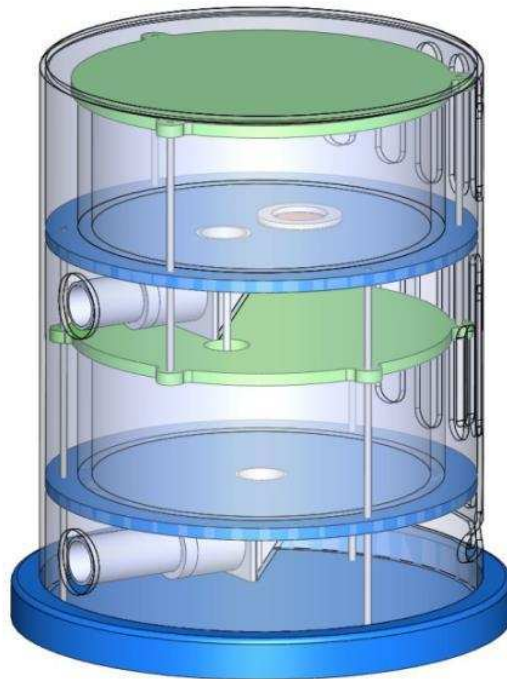


ME 450 Final Report

Patient Powered Device for the Treatment of OSA

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Team 6 Authors:	Katya Christenson Steven Fannon Joseph Jacquemin Davina Widjaja	Section Leader:	Professor Kathleen Sienko, PhD
		Sponsor:	University of Michigan Sleep Disorders Center
		Mentor:	Dr. Ronald Chervin, MD



ABSTRACT

Obstructive sleep apnea (OSA) is a disorder causing throat muscles to relax during sleep such that the patient cannot breathe until a brief awakening restores muscle tone and reopens the airway. Untreated sleep apnea contributes to a multitude of health issues. Treatment most commonly consists of nightly use of a continuous positive airway pressure (CPAP) device, which through applied air pressure physically splints the upper airway open and allows normal breathing throughout the night. The aim of this project is to develop an inexpensive, quiet, lightweight device, which operates independent of electrical power.

EXECUTIVE SUMMARY

Obstructive sleep apnea (OSA) is a disorder that occurs when throat muscles that normally maintain upper airway patency relax during sleep and cause the patient to choke until a brief awakening restores muscle tone and reopens the airway. Diagnosis and treatment are critical because untreated sleep apnea is believed to contribute to a multitude of health problems. The analyzed outcomes of user interviews, a user survey, and benchmarking results were combined to generate a list of user requirements and their corresponding engineering specifications. The top six requirements(excluding safety reqs.) are: no electrical dependence, a pressure tolerance of ± 0.5 cm H₂O, costs less than \$100, has a dead volume less than 102ml, is smaller than 20x10x10cm, produces less than 30dB, and weighs less than 2kg. Using these requirements we brainstormed designs, then selected concepts which we used to develop a Beta Design. We then built a prototype to verify that our concept functioned as expected; it consists of two bags, three custom made one-way valves, six rods linking the chambers, a backflow valve for joining the fresh/used air tubes to the mask, two hoses, a mask, a custom made elbow valve, and weight.



Figure 1: Working Prototype

Device Operation

As the user exhales (Figure 1), the CO₂ exhaled is forced through an elbow valve into Chamber 2. This action expands the bag in Chamber 2 and raises the moving plate of Chamber 2, which is connected to the moving plate of Chamber 1 through six rods, such that both chambers expand in unison. As Chamber 2 expands and thus Chamber 1, a low pressure area is created in Chamber 1, which subsequently draws fresh air into Chamber 1. Weight applied to the top of Plate A provides force to the system that the user breathes against. As the user inhales (Figure 2), the chambers relax and transfer fresh air via a hose to the user from Chamber 1. Meanwhile, the used air in Chamber 2 is expelled from the chamber through the elbow valve.

Results

The current method of treating OSA with existing electronic CPAP machines has several drawbacks which include: dependence on an electrical outlet, lack of portability (size and weight), machine noise, and high cost. We addressed these limitations by invention of a novel, mechanical CPAP system that requires no external energy source, emits less than 30 decibels, costs less than < \$60, and provides easily adjustable pressures ranging from 0-20 cm H₂O. In comparison, standard CPAP machines require an electric outlet, emit 30 decibels, and cost \$200 or more. However, standard CPAP units are slightly smaller than the mechanical prototype. Preliminary validation experiments show a linear correspondence between the pressure supplied to Chamber 2, as determined by the weight applied, and the pressure fed back to the user from Chamber 1. Results also show that the device, equipped with a working safety valve, can handle variable breath volumes.

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1 INTRODUCTION

Obstructive Sleep Apnea (OSA) is the anatomical blockage of the airway in the throat during sleep, which causes severe interruptions in sleep in over 20 million Americans [1]. OSA affects 4% of men and 2% of women, 70% of obese people, and is 2.5 times as likely to occur in African Americans [2]. It poses serious health effects such as cardiovascular disease, metabolic syndrome, cognitive impairment, and, in general, an overall decrease in the quality of life. There are four general types of treatment for OSA, with Continuous Positive Airway Pressure (CPAP) machines being the most common [2]. Despite the fact that CPAP machines are nearly 100% effective, they are not used by 60% of the people who own one and 45% of users use it for less than 4 hours a night [2]. The lack of use of the machine is a result of several problems that have been outlined to us by our mentor, Dr. Ronald Chervin—director of the Sleep Disorder Center at the University of Michigan. These include reliance on electricity, cost, portability, noise, weight, comfort, and esthetics. We have been challenged to create a novel constant positive airway pressure device that would make OSA treatment more available to the developing world by removing the machine’s reliance upon electricity, and reducing the cost of the machine by nearly half, while maintaining industry health standards.

2 BACKGROUND

2.1 Sleep Apnea

“An apnea is defined as the cessation of airflow in the nose and mouth for 10 seconds or longer” [3]. The average sleep apnea sufferer experiences between 30 and 60 apneas per hour, while 100 apneas per hour would be classified as a severe case of sleep apnea [4]. There are three types of sleep apnea: central, obstructive, or mixed/complex. Among sufferers of sleep apnea, 0.4% have central sleep apnea, 84% have obstructive sleep apnea, and 15% have complex sleep apnea [5]. Obstructive sleep apnea (OSA) is caused by the upper airway being obstructed in some way during sleep. For example, while in the supine position, the soft palate and/or the tongue collapse and rest in the airway due to a reduced muscle tension in the airway. However, central sleep apnea is caused by the absence of a brain signal to initiate breathing, while mixed or complex sleep apnea is a combination of central and obstructive, but physicians do not fully understand its origin [3].

From the creation of a blockage at the beginning of an apnea, to the initiation of a true breath at the end of an apnea, a series of events must occur to allow the person to breathe again. First, the person’s blood-oxygen level decreases, which will cause the body to undergo a fight-or-flight reaction. This reaction stimulates adrenaline to be sent to the heart, and a brain signal to be sent to the muscles in the airway to contract, which allows for a breath to occur [4]. Unfortunately, the brain must subconsciously wake up momentarily to produce these signals. Every time the person begins to fall into a deep sleep, they suffer an apnea and are awoken, such that they can never fall into Random Eye Movement sleep throughout the night. Consequently, sleep apnea can have many adverse effects on sufferers of sleep apnea. Diagnosis and treatment are critical because untreated sleep apnea is believed to contribute to daytime sleepiness, cognitive impairment, motor vehicle crashes, hypertension, heart failure, arrhythmia, myocardial infarction, stroke, diabetes, metabolic syndrome, and a shortened lifespan[1]. The most significant problem is the cardiovascular stress imposed; during each apnea, the patient’s blood pressure rises and adrenaline stimulates the heart, both of which increase the strain on the heart [3].

2.2 Anatomy

Obstructive sleep apnea occurs in the mouth and upper throat area of the body. This area is unique in the body as it is associated with both the respiratory and digestive system, while also being responsible for formulating vocal sounds. The anatomy of the mouth and upper throat is known as the pharynx and can be divided into three main subsections—the nasopharynx, oropharynx, and laryngopharynx [6]. A cross-section of the mouth and upper throat areas, shown below in Figure 1, displays the general location of these areas.

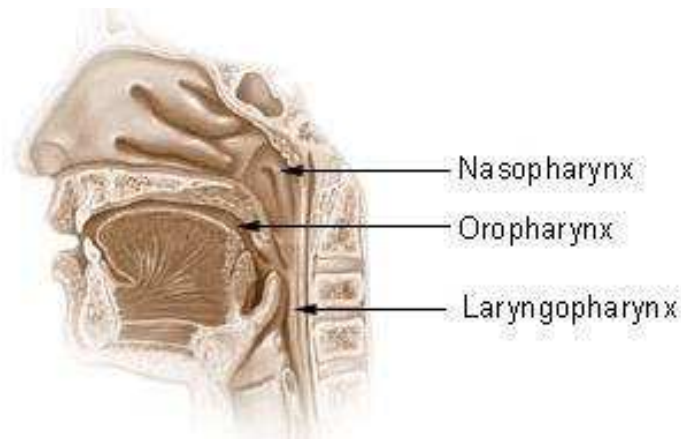


Figure 1: Cross-section exhibiting the pharynx [6]

OSA events occur mainly in the oropharynx when the muscles in that area relax. This causes the soft palate, tongue, and epiglottis, shown in Figure 2 below, to fall back into the airway blocking it. The muscles which make up the soft palate are the levator veli palatini and tensor veli palatine, which are responsible for swallowing, the palatoglossus and palatopharyngeus, which are responsible for respiration, and the musculus uvulae which is responsible for moving the uvula [7]. The uvula helps formulate certain sounds during speech and also helps close off the nasal passage when necessary [7]. Light snoring during sleep is often times caused by this part of the body. The epiglottis is a cover of elastic cartilage that blocks the airway during swallowing. A relaxed soft palate, tongue, and epiglottis can be seen in Figure 3, exhibiting a blocked airway [7, 8].

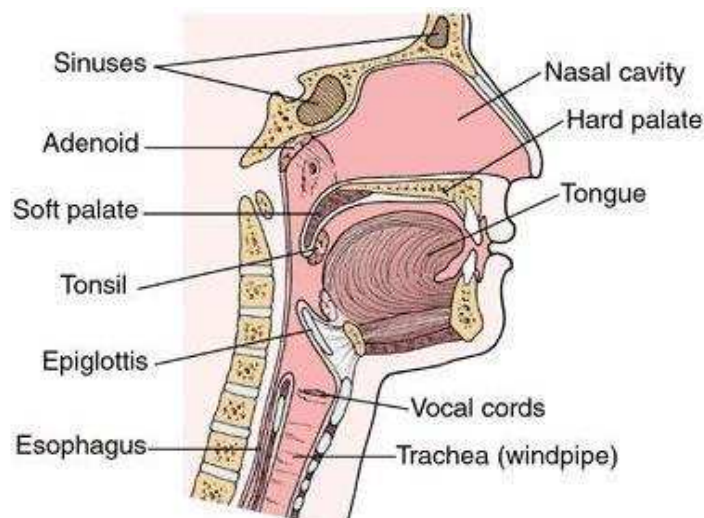


Figure 2: Cross-section exhibiting throat and oral cavity [9]

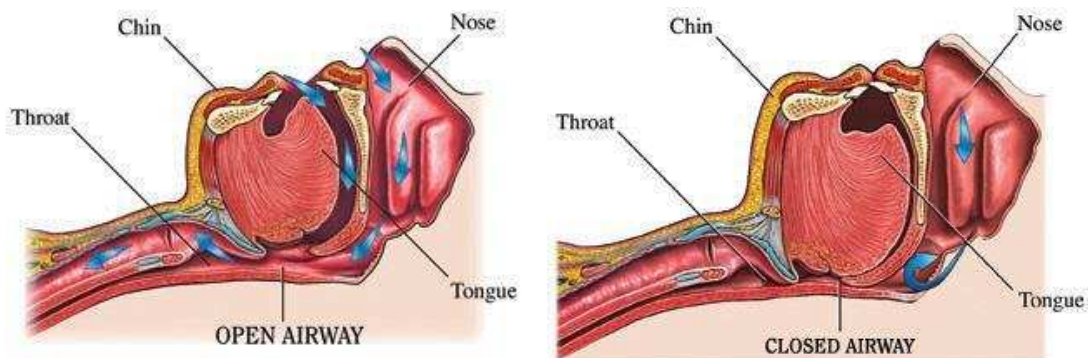


Figure 3: Cross-section comparing the passage of air in an open airway versus a closed one [8]

2.3 Breathing

In Michael Levitzky’s book *Pulmonary Physiology* [10], he describes how humans breathe by way of negative airway pressure. When the lungs do not contain air, the chest muscles tense and the diaphragm shifts downward to promote air movement. This creates a vacuum within the lungs, where there is a lower pressure in the lungs than the surrounding atmosphere outside the body. The oral cavity and airway open to allow fresh air to flow into the lungs. The lungs then complete a gas exchange of CO_2 , from deoxygenated blood, to fresh air, which re-oxygenates the blood. When the diaphragm relaxes, the CO_2 is pushed out of the lungs.

Breathing requires air movement in and out of the lungs. Mechanical ventilation is the act of forcibly inflating and deflating an individual’s lungs through the use of a machine. Patients can be on a ventilator for a multitude of reasons, from complete paralysis or coma, which requires constant ventilation, to sleep apnea, which only requires ventilation during sleep. Although there are other forms of treatment for sleep apnea, to be described later, mechanical ventilation is the most common type. The most common type of treatment is through the application of positive airway pressure: CPAP, constant positive airway pressure; APAP, automatic positive airway pressure; or BiPAP, bi-level positive airway pressure. The individually-tailored positive airway pressure treatment is produced by an air pump that delivers air from the machine to a face mask via a hose. The airflow physically splints the upper airway open and allows normal breathing through the night. CPAP is the industry standard, while APAP and BiPAP are relatively new in the market. APAP is supposed to automatically adjust the airflow supplied to the patient based on the previous breath [11]. BiPAP adjusts the airflow based on when the patient is inhaling or exhaling, such that there are two different, pre-set airflow pressures. When the patient is using BiPAP during inhalation, the airflow is at the higher pre-set airflow, but when the patient is exhaling, the airflow drops down to the lower, pre-set airflow—thereby promoting breathing comfort [11].

2.4 Diagnoses

Although symptoms can be severe and can significantly decrease one’s quality of life, many people are unaware that they even suffer from sleep apnea [4]. They have become accustomed to constantly being exhausted and convince themselves it is normal. Often times a family member notices their breathing habits during sleep and this prompts them to see a physician for diagnosis. During diagnosis of sleep apnea, the patient participates in a sleep study, or polysomnograph, to

determine their severity of sleep apnea, its cause, and the method of treatment to be administered. High cost is a prohibitive factor to many people suffering from sleep apnea, as the polysomnogram requires a physician to watch over and analyze a patient's sleep cycle for an entire night [4]. The physician gathers data on eye, chin, chest, and abdomen movement, as well as, mouth and nose breathing, EKG data, and to determine if the patient has sleep apnea [3]. When positive airway pressure (PAP) is chosen for treatment, the level of air pressure must be determined; this process is called titration [4]. If the air pressure is too low, the patient will continue to suffer from sleep apnea and its effects, and treatment will be ineffective. If the air pressure is too high, the patient will struggle to exhale and inhalation will be uncomfortable. This sensation can be compared to the sensation felt when a person sticks their head out the window while driving down the interstate; Air is forced in when they inhale, but it is difficult to exhale.

3 CURRENT TYPES OF TREATMENT

The types of treatments that can be utilized are based on the level of severity of the patient's sleep apnea. Although we discuss CPAP in detail, we also explore a wide variety of other treatments through researching patents and benchmarking products used in the market today.

3.1 Severity Determines Treatment

If a patient has a mild form of sleep apnea, they can often merely alter their sleep position to lie prone or lie on their side. Mild sleep apnea sufferers can also wear a jaw device that forces their mandible forward, as shown in Figure 4 below.



Figure 4: Example dental device [13]

Mild sleep apnea sufferers can also receive surgery to reduce their tongue size, reconfigure the soft palate and the uvula, permanently shift the jaw, or reposition the hyoid bone [3]. However, surgery is expensive and has inherent risks involved. In the case of severe apnea, mechanical ventilation, such as CPAP, is often times the only option. In the past, tracheotomies, a surgical incision in the trachea to allow breathing via a hole in the neck, were common. In general, children who suffer from sleep apnea will typically have their tonsils removed and this solves the majority of problems; in adults, CPAP is most commonly recommended and employed [4]. The categories of treatments are linked to the severity of sleep apnea below [4]:

1. PAP—mild through severe
2. Behavior therapy—mild apnea
3. Surgery—mild through severe
4. Oral devices—mild apnea

3.2 CPAP

Constant Positive Airway Pressure, or CPAP, is one way to treat sleep apnea. It supplies a constant airflow into the oral or nasal cavity such that if there is a blockage in the airway (i.e. patient's tongue, soft palate, or epiglottis), it is removed and the airway remains free from obstruction. To further investigate how this treatment is administered, we disassembled a common CPAP device called the REMstar Pro, which was manufactured by Respironics. Most notably, we discovered a fan, shown in Figure 5, which draws air into the machine at a designated speed to produce the desired pressure specified by the user. The pressurized air is then directed from the machine, through the hose and mask, and into the patient's lungs. Typical components of a CPAP machine are [12]:

- Air filter (not shown)
- Sound-absorbing foam, Figure 5 below
- Fan, Figure 6 below
- Sensors(two) measuring the administered airflow pressure, Figure 7 below
- Mask with a head strap to secure during sleep (not shown)
- Plastic air tube(approximately 1 inch diameter), Figure 7 below
- Electrical plug (not shown)
- Humidifier to provide more comfortable airflow—not required (not shown)
- Heat plate to provide more comfortable airflow—not required (not shown)
- SmartCard to collect information and control the CPAP machine based on the physicians instructions (not shown)

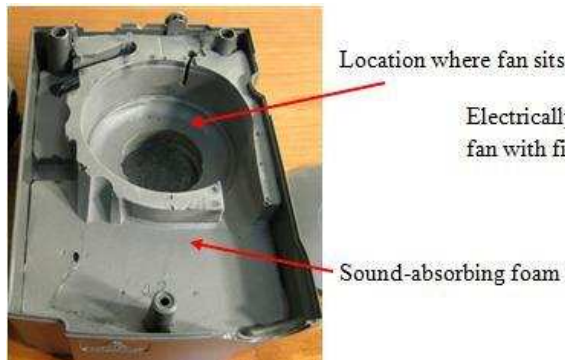


Figure5: Sound dampening foam

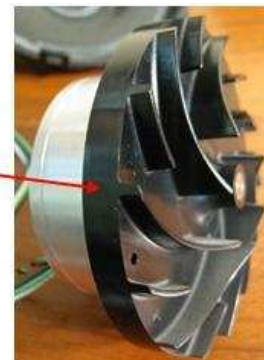


Figure 6: Fan



Figure 7: Disassembled CPAP machine exhibiting electrical and mechanical components

3.3 Patents

Through our research we have discovered a variety of patented ideas in reference to CPAP devices and other treatments that focus on relieving sleep apnea (Table 1 below). Many current treatments require electric power to run an air compressor, which creates the continuous air pressure in the CPAP. An interesting design for an Expiratory Positive Airway Pressure (EPAP) device, which does not require electric power, was recently developed [4]. This device uses a mask with valves which creates positive airway pressure during expiration using the natural process of respiration by resisting expiration (breathing out). However, this device does not provide continuous pressure, which many OSA patients require. Additional patents are listed in Figure A1.

Patent Number	Name	Description
5465734	Adjustable tongue positioning device and method	Device that utilizes a sleeve which brings the tongue forward to decrease the obstruction in the user's airway
5794627	Disposable mandibular advancement appliance	Device worn while sleeping to advance the mandible and open the airway
6587725	Close loop stimulation of hypoglossal nerve	Method and apparatus to treat obstructive sleep apnea- An implant that sends electrical impulses to the nerves in the tongue to keep the tongue muscles retracted and the airway open
7516743	CPAP machine and configuration	Portable CPAP machine that may be strapped against the chest

Table 1: List and description of notable patents [14]

3.4 Benchmarking

To better understand the industry of OSA treatment in the market today, we compared CPAP machines, dental devices, behavior therapy, and surgery for our product benchmarking (Table 2).

When choosing the CPAP machines, we recognized several key features to focus on based upon our user requirements and specifications, as shown in Table 4. These include: price of the machine (US\$), noise level produced at 10 cm H₂O measured from 1 m away (dB), machine weight (kg), size of the machine (L x W x H in centimeters), ability of the machine to deliver continuous pressure (4-20 cm H₂O), need of electrical outlet or battery, and manufacturer's warranty to give us a sense of the machine's service lifetime. Our research showed that all CPAP machines are still powered by electricity either by direct AC power or battery. The machines cost from US\$189 – US\$739 and weigh from 0.77 – 2.1 kg. The product specifications of the chosen CPAP machines are obtained from an online store called CPAP.com [15].

When choosing alternative treatments we focused on electrical dependency, effectiveness in treating the three types of OSA, and cost. The dental/tongue devices range from \$76-150, do not require electricity, but are effective for mild and some moderate sleep apnea cases. Surgery costs more than \$1000, varying by each healthcare provider and is effective for most but not all OSA cases.








	CPAP Machines			Tongue Lifting Devices			Alternate Treatments	
	Zzz-Pap Silent Traveler	Everest 2	REMstar Pro	AveoTSD	MPowRX	Anti-Snoring Appliance	Surgery	Dental Device
							N/A	
Price (US\$)	209	189	459	149	150	75.95	> 1000	> 200
Manufacturer	Probasics	AEIOMed	Respironics	Aveo	MPowRx	Snor-X	Physician	Dentist/Orthodontist
Sound Level (dB)	30	31	30	0	0	0	0	0
Deliver Pressure (4-20 cm H2O)	Yes	Yes	Yes	No	No	No	No	No
Requires electricity	Yes	Yes	Yes	No	No	No	No	No
Volume (cm ³)	24 x 15 x 10	19 x 13.3 x 21.6	33 x 18 x 14	5 x 3 x 6.4	7.6 x 3.5 x 6	5 x 3.5 x 1	N/A	7.5 x 5 x 2.5
Weight (kg)	0.77	1	2.1	0.5	0.5	0.5	N/A	0.7
100% effective (mild, moderate, severe OSA)	Yes	Yes	Yes	No	No	No	No	No

Table 2: Benchmarking OSA treatments [14, 16]

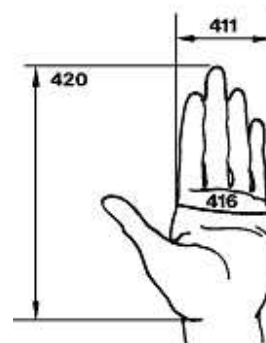
Featured Benchmarks

Respironics REMstar Pro (obtained from sponsor): With a price of \$459, this CPAP model is relatively expensive compared to the other models.

Zzz-Pap Silent Traveler: This model of the CPAP machine is comparatively the most portable among other models. It only weighs 0.77 kg and has dimensions of only 24 x 15 x 10 cm³. We compared these dimensions with anthropometric data of hand sizes of a Caucasian male [17] to the 95th percentile and determined that the machine also fits nicely in the palm of an average Caucasian male as show in Table 3. The length (24 cm) and width (15 cm) may be a little longer and wider than the average Caucasian male hand, which has a length and width of 20.6 cm and 9.6 cm, respectively. However, the height of the machine, only 10 cm, allows the machine to be held comfortably when gripped.

No.	Dimension	95th percentile (cm/in)
420	Hand length	20.6 (8.1)
411	Hand breadth	9.6 (3.8)

Table 3: Description of average male hand [17]



Sleep Behavior Therapy: While this is the simplest treatment, it can be quite problematic. Sleep behavior therapy involves possibly changing sleep behavior to sleep in a position that will assist in and allow the airway to remain open during sleep (generally on the stomach). This treatment is inexpensive and does not require the aid of any external device. However, it does not work for all types of sleep apnea.

Surgery: Surgery has a fairly high success rate and does not require any external device to keep the airway open. Surgery can remove parts of the soft palate, reduce the size of the tongue, remove the tonsils, create an alternate airway to bypass the throat (tracheotomy), or extend the

lower jaw[4]. While effective, it is the most expensive treatment option with costs in the thousands of dollars.

Dental Devices: Dental devices open the airway by one of two methods, by holding the tongue forward using a suction cup (as shown in the AveoTSD, MPowRX, and Snor-X devices) or by holding the lower jaw forward during sleep (APM Ultra). These devices are relatively unobtrusive, easy to use, portable, and do not require electrical power. However, they do not have the efficacy of traditional CPAP machines in that they cannot treat moderate-severe sleep apnea. Utilizing this kind of treatment can be expensive, because the device and required dentist/orthodontist visits and fees can cost several hundred dollars. They can also cause joint pain and discomfort of the tongue.

4 USER REQUIREMENTS

4.1 Project Path

Our literature search and benchmarking of available treatments opened doors to the possibility of improving any of the treatments discussed above. For the purpose of generating our list of user requirements, it should be mentioned that some of the user requirements and the target values are heavily influenced by the use of a CPAP, the most common form of sleep apnea treatment. However, during the brainstorming process we considered all forms of treatment.

Determining User Requirements

To supplement our literature findings of problems with current sleep apnea treatment, we determined what the users' needs and wants are in an effective treatment method. This was achieved by conducting an online Facebook Sleep Apnea Group survey (September 20-27th), 2009, and interviewing with members of the Ann Arbor CPAP User Support Group (October 20th, 2009) [18]. The results of our 340 person survey can be seen in Appendix B. We discovered that 94% of the people with OSA who responded use a CPAP machine and 74% of these people use it every night. Over 70% of CPAP machine users would be more likely to bring their machine on vacation if it was smaller. The majority of people who have a CPAP machine agree that the areas most in need of improvement are size, noise level, electrical dependency, and cost.

The highest priority requirements from the perspective of our mentor are:

1. No Electricity
2. Low Cost
3. Small
4. Quiet

The analyzed outcomes of our user interviews, the user survey, and benchmarking were combined with our mentor's feedback to generate a list of ranked user requirements. These user requirements can be viewed in the far left column of Table 4 below. These requirements were ranked on a scale of 1 to 10 with 1 corresponding to the least important feature and 10 corresponding to the most important feature.

5 ENGINEERING SPECIFICATIONS

Engineering specifications were determined through the analysis of our user requirements. We used manufacturers' websites as a benchmark to provide the baseline for many of the industrial engineering specifications for device. From these benchmarking results, we determined if the

values should be higher or lower than the standard to meet the user’s requirements. In determining our engineering specifications, the ability to test our device against the target values was considered. We then employed a Quality Function Deployment (QFD) Figure A2, to evaluate the correlations between the customer requirements and the engineering specifications. In Table 4 below, we have linked the user requirements to the engineering specifications and determined target values.

User Requirement	Importance (1-low, 10-high)	Engineering Specifications (units)	Target Value
Safe to use	10	Minimum part width to prevent choking hazards (mm)	20.9 [19]
	10	Toxic materials/chemicals (#)	0
	10	Sharp edges (#)	0
	10	Airflow allowed with machine powered down (ml/s)	250 [20]
Works	10	Minimum air pressure supplied (cm H ₂ O)	4 [4]
	9	Minimum continual operation time (hours)	10 [21]
	3	Range of deliverable pressure (cm H ₂ O)	4 – 20 [22]
	9	Diff. between inhalation/exhalation pressures (cm H ₂ O)	± 0.5 [4]
	7	Dead volume (ml)	102 [23]
Low Cost	9	Purchase price(\$)	≤ 100 [4]
	9	Cost of replacement parts per year (US\$)	≤ 40 [18]
	8	Sanitation cost per year (US\$)	≤ 10 [18]
	8	Consumable Parts (#)	0
	6	Years before replacement (#)	≤ 5 [18]
Quiet	6	Sound level (dB)	≤ 30 [24]
Small	6	Dimensions (LxWxH [cm])	20x10x10 [17]
Continues to operate during power outage	9	Voltage at which machine switches to backup power (V)	100
	9	or Voltage required to operate (V)	0
Stable	7	Stable surfaces (#)	≥ 1
Easy to use	8	Compatible hose adaptor inner diameter (mm)	≤ 22 [25]
	4	Time required to turn on/off (s)	5 [18]
	2	Pieces to sanitize (#)	≤ 5 [18]
	3	Buttons/Switches/Levers (#)	≤ 3 [18]
Manual emergency shutoff function	6	Time required to stop applying pressure (s)	≤ 5 [18]
Lightweight	5	Weight of device (kg)	≤ 2.0 [15]

Table 4: Linking customer requirements to engineering specifications and our target values

5.1 From Customer Requirements to Engineering Specifications to Quality Function Deployment

Safe to use

Safety is a number one priority in any medical device involving direct human interface. Each component of this requirement is therefore rated 10 (high) in importance. In the Facebook

survey, patrons mentioned that they want a machine that is safe to use but generally did not describe in detail what comprises a “safe-to-use” device. Our research on safety standards of products used by humans yields some factors that help us form our engineering specification goals for safety. We plan to minimize the number of small parts interacting with the oral cavity, which could cause choking hazards. The target value for the minimum size of each part of the device is at least 20.9 mm. This was determined because the average male trachea has a width of 20.9 ± 0.32 mm [19]. The male trachea was chosen because it is larger than the female trachea on average, providing a more restrictive dimension for the minimum part size. If each object is larger than 20.9 mm, then it would likely not become lodged in the trachea. We plan to reduce the number of toxic materials or chemicals used in production, as well as eliminate any sharp edges. All of these factors will pose a high degree of danger to the well-being of the user, so our target values for these specifications are 0, or in other words, none at all.

It is also vital to ensure that airflow to the breathing passage remains at a certain level to allow the patient to continue breathing when the machine is not functioning, as long as the patient is not suffering an apnea. The airflow allowed is targeted at 250 ml/s [18]. This number is derived by studying how a normal human breathes. The amount of air inhaled and exhaled during normal respiration is called the tidal volume. An average male usually has a tidal volume of 500 ml [18]. Because a breath requires approximately 2.5 seconds to complete, the airflow rate for this specification is half of the tidal volume per second. This specification is rated 10 for importance.

Works

Other than safety, users require that the device actually treats sleep apnea effectively. One consideration is the minimum air pressure (cm H₂O) that should be supplied when the device is used. When using air pressure to treat apnea, different severities of sleep apnea require different levels of air pressure, with severe OSA requiring higher pressure. The range of pressure provided in a standard CPAP machine is 4 – 20 cm H₂O [22]. Thus, the minimum air pressure supplied should cover the lower bound of that range, which is 4 cm H₂O [4]. We plan on treating all severities of sleep apnea with this new device. Another highly ranked goal for this requirement is to achieve a minimum continuous operation time of 10 hours. On average, people sleep between 6 – 8 hours [21], so an operation time of 10 hours seems reasonable for the device. The device must provide specified pressure within a tolerance of ± 0.5 cm H₂O. In other words, the inhalation pressure cannot differ more than 0.5 cm H₂O from the exhalation pressure. Also, the device cannot contain more than 102 ml of dead volume or the oxygen content of the inhaled air will not be at the minimum safe level [23].

Low cost – Cost (US\$)

Consistent with our goals to make our device affordable to low-income sleep apnea sufferers or those in developing countries, we developed five engineering specifications for the cost requirement. From benchmarking apnea treatment devices (Table 2) and incorporating our sponsors design goals, we determined that the target value for the purchase price should be less than \$100. The cost of replacing parts and sanitation cost per year are targeted at less than \$40 and less than \$10, respectively. These values are determined by meeting with the Ann Arbor Sleep Apnea support group and discussing current costs for device maintenance. In addition, we plan to limit the number of consumable parts to zero, such that the product does not require a continual supply of replacement parts—this makes the product more appropriate for use in the

developing world. We also plan to design the machine to last at least five years before requiring replacement. This value is obtained from studying standard CPAP machines currently being used on the market, determined through the Ann Arbor Sleep Apnea support group. To make the machine smaller and more portable, we may need to use special materials or methods, which would increase the cost. Also, if we decided to develop a mechanical device that could function without electricity, this could reduce the price significantly. However, it could increase maintenance costs. And, if we reduce the number of consumable parts, then we likely increase the parts that require cleaning. Cost is also related to the manufacturing methods of the parts. While we may want to reduce cost with cheaper manufacturing methods, we could be sacrificing aesthetics.

Quiet

Our targeted maximum noise level for the sleep apnea device is mostly influenced by the CPAP machine. The simplest PAP systems involve a motor/blower setup with pressure-flow characteristics to provide PAP. This creates a substantial amount of noise to operate, unlike the other static treatment devices, such as surgery and oral/dental devices. The majority of CPAP machines we studied have an average noise level of 30 dB. Reducing noise level will result in a more desirable product as the user and any nearby sleepers could possibly obtain better sleep through the reduction of noise in the sleeping environment.

Small

Our Facebook survey results show that over 72% of customers would be willing to travel with a CPAP machine if it was smaller. Having this large percentage of people respond positively is a strong indication that the device should be a compact piece of equipment, thus it received a high importance rating of 6. Our target value, after considering benchmarked products, is approximately 20 x 10 x 10 cm (the size of an average carry-on). This dimension is obtained by referencing the average adult male's hand size in Table 3 and considering what the average hand could comfortably wrap around. Although the user will likely not be carrying the device in their hand, surveyed users implied that the device should be approximately that small. It is worth noting that the values could potentially be iterated over the course of the project. Currently, the dimensions listed assume the device is providing PAP. Dimensional consideration for oral or dental devices would require the dimensions to be reduced significantly so as to fit the oral cavity and not block the airway. We must keep in mind that smaller device dimensions could potentially negatively affect the space for emergency human interface as there will be less space to work with.

Continues to operate during power outage

One safety concern mentioned in the Facebook survey results was when the CPAP machine stopped functioning in the middle of the night during a power outage. Having an emergency backup power supply to be triggered when voltage drops below 100V is one solution. This specification is ranked relatively high (9) as safety of the patient is important.

Another point to note is the fact that all PAP machines currently available require electricity or some kind of battery-powered source to be operated. Our aim is to develop a device that uses no electricity; thus, the required voltage to operate is targeted at 0V. This could possibly be achieved by a mechanical PAP device. It should be noted that our initial research scope covered a wide

breadth of topics, from using an oral device to physically move the obstruction, to developing a new power source. It would be a potential design breakthrough if the device could operate mechanically without electricity. This could significantly reduce purchase price, as well as, the maintenance cost in terms of electricity used. The device would also be more portable and versatile if it could be used without the need of a power outlet.

Stable

Given that the device will be used in the night while sleeping, it is important that it can be mounted on a steady and reliable tabletop or other mounting device. This need calls for at least one stable outer surface (i.e. a flat surface), to ensure that the machine can be mounted securely without risk of falling over. Other methods to stabilize the device could be fasteners, nails, or hooks to allow attachments to walls or other surfaces. This feature could be negatively impacted when the machine is made too small or light, because it increases the chance that it could be yanked off the mounting surface.

Easy to use

If we engineer something that is very complicated to operate, it is unlikely that someone will use it. Simplicity is a major feature consideration for determining if a machine/device is easy to use. If we decide to develop a device that requires a mask and hose, we need to ensure that the tube adaptor outlet is compatible with the air hoses currently sold in the market. The standard inner diameter of the hose adaptor is 22 mm, which is our target value for the machine-hose interface. The size of the tube adaptor inner diameter could affect cost related to manufacturing the bore of the outlet with tight tolerances. In addition, if the machine requires a long, awkward hose, it could potentially negatively impact the convenient mounting feature prescribed previously, as the air hose would still be a hassle to set up even though the device itself is small.

We determined that the time required to start or stop the machine would be a good reflection of the machine's ease of use. Based on current PAP machines, we hypothesized that 5 seconds is a reasonable value for this specification. Also, the number of interface points (buttons, switches or levers) to start or stop the machine can directly determine the device's ease of use. We set this to 3 interface points based on current PAP machines available on the market. Because this project involves opening the airway either through delivering pressure through the breathing passage or placing an object in the oral cavity, sanitation of the device is a necessity for its function. Thus, another specification included is the number of parts to be sanitized, which we set to be less than 5 parts, as determined from current CPAP machines. In addition, ease of use is strongly correlated with the size and portability of the machine.

Manual emergency shutoff function

During an emergency, there could be a need to immediately stop the device, so a manual emergency shutoff function should be provided. The engineering specification to quantify this is the time required to stop the device when the manual shutoff function is deployed. The target value is less than 5 seconds, as this is a reasonable time for which a human being can comfortably go without a breath. Also, the emergency shutoff time should be shorter than the standard shutoff time of 5 seconds. It is given a rating of 6 in importance for its relation to safety; however, it might not be necessary if our device design does not require an electrical source.

Lightweight

As previously mentioned, one of the Facebook survey results concluded that if the machine was more portable, survey respondents would more likely travel with it. Portability not only implies size, but also weight. The target value for this specification is preferably less than 2.0 kg, Many CPAP machines currently available are at least 2.0 kg and are quite large, which makes them difficult to transport. The lower the size and weight, the more portable it will be. Currently, the dimensions listed assume the device is providing PAP. Consideration for oral or dental devices would require the weight to be reduced significantly such that it is comfortable for sleep apnea patients. It is rated 5 in importance in relation to others as it is quite important to make the user happy but not particularly necessary.

6 CONCEPT GENERATION

6.1 Our Brainstorming Approach

Because we were provided a CPAP machine, we first focused on understanding how the CPAP machine functions. After we disassembled it, we were able to investigate it and form its function decomposition, which is shown in Figure A3.

From this functional decomposition, we were able to expand our realm of thinking to other areas besides just the CPAP machine. Each team member was tasked to create at least four concepts. Next, we generated concepts using each others' ideas. Then, we invented a more systematic approach to our brainstorming by forming a more comprehensive functional decomposition consisting of the inputs, component functions, and outputs (Figure 8). We determined the inputs and outputs of the system device along with the basic function the device could use to maintain an open airway. We generated ideas by attacking the processes outlined in the functional decomposition.

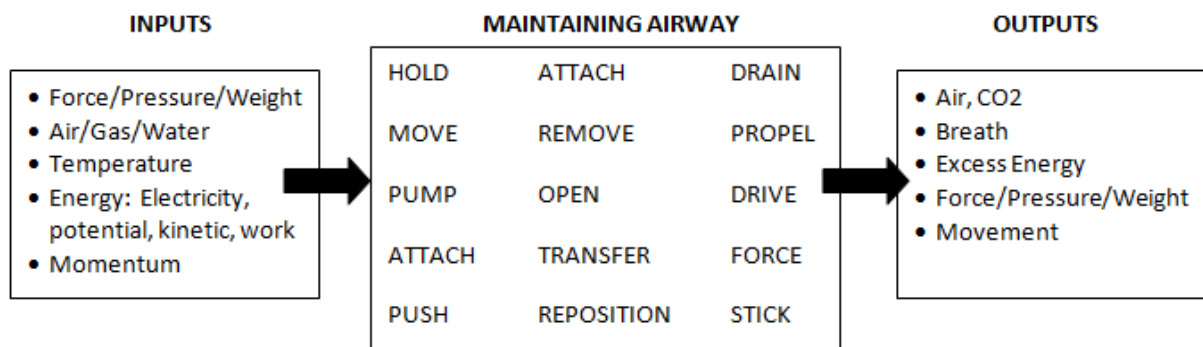


Figure 8: Transformed functional decomposition, which better represents our design problem. Our overarching approach to concept generation can be best described through the visual representation shown in Figure 9 below. On the left is how we generated our concepts, and on the right is how we selected our final concept, as discussed later. This figure shows how we individually generated ideas and brought those ideas together and converged as a group. Next, we attacked concept generation by functions, using the functional decomposition.

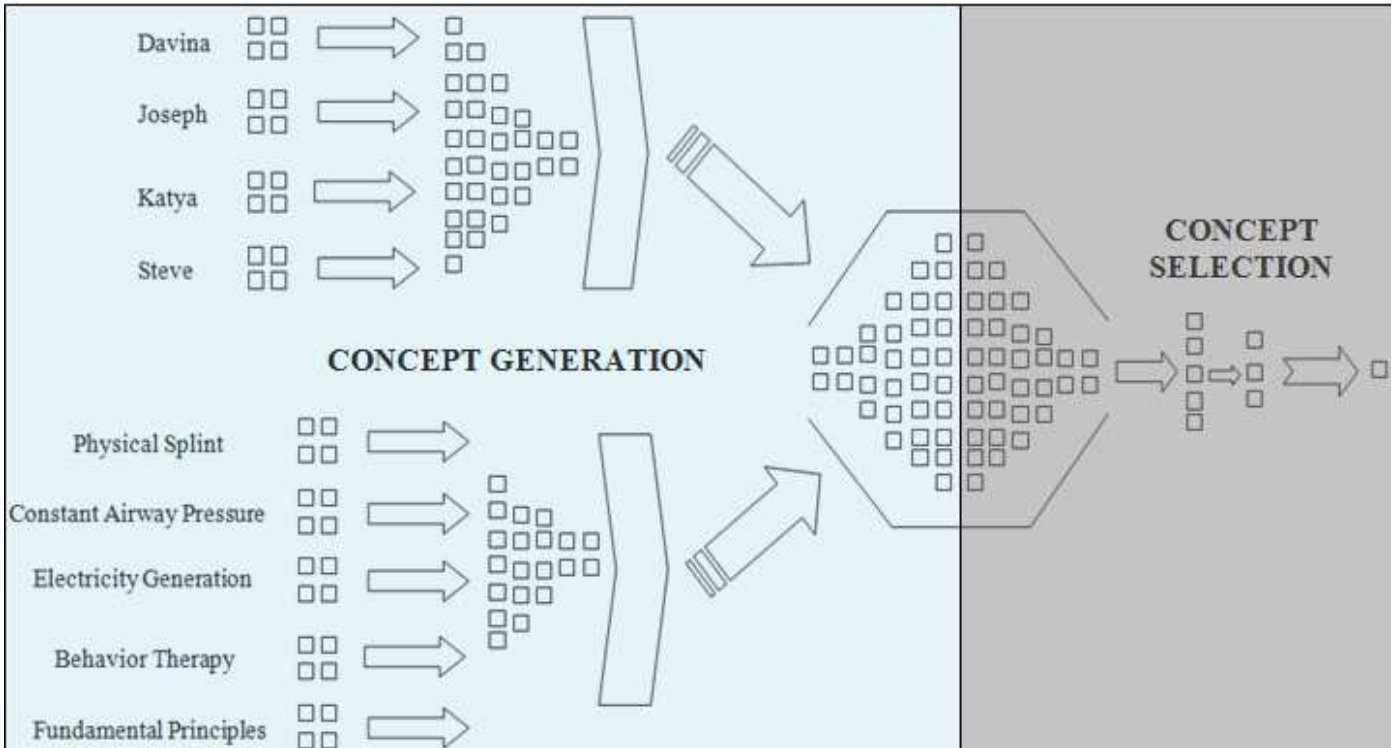


Figure 9: Schematic representing our concept generation and selection process

6.2 Our Designs

We created 32 design ideas to treat the problem of obstructive sleep apnea; these designs are all documented and described in Appendix C. Please note, the design number allocated to each design is arbitrary. These designs can be separated into 5 major concept categories:

- 1) Physical Splint, Table C1
- 2) Constant Airway Pressure, Table C2
- 3) Electricity Generation, Table C3
- 4) Behavior Therapy, Table C4
- 5) Fundamental Principles, Table C5

Physical Splint

If an object could be placed in the throat such that the airway remains unobstructed, sleep apnea could be alleviated. Designs 1-5 naturally fall into this category. For example, Design 1, shown in Figure 10, suggests permanently placing a semi-flexible, porous tube in the pharyngeal airway so that the tongue, epiglottis, and soft palate can not obstruct the airway. Therefore, during the night when these anatomical bodies relax, they cannot compress the tube.



Figure 10: Physical splint design example of a semi-flexible porous tube

Constant Airway Pressure

Many of the initial concepts generated identify with this category. The constant airway pressure category includes design concepts that provide constant pressure that is “self-propelled”, such as in Designs 6-13, or that use a storage tank for air, such as in Designs 14-17. Constant pressure applied to the airway is the fundamental theory of the CPAP machine. Therefore, if we could invent a device that created pressure without use of an electrical pump, sleep apnea could be managed more effectively. For example, Design 7, shown below in Figure 11, suggests developing a mattress that will provide constant pressure to the patient. The mattress is pumped with air during the day. Then, at night, a hose and mask is attached to an outlet valve that provides a specified pressure to the patient throughout the night. This pressure is provided by the weight of the patient on the mattress, which will slowly deflate during the night.



Figure 11: Constant airway pressure example design of an inflated mattress providing pressure

Electricity Generation

If enough electricity could be provided to the machine, then the device would not be reliant on an electrical outlet. Physical labor can produce electricity, which can subsequently be stored in batteries to provide enough electricity for an electrical device to function throughout the night. Designs 18-19 fall into this category. Design 19, shown below in Figure 12, suggests designing a way to generate electricity using a bicycle. While riding the bicycle, energy will be generated and stored in a battery nearby. Then, at night, a CPAP-type device uses the battery for energy.

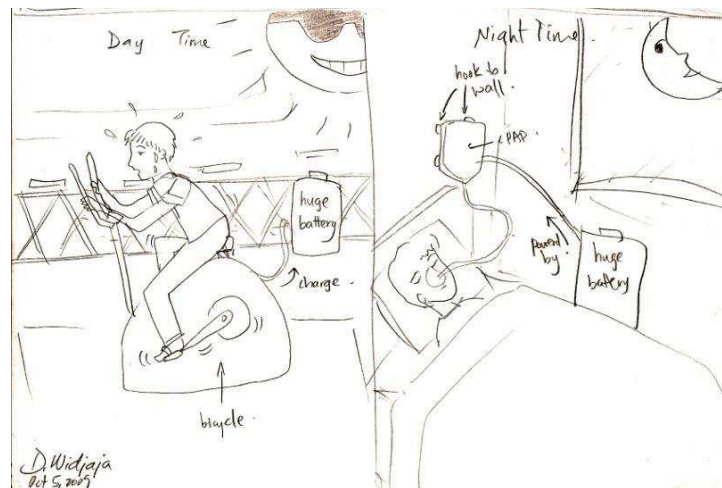


Figure 12: Electricity generation example design of creating energy using manual labor

Behavior Therapy

It was difficult to form ideas that fit into this category, and thus only one was created. Design 20 shown below in Figure 13, suggests creating a pillow with a hole in the center for the patient to sleep face down in. The bottom side of the pillow has semi-circular openings to allow fresh air to enter and CO₂ to exit. Requiring the patient to sleep on their stomach uses gravity to cause the tongue, epiglottis and soft palate to “fall down” away from the back of the throat, opening the pharyngeal airway.

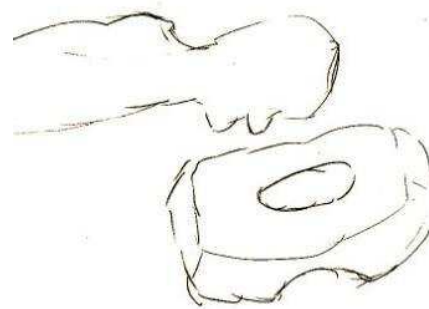


Figure 13: Design example of a person sleeping on a pillow with a hole in it for the patient's face

Fundamental Principles

Our functional decomposition, shown in Figure 8 Page 16, was especially useful for this category as we specifically focused on applying engineering and physics principles to the problem of treating sleep apnea. We specifically thought of topics from an engineering mindset to generate

ideas. Examples of topics we thought of included: hot air rises; differences in air velocity can create low pressure zones; electricity and magnetism are related; what can create a force; etc. Designs 21-32 fall into this category. Design 25, shown below in Figure 14, suggests requiring the patient to get a tongue and nose ring. Then at night, a string is tied between the two rings, such that the nose ring will hold the tongue anteriorly in the oral cavity and provide an unobstructed airway throughout the night.

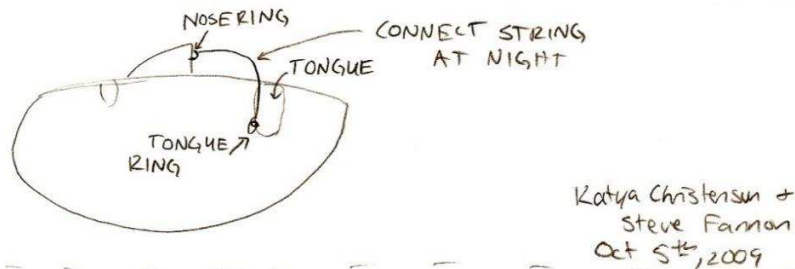


Figure14: Fundamental principles design concept of a tongue and nose ring lifting the tongue

7 CONCEPT SELECTION

This section discusses how we chose our top designs, and their advantages and disadvantages. Each design is compared against our user requirements and considered based on its compatibility and feasibility with each requirement.

7.1 Our Selection Process

To select our top five designs we used a voting system where each of the four members of our group received five votes. All of the designs were laid out on a table and each member walked around putting a sticky note with their initials on the five designs they chose. Each member took into account how feasible each design was and if it seemed like it might actually keep the airway open, the ease of use by the user of the device, and the cost of the device when deciding what designs to put their sticky notes on. The top five designs with the most votes were determined to be our final five preliminary designs.

After determining our top five designs, a Pugh chart was used to systematically determine which design was best using a weighting system based on our user requirements (Table A4). Each design was rated against a datum of an oral-insert device, as that treatment category was not one of our top five designs and would thus be the least biased. The Pugh chart can be seen in Figure A4. Our Pugh chart analysis concluded the Re-breather design concept, to be described shortly, fit our engineering specifications best. We independently evaluated each advantage and disadvantage of each of the top five designs to validate our results.

Top Five Designs

The top five designs we selected were: the Pressure Mattress (Figure 15), Donut Pillow (Figure 16), Waterfall (Figure 17), Spinner (Figure 18), and Re-breather (Figure 19). These designs are outlined in the following sections.

The Pressure Mattress



Figure 15: The Pressure mattress initial design concept

The Pressure Mattress design (Figure 15), uses a blow up mattress type container which is placed underneath the user's normal mattress. The weight of the normal mattress and the user lying on it pressurizes the pressure mattress. A tube connects the pressurized container to a mask, keeping a positive pressure in the airway the whole night. This is a good design because no electricity is used when providing pressure. Unfortunately, there are many problems with this design. First, the Pressure Mattress might not be capable of providing a precise, constant airflow throughout the night. Second, it would require manual labor to refill the mattress with air each night, and thus some kind of pump. Third, to hold the required 10 hours of air, the mattress would be very large when fully inflated, and thus could be awkward and unsafe to climb and sleep on initially. Plus, it would be so large, the mattress would likely not fit in anyone's bedroom, nor would the unfilled mattress be easy to carry around and transport. Finally, it would be difficult to clean the mattress, and the stale air would be uncomfortable to breathe.

