Device to Aid in Mechanical Ventilation of Obese Patients

Major Qualifying Project

A Major Qualifying Project submitted to the Faculty of WORCESTER POLYTECHNIC INSTITUTE in partial fulfillment of the requirements for the Bachelor of Science

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Date:

April 25th, 2023

This report represents the work of WPI undergraduate students submitted to the faculty as evidence of completion of a degree requirement. WPI routinely publishes these reports on its website without editorial or peer review.

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Chapter 0: Abstract

Positive pressure ventilation (PPV) treatments in obese patients are more likely to lead to ventilator-induced lung injuries (VILI) and further respiratory complications. The purpose of this project was to develop a constant negative abdominal pressure ventilator (CNAP) to work in tandem with PPV to reduce the positive pressure needed. The major design requirements deemed necessary are function, ease of removal, and accessibility, which were all applied to the Shell, Sealing, Locking, Frame, and Pump subsystems on the small and large scale iterations. The final design consists of a clear shell clasped onto a frame, which can be attached to any standard medical bed, and neoprene sealing attached to the patient. The neoprene creates an airtight seal with the shell using custom gasketing that achieves emergency chest access in 10 seconds. The lightweight device extends from the top of the sternum to the hipbone line. It maintains a vacuum range of -10 to -30 cmH2O for 6 hour work-2 minute rest cycles for 3-4 weeks. The combination of the CNAP and PPV can potentially reduce the occurrence of VILI.

Chapter 1: Introduction

Ventilation devices serve as a mechanical aid to respiration, providing oxygen to the patients as they inhale and assisting in the removal of carbon dioxide upon exhale. Cases requiring ventilation can include COVID-19, strokes, brain injuries, chronic obstructive pulmonary disease (COPD), etc (National Institute of Health). The modern design of a ventilator creates a positive pressure gradient in the lungs pumping air through a breathing tube. It is inserted into the nasal cavity/trachea directly or through surgery in some cases and monitored by clinicians until patients are healthy enough to no longer need the device. Once the patient is believed to be able to handle breathing without assistance, the patient is slowly weaned off by decreasing the pressure applied that induces artificial airflow.

Despite the ability of these positive pressure mechanical ventilators (PPV) to combat weakened respiration in patients with severe illnesses, preexisting conditions—such as obesity—lower the efficacy of these devices as lung strength prior to illness exposure is already reduced. Obesity is a chronic disease prevalent in 41.9% of the US population and it is associated with a higher need of mechanical ventilation in a hospital setting (CDC, 2017). This is because obesity directly decreases respiratory system compliance, lung volume achieved by each breath is minimized, ultimately causing greater risk for lung collapse. However, mechanical ventilation also increases the propensity for lung collapse and the risk of ventilator-induced lung injury (VILI) as the pressure gradient applied does not directly mimic that of natural respiration, counteracts the lungs' natural negative pressure gradient, and imposes stress on the weaker portions of the lung. Although the PPV's demand increased over time due to its compact size and speedy production time, it can ultimately pose greater risks for lung collapse—especially for those with preexisting medical conditions. Therefore, the development of more effective ventilation devices is crucial. The downside of PPV has led researchers to look towards negative pressure ventilators (NPVs). Negative Pressure ventilation has been proven effective before. The last widely-used negative pressure ventilator was the iron lung, during the polio epidemics in the early twentieth century. However, their bulkiness and lack of airway protection led to their falling out of favor. Nowadays, with the negative effects of PPV, researchers have been investigating how NPV could be implemented in a more accessible way for those who would benefit from it.

Recognizing the benefits of a negative pressure ventilation device, while also considering the accessibility drawbacks posed by the traditional iron lung, provide an opportunity to combine the beneficial aspects of PPV and NPV devices. Combining the devices would allow for continuous negative pressure to be applied to a patient while attached to a positive pressure ventilator; therefore,

minimizing the amount of positive pressure needed to expand the patient's lungs. However, current research does not indicate much experimentation in the idea of using both of these devices in tandem. The few patented NPV devices in existence increase production time due to their cumbersome nature and are less accessible in hospitals. As a result, the risks associated with positive pressure ventilation are seen as less important.

It is evident that there is a high demand for ventilation devices in today's climate, and obese patients are at a higher risk with the weakened effects of positive pressure ventilators, based on their already worsened respiratory strength. Therefore, this project is aimed towards the design of a new negative pressure mechanical ventilation device that functions in tandem with the modern PPV. The device provides continuous negative abdominal pressure (CNAP) at a range from -10 to -30 cmH2O during a 6 hour work-2 minute rest cycle for 3-4 weeks. Additionally, it must be accessible and convenient to hospitals. In other words, it should be cost-effective, it should adapt to a standard hospital bed, be removed in less than 10 seconds, and weigh less than 10kg. By supplementing PPV with continuous negative pressure ventilation, the positive pressure needed will be reduced giving the device the potential to minimize VILI and further respiratory complications.

During the design process the team created five main subsystems: Shell, Sealing, Locking, Frame, and Pump. Each of these subsystems had three to five different iterations that were chosen using decision matrices. The final design consists of a clear shell that extends from the top of the sternum to the hipbone line. The shell is clasped onto a frame and uses neoprene to attach to the patient in order to maintain vacuum. The design maintains the CNAP and it is very intuitive to use.

The following chapters describe the different steps and considerations of the engineering design process. The second chapter introduces the clinical need in addition to literature review relevant to the making of the device. Chapter 3 discusses the project strategy with all the design requirements and constraints. Chapter 4 focuses on the iterations of the different subsystems and how the final design was chosen. Chapter 5 describes the testing process of the prototype. Chapter 6 describes the manufacturing implementations. Chapter 7 discusses the design validation and how it fulfills the requirements. Lastly, chapter 8 concludes the project with future recommendations.

Chapter 2: Background

2.1 - Clinical Need

Obesity is a chronic disease that affects both adults and children worldwide (Centers for Disease Control and Prevention [CDC], 2022). Since 1975, obesity prevalence in the world has nearly tripled (World Health Organization [WHO], 2021). In 2017, 41.9% of the US population was found to be obese (CDC, 2022). Additionally, obese people utilize the healthcare system more often than non-obese people (Kukielka, 2020). Due to the high prevalence of obesity and their predominant use of the healthcare system, it is essential to ensure these patients receive quality service. However, that oftentimes is not the case. A study conducted with the assistance of over 22 physicians from a variety of backgrounds and specialties, found that gaps in the healthcare system needed to be addressed in order to provide obese patients equitable access to its resources (Agaronnik et al., 2021). One example of non-equitable access presented in the study was a lack of medical diagnostic equipment for obese patients (2021). This information is confirmed by another study, in which event reports relating to obese patient monitoring and care were analyzed. The researchers of the study found many of these event reports summarized cases in which equipment, such as wheelchairs and MRI's, was not fit for bariatric populations (Kukielka, 2020).

In addition to a lack of accessibility, conditions related to obesity must also be considered. Obesity is associated with comorbidities such as cardiovascular disease, stroke, diabetes, and cancer (CDC, 2022). The scope of this project is most focused on the obesity-related condition of reduced respiratory compliance (Littleton, 2012). Obesity results in changes to the mechanical properties of the lungs and chest wall; therefore, obese patients are more prone to lung collapse as well as aggravating respiratory conditions, such as acute respiratory distress syndrome (ARDS) (Littleton, 2012; Jong et al., 2020). Consequently, while in the hospital, obese patients tend to more frequently need the assistance of a mechanical ventilator compared to non-obese patients (Jong et al., 2020). A study conducted at the Washington Hospital Center with 504 patients, 198 of which were obese, found that 39.5% of obese patients required invasive mechanical ventilation in the ICU (Lee & Colice, 2014). Although mechanical ventilation treatment is essential to the care of some patients, it can cause ventilator-induced lung injuries (VILI) (Vianna & Neto, 2018; Zheng et al., 2019). While on a mechanical ventilator, obese patients have a higher risk of respiratory complications, including lung collapse; therefore, they may require higher pressure settings (positive-end expiratory pressure) to facilitate an effective treatment.

Receiving mechanical ventilation induced by higher pressures is often associated with an increased potential of ventilator-induced lung injuries; however, this area still requires further study (Vianna & Neto, 2018; Zheng et al., 2019).

Considering the prevalence of obesity in the population, their elevated need for mechanical ventilation, and their higher propensity for respiratory complications while on the PPV, it is essential to make a device to aid them during the treatment. With that, there is an opportunity to look into negative-pressure ventilation—which is more natural to the body—in order to create a device that could work in tandem with the positive-pressure mechanical ventilator to decrease the positive pressure needed for breathing.

2.2 - Anatomical Respiration

2.2.1 - Negative Pressure in Our Lungs

Natural respiration is accomplished by negative pressure ventilation (Fox, 2019). Respiration, also known as pulmonary ventilation, is a mechanical process that consists of inspiration and expiration to oxygenate the body (Marieb & Hoehn, 2019). Changes in lung volume induce the pressure difference necessary between the two ends of the airways—structures responsible for conducting air from the nose and to the bronchioles—for this process to work (Fox, 2019).

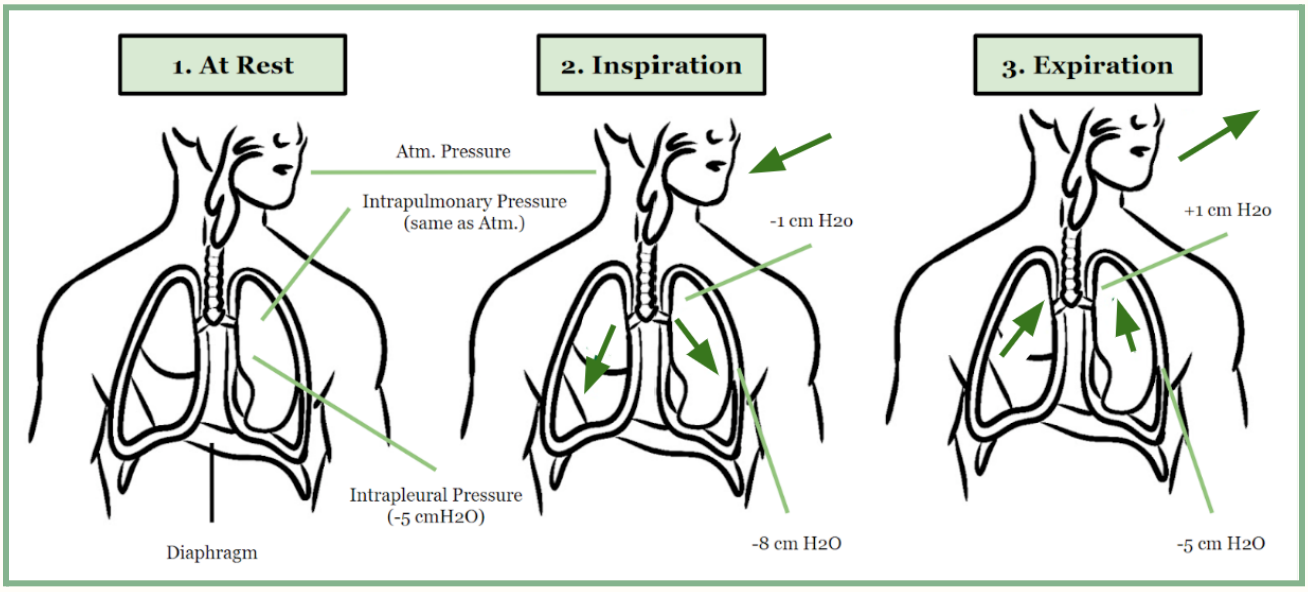

Figure 1: Pulmonary Ventilation.

The differences between atmospheric, intrapulmonary, and intrapleural pressure are measured by respiratory physiologists in cmH2O (Fox, 2019). In this system, the relative atmospheric pressure is considered to be zero cmH2O and any other value of pressure, such as -1 cmH2O, is the difference from the atmospheric pressure (2019). Atmospheric pressure does not change; therefore, there is a need for a decrease in intrapulmonary, or intra-alveolar, pressure for air to flow into the lungs (2019). During inspiration, the diaphragm lowers and flattens as it contracts, increasing the height of the thoracic cavity; whereas the intercostal muscles' contraction lifts and draws together the ribs, promoting an increase in the size of the thoracic cavity laterally (Fox, 2019; Marieb & Hoehn, 2019). The increase in lung volume—possibly due to the high compliance of the lungs—decreases the intrapulmonary, or intra-alveolar, pressure to -1 cmH2O leading air to enter the lungs (Fox, 2019; Marieb & Hoehn, 2019). As air fills the lungs, the intrapulmonary pressure gets closer to the atmospheric pressure at 0 cmH2O, and once it is the same, inspiration ends (Fox, 2019; Marieb & Hoehn, 2019). For expiration to happen, the intra-alveolar pressure must be higher than the atmospheric pressure (Fox, 2019; Marieb & Hoehn, 2019). During expiration, the diaphragm and other thoracic muscles relax and the lungs recoil due to their high elasticity, and their volume is decreased (Fox, 2019; Marieb & Hoehn, 2019). This results in the compression of the alveoli, which increases the intrapulmonary pressure to +1 cm H2O causing air to flow out of the lungs (Fox, 2019; Marieb & Hoehn, 2019). With the air leaving the lungs, the pressure decreases until it reaches atmospheric pressure (Fox, 2019; Marieb & Hoehn, 2019).

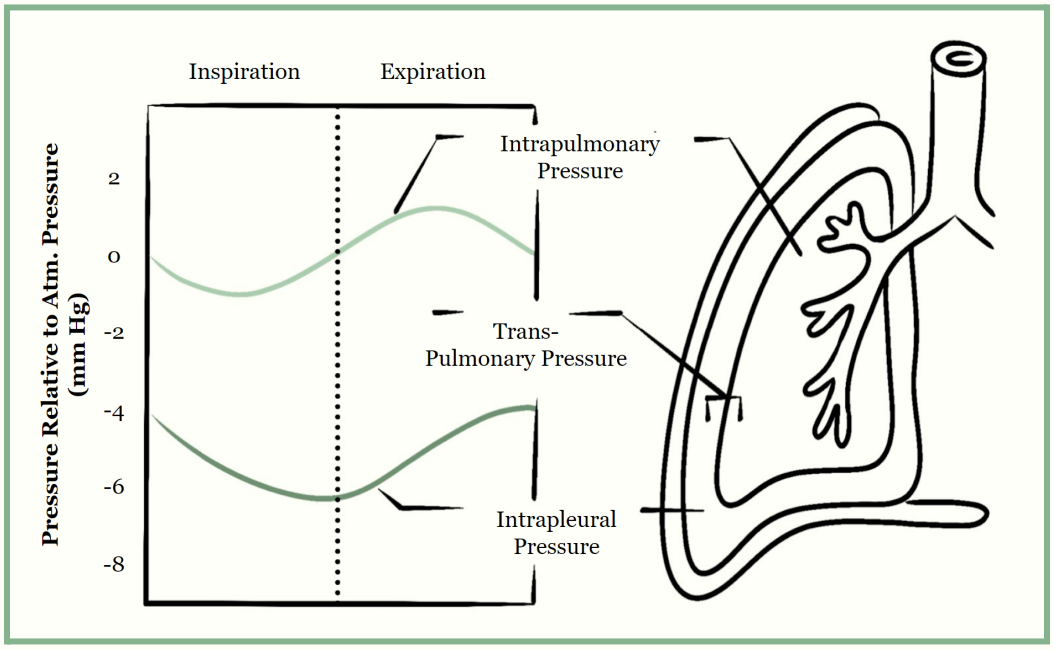

Figure 2: Pressures During Breathing (Adapted from (Marieb & Hoehn, 2019)).

While the elastic recoil of the lungs makes them pull in one direction as they “attempt to collapse”, the chest wall recoils in the opposite direction (Fox, 2019; Marieb & Hoehn, 2019). This results in pressure in the pleural cavity known as intrapleural pressure (Fox, 2019; Marieb & Hoehn, 2019). This pressure is always negative in relation to the intrapulmonary pressure: during inspiration, it is -8 cmH2O, while during expiration it is -5 cm H2O (Fox, 2019; Marieb & Hoehn, 2019). The difference between intrapulmonary and intrapleural pressures is known as transpulmonary pressure. The transpulmonary pressure is always positive during inspiration and expiration, keeping the lungs tight to the chest wall, which allows the lung volume to change and avoids lung collapse (Fox, 2019; Marieb & Hoehn, 2019).

The respiration process is dependent also on the functioning of the lungs’ physical properties, which include compliance, elasticity, and surface tension (Fox, 2019; Marieb & Hoehn, 2019). Lungs need to be able to stretch under pressure; in other words, they need to have high compliance, which can be described as the change in lung volume over the change in transpulmonary pressure. Therefore, factors that create resistance to expansion reduce the lung’s compliance. For the lungs to recoil to their initial size after being stretched, they need to have high elasticity. Considering the lungs' tight attachment to the chest wall, they are constantly in a state of elastic tension, which increases during inspiration due to distension and decreases during expiration due to lung relaxation (Fox, 2019). In addition to the elasticity, the surface tension in the alveoli assists in the resistance to distension (2019). The alveolus has a thin film of fluid that has a surface tension as the water molecules attract each other (Fox, 2019; Marieb & Hoehn, 2019). This surface tension acts to reduce the alveoli to their smallest possible size, leading them to collapse and increasing the pressure within the alveoli (Fox, 2019; Marieb & Hoehn, 2019). The collapse of the alveoli is avoided by a substance called surfactant that reduces surface tension (Fox, 2019; Marieb & Hoehn, 2019). This reduction of the surface tension leads to reduced energy expenditure when expanding the lungs and avoids alveolar collapse (Fox, 2019; Marieb & Hoehn, 2019). The deficiency of surfactant is associated with various lung conditions and respiratory diseases, such as atelectasis and acute respiratory distress syndrome (ARDS), and has been shown to decrease ventilation time in some studies, although the latter still needs to be further investigated (Lopez-Rodriguez & Pérez-Gil, 2014; Albert, 2012).

Table 1: Lung volumes and their descriptions (Fox, 2019; Marieb & Hoehn, 2019)

Tidal Volume (TV)	Volume of gas inhaled or exhaled under a resting respiration cycle
Inspiratory Reserve Volume (IRV)	The maximum volume of gas that can be forcefully inhaled in addition to a tidal inspiration
Expiratory Reserve Volume (ERV)	The maximum volume of gas that can be forcefully inhaled in addition to a tidal expiration
Residual Volume (RV)	The volume of gas remaining in the lungs after a forced expiration

Lung capacity consists of the sum of two or more lung volumes (Fox, 2019; Marieb & Hoehn, 2019).

Table 2: Lung capacities and their descriptions (Fox, 2019; Marieb & Hoehn, 2019)

Total Lung Capacity (TLC)	The total amount of air contained in the lungs after a maximum inspiration (TLC = TV + IRV + ERV + RV)
Vital Capacity (VC)	The maximum amount of gas that can be expired after a maximum inspiratory effort (VC = TV + IRV + ERV)
Inspiratory Capacity (IC)	The maximum amount of gas that can be inspired after a normal tidal volume expiration (IC = TV + IRV)
Functional Residual Capacity (FRC)	The amount of air that remained in the lungs after a normal tidal volume expiration (FRC = ERV + RV)

Another index of effective ventilation is the alveolar ventilation rate (AVR) (Marieb & Hoehn, 2019). Some of the air that is inspired does not reach the alveoli, and, consequently, does not take part in the gas exchange (Fox, 2019). These areas are known as dead space (Fox, 2019; Marieb & Hoehn, 2019). With that AVR takes into account the volume in dead space and measures gas flow in and out of the alveoli for a period of time (Marieb & Hoehn, 2019). It follows the equation:

$$AVR\ (ml/min)\ =\ frequency\ (breaths/min)\ x\ (TV\ -\ dead\ space)$$

In healthy subjects, the AVR value usually is 4200 mL/min, which is approximately 12 breaths per minute times 500 ml (TV) - 150 ml (dead space) (2019).

2.2.2 - Breathing in Obese Patients

Obesity is a prevalent health condition that, in 2017-2018, was found to affect 42.4% of the US population (Brock et al. 2021). The mechanical effects of obesity on pulmonary function are a broadening area of research (Brock et al. 2021; Littleton, 2012).

Obesity reduces respiratory system compliance, which, as mentioned before, is necessary for lung volume increase, as it significantly alters the mechanical properties of both the lungs and chest walls (Littleton, 2012; Dixon & Peters, 2018). It is not yet proven whether this decrease in respiratory system compliance is primarily due to the property changes—reduced compliance—of lungs, chest wall, or a combination of both (Littleton, 2012; Dixon & Peters, 2018). Fat deposits in the mediastinum and abdominal cavities are one of the main reasons for these reductions in compliance (Dixon & Peters, 2018). More specifically, the decrease in lung volume, which leads to a microatelectasis (partial collapse of an area of the lung), likely results in the reduction of compliance (Littleton, 2012). As for the chest wall, the decreased compliance is most likely related to the location and pattern of fat distribution; in a supine position subject, fat presence in the lower thorax and upper abdomen affects chest-wall compliance more than in other areas (2012).

This compliance reduction in the respiratory system has a direct impact on the breathing pattern (Littleton, 2012; Dixon & Peters, 2018). Due to the fat accumulated in the abdominal and thoracic cavities, the diaphragm's downward movement and outward chest movement are limited (Dixon & Peters, 2018). This increases intra-abdominal and pleural pressure and alters the breathing pattern (Littleton, 2012; Dixon & Peters, 2018). Obese people have a higher respiratory rate (15.3-21 breaths per minute) than non-obese people (10-12 breaths per minute) (Brock et al. 2021; Littleton, 2012). The most substantial change in breathing for obese people is the reduction of the expiratory reserve volume (ERV) and the functional residual capacity (FRC) (Dixon & Peters, 2018). As the person's body mass index (BMI) increases, the ERV decreases (Littleton, 2012). A study done with 373 patients showed that those with a BMI of 30-35 kg/m^2 (mild obesity) had an ERV of only 42.43% of what was predicted (2012). Similarly, the decrease in FRC is related to the degree of obesity as overweight, mildly obese, and severely obese subjects had reductions of up to 10%, 22%, and 33%, respectively (Dixon & Peters, 2018). Furthermore, tidal volume tends to be slightly lower in obese patients, although there is no consensus on this matter (Littleton, 2012; Dixon & Peters, 2018).

There is an increase in respiratory system resistance as obesity can lead to airway narrowing and closing (Littleton, 2012; Dixon & Peters, 2018). Increased airway closure is proportional to an increase in abdominal obesity as the decrease in FRC reduces the forces of interdependence between the airways

and parenchyma (Dixon & Peters, 2018). A study with 190 subjects showed that obese men had airway resistance almost twice as high as the one for non-obese subjects (Littleton, 2012). This can facilitate the advancement of lung diseases as airway narrowing can increase gas trapping, which would contribute to the resistance of inhaled medications, and airway closure could aggravate obstructive lung diseases (Dixon & Peters, 2018). Furthermore, obesity changes the distribution of ventilation, leading to a ventilation-perfusion mismatch, which, as mentioned before, is very significant for ideal gas exchange (Littleton, 2012; Dixon & Peters, 2018). While the perfusion distribution is primarily present in the lower lungs, when FRC is significantly decreased, ventilation is distributed mainly to upper lung zones (Dixon & Peters, 2018). This mismatch likely leads to less ventilation, constriction of pulmonary arterioles, and widening of the A-aO2 gradient—the difference between the alveolar concentration (A) and arterial concentration (a) of oxygen (Marieb & Hoehn, 2019; Littleton, 2012).

Overall, obesity can aggravate and modify the clinical presentation of different respiratory conditions (Littleton, 2012; Dixon & Peters, 2018). Some respiratory diseases correlated with obesity are wheezing, orthopnea, asthma, hypoxia, and dyspnea (Dixon & Peters, 2018).

2.3 - Introduction to Ventilation

2.3.1 - What are Ventilators?

Ventilation devices assist in facilitating patients' breathing when they cannot do so independently, such as during surgery or when suffering from a critical illness. Some common conditions that result in the need for a ventilation device include pneumonia, chronic obstructive pulmonary disease (COPD), stroke, and brain injuries (ATS Patient Education Series). Even though ventilation devices have helped patients recover, their use also poses certain risks (ATS Patient Education Series).

2.3.2 - Risks Ventilators Pose to Obese Patients

Specifically, obese patients have a higher risk of developing injuries from mechanical ventilation. One of the main concerns for obese patients when using a ventilation device is ventilator-induced lung injury (VILI). There are four primary pathophysiologic mechanisms that are associated with VILI which include atelectrauma, barotrauma, volutrauma, and biotrauma, described in Table 3 below:

Table 3: Four primary pathophysiologic mechanisms that are associated with VILI (Haribhai, S., & Mahboobi, S. K.).

Atelectrauma	When a large shear force causes the lungs to collapse
Barotrauma	Caused by mechanical ventilation over-inflating the lungs that leads to high transpulmonary pressure, ultimately causing the lungs to over-stretch and air leakage
Volutrauma	Caused by the lungs' alveoli being over-inflated
Biotrauma	When lung injury causes a harmful inflammatory response resulting in more injuries elsewhere

Ventilator associated lung injuries (VALI), a term used synonymously with VILI, has a greater impact on obese patients compared to non-obese patients. In a study conducted with 976 patients, VALI occurred in 56% of obese patients with a BMI of 30 or greater compared to 44% of non-obese patients (Kumar & Anjum, 2022). The VALI that were considered included injuries associated with positive end-expiratory pressure (PEEP) and FiO2 criterias. The study concluded obese patients developed VALI due to increasing the frequency of PEEP compared to the increase in FiO2 (Kumar & Anjum, 2022).

Additionally, atelectrauma, or specifically atelectasis is further exacerbated when the patient is ventilated in the supine position and/or is under general anesthesia. Strategies have been developed to try to prevent VILI, such as reducing the metabolic demand of ventilation, having the patient in a prone position, or having the patient receive extracorporeal membrane oxygenation (ECMO).

2.4 - Positive Pressure Ventilation (PPV)

2.4.1 - What is PPV?

Positive pressure ventilators create a gradient from which a mixture of oxygen and other gasses naturally move from the high-pressure area (the tank) to the low-pressure area (the patient's lungs). The mixture is continuously delivered until the intra-alveolar pressure reaches a certain threshold, ending inspiration. Expiration then occurs passively due to air escaping the now higher-pressure alveoli to the lower-pressure airway (Potchileev, I., Mohammed, A. N., & Doroshenko, M.).

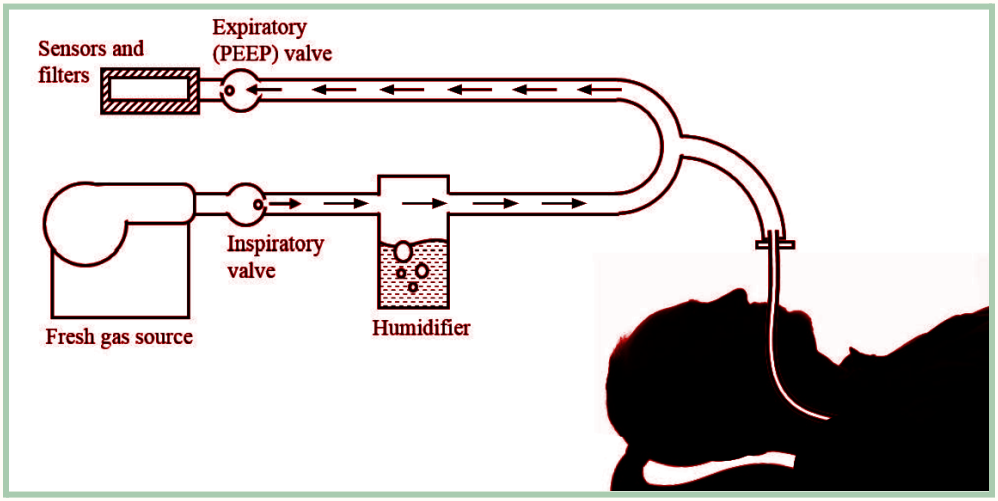

Figure 3: Schematic of a Positive Pressure Ventilator.

