manikin, to evaluate the intuitiveness of the device and observe for harmful unintended usage of the device. Observing their usage as well as engaging in related interviews will help us to improve device design and to write a comprehensive user manual with intuitive instructions and relevant warning messages.

During our prototyping stage, accessibility is a significant consideration. Within the US, local healthcare funding per person varies greatly by state; in fiscal year 2014-15, healthcare funding per person varied from as low as 4.10 dollars in Nevada to 220.80 dollars in West Virginia [22]. Therefore, the cost-effectiveness of our product is important to ensure its accessibility to people of different socioeconomic statuses. While maintaining the safety, functionality, and durability features of the device, we aim to consider factors for cost reduction in areas including case structure, case material, and chemical composition.

Financial Viability Plan

Sponsoring Company

The sponsor for our project is Christopher A. Yen, MD, an Assistant Professor of Anesthesiology at Geisel School of Medicine, Dartmouth, with experience in critical care medicine and medical field work in the military. As our project is initiated without an existing company, our sponsor intends to bring this device to the market after its development, through either starting and operating a small business, establishing licensing agreements and partnerships of the IP we developed with manufacturing companies to generate revenues, or sell our device to a larger company for a larger immediate revenue.

Market Context, Key Stakeholders, and Available Alternatives

As a colorimetric, lightless, and soundless detector to output the patient's $EtCO_2$ levels (too high, too low, within healthy range) reflective of the patient's conditions, our device is designed for EMTs / medical personnel working in medical facilities and environments lacking/cannot afford the more expensive digital capnograph; rural areas and combat fields are examples of such settings. Our target user groups therefore include emergency medical technicians (EMTs), military medics, emergency medical services, and healthcare facilities in developing countries. While some of these customers can be directly targeted, healthcare coalitions that batch purchase and distribute medical products are important purchasers. These coalitions include group purchasing organizations (GPO) that aid hospital finances, emergency preparedness programs in federal, state, county level, non-profit medical aid organizations that focus on under-resourced communities, and the Defense Logistic Agency (DLA) that purchase medical supplies for military doctors and medics. Specifically, GPOs negotiate purchasing contracts for hospitals, and their purchasing volumes have been growing steadily [23]. Hospital preparedness program (HPP) operated by the Administration for Strategic Preparedness & Response (ASPR), a Department of Health and Human Services (HHS) branch, receives federal funding and collaborates with state and local health departments, and can facilitate the scaling up of our product [24]. Furthermore, the DLA is interested in purchasing affordable medical devices for supplying to medics because of budget constraints, in line with our device specifications [25].

Our device provides a cost-effective, durable alternative to digital capnographs for continuous $EtCO_2$ measurements in austere settings. It is an improvement of state of the art colorimetric devices that provides binary readings of $EtCO_2$ levels. To obtain market attraction and widespread adoption, however, the added features and intended use of our device must be clearly communicated to our end users and purchasers. As some medics we talked with initially expressed minimal interest in incorporating our device into emergency field medical responses, our device's ventilation monitoring capability (hyper and hypo ventilation detection) should be communicated in the beginning of our discussions with stakeholders. In addition, it is important to educate users to put the device on the endotracheal tube circuit for an extended period of time (ex. up to 72 hours, which is the ideal lasting period of our device), rather than for just the first few minutes of the tubulation, for continuous monitoring of correct tube placement and of the patient's ventilation status. These monitoring capabilities are lost if our device is removed while the patient is still intubated, risking hyperventilating or hypoventilating the patient, and risking overlooking an accidental misplacement of the tube onto the esophagus, which can occur even if the tube

is placed at the correct location initially. In sum, the intended use of our device must be adopted for it to be recognized as an upgrade to the existing colorimetric devices; if our device is used similarly to how existing colorimetric devices is used, i.e., it is used only for the first few minutes of the intubation, then our device will not be recognized as being more capable compared to the existing ones.

To fill the market gap between rudimentary, binary EtCO2 monitoring devices and expensive digital capnographs, we are aware that large, diversified companies hold the majority of the market share of EtCO2 monitoring devices; prominent medical device companies holding large market share in capnography include Smiths Medical, Masimo, and Medtronic [26]. Large companies that produce many types of medical devices for several healthcare sections have more resources allocated to research and development, which may lead to better market capture [27]. Because of their financial resources and marketing potential, they are also more capable of expanding their services and product sales to different regions compared to smaller companies. Furthermore, venture capital investment for medical device companies has declined in recent years, from $3.7 billion to less than $2.9 billion between 2007 and 2017 [28]. Small medical device companies are the most affected by this decline in investment, because of their size and limited financial resources. Therefore, we anticipate that our major market competitors are large medical device companies with diversified portfolios.

IP Plan

Our sponsor has indicated interest in obtaining a patent for our device design and implementation, not any new chemistry, so we would not violate any currently-patented technologies. To get protection from IP regarding the work generated in the project, each member signed a non-disclosure agreement at the beginning of the term, which assigned the IP to Dartmouth. If our sponsor decides to apply for a patent, we will work with our sponsor and Dartmouth Technology Transfer Office, and eventually with the United States Patent and Trademark Office (USPTO). The patent application includes detailed descriptions of the device, drawings and related descriptions , and an oath mandated by USPTO [29]. Until then, team members will maintain privacy during stakeholder interviews, focusing on device functionality. Our device's features such as low cost, durability, comparability with digital capnography will be highlighted rather than device design.

Production/ Implementation Plan

Regulatory approval is an important aspect of the $EtCO_2$ device we seek to create because our device falls under Class II medical devices regulated by the Food and Drug Administration (FDA). The FDA designated carbon dioxide gas analyzers "to aid in determining the patient's ventilatory, circulatory, and metabolic status" as class II devices, having moderate to high risk [30]. FDA's Center for Devices and Radiological Health (CDRH) is the relevant FDA branch for our regulatory processes; it regulates groups that manufacture medical devices in the US [31]. Therefore, obtaining regulatory approval from the FDA is necessary to be able to bring the product to market. Regulatory considerations should be held from the beginning of the project and throughout the product development process to save time and money.