The Donut Pillow

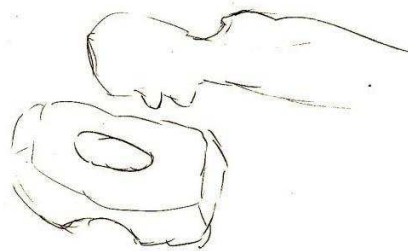


Figure 16: The Donut Pillow initial design concept

The Donut Pillow design, in Figure 16 above, forces the user to sleep on their stomach by having them place their head into the hole in the middle of the pillow. By sleeping on their stomach, gravity pulls the tongue, epiglottis, and soft palate away from the back of the throat opening up the airway. This is a good design because it has no moving parts or complex pieces to the product. The pillow is robust and hard to damage. A significant disadvantage, however, is that not all users are stationary sleepers and may roll off the pillow and onto their back throughout the

night. Also, this method of treatment only works for mild and some moderate cases of OSA. In addition, sleep behavior therapy often is only effective for mild sleep apnea patients.

The Waterfall

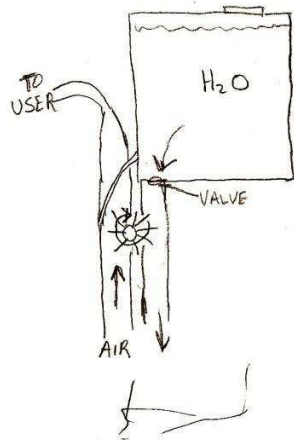


Figure 17: The Waterfall initial design concept

The Waterfall design, in Figure 17 above, uses falling water from a water reservoir to spin a rotating turbine. The turbine is connected to an airway on the opposite side which draws air to the user's mask, creating positive pressure. The water reservoir could be different sizes to provide the required constant pressure for the individual. An important concept advantage is that water can be a very abundant and cheap resource in low-income areas. The water does not have to be sanitary because it would not come in contact with air being pumped. Water could also be reused from night to night. One negative aspect is that a lot of water would be required to pump through a whole night. The reservoir would need to be very large and might not fit in the patient's bedroom. Secondly, there would need to be two water reservoirs, one to provide water at the top, and one that collects water at the bottom.

The Spinner

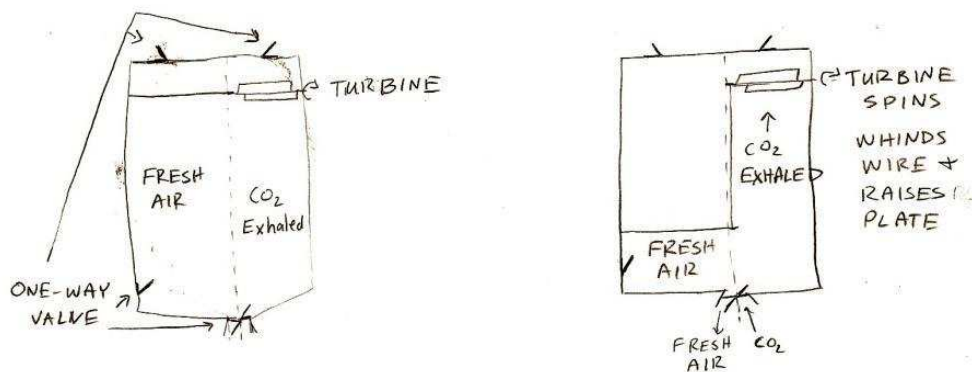


Figure 18: The Spinner initial design concept

The Spinner design, in Figure 18, directs the flow of air from the user's exhalation into a chamber with a turbine. When the turbine spins from the flowing air, it cranks up a heavy plate located inside the adjacent chamber via a connecting "string". The plate moving up produces a lower pressure inside the chamber, which draws fresh air into the chamber. When the user stops exhaling and begins inhaling, the plate falls down, pushing the fresh air out and into the tube and mask delivering air pressure to the breathing passage. Four one-way valves allow the control of air required to provide constant pressure, such that air can only enter or exit at certain times. The advantage of this design is that the only energy necessary to power this machine would be the user's own breath being exhaled. The exhaled breath, however, might not be enough to power the turbine in the desired way. Also, not all of the energy from the exhaled breath is being used because it likely will only blow past the turbine and not be fully captured. In addition, friction would play a large role in the loss of energy in this design.

The Rebreather

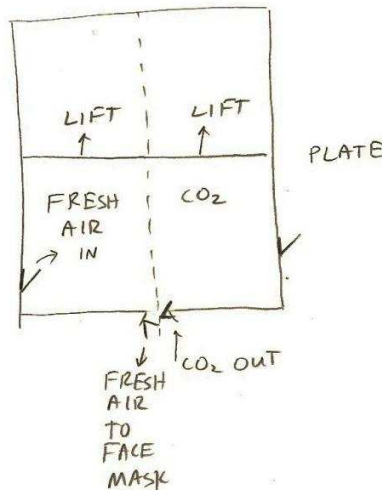


Figure 19: The Re-breather

The Re-breather design, in Figure 19 above, captures exhaled air into a chamber (labeled "CO₂"). As more air is exhaled the chamber pressurizes and lifts up a plate to the top of the chamber. This plate moves in unison with a plate in a separate chamber (labeled "Fresh Air") in the machine. As both plates move up, fresh air is drawn into the adjacent chamber. A "spring-like" device, located in the middle of the connecting plates, pulls the plates back to their original position, pressurizing the fresh air and forcing it into the mask and throat. This design is the best design out of the top five because it converts all of the energy from the user's exhalation into potential energy, and then uses that potential energy to pressurize the inhaled breath. Exhaled air and fresh air do not mix at any point. It also does not require electricity, but does provide PAP. In addition, it could be as small as the required amount of air needed for each breath—on average 500ml [18]. Unfortunately, this device relies heavily on the valves and seals inside the device. This could pose a major problem if the quality of materials is not adequate. There will also be a lot of friction to overcome along the seals of each chamber depending on how it is designed. Friction could hinder the affect of the pressure provided via weight during inhalation depending on its intensity on the surface. Another disadvantage of this design is that exhalation pressure will be slightly greater than inhalation pressure. We believe these disadvantages can be managed

accordingly. Therefore, based on these advantages and the results of our Pugh chart analysis, this concept will be our Alpha Design concept that we will develop further.

8 ALPHA DESIGN

The initial system design concept of the Re-breather previously illustrated was analyzed and further identified. For each sub-component (listed below) of our design, we brainstormed and selected ideas employing the same process used in selecting our Alpha Design. The results of the brainstorming sessions can be seen in Appendix D.

The alpha design consists of:

- One-way valves(2)
- Air chambers(2)
- “Spring-like” device
- Pistons (2)
- Linkage device
- Valve opening mechanism

The most notable feature of this design is that all of the power required to operate the device is supplied by the user, removing any electrical dependence. It functions by storing the energy produced during exhalation and uses this energy to apply positive airway pressure during inhalation. Positive airway pressure is applied during inhalation through the energy generated from exhalation, which is stored in the “spring-like” device.

Device Operation

For the following explanation, please see Figures 20 and 21.

Exhalation:

As the user exhales, the CO₂ exhaled is forced through a one-way valve into Chamber 2. This action raises a piston connected through a linkage to another piston in adjacent Chamber 1, such that both pistons rise in unison. As the piston in Chamber 1 rises, a low pressure area is created which draws in fresh air. The linkage device is connected to a spring which compresses as the pistons rise; this spring will be easily adjustable for different required pressures. A functional decomposition of our device during exhalation is shown in Figure A5.

Inhalation:

During inhalation, the spring relaxes, causing the pistons to fall and transfer fresh air via a hose to the user from Chamber 1. Meanwhile, the used air in Chamber 2 is expelled from the chamber. A functional decomposition of our device during inhalation is shown in Figure A6.

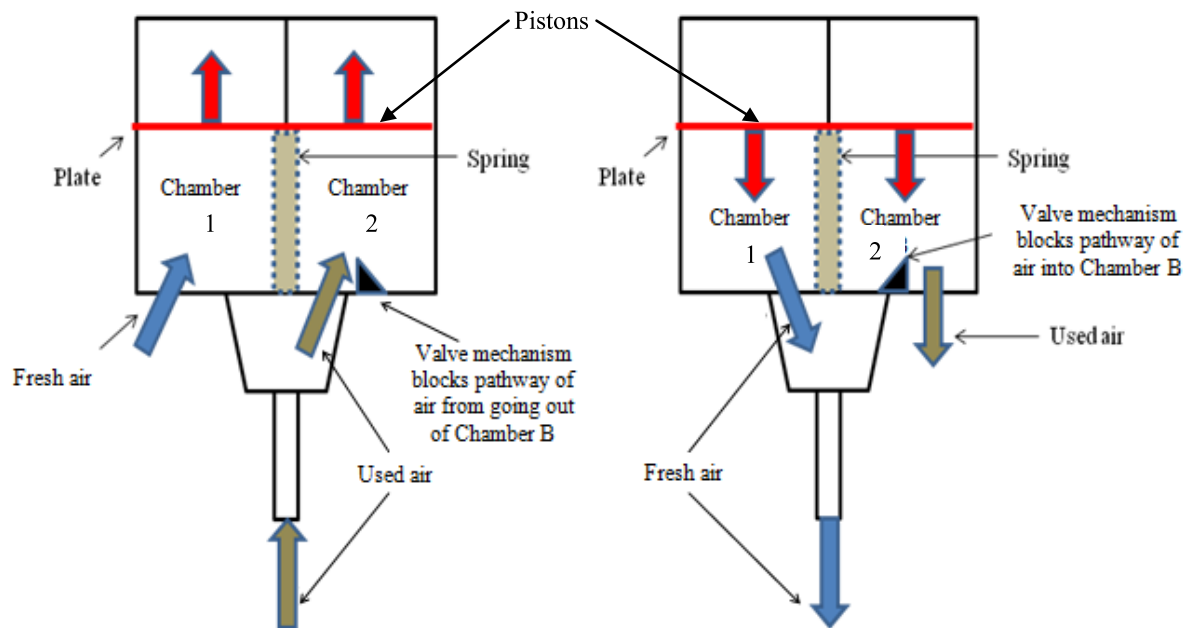


Figure 20: Device operation during exhalation **Figure 21: Device operation during inhalation**

The operation of the device is summarized in the following two steps:

- 1.) User exhales
 - a. Used air flows into exhalation chamber
 - i. Valve mechanism is tipped, closing air outlet valve
 - ii. Pistons rise (connected with linkage)
 - iii. Spring is compressed
 - b. Fresh air flows into inhalation chamber through a one-way valve
- 2.) User Inhales
 - a. Fresh air flows to the user
 - i. Spring relaxes
 - ii. Pistons fall
 - b. Used air closes valve mechanism, opening air outlet valve and closing air inlet valve to exhalation chamber
 - i. Used air flows out of the chamber

Further Defining the Initial Concept

Valve Mechanism

In addition to two, one-way valves located in Chamber 1, a valve-opening mechanism is required for Chamber 2. This is required for multiple reasons: the resistance of the CO₂ outlet valve would either be too low and upon exhalation, the CO₂ would flow out of the chamber without raising the pistons; or, the valve resistance could be too high and upon inspiration, the exhalation chamber would provide significant resistance, which would substantially reduce or eliminate the inspiration positive airway pressure being supplied.

Energy Storage

A spring will be used for the storage of the exhalation energy. A spring is used because it can be easily adjusted with a nut and a threaded rod. The spring is placed against a plate mounted

between the two chambers. The linkage connecting the two pistons has a rod that slides through this mounted plate. The end of the rod is threaded with a nut which presses against the other end of the spring. The nut can then be tightened or loosened to adjust the pressure supplied to the user. The spring is currently oriented to be compressed and is positioned towards the bottom end of the chambers. This will make the spring easier to mount and will also conserve overall required volume, respectively.

Evolution

Our Alpha Design originally used two cylindrical chambers with pistons which would provide positive airway pressure, as shown in Appendix D. As shown, it also used a lever device with plungers for the valve-opening mechanism. After reviewing our design with our mentor, a local support group, and further design development sessions, we made several modifications. These are outlined below and our revised design can be seen in Figure 24.

- The valve-opening mechanism now consists of a flap contained inside an elbow in the air tubing. With no airflow, the flap will be in the middle of the tubing. This flap will cover a hole in the elbow during exhalation and will obstruct the tubing and open the hole during inhalation, allowing the used air to escape. This design is simpler and quieter than our original concept. Due to its simplicity, it will be much easier to manufacture as well. This mechanism is shown in Figures 22 and 23.

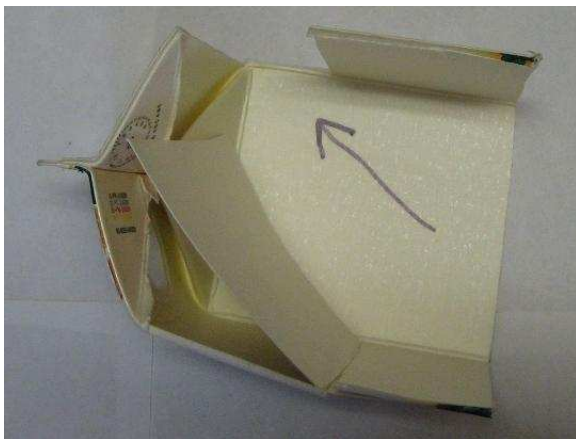
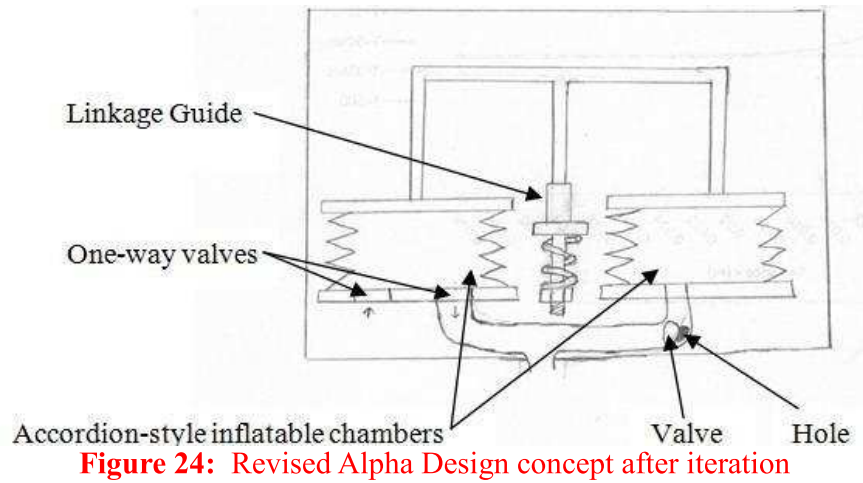


Figure 22: Valve open



Figure 23: Valve closed

- We originally contemplated that the device would have the ability to disassemble into separate components to promote compact transport, but the Ann Arbor Sleep Apnea support group stated the need for a box instead. As an alternative, we plan to enclose the device in a box. Consequently, the device will still be compact during travel, but will also protect the device's sub-components.
- The cylindrical chambers will be replaced with accordion-style inflatable bags. By removing the chambers, a guide will be required for the linkage mechanism to ensure vertical movement and that both bags inflate in unison. This design will remove any energy loss due to friction from the airtight pistons and significantly reduce the design's sealing issues.



Mock-Up 3D Model

After deciding on our Alpha Design, a mock-up 3D-Model of the design was constructed, as shown in Figure 25 below.



Figure 25: Mock-up 3D model.

Common everyday household items were employed to construct the 3D model. The model is not made to scale and does not function as how the Alpha Design should, however the model allows the team to get a better understanding of the Alpha Design concept through physical feel and representation. Table 5 describes in detail how each household product is manipulated to represent the components in the Alpha Design.

Alpha Design Components

Two air chambers

Two one-way valves in fresh air chamber (blue bottle)

Valve elbow mechanism in used air chamber (red bottle)

Two air seal pistons

Piston Linkage

Spring

Mock up model components

Two 500mL soda bottles were used to represent the different air chambers with blue containing fresh air and red containing used air (CO₂). The bottle caps were removed and the bottle bases were cut out. They are then positioned upside down with the bottle opening (now below) acting as the valve and hose interface and the cut-out base (now on top) providing an outlet

There are two one-way valves connected to the fresh air chamber. One to bring in fresh air from the surroundings and another to bring it out into the hose connected to the user breathing passage. The first valve is represented with a crosshair cut-out on the side of the fresh air chamber bottle and the second valve is represented by a packing peanut stuffed into the bottle opening.

To represent the valve mechanism we used the top half of an orange juice carton that has a screw-cap hole at the top. The carton is rotated 90 degrees such that the screw-cap opening hole faces diagonally downward to one side. The elbow valve is pivoted at the base of the air passage and is going to be made of a flexible and elastic material. During exhalation, the valve will be in position shown in Figure 22, where the arrow shows the exhaled airflow from the user to the used air chamber. During inhalation, the valve will be positioned such as in Figure 23 where the arrow shows the air flow of used air coming out of the used air chamber into the surroundings through the carton opening hole.

Two yogurt container bases were cut out and the remaining walls were cut vertically in four slots. These were inserted into the bottles and represent the pistons with blue representing fresh air and red representing used air.

For this function, an “M” shape is cut out of a cardboard. The side stems of the “M” shape were reinforced with tape to represent a rigid piston pusher for each chamber. The center stem of the “M” shape acted as the spring mechanism that supplied the force to the plates which would then be translated as pressure into each air chamber.

One small vertical slot was cut out at the top of each of the chambers. Two rubber bands were inserted into these slots and looped around the linkage device. These bands represent the spring in our Alpha Design.

Table 5: Description of 3D-model mock-up

9 BETA DESIGN

9.1 Beta Design Description

After analyzing our alpha design further, we noticed significant problems arising from the linkage between the moving plates. The linkage between the two plates would cause a significant torque problem and it would make the design more complicated, difficult to manufacture, and

require more parts. Also, the design was not volume efficient. Because of these issues, we reconfigured our design to look as shown in Figures 26 and 27.

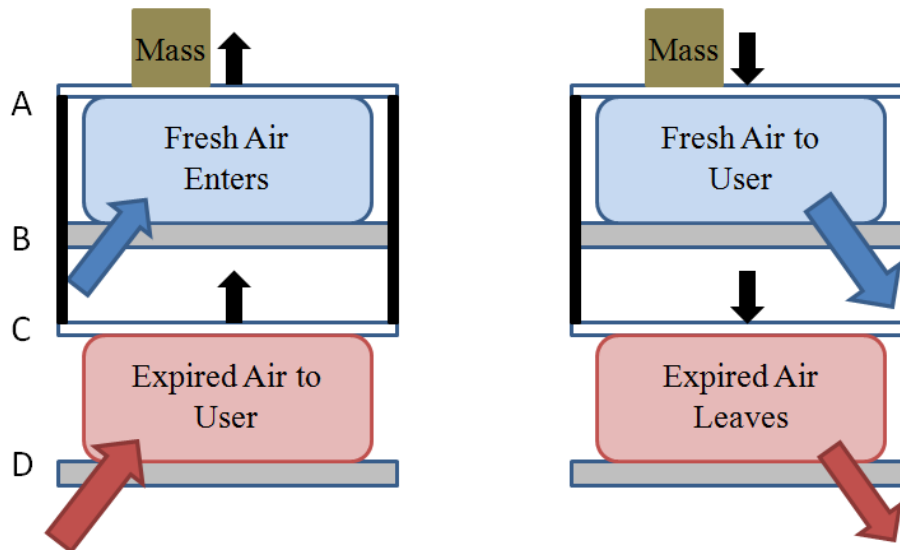
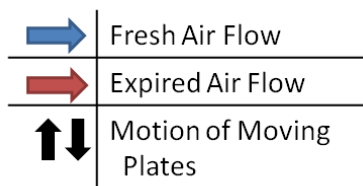


Figure 26: Device operation during exhalation **Figure 27:** Device operation during inhalation



The chambers are now stacked vertically on top of one another, where the moving plates and rigid plates are connected with rods. This rod assembly provides stability to the plates and also eliminates torque-related issues. Secondly, the device could have a slightly larger height, but half the footprint size. This new design would be much easier to

prototype, assemble, and mass produce.

The initial, system design concept of the Re-breather previously illustrated was analyzed and further identified.

The beta design consists of:

- Inflatable air chambers(2)
- Weight
- Linkage rods(6)
- Elbow valve
- One-way valves (one is a safety valve in the CO₂ chamber)(3)
- Backflow valve
- Epoxy

The most notable feature of this design is that all of the power required to operate the device is supplied by the user, removing any electrical dependence. It functions by storing the energy produced during exhalation and uses this energy to apply positive airway pressure during inhalation. Positive airway pressure is applied during inhalation through the energy generated from exhalation, which is stored as potential energy when the weight rises.

Device Operation

For the following explanation, please see Figures 28 and 29.

Exhalation:

As the user exhales, the CO₂ exhaled is forced through an elbow valve into Chamber 2. This action expands the bag in Chamber 2 and raises the moving plate of Chamber 2, which is connected to the moving plate of Chamber 1 through three rods, such that both chambers expand in unison. As Chamber 2 expands and thus Chamber 1, a low pressure area is created in Chamber 1, which subsequently draws fresh air into Chamber 1. The weight provides force to the system that the user breathes against; this weight will be adjustable for different required pressures.

Inhalation:

During inhalation, the chambers relax and transfer fresh air via a hose to the user from Chamber 1. Meanwhile, the used air in Chamber 2 is expelled from the chamber through the elbow valve.

Overview:

This design consists of two plates mounted to a container roughly 6” apart and aligned axially. Two inflatable accordion-style chambers will be mounted upon one end of these plates. Two plates will be mounted to the other end of the chambers; these plates will be connected via rod linkages which will slide through guiding holes in the central mounted plate (plate B). Plates A and C move in unison, inflating and deflating the chambers together. Two valves will be mounted in plate B for the inhalation chamber, and one elbow valve will be mounted to plate D. Also, weight will be mounted to the top of Plate A providing constant force to the system. Pictures of our Beta Design CAD model are shown below in Figures 28 and 29.

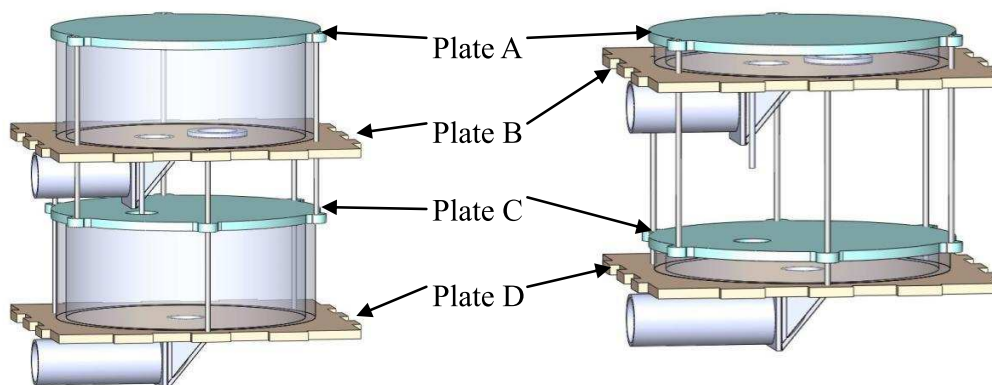


Figure 28: Device operation after exhalation **Figure 29:** Device operation after inhalation

The operation of the Beta Design is summarized in the following steps.

- User exhales
 - Used air flows into exhalation chamber
 - Valve mechanism is tipped, closing air outlet valve
 - Chambers expand (connected with rods)
 - Weight rises
 - Fresh air flows into inhalation chamber through a one-way valve.
- User Inhales

- Fresh air flows to the user
 - Chambers relax
 - Weight falls
- Used air closes valve mechanism, opening air outlet valve and closing air inlet valve to exhalation chamber
 - Used air flows out of the chamber

Further Defining the Initial Concept

One-way Valves

Two one-way valves will be made using two pieces of acrylic and a thin rubber piece glued between the two pieces of acrylic. The rubber piece will be made larger than the holes they need to cover, and will be glued on one edge of the piece so that airflow can cause the rubber to deflect, allowing airflow in one direction (Figure 30). This will serve to prevent fresh air from leaving the chamber through the air intake, forcing the fresh air to the user. Another one-way valve operates on the same principle using a rubber piece covering a hole, but is placed at the end of a 90° elbow (Figure 31).

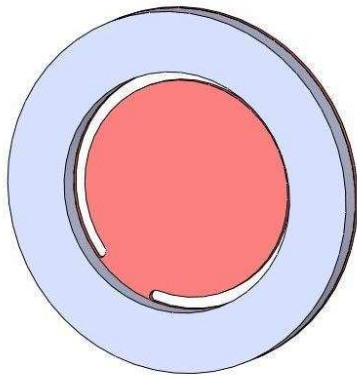


Figure 30: One-way valve CAD design

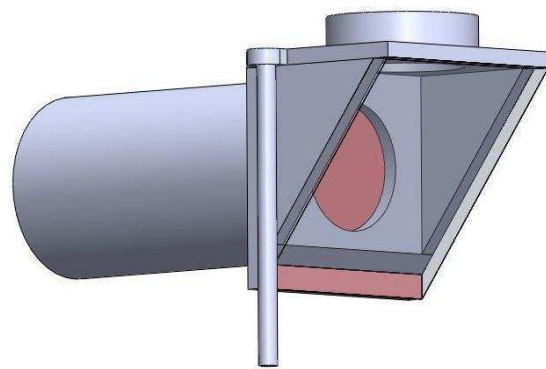


Figure 31: One-way elbow valve CAD design

Backflow Stopping Valve

A backflow stopping valve is required at the junction of the fresh air tube and the used air tube to prevent fresh air (being supplied to the user) from escaping into the exhalation chamber. This mechanism will be made by cutting an outlet of a Y-shaped airway junction made from PVC and gluing a rubber piece glued between two acrylic plates (with holes) in between the junction and the outlet. With no airflow, the rubber flap will be in the middle of the tubing. This flap will cover a hole in the elbow during exhalation and will obstruct the tubing and open the hole during inhalation, allowing the used air to escape. This design concept is already available in current CPAP masks available on the market. This valve is shown below in Figure 32.

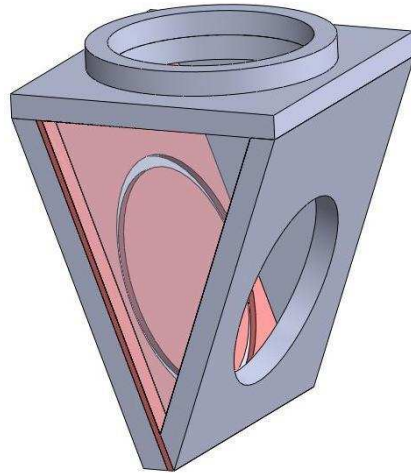


Figure 32: Backflow valve CAD design

Exhalation Safety Valve

A valve will be installed on plate C, such that during an abnormally large exhalation the chamber will inflate to the maximum height position where a pin mounted to plate B will open the valve (Figure 33), allowing the user to continue to exhale normally. This will be the same as the one-way valve made with a rubber piece covering the intake hole in plate B.

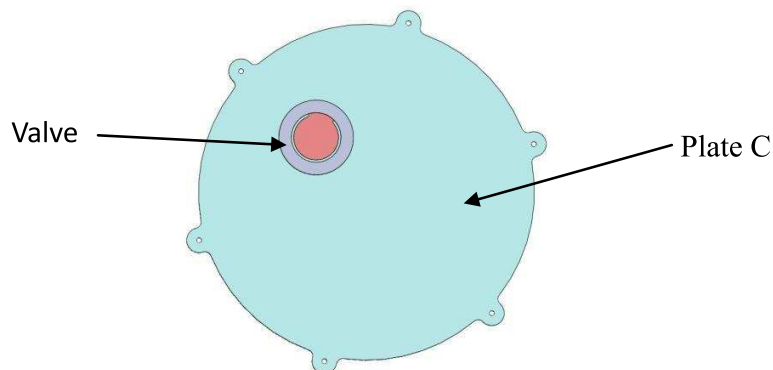


Figure 33: Exhalation safety valve CAD design

Elbow Valve

In addition to two, one-way valves located in Chamber 1, a valve mechanism is required for Chamber 2. This is required for two reasons:

- 1.) The resistance of the CO₂ outlet valve would either be too low and upon exhalation, the CO₂ would flow out of the chamber without expanding the chambers
- 2.) The valve resistance could be too high and upon inspiration the exhalation chamber would provide significant resistance, which would substantially reduce or eliminate the inspiration positive airway pressure being supplied. An elbow valve that functions off the same principles as the backflow stopping valve will be used and manufactured as shown in Figure 34 below.

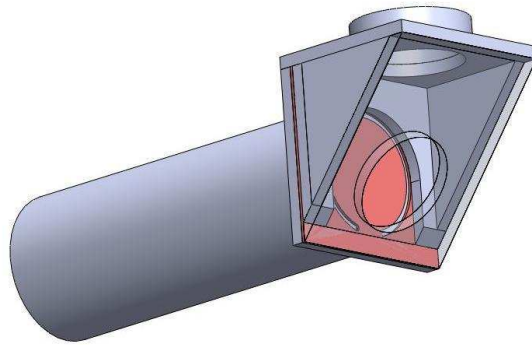


Figure 34: Elbow valve CAD design

Energy Storage

A weight will be used for the storage of the exhalation energy. Pressure supplied will be adjustable by installing different weights in the device. The weights will be placed on the top of Plate A.

Container

We plan to enclose the device in a box to protect the components. The acrylic box will have holes for air ventilation and holes for the hoses to the user as shown in Figure 35.

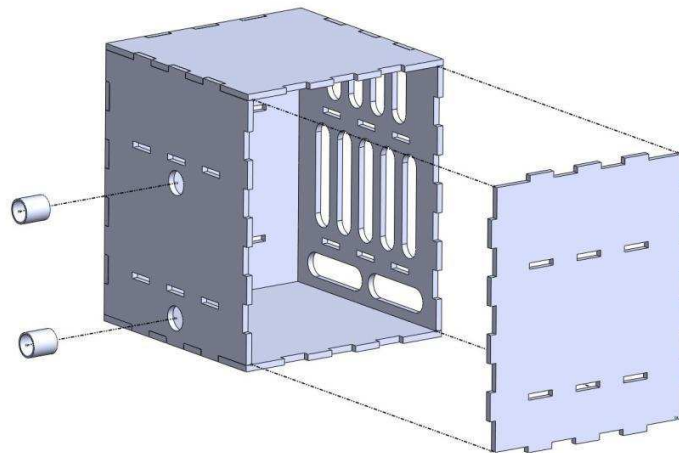


Figure 35: Beta Design Container CAD design

Chambers

The cylindrical chambers will be made of accordion-style inflatable bags, as shown in Figure 36. The chambers will be aligned vertically to eliminate any torque produced in a side-by-side configuration. This design will reduce any energy loss due to friction.

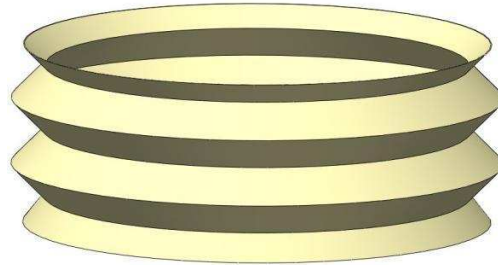


Figure 36: Accordion-style bag design example

Figure 37 shows the working Beta Design prototype with the backflow stopping valve and mask.



Figure 37: Beta design prototype

Pivotal Design Decision

After completing our Proof of Concept Prototype, we decided to alter our plans of our Beta Design. We decided to use an adjustable weight instead of a constant force spring to store energy during exhalation. We did this for multiple reasons:

- The spring used in the design was a constant force spring, so each machine could only be set to one pressure. If a different pressure was required, a new spring would have to be bought and installed.

- The use of a spring would increase the cost of use of the machine as manufacturing the springs would be expensive as the process requires a water jet cutter. Also, the bottom of Plate B and top of Plate C would require mountings for the spring.
- For the force required from the spring, the dimensions and displacement of the spring would increase the overall volume of the device. Currently there is roughly 2” between Plates B and C (where the spring would have been mounted), if a spring was used this distance would increase to roughly 4”. The distance depends upon the spring design, which is dependent upon the desired pressure.

For our adjustable weight, a collapsible, water-tight container with markings for different water levels will be used. We chose this design for three reasons:

1. By using the weight provided by water, the device weight does not increase significantly during travel. The container can be emptied and filled at a new location, this increases the portability of the device. The weight during travel would only increase by the weight of the container, which would be equivalent to the weight of a spring and the mountings.
2. The volume of the device during travel would not increase as the volume of the collapsed container would fit inside the housing.
3. With the various markings of different water levels, the pressure the machine provides would be easily adjustable through the addition or removal of water.

9.2 Beta Design Manufacturing Plan

To manufacture our final system prototype of the Beta Design for the Expo, we will need the following listed materials and tools. Each sub-component will be manufactured except the hoses and mask.

Materials Required

- Adhesive-Epoxy (20ml)
- Steel rod-6' x 1/8" DIA.
- Acrylic/PLASTIC plate- 30"x30"x0.22"
- Hard tubing 0.87" outer diameter
- Masks-1 with elbow valve
- Tubing
- Bellows-Ventilation Duct Hose-6.25" DIA. 8" long
- Thin rubber sheet 15"x15"

For a complete bill of materials see Appendix B.

Tools Required

- Drill/bit-1/8" & #23
- Hack saw
- Laser-cutter
- Scissors
- Wire Cutters
- Sandpaper

Components

Note: For all of the following components, Appendix G contains dimensioned drawings in the Safety Report to aid in the explanations of the following components.

Pistons/Base Plates: These plates will be made of a durable, safe plastic; two plates will be square and mounted to the box and two will be circular and will move together. There will be six plates cut on the laser cutter in the mechanical engineering undergraduate workshop.

- One plate (plate B) will be the base of the inhalation chamber; this plate will have two holes laser cut into it for mounting two one way valves and three holes (1/8") for housing the linkage rods. These holes will be drilled through the plate. This plate will be square with key joints that fit into the wall panels
- The exhalation chamber base plate (plate D) will have one hole laser cut for mounting the elbow valve and six holes for the linkage rods. Three for mounting plate B to plate D (use 1/8" bit) and three slightly larger holes to guide the three linkage bars connecting plates A and C (#23 bit). This plate will be square with key joints that fit into the wall panels.
- One plate (plate C) will be the exhalation chamber which will have three holes (1/8") drilled through the plate to house the linkage rods (plates A, B, & D) and one hole .82" in diameter for the safety release valve
- One plate (plate A) will be the inhalation piston which will have three holes (1/8") drilled through the plate to house the linkage rods

Linkages: Six steel rods will be cut to length 6.25" and filed.

Safety Release Valve Pin: One steel rod will be cut to 2" and filed.

Energy Storage mechanism: A container will be used that can be filled with differing amounts of water, up to a maximum of roughly two liters.

Tubing: 12' of standard flexible CPAP machine tubing will be used in addition to two 4" pieces of hard tubing with an outer diameter of .87".

Chambers: We plan to use a flexible vinyl duct hose as used in household vents. This will be cut to length with scissors and wire cutters. They will be 6.25" in diameter.

Valves: The valves will be made by cutting rubber sheets to size with a laser cutter as shown in Figures 38A and 39B shown below. The outer area of the cut rubber pieces will be epoxied to the valve plate. The pivoting edge of the rubber piece will be the functional portion of the one-way valve. For the back-flow stopping valve, an acrylic Y-shaped tubing connector will be cut using the plastic band saw in the ME undergraduate workshop. A rubber piece will be glued to two plates; the Y-shaped connector will be epoxied back together with epoxy.

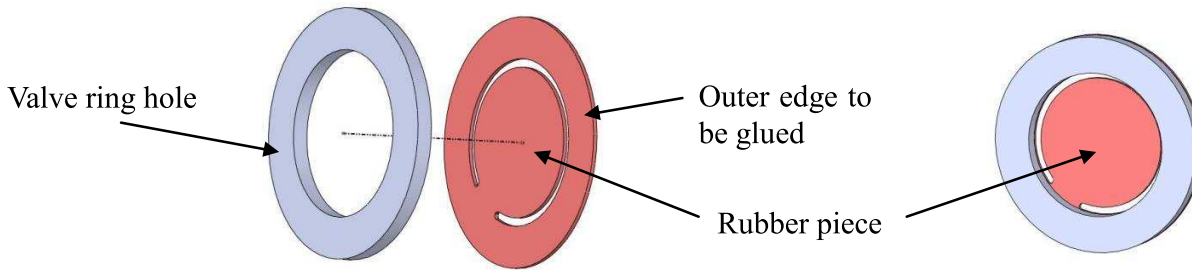


Figure 38A: Valve plate and rubber piece

Figure 38B: One-way valve

The L-shaped valves are to be manufactured as shown in the Figure 39, Page 36. The ring top of the L-shaped valves of the device will be attached to the holes on the fixed square plates using epoxy. The difference between the L-shaped valves for the fresh air chamber and the used air chamber is shown in Figures 40A & 40B.

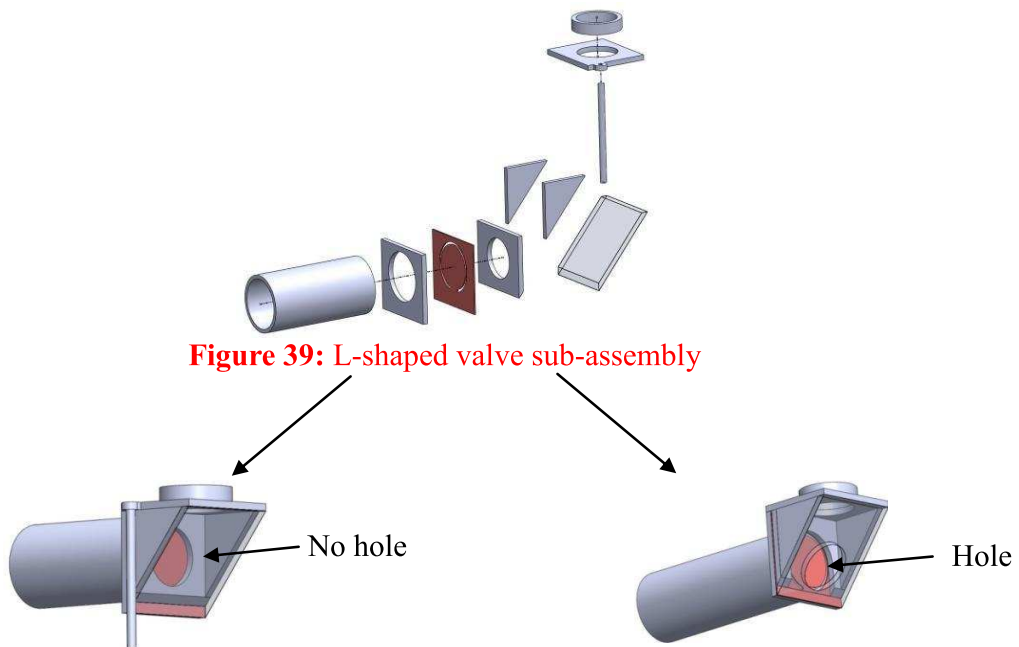


Figure 39: L-shaped valve sub-assembly

Figure 40A: Fresh air chamber L-shape valve without a hole on the other side as its only function is to let fresh air flow into a patient's breathing passage.

Figure 40B: Used air chamber L-shape valve with a hole on the other side to let used air out when air chamber is deflated.

Linkage Rods: The linkage rods are made from 1/8" steel rod cut to length using a hack saw in the workshop, six 7" rods and one 2" rod will be required. The ends will be smoothed using a file. A hack saw is used in this process because tight tolerances are not needed.

9.3 Beta Design Assembly

The components are going to be assembled in the University of Michigan Mechanical Engineering (ME) machine shop under the supervision of Mr. Bob Coury and Mr. Dan Johnson.

Used Air Chamber (bottom) Sub-Assembly

The used air chamber sub-assembly consists of the system that will receive exhaled air from the patient/user and be the platform for the moving plates to be supported. Figure 41 shows a CAD model of the used air chamber sub-assembly.

The used air chamber sub-assembly was constructed using the following steps:

1. Using epoxy, adhere a cut vinyl air chamber onto the base square plate (plate D) with one valve hole.
2. Place three 7” linkage rods into the holes on the base square plates such that the top parts of the rods are exposed.
3. Position the plate C such that the three exposed rods are slid into three holes which are not next to each other. This is completed while the rods are perpendicular to plate D. Using epoxy, adhere the opposite side of the vinyl air chamber onto the round plate, plate C.

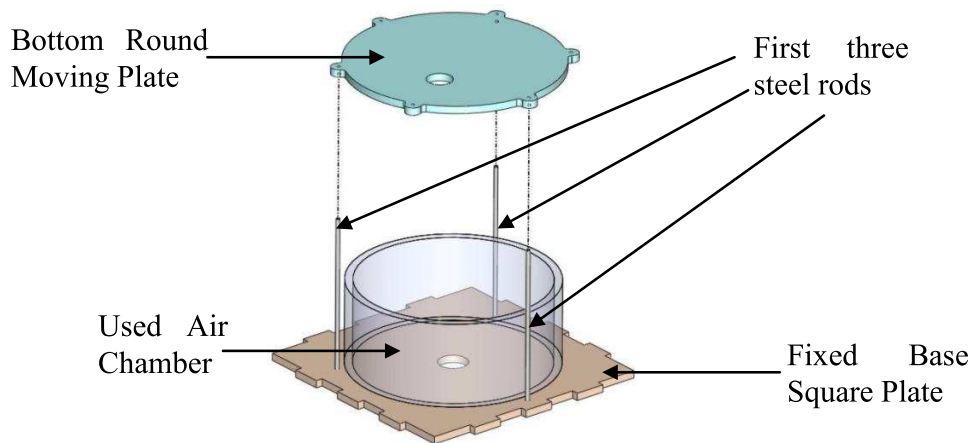


Figure 41: Used air chamber sub-assembly CAD model

Fresh Air Chamber (top) Sub- Assembly

The fresh air chamber sub-assembly consists of the system that will be inflated as the used air chamber is being filled with exhaled air through the linked moving plates. The fresh air chamber will also provide the continuous air pressure to treat sleep apnea.

The fresh air chamber sub-assembly was constructed using the following steps as shown in Figure 42A and 42B:

1. Slide in the base square plate, plate B, with two valve holes onto the first three rods exposed from the used air chamber assembly.
2. Position the remaining three rods in place in the three holes on the first round plate, plate A.
3. Using epoxy, adhere the other vinyl air chamber onto the top part of the square base plate.
4. Position the remaining round plate such that the holes slide onto the top of the three rods then adhere the opposite side of the vinyl air chamber onto the round plate.

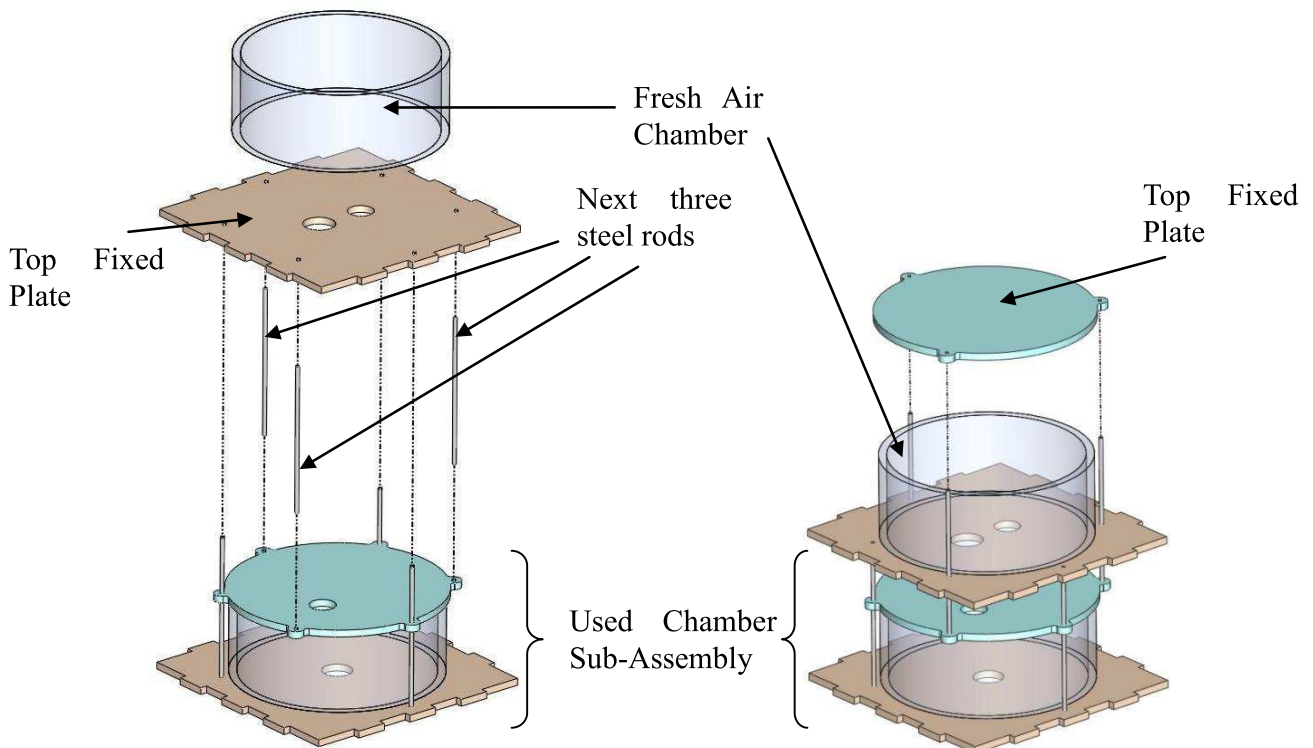


Figure 42A: Step 1, 2 and 3

Figure 42B: Step 2

Valve Sub-Assembly

The next step of the assembly is to attach the L-shaped valves and the one-way valve onto their respective holes as shown in Figure 43A and 43B and 43C. The valves are to be connected to the holes using epoxy.

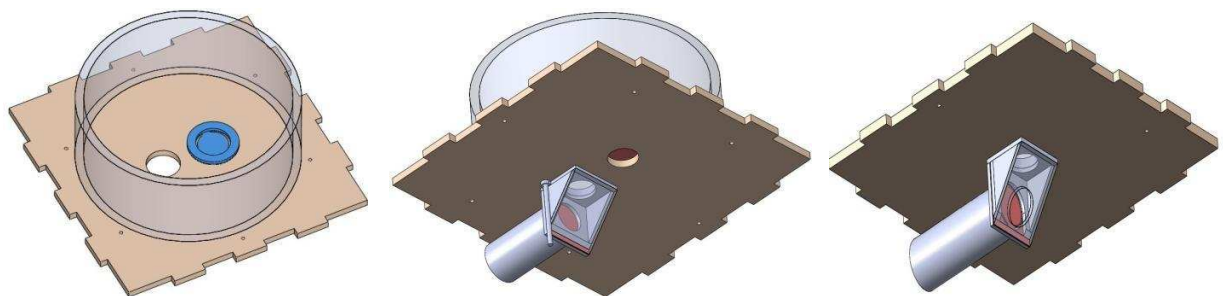


Figure 43A: Used air chamber one-way valve attached to one hole on the top fixed plate, plate B.

Figure 43B: Fresh air chamber L-shape valve without a hole on the other side attached to the other hole on the top fixed plate, plate B.

Figure 43C: Used air chamber L-shape valve with a hole on the other side attached to the one hole on the bottom fixed plate, plate D.

Box and Final Sub-Assembly

The assembly of the device box is quite simple as there are puzzle-like ridges on the edge of each cut acrylic sheet to form clean connections amongst the parts. The concave portions of the edges are to have epoxy applied before being attached to its complementary sheet. The acrylic sheets are transparent and have the same texture all over such that confusion on the symmetric portions of the box will not be a big issue to the functionality of the device. The cylindrical hose attachment interfaces are to be epoxied onto the holes on the left side of the box. The final sub-assembly consists of putting all the other sub-assemblies together in an organized fashion as shown in Figure 44.

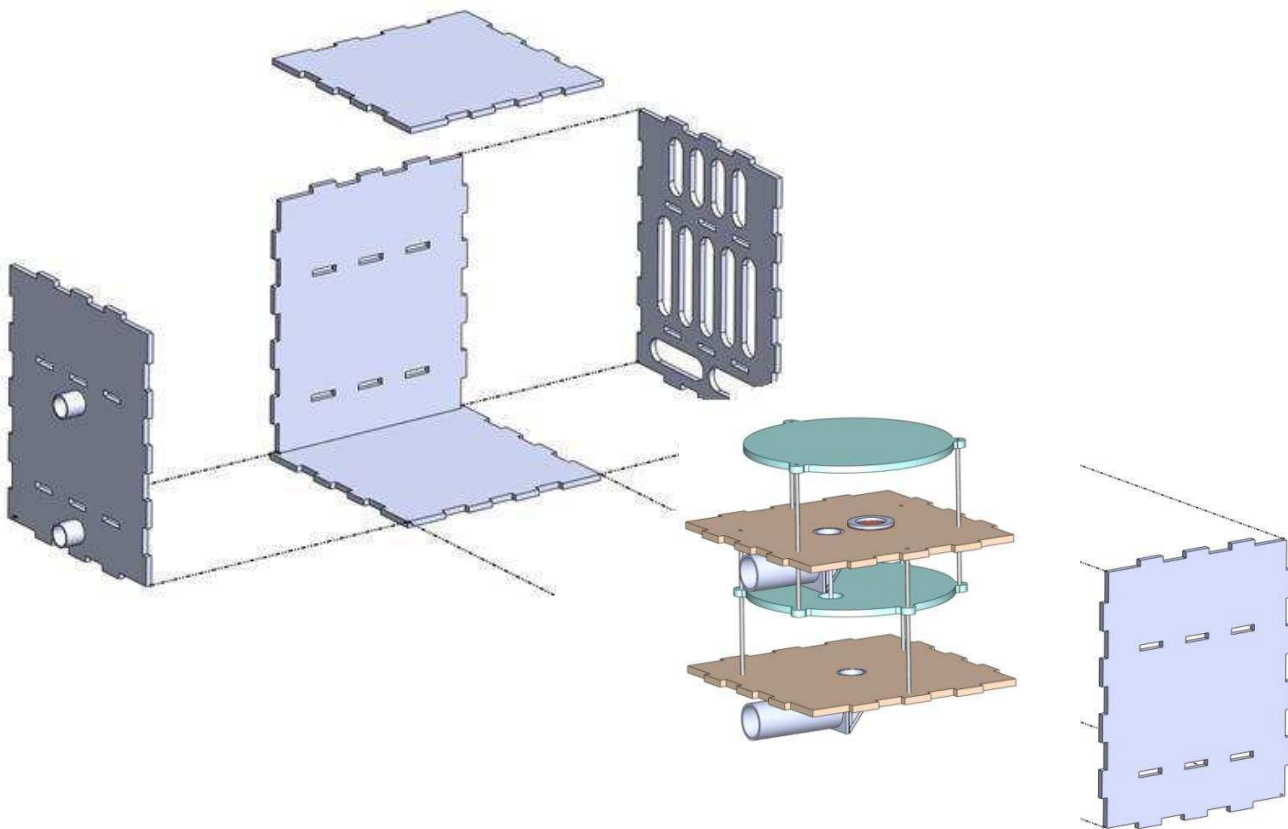


Figure 44: Box and final sub-assembly

10 PARAMETER ANALYSIS

System Model

Our system can be modeled as a simple spring, mass, and dampener system to predict the motion of the plates. The friction from the sliding of the rods and the bags themselves provide damping forces on the system, so they can be modeled as dampeners. The chambers are somewhat elastic, so they may be modeled as springs. The model of the system is shown in Figure 45, below.

