

Easy Access for Easy Extubation (EZ-X)

BE 495 Final Fall Design Report

University of Pennsylvania

May 2023

Team 9

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ABSTRACT

Mechanical ventilation is a life-saving intervention that assists individuals unable to breathe for themselves, where the management of pressure and other parameters within the breathing tube is particularly to prevent lung collapse. Effective management of ventilation parameters requires careful monitoring to avoid life-threatening complications. Currently, no technology exists that can enhance standard ventilators to allow for high-acuity functionality, namely, remote access to ventilator measured data and settings. To address this gap, we have developed EZ-X, a low cost ventilator attachment that enables healthcare professionals to monitor and adjust ventilator parameters remotely, improving workflow efficiency, increasing care availability, and reducing in-person visits. A novel valve system adjusts pressure within ventilator tubes by sliding a door that divides ventilator airflow output between the patient and open air at atmospheric pressure. During validation testing, the device closely followed the Hagen-Poiseuille equation (R^2 of 0.976) that dictates how pressure should change within a tube of constant diameter with respect to varying volumetric flow rate. To achieve remote control of our device, we implemented wireless technology that transmits pressure data from the EZ-X device to its mobile app counterpart, enabling doctors to control ventilator pressure and view corresponding patient's vital sign data. In the next few months, we will continue to integrate our application with Epic and begin testing in a hospital setting. EZ-X has the potential to improve the standard of care for patients on long-term ventilation care and reduce the financial burden on the healthcare system by transforming standard ventilators into high-acuity devices for community hospitals.

BACKGROUND

The COVID-19 pandemic exposed the inadequacies of hospitals and respiratory care management, especially with respect to gaps in resources. Many patients that entered the intensive care unit (ICU), and were hospitalized for COVID-19, were placed on mechanical ventilators. Mechanical ventilation is a life-saving intervention used in hospitals for patients experiencing respiratory failure. A ventilator is a machine that helps people breathe when they cannot on their own by delivering a set amount of air into the patient's lungs through varying oxygen levels and pressure support. They are typically used in hospital settings for patients with severe respiratory problems. We primarily focus on the 10% of the patient population under long-term – defined as over 14 days – ventilation (Ambrosino), where the standard practice is to use high acuity mechanical ventilators which can support life on a prolonged basis. A variety of situations can place patients on long-term ventilation, including respiratory diseases, spinal cord injuries, and neuromuscular diseases, which could inhibit the muscles of the human body from carrying out the respiratory process. There are three main pain points in the current standard of care for long-term ventilator management:

1. Diligent monitoring is required to avoid complications such as sepsis or pneumonia. Yet, despite best efforts, extubation failure rates are relatively high. Ventilator monitoring is currently a discrete process, with no way to monitor multiple patients at a time.
2. Routine and minor ventilator adjustments require a physician or respiratory therapist to don personal protective equipment, adding 6 minutes per patient per check-up wasting critical time which could be spent delivering high-quality patient care (CDC).
3. Extubation failure is associated not just with an increased risk of death but also with more prolonged ICU stays and the use of hospital resources.

There are two broad categories of mechanical ventilators: standard ventilators and high-acuity ventilators. Standard ventilators are not typically used for long-term breathing support and require doctors, nurses, and respiratory care teams to enter the patient's room every time adjustments need to be made. The primary advantage of these ventilators are that they can be very cheap, thereby allowing doctors to perform short-term mechanical ventilation under significant hospital budget constraints. High-acuity ventilators, on the other hand, are built to support long-term care options and have significantly more features, namely remote control support, giving clinicians continuous access to the monitoring and adjustment of ventilator settings and respective patients. Unfortunately, because of the high cost, most hospitals in lower resource settings (i.e. community hospitals) cannot access this technology for their patients. There currently exists no solution on the market that offers the remote control capabilities of high-acuity ventilators and high savings potential of standard mechanical ventilators.

The global mechanical ventilator market, valued at \$6.8 billion in 2020, is projected to grow at a Compounded Annual Growth Rate of 5.8% during the forecast period 2021-2031 (Visiongain). Primary factors that influence the market's growth include the prevalence of respiratory diseases and disorders, such as COVID-19, the rise in the geriatric population, the availability of funding and resources for developing and distributing ventilators by government initiatives, and the regulatory environment for medical devices. With more patients requiring ventilation, it has never been more critical for clinicians to have the resources to quickly make necessary interventions to support adequate respiratory function. There is a need for improved ventilator management strategies that can reduce the risk of complications and improve the quality of life for long-term ventilation patients. The need specifications used in the design and

fabrication of a device to address these pain points in ventilation management can be viewed in

Table 1:

Category	Specification	Value
Accessibility	Cost	Affordable attachment avoids the need of purchasing an entire new and renovated ventilator system
		< \$300
	Compatibility	To be made available with a variety of attachments to ensure proper fit with all ventilators in the market
	Remote Control	Pressure control accessible via smartphone app.
Physical	Dimensions	Maximize available space in ICU & operating rooms
		<= 1 ft ³

Performance	Pressure Support	5 - 30 cmH ₂ O (standard range of pressure support for ventilators)
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Table 1: Need Specifications for EZ-X.

Our external ventilator attachment, EZ-X, enables remote pressure control in a standard mechanical ventilator system through an app. Remote control access to ventilators can provide a significant value proposition to hospitals that address the three main pain points in the current standard of care for management of long-term patients:

1. With the ability to rapidly monitor and respond to clinical changes, the quality of patient care will be improved. Remote control access allows medical professionals to simultaneously access and adjust the settings on a single ventilator, reducing the risk of error. This can be especially useful when a patient's condition is rapidly changing or a healthcare provider cannot be physically present at the bedside.
2. Remote control access would reduce the need to enter the room, saving doctor time and reducing the risk of cross-contamination or exposure to infectious material.
3. Remote control access to ventilators has the potential to reduce the financial burden on healthcare systems by improving workflow efficiency and lessening patient ICU time.

Looking beyond our current target population, remote control access capabilities provided by EZ-X has to potential to impact other end users, such as those in-home care or elderly care centers.

Remote control access to ventilators has been adopted by various companies, including General Electric (GE), Philips, Medtronic, and ResMed. However, our device provides the specifications that existing solutions lack: It is significantly less expensive and can integrate with current traditional ventilator systems by attaching externally to equipment output (See **Table 2**).

Options → Properties ↓	ResMed: AirView	Philips: IntelliVue Remote Control	Johns Hopkins University: Robotic Arm	Our Solution: EZ-X
Able to remotely adjust output pressure	✓	✓	✓	✓
Cost to Implement (< \$300)	✗	✗	✗	✓
Compatibility with any ventilator	✗	✗	✗	✓

Table 2: Differentiation from Available Remote Control Technology for Ventilators.

PROJECT OVERVIEW

Objectives/Impact

Our solution, EZ-X, is an intricate valving mechanism along with a doctor-facing app to remotely control a mechanical ventilation system's pressure (**Figure 1**). The valve mechanism is connected to ventilator breathing tubes as a method of changing the amount of respiratory assistance being supplied to the patient independent of the ventilator itself. Our device is also enclosed in a casing that allows it to be hung from a patient's bedside to keep the operating room clean and with less occupied space. When a doctor wants to treat a patient, our solution allows for the following workflow: First a doctor can view an intubated patient's vital sign data on our app. If they want to change the pressure support going towards the patient, they can navigate to that page on the app and subsequently change the pressure. This value is communicated wirelessly to our device hardware which then undergoes a loop. Our valve mechanism incrementally adjusts its door position and after each adjustment reads the new pressure. Once the pressure in the system matches the pressure set by the doctor the loop ends and the process is complete. This workflow highlights EZ-X's ability to allow for remote treatment over a patient on mechanical ventilation, freeing up doctor time and improving workflow efficiency.

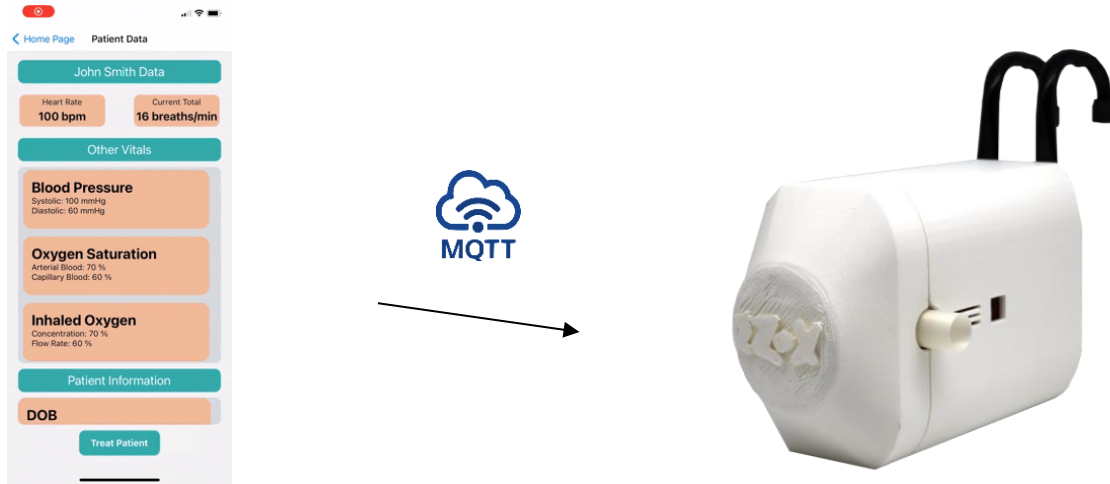


Figure 1: Device Components

By enabling healthcare providers to adjust ventilator settings remotely, our solution also helps reduce the gap in care between large university hospitals and community hospitals. Well funded university hospitals have greater access to high-acuity ventilators, subsequently increasing the care potential for any given patient. However, less funded community hospitals cannot afford these ventilators with long-term capabilities. Our device can be used as an attachment to standard mechanical ventilators to provide them with high-acuity abilities while avoiding the expensive purchase of a brand new high-tech ventilator, thereby creating new care possibilities in less funded hospitals in an affordable manner.

Limitations

There are several additional challenges associated with the current standard of care for ventilation management of long-term patients. One of the main challenges is the risk of complications arising from infection, such as when bacteria enter the lungs through the ventilation tube. As we continue to develop EZ-X, device sterility is a key concern, which we

plan to address through a replaceable filter, and using material that allows our device to be sterilized following typical respiratory device clearing protocols: i.e. a washer-disinfector (World Health Organization). Another limitation of our device is that currently we only have the ability to adjust pressure, however, ventilators have many other tunable parameters that we do not have currently control over. Finally, our device still has room for improvement, given a significant difference exists between the trends found through validation and the expected behavior as described by fluid dynamics, namely, the Hagen-Poiseuille equation. This difference is expected due to limitations in air tightness in our device which can be improved through further development of the valve mechanism.

Standards and Regulations

The U.S. Food and Drug Administration (FDA) will be the primary regulatory agency for our device and we will utilize a mixture of current FDA accepted devices to gain approval for EZ-X. Ventilator tubing is a medical device with product code QOO; a continuous ventilator is a medical device with product code QoS. Additionally, since our device is part of the process supporting human life, it is a Class III device. Class III devices are subject to a rigorous approval process. First, an IDE (Investigational Device Exemption) has to be obtained from the FDA to begin clinical trials. We will also submit a 501(k) application to obtain FDA clearance. PMA (Premarket Approval), the most stringent form of approval from the FDA, will have to be obtained in order to properly prove the safety and effectiveness of the device.

Design And Development

For POC, a crude device was built to successfully show that the release of pressurized air to atmospheric pressure from a section of tubing would decrease the overall pressure in a

network of tubes (**Figure 2**). The input of airflow into the system was controlled through a solenoid valve that opened to release a portion of the oxygen to the open air and closed to direct all flow towards the hypothetical patient output. A pressure sensor was placed at the end of the tubing system where oxygen would be supplied to the patient. The data read by the pressure sensor was output to an LCD screen to allow for realtime observation of pressure change due to the opening of the opening and closing of the valve.