Note: Adapted from *Breathing circuits for manual and mechanical ventilation*, 2023

2.4.2 - Positive Pressure Compared to Negative Pressure

At the start of the pandemic, hospitals utilized both positive and negative pressure ventilation devices. However, positive pressure ventilation devices, at the time, caused gastric insufflation and required covering the patient's face, while negative pressure ventilation devices did not (Eichel & Dreux, 2017). Positive and negative pressure ventilation achieve similar dynamic and static lung volumes. However, studies have shown that negative pressure improves oxygenation levels and causes less injury to the lungs when compared to positive pressure. The major difference between these two ventilation methods is negative pressure ventilation is applied to the patient's thorax and abdomen, allowing the lungs to inflate due to the swelling of the rib cage and abdomen, whereas positive pressure ventilation causes lung distension by increasing the pressure in the patient's airways (Potchileev, I., Mohammed, A. N., & Doroshenko, M.). The pressure gradient for the two devices is best illustrated in the following images:

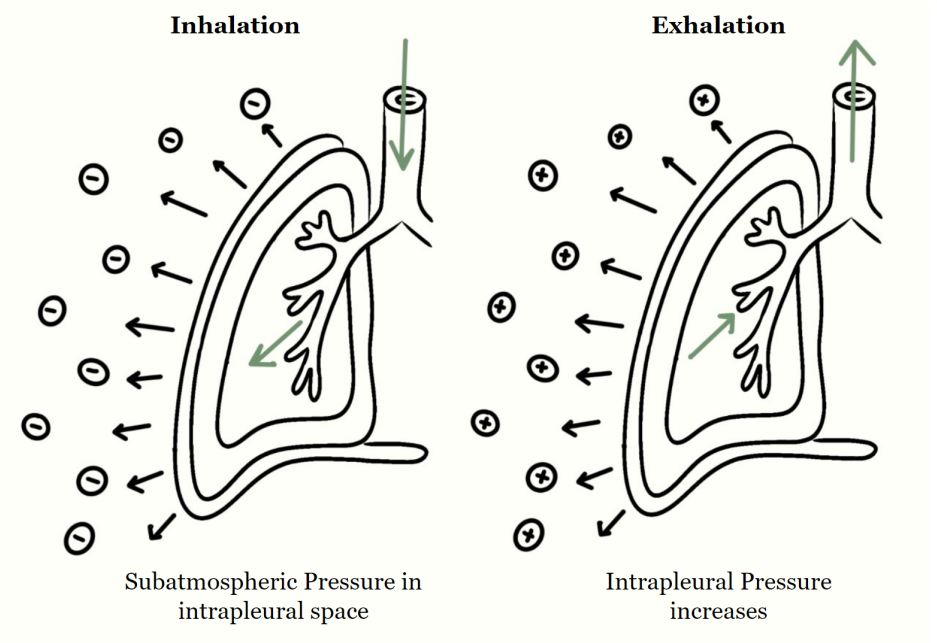

Figure 4: Airflow in a traditional NPV (Like the Iron Lung).

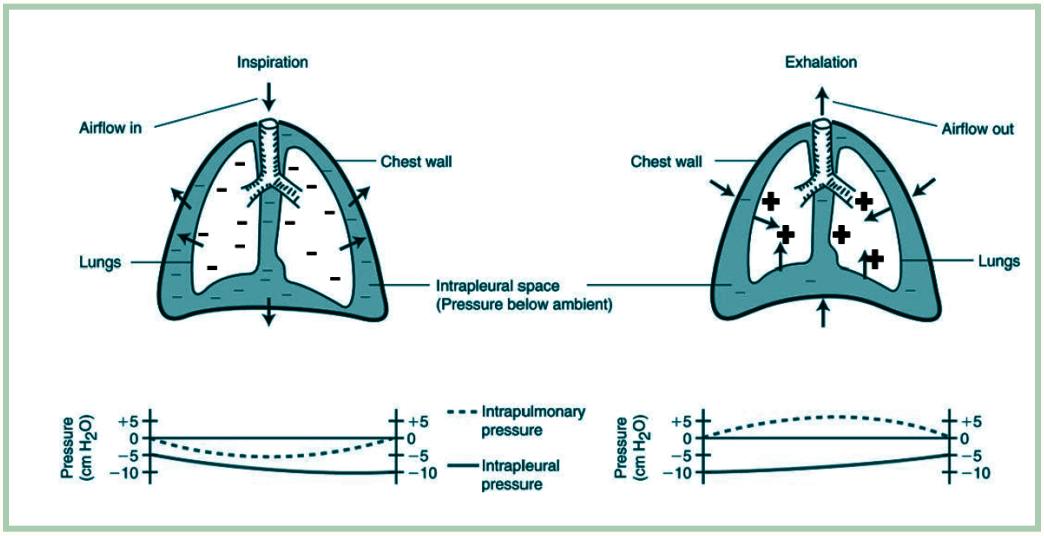

Figure 5: Airflow in a Modern Positive Pressure Ventilator.

Note: Adapted from *Basic terms and concepts of mechanical ventilation*, by Thoracic Key, 2016. (https://thoracickey.com/basic-terms-and-concepts-of-mechanical-ventilation/)

2.4.3 - Purpose of PPV

Positive Pressure ventilation (PPV) became common in the 1950s amidst the polio epidemic, replacing the iron lung. The iron lung proved to be too bulky, heavy/difficult to move, and also limited the doctor's access to the patient's body (Thomson, A. ,1997). Their size and shape additionally made these devices more complicated to manufacture resulting in an insufficient number of iron lungs being available (Potchileev et al., 2022). Use of the iron lung was also greatly restricted to neuromuscular disorders (Thomson, A. ,1997). The following image demonstrates the modern PPV device, illustrating its adaptability and potability:

Figure 6: A Positive Pressure Ventilator on a Patient.
Note: Adapted from *When do you put a patient on a ventilator?*, 2022.
(https://betteroptionsventilator.com/when-do-you-put-patient-on-ventilator/)

2.4.4- Mechanical Design of PPV

There are two types of positive-pressure ventilation, invasive and non-invasive. Non-invasive ventilation (NIPPV) is usually administered through a continuous positive pressure airway (CPAP) (Potchileev et al., 2022). A CPAP machine typically consists of an air pump attached to a tube, which is then attached to a face mask. This machine then delivers positive end-expiratory pressure (PEEP) ranging from 5-12 cm H2O to the patient. The reason behind the use of constant positive pressure is it opens both the upper and lower portions of the airway, which prevents issues from occurring during and after exhalation (Potchileev et al., 2022).

Another form of non-invasive PPV is BiPAP machines. Similar to CPAP, BiPAP machines deliver constant positive pressure to the patient within a range of 3 to 12 mm Hg (Potchileev et al., 2022). However, a BiPAP machine differs as it also provides positive inspiratory pressure, ranging from 5 to 25 mm Hg, to help the person initiate taking a breath. BiPAP machines require the patient to wear a mask over their face that also creates a tight seal. This seal then prevents positive pressure from escaping from the mask, making the therapy more effective (Potchileev et al., 2022).

Invasive positive pressure ventilation requires the patient to be intubated (Potchileev et al., 2022). Intubation can occur with an endotracheal tube or a tracheostomy tube that is ventilated, which creates an artificial airway to deliver the oxygen mixture directly to the patient's lungs. This type of ventilation can be used to assist the patient with their breathing or fully facilitate their breathing (Potchileev et al., 2022).

2.4.5 - Challenges Associated with PPV

Despite the benefits associated with the adaptation of PPV, which remains as the primary method of conducting mechanical ventilation, drawbacks are still present. The use of positive pressure ventilation can lead to sepsis, atelectasis, pulmonary edema, ventilator-associated pneumonia, and acute respiratory distress syndrome. Due to the prolonged usage of a tube in the throat or nasal cavity, the build-up of fluids and toxins increases the propensity for infection. These complications can increase the duration of ventilation use on the patient, as well as their hospital stay (Haribhai, S., & Mahboobi, S. K.). Besides infection, positive pressure ventilators can also induce VILI, which are caused by atelectrauma, barotrauma, volutrauma, and biotrauma as described in Table 3 above. Not only does this inflammatory response affect the lungs, but it also affects other organs in the body increasing the mortality rate (Haribhai, S., & Mahboobi, S. K.).

2.5 - Negative Pressure Ventilators (NPV)

2.5.1 - What is NPV?

Corrado & Gorini define negative pressure ventilation as, "a type of ventilation in which the surface of the thorax is exposed to subatmospheric pressure (i.e., negative pressure) during inspiration" (Corrado & Gorini, 2002). The low pressure environment around the outside of the chest cavity induces the alveoli in the lungs to fill with air entering from the airway. As the pressure outside the chest cavity returns to atmospheric pressure, the lungs and chest muscles recoil, inducing expiration (Corrado &

Gorini, 2002). Any device that creates a subatmospheric environment around the thorax to facilitate inspiration and then returns to atmospheric pressure or greater to facilitate expiration is a negative pressure ventilation (NPV) device.

2.5.2 - The First Ventilators: The Iron Lung

Mechanical ventilators did not achieve widespread use until the poliomyelitis epidemics that occurred in the first half of the 20th century. While 98% of cases only resulted in flu-like symptoms or were asymptomatic, in 2% of cases the disease invaded the central nervous system and caused acute flaccid paralysis (Eichel & Dreux, 2017). In 50% of cases, the patients' paralysis was permanent (Eichel & Dreux, 2017). Paralytic poliomyelitis became more deadly when it paralyzed the respiratory muscles, meaning a patient could no longer independently breathe. As a result, when Drinker and Shaw designed their tank ventilator in 1928, it became the first iron lung to achieve widespread commercial success. In the UK and Australia, the Both ventilator became commonly used. Both Equipment Ltd. modeled their device after the Drinker ventilator but constructed it out of cheaper and more portable plywood rather than sheet iron (Eichel & Dreux, 2017). These ventilators saved thousands of lives across the western world.

2.5.3 - Mechanical Design of NPV

Drinker and Shaw constructed the body and lid of the Drinker Ventilator out of sheet iron (Shaw & Drinker, 1929). The iron bed frame was attached to the lid, so removing the lid would pull the bed frame out of the body (Shaw & Drinker, 1929). A rubber collar is attached to the lid, which only the patient's neck and head protrude from. The lid and the tank are sealed with a rubber gasket. As a result only from the neck and above is at atmospheric pressure, while the rest of the body is in the airtight chamber of the tank (Shaw & Drinker, 1929). The tank itself can rotate 75 degrees to either side, and 15 degrees above and below the horizontal (Shaw & Drinker, 1929). Drinker and Shaw state that the purpose of giving the tank mobility was to accommodate patient comfort, which could also prevent bed sores. The tank body also has portholes that allow medical professionals to conduct the patient observation. The body also has small holes in which nurses can insert or attach tools used for patient assessment: thermometers, manometers, pneumographs (devices measuring thoracic volume), etc. (Shaw & Drinker, 1929).

The device in Figure 7 has two pumps in the below compartment that can produce varying pressures within the tank. Each pump contains two concentric cylinders. The outer cylinder remains

stationary while the inner cylinder is driven by a variable-speed motor. The device can achieve a maximum pressure of 60cm of water and can facilitate 10 to 40 breaths per minute. The typical pressure gradient needed by a patient is -10 to -15mmHg and +2 to +5mmHg (Eichel & Dreux, 2017).

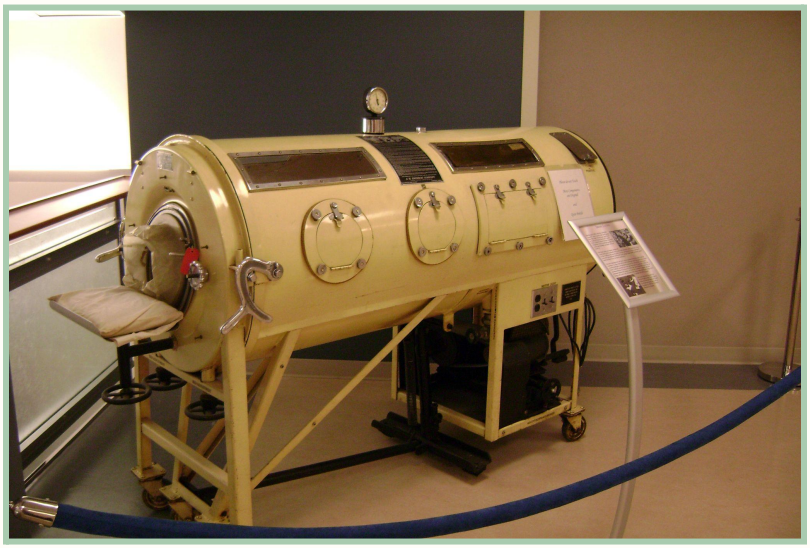

Figure 7: Drinker Ventilator (i.e., Iron Lung).

Note: From "Iron Lung" by Just Us 3 is licensed under CC BY-NC 2.0. To view a copy of this license, visit https://creativecommons.org/licenses/by-nc/2.0/?ref=openverse.

2.5.4 - Challenges Associated with NPV

While iron lungs prevented many deaths, patients still suffered from airway soiling from blood, vomit, and other detritus (Eichel & Dreux, 2017). In response, the Los Angeles County Hospital began using the Bennet 'Flow-sensitive Pressure Breathing Unit' with Iron Lung ventilators in 1949 (Eichel & Dreux, 2017). This supplemented the negative pressure from the Iron Lung with intermittent positive pressure (Eichel & Dreux, 2017). Creating a positive pressure environment in the lungs required either a tracheostomy, a tracheal tube, or a mask. Two of these options, tracheostomy and a tracheal tube, both offer airway protection, preventing detritus from obstructing the airway. As a result, mortality results within the hospital fell from 70% to 17% (Eichel & Dreux, 2017).

The same phenomenon occurred in Copenhagen at Blegdam's Infectious Disease Hospital in 1952. Medical staff had believed that the high number of deaths were from renal failure, not respiratory failure. However, anesthetist Dr. Isben hypothesized that a large number of deaths were instead due to respiratory failure. He changed the procedures for treatment at the hospital, so that if a patient

experienced upper airway paralysis, a tracheostomy was performed (Eichel & Dreux, 2017). From July to August of 1952, polio mortality rates dropped from 87% to 54% (Eichel & Dreux, 2017). Since case numbers from each month had stayed relatively constant, these statistics indicated that the drop in mortality resulted from the change in treatment of patients suffering respiratory paralysis from poliomyelitis. Since positive pressure ventilation protects the airway and allows for bodily freedom for patients, it has become the standard for ventilation.

2.6 - Current Solutions

2.6.1 - Continuous Negative Abdominal Pressure

To understand the benefits of negative pressure ventilation compared to modern positive pressure ventilators, the mechanical differences and the resulting biological differences must be examined. In a traditional PPV, there is a driving pressure applied through the machine, and a PEEP, or positive end-expiratory pressure, is applied at the end of every breath to support airflow volume in the lung and prevent the collapse of the alveoli. Understanding biological respiration and the pressure gradient in figures 5 and 6, it can be seen that in a PPV, the PEEP applies stresses on the upper chambers of the lung as the air circulates upwards as opposed to natural breathing, which concentrates that stress on the lower chambers. Over time, it has been proven that this non-traditional pressure gradient can negatively impact lung volume, ultimately minimizing oxygenation.

As a result, researchers and engineers have been investigating how to create a compact device that can achieve a sufficient end-expiratory pressure in a negative pressure gradient. Recently, there have been preliminary developments of new compact negative pressure ventilation devices called CNAPs, which stimulate Continuous Negative Abdominal Pressure. A CNAP, as opposed to producing PEEP, creates “NEEP” to better stimulate natural pressure flow in the lungs to increase expansion. PEEP causes atelectasis, or lung collapse, because lungs are inherently elastic and the increased intra-abdominal pressure gradient imposes a larger strain on the upper chamber ultimately redesigning the force distribution of the lung and changing the position and shape of the lungs and diaphragm (Yoshida et al, 2018). Upper airway (UA) collapse is largely associated with airway deflation due to the anatomical description of the lungs, therefore it is important to be cautious during artificial ventilation that the applied pressure is directed in the dorsal chambers that can withstand greater applied pressure. Preliminary studies on CNAP have been conducted on regulating shape-matching between the lung and chest wall as intra-abdominal hypertension is hypothetically reduced.

Despite a low amount of human subject testing on preliminary adaptations of the CNAP in combating lung collapse, studies performed on pigs had shown beneficial outcomes. According to a study where two hours of VILI were induced into the pigs as PEEP was adjusted every 15 minutes for a two-hour range. Although the pressure was not being directly transferable because of the difference in anatomical limitations of pigs versus humans, a rotational period of higher and lower driving pressure and PEEP were applied until the compliance of the respiratory system (Crs) decreased by 20%. Following the establishment of initial conditions, a CNAP device was created through a custom plexiglass chamber with a transduction device inside to regulate pressure as the animal's lower half was contained in the chamber. In testing efficacy the center of ventilation was measured according to the following equation:

$$Center\ of\ Ventilation\ =\ [\Delta Z\ (Dorsal\ Half)]\ x\ 100]\ \div\ \Delta Z\ (Whole\ Lung)$$

(Adapted from Yoshida et al, 2018)

Therefore, quantitatively, the center of ventilation approaches 0% as electric impedance tomography shows the ventilation area approaching the non-dependent regions of the lung. Pleural pressure was determined using catheters and a latex balloon, and computerized tomography (CT) scans recorded the shape of the diaphragms. Results regarding CNAP versus PEEP alone decreased lung collapse, re-centered the ventilation in the lungs, increased dorsal aeration, and led to greater overall oxygenation (Yoshida et al, 2018).

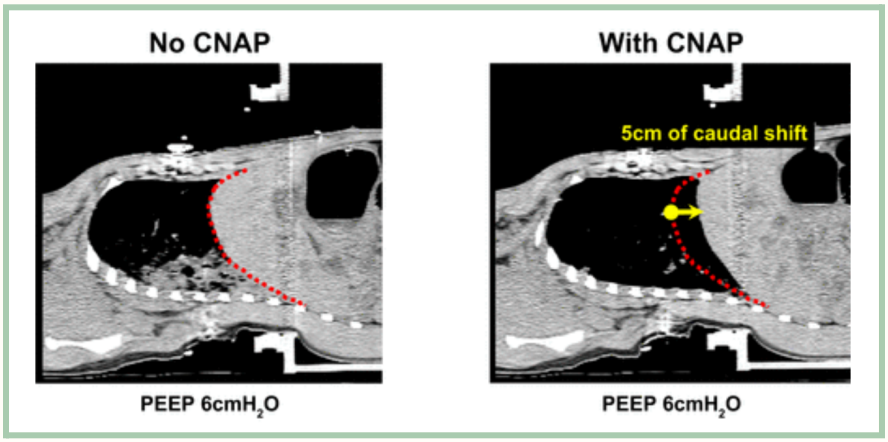

Figure 8: CT Scan of Yorkshire Pigs with/without CNAP.

Note: From *Continuous negative abdominal pressure: mechanism of action and comparison with prone position*, by Yoshida et al., 2018. (https://doi.org/10.1152/japplphysiol.01125.2017)

Other studies have produced similar sentiments regarding atelectatic lungs, as imaged in Figure 9 below showing a test on surfactant depleted rabbits:

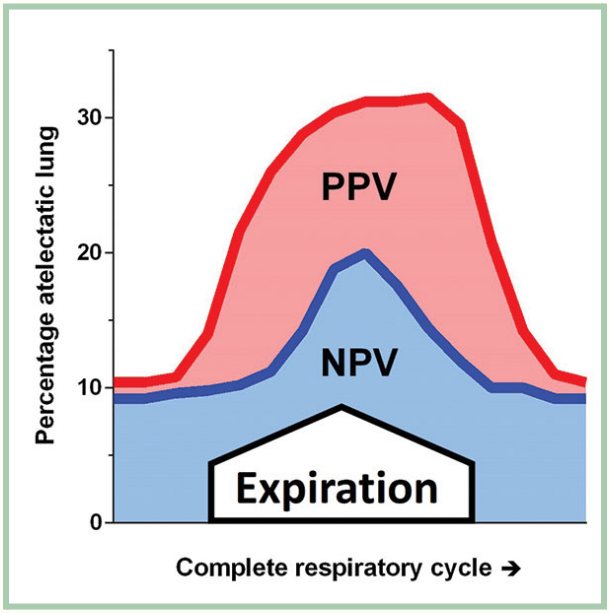

Figure 9: Percentage of Atelectatic Lung During PPV and NPV.

Note: Used with permission from *Exovent: a new development from an old technology*, by Association of Anaesthetists, 2021 (https://anaesthetists.org/Home/Resources-publications/Anaesthesia-News-magazine/Anaesthesia-News-Digital-May-2021/Exovent-a-new-development-from-old-technology)

Looking at CNAP stand alone, it was presumed the device itself would still be responsible for lung collapse. That is on account of the decrease in lung volume for CNAP versus traditional breathing due to the nature of mechanical ventilation in addition to the weaker nature of the UA chambers of the lungs. A study on sleep apnea-hypopnea syndrome (SAHS) sought to quantify the relationship between decreased upper airway resistance (UAR) to pressure change in CNAP as artificial ventilation versus continuous positive extrathoracic pressure (CPEP, a PPV that runs without tracheal insertion). SAHS as a condition is due to the presence of UA obstructions; therefore, it implies a decreased UAR for patients with an increased propensity for lung collapse. The results of the study showed that, especially with the use of a nasal stent to account for medically induced decrease in UAE, it is important to recognize that

regardless of the type of ventilation, lungs are still prone to collapse after deflation due to the transpharyngeal pressure gradient impacting all portions of the lung—despite the shift in the pressure gradient from positive to negative to lessen the impact on the UA with the implication of a CNAP versus CPEP. The Bernoulli principle supports this sentiment as the conservation of energy present in a streamline of a fluid shows that the sum of the kinetic, potential, and internal energy remains constant at every point on the steady flow (Series and Marc). Recognizing this limitation is important because despite the nature of the NPV replicating traditional breathing and applying pressure on the stronger portion of the lung, the clinician must ensure that mechanical pressure in the lung is most efficiently applied as to decrease propensity for lung collapse.

2.6.2 - Exovent and Vest Models

Looking into the modern negative in the pre-patenting stage of testing is the Exovent which solely used NPV to stimulate more natural lung movements without tracheal intubation and issues like barotrauma or cardiac problems. This device generates CNAP to create that NEEP which ultimately is best to contradict lung collapse. Design-wise, the device pictured in Figure 10 below shows that it allows for bed angle adjustment in the prone, laying down on the back, and position, to a semi-recumbent angle of 30 degrees. The portholes allow for repositioning and removal relatively quickly as they allow control over the vacuum by both the patient and the clinician, making patients less prone to feelings of claustrophobia. Accessibility-wise, patients were able to speak, drink with a straw, and eat with assistance. They also described the seals as easily adjustable and felt that they could stretch without compromising the integrity of the chamber. Cost-wise, production averaged $652 and the retail cost was $10,496. Despite all of the benefits associated, this particular preliminary study only analyzed respiratorily healthy patients for a two-hour long testing period, and there is more experimentation to be done (Exovent).

Figure 10: Exovent Model.

Note: Used with permission from *Exovent: a study of a new negative-pressure ventilatory support device in healthy adults*, by the Exovent Development Group, 2021. (https://doi-org.ezpv7-web-p-u01.wpi.edu/10.1111/anae.15350)

Other more common adaptations of CNAP include a life vest shaped design that straps and seals to the neck, abdomen, and arms to use the change in internal pressure versus environmental pressure to produce the negative pressure gradient that helps stimulate natural breathing (Appendix A). Further modifications of CNAP include the theorization activation to synchronize PPV to detect neural inspiratory (Appendix A). This activation would limit excessive positive pressure entering the patient's airways which would lessen the potential of lung injuries. However, many studies have proven this method of CNAP to be unfavorable as the seals are often not airtight and the sheer structure of a chamber in the Exovent or the traditional iron lung provides more natural defense against chest compression (The Exovent Development Group).

2.7 - Patent Requirements and Laws

Patent research is important in understanding the types of devices that currently exist on the market and where there is space for innovation. A team member conducted a patent search on negative and positive ventilation devices in order for the team to decide on design requirements for this project. Two patents were found that relatively applied negative pressure in a ventilation device. One patent described a device that provided continuous negative abdominal pressure to patients (Kavanagh et al., *Device for producing continuous negative abdominal pressure*). The second described a device that oscillated between positive and negative pressure to assist in ventilating patients (Sinderby et al.,

Combined Positive and Negative Pressure Assist Ventilation). The patent *Device for Producing Continuous Negative Abdominal Pressure* provided insight into the similar device classified as the "iron lung" and discussed the device specifications such as pressure sensors, frame shapes, and adjustable device sizes. More details of the patent can be found in Appendix A. The second patent called *Combined Positive and Negative Pressure Assist Ventilation* is more closely related to the project goals of designing a device that converts positive pressure ventilation to negative pressure ventilation to use in tandem with a positive pressure ventilation device. This patent is currently still active and explains the application of how positive and negative pressures are synchronized. However, this patent describes that patients must wear a vest to apply set pressures, which differs from the design goals of this current project. More details regarding this specific patent can also be found in Appendix A. Throughout the patent search process, there were no active patents that only focused on providing negative pressure. The only similar patent to negative pressure is patent pending in Great Britain, but there was no further information beyond that.

Chapter 3: Project Strategy

In order to successfully develop the device within the given academic timeline, budget, resources, and parameters, this section maps out the team's strategy for completing the project, specific objectives, requirements for function and the means for achieving them, and preliminary design alternatives.

3.1 - Initial Client Statement

From ideas collected from the preliminary conversations with the client, the team formulated the following initial client statement: Design a negative-pressure mechanical ventilator to work in tandem with a positive-pressure ventilation device in order to minimize ventilator-induced lung injuries in obese patients.

3.2 - Objectives

The objectives for this project were defined by the client's specifications and supported by a literature review. The categories and specifications are reflected in Table 4 below, followed by a brief explanation of each section.

Table 4: Design Objectives by Category

Objective	Requirements
Maintain CNAP	• Create a negative pressure gradient CNAP of -10 to -30 cmH2O • Work in tandem with a PPV • Tidal volume of 500mL
Patient Comfort	• No adverse reactions to device material • Patient can lay with back relatively straight
Time to Assemble to Patient	• Quick and reasonably simple assembly • Should not exceed 10 minutes
Robust Design	• Designed to account for variations in devices from production and time
Ruggedness	• Withstand excessive forces to reasonable extent
Adaptability to different patients	• Fits patients with a BMI of 30-39.9
Adaptability to hospital beds	• Attach to 36” wide and 88” long standard-size hospital bed
Cost	• $1250 project budget
Performs for Maximum Treatment Time	• 6-hour work - 2-min rest cycle • Pressure-withstanding material • 3-4 weeks of performance • No external gas exchange
Accessibility: Doctors	• Fast assembly and disassembly • Chamber for vacuum release and chest access • Weight less than 10 kg

<u>Maintain CNAP:</u>

The device must create a negative pressure gradient to redirect airflow toward the lower chambers of the lungs and reduce the positive pressure needed for treatment. The continuous negative abdominal pressure must remain static between -10 and -30 cm H2O with +/- 5 cm H2O accuracy.

When the device is used in tandem with a PPV, a driving pressure of 15 cm H_2O and PEEP of 10 to 15 cm of H_2O is needed.

With each breath, the goal is to achieve a tidal volume of approximately 500mL, which, as seen in section 2.1.2, is the normal tidal volume used to calculate the average alveolar ventilation rate (AVR). Especially considering pre-existing conditions imposing on the lung volumes of obese patients, it is important to recognize that exact input pressure can vary due to the anatomical condition of each patient. The preceding ranges were provided by the client based on previous experience dealing with a diverse sample of subjects. In order to ensure the pressure input directly impacts the lung volume, the device must maintain a vacuum seal to optimize energy usage and ultimately accuracy. Regarding accuracy, the pressure itself must be monitored with a barometer with an accuracy of at least 0.3 cm H_2O.

Patient Comfort:

Any adverse reactions caused by the device to the patient must be minimized. The device is meant to reduce harm caused by current ventilators, so any situation where equal or further harm is caused is unacceptable. However, the patient will be sedated the entire time they are on the device, so minor discomfort should be a nonissue. The team's main concerns are materials that will react negatively with patients' skin, or cause lasting pain to the patient due to how they are rested on the frame of the device.

Time to Assemble to Patient:

The device should be assembled and ready to perform in less than ten minutes. This measure is to ensure the device is not so complicated to set up that it introduces unnecessary error. Clinicians may also be working on fast-paced schedules, and are unlikely to use a device that is overly complicated.

Robust Design:

The device will still function as expected despite variations in production, deterioration, and to some extent, unintended use. Essentially, despite not every device being exactly perfect, it can still perform as it is supposed to.

Ruggedness:

The device can withstand rough handling and still function. In a hospital setting, the shell may get dropped, experience excessive force, be opened forcefully, etc. The device must handle a reasonable amount of this mishandling, as there are bound to be accidents.

Adaptability to different patients:

The device should work on a wide range of patients. Obese patients compensate for a large size range, varying from a BMI of 30-39.9 (NHS, n.d.). This population also varies in torso length (often ranging 45-50cm) and in width. Narrowing down this variety within the set scope will decrease its potential application to the largest number of patients.

Adaptability to different hospital beds:

The device must be able to attach to a standard-size hospital bed, which is 36" wide and 88" long with a 80" sleeping area (What are the Dimensions, 2021). This implies the device can be low-cost and applied in various different settings without costly adaptors.

Cost:

The device is meant to be cost-effective. Any opportunities to reduce cost should be taken, as this means the device can be sold for less and reach as many patients as possible. The maximum research budget for manufacturing this device is $1250.