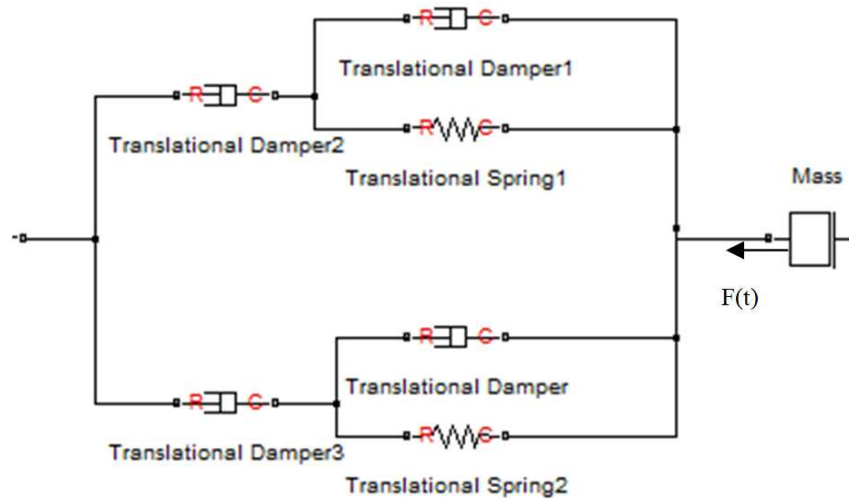


Figure 45: System Model

You can see the two mass-damper systems connected in parallel, these are the chambers. Translational Dampers 2 & 3 represent the damping on the system from friction of the linkage rods. Using this model, the equation of motion of the system was predicted to be:

$$m\ddot{x} + b_{eq}\dot{x} + k_{eq}x = F(t) \quad \text{Eq. 1}$$

where b_{eq} is the equivalent combined damping coefficient of the system, k_{eq} is the equivalent spring coefficient of the system, and $F(t)$ is the force provided by the user (during exhalation) or the weight (during inhalation).

Design Parameters

The Beta Design requires a few critical design decisions that must be made. The device will be required to hold a certain pressure, up to 20 cm H₂O, and will have to be designed and built accordingly. The chamber, plate, and rod parameters will all need to be calculated to guarantee they are able to withstand the stresses placed upon them by the pressure. The ability to seal the chambers and hold the necessary pressure also influences the design. A summarized approach of our system parameter analysis can be best described through the visual representation shown in Figure 46A.

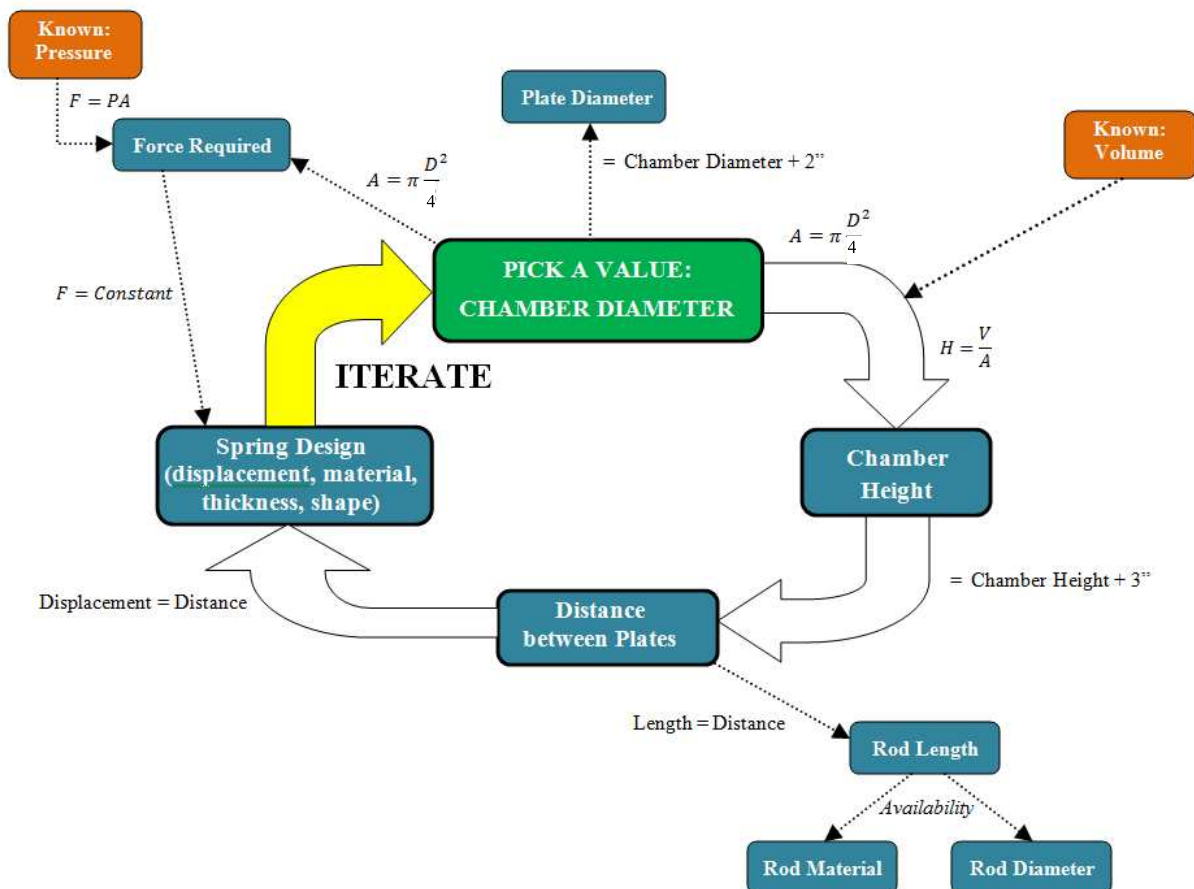


Figure 46A: Schematic representing our summarized parameter analysis

This diagram exhibits the iterative nature of our design problem. The desired pressure provided by our system, the time per breath, and the average air volume per breath (650 mL) are all known quantities that factor into this cyclic analysis. These are determined from Table 6 below.

	Tidal Volume, liters	Minute Ventilation, l/min	Inspiratory Time, s	Breath Time, s	Resistance at 0.1 l/s, $\text{cmH}_2\text{O} \cdot \text{l}^{-1} \cdot \text{s}$	Resistance at Peak Pressure, $\text{cmH}_2\text{O} \cdot \text{l}^{-1} \cdot \text{s}$
			<i>Awake</i>			
Normal elderly	0.63 ± 0.07	8.28 ± 0.60	1.99 ± 0.13	4.56 ± 0.33	4.33 ± 0.73	$6.66 \pm 0.90^*$
Normal young	$0.60 \pm 0.06^*$	7.09 ± 0.47	$2.25 \pm 0.13^*$	$5.07 \pm 0.33^*$	4.07 ± 0.46	7.64 ± 0.56
			<i>Stage 2 sleep</i>			
Normal elderly	0.50 ± 0.05	7.21 ± 0.81	1.86 ± 0.09	4.24 ± 0.20	7.21 ± 1.63	$16.37 \pm 3.54^*$
Normal young	$0.45 \pm 0.03^*$	6.91 ± 0.56	$1.79 \pm 0.09^*$	$4.00 \pm 0.20^*$	5.66 ± 1.03	11.88 ± 2.70

Table 6: Breath data during sleep [26]

Although this diagram only exhibits nine of our twenty system parameters, these nine parameters were specifically determined using the subsequent equations, while the other system parameters were often based off of cost or availability of the materials used. For example, Figure 46B (below) shows three system parameters not based on analytic reasoning.



Figure 46B: Schematic representing three parameters not based on analytic analysis

See Table E1 for a complete list and description of each design parameter in our system, as well as, the equations, the engineering logic, and the corresponding value of those twenty parameters.

Chamber Volume

Calculations of pressure and volume in the chambers will require the Ideal Gas Law, Equation 2, with P representing pressure in Pascals, V representing volume in m^3 , n representing the number of moles, R representing the molar gas constant of $8.314 \text{ J/K}\cdot\text{mol}$, and T representing temperature in degrees Kelvin.

$$P \cdot V = n \cdot R \cdot T \quad \text{Eq. 2}$$

Assuming isothermal conditions, we can instead use Equation 3 assuming that the mass in Chamber 2 (the CO_2 chamber) is equivalent to the mass in Chamber 1 (the fresh air chamber). This is the case because the air compresses less than 1% at the pressures experienced in our device, so we can assume that both chambers hold equivalent masses and volumes of air. If we know the volume of Chamber 2, V_2 , the pressure into Chamber 2, P_2 , and the volume of Chamber 1, V_1 , we can determine the air pressure in Chamber 1, P_1 .

$$P_1 V_1 = P_2 V_2 \quad \text{Eq. 3}$$

However because our system is not perfect, the pressure from Chamber 1 will experience some losses. These losses can be attributed to the friction of the rods on the acrylic plates, the potential non-linear expansion of the bags when fully expanded, and air leaks in the valves.

Chambers

The chambers will be made from vinyl ventilation duct tubing. This tubing has wires built in it for strength against bulging and provides low resistance to stretching. It also folds nicely in an accordion-style, is air-tight, and can be easily epoxied to form airtight seals; all of these things have been verified with our initial prototype. The tubing is also inexpensive, easily available, and available in different diameters. The chambers will have diameters of 6.25" and a displacement equal to the required breath volume of the chambers of 650ml. A normal breath volume is 500ml, but breath volume varies greatly while sleeping, so 650ml was chosen to encompass the majority of breath volumes produced while sleeping. Secondly, the average tidal volume while awake is 630ml, as shown in Table 6 Page 35. The chambers were aligned both axially and vertically to reduce the energy losses of the linkage resulting from friction due to torque.

Weights

The design incorporates engineering fundamentals which together allow the device to operate solely off potential energy gathered from exhalation. When exhalation occurs, air is forced into Chamber 2. The force of this air pushes out on all surfaces of the chamber, including the plates. The force of air pushing on the moving plate, F , will be equal to the pressure, P , of the chamber multiplied by the area, A , of the plate, as seen is Equation 4 below.

$$F = PA \quad \text{Eq. 4}$$

The force on the moving plate will raise the weights. The distance traveled, x , is determined by the breath volume, and the force will be constant as the mass of the weight will not change during operation. The weights store potential energy when raised according to Equation 5 below, where E is the potential energy, m is the mass of the weight, and h is the vertical displacement of the weight.

$$E = mhg \quad \text{Eq. 5}$$

After exhalation, the potential energy will cause the plates to fall to their original positions. During inhalation, the force the weights exert against the air in the fresh air chamber will keep the inhalation chamber pressurized, providing pressure to the mask.

We will be using a container that can be filled with various amounts of water to adjust the weight and pressure provided. This container will have water level markings which will correspond to various pressures. This method will make the pressure provided easily adjustable without adding weight to the system that would make the device less portable. The container will be designed to hold the water necessary to provide a range of forces varying from 0-5 lbs. This design does assume that the user has access to water.

Sealant

For assembling our Beta Design we will use epoxy as it is inexpensive, strong, compatible with our materials, safe (does not produce toxic fumes) when cured, and creates airtight seals.

Plates

We made our fixed and moving chamber plates out of 0.22" thick acrylic plates. This material was chosen because it is easily available, inexpensive, easy to machine, and can be cut using the ME undergraduate laser cutter. It is also adequately strong for our application and provides an exceptional surface for epoxy to form airtight seals. Our moving plates were circularly cut with a diameter of 7.5", which based off the chamber circular shape and diameter plus extra (1.25") room for mounting the linkage rods. The fixed plates were made to be square with keyed edges so they can be solidly glued to the walls of the box for strength. The distance between both the moving plates and the fixed plates is 5"; this is determined by the displacement of the chambers and the space required between the moving plate of the exhalation chamber and the fixed base plate of the inhalation chamber for the junctions of the fresh air tube and a one-way valve.

Strength of Linkage Rods

The rod length was determined by the distance between Plates B and D. The diameter was then chosen to be of sufficient size such that the rods do not deflect or buckle during use to ensure straight movement of Plates A and C. The force each rod can undergo before yield was not important during rod selection as the tensile and compressive forces each rod undergoes are insignificant (<2lb).

Rods

The periodic tensile forces, F , being applied and released to the rods (of radial area, A) each time the user breathes in and out should not exceed the yield strength, σ_y , of the material, and thus remain in the elastic region of the material, as seen in Figure 40 below. If the stresses from Equation 6 exceed the elastic limit in Figure 47 (below), the rods will begin to fail.

$$\sigma_y = \frac{F}{A} \quad \text{Eq. 6}$$

Fatigue life of the material will also need to be considered for the life of the device and to meet our engineering specification of at least five years before potential replacement of the device.

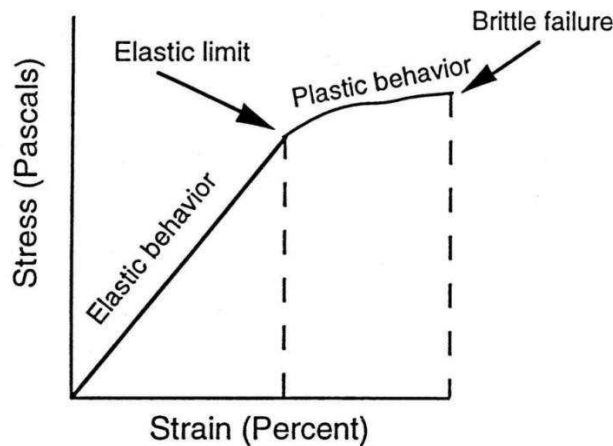


Figure 47: Elastic and plastic behavior of a generic Newtonian material [28]

However, because the rods in our device experience forces undeniably below 25 psi, determining the rod material properties and the rod shape based on these equations is not necessary. Determining other material characteristics such as brittleness or stiffness are also not necessary as the cost of the material already available to us was cheaper than all other materials applicable (steel is \$0.3/ lb) [CES], and it also met our basic requirements.

Our linkage between the inhalation and exhalation chambers consists of six 1/8" steel round rods. Three rods connect the moving plates and three rods connect the fixed plates to provide a guide for the moving plates. Three rods were used to minimize friction and to provide stability in all 3-axis for the moving plates. Steel was used because it is stiff, easily available, inexpensive, provides low friction, and it is easy to work with. The rods were chosen to be 1/8" diameter to provide the stiffness necessary to ensure vertical movement of the plates without adding unnecessary mass, as well as, they were available to us. They are 5" long, as determined by the distance between the fixed plates.

Hoses

We will use two hoses, one will carry fresh air from the chamber to the mask and the other will carry used air from the mask to the exhalation chamber. The use of two tubes eliminates the dead volume that would be present in using one tube. The tubes will be taken from existing CPAP machines where they have proven successful in handling the volume of airflow required for breathing and in user comfort while sleeping. In using these tubes we also know that they will be compatible with existing mask outlet diameters. The tubes will be 6 ft. long to provide enough length from the mask to reach a bed stand.

Valves

Our valves will be made using rubber flaps due to their effectiveness in forming airtight seals as seen in existing CPAP masks. Rubber is also easy to work with, inexpensive, and easily

available. The backflow stopping valve will be located at the mask inlet/outlet to minimize dead volume and to make sure the fresh air that is supposed to go to the user, does not go directly to the CO₂ chamber instead. The backflow valve is crucial to the entire device's functionality.

Device Stability

The device was designed to have a minimized height to width ratio to ensure stability. It has a large base which provides a stable surface and the chambers were positioned to be as low as possible to minimize volume and to lower the center of gravity.

Material and Manufacturing Process Selection Summary (Full report in Appendix J)

In Appendix J, we describe our selection process of the final design materials to be used for the chamber bags and the housing/plates. Using the CES software, we became keenly aware of the wide variety of materials available. However, even though there are some very useful materials available, they are likely not economically feasible to be broadly used. The material properties required must be balanced by economic and manufacturing feasibility. Often times, by slightly changing the design, one material and/or its manufacturing process can become more or less feasible. This selection process is inherently an iterative process by which the successfulness of your design can hinge upon.

Design for Environmental Sustainability Summary (Full report in Appendix J)

Using SimaPro, we learnt that the choice and the amount of material used in our design impact the environment in so many different ways. So far, we only used to know the qualitative part of sustainability and environmental care. For example for sustainability, we need to select materials with good recyclable properties and take note if it would produce harmful chemical substances when processed, burnt or otherwise altered. However, sometimes the effort to use one non-toxic material than another to reduce toxic gas emissions could backfire because the non-toxic material could generate more solid waste and thus affect the environment in another negative way.

Now we are able to take this knowledge a step further by quantifying the environmental effects (which SimaPro allows us to do) and analyze the impact in a more scientific approach. For example, given the mass of materials used, we could assess its environmental effects from the general characterization of the materials to each of their single scores in terms of environmental effects. From there, we could also calculate the amount (masses) of waste that each material produced in terms of raw materials, air emissions, water emissions and solid waste. This way, we could picture the impact of each material more realistically and make numerical adjustments in production methods to reduce the impact.

Design for Safety Summary (Full Report in Appendix I)

The safety reporting assignment reminds us that everyone who will come in contact with the product you manufacture has a risk of getting injured or harmed if the design is not properly considered. We understood that as a potential home medical device, it is important for the device to work properly, has no sharp edges or any choking hazards, and most importantly sleep apnea instead of suffocating the user. We also understood that it should be safe to manufacture as there are safety standards to be followed while manufacturing the products. However, there are more to that than just making sure it is safe from our perspective. The safety report also taught us ways to improve our design. For example, using FMEA table we are able to analyze potential failures

inherent in the product. From there, we could see which subassembly is more likely to fail. Designsafe software also made us think about the severity, exposure and the probability of the hazards that may occur. We also learned that due to the uncertainty in safety, it is important that we refer to the Material Safety Data Sheet (MSDS) when working with unfamiliar materials or chemical substances. This way we reduce the risk of getting hurt while working on the project.

We feel that the use of the FMEA and DesignSafe program helps us in our design process. This because the results from the various safety analysis programs help us focus on problem areas and work from redesigning that specific problem instead of redesigning the whole product.

Also we realized that safety issues are mostly subjective, even though we are quantifying it with numbers. Without reliable feedback data on injuries sustained and other harmful effects of the product we will not be able to improve safety design. It is not a one-time analysis but rather a continuous process and should be improved and built upon even after the product is marketed.

11 PROOF OF CONCEPT

11.1 Proof of Concept Description

Our prototype is contained in a housing made from two acrylic sheets epoxied together in an L-shape. It then has two acrylic plates adhered to the housing using epoxy and are fitted into slots cut into the housing. These plates have three linkage rods securely fastened between them. A circular plate (plate C) is mounted on these rods that can slide freely. This plate is connected to plate A with three additional linkage rods that slide freely through holes drilled into plate B. Vinyl ventilation ducting is mounted between plates A & B and C & D. It is glued to be airtight using epoxy. For the exhalation chamber, (between plates C & D) one elbow valve is glued into place in the center of plate D. For the inhalation chamber, two one-way valves are glued into holes in the bottom of plate B. These valves are simple one-way valves cut from kerosene hand pumps. The whole setup is mounted vertically and pressure is provided by simple steel/lead weights added/removed from the top of plate A. During an iteration of our design, we had planned to use a constant force spring mounted between Plates B and C as shown in Figure 48 and 49. However, this idea was eliminated, as described on page 34. The prototype is shown at two stages of operation, after exhalation and after inhalation in Figures 48 and 49, below.

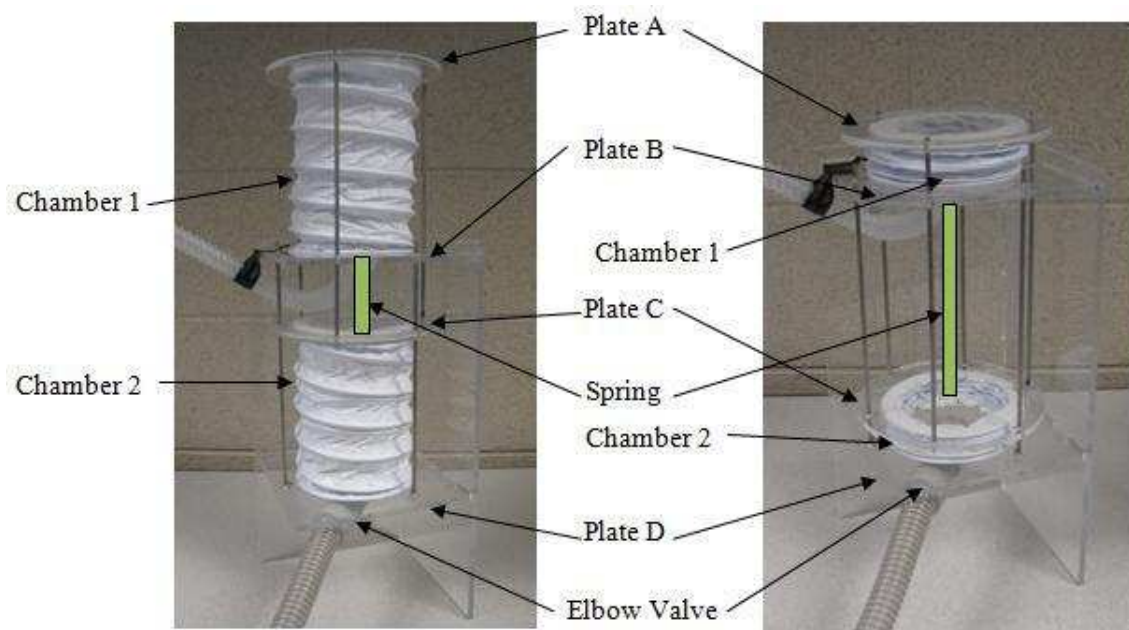


Figure 48: Device operation after exhalation **Figure 49:** Device operation after inhalation

This prototype was effective in proving that positive pressure can be provided to the user during inhalation and exhalation. Through our preliminary validation, we determined that the difference between inhalation and exhalation pressures was $<1 \text{ cm H}_2\text{O}$. Overall, it proved that our concept is feasible.

11.2 Proof of Concept Validation Plan

Goals

We plan to prove our theoretical design concept is feasible and could potentially treat obstructive sleep apnea. We will also determine if there are any potential problems in our design—whether they are foreseen or unforeseen. The following questions give a comprehensive view of the issues we are especially concerned with (order is irrelevant):

Chamber Systems

- Do the accordion-style bags inflate and deflate without changing their structure?
- Do the bags ever collapse and/or block any of the valves?
- Does the bag-plate system fall or lean to one side ever? If so, does this cause binding or torque issues?
- Does the epoxy seal leak at any connection points between the vinyl bag and its mounting (acrylic plates)?
- Do the bags make noise? Is it louder than a loud whisper (30dB)?

Valves and Hose System

- Do the valves allow air and hold air when required? Is there leaking by the valve itself?
- Does the CO₂ L-valve have a large enough hole to allow release of CO₂ from the system?
- Does the epoxy seal leak at any connection points between the valve and its mounting?
- Do the valves make noise? Is it louder than a loud whisper (30dB)?

Force System

- Are there any problematic torque issues in the spring/weight or rod-plate system?
- Is the theoretical weight required enough force to provide the pressure we expected?

Is there a linear correlation between the supplied pressure to Inlet 2 and the provided pressure from Outlet 1?

Could a person comfortably exhale at the pressure required to be provided the inhaled pressure required to treat their sleep apnea?

Procedure for Proof of Concept/Initial Prototype and General Device Testing

The following section explains how we will validate the issues outlined in the previous questions and what equipment we will require to do so.

Equipment Required for Validating Concept:

- Stable Surface
- Prototype with two hoses
- Weights in grams (approximately 200 grams each) in small increments—ME395 Lab
- CPAP machine with variable pressure setting control—supplied by Sleep Disorder Center
- Manometer—supplied by Sleep Disorder Center
- Stopwatch—supplied by Team 6

Note: When referencing the fresh air chamber, moving plate, or valves it will be labeled 1. When referencing the CO₂ chamber, moving plate, or valves it will be labeled 2.

1. After the entire device is assembled and stable, physically move Plate 1 up and down by hand slowly and carefully to determine by inspection:
 - a. If Plate 2 follows appropriately
 - b. If air is captured in Chamber 1 when Plate 2 rises
 - c. If the valves initially seem to function
 - d. If the seals initially seem to hold
2. If the initial test seems to function appropriately, then attach one hose to Inlet 2
3. Attach the manometer to Outlet 1
4. Place 14 grams on top of the Plate 2
5. Turn on the CPAP machine to a pressure setting of 5 cm of H₂O
6. After the CPAP machine has fully ramped up, connect the device to the Y-valve connection port (where the mask normally would have been attached)
7. Remove device within 2 seconds—use stopwatch if needed. Beware that the CPAP setting or the mass could be too high or too low to allow the machine to function properly. This testing could break the machine!
8. Record the manometer reading.
9. Repeat steps 6 and 7 without the manometer attached to check flow rate from Outlet 1 with the flow meter. Record your result.
10. Based on these two results, determine whether more or less weight should be added to the system, then retest.
11. Repeat steps 6-10 until the weight applied is determined to provide an adequate Outlet 1 pressure based on Inlet 2's pressure.
12. Now, increase the CPAP machine pressure to 7 cm of H₂O and repeat steps 6-11.
13. Continue to adjust the weight added to the system and the pressure supplied to the system by the CPAP as need until the system cannot handle any more increase in pressure, or the CPAP machine cannot provide a higher pressure (approximately 30 cm of H₂O).

12 VALIDATION

We discuss our experimental method and results of the tests used to determine whether or not our design fulfills the engineering specifications. We plan to prove our Beta Design, and thus our prototype, function appropriately and meet all engineering specifications. Within each user requirement, we discuss how we are meeting each engineering specification.

We will not be testing all engineering specifications for a number of reasons. During the design phase, no toxic materials or chemicals were used, so Engineering Specification #2 will not be tested but instead the material could be checked to make sure it correlates with our manufacturing plan. Because the minimum air pressure required for our device to be considered functional is 4 cm H₂O and because our device functions already, we will not test Engineering Specification #5. Currently, we cannot test engineering specification #7, because the manometer used to measure pressure and how the pressure changes was not accurate enough. Further testing needs to be completed using pressure sensors. Some specifications cannot be tested in our project timeline, such as the number of years before replacement of the machine (Engin. Spec 14), or cost of replacement parts per year (Engin. Spec 11); other specifications cannot be tested such as the purchase price (Engin. Spec. 10), or sanitation cost per year (Engin. Spec. 12) without further mass manufacturing analysis. Zero voltage required to operate the device, Engineering Specification #17, is inherently part of our design, so it is not tested, but just identified. The number of buttons/levers/switches required for operation (Engin. Spec. 22), the number of consumable parts (Engin. Spec. 13), or the number of pieces to sanitize (Engin. Spec. 21) cannot be tested, but could be easily counted.

Equipment Required for Validating our Final Prototype

- Stable Surface
- The ME450, Team 6 prototype with 2 hoses, 1 mask*, and the Y-valve
- Tape measure
- Weight set (0-3kg)
- Scale
- Microphone
- Manometer
- Stopwatch
- CPAP machine
- University of Michigan School of Music and Theater Recording Studio/Sound Room

*Current masks utilize air outlet holes which must be plugged for our device to operate.

12.1 Experimental Setup

Safe to Use

Engin. Spec 1: Is each part that interfaces with the user at least 3 cm?—requires inspection

Engin. Spec 3: Is every edge smooth? –requires inspection

Engin. Spec 4: If the device is broken, can a person still trying to breathe, breathe if they are not suffering from an apnea?

A standard CPAP machine was hooked up to the exhalation tube and run for an extended duration; this test simulated a larger than normal exhalation. The safety valve was observed to

determine if it operated as intended. To test whether the device can handle larger than normal inhalations the chambers were deflated and air was drawn through the system to see if inhalation was still possible.

Works

Engin. Spec 6: Can a person comfortably breathe for 5 minutes—if so, then they can likely use the device during sleep for 10 hours.

Engin. Spec 8: What is the maximum air pressure variation produced? Do we reach the desired pressure output consistently?

Engin. Spec 9: What volume of dead volume exists in the system?

Pressure

A manometer, supplied by the Sleep Disorder Center, will be used to measure the pressures associated with our devices inputs/outputs. A manometer measures the change in height, H , of a liquid—in this case water—from one area to another, as seen in Figure 50. Equation 7 can then be used to calculate the pressure difference between two locations, P_A and P_o , where g represents the gravity on the system and ρ represents the density of the fluid. In this case, the pressure produced by the device is compared to the atmospheric pressure, P_o , of the room. This measurement difference is called the gauge pressure.

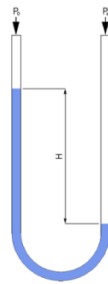


Figure 50: Manometer used to measure the pressure supplied by our device [27]

$$H = \frac{P_A - P_o}{g \cdot \rho} \quad \text{Eq. 7}$$

Exhalation Pressure

The device was connected to a standard CPAP machine set to run at a desired pressure via the exhalation chamber hose. We repeated this process at different pressures using the same weight on the chambers to determine the maximum weight that can be used while the chambers still inflate for a given pressure. The weight was then varied and the test was run again.

Inhalation Pressure

The weight-pressurized chambers were inflated by the standard CPAP machine to their maximum capacity. The standard CPAP was then disconnected. The fresh air chamber outlet tube was connected to a manometer to record the pressures provided for inhalation and their correlation with the weight that was used. The weight was then varied and the test was run multiple times.

Pressure Difference

The exhalation pressure required to raise a given weight was compared to the inhalation pressure provided by the same weight.

Breathing Pressure

The breathing pressure was determined by attaching a manometer to a mask with a user breathing into the machine. The pressures were then recorded over time for a given weight. The manometer could not provide accurate readings due to the water level gyrating after each inhalation and exhalation.

Dead Space Volume

The dead space volume of the tubing was measured by plugging the back-flow stopping valve outlet/inlet to the air chambers and filling the valve with water. This water was poured into a beaker and measured. This value must be added to the associated dead volume of the mask used.

Cost

The final cost of our device cannot be evaluated within the project timeline, however the cost to produce our prototype can be determined. Please note, a list of the project Bill of Materials is located in Appendix B.

Quiet

The sound generated by the device was compared to the sound generated by a CPAP machine using the University of Michigan School of Music and Theater Recording Studio/Sound Room.

Engin. Spec 15: How loud is the device?

Small

The prototype was measured with a ruler.

Engin. Spec 16: How large is the device—maximum and minimum if they are not the same?

Electrical Power

The data from the inhalation and exhalation pressure testing was analyzed to determine if the device functions. This determined if the non-electric concept works.

Engin. Spec 17: The device is a purely mechanical system powered by the users breathing.

Stable

The device was placed on a surface similar to that of a bedside table and tipped until it reached a balancing point. The angle of the device was then measured at this point.

Engin. Spec 18: Can it stand stably without risk of falling over? If it does fall over, does it still function correctly?

Easy to use

The device was observed to see if it functioned with the CPAP machine tubing. The time required to place weight on or off the machine was measured. The number of pieces that have exhaled air were counted. The number of buttons, switches, and levers were counted.

Engin. Spec 19: Is the device compatible with hoses and masks in the market?

Engin Spec 20 and 23: How long does it take to stop applying pressure and turn on/off the device?

Manual Emergency Shutoff Function

The time required to remove the weight from the machine was measured.

Lightweight

The device was weighed to be 1.7kg which meets our target weight of 2kg.

Engin. Spec 24: How much does the device weigh?

12.2 RESULTS & DISCUSSION

The results discussed here were obtained from a Beta Design prototype of the device, it is expected that a refined device would produce more desirable results.

Safe to Use

All engineering specifications were met. Our device has no components that are loose that can create a choking hazard. It also contains no toxic chemicals or materials after manufacturing. There are no sharp edges as the acrylic edges are not sharp and the metal rods have been filed to be smooth. The device can handle our desired airflow of 250 ml/s and does not prevent breathing for any inhalation or exhalation size.

Works

All engineering specifications were met that could be testing for.

Exhalation Pressure

We determined that the exhalation pressure provided is constant while breathing out. The pressure can be adjusted by adding/removing weight from Plate A. The pressure range fulfills our target range of 4-20 cm H₂O using weight ranging from 400-3100g. The weight to pressure correlation is linear and is shown in Figure 51. This shows the minimum pressure required to inflate the chambers for various weights. The weight required can be altered by changing the diameter of the chambers, as this will change the area the pressurized air presses upon in Eq. 3.

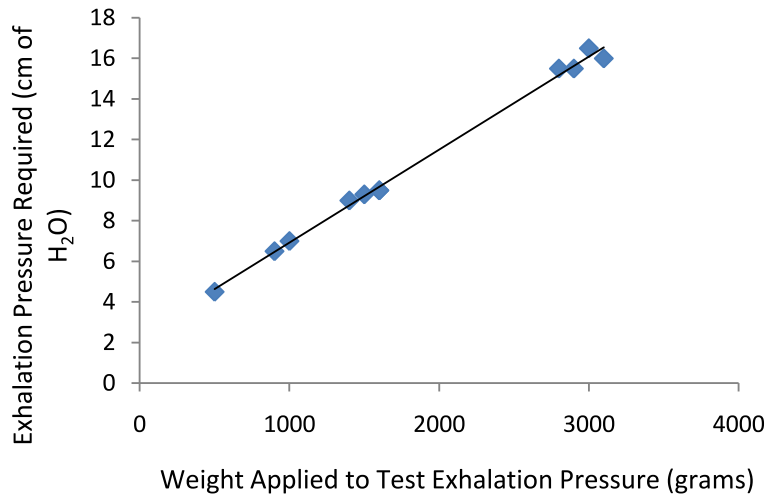


Figure 51: Linear relation between weight and pressure for exhalation

Inhalation Pressure

The pressure provided upon inhalation is determined by the amount of weight currently on the system and the rate at which the user breathes in. Accurate human testing has not been conducted yet, so the pressure provided to the user during inhalation cannot be determined. The pressure provided for various weights (400-3100g) with the inhalation tube plugged has been determined. This relationship is linear and is shown in Figure 52.

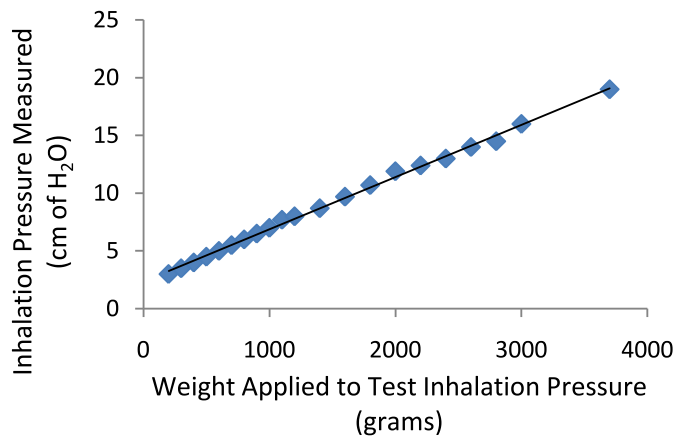


Figure 52: Linear relation between weight and pressure for inhalation

Pressure Difference

The chambers are very effective in capturing the energy in exhaled air, storing the energy, and provided pressurized air back to the user. For example, with 500g of weight, the chambers require 5cm H₂O to inflate and can provide 4.5 cm H₂O. Table 7 below shows the pressure required to inflate the chambers and the pressure provided as the weights fall for various weights.

Pressure Required to inflate from CPAP (cm H ₂ O)	Weight Applied (g)	Pressure Provided (cm H ₂ O)
5	500	4.5
7	1000	7
10	1600	9.6
15	3100	16

Table 7: Pressure required to inflate bags and pressure provided for various weights

However, these pressures were generated with the outlet of the inhalation tube plugged. The inhalation pressure with a user inspiring is less than 4.5 cm because of the expansion of the volume of the lungs. The air being forced to the user is used to fill the lungs rather than pressurize them. Also, while the chambers can be inflated at 5 cm H₂O with XX g, they cannot be inflated in the time of a normal exhalation at 5 cm H₂O. To inflate within the exhalation period of roughly 2.5 seconds, the exhalation pressure required is greater than 5 cm H₂O. Both of these effects increase the difference in inhalation and exhalation pressures.

Breathing Pressure

Shown below (Figure 53) is a timeline of the expected pressure provided to a user with 1 kg of weight. For our simulated breathing tests the water level of the manometer could not respond accurately to the pressure changes to map the pressure as function of time. Therefore the numbers are not accurate as different pressure measurement equipment is required. The difference between inhalation and exhalation pressure is shown with the two different pressure levels during inhalation (low pressure) and exhalation (higher pressure). The effectiveness of our device depends upon how large this pressure difference is in relation to the maximum pressure difference allowable that still provides treatment to the user. The estimated numbers used in Figure X do not satisfy our user requirement of ± 0.5 cm H₂O.

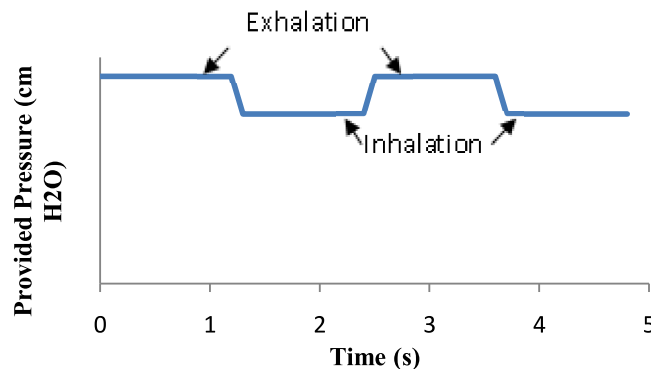


Figure 53: Estimated provided pressure timeline

Dead Space Volume

The dead volume of our system is limited to the volume of air contained in the backflow stopping valve (Figure 32), the tube connection between this valve and the mask, and the mask volume itself. The dead volume for the valve is 2 ml, the connection is 8.8 ml, and the mask ranges from roughly 88-200 ml. The device tube diameter is compatible with most of the existing masks on the market, however smaller masks may work better with our device as their dead volume is much smaller than some larger masks. The smaller masks generally only cover the

nose, instead of both the mouth and nose. To use masks designed for CPAP machines with our device, the air outlet holes of the mask must be plugged to allow all exhaled air to reach Chamber 2 and all pressurized fresh air to meet the user.

Low Cost

All engineering specifications that could be determined in reference to our prototype were met. The fully functioning prototype material cost was <\$60, which satisfies our target of \$100. This will increase the availability of the machine to low income patients. The device does not have any components that need to be replaced regularly, reducing the cost of replacement parts per year to be \$0 per year. The device will require cleaning on a regular basis, most likely 3 times per week. This will create a sanitation cost of ~\$10 per year from the cost of soap. The device uses 0 consumable parts. The lifetime of the device could not be determined as long term testing has not been possible due to the timeline of the project.

Quiet

This engineering specification was met. The prototype with a mask attached produces an estimated 25 dB of noise compared to the RemStar Pro CPAP machine which produces 30 dB without a mask. The REMStar Pro CPAP machine also produces more than their provided 30 dB spec with the attachment of a mask, which produces noise at the air release holes. This difference in sound produced, between the prototype with a mask attached and the RemStar Pro with a mask attached, can be seen in Figure 54A and 54B below. The figures are shown at the same magnification and scale over a 10 second duration. The dramatically smaller amplitude waves of the prototype, on average about 1/6 of the CPAP machine, show that it is producing sound at a much lower audible level.



Figure 54A: Sound level of CPAP machine

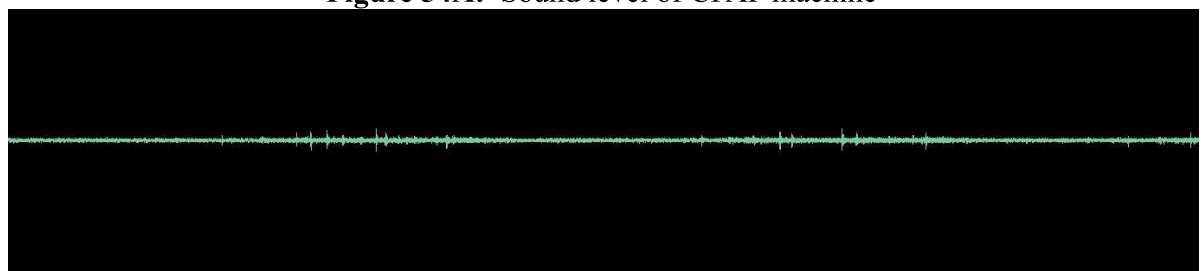


Figure 54B: Sound level of prototype

Small

The prototype was 8.15x9x9 in. This is larger than our target volume because the device must contain two air chambers that are 650 ml when inflated.

Electrical Power

This engineering specification was met. Our design functions without electrical power, which also allows it to fulfill the user requirement of functioning during power outages and increases portability.

Stable

This engineering specification was met. Our device is stable until it reaches a tipping angle of 28.12°. It has one stable surface for operation that is suitable for use on most bedside surfaces. When the device is tipped over, the device does not break, however it does not function correctly.

Easy to use

All engineering specifications were met. The design is compatible with existing CPAP machine tubing. The time required to turn the machine on or off with the mask on is 2 ± 0.5 seconds. This is the time required to remove or place the water weight on the device assuming that it is already at the required water level. The design has three pieces to sanitize excluding the mask: the backflow stopping valve, the exhalation tube, and the exhalation chamber. The design has 0 buttons, switches, or levers to operate.

Manual Emergency Shutoff Function

The pressure from the device can be stopped in 2 ± 0.5 seconds. This is the time required to remove the water weight from the device.

Lightweight

This engineering specification was met. The current prototype weighs 1.7 kg. This is due primarily to the excessively thick acrylic used due to availability.

13 FINAL DESIGN

13.1 Description and Manufacturing

There will be a number of design changes between the prototype and the final design. With these design changes, The Rebreather will be smaller, more portable, more robust, and easier to clean for the user. Additionally, these design changes, will make the Rebreather easier and cheaper to mass produce, easier to assemble, and more marketable. To summarize, the chambers will be custom made of a light weight, flexible, and durable plastic with molded threaded ends, plates A, B, C, D will be slightly thicker with threaded grooves for the threaded ends of the chambers to screw into. There will be a fifth plate, plate E, that the entire device will rest on. Plate E will be larger than the other four plates and will have a recessed threaded inside. The rods will be extended through to plate E. And, the entire housing will be one cylindrical piece and threaded into plate E. It will have a hole in the middle and a hole at the bottom edge for the inhalation and exhalation tubes. It will also have cut-out holes for air flow. The Final Design is exhibited in Figure 55 and 56 below.

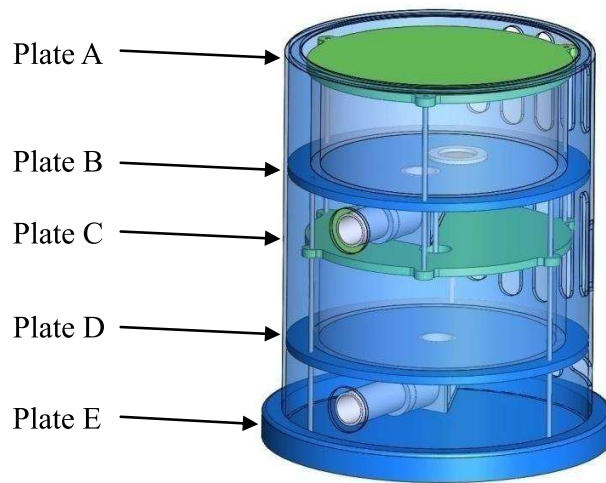


Figure 55: Final Design CAD Model

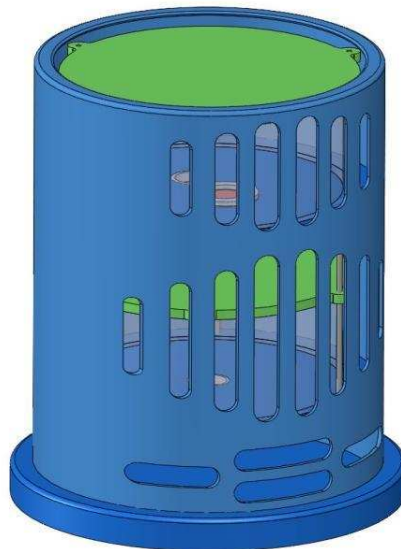


Figure 56: Back view of Final Design

Chambers

Currently, the prototype utilizes vinyl air duct bags, but a number of issues result from this. The bags are difficult to attach to the plates as they use epoxy, they cannot be removed once attached, and they cannot be cleaned after attachment. The accordion-style bags will be manufactured with threaded ends, which will allow the bags to be just as flexible, but will also allow them to be unscrewed from the plates and washed. The bags will also have threads at each end for easier attachment and removal and a gasket at each end to provide a good seal. For example, common water bottles function on this same concept, but seal liquid instead of gas.

To determine the material the chambers will be manufactured from, we knew the material needed to be a thermoplastic, not an elastomer or thermoset, as the material needs to be very flexible but still retain its shape. Secondly, if the material was 0% filled, or unfilled, then the material would

be homogeneous and isotropic. Thirdly, the material must be impermeable to air and absorb minimal amounts of water, as it will be used as an air tight breathing chamber for moist air and may be washed often. The material should also be non-flammable, durable under UV radiation, and not biodegradable. So, as long as it met these conditions, the yield strength, the fatigue strength and the cost needed to also be appropriate. Using these 10 parameters in CES, we were able to narrow our search to a total of 9 materials. We then selected PVDC (copolymer, barrier film resin, plasticized) to be injection blow molded. According to CES, injection blow molding provides high tolerances and small wall thicknesses. Although injection blow molding has slightly higher capital costs than extrusion blow molding, it is capable of producing hollow 3D-objects with wide-mouthed containers, where the neck areas can be threaded.

Housing

The housing will consist of a cylinder with two open ends with one end having a threaded outside. The top end of the housing will be open to allow for the weight container to rest on Plate A. It will have lightening (weight reduction) holes that serve as air intake/outtake holes and hose outlet/inlet holes. The entire assembly will be inserted inside the cylindrical housing and screwed into place. The hose outlet/inlet holes will be aligned with the hard tubing extending from the elbow valves from the fresh and used air chambers when the assembly is fully screwed into position. This is shown below in Figure 57 and again with the housing removed in Figure 58.

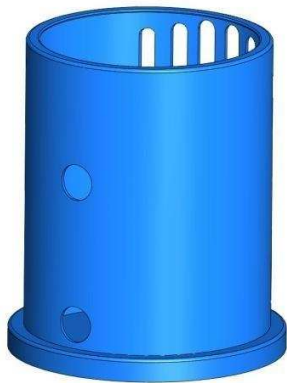


Figure 57: Final Design Housing

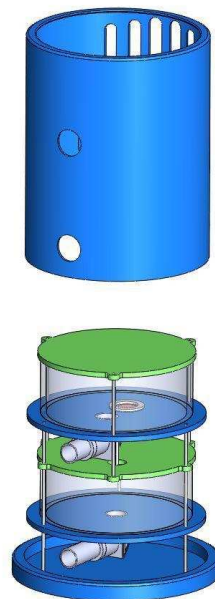


Figure 58: Final Design with housing removed

To determine the material the housing will be manufactured from, we knew the material we wanted needed to be a cheap, rigid, lightweight plastic that could be manufactured using a precise enough process that threads could be created. Through our CES material search, we narrowed the material down to a type of PVC. We then selected PVDC (rigid, molding, extrusion) because it has one of the highest Young's Modulus of 500 ksi, the lowest cost (\$0.4/lb) and a high yield strength of 7600 psi. This PVC can be injection molding using any color plastic

desired to make the device more aesthetically pleasing. We validated that this material would be sufficient as PVC/PMMA, or acrylic, has very similar material characteristics including density, except the acrylic is twice as expensive and is transparent. A view of the back of the housing can also be seen in Figure 51. It was determined that manufacturing a collapsible housing would be difficult to manufacture, require many steps, and would not result in a large volume reduction for travel; therefore, the final design does not incorporate a collapsible housing as was originally planned when discussing our prototypes.

Plates

Currently, the prototype utilizes acrylic plates, which provides a light-weight, transparent material, as it was an accessible material at the prototype manufacturing stage. The final design of the plates will be manufactured from PVC (rigid, molding, extrusion) using injection molding, just like the housing. It provides a rigid attachment for the chambers, is lightweight, and it can have threads engraved. In the final design, all of the fixed plates will be made to be circular so that the entire assembly can be inserted into the cylindrical housing. With this design, a rubber gasket is required around plate D to form an airtight seal with the housing to prevent used air exiting the used air chamber from entering the air space between plates B and D, where the fresh air intake is located. Also, plates A, B, C, & D will have threaded grooves for screwing in/out the bellows for easy cleaning. The housing and plates in the prototypes are made of 0.22” thick acrylic. For the final design this thickness is not required for the forces the device undergoes. An acrylic thickness of 0.093” would be ideal as it is commonly found in stores and would reduce the weight of the system significantly.

