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PORTABLE EMERGENCY VENTILATOR PHASE 2

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ABSTRACT

A Portable Emergency Ventilator (PEV) is a device that can provide positive pressure ventilation to a person who is incapable of breathing on their own. This device can eliminate the need for mouth-to-mouth resuscitation used by first responders during CPR, thus drastically eliminating the spread of diseases. The device can also be used when transporting patients or in home use when a large ventilator is too expensive and impractical. This project focuses on improving a PEV originally developed in the late 1980s by Jeff Gutterman and Roman Press as well as the updated model developed by MSD Group 13026. The major objective is to update the models using modern day technology while focusing on portability, usability and providing familiar feedback to the user. The expected end result is a functional prototype which can be marketed to companies and manufactured by 2015.

INTRODUCTION

A Portable Emergency Ventilator (PEV) is a device that can provide positive pressure ventilation to a person who is incapable of breathing on their own. Reasons for this lack of ability to breathe include cardiac arrest, heart attack, smoke inhalation, and many others. This device can eliminate the need for mouth-to-mouth resuscitation used by first responders during CPR, thus drastically eliminating the spread of diseases. The device can also be used when transporting patients or in home use when a large ventilator is too expensive and impractical.

Many PEVs already exist and are being used by EMTs and physicians today. This project focuses on improving a PEV developed in the late 1980s by Jeff Gutterman and Roman Press. The device is patented and has been approved by the FDA to market and manufacture. The PEV device includes different modes which can be used based on different situations. These modes are Constant Mandatory Ventilation (CMV), Assist, CPR, and Manual. The mode which would be most useful to first responders is CPR. In this mode, the rescuer would perform CPR on the patient just as they normally would, using only chest compressions. The PEV would keep track of the number of compressions through a feedback network, and, based on a setting applied by the rescuer, provide clean air to the patient after a specific number of compressions were performed.

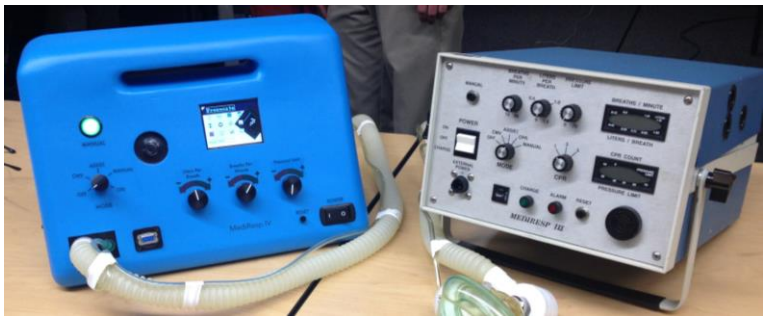

Figure 1 – Mediresp IV and Mediresp III

The current device has many characteristics which we plan to keep in the updated model. First, since the device has already been approved by the FDA, the general operation cannot deviate from the current design. Second, the PEV is durable so it can be dropped or used in inclement weather and still provide its life saving function. Third, the device has redundancies so that if a malfunction occurs, the patient can still be ventilated by other means. Finally, the device is easy to use with paramedics. The large knobs and audible feedback allows the PEV to be used by those wearing gloves and greatly reduces the possibility of incorrect use.

The goal of this project is to update the model using modern technology by making it lighter, more efficient, and easier to use. To make it is portable as possible, we plan on make this device less than 8 kilograms. Also, this device will run on a battery, which should have the ability to operate the device for at least 2 hours without requiring a recharge. This should provide sufficient time for the patient to be transported to a larger machine not running on battery power. Lastly, one very important aspect of this device is that it will be able to record the patient's vitals as resuscitation is occurring. This will benefit the rescuer from this feature since he/she will no longer have to worry about writing down this information, along with the time it was taken. We expect to market our device once a final product is built and extensively tested.

DESIGN PROCESS

Due to the nature of follow-on teams, the high-level design of the system was based on the MEDIRESP IV created by team P13026. Their update of the original MEDIRESP introduced electronic controls, a smaller pump and well as a smaller and reliable battery. Usability and ergonomics were significant constraints when the device was designed. As for the next revision of the MEDIRESP, the proposed redesigned includes reducing the circuit board size, further decreasing battery size in addition to the overall size and shape of the ventilator while staying substantially equivalent to sustain the FDA approval as per customer's specification.