Performs for Maximum Treatment Time:

Ventilators are used for an average of four to five days; however, due to some conditions, a patient can remain on the device for up to three to four weeks. In that time frame, the device cycles between a targeted active ventilation time of six hours and a rest period of two minutes. Considering that timeframe, the device's material and seal must withstand the target pressure and prevent external gas exchange to maintain the vacuum and ensure full performance for that given time range. Additionally, it must be quickly and easily sterilized without damage to the material or the performance of the device.

Accessibility for Doctors:

The device is to be used in an emergency environment. In this context, accessibility refers to optimizing access to the patient during use and disassembly. The removal of the device should not

exceed 10 seconds due to the possibility of an emergency situation that requires immediate access to the chest and abdominal area. Furthermore, while being used on the patient, the design must include a mechanism for quick access to the torso in non-emergency scenarios as well as a mechanism to release the vacuum for patient comfort. In order to facilitate the use of the device in these situations, the ventilator must weigh a maximum of 10kg, contain chambers that allow for rapid release and access, and be practical/user-friendly.

To better understand the design requirements and priorities, the team made a Pairwise analysis in Table 5 below. This analysis compares the importance of each specification for the design. To fill out a Pairwise analysis the requirements are compared to one another using three different scores:

- 0 (zero) — the specification in the row is less important compared to one in the column
- 0.5 (half) — both specifications are equally important
- 1 (one)— the specification in the row is more important compared to one in the column

Table 5: Pairwise Comparison Chart of Objectives

	Cost	Robust Design	Ruggedness	Adaptability to different patients	Performs for maximum treatment time	Accessibility: Doctors	Maintain CNAP	Adaptability to hospital beds	Patient Comfort	Time to Assemble to Patient	Total	Weights
Patient Comfort	0	0	0	0	0	0	0	0	X	0	0	0
Time to Assemble to Patient	0	0	0	0	0	0	0	0	1	X	1	2
Robust Design	0	X	0.5	0	0	0	0	0	1	1	2.5	5
Ruggedness	0.5	0.5	X	0	0	0	0	0	1	1	3	6
Adaptability to different patients	0	1	1	X	0	0	0	0.5	1	1	4.5	9
Adaptability to hospital beds	0.5	1	1	0.5	0	0	0	X	1	1	5	10
Cost	X	1	0.5	1	1	0	0	0.5	1	1	6	12
Performs for maximum treatment time	0	1	1	1	X	0.5	0	1	1	1	6.5	13
Accessibility: Doctors	1	1	1	1	0.5	X	0.5	1	1	1	8	16
Maintain CNAP	1	1	1	1	1	0.5	X	1	1	1	8.5	17

Through the Pairwise analysis, the team managed to effectively understand the importance and relationship between objectives. The most important objective is maintaining CNAP, which is to ensure that the device maintains a negative pressure gradient. Doctors' accessibility, which is optimizing patient access during treatment, is the second most important objective. Accessibility is followed closely by "Performs for Maximum Treatment Time", which is the ability of the device to effectively perform for the necessary period of time; therefore, this category has the third highest score. Cost is the next most

important objective. Again, the team has a budget of $1250. Next is “Adaptability to Hospital Beds”, closely followed by “Adaptability to Different Patients”. The device needs to be applicable within the full scope of obese patients on standard-sized hospital beds. After that is ruggedness, meaning the device must withstand an expected amount of excessive force, in situations such as the device being dropped or close too forcefully. Following ruggedness is “Robust Design”, meaning the device must function despite variations due to production and deterioration with time. Second to last is “Time to Assemble to Patient”, indicating that the device must go from unassembled to assembled in less than ten minutes. Last is “Patient Comfort”, to ensure the patient has no adverse reactions due to the device.

3.3 - Constraints

The team must only innovate within the bounds set by the constraints of each objective. Table 6 lists each objective and its constraints. Staying within these constraints gives clear guidelines for what accessibility is for this project and how it can be achieved.

Maintain CNAP:

The objective of mechanical performance is ensuring the device is successfully ventilating the patient without unexpected complications. The client stated that the main constraint is maintaining a tidal volume of 500mL, meaning the lungs fill with 500mL of air during inspiration. The pressure must be measured with an accuracy of 0.30cm H_2O.

Accessibility for Doctors:

The objective of accessibility is to ensure that the doctors can easily remove the device in an emergency situation, as well as transport the device. The client, therefore, requested that the initial setup takes a maximum of ten minutes, that the chest and abdominal area can be exposed in less than 10 seconds in an emergency situation, and that the device weighs a maximum of 10kg. The device needs to be easily set up as required by the client. The client stated that the device must be removed extremely fast if the patient goes into cardiac arrest and needs compressions. In that scenario, each second counts and may be the difference between life and death. Finally, the device must weigh a maximum of 10 kg so hospital staff can easily lift and move the device without injuring themselves.

Performs for Maximum Treatment Time:

The objective of maintenance is to ensure the device can function continuously for maximum expected duration of treatment, and that these results are reproducible and repeatable. The device must function for a maximum of 3 to 4 weeks, and operate in intervals of six hours on, followed by 2 minutes of rest. The client stated that this is the maximum capacity for which the device will operate. After six hours, suction resulting from the device may damage the skin.

Budget:

The objective of cost is for the team to remain within to create a fully functioning device. Each team member receives $250 towards their major qualifying project, making the maximum budget $1250.

Adaptability to Hospital Beds:

The device must function successfully when attached to a standard-sized hospital, which is 36" wide and 88" long with a 80" sleeping area (What are the measurements, 2021).

Adaptability to Different Patients:

The objective of adaptability is to ensure the team treats as many patients as possible within the obese patient population and within the client's specifications. The client requested that the device must fit patients with torso heights ranging from 45-50cm. Therefore, the length and diameter of the device are, respectively, 16in and 33 in . The team also agreed that within these constraints, the device must fit patients with a BMI range of 30-39.9 (NHS, n.d.). This is the range of BMI that fall within the obese category.

Ruggedness:

The device must be able to withstand excessive force to a reasonable extent. The device should survive being dropped and someone pressing down on it.

Robust Design:

The design must still function despite variations in production and deterioration over time. This is more of a concern once the device is brought to manufacturing.

Time to Assemble to Patient:

The client requested that the device take less than ten minutes to be assembled to the patient. This is for ease in the clinician's workflow and to ensure the device is not overly complicated to put together.

Patient Comfort:

The device must not cause any reactions with the patient's skin or cause back pain once the patient is conscious again.

Table 6: Design Constraints, by Category

Objective	Constraint(s)
Maintain CNAP	Maintain tidal volume of 500mL Pressure measured to an accuracy of ±0.3cm H2O Range of -10 to -30 cmH2O ± 5cmH2O Time to reach the desired pressure of XX minutes
Accessibility: Doctors	Chest access in ≤10s Weight ≤10kg
Performs for Maximum Treatment Time	Able to perform 6hrs with 2min breaks for 3 to 4 weeks straight
Cost	Work within budget of $1250
Adaptability to Hospital Beds	Attach to standard hospital bed (36" wide and 88" long with a 80" sleeping area)
Adaptability to Different Patients	Fits patients with a torso length of 45-50 cm and a BMI of 30-39.9
Ruggedness	Device does not incur damage when dropped from the height of a standard hospital bed
Robust Design	Material easily sterilized
Time to Assemble to Patient	Setup ≤10min
Patient Comfort	No adverse reactions with patient's skin The patient's back is relatively flat against the bed

3.4 - Revised Client Statement

Considering the reviewed constraints and objectives the initial client statement was revised to the following: Design a continuous negative abdominal pressure ventilator that works in tandem with a positive pressure ventilation device to convert airflow to a more natural direction of pressure which

optimizes respiration and minimizes the occurrence of ventilator-induced lung injuries in obese patients. The ventilator will apply a range of -10 to -30 cm H2O with an accuracy of +/- 5 cmH2O. The device will cost less than $1250 to manufacture. The design will be lightweight (under 10kg) and allow for a disassembly of less than 10 seconds. It can fit standard-size hospital beds and accommodate obese patients with heights of 5'7" to 6'2". Lastly, it must perform considering a cycle of 6 hours on and 2 minutes off for 3 to 4 weeks. The design must still function after being dropped off the bed, be easily sterilized, pose no adverse reactions to the patient's skin, and not cause any harm to the patient's back.

3.5 - Functions and Means

Table 7: Functions and Means of the Design (made with Canva)

Function	Means
Adaptable to fit different-sized patients in reference to height, physical attributes, and neck/arm range of motion.	• The device covers only the abdominal area and is adjustable using ranges (like a belt) to fit different size patients • The device has multiple snap fits that coordinate with a standard patient dimension • Lever mechanisms are used to adjust the width and height of the device
When the device is used in tandem it produces... • For PPV - A driving pressure of 15cm H2O and PEEP of 10 to 15 cm of H2O • Regarding CNAP- A static pressure of (-10) - (-30) cm of H2O	• Use a negative pressure system with PPV • Create a vacuum in which pressure is measured at 30cm H2O, measured with a barometer • Acquire or borrow a PPV and balance negative pressure into the system • Incorporate a direct reading gauge to determine the exact amount of either negative or positive pressure • Use a PCB board and python to create a pressure sensor that stops when a certain negative or positive pressure is reached
Pressure is displayed and can be adjusted by user	• A barometric pressure sensor that communicates to the clinician on a screen with an accuracy of .03 cm H2O • The device will have a screen that displays the pressure to the nurses, using sensors (such as a barometer) to determine the pressure in the device • Conduct multiple tests prior to finalizing the design to create a type of standard so that practitioners could follow when using the device • The device will also have set limits that if it goes above a certain limit based on the patient's criteria, it would send an alert to the practitioners
Opens and closes for emergency abdominal access	• There will be a door over the patient's abdomen for non-emergency upkeep scenarios that do not require the removal of the entire chamber • There could be a door that hinges upwards which is accessible from the side so that whoever is in charge can have first access

	• There could be doors that are similar to French doors of a house interior so that the practitioners can access the patient on either side
Creates a continuous negative abdominal pressure vacuum without leaking	• Use a negative pressure vacuum pump and measure trials determining how much time it takes to achieve each pressure using Neoprene and the hospital bed • Use a negative pressure vacuum pump (determine the time it takes to get to specified pressures) • Use a negative-pressure vacuum pump and increase the pressure in intervals • Use a negative pressure vacuum pump and increase the pressure using a constant pressure increase • Using Neoprene to enhance the seal between patient and the device • Using the hospital bed but need to determine the type of material for the hospital bed sheet to see if a vacuum seal would be possible • Spray the device with a type of plastic sealant that adheres to the hospital bed
Accommodates patients with decompensated heart failure, acute respiratory distress syndrome, and cardiac arrest	• The device will have a quick-release system in order for the physician to have access to the abdomen to tend to any respiratory issues and maintenance • Instead of having a quick-release system, incorporate a vacuum pressure chamber with gloves so that practitioners can access the patient without removing the patient from the device
Can withstand usage for up to 3-4 weeks (though average duration is 4-5 days) on intervals of three hours on and ten minutes off	• The device will receive energy from a wall outlet and have a backup battery power system • Patient comfort will be optimized maximizing mobility • The device should have an alarm system and tally system that signals the practitioners when the intervals of pressure are completed and how many intervals the patient has received

Suits a standard 36" wide and 80-88" long hospital bed (headboard to footboard)	• The design will adapt to attach to the bed provided these size parameters • The device should have enough free space so that the patient can comfortably fit inside it • The walls of the device could be thin enough to snuggly fit against the walls of the hospital bed
Allows patient to maintain ventilation at the prone position at a semi-recumbent angle of 25 degrees	• The device will adjust with the bed as the angle is increased to 25 degrees from a flat-back position • Ensure the bed can elevate the torso to 25 degrees without interference with the device • If a 25 degrees is not achievable, allow for the device to be flexible to move with the patient when in a prone position

After brainstorming multiple means for each function listed in Table 7 above, the team needed to decide which means were best suited to perform based on functionality, time constraint, capability, and feasibility. Each idea that was thought of as a possible option required further understanding of whether it could be an achievable outcome.

After careful consideration and research, the team has separated the device into specific subsystems, which can be found in section 4.2, and used Table 7 to come up with different design concepts for each of those subsystems. Each of the concepts was designed to achieve the outline functions and requirements set up in this chapter. The goal was to compare those concepts and narrow down the list of means to just one mean per function.

3.6 - Engineering Standards

Engineering standards are important to consider for medical devices in order to maximize the efficacy of research as well as protect the safety of the patients. For a mechanical ventilator, there are quite a few standards to consider in protecting these outcomes. Primarily, ISO (or the International Organization for Standards) 80601-2-12:2011 is a standard regarding the safety of ventilator usage in conjunction with other related medical equipment. This ensures that the device will be utilized by a trained medical professional and can only be utilized in a medical setting, whether that be a hospital or emergency transportation vehicle. ISO 10651-3:1997 has requirements for testing before usage in a medical setting in regard to environmental effects, acoustic interferences, alarm conditions, and mechanical strength (ISO). Secondly, the FDA has a list of authorized requirements for a medical

setting to sponsor ventilator usage. Certain parameters including pressure specifications, respiration rate, tidal volumes, patient interaces, and battery specifications are required to be submitted. On the engineering side, it is recommended that material strength, gas compatibility, leak tests, circuit analysis, and compliance on ISO 5356, 5366, 18190, and 18562 in terms of circuitry. Lastly, IEC (International Electrotechnical Commission) 60601 components 1,2, and 11 are essential in terms of the medical electrical components for basic safety, minimizing electromagnetic disturbances, and requirements for the use of this device at home (FDA).

3.7 - Management Approach

During A-term, the team's main focus was to identify and understand the project's needs. Several meetings and an interview were conducted with the client to understand the goals of the project. Additionally, the team undertook research on the background of the problem, which included understanding the anatomy of breathing, positive and negative pressure ventilators, current solutions, and patent laws. Based on the information gathered from these tasks, the team revised the project's client statement, created objectives and specifications for the device, in addition to brainstorming of the initial design concepts.

During B-term, the team visited Saint Vincent Hospital and interviewed Dr. Rosiello, the Chief of Pulmonary and Critical Care Medicine at Saint Vincent Hospital, to further understand specifications and the conditions in which the device will be used; the team also had to familiarize themselves with the hospital environment and the design specifications of hospital beds. Additionally, the team separated the device functions into subsystems and brainstormed different design concepts. The main design for each subsystem was chosen based on objectives and specifications found in Chapter 3 with the use of the Pugh Analysis. The team performed several proof of concepts and performed research in order to make conscious choices when considering design alternatives and materials. After the determination of the final design, the team modeled the device using SolidWorks. A bill of materials was also created for this initial prototype, and all components were ordered. The prototype was then assembled and tested.

In C-term, a full-scale prototype was designed and built. The design was changed from the small-scale model based on testing results and feedback from subject matter experts. Once the full-scale design was finalized, a model of the prototype was created in Solidworks, and the components for a new bill of materials were ordered. Assembling a larger device presented several challenges, such as not being able to mold the material chosen for the shell to the necessary specifications, and components not working as initially intended.

In D-term, the full-scale prototype was tested and modified in order to establish a seal. Writing for the paper was finished, and a poster was created explaining the project for Project Presentation Day.

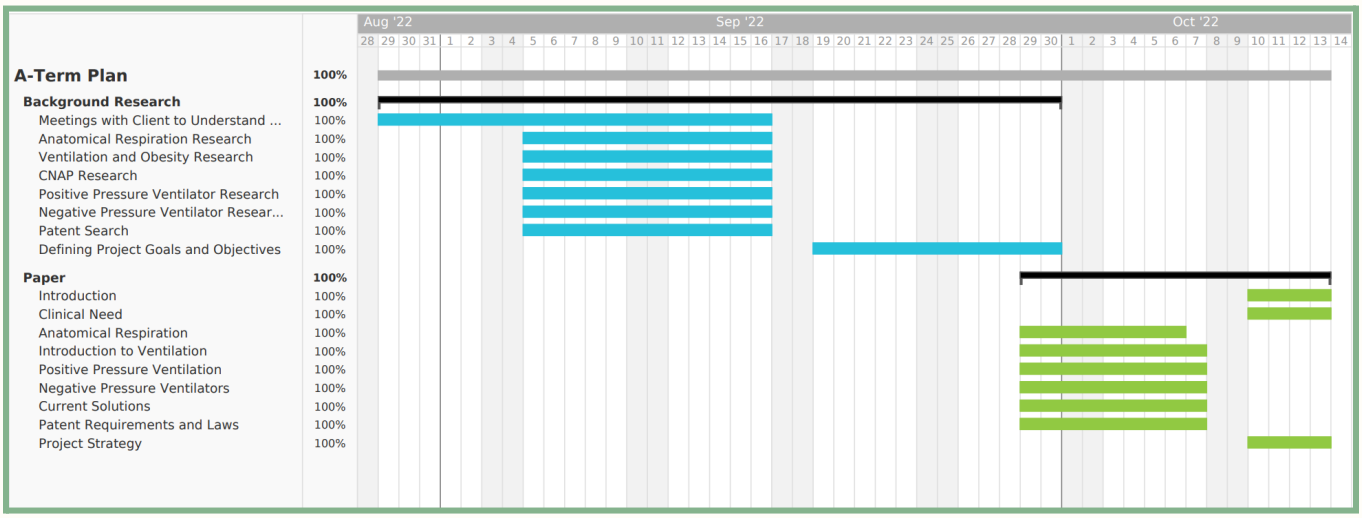

Figure 11: Gantt Chart for A-term (made with TeamGantt).

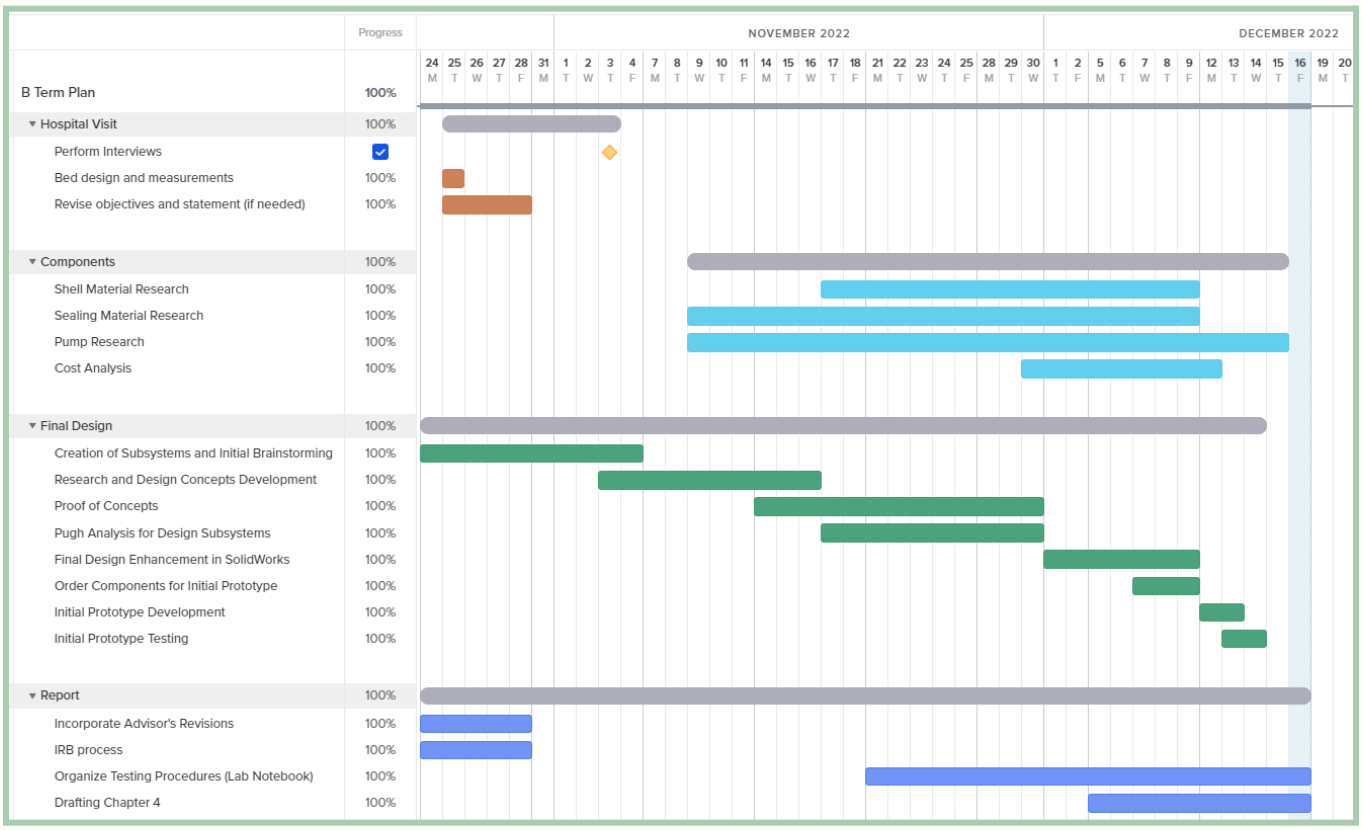

Figure 12: Gantt Chart for B-term (made with TeamGantt).

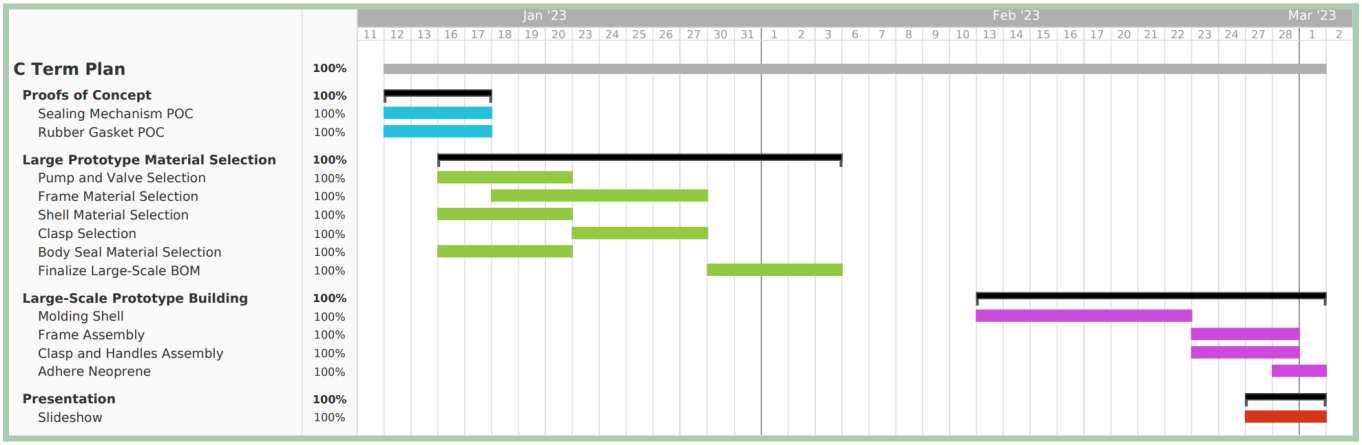

Figure 13: Gantt Chart for C-term (made with TeamGantt).

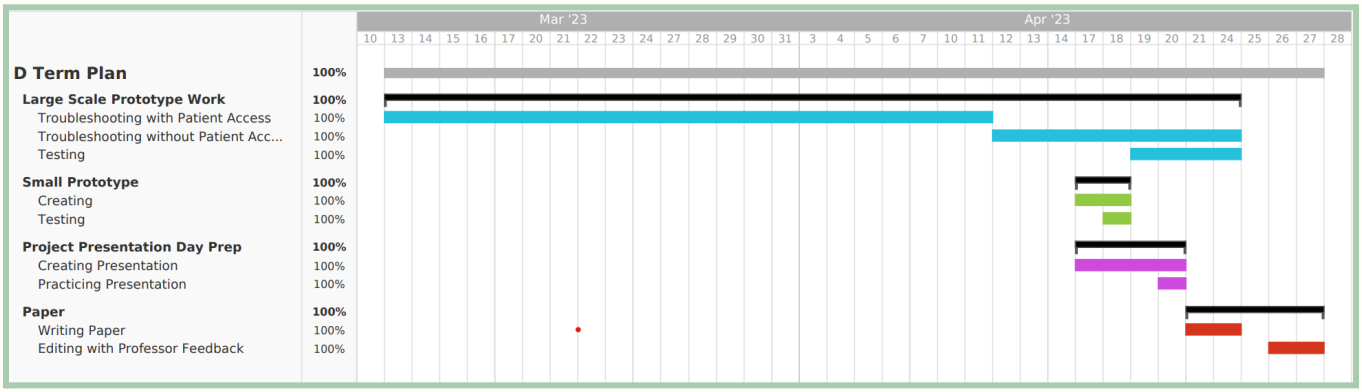

Figure 14: Gantt Chart for D-Term (Made with TeamGantt).

Chapter 4: Design Process

Considering the new idea of using a CNAP device in tandem with a PPV, the team must consider how to create a final prototype that can be iterated on the manufacturing scale. In order to tackle the expectations of the client as well as augmenting functionality given the different parameters aforementioned, it is important to consider the results from the pairwise chart in maximizing all of the subsystems' potential. This section will introduce said subsystems, the design choices for each, explain the best design alternative given the options, and analyze new ideas brought about from different proofs of concepts and implementations in a small-scale prototype. This information is synthesized in the end of the section as it breaks down the bill of materials needed to proceed with the most optimal full-scale prototype.

4.1 - Needs Analysis

In order to better assess the most pertinent needs for the design process, the team conducted a pairwise analysis of all the objectives for the project, as explained in Chapter 3. The objectives the team determined as most important and their reasonings are elaborated on in the following table:

Table 8: The Most Important Objectives and the Reasoning for Their Importance

Objective	**Reasoning**
Maintain CNAP	• Purpose of the device
Accessibility: Doctors	• Device must be transportable • Must be able to remove in emergency situations

Performs for Maximum Treatment Time	• Ensures treatment effective
Cost	• Must work within the team budget

4.2 - Conceptual Designs: Subsystems

Considering the main requirements of the design prototype, specified in the section above, the team separated the model into subsystems. Preliminary designs were created for each subsystem to better accomplish the needed specifications. The subsystems and preliminary designs can be found in the table below:

Table 9: Design Concepts for Device Subsystems

Subsystem	1	2	3	4	5
Shell Material	Acrylic	Polycarbonate	Polypropylene	Polyethylene	
Sealing Material	Neoprene	Nitrile Rubber	Polypropylene	Polyethylene	
Lower Body Seal	Snap-On Pants	Air-tight Zipper	Abdominal Seal	"Footie Pajamas"	
Locking Mechanism	Pelican Case Latch	Window Latch	Velcro Snap-on	-	
Attachment to Frame	Straps and Frame	Suction Cup Line	Sheet and Clasp	-	
Pump	2- Stage 50 L/m Oil Free Lab Vacuum Pump	DC 12V Vacuum Pump	24L Lab Diaphragm Vacuum Pump	Oil-Free Electric Vacuum Pump	TMD40A-A

Given the crucial objectives explained in Table 8, and considering the others from the Pairwise analysis in Chapter 3, a Pugh Analysis was created for each subsystem. These are depicted in the following sections. Each concept for the subsystem is analyzed to determine how well it fulfills each objective, relative to its alternatives. If the concept best meets the objective, it is rated with a "1". If the concept somewhat meets the objective, it is rated with a "0". If the concept is the relative worst at meeting the objective, it is rated with a "-1".

4.2.1 - Shell Material

The shell is one of the most important components of the device. In addition to the requirements in the Pairwise chart, found in the Need Analysis section, the team spoke to the sponsor and specific requirements were decided upon. These requirements are shown below (in order of importance):

Table 10: Main Requirements for Shell Material

Pressure Resistance	The material must withstand the pressure range of -10 to -30 cm H2O without damage or change to the shell shape
Morphability	The material must be easily morphed into the necessary shape
Machinability	The material must be easily altered—drilled, laser cut, etc.—to allow for a connection with the other subsystems
Sterilization	Considering the hospital environment, the material must be easily sterilized (with the use of common methods)
Cost	The material must be budget and not overly expensive compared to the competition

Additionally, other properties were considered including:

- Health Concerns: *Is the material medical grade? Are there any hazards related to it?*
- Impact Resistance: *How likely is the material to break under stress?*
- Environment Impact: *Is the material easily recyclable?*
- Light Transmittance: *How easily can it be seen through?*
- Scratch Resistance: *How easily does the material scratch?*

Four materials were considered and will be discussed in this section: acrylic, polycarbonate, polyethylene, and polypropylene.

4.2.1.1 Acrylic

Polymethyl methacrylate (PMMA), commonly known as acrylic, is lightweight plastic with high tensile and flexural strength, stability, and clarity (Turner, 2018; “Better Plastics for medical devices”,

2022). Due to its strong mechanical properties, medical-grade acrylic is commonly used in the manufacturing of medical devices, such as bone cement, cranial implants, incubators, among others. (Turner, 2018; "Better Plastics for medical devices", 2022).

