AER: Handheld Air Filtration System

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I.Executive Summary

Air pollution is the world's largest environmental health threat, accounting for 7 million deaths around the world every year [1]. Adverse effects of air pollution have disabled many people around the world and kept them from breathing fresh air, their birthright. Despite the recent efforts at a global level, there is an unprecedented amount of air pollution being generated every day. Hence, for the biodesign project, as a group of engineers we dedicated ourselves to create technology that not only helps mitigate but also prevents the harmful effects caused by air pollution to humans.

The basis of every great invention is an unmet need. Existing personal pollution control technologies have drawbacks ranging from being ineffective to being user-unfriendly. For example, the two most used point of care pollution control technologies are face masks and air filters. A few drawbacks for face masks are that they feel constrictive and fail to effectively filter out pollutants. Similarly, the drawbacks for air filters are very expensive and too bulky to carry around all day. Another main issue not being addressed by both these technologies is that there exists no current technology which not only provides patients with fresher air but also helps regulate their breathing patterns.

AER stick is a lightweight handheld air filtration system with embedded system feedback to regulate the user's breathing pattern – the slick design will satisfy the user's need of purified air from a small, portable device that is simple, safe, inexpensive, and effective. In order to do so the device consists of two shells. The inner shell of the device has a unique filtration system (patent pending) which is designed specifically to filter out pollutants and dust particles at a higher efficiency rate than commonly used face masks. Meanwhile, the outer shell consists of an LED system that guides the users breathing patterns.

Hence, AER stick's value proposition is to filter the inhaled air and empower the users to overcome stressful situations in polluted environments by regulating their breathing patterns.

II. Introduction

The problem that the group is trying to solve is that of the breathing pattern disorders caused by environmental factors such as air pollution. According to several studies, 9 out of 10 people worldwide breathe in polluted air [1]. What is even more harmful than the pollutants itself to a person in polluted areas is the problem of irregular breathing.

Irregular breathing patterns lead to problems with low respiratory volumes. The person breathing in polluted air already is inhaling high amounts of carbon dioxide and pollutants. Hence, irregular breathing adds to the problem by causing even less oxygen to be absorbed by the lungs. If the breathing rates of the person in these environments are controlled, it will lead to lower blood pressure and higher metabolic rates [2].

Following the principle explained above, the group designed a handheld breathing device that not only purifies the inhaled air but also helps regulate the breathing pattern of users. This would solve the problem that current personal pollution-control technologies don't address. The three most commonly used personal pollution control technologies are face masks, air filters, and oxygen tanks, all of which suffer from a few drawbacks. For example, face masks often feel constrictive, and only filter dust effectively and not pollutants. Furthermore, air filtration devices are very expensive, most cost over $200 while having no integrated regulation feature. Similarly, oxygen tanks are also bulky and don't filter air nor do they help regulate breathing patterns. A table that summarises the competitive advantage of the design is shown below (Figure 1). It is clear to understand that with AER, people will be able to breathe better and take charge of their breathing.

Product		Logo	Cost	Portability	Filter Pollutants	Regulate Breathing Pattern
1	AER		✓	✓	✓	✓
2	Masks (e.g. CoolBELL)		✓	✓	X	X
3	Air Filters (e.g. TruSens)	TruSens	X	X	✓	X
4	Oxygen Tanks (e.g. Boost)	BOOST	X	✓	X	X

Figure 1: Comparison Table

III.Initial Design Phase and Design Controls Regulation

Initially, the device concept that was proposed was a just a sketch of a design that consisted of filters placed in a vertical arrangement inside a tube shell and an embedded LED feedback system in the form of a LED bar that could help regulate the breathing of the users. The figure below (Figure 2) illustrates the concept. The device

was designed with the user experience in mind The user would breathe through the device after pressing a switch located behind the shell and the LED bar would guide the inhalation and exhalation process.

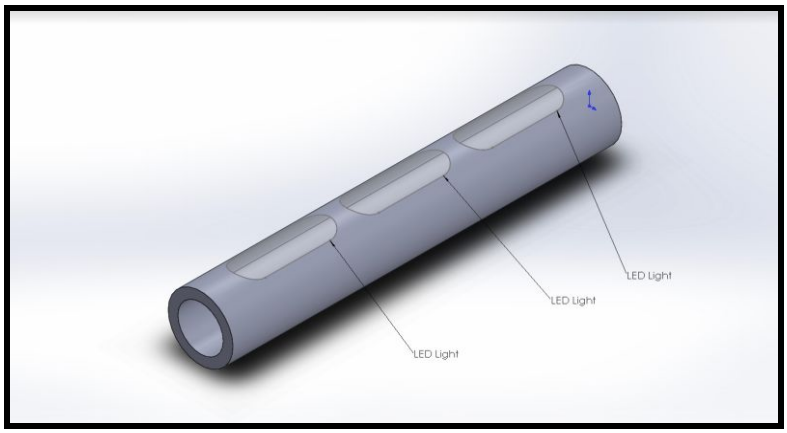

Figure 2: The first concept design for the device design.