Battery

The battery was significantly improved by P13026 from the original MEDIRESP; however, there was still some room for improvement. The main goal was to minimize the shape and size as well as weight of the battery while maintaining solid and reliable power sourcing. The battery chosen to power the device was Tenergy lithium-ion. Weighing only 0.379 kg, this battery was capable of outputting 14.8V. Based on theoretical calculations, with a capacity of 65.12 watt-hours (Wh) and operating at 14.8V with 19.8 watts of power consumption, the battery is expected to last over 3 hours. The calculation assumed 100% duty cycle, which is not expected to be the typical running condition of the ventilator.

Pump

The pump used in this device is a Parker 32 LPM Diaphragm pump that was selected by team 13026. After performing some preliminary benchmarking, it appears as this pump to be the most suitable for the application of this project.

Pressure Sensor

The pressure sensor had a relatively simple selection process. The system needed to be able to sense pressures in the rage of 10 to 70 cm of H_2O and be within 10% of the target value over a temperature operating range of 0 to 40 degrees Celsius. The sensor ideally had to be able to run on 3.3 volts and use minimal amperage. It was determined that a gauge pressure sensor would be optimal since the pressure difference between the lungs of the patient and the atmosphere is what needs to be measured. The group chose to use FreeScale's MPXV5050GP pressure sensor based on many of its favorable characteristics. The 5050GP sensor can sense pressures of 0 to 7.25 psi with a max error of 2.5% over 0 to 85 degrees Celsius, far exceeding our requirements. Other notable characteristics are the facts that the 5050GP weighs next to nothing, is less than 1 inch on its longest side, is board mountable, and draws less than 10 milliamps. \

The feedback pressure alarm also, as an added feature, needs to go off when the pressure in the patient's lungs exceeds 1 psi. As a failsafe, a mechanical pressure relief valve has also been installed in the sensing flow path to release at 1 psi.

Differential Pressure Sensor

The purpose of the differential pressure sensor is to ensure that the user specified flow rate is accurately delivered to the patient. The original MEDIRESP III used the Honeywell AWM2300V mass flow sensor with a bypass line to lower the amount of airflow passing through the sensor. This sensor costs over $100 and has specifications that limit it to 1 liter per minute and a 0 to 40 degrees Celsius operation range. Team 13027 proposed a Venturi design using a differential pressure sensor in correspondence to the static pressure sensor to calculate the flow rate of the air in the system. Through theoretical calculations it was determined that the differential pressure should not exceed 1 psi and reasoned that high accuracy was an important necessity. Like the pressure sensor the flow sensor needed to be board mountable, run on 3.3 volts, be light weight, small, and operate with temperatures from 0 to 40 degrees Celsius. The FreeScale MPXV50150DP was determined to be the optimal sensor for the project and met all requirements at a cost of about $14. This pressure sensor is able to measure pressures from 0 to 1.45 psi over an operating range -40 to 85 degrees Celsius with a max error of 5%. The Venturi design and the MPXV5010DP add a significant cost savings to the project as well as reduce size, weight, and power consumption while increasing accuracy and manufacturability.

Custom PCB

A custom Printed Circuit Board (PCB) was designed to power the Mediresp V. On the board there are connections to everything within the ventilator. The design of a custom circuit board was a large upgrade from the previous generation of the system. The design of a custom circuit board allowed for the implementation of special functions such as a battery charging circuit and sensor averaging circuitry. On the PCB there is power regulation circuitry which enables the entire system to be run off of the battery. The single-PCB design also makes the product much easier to mass produce. As the product is put into production, the simplified design will cut down on fabrication and assembly time and in turn, production cost. This is a large improvement from the previous generation of the device and improves the functionality as well as the physical design of the device.

MCU

The MCU chosen to perform all of the functionality of the custom PCB for the Mediresp V was a Freescale Kinetis K60 MicroControl Unit (MCU). This specific MCU was chosen on a basis of its' performance and capabilities. The Freescale K60 is armed with an ARM Cortex M4 processor, an array of input/output communication interfaces, programmable flash memory, a multitude of timers, built in DACs and ADCs, and even touch screen capability. Being the "brains" of our device, proper MCU selection was vital in the design of our system.