Considering acrylic's high tensile strength, it is able to withstand the pressure range necessary to maintain the CNAP. Furthermore, acrylic is very durable and morphable, in addition to its machinability in applications of sawing, milling, laser cutting, and engraving (Acrylic, n.d.). However, drilling close to the edge of the material increases its tendency to crack; therefore specific drilling techniques might be required—such as not using a new drill bit—to properly create holes (PJ, 2022). Laser cutting could be easily substituted for drilling needs. It is important to only consider high-impact acrylic to increase its capacity for impact, since that is one of the main disadvantages of this material. In the case that the material cracks, it will not shatter; it will fracture into large pieces, which the team deemed important due to patient safety in the hospital setting.

Furthermore, another important factor to consider in the hospital environment is sterilization. For acrylic, sterilization with disinfectants, such as isopropyl alcohol is not recommended; it needs to be cleaned using a cloth or microfiber with warm soap water, or an acrylic cleaner, which is fairly simple and accessible (PJ, 2022). Lastly, environmentally speaking, acrylic is easily recyclable, which is especially important for the biggest component of the project ("Everything you need to know about acrylic (PMMA)", 2016).

The high-impact acrylic properties can be found in this table[1]. The cost will be discussed in the decision matrix of this section (section 4.2.1.5).

4.2.1.2 Polycarbonate

Polycarbonate (PC) is a lightweight, tough, stable, machinable, transparent thermoplastic used in various medical applications, defense mechanisms, and automotive parts, among others. Some examples include surgical instruments, cardiac surgery products (blood oxygenator), and IV connection components (British Plastics Federation, n.d.; "Technical data sheet", n.d.).

Polycarbonate has a high tensile strength that allows it to withstand the necessary pressure range of -10 to -30 cm H2O for this project. Additionally, it is an amorphous thermoplastic that can be configured into various shapes (British Plastics Federation, n.d.). When it comes to machinability, polycarbonate can be easily drilled , milled, die-cut, among others ("Technical data sheet", n.d.; Powell, 1998). Laser cutting and other heat morphing techniques, however, are not as feasible due to the toxic

[1] High-Impact Acrylic Data Sheet can be accessed through https://www.tapplastics.com/image/pdf/Acrylite_Resist_Tech_Data.pdf

fumes released at high temperatures . Another disadvantage is that a polycarbonate sheet can be 35% more expensive than an acrylic sheet (PJ, 2022).

On the other hand, its impact resistance is 250 times that of glass (PJ, 2022). The material's impact resistance would ensure the product's durability regardless of any accidents and collisions that might occur at the hospital. Similar to the acrylic, the polycarbonate does not shatter, but rather breaks into bigger pieces—making it safer for patients. It can also be easily sterilized with common disinfectants, such as isopropyl alcohol or ethylene oxide (EtO), as well as steam autoclaving and irradiation (Powell, 1998). Lastly, the PC is fully recyclable, which makes the device more eco-friendly.

More specific values and properties can be found in this table[2]. The cost will be discussed in the decision matrix of this section (section 4.2.1.5).

4.2.1.3 Polyethylene

Polyethylene (PE) is a semi-crystalline material that has high strength, chemical resistance, low coefficient of friction, and good wear, impact, and temperature resistance (*Chapter 1 Engineering Properties of Polyethylene* 2006). Due to the properties of polyethylene, it is widely used in medical applications for surgical implants and other devices, in addition to being commonly used to create sanitary packaging (*Polyethylene properties*).

The three main types of polyethylene include low density polyethylene (LDPE), high density polyethylene (HDPE), and ultra high molecular weight polyethylene (UHMW). With the consideration of the team's material criteria, the team focused its research on HDPE due to its high tensile strength which can tolerate the necessary pressure range of the device specifications (Dielectric Manufacturing, 2023). In addition, HDPE can be molded, thermoformed and easily machined through drilling and cutting (similar to wood). Furthermore, it has a high scratch resistance and is able to be sterilized using EtO gas, disinfectants (ie. hydrogen peroxide and isopropyl alcohol), and radiation with gamma or beta irradiation, which, as mentioned before, are some common methods used in the hospital (*High-density polyethylene (HDPE) Labware: Thermo Fisher Scientific - US*).

However, PE has lower impact resistance compared to other materials such as polycarbonate. Additionally, the material begins to lose its strength and can become brittle at low temperatures *(The Editors of Encyclopaedia Britannica, 2023)*. It also has poor transparency properties which can make this material less suitable for the design, since having a transparent shell is preferred. Nonetheless, the material is recyclable, which fulfills the sustainability requirement of the component.

[2] Polycarbonate Data Sheet can be accessed through https://laminatedplastics.com/polycarbonate.pdf

More specific values and properties of polyethylene can be found in this table[3]. The cost will be discussed in the decision matrix of this section.

4.2.1.4 Polypropylene

Polypropylene (PP) is a type of thermoplastic polymer that is lightweight, tough, moisture resistant, and chemical resistant (British Plastics Federation). It is overall a versatile material that has been used in medical, electrical, outdoor, and automotive applications. Due to its good physical and chemical properties, some medical applications for polypropylene include surgical suture material, medical implants, medical devices, and containers and packaging of medical products such as pharmaceuticals and syringes (Akre, 2012).

There are two main types of polypropylene: homopolymers and copolymers (Martin, 2018). For the purpose of shell material selection, the team chose to focus on the characteristics of homopolymers since they are less malleable than copolymers (Martin, 2018). Polypropylene homopolymer (PPH) has a high tensile strength, increased durability, and material stiffness which is advantageous for applications that require effective impact and chemical resistance (*Polypropylene homopolymer*). This specific type of polypropylene has a tensile strength of 4,800 psi which will withstand the required pressure range for the device specifications. Furthermore, this plastic achieves the requirements of machinability. It is easy to laser cut, drill, and has the capabilities of being CNC machined. Additionally, the material can be sterilized through autoclaving, EtO gas, and disinfectants (ie. isopropyl alcohol) (British Plastics Federation).

Even though polypropylene can be easily molded and shaped, it deforms under high temperatures. It also fails to satisfy the need for transparency. Nonetheless, this material is also recyclable.

More specific values and properties of polypropylene can be found in this table[4]. The cost will be discussed in the decision matrix of this section (section 4.2.1.5).

4.2.1.5 Decision Matrix

The requirements from the Pairwise analysis made in Chapter 3 are not sufficient to assist in the decision making of the shell material. With that, a Pugh Analysis was made using the requirements in

[3] Polyethylene Data Sheet can be accessed through https://laminatedplastics.com/polyethylene.pdf
[4] Polypropylene Data Sheet can be accessed through https://laminatedplastics.com/polypropylene.pdf

Table 11. The following table presents the requirements of the shell material next to the properties of all four materials.

Table 11: Requirements and Material Properties

Requirements	**HI-Acrylic**	**Polycarbonate**	**HDPE - Polyethylene**	**Homopolymer -Polypropylene**
Pressure Resistance (Tensile Strength) at 72℉	8,600 psi	7,000 psi	4,600 psi	4,800 psi
Morphability	Easily Thermoformed and re-molded	Moldable and thermoformed	Moldable with low fracturing and thermoform	Easy to mold, thermoformed, Deforms under high heat
Machinability	Easily laser cut Limited Drilling	Cannot be laser cut Easily drilled	Capable of CNC and cut similar to wood Easily drilled	Easily laser cut, capable of CNC machining Can be drilled, recommend using spur-point drill bits to reduce stress
Sterilization	Microfiber Cloth with soap and water or acrylic cleaner	isopropyl alcohol, (EtO), irradiation, and steam autoclaving	EtO gas, disinfectants, radiation	Autoclaving, EtO gas, disinfectants
Cost W -24” L -48” T -¼”	$ 139.20[5]	$125.60[6]	$44 (Natural Sheet)[7]	Natural Sheet = $46 (12”x 36”; ¼”)[8] Transparent Sheet = $27 (21”x51”; ¼”)[9]
Impact Resistance	Low	High	Medium	Medium
Clarity	Transparent	Transparent	Translucent/Opaque	Transparent/Opaque
Light Transmittance	91%	86%	85-90%	85-87%

[5] Price estimated from https://www.tapplastics.com/product/plastics/cut_to_size_plastic/acrylite_plus_clear/509

[6] Price estimated from https://www.tapplastics.com/product/plastics/cut_to_size_plastic/polycarbonate_sheets/516

[7] Price estimated from https://www.ebay.com/itm/144068210312?chn=ps&mkevt=1&mkcid=28&var=443368369691&srsltid=AfAwrE4lj5nJnjmkM2T1E8PiMrf9HZdDt1ul5l4VMC-3BfhPVCaidULpR9k

[8] Price estimated from https://www.amazon.com/Natural-Polypropylene-Thick-Pick-Your/dp/B075M36S63?th=1

[9] Price estimated from https://www.usplastic.com/catalog/item.aspx?itemid=31848&v1=&v7=&gad=1&gclid=CjwKCAjwuqiiBhBtEiwATgvixLFNb_6T1GxVMuZctlr2RtwqT_prhr2E4T26X4TyZWFX6ZlisvFyOhoCxmcQAvD_BwE

Scratch Resistance	High	Low	High	Low
Health Concerns	BPA-Free; Irritating fumes Fractures into large pieces	Toxic fumes Fractures into large pieces	Non-hazardous; BPA-Free; generally considered safe	BPA-Free; inhalation of fine particles may cause respiratory irritation
Environmental Impact	Recyclable	Recyclable	Recyclable	Recyclable

With assistance from the table above, the Pugh analysis below was performed. The weights for each requirement were based on the conversations with the sponsor.

Table 12: Pugh Analysis Shell Material

Requirements	**Weight**	**HI-Acrylic**	**Polycarbonate**	**HDPE - Polyethylene**	**Homopolymer -Polypropylene**
Pressure Resistance	5	1	1	1	1
Morphability	4	1	1	0	-1
Machinability	4	1	1	1	1
Sterilization	3	0	1	1	1
Cost	2	-1	0	1	0
Impact Resistance	2	0	1	0	0
Clarity	2	1	1	-1	0
Light Transmittance	1	1	1	0	0
Health Concerns	1	1	-1	1	0
Scratch Resistance	1	1	0	0	0
Environmental	1	1	1	1	1
Total	-	14	**21**	14	9

According to the analysis made above polycarbonate is the most suitable material for the shell. Acrylic and HDPE are tied in second, which allows for reputable backups.

4.2.2 - Shell-Frame Sealing Material

One of the major opportunities for leakage lies in the connection between the shell and the frame. In order to minimize leakage, several different medical grade materials were considered in o-ring tubing and gasketing to maximize efficiency while minimizing cost. The design requirements of functionality for CNAP, accessibility to minimize additional complexities in removal or assembly, and durability to limit long-term wear and tear were heavily considered for this subsystem.

4.2.2.1 Nitrile Rubber

Primarily, nitrile rubber was considered due to its popularity in industrial sealing (*All about Nitrile Rubber - Properties, Applications and Uses)*. It is also abrasion resistant and maintains shape when undergoing compression. In terms of cost it is relatively cheap compared to opposing options. Nitrile rubber does meet medical grade requirements; doctors and other medical staff commonly wear gloves made of nitrile rubber when working with patients as they are hypoallergenic. It is known to be used in gaskets and o-rings, so it is adaptable to many design variations. There were no apparent disadvantages for this application. More specific values and properties of nitrile can be found in this table[10]. The cost will be discussed in the decision matrix of this section.

4.2.2.2 Polyethylene - O-Ring

The material properties of polyethylene are previously explained in Section 4.2.1.3 when determining the type of material to consider the shell design. This material is also an option to consider for the focus of the sealant between the patient and the device. When considering polyethylene as a sealant, ultra high molecular weight polyethylene (UHMW) is the subset of polyethylene that is most compatible for sealing applications (Kaman, 2023). It is a wear-resistant plastic that has a low coefficient of friction and excellent moisture resistance (*Primers adhesion promoters for UHMW*). This material is biocompatible and has been used in medical devices seals such as syringes, dosing pumps, and atherectomy drive units (Kaman, 2023). It is quite versatile and utilized by many companies, including 80-20, for gasketing. Even though polyethylene has excellent vapor barriers, it often has very poor air barriers (Lstiburek, 2000). More specific values and properties of polyethylene can be found in this table[11]. The cost will be discussed in the decision matrix of this section.

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[10] *Nitrile Butadiene Rubber Data Sheet can be accessed through https://www.tdiinternational.com/technical-source-product-info/material-data-sheets-spec-sheets/nitrile-rubber-data-sheet/*

[11] Polyethylene Data Sheet can be accessed through https://laminatedplastics.com/polyethylene.pdf

4.2.2.3 Ethylene Propylene

Ethylene propylene is another material considered for shell-frame sealing. This material is classified under the family of synthetic elastomers and can be applied to applications for solvents, acids, and mild chemicals (*EPDM O-rings (ethylene propylene) selection guide* 2023). Ethylene propylene has also been used for medical applications because of its good compression set resistance, good heat stability, good permeation resistance, and excellent electrical insulation (which is important for maintaining a vacuum seal for the device) (*EPDM O-rings (ethylene propylene) selection guide* 2023). Its specialty resistance includes resistant to steam less than 300℉ which is important for sanitization of the device (*EPDM O-rings (ethylene propylene) selection guide* 2023). More specific values and properties of ethylene propylene can be found in this table[12] (*E1000 MATERIAL SUMMARY* 2023). The cost will be discussed in the decision matrix of this section.

4.2.2.4 Decision Matrix

The material property requirements for each type of sealing material is shown in Table 13. The team first performed a pairwise analysis to determine the factors of importance for a sealant using the requirements from Table 11. From there, Table 14 represents the pairwise analysis for the sealant requirements. From here, a pugh analysis was performed to assist in the decision for the type of sealing material that will be used to create a seal between the patient and the device. Table 15 below represents the requirements needed for the seal and how each material compares.

[12] Polyethylene Data Sheet can be accessed through https://www.marcorubber.com/downloads/Marco-Material-Datasheet-E1000.pdf

Table 13 : Material Properties for Sealant

Requirements	Nitrile Rubber	UHMW - Polyethylene (Polypropylene)	Ethylene Propylene
Elasticity (Young's Modulus)	4 MPa	88,000 psi	800 psi
Tensile Strength	15 MPa	5,800 psi	12.8 psi
Air Permeability	excellent	poor	poor
Heat Resistance	high	low	high
Wear Resistance	excellent	excellent	excellent
Sterilization	Autoclaving, natural detergents, EtO Gas	Cold plasma oxidation (CPO), ethylene oxide (EtO), hydrogen peroxide plasma (HPP), and steam autoclave (SA)	Autoclaving, EtO gas, disinfectants
Skin Allergy	Hypoallergenic	Not expected to cause skin irritation	Usually safe but can cause contact allergy
Cost	$7.43 (⅛" x 6"x 6")[13]	$17.88 (½' x 36 yd) [14]	$1.40/Count (1/16")[15]

[13] Price estimated from https://www.amazon.com/U-Turn-Fasteners-Nitrile-Rubber-Material/dp/B08S3BM6H2/ref=sr_1_1_sspa?crid=A33NYKSDEFPU&keywords=nitrile%2Brubber%2Bsheet&qid=1682610217&s=industrial&sprefix=nitrile%2Brubber%2Bsheet%2Cindustrial%2C98&sr=1-1-spons&spLa=ZW5jcnlwdGVkUXVhbGlmaWVyPUEzU05DNjc4RFAwUzhEJmVuY3J5cHRlZElkPUEwMDM1NzE0MUs2OEk0Q1lYMDg0QyZlbmNyeXB0ZWRBZElkPUExMDMxNDM5M1VNVlE1S05XM0ZRUyZ3aWRnZXROYW1lPXNwX2F0ZiZhY3Rpb249Y2xpY2tSZWRpcmVjdCZkb05vdExvZ0NsaWNrPXRydWU&th=1

[14] Price estimated from https://www.amazon.com/WOD-Polyethylene-Transparent-Tape-Aggressive/dp/B07JFTKQ6H

[15] Price estimated from https://oringsandmore.com/epdm-70-o-rings-fda-nsf-size-277-price-for-1-pc/

Table 14: Pairwise Analysis Sealant

	Patient Comfort	Elasticity	Tear resistance	Air permeability	Sterilization	Skin Allergy	Cost	**Total**	**Weight**
Patient Comfort	-	0	0	0	0	0	0	0	0
Elasticity	1	-	0	0	0	0	1	2	4
Tear resistance	1	1	-	0	0	0	1	3	6
Air permeability	1	1	1	-	1	0.5	1	5.5	11
Sterilization	1	1	1	0	-	0	1	4	8
Skin Allergy	1	1	1	0.5	1	-	1	5.5	11
Cost	1	0	0	0	0	0	-	1	2

Table 15: Pugh Analysis Sealing Material

Requirements	**Weight**	**Nitrile Rubber**	**Polypropylene**	**Ethylene Propylene**
Patient Comfort	0	0	0	0
Elasticity	4	0	-1	-1
Tear resistance	6	0	1	0
Air permeability	11	1	0	0
Sterilization	8	1	1	0
Skin Allergy	11	-1	1	0
Cost	2	1	-1	1
Total	-	10	19	-2

Based on the pairwise comparison analysis and pugh analysis for the sealing material, the chosen sealing material is polypropylene. There was a large focus on the adaptability which would allow the gasket to be used with prototype frames, and last for several uses without wear and tear. The consideration for skin irritation was also heavily weighed because the choice of material should be safe for a patient to be in contact with. Considering the alternatives were not as effective when comparing the heavily weighed objectives, polypropylene was the obvious choice.

4.2.3 - Body Seal

This component is crucial because it is responsible for creating the seal between the patient and the device. The material selected must form a natural seal with the skin and maintain the vacuum facilitated by the device. The sealing material must also be adjustable for different-sized patients with a torso length of about 16 inches and a BMI of 30-39.9, limiting the likelihood of any adverse reactions with a patient's skin through referencing the medical grade alternatives. In order to prevent leakage and overworking of the vacuum pump, the shape and mechanism of this material is important to consider. For the material itself, as heavily suggested by the sponsor, the team utilized neoprene. To optimize the shape of the sealing mechanism itself, several constraints were taken into consideration. These consist of patient comfort, time to assemble to patient, robustness, ruggedness, adaptability to patients and hospital beds, cost, ability to perform for maximum treatment time, accessibility to doctors and maintain CNAP.

4.2.3.1 Neoprene: The Airtight Material in Wetsuits

Primarily, the group considered Neoprene as a part of the sealing mechanism around the patient. The advantages of using this material are that it is both durable and versatile (*The Evolution and Benefits of Neoprene*). Neoprene has a strong resistance to cuts and does not receive damage through flexing, twisting, and abrazon. The material itself remains flexible over a wide range of temperatures, adheres well to fabric and metal, and its material compounds can be modified to have varying physical properties depending on what is needed. The disadvantages of using neoprene is it is rather expensive, costing about $19.99 per square yard[16]. Despite the cost incurred, neoprene is commonly used in the medical field and as a form of sealant for building braces and supports for injured patients (*Neoprene traits and applications*). Neoprene has also been used in the automotive industry as a window and door sealant, which demonstrates its efficacy in terms of functionality alongside medical safety. More specific values and properties of neoprene can be found in this table[17].

[16] Price esrtimated from: *Amazon.com: 2mm blue neoprene fabric cloth, scuba wetsuit material ...* (n.d.). Retrieved December 17, 2022, from https://www.amazon.com/Neoprene-Fabric-Wetsuit-Material-Stretch/dp/B0B14GLXHY

[17] Neoprene Data Sheet can be accessed throughhttps://www.mechanicalrubber.com/materials-compounds/polymers/neoprene/neoprene-technical-data-sheets/

4.2.3.2 Snap-On Pants

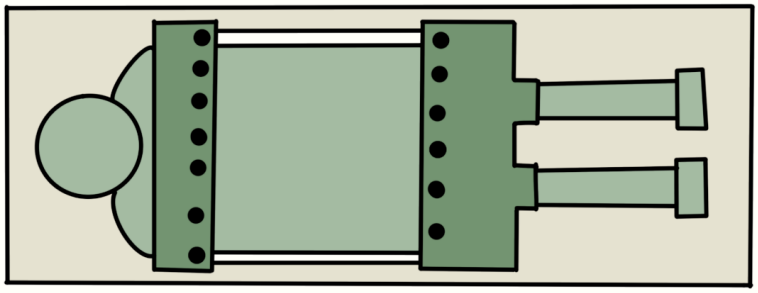

Figure 15: Snap on Pants Design.

Primarily, the first consideration was a pair of snap-on neoprene pants. Once the patient lays on the frame and the shell is attached over them, the pants would snap on at the interface between the shell and the top of the "pants" image above in Figure 12 with the circles at the seams. Different sizes would be available and there would be elastic bands around the legs for adjustability. This allows for relatively quick removal, a variety of patients who can use the device, and remains within the cost parameters.

4.2.3.3 Air-Tight Zipper

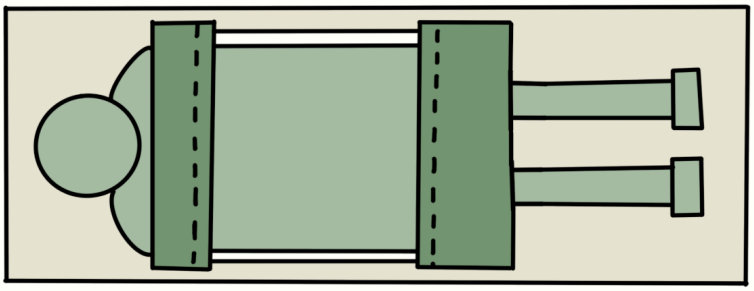

Figure 16: Airtight Zipper Design.

The second design that was developed was the idea to use an airtight zipper. Similar to the previous design, the patient would be given a pair of pants made from neoprene which would fit snugly around their ankles to prevent air leakage. However, instead of the waist of the pants attaching directly to the ventilator, a separate sleeve of neoprene would be held onto the device using epoxy glue. The

opposing side of the sleeve which is not attached to the ventilator, would have an airtight zipper on the edge, to attach itself to the waist of the neoprene pants.

4.2.3.4 Abdominal Seal

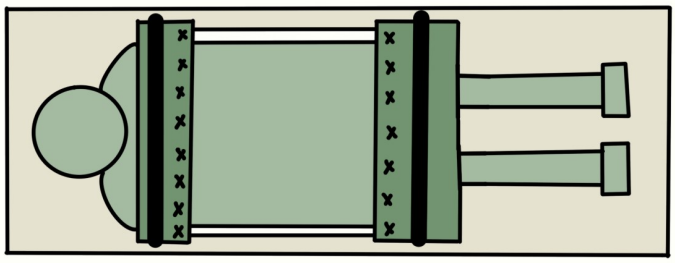

Figure 17: Abdominal Seal Design.

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Unlike the previous designs, design three ends at the patient's waist. As depicted in green in Figure 14, a neoprene sleeve would fit snugly around the patient's waist, preventing air leakage. The edge of the sleeve closest to the ventilator would then be attached with air tight velcro.

4.2.3.5 "Footie Pajamas" Design

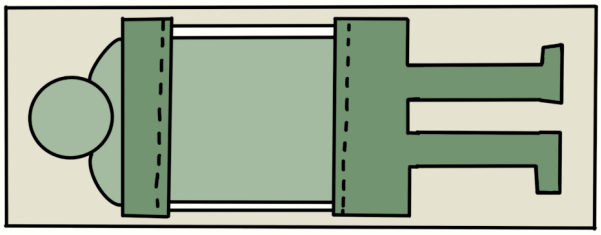


Figure 18: Depiction of the "Footie Pajama" Design

The final design that was developed was the idea to use an airtight zipper. Similar to the previous designs, the patient would be given a pair of pants made from neoprene which in this case would cover their feet as well to prevent air leakage. However, instead of the waist of the pants attaching directly to the ventilator, a separate sleeve of neoprene would be held onto the device using epoxy glue. The opposing side of the sleeve which is not attached to the ventilator would have an airtight zipper on the edge to attach itself to the waist of the neoprene pants.

4.2.3.6 Decision Matrix

Table 16: Pugh Analysis of Lower Body Sealing Mechanism

	Concepts					
Criteria		Weight	Snap-on Pants	Air-tight Zipper	Abdominal Seal	Footie Pajamas
	Patient Comfort	0	0	0	1	-1
	Time to Assemble to Patient	2	-1	0	1	-1
	Robust Design	5	-1	0	0	0
	Ruggedness	6	-1	1	0	0
	Adaptability to different patients	9	0	1	-1	-1
	Adaptability to hospital beds	10	0	0	0	0
	Cost	12	0	0	1	-1
	Performs for maximum treatment time	13	0	0	0	0
	Accessibility: Doctors	16	-1	-1	1	0
	Maintain CNAP	17	0	0	0	0
	Total:	-	-29	15	21	-23

After applying the Pugh analysis, it is clear the abdominal seal would be the most effective. It requires less neoprene compared to the other designs and is, therefore, cheaper. This would also take less time to assemble and remove compared to the other designs. In terms of robustness, ruggedness, adaptability to hospital beds, long term performance, and ability to maintain CNAP, it meets the baseline requirements. The one downside to this design is the sleeves lack of adaptability to fit different sized patients. In order to resolve this issue, several different size sleeves would be made that can attach to the ventilator using velcro. In case the sleeve is too large on the patient, an elastic belt will be used to cinch it to the patient.

4.2.4 - Locking Mechanism

The locking mechanism will hold the shell closed and help maintain the vacuum seal while the device is functioning. Part of the locking mechanism will attach to the bottom edge of the shell, while another component attaches to the frame. When the shell is closed against the frame, the locking mechanism must be able to maintain a seal for six hours. The locking mechanism must open in less

than ten seconds in an emergency situation, per the team's objective. The three concepts included a pelican case or a window latch.

4.2.4.1 Pelican Case Latch

The clasps chosen are modeled off those on a pelican case. These latches rotate on a pin to open and close. The latch is within clearance of pieces from the lip on the case. With minimal force, these latches will lock into the lip, as demonstrated on vendor websites.[18] (*Pelican™ 1610 equipment case H-7695*). Figure 16 shows the latches, which jut out to secure to the edge of the case and will slide into the extension on the sides of the case.

Figure 19: Image of Pelican Case.

Note: From "ContourHD POV in Pelican Case" by Sridgway is licensed under CC BY 2.0. To view a copy of this license, visit https://creativecommons.org/licenses/by/2.0/?ref=openverse.

The latch on the pelican case can engage and disengage quickly, which will be necessary for clinicians if the patient enters an emergency situation. Minimal force is needed to secure and open the latching mechanism. However, this latch also is stable enough to remain closed regardless of any kind of jostling. The purpose of pelican cases is to protect sensitive material despite rough forces or weather, so using the same kind of latching mechanism is logical (*What are Pelican Cases Made Of*, 2022).

[18] The product discussed, the Pelican™ 1610 equipment case H-7695, can be found at https://www.uline.com/Product/Detail/H-7695/Special-Use-Boxes/Pelican-1610-Equipment-Case.

4.2.4.2 Folding Latch

Folding latches are typically found on windows hinged at the top (DI Editorial Team, 2021). When the latch handle is parallel to where the window and the frame meet, the window is locked. When the latch handle is perpendicular, the window is open (DI Editorial Team, 2021).

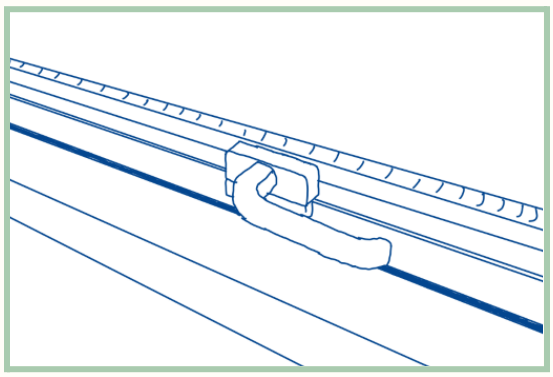


Figure 20: Closed Window Latch.

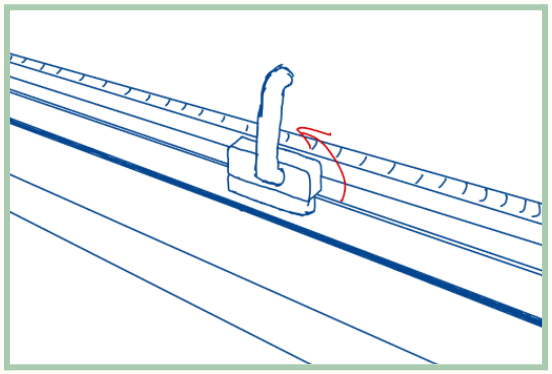


Figure 21: Open Window Latch.

This subsystem will hold the shell closed for the maximum time frame of six hours. Since these latches are typically used in windows, they must help facilitate a seal that prevents drafts into buildings. Therefore the folding latch should help maintain the vacuum within the shell.

