# Medflight Manual Hands-Free Ventilator Project

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**BME 201**

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**Client: Michael K. Abernethy, MD, FACEP**

**University of Wisconsin Medflight**

**Advisor: Dr. Paul Thompson, University of Wisconsin**

**Abstract: The existing manual ventilator bag (or AMBU bag) is researched and analyzed. Three new designs are presented that allow for the manual ventilator to operate as a hands-free operation. The goal of these designs is to create a product that meets the standards of the current AMBU bag while allowing the doctor another means to manually ventilate the patient while maintaining free use of his or her hands. The product must adequately replicate the respiratory function of traditional ventilators in order to provide the patient with sufficient oxygen and prevent overexposure to harmful toxins that plague the respiratory process. The creation of a hands-free ventilator that has all the performances capabilities as the traditional manual ventilator is explained.**

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## I. Problem Statement

The goal of the project is to create a ventilator that replaces the traditional hand-powered manual ventilation method with a hands-free method that gives the client greater ability to assist victims. The hands-free ventilator must meet the performance of its counterpart, the hand-operated AMBU bag, and allow for simple operation to allow for multi-tasking. The incentive of the hands-free method is that it allows the doctor to devote more attention to the patient while still adequately ventilating the patient. A common complaint problem that those who a use hand-operated ventilator often face is that it is often too risky ventilate the patient while performing other tasks. Medflight helicopter conditions are characterized as being cramped, due to the large amount of medical equipment on board, leaving the doctor often alone during field operation. The project is intended to allow for the doctor on board to perform other tasks along with the ventilation process, catalyzing the process of individually providing life-saving treatment.

## II. Product Function

The product described previously is to be used by doctors, nurses, or other hospital personnel during field operation. The immediate aim of the project is three-fold: to properly ventilate, to allow the doctor greater flexibility (multi-task, use of hands), to allow for faster treatment during field operation. Currently, there is no problem with the ability of AMBU product to ventilate a patient. However, they are hand-operated and require a significant amount of effort and concentration.  That is why the hands-free project aims to mimic the ventilation process of the AMBU bag, but allow a significantly smaller amount of concentration and leave the doctor’s hands free for other tasks. In return, patients will be receiving faster, more effective treatment because the doctor will be able to commit to the patient. Thus, improving field treatment standards and allowing for faster, more effective care.

The AMBU device does satisfy the current client, so the task at hand is centered at simplifying the ventilation process demonstrated by the AMBU device and altering it for hands-free operation. Due to cramped helicopter conditions, the new prototype is not intended to be an elaborate gadget but merely a compact product that ventilates and doesn’t take up unnecessary helicopter space.

## III. Background Information

The product's function is extremely important for members of the Medflight team. Medflight is composed of physicians, nurses, pilots, and dispatchers that are specially trained in transporting patients in emergency situations. This flight service has provided emergency care and transport for victims of crashes and disasters for more than twenty years. The University of Wisconsin's Medflight has three rotating helicopters available at all times. This Medflight team works in a 225 mile radius around Madison. The helicopters can be in the air within minutes of receiving word of an accident. Many pieces of emergency equipment are carried in flight such as: ventilators, blood pressure monitor, heart monitors, IV equipment, defibrillators, pacemaker equipment, emergency medicine, and medication. During the transportation of a patient, the physician's task is to maintain life and stabilize the person until they arrive at a location where better care or treatment can be provided.

During the research process we have consulted with our client, Dr. Michael Abernethy, when analyzing the feasibility of the several of the proposals we will discuss later in the text. While researching the project several websites highlighted the importance of the Positive End Expiratory Pressure Valve (PEEP Valve) as being critical to providing safe ventilation and avoiding harmful toxins that are part of the respiratory process. While the PEEP Valve (which is commonly referred to in the text) is in important, its main function is not to protect the patient from toxic gases that are a product of respiration, but rather to control the rate of air flow in the respirator to keep the patient's lungs from reaching zero pressure during exhalation. During normal respiration, the lungs do reach a moment of zero pressure during exhalation. However, in times of trauma, always maintaining some pressure in the lungs is beneficial. This pressure eases the burden that is placed on the patient who is having trouble breathing, providing them with sort of a reservoir to continue the breathing process with.

Having had some members with prior experience working with Dr. Abernethy and Medflight, the factors were clear and concise from Day 1. The important factors that are being considered when making decisions pertaining to these proposals mainly have to do with the pressure the proposed ventilator delivers or is expected to deliver to the patient, its ease of operation, and the logistics of operating the device in the cramped conditions that are part of basic Medflight operation.

It is hard to understand the amazing efficiency of the hand-operated AMBU bag. The AMBU bag does not require strenuous pumping because it efficiently delivers sufficient volumes (1300 mL) within safe pressure ranges. For this reason, Dr. Abernethy has clearly stated that it is imperative to maintain standards within acceptable ranges of the AMBU design. Failure to do this would create more problems than not having the ability to work with your hands and compromise patient care. Dr. Abernethy often deals with patients that are in tremendous need of medical attention, along with respiratory assistance. His advice has led us to make sure that product efficiency and performance goes hand-in-hand with the ergonomics of each design. After all, a sleek design that compromises efficiency does not make Medflight operation any easier for the client. Having done extensive research on manual respiration and PEEP Valve function, we were able to break down the process try to build a design that fit the setting along with operating efficiently with acceptable performance.

In order to make hands-free operable AMBU bag, it became clear that the compressible “bubble” portion of the AMBU bag, traditionally compressed by the hand, needed to be replaced or relocated for hands-free use. One possible replacement is bellow pump, a foot pedal type pump often used for inflating air mattresses or similar items. Several manufacturers produce bellow pumps. We found the Sevylor to be one of the most common manufacturers, with a small variety of pumps to choose from. The ergonomics of the bellow pump were immediately pleasing. These pumps are designed to be manually pumped by foot for a short duration, and given their shape, could easily have a pumping force generated by some part of the body other than the foot. One drawback, however, of the bellow pump, is the way it moves air. The bellow pump is designed to move as much air as possible for a reasonable amount of effort. As a result, even smaller versions of these pumps move volumes of air as large as 3000 mL with each pump, nearly three times the accepted value of 1300 mL for an AMBU bag. Another issue is the amount of pressure that a bellow pump could possibly generate. Due to its design, the pressure in the bellow pump is dependent upon the force exerted on it, much like the AMBU bag. Being operated by foot, the bellow pump may lack the tactile feedback of an AMBU bag, making it more difficult for the user to control rate and volume of air moved as opposed to the AMBU bag. In order for a bellow pump to be safely incorporated into a design, it must be capable of delivering a sufficient volume of air at a safe pressure, without potential of exceeding accepted values.

Another important consideration in our designs is the concept of “dead space”. During the process of respiration, the patient inhales and exhales air through the same tube. Ideally, when the patient exhales, all of the gases would be released, not to be inhaled again. However, it is inevitable that exhaled air will stay in the tube in the length of tubing that runs from the patient to the respective location were the exhaled gases are exhausted. This air is then inhaled again with the next breath. “Dead space” refers to the volume of this length of tube that contains exhaled air that will be reinhaled. It is very important that this volume is not of significant size when compared to the average breath volume of 1300 mL to ensure that the patient is not overexposed to the toxic products exhaled during respiration.