Pulse Oximeter

The Pulse Oximeter or SPO_2 sensor was included in the previous generation of the ventilator, the Mediresp IV, as an external option. In the design of the Mediresp V, the circuitry for the sensor was implemented into the design of the PCB. Using this device, Mediresp V users will be able to monitor patient's vitals such as blood oxygen level and pulse. This function is currently not fully implemented in our finished design but the capability to use this technology was included in the design of the system.

User Interface

The user interface of the Mediresp V was designed to make the ventilator usable by not only medical professionals but for the average user as well. In order to accomplish this, a usability study was performed at Imagine RIT to understand the overall functionality, clarity and aesthetic of the product. Using this information the best selection, arrangement, and labeling of components could be achieved. The LCD display of the Mediresp V is 770% larger than the previous generation of the product and allows for the user to clearly read important information being displayed. Another large improvement that can be seen in the design of the Mediresp V is the reduction in size and weight of the product. The intuitive, condensed design of the pneumatic and electrical systems allowed for the conservation of space inside the enclosure of the ventilator. Another improved feature of the Mediresp V is its' improved ease of carrying. Previous generations of the ventilator have been large and awkward to handle. The Mediresp V weighs 9.33 lbs (4.2 kg) and is equipped with a well-fitting handle that allows the device to be easily carried.

Housing

The overall aesthetic was derived from the combination of research and work from the previous revision with MSD Team 13026, and also a usability study. A few different options were considered for creating the enclosure for the PEV. The easiest solution was to use a premade fixture and machine the required modifications ourselves. Even though it may be the simplest option, it will most likely yield lower visually pleasing results, would not reflect usability test studies and the previous team's work for ergonomic use. When considering custom enclosures, there were different paths to investigate. (At the end of spring quarter 2013, the team had hopes of working with an Industrial Design student in the fall to help with the overall aesthetics and ergonomics of the device; however, there was no opportunity to get in touch with such student). Another option considered was 3D printing the enclosure. Even though this option would create the most identical enclosure to the SolidWorks drawings, the cost of this operation would be too high for a prototype stage model. Thermal molding panels of styrene was an option that was affordable as well as most accessible to the team. In order to successfully create the enclosure, substantial practice time and technique development was required. Due to the timeline of the project, the team decided to proceed with the thermally molded enclosure.

Figure 2 – Mediresp V

EXPERIMENTAL SET-UP & PROCEDURE

Battery

In order to characterize the performance of the battery, life testing was executed. The battery was fully charged prior to this experiment. It was directly connected to the pump at 12V and 100% duty cycle with no additional components connected. As the pump drained the battery, time and voltage of battery were recorded using a data collection system. To understand the rate at which the battery charges, a charging data collection occurred which recording the time and the current voltage of the battery during pump use.

Additional battery testing was performed once the complete system had been assembled. The goal of the testing was to characterize the lifetime of our system when operating at maximum breathing rate and flow rate. The test began with fully charged battery driving pump at maximum breathing and flow rate on CMV mode. High and low battery percentage was recorded at every increment until the battery was drained.

Pump

In order to ensure our system met the engineering specifications laid out by our customer, test plans were developed to produce results conclusive of proper functionality.

In regards to the specifications set for breathing rate (4-15 BPM), flow rate (15-60 lpm), and pressure control (10-70 cm H20), specific test plans were drawn up to validate functionality. The test plans set required us to verify whether or not our pump could deliver acceptable results spanning the entire range of values defined in the engineering specifications. For the specification of a flow rate of 15-60 lpm, a very accurate mass flow sensor was used to compare actual readings from the mass flow sensor with the flow sensor within our system. Once we could correctly measure flow and time, we used our tidal volume to work backwards to calculate the breaths per minute. These results would help us understand our system operating range. For testing of the pressure control within our system, a mechanical pressure gauge was used to ensure that our system isn't applying too little or too much pressure to the patient while operating over the full input range of our pump. Following each of these tests, the data gathered was used to calibrate our pressure and flow sensors such that we could display accurate readings on the LCD display of our system in relation to the input range of our system.

Pressure Sensor

Testing was necessary to understand the sensitivity of the mechanical relief valve which is supposed to blow at 75cm ofH2O (~ 1psi). Using a variety of voltages and pump running speeds at 100% duty cycle, the impact of pump speed on the relief valve should become apparent. The test started with the pump operating at 6V for 100% duty cycle and the pump input voltage increased by 3 volts until 12 volts were reached. At each pump input voltage, the pressure was read and recorded.