4.2.4.4 Decision Matrix

A Pugh Analysis was calculated to determine which locking mechanism was the best, which is displayed below.

Table 17: Pugh Analysis of Locking Mechanisms

	Concepts			
Criteria		Weight	Pelican Case Latch	Folding Latch
	Patient Comfort	0	0	0
	Time to Assemble to Patient	2	0	0
	Robust Design	5	0	0
	Ruggedness	6	0	0
	Adaptability to different patients	9	0	0
	Adaptability to hospital beds	10	0	0
	Cost	12	-1	1
	Performs for maximum treatment time	13	1	-1
	Accessibility: Doctors	16	-1	1
	Maintain CNAP	17	1	-1
	Total:	-	2	-2

As a result, the Pelican Case latches were determined to be the best locking mechanism. Due to the ability to implement sealing material around the latch location, this mechanism is superior at maintaining the vacuum within the shell for six hours. These advantages justify the extra cost. While it may take more effort to open the shell, this difference is minimal compared to the folding window latch.

4.2.5 - Connection to Bed Frame

A frame must be developed to provide stability and airtight sealing to the patient's bed, and to the shell. The frame will house the interface between securing and releasing the shell in the case of emergency or cleaning to which abdominal access may be deemed necessary. This section explores the best way to secure the frame of the device to the bed, whether it be through the addition of straps to tie it down, clasping it to a large sheet of stiff materials, or a combination of one of these methods with a suction cup-lined interface. Pugh analysis was used with proof of concepts to validate the decision.

4.2.5.1 Straps and Frame

The first concept addressed would be to design a frame for the device to secure it to the bed, with the addition of straps to limit movement and opportunity for air leakage. This frame could be laser cut or rapidly prototyped from one of the plastics discussed in the shell section, dependent on their response to impacts and manufacturability through different methods regarding safety concerns and ductility. Lightweight yet durable metals such as aluminum or titanium could be implemented as well. The proposed implementation for the concept of this subsystem is demonstrated in Figure 19 below. It illustrates the opportunity for backpack-esque straps to lock in and be tightened underneath the hospital bed frame. Additionally, the interface for the clasp to lock onto the frame is implemented in this subsystem. Sample straps are detailed in Figure 20.

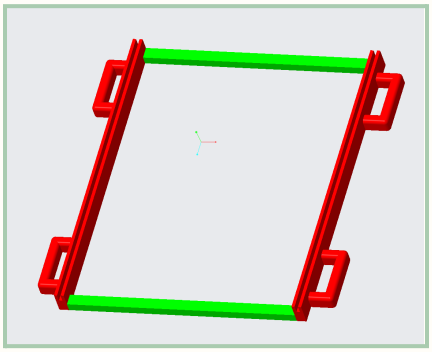


Figure 22: Custom Frame Modeled to Secure Shell to Hospital Bed using Straps.

Figure 23: Sample Straps to Secure Frame to Bed.

Looking at Figure 19 of the custom frame, the straps loop into the handles of the device and around the bed. Additionally, the divets in the frame allow for a nitrile rubber or silicone O-Ring to be inserted to prevent air leakage. Additionally, the parts of the frame depicted in green allow it to

maintain strength and shape. To ensure patient comfort, it will be coated with a vinyl-sealed foam that mimics Figure 21 below. The foam size will be dependent on the sealing subsystem so it can accommodate any cavities created between the patient and the neoprene.

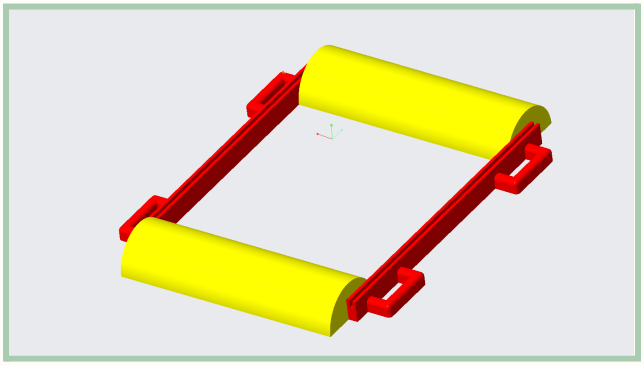


Figure 24: Custom Frame with the Addition of Vinyl Covered Foam.

4.2.5.2 Suction Cup Line

The second alternative works similarly to the first but considers the possibility that the straps and the frame alone may not hold the frame tight enough to prevent movement on impact and reduce the seal. Therefore, a rectangular suction component could be placed in, whether it be nitrile rubber or a custom suction cup. The two alternatives are provided below. The only drawback to considering this option is that this extra material, and depending on which material is selected presents a significant cost increase. The increased stability versus cost were considered in pugh analysis which is reviewed further in Table 24 below comparing all of the concepts for this subsystem.

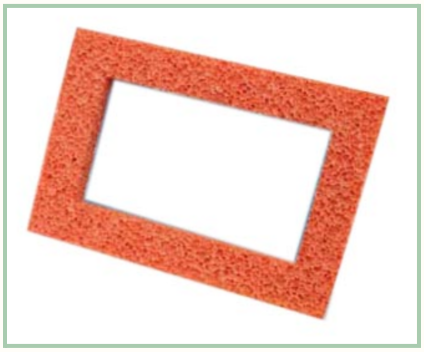


Figure 25: Custom Ordered Rectangular Suction Cup.

4.2.5.3 Sheet and Clasp

An alternative idea is to secure the CNAP device to a hospital bed using clasps and a large sheet of plastic. The CNAP device is placed on the bed in a position that is easily accessible to the patient and healthcare professionals by cutting a piece of plastic sheeting that is large enough to cover the entire CNAP device and bed. The plastic sheeting should be at least 6 inches wider and longer than the CNAP device. Clasps are used to fasten the plastic sheeting to the bed frame at regular intervals, placed at the corners of the bed and along the sides, about 6 inches apart. There would be a groove for the O-Ring insertion in this method as well, in addition to an interface for clasps to hook to. This method of securing a CNAP device to a hospital bed using clasps and plastic sheeting can help prevent the device from being accidentally bumped or knocked off the bed, which can disrupt patient care and potentially compromise the seal created by the device.

4.2.5.4 Decision Matrix

Table 18: Pugh Matrix for Different Concepts

	Concepts				
Criteria		Weight	Straps & Frame	Suction Cup Line	Sheet & Clasp
	Patient Comfort	0	0	0	0
	Time to Assemble to Patient	2	1	-1	-1
	Robust Design	5	1	0	-1
	Ruggedness	6	-1	1	0
	Adaptability to different patients	9	0	0	0
	Adaptability to hospital beds	10	0	0	-1
	Cost	12	1	-1	-1
	Performs for maximum treatment time	13	1	1	0
	Accessibility: Doctors	16	0	0	0
	Maintain CNAP	17	0	0	0
	Total:	-	**26**	9	-29

There are several ways to secure the new CNAP device to a hospital bed. The best method depends on the specific requirements and characteristics of the device, as well as the bed and the environment in which it is being used. Considering the weighted design metrics based on their importance from the Pairwise analysis, the most effective option would be to implement the strap and frame method. The suction cup lining along with the sheet and clasp method takes much longer to assemble and is significantly more costly than the alternatives.

4.2.6 - Pump Selection

The vacuum pump will induce a negative pressure environment within the shell. In order to do this, the pump must maintain a vacuum of -10 to -30 cmH2O within an accuracy of +/- 5 cmH2O for a maximum of six hours. The pump must be able to facilitate this for a maximum of four weeks. The vacuum within the shell must take less than ten minutes to establish. The pump must also fit within the team budget, with the consideration that there is only $1250 available to spend.

More specific requirements, in addition to the ones in the previous paragraph, were also established. These are expanded on in the following table.

Table 19: The factors that affected pump decision-making and the resulting requirements.

Factor	**Need**	**Pump Requirement**
Pressure	Achieves -10 to -30 cm H2O below atmospheric pressure	Vacuum not past -100 cm H2O
Performance	Maintain CNAP	Works continuously for six-hour intervals for four weeks
Weight	Easily transportable by healthcare personnel	Weighs less than 7kg
Flow Rate	Takes less than ten minutes to establish vacuum	Final prototype volume is roughly 22L, so flow rate must be greater than 2L/min
Loudness	Must be comfortable volume for clinicians and not result in hearing damage	Below 60dB: loudness of a conversation Below 70dB: Prolonged exposure causes hearing loss
Cost	Not take up a large portion of the budget	Ideally cost less than 10% of budget ($125), max of 15% ($187.50)

Table 20: Each Pump Concept

Concept 1:	2- Stage 50 L/m Oil Free Lab Vacuum Pump Oilless Medical Mute Pump HZW-165 (110V)
Concept 2:	DC 12V Vacuum Pump, 42W Brushed Mini Small Oilless Vacuum Pump -85KPa Flow 40L/min
Concept 3:	24L Lab Diaphragm Vacuum Pump Oil Free Oilless Medical Mute Pump -95Kpa Air Pump with Air Filter
Concept 4:	Oil-Free Vacuum Pump
Concept 5:	TMD40A-A

4.2.7.1 - Pump 1: 2- Stage 50 L/m Oil Free Lab Vacuum Pump Oilless Medical Mute Pump HZW-165 (110V)

The 2- Stage 50 L/m Oil Free Lab Vacuum Pump, pictured in Figure 27, is a piston diaphragm pump ("2- Stage Oil Free Lab Vacuum Pump", 2019).[19] Figure 28 shows how a piston diaphragm pump works. A motor drives a crankshaft which moves the piston. The piston oscillates a diaphragm by pressing it down and pulling it up. When the diaphragm is pulled up, the pressure in the chamber decreases, letting air flow in through the inlet valve. A vacuum is therefore created outside of the pump. The outlet valve remains closed. When the diaphragm is compressed, the chamber pressure increases. This results in the inlet valve closing and the outlet valve opening, for air to rush out. This air leaves through the exhaust channel (Zelle, 2021). The pump also comes with all the additions depicted below, which will make setting up the pump for the final prototype easier. The main two benefits are that the pump can stand on its own and has a filter to prevent contamination to its components (Hurlbatt, 2016).

[19] The full product name as listed on Amazon at https://a.co/d/blq3vXn is "2- Stage 50 L/m Oil Free Lab Vacuum Pump Oilless Medical Mute Pump HZW-165 (110V)".

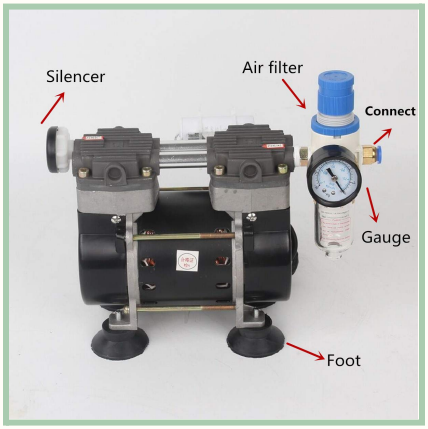


Figure 26: 2- Stage 50 L/m Oil Free Lab Vacuum Pump Oilless Medical Mute Pump HZW-165 (110V).

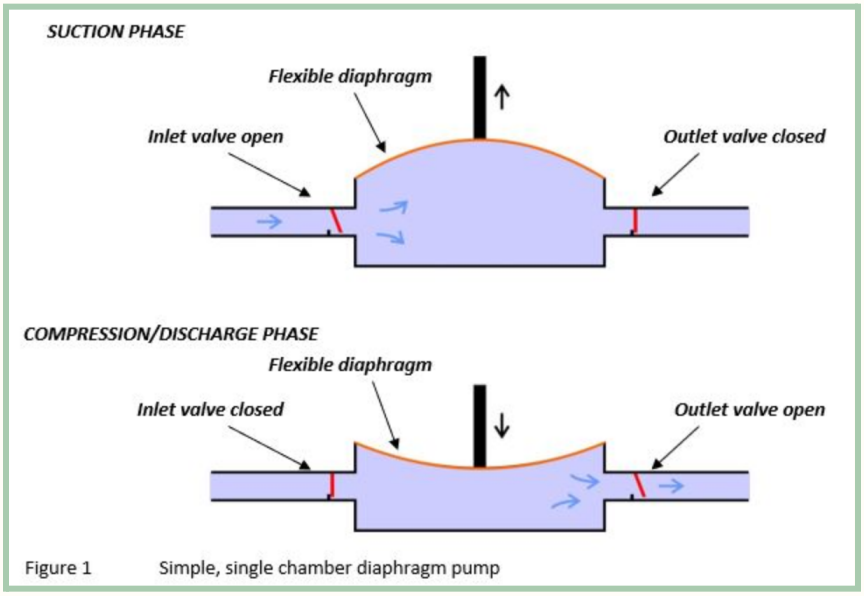


Figure 27: Piston Diaphragm Pump Function.

Note: Used with permission from How do vacuum pumps work?, by *Zelle, B., 2021.* *(*https://www.andersonprocess.com/how-do-vacuum-pumps-work/*)*

The following table shows the pump specifications and how well those specifications meet the pump requirements. The pump fulfills most requirements, except having too strong of a vacuum and being somewhat more expensive.

Table 21: 2- Stage 50 L/m Oil Free Lab Vacuum Pump Requirements Analysis

Factor	Pump Specification	Fulfills Requirement?
Pressure (by Maximum Vacuum)	-870 cm H2O	Fails
Performance	Customers give mixed reviews	N/A
Weight	4kg	Exceptionally
Loudness	55dB	Exceptionally
Flow Rate	50L/min	Exceptionally
Cost	$136	Passes

4.2.7.2 - Pump 2: DC 12V Vacuum Pump, 42W Brushed Mini Small Oilless Vacuum Pump -85KPa Flow 40L/min

The DV 12V is depicted in the figure below. The webpage does not specify pump type beyond being a vacuum pump ("DC 12V Vacuum Pump", 2018).[20] However, pumps of low vacuum level tend to be diaphragm pumps, like the pump above (Zelle, 2021). The pump will create a vacuum.

Figure 28: DC 12V Vacuum Pump, 42W Brushed Mini Small Oilless Vacuum Pump -85KPa Flow 40L/min

[20] The full product name as listed on Amazon at https://a.co/d/1TtJLnm is "DC 12V Vacuum Pump, 42W Brushed Mini Small Oilless Vacuum Pump -85KPa Flow 40L/min".

The following table shows the pump specifications and how well those specifications meet the pump requirements. The pump is extremely light, has a good flow rate and is very cheap. However, the pump is also too loud, and creates too big of a vacuum. The vacuum is non-adjustable.

Table 22: DC 12V Vacuum Pump Requirements Analysis

Factor	**Pump Specification**	**Fulfills Requirement?**
Pressure (by Maximum Vacuum)	-870 cm H2O	Fails
Performance	Seller says more than 30min, other customers give mixed review	Most likely fails
Weight	0.5kg	Exceptionally
Loudness	70dB	Fails
Flow Rate	50L/min	Exceptionally
Cost	$44	Exceptionally

4.2.7.3 - Pump 3: 24L Lab Diaphragm Vacuum Pump Oil Free Oilless Medical Mute Pump -95Kpa Air Pump with Air Filter

This pump, depicted in Figure 30, is also a diaphragm pump, so it functions similarly to the other two ("24L Lab Diaphragm Vacuum Pump", 2020).[21] Although not depicted, comments say that the pump has four rubber feet. The comments also say that the speed is non-adjustable.

[21] The full product name as listed on Amazon at https://a.co/d/gsiugu4 is "24L Lab Diaphragm Vacuum Pump Oil Free Oilless Medical Mute Pump -95Kpa Air Pump with Air Filter".

Figure 29: 24L Lab Diaphragm Vacuum Pump Oil Free Oilless Medical Mute Pump -95Kpa Air Pump with Air Filter.

The following table shows the pump specifications and how well those specifications meet the pump requirements. The pump is well-priced, has a great flow rate, and is light. In addition, a commenter confirmed that it can run more than six hours. Like pumps 1 and 2, pump 3 has too big of a vacuum for the project.

Table 23: 24L Lab Diaphragm Vacuum Pump Requirements Analysis

Factor	**Pump Specification**	**Fulfills Requirement?**
Pressure (by Maximum Vacuum)	-970 cm H2O	Fails
Performance	Commenter says can run 3-4 days straight with no issue	Passes
Weight	3.5kg	Exceptionally
Loudness	N/A	N/A
Flow Rate	24L/min	Exceptionally
Cost	$116	Exceptionally

4.2.7.4 - Pump 4: Oil-Free Electric Vacuum Pump

The Oil-Free Electric Vacuum Pump is depicted in Figure 31 (“Oil-Free Electric Vacuum Pump”). The website does not specify what type of pump beyond what is given in its name. However, it

does provide that the pump is powered by a motor, and is more powerful than air-operated pumps (*About Vacuum Pumps*).

Figure 30: Oil-Free Electric Vacuum Pump.

The following table shows the pump specifications and how well those specifications meet the pump requirements. Like all the other pumps, the vacuum is too strong for the application. The pump can most likely run for six hours, given the high pricing and the general statement on the website about the pump being for long-term use. However, the pump is very out of budget and is too loud. The main appeal is its high flow rate, but this is comparable to all the other pumps shown so far.

Table 24: Oil-Free Electric Vacuum Pump Requirements Analysis

Factor	**Pump Specification**	**Fulfills Requirement?**
Pressure (by Maximum Vacuum)	-690 cm H2O	Fails
Performance	No information on how long it can run. The website states that electric vacuum pumps are made for long-term, continuous use.	Passes
Weight	N/A, but dimensions (7 ¼” x 4” x 5 ½”) indicate that the pump is small	Passes
Loudness	72dB	Fails
Flow Rate	17L/min	Exceptionally
Cost	$550	Fails

4.2.7.5 - Pump 4: TMD40A-A

The TMD40A-A is depicted in Figure 32 and is also a diaphragm pump ("TMD40A-A", 2014).[22]

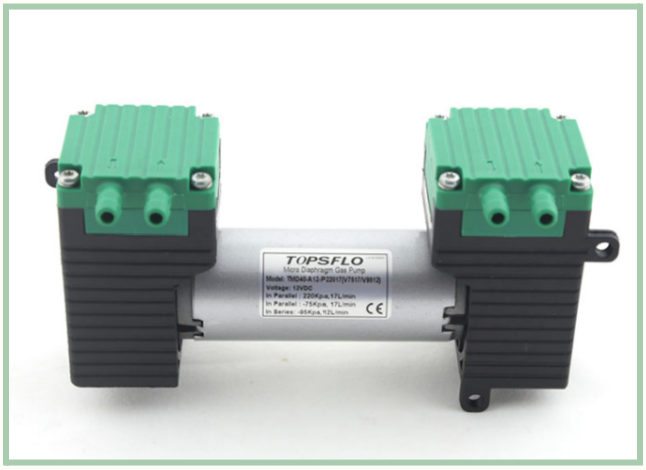


Figure 31: TMD40A-A.

The following table shows the pump specifications and how well those specifications meet the pump requirements. Again, the vacuum is too strong for the project. The website does not give direct information of how long the pump can function, but states that it has a lifetime of 3000 hours. This pump otherwise meets the set of specifications.

Table 25: TMD40A-A Requirements Analysis

Factor	Pump Specification	Fulfills Requirement?
Pressure (by Maximum Vacuum)	-760 cmH2O	Fails
Performance	Does not say, lifetime is 3000 hours	Passes
Weight	0.45kg	Exceptionally
Loudness	50dB	Exceptionally
Flow Rate	12 or 17L/min	Exceptionally
Cost	$76.35	Exceptionally

[22] The TMD40A-A can be found on Topsflo at http://www.topsflo.com/mini-diaphragm-pump/tmd40-a.html.

4.2.7.1 Design Matrix/Rational

Table 33 includes all the information given about the pumps in the previous sections, as well as how well they fill the pump requirements.

Table 26: Summary of pump requirements analysis

	Pump Name				
Pump Requirement	**2- Stage 50 L/m Oil Free Lab Vacuum Pump**	**DC 12V Vacuum Pump**	**24L Lab Diaphragm Vacuum Pump**	**Oil-Free Electric Vacuum Pump**	**TMD40A-A**
Pressure (Maximum Vacuum)	-870cmH2O	-870cmH2O	-970cmH2O	-690cmH2O	-760cmH2O
Fulfills Requirement?	Fails	Fails	Fails	Passes	Fails
Performance	No specs, mixed reviews	More than 30 min	Runs 3-4 days continuously	No specs	No specs, lifetime is 3000 hours
Fulfills Requirement?	N/A	Passes	Exceptionally	N/A	Passes
Weight	4kg	0.5kg	3.5kg	N/A, but dimensions (7 ¼" x 4" x 5 ½") indicate that the pump is small	0.45kg
Fulfills Requirement?	Exceptionally	Exceptionally	Exceptionally	Passes	Exceptionally
Loudness	55dB	70dB	N/A	72dB	50dB
Fulfills Requirement?	Exceptionally	Fails	N/A	Fails	Exceptionally
Flow Rate	50L/min	50L/min	24L/min	17L/min	12 or 17L/min
Fulfills Requirement?	Exceptionally	Exceptionally	Exceptionally	Exceptionally	Exceptionally
Cost	$136	$44	$116	$550	$76.35
Fulfills Requirement?	Exceptionally	Exceptionally	Exceptionally	Fails	Exceptionally

According to this chart, the 2- Stage 50 L/m Oil Free Lab Vacuum Pump is the best for the team's purposes. In addition to performing best considering the chosen parameters, the pump comes with many accessories that increase ease of use. Although the pressure from the pump will be adjusted with other components, it may still be helpful to have a gauge that reads the initial pressure output of the pump. While this is the heaviest pump of the options, the pump will have the power to last the full six hours for this application.

Table 33 all conveys that all the pumps have too large of a vacuum range for the purposes of this project, and that little information is provided on how long each pump can run. To address the issue of the vacuum, a vacuum regulator will be implemented. As for performance, most reviews state that the pumps' performance depends on the load placed on the pump. Since it will be using such a small amount of the power, the pumps may be able to run for a longer period of time.

The decision for the pump is also backed up by the Pugh Analysis below.

Table 27: Pumps Pugh Analysis

	Concepts						
Criteria		Weight	1	2	3	4	5
	Patient Comfort	0	0	0	0	0	0
	Time to Assemble to Patient	2	1	-1	1	-1	-1
	Robust Design	5	0	0	0	0	0
	Ruggedness	6	1	-1	1	0	-1
	Adaptability to different patients	9	0	0	0	0	0
	Adaptability to hospital beds	10	0	0	0	0	0
	Cost	12	0	1	0	-1	0
	Performs for maximum treatment time	13	0	-1	0	0	1
	Accessibility: Doctors	16	0	0	0	0	0
	Maintain CNAP	17	1	0	1	0	0
	Total:	-	25	-9	25	-14	5

As demonstrated by the table, the 2- Stage 50 L/m Oil Free Lab Vacuum Pump performs well. Its scoring ties with the 24L Lab Diaphragm Vacuum Pump. These pumps are very similar, except the 2- Stage 50 L/m Oil Free Lab Vacuum Pump comes with some additional accessories that justify the extra cost.

4.2.7.1 - Pump Accessories

Due to the high vacuum of the selected pump, accessories are needed to maintain the vacuum range needed for the device. Some potential accessories are vacuum regulators, vacuum transducers, and pressure gauges. Vacuum regulators can control the power of the vacuum facilitated by the pump (DI Editorial Team, 2021). Most vacuum regulators on the market have a higher vacuum range than required for the project, and those measured in cm H2O are only sold for industrial purposes. Pressure transducers can be adjusted to a certain pressure range, and provide a pressure measurement based on that range (Lavaa, 2023). This is done by measuring the pressure, converting this measurement to an

electrical signal, which can then be displayed on a pressure gauge. The pressure gauge simply displays the pressure flowing through the device.

For the purposes of this project, a vacuum regulator and pressure gauge were deemed necessary. First the vacuum regulator would connect to the pump, and then the pressure gauge would connect with the vacuum regulator. This would be done with hose and tee fittings.

The selected pressure regulator, Plastic Panel-Mount Vacuum-Regulating Valves for Air and Inert Gas, is depicted in Figure 32 below.

Figure 32: Plastic Panel-Mount Vacuum-Regulating Valves for Air and Inert Gas.

The pressure range of the regulator is 0 - 30 inches of Mercury, which is equivalent to 0 - 1036 cm H2O. While this is significantly larger than the intended vacuum range of the system, it will allow for a higher vacuum when the device is first turned on, which can then be adjusted once the desired vacuum is reached.

Figure 33 depicts the pressure gauge selected, Pressure Gauge for Gas Ø 60 mm 600 mmH2O. This will be connected in sequence after the regulator, using a tee fitting.

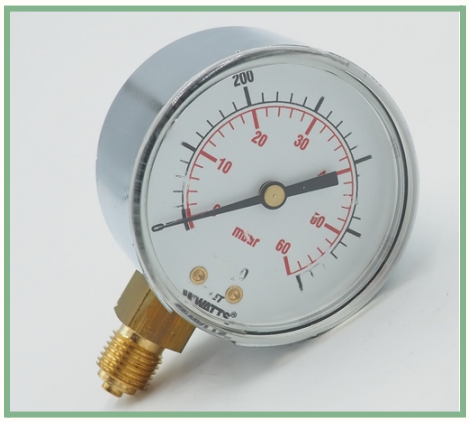


Figure 33: Pressure Gauge for Gas Ø 60 mm 600 mmH2O.

The pressure gauge displays a range of 0 - 600 mm H2O, which is equivalent to 0 - 60 cm H2O. Therefore, the gauge gives the necessary definition to determine the vacuum produced by the pump with the vacuum regulator.

4.3 Conceptual Designs: Device

After the selection of the subsystems, the team took into consideration two main design alternatives. In this section, each of those designs will be described and the reasoning for the final design choice will be explained.

4.3.1 - Pelican Device

The first design works similarly to a Pelican Case. In addition to implementing all of the chosen subsystems described in Section 4.2, the clasp on one side helps maintain the sealing of the device when shut while also allowing quick access to the patient's abdominal region. This "door opening" system is effective for emergency accessibility and quick performance of daily procedures. In this design, the shell is still attached to the frame when open, and will rest on one side of the frame. Furthermore, the bed frame design allows for easy assembly and removal with limited opportunity for damage to the integrity of the seal upon impact. In Figure 33 below, the combination of the subsystems is illustrated with a sample patient enclosed. The seal is created on the patient's chest and pelvis by securing the neoprene sealing material with a belt. This device will allow for the effective combination of CNAP with PPV to limit positive pressure exposure to the lungs. These specifications will ultimately decrease chances of

VILI, which obese patients are more prone to, given their medical limitations of decreased respiratory strength. The main drawback to this alternative is the stress imposed on the hinges.

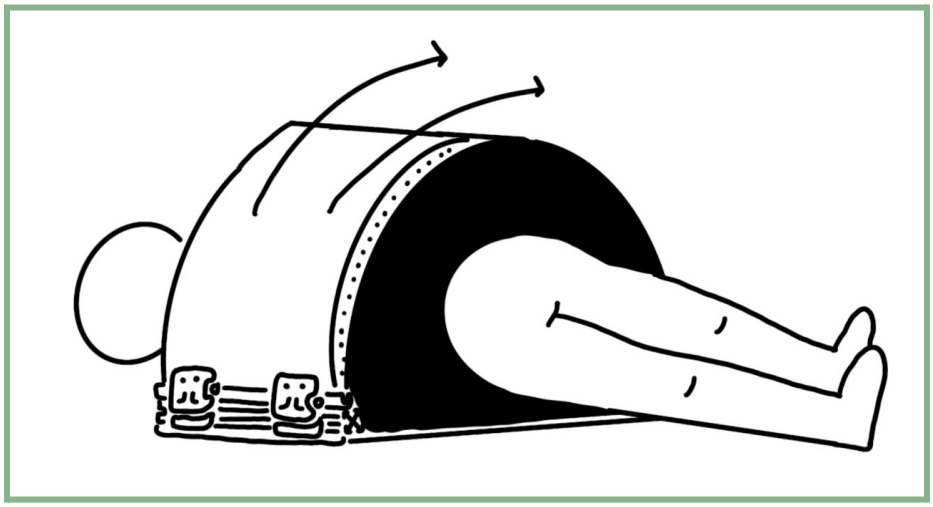


Figure 34: Pelican Device.

4.3.2 - Unhinged Shell

Another design alternative is having a shell that is not hinged to the frame, as shown in Figures 34 and 35. The shell will latch onto the frame on both sides. When the latches are opened, the shell can be completely removed from the frame and moved out of the way. The latches on both sides of the unhinged shell will ensure security to the frame. This may also induce a stronger seal to better maintain the vacuum within the shell over the maximum period of six hours. Another advantage of an unhinged shell is that it can be completely removed, providing full access to the patient on both sides of the bed. Both latches can be seen in the view of the shell in Figure 33.