As a class II medical device, a 510(k) premarket submission is likely required by the FDA for regulatory approval, given that a device similar to ours may be found in the market. A 510(k) premarket submission is a document that demonstrates the safety, and efficacy of a medical device, as well as the device's

substantial equivalency to an approved medical device in the market [32]. Components of a 510(k) document are descriptions of a predicate device, intended use, technological characteristics, and additional information requests from the FDA. Phases of a 510(k) process include technical screening, substantive review, and additional information request, and the time for each of these phases vary on a case by case basis. The 510(k) program is therefore an involved process for obtaining FDA approval for a medical device, which may take more than a year to complete despite the nominal timeline being 90 days.

The alternative FDA requirement for Class II medical devices is a de novo classification- a more recent pathway for novel medical devices with no legally marketed predicate device determined by the FDA or claimed by the product sponsor [33]. While the 510(k) premarket submission is the more common pathway historically for class II devices and has a shorter average approval time (150 days in Aboy et al.'s study), de novo classification has varied approval time (ranging from <1 month to >30 months in the same study) and can be advantageous for a novel technology [34]. Given our current plan is to utilize changes in pH to change the color of the device, we believe our device likely requires a 510 (k) submission. But, if our device's design and implementation turns out to be completely different from any of the current colorimetric devices, we may consider de novo classification as the alternative.

Regardless of the pathway we choose for obtaining FDA approval, our project's first interaction with the FDA is likely going to be related to IDE (investigational device exemption), an application for an investigational device to be used in a clinical study to collect safety and effectiveness data. An approved IDE will be used to conduct clinical studies, and the results will be used to support 510(k) or de novo application. Unlike the 510(k) nor the de novo applications, the results of the IDE application come much faster (about 30 dates after submission) [35]. Communication between a product sponsor and the FDA usually occurs before submitting the IDE application via a premarket online meeting or an email thread. Our project group should be ready to thoroughly communicate the design, safety, and efficacy of our device to the FDA representatives then and take note of their feedback for potential adjustments.

Pro Forma Financials

Our financial model includes fixed costs, variable costs, FDA related costs, as well as revenues estimated from market size and capture. These costs and revenues are estimated based on market research, FDA sources, and published finance data from competitor products. Specifically, variable costs are estimated through referencing material costs from chemistry suppliers like ThermoFisher, Sigma Aldrich, and from electronic suppliers including Arduino, Seed Studio, and Sandbox Electronics. FDA related costs are estimates of annual medical device fees and the 510(k) related costs (application costs, clinical trials costs, etc.). Marketing costs and group purchasing organization fees are included as percentages of revenues. Revenues are estimated as percent capture of the endotracheal tube market size in 2022 ($1.821 billion in 2022) [19]. For a time span of 10 years, the financial model yields a net present value of $136 million and an equivalent annual revenue of $14 million, indicating financial sustainability of our product. We acknowledge that several costs and revenues are approximations and are subject to adjustments as a specific regulatory pathway is chosen and a business plan refined.

References

1. Vithalani, Veer D., et al. “Unrecognized failed airway management using a supraglottic airway device.” *Resuscitation*, vol. 119, Oct. 2017, pp. 1–4, https://doi.org/10.1016/j.resuscitation.2017.07.019.
2. Katz, Steven H., and Jay L. Falk. “Misplaced endotracheal tubes by paramedics in an Urban Emergency Medical Services System.” *Annals of Emergency Medicine*, vol. 37, no. 1, Jan. 2001, pp. 32–37, https://doi.org/10.1067/mem.2001.112098.
3. Richardson M, Moulton K, Rabb D, et al. Capnography for Monitoring End-Tidal CO2 in Hospital and Pre-hospital Settings: A Health Technology Assessment [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2016 Mar. (CADTH Health Technology Assessment, No. 142.) Executive Summary
4. StatCO2® Mini StatCO2® Neo-StatCO2®. Mercury Medical. October 8, 2022. Accessed November 23, 2024. https://www.mercurymed.com/product/statco2-mini-statco2-neo-statco2/
5. Nellcor™ Colorimetric Adult-Pediatric CO_2 Detector. Medtronic. Accessed November 23, 2024. https://www.medtronic.com/en-us/healthcare-professionals/products/respiratory/intubation/co2-detectors/nellcor-colorimetric-adult-pediatric-co2-detector.html
6. Mills, A. (2009). Optical Sensors for Carbon Dioxide and Their Applications. In: Baraton, MI. (eds) Sensors for Environment, Health and Security. NATO Science for Peace and Security Series C: Environmental Security. Springer, Dordrecht. https://doi.org/10.1007/978-1-4020-9009-7_23
7. Mills, A., & Monaf, L. (1996). Thin plastic film colorimetric sensors for carbon dioxide: effect of plasticizer on response. *Analyst*, *121*(4), 535-540.
8. Mills, Andrew., et al. “Equilibrium Studies on Colorimetric Plastic Film Sensors for Carbon Dioxide.” *Analytical Chemistry*, vol. 64, no. 13, July 1992, pp. 1383–89. *ACS Publications*, https://doi.org/10.1021/ac00037a015.
9. Ratner, Jeffery, et al. “Rapid-response reversible dry surface CO2 detector”. 25 August 2009 US Patent 7578971B2.
10. F Hoffmann La Roche AG. “Dry optical-chemical carbon dioxide sensor”. EP1965198. 3 September 2008
11. Raemer, Daniel et al. “CO_2 indicator and the use thereof to evaluate placement of tracheal tubes” US Patent 5005572. 9 April 1999.
12. *Endotracheal Tube Market Size & Share Analysis Report, 2030*. (n.d.). Retrieved October 22, 2024, from https://www.grandviewresearch.com/industry-analysis/endotracheal-tubes-market
13. Olatunji, G., Kokori, E., Aderinto, N., & Alsabri, M. A. H. (2024). Emergency airway management in resource limited setting. *International Journal of Emergency Medicine*, *17*, 41. https://doi.org/10.1186/s12245-024-00607-3
14. *Chronic respiratory diseases death rate*. (n.d.). Our World in Data. Retrieved November 14, 2024, from https://ourworldindata.org/grapher/respiratory-disease-death-rate?time=2021
15. *Intubation: Purpose, Procedure and Potential Risks*. (n.d.). Cleveland Clinic. Retrieved November 14, 2024, from https://my.clevelandclinic.org/health/articles/22160-intubation
16. *Impact of capnography on patient safety in high- and low-income settings: A scoping review—British Journal of Anaesthesia*. (n.d.). Retrieved November 14, 2024, from https://www.bjanaesthesia.org/article/S0007-0912(20)30272-5/fulltext