The mechanical relief valve was then examined to see if the air has passed through or blown the valve. If the valve was blown, the pump was stopped and the results were recorded. If not, the pump remained operating and the pressure was increased.

The primary goal of the pressure sensitivity testing was to characterize the static pressure sensors to the appropriate pressure as seen by the mechanical pressure gauge. By calibrating the static sensor to the sensitivity of the mechanical pressure gauge, the venturi system designed will be able to provide that sensitivity when in operation.

RESULTS AND DISCUSSION

Battery

The main objective of the experiment was to test the battery life of our model. From customer engineering specifications, a battery life time of over 2 hours is necessary, to maximize use during an emergency Scenario. The results have proved that the amount of time it takes a full battery to discharge is 212 minutes, roughly 3.5 hours. Thus this concludes that the battery chosen passes the engineering specification requirements.

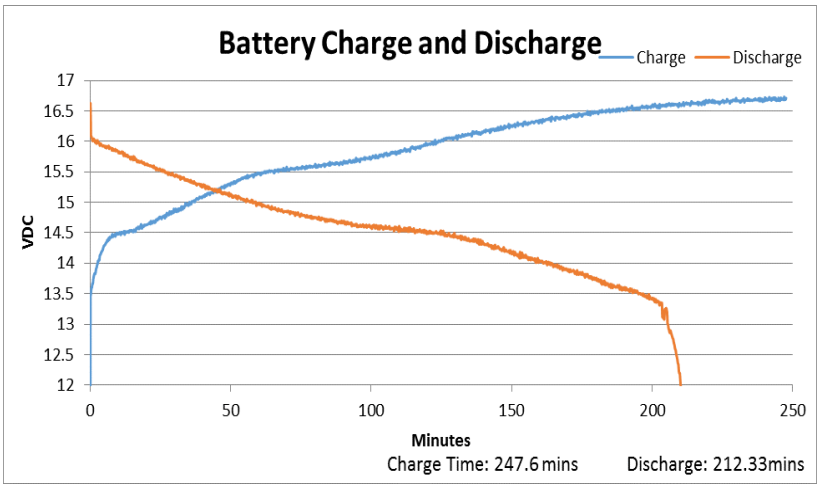

Figure 3 – Initial Battery Life Testing

Further the charging time was investigated. The experiment tested the battery charge time required to obtain a full capacity charge. This information is indicative to the user as it will allow them to understand the time needed on a charger prior to operating at maximum capacity. The results have proved that the amount of time it takes to charge a battery to maximum capacity is 247 minutes, roughly four hours. This test was performed using a 1.5Amp charger while the charger used for the final prototype will be 2 Amps; therefore, the charging time is expected to be a bit shorter.

Additional battery testing was done once the complete system had been assembled. The goal of the testing was to characterize the lifetime of our system when operating at maximum breathing rate and flow rate. The battery of the system was fully charged and the ventilator was let run at the maximum breathing rate and flow rate settings until the battery was fully discharged. Figure 4 shows the battery life of the system over time. The resulting battery life of the system is 4 hours, 20 minutes which is more than twice the standard set by the customer.

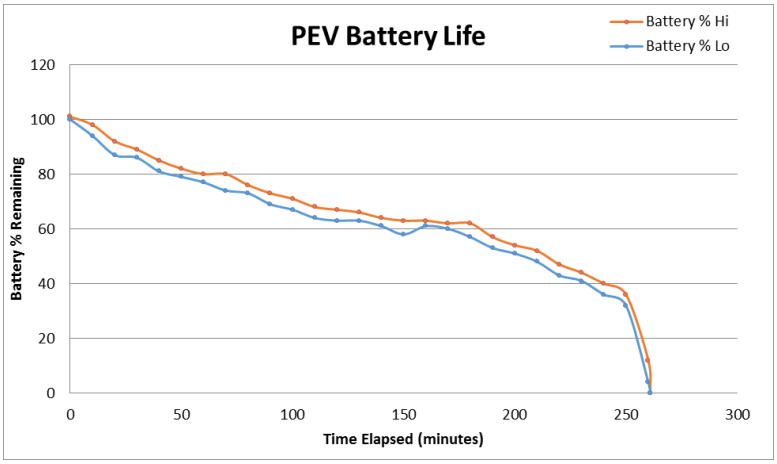

Figure 4 – Battery Life Test with complete system

The ability of a ventilator to perform for this long is an exceptional feature to have in the time of a medical crisis.