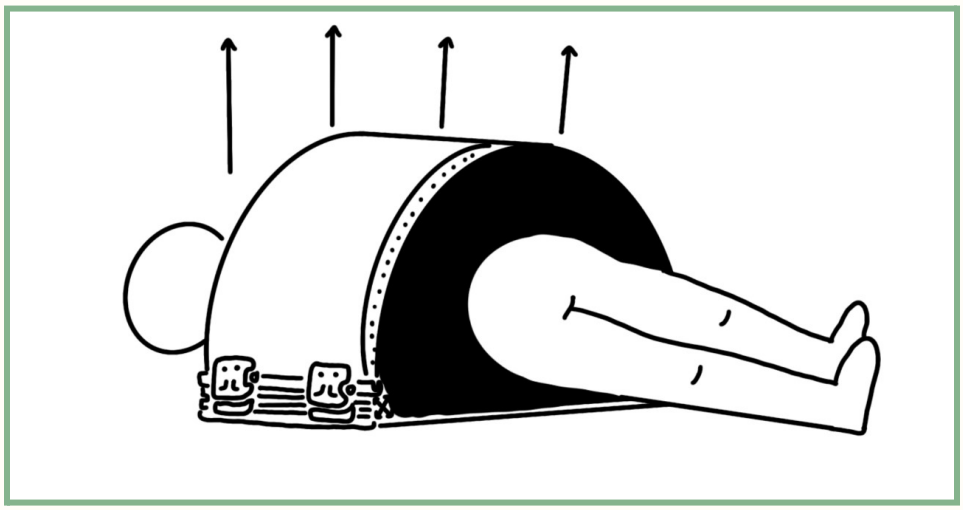


Figure 35: Closed Unhinged Shell.

4.3.3 - Design Choice

Considering the requirements found in the Pairwise Comparison in Table 5, the team created a Pugh Analysis to choose the final design.

Table 28: Pugh Analysis of Design Alternatives

	Concepts			
Criteria		Weight	Pelican Device	Unhinged Shell
	Patient Comfort	0	0	0
	Time to Assemble to Patient	2	-1	1
	Robust Design	5	-1	1
	Ruggedness	6	0	0
	Adaptability to different patients	9	0	0
	Adaptability to hospital beds	10	0	0
	Cost	12	0	0
	Performs for maximum treatment time	13	0	0
	Accessibility: Doctors	16	1	-1
	Maintain CNAP	17	-1	1
	Total:	-	-8	8

Based on the Pugh Analysis, the Unhinged Shell design is preferable. The unhinged design better secures the shell to the frame by having latches on both sides, increasing the chances of maintaining the seal. Additionally, the shell can be entirely removed from the frame, and does not have to remain adjacent to it, allowing clinicians better access to the patient on both sides of the bed. This design will also remove additional stress on the frame caused by the shell hanging off the side of it. However, the extra latches result in extra time needed to open the shell, which can be harmful in an emergency situation. Therefore, the team will share with clinicians the instructions on the most efficient and less time consuming way to open the shell. A less important but still noteworthy factor is that over time the shell may get separated from the frame, leading clinicians to have to search for it.

4.4 - Final Design

The final design is a changed version of the initial prototype, scaled up to the full-size dimensions needed for the device. While it contains the same subsystems, these are modified to better achieve the objectives set for the device.

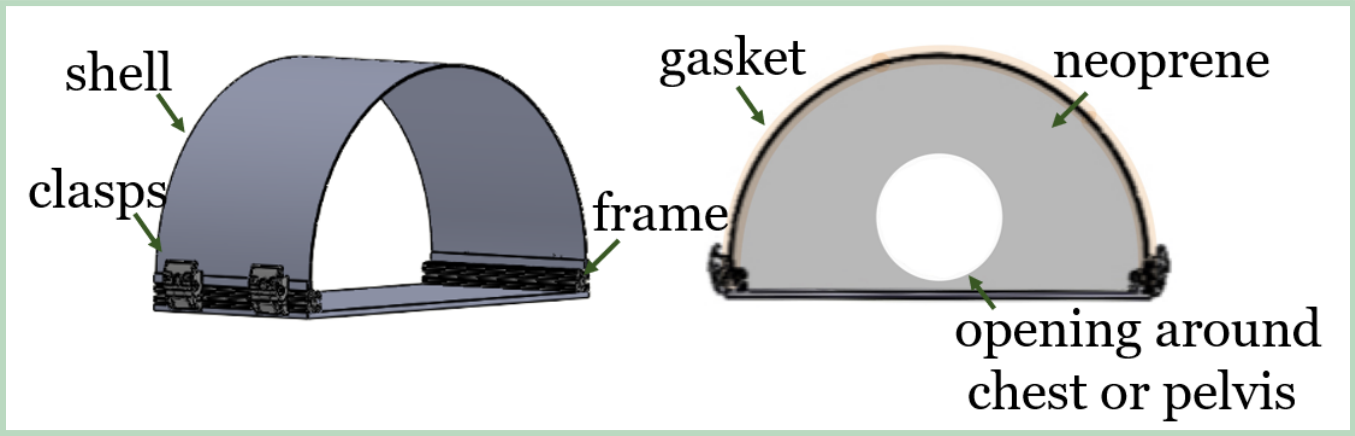


Figure 36: Final Design.

4.4.1 - The Shell

The molding for the final shell model was done with polycarbonate reinforced with stainless steel bars, bent to the shape of the shell. Aluminum u-channels line the bottom edges of the shell, to protect the PC material. Neoprene was then adhered to the bottom of the u-channels, to provide a better seal with the 80-20 gasket. These materials and components will provide a better seal and have improved ruggedness compared to the initial prototype.

4.4.2 - The Straps and the Frame

In order to address early prototypes that did not allow a 3D printed mockup of the frame to seal with the shell, the frame was instead constructed with 80-20s for the initial mockup of the final design. One of the main features of this product is the increased flexibility provided in where components can be attached. This implies the railings the patient lays on could be adjusted to any place along the perpendicular railings where the shell connected. The railings were connected perpendicularly using L-brackets, and secured nuts specifically for 80-20s and screws.

A gasket was selected to be inserted into the slot of the 80-20s where they made contact with the shell. This was to reduce any gaps caused by the slots and to provide a non-metal surface for the frame

to make contact with the shell. Handles were secured along the outside of the shell 80-20s for straps to feed and click through. The bottom components of clasps were also secured, with the top components being secured near the edges of the shell. Foam coverings were still using the cover the railing the patient lays on, just adjusted to the size of the 80-20s.

4.4.3 - Sealing Mechanism

Neoprene was used with a velcro lining for the initial mockup of the final design. The velcro was not directly adhered to the neoprene, as the nitrile rubber reinforces the neoprene. The velcro on the nitrile rubber adheres to the shell, creating a gapless seal. The velcro was lined with silicone caulk to simulate airtight velcro as seen on spacesuits.

The elastic belts were used to cinch around the patient, in order to create a tight seal around the torso and the lower abdomen. This was changed from the non-elastic belts of the initial prototype, with the hopes of creating a better seal.

4.4.4 - Pump

An opening for the pump was drilled into the side of the shell. For the purposes of this prototype, a hospital wall vacuum was used, since it is already within the correct pressure range.

4. 5 Feasibility Studies

4.5.1 - Polycarbonate Molding

A polycarbonate sheet with the required dimensions was acquired. The team attempted to mold the sheet using a cylinder pipe, clamps, and a heat gun. However, the polycarbonate shape would not stay molded in the needed semi-circular form. The clamps and overall structure of the prototype would not be sufficient to ensure the shell stayed in the correct form. Figure 37 represents the first attempt to mold the polycarbonate sheet.

Figure 37: First Attempt to Mold Polycarbonate Sheet.

To better understand what could be done, the team contacted the company that sold them the polycarbonate, asking for suggestions on handling and molding the shell to the necessary shape. The representative suggested the use of a stainless steel rectangular bar. The stainless steel would be molded into a semi-circular shape and drilled to the edges of the polycarbonate. With this, the shell would remain clear, allowing the doctors to see the patient's torso while remaining in shape. This could not be easily accomplished on campus; therefore, the team hired these services from the metal fabric. This brought into consideration new aspects of the manufacturability of the product.

4.5.2 - Neoprene Sealing Properties

To ensure that neoprene can maintain a seal, a small feasibility test was conducted. A 14.3" x 22" x 12.6" polypropylene plastic container was used along with neoprene, the Practice Point O2 wall vacuum, and a digital manometer. A 0.5" hole was drilled into the container to fit the wall vacuum tube as well as the manometer. A flat sheet of neoprene was placed on the floor; the container was placed upside down on top of the sheet; the tubes were inserted inside the container and the hole was sealed with tape to prevent major leakage. For this first test, a less powerful pump was used (wall vacuum O2). The digital manometer reading was -5 cmH2O and after the vacuum was turned off, it maintained that vacuum for approximately 2 minutes until the container was lifted. Figure 38 represents the set-up procedure for this feasibility test.

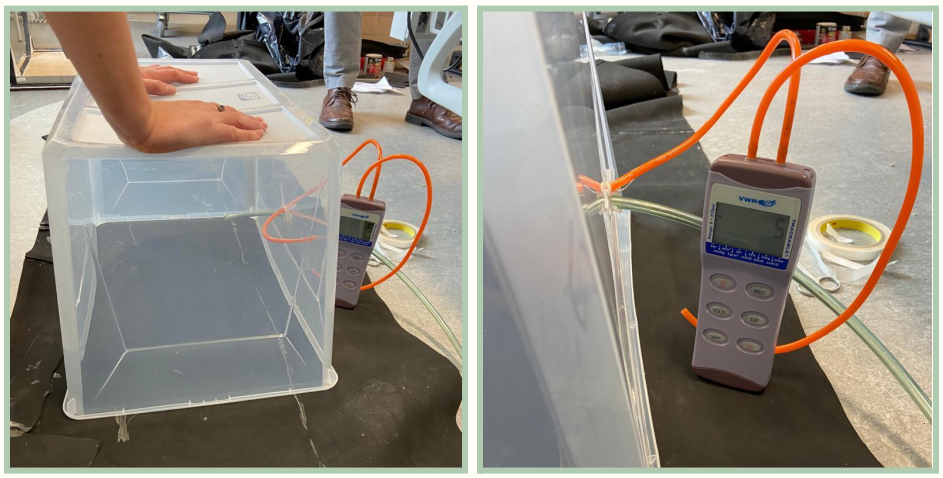


Figure 38: Polypropylene Container Sealing Test Against Neoprene Sheet Using Wall O2.

The same test was attempted using the same environment set-up, this time with a stronger vacuum pump. The reading shown with the manometer got to -29 cmH2O. These tests proved that neoprene can maintain a vacuum. Figure 39 represents the polypropylene plastic container sealing test using a stronger vacuum pump.

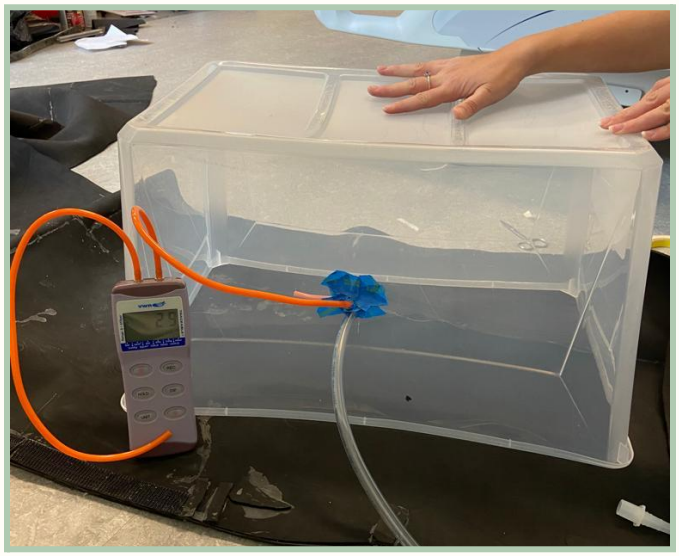


Figure 39: Polypropylene Container Sealing Test Against Neoprene Sheet Using Stronger Pump.

Chapter 5: Design Verification

The verification of the design was done by testing two prototypes: a small scale prototype, and a large scale prototype. The testing focused on CNAP maintenance, performance time, weight, and removal time in addition to other functional requirements. This chapter will describe the iterations of the prototypes in addition to the testing.

5.1 - Approach

In order to validate the CNAP device created based on the determined function requirements, the team developed 2 prototypes: a small scale prototype and an up-to-scale prototype.

The small scale prototype was made to test the sealing mechanism of the device, CNAP maintenance, and emergency removal time. It can be seen in Figure 40. This prototype isolated the sealing mechanism by having the shell permanently adhered to the frame, which, in this prototype, was meant to mimic a bed mattress. A custom gasket was made to ensure sealing between the neoprene and shell as well as easy removal of the patient. A doll was used to simulate a patient. The materials used for each subsystem can be found below (Table 29).

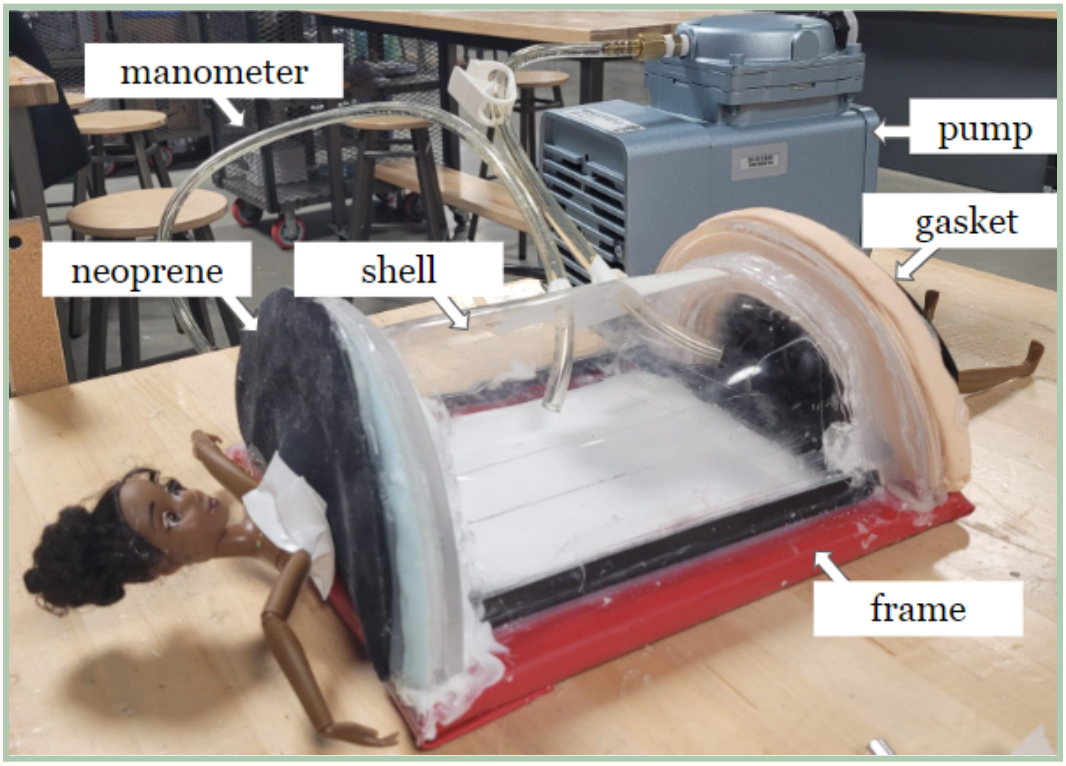


Figure 40: Components of Small Scale Prototype.

Table 29: List of Materials & Methods of Small Scale Prototype

Subsystem	Material	Method/Observation
Shell	Acrylic	Molded with a hot air gun
Sealing	Neoprene Gasket (acrylic | corn starch + silicon 1) Pro Tape	Cut to size Laser cut | Mixed together Mimicking cinch straps
Frame	Acrylic + Vinyl	Vinyl around the acrylic
Locking	—	Attached to frame
Pump (Testing)	Wall vacuum with regulator	Used at Practice Point

The following are the testing performed to validate the small scale prototype:

- Sealing & CNAP Test
- Emergency Removal Time Test

The up-to-scale prototype was made to test the CNAP maintenance at a larger scale and the device's performance. It can be seen in Figure 41. This prototype was made considering the dimensions of the bed and circumference of an obese patient—given by the sponsor. It has a length of 33in, a width of 16in, and a height of 21in. The prototype is made of a polycarbonate shell that is clasped onto a wooden frame. The sides are filled with a flat sheet of neoprene. Since, the testing is focused on the maintenance of CNAP in an up-to-scale device, there is no hole to fit the patient and all connections were sealed with silicone caulk. The materials used for each subsystem can be found below (Table 30).

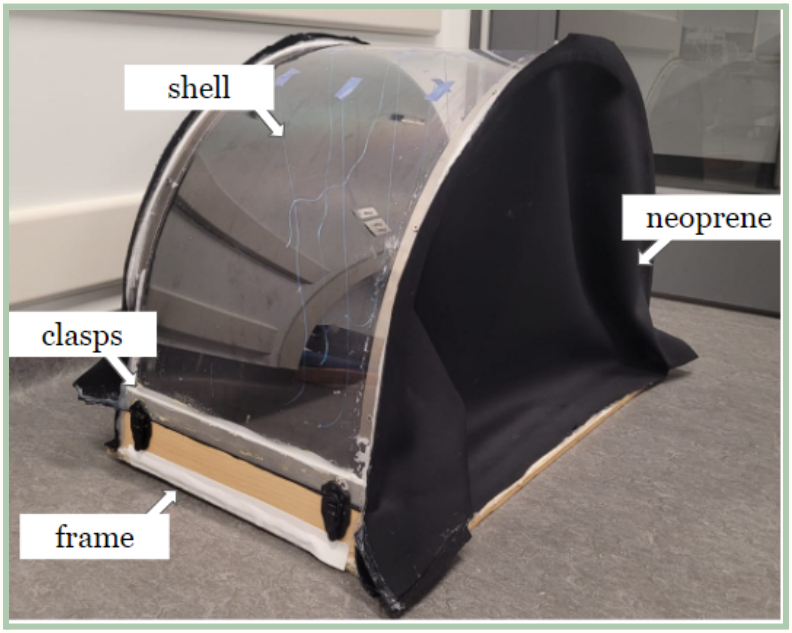


Figure 41: Up-to-Scale Prototype.

Table 30: List of Materials & Methods of Up-to-Scale Prototype

Subsystem	Material	Method/Observation
Shell	Polycarbonate Aluminum U-channel	Molded with stainless steel rod
Sealing	Neoprene Glue + Silicone Caulk	Cut to size Glued neoprene to shell
Frame	Wood rectangular prism Wood Board	Cut to size of the shell
Locking	Metal Clasps	Drilled to frame and shell
Pump (Testing)	Wall vacuum with regulator	Used at Practice Point

The following are the testing performed to validate the small scale prototype:

- Sealing & CNAP Test
- Performance Test
- Weight

5.2 - Small-Scale Prototype

The creation of a functioning small-scale prototype isolated the sealing mechanism to maintain CNAP along with testing the assembly time, removal time, and validation of the internal pressure gauge. In this section, the iterations made for a working small-scale prototype to be applied to a full-scale prototype will be explained.

5.2.1 - Gauge Internal Pressure

The first internal pressure gauge used for testing was a digital manometer, represented by Figure 42, to record the amount of pressure being achieved within the small-scale prototype. This digital manometer was originally utilized during the initial phases of testing, however inconsistencies insinuated a need for validation on its ability to provide accurate readingsThe polypropylene plastic container POC cycled through multiple rounds of testing using the digital manometer to visualize the targeted pressure range between -10 cmH2O and -30 cmH2O, as seen in Sections 4.6.2 and 5.1.2. Validating the digital manometer first occurred with the use of Practice Point's wall vacuum O2 that was connected to a regulator. The regulator provided the freedom for manual pressure adjustment. This setup allowed the amount of pressure being released from the wall vacuum O2 to be visualized on the digital manometer for direct comparison with the regulator. The conclusion of these experiments suggested the digital manometer was reading a 15-25 cmH2O difference from the regulator. Because the device handles such a small amount of pressure a very precise and accurate manometer within the correct range of vacuum was necessary. This particular gauge had not been calibrated since 2013.

Figure 42: Digital Manometer (Units in cmH2O).

After concluding the digital manometer did not work properly, a U-tube differential manometer was created. A peg board, zip ties, water, and plastic tubing were used to create the device, as shown in Figure 43.

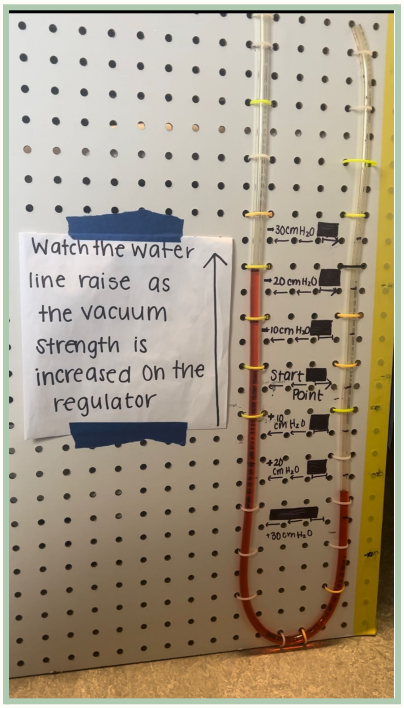


Figure 43: U-Tube Differential Manometer: With and Without Pressure.

5.2.2 - Continuous Actuation

Initially, a velcro sealing test was conducted with a plastic cylinder container, velcro and neoprene. Velcro was lined around the perimeter of the plastic container and adhered to the neoprene. The opening of the container was sealed with the remaining neoprene flaps. The digital manometer and wall vacuum O2 tubings were placed inside the container to test the sealing of the velcro and neoprene against the cylinder container. From the testing, a pressure of -30 cmH2O was thought to have been achieved with velcro being a main component for the sealing mechanism. However, this test did not properly test the application of the sealing mechanism to the full scale model as the neoprene was the main component creating the seal. Figure 44 represents the set-up for the plastic cylinder container with velcro sealing test.

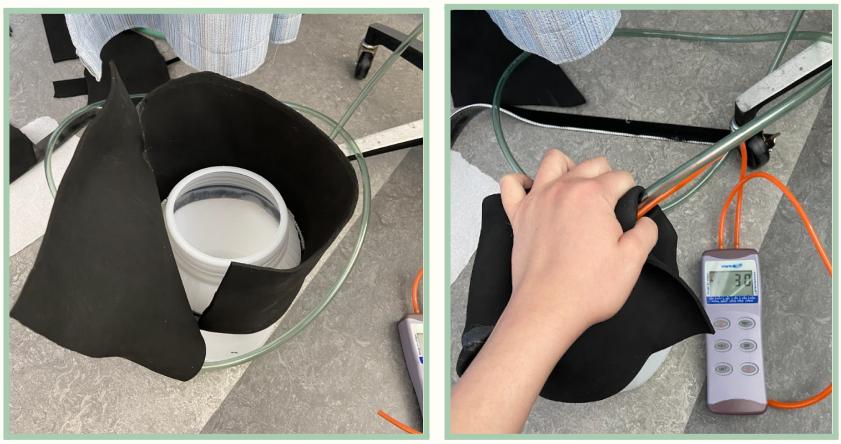


Figure 44: Plastic Cylinder Container with Velcro Sealing Test.

Unfortunately, the initial velcro test presented misleading results. The velcro was applied onto a small-scale prototype and it was re-tested using a water submersion test. Once the small-scale prototype was submerged into a bathtub filled with water, the internal area of the prototype filled with water. This confirmed the velcro had not been a proper sealing mechanism for the interface between the shell and neoprene. Figure 45 depicts the progression of the water submersion test using the small-scale prototype.

Figure 45: Water Submersion Test Using Small-Scale Prototype.

A final test for the sealing mechanism between the shell and neoprene was developed by creating a gasket seal. A laser cut arc was created to be permanently adhered to the neoprene, with an interlocking casing to be adhered to the shell. This served as the mold for the gasket to interlock with to create the airtight seal. The gasket was created using a mixture of All Purpose Silicone 1 Sealant, cornstarch, and food coloring. Figure 46 represents the outcome of mixing the silicone sealant and cornstarch together with a mild use of food coloring to add some color to the gasket. The silicone sealant releases a heavy amount of acetic acid when combined with cornstarch which acts like a catalyst to thicken the compound and increase the curing process to create an airtight rubber gasket. Figures 47 and 48 illustrate the gasket shape that was molded on the laser cut acrylic pieces.

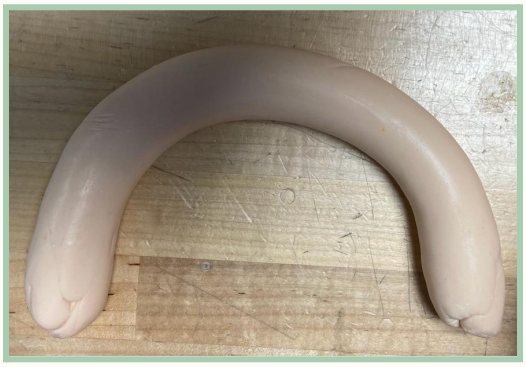


Figure 46: Combination of Silicone Caulk and Cornstarch.

Figure 47: Silicone Rubber Molded to Acrylic Gasket Part.

Figure 48: Gasket Shape Formed to Acrylic Gasket Mold.

Once the rubber gasket cured in the acrylic mold for a total of 15 minutes, the gasket was assembled onto the small-scale prototype and tested. Figure 49 represents the gasket sealing mechanism on the ends of the shell. Testing for this gasket occurred with the use of the vacuum pump and verified with a U-Tube Differential Manometer. The small-scale prototype accomplished a seal of -10 cmH2O to -30 cmH2O.

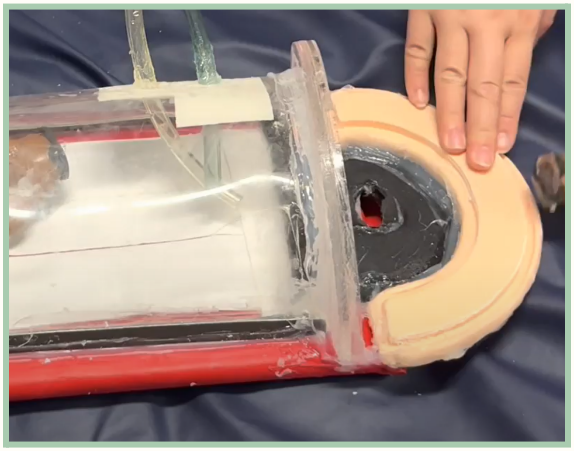


Figure 49: Gasket Sealing Mechanism Secured on Shell.

A series of three trials were performed using the final iteration for the small-scale prototype to obtain data on its sealing capabilities. With each test, the Practice Point's wall vacuum O2, regulator, and U-tube differential manometer were used to determine the amount of time it took for the device to reach -30 cmH2O. The regulator was set to 95 mmHg for each trial and the time for the device to achieve -30 cmH2O was recorded with a stopwatch. The table below, Table X, represents the data gathered for each of the three trials:

Table 31: Small-Scale Prototype Sealing Test

	Regulator Pressure Set Value (mmHg)	U-Tube Manometer Value (cmH2O)	Time for Device to Achieve -30 cmH2O (seconds)
Trial 1	95	-32	49.62
Trial 2	95	-30	36.21
Trial 3	95	-31	19.17

The data was further analyzed using MATLAB to obtain a simple statistical analysis of the tests. The written code for the analysis can be found in Appendix E. The following results from the statistical analysis represent the mean, standard deviation, and range for each system involved in testing including the U-tube differential manometer, regulator, and total time of performance. Table 32 represents the determined results. A graph was also created using MATLAB to easily visualize the data after it was collected as shown in Figure 50.

Table 32: Statistical Analysis of Small-Scale Prototype Sealing Test

	U-tube Manometer	Total Time
Mean	-22.80 mmHg	35.00 seconds
Standard Deviation	0.74 mmHg	15.26 seconds
Range	1.47 mmHg	30.45 seconds

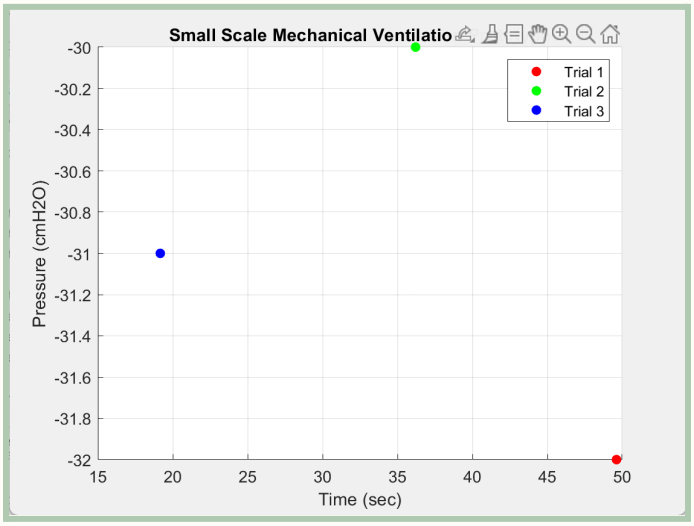


Figure 50: Graph of the Three Vacuum Test Trials for the Small-Scale Prototype.