Again as pointed in the introduction section, even the initial product design has several competitive advantages over the current state of the art personal pollution control technology (figure 1). Mainly, the product design has a state of the art regulation system that is necessary for polluted environments. Other device strengths can be summarised as being portable, easy to use, and comfortable while filtering dust, pollen, and carbon dioxide.

For the design, it was understood that the device needs to be lightweight, portable, inexpensive, and contain all of the components listed previously. More specifically, the design criteria was set to be one where the device would weigh around 20 grams, be 11 cm in size, and be sold between the price of $20 and $25. Similarly, the device acceptance criteria were conceptualized as one where the device should be able to filter particles greater than 2.5 PM, and the motor must run for 6 seconds so that the user has enough time to take in air. The table (Figure 3) below indicates both the acceptance and the design criteria.

Design Criteria	Acceptance Criteria
❑ Lightweight (≤ 20 grams) ❑ Portable (≤ 15 cm) ❑ Inexpensive (≤ $20 to manufacture) ❑ Contains 1 LED Strip with 5 LEDs ❑ Contains 1 Fan ❑ Contains all 4 Filters (pre-filter, HEPA filter, and Activated Carbon Filters)	❑ Air must be able to pass through all filters. ❑ Filters out 99.5% of dust, pollen, and reduces carbon dioxide ❑ Motor fan must run for at least 6 seconds. ❑ Particles ≥ 2.5 PM in size must be filtered out.

Figure 3: Design and Acceptance Criteria Table

Furthermore, after research, it was deemed that the AER stick will fall under FDA classification as Class 1. Class 1 medical devices are devices with low or moderate risk to patient health and safety. A 510(k) will most likely not have to be filled, as some existing devices on the market similar to AER stick like BreatheSmart are exempt from filing for 510(k). This usually happens if the FDA determines that a 510(k) is not required to provide reasonable assurance of safety and effectiveness for the device. Devices that may be exempt from 510(k) requirements are still required to abide by the normal regulatory controls. Hence, there will be manufacturing controls abiding by those regulatory controls that will be taken into account when creating the finished product. Also, the device would need ISO and IEC standards to test the final product. Specifically, ISO 10993 Biocompatibility as the product will come into “direct contact... with… the user’s body” through the mouth. A risk management process will be carried out for the identification of biological hazards, estimation of biological risks, and determination of their acceptability. Secondly, IEC 60601 Medical electronics safety will also apply to the device as it contains electronic parts. To test the enclosure of the device, a measuring device of approximately 1,000 Ohms will be used to test “parts of the enclosure(s) that are not protectively earthed”

Finally, the estimated timeline that was created in the fall quarter is illustrated by a Gantt chart given on the next page.

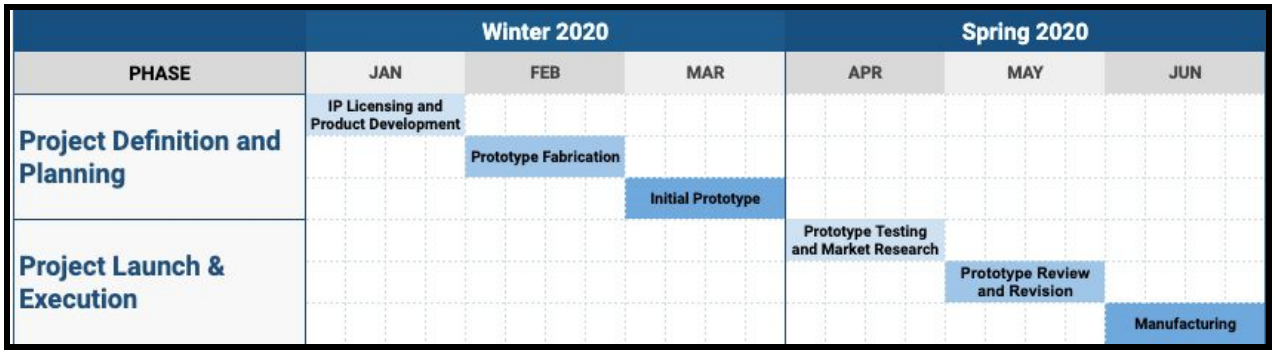

Figure 4: Initial Gantt Chart

The budget is $25 to purchase the parts and manufacture the working prototype for the device. This includes the aluminum shell, filters and a fan. A more detailed explanation of the costs can be seen in the Manufacturing Documentation section.