Pressure Sensor

The test performed challenged the customer engineering specification which required design of a secondary pressure relief of 75 cm of H20. This test utilized a variety of pumping speeds to understand the impact of pump speed on the senitivity of the valve. In all cases, were the pressure sensor was reading larger than 75 cm of H2O, the mechanical relief valve blew and release the built up pressure. This yields a good result, showing functionality of the mechanical relief valve to blow consistently at 75 cm of H2O. As far as sensitivity, a partial blow during high flow rates from the pump is visible. A partial blow off means that the relief valve release some of the pressure within the system, but it did not release 100% of the pressure. This is a positive result, as it means the valve is still blowing off after 75 cm of H20 is reached. The entire pressure was not able to pass throught the relief port at the high velocity of the pump. Thus safety of the patient is still within a concerning range.

In future designs, to better acheive a full range of function, a new relief valve would need to be designed to be able to relieve high velocity flows. This would be the best method of addressing the issure. Another idea would be to put multiple mechanical relief valves in series with one another to catch all of the missed high pressure flow in other relief systems since not all the air would be relieved in the first valve.

From the tested results, a column of water was used to calibrate and understand the accuracy of the pressure sensing capabilities. The shut off valve was utilized in line to adjust the pressure experienced at a flow rate. The mean flow rate 20 L/min was used. According to the results, the pressure seen by the statics pressure sensor and column of water were very similar. At lower flow rates, the sensors match almost perfectly, fitting within the given specification of 10% accuracy. However as the pressure builds, the pressure sensor was lower than the pressure experienced by the column of water. This would be concerning if we could not calibrate our sensors. However, the equations shown below in Figure 5 will allow us to calibrate our accuracy of the sensor reading to the sensitivity ot he mechanical flow sensor reading in our microprocessor.

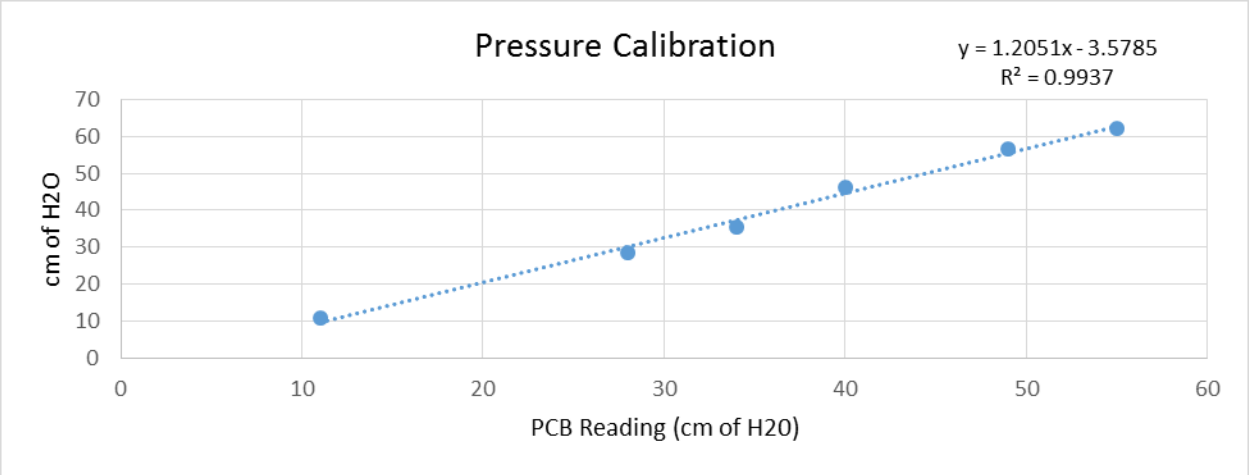

Figure 5 – Pressure Sensor Equation Derivation

Flow Sensor

One characteristic which was derived from calibrating the pump flow rate to the sensitivity testing was the equation $y = -0.0239x2 + 2.1019x - 12.178$, $R^2 = 0.9984$. This equation will be programmed into the microprocessor feedback of the flow sensing to further equate the readings to our digital flow sensor accuracy. Thus the limits of flow over the time are understood.