5.2.3 - Assembly Time

Utilizing the small-scale model, the assembly time of the device was determined to be 2 minutes. Only two people were needed to assemble the prototype. The red colored mattress was permanently fixed to the shell for the purpose of creating a seal, but would be removable using latches in the full-scale prototype. The mock patient would be placed through the shell and the gasket would attach through the mock patient's torso and legs. Sealant tape was used in replace of a snitch strap to ensure an airtight seal around the device.

5.2.4 - Removal Time

The removal time of the device from a patient in an emergency situation was still considered even though the device testing was on a small-scale prototype. The model was able to be fully removed in 30 seconds and the chest was able to be accessed in 10 seconds.

5.3 - Up-to-Scale Prototype

5.3.1 - Frame Development

The initial full-scale prototype included 80-20 T-slotted bars built as a rectangular frame, as shown in Figure 51. This frame provided a secure base for the shell to latch onto and for the physician to easily transport the device with the side handles. During testing, there were visible leakages coming from the frame and a seal was not properly formed despite the gaskets. There were too many ridges and corners on the 80-20s, causing many sources of errors.

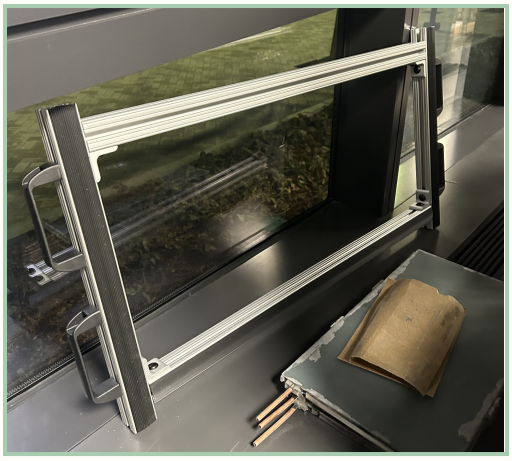


Figure 51: 80-20 Rectangular Frame.

During the initial build of the up-to-scale prototype, there were noticeable gaps between the 80-20s and the shell interface. Foam inserts were cut to shape to fit into the corners of the interface to minimize air leakages when the device was tested, represented in Figure 52. However, this method did not rectify the air leakage problem.

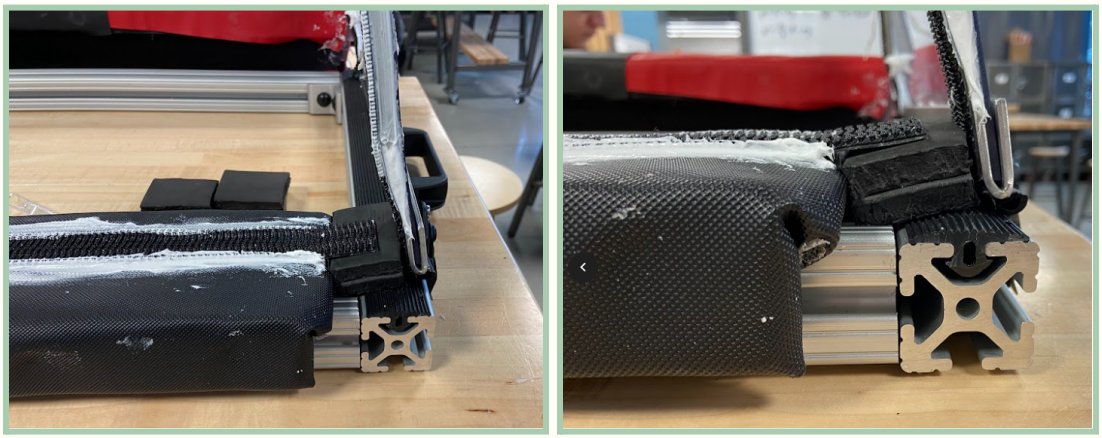


Figure 52: Foam Inserts to the Corner of the Shell.

The team then decided to remove the middle 80-20s that were connecting the sides of the frame and replace it with a flat sheet of plywood. The plywood was originally too large in width and too small in length; therefore, a piece of the plywood was laser cut and reattached to fit the length of the shell, as shown in Figure 53.

Figure 53: Plywood Base for Device (Minus Velcro).

The plywood was a successful addition as the shell base simply for its lightweight material and cost efficiency due to the budget the team had left for the project. Additionally, the idea of using a flat sheet of plywood would simulate a similar approach as to when patients go into cardiac arrest and

would need a CPR cardiac board placed before receiving compressions. Furthermore, although plywood is considered to be a reliable air-barrier, the team still added coats of polyurethane in order to fortify this characteristic. The 80-20s were screwed into the wood sheet, as seen in Figure 54. Additionally,a hole for the pump was tapped to prevent leakages.

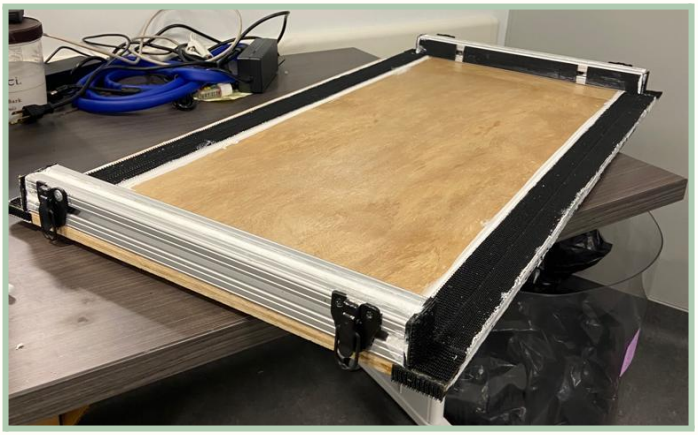


Figure 54: New Frame with 80-20s Screwed Into Wood Sheet.

The open slots of the 80-20 were filled with a gasket, silicon caulk and the ends were covered with neoprene in order to ensure sealing. However, after testing with a new shell and neoprene and still not getting reading in the manometer, the team decided to troubleshoot the pump's connection with the 80-20s. When a piece of paper was directly connected to the tube of the pump it would be sucked in; however, once the tube was connected to the 80-20 tap, the vacuum force on the paper would decrease significantly. This could be due to the slots in the 80-20s decreasing the amount of vacuum actually acting in the main area of the shell. With that, the 80-20s were replaced with wood rectangular prisms.

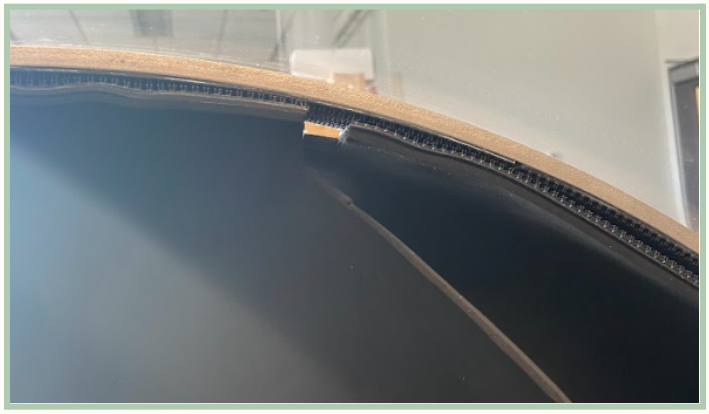
Wood was used to replace the 80-20s due to time constraints and ready availability. The pieces of wood were cut to the size of the frame. Then, two holes were drilled for the manometer and a pump, respectively and the clasps were attached to the wooden frame. These prisms were then glued onto the wood base. Pro-tape was placed in the intersection of the wood frame and sheet on the inside while the outside of that intersection was lined with silicone caulk.

5.2.3 - Sealing Development

Initially, the sealing mechanism was made with a large piece of neoprene that would be attached to the shell with velcro and tightened around the patient with straps. The velcro would be connected on the inside of the shell as seen in the Figures 55 below. However, the team found there were sealing

issues where neoprene connected with neoprene on the top of the shell as well as the intersection between the 80-20 frame and shell, which can be seen in Figures 56 and 57, respectively.

Figure 55: Neoprene Connected to the Shell Through Velcro on the Inside of the Shell.



Figures 56 and 57: Sealing Holes at Neoprene Connections on the Top of the Shell and Intersection with Frame, respectively.

Since this system did not hold a vacuum, the team decided to change the velcro connection between the neoprene and shell to the outside of the shell. In order to do that velcro was attached to the other side of the neoprene with the use of nitrile rubber and velcro was attached to the outer edge of the shell. Additionally, to provide a better transition between the neoprene inside the shell, foam was added in the form of an arc, as seen in Figure 58. This foam was then lined with silicone caulk to prevent further leakage. Initially this new sealing method was tested with just the shell and the wood sheet—if successful, the team would adapt the frame to the method. The wood sheet was lined with velcro as seen previously in Figure 53. The testing of this method also did not result in the needed vacuum.

Figure 58: Foam Arc Added to Corners of Shell.

After performing a drown test with the small prototype and concluding that the velcro is not as airtight as this project requires, the team decided to simply use glue and silicone caulk to attach the neoprene to the shell. This is because the team did not have the manufacturing abilities to make the gasket used in the small prototype at the needed scale. To provide a better sealing, the team decided to use a flat sheet of neoprene—such as the one used on the smaller prototype. Considering this prototype would provide an ideal situation (with no hole for the patient), the neoprene was glued to the shell and frame edges as well as the edge of the wood base. The final up-to-scale prototype can be seen in Figure 59 below.

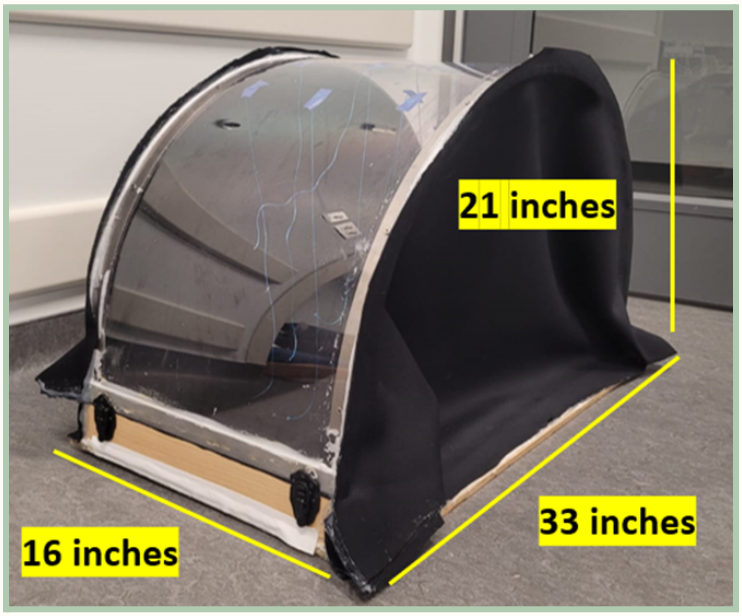


Figure 59: Final Up-to-Scale Prototype Design.

5.2.3.1 - Additional Sealing Troubleshooting

After the success of the small-scale prototype in holding a vacuum, troubleshooting was conducted on the full-scale prototype to try to obtain a pressure reading of -10cmH2O to -30 cmH2O, and to see if the pressure could be maintained within the prototype while the device was off.

While the large scale prototype had visible signs of drawing a vacuum, the manometer did not indicate a pressure differential. This demonstrated that significant leaks still existed in the device, despite sealing it with silicone caulk. Due to the success of the gasket putty maintaining an airtight seal in the small-prototype, it was adapted on the full scale to the interface between the neoprene and the shell. After this, the full scale mockup was able to reach -10 to -30cmH2O.

The significant difference in performance indicated the exposed form edges of the neoprene may also have led to leakage. Leakage was also heard at the corners of the prototype with the use of a stethoscope. In order to further detect leaks, incense was held up to different areas of the device to see visible smoke entering the device indicative of a leak. This method further verified leaks at the corners of the device. Proto-putty was then applied to cover these exposed edges and corners, as seen in Figure 60.

Figure 60: Proto-putty Encasing Edges of Neoprene.

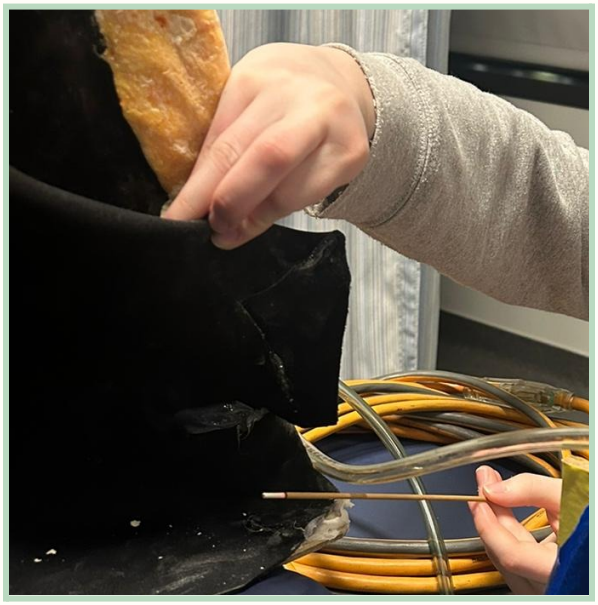


Figure 61: Conducting Smoke Test.

To protect against additional leakage that a wooden frame and base may be causing, a plastic sheet was glued to the bottom of the base board, with its edges encased in the gasket putty. The plastic was also applied to exposed areas of the wooden frame.

Figure 62: Plastic Sheet Covering Wooden Frame.

A stopcock was also integrated into the pump subsystem because the vacuum-regulator system drew vacuum out of the device when turned off. Thus, the stopcock allowed the vacuum to be cut off without that problem occuring.

Figure 63: Picture of Stop Cock.

For this iteration, a vacuum of -30 cmH2O was maintained for 10 minutes, for 3 trials. The exact measurements can be seen in the table below.

Table 34: Large Prototype Gauge of Internal Pressure

Trial	Pressure (cmH2O)	Time (minutes: seconds)
1	-30	10:11
2	-30	10:03
3	-30	10:07

5.2.4 - Gauge of Internal Pressure

The internal pressure of the device was determined using the U-tube manometer. The water in the tube was dyed red to make the change in water height more visible against the white background of the pegboard. A regulated vacuum pump, set at -200 mmHg was attached to the device. After an average of one minute and 12 seconds, the device reached -30 cmH2O, at which point the regulator was

reduced down to -40 mmHg to maintain the pressure. This test proves that the full scale prototype of the device meets the requirement to reach the desired pressure in under ten minutes, and can maintain the required pressure.

5.2.5 - Device Weight

The weight of the device is 22.2 pounds or 10.07 kg. Due to its low weight, the device is easy to maneuver and can be transported by two individuals.

5.2.6 - Patient Comfort

In order to determine patient comfort, members of the team laid on the frame for several minutes. Despite being stiff the neoprene added a layer of cushion to the plywood, making the frame relatively comfortable.

Chapter 6: Final Device and Validation

The team was given many functional requirements in order to develop the device. Different iterations were made and tested with the goal of fulfilling those specifications. The final device would imply the features of the small prototype are scaled up to the full size. This would include the silicon based putty scaled up to the size of the bed and torso for use on real patients. Given the time and financial constraints of this project, that was unable to be acheived on the full scale. However, the mockup shown in Figure 64 below illustrates the implementation of the technology developed for patient use. This chapter validates the final design in terms of the user requirements provided by the client. The objectives are presented in order of importance below along with an explanation of how they were accomplished. Additionally, the economic, societal, and ethical impact of the device are explained.

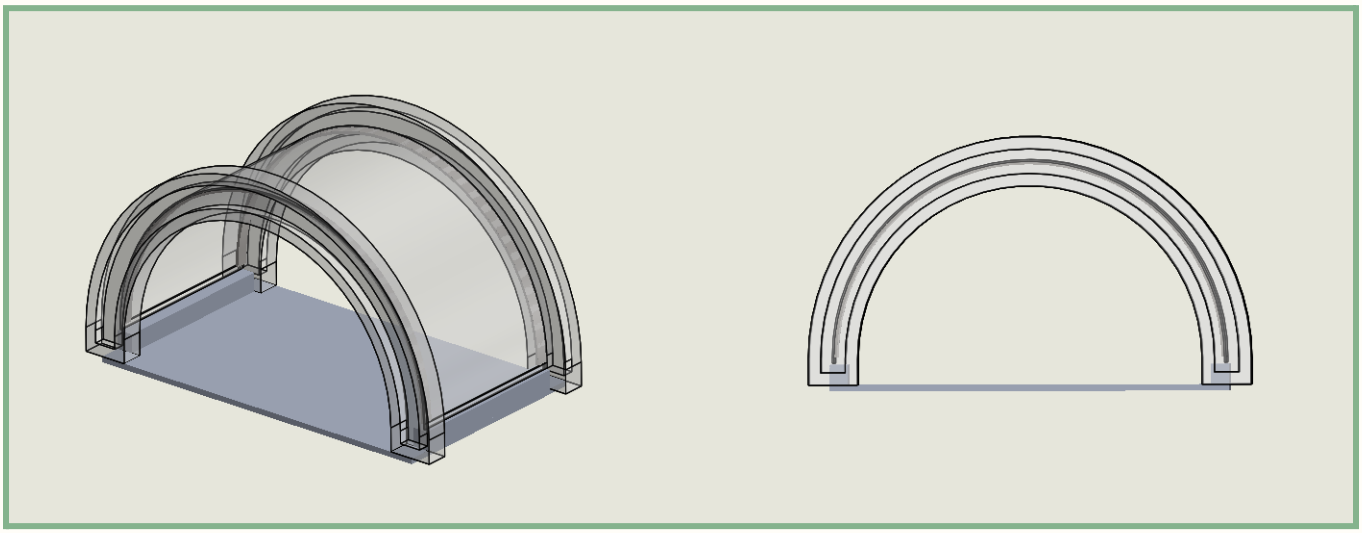


Figure 64: Model of Final Device.

6.1 - Maintain CNAP

The client and team deemed maintaining CNAP as the most important objective, in order to allow sufficient ventilation to the lower chambers of the lungs and reduce stress on the upper chambers. As a refresher, Maintaining CNAP was defined in Table 4 as:

- Creating a continuous negative abdominal pressure gradient of -10 to -30 cmH2O to maintain a tidal volume of 500mL
- Functioning in tandem with a PPV

Each of these components of the objective will be assessed to determine whether the prototypes meet these specifications.

6.1.1 - Creating a Negative Pressure Gradient CNAP of -10 to -30 cmH2O

Both the small-scale and full-scale prototype can maintain a negative pressure reading of -10 to -30 cmH2O, as indicated by the previously validated u-tube. The significance of this achievement on the small-scale prototype is that the method for accessing the patient does not interfere with the device's ability to maintain pressure. The significance of this achievement on the full-scale prototype is that it is possible to create a vacuum chamber up to scale with the components of two neoprene sheets, a frame, and a polycarbonate shell. Since the putty was significant in sealing leaks in the small-scale device, using it as a gasket on a larger scale was a viable method for achieving vacuum.

6.1.2 - Functioning in Tandem with a PPV

On the small scale model, it was demonstrated that the device will seal to the patient's chest, leaving their face exposed. This provides doctors with the capacity to intubate with a PPV in tandem with the device. Since a constant negative pressure is applied, this will not interfere with PPV or diminish its effectiveness.

6.2 - Accessibility: Doctors

On the small scale model, the device can be removed in 10 seconds to access the chest in the case of an emergency. If scaled up to the size of a hospital bed, it would completely satisfy the needs presented by the client.

6.3 - Performs for Maximum Treatment Time

To determine whether or not the large device could maintain CNAP for the maximum treatment time, the team ran a series of tests. Due to the time constraint, the team was unable to test the device for the maximum treatment time of six-hour intervals for a matter of four weeks. As a result, the team opted to run the device for one hour, checking the pressure in the shell at regularly scheduled intervals, in order to partially validate the device.

6.4 - Cost

The affordability of the final device was another requirement for the team. Although the client did not specify a maximum price, the goal was a cost-effective design and expenses for testing within the $1250 the team was allotted for this project. The small scale prototype had a cost of $31.83. When considering the up-to-scale prototype, the team spent $345, since the group took advantage of free materials at WPI (the bill of materials can be found in Appendix B). However, in a manufacturing environment, the device would cost $941.13 (BOM can be found in Appendix B). When considering the manufacturing process of the device, the price for labor will be added in addition to improvements recommended in Chapter 7. Furthermore, when purchasing some of these materials from manufacturers, the team contacted the shops and managed to get discounts, which helped decrease the overall price. In the future, it is recommended that those parts should also be bought from manufacturers in bulk to assist in decreasing prices. Overall, these improvements and recommendations will add to the price; however, considering the competitive price is approximately $10,000 (Exovent), the device will still be more affordable and accessible.

6.5 - Adaptability to Hospital Beds

One of the additional requirements for the device for its adaptability to hospital beds. The large scale prototype was specifically measured to fit and be adaptable to various ICU hospital beds. Its device size of 33in x 16 in x 21 in allows for 3 inches of extra space on each side of the bed for adjusting the device. Each of the goals were met from the previous Function and Means in Section 3.5. The large scale device was able to be securely attached to the edge of the ICU bed to prevent the device from moving around when connected to a patient.

6.6 - Adaptability to Different Patients

This device lacks in its adaptability to different patients. Since the neoprene can be removed between patients, having multiple different sized neoprene sheets is not a problem for ease of use. It will however incur more cost. Nonetheless, this was the most practical outcome considering the team's time frame and budget.

6.7 - Ruggedness

In chapter four, the Ruggedness objective was defined as the device's ability to withstand excessive force to a reasonable extent. Both the small-scale and full-scale prototypes were able to withstand a vacuum of -10 to -30 cm H2O, which is the range at which the device will be performing. Leaning on the large scale device, moving it around on and off the bed, resulted in no harm coming to the device. In the end the large-scale device did break as the original wooden base consisted of two pieces of wood glued together. Due to the strain caused by the repetitive use of the vacuum, the glued seam snapped. However, the large scale prototype was fixed by reapplying glue to the broken seam and then screwing a new piece of plywood to the existing base, in order to make the glued seam more secure. When another piece of polycarbonate was dropped, bent, and stepped on, the material did not break, showing the ruggedness of the shell.

6.8 - Robust Design

Another requirement for the device was to have a robust and rugged design, which was accomplished through the chosen materials. Polycarbonate was chosen for the shell as it is sturdy and scratch resistant with high tensile strength in addition to a metal frame. Therefore, if the device were to be knocked off of the hospital bed, little to no damage would occur to the device. Any additive components were minimized to ensure the design was efficient for manufacturing implications, and, therefore robust

6.9 - Time to Assemble to Patient

Device assembly time to the patient was another requirement in the development of the device that was achieved with designing the device in a robust fashion. Specifically for the small-scale prototype, the frame, the neoprene, and the gasket would be one full component and the shell would be

the second component. Patient assembly time would be significantly shorter given that the first frame component would slide underneath the patient and the shell would only have to be latched onto the frame along with snapping the gasket into place. With a time of 2 minutes for assembly of the small-scale prototype, the assembly for the full-scale prototype would also be achieved in a considerable time frame.

6.10 - Patient Comfort

While not one of the top priorities due to the statement of the patients using the device because they are anesthetized, comfort was still considered in the team's final design. The client had no requirements for patient comfort because the patient is intubated, so the measurements were made subjectively by the teammates. The team found the device objectively comfortable, and more importantly, it is not at risk of harming any patient who is intubated in that position for a substantial amount of time.

6.11 - Project Impact

6.11.1 - Economic Impact

The device could potentially decrease the energy bill from the electricity used by PPVs. Since hospitals leave their machines on 24/7 and treatments with PPVs can last weeks or months, any small decrease can benefit the hospital. Additionally, positive-pressure mechanical ventilators cost around $25,000. This device does not exceed $1,000, even when adapted to manufacturing implications. According to one source, the markup on medical devices is typically 20 - 30%, making the highest selling price $1300 (Hage, P, 2019). Furthermore, although this treatment will add to the PPV cost as it is used in tandem, it will help prevent ventilator-induced lung injuries. Therefore, it is worth investing in this treatment as it will improve the patient's quality of life and potentially prevent further treatments due to VILI.

6.11.2 - Environmental Impact

The primary materials of the device, polycarbonate and aluminum, are both recyclable and readily available. Since the device does not require complicated electronic components and is made of sturdy materials, it will last a number of years when properly handled. A caveat of the materials is the neoprene sealant. Wetsuits, also made of neoprene, usually last four to ten years (Admin, 2017). Their

longevity also depends on the frequency and duration of time they spend underwater. The neoprene for the device will only potentially be submerged for washing. However, neoprene is not recyclable (Wetsuits, 2019). Further research must be conducted to see if worn-out neoprene for the device can be repurposed for new sealant fabric.

The device consumes little electricity. Despite the use of an external vacuum pump that requires electricity, the range of vacuum required by the device is so small in comparison to other medical devices, less electricity is consumed. This makes the device beneficial to places that have less electricity available.

6.11.3 - Societal Influence

Obese patients have a difficult time relating to the healthcare system as medical tools, devices, and treatments are often not made with the needed adaptations to fit those patients—consequently, they receive a lower quality of care. Ventilator-induced lung injuries (VILI) are more common in patients with predisposed respiratory issues, such as obese patients. Considering that the target population of this device is obese patients and the dimensions made for a wide range of this demographic, there should be no difficulty with providing this treatment. This should prevent stress and discrimination in the hospital setting while still providing quality care. On the other hand, other groups could benefit from this device, such as people with heart conditions and other respiratory issues. Considering the simple functionality of the device, the dimensions could be changed in order to accommodate these other groups.

The device is minimalistic and robust, which allows it to be easily accessible and intuitive to use. This simplicity can reduce the stress in a hospital environment where doctors, nurses, and respiratory therapeutics have to deal with diversified conditions and varied medical devices. Additionally, this device is helping to prevent VILI and lowering the pressure used by the positive pressure ventilator (PPV) by maintaining a small range of negative abdominal pressure. With that, there should be no major complications if the device is misused as it is there to assist the PPV treatment.

Current patents exist for other devices that induce a negative-pressure environment around a patient's torso to facilitate ventilation. Unfortunately, many of these devices have not been manufactured and tested, or they require a special hospital bed in order to function, making them expensive. The device described in this paper is meant to support ventilation in tandem with PPV, rather than fully facilitate it. This device is also made of sturdier materials, while some competitors designs consist mostly of fabric in their patents. It can also be used with all standard hospital beds. The

device is built off past patents to create one that is more functional and more easily applicable to many hospital environments.

6.11.4 - Political Ramifications

When considering the device's use on a global scale, it is important to consider other countries' cultures, populations, and conditions. This device was made considering the United States, which has an obese population of 42.4% (Brock et al. 2021). However, when considering other countries where obesity is not as prevalent, some changes would have to be made about how the device is made and marketed. Due to the device's simplicity, most of the design changes would be in the dimensions and materials. The dimensions would be modified to address the range needed by the specific population, whereas the materials would be changed to what is most available and abundant in that area.

One of the device's advantages is that the vacuum created has a minimal range; therefore, many plastics and other materials can be used to sustain that vacuum. The most difficult part of producing locally would be the sealing mechanism. Neoprene is more expensive and might not be as available in different areas. Overall, the device's subsystems can be adaptable while also maintaining CNAP. In Mexico, for instance, 73% of the adult population is overweight or obese; therefore, the device's main focus can still be improving the quality of treatment for obese patients (Gurria, 2020). On the other hand, in India, the percentage of obese people is around 20% of the population, which means that the device can be marketed to assist those with heart and respiratory diseases (Kanwal, 2022).

6.11.5 - Ethical Concerns

The goal of this device is to reduce the number of ventilator induced lung injuries in obese patients. As a result, the team wants to ensure that the device works properly and is safe to use. After testing the device and thoroughly researching how lungs work, the main ethical concern is if the negative pressure ventilator reaches an internal pressure greater than -30 cmH2O, it could cause the patient's lung to collapse/pop. To resolve this issue, a pressure gauge is attached to the device regularly to make sure it is in a safe range.

Another ethical concern the team came across is in regards to where the device is manufactured. It is important that the polycarbonate shell is produced in a facility that is well ventilated, as when the polymer is heated it releases toxic fumes. The other concern is manufacturing facilities all over the world do not necessarily have the same safety standards as the United States, resulting in individuals receiving low pay, working long hours in poor conditions, and not receiving health benefits. To ensure

the finalized device is produced in an ethical and safe way, the team will handpick the manufacturing companies to produce the product.