Weight

The weight using to provide pressure would consist of a flexible water container with markings for different water levels that would correspond to various pressures. The user would fill the container to the desired pressure marking before using the device. Plate A will have an alignment circle painted on it to ensure that the bottle is placed on the center of the plate so the device will not tip and also to reduce any additional friction caused by an off center weight distribution. This is shown below in Figure 59.

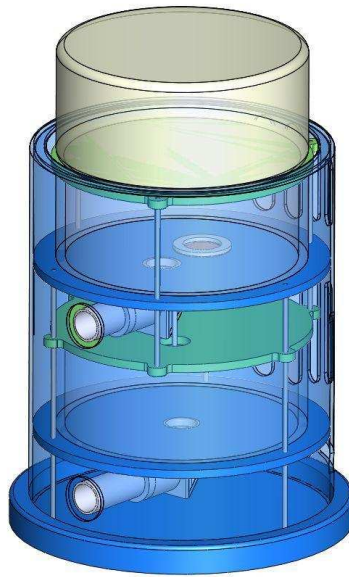


Figure 59: Final Design with water container weight on top

Rods

Currently, the prototype utilizes solid, thin, steel rods, which are press fit and epoxied to the acrylic plates. Steel worked well as the rods are light, stiff, and smooth. The final design will utilize the same type of linkage system. For mounting plate E to protect the elbow valve to the exhalation chamber, the three linkage rods connecting plates B & D will be extended so that they can be press fit and glued to plate E to provide vertical support.

To determine the material the rods will be manufactured from, we knew the material we wanted needed to be cheap, rigid, lightweight, not too brittle and easy-to-use. Using CES, we were able to narrow down the materials to many types of aluminum and steel. We selected steel because even though it is heavier, it is almost three times as cheap. Ease-of-assembly, cost, availability and minimization of deflection were our biggest design drivers for the rods. The stock steel rods (Part #: 5227T21) could be purchased from McMaster-Carr.

Valves

The valves used in our Beta Design were completely manufactured from scratch. They are lightweight, small and function appropriately, but are difficult to install as they need to be assembled and sealed with epoxy. They do not function as efficiently as will be required for the final design however this is due to the thickness of the rubber used. The rubber is too firm to bend to a complete air-tight seal with the plastic. With a thinner, more flexible rubber these valves will seal tightly. The Y-backflow valve housing would be manufactured from PVC using injection molding (Figure 60).

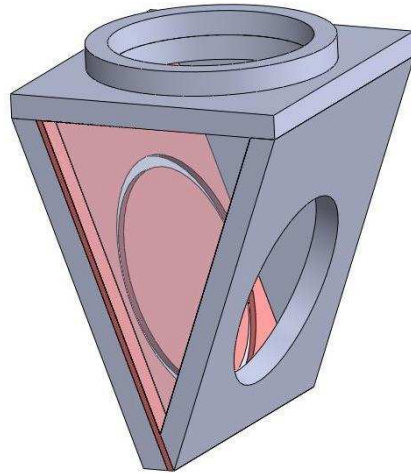


Figure 60: Backflow Stopping Valve

Hose and Mask

The two hoses used in the prototype are the same hoses as used in the market today. We recommend the Respironics Pure White 6 Foot Performance CPAP/BiPAP Tubing (Part #: 1032907). There are also many masks in the market today that could be utilized except that they have a few small holes in the mask itself. These both could be manufactured as well, or easily outsourced to another company. A previous CPAP user likely owns a hose and mask, such that they could personally just cover the mask holes with tape, use their existing hose, and buy an additional hose without great difficulty and little extra monetary costs to themselves.

Filter

Low-resistance filter paper will be lined around interior of the housing, covering the lightening holes to provide filtration of the air drawn into the system.

13.2 Final Design Validation Plan

For the final design to reach the market, a multitude of validation steps are federally required. In general, the device must be clinically tested. To do so, it must receive Investigational Device Exemption (IDE) and then seek IRB (Institutional Review Board) approval. To gain approval, which requires approximately two months, the site to conduct the clinical trials must be selected and a Clinical Trial Protocol must be submitted according to ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) formatting. IRB approval allows testing to determine safety and efficacy of the device for the patient, but it also provides an oversight to protect the rights, safety and welfare of research subjects. Clinical trials are performed in multiple stages with increasing number of participants per stage. First, a few healthy people test the device, then small pilot studies begin and develop into larger scale studies comparing the current treatment options to the new device in question, as long as the device continues to perform safely and effectively. Then, it is finally tested on people who actually need the device. The clinical trial process would likely require a few months for this device [29].

After all clinical trials have been conducted, the investigators for the device apply for FDA (US Food and Drug Administration) approval under the Center for Devices and Radiological Health

(CDRH), which is specifically responsible for the approval of medical devices. The FDA regulates the manufacturing, performance and safety of items that interact with the public. There are three classes of devices that the FDA regulates. Based on our research, we suspect the final design would be considered a Class II device for a number of reasons. First, it is not a “new” device, but instead is substantially equivalent to Class I and II items already approved. However, because the final design experienced significant design modifications to other CPAP machines already approved, the device must be approved. Secondly, the device is non-invasive. And thirdly, the device is only a medium-risk device, which could not perform substantial injury to users. Because it is a Class II device, it must apply for 501(k) approval by describing the indications of use of the device, describing the device itself, labeling the device and its’ required precautions, listing the device’s risks, and describing alternative practices and procedures of treatment. Because the final design likely does not require Premarket Notification (PMN), on average approximately 30 days is required for this final approval. After FDA approval is achieved, the device can be manufactured and sold in the US market [29].

14 DISCUSSION

Design Strengths:

The refined prototype produces 15 dB which is quieter than current CPAP machines by 50%. It does not require electrical power and costs < \$60, whereas current CPAP machines generally cost from \$250 to \$1300. The device weighs 1.7 kg, which is less than the average 2 kg weight of CPAP machines available on the market. In addition, the device can provide a variety of pressures (4-20 cm H₂O) by simply increasing or reducing the water-weight applied to the system. The design is also safe, as it can handle any inhalation or exhalation size, does not contain any choking hazards, and continues operation during power outages.

Design Weaknesses:

The design is larger than current CPAP machines with a volume of 576 in³, which is slightly more than most machines. The pressure provided is not perfectly constant—there are pressure spikes and losses during the breathing cycle. These pressure differences determine if the device functions in treating OSA. The maximum difference allowable was determined to be ±0.5 cm H₂O. Also, if this difference is appreciable, the user would find the device uncomfortable because breathing would feel irregular. It also does not provide pressure to the airway if the breath size varies enough that the chambers are not large enough to handle the volume of air inhaled/exhaled. This is not a significant issue because the chamber size can encompass a large percentage of breaths throughout the night. Also, the elbow valve to the exhalation chamber still has some air losses associated with it. These air losses will not be associated with our final design because we will be using a pre-manufactured valve with no air losses.

15 RECOMMENDATIONS

We have recommendations for the design to improve the overall effectiveness of the device for our sponsor continuing forward. We also recommend that the design and principles of this device be submitted to obtain a patent.

Housing- Ideally the housing would be collapsible so that the device is more portable when not in use. Appendix G contains a proposed design drawing. Also, it could be made to be half as

thick, as the current thickness is not necessary for the forces the device undergoes, this would reduce the weight of the device significantly.

Rods- The rods could be collapsible such that the device is more portable when not in use. Appendix G contains a proposed design drawing.

Chamber Placement- The chambers could be placed inside one another, so that only two plates are required. One chamber would have a relatively small diameter, while the other would be shaped like a donut and would surround the inner chamber. This would complicate manufacturing, but would allow the device to be much smaller by eliminating all wasted volume. Appendix G contains a proposed design drawing.

Weight-The water bottle could be replaced by a collapsible container to make the device more portable when not in use.

Valves- Pre-manufactured valves could be bought that do not leak air.

16 PROJECT PLAN

The next steps in the design process are to submit our conference paper to the 2010 Medical Devices Conference on December 15th, 2009 and to obtain a patent for our device with our sponsor within the next year. Katya will lead further project development along side Dr. Chervin. She will be Dr. Chervin's main contact to reach the group. Her duties will be to assist Dr. Chervin in gathering information for the project, contacting the rest of the group if needed, keeping the group updated on developments, and assisting wherever needed with the patent application. By mid-January, the team will need to meet with Dr. Chervin and Dr. Sienko to discuss further details about the patent and further requirements to put our device into production.

17 BIOGRAPHIES

Our team is enthusiastic about our project. We are excited about patenting, marketing, and producing our design. We are continually refining our roles as we continue to learn about each other to make our team as efficient as possible. Katya is excellent at keeping the team on track and organized, for this reason, she is the project communicator. Davina is great at developing ideas, and her consist attention to detail has been invaluable for the Formal Safety Report. For this reason, she is also the project team facilitator. Steve generates innovative ideas and has an ability to understand differing viewpoints, such that his input was indispensable during Beta Design generation, valve design, and CAD drawing development. Joe is a great listener and has a conceptual mindset, great for visualizing designs and producing a feasible prototype. Joe's and Steve's experience with the laser cutter was invaluable to this project.

Ms. Katya Christenson

Undergraduate Student

B.S. Mechanical Engineering and Manufacturing Concentration at the University of Michigan, Ann Arbor, December 2009



Katya was born in Sioux Falls, SD. She originally became excited about engineering in seventh grade and has had a desired to focus on biomedical engineering since. Her research experience and internship experience each summer has been invaluable to her further education. After graduation in December, she plans to work for an engineering company for a number of years. She would then like to return to school to earn her masters in the field most suitable for the company she most likely plans to stay with. Outside of school, she enjoys many outdoor activities such as waterskiing, rock climbing, camping and volleyball. Although, she also enjoys just hanging out with friends and playing pool, watching movies or going dancing.

Mr. Steven Fannon

Undergraduate Student

B.S. Mechanical Engineering at the University of Michigan, Ann Arbor



Steve is from Novi, Michigan and has lived in Michigan his whole life. Ever since he was a little kid Steve has always loved building make-shift contraptions out of things he can find around the house. He has had an internship every summer of college. His first summer was spent working at General Motors in their Body Test Lab testing door lock/latches in weather chambers. His second summer was spent at General Motors in a transmission plant testing milling equipment and cutting processes using a laser surface imaging device. That fall he was hired part time by the company which built the laser surface imaging device, Coherix, to assist with product development. This past summer Steve worked at an engineering company called Superior Controls. The first half of the summer he was in Houston, TX consulting at a military vehicle assembly plant to help improve production. The second half of the summer he worked at the main office in Plymouth, MI designing and building custom gauging equipment for a Ford exhaust line. In Steve's spare time he likes photography, running, and playing sports.

Mr. Joseph Jacquemin

Undergraduate Student

B.S. Mechanical Engineering at the University of Michigan, Ann Arbor



Joe was born and raised in Alpena, Michigan in 1988. His favorite toy as a child was a screwdriver, and he went everywhere with it despite protests from his mother. He has two older sisters which tortured him mercilessly with awful girly movies and took eons in the shower. He swam competitively and played tennis in high school. He forgot the tickets to prom after his date told him to remember them, and consequently was berated. He went into mechanical engineering because he loves building things and problem solving. He plans to get a job this Spring or go to graduate school to get a Master's in an engineering field. He would like to work in the energy or defense industry. His ultimate plan for world dominion is to eventually get an MBA and to own his own company.

Ms. Davina Widjaja

Undergraduate Student

B.S. Mechanical Engineering at the University of Michigan, Ann Arbor



Davina was born in Jakarta, Indonesia. She grew up in Jakarta for about ten years before her parents sent her to Singapore to attend the last half of elementary school and middle school. She spent most of her formative eight years in Singapore joining various student organizations including the Mechatronics Club. It was her experience in the Mechatronics Club that made her decide to be a Mechanical Engineer like her father. She then left for Michigan, USA at the end of 2005 and started her University of Michigan career in Mechanical Engineering in Winter 2006. In the summer of 2007, she worked on a project on Internal Combustion Engine in Technische University at Berlin in Germany and became interested in learning more about the automotive industry. Her trip to Germany also made her realize about her interest in manufacturing. Being educated overseas for most of her life, she has always considered herself to be an international citizen who loves to travel. She can speak Indonesian, English and Chinese (Mandarin). She has always been interested in languages and bettering the education system in Indonesia and hopes one day she could build and run a school.

18 CONCLUSION

Our comprehensive research has shown that existing CPAP devices have a low compliance rate due to their lack of portability (size and weight), electrical outlet dependence, and high cost. Our challenge is to address these issues through an innovative design.

The first task in the design process was to research the issues with existing treatment devices. This was completed through meetings with Dr. Chervin, research at the University of Michigan Sleep Disorders Center, online research, the Ann Arbor CPAP user support group, and an online user survey. With this information, we determined the top user requirements and specifications. Our new device should produce less than 30 decibels, cost less than \$100 and not require an electrical outlet for operation.

We have developed an Alpha Design concept which does not require electrical power. This design was chosen through a selection process to fulfill our user requirements. Based off the Alpha Design, we developed a more functional Beta Design concept. We then manufactured a working proof of concept prototype based off of this Beta Design. Our initial prototype met our main goal of developing a device to treat sleep apnea that does not electrical power, but to satisfy other requirements, we refined our Beta Design and will manufacture a final prototype for the Expo. Each design decision of our Beta Design is justified in our parameter analysis either through equations or engineering logic. Some challenges for our Beta Design prototype include issues with: valves, seals, energy loss, and limited time. We have developed design and manufacturing plans for both our Beta and Final Designs with detailed models. Testing procedures have been outlined for our Beta Design to demonstrate how it has met the engineering specifications. We have thoroughly tested our device to determine if it has met the user requirements set forth early in the design process. Validation plans have been researched for what the required steps would be to validate our Final Design for manufacturing and marketing to the public.

The next steps in our project plan are to submit our conference paper to the 2010 Medical Devices Conference and to apply for a patent for our device.

ACKNOWLEDGEMENTS

We would like to thank all of the people who helped us with our project. We could not have accomplished so much in such a short period of time without the help of everyone involved, whether it was design, manufacturing, research, feedback, guidance, or any number of other areas. Specifically we would like to thank our sponsor Dr. Ronald Chervin and section instructor Dr. Kathleen Sienko for their knowledge, feedback, and support. We would also like to thank Mrs. Fay Johnson, Mr. Dan Johnson, and Mr. Bob Coury for their contributions to our project.

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APPENDIX B: Bill of Materials for Beta Design Prototype

Item	Quantity	Source	Catalog Number	Cost	Contact
6.25" Dia. Aluminum Ventilation Ducting	1.5'	Home Depot		\$1.86	homedepot.com
1/8" Steel Rod	6'	Home Depot		\$	homedepot.com
.22" Acrylic	18"x24"(2)	Lowe's	239981	\$28.60	Lowes.com
.093" Acrylic	11"x7"	Home Depot	074507993042	\$0.99	homedepot.com
CPAP machine tubing	2x 5.5'	UofM Sleep Center	CSLT-1006	\$9.80	cpapplus.com
Thin rubber sheet	4"x15"	Home Depot	037155008766	\$1.06	homedepot.com
.75" inner Dia. PVC Tubing	4"	Home Depot	697285360051	\$0.82	homedepot.com
Epoxy	3oz.	Home Depot	075353068243	\$7.93	homedepot.com

APPENDIX C: Engineering Changes since Design Review #3

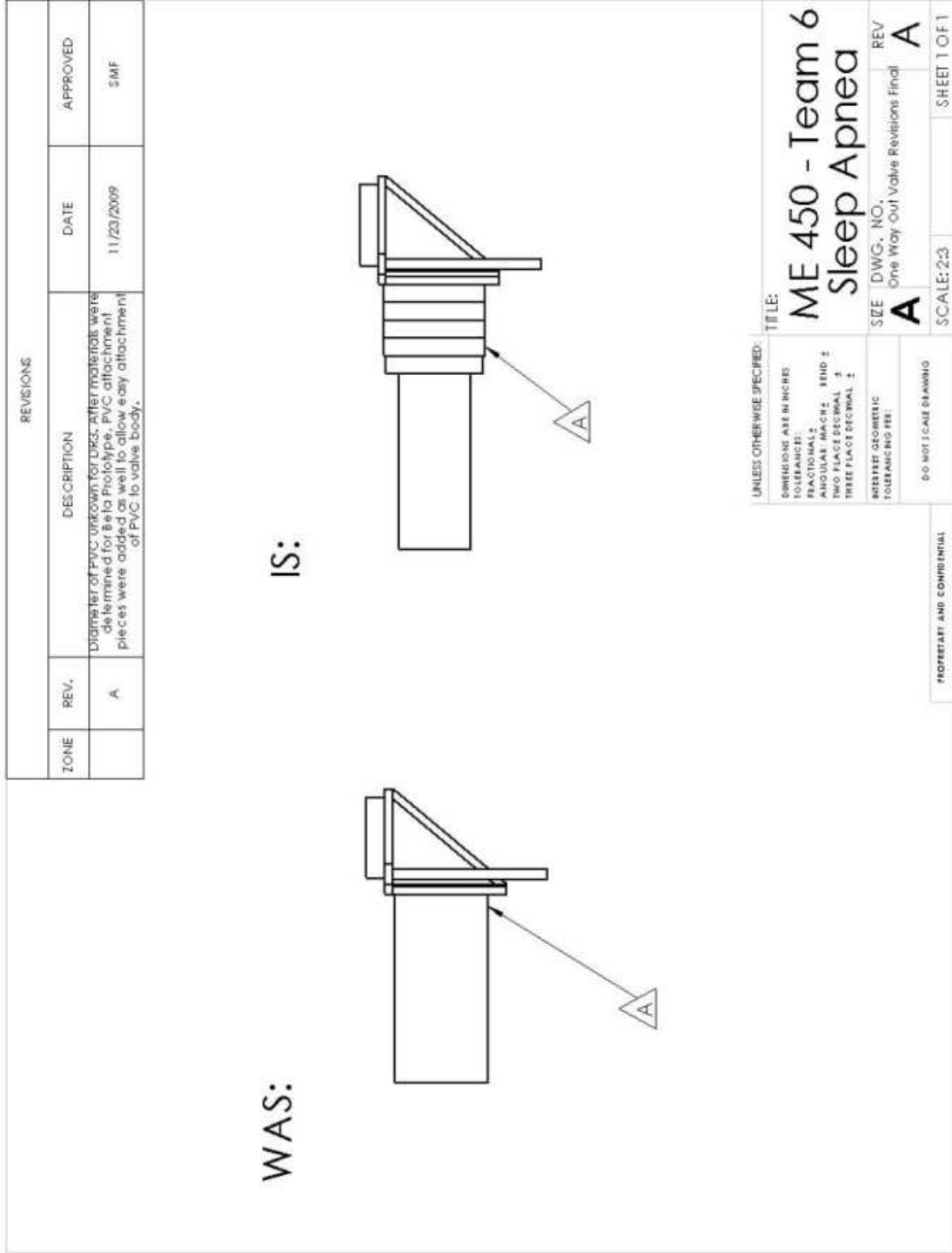
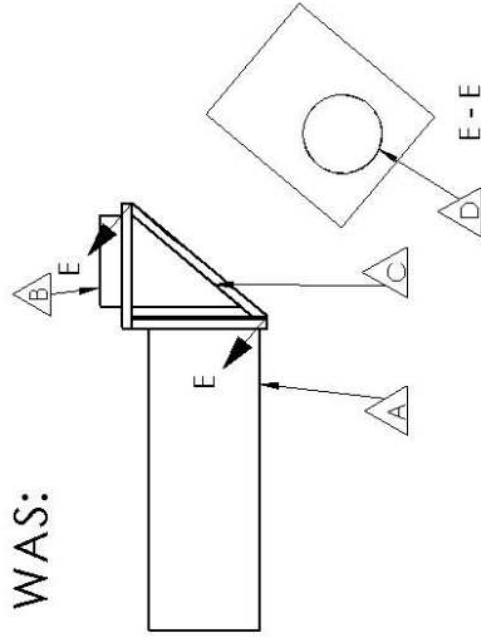


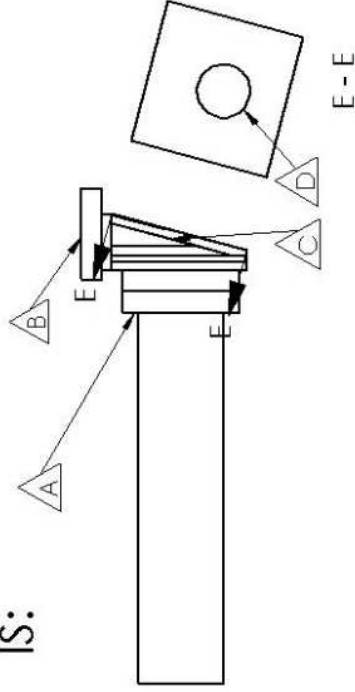
Figure C1: Changes made to One Way Valve for fresh air chamber. Dimensions of new parts can be seen in Figures C4 – C15
 *Old dimensions can be seen in 2D CAD drawings in Appendix I

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED
	A	Diameter of PVC unknown for DRG. After materials were determined for Beta Prototype, PVC attachment pieces were added as well to allow easy attachment of PVC to valve body.	11/23/2009	SMF
	B	Diameter and shape of inside air hole cutout changed to allow for decreased angle of diagonal valve stop.	12/07/2009	SMF
	C	Angle of diagonal valve stop decreased to allow for better seal with rubber flap during normal breathing conditions.	12/07/2009	SMF
	D	Diameter and location of diagonal valve stop hole changed to allow for better seal with rubber flap during normal breathing conditions.	12/07/2009	SMF

WAS:



IS:

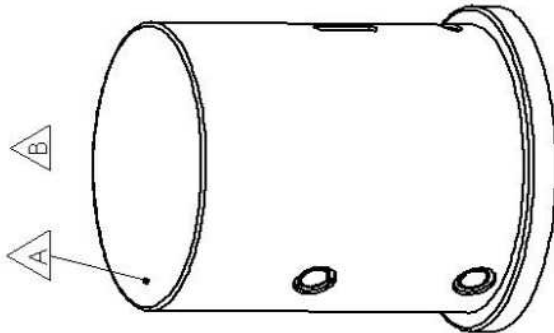


UNLESS OTHERWISE SPECIFIED:	
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TOLERANCES:	
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ANGULAR: 1/4	BEND 1/2
TWO PLACE DECIMAL: 0.01	
THREE PLACE DECIMAL: 0.001	
INTERPRET GEOMETRIC TOLERANCING PER:	
DO NOT SCALE DRAWING	
PROPRIETARY AND CONFIDENTIAL	
TITLE:	
ME 450 - Team 6	
Sleep Apnea	
SIZE	DWG. NO.
A	Two Way Valve Revisions Final Report
SCALE: 2:3	REV
	D
	SHEET 1 OF 1

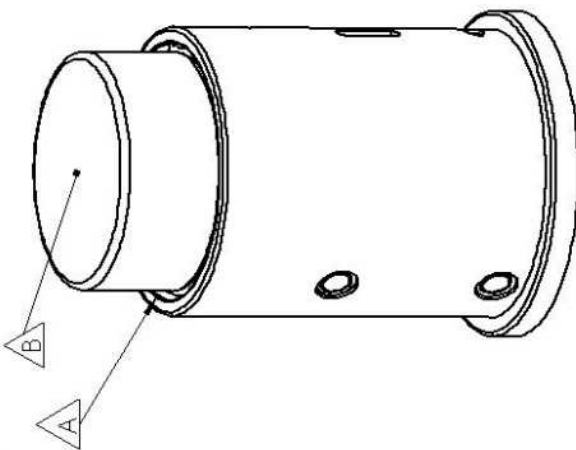
Figure C2: Changes made to Two Way Valve for exhaled air chamber. Dimensions of new parts can be seen in Figures C16 – C25
*Old dimensions can be seen in 2D CAD drawings in Appendix I

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED
	A	A water jug was decided as the best method of applying pressure to the moving plates. To allow for water jug upper portion of device case was removed.	12/08/2009	SMF
	B	Water jug was decided as the best method of applying pressure to the moving plates and was added into the design.	12/08/2009	SMF

WAS:



IS:



UNLESS OTHERWISE SPECIFIED:	
DIMENSIONS ARE IN INCHES	
TOLERANCES:	
FRACTIONAL:	
ANGULAR: \pm MACH \pm	BEND \pm
TWO PLACE DECIMAL	\pm
THREE PLACE DECIMAL	\pm
INTERPRET GEOMETRIC TOLERANCING PER:	
SIZE	DWG. NO.
A	Final Design Revisions Final
	REV
	B
SCALE: 1:4	SHEET 1 OF 1

TITLE:
ME 450 - Team 6
Sleep Apnea

PROPERTY AND CONFIDENTIAL

Figure C3: Changes made to Final Design.

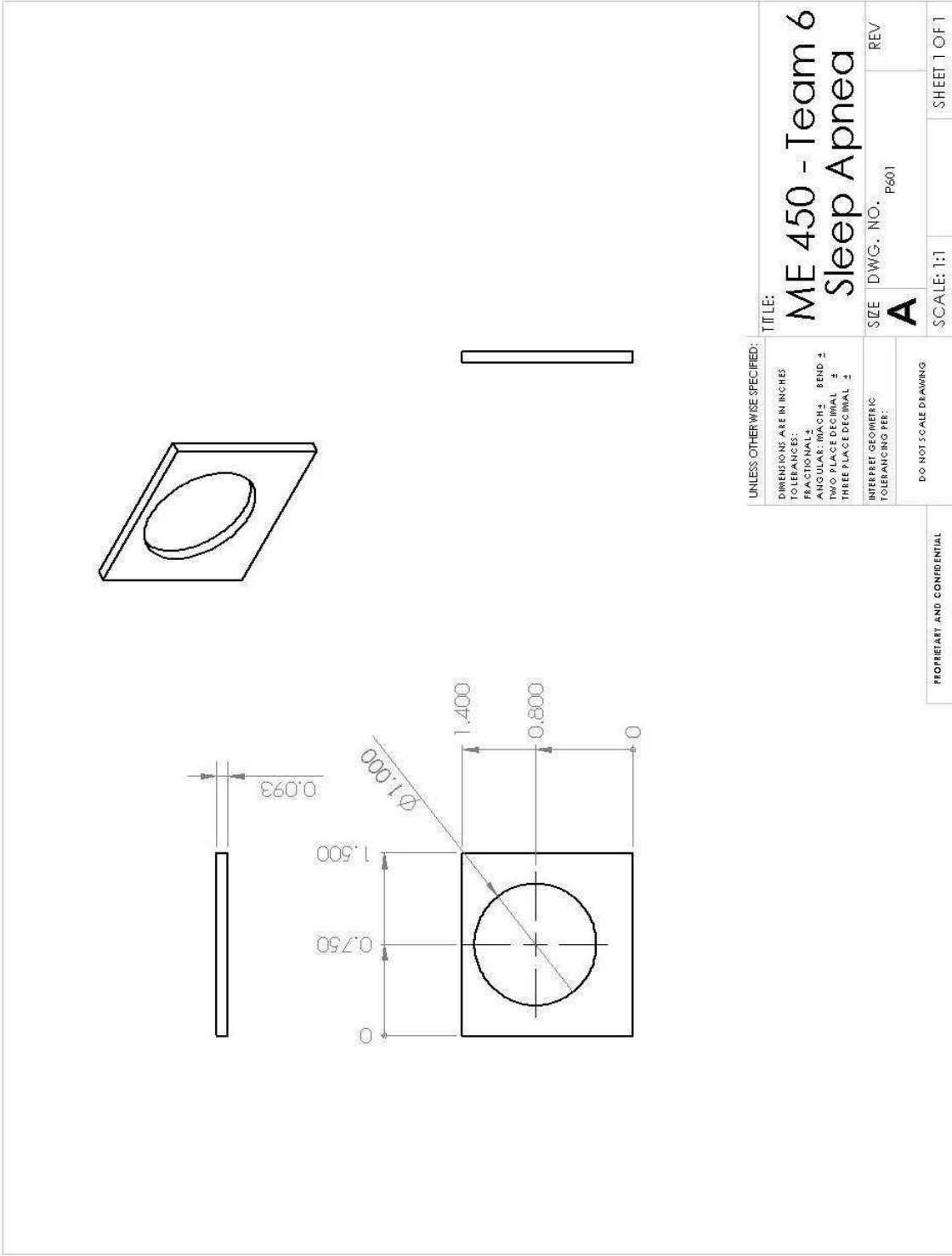


Figure C4: One Way Valve for fresh air chamber - Part P601.

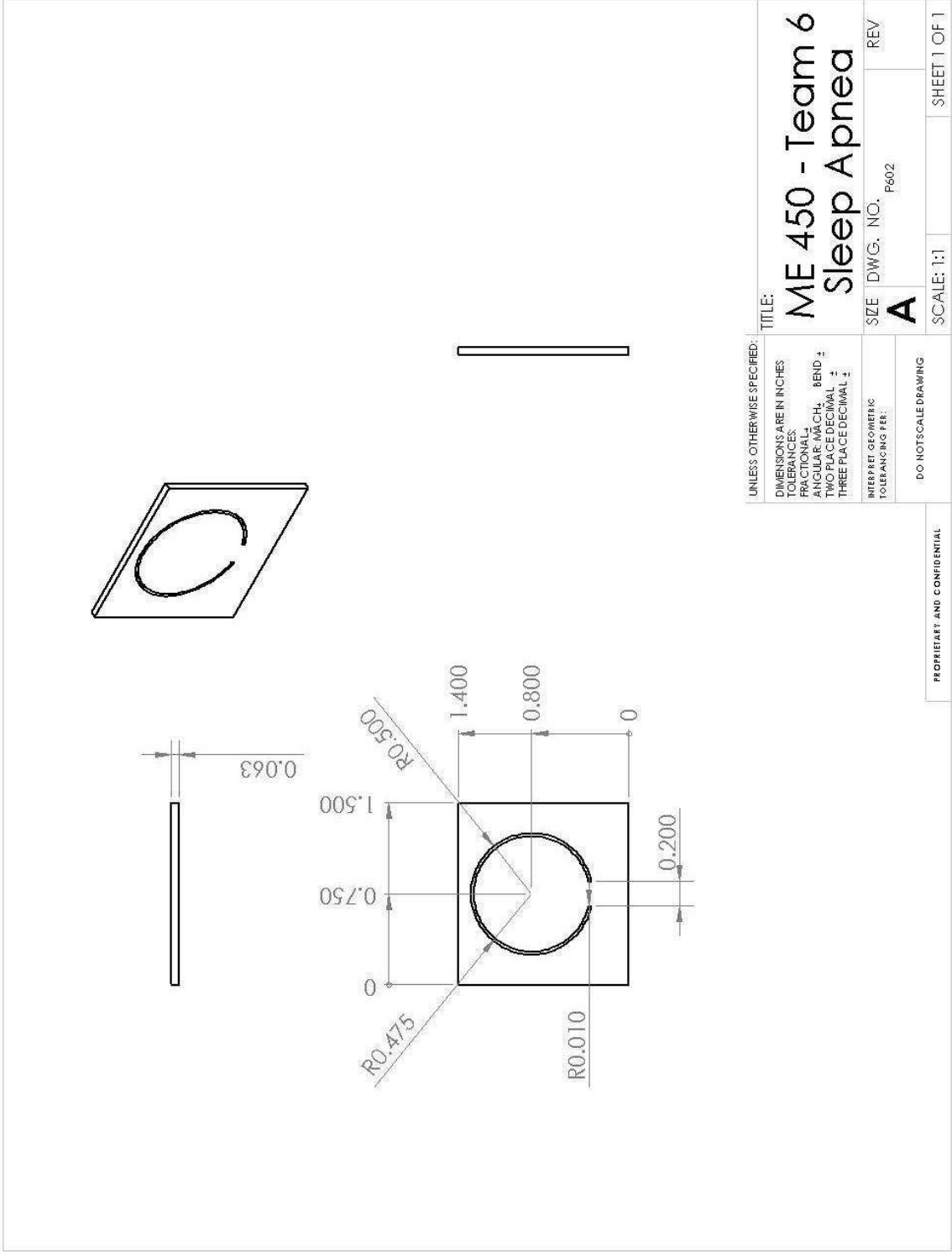


Figure C5: One Way Valve for fresh air chamber - Part P602.

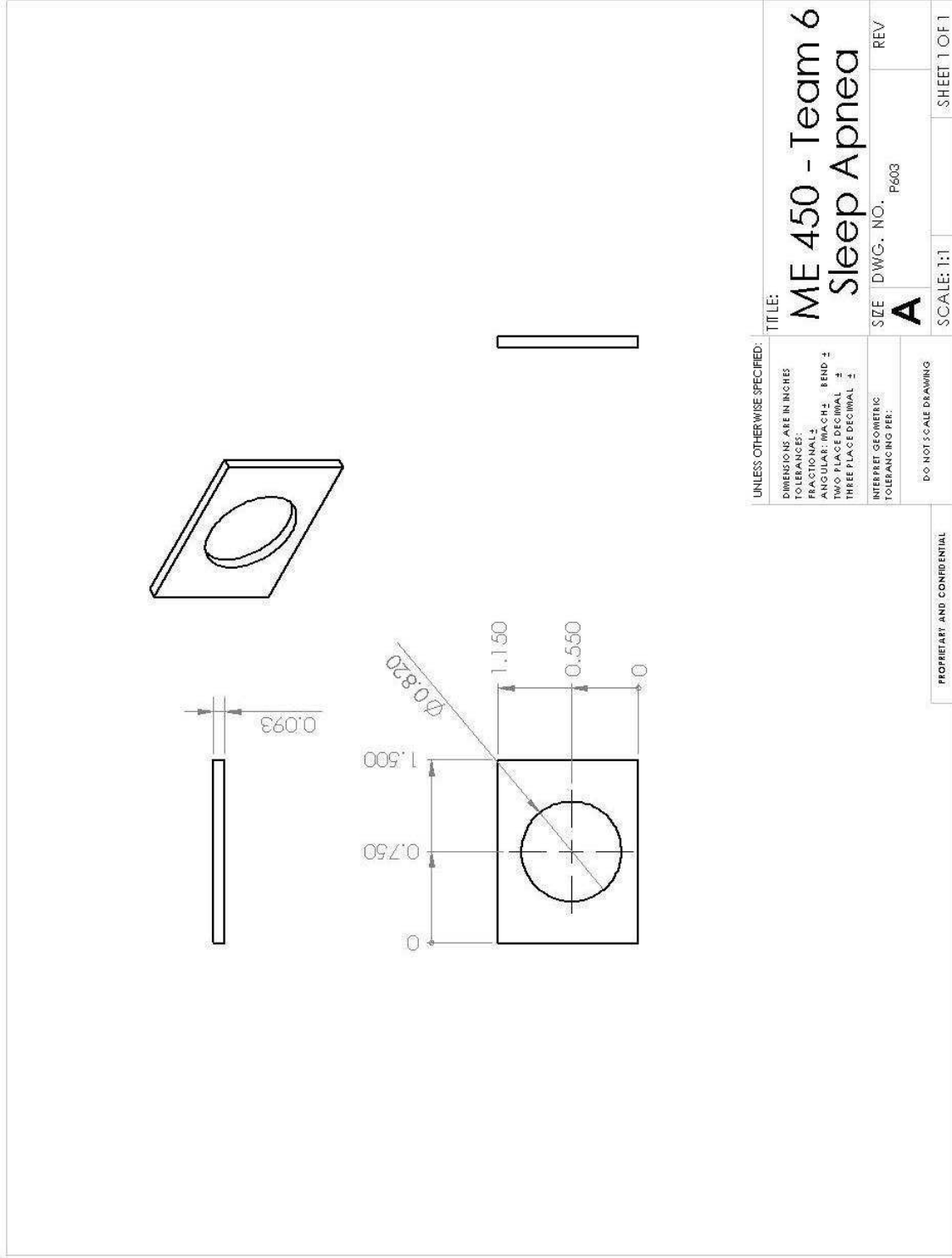
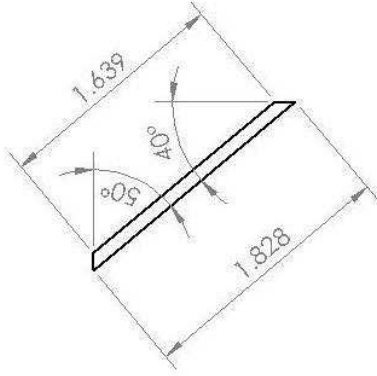
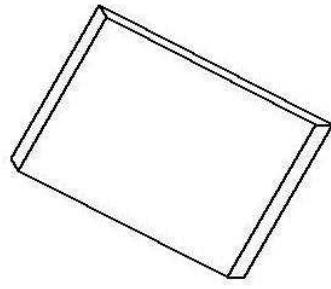
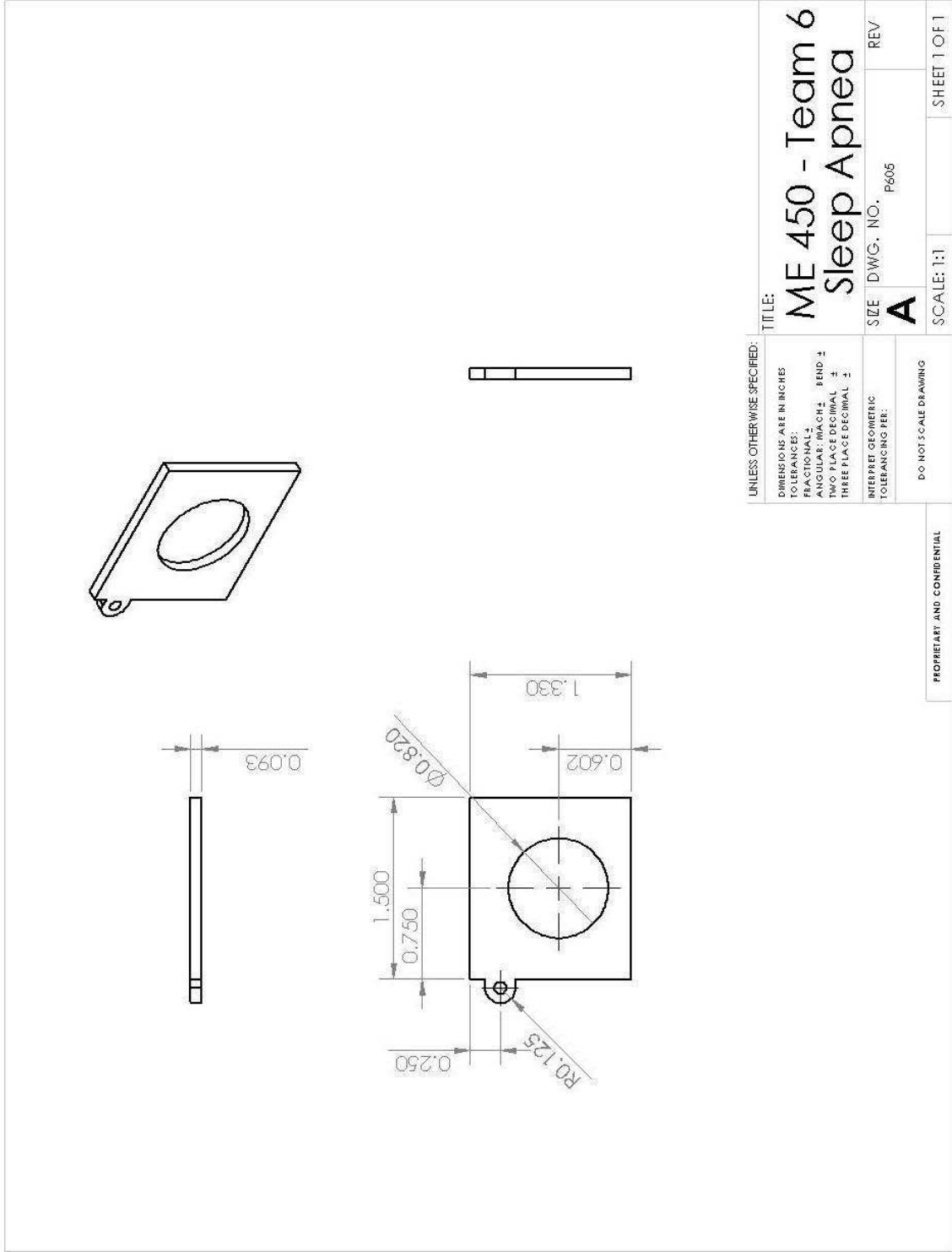


Figure C6: One Way Valve for fresh air chamber - Part P603.



UNLESS OTHERWISE SPECIFIED:		TITLE:	
DIMENSIONS ARE IN INCHES		ME 450 - Team 6	
TOLERANCES:		Sleep Apnea	
FRACTIONAL: ±	ANGULAR: MACH: ± BEND: ±	SIZE: DWG. NO. P604	REV
TWO PLACE DECIMAL ±	THREE PLACE DECIMAL ±	A	
INTERPRET GEOMETRIC TOLERANCING PER:		SCALE: 1:1	SHEET 1 OF 1
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL			

Figure C7: One Way Valve for fresh air chamber - Part P604.



UNLESS OTHERWISE SPECIFIED:		TITLE:	
DIMENSIONS ARE IN INCHES		ME 450 - Team 6	
TOLERANCES:		Sleep Apnea	
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TWO PLACE DECIMAL ±	THREE PLACE DECIMAL ±	A	
INTERPRET GEOMETRIC TOLERANCING PER:		SCALE: 1:1	SHEET 1 OF 1
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL			

Figure C8: One Way Valve for fresh air chamber - Part P605.

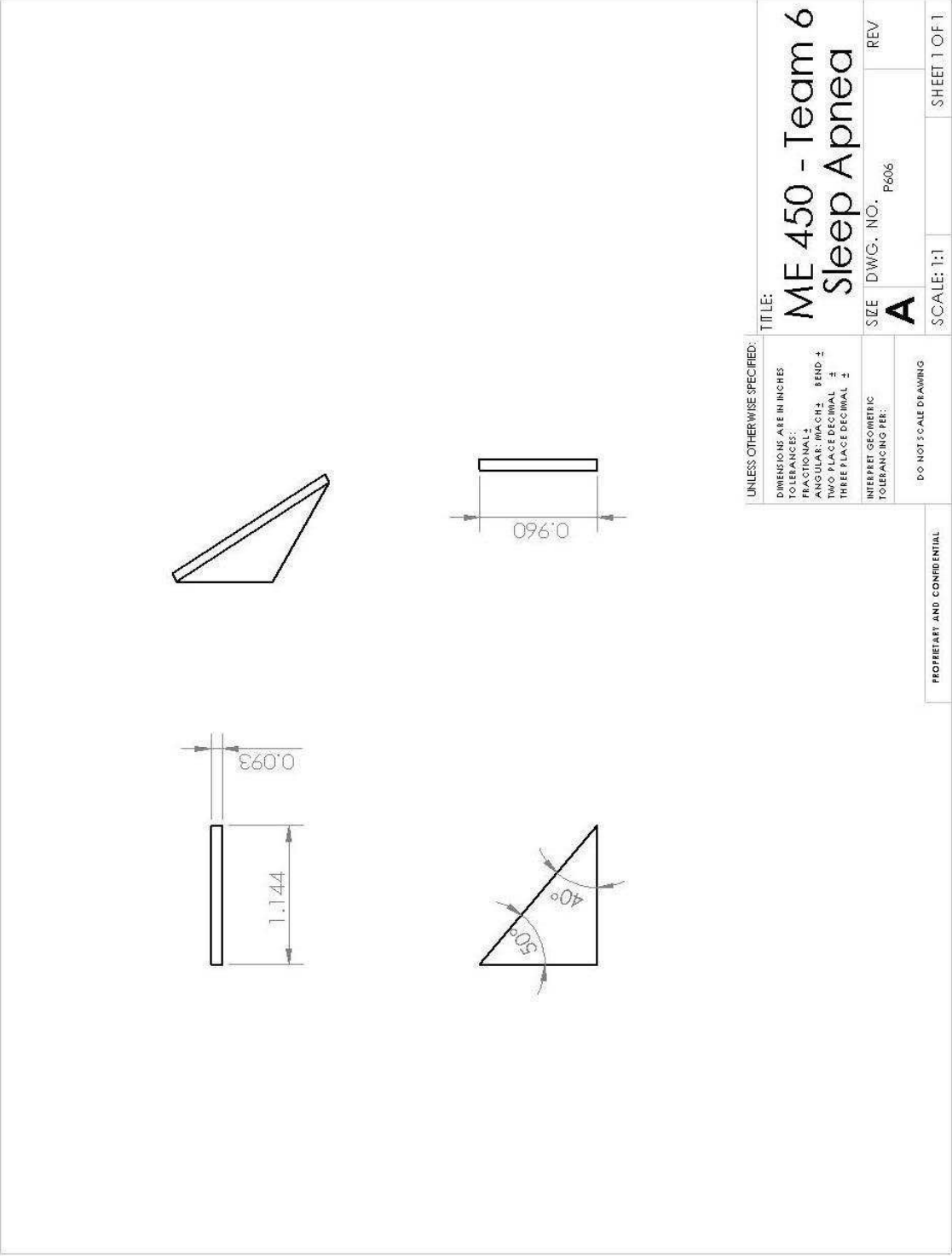


Figure C9: One Way Valve for fresh air chamber - Part P606.

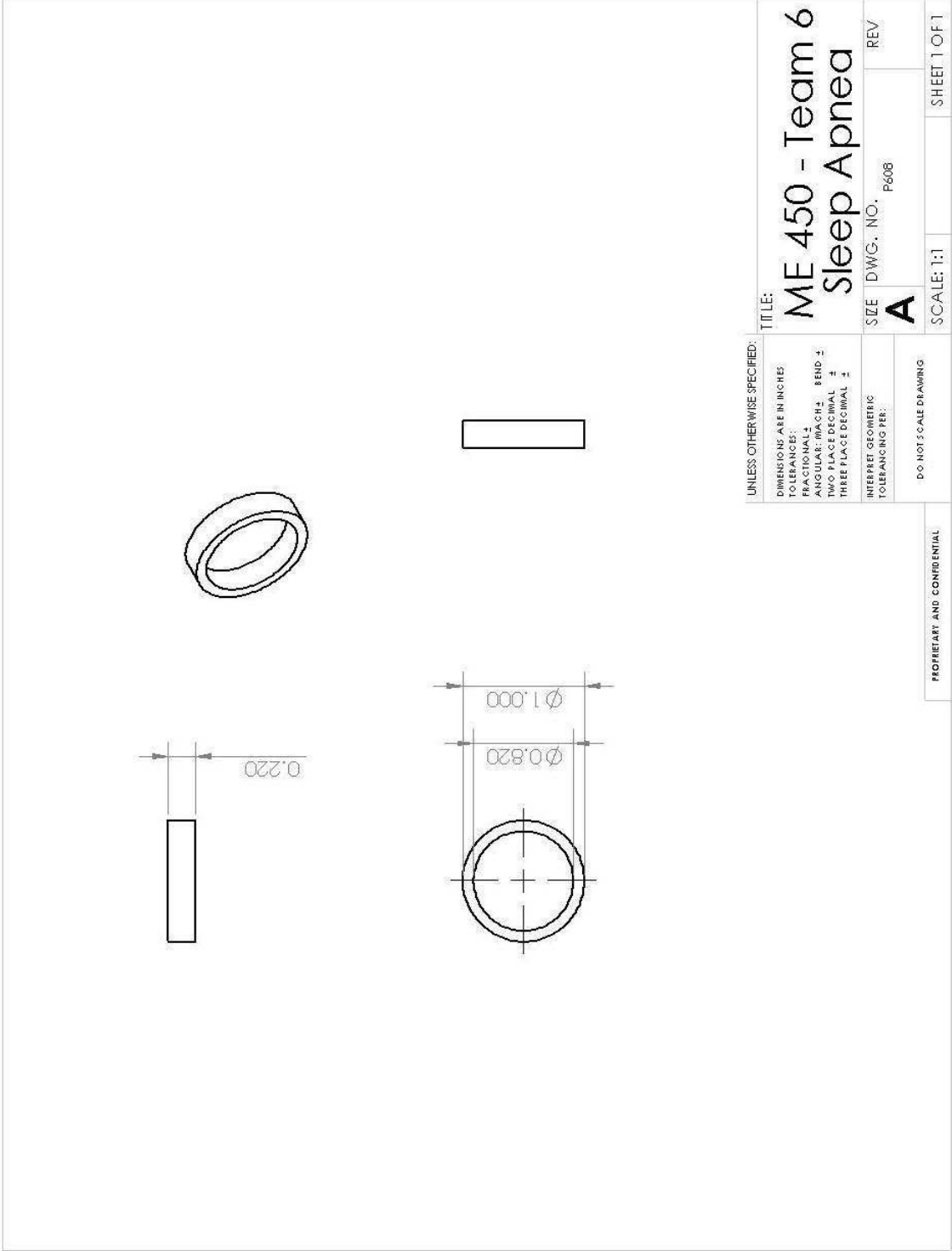


Figure C10: One Way Valve for fresh air chamber - Part P608.