17. *Financing Healthcare.* Retrieved November 14, 2024, from http://www.news-infographics-maps.net/financing-healthcare.html
18. Ortiz-Ospina, Esteban, and Max Roser. "Healthcare Spending." *Our World in Data*, June 2017. *www.news-infographics-maps.net*, http://www.news-infographics-maps.net/financing-healthcare.html.
19. *Global Health Organizations Unite at the All Africa Anaesthesia Congress to Address Capnography Gap*. (2024, September 16). Lifebox. https://www.lifebox.org/news/action-letter-capnography-gap/
20. *How do you fix healthcare's medical waste problem?* (n.d.). Retrieved October 22, 2024, from https://www.bbc.com/future/article/20200813-the-hidden-harm-of-medical-plastic-waste-and-pollution
21. US EPA, O. (2016, February 17). *Medical Waste* [Other Policies and Guidance]. https://www.epa.gov/rcra/medical-waste
22. *Investing in America's Health: A State-by-State Look at Public Health Funding and Key Health Facts*. (n.d.). TFAH. Retrieved October 22, 2024, from https://www.tfah.org/report-details/investing-in-americas-health-a-state-by-state-look-at-public-health-funding-and-key-health-facts-1/
23. GPOs: Helping to Increase Efficiency and Reduce Costs for Healthcare Providers and Suppliers from https://www.supplychainassociation.org/wp-content/uploads/2018/05/Applied_Policy_Report_2014.pdf
24. *Hospital Preparedness Program (HPP)*. (n.d.). Retrieved October 22, 2024, from https://aspr.hhs.gov:443/HealthCareReadiness/HPP/Pages/default.aspx
25. *Medical Home Page*. (n.d.). Retrieved October 22, 2024, from https://www.dla.mil/Troop-Support/Medical/
26. *Capnography Devices Market Size & Share Report, 2030*. https://www.grandviewresearch.com/industry-analysis/capnography-device-market. Accessed 24 Nov. 2024.
27. AdmiralKhairul. "Big vs Small Pharma Companies Driving Innovation." *Within3*, 14 Oct. 2022, https://stg-www.within3.com/blog/big-vs-small-pharmaceutical-companies.
28. Report to the Congress: Medicare and the Health Care Delivery System. *An overview of the medical device industry.* June 2017. Retrieved November 2024, from https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch7.pdf.
29. *Applying for Patents | USPTO*. (n.d.). Retrieved November 14, 2024, from https://www.uspto.gov/patents/basics/apply#utilityoath
30. *CFR - Code of Federal Regulations Title 21*. (n.d.). Retrieved October 22, 2024, from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=868.1400
31. Health, C. for D. and R. (2024, January 31). *Overview of Device Regulation*. FDA; FDA. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation
32. Health, C. for D. and R. (2024, August 22). *Premarket Notification 510(k)*. FDA; FDA. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k

33. Health, C. for D. and R. (2024). De Novo Classification Request. *FDA*. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request
34. Aboy, M., Crespo, C., & Stern, A. (2024). Beyond the 510(k): The regulation of novel moderate-risk medical devices, intellectual property considerations, and innovation incentives in the FDA's De Novo pathway. *Npj Digital Medicine*, *7*(1), 1–8.
35. Health, C. for D. and R. (2023). IDE Approval Process. *FDA*. https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-approval-process
36. Barnard, E. B. G., Ervin, A. T., Mabry, R. L., & Bebarta, V. S. (2014). Prehospital and en route cricothyrotomy performed in the combat setting: a prospective, multicenter, observational study. *Journal of special operations medicine : a peer reviewed journal for SOF medical professionals*, *14*(4), 35–39. https://doi.org/10.55460/62V1-UIZC
37. Ahmed RA, Boyer TJ. Endotracheal Tube. [Updated 2023 Jul 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK539747/
38. "Guide in Medical Endotracheal Intubation Market." *Guide In Medical*, 2015, www.guideinmed.com/guide-in-medical-endotracheal-intubation-market.
39. Trigo, Andreia. "Key Facts in End Tidal CO2 Monitoring." *Medtronic*, Medtronic , 2019, www.medtronic.com/covidien/en-gb/respiratory-and-monitoring-solutions/patient-monitoring-respiratory-interventions-blog/emergency-room/key-facts-in-end-tidal-co2-monitoring.html
40. *Social determinants of health*. (n.d.). Retrieved October 22, 2024, from https://www.who.int/health-topics/social-determinants-of-health
41. *Neo-StatCO2 -Kg End Tidal CO2 Detector | Bound Tree*. (n.d.). Retrieved October 22, 2024, from https://www.boundtree.com/monitoring-diagnostics/etco2-parts-accessories/neo-statco2-kg-end-tidal-co2-detector/p/661611?searchText=statco2
42. *Easy Cap and Pedi Cap CO2 Detectors | Bound Tree*. (n.d.). Retrieved October 22, 2024, from https://www.boundtree.com/airway-oxygen-delivery/intubation-aids/easy-cap-and-pedi-cap-co2-detectors/p/group000153?searchText=nellcor
43. *Masimo EMMA Mainstream Capnograph Kit (Displays numbers and waveforms)*. (n.d.). Medical Device Depot - Store 1. Retrieved October 22, 2024, from https://medicaldevicedepot.com/ProductCode-3639-MASIMO/
44. Nellcor™ Adult/Pediatric Colorimetric CO2 Detector from https://www.healthcare21.eu/?attachment_id=8407
45. StatCO2 Products Brochure from https://www.mercurymed.com/wp-content/uploads/StatCO2_Products-1.pdf
46. Ambrosino, Nicolino, and Michele Vitacca. "The patient needing prolonged mechanical ventilation: a narrative review." Multidisciplinary respiratory medicine vol. 13 6. 26 Feb. 2018, doi:10.1186/s40248-018-0118-7
47. Gnugnoli, David, et al. "EMS Field Intubation". https://www.ncbi.nlm.nih.gov/books/NBK538221/. Accessed 22 Oct. 2022.
48. Senthilnathan, M., Ravi, R., Suganya, S., & Kumar Sivakumar, R. (2022). Manual vs. mechanical ventilation in patients with advanced airway during CPR. *Indian heart journal*, *74*(5), 428–429. https://doi.org/10.1016/j.ihj.2022.07.007