IV.Project Team

The team consisted of five people. Aditya Bhandari was the team lead and the lead engineering designer, Jasmine Khezri was the Business lead, Jiyuan and Zixu were the manufacturers, while Danessa was the prototype developer. The major task of Aditya was to come up with the device design and make a prototype of the device. Additionally, his duties were to ensure that all teammates were communicating effectively and to manage project timelines. The major tasks performed by both the manufacturers Zixu and Jiyuan were to check whether the materials used in the device were efficient and conduct an overall theoretical efficiency test. The business lead, Jasmine, had a major task of collecting customer surveys and conducting extensive market research. She was also responsible for ensuring that the marketing goals of the project were achieved effectively. Meanwhile, the major task of Danessa was to check class submissions for the project and assess the risks and failure modes. A more detailed explanation of personal responsibilities is described below.

Aditya Bhandari: Aditya was the team lead and the lead engineering designer for the project. He conceptualized the device design and worked on making a working prototype based on the design. The materials and constraints included in the design were chosen to meet particular requirements found by extensive research. Additionally, as a team lead his duties were effectively managing both team communication and dividing workload according to project needs. Furthermore, the design validation was conducted by him in order to retrieve data that was necessary to make design changes and decide whether the prototype met design and acceptance criteria. Finally, he also worked on business strategies required for report submissions.

Zixu Han: Zixu was a manufacturer and worked jointly with Jiyuan on checking whether the materials used in the device design were efficient by conducting research. He also worked on Solidworks models with the designing team. He followed the design constraints, which changed after each test run when designing the initial CAD models. Additionally, he also worked on class submissions for the project.

Jiyuan Chu: Jiyuan was also a manufacturer and similar to Zixu worked on conducting research on the efficiency of the materials used in the device, specifically the inner shell. He also conducted cost research to find out the costs of materials used in the device. He also worked on class submissions for the project.

Jasmine Khezri: Jasmine was the business lead and conducted market research required to find the target markets. She also was the lead creator for customer surveys which were crucial to understanding the population needs better. She also worked on business and marketing strategies that were based on the market research conducted. More specifically, she worked on a personalized network effect model mentioned in reports and posters. Finally, she was in charge of the marketing materials required in the project including both the presentation and poster visuals.

Danessa Yip: Danessa was the prototype developer, and her major tasks were to check the class submissions for the project and assess the risks and failure modes involved with building the device. She worked on writing reports, proofreading assignments, analyzing the design for possible failure modes, and addressing the risks and failures involved. She also cross-checked that the design met the criteria listed in the presentation (including the device being lightweight-less than 20 grams), portable (less than 15 centimeters), inexpensive (less than $20 to manufacture), and contained 1 fan and all four filters. She also verified with the data obtained via validation testing that the design met the acceptance criteria for the device (such as air passing through all filters, the filters working as intended, and motor fan running for at least 6 seconds), from which she analyzed the risks and failures that came with the device. With this, she was able to work with the project lead to ensure that the device met the specified criteria listed above.

V. Detailed Design Phase

Keeping in mind the unmet needs in the pollution control technology, the final AER stick design was made to be a lightweight handheld air filtration system with embedded system feedback to regulate the user's breathing pattern – the slick design satisfies the

user's needs for purified air from a small, portable device that is simple, safe, inexpensive, and effective.

To explain the design in detail: the device consists of two shells. One of the main inspirations behind the device's design are vacuum systems and turbine structures which operate in a similar fashion with a rotor fan attached at the end in order to push the air inside the tube. For the project design, the motor fan is attached to a helical shaft which upon starting will cause the air inside the tube to move in a helical manner. This will provide a minute amount of thrust to the air which is necessary as the filtration process works best when the air is traveling at a higher velocity. The outer shell also has a LED guidance system which will help regulate user breathing rates. Figure 5 below illustrates the outer shell of our device.