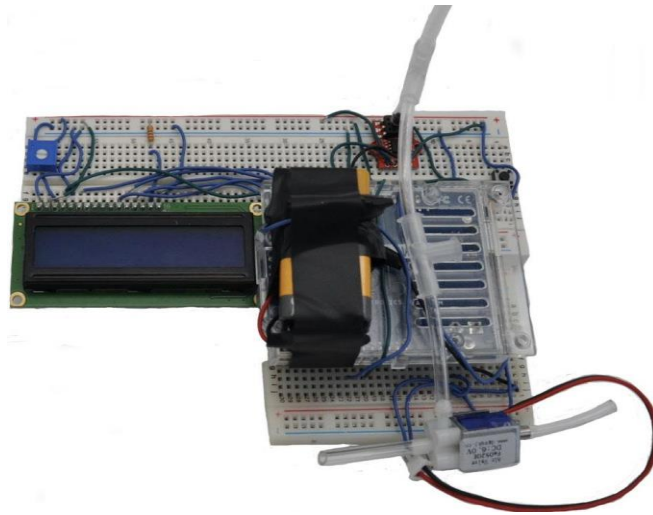


Figure 2: POC design

Testing the POC occurred in the Penn Biology Labs (Levin Building). The built-in table gas output was used as a pressurized air source to pass through our tubes and into our solenoid valve mechanism. We were able to successfully show that when the valve was open to atmospheric pressure, our pressure sensor reading was lower, and when it was closed, it was higher. Although these solenoid valves were useful for POC, they can only switch between open closed states, therefore they do not have the capacity to be partially open to support a range of pressure control.

For a minimum viable product (MVP), we developed our own valve mechanism to adjust system pressure at a more granular and dynamic level while adhering to traditional

ventilator tubing size requirements. The valve is built to adjust pressure through the use of a rack and pinion for the movement of a partition that divides the air flow in the system (**Figure 3**). The valve was designed with a door containing specifically placed holes where, when it moves in and out of the valve body, it lets a proportional amount of airflow into either the pathway to the patient or the open air at atmospheric pressure. The process of airflow management can be better visualized in **Figure 4**. For the MVP, we also designed casing for the device as the valve would need to be enclosed in a clinical setting for safety concerns. We developed a basic box casing design that packages our device as per design specifications with the intent of being placed on a tabletop setting between a ventilator and the patient. This casing had the required holes for proper electrical connection and for breathing tubes to be attached. A user interface comprising a single screen on an app was also built for system control and data visualization which displays real time pressure readings from the system and provides an easy way for a doctor to set system pressure (**Figure 5**). The app communicated with the hardware device using the MQTT communication protocol over WiFi. This two way communication involves the app sending desired pressure set points to the hardware, and the hardware subsequently communicating the current system pressure read by a sensor back to the app.

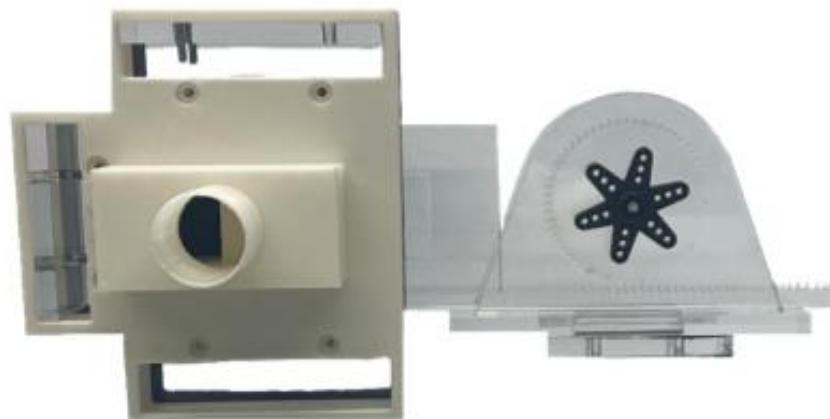


Figure 3: Rack and Pinion based mechanical valve built for MVP

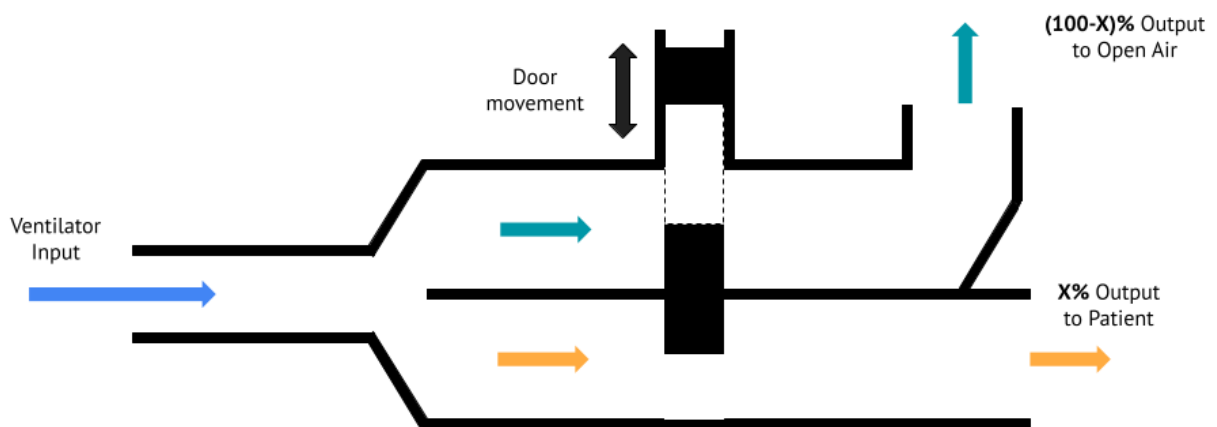


Figure 4: Valving Mechanism Schematic

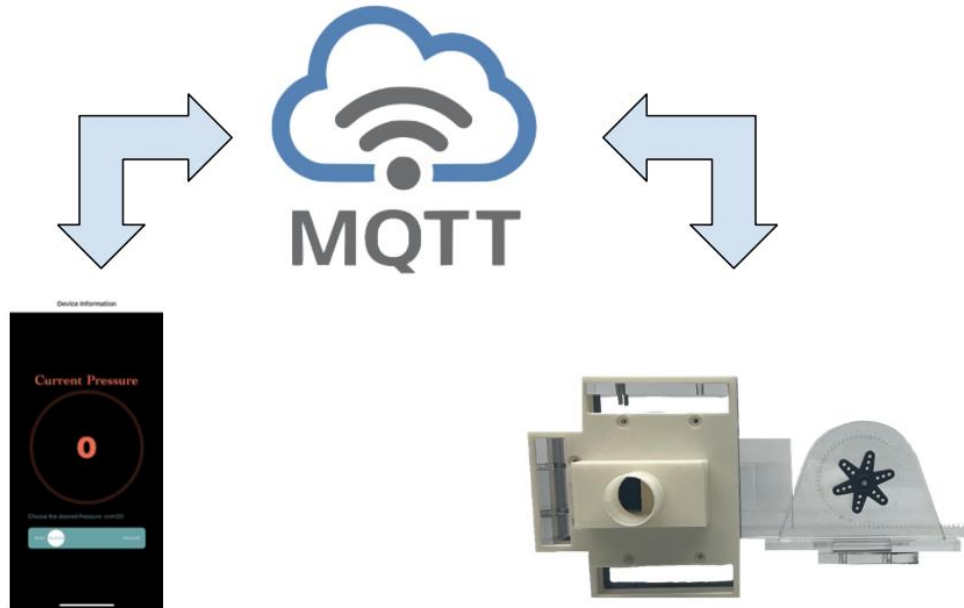
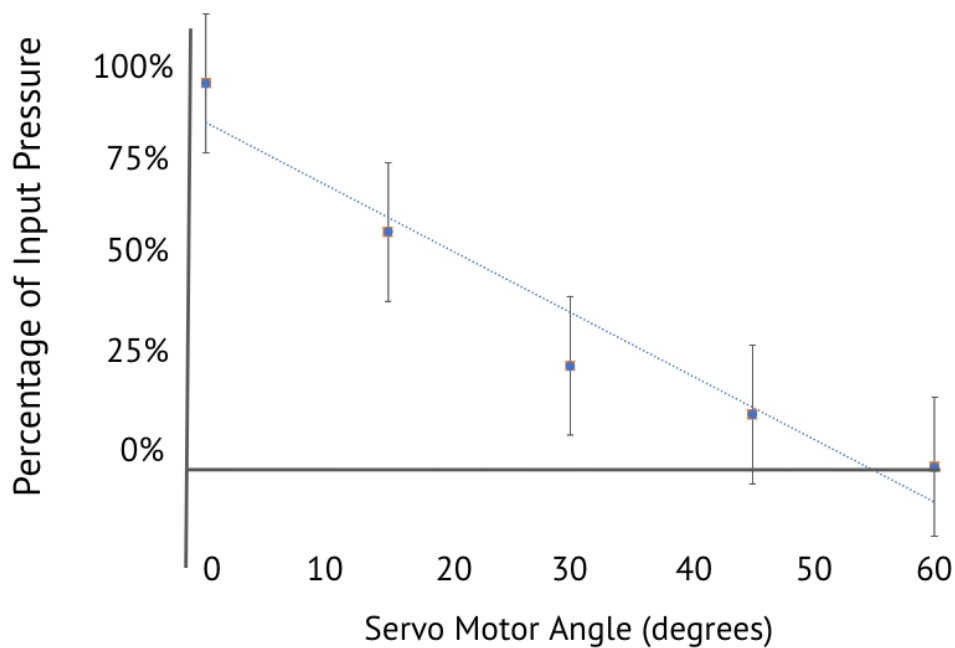


Figure 5: MVP System Design

MVP testing was carried out using an electric ball pump as a constant pressure source to mimic the input received from a ventilator. We validated our device by observing the output as a percentage of the input. We tested over 5 different servo motor positions, with 0 degrees representing 100% open to the patient and 60 degrees representing 0% open to the patient. **Figure 6** demonstrates a clear linear trend in pressure over various servo motor positions and fits a regression with an R^2 of 0.93, proving that our device can vary pressure for the patient with significant reliability.

Output Pressure Profile



$$R^2 = 0.93, \text{ Avg, S.E.} = 0.017$$

Figure 6: Output Pressure Profile Results for Testing of MVP.

Our final prototype took all of the components of our MVP and enhanced them to give our product increased accuracy and a professional appearance (**Figure 1**). With respect to the device hardware, we redesigned the valve mechanism to reduce air loss and repositioned the pressure sensor to give it closer proximity to valve door, thereby increasing the accuracy of its readings. From a software standpoint we made significant improvements to the mobile application, moving from a single screen user interface to an app that has the look and feel of a full healthcare platform. **Figure 7** shows all the different pages contained in our app and how to navigate to each of them. A full description of how the doctor is intended to interact with the app along with each of its pages is described in the user manual which can be found in the Appendix.

For the casing of our final prototype, it was first decided to change the design with the intent of making the device's placement in the ICU more convenient. This involved reducing the overall volume of the device as the MVP casing gave rise to significant unused space on the interior of the device. Additionally, bedside hooks were added to the casing during this modification period to support convenient placement of the device directly next to the patient. These improvements follow our goal of minimizing the space the device occupies in what are already cluttered ICUs and removes the need of tabletop space in order for the device to be used. Apart from these changes, the casing was also modified with the intent of having a more professional and aesthetically pleasing appearance, leading to a change from the boring boxed shape to a more artistic and creative design of the casing, including the extruded EZ-X logo on the front along with a lot more curvature to the casing design.

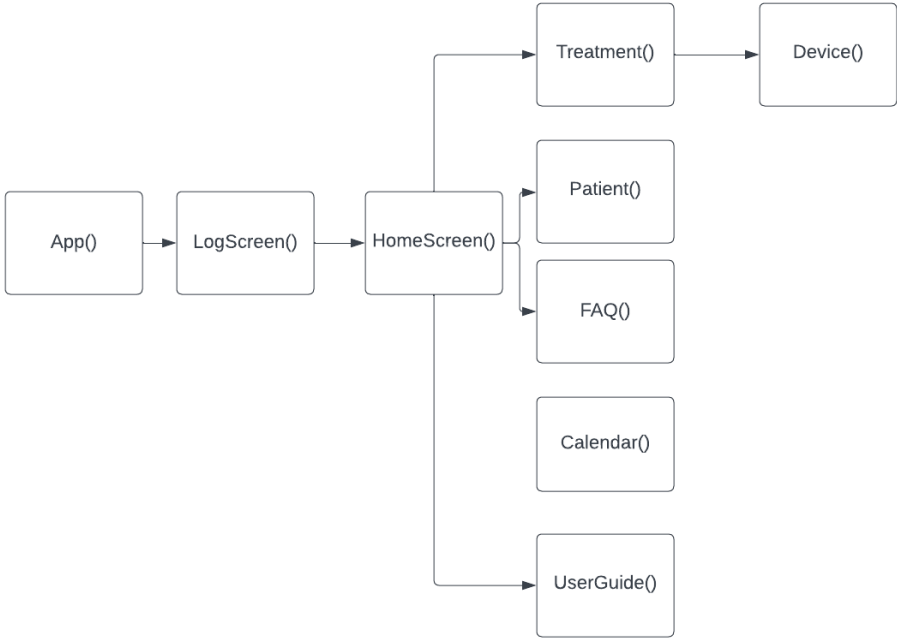


Figure 7: Block diagram showing the various app screens

TESTING AND EVALUATION

1. Methods

For our final prototype, two separate experiments were derived to ensure the accuracy of reading and setting pressure on the EZ-X device. Validating the pressure sensor's ability to correctly read the pressure was necessary before conducting experiments to test the accuracy of the pressure setting, as control of the EZ-X valve mechanism relied on the data from said sensor.