6.11.6 - Health and Safety Issues

As mentioned previously, the device being at such a low cost means it will most likely be accessible to patients from various socio-economic backgrounds. However, this would only be within the regions in which the device would already be available. No investigation has taken place -into how to manufacture the device in places where all the materials may not be readily available. Therefore, the device may not be available in lower-income countries.

Considering that obese patients are more likely to face adverse effects from standard PPV, the device will address a specific health disparity in its purpose to minimize these effects. The device will also benefit patients suffering from heart failure or a big heart, another group likely to face adverse effects from PPV.

The current research and proofs-of-concept demonstrate no difference in treatment between men and women. However, the device may not be suitable for pregnant women since a negative pressure environment is induced around the abdomen. The device currently has not been sized in a range suitable for pediatric patients. However, obese children are more at risk for experiencing negative effects from PPV, since they have smaller lungs and a smaller heart. Due to this need, the team recommends that if the adult-sized device succeeds, child-sized versions are made.

6.11.7 - Manufacturability

The full-scale prototype was made out of plywood, 2 by 4 wooden beams, polycarbonate, steel, polyurethane, industrial grade shrink wrap, proto putty, neoprene, and concrete vapor plastic. These materials were obtained from home, Joanne's Fabrics, and Home Depot. The shell itself was manufactured at Quality Fab. The wood was cut using a laser cutter and drilled based on the requirement needed.

Overall, most of these materials, such as the wood and shrink wrap, are not ideal for manufacturing the device to be put on the market. This is because most of these materials do not meet the FDA guidelines for medical grade materials. As a result, new materials should be selected, and a proper manufacturing method should be developed, as the team did not have the money or access to these tools. With a basic knowledge of manufacturing the team believes that the device that will be put on the market should have a machined frame, plastic injected molded gaskets, higher quality neoprene,

and stronger metal clasps. In the future, manufacturing companies should be addressed and supply chain experts should be contacted as well to determine if this would be the correct course of action.

6.11.8 - Sustainability

When it comes to sustainability of a device it can be looked at from two perspectives, the waste produced from the manufacturing/shipping of the device and the longevity of the device. In terms of manufacturing and shipping, there will be a high amount of waste produced when production begins, as the theme will not have the resources to mass produce and ship the product. However, once the device begins to sell on the market, the manufacturing can improve and become more automated, reducing waste. Waste produced from shipping will reduce as well, since hospitals will be able to make orders in bulk.

In terms of the longevity of the device, the team predicts that it will last for about ten years based on how frequently it is used. Replacements to certain aspects of the device such as the neoprene and the vacuum pump may need to be replaced after four to five years if the device is frequently used. However, this will not pose a problem as the neoprene is detachable and will come in a variety of sizes to adapt to patients. The pump will be detachable as well so it may also be replaced if necessary.

Chapter 7: Discussion

This chapter analyzes the results of the prototype development and testing, and its more general implications. Limitations faced during prototype development, suggestions for manufacturing, and a market comparison for the final design are all discussed.

7.1 - Limitations

In this subsection, the limitations faced in achieving each of the set objectives are discussed.

7.1.1 - Maintain CNAP Limitation

In regards to CNAP maintenance, the results did not demonstrate the full scale model in its fully assembled form with all of the subsystems put together. CNAP was able to be achieved in both fronts, with different components isolated in each design. The limitation of time and finances to scale up the ultimately maximized sealing mechanism did not allow for the idealized metal frame and perfected gasket to be adapted to the full sized model. Section 7.2 fully addresses the improvements for maintaining CNAP the recommended manufacturing of the ideas confirmed as successful by this project.

7.1.2 - Patient Comfort Limitation

Due to the fact that the patient is intubated during the use of the device, the patient's comfort is not the most important objective. Nonetheless, a full body frame was added to the final design to maintain a full seal, so for the full scale model, a wooden panel would not be safe for the patient to lay on for 3-4 weeks. If it were to mock the small scale prototype, with a foam covering and vinyl on top, it would be more comfortable. Similar technology would be needed in the full scale model.

7.1.3 - Time to Assemble to Patient Limitation

The client expressed that the assembly of the device should be intuitive and take a maximum of ten minutes. There were no specific tests that demonstrated this assembly in the up-to-scale model. There was a limitation in regards to manufacturing processes, time, and budget that did not allow for the demonstration of this feature. Considering the Pairwise analysis (table 5), the maintenance of CNAP and other requirements were at a higher priority for the team. Ideally, considering a design with the

gasket from the small prototype, the frame and shell of the up-to-scale prototype, and how these subsystems go together, the assembly of the device should take less than 10 minutes.

7.1.4 - Robust Design Limitation

Due to the device being used in a hospital setting, as well as on more than one patient, the device needs to be sterilized between uses. Since the prototype of the device is not made from medical grade materials, such as wood, it can not be sterilized in any of the ways that meets hospital standards. Ideally the shell and frame of the device would be able to be sterilized with the use of ethanol alcohol between uses or steam autoclaving. In terms of the neoprene it would detach from the device and be machine washable.

7.1.5 - Ruggedness Limitation

When the 8020's were found to be an ineffective outlet for the vacuum, it was determined that the frame pieces had to be substituted with another material. Due to time constraints, the only available material was wood. While this better facilitated the flow of the vacuum, it decreased the ability of the frame to withstand excessive force. Ideally, the frame of the device would be made of a durable metal, such as aluminum or steel. The baseboard and the frame would also all be one piece, to decrease the chances of breakage where different parts are adhered.

7.1.6 - Adaptability to Different Patients Limitation

The prototype cannot fit patients who are larger than 33 inches from side-to-side, which could potentially be the case for extremely obese patients. Treatment may also not be effective for patients with very long torsos, since the device may not be applying negative pressure everywhere from their chest to their pelvis. Human testing was also not conducted due to the timely process for approval while energy could be spent further developing the device. While the dimensions are devised based on what was researched to be the most accessible within the obese population, human testing could be conducted to validate this research. Human testing could also help find out if creating multiple-sized devices is worth the investment and determine the sizing of different neoprene sheets.

7.1.7 - Adaptability to Hospital Beds Limitation

The final large scale prototype did not have a connection to the bed, due to the sealing of the device. While the determined strapping to underneath would work, some hospital beds have machinery

underneath that may prevent this. A larger study of hospital beds would need to be conducted in order to determine whether the straps would be sufficient in nearly all scenarios.

7.1.8 - Cost Limitation

The design of the full-scale prototype was significantly limited by the budget the team had remaining which is a reason why the small-scale prototype focussed on achieving working mechanisms for the additional requirements and goals of the project. The cost for the purchase of the full-scale prototype shell and the cost to mold it had decreased ⅕ of the team's budget. Additionally, the device required multiple iterations to be created and tested which required strategic budgeting in the types of materials that were chosen for the prototypes; therefore, the team was unable to select higher quality materials for the device. Idealistically, the gasket sealing mechanism would be plastic injection molded, but due to the budget limitations, that was not possible. Furthermore, the team was unable to obtain a working digital manometer, so they created their own U-tube differential manometer. Multiple times, there were extra materials found not in use that were repurposed for the goal of a working prototype.

7.1.9 - Performs for Maximum Treatment Time Limitation

Due to the time constraint, the team was unable to test the large scale device for six hour intervals, with two minute breaks, for a total of four weeks. As a result, the large-scale prototype was tested for an hour to ensure it maintained -30 cmH2O for a prolonged period of time.

7.1.10 - Accessibility Limitation

One major limitation in accessibility to doctors is that it may take two doctors to remove the shell entirely from the patient given clasps were administered on both sides of the shell as opposed to hinges. Despite this limitation, the doctors are able to access the patient in an emergency situation relatively quickly and successfully. After consulting our client, noting that it may take two medical professionals to remove the device entirely was not a drawback.

7.2 - Manufacturing Suggestions

Considering the limitations found in the section above, the team proposed a few manufacturing suggestions based on each subsystem.

For the shell, the team still recommends the use of polycarbonate. The use of stainless steel rods for the molding of the shell is also recommended because they are stronger than aluminum and will help the polycarbonate maintain shape. However, the stainless steel used should be medical grade and attached to the outside of the shell so it does not come in contact with the patient. Additionally, the aluminum u-channels at the edge of the shell should be made to fit perfectly the thickness of the shell while also being medical grade steel.

Another manufacturing suggestion is to have the frame of the device be machined together. By having a machined frame, the slides would be a uniform length and fit the hospital bed and attach to the shell with little to no error. The frame should be made from solid aluminum as it is both lightweight and durable. Despite being more expensive, the machined frame would be more airtight, making the device more efficient overall.

Further manufacturing suggestions include plastic injection molding the gasket material. In a manufacturing setting, it would be best to have standardized parts. Plastic injection molding would provide that standardized part for each device created. This solution, however, could increase the cost of the device significantly given that plastic injection molding cost is determined by the material cost, manufacturing cost, overhead cost, profit, tax, and technical value. Another suggestion for the gasket seal production could be using rubber compression molding. The cost of this process would range between $750 - $1500, a more reasonable price than plastic injection molding.

Regarding the locking mechanism, it is important that any fasteners be fully tapped, vacuum greased, and attached in a completely airtight fashion during manufacturing. There are sealing fasteners specifically designed to withstand high pressures, temperatures, and a variety of chemicals and additional conditions. They are used in applications where any sort of fluid cannot be exposed to one side of a surface, similar to this design (Fast Fix Technology). The latches themselves were fairly effective as is, but a heavier duty iteration could be adapted to increase their shelf life during wear and tear.

To make the device completely standalone, an individual vacuum pump, a regulator, and a digital manometer would come with the device. While a u-tube manometer was validated to be accurate, a digital manometer would be more easily portable, and could attach to the side of the shell.. The pump and regulator system would be housed in one unit and clamp to the edge of the bed, similar to other pneumatic products. The pump would also have a mechanism to shut off at any vacuum stronger than -30cmH2O, in order to prevent lung damage.

7.3 - Final Design Market Comparison

As mentioned previously in Sections 2.6.2 and 2.7 of the background, there are three main devices in development that utilize negative pressure:

1. Exovent
2. Device for Producing Continuous Negative Abdominal Pressure (Appendix A)
3. Combined Positive and Negative Pressure Assist Ventilation (Appendix A)

There is limited information provided about each of these devices. While these three devices are functional options, there are differences in goals, function, and design in relation to the team's requirements. Therefore, when considering the goals established for the CNAP device developed by the team, the device created has various advantages over the initial researched devices that are in development. When considering the Exovent, it is important to take notice that it has a different goal than the CNAP Device. The Exovent was developed as a therapeutic treatment that completely mimics the natural breathing pattern of the body; in other words, it does not work in tandem with a PPV, making the hospitals have to invest in a completely new treatment. Additionally, it requires a specific bed to be bought to be used with the device, which considering the retail price of the device alone $10,496, decreases the adaptability and accessibility of this technology. In contrast, the CNAP device made by our team is designed to fit a standard hospital ICU bed while providing assistance to the existing mechanical ventilators in hospitals. Furthermore, in the case of an emergency, the Exovent does not provide full accessibility to the chest area in a short amount of time whereas the CNAP device is made to ensure doctors can have that access in less than 10 seconds.

Another device that utilizes CNAP is the Device for Producing Continuous Negative Abdominal Pressure. There is not much information about this specific device. From known specifications, similarly to the CNAP device, it has a chamber that extends at the patient's abdominal area. However, it only produces -5 to -10 cmH2O of vacuum inside the chamber whereas the target CNAP device has a higher range of -10 to -30 cmH2O to maximize tidal lung volume. In addition, while the validation of the small scale CNAP prototype (section 5.2.2) has shown an airtight sealing, this device does not provide an airtight sealing mechanism. Lastly, the Combined Positive and Negative Pressure Assist Ventilation is a vest design with two non-identical half shell sections. This design reduces the adaptability of the device to different demographics of patients, more specifically, for obese patients while the CNAP device can more easily adapt to different demographics and body types. Additionally, this design requires inserting a sensor detector of abdominal pressure through a gastric balloon.

The CNAP device is made to assist the current ventilator technology and can be easily adapted to the current hospital environment. It is aimed towards obese patients; however, it can be easily adapted to different demographics and size patients. It has a validated airtight sealing mechanism that maintains a continuous negative abdominal pressure between -10 and -30 cmH2O. Unlike other devices, in the case of an emergency, it allows for full access of the patient's chest in 10 seconds. The CNAP device is a new innovative technology that achieves requirements that other current devices or soon to be on the market devices. With the current extensive patent research conducted, this device has the potential for a future patent. It is a possibility to research further into the patent potential for the sealing mechanism of the device that allows for an airtight seal as well as access to the patient.

Chapter 8: Conclusions & Future Work

Throughout this project the team developed a negative pressure ventilator to aid in the ventilation of obese patients by being used in tandem with a positive pressure ventilator. In this section the accomplishments throughout the past year will be discussed in addition to future work that can be conducted.

8.1 - Conclusions

Obese patients have weakened respiratory systems, and when they are on PPV for an extended period of time lung injuries occur, often leading to the patient to depend on the ventilator to stay alive. Our device to aid in the ventilation of obese patients combines the mobility and ease of use of a modern day ventilator, with the more natural respiratory effects of negative pressure provided by the iron lung. Although the device is not ready to be sold on the market, the proof of concepts we have conducted show the device has great potential and can be improved upon with future iterations. Due to the lack of professional manufacturing techniques, time constraints, and little funding, we were not able to meet the requirement of maintaining CNAP for six hour intervals, for a total of four weeks. Other limitations of the device are its inability to be properly sterilized and adapt to different sized patients.

Although our large-scale device is completely sealed and not able to accommodate a patient in order to maintain pressure, the proof-of-concepts conducted on both the large and small-scale prototypes demonstrate how the device successfully creates a vacuum similar to the iron lung, but more accessible, which can still be used to reduce VILI. Our design allows for doctors to have access to the patient, the device fits standard hospital beds, and it can reach the ideal pressure range of -10 to -30 cmH2O. The issues faced in the production of this device can be corrected through future iterations.

8.2 - Future Work

Since the team was unable to get the large scale prototype to maintain a seal with a patient lying in it, there is still much room for improvement. Future work should focus on improving the manufacturing of this device. The reason for this is the prototype is entirely handmade aside from the shell. Further improvements could be made by using automated manufacturing processes to produce higher quality gaskets, along with tools to make more precise cuts, leaving less room for error in

assembly. These changes would also leave less room for air leakage, allowing the vacuum seal to be more efficient.

Other future work consists of utilizing different materials. Most of the supplies used were required from Home Depot, meaning they are not medical grade. Using the same design, the device could be iterated using new medical grade materials, such as aluminum for the frame, and plastic injected molded gaskets. These changes would allow the new iteration to better represent what would be sold on the market.

Further testing on the large scale prototype would be required as well in order to determine its efficacy. Due to the time constraints, the team was unable to determine if the device could maintain a pressure of -30 cm H_2O for six hour intervals, for a total of four weeks. Future testing could be done to determine whether the device is capable of these requirements. Once all of the previously mentioned future work is accomplished, human testing of the device in tandem with positive pressure ventilation could be accomplished, following the IRB guidelines.

With the future work outlined above, the team believes that the negative pressure ventilator is capable of helping to reduce lung injuries in obese patients. It is an ideal device as it combines the ease of use of the modern day positive pressure ventilator, with the more physiologic negative pressure treatment of the iron lung, while being affordable to hospitals. Our project, if continued, has the capability to improve the lives of thousands, and to reduce the number of patients dependent on ventilators to stay alive.

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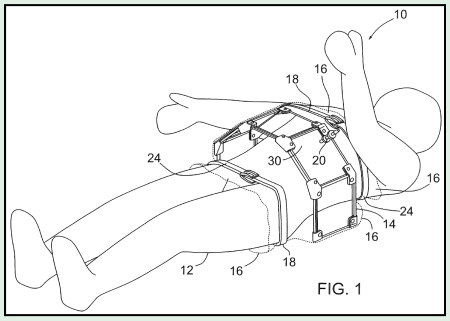
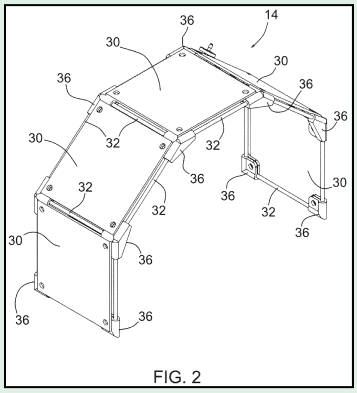
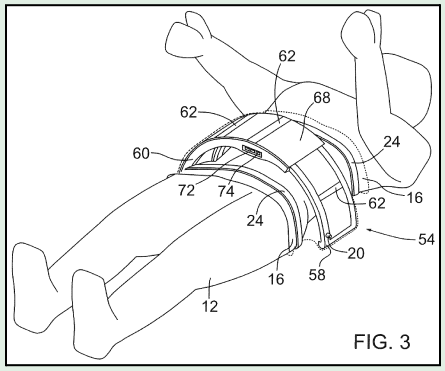
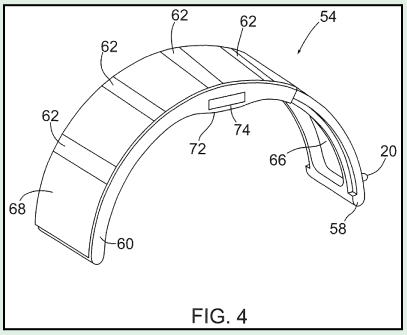
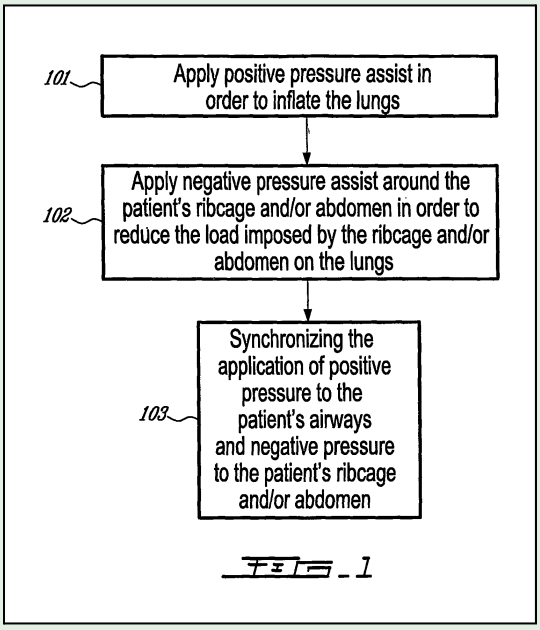
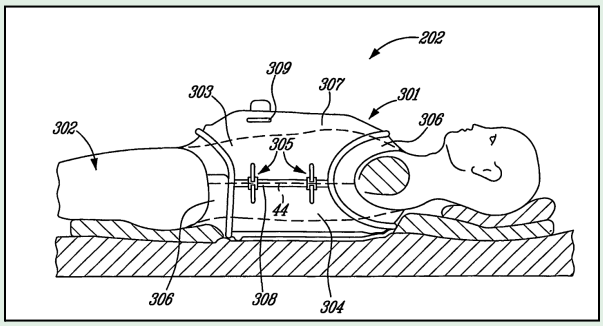
Appendix A: Patent Requirements and Laws

Patent:	Patent Information:
Device for Producing Continuous Negative Abdominal Pressure	Patent Status: Pending 2020-11-19 Publication of US20200360229A1 Claims: Device specs: pressure sensor, flat panels, frame with two arcuate shaped frames for sliding motion, adjustable per overall device size CNAP device that contains a rigid frame that encompasses the patient's abdominal area and lower chest. Design Specifications:  FIG. 1  FIG. 2  FIG. 3  FIG. 4

Combined Positive and Negative Pressure Assist Ventilation	Patent Status: Active 2027-04-22 Adjusted expiration Main Claims: (Claim 1) Device Capabilities: detect neural inspiratory activation, apply PP to inflate lungs, apply NP around rib cage and/or abdomen, control amount and levels of P/N pressures in response to neural inspiratory activation detection (Claim 23) System Capabilities: sensor of neural inspiratory activation, PP ventilator connected to airway, NP ventilator, controller connected to sensor of neural inspiratory activation (Claim 44) System Capabilities: detect neural inspiratory activation, first means of PP, second means of NP, connect first and second means to detect neural inspiratory activation Synchronized pressure being applied through a combination of positive pressure and negative pressure  FIG. 1

	Design Specifications: 
Negative Pressure Ventilation Device	No information provided on this patent

Appendix B: Bill of Materials

Bill of Materials—Small Prototype

Material	**Total Price (w/o shipping)**	**Quantity**	**Size**	**obs:**
Acrylic Shell	$4	1	8” x 10”	From Home Depot
Neoprene	$6	1	¼ yard x 60”	From Jo-Ann Fabrics
Corn Starch	—	—	—	One of the teammates had it
Silicone Caulk	$9.84	1	—	From Home Depot
Glue	—	—	—	Used from WPI
Acrylic Frame	$4	1	8in x 10in	From Home Depot
Vinyl	$11.99	1	1.5ft x 54"	From Amazon https://www.amazon.com/VViViD-Bycast65-Pattern
Pump + Regulator	—	1	—	Borrowed from Practice Point
Total Cost	$35.83			

Bill of Materials—Up-to-Scale Prototype

Material	**Total Price (w/o shipping)**	**Quantity**	**Size**	**obs:**
Polycarbonate Shell + Molding + U Channel	$260	1	56”x 16”x 1/8”	Made by Quality Fab
Neoprene	$45	1	2 yards x 60”	From Jo-Ann Fabrics
Glue	$10	1	—	From Home Depot
Silicone Caulk	$25	2	—	From Home Depot
Wood Base	—	—	33”x16”	One of the teammates had it
Wood Frame	—	—	16”x3”	Taken from ME MQP lab
Metal Clasps	$7.86	4	—	From Home Depot
Pump	—	—	—	Borrowed from Practice Point
Total Cost	$347.86			

Bill of Materials—Professionally Manufactured Device (Recommended)

Material	**Total Price (w/o shipping)**	**Quantity**	**Size**	**obs:**
Polycarbonate Shell + Molding + U Channel	$260.00	1	56”x 16”x 1/8”	Made by Quality Fab https://qualityfabandmachine.com/
Neoprene	$45.00	1	2 yards x 60”	From Joanns
Aluminum Frame (base sheet)	$43.97	1	16” x 33” x 0.025"	Estimated from Online Metals https://www.onlinemetals.com/en/buy/aluminum/0-025-aluminum-sheet
Aluminum Frame (Side Frames)	$14.36	1	36” x 1.5" x 0.25"	Estimated from Online Metals https://www.onlinemetals.com/en/buy/aluminum/0-25-x-1-5-aluminum-rectangle-bar-
Injection Molded Gasket (TPU)	$400	—	—	Price varies**
Handles	$30.82	2	—	https://www.mcmaster.com/47065T54/
Metal Clasps	$7.86	4	—	From Home Depot
Pump	$136	1		borrowed from the ME Lab
Total Recommended Cost	$941.13			

Appendix C: MATLAB Code

Small Scale Prototype Statistical Analysis

```
% Data for Small Scale Mechanical Ventilation Prototype Tests
utube = [-32, -30, -31]; % cmH2O
regulator = [95, 95, 95]; % mmHg
total_time = [49.62, 36.21, 19.17]; % seconds

% Convert units from cmH2O to mmHg using the correct conversion factor
utube_mmHg = utube * 0.73556;

% Calculate mean, standard deviation, and range for each variable
mean_utube = mean(utube_mmHg);
std_utube = std(utube_mmHg);
range_utube = range(utube_mmHg);

mean_regulator = mean(regulator);
std_regulator = std(regulator);
range_regulator = range(regulator);

mean_time = mean(total_time);
std_time = std(total_time);
range_time = range(total_time);

% Print the results
fprintf('Statistics for Small Scale Mechanical Ventilation Prototype Tests:\n');
fprintf('-----------------------------------------------------------------\n');
fprintf('U-tube Manometer:\n');
fprintf('Mean: %.2f mmHg\n', mean_utube);
fprintf('Standard Deviation: %.2f mmHg\n', std_utube);
fprintf('Range: %.2f mmHg\n\n', range_utube);

fprintf('Regulator:\n');
fprintf('Mean: %.2f mmHg\n', mean_regulator);
fprintf('Standard Deviation: %.2f mmHg\n', std_regulator);
fprintf('Range: %.2f mmHg\n\n', range_regulator);

fprintf('Total Time:\n');
fprintf('Mean: %.2f seconds\n', mean_time);
fprintf('Standard Deviation: %.2f seconds\n', std_time);
fprintf('Range: %.2f seconds\n', range_time);
```

Figure 65. MATLAB Code for Small-Scale Prototype Statistical Analysis.

```
U-tube Manometer:
Mean: -22.80 mmHg
Standard Deviation: 0.74 mmHg
Range: 1.47 mmHg

Regulator:
Mean: 95.00 mmHg
Standard Deviation: 0.00 mmHg
Range: 0.00 mmHg

Total Time:
Mean: 35.00 seconds
Standard Deviation: 15.26 seconds
Range: 30.45 seconds
fx >>
```

Figure 66. MATLAB Results From Small-Scale Prototype Statistical Analysis.

```
%%
% Data for the three trials
trial1 = [-32, 95, 49.62];
trial2 = [-30, 95, 36.21];
trial3 = [-31, 95, 19.17];

% Create a new figure window
figure;

% Plot the data points for each trial
hold on;
grid on;
scatter(trial1(3), trial1(1), 'r', 'filled');
scatter(trial2(3), trial2(1), 'g', 'filled');
scatter(trial3(3), trial3(1), 'b', 'filled');

% Set the x-axis and y-axis labels
xlabel('Time (sec)');
ylabel('Pressure (cmH2O)');
title('Small Scale Mechanical Ventilation Prototype');

% Add a legend
legend('Trial 1', 'Trial 2', 'Trial 3');
```

Figure 67. MATLAB Code for Three Vacuum Test Trials Graph of the Small-Scale Prototype.

```
% Create a matrix to store the data
data = [53.11, 52.06, 73.71;
        610.78, 602.97, 607.22;
        189.57, 164.13, 77.41];

% Define RGB colors
rgbColors = [133, 179, 141;
             186, 217, 192;
             225, 239, 228] / 255;

% Create a bar graph of the data with RGB colors
b = bar(data, 'grouped');
for i = 1:length(b)
    b(i).FaceColor = rgbColors(i,:);
end

% Set the x-axis labels and title
xticklabels({'Time to reach -30 cmH2O', 'Maintained Seal', 'Maintained Pressure'})
xtickangle(45)
xlabel('Measures')
ylabel('Time (seconds)')
title('Summary of Trial Results')

% Add a legend
legend('Trial 1', 'Trial 2', 'Trial 3', 'Location', 'northwest')
```

Figure 68. MATLAB Code for Full-Scale Prototype Testing Analysis.

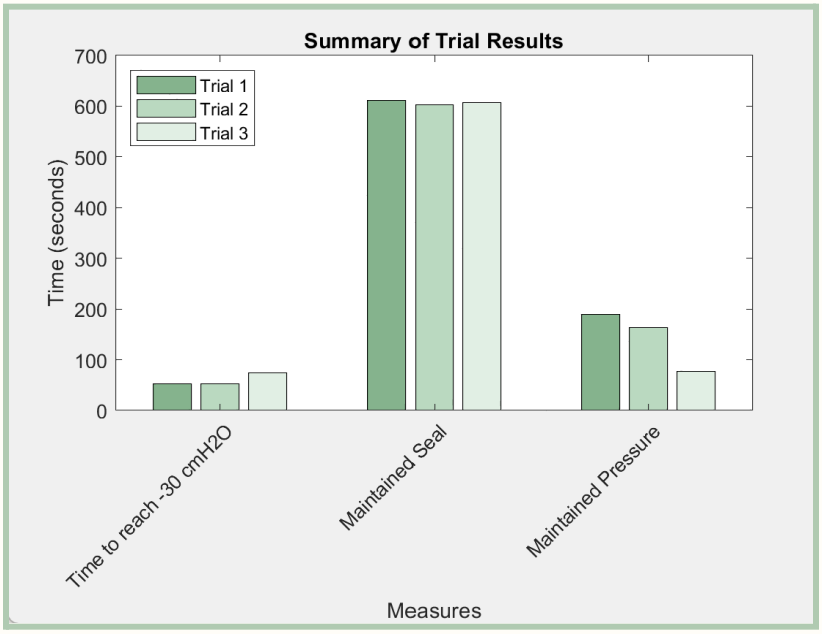


Figure 69. MATLAB results of the time taken for a total of three trials for the full-scale prototype. Time (seconds) corresponds to the time taken to reach a vacuum pressure of -30 cmH2O, the maintenance time for the vacuum to hold a total of 10 minutes while the pump is turned on, and the amount of time taken to maintain the pressure with the pump turned off until the pressure decreases to -10 cmH2O.