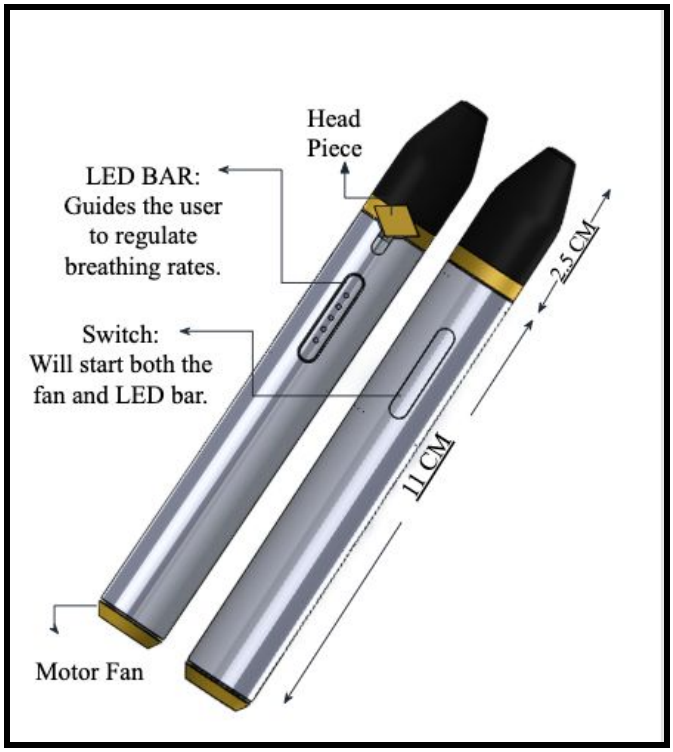

Figure 5: Outer shell

The inner shell of the device consists of a unique filtration system (patent pending) which is designed specifically to filter out pollutants and dust particles at a higher efficiency rate than commonly used face masks. It contains three filters and a copper based carbon-absorbing compartment. The first filter is a pre-filter that is perfect for capturing large debris such as hair, dust, and some pollen. Then the air passes through an activated charcoal filter that captures odor, smoke, and chemical particles. Finally,

the air passes through a HEPA filter which traps 99.7% of all particles larger than 0.3 microns and removes most bacteria as well. Figure 6 below illustrates the inner shell of our device and its working.

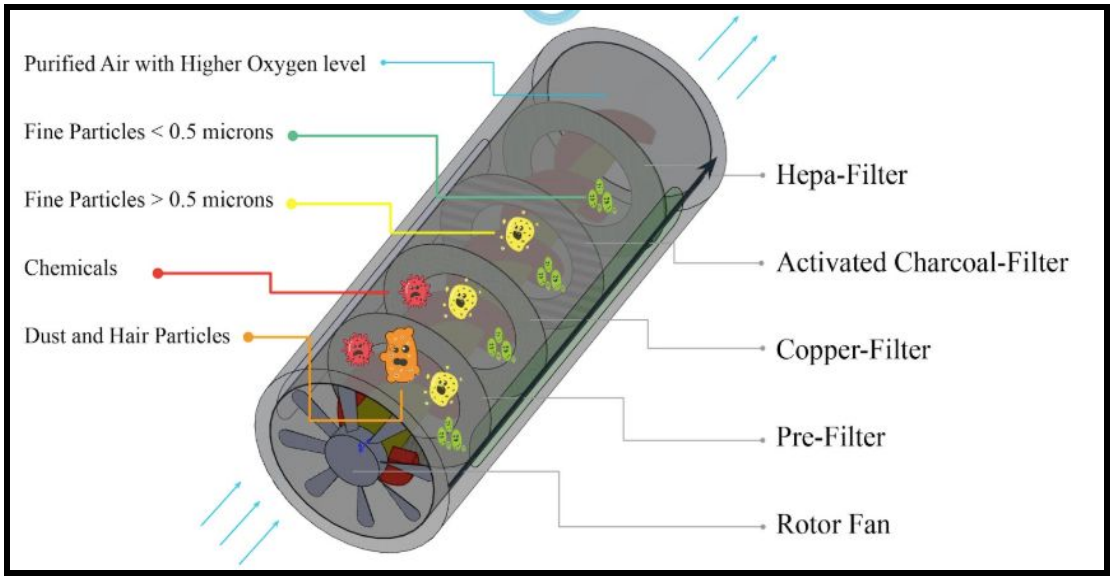

Figure 6: Inner Shell and its working

The prototype costs about 25 dollars to create. For the inner shell, the cost of the pre-filter was about $4.99 per sheet. The second filter, which was the activated carbon filter, cost about $7.79 per sheet. The last filter which was the HEPA filter costs about $11.80 per sheet. Each of these sheets was further cut in multiple smaller pieces to be used in our inner shell. During production, the approximate cost of all the filters combined for the inner shell of 1 unit is going to be around 8.5 dollars. Additional parts such as the outer tube cost about 4 dollars. This brings the total cost of the first working prototype that was later used in validation testing to be around 25 dollars as mentioned.