1.1 Methods for Testing the Adafruit MPRLS Ported Pressure Sensor

The goal of this experiment is to calibrate the pressure sensor by creating a relationship between the pressure inputted into the sensor and the pressure read by the sensor. The input pressure was set constant through using a syringe model. The pressure in a syringe can be modeled using surface area and force. By keeping force constant, and varying the distance of the syringe plunger, the pressure outputted by the syringe can be changed.

To calibrate the sensor, the difference between the theoretical pressure sensor and experimental response of the pressure sensor should be quantified. The theoretical response was modeled using the data sheet equations provided for the voltage value that the pressure sensor should read given an input pressure. The experimental curve was then created using the same range of pressures, and the corresponding voltage value that was outputted was documented.

In order to calibrate the pressure sensor, a syringe-tube setup was used (**Figure 8**). In this setup, the pressure sensor and syringe are connected using thin tubing between them, ensuring that there is a tight fit to avoid air loss.

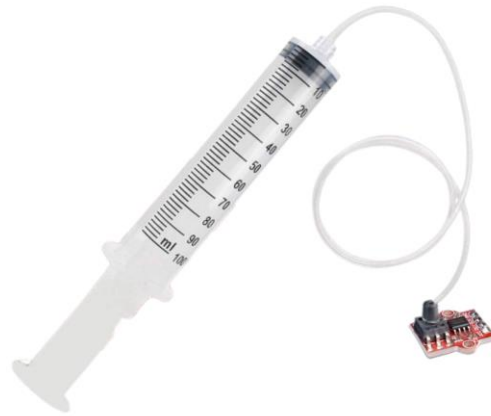


Figure 8: Pictured above is syringe-tube structure that was used to calibrate the attached pressure sensor

1.2 Validation for Testing the EZ-X Valve Mechanism

To validate the accuracy of pressure control through the EZ-X valve mechanism, an experiment was designed to replicate how the device would work in the pathway between ventilator output and patient lungs. To do this, it was necessary to find sufficient replacements for a mechanical ventilator and human lungs to validate the device outside of the hospital setting.

Considering EZ-X operates via a constant input from the mechanical ventilator, this airflow can be represented through another constant source. In order to meet budget requirements, be transported easily, and allow for quick setup, a traditional hair dryer (**Figure 9**) was used to replicate the performance of a mechanical ventilator if it were set to a consistent

flow setting. To connect the output of the hair dryer with the input of EZ-X, a small attachment piece was constructed that acts as a funnel to move from a larger cross sectional area to a smaller one.



Figure 9: Pictured above is a Revlon hair dryer, used to replicate a mechanical ventilator input to the EZ-X device. This includes a special attachment (in blue) to allow for proper connection to the input side of the device.

The lungs of a patient were replicated using a balloon (**Figure 10**) that was attached to the output side of the EZ-X device. The use of this balloon allowed for a build-up of pressure that would normally occur to the human lungs when receiving oxygen from a mechanical ventilator. It is important to note that the size of the balloon is not comparable to the lungs of a human being as it must be scaled down to match the reduced output of the hair dryer as compared to the output of a mechanical ventilator.

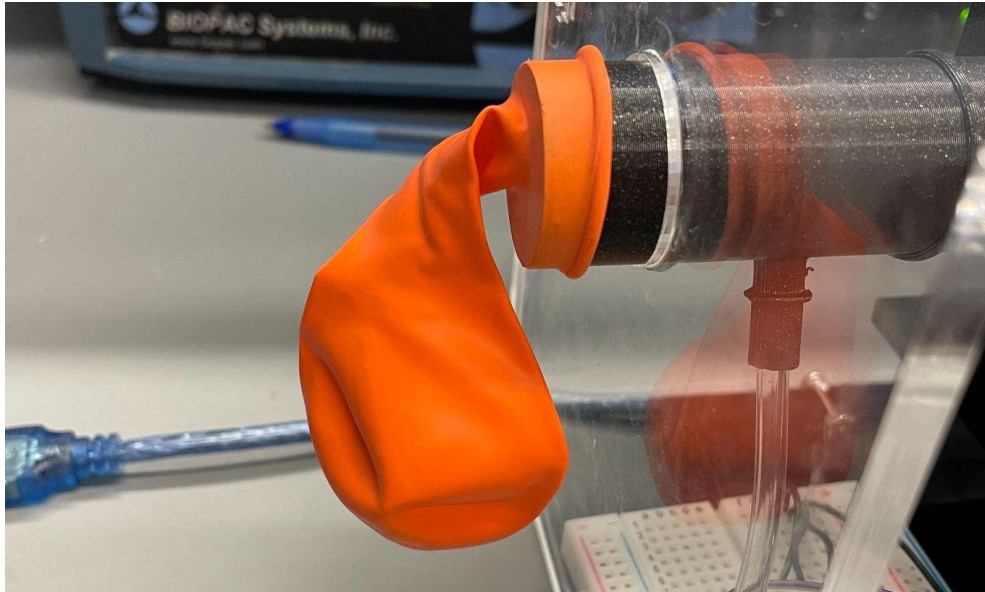


Figure 10: Pictured above is a traditional balloon used to replicate the pressure build up associated with the human lungs when receiving oxygen from a mechanical ventilator.

For the experiment, the hair dryer with the attachment piece and balloon were placed onto the input and output sides of the EZ-X device, respectively (**Figure 11**). Using a simple Arduino script to manually control the operation of the door in the valve mechanism, pressure readings were taken from the output half of the device over varying door positions ranging from 0% to 100% open with a percentage step of 10%. A delay of about 5 seconds was performed between measurements at a given position, after which the door position would change. This was performed 5 times for each of the door positions, moving from a fully closed position at 0% towards a fully open position at 100%. The data from the pressure sensor was printed to the Serial Monitor of the Arduino IDE and read into an excel spreadsheet for subsequent analysis.



Figure 11: The EZ-X testing mechanism comprising a hair drier to replicate the airflow patterns of a ventilator (left), the EZ-X device itself (center), and a balloon to simulate pressure build up, similar to that of a lung (right).

2. Results

2.1 Pressure Sensor Validation Results

The theoretical response for the pressure sensor was devised using the equations in the pressure sensor data sheet.

$$P = \frac{V_R}{S} + \frac{b}{S}$$

Figure 12: The response of the MPS20N0040D sensor between electrical signal and measured pressure, where V_R is the Voltage, S is the sensitivity of the system, and b is the DC offset.

$$P = 200X \cdot \overbrace{S}^{\text{Voltage Reading Sensitivity}} \cdot \overbrace{ADC}^{\text{Pin Reading}} + 500$$

Pa to cmH2O constant

Figure 13: Equation to convert the pressure sensor reading to pressure value for experimental readings.

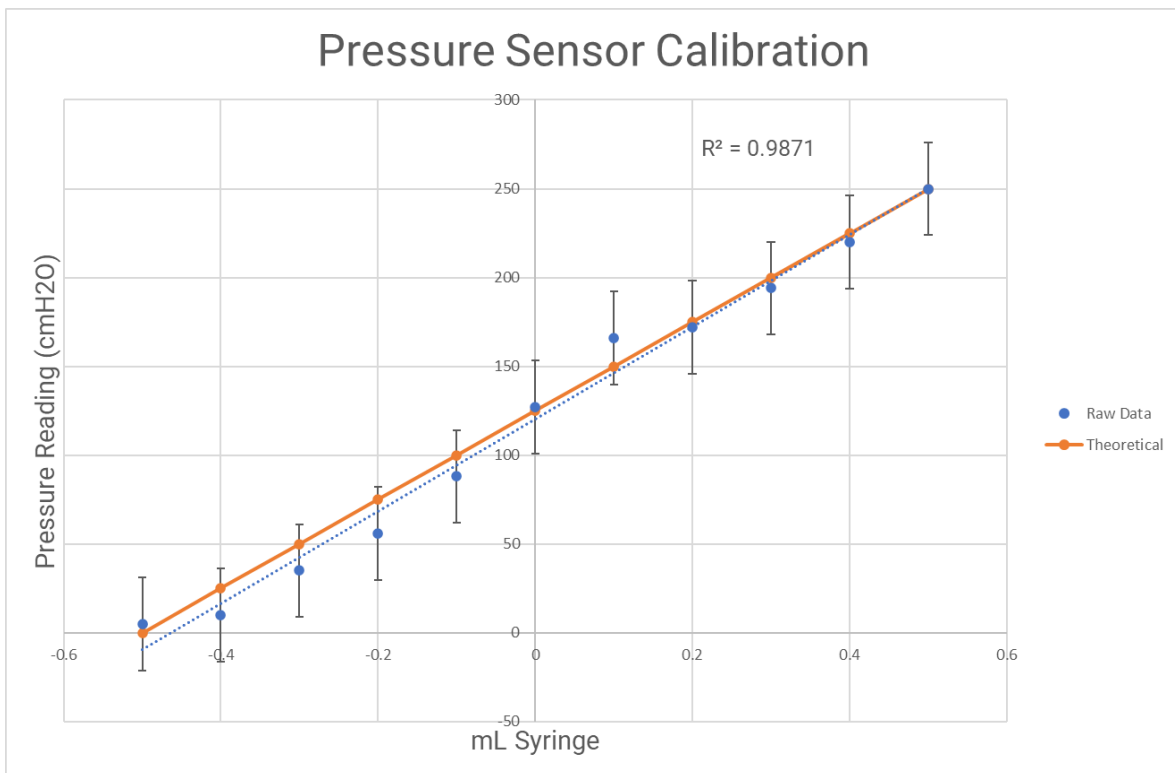


Figure 14: The results from experiment 1.1 are shown. The raw data (shown in blue) was collected over 5 trials and averaged for each of the pressure values gathered from varying the plunger position of the syringe. Given the error between the theoretical (orange) and raw data,

the pressure sensor is minimal enough to not account for a calibration offset in taking measurements from our sensor moving forward.

2.2 EZ-X Valve Mechanism Validation Results

For each door position of the valve mechanism ranging from 0% open to 100% open, measurements were averaged across the 5 trials and plotted with standard error. As shown in **Figure 15**, the data collected follows a linear regression with a relatively high degree of accuracy ($R^2 = 0.9759$). Considering varying door positions is truly a change in the volumetric flow rate entering the output section of the device, it is reasonable to compare the raw data trendline to one predicted by the Hagen-Poiseuille equation (**Figure 16**). This equation directly relates the volumetric flow rate to the internal tubing pressure by a scalar determined by system properties. As shown in the figure, this trendline is also linear and is closely related to the results of the measured data.