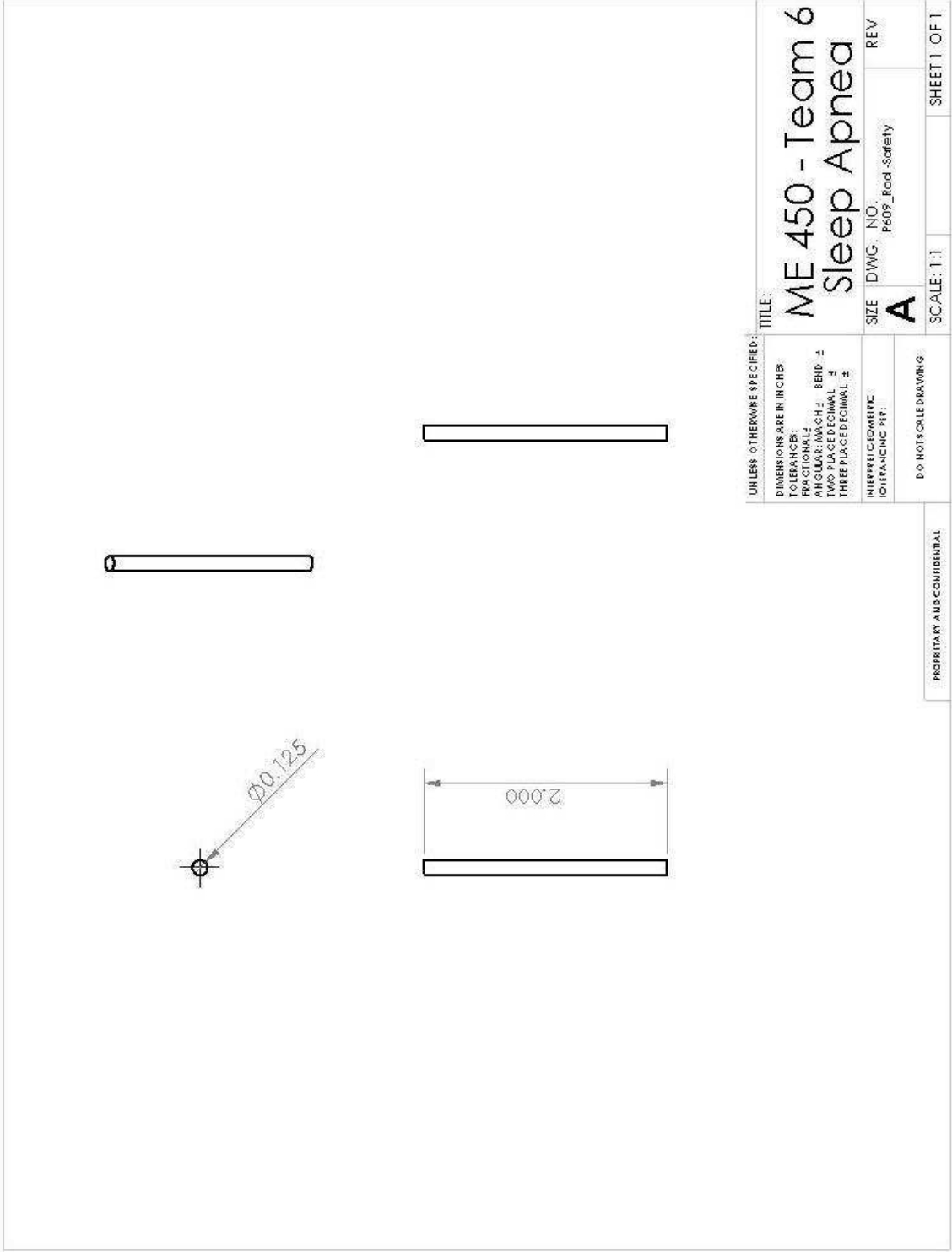


Figure C11: One Way Valve for fresh air chamber - Part P609.

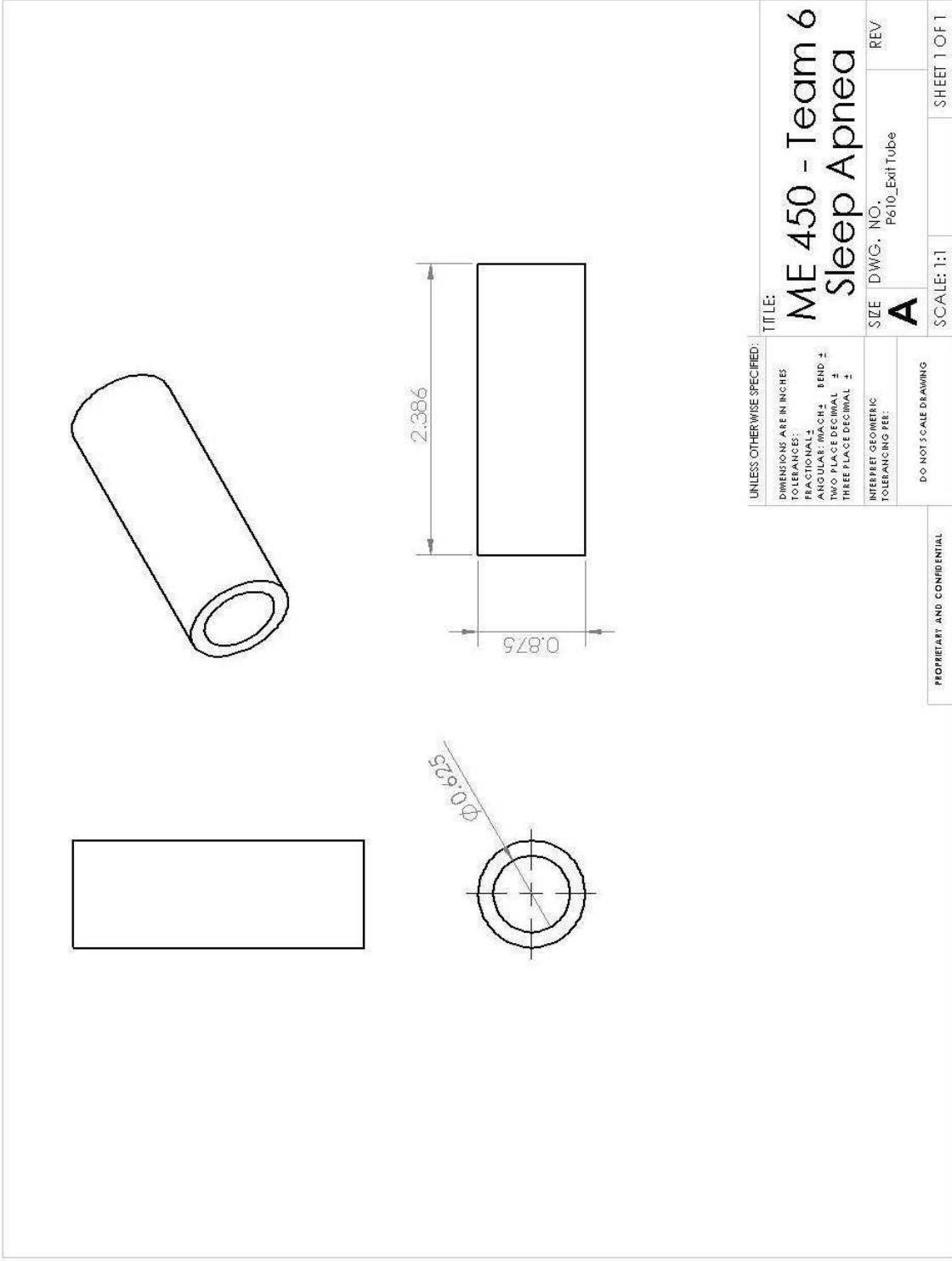


Figure C12: One Way Valve for fresh air chamber - Part P610.

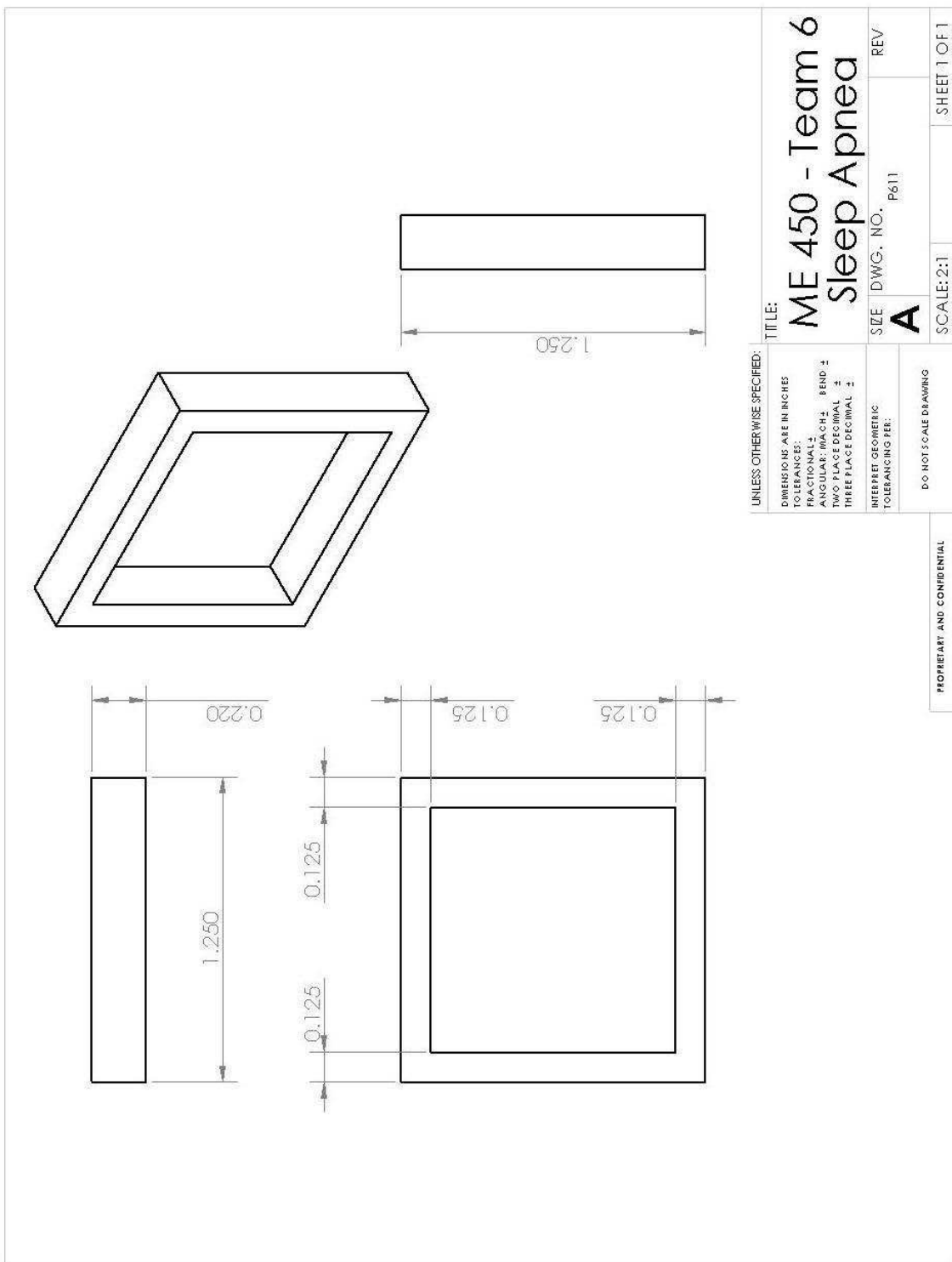


Figure C13: One Way Valve for fresh air chamber - Part P611.

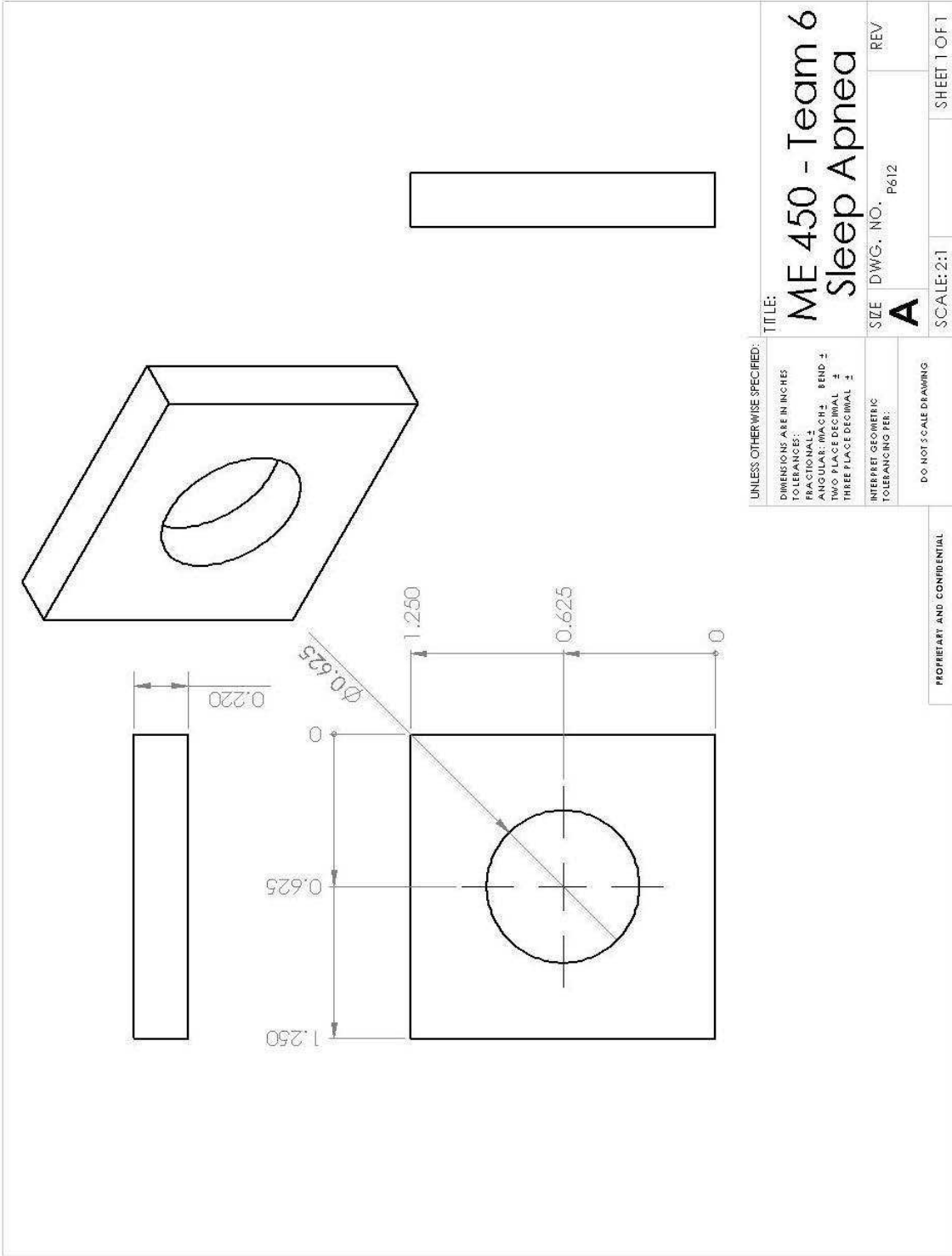


Figure C14: One Way Valve for fresh air chamber - Part P612.

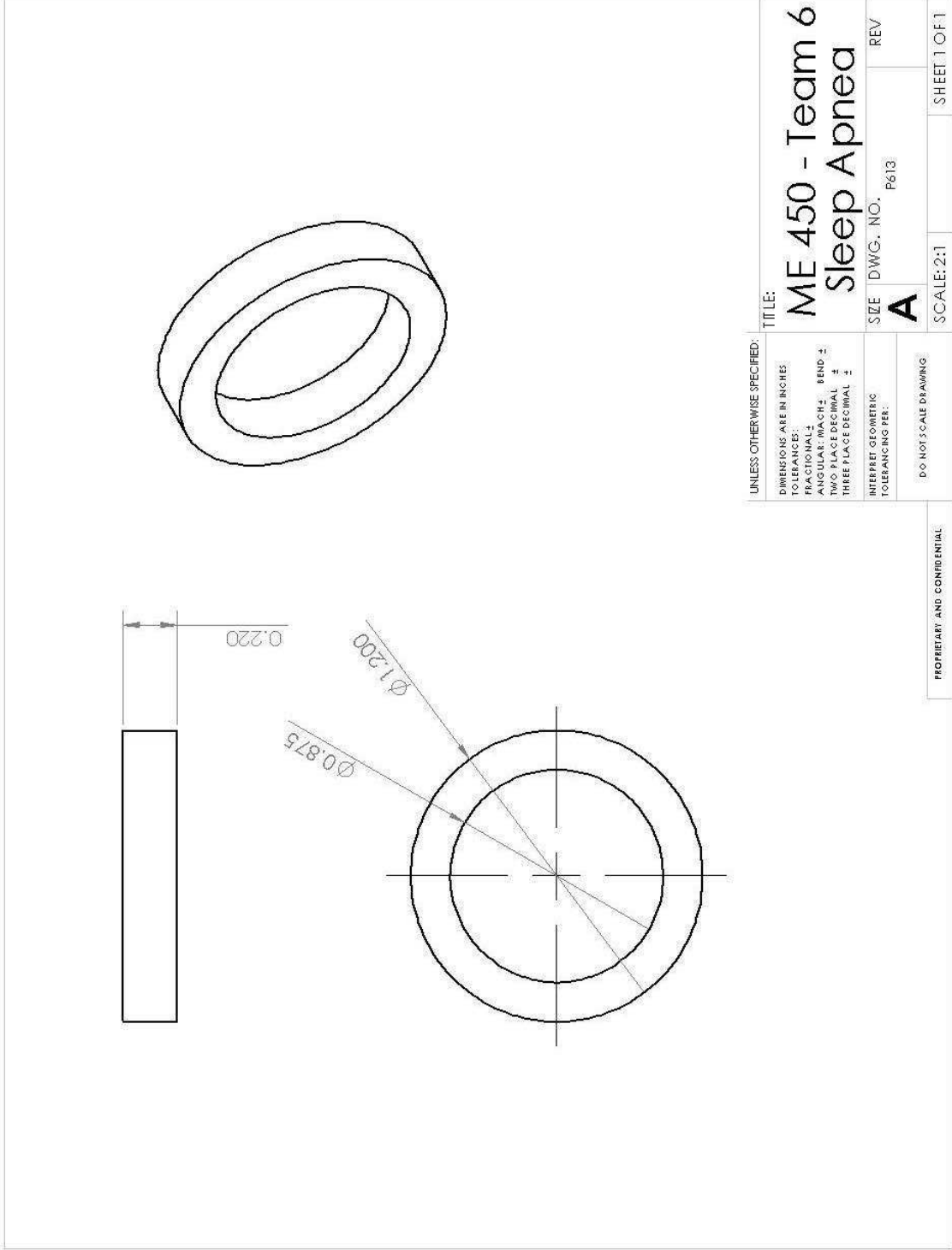


Figure C15: One Way Valve for fresh air chamber - Part P613.

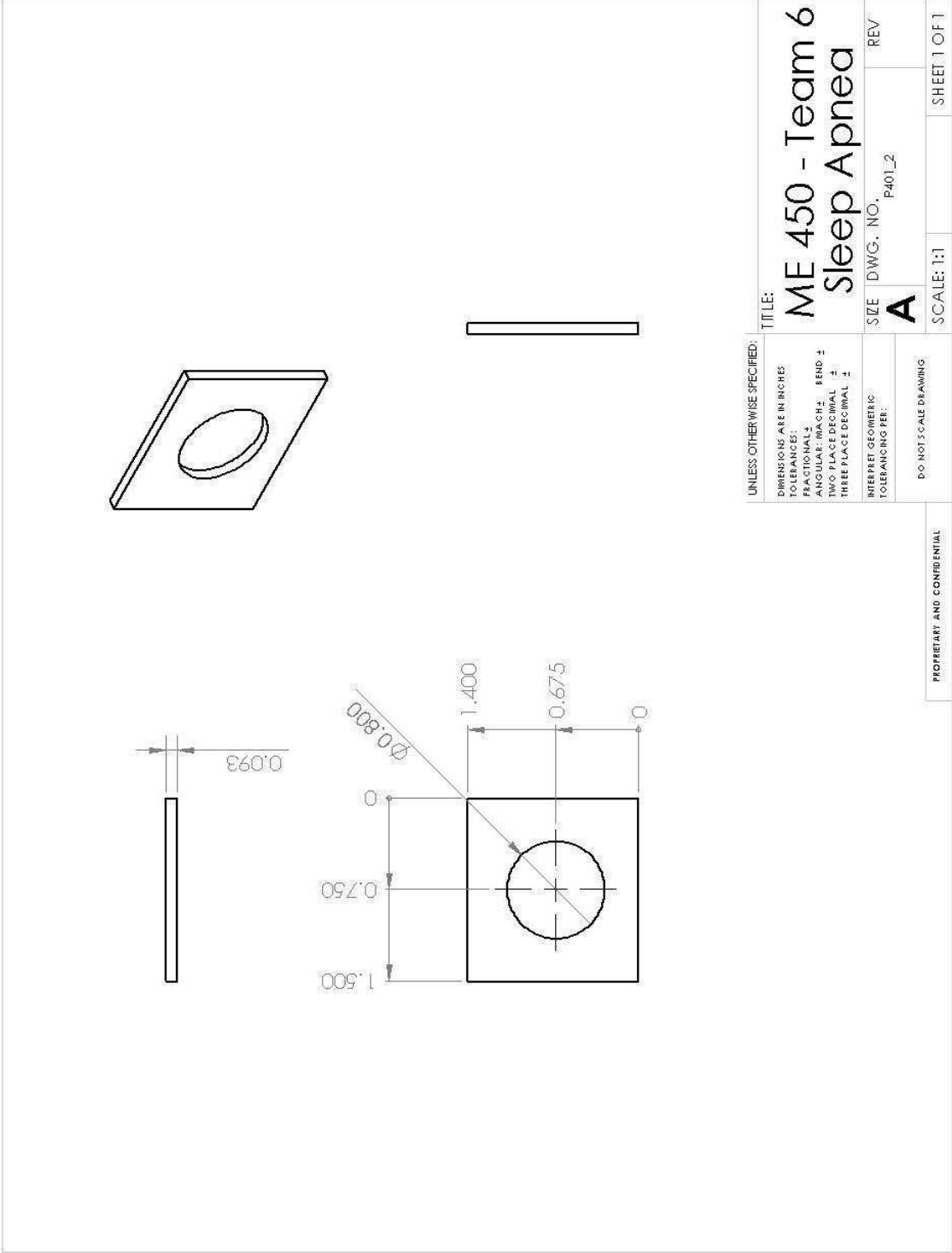


Figure C16: Two Way Valve for exhaled air chamber - Part P401_2.

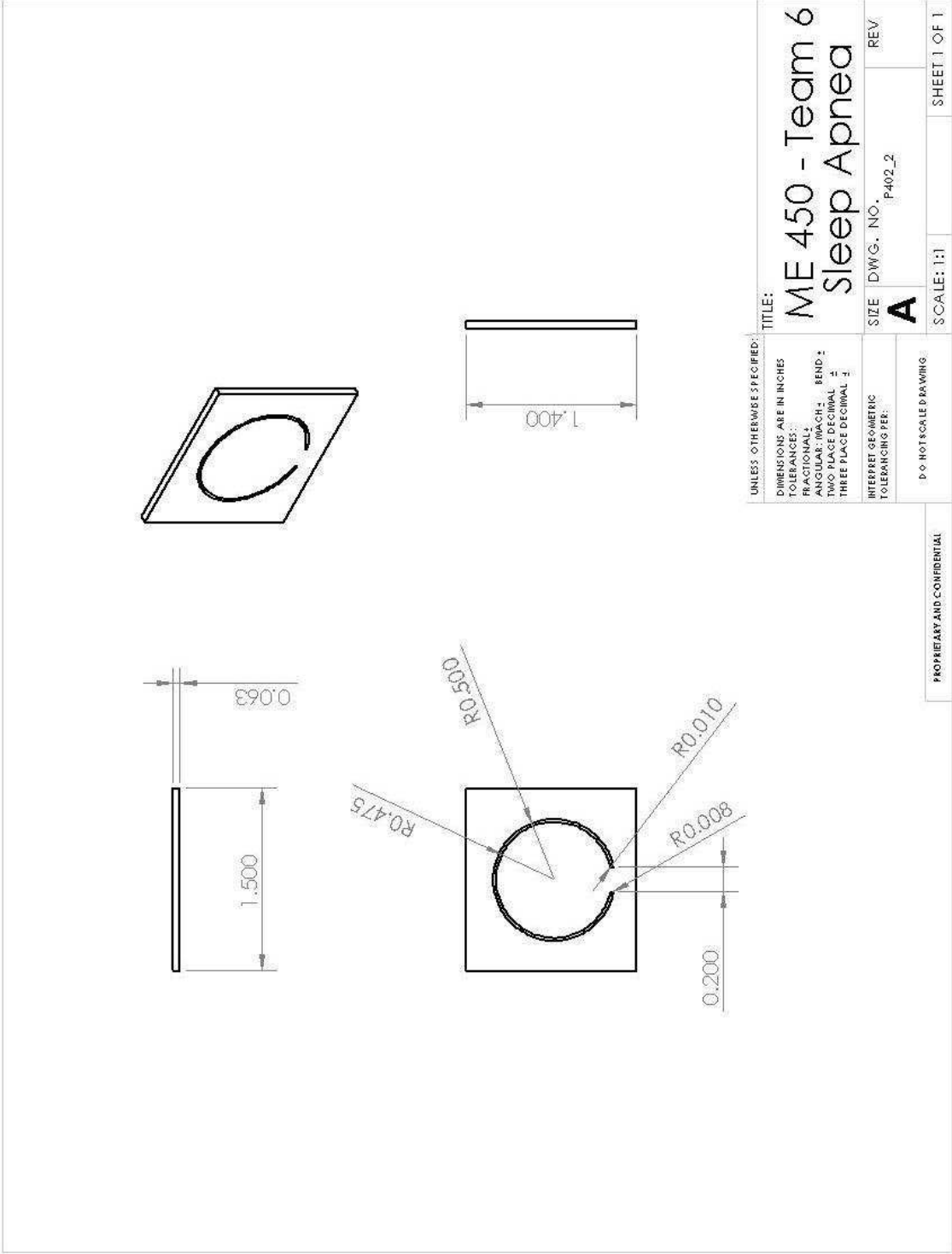
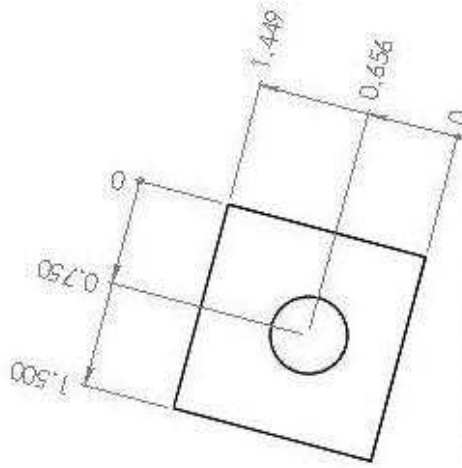
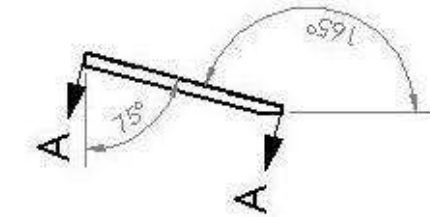


Figure C17: Two Way Valve for exhaled air chamber - Part P402_2.



SECTION A-A

UNLESS OTHERWISE SPECIFIED:		TITLE:	
DIMENSIONS ARE IN INCHES	FRAC TIONS	ME 450 - Team 6	
DECIMALS	THIRDS	Sleep Apnea	
ANGULAR MARKS	8 POINTS	SIZE	DWG. NO.
TWO PLACE DECIMAL		A	P403_2
FIRST PLACE DECIMAL		REV	
INTERFERING PARTS			
DO NOT SCALE DRAWING		SCALE:	1:1
PROPRIETARY AND CONFIDENTIAL			SHEET 1 OF 1

Figure C18: Two Way Valve for exhaled air chamber - Part P403_2.

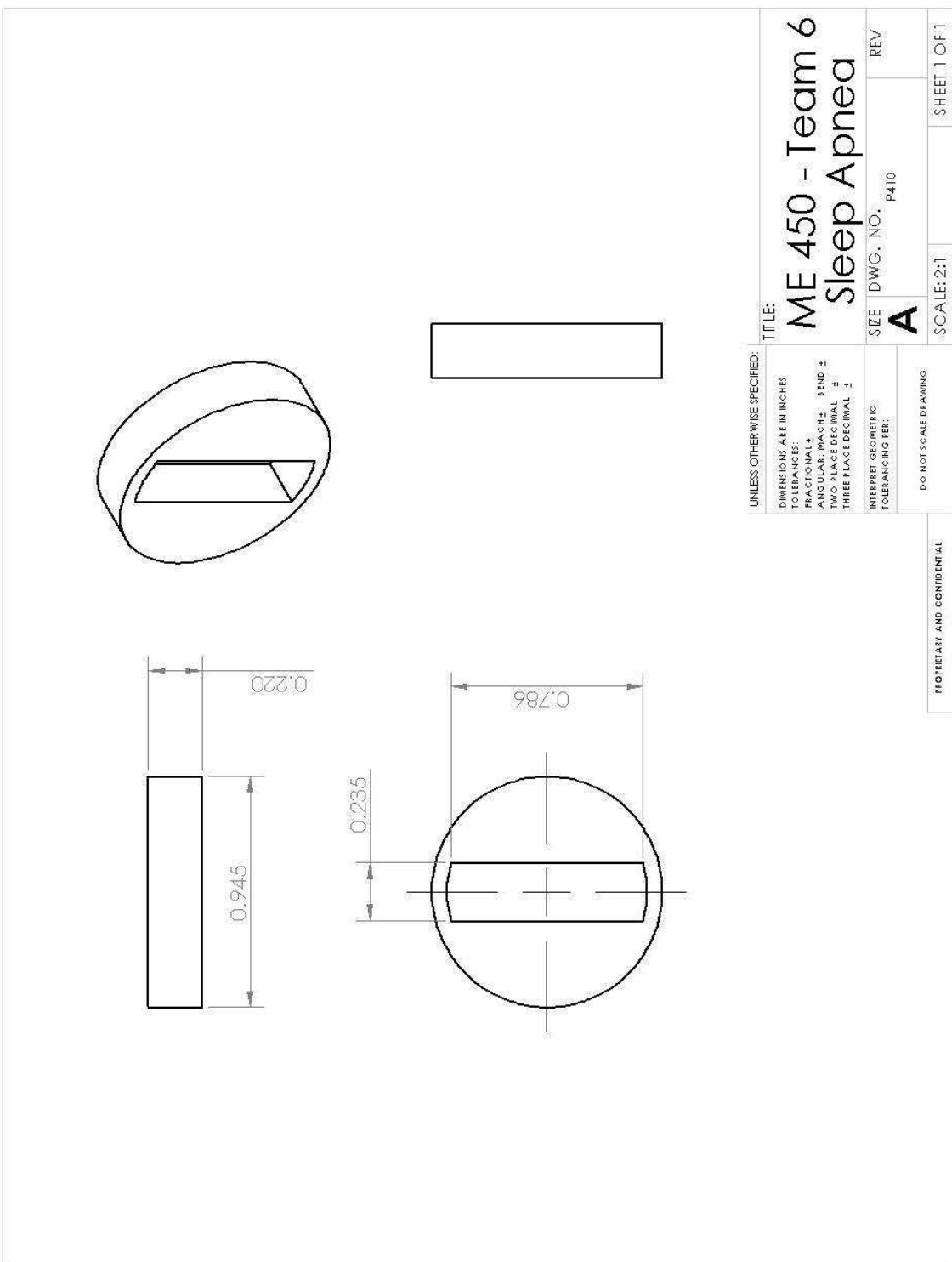


Figure C19: Two Way Valve for exhaled air chamber - Part P410.

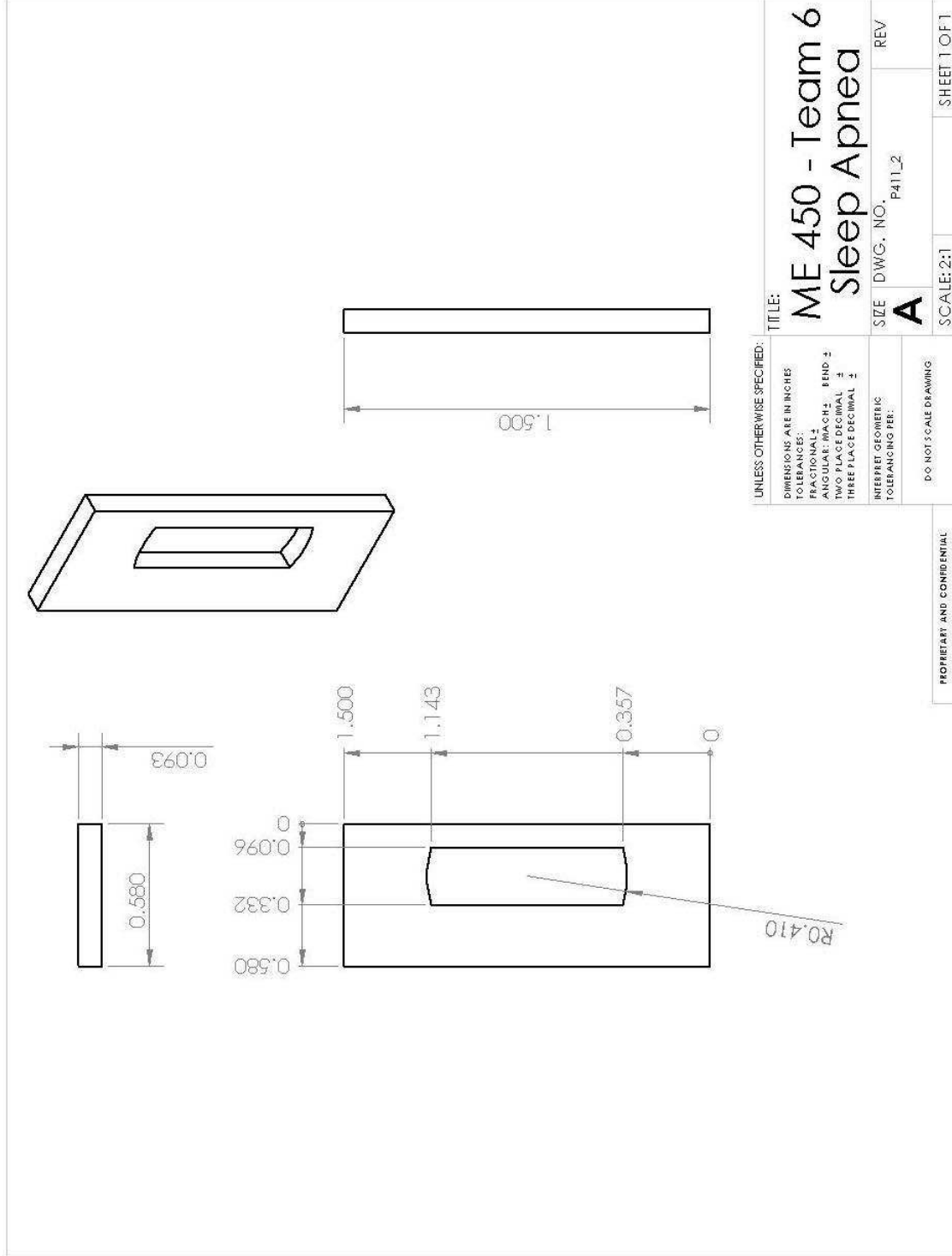


Figure C20: Two Way Valve for exhaled air chamber - Part P411_2.

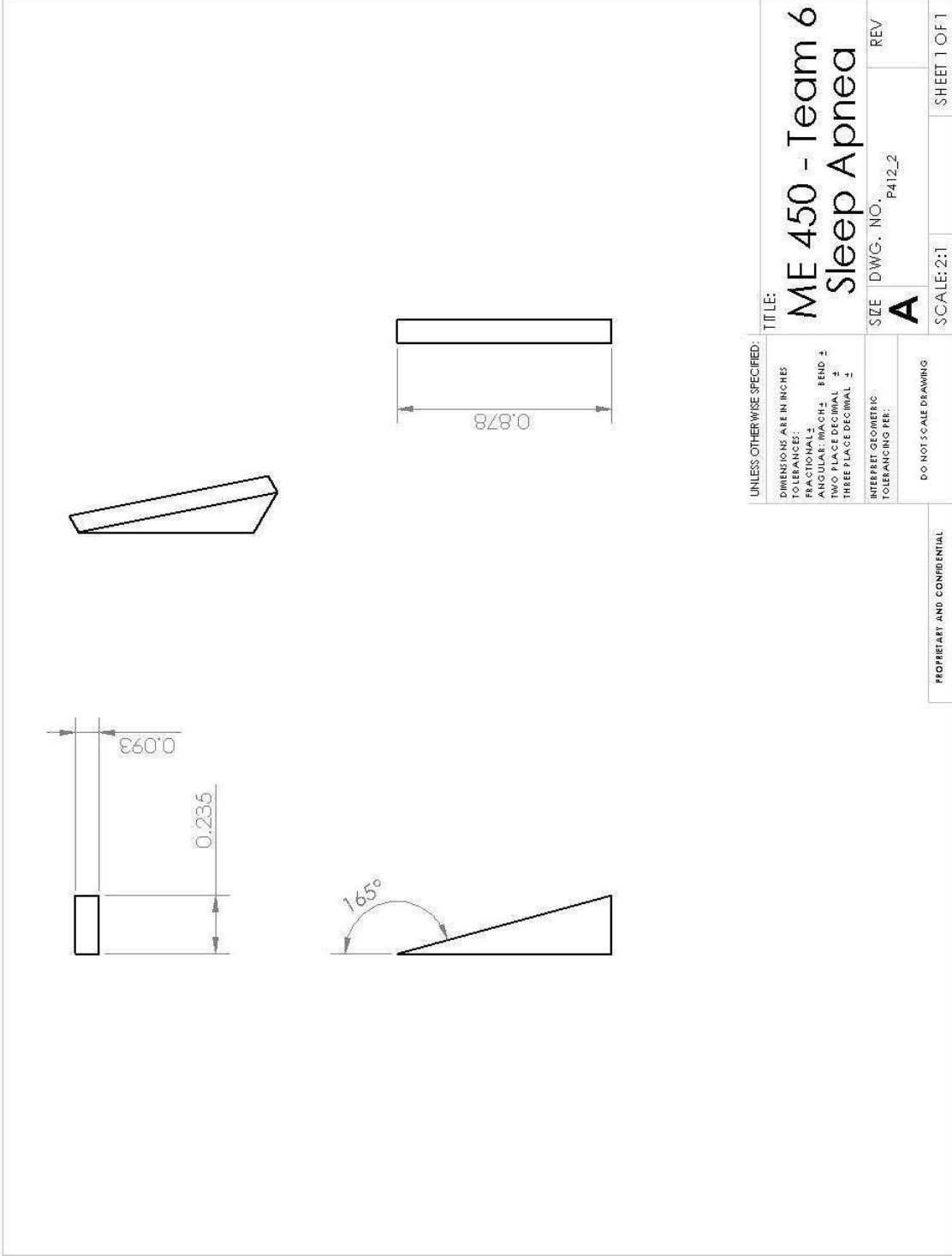


Figure C21: Two Way Valve for exhaled air chamber - Part P412_2.

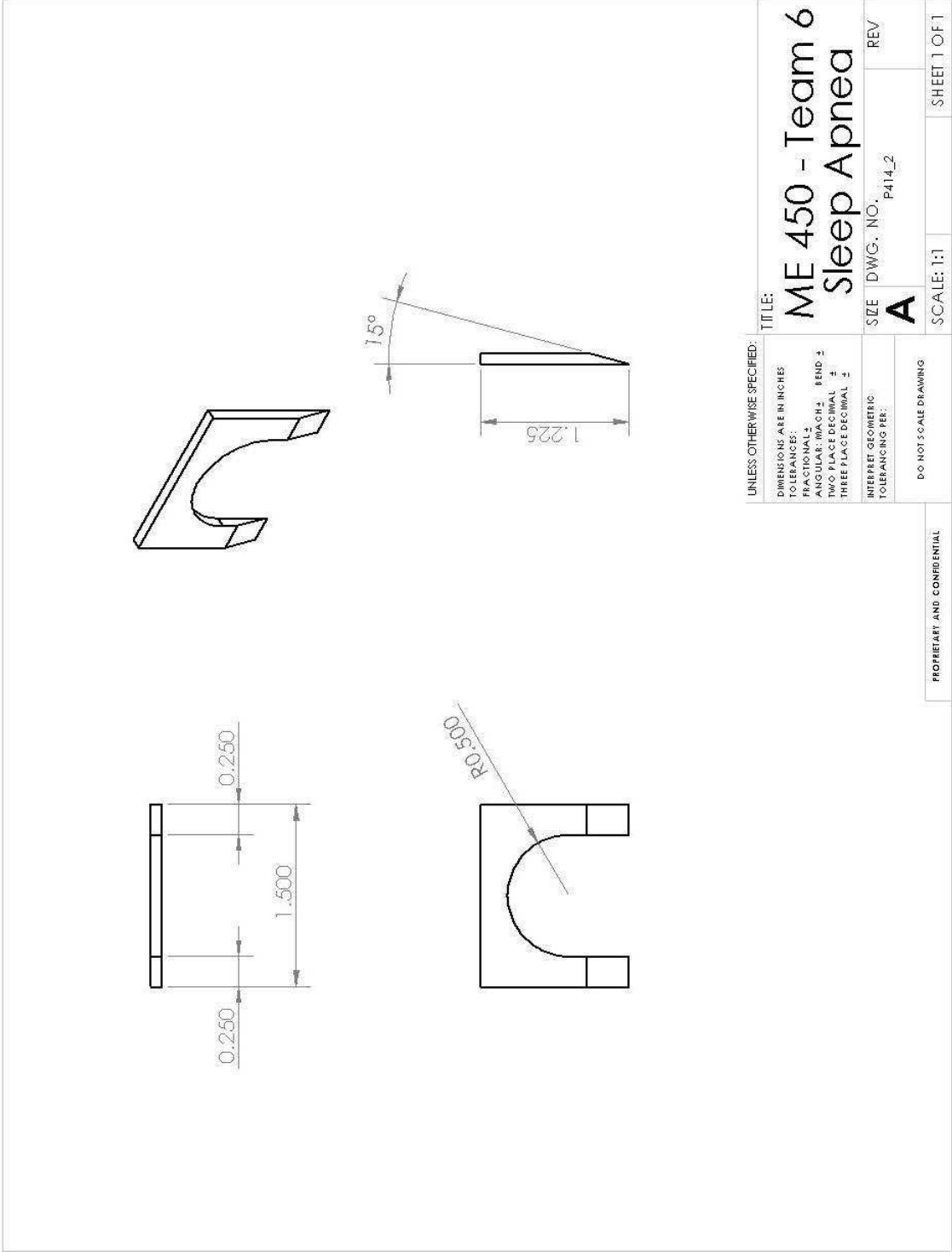


Figure C22: Two Way Valve for exhaled air chamber - Part P414_2.

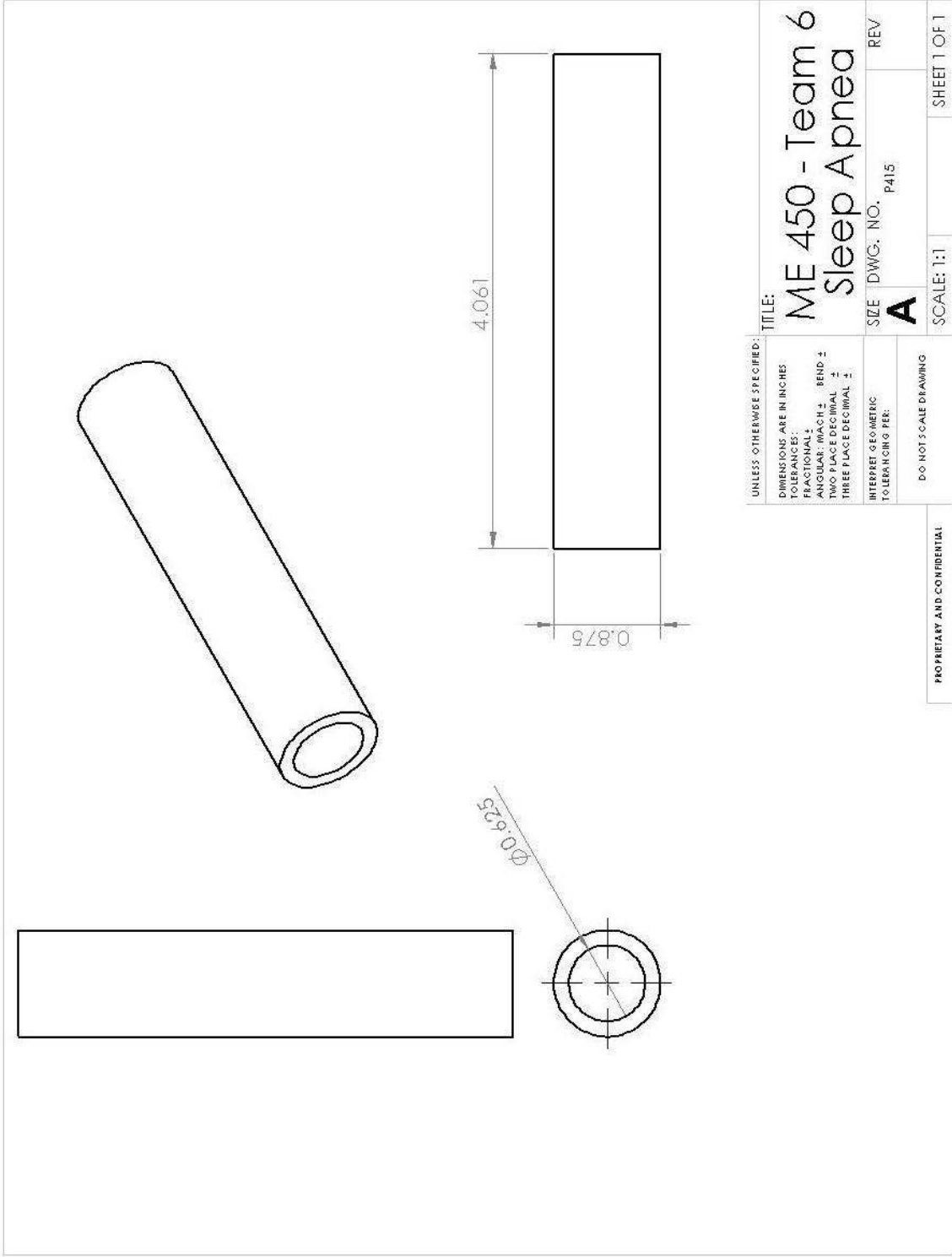


Figure C23: Two Way Valve for exhaled air chamber - Part P415.

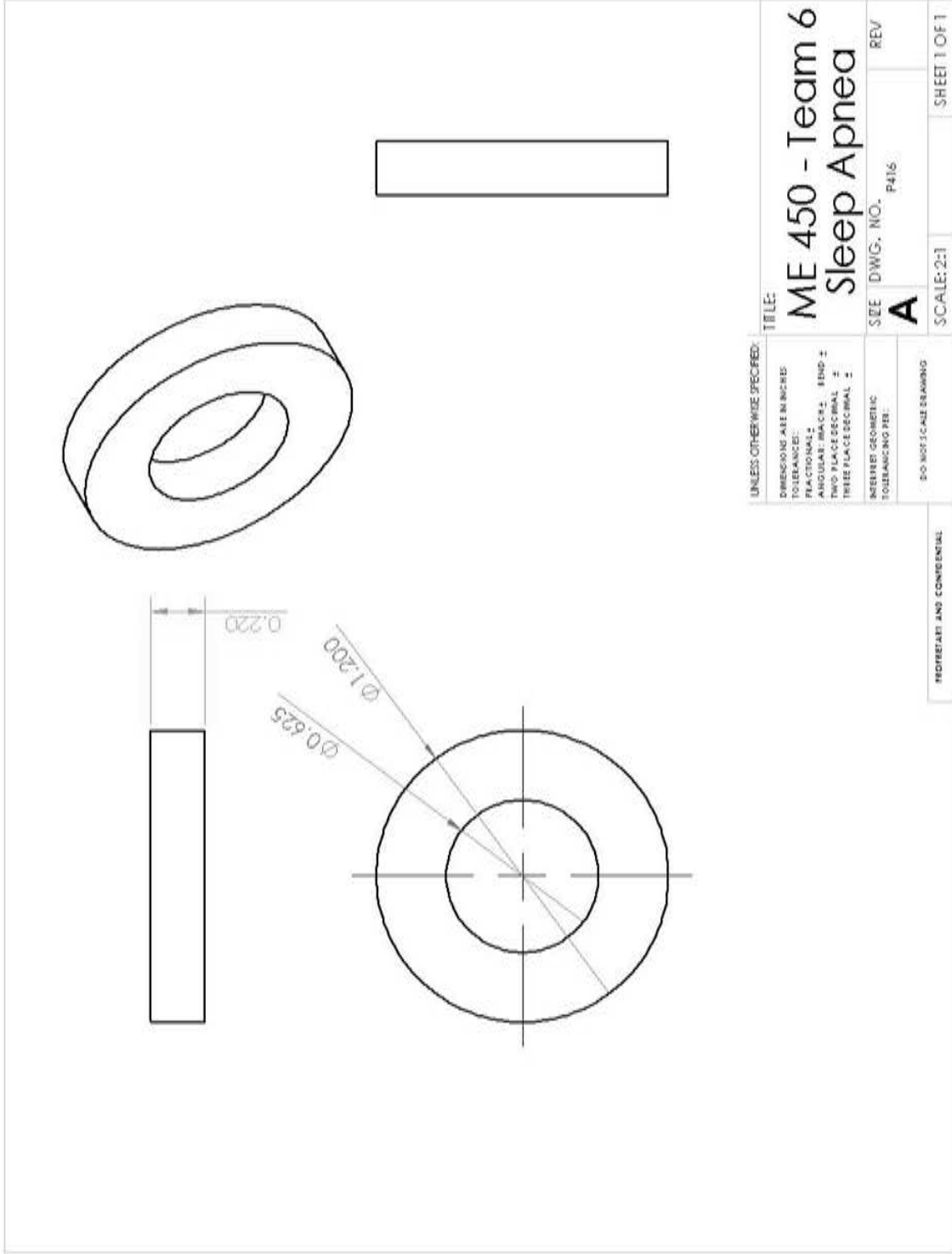


Figure C24: Two Way Valve for exhaled air chamber - Part P416.