Finally, the project timeline estimated initially, as shown in the fall quarter Gantt Chart (Figure 4) could not be exactly completed due to the COVID-19 pandemic. As it is clear from the chart that the product revisions and further addition of the LED system to the prototype, scheduled for Spring Quarter 2020, could not be met. For the product revisions it was crucial to get feedback from customer reviews that could not be completed due to lockdown restrictions. Similarly, a LED bar could not be coded in time for the outer shell.

VI. Manufacturing Documentation

Bill of Materials (BOM)			
Product	**Amount**	**Vendor**	**Cost**
Aluminum Shell	1	Target	$4.00
Pre-Filter Sheet	1	PureBurg	$4.99
HEPA Filter Sheet	1	Holmes	$11.80
Activated Carbon Filter Sheet	1	Veva	$7.79
Fan	1	Amazon	$6.99
Air Tight Containers	2	Komax	$21.99
Air Monitors	2	Temptop	$125.99
Total Cost:			**$331.53**

Table 1: Bill of Materials

The product design as stated in the previous sections is divided into two sub-assemblies. The first one is an inner shell and the other is an outer shell. An inner shell was created for validation testing using the materials shown in Figure 7 below. The materials were a glass shell, a pre-filter, a HEPA filter, and an activated carbon filter. The building procedure for the inner shell sub-assembly was as follows: Firstly, the filter sheets were cut into rectangles of 1.5 cm X 3 cm and then were rolled using a small cylindrical roll. Secondly, these small roles were compressed and flattened. Lastly, they were placed inside the glass tube in the following sequence: pre-filter, activated charcoal filter and hepa filter. This inner shell was then placed between the two air chambers used for overall device validation testing.

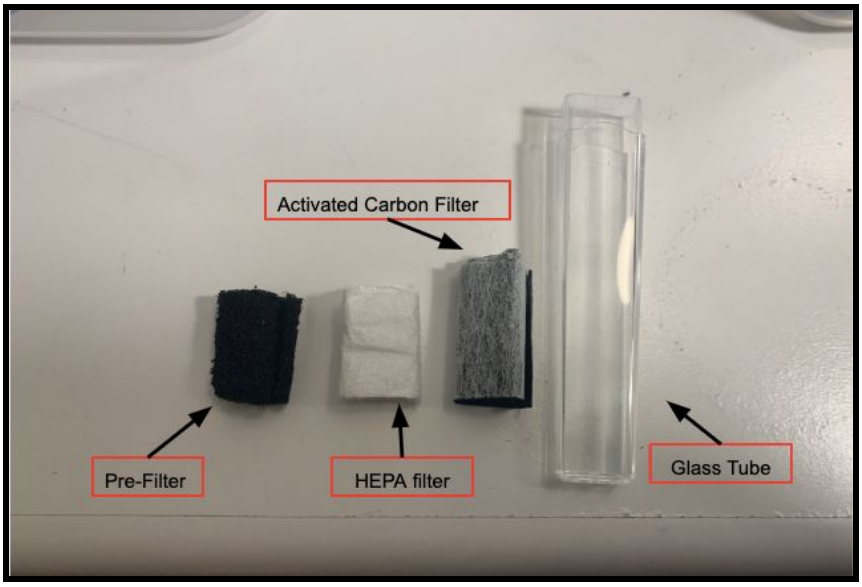

Figure 7: Inner Shell Sub-Assembly.

The second sub-assembly simply consists of an aluminium shell with a switch-controlled LED system placed on top, a headpiece and a motor fan attached at the bottom of the tube. The designing group could not physically construct this sub-assembly as the LED system could neither be ordered or coded due to the COVID-19 restrictions. However, the building procedure for the outer shell would be as follows: Firstly, an aluminium shell of desired length would be taken and holes would be drilled to place the coded LEDs along with a switch. Secondly, a small motor fan would be placed at the bottom of the shell. Thirdly, the entire electrical system would be connected to a small cell that would be placed just above the motor fan. Finally, a headpiece would be placed on the other opening of the shell. Figure 5 above illustrates the entire outer shell sub-assembly. Ideally, the outer shell would encapsulate the inner shell, completing the top-level assembly of the device.

The entire high-level arrangement cannot be manufactured at a large scale right away due to the reasons mentioned above. As a recap, one of the reasons is that the second sub-assembly could not be prototyped and tested. Also, there would be many product revisions and customer surveys undertaken before the product design can be changed into a version which better suits the market needs.