## IV. Management Planning

In the planning stages of the project, we determined that we would be able to fabricate our prototype without any outside assistance from fabrication shops on campus or commercial shops. We estimated that it would take approximately 20 hours to build an acceptable working prototype using the materials given to us and this estimate was accurate. Necessary materials such as AMBU bags and ventilation tubing were supplied by the client, saving us anywhere between 100 to 200 dollars. The Foot Bellow equipment can be purchased from various camping or outdoor supply retailers, for prices ranging from 10 to 30 dollars. Accessory materials did not provide with any financial burden and mainly consisted of plastic parts that were used to attach parts together and provide aesthetic detail. The final prototype did not cost the group more than 40 dollars because of the materials given to us. However, if the materials were not provided the unit production price would be approaching 250 dollars including the cost of ventilation tubing. The strategy of the group during the construction phase of the project involved devoting a single period to working on one aspect of the project (i.e. the input bellow joint, the oxygen valve joint, etc.) and then refining that aspect before moving on. Carrying out our strategy allowed us to solve minor problems we encountered them and to efficiently build our prototype.

## V. Alternative Solutions

### i. Belt Attachment

**Figure 1: Front view of the belt attachment design**

The belt attachment design involves a customized belt that attaches around the AMBU bag. This belt is used to mount the “bubble” portion of the ventilator to the leg of the operator securely and can be easily detached. After placing it at the most comfortable location, the valve end of the AMBU bag would be placed beside the knee. This prevents the respirator from separating from the extension tubing. By moving the knees together, the operator can compress the bag and force air from the bag into the patient’s lungs through extended tubing. The end of the extended tubing, distal from the operator, is connected to a PEEP exhaust valve which prevents the accumulated carbon dioxide from reaching the patient and maintains some beneficial pressure in the lungs. The belt should be adjustable from 15 inches to 20 inches so that it can fit the majority of leg sizes.  The operator must also be able to attach and detach the AMBU quickly and easily.

**Figure 2: Back view of the belt attachment design**

A major advantage of the belt design is its ability to be set up in a small amount of time. This is because the only detachable components are the belt and the extension tubing. This feature also allows the respirator to be stored easily and reduces the cost of production. The oxygen flow supplied by this design is already within human respiratory regulations because the original AMBU bag is used.

The disadvantages of this design, however, limit its potential of being widely used. The motion that this design requires is non-intuitive and provides much less tactile feedback when compared to the hand model, possibly making it difficult for the operator to control the air flow. This may cause the user to be preoccupied with operating the respirator and prevent him or her from performing other critical tasks.

### ii. Hinge Design

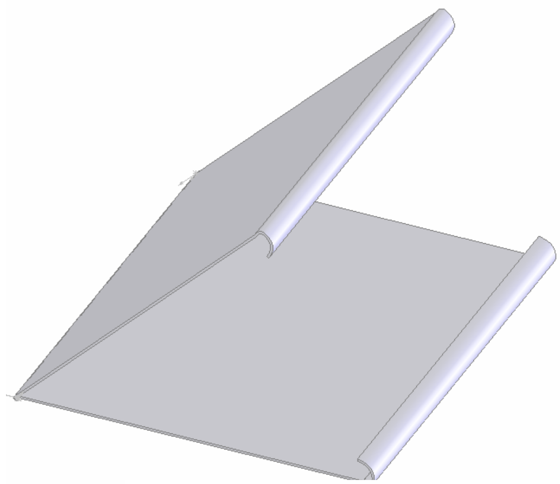


**Figure 3: A mechanical hinge**

The hinge design compresses an AMBU bag with the movement of a customized mechanical hinge. The hinge would be controlled by a hydraulic pedal actuated by highly compressed fluid through tubing. Once activated, the upper part of the hinge will lower and thereby, compressing the AMBU bag. As expected, the top of the hinge will rise once the pedal is released causing the AMBU bag to re-inflate. This hinge rests on top of the patient and only requires a short extension tube.

This system allows the operator to accurately control the air flow to the patient. The motion of activating the pedal is intuitive and allows the user to use his or her hands for other important duties.

The construction process for this design, though, will be relatively complicated as there are basically three components: a hinge, a pedal and a hydraulic system. All these contribute to the manufacturing cost of the prototype. The placement of the device on top of the patient is not as stable as a system placed on a fixed surface. Further development and advanced design may be able to make this concept a viable option in the future.

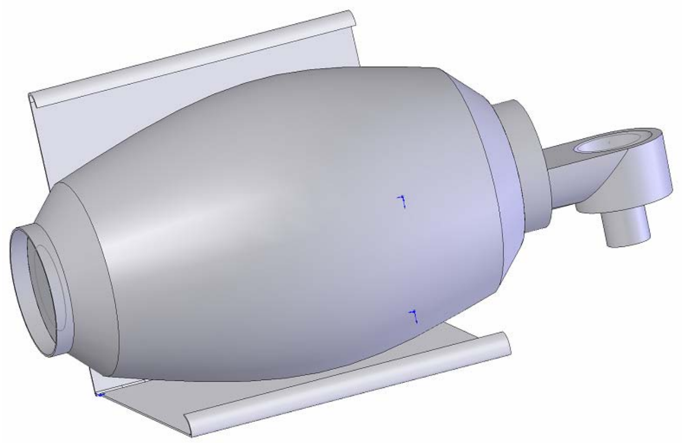


**Figure 4: Hinge combined with respirator**

## VI. Final Design

**Figure 5: Top View of Sevylor Bellows Pump**

The final design involves a separate foot pump that the client can place on the ground and operate without any compromise of his hands. This design stresses the intuitive foot pedal motion that drivers employ when controlling the throttle of the car and allows the doctor to control the flow of oxygen with the amount of foot pressure on the pump. This design utilizes four main elements to replace the function of traditional respirators: a bellows foot pump, an extension for the ventilation circuit, an exhaust valve and an oxygen reservoir with an oxygen tank inlet.

The primary component of the pump design is the actual bellows pump itself. The average size for an AMBU bag respirator on the market is 1300 mL, therefore, the bellows pump should have a comparable volume in order to deliver the same volume of oxygen. For our prototype, we used a Sevylor Bellows Pump originally intended for outdoor recreational activities. As a force is applied forward from the operator's foot, the pump chamber collapses and forces air from the reservoir and the pump to the ventilation circuit. The underside of the bellows pump was coated with a non-slip pad to grip the floor of the helicopter and prevent the pump from slipping during operation.

Since the operation of our respirator dictates that the pump be placed on the floor, the patient is separated from the oxygen source by at least three feet of ventilation tubing at all times. To connect the Sevylor pump to the patient, we used hospital standard ventilation tubing in conjunction with the Sevylor tubing supplied with the bellows pump. The Sevylor tubing is more durable than the ventilation tubing and contains a wire coil to prevent collapsing, making it suitable for its location on the floor of the helicopter. The Sevylor tubing threads directly into the output valve of the pump, allowing the joint to be secure and free of air leaks. The junction between Sevylor tubing and the standard ventilation tubing was created using a two-part epoxy (resin & hardener), which provided a strong, airtight junction between the plastics.

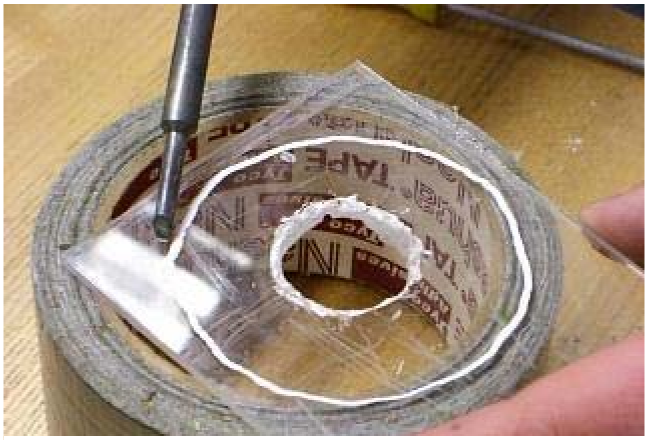


**Figure 6: Plastic Attachment Construction**

As alluded to previously, the extension circuit creates dead space and carbon dioxide build up if proper exhaust is not implemented.  The exhaust is needed at the patient end of the ventilation tubing in the form of a one-way valve that permits carbon dioxide to leave the system or as a previously mentioned PEEP valve.  In our research, we encountered an elegant solution, a hybrid valve, which involves an exhaust valve with the option for an attachable PEEP valve.  We decided to use one of these hybrid valves from a disposable AMBU bag instead of having one specific valve.  This allows the operator to interchange the exhaust mechanisms simply by unscrewing the valve.  To join the exhaust to the tubing, we fabricated an adapter from a sheet of Lucite in order to create the appearance of a one-piece system.  Lucite is a durable plastic, and was obtained from a sheet of plastic that was designed to serve as a shock resistant window.  Again, a two-part epoxy was used to join the tubing, the adapter and the exhaust.