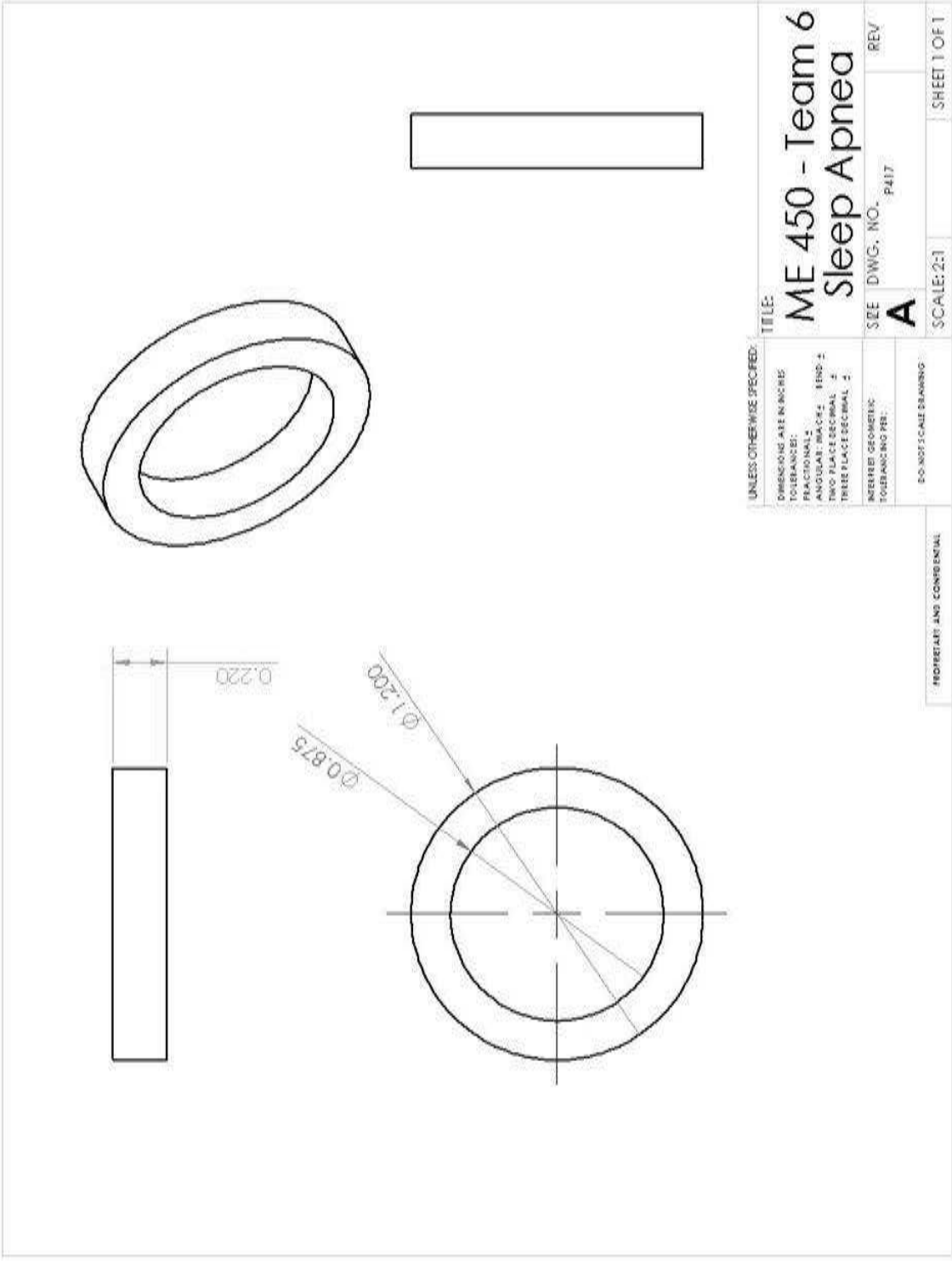


Figure C25: Two Way Valve for exhaled air chamber - Part P417.

APPENDIX D: Existing Patents

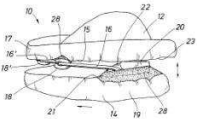
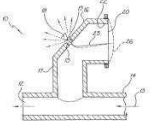
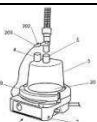
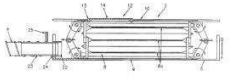


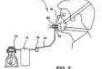
Patent Number	Name	Description	
5947724	Elastic mandibular advancement appliance with slide-in bite planes	Device worn while sleeping to advance the mandible and keep the jaw open using bite planes and elastic bands	
7059325	Vent Assembly	Vent valve that restricts the flow of gas in response to increased pressure in the gas supply to regulate the volumetric flow of gas over a range of pressures	
7106955	Humidity Controller	Controls the airflow and heating element of humidifiers to control humidity levels	
7284554	Continuous Positive Airway Pressure device	CPAP machine that utilizes an air reservoir which contains a movable plate used to apply a uniform pressure on the reservoir	
7296573	Positive Airway Pressure Device	Adjusts airway pressure upon inspiration and expiration	
7523754	Mask Cushion	Cushion used to increase the effectiveness of the seal against the skin of the face	
7562659	Respiratory aid apparatus and method	Positive airway pressure device including tube and mask	

Table D1: List and description of other important patents

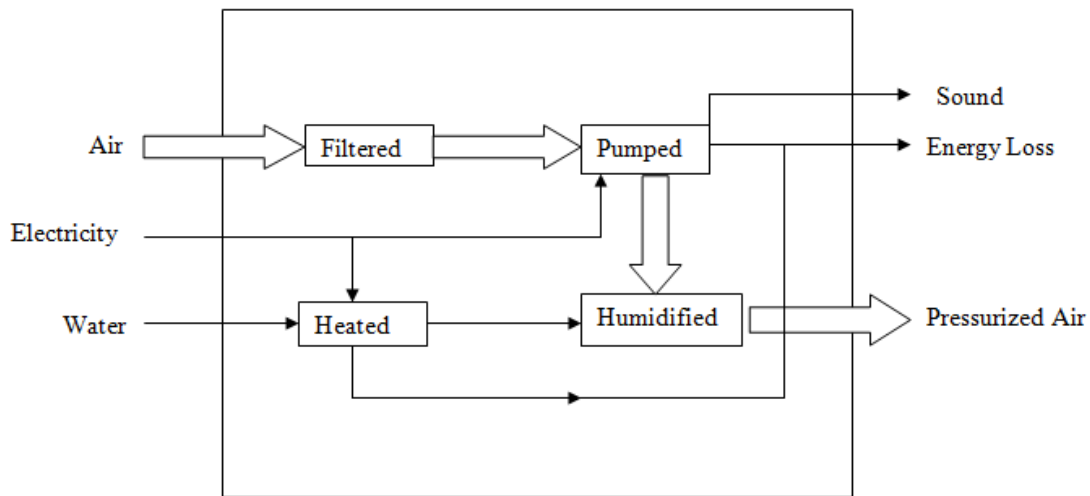


Figure D3: Standard CPAP Machine Functional Decomposition

Selection Criteria	Weights	(Datum)						
		Oral/Dental Device	The Waterfall	The Rebreather	The Donut Pillow	The Spinner	The Pressure Mattress	
Safe to use	10	0	3	2	1	1	2	
Works	10	0	-2	2	-1	-1	1	
Low cost	9	0	-1	0	3	-1	2	
Quiet	8	0	-3	-2	0	-2	-1	
Small	8	0	-3	-1	-1	-2	-3	
Continuous operation during power outage	7	0	0	0	-1	0	0	
Stable	7	0	2	3	0	3	-2	
Easy to use	6	0	-3	2	3	2	0	
Manual emergency shutoff function	6	0	0	0	0	0	0	
Lightweight	5	0	-3	-2	-1	-2	-2	
		+	0	44	73	55	43	48
		0	76	13	22	21	13	19
		-	0	-110	-34	-30	-61	-56
		Net Score	0	-66	39	25	-18	-8
		Rank		5	1	2	4	3

Scale: Definition

- 3 Most unlikely
- 2 Unlikely
- 1 Somewhat unlikely
- 0 Same
- 1 Somewhat likely
- 2 Likely
- 3 Most likely

Table D4: Pugh Chart for selecting Alpha Design

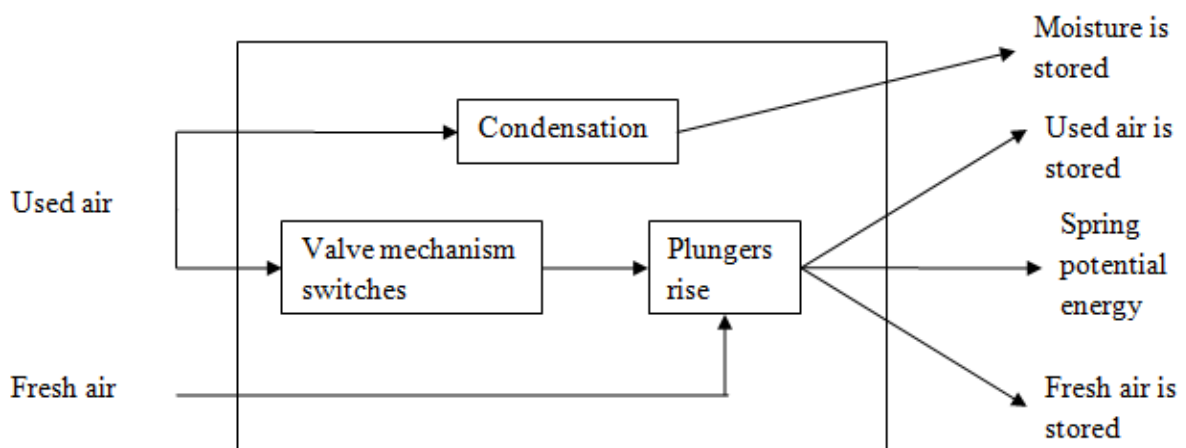


Figure D5: Alpha Design functional decomposition during exhalation

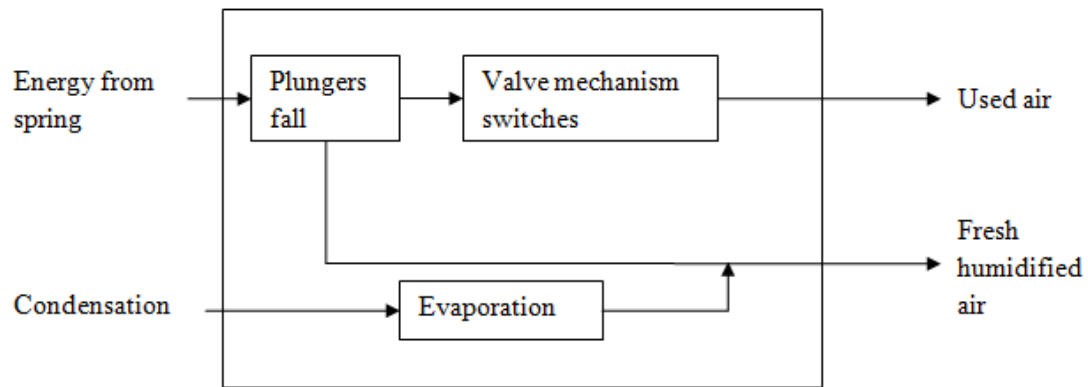


Figure D6: Alpha Design functional decomposition during inhalation

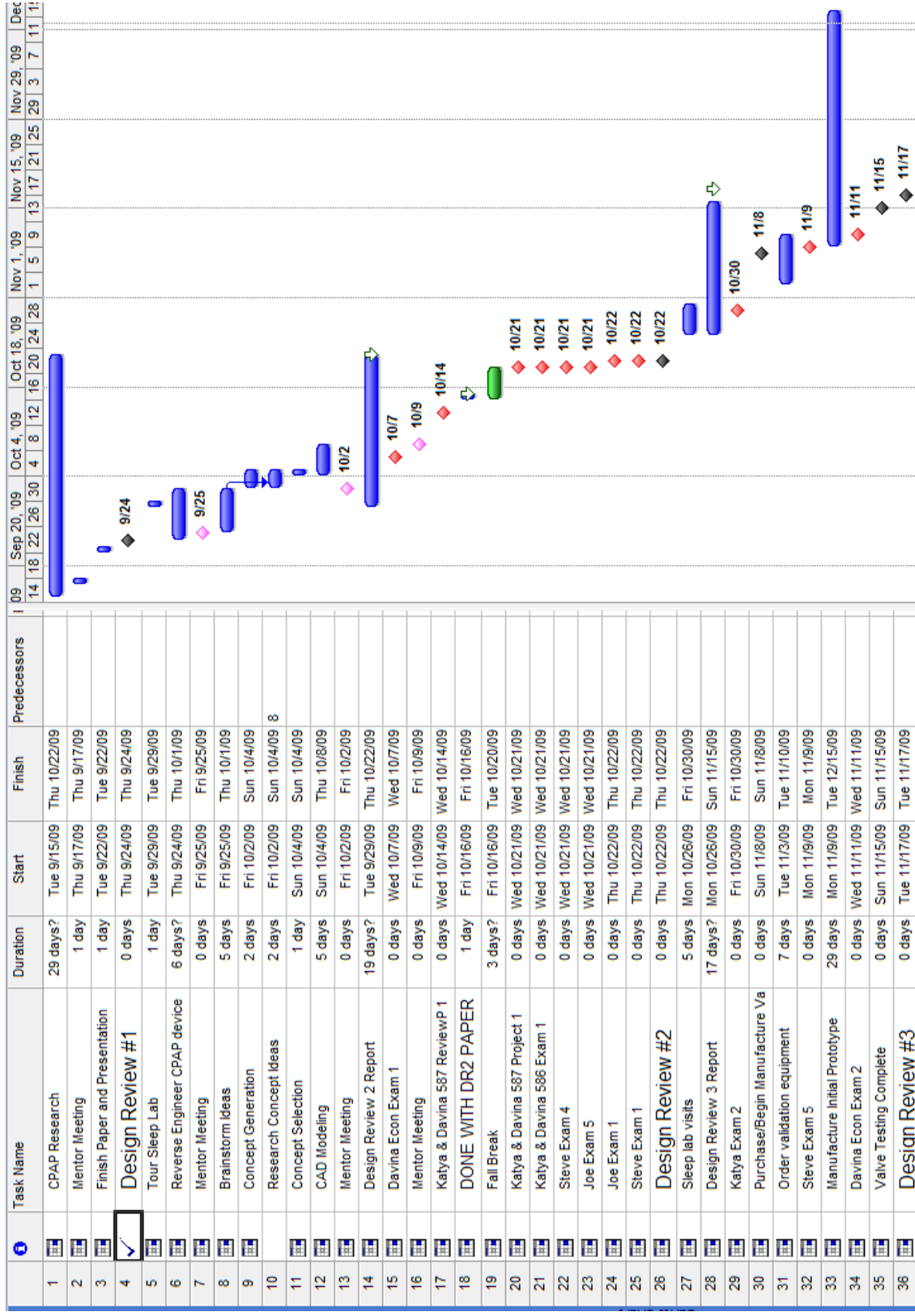


Figure D7A: Gantt Chart

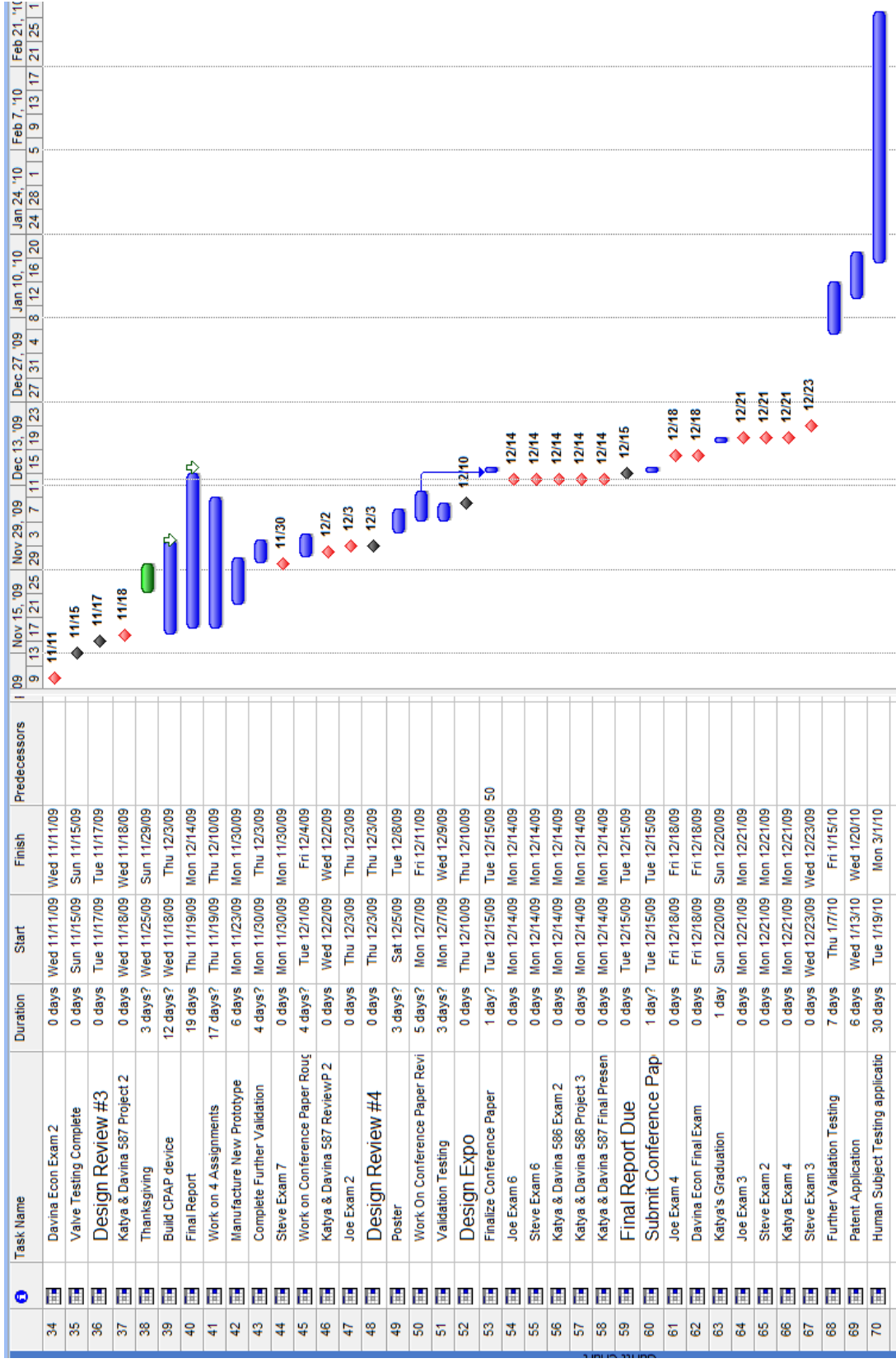


Figure D7B: Gantt Chart

1) Do you have Obstructive Sleep Apnea?

Answer Options	Response Percent	Response Count
Yes	98.5%	335
No	1.8%	6
answered question		340
skipped question		0

2) Do you have a Continuous Positive Airway Pressure machine?

Answer Options	Response Percent	Response Count
Yes	93.5%	318
No	7.1%	24
answered question		340
skipped question		0

3) If so, how often do you use it?

Answer Options	Response Percent	Response Count
7 Times a week	74.0%	248
5-6 Times a week	8.1%	27
3-4 Times a week	5.7%	19
1-2 Times a week	3.0%	10
Never	5.1%	17
I do not have one	5.7%	19
answered question		335
skipped question		5

4) If you have Obstructive Sleep Apnea and do not have a CPAP machine, why do you not have one?

Example Responses

Too expensive and noisy
 It's expensive and annoying machine.
 Too cumbersome for sleeping
 Cant afford one
 I use a BiPAP instead of CPAP. Can't tolerate CPAP.
 I don't have the money for one, nor do not know where to get one
 Actually mine is APAP

5) **If you do not use it or do not use it all the time, what are your reasons for not using the machine?**

Example Responses

I can't tolerate the machine , i remove it during sleeping.
 Cleaning Mask/Tubing Daily before use.
 Supply cost
 Feel uncomftable using it sometimes
 The mask is uncomfortable and cumbersome
 Painful around mouth. clastrophobic
 Fall asleep elsewhere or leakng due to old seal.

6) **Do you bring your CPAP machine with you when you travel?**

Answer Options	Response Percent	Response Count
Always	68.0%	229
Sometimes	15.7%	53
Never	7.1%	24
Do not travel	3.9%	13
Do not have a machine	5.6%	19
answered question		337
skipped question		3

7) **If your CPAP machine was a smaller size would you be more likely to bring it with you during travel?**

Answer Options	Response Percent	Response Count
Definitely	70.9%	224
Maybe	13.3%	42
No	7.9%	25
Do not travel	3.2%	10
Do not have a machine	5.1%	16
answered question		316
skipped question		24

8) **Would you be more likely to use a CPAP machine if**

Answer Options	Response Percent	Response Count
it was more quiet	29.5%	94
it was smaller	27.9%	89
it did not require an electrical outlet	26.6%	85
it cost less	21.6%	69
Other	14.7%	47
Not applicable	34.2%	109
answered question		319
skipped question		21

9) **Would you be willing to use a CPAP machine without a humidifier?**

Answer Options	Response Percent	Response Count
Yes	32.5%	108
No	47.0%	156
Yes, if the machine was smaller, more quiet, and/or less	16.3%	54
Not applicable	6.0%	20
<i>answered question</i>		332
<i>skipped question</i>		8

10) **If you have a CPAP machine, what would you change about it? Include any final comments.**

Example Responses

Patients should be instructed to wait until they are absolutely tired and ready to fall asleep before they put their mask on. learning this helped me to tolerate the machine better.

No blue light on the display

Be more quite

The hose output location and a swivel on it

i would like to have the ability to see if I'm having any apneas. As the patient i really ahve no way of knowing whether I'm still experiencing any apneas. Other than if I'm rested in the morning or not.

Make it universal in power supply show I can use it on battery when am camping or in car's and truck's on a long trip

The lights need to shut off or have option to shut off, too bright.

Smaller, lighter weight, with rechargeable battery power.

Make it smaller.

APPENDIX F: Initial Design Concepts

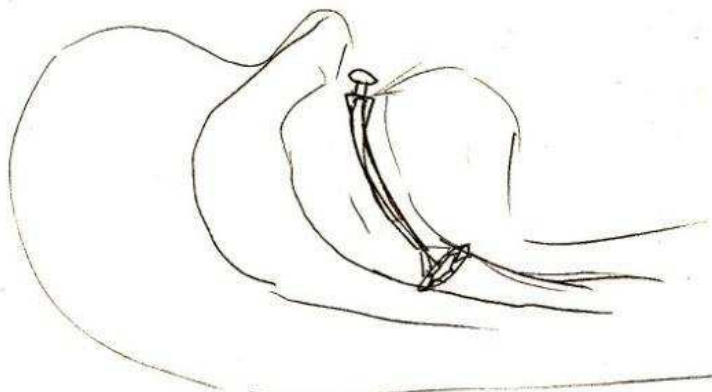
Table F1: Physical Splint Initial Design Concepts

Design 1



A semi-flexible, porous tube is permanently placed in the pharyngeal airway such that the tongue, epiglottis, and soft palate can not obstruct the airway.

Design 2



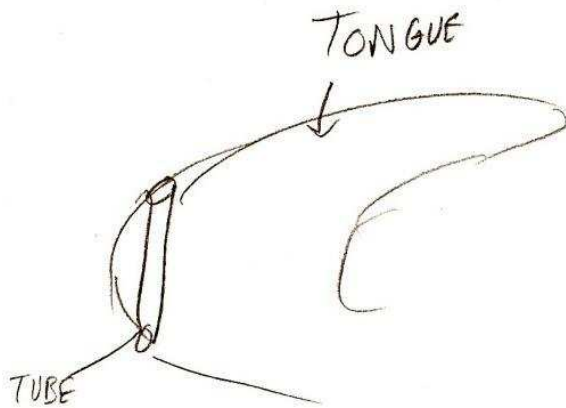
Each night the patient places a tube into their pharyngeal airway. One end has the ability to expand when prompted which will provide an unobstructed airway; the other end of the tube has a lever that activates the expansion.

Design 3



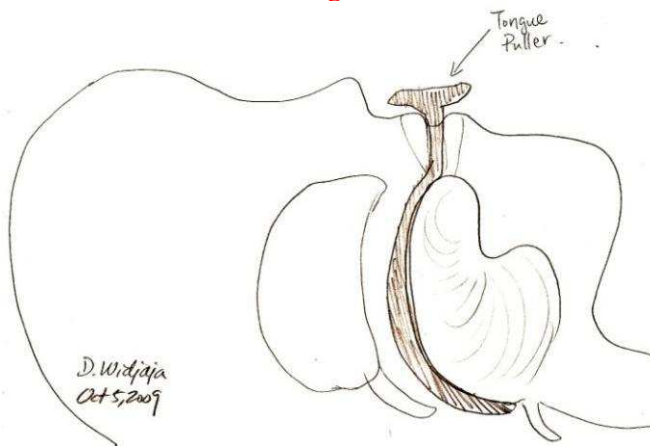
Each night the patient self-intubates themselves, such that the tube provides an unobstructed throughout the night.

Design 4



A small tube is placed in the tongue that can provide an unobstructed airway through the tongue.

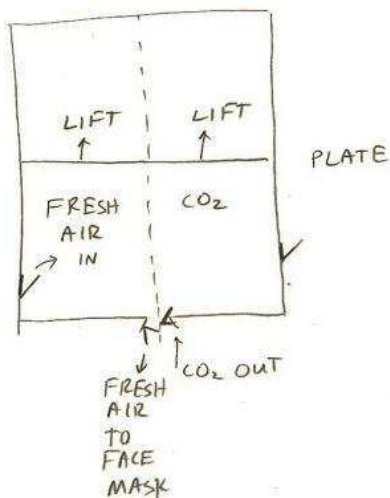
Design 5



A semi-flexible, semi-circular shaped rod is placed in the oral cavity that hold the tongue forward—it holds the tongue up, so that it does not fall into the pharyngeal airway.

Table F2: Constant Airway Pressure Initial Design Concepts

Design 6



Constant pressure is supplied through a mask attached to this device, which has 2 chambers to hold fresh air and CO₂. As the patient breathes out CO₂ into 1 chamber, the plate is lifted. As the plate travels upward, a low pressure area sucks fresh air into the other chamber through the use of valves. There are a total of 4 valves, 2 for each chamber.

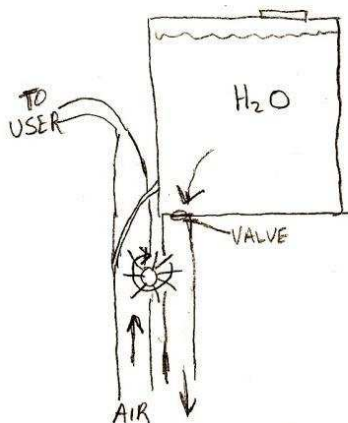
Design 7



During the day, the patient would pump air into a mattress. At night, the patient wears a mask attached to the mattress that supplies constant air pressure throughout the night such that the next morning the mattress is partially deflated.

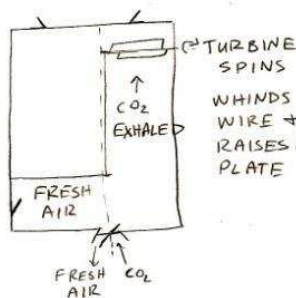
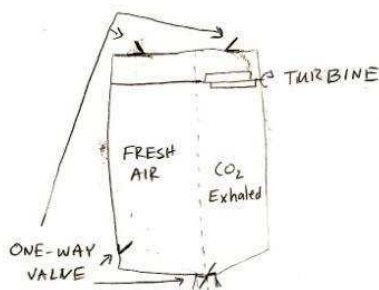
Design 8

JOE JACQUEMIN
10-1



One tank above the device is filled with water, while another tank below the device is filled with air. As the water falls through the tube, it spins the turbine, which sucks air up to the user. There is a third tank, also below the device which collects the fallen water.

Design 9

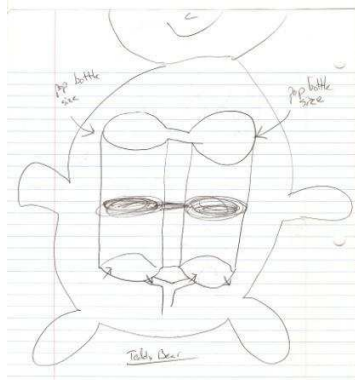


Constant pressure is supplied through a mask attached to this device, which has 2 chambers to hold fresh air and CO₂. As the patient breathes out CO₂ into 1 chamber, the turbine spins, which winds up a plate. As the plate travels upward, a low pressure area sucks fresh air into the other chamber through the use of valves. There are a total of 4 valves, 2 for each chamber.

Katya Christenson
Sept. 10th, 2007

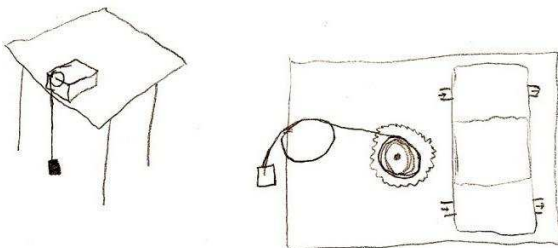
Design 10

The same as Design 1 except



Design 11

that a teddy bear around the device makes it more aesthetically pleasing and comfortable to sleep with—especially for children.



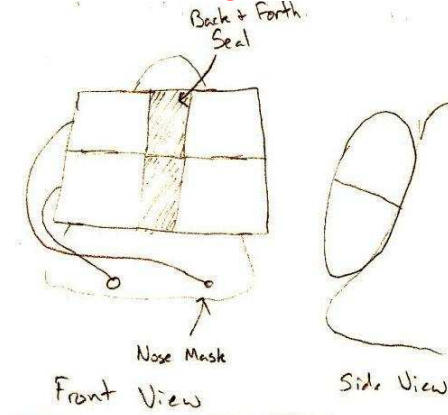
Design 12

A CPAP-type device is connected to a pulley and weight system. At night, the weight is placed at the end of a table. It slowly falls to the ground throughout the night, providing constant pressure.



Design 13

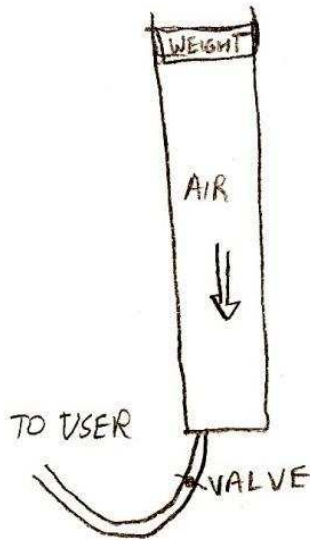
A windsock outside the window blows in the wind and collects air. This airflow provides constant pressure to the user via a mask and air hose, as the patient sleeps peacefully indoors.



Design 14

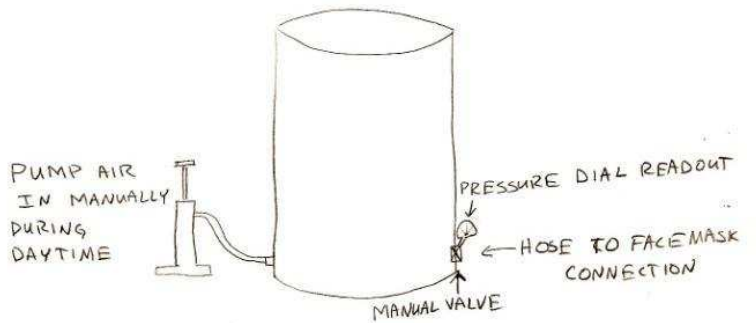
A device placed over the nose that provides constant pressure to the nasal airway.

Air is stored in a tank, which contains a weight at the top and



Design 15

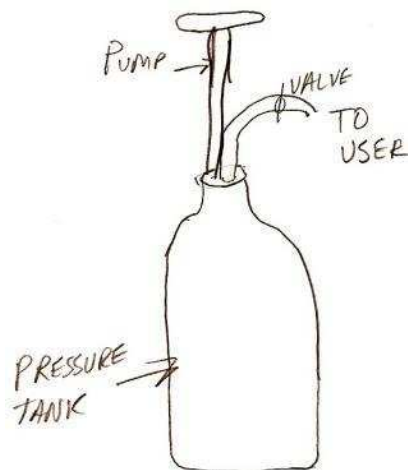
a valve at the bottom. At night, the valve is opened to allow air to pass through the hose to the mask at a specified pressure throughout the night.



During the day, air is manually pumped into a large storage tank. At night, the valve is opened to allow air to pass through the hose to the mask at a specified pressure throughout the night.

Katya Christensen
Sept. 10th, 2009

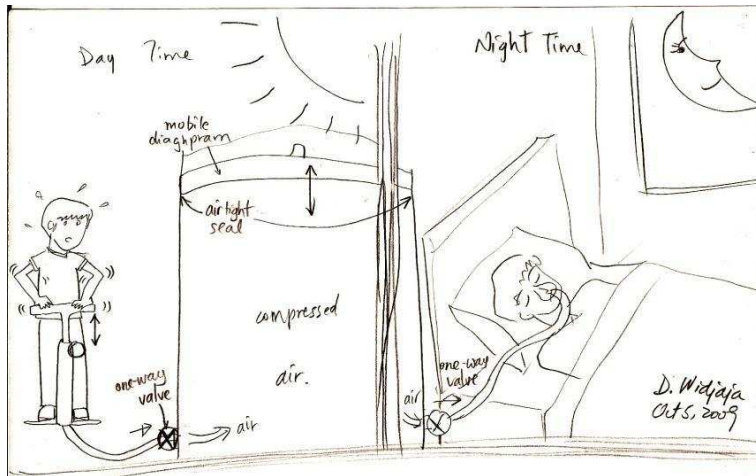
Design 16



During the day, air is manually pumped into a large storage tank. At night, the valve is opened to allow air to pass through the hose to the mask at a specified pressure throughout the night.

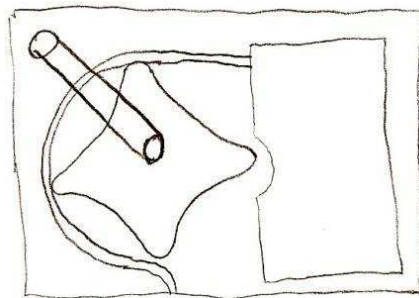
Design 17

During the day, air is manually



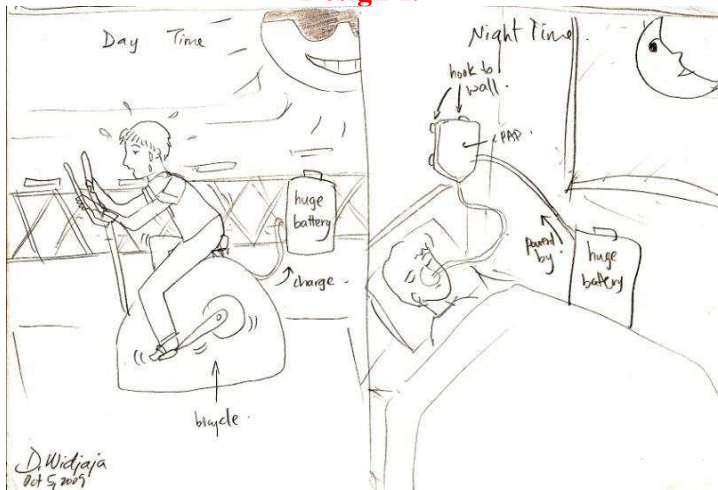
pumped into a large storage tank. At night, the valve is opened to allow air to pass through the hose to the mask at a specified pressure throughout the night.

**Table F3: Electricity Generation
Design 18**



During the day, the hand crank is spun to generate electricity to a battery. At night, a CPAP-type device uses the battery for energy.

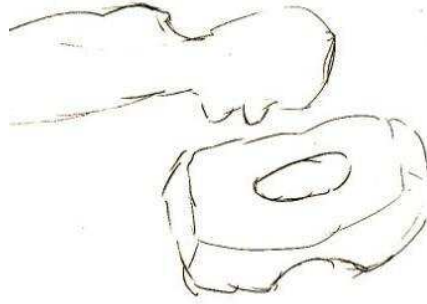
Design 19



During the day, the bicycle is rode to generate electricity to a battery. At night, a CPAP-type device uses the battery for energy.

Table F4: Behavior Therapy Initial Design Concept

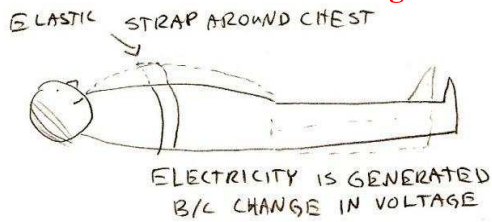
Design 20



This pillow has a hole in the center for the patient to lay there face down into. The bottom side of the pillow has semi-circular openings to allow for fresh air to enter and CO₂ to exit.

Table F5: Fundamental Principles Initial Design Concepts

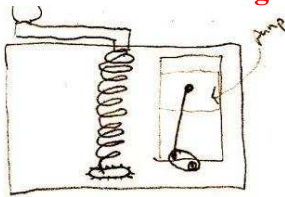
Design 21



Katya Christensen
Sept. 25th, 2009

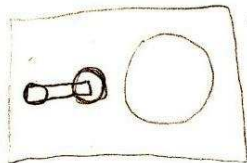
A strap is placed around the thoracic cavity that stretches and contracts as the patient breathes. This stretching causes a change in voltage and thus electrical generation.

Design 22



Wind Up
Torsion Spring

During the day, a torsion spring is spun tight using a hand crank. The torsion spring is attached to an air pump. At night the torsion spring is released such that the air pump is forced to spin and provide airflow to the patient wearing a hose and mask.



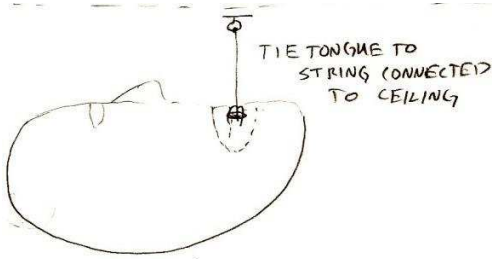
Design 23



A tongue ring is placed in the tongue of the patient. At night, a string is attached to the tongue ring and to a cockroach. At night the cockroach is awake, so it will constantly try to run away. Thus, the cockroach will provide force to the tongue and provide an unobstructed airway.

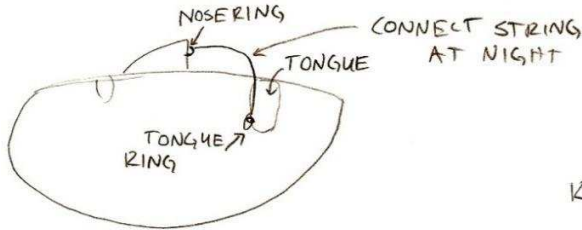
Design 24

A tongue ring is placed in the tongue of the patient. At night,



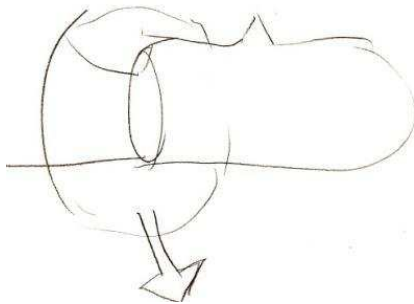
Katya Christensen
Oct. 5th, 2009

Design 25



Katya Christensen +
Steve Farnon
Oct 5th, 2009

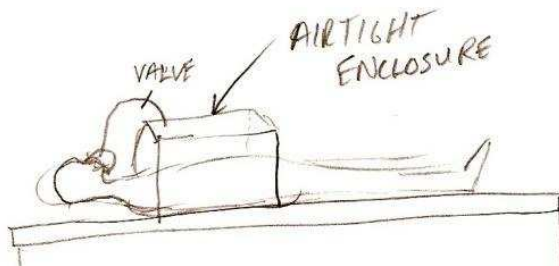
Design 26



Design 27



Design 28



Design 29

a string is attached to the tongue ring and to the ceiling, such that the ceiling will hold the tongue forward and provide an unobstructed airway.

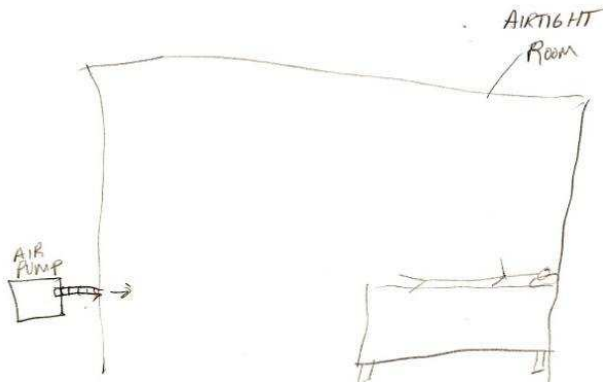
The patient has a tongue ring and a nose ring. At night, a string is tied between the two rings, such that the nose ring will hold the tongue forward in the oral cavity and provide an unobstructed airway.

A tube is placed around the neck that provides suction to the skin and throat area, which lifts and expands it such that the airway cannot be obstructed.

Liquid oxygen slowly drips down the throat and evaporates before it reaches the lungs, such that air is provided to the lungs.

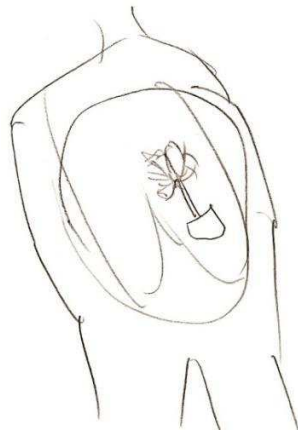
An airtight enclosure is placed around the thoracic cavity that uses the volume displaced from chest movement while breathing to provide positive pressure to a mask.

An airtight pressurized



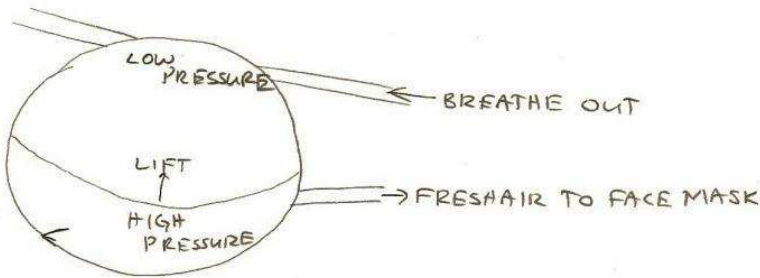
Design 30

enclosure is placed around the entire room.



Design 31

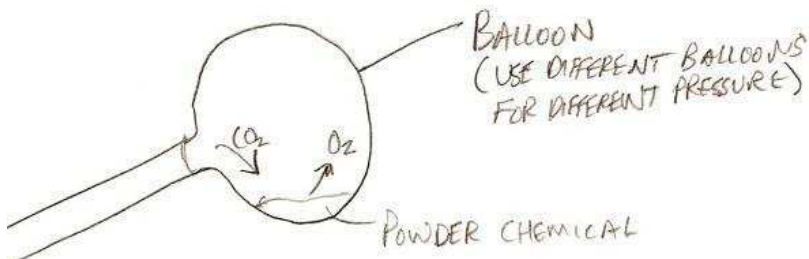
A plant is placed inside the lungs. The plant uses the CO₂ in the lungs and produces oxygen for the patient such that it does not matter if the airway is obstructed or not.



Katya Christensen
Sept 10th, 2009

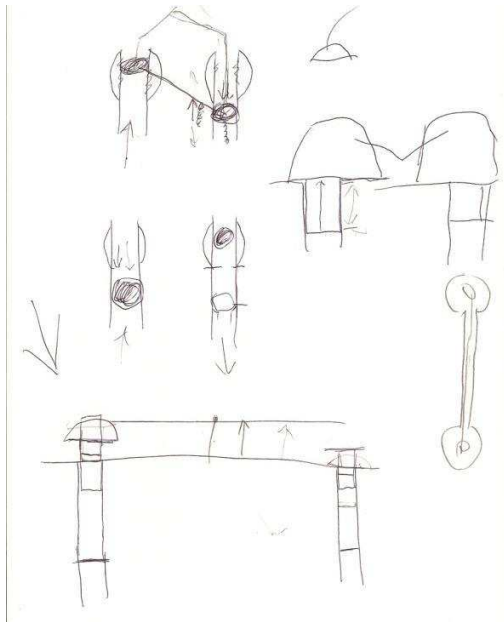
Design 32

As the patient breathes out, the air passes by an enclosed area. The velocity of the air moving creates a low pressure zone. The low pressure zone then lifts a flexible membrane. When the membrane lifts, fresh air rushes into a second enclosure and provides fresh air to the patient.



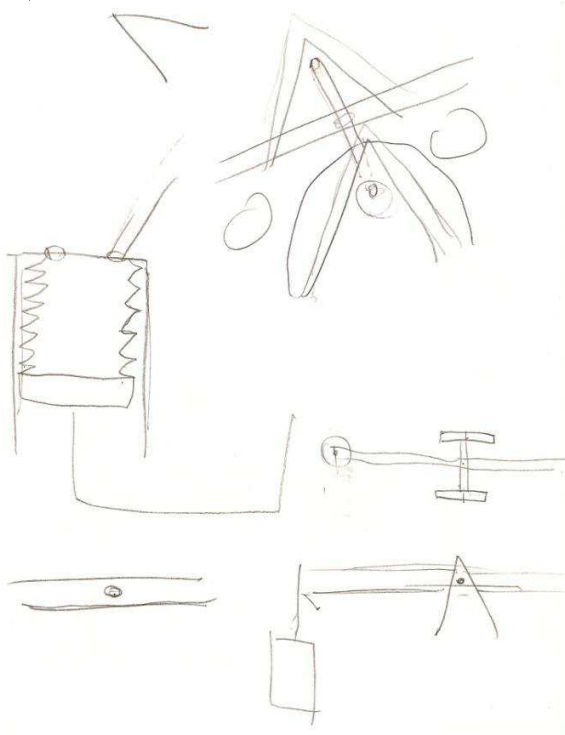
A specified balloon size contains a powdered chemical that converts CO₂ to fresh air. The patient breathes into the balloon to produce CO₂ and then breathes out of the balloon to receive fresh air.

APPENDIX G: Alpha Design Brainstorming

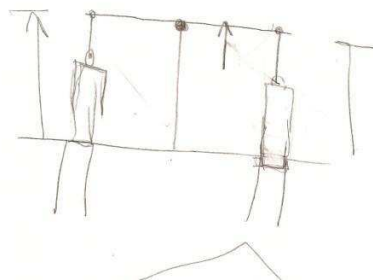


Two different valve mechanism designs. The first design uses two balls connected with a linkage that pivots, blocking airflow on one side while allowing airflow on the other. The balls block the airway.

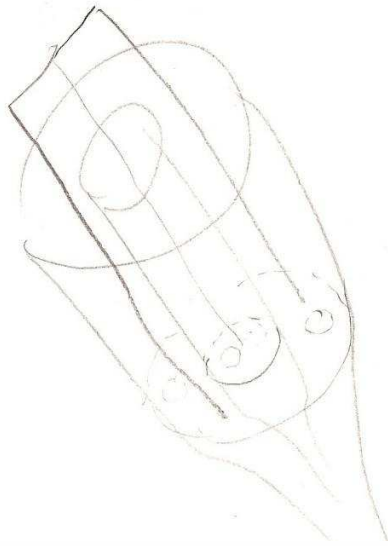
The second design uses two plugs connected on a pivoting linkage to ensure that the mechanism pivots a certain amount defined by the length of the plugs.



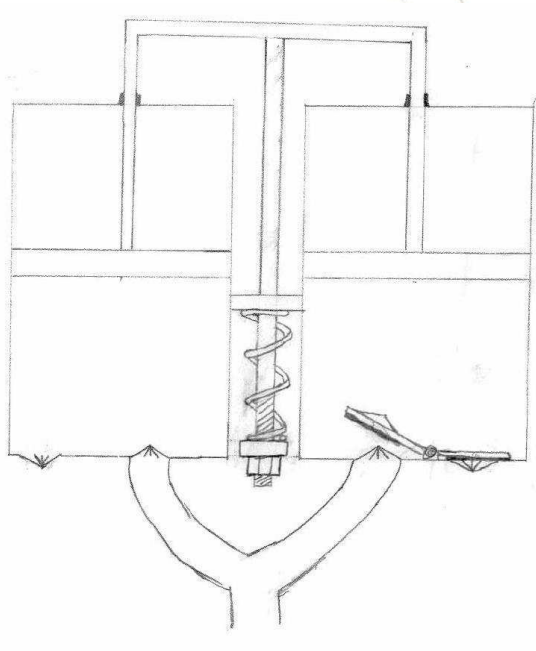
Designs developing the pivot of the original valve mechanism and the inflatable chamber accordion-style bags.



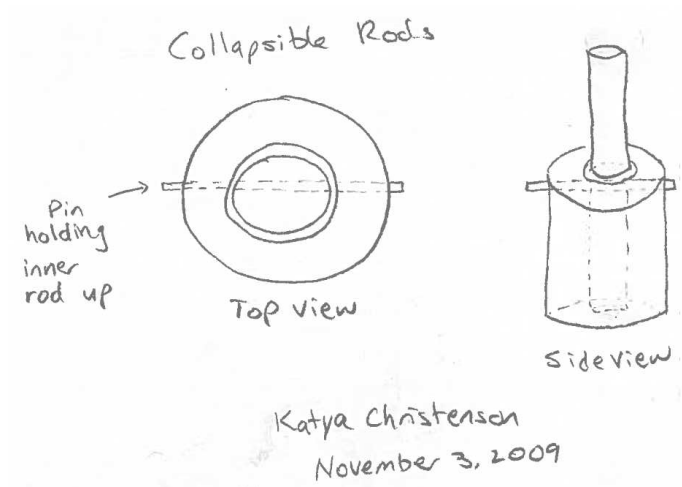
A more finalized valve idea where one valve is slightly higher than the other on the pivot to prevent unwanted middle "dead zone" where air can flow without pressurizing the chamber.



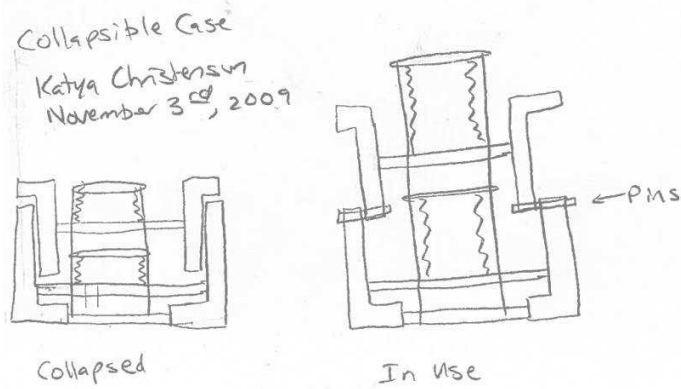
A design with the exhalation and inhalation chambers concentric with one inside the other. This design would eliminate the wasted space that currently exists between the two chambers in the Alpha Design. However issues with mounting the linkage, difficult manufacturing, and complex valves caused us to choose our current design.



An iterative, system design concept of our Alpha Design that contains solid cylinders and a complex valve mechanism that works like a teeter-totter with suction cups. Please note, this is not our most up-to-date concept.



To make the device collapsible, the rods must be collapsible. This shows a small rod annularly within a hollow cylinder. The smaller rod can move up and down along the axis of the cylinder and rod to extend or collapse the rod. To keep the rod in extension, some type of "pin" must be used to fasten it.