VII.Materials Validation

For the materials used in the shell, the designing team considered the weight of the material, the durability of the material, and the filtration abilities of the filters. Aluminum

was selected for the outer shell because it is one of the most versatile metals, is lightweight, and durable. In order to test the entire outer shell made by aluminium for both the efficiency as well as corrosive properties, an ICP metal testing will need to be conducted in the future. Meanwhile, the tensile properties of the device can be tested using a Lloyd's testing machine. The acceptance criteria for the outer shell was decided to be a case where the shell lasts longer than 1 year without showing any corrosive or tensile defects.

The materials in the inner shell are composed of a pre-filter, 2 HEPA filters, and 1 carbon dioxide-absorbing compartment. These filters were chosen because they are durable and will continue to filter air for 30 days. The carbon dioxide-absorbing compartment made of copper coils was also selected because it can filter air and provide the user with less carbonated air. Figure 8 below shows the filtration capacity of each individual filter. These are the desired acceptance values for the inner shell design.

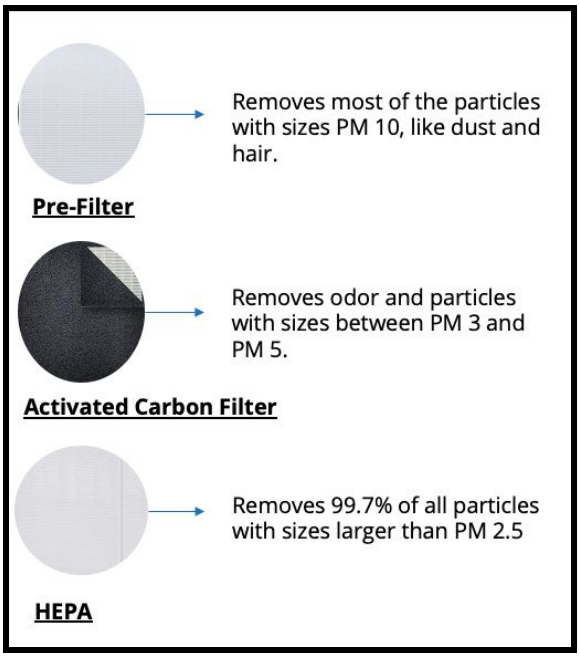

Figure 8: Specifications of the Filters used.

The acceptance criteria decided for the entire filter arrangement were: air must efficiently pass through all filters, filter out 99.5% of dust, pollen, and reduce carbon dioxide levels. Furthermore, particles larger than 2.5 PM in size must be filtered out. From validation testing for the overall design described in the section below, it was shown that air can pass through the device, and particles larger than 2.5 PM are filtered out .The filters are also capable of filtering out 99.5% of dust, pollen, and carbon

dioxide. Additionally, in the future it would be required to test each filter using laboratory tests to determine the optimal sizes and diameters for the required device length to increase the filtration capacity.

VIII.Design Validation

As the available prototype for our design consisted of only the inner-shell of the device, the acceptance criteria for it was chosen keeping in mind the scope of possible validation testing. Firstly, it was decided that the prototype should decrease both PM 2.5 and PM 10 sized particles passing through it effectively (an overall decrease of more than 90 percent). Secondly, the filtration process should continue to work at a high efficiency for more than 20 minutes. This would indicate that the inner shell is durable. In order to test the above described design criteria for our prototype, a personalised two way chamber system was created. The two way chamber is used in most air-particulate research settings as it helps understand both the filtration rate and efficiency at which the filtration mechanisms work .The building procedure for the testing system was : firstly, two 11.5 litres air tight containers were bought and then one air hole was drilled on each of the boxes. The inner shell prototype was then placed between these two holes and a seal was used to ensure that the air only passes through the prototype. Figure 9 below illustrates the entire arrangement. The chamber on the right was then filled with smoke and closed. While, an air monitor (Temptop) was placed in the left chamber. The readings on the air monitor were then observed and recorded.

Figure 9: Two-Way Air Chamber.

As described above, the amount of pollutants travelling through the air from the left chamber are then recorded and graphed in order to determine the efficiency of the prototype. Figure 10 and 11 below show the graphs that were obtained after the validation testing. From graph 1, it can be seen that particles with both sizes-PM 2.5 and PM 10 decrease drastically. Meanwhile Graph 2 confirms that there is a decrease in the overall number of particles.This proves that the system effectively reduces the pollutant particulates that are necessary to be filtered out to ensure better respiration. If the filtration system was not effective, the graphs would not have a downward slope, as the number of particles in the system would be increasing at a higher rate. Further laboratory testing would be required in the future to determine how many “puffs” of fresh air can be guaranteed by the device. But, according to the available data, it is clear that the prototype meets the described design criteria above.