49. Patel, S., & Sharma, S. (2024). Respiratory Acidosis. In *StatPearls*. StatPearls Publishing. http://www.ncbi.nlm.nih.gov/books/NBK482430/
50. Magnusson, C., Hagiwara, M. A., Norberg-Boysen, G., Kauppi, W., Herlitz, J., Axelsson, C., Packendorff, N., Larsson, G., & Wibring, K. (2022, May 23). “Suboptimal prehospital decision- making for referral to alternative levels of care – frequency, measurement, acceptance rate and room for improvement”. BioMed Central. Retrieved October 22, 2022, from https://bmcemergmed.biomedcentral.com/articles/10.1186/s12873-022-00643-3
51. Ray, Mike W. “EMS Requires Training, Expensive Equipment.” *Southwest Ledger*, 15 Oct. 2020, https://www.southwestledger.news/news/ems-requires-training-expensive-equipment.
52. Su L, Pan P, Liu D, Long Y. Mean airway pressure has the potential to become the core pressure indicator of mechanical ventilation: Raising to the front from behind the clinical scenes. J Intensive Med. 2021 May 28;1(2):96-98. doi: 10.1016/j.jointm.2021.04.002. PMID: 36788801; PMCID: PMC9923962.

Appendix

A.1 Stakeholder quotes

"It would be awesome to be able to track End Tidal CO_2 but the Army won't buy us EMMAs, we don't have enough money." (Army Special Forces Medic (18D))*

"It's critical to be able to continuously monitor end tidal CO_2 to help guide ventilation in prolonged patient care settings, critical care evacs, etc. The typical colorimetric $EtCO_2$ detectors don't help much other than showing CO_2 is present. It would be nice to have something that can last a while, is durable and give quantitative feedback about EtCO<2 level." (Army forward surgical team ER/anesthesiology/critical care physician)*

"Continuous, visual quantitative $EtCO_2$ feedback in the form of a small footprint, low tech, high durability item is critical to proving appropriate airway placement, monitoring for airway disruptions, guiding ventilation/respiratory rates and having a sense of global perfusion." (Air Force Special Operations Surgical Team anesthesiologist/critical care physician)*

"I loved the EMMA and being able to monitor $EtCO_2$, but sometimes the adapters were hard to find, there was no way to turn off the light and the standard colorimetric $EtCO_2$ detectors didn't give the same info and were only good for short-term/limited use and weren't reusable." (Air Force Special Operations Pararescue Jumper (PJ))*

Hayden, who works at the U.S. Army Corps of Engineers Cold Regions Research and Engineering Laboratory, has been in contact with 5–10 members of the military who were previously deployed in various parts of the Middle East and Africa. Amongst these service members, at least three of them were formally trained as Army medics. Through conversations with these service members, it became increasingly obvious that our device would fill a significant gap in their emergency response sequence.

When someone is wounded in combat, the army medics' catchphrase is "stop the bleeding, then start breathing". Around 60% of combat deaths are due to blood loss, which is why this is the first priority. Because of this, breathing assistance is often already delayed, meaning that the medics have less time to correctly intubate and breath for the patient before the patient reaches a critical point of hypoxia. The service members who I spoke to indicated that having a device that allowed them to ensure they were not leading the patient to be hyper- or hypoxic would be incredibly helpful, since ensuring proper breathing is already in a critical timeframe by the time intubation starts. When there are combat injuries, the injured are typically moved via helicopter first to a Roll 1 hospital, which has minimal resources. Roll 1 hospitals do not have digital capnographs, or ultrasounds or X-Rays for intubation placement purposes. Despite this, the information I received indicated that these Army medics typically do not even attempt to use the analog state-of-the-art, because they feel it does not provide enough information to be useful. These Roll 1 environments are purely for stabilizing the patient enough that they can be transported to a Roll 2 hospital, which is a fully stocked hospital, typically in Germany.

The typical transition time from initial intubation in a combat scenario to leaving a Roll 1 hospital is two hours or less, and each Roll 1 hospital must be two hours or less from a Roll 2 hospital (this is the standard that must be upheld in normal combat conditions). Because of this, having our device last a minimum of two hours covers each of these transition times.

*Sourced from previous group

A.2 State-of-the-Art Products

Figure. Nellcor Easy Cap II detector.