To make the device collapsible, the housing must also be collapsible. This shows a cut-out of the housing walls collapsed and also when the device is in use (extended). The fixed plates are fixed to the "moving" walls. The required space between these plates is purely based on the size of the valves, and the size of the bags when compressed. To keep the housing in extension, some type of "pin" must be used to fasten it.

APPENDIX H: PARAMETER ANALYSIS CALCULATIONS

Parameter	Reasoning/Logic	Equation	Value
Chamber Diameter	Product height Necessary weight		6.5"
Chamber Height	Required volume and chamber diameter	$V=500\text{ml}$ $A = \pi \frac{D^2}{2}$ $H = \frac{V}{A}$ A=area H=height V=volume D=Diameter	3.5"
Chamber Shape	-Sturdy -Compressible		Circular
Chamber Material	Minimize energy losses from friction		Vinyl
Chamber Alignment	-Reduce energy losses from torque -Reduce weight -Reduce footprint		Vertical
Plate Diameter	Chamber diameter	$D_{\text{Chamber}} + 2'' = D_{\text{Plate}}$	8.5"
Distance between plates	Chamber height		6"
Plate thickness	Availability		0.22"
Plate material	Availability		Acrylic
Rod length	Distance between plates		6.25"
Rod material	-Smooth -High Young's Modulus -Low deflection -Inexpensive -Availability -Easy to machine		Round stock steel
Rod diameter	Desired stiffness to prevent deflection		1/8"
Number of rods	-Reduce energy losses -Smooth, stable motion		6
Force Applied to System	Desired pressure	$F = PA$	0-3lbs
Valve diameter	Standard mask outlet diameter		0.87"
Valve flap material	-Inexpensive -Seals air well -Availability		Rubber
Hose junction location	Reduce dead volume		30mL
Number of hoses	Reduce dead volume		2

Table E1: Parameter Analysis

APPENDIX I: FORMAL SAFETY REPORT WITH BETA DESIGN DRAWINGS

1. **Executive Summary.** Answer the following questions: What activities or designs are covered by this report? What hazards have you identified and eliminated? What analysis have you performed and why do you conclude that the activities/designs are low risk? Be sure you consider all aspects of your project: experimental data collection, component design, system design, manufacturing, assembly, and testing.

This report details the fabrication of a prototype of a redesigned Continuous Positive Airway Pressure (CPAP) machine that operates without the use of electricity. This prototype will be fabricated in the Mechanical Engineering shop with the help of Mr. Bob Coury and Mr. Dan Johnson. The prototype will be built from basic materials using machine shop equipment, common hand tools, as well as, the laser cutting machine.

Initial Experimentation:

No initial experimentation is required for this project.

Design Elements:

The design has been developed such that its usage poses little danger. The air pressure associated with the device is less than 0.1 psi so the chambers need not be very strong to withstand it. The container of the device will not have sharp edges. The final design will involve injection blow molding of the components to reduce the usage of epoxy when joining some components to another.

Manufacturing Elements:

The processing involved in the manufacturing of some parts include the use of the machine shop equipment such as the laser cutter, hacksaw, drill, plastic mallet, scissors, wire cutter, file, epoxy, etc. Hazards inherent in these tasks include burns (from the laser cutter), fast moving equipment, sharp edges, flying debris, cutting, crushing, puncturing, pinching, abrasion and inhalation of toxic fumes. Standard machine shop training, clothing, safety gloves, safety glasses, and supervision are considered sufficient to minimize the risks of these hazards. Extra precautions to protect the eyes and the skin should be taken while using the laser cutting machine as it may penetrate the skin and burn anything beneath it.

Assembly Elements:

Assembly of the prototype is regarded as a very low-risk process. Most of the components will be assembled by joining components with epoxy. Only the edges of the air chamber bags require full contact with the epoxy, most of the parts are also designed such that they could be aligned easily and fitted snugly to one another such that epoxy is applied only on the seams. There will be no joining operations that require heat or electricity and only low levels of force are required to secure all pieces.

Testing Elements:

The device is to be tested using a variety of weights to assess its ability to provide continuous positive airway pressure (CPAP) using a manometer. Testing of the device will not pose much danger as the air pressure associated is not very high. The only potential hazards could be crushing and pinching by the weights.

2. **Experimentation Plans Prior to Design Completion.** For your experimentation, list what data you will be collecting and why. Are any experiments that might have safety risks unnecessary? Why/Why not?

Experiment Safety

Once completed, we will test our design to see if the overall concept is feasible. We will be testing the following items:

1. Expiration Pressure

We will measure the amount of expiration pressure by connecting our market CPAP machine up to our device at various pressures and determine at what, if any, pressures our device operates at. This will be done by observing whether the chambers inflate while incrementally increasing the pressure provided. Some safety risks involve pinching and crushing of the hands in between the moving plates. During data-taking ensure that no parts of the body are anywhere near the moving parts so as to reduce risk of injury. Although the injury sustained if this occurs is not very serious as the acrylic plates are very light, it is worth noting that we will be putting on weights on subsequent tests so experimenters still need to be aware.

2. Inspiration Pressure

Inspiration pressure will be measured by connecting a manometer to the expiration tube to measure the cm of H₂O provided during inhalation. Safety risks involved in this procedure is similar to the expiration pressure as that is when the plates are moving up and down. Again, safety precautions include being aware of one own's body parts (hands, fingers, etc) while the device is operating.

3. Pressurizing Mechanism (Weights)

The initial plan was to place weights to our system and repeat the expiration pressure test to see the difference of pressure provided upon exhalation using a manometer. We will be using weights ranging from 5 – 1000 grams placed on top of the top moving plate. This will give a downward force. Some safety concerns could be injuries of getting fingers pinched or crushed if the weights accidentally drop on them while testing.

4. Airtight seals

We will inflate the chambers and close off the tube outlets and see how much air is lost over a period of time. This will test the quality of our airtight seals. The air pressure associated with the device is very low and is physically impossible to pose an exploding threat like that of high-pressure systems. However, the seals themselves are constructed using the toxic epoxy adhesive. This may cause reaction on the skin when touched or smelled. This could be harmful in the long run. One safety precaution is to use gloves while handling the device and keeping some distance from the device while experimenting with it.

5. Backflow- Stopping Valve

We will breathe into the device and see if the fresh air flows to the user or into the exhalation chamber. One safety risk involved is the inhalation of the toxic epoxy vapor that may linger in the air chambers since epoxy is used to seal them. While breathing into the device, experimenters

must ensure that they let go of the mouthpiece as soon as they finished their exhaled breath so as to reduce this risk.

6. Valves

We will force air into the device in the opposite way of normal airflow and verify that the valves stop airflow and/or how much air leaks through them over time.

7. Dead Volume

Using a ruler or a fluid such as water with a beaker we will measure the dead volume associated with the mask and backflow stopping valve. There is no safety risk associated as the device is stationary and passive while its size is being

8. Noise

The volume of the device will be compared with the volume of a standard CPAP machine. There is no safety risk associated as the device is stationary and passive while its size is being measured.

9. Size

The device will be measured to determine its size. There is no safety risk associated as the device is stationary and passive while its size is being measured.

10. Weight

The device will be weighed to determine its mass. One safety risk involved is falling of the device onto one's foot and injuring while moving the device from the tabletop onto a weight machine. Unless the weight machine is on the same table, this risk will be significantly reduced. Injuries from the box sharp edges could be sustained when handling the device. Precautions taken should be ensuring the carrier handles the device at the right place such that the hands are nowhere near sharp edges and be carried with two hands.

11. Breath Variation:

A volume of air larger than a normal breath will be put into the system to see if it can safely handle larger than normal breaths. The same test will be conducted to test if it can handle larger than normal inhalations. Safety risks involved in this procedure is similar to the expiration pressure as that is when the plates are moving up and down. Again, safety precautions include being aware of one own's body parts (hands, fingers, etc) while the device is operating.

12. Allows breathing if broken:

A person will breathe into the machine and see if breathing is possible while the plates are locked into both the inflated and deflated positions. Safety risks involved in this procedure is pinching or crushing of the hands as the plates are going to be suspended up at the inflated position. If the locking mechanism fails, the plates may fall right onto one's hands if they are carelessly placed on the fixed plates. Safety precautions include being aware of one own's body parts (hands, fingers, etc) while the device is operating.

In all of these tests there will be no significant safety risks. Since the device will not be tested with a human many safety considerations are eliminated. We will be using low pressures and no

harmful chemicals or materials. Electricity will not be used and testing will not begin until the epoxy has hardened, so there will be no risk of contact with uncured epoxy. There should be no loose parts that present a choking hazard and the metal rods and acrylic will be filed to eliminate sharp edges.

3. **Purchased Component and Material Inventory.** Provide an inventory of all materials (solid materials such as aluminum/wood/etc.) and purchased components you will be using. Why are these materials and components necessary?
 - a. Complete an FMEA for any purchased components that have safety risks. Provide the FMEA table as an appendix to this Safety Report and summarize the results in your own words for the main report body.

Prototype Material Inventory:

The final prototype will contain a combination of ready-to-purchase on-shelf products that we further process and modified as well as the available materials in the Mechanical Engineering machine shop. The figure below is the first prototype manufactured which could show a close approximation to the final complete prototype. It has been labeled to show its position in the prototype.

Machine shop materials inventory:

The machine shop has a variety of materials in stock which would be

1. Round stock Steel rod – 1/8” diameter, 72”
 - a. Quantity: 1
 - b. Manufacturer: Small Parts, Inc.
 - c. Model: Steel Type C1018 Cold Rolled Rod

Description:

The steel rods are smooth enough to provide a railing for the moving plate set-up and strong enough to withstand the weights of the acrylic plates. They are also easily cut into smaller pieces with a hacksaw. The rod is made of C1018 stainless steel. It has a high Young’s Modulus to prevent too much deflection of the structure while withstanding the weight of the acrylic plate.

Purchased component Inventory:

Since the air pressure we are dealing with in the system is relatively low, a large percentage of the mechanical components used on the device were purchased from a local hardware and home improvement stores. For example, the system needs an airtight seal to prevent air leakages, but a normal household sealant could be used without requiring a specially manufactured airtight container. Each of the components is described below:

1. Vinyl Ventilation Duct – 4” diameter, 8”
 - a. Quantity: 1
 - b. Manufacturer: ACE Hardware Corp.
 - c. Model: #47458

Description:

The vinyl duct has a perfect accordion-style cylindrical structure that retains a study shape while being expanded or compressed when air flows in and out respectively. The spring-like wire that contributes to the sturdy shape of the vinyl duct ensures that the bag will not bulge to the sides when air flows in. When air flows out the air bag the bag will remain on the sides and will not collapse to the center to block the valve openings.

2. Acrylic sheets – 0.22” thickness, 18” × 24”
 - a. Quantity: 2
 - b. Manufacturer: Plaskolite, Inc.
 - c. Model: Optix® Acrylic Sheet

Description:

The transparent acrylic sheets are lightweight yet strong enough to withstand forces encountered during usage. It is also easily processed and shaped for our project requirement. It is also quite compatible with epoxy adhesive. The transparency of the acrylic is useful to help us see the happenings within the system which could be difficult to see using colored acrylic. The MSDS report provided by the manufacturer of the acrylic sheet could be reviewed in Appendix C.

3. Epoxy Adhesive
 - a. Quantity: 1
 - b. Manufacturer: ITW Devcon®
 - c. Model: 5 Minute® Epoxy, NSN Stock#8040-00-264-6816

Description:

The epoxy adhesive provides a good joining strength to the acrylic and steel rod. It is fast-curing and could provide a good seal for the air chamber which needs to be airtight. The MSDS report provided by the manufacturer of the epoxy could be reviewed in Appendix C.

4. Plastic Siphon Pump
 - a. Quantity: 2
 - b. Manufacturer: DuraHeat
 - c. Model: DH-10, Internet Catalog #100372238

Description:

The siphon pumps were purchased for its ready-made one-way valves. They one way valves (2) are to be cut out from the siphon pump set-up. An X-Acto knife is used to cut out the small device and the valves are to be glued into the holes on the acrylic sheet. The one-way valves function in a different direction and are perfect for this installation.

FMEA Analysis Results of Purchased Components

The purchased components were analyzed for its potential to fail using the FMEA Analysis. Refer to Appendix A for the FMEA Analysis Table of the purchase components.

The components deemed most likely to fail are the epoxy air seal in between the air chamber and the acrylic plates. However, a complete failure of any of these components would not be too serious to passers-by as the pressure is not very high and it is physically impossible to have any

explosion of some sort that could send flying debris. The risk of leak through the epoxy seal is reduced by ensuring from the other side of the transparent acrylic plate that the epoxy covered a substantial amount of the plate-bag interface so that leaks are less likely to occur.

The air leak, which can result from a loosely-connected air chamber and acrylic plate, could deem the device as not being functional to be a home medical device as this device requires to be constantly working for 10 hours while a patient is sleeping. If the machine does not work properly, the prescribed air pressure required by the patient could be severely reduced and thus does not treat sleep apnea effectively.

Experimental/Validation Equipment Inventory

The prototype performance will be tested using several lab equipments and data will be easily collected by hand, no special electronic instruments is necessary. The testing required includes providing a known amount of pressure into the device and measuring the pressure produced at the outlet. The effect of the weight on the air pressure produced also needs to be tested. Different weights will be placed on top of the fresh air chamber to measure how differing weights affect the amount of air pressure produced by the fresh air chamber. The outlet hose of the device will be connected to the manometer filled with water.

1. Continuous Positive Airway Pressure (CPAP) Machine

- a. Quantity: 1
- b. Function: Provide continuous airway pressure at desired pressures measured in mm H₂O. The air pressure from the CPAP machine would inflate the used air chamber, along with the fresh air chamber, and then stopped. The air pressure produced at the fresh air chamber outlet hose will be measured when the fresh air chamber starts deflating.

2. Manometer (U-tube):

- a. Quantity: 1
- b. Function: Measure incoming pressure from the outlet hose of the device by calculating difference in pressure of the fluid in the manometer. Water is used in this experiment as is it non-toxic and easily accessible.

3. Brass weights – 5 – 1000 grams

- a. Quantity: 1 box set
- b. Function: The brass weights would provide downward force on the fresh air chamber and provide a variety of pressures onto the air chambers

4. Breathing hoses

- a. Quantity: 2
- b. .Function: The hoses are to be used a the connection between the device to the facial mask.

5. Tape Measure

- a. Quantity: 1
- b. Function: Measure the size of the device.

6. Weight Scale

- a. Quantity: 1
- b. Function: To measure the weight of the device.

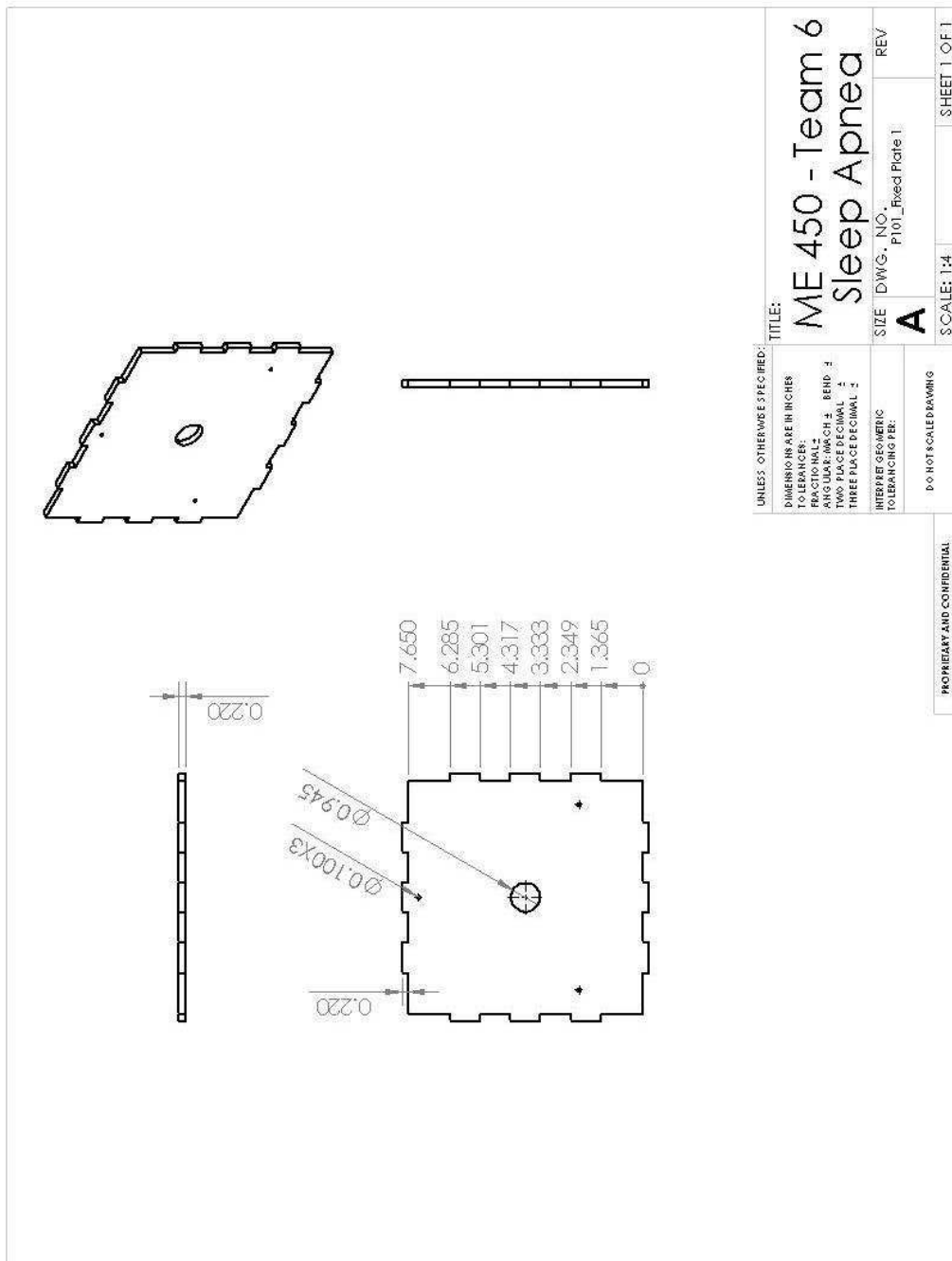
7. Stopwatch

- a. Quantity: 1
- b. Function: Measure time taken for an induced pressure maintained.

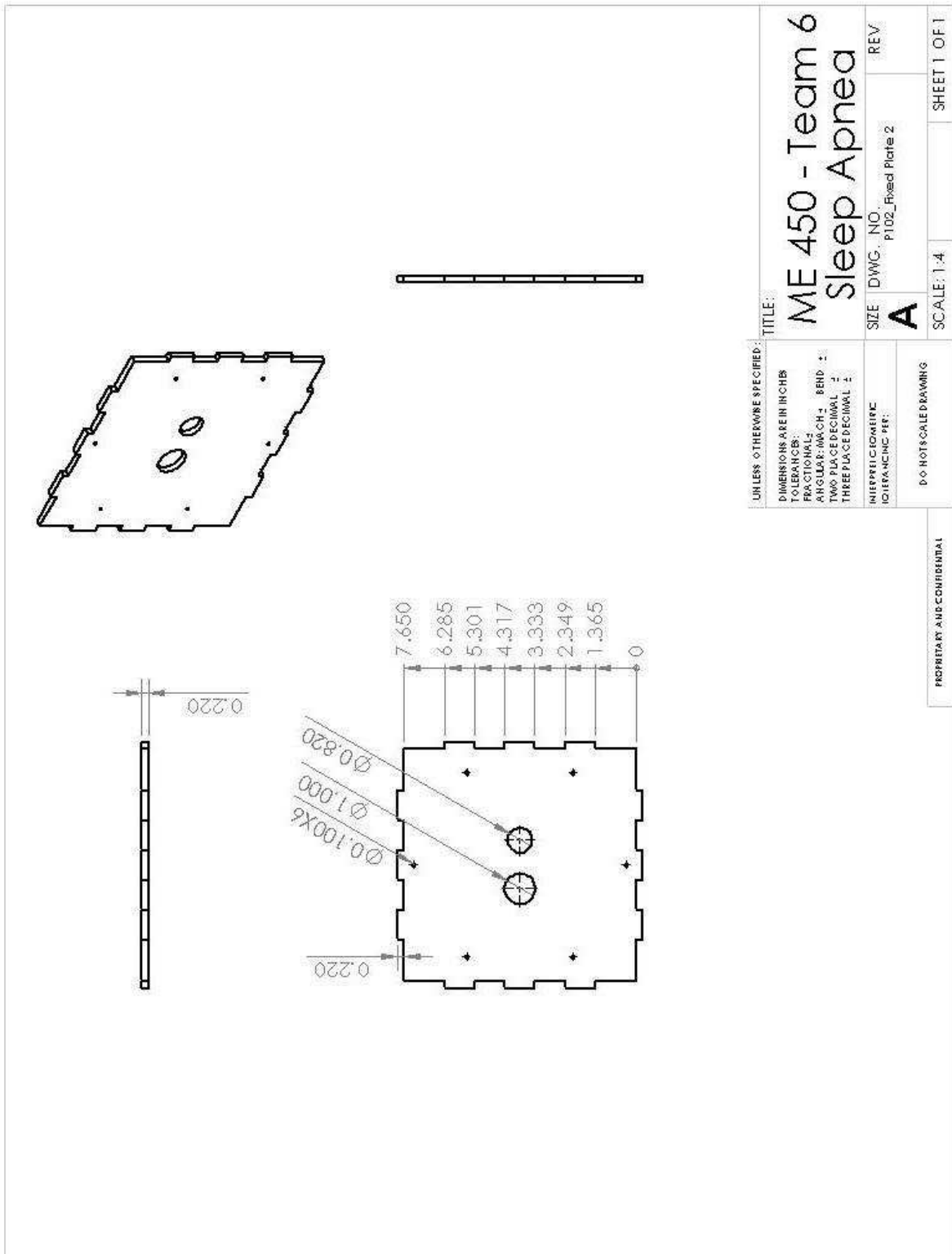
4. **CAD Drawings and DesignSafe Summary for Designed Parts.** Provide CAD drawings for components you have designed and will manufacture.
- Conduct a risk assessment using Designsafe software (available on CAEN) for each designed component and for the full assembly of components constituting your design. Provide the Designsafe output as an appendix to this safety report and summarize the results in your own words for the main report body.

Refer to Appendix B for the DesignSafe Report.

Bottom Fixed Plate



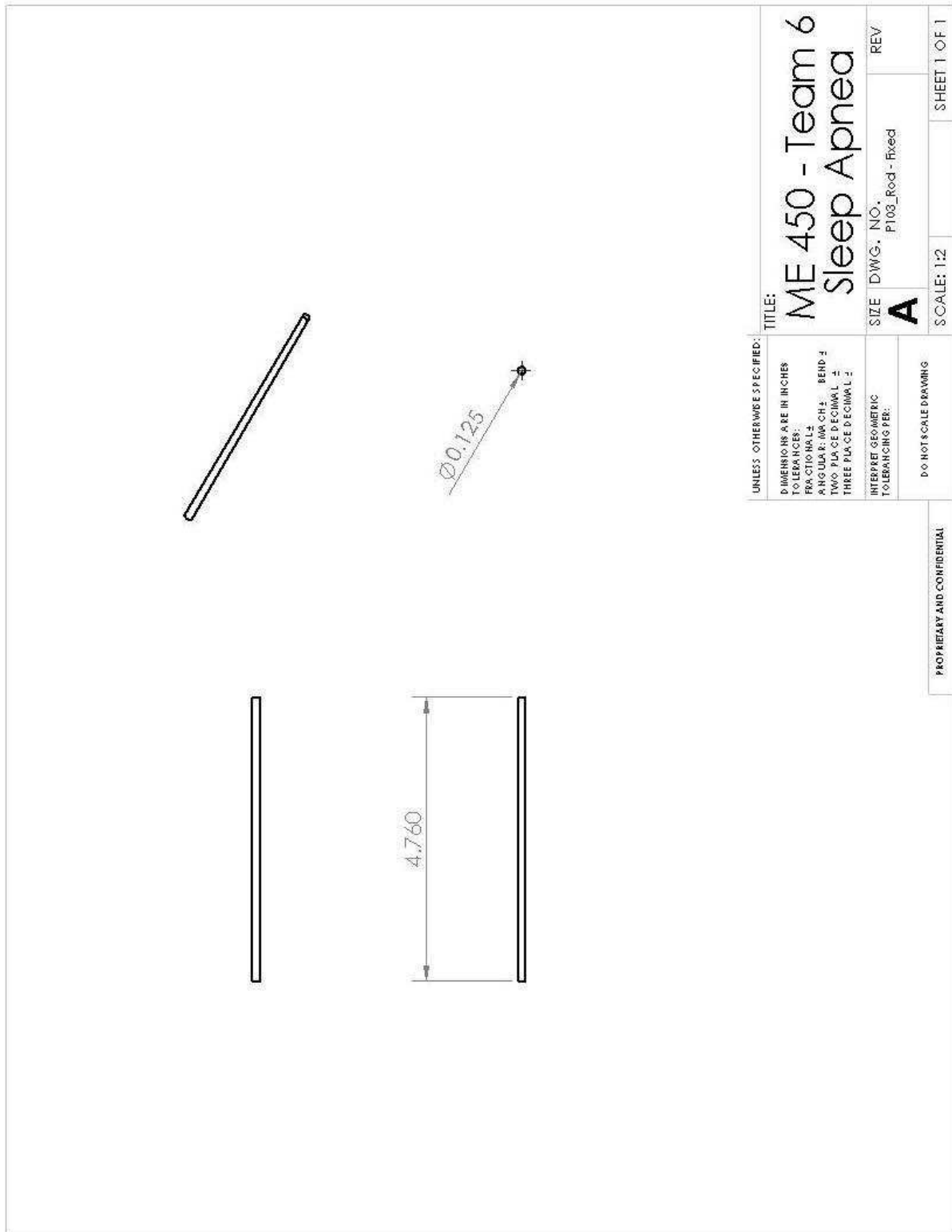
Top Fixed Plate



UNLESS OTHERWISE SPECIFIED:		TITLE:	
DIMENSIONS ARE IN INCHES		ME 450 - Team 6	
TOLERANCES:		Sleep Apnea	
FRACTIONAL: MACH ±		SIZE: A	REV:
ANGULAR: MACH ±		DWG. NO. P102_Fixed Plate 2	
TWO PLACE DECIMAL ±			
THREE PLACE DECIMAL ±		SCALE: 1:4	SHEET 1 OF 1
INTERPRETING PER:			
DRAFTING PER:			
DOWNSCALE DRAWING			

PROPRIETARY AND CONFIDENTIAL

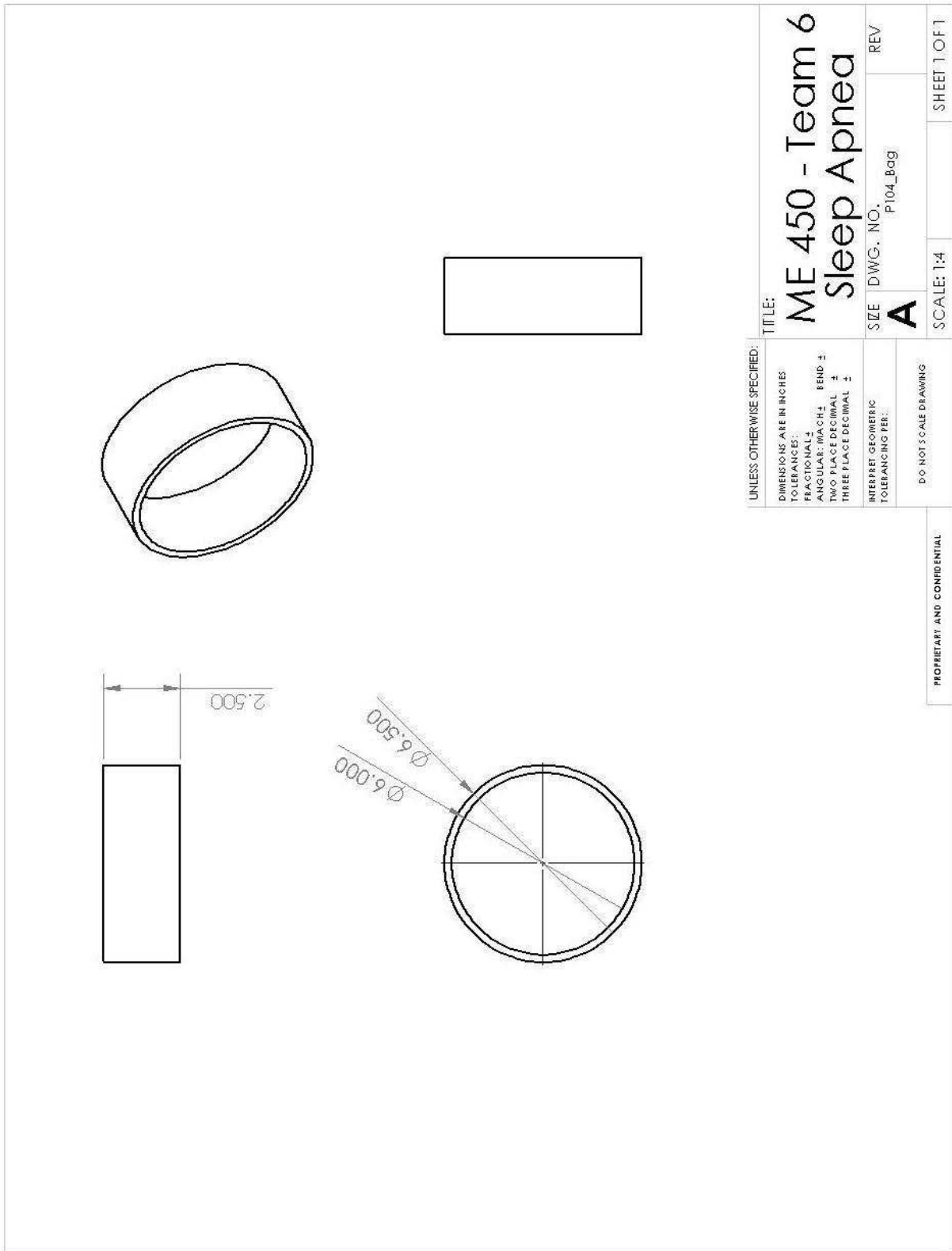
Steel Rods (x6)



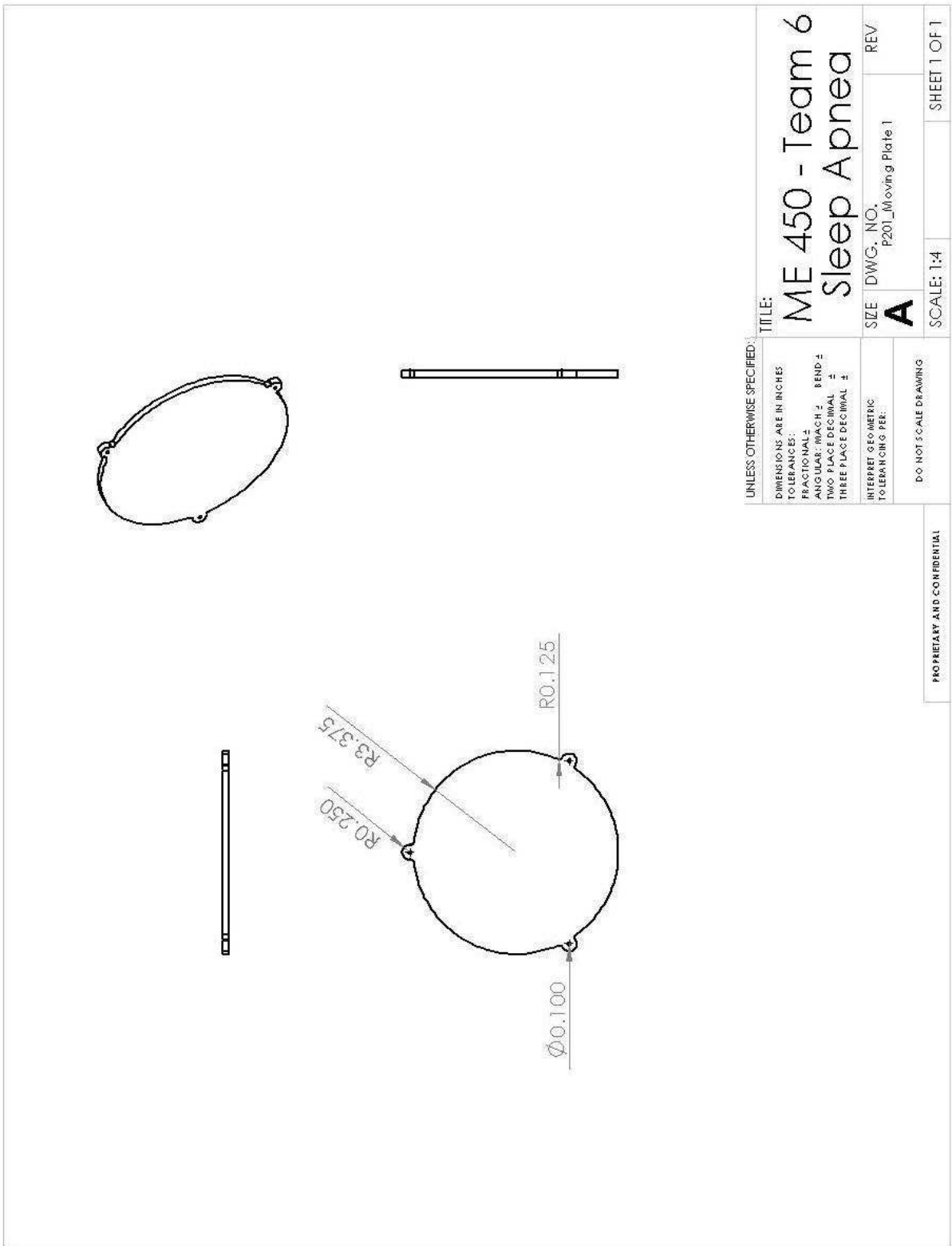
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TOLERANCES:		Sleep Apnea	
FRACTIONAL ±	ANGULAR: MM CH ± BEND ±	SIZE DWG. NO.	REV
TWO PLACE DECIMAL ±	THREE PLACE DECIMAL ±	A	P103_Rod - Rxed
INTERPRET GEOMETRIC TOLERANCING PER:		SCALE: 1:2	
DO NOT SCALE DRAWING		SHEET 1 OF 1	

PROPRIETARY AND CONFIDENTIAL

Air Chamber



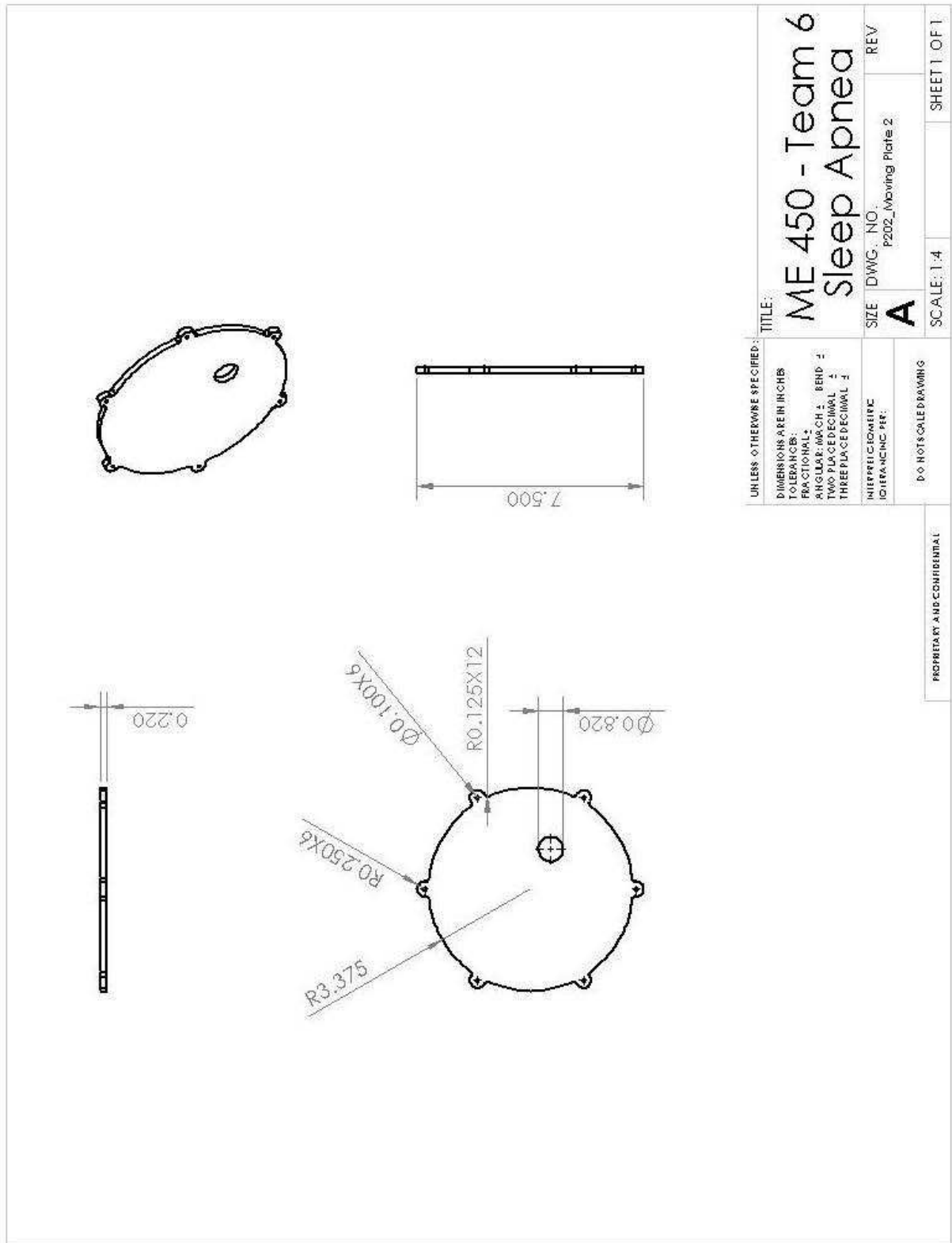
Top Moving Plate



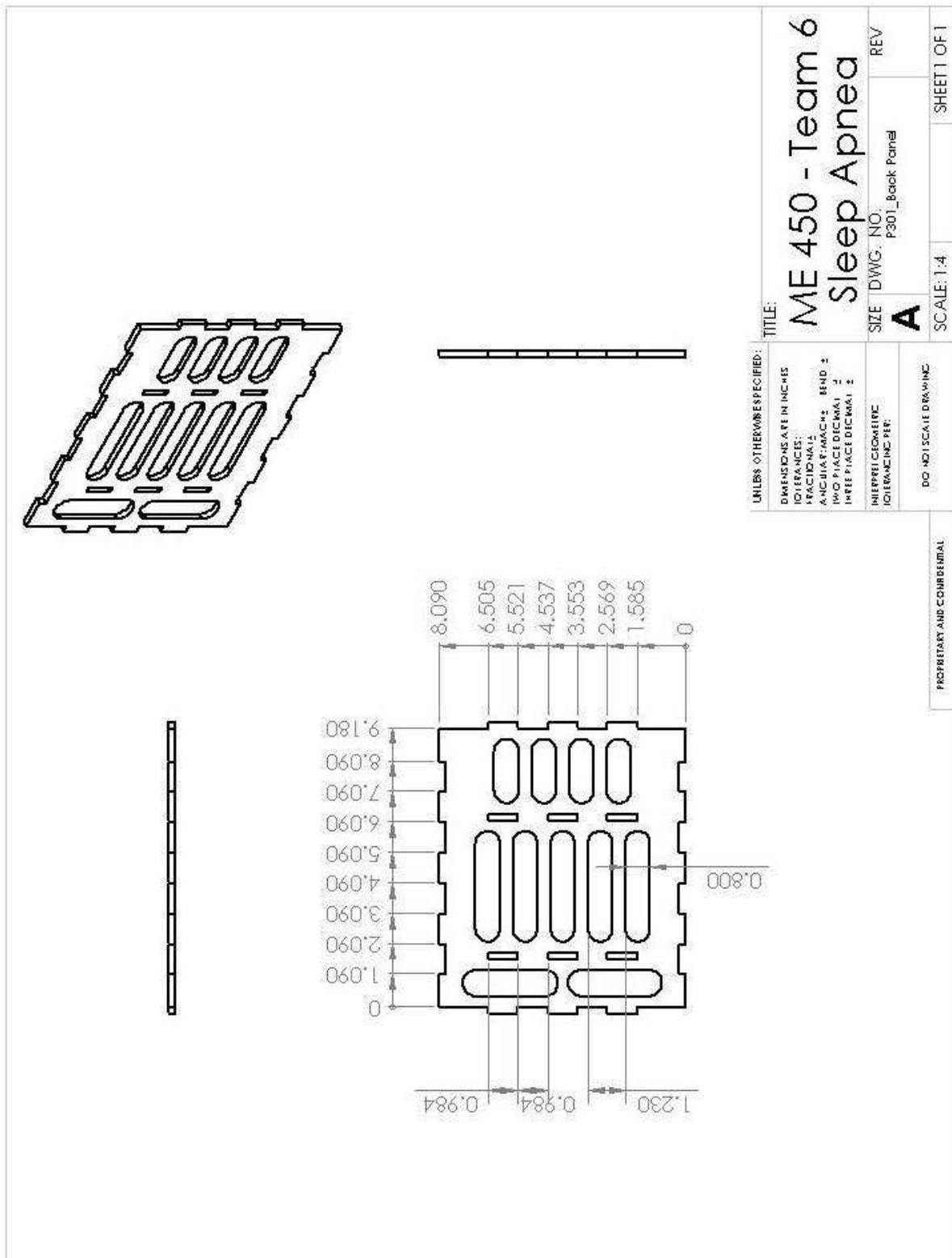
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TOLERANCES:		Sleep Apnea	
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ANGULAR: MACH 2	BEND 2	A	P201_Moving Plate 1
TWO PLACE DECIMAL	±	REV	
THREE PLACE DECIMAL	±	SCALE: 1:4	SHEET 1 OF 1
INTERPRET GEOMETRIC TOLERANCING PER:			
DO NOT SCALE DRAWING			

PROPRIETARY AND CONFIDENTIAL

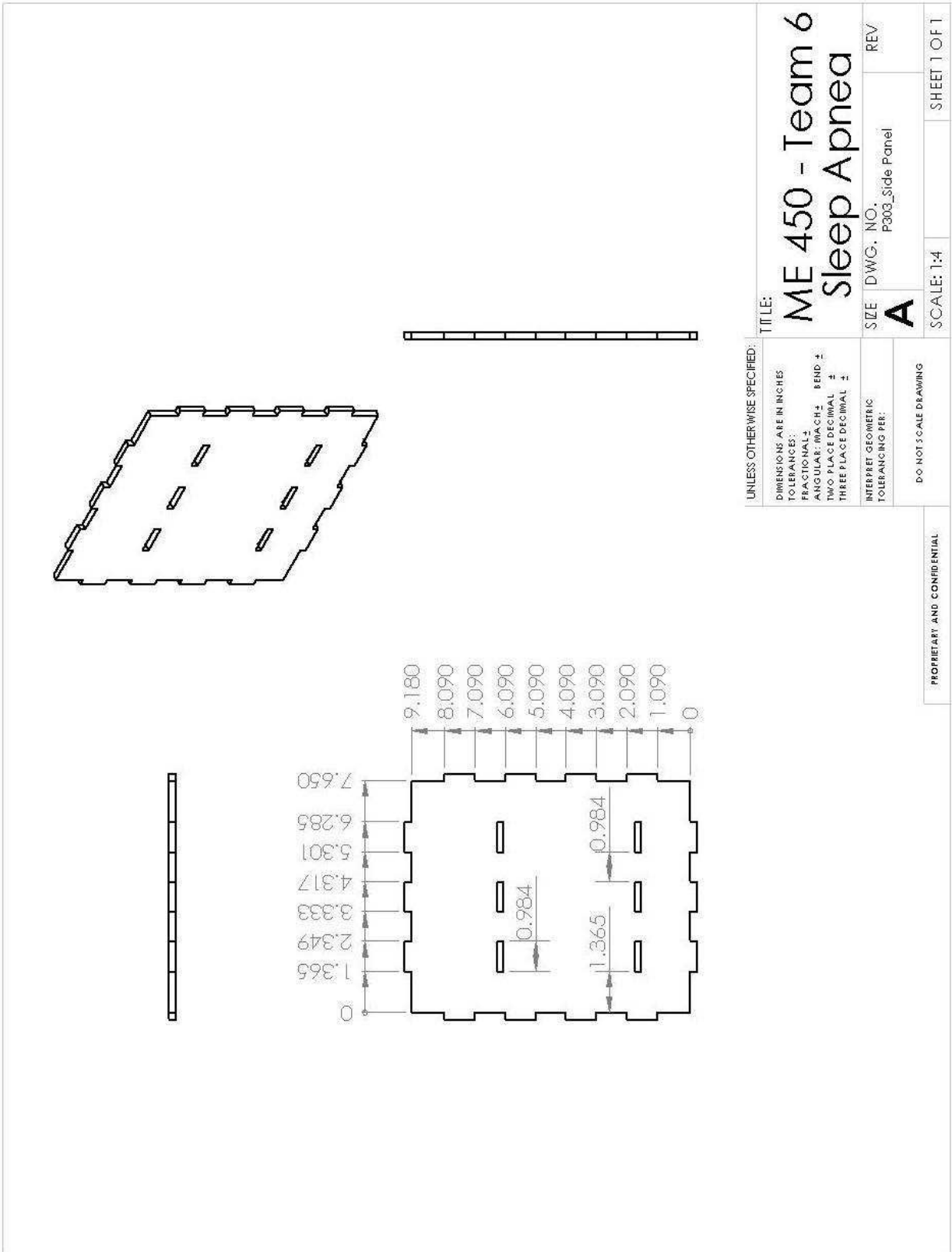
Bottom Moving Plate



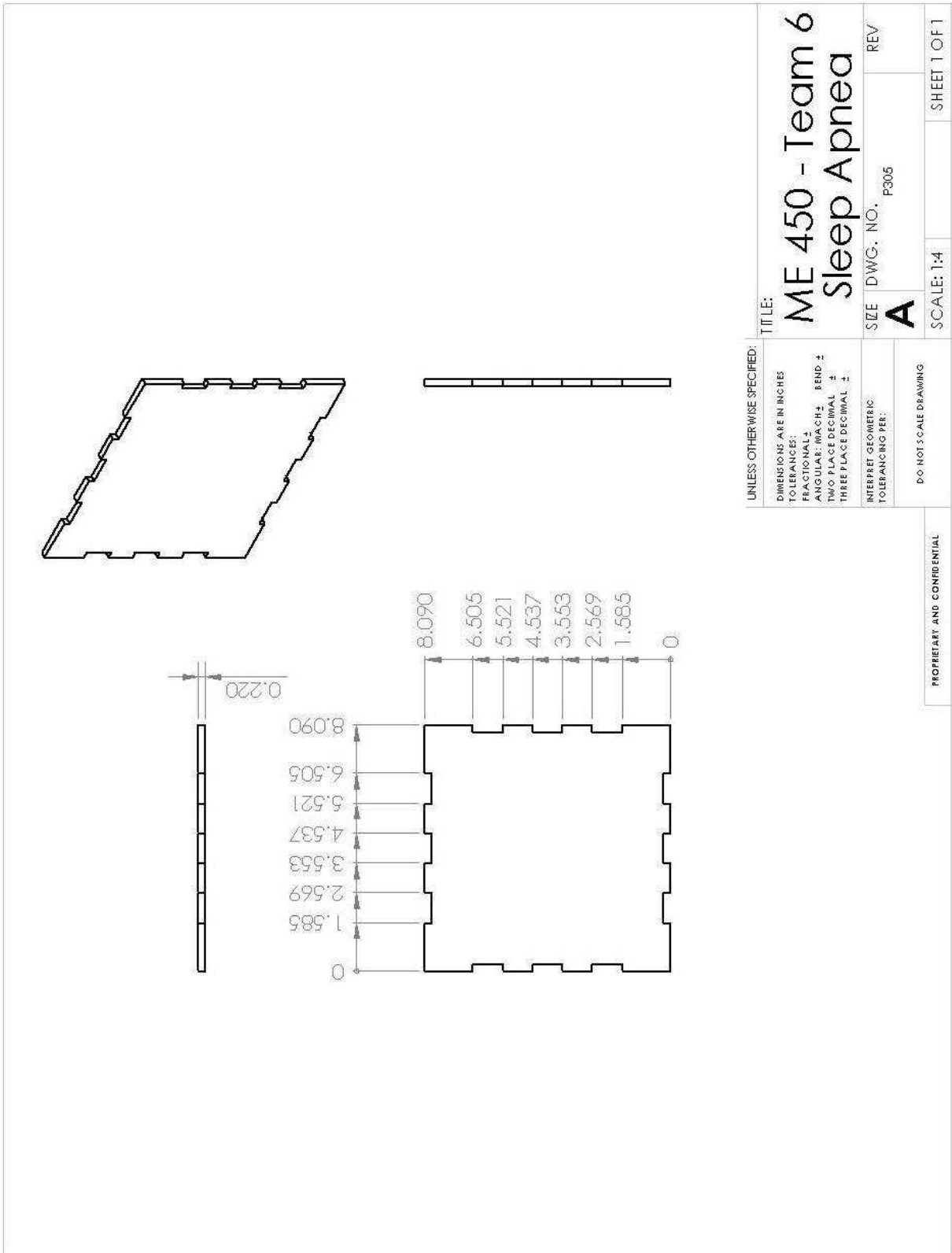
Box Back Panel



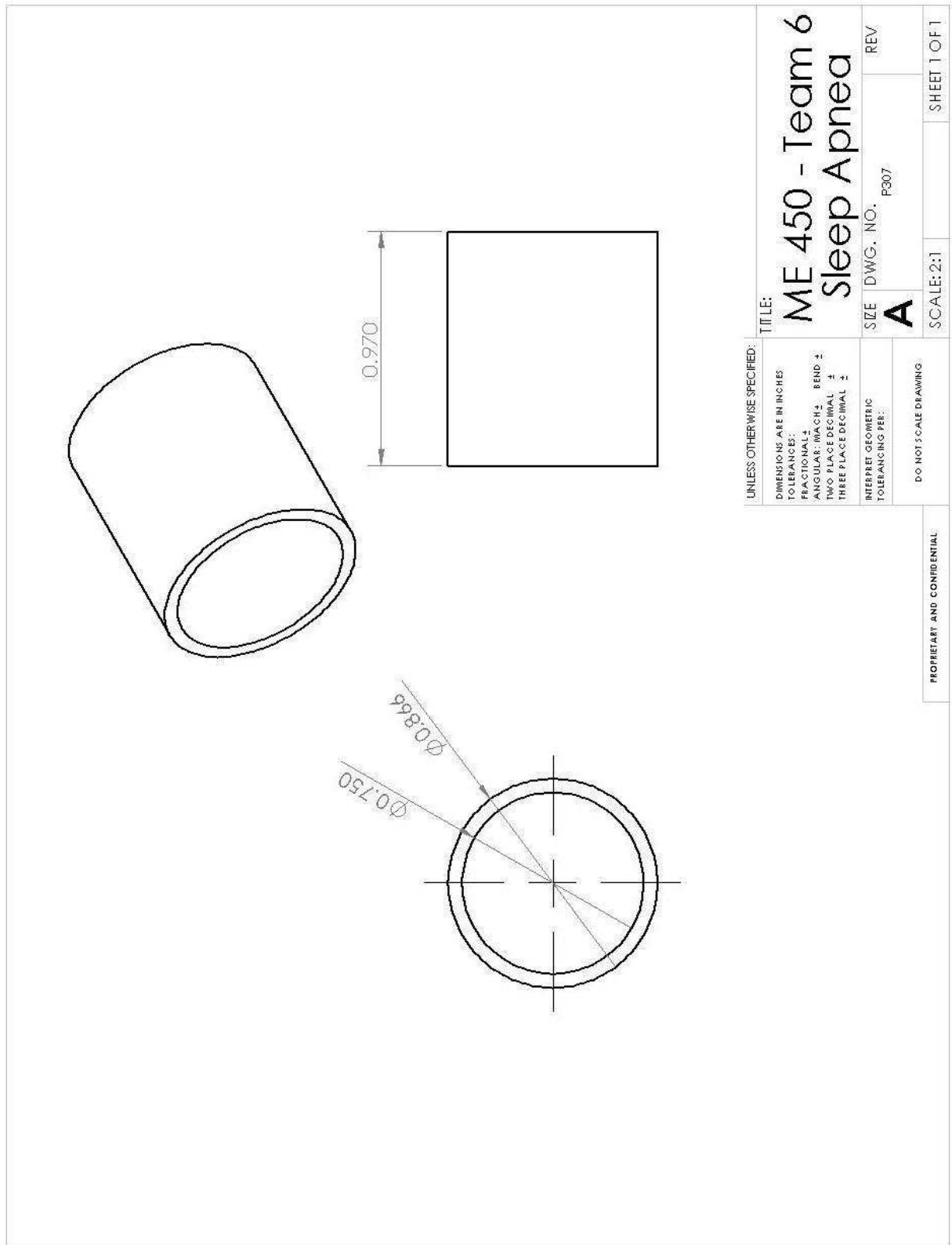
Box Side Panel (x2)