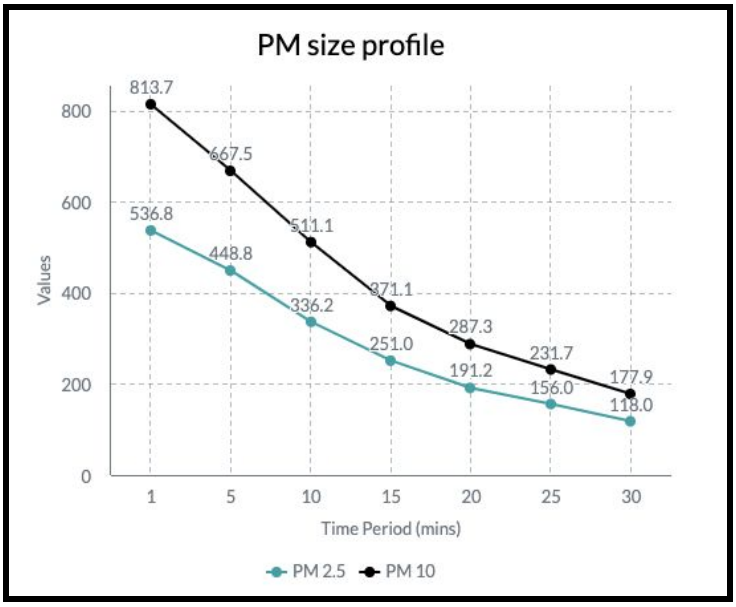

Figure 10: Graph 1 for particles sizes PM 2.5 and PM 10

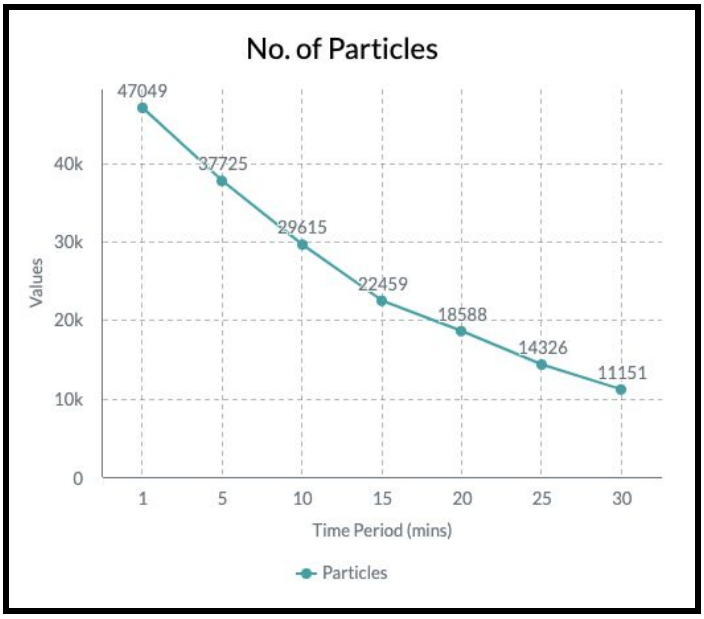

Figure 11: Graph 2 for the number of particles in the chamber setting

IX.Failure Mode and Effects Analysis (FMEA)

First, the failure modes of the device include loose pieces in the device, which may present a choking hazard; the outer shell becoming damaged due to polluted environments; and the filters reaching the maximum capacity for filtering the air. Additionally, the failure modes may occur due to shaking the device vigorously and breaking off the pieces, chemical reactants or gases in the polluted environments reacting with the outer shell, and a buildup of particles such as dust blocking the filters, respectively. Furthermore, the consequences of the failure modes include: presenting a choking hazard, especially to children, the unit becoming damaged, and the breathing stick not being able to filter air. Moreover, the severity of the failure modes include: a score of 8, indicating that the device not operating as it should without the pieces; a score of 5, indicating the device being operable for a short period of time before being replaced; and a score of 6, indicating the filters no longer working as they should. To address these concerns, the group would use manufacturing controls that will prevent discrepancies between the device and the design, such as using a scanning machine to ensure all pieces are where they should be; including instructions directing the operator to watch the device for changes in its appearance; and designing an app to tell the operator when the filters need to be changed. One of the failure modes that have been left unaddressed is what would happen if the LED bar system fails to operate properly. The group has not addressed this since the LED bar was not placed on the prototype and has yet to be tested. This affects the user experience because the user will not have the proper guidance for breathing regulation. This may cause breathing issues

and reduce the overall function of the device. It does not have a direct effect on the lifetime of the device, but may affect user experience and usage.