Figure. Maximo Emma capnograph

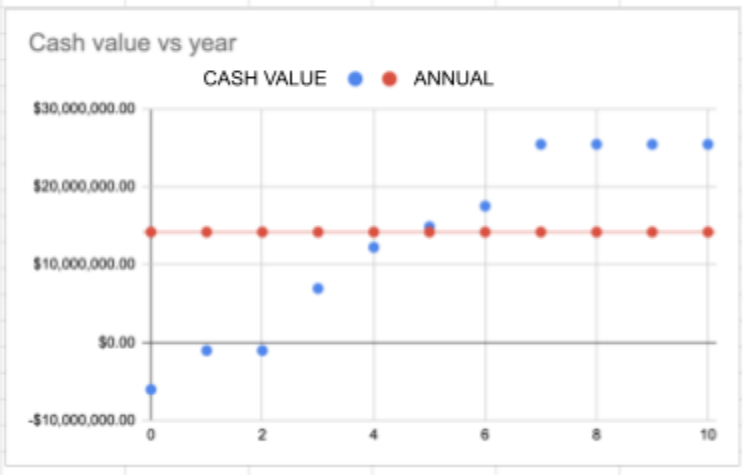
Left: Nellcor Easy Cap Detector ***Middle:*** StatCO2 ***Right:*** EMMA Capnograph

A.3 Cash Flow Analysis

*Working document that will be updated as more information becomes available in finance.

Fixed Costs			**Variable Costs**			**Market size**					
Rent	100,000		chemicals	10		endotracheal (20	1,821,000,000				
Operations (equipment like fume hoc	9,000		case and filter paper	5		ambulatory+othe	546,300,000				
Payroll (avg for 60000/employee)	900000		Assembly (12 units/	5							
Insurance	5000		Marketing	2% of sales							
Total	1,014,000		Total per device	20	markup price (1(	20					
			sale price	40							
interest	0.75%							10%			market capture
				3%	5%	6%	7%		10%	10%	10%
Year	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Fixed Costs	-1,014,000	-1,014,000	-1,014,000	-1,014,000	-1,014,000	-1,014,000	-1,014,000	-1,014,000	-1,014,000	-1,014,000	-1,014,000
Obtaining 510(k)	-5,000,000	0	0	0	0	0	0	0	0	0	0
FDA Annual Regulatory Fee	-7653	-7653	-7653	-7653	-7653	-7653	-7653	-7653	-7653	-7653	-7653
Sales Earnings (% of market)	0	0	0	16389000	27315000	32778000	38241000	54630000	54630000	54630000	54630000
- variable costs (50% of sale)	0	0	0	-8194500	-13657500	-16389000	-19120500	-27315000	-27315000	-27315000	-27315000
Total before marketing and GPO	-6,021,653	-1,021,653	-1,021,653	7,172,847	12,635,847	15,367,347	18,098,847	26,293,347	26,293,347	26,293,347	26,293,347
Marketing Cost (2%)	0	0	0	-143456.94	-252716.94	-307346.94	-361976.94	-525866.94	-525866.94	-525866.94	-525866.94
GPO Fees (1.12%)	0	0	0	-80274.164	-141430.164	-171958.164	-202486.164	-294285.164	-294285.164	-294285.164	-294285.164
Annual Total	-$6,021,653.00	-$1,021,653.00	-$1,021,653.00	$6,943,315.90	$12,231,499.90	$14,875,591.90	$17,519,683.90	$25,451,959.90	$25,451,959.90	$25,451,959.90	$25,451,959.90
NPV	**$136,224,730.15**										

YEAR	CASH VALUE	ANNUAL
0	-$6,021,653.00	$14,190,697.53
1	-$1,021,653.00	$14,190,697.53
2	-$1,021,653.00	$14,190,697.53
3	$6,943,315.90	$14,190,697.53
4	$12,231,499.90	$14,190,697.53
5	$14,875,591.90	$14,190,697.53
6	$17,519,683.90	$14,190,697.53
7	$25,451,959.90	$14,190,697.53
8	$25,451,959.90	$14,190,697.53
9	$25,451,959.90	$14,190,697.53
10	$25,451,959.90	$14,190,697.53



A.4 Non-Comprehensive list of Literature Reagents for a reversible dry surface CO_2 detector [4]

Brij 78 polyoxyethylene 21 stearyl ether
TDA-1 Tris[2-(2-methoxyethoxy)ethyl]amine supplied
TDA-3-polyoxyethylene (3) tridecyl alcohol
TDA-15 polyoxyethylene (15) tridecyl alcohol
2EH-5-Polyoxyethylene (5) 2 ethyl hexanol
LA-4-polyoxyethylene (4) lauryl alcohol
CSA-3-polyoxyethylene (3) cetyl stearyl alcohol
RW-20 Alkylamine Ethoxylate
Triton X-15 Octylphenol ethoxylate
Triton X-100 Octylphenol ethoxylate
Polyethylene glycol
m-cresol purple, sodium salt
Thymol Blue
Thymol blue free acid
Thymol blue sodium salt
Methanol
ethanol
dichloromethane
toluene
potassium hydroxide
potassium tert-butoxide
sodium methoxide
25 wt % sodium methoxide in methanol
30 wt % sodium methoxide in methanol
sodium phenoxide trihydrate
trisodium phosphate
HPLC grade hexane
distilled water
tetrabutylammonium hydrogen sulfate
methyltributylammonium hydrogen sulfate
methyltricaprylylammonium hydrogen sulfate

methyltricaprylylammonium chloride

tetraoctylammonium hydrogen sulfate

18-crown-6 ether

dibenzo-18-crown-6 ether

dibenzo-18-crown-6 ether (Aliplex® 186)

di(tert-butyl)dibenzo-18-crown-6 ether

A.5 Example Procedures for Hydro-stable rapidly reversible CO_2 detectors from [4]