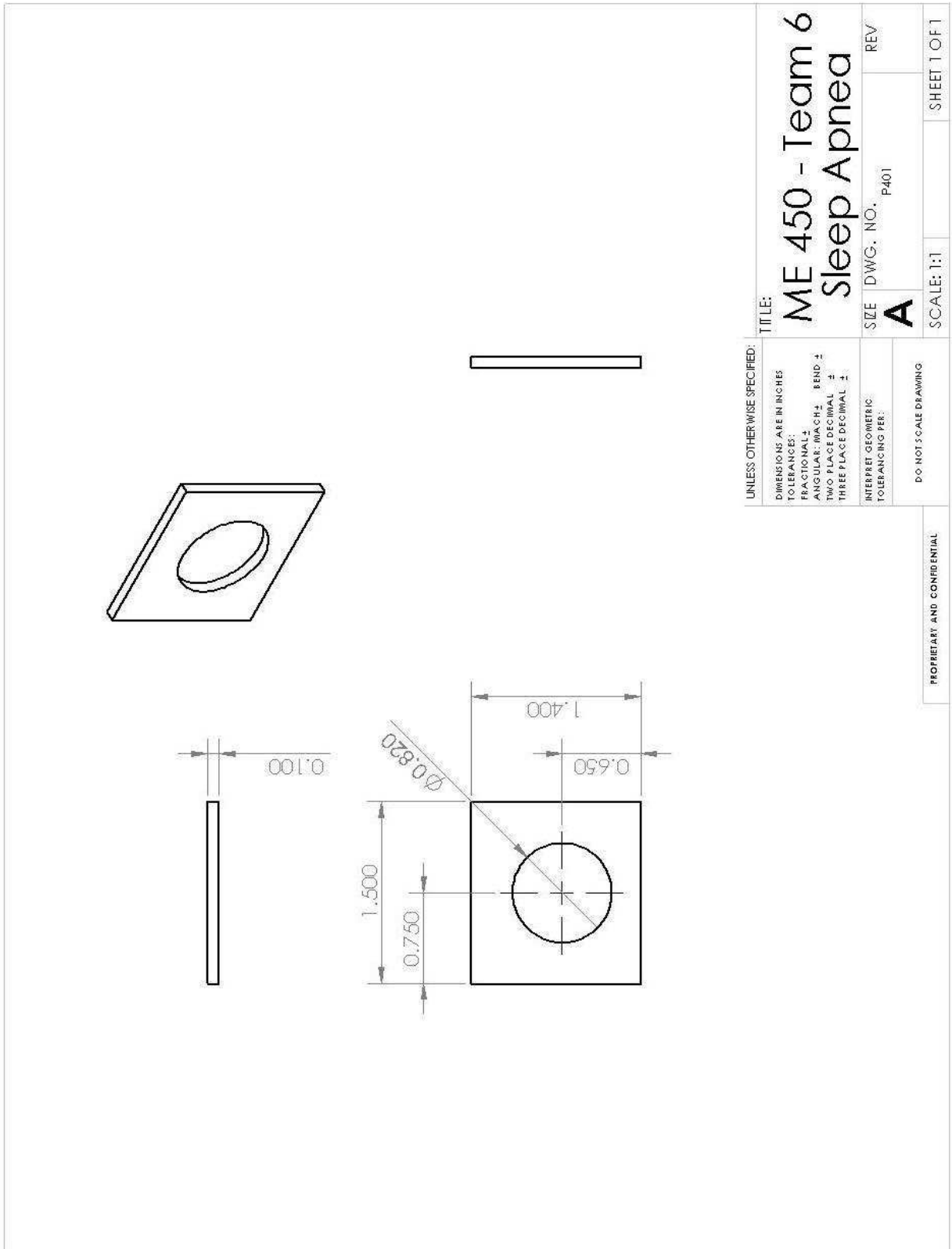
Box Top & Bottom Panels



Air outlet – Hose attachment connector 1



Valve Flap Attachment (Blocker)



UNLESS OTHERWISE SPECIFIED:

- DIMENSIONS ARE IN INCHES
- TOLERANCES:
- FRACTIONAL ±
- ANGULAR: MACH ± BEND ±
- TWO PLACE DECIMAL ±
- THREE PLACE DECIMAL ±

INTERPRET GEOMETRIC TOLERANCING PER:

TITLE:

ME 450 - Team 6
Sleep Apnea

SIZE DWG. NO. P401 REV

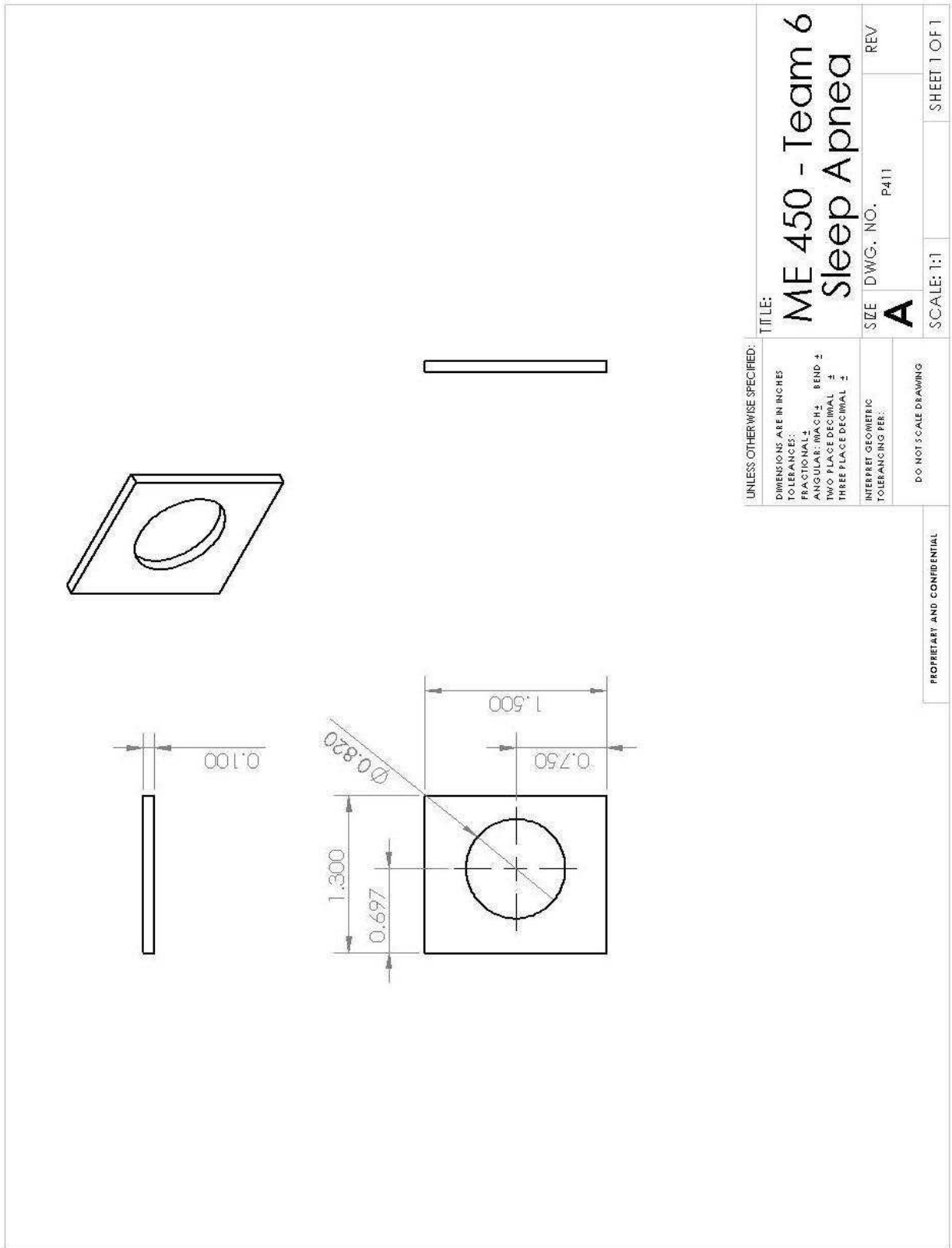
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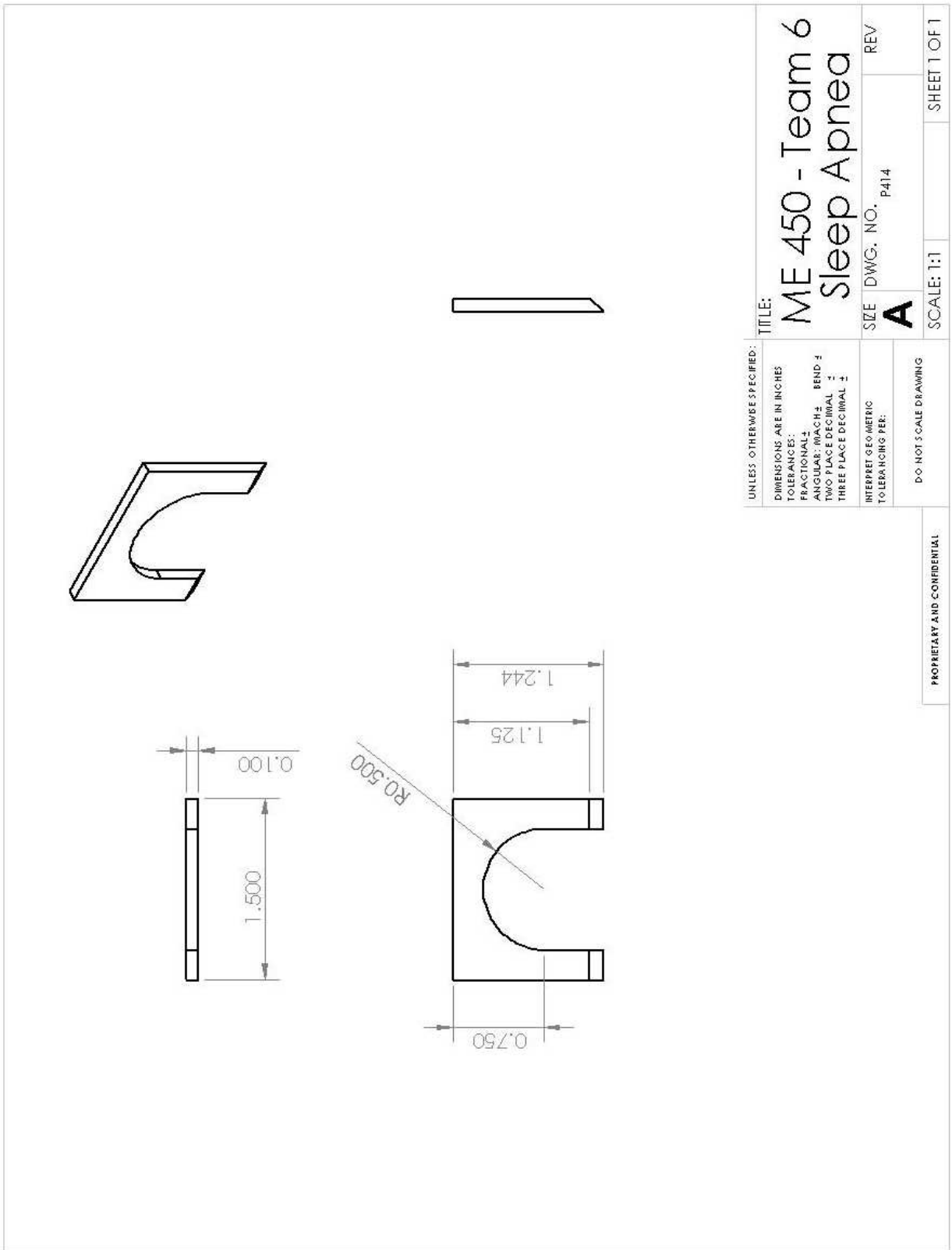
SHEET 1 OF 1

PROPRIETARY AND CONFIDENTIAL

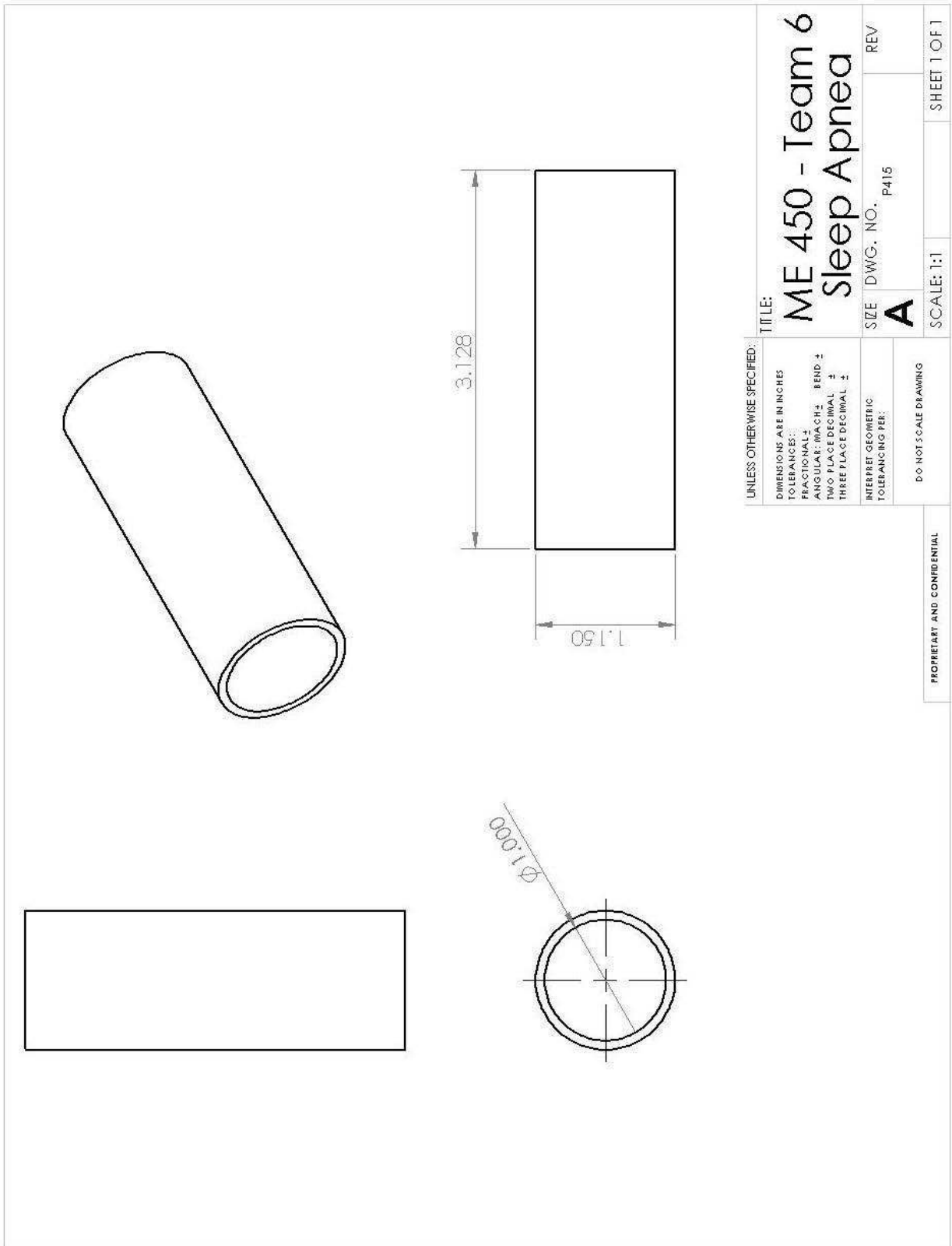
Valve Flap Attachment (Release)



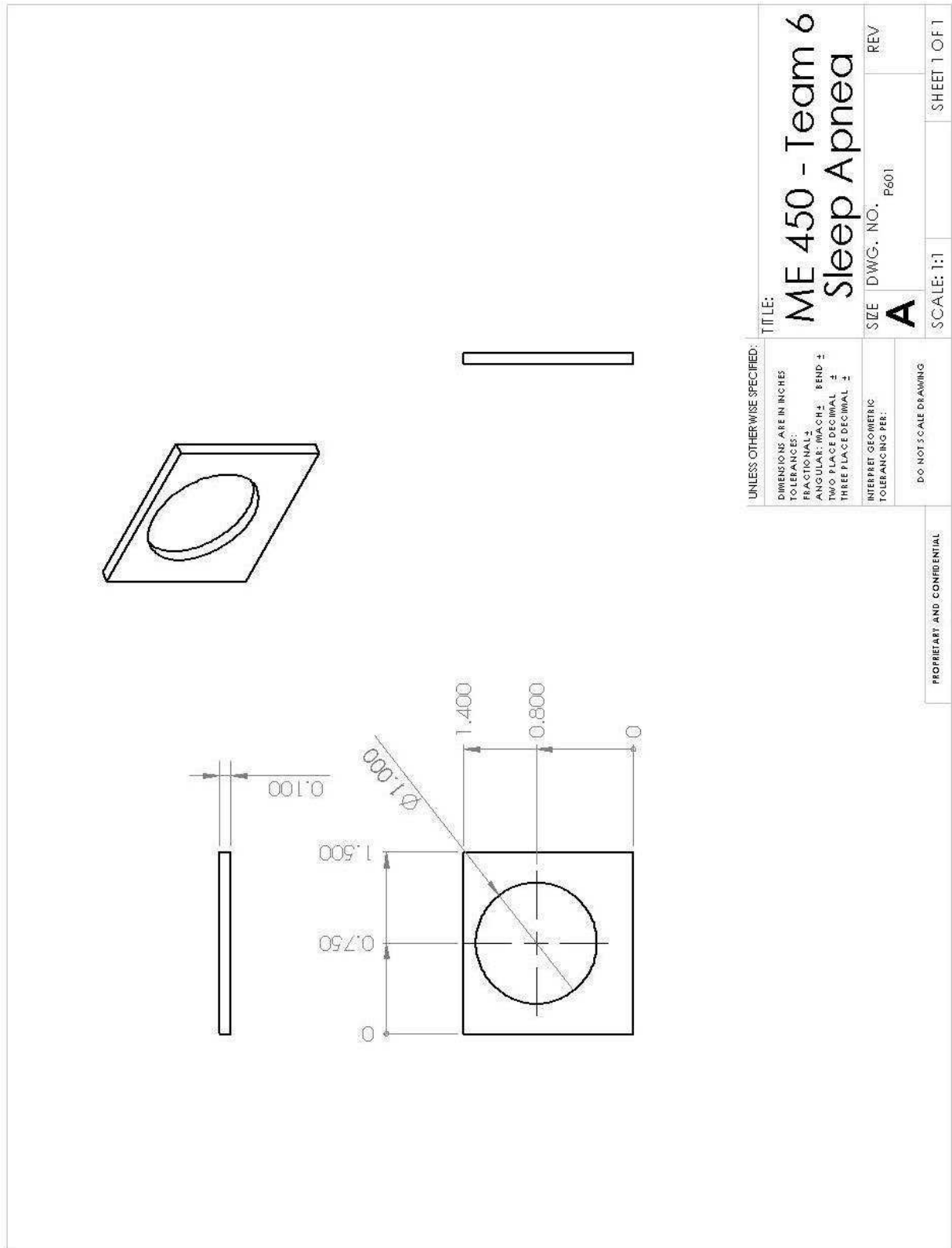
Rubber valve flap holder



Air outlet – Hose attachment connector 2



Rubber Flap Holder



UNLESS OTHERWISE SPECIFIED:

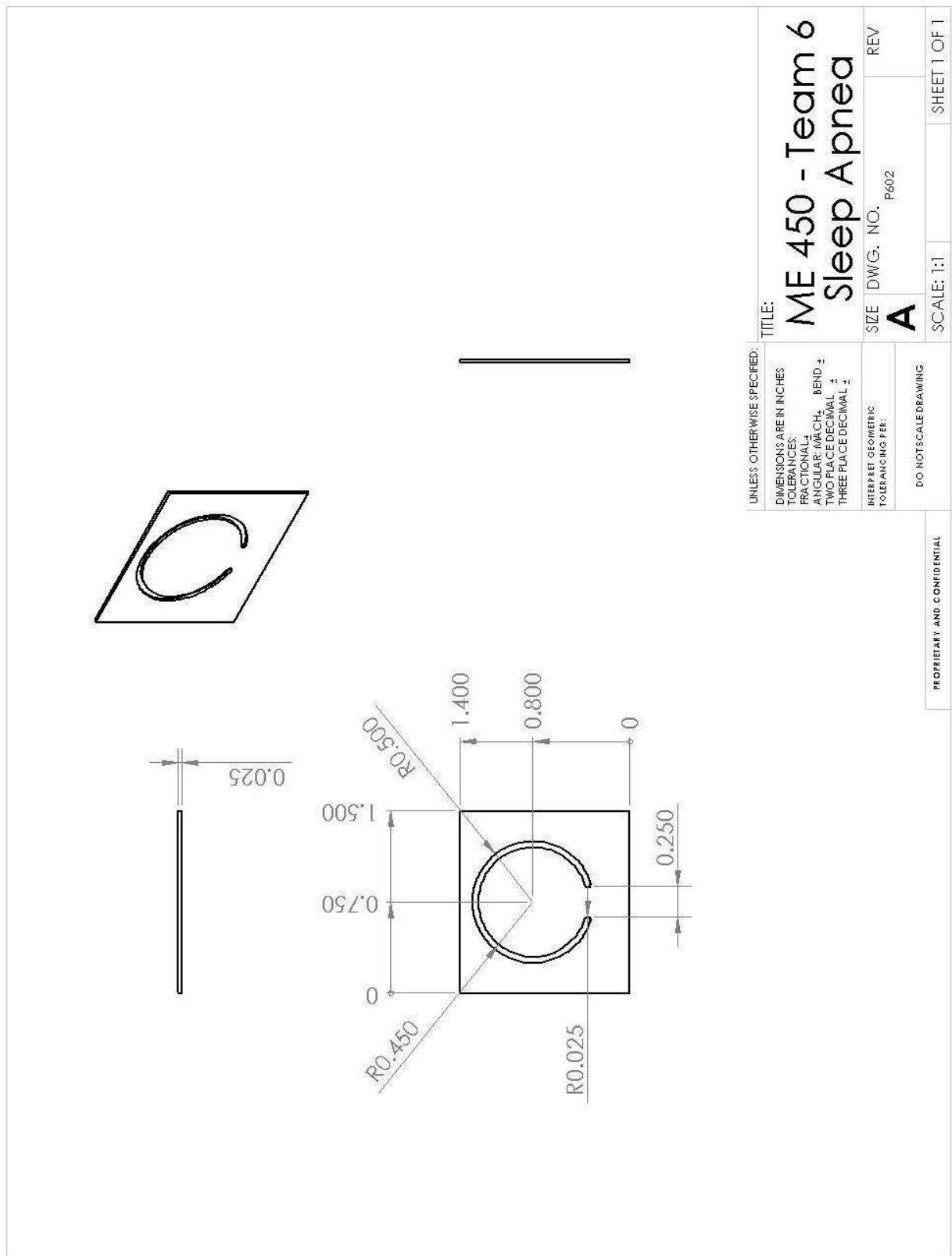
DIMENSIONS ARE IN INCHES
 TOLERANCES:
 FRACTIONAL: ±
 ANGULAR: MACH ± BEND ±
 TWO PLACE DECIMAL ±
 THREE PLACE DECIMAL ±

INTERPRET GEOMETRIC
 TOLERANCING PER:

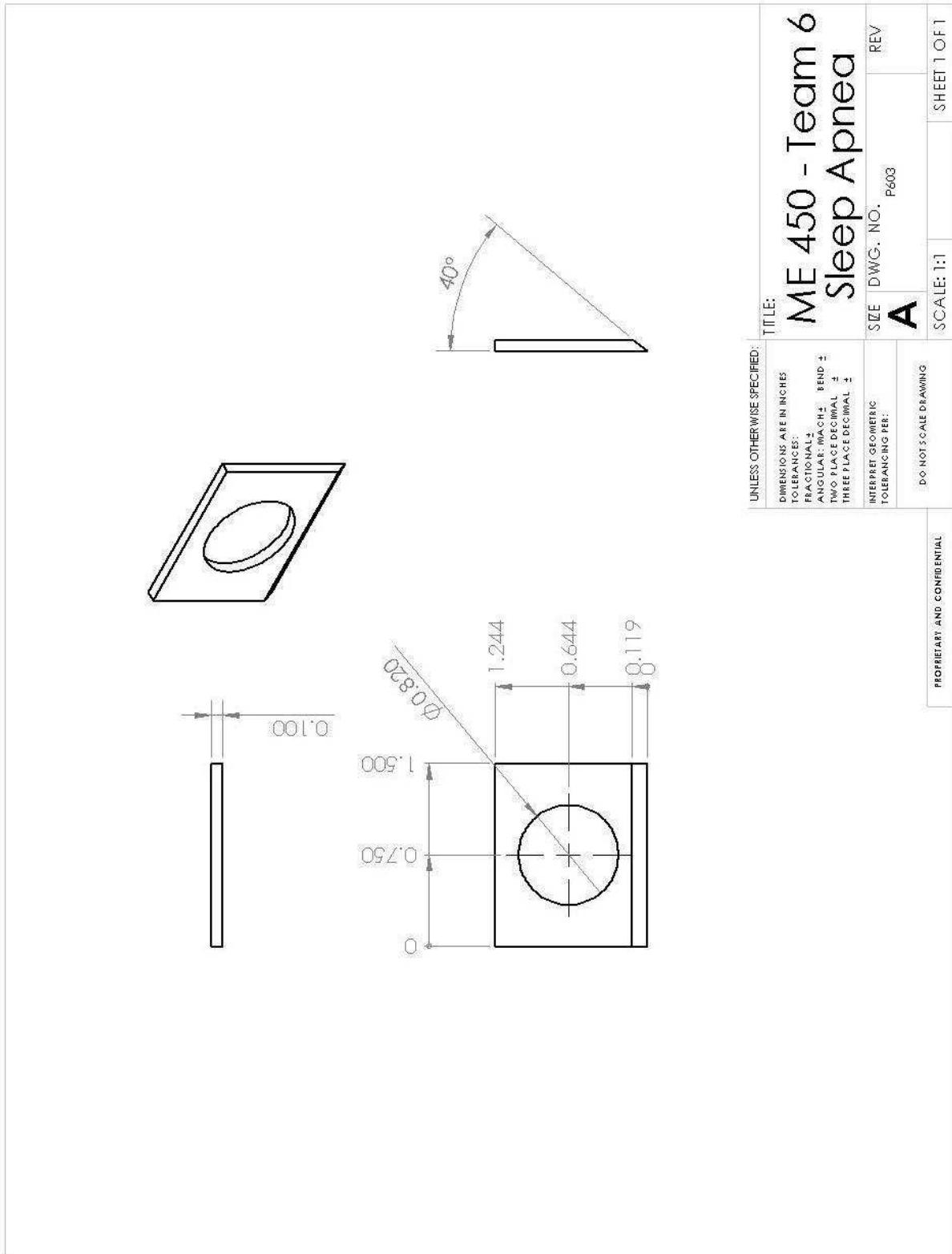
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ME 450 - Team 6	
Sleep Apnea	
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A	REV
SCALE: 1:1	SHEET 1 OF 1

PROPRIETARY AND CONFIDENTIAL
 DO NOT SCALE DRAWING

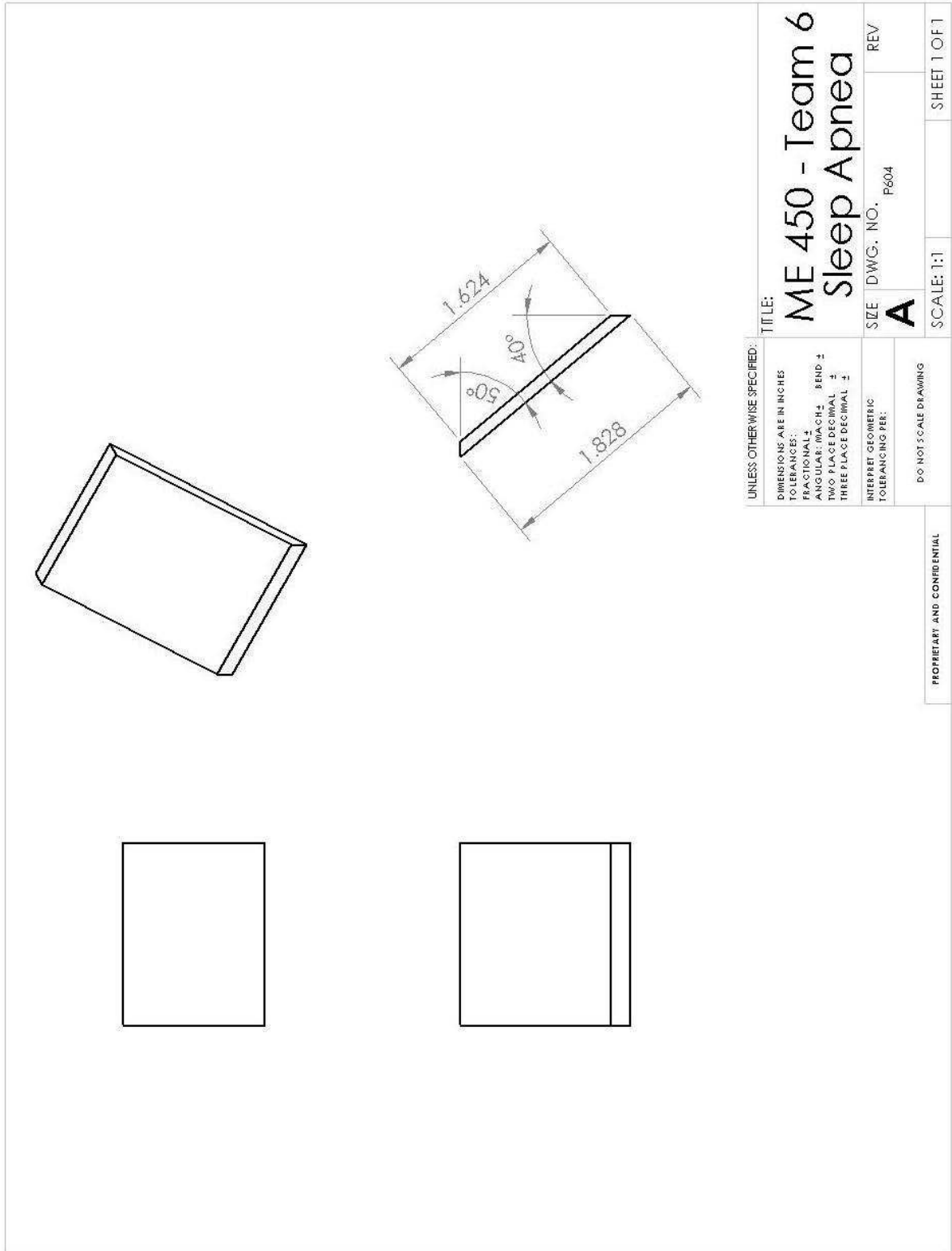
Rubber Flap with Square Perimeter



Rubber Flap Support



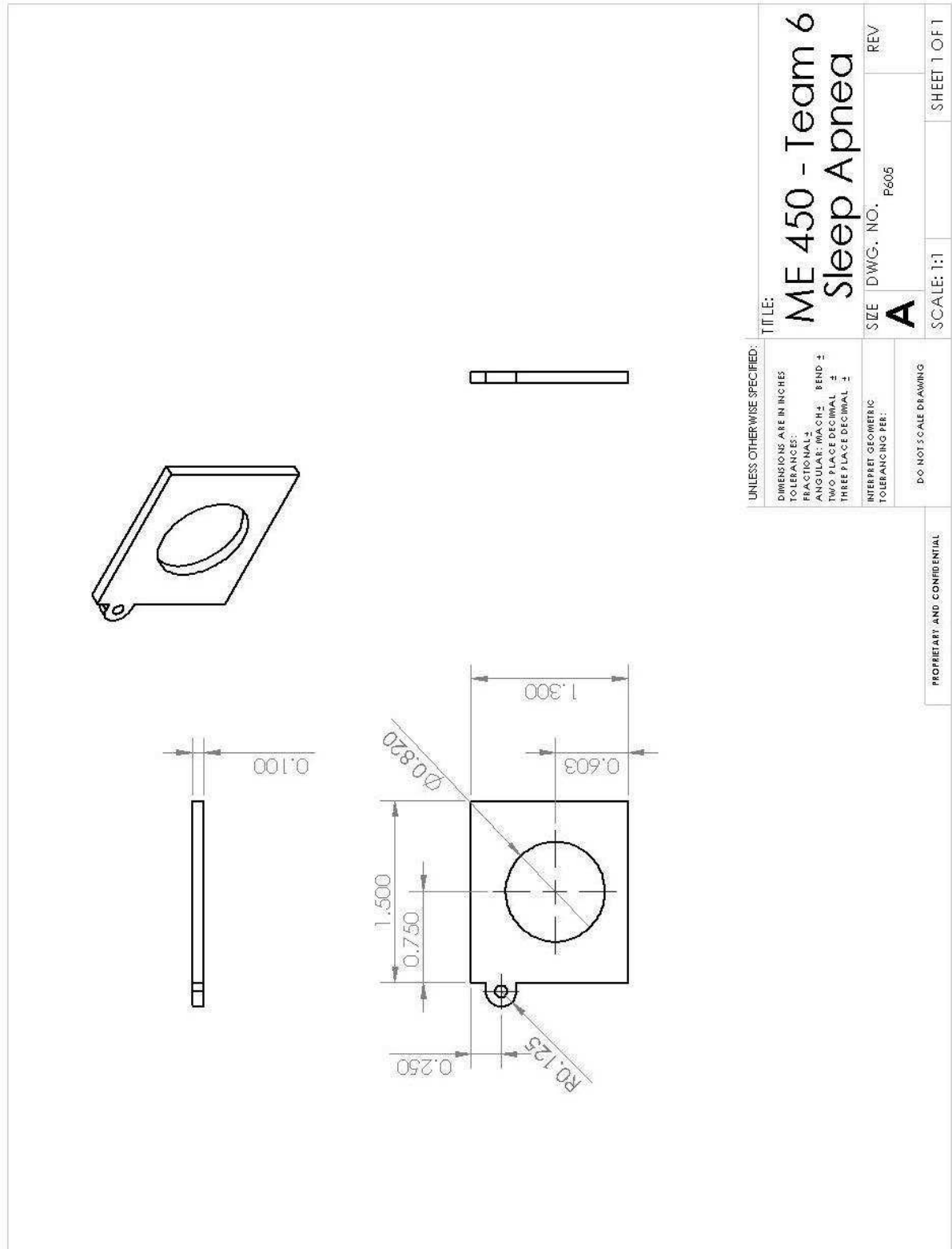
L-shaped Valve Elbow



UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± DECIMAL: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	TITLE:	ME 450 - Team 6 Sleep Apnea	
	SIZE: DWG. NO. P604	REV	
INTERPRET GEOMETRIC TOLERANCING PER:	A		
DO NOT SCALE DRAWING	SCALE: 1:1		SHEET 1 OF 1

PROPRIETARY AND CONFIDENTIAL

Rubber Flap Holder



UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN INCHES
 TOLERANCES:
 FRACTIONAL: ±
 ANGULAR: MACH ± BEND ±
 TWO PLACE DECIMAL ±
 THREE PLACE DECIMAL ±

INTERPRET GEOMETRIC
 TOLERANCING PER:

DO NOT SCALE DRAWING

TITLE:

ME 450 - Team 6
 Sleep Apnea

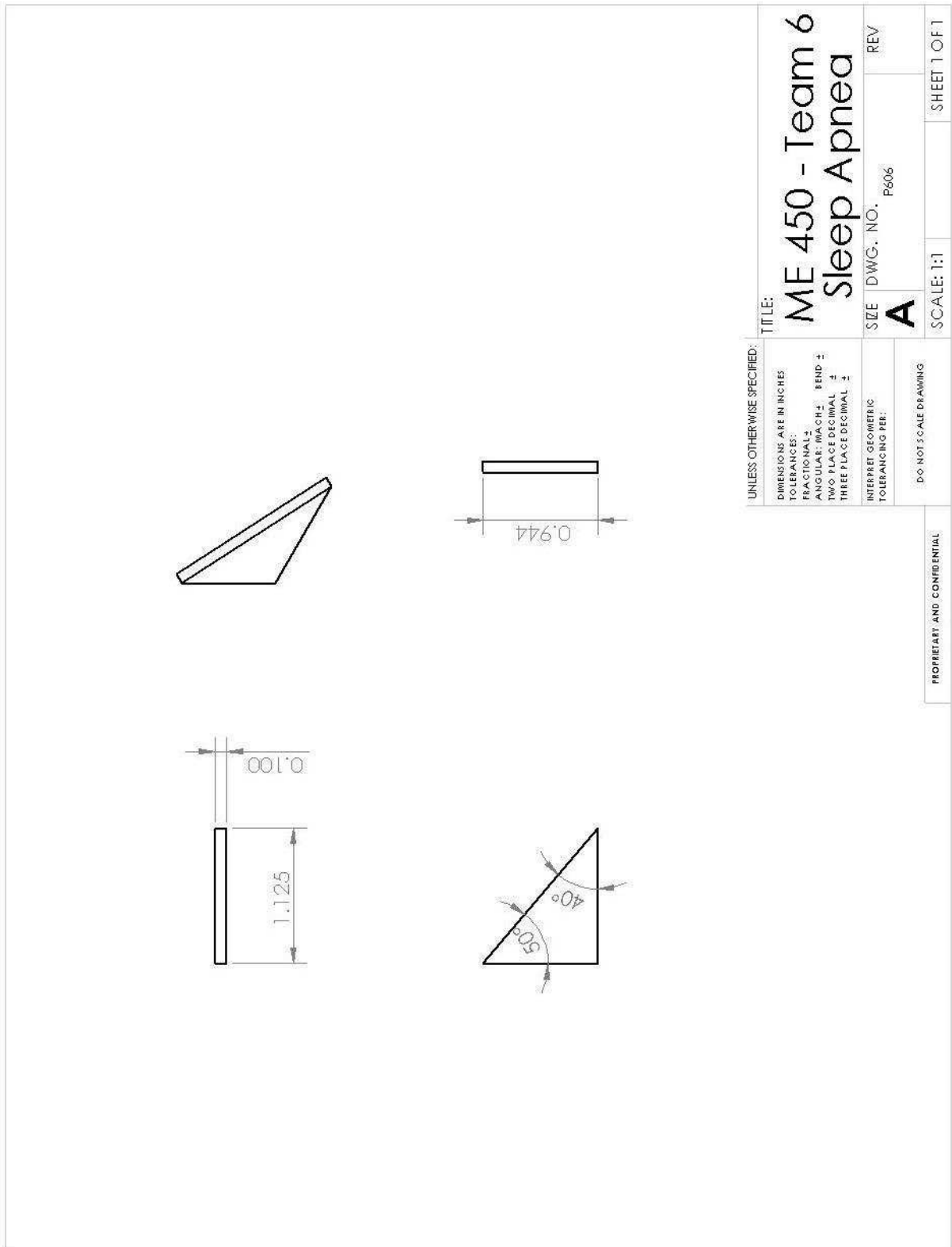
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 A REV

SCALE: 1:1

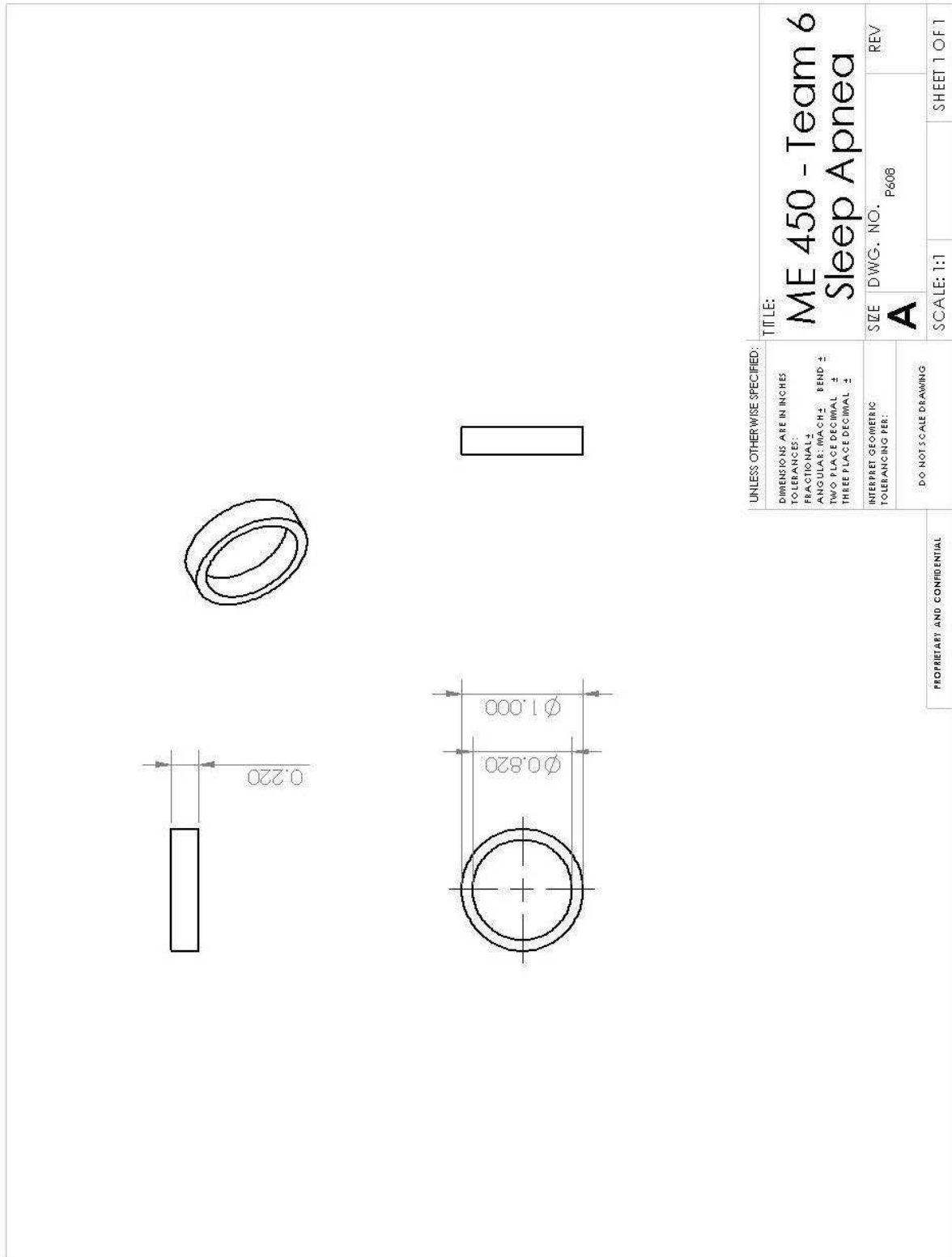
SHEET 1 OF 1

PROPRIETARY AND CONFIDENTIAL

Valve Flap Side Support



Round Rubber Flap Holder 1



UNLESS OTHERWISE SPECIFIED:
 DIMENSIONS ARE IN INCHES
 TOLERANCES:
 FRACTIONAL: ± 0.005
 ANGULAR: ± 0.0315°
 TWO PLACE DECIMAL: ± 0.005
 THREE PLACE DECIMAL: ± 0.001

TITLE:
ME 450 - Team 6
Sleep Apnea

SIZE: **A** DWG. NO. P608 REV
 SCALE: 1:1 SHEET 1 OF 1

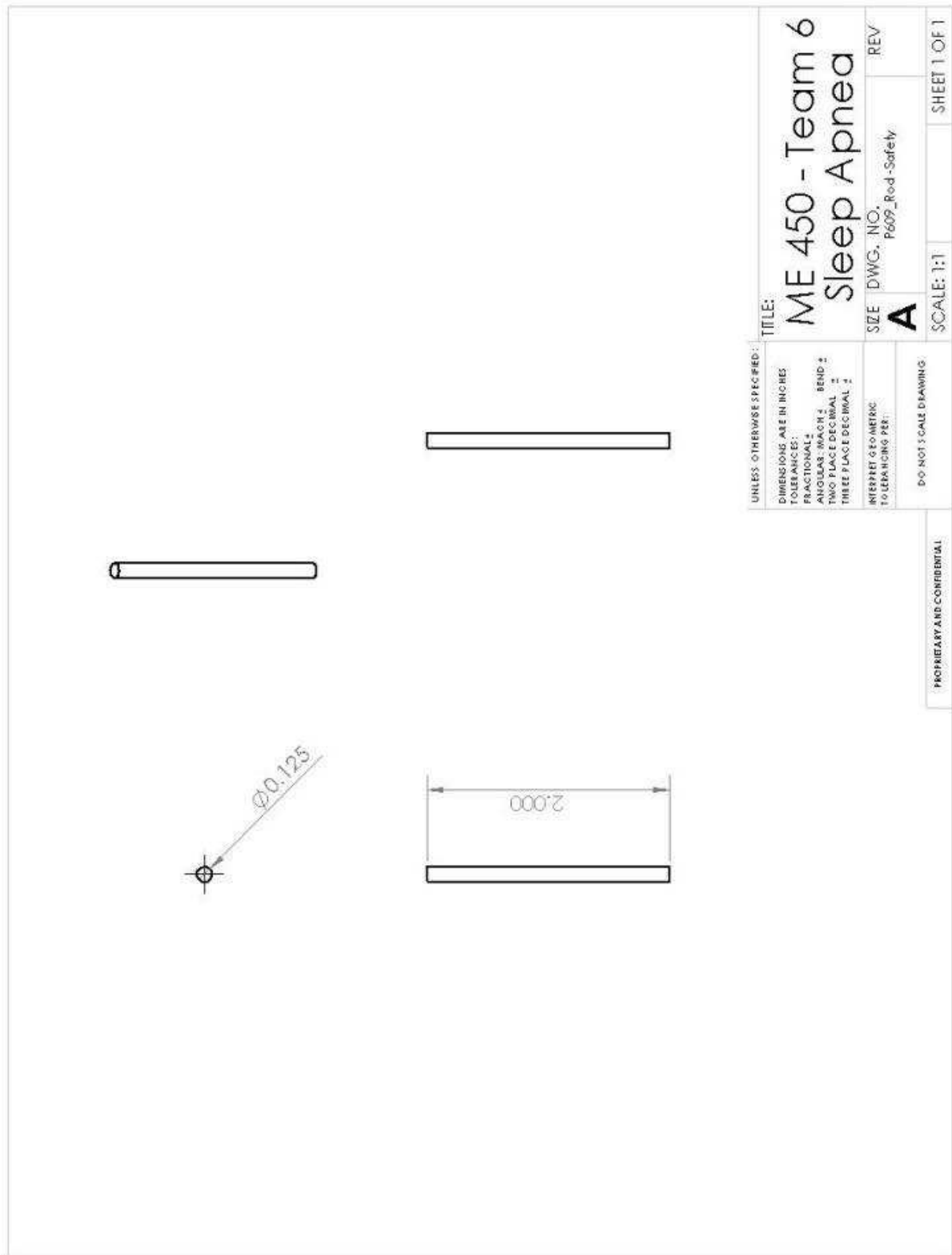
PROPRIETARY AND CONFIDENTIAL

DO NOT SCALE DRAWING

INTERPRET GEOMETRIC TOLERANCING PER:

ANGULAR: ± 0.0315°
 BEND: ± 0.0315°
 TWO PLACE DECIMAL: ± 0.005
 THREE PLACE DECIMAL: ± 0.001