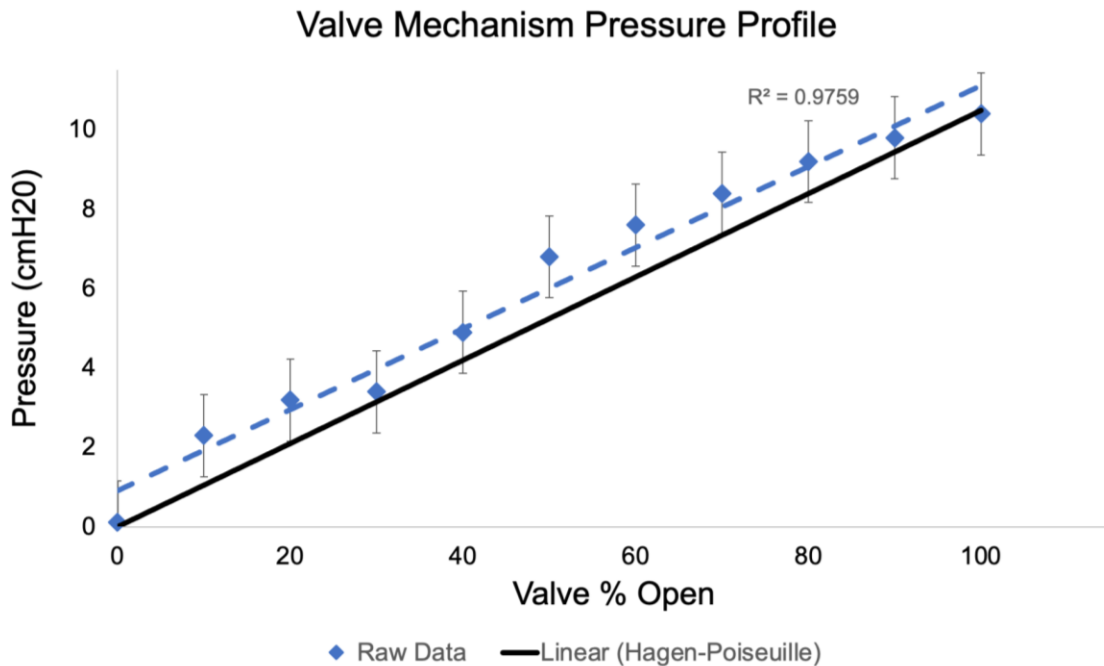


Figure 15: The results of Experiment 1.2 are shown above. The raw data (in blue), was collected over 5 trials and averaged for each of the door positions. Considering the regression on the raw data matches an R^2 value of 0.9759, there is enough confidence to say that it follows a linear relationship. This is also confirmed by the Hagen-Poiseuille equation (in black), which dictates how pressure changes in response to varying volumetric flow rates (via door position).

$$P = \frac{8\mu LQ}{\pi R^4}$$

Figure 16: The Hagen-Poiseuille equation relates the output pressure (P) to the volumetric flow rate (Q) by a scalar, which is comprised of μ (the viscosity of air), R (the radius of the tubing), and L (the length of the tubing).

3. Discussion

While a mechanical ventilator typically provides a maximum pressure of 30 cmH₂O, the maximum air pressure provided by the hair dryer was 10 cmH₂O. However, this was sufficient for testing purposes since our goal was to see if EZ-X could modulate the pressure output between 0 and a given maximum value. It should also be noted that the current validation model does not replicate actual breaths, but rather only the initial filling of the lungs during inhalation. Thus, a more robust lung model would be necessary for future testing. Therefore, procurement of an advanced lung simulator is required to introduce more elaborate methods of validation and testing of the EZ-X device.

When analyzing the results of the valve mechanism validation experiment, the difference between the expected linear Hagen-Poiseuille relationship and our calculated regression of the results is certainly a result of error. These errors may be a result of the simple ventilator and lung replicants discussed above, however, it is most likely due to sources of air loss in the device, as the device is built from plastic through 3D printing methods which is not particularly air tight.

4. Conclusion

As determined by the results of each of the validation experiments, it is concluded that the EZ-X operates reliably within the pressure range of 0 to 10 cmH₂O. Although there is a significant difference between the measured values and the theoretical, a clear linear trend is observed with an R² value of 0.9759, therefore the pressure can be easily adjusted to fit deployment use cases. For the future of the device, it is important to recognize that there are a series of improvements that can be made, namely, reducing the air loss. Moreover, it is clear through this testing that additional sensors be used in the control of the device to reduce error overall.

FUTURE

Looking beyond the scope of this class, there are a few key next steps in developing EZ-X. From a software perspective, we want to continue working on getting real patient data into our app. We spent a lot of time this semester trying to integrate with Epic's Sandbox API, however, we couldn't quite get over the hurdle in time. Our first step would be to successfully integrate our app with this API as this would show we can successfully integrate with Epic,

albeit their sandbox platform. Once we integrate with this API, we can move on to full integration with Epic software at which point we'd have patient data completely integrated into our app. The last step for our app would be deployment for widespread use amongst hospitals.

On the hardware side we have a couple developments we'd like to incorporate. From a device usability standpoint we would like to develop an assortment of external attachments for our device to ensure it is compatible with all industry standard ventilators. From a functionality standpoint we would like to expand the capabilities of our device to include control over other ventilation parameters such as oxygen concentration to make our device more all-encompassing.

One of the final steps would be the implementation of EZ-X in the clinical setting. In order to get our device clinically approved, the process would start with applying for IRB approval. In this case, EZ-X classifies as a Class III medical device, being part of the process that supports human life. Therefore, EZ-X would also require IDE approval from the FDA before the clinical studies begin at any site. Once receiving IRB and IDE approval, EZ-X would be implemented into the hospital setting at Penn Medicine, hanging the device by the bedside of patients in order to remotely adjust the degree of ventilator assistance being supplied to the patient through the app. This would be the start of a long process of thorough clinical trials, which could be expected to last for about 2 years for Class III medical devices. This clinical testing is done to support PMA (pre-market approval) from the FDA, the most stringent form of market approval that all Class III devices need to obtain. This helps obtain sufficient valid scientific evidence demonstrating the device's safety and effectiveness. Finally, it would also require a one year follow-up after treatment has been provided with the device.

We expect some difficulty when seeking regulatory approval for our device as being a class III device requires an extremely rigorous process as outlined above. The primary challenge that we expect to face during this process is proving that the breathing tubes connected to EZ-X can interface with the open air in a given intensive care unit without posing a threat to the patient. This would require developing and validating a filtration system that can prevent contamination of the airway while keeping airflow properties and manipulation techniques unaffected. Considering no device similar to EZ-X that interfaces the airway with the open environment has been approved by the FDA, we expect to conduct separate clinical trials that particularly address the filtration system.

REFLECTION

We initially proposed a software-backed ventilator attachment that would automatically adjust ventilator pressure support and oxygen concentration supply based on patient breathing. The desired outcome for this project was to shift the treatment paradigm from a subjective ventilator adjustment to objective values tailored for each patient. However, our understanding of how medical personnel manage long-term ventilation patients changed our intended value proposition. Given that the current standard of care requires doctors' input, we found new value in allowing continuous monitoring by a doctor rather than an automated adjustment system. Once we understood our problem, our development process was quite dynamic in certain aspects but more streamlined in others. From a hardware perspective our designs changed multiple times from the use of solenoid valves to ultimately building a custom valve. This came with a lot of learning curves as building a new valving mechanism came with a ton of trial and error. Designing the valve required a lot of thought in how the fluid dynamics should work to fit

our intended use case and as a team we learned a lot about fluid dynamics throughout the process. Understanding how the air should flow through the valve while accounting for factors such as air loss was a rewarding process. From a software perspective the development process was more streamlined as we knew from the start we would need a sophisticated doctor facing app with certain functionalities. We also knew that we would want wireless communication going between our app and device so we started developing the capabilities for this early on. Overall, the project was a good learning experience involving the integration of hardware and software components while also being cognizant of underlying scientific principles.

If we were to do this project again, we would map out our hardware time-line and workflow more precisely rather than taking a “seeing where it goes” approach. For a majority of the development process, we lacked a clear idea of what the final product would look like or fully function as, which held us back from including all the features that could have been integrated in the final design. We would also try to get into a hospital setting to see how ventilators play out in real-time, both in terms of clinical care cycles and testing of EZ-X. A majority of our research relied on either clinicians or engineers, but we found that it was difficult to bridge the gap between the two. In the future, we can expand our search of mentors and advisors to talk to that have both a clinical and theoretical understanding. We pivoted to this project late in the fall semester which prevented us from doing full due diligence during that phase of the semester, but this is definitely something we would do if we could restart.

Appendix

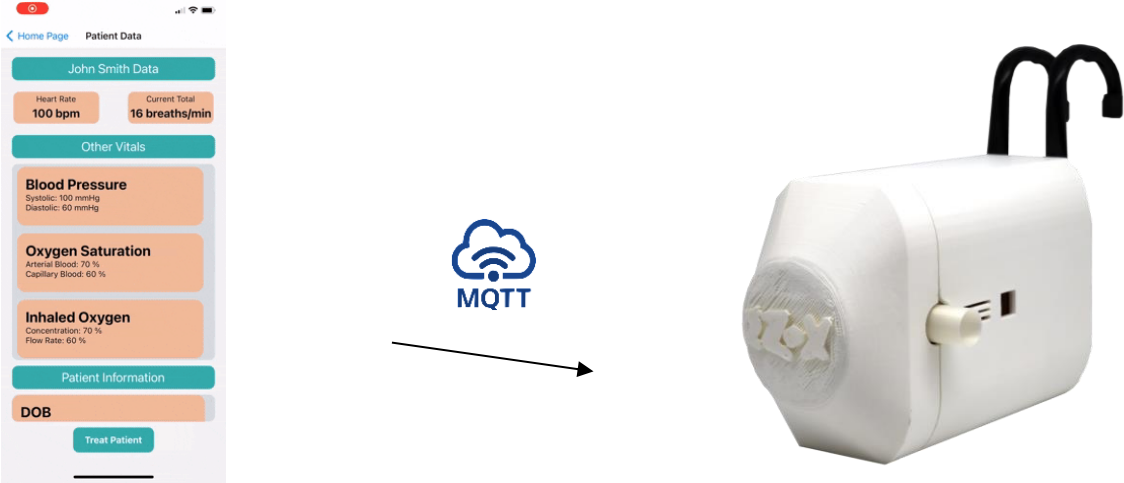


Figure 1: Device Components

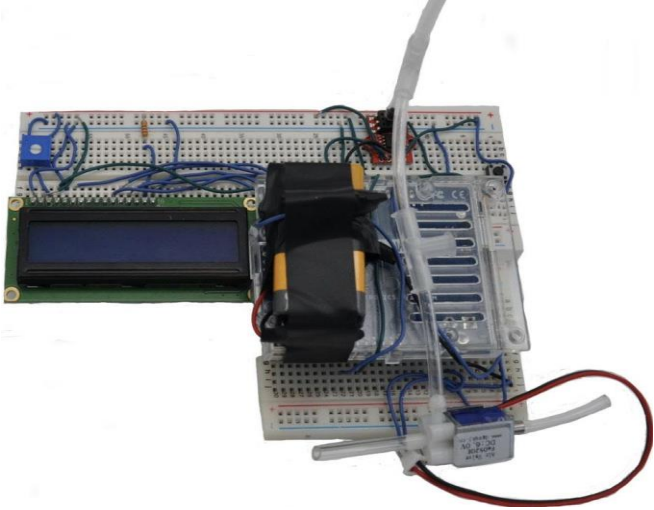


Figure 2: POC design



Figure 3: Rack and Pinion based mechanical valve built for MVP

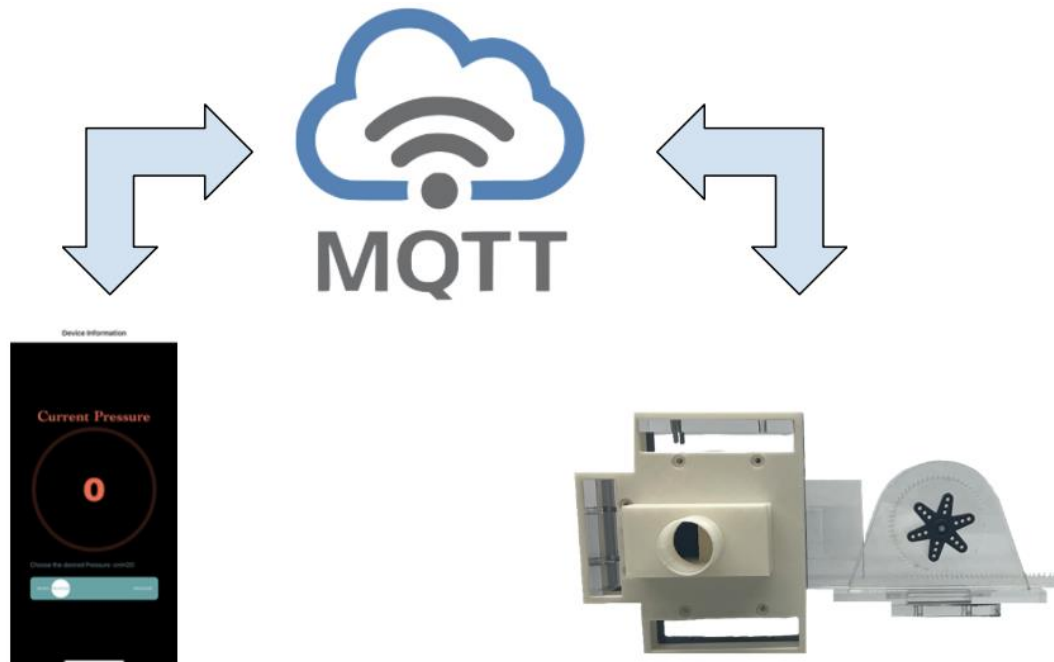
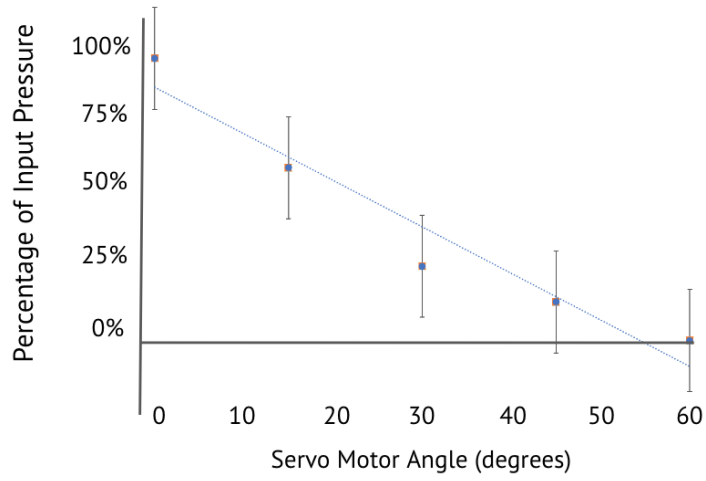