The final element of the system is the reservoir with an oxygen tank inlet.  The function of the reservoir in a respirator is to provide a small supply of oxygen to the pump when the rate of pumping is too high to allow for the pouch to be filled quickly enough by the oxygen tank.  The reservoir was incorporated in the pump design as an integrated mechanism that included one-way valves, a reservoir bag and an inlet adapter for an oxygen tank.  This will allow the reservoir to be filled with oxygen first before the pump.

**Figure 7: Oxygen reservoir with oxygen source attachment**

To construct the reservoir element of the system, we removed a suitable reservoir piece from an existing hand-held respirator and modified the input valve of the bellows pump to compensate. To join the reservoir to the bellows, we needed to sand, mold, and file the bellows plastic. The two-part epoxy again created an airtight and secure seal. An important feature of this element is the oxygen inlet with safety one-way valves. An oxygen tank can be easily connected to and detached from the inlet and the safety one-way valves prevent the reservoir bag from bursting. If an oxygen tank is not attached, the oxygen inlet is bypassed through other one-way valves so that the patient can be ventilated with ambient air.

**Figure 8: Sanding and Filing Bellows Pump**

## VII. Design Constraints

There should an adequate exchange of oxygen and carbon dioxide when assisting patient's respiration with any respirator. Failure of the extension piece to adequately replicate the respiratory function of the traditional AMBU bag would result in patients becoming overexposed to carbon dioxide and also suffering oxygen deprivation. The oxygen attachment tube had to be included in our design to ensure that a high concentration of pure oxygen was delivered to the patient.

Since the space on a helicopter is very limited, we had to minimize the size of our design without altering basic ventilation requirements. The height of the foot bellow is 5 inches tall when uncompressed so that the operator will not be confined when operating it. Also, the supply tube is detachable for storage.

The entire design has to be sufficiently airtight. Any air leakage will result in a design will result in the decrease of oxygen that reaches the patient. All connecting joints have to be examined carefully to eliminate air leakage.

## VIII. Materials and Methods

As stated earlier, our client provided us with sufficient ventilation equipment for the prototype, in the forms of reusable AMBU bags, non-reusable AMBU bags and ventilation tubing. In summary of the methods used, necessary components were extracted and adapted from the AMBU bag and the old respirator was discarded.

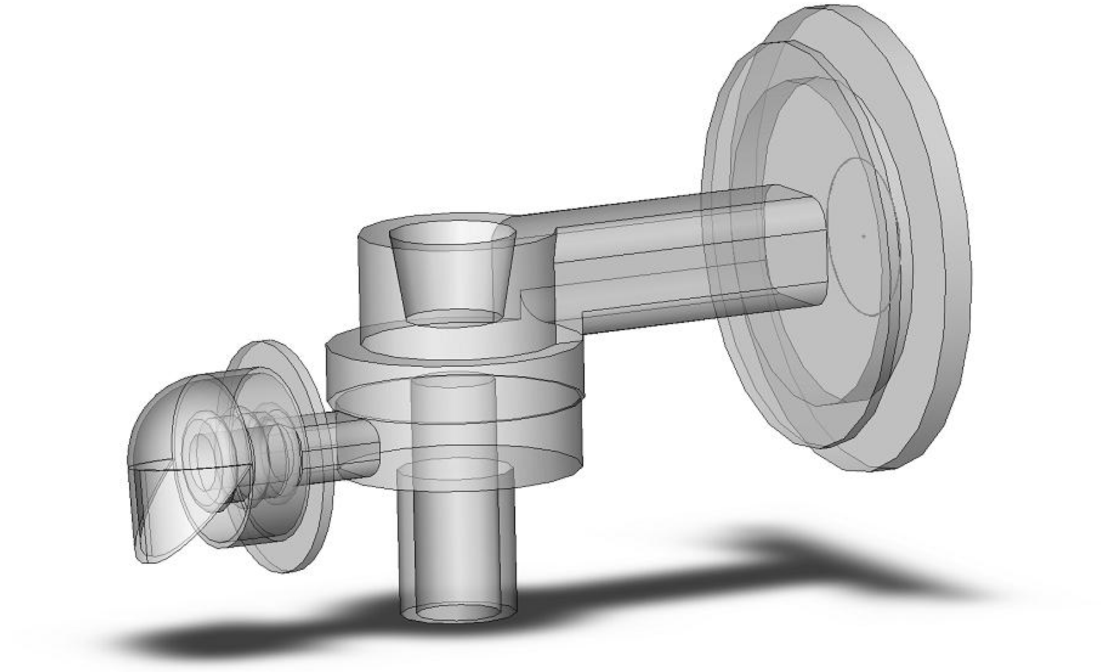


**Figure 9 : Oxygen output and exhaust**

The first part of the respirator that was extracted was the oxygen output and the exhaust piece. The component was attached directly to the patient end of the ventilation circuit with a two-part epoxy.

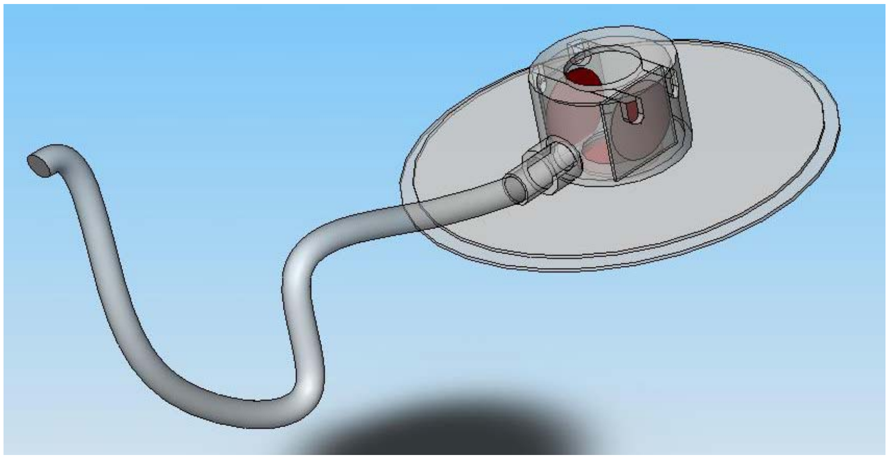


**Figure 10 : Reservoir with Oxygen inlet**

The second main component that was extracted was the reservoir with the oxygen tank inlet.  This piece was attached to the input valve of the bellows pump, again, using a two-part epoxy.  The ventilation tubing was sealed to the supply tube using the same epoxy.  To test the prototype, the client provided us with a monometer, or pressure gauge, and artificial lungs to determine pressures and volumes.

## IX. Evaluation

| **Factor** | **Weight** | **Belt Attachment** | **Hinge** | **Foot Bellow** |
|---|---|---|---|---|
| **Design Feasibility** | **3** | **5** | **3** | **5** |
| **Expected Performance Output** | **5** | **3** | **3** | **4** |
| **Comprehensive Design** | **3** | **4** | **3** | **5** |
| **Reliability** | **5** | **4** | **3** | **4** |
| **Ease of Use in Medflight Conditions** | **4** | **3** | **4** | **5** |
| **Cost** | **2** | **5** | **3** | **4** |
| **Total** | | **87** | **70** | **98** |

**Figure 11: Design Matrix**

When analyzing the three designs, we focused on six main factors, design feasibility, expected performance output, comprehensive design, reliability, ease of use in Medflight conditions, and finally cost. When considering these factors, it was decided to give more weight to those concerning performance and function due to the life-sustaining function the ventilator provides, as seen in Figure 5.