Risk Priority Numbers (RPN)

	Severity	Occurrence	Detection	RPN
Pieces become loose	8 The device does not operate as it should without the pieces.	2 There is a very little chance of occurence	2 We hope to use manufacturing controls that will prevent discrepancies	32
Outer plastic shell may react with air pollutants	5 Device is still operable for a short period of time; however, it must be replaced.	3 There is a very little chance of this happening in polluted areas.	7 The operator will need to look out for changes in the appearance of device	105
Filters may reach maximum capacity for pollutants	6 Filters will no longer work as intended. Regulation still works.	5 Occasional chance of occuring.	5 The design control will need the operator to use an app to keep track of changing the filter.	150

Figure 12: Table for Risk Priority Numbers

X. Lessons Learned Documentation.

There were a few lessons learned along the way, mostly during the validation testing of the prototype. After placing the inner shell between the two chambers it was observed that the rate of air passing through the shell was not enough to give conclusive results. The reason for that was the filters were too close to each other, hence causing the entire structure to be packed. After several re-trials, it was noted that an arrangement of filters which have a space of at least 0.5 cm between them gave the best results. Hence, to solve the issue for each subsequent validation trial, the space between the three filters was set to be 0.5 cm.

Another lesson learned was that the air monitors used during the initial trials ran out of batteries due to longer durations of the trials. In order to solve this problem a power bank was connected in the subsequent trials in order to take even longer readings. Finally, the first version of the prototype did not filter enough particulates to generate conclusive results, upon checking the materials it was observed that the quality of filters ordered via Amazon.com was not desirable. Hence, to solve this problem the filters were handpicked from stores in order to maintain high filtration efficiency of the device.

XI. User Documentation and Training.

The usage of the device is fairly simple and easy to understand. Firstly, the user starts the process by holding the device in their hand and pressing the switch located at the back of the outer shell. The user then places the device on their lips prepared to breathe through it. As soon as the switch is pressed, the small motor starts which is located at the end of the device pushes the air inside the tube in order to pass through the filtration shell. The switch also initiates a led system located on the outer shell. This LED system is pre-set in order to regulate the breathing of the user. Both inhalation and exhalation are pre-timed and the user follows the sequential led lights. The entire user training process can be summarized into three phases : 1) Activation, 2) Filtration and 3) Respiration.

XII. Functional Trials.

To demonstrate the functionality of the device, the results in section VII are testament to the device's efficiency filtration capability. Graphs 1 and 2 show how the device will be able to remove particulate matter both effectively and efficiently. Because the inner shell of the device design is the most important part in the process , these results help prove that the device has a functionality that can help users.

Due to the limitations posed by COVID-19, the team tried to find the potential functionalities of the outer shell by figuring out the possible future interface of the shell. Figure 13 shows the two potential outer designs. The gold colored aluminum shell on the left felt more comfortable and lightweight, whereas the larger aluminum shell on the right will have more filtration capacity due to having a larger diameter. The ideal outer shell for the device needs to be lightweight, portable and have enough length to help improve the filtration capacity.

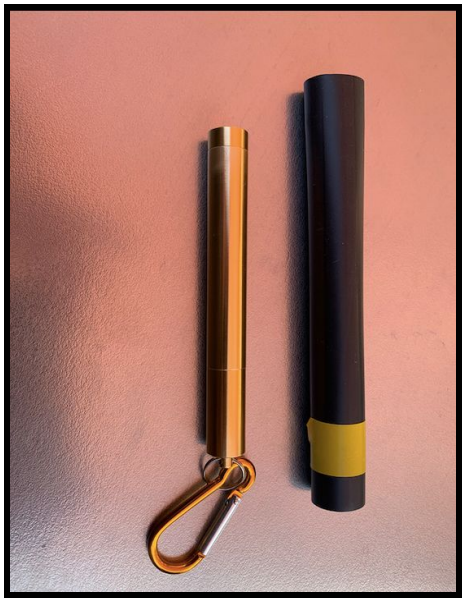

Figure 13: Potential Outer Shell Prototypes

XIII. Future Goals.

If the team was given an additional year and a $1 million R&D budget there are a few actions that would be taken. Firstly, an LED bar system along with the motor fan would be both coded and placed on the outer shell of the device. Secondly, there would be many customer interviews taken in order to understand the updated needs of the customers and changes that would be needed to be taken into consideration for the design. Thirdly, more testing would be done on the inner shell of the device to understand how many times the user can use the device before they need to replace it. Fourthly, an app would be designed with the R&D budget that could tell the user the level of pollution in their environment and the necessary steps they can take to breathe better using AER. Finally, a few full working models of the device would be manufactured and given to chosen samples to understand market reception.

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