Figure 4: MVP System Design

Output Pressure Profile



$R^2 = 0.93$, Avg, S.E. = 0.017

Figure 5: Output Pressure Profile Results for Testing of MVP.

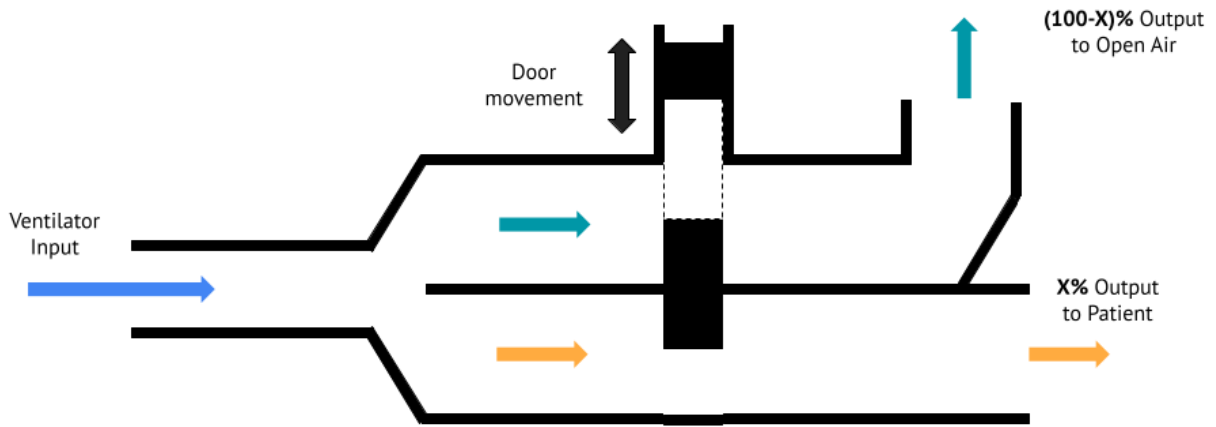


Figure 6: Valving Mechanism Schematic

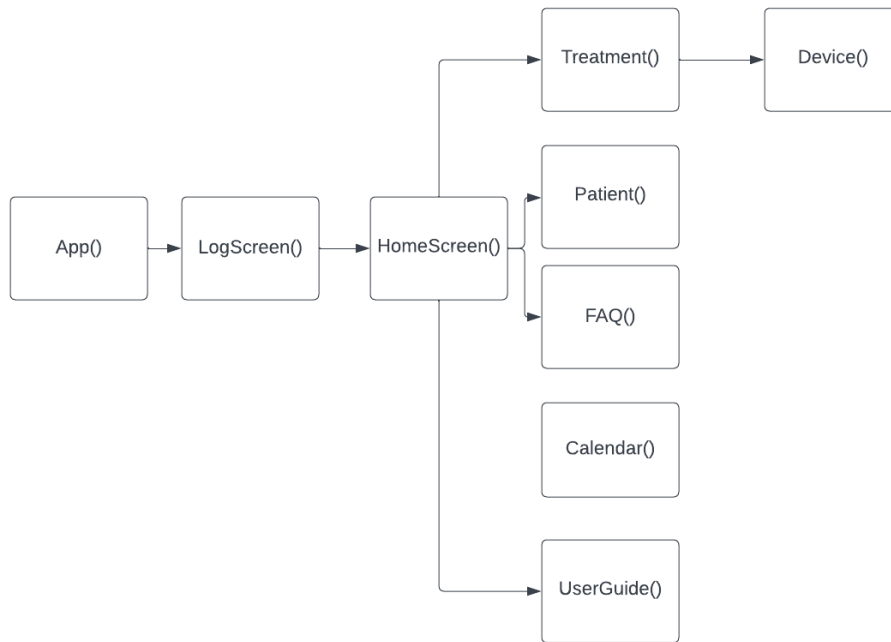


Figure 7: Block diagram showing the various app screens

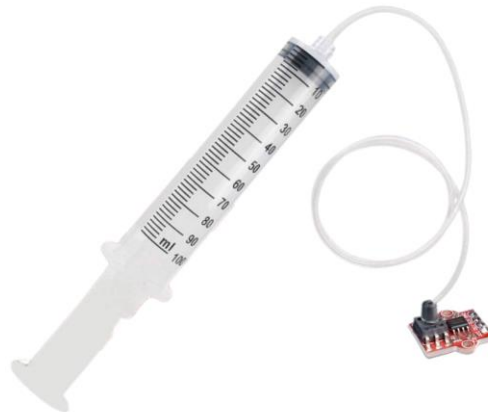


Figure 8: Pictured above is syringe-tube structure that was used to calibrate the attached pressure sensor



Figure 9: Pictured above is a Revlon hair dryer, used to replicate a mechanical ventilator input to the EZ-X device. This includes a special attachment (in blue) to allow for proper connection to the input side of the device.

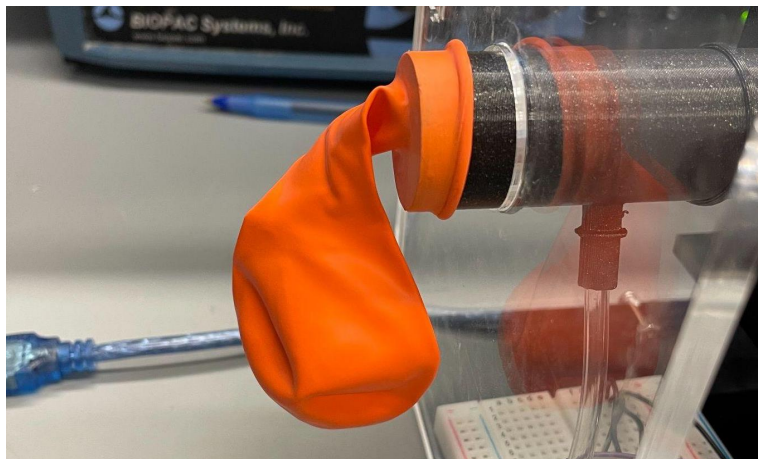


Figure 10: Pictured above is a traditional balloon used to replicate the pressure build up associated with the human lungs when receiving oxygen from a mechanical ventilator.

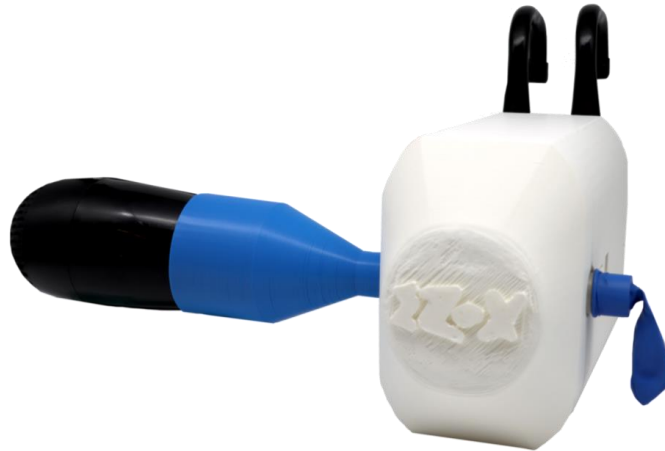


Figure 11: The EZ-X testing mechanism comprising a hair drier to replicate the airflow patterns of a ventilator (left), the EZ-X device itself (center), and a balloon to simulate pressure build up, similar to that of a lung (right).

$$P = \frac{V_R}{S} + \frac{b}{S}$$

Figure 12: The response of the MPS20N0040D sensor between electrical signal and measured pressure, where V_R is the Voltage, S is the sensitivity of the system, and b is the DC offset.

$$P = 200X \cdot \overbrace{S}^{\text{Voltage Reading Sensitivity}} \cdot \overbrace{ADC}^{\text{Pin Reading}} + 500$$

Pa to cmH2O constant

Figure 13: Equation to convert the pressure sensor reading to pressure value for experimental readings.

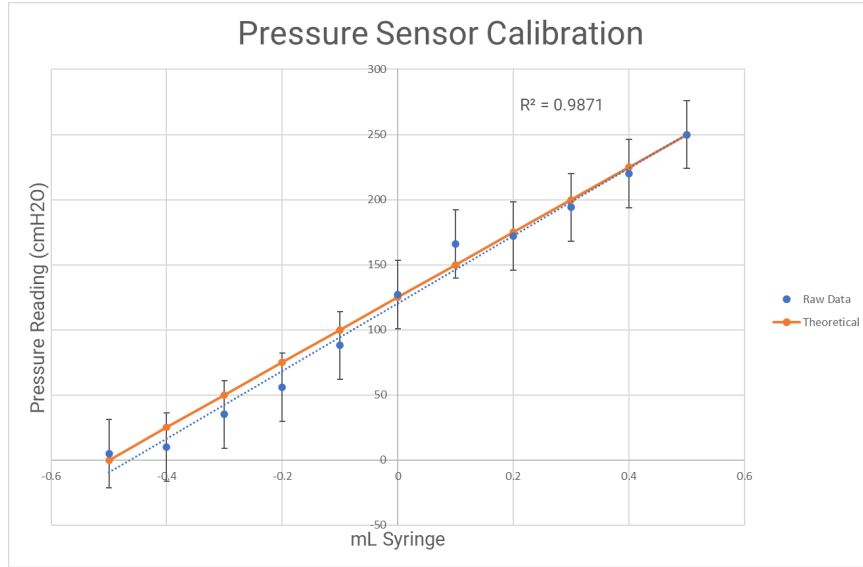


Figure 14: The results from experiment 1.1 are shown. The raw data (shown in blue) was collected over 5 trials and averaged for each of the pressure values gathered from varying the plunger position of the syringe. Given the error between the theoretical (orange) and raw data, the pressure sensor is minimal enough to not account for a calibration offset in taking measurements from our sensor moving forward.