We feel that all three of our designs our capable of solving Dr. Abernethy's problem and allowing hands-free ventilation, but when all things are considered, the foot bellow design is the most logical choice. One of the main appeals of the foot bellow design is the foot pumping motion required for its operation. This motion is very intuitive, much like the motion of pressing a gas pedal in an automobile. Since this motion is more familiar than those that would be required to operate the other designs, the learning curve would be shorter for the operator in respect to the other designs. This device would also fit well in the small confines of the Medflight helicopter, where the bulk of the device would rest on the floor, out of the way of the flight physician and the other equipment.

## X. Solution

The bellow apparatus mimics the respiratory process of the AMBU bag by providing an air force throughout the ventilation system. The oxygen reservoir attachment provides a pure oxygen source attachment and prevents the ventilator from delivering an overpowering oxygen source.

The one-piece function of the product makes it ideal for the helicopter setting because it is free from excess appendages that could come loose and disrupt field operation. The product also exhibits impressive performance capabilities in terms of pressure delivery and oxygen content. The prototype is ready to be used in field operation.

## XI. Testing

Testing was done to determine the functional performance of the product. To facilitate testing, our client supplied us with a monometer as well as two artificial lungs. The monometer is attached at the output of the device and measures the pressure delivered. The artificial lungs are used to ensure the product delivers the proper volumes of air necessary to properly ventilate a patient. One of the test lungs even incorporates an element of resistance, simulating the natural ventilation process.

When using the product with these devices, it was found the product is capable of delivering the proper 1300 mL volume at a range of desirable pressures. This pressure range varies from 20 to 45 mm Hg above the normal atmospheric pressure of 760 mm Hg. Lower pressures can be used for normal ventilation, where higher pressures may be necessary for patients with crushing-type injuries to the chest. We also found that it is not difficult to maintain a rhythm using the hands-free ventilator, and the motion required is one that could easily be sustained for 20 to 30 minutes.

## XII. Ethical Considerations

Due to the fact that the hands-free-respirator performs a life sustaining function for a trauma patient, it must operate effectively and reliably at all times. To ensure the safety of the patient, the hands-free respirator must function within pressure, volume and air quality limits of a traditional respirator. Breathing pressure in the lung is measured in centimeters of water above normal atmospheric pressure. Typically, normal breathing inflates the lungs to 36 cm $H_2O$ above atmospheric pressure, causing the lung to be 70% inflated. This is equivalent to 26.47 mm Hg above the normal atmospheric pressure of 760 mm Hg. The ventilator is capable of delivering these pressures, as well as higher pressures necessary to ventilate patients suffering from crushing-type injuries, yet is not capable of delivering air at harmful pressures without excessive use of force. The oxygen concentration should be kept as high as possible. With an oxygen tank attached, the concentration of oxygen should be kept close to 100% with the aid of the reservoir.

## XIII. Future Work

In the future, the hands-free-ventilator design could be revised to function better in the Med Flight environment with customary replaceable parts. Traditionally, manual ventilators are either disposable, or have a reusable pumping portion of the ventilator (consisting of the $O_2$ reservoir and compressible portion) along with a disposable circuit (consisting of the ventilation tubing and the exhaust/PEEP valve). Adapting the hands-free-ventilator design to use a simple, disposable circuit would allow for cost-effective long-term use of the ventilator in the Med Flight program.

The hands-free-ventilator design currently incorporates an $O_2$ reservoir obtained from a standard AMBU bag. This reservoir was designed to function with a ventilator of smaller volume, with a slower refill rate after the compressible portion is exhausted. This has led to concerns that the reservoir may not be of sufficient size to handle the additional volume associated with the bellow portion of the hands-free ventilator. In the future, the design may incorporate a modified reservoir that ensures the larger volume is fed a constant supply of $O_2$.

Other changes may be considered to improve the overall layout and ergonomics of the hands-free-ventilator. Due to the nature of the bellow pump and manufacturer's placement of the inlet and exhaust valves on the top of the pump, the $O_2$ reservoir and ventilation tubing are right next to the operator's foot while pumping. This does not necessarily inhibit the function of the ventilator, but gives the user less variety as far as foot placement options and requires some caution to avoid the reservoir.

After discussing a possibly niche in the market for a hands-free ventilator, our client expressed the need for automatic versions of a product like ours for use in mass casualty situations. The example mass casualty situation that was used was a large exposure to nerve gas. The largest problem from a patient care standpoint in a situation like this is determining a way to ventilate a large number of patients on short notice with a limited number of care providers. This creates a demand for disposable, self-powered ventilators. Our product could be adapted to operate in this type of situation with the addition of a small motor and power source.

## XIV. Product Design Specifications

**Product Design Specification**

**Hands-free Ventilator Project**

**April 28, 2006**

Team Members:

| | |
|---|---|
| Peter Ma | *Leader* |
| Richard Long | *Communications* |
| Jimmy Fong | *BSAC* |
| Matt Valaskey | *BWIG* |

Function:

The product function is to modify the disposable manual ventilator (AMBU bag) to allow hands-free operation. The prototype consists of a modified foot bellow that is equipped with an oxygen reservoir. The bellow base is also connected to ventilation tubing that is connected to a mouthpiece with PEEP valve capabilities. The hands-free ventilator or bellow apparatus mimics the AMBU bag and provides a respirator resource to patients in need.

Client Requirements:

The project will allow for hands-free operation of the manual ventilator (AMBU bag), using the client's legs. Traditionally, AMBU bags operate as an inflatable bag by hand. To allow for the AMBU bag to be operated using legs, an extension piece (ventilation tubing) was engineered to reach the patient and provide oxygen. The extension piece maintains the current capabilities of the manual ventilator and provides adequate assistance in respiration (adequate exchange of oxygen and carbon dioxide). Failure of the extension piece to adequately replicate the respiratory function of the traditional AMBU bag would cause the patient to suffer from oxygen deprivation. The oxygen reservoir attaches to an oxygen source which pumps pure oxygen into the ventilation system.

Design Requirements:

1) Physical and Operational Characteristics

    a. *Performance Requirements:* Product maintains the current capabilities of the AMBU manual ventilator and assists in respiration (adequate exchange of oxygen and carbon dioxide). Product provides pure oxygen to the patient at an air pressure ranging from 20-45 cpm, which is the designated pressure range of trauma victims.

    b. *Safety:* Product adequately replicates the respiratory function of the traditional AMBU bag to prevent patients from becoming overexposed to harmful carbon dioxide and also suffering from oxygen deprivation. The oxygen reservoir provides the bellow with a pure oxygen source that eliminates dead space (often containing harmful toxins such as carbon dioxide) in the prototype.

    c. *Accuracy and Reliability:* Mouthpiece sufficiently allows for oxygen-carbon dioxide transmission. Product provides adequate oxygen to the patient while eliminating carbon dioxide buildup in the tubing. Product has PEEP valve capability which controls the end respiratory pressure in the lungs.

d. *Life in Service:* Product should be able to tolerate traditional helicopter conditions. Damage and wear can be repaired by tubing and plastic repair. Product is repairable. No disposable model is being made.

e. *Shelf Life:* Shell life should last the same length of the traditional AMBU bag which traditionally last 1-2 years without leaks.

f. *Operating Environment:* Since Medflight operation takes place year round, the device will be able to endure a variety of weather conditions including moisture, high and low temperatures. Traditional AMBU Bag is operable in temperatures ranging from 0°F to 122°F.