Example	Procedure	Results
1	5 g Methyltricaprylylammonium chloride was added to 20 ml of 10% Sodium phenoxide trihydrate in water in a separatory funnel. The mixture was shaken for 1 min, then allowed to separate. The aqueous layer was removed. The remainder was washed with 10 to 20 ml water 3 more times, allowing separation and removal of water each time. The organic layer was then removed. This is the isolated Methyltricaprylylammonium phenoxide. Into a 5 ml volumetric flask was added 0.80 g 1% Thymol Blue Free Acid (supplied by Acros) in methanol, then 0.21 g Methyltricaprylyl ammonium phenoxide. The contents were swirled well to mix. 0.59 g Triton X-15 Octylphenol ethoxylate was added, then methanol to the 5 ml mark. The contents were shaken to mix. With a cotton ball, a small amount of the mixture was applied to the top of a polyethersulfone filter strip and allowed to air dry for 1 hour.	A rapid functioning reversible CO2 detector whose overall color change, based on change of hue, change of luminosity and speed of color change, was moderate (rated 7 on a scale of 1 to 10). The rate of substantially complete change of color exceeded 180 one-way changes/minute. The detector was humidity and water resistant, continuing to function for more than 24 hours at 100% humidity.
2	2 g Sodium Phenoxide trihydrate was dissolved in 50 ml methanol (4% solution). 2.8 g Methyltricaprylylammonium hydrogen sulfate was added with stirring for 5 minutes. 0.45 g aliquot of the mixture was removed to a small beaker. 0.45 g Triton X-15 Octylphenol ethoxylate (supplied by Sigma Aldrich), 0.005 g Thymol Blue Sodium Salt (supplied by Acros), and 1.45 g methanol were added. With a cotton ball, a small amount of the mixture was applied to the top of a polyethersulfone filter strip and allowed to air dry. Half of the detector was transferred to a beaker of deionized water and stirred for 10 min, then air dried again.	2 rapid functioning reversible CO2 detectors (one water-washed and one unwashed) whose overall color change, based on change of hue, change of luminosity and speed of color change, was excellent (rated 9 on a scale of 1 to 10). The rate of substantially complete change of color exceeded 180 one-way changes/minute for both detectors. The detectors were humidity and water resistant. Both water washed (and dried) and unwashed detectors were fully functional after 4 hours at 100% humidity. It

		was apparent that they would continue to function for a significantly longer time but the actual longevity of function was not tested.
3	2.5 g Tetraoctylammonium hydrogen sulfate was added to 30 ml of 10% Sodium phenoxide trihydrate in methanol in a beaker with stirbar. The mixture was stirred vigorously for 1 hour and then transferred to a 60 ml separatory funnel. Water was added to the top, forcing product to separate. The lower water/methanol layer was removed. The organic layer was washed with 30 ml water 2 more times, allowing separation and removal of water each time. Then the organic layer was removed. This is the isolated Tetraoctylammonium phenoxide. Into a 5 ml volumetric flask was added 0.8 g 1% Thymol Blue Free Acid (supplied by Acros) in methanol and then 0.4 g Tetraoctylammonium phenoxide. The contents were swirled well to mix. 1.2 g Triton X-15 Octylphenol ethoxylate was added, then methanol to the 5 ml mark. The contents were shaken to mix. With a cotton ball, a small amount of the mixture was applied to the top of a polyethersulfone filter strip and allowed to air dry for 3 hours.	A rapid functioning reversible CO2 detector whose overall color change, based on change of hue, change of luminosity and speed of color change, was moderate (rated 6 on a scale of 1 to 10). The rate of substantially complete change of color was at least 180 one-way changes/minute. The detector was humidity and water resistant, remaining functional for more than 24 hours at 100% humidity.

Statement of Work Dated 11/19/2024
Project No. 24-738

ENGS 89-90 STATEMENT OF WORK

I. Project Organization

PROJECT TITLE: Novel End-Tidal Carbon Dioxide Monitoring Device

DARTMOUTH TEAM:

Name	Role	Email
Hayden Barry	Project Manager	hayden.c.barry.25@dartmouth.edu
Achla Gandhi	Sponsor Liaison	achla.h.gandhi.25@dartmouth.edu
Zihao Yuan	Treasurer	zihao.yuan.th@dartmouth.edu
James Dodge	Chemistry Lead	James.t.dodge.iii.25@dartmouth.edu
Kimberly Samkoe	Faculty Advisor	Kimberley.S.Samkoe@dartmouth.edu
Emily Monroe	ENGS 89/90 Course Director	emily.h.monroe@dartmouth.edu
Sol Diamond	ENGS 89/90 Course Director	solomon.g.diamond@dartmouth.edu

SPONSOR:

Company/Organization: Dartmouth Hitchcock Medical Center

Website: https://www.dartmouth-hitchcock.org/anesthesiology

Industry/Field: Medical Devices/Healthcare

Sponsor Name, primary point of contact (POC): Christopher Yen, MD

Sponsor Job Title: Staff anesthesiologist, Assistant Professor of Anesthesiology (Geisel School of Medicine)

Sponsor Address: 1 Medical Center Drive, Lebanon, NH 03756

Sponsor Phone: +1 (617) 548-3907

Sponsor Email: Christopher.A.Yen@hitchcock.org

II. Project Specification

A. Essential Context and Background

25% of field intubations placed on people who need help breathing are misplaced, which can lead to hyperventilation or transient hypoxia. End tidal CO_2, which is the air released at the end of the breath, is typically measured with expensive and delicate digital capnographs to ensure intubations are placed properly and the correct amount of air is being given to the patient.

B. Problem/Need Statement

There is no affordable and durable device to continuously monitor patient $EtCO_2$ levels and display them in medically relevant ranges to medical personnel working in various environments.