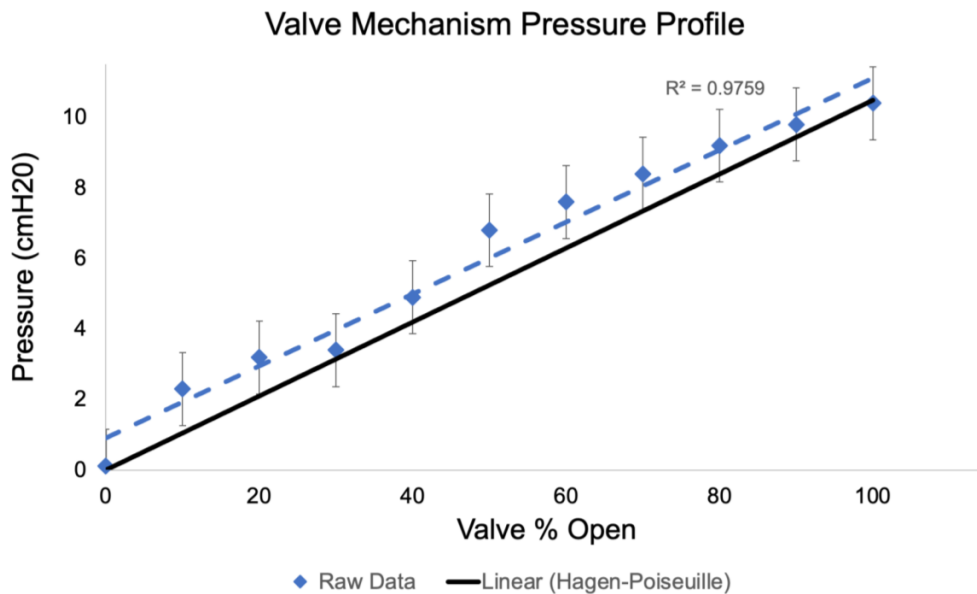


Figure 15: The results of Experiment 1.2 are shown above. The raw data (in blue), was collected over 5 trials and averaged for each of the door positions. Considering the regression on the raw data matches an R^2 value of 0.9759, there is enough confidence to say that it follows a linear relationship. This is also confirmed by the Hagen-Poiseuille equation (in black), which dictates how pressure changes in response to varying volumetric flow rates (via door position).

$$P = \frac{8\mu LQ}{\pi R^4}$$

Figure 16: The Hagen-Poiseuille equation relates the output pressure (P) to the volumetric flow rate (Q) by a scalar, which is comprised of μ (the viscosity of air), R (the radius of the tubing), and L (the length of the tubing).

Category	Specification	Value
Accessibility	Cost	Affordable attachment avoids the need of purchasing an entire new and renovated ventilator system
		< \$300

	Compatibility	To be made available with a variety of attachments to ensure proper fit with all ventilators in the market
	Remote Control	Pressure control accessible via smartphone app.
Physical	Dimensions	Maximize available space in ICU & operating rooms
		$\leq 1 \text{ ft}^3$
Performance	Pressure Support	5 - 30 cmH ₂ O (standard range of pressure support for ventilators)

Table 1: Need Specifications for EZ-X.

Options → Properties ↓	ResMed: AirView	Philips: IntelliVue Remote Control	Johns Hopkins University: Robotic Arm	Our Solution: EZ-X
Able to remotely adjust output	✓	✓	✓	✓

pressure				
Cost to Implement (< \$300)	×	×	×	✓
Compatibility with any ventilator	×	×	×	✓

Table 2: Differentiation from Available Remote Control Technology for Ventilators.

EZ-X User Manual

Safety Considerations and Caution Statements

Before using EZ-X, please note the following:

1. **Ventilation Pressure Support:** EZ-X assumes that ventilator pressure support is set to 30 cm/H₂O and does not deviate from this value. It is critical to ensure that the pressure support is set to the correct value before using EZ-X, as the device takes this output and carves it down to the desired pressure.
2. **Limited Adjustment Capabilities:** EZ-X can only be used to adjust pressure support going towards a patient, it cannot adjust other parameters that are part of a mechanical ventilator.
3. **Secure Tubing Attachments:** To avoid air loss, tubing attachment must be done securely. Any air loss would significantly alter the effectiveness of our device and make it dangerous to use.
4. **Network Considerations:** The remote access of EZ-X is most secure when within the same network as the hospital, but it can still be used across different networks with a chance of network disruption as in all Internet of Things devices.

Use Procedure

To use the EZ-X device, please follow the use procedure below:

1. **Attach EZ-X:** Attach device to mechanical ventilator tubes. Ensure that the tubing connected to the mechanical ventilator output is attached to the port on the EZ-X device labeled as “Input”. Alternatively, ensure that the breathing tube leading to the patient is connected to the port on the EZ-X device labeled as “Output”.

2. **Turn on the ventilator:** Turn on the mechanical ventilator as you normally would.
Make sure that the pressure support is set to 30 cm/H₂O before moving to the next step.
3. **Turn on EZ-X device:** Turn on the EZ-X device by plugging in the device to the proper electrical outlet. Again, make sure that the proper connections are made between the ventilator and the device and the device and the patient.
4. **Launch application:** Open the application associated with the EZ-X device. You can find the intended app workflow below.
5. **Adjust pressure:** Using the app slider, adjust the pressure to the desired setpoint. You can monitor the real-time pressure readings through the app to ensure that the patient is receiving the correct level of pressure support.
6. **Further adjustment of pressure:** Repeat Step 5 (as necessary) if current metrics/patient data suggest the need to readjust the pressure of ventilator support being supplied to the patient.

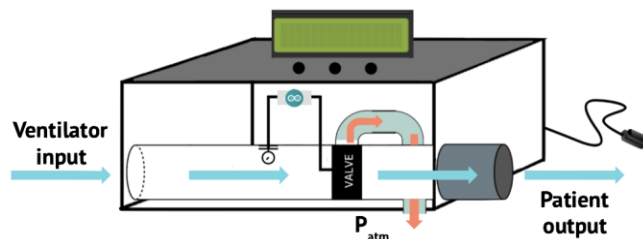
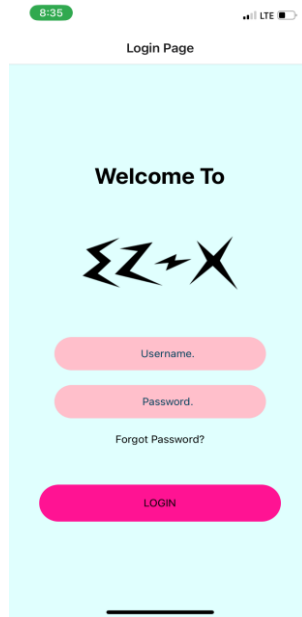


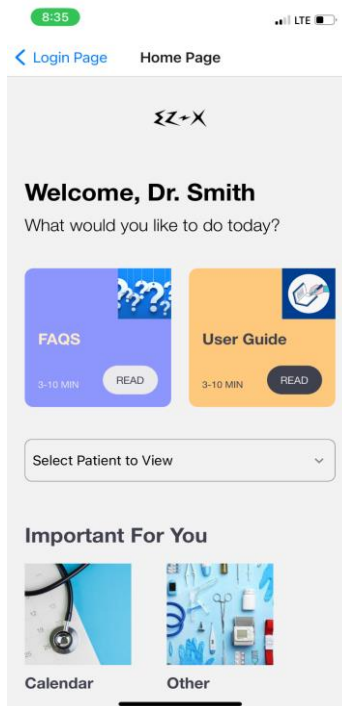
Figure 1. The EZ-X device is connected between the ventilator (ventilator input) and the patient (patient output). The device’s valve mechanism reacts to a pressure sensor placed in the air pathway, allowing control over patient breathing support (blue arrow). The vent (orange arrows) acts both to dispense excess air from the ventilator and to allow for a modification of the input airflow.

App Workflow

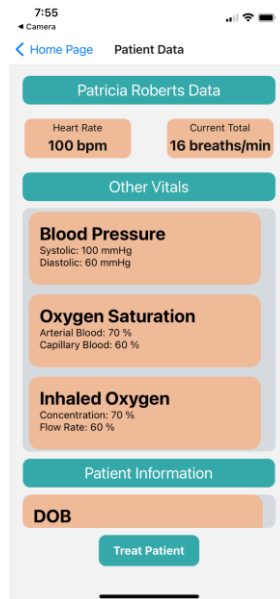
1. **Login Page:** First a doctor must verify their credentials on the login page



2. **Home Page:** After logging in, a doctor is navigated to the home page where they have a multitude of options. Amongst these is the choice to select which patient to treat.



3. **Patient Data Page:** After selecting which patient to treat, a doctor is navigated to that patient's data page to view key vital signs and other information on patient condition.



4. **Device Page:** Should the doctor elect to treat the patient, they can navigate to this page that allows them to adjust pressure support going towards the patient.



EZ-X Build Procedure/BOM

Software Build Procedure

Embedded:

Initialization:

- Make sure to define pin numbers for servo motor and pressure sensor circuitry.
- Store the wifi you are currently on and the corresponding password in character arrays
- Initialize a Wifi Client and an MQTT client.
- Define a mqtt broker in a character array. This could be your laptop running some form of mqtt broker software. In this case you would put your computer's ip address.
- Initialize a port variable to port 1883.
- Define topic names and other mqtt boiler plate variables.

Connection():

- Tests to make sure you can connect to your wifi network.
- Tests to make sure you can connect to mqtt broker.
- Point incoming broker traffic to your device.

findParameters():

- Check to make sure the pressure sensor is correctly connected.
- Calibrate pressure sensor to make sure that changes in surroundings do not affect readings. This simply involves finding a value to zero out the initial pressure sensor reading.
- Initialize servo motor.

loop():

- Calls a function called `mqttClient.poll()`. This simply keeps the mqtt connection alive and makes sure the device is listening for incoming traffic.

`onMqttMessage()`:

- **Input:** The size of the incoming message in bytes.
- Receives a message from phone connection specifying the desired pressure set point.
- This function is triggered whenever a message is received.
- Once it parses the value, it calls a function called `Control()`.

`Control()`:

- This is where our control algorithm takes place. Depending on the value received by `onMqttMessage()` and the current position of the servo motor (controls the door), `Control()` subsequently adjusts relevant parameters.
- Upon Conclusion, it calls a function called `findPressure()`.

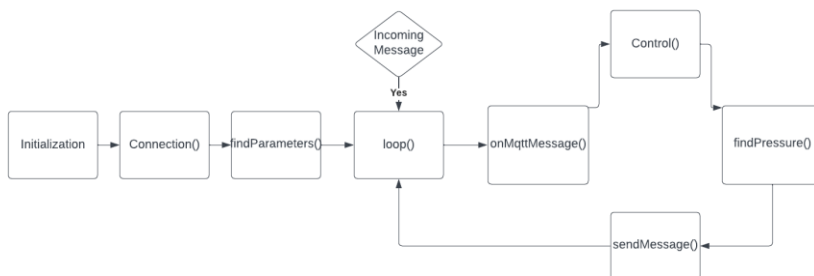
`findPressure()`:

- Reads the new system pressure and converts units to cm H2O.
- Upon completion, it calls a function called `sendMessage()`.

`sendMessage()`:

- Sends the new system pressure to the phone connection.

Function Flow Diagram



Mobile (React Native):

App():

- App.js is a file that tells the app about all the different pages that exist within the app.
This allows for navigation between pages using react-navigation.

LogScreen():

- **Input:** Navigation object
- Login Screen that allows a user to login with their credentials before being able to access the contents of the app

HomeScreen():

- **Input:** Navigation object
- Home Screen allows the user to select what action they would like to perform. They can view frequently asked questions, decide what patient to treat, or learn how the EZX device works.

Device():

- **Input:** Navigation object
- Stores pressure value on the app side (last read value)
- Initializes and mqtt connection with the same broker that the arduino is connected to
- onMessageArrived(): This is a function that listens for incoming messages from the arduino and parses them. Accordingly, the display of the app is adjusted.
- Provides a slider to send a message to the arduino specifying desired pressure. This is achieved using a function called setPoint() which takes in the new value and sends it to the broker.