g. *Ergonomics:* Product is designed to comfortably fit at client's feet or on his leg and stretch to the patient. Product will feature traditional bag base and tubular extension. Tubular extension has been measured and modified to adequately stretch to the patient. Oxygen reservoir is equipped with a reservoir bag that maintains a constant supply of oxygen in the bellow and ventilation tubing.

h. *Size:* Extension piece will stretch from bellow to patient. Extension piece will be in tubular shape to allow for oxygen-carbon dioxide transmission. Bellow piece fits on the floor of the helicopter to allow for easy-operation by Medflight personnel.

i. *Weight:* Final weight of the prototype is 2.5 lbs, approx. Traditional AMBU bag weight is .92 lbs (without oxygen), approx.

j. *Materials:* Ventilator extension was crafted using tubing material and plastic that was provided by the client and is common in medical ventilation devices. Bellow piece was engineered from a traditional camping bellow to allow for an oxygen-source attachment and bag reservoir. Mouthpiece was provided by the client and is identical to those found on the AMBU ventilation device.

k. *Aesthetics, Appearance, and Finish:* Product is free from excess appendages that take up excess space. Product has red paint detail and functions as a one-piece compact model.

2) Production Characteristics

a. *Quantity*: 1, with the possibility of further replication.

b. *Target Product Cost:* Cost: $35.00, which is comparable to the price of traditional AMBU bag. Target Product Cost includes the cost of disposable AMBU bag, extension materials (crafted with similar materials used in AMBU products), oxygen reservoir and bellow instrument.

3) Miscellaneous

a. *Standards and Specifications:* none.

**b.** *Customer:* Product needs to be free from “dead-space” that could develop in extension piece and become contaminated with carbon dioxide. Oxygen source believed to eliminate dead space by maintaining continuous supply of oxygen in the prototype. Traditional AMBU bags contain less than 5 mL dead space.

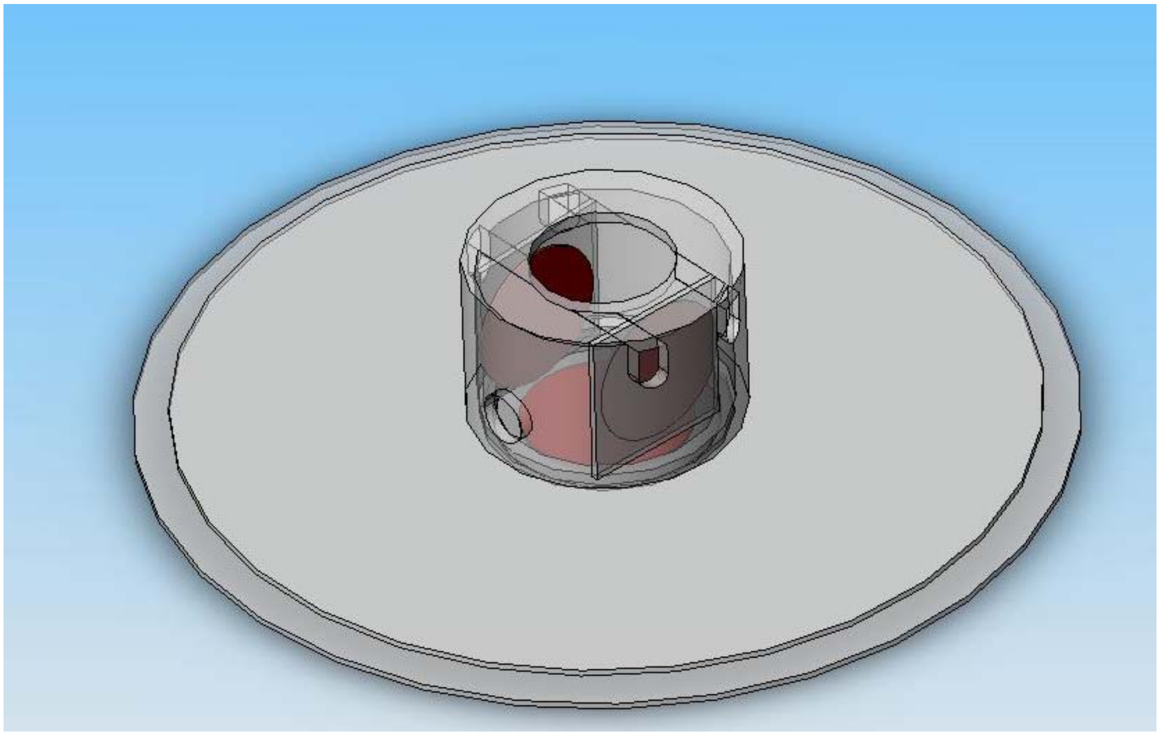
**c.** *Patient-related concerns:* Product needs to be free from harmful materials (i.e. carbon dioxide) and have all performance capabilities as original AMBU bag. Product needs to adequately replicate respiratory function of the AMBU bag.