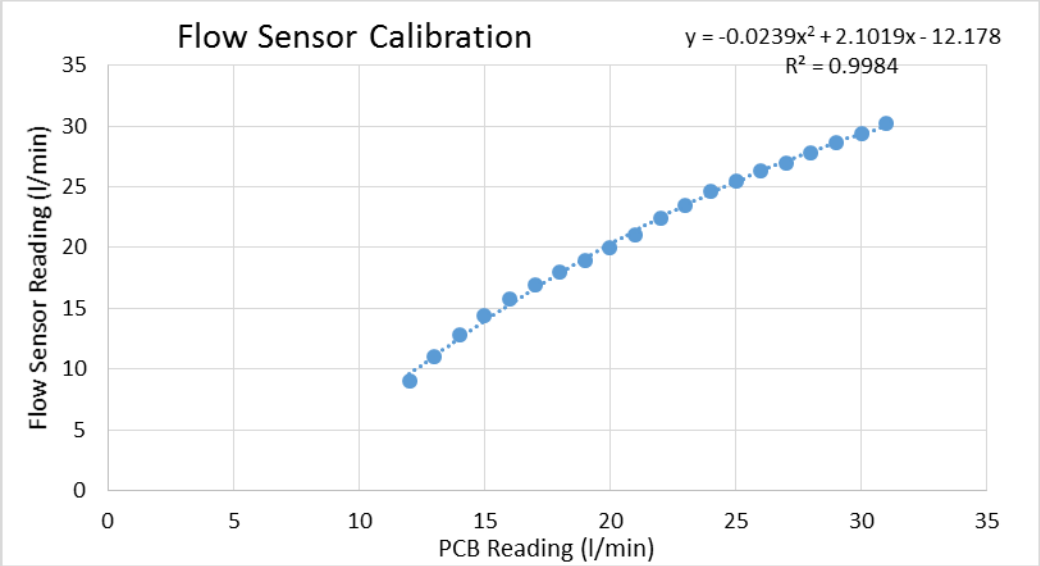

Figure 6 – Flow Sensor Calibration

Operating Range- Pump

Pump Operating Range is from 12 L/min to 32 L/min, as shown in pressure sensitivity testing. This was determined by plotting the maximum and minimum flow rates and volumes that the Mediresp V is able to achieve and finding the range of intersection. Figure 7 depicts the large operation range of the Mediresp V and compares it to the mean adult breathing range. The Mediresp V is clearly capable of supplying the amount of air needed for the average adult to survive. The implementation of a double-headed pump in future generations of the device could increase the operating range further allowing for the use of the Mediresp V on teenagers and children.