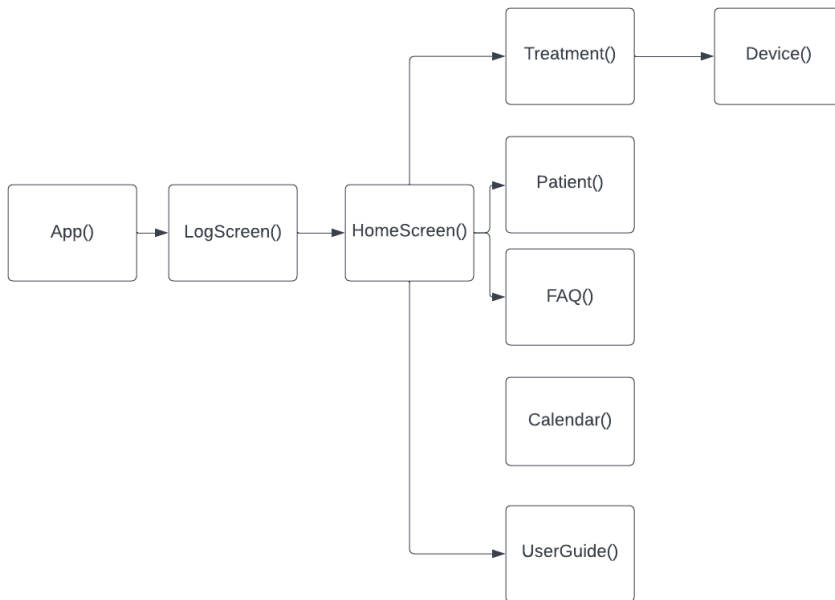
PatientScreen():

- **Input:** Navigation object
- View selected patient's vital sign data and other data

Helper Files:

- Styles.js
- Colors.js
- Donut.js
- All of these files are for styling purposes

Function/Files Flow Diagram



Hardware

Bill of Materials

PLA filament for 3D Printing: \$9.28

5.5cm×8.2cm×0.85cm Breadboard: \$5.99

9g Micro Servo Motor: \$2.99 → Comes with additional parts

32 SPN4-40x ½ Screws: \$0.79

32 Hex machine screw nuts, Zinc plated steel, #4-40: \$0.53

1/4in Acrylic Sheet: \$8.49

1/8in Acrylic Sheet: \$0.89

MPS20N0040D Ported Pressure Sensor Breakout Board: \$12.00

Pneumatic Air Tubing, 4mm OD x 2.5mm: \$0.14

Arduino Uno WiFi Rev2: \$53.80

Adtech W220-34ZIP30 Hot Glue Sticks, 30-Pack of Non-Yellowing, Clear, 30 Count: \$2.92

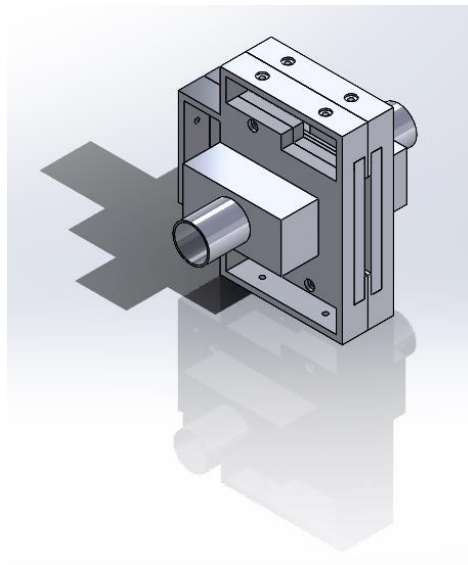
3M Arduino UNO USB Data Sync Cable for Arduino: \$4.99

Total: \$102.81

Build Procedure

1. First, produce all parts that make up the EZ-X device by laser cutting and 3D printing using $\frac{1}{8}$ inch and $\frac{1}{4}$ inch acrylic and PLA filament, respectively.
 - a. All pieces that need to be 3D printed and laser cut can be found here:
https://drive.google.com/drive/u/0/folders/1pkOJ4nw3kafHs7-1m_TZjMHlr8Y-1GdB
 - b. Make sure to produce one of every file with the exception of the following pieces which should be produced multiple times:
 - i. “RandP Stand.SLDPRT” → Cut twice
 - ii. “RandP Leg Piece.SLDPRT” → Cut 10 times
 - iii. “Acrylic Layer.SLDPRT” → Cut twice
 - iv. “side_walls_exterior.SLDPRT” → Cut twice

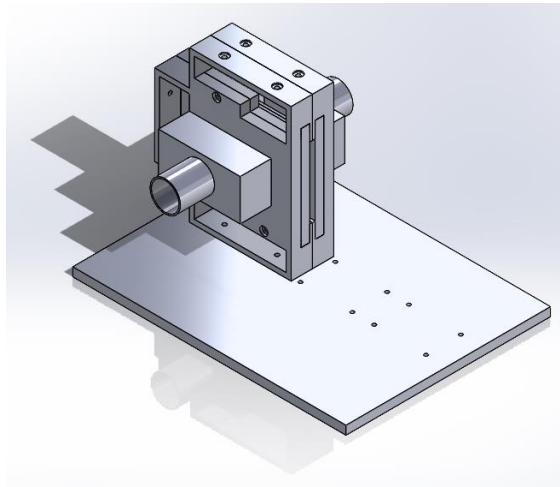
2. First build the valve mechanism, which is the majority of the device and is crucial for the operation of its entirety:
 - a. Be sure that all parts have been printed before moving on.
 - b. Take each half of the main valve, with SolidWorks part files named “Valve Input Half.SLDPRT” and “Valve Output Half.SLDPRT”, and attach an “Acrylic Layer.SLDPRT” to each. This will give the valve the ability to have a door slide in between said layers.
 - c. Take the two halves of the main valve and screw them together using SPN4-40x $\frac{1}{2}$ screws and placing screw nuts on the other side. To do this, use the appropriate connector pieces (“Connector 1.SLDPRT” and “Connector 2.SLDPRT”)that fit across each of the halves in various locations to bind the two halves together. The resulting piece should look as follows:



Note: it is important to screw in from the outside inwards. Additionally, one short connector piece should be used to bind the halves together and one long connector piece should be used to bind on the top. Although a long connector

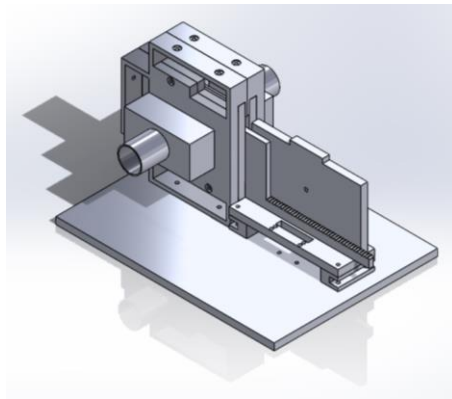
piece could fit on the bottom of the halves, this space should be left open to eventually screw to a base.

- d. Next, what has been built thus far and screw it into the base plate (“Base Plate.SLDPRT”) using the same screws and screw nuts as before. Again, make sure to screw from the outside in. The resulting construction should look as follows:



3. This step is dedicated to building the rack and pinion that will control air flow through the valve mechanism:
 - a. Slide the door piece (“RandP Rack.SLDPRT”) into the large gap of the valve mechanism, making sure that the rack portion is oriented closer to the base side of the device.
 - b. Place the rack and pinion stands (“RandP Stand.SLDPRT”) over the two sections of holes with two holes each, with the holes on the parts aligning with those on the base and the flat portions facing inwards. Use the screws and nuts listed.

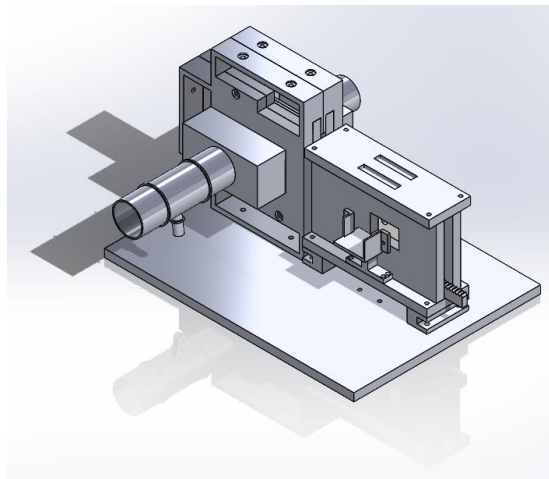
- c. Place the rack and pinion base (“RandP Base.SLDPRT”) on top of the stands and screw it into them. This is to be done from the top down (screwing towards the stands).
- d. Place each of the holder pieces (“RandP Holder 1.SLDPRT” and “RandP Holder 2.SLDPRT”) into the holes on the rack and pinion base piece. Make sure that the piece with the larger hole is on the side of the base with the screws, while the other with the tiny hole is placed on the other side. Note that the rack portion of the door slides in between these two pieces. After placing just the holder piece with the smaller hole, the build should look as follows:



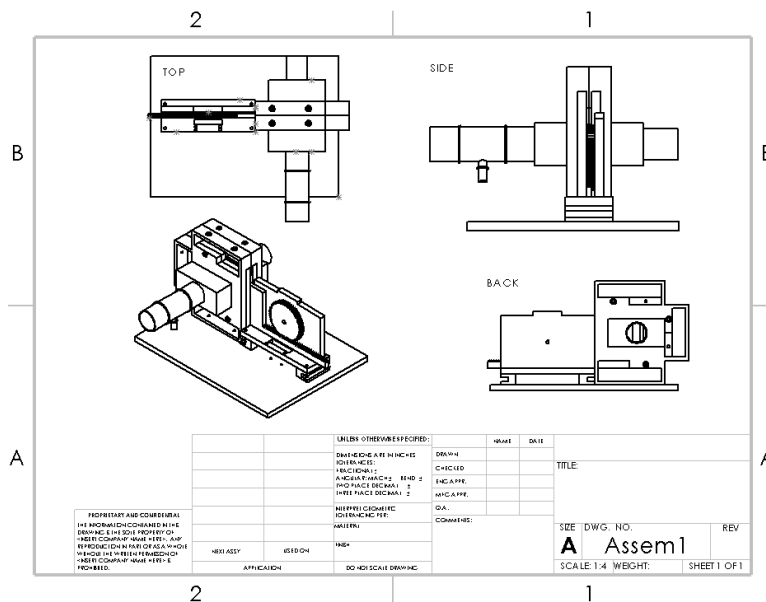
- e. Next, screw the servo motor stand (“Servo Holder.SLDPRT”) into the remaining holes of the rack and pinion base piece. Then, place the servo motor into this piece and screw it in accordingly using the screws that come in the motor packaging.
- f. Then, place the gear (“RandP Gear.SLDPRT”) onto the rack so that it falls onto the servo motor axel. From the other end, take the long screw and tiny black tube that come with the motor to attach the gear tightly to the servo. To do this, place the smaller end of the tiny black tubing through the hole on the holder opposite

the servo so that it also threads through the gear, then use the screw to attach it on tightly.

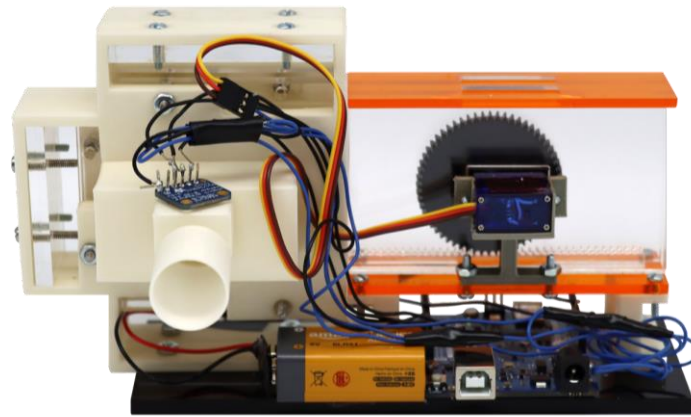
- g. Lastly, attach the top piece to the rack and pinion (“RandP Top.SLDPRT”) by pressing it on. Additionally, add the pressure sensor T piece (“T Tubing Attachment.SLDPRT”) to the valve output half. The final result should look as such:



You can also refer to the following diagrams to check against your work:



4. The last portion of this build involves orienting the valve and rack and pinion inside of casing:
 - a. Firstly, use a hot glue gun to glue 5 of the square leg pieces together (“Square Leg Piece.SLDPRT”), making sure to connect them together via the larger surface area. Do this twice to produce two acrylic legs. Attach each of these legs to either end of the valve and rack and pinion mechanism on the bottom side. Note that these pieces are used for stability purposes when inside of the casing.
 - b. Start constructing the casing by placing the two side pieces and the base onto the device. Each of the side pieces should fit over the output tube and input tube on the valve, respectively. These side pieces can then be screwed into the base.
 - c. Thread the USB cable through the one end of the casing with the access port before screwing it into the rest of the casing. Plug the one end into the arduino and leave the USB end hanging out of the casing.
 - d. Place the arduino and breadboard on the base of the casing on the interior, making sure that the pressure sensor on the breadboard is right under the smaller port on the T Tubing piece.
 - e. Attach the 6 inches of tubing to the port on the T Tubing piece coming from the output half of the valve mechanism. Attach the other end of the tubing to the pressure sensor.
 - f. Add the remaining two pieces of the casing to the device and screw them in properly using the screws and nuts available from the list. The final result of the device should look something like this:



g. And with the casing it will look like this:

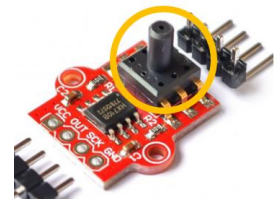


Circuit Assembly

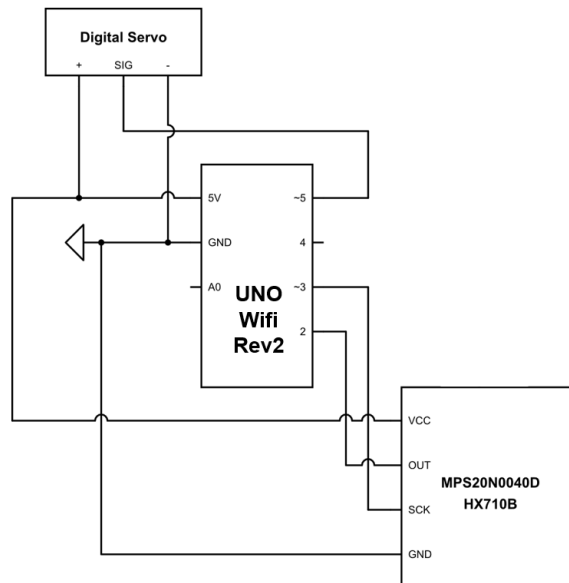
1. The Arduino Uno Wifi Rev2 will be used as a central hub for all circuit components.