**d.** *Competition:* AMBU hand-operated ventilator

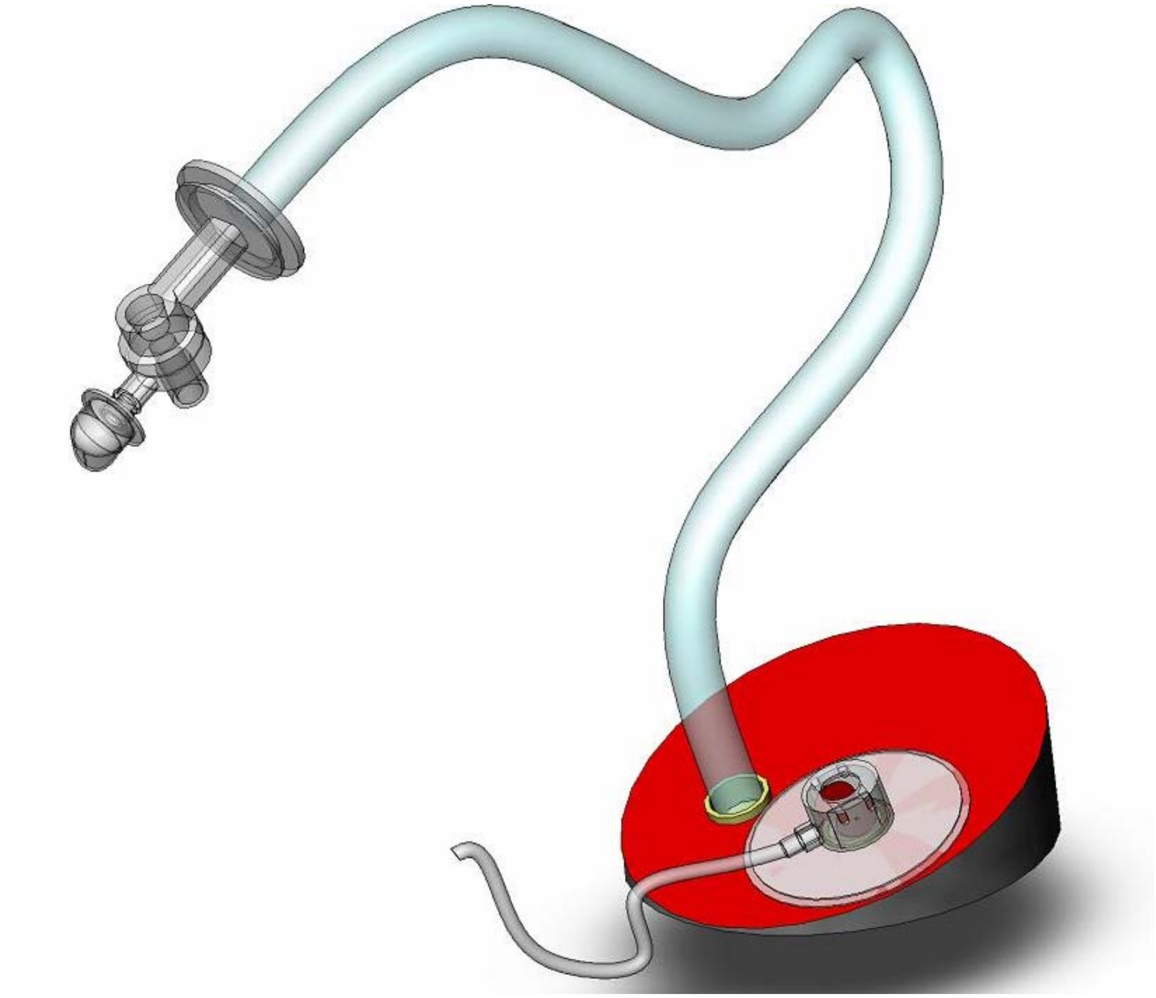
## XV. Appendix

### i. Technical Drawings

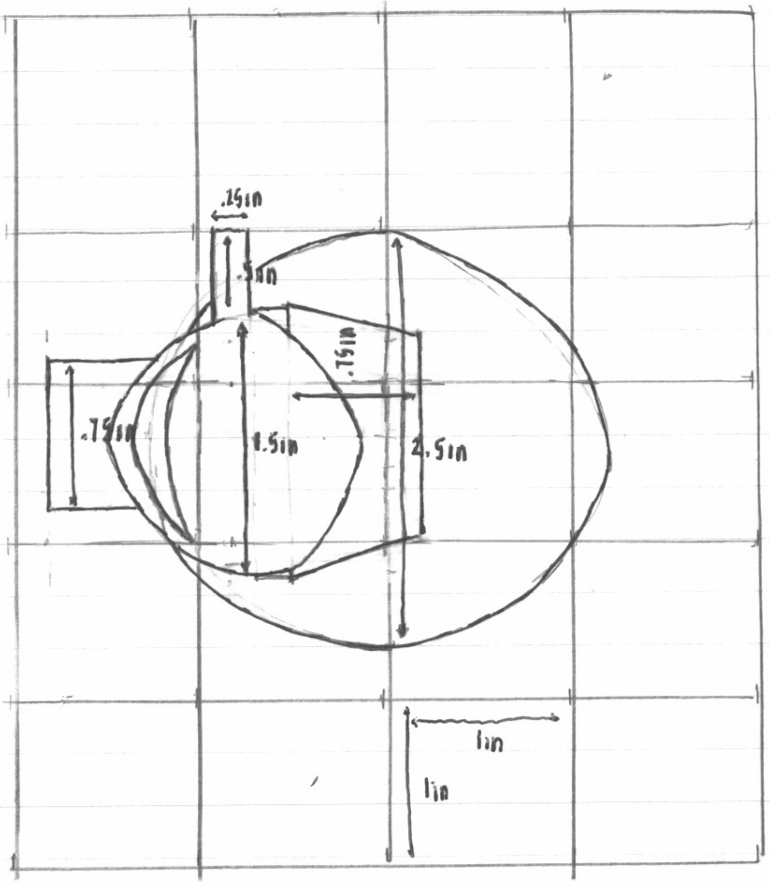
#### a. Solid Work of Oxygen Reservoir



**b. Solid Work of