C. Deliverables

Deliverable	Component	Team Member	Est. Completion Date
Fully functioning Air Simulation System	Demonstrate the ability of the device to pass only compressed air through the output tube	Achla Gandhi	1/13/2025
	Show the ability to dynamically change the partial pressure of CO_2 through the device between 0.3 mmHg and 75 mmHg	Achla Gandhi	1/20/2025
	Demonstrate the ability to change the humidity of the output in a range of 10% to 100%	Zihao Yuan	1/27/2025
	Demonstrate the output pressure of the device is maintained at 1.02 atm	Zihao Yuan	1/20/2025
Prototype of pH indicator device	Identify Starting Solvent Concentration	James Dodge	1/20/2025
	Determine the solvent's mathematical relationship with pKa	James Dodge	1/27/2025
	Match the pH corresponding to 30 mmHg CO_2 and 45 mmHg CO_2	James Dodge	2/3/2025
	Analyze colorimetric responses with digital color software to find the sensitivity of our dye, the speed of color change, and effect of humidity on dye	Hayden Barry	2/10/25
	Create form factor which is integrated with current breathing setups and allows air to pass through indicator	Hayden Barry	2/10/25
Customer feedback and testing	Gather results from customer use survey from Dartmouth Ski Patrol	James Dodge	2/20/2025
	Gather results from customer use survey from VT State Guard	Hayden Barry	2/20/2025
	Gather results from customer use survey from doctors at DHMC	Achla Gandhi	2/20/2025

Project safety plan

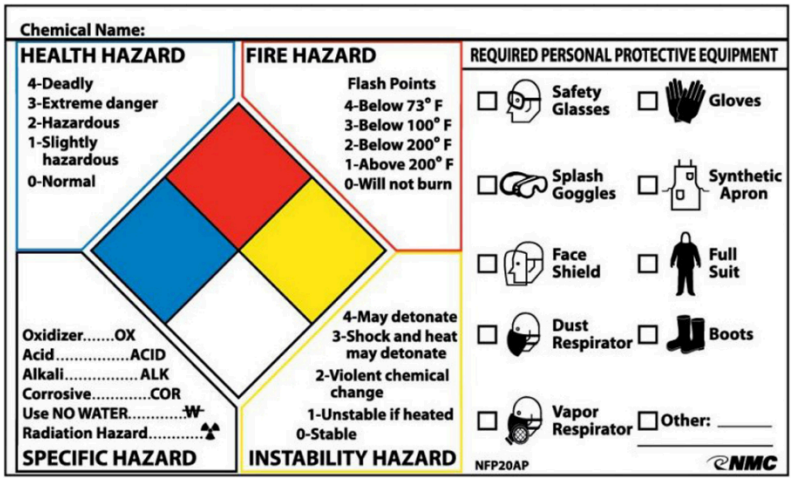
THAYER SCHOOL OF ENGINEERING AT DARTMOUTH

Project Safety Plan

Project Name: 24-738

Members: Achla Gandhi, Hayden Barry, Zihao Yuan, James Dodge

Date: 11/19/24



This document is intended to give the students a platform to lay out the hazards they expect to be creating during their project. This is also a space for them to describe (through formulas and descriptions) how they intend to mitigate such hazards.

Project Name Project Safety Addendum Plan

Table of Contents

Title **Page**

Section 1: Scope of Work

1.1 Description

Considering the accessibility of $EtCO_2$ monitors that provide critical life-saving information, there is a gap in the market for measuring $EtCO_2$ in a useful and easy way. This gap informs the problem that we intend to address in our project: there is no affordable, analog, and durable device to continuously monitor patient $EtCO_2$ levels and display them in medically relevant ranges to medical personnel working in various unstable and rural environments. Our device will overcome the shortcoming of the binary CO_2-presence detecting devices by using two different chemical indicators with pKa's set to the upper and lower ends of the healthy range of $EtCO_2$. When used in tangent to each other, they will not only indicate if a tube has been placed correctly, but also if the medical personnel is ventilating at a healthy rate.

We will construct two colorimetric $EtCO_2$ monitors using prior academic work as a resource. By changing the initial pH of the solution on the colorimetric monitors, we will tune the dye color shift to match the 35 mmHg and 45 mmHg partial pressure of CO_2. To tune the initial pH values, we will construct a breathing simulator to match the breathing cycles of an intubated patient. With a functional prototype, we will then iterate to make the device resistant to humidity, wear, and intuitive to use. This device would improve the quality of care for those in environments where highly technical devices, like digital capnographs, cannot be used. It would reduce the 25% of field intubations misplaced, 13.4% of patients who received hyperventilation, and 57% of patients who experienced transient hypoxia [1,2].

1.2 Timeline

Week	F8	F9	F10	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10
Team members obtain chemical safety training													
Purchase chemical reagents and components of breathing simulator													
Prototype casing for pH-dye strip													
Construct Airstream Simulation Test Bed													
Construct MATLAB color analysis code and set up													
Test Airstream Simulation Test Bed against technical requirments													
Construct Working CO2 sensitive test strips													
Construct first full prototype and test on the Airway Simulation Testbed													
Tune color change to 35 and 45 mmHg CO2 by varying amount of base													
Tune sensitivity of pH-sensor with transfer agents													
Test pH-sensor interaction with humidity													
Test ease of use for medical professtionals													
Construct the best prototype possible using our gained knowledge													
Test our prototype against our benchmarks from our preproposal													

1.3 Location

1.3(a) Assembly Location:

Fluids lab: Cummings 003, 10 Thayer Dr., Hanover, NH 03755

Biotech lab: Engineering and Computer Science Center 143, 15 Thayer Dr, Hanover, NH 03755

1.3(b) Testing Location:

Biotech lab: Engineering and Computer Science Center 143, 15 Thayer Dr, Hanover, NH 03755