The circuit's power supply (5V) and ground will be connected here.

2. Connect the MPS20N0040D Ported Pressure Sensor. There are four labeled pins: Vcc, OUT, SCK, and GND. Connect them to the Arduino, respectively: power supply line, PWM signal pin (i.e. ~3), digital signal pin (i.e. 2), and ground line.



- a. The black extrusion from the pressure sensor (as indicated by the orange circle) is the part that reads in the pressure. Connect the part of the tube where the pressure needs to be read to this component.
3. The digital servo consists of three pins: +, Signal, and -. Connect the + to the power supply line and - to the ground supply line. Connect the signal pin to any digital PWM Arduino pin (i.e. ~5).
4. See circuit diagram below for a sample setup.



Updated Business Analysis for M&T:

Problem

EZ-X is a low-cost retrofit for basic ventilators that provides remote capabilities for doctors. It features a novel valve mechanism that allows doctors to dynamically adjust ventilator settings for a patient through an app. Our device addresses a two-fold problem in the current standard of care for ventilator management of long-term patients. Basic low-tech ventilators lack remote capabilities, while high-tech ventilators are too expensive.

For low-tech ventilators, the current standard of care results in an inefficient workflow for doctors, and discontinuous monitoring of patients limits patient care. These patients require meticulous monitoring to avoid complications such as sepsis or - pneumonia, yet despite best efforts, extubation failure rates are still relatively high. Putting on and taking off PPE adds 6 minutes to the process of adjusting a ventilator, time which could have been spent delivering high-quality patient care (2). Extubation failure is associated not just with an increased risk of death but also with more prolonged ICU stays and the use of hospital resources. The current process burns through limited supplies.

High-tech ventilators offer remote control capabilities, but they are extremely costly and lack compatibility with ventilators. Currently, there is no technology on the market that is compatible with every ventilator for continuous remote control monitoring of patients.

Value Proposition

EZ-X provides a low-cost solution that offers remote control capabilities of advanced high-tech ventilators and high savings potential of basic low-tech ventilators. Not only does EZ-X improve patient care, reduces hospital costs, and increases workflow efficiency of medical professionals.

Unlike other technologies on the market, EZ-X is compatible with every type of ventilator and offers remote control capabilities, which can benefit hospitals in several ways. The hardware design of EZ-X includes a unique valve mechanism that allows doctors to adjust ventilator settings remotely through an app. The EZ-X device now includes a multi-patient support feature, which allows doctors to treat multiple patients simultaneously, increasing efficiency and reducing wait times for patients. In addition to saving doctor time and reducing the risk of exposure to infectious materials, remote control access can prevent cross-contamination and help protect both patients and healthcare workers. EZ-X also improves the quality of patient care by enabling healthcare providers to monitor and respond to clinical changes rapidly. Furthermore, EZ-X offers a low-cost solution that can reduce hospital costs by wasting less PPE and improving workflow efficiency.

Stakeholders

Stakeholders involved in the design and implementation of the device include patients, healthcare providers, regulators, insurance companies, and manufacturers. Patients and their families are directly impacted by the performance and reliability of the device and may have concerns about safety, effectiveness, and affordability. Healthcare providers administer the device and provide patient care, and may have concerns about the availability, accessibility, and

compatibility of the device with other medical equipment. Regulators, such as the FDA, play a critical role in ensuring safety and effectiveness, and may have concerns about the quality and performance of the device. Insurance companies are responsible for covering medical care costs, and may have concerns about the cost and value of the device. Manufacturers are responsible for designing, producing, and distributing the device and may have concerns about market demand, profitability, and competitiveness. Throughout the development process, it is important to ensure that the needs of all stakeholders are met.

Market Research

Many companies are investing in research and development to develop new and innovative ventilator technologies that can improve performance and functionality. For example, some companies are developing ventilators with advanced wireless connectivity, advanced monitoring, and control capabilities, and improved user interfaces.

Another factor driving competition in the market is the availability of cost-effective and user-friendly solutions. Many companies are looking for ways to provide remote control capabilities for ventilators that are affordable and easy to use for healthcare providers and patients. This can involve developing ventilators compatible with existing smartphone and mobile device platforms or developing dedicated apps that can monitor and control the ventilators remotely.

The competitive landscape for remote control monitoring of ventilators is dynamic and evolving, with many companies competing to provide the best products and services. The

market is likely to continue to grow and evolve in the coming years as new technologies and innovations are developed and introduced.

Customer Segments

EZ-X's primary customer segments are hospitals and other medical facilities that use ventilators to assist patients with breathing. These facilities can benefit from the EZ-X device by allowing medical staff to monitor and control ventilators remotely, reducing the need for staff to be physically present in the room with the patient. Additionally, small hospitals and clinics may require a simplified version of the EZ-X app for easy access to the device's functions.

Other potential customer segments for EZ-X include home health care providers who may use the device to monitor patients receiving ventilator support at home remotely, and individuals who use ventilators themselves and want more control over their breathing support. EZ-X can cater to these segments by providing an easy-to-use interface and reliable remote monitoring features that enhance the overall user experience.

Market Size and Growth

The global market for mechanical ventilators is significant, with a value of US\$6787 million in 2020 and a projected CAGR of 5.8% during the forecast period 2021-2031 (4). The growth potential for the ventilator market is driven by several factors, including the prevalence of respiratory diseases and disorders, the rise in the geriatric population, and the availability of funding and resources for developing and distributing ventilators. The Covid-19 pandemic has

also significantly impacted the market, increasing the demand for ventilators due to respiratory illnesses induced by the virus.

Other market drivers include rising number of geriatric patients on mechanical ventilators and government and organizational initiatives to boost ventilator production. With more patients requiring mechanical ventilation, it has never been more critical to have access to the information you need to make necessary interventions to support adequate respiratory function.

There is significant potential for the EZ-X device in the growing ventilator market, particularly in hospitals and other medical facilities that use ventilators to help patients breathe. With the rise of remote control monitoring technology, the EZ-X device has the potential to improve patient care and reduce the need for staff to be physically present in the room with the patient. Additionally, the increasing demand for cost-effective and user-friendly solutions in the market presents an opportunity for the EZ-X device to differentiate itself and capture a share of the market.

Competition

In the ventilator management market, General Electric (GE), Philips, Medtronic, and ResMed are some of the key players. These companies offer ventilators with remote control capabilities, which can improve patient outcomes and increase efficiency and care availability. For example, ResMed's ventilators are equipped with wireless technology that enables healthcare providers to monitor and adjust settings remotely using a mobile device. Philips offers advanced wireless

technology that allows healthcare providers to monitor and adjust settings remotely using a dedicated app on a mobile device (4).

In addition, Philips is another company that offers ventilators with remote control capabilities. The company's ventilators are equipped with advanced wireless technology that allows healthcare providers to monitor and adjust the settings remotely using a dedicated app on a smartphone or other mobile device (5). Furthermore, researchers at Johns Hopkins University have developed a new robotic arm system that allows for remote control for COVID-19 patients on ventilators. While the system is still being tested, initial trials demonstrated how it could be deployed to aid hospitals in preserving PPE, limiting staff exposure to infectious materials, and providing increased workflow efficiency (6).

Many companies offer ventilators with remote control capabilities, and the market for these devices is growing. Remote control access to ventilators can provide many benefits, including improved patient outcomes and increased efficiency and care availability. Nevertheless, there still needs to be technology compatible with every ventilator for remote control monitoring of ventilators for long-term ventilation patients.

To differentiate itself from similar products, EZ-X will need to identify its unique value proposition and focus on improving areas where competitors fall short. One potential area for improvement could be providing a simplified user interface that is easy to navigate, especially for non-technical users. EZ-X may also consider developing additional features that offer

unique value to customers, such as real-time alerts and predictive analytics to help healthcare providers proactively manage patient care.

Brief Project Overview

Our solution, EZ-X, involved the development of an intricate valve mechanism to control the pressure in the system through an app remotely (see Figure 1 and Figure 2 in Appendix). One of the primary goals of our design was to minimize the cost of maintaining ventilator assistance, with the intent of reducing the cost of hospital stays and healthcare overall.

Since this device will be an affordable attachment to existing ventilators, avoiding purchasing a brand new ventilator at a higher price, our design will successfully keep the total expenditure on the low end below \$300. We also wanted our device to occupy as little space as possible since ICU and operating rooms tend to be cluttered with a lot of advanced technology, tubing, and hospital staff. Our device is expected to be less than one cubic foot, with the intent of being placed on a tabletop setting. Our device is also expected to control the pressure in the system between 5 - 30 cmH₂O, which is the standard range of pressure support for ventilators. This provides a manner of weaning patients off ventilator assistance over time as their condition improves. We also want this device to be compatible with ALL standard ventilators available in the hospital setting. Our device will have various attachments to ensure proper fit with all available ventilators.

Cost

The cost of creating an external ventilator attachment that allows for remote control access through an app will vary depending on a number of factors, including the complexity of the attachment, the materials and components used, and the development and testing processes involved. We currently value the cost of our device to be \$300 based on the raw materials necessary for its production, as well as the integration processes of these materials. We anticipate that the price of the device will be around \$1000, which is significantly lower than the other remote control ventilators on the market.

Revenue Model

The revenue model for our external ventilator attachment for remote control monitoring would be a one-time sale or perpetual license or access to the remote monitoring and control features. The attachment could be sold as part of a package that includes the ventilator, remote monitoring, and control features. In this case, the customer would pay a single upfront fee for the complete package. This would provide quick, accessible communication and a low-maintenance relationship with a consumer. However, this transaction's singular nature may limit this device's monetization model. Upon purchasing the device, we would also provide the necessary tubing attachments to ensure compatibility with any ventilator on the market.

IP

Since EZ-X is a novel valving mechanism for mechanical ventilator attachments, obtaining intellectual property (IP) clearance and protection may be necessary before introducing it to the market. Due to the unique features of the attachment, it may be possible to obtain patents, trademarks, or copyrights to protect the technology and prevent unauthorized use. IP can be crucial in establishing a successful business by preventing competitors from copying the

product and providing a competitive edge in the market. Furthermore, having IP protection can increase the attractiveness of the product to potential investors and partners, giving them added confidence in the value and potential of the device.

Final Presentation:

https://docs.google.com/presentation/d/1jgT5ncHfkl16aUjZPcBp_U6SF72SyD_ocnT-I8kfkAU/edit

Final Abstract:

https://docs.google.com/document/d/1ueFfzZJH0_Ja-SMYgThu61Df39jbFHSEikmLg17imEg/edit

Testing and Validation Report:

<https://docs.google.com/document/d/1KnVPfS-1hf5U9bj4pwwukoKUx3FfAxm19mPSMKf5Vk0/edit>

Ben Talk:

<https://upenn.hosted.panopto.com/Panopto/Pages/Embed.aspx?id=24aa4d7e-f5d9-4231-9140-afd6014c42bd&query=Madeline>

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