Prototype**

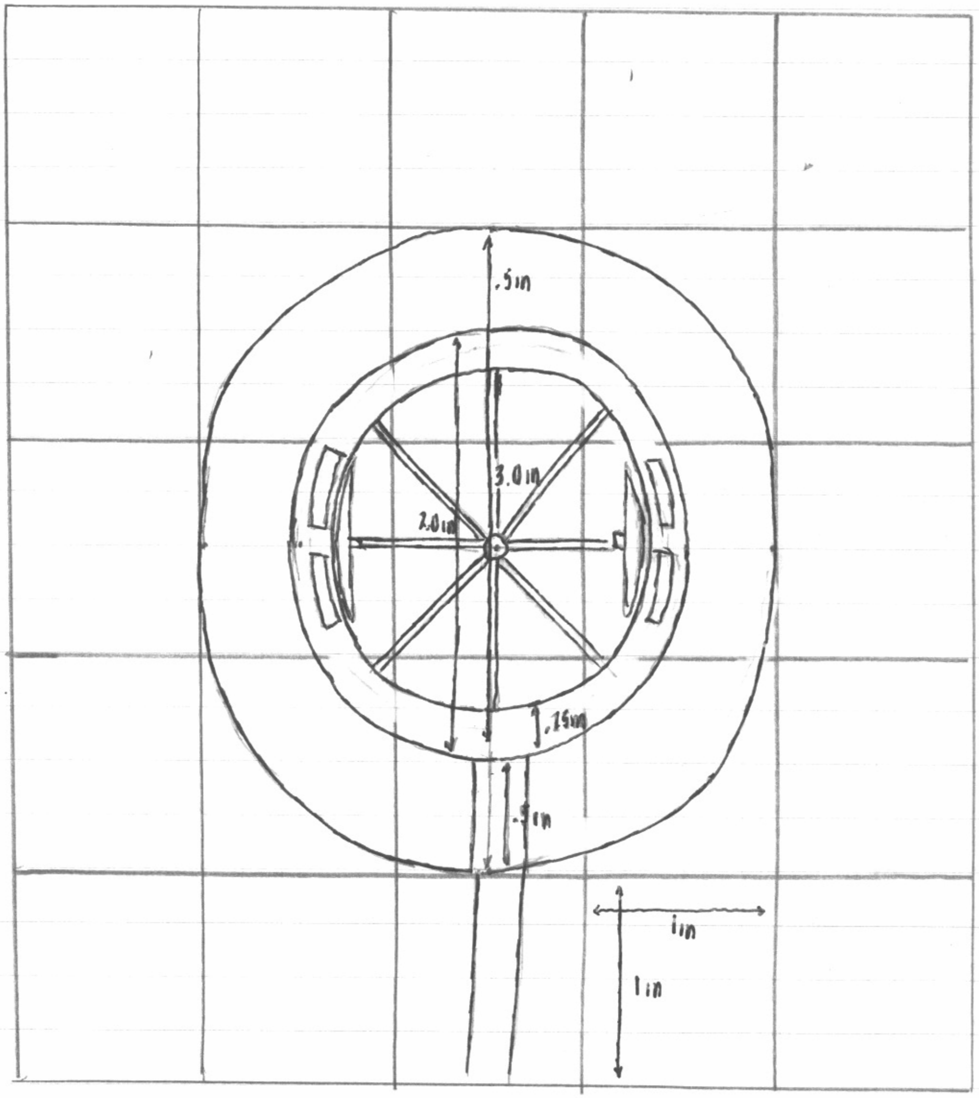


### c. PEEP Valve Attachment-Top



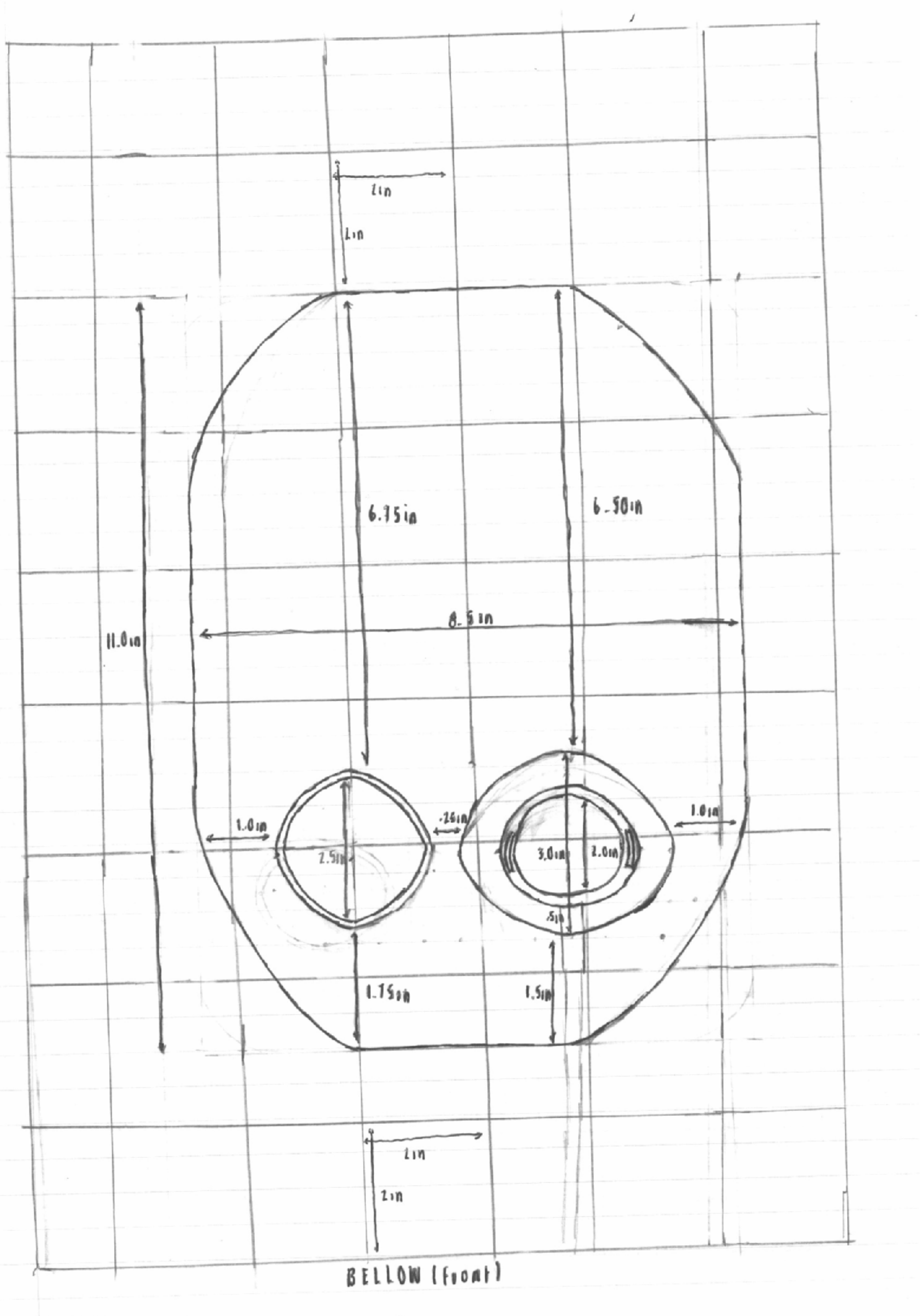
PEEP VALVE (top)

### d. Oxygen Reservoir Insert-Top

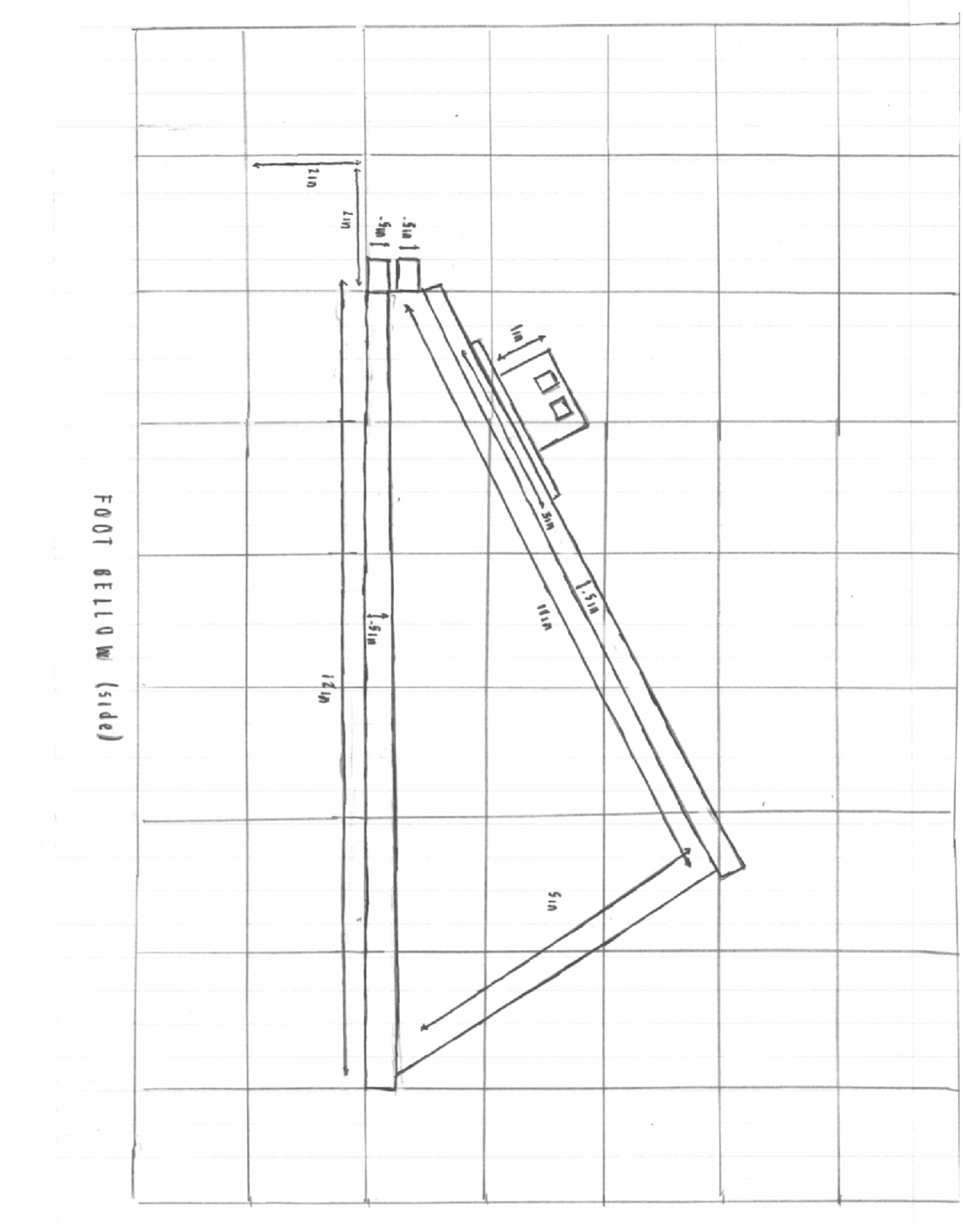


RESEVOIR INSERT (top)