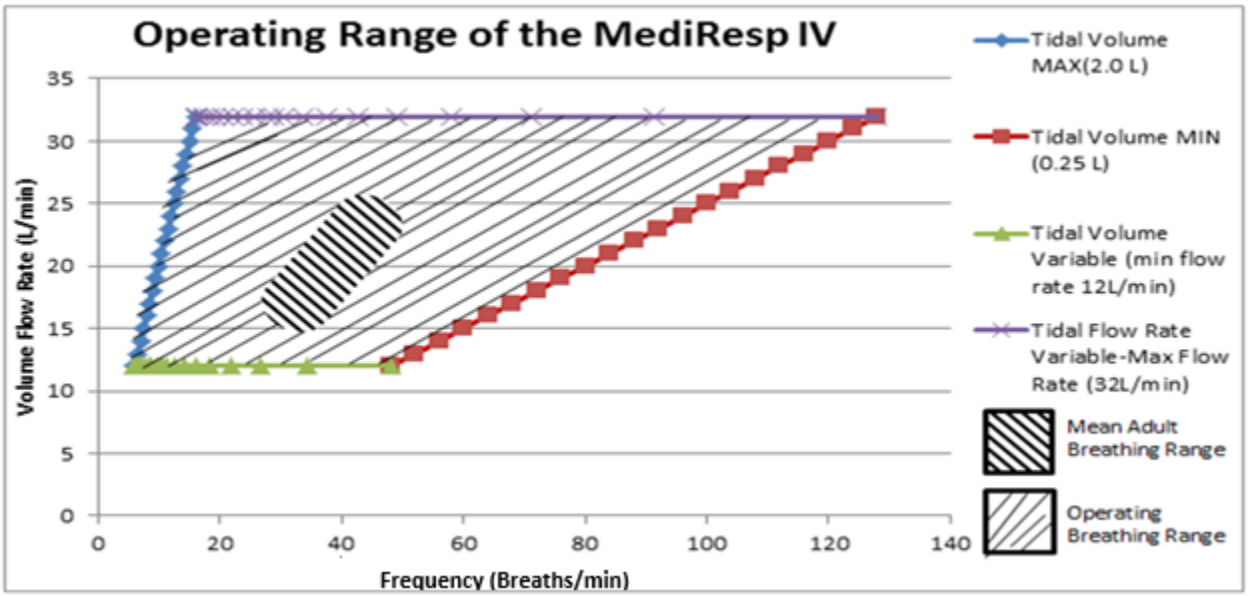

Figure 7 – Operating Range of MEDIRESP V

Understanding the volume per breath of the pump flow other known as tidal volume allows to calculate the upper and lower limits of air per breath. Since the inhale to exhale ratio in CMV mode is 1:3, the upper and lower limits of air per breath are .25L/breath and 2.0 L/breath. These limits are hard wired into the system which allows to map the frequency and operating range of the device.

The system above uses the flow rate divided by the tidal volume to map the frequency (on x-axis) of Breaths per minute. The ventilator can reach as low as 5 Breaths/min, and as high as 128 Breaths/ min (although this would be

an ideal function, most likely not feasibly by our pump). The graph also shows the mean or average breathing range for an average adult. The ventilator well exceeds the range in all breathing directions. This is to ensure the ventilator can acheive all styles of breathing as needed by the EMT.

CONCLUSIONS AND RECOMMENDATIONS

Even though the team succeeded in many areas; there are still some improvements that could be made to the next revision of the MEDIRESP. One of the specifications that the customer initially listed was for the device to be able to withstand a drop test as well as vibration testing to simulate common usage scenarios. At the end of spring quarter 2013, the team had hopes of working with an Industrial Design student in the fall to help with the overall aesthetics and ergonomics of the device; however, there was no opportunity to get in touch with such student. The current enclosure that is used on the MEDIRESP is user friendly and portable; however, collaborating with an industrial design student would have further the usability and ergonomics of the case. In the next iteration of the project, an addition of such student to the team could help to focus on the durability of the enclosure as well as improve mounting brackets for the interior components of the ventilator.

The mechanical pressure relief valve was incorporated into the system to release at 1 psi as a failsafe to protect the patient's lungs. Due to the high velocity of the pump, the current valve is unable to relieve the entire pressure through the port; thus, the safety of the patient is still within a concerning range. In future designs, to better acheive a full range of function, a new relief valve would need to be designed to be able to relieve high velocity flows. This would be the best method of addressing the issure. Another idea would be to put multiple mechanical relief valves in series with one another to catch all of the missed high pressure flow in other relief systems since not all the air would be relieved in the first valve.

The pump selected for this project operates in the range from 12 L/min to 32 L/min. This range does not meet the specifications originally given by the customer. The pump only reaches half of the spectrum listed. In a future model it would be advantaggeous to use the double head pump (same pump brand and style). This would allow twice the amount of volume to be pushed out of the pump, which would yield a range closer to the customer's request.

Throughout the testing and build phase of the project, there were some mistakes found in the design of the PCB that could be fixed if another revision of the circuit board were to be made. A major improvement would be fixing the battery charging circuit which would allow the battery of our ventilator to be charged using a wall supply. The current design requires the battery to be removed from the enclosure and charged externally. Additional improvement would allow the battery to be charged while the device is in use. Various small changes to the board such as cutting unnecessary traces, creating solder joints, and fixing simple layout mistakes such as the misplacement of passive components would be made in a second revision as well.

The main goal of this project was to reduce the weight and volume of the device by reducing the circuit board size, further decreasing battery size while staying substantially equivalent to sustain the FDA approval as per customer's specification. Overall, this project can be considered as a success as the Mediresp V is fully functional prototype that satisfies the criteria mentioned previously. This is a significant milestone towards creating a viable production model.

REFERENCES

[1] Press, Roman J., and Jeffrey S. Gutterman. Portable Emergency Respirator. Patent 5,398,676. 21 Mar. 1995. Print.

[2] Press, Roman J. Portable Emergency Respirator. Patent 5,211,170. 18 May 1993. Print.

ACKNOWLEDGMENT

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