Section 2: Safety and Emergency Contacts

2.1 Safety Manager Designation

Thayer Safety Director: *Jonathan Stark*

Phone Number: +1 (603) 667-3399

Email: *jonathan.h.stark@dartmouth.edu*

Project Safety Advisor: *Molly Carpenter*

Phone Number: *404-849-3705*

Email: *example@dartmouth.edu*

Project Group Safety Manager: *James Dodge*

Phone Number: *509-668-8505*

Email: *James.t.dodge.iii.25@dartmouth.edu*

Section 3: Hazard Acknowledgment and Assessment

3.1 Hazard Assessment (Risk assessment and mitigation at time of the test)

	Hazard	Present Y/N	Hazard Mitigation
1	Hearing Protection	Y	Ensure the pressure vessel is within acceptable pressure range to lower the volume it produces when releasing air.
2	Explosives	N	
3	Confined Space	N	
4	Eye Protection	Y	Use Laboratory Goggles when working with reagents. Work in a space with an emergency eye wash station.
5	Projectile	N	
6	Chemical Burn	Y	Wear lab safety gear, defined as closed-toed shoes, pants, lab gown, lab goggles, and gloves at all points when around reagents. Work in a space with an emergency eye wash station and emergency showers. Only work with reagents in lab environments.
7	Heat Burn	Y	Wear lab safety gear, defined as closed-toed shoes, pants, lab gown, lab goggles, and gloves at all points when around reagents. Work in a space with emergency showers.
8	Weather	N	
9	Water	N	
10	Unstable Load	N	
11	Heavy Objects	N	
12	Fire Hazard	Y	Store flammable reagents in a fire cabinet. Do not expose flammable reagents to heat at or above their autoignition point. Work in a space with fire extinguishers and emergency showers. Only work with reagents in lab environments.
13	Unstable Chemical	N	

14	Oxidizer	Y	Wear lab safety gear, defined as closed-toed shoes, pants, lab gown, lab goggles, and gloves at all points when around reagents. Work in a space with an emergency eye wash station and emergency showers. Only work with reagents in lab environments.
15	Corrosive Agent	Y	Wear lab safety gear, defined as closed-toed shoes, pants, lab gown, lab goggles, and gloves at all points when around reagents. Work in a space with an emergency eye wash station and emergency showers. Only work with reagents in lab environments.
16	Radiation	N	
17	Containment and Storage	Y	Store flammable reagents appropriately in a fire cabinet. Store all other reagents in a dry, cool place. Ensure CO2 tank is secure at all times.
18	Lockout Tag out of Energy	N	

If you have answered YES to any hazard then proceed to Sections 4 (Hazard abatement) and Section 5 (Signatures). If NO hazards are present then stop here because no abatements or signatures are needed, and attach to your proposal.

Section 4: Hazard Abatement

4.1 Significant or High-Risk Activities (Risk assessment and management in preparation)

4.1(a): *Irritant Reagents*

- Safety Considerations
    1. *Exposure of these reagents to skin or other tissue results in inflammation and or chemical burns*
- Hazard Acknowledgement
    1. *Interactions between chemically active substituents on the molecule and biological tissue result in the degradation of said tissue*
- Measures taken to Address Hazards
    1. *Wear lab safety gear, defined as closed-toed shoes, pants, lab gown, lab goggles, and gloves at all points when around reagents. Work in a space with an emergency eye wash station and emergency showers. Only work with reagents in lab environments.*

4.1(b): *Compressed Gas*

- Safety Considerations
    1. *The piping attached to our CO_2 container could fly off.*
- Hazard Acknowledgement
    1. *Too high of a pressure in the tank could cause the tank to release it in through the path of least resistance (the pipe fitting).*
- Measures taken to Address Hazards
    1. *Under the guidance of Daniel DeNauw, we are only filling the tank to a maximum of 60 psi.*
    2. *During filling we will also be following safety precautions of holding the piping in place.*
    3. *Furthermore, we will be ensuring that no one is standing in front of the piping at any point during our experimentation.*
    4. *The CO2 tank will be secured at all times*

4.1(c): *Flammable*

- Safety Considerations
    1. *Solvents are flammable.*
- Hazard Acknowledgement
    1. *People or items could catch on fire.*
- Measures taken to Address Hazards

1. *Follow all common chemical laboratory safety procedures.*
2. *Work in a chem lab with a fume hood in gown gloves goggles.*
3. *Store in fire cabinet.*

4.1(d): *Electrical Components*

- Safety Considerations
    1. *Current can exceed the allowable limit of the circuit, causing a fire.*
- Hazard Acknowledgement
    1. *The power supply can supply a voltage that exceeds the current limit of the relay.*
- Measures taken to Address Hazards
    1. *Ensure the power supply is always set to a voltage below 12V.*

Section 5: Project Safety Management Plan Approval

5.1 Approval Signatures (only required if hazards are present)

Name	Signature	Date
___Jonathan Stark___ (Thayer Safety Director)	___Jonathan Stark___	_____11/25/2024_____
____Margaret Carpenter___ (Project Safety Advisor)	_Margaret Carpenter__	_____11/25/2024_____
____James Dodge_____ (Project Group Safety Advisor)	_____*James Dodge*_____	_____11/19/24_____

James Dodge
445 Lombard ln Wenatchee WA 98801
james.t.dodge.iii.25@dartmouth.edu| 509-668-8505

Education
Dartmouth College — Hanover, NH
Bachelor of Science in Bioengineering
Expected Graduation: June 2025

- **GPA:** 3.72

Research Experience
Undergraduate Research Assistant
Dr. Pletneva's Lab, Dartmouth College — June 2024 – Present

- Conducting biochemical experiments focused on enzyme kinetics
- Analyzed data using MATLAB
- Presented findings at weekly lab meetings and collaborated with graduate students on ongoing projects.

Thesis Research: Bioelectronic Neural Implants
Professor Boys' Lab, Dartmouth College — September 2024 – Present

- Investigating pure polymer bioelectronic neural implants.
- Designed experimental protocols and conducted trials to test.

Leadership & Extracurricular Activities
Leader, Dartmouth Mountain Biking Trips — 2021 – Present

- Organized and led two biking expeditions to Moab, UT, coordinating logistics for groups of 10+ participants.
- Mentored new members, teaching trail safety and advanced mountain biking techniques.

Ski Patroller, Dartmouth Ski Way — January 2022 – Present

- Provided emergency response services and ensured skier safety on the mountain.
- Participated in training for first aid and outdoor survival.

Skills

- **Technical:** Biochemical laboratory techniques, data analysis (MATLAB, R).
- **Research:** Experimental design, scientific writing.
- **Outdoor:** Wilderness first aid, trip planning, advanced mountain biking, and skiing.