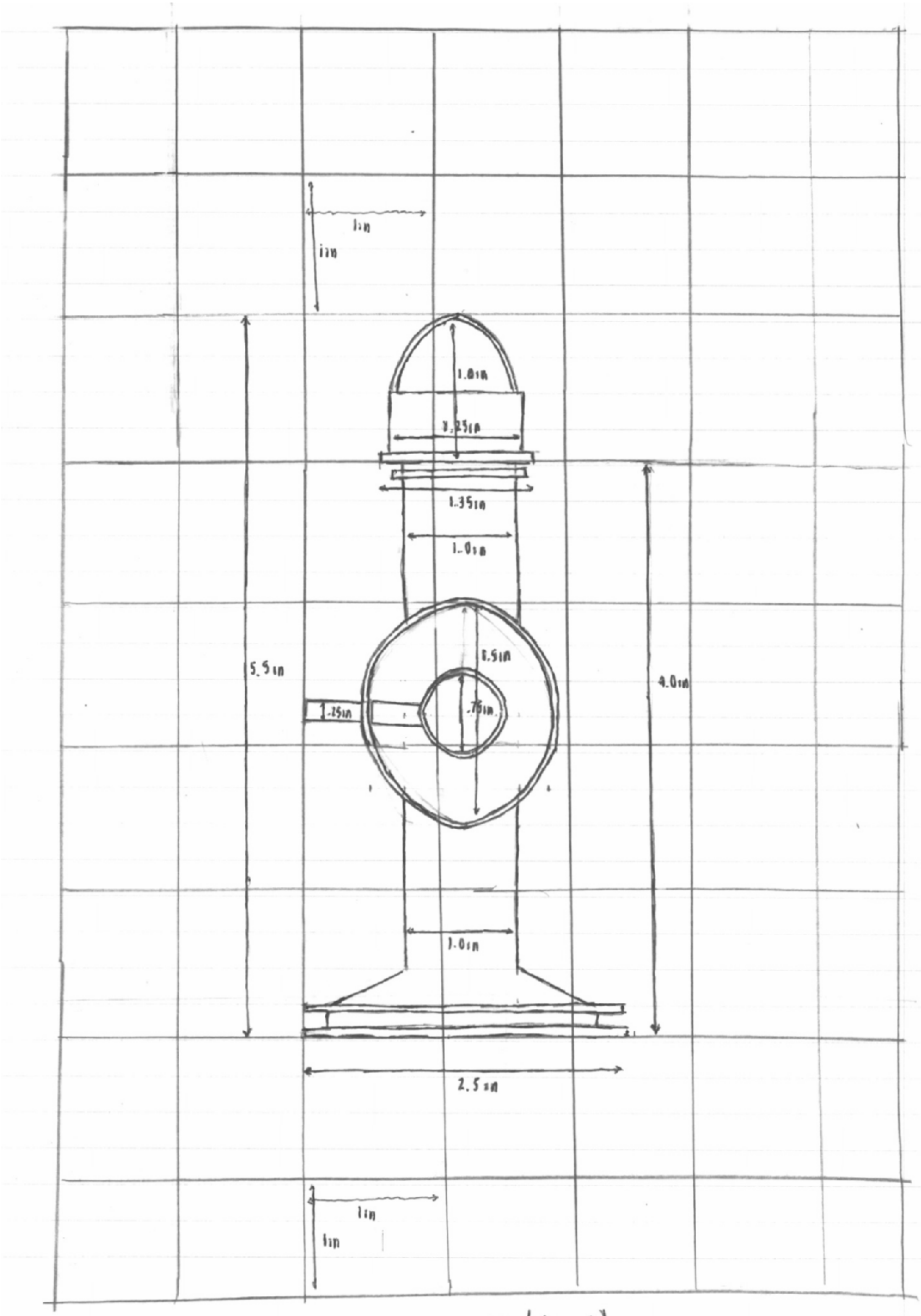
### e. Bellow Apparatus-Front



**f. Bellow Apparatus-Side**

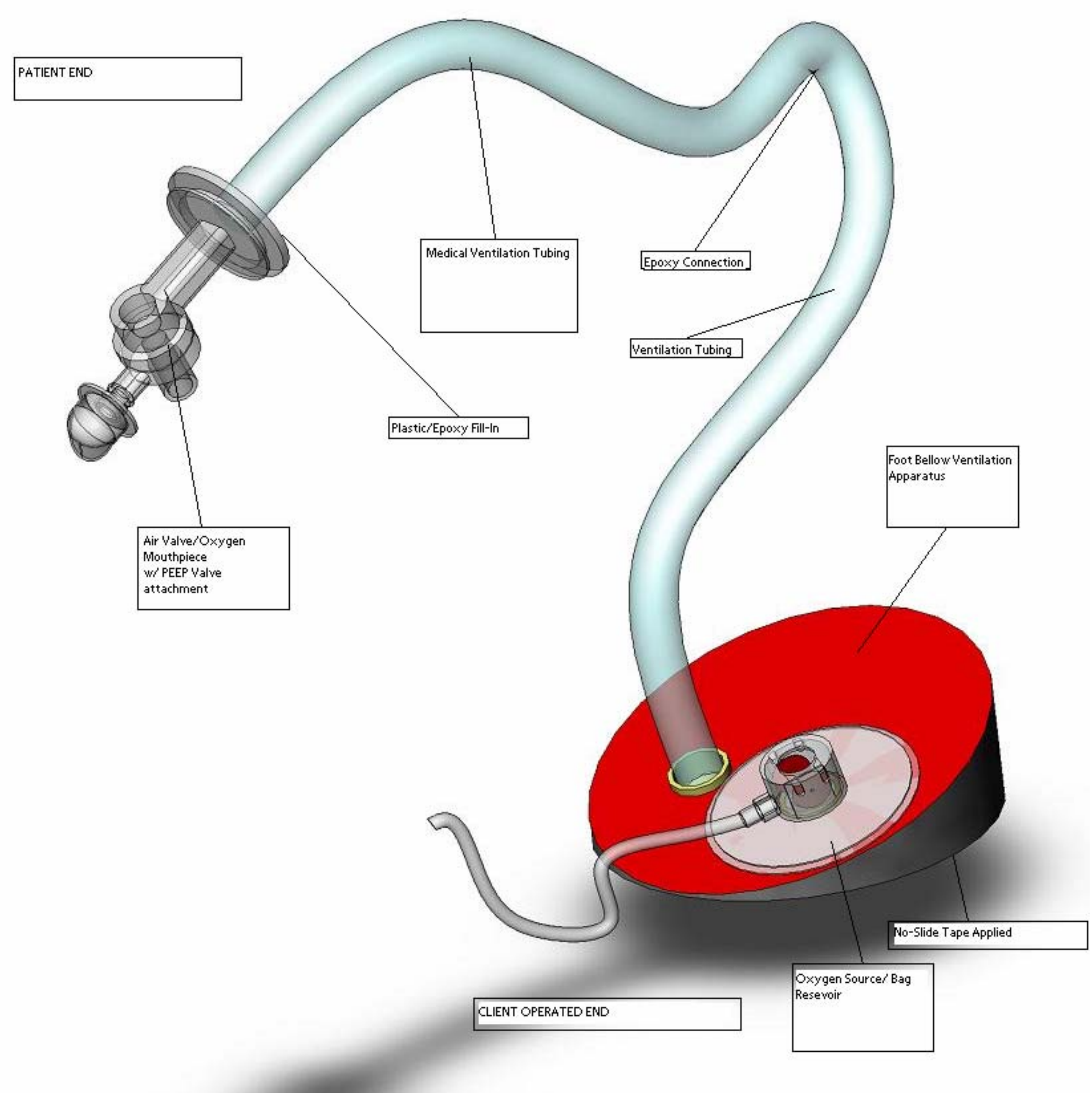


### g. Mouthpiece/PEEP Valve Attachment-Front



PEEP VALVE (front)

### ii. Parts List



**a. Air Valve/Oxygen Mouthpiece w/ PEEP Valve Attachment**

**Cost: Supplied by client, generally $5-10**

**b. Plastic/Epoxy Fill-In, Epoxy Connection**

**Cost: $2.00, includes Epoxy**

**c. Medical Ventilation Tubing**

**Cost: Supplied by client, generally $5**

**d. Foot Bellow Ventilation Apparatus**

**Cost: $15-22.00, prototype model $20.00**

**e. Oxygen Reservoir/Oxygen Source**

**Cost: Supplied by client, generally $5**

### iii. Prototype Pictures

**a. Prototype inflating Artificial Lung-1**

### b. Prototype inflating Artificial Lung-2

### c. Prototype in Medflight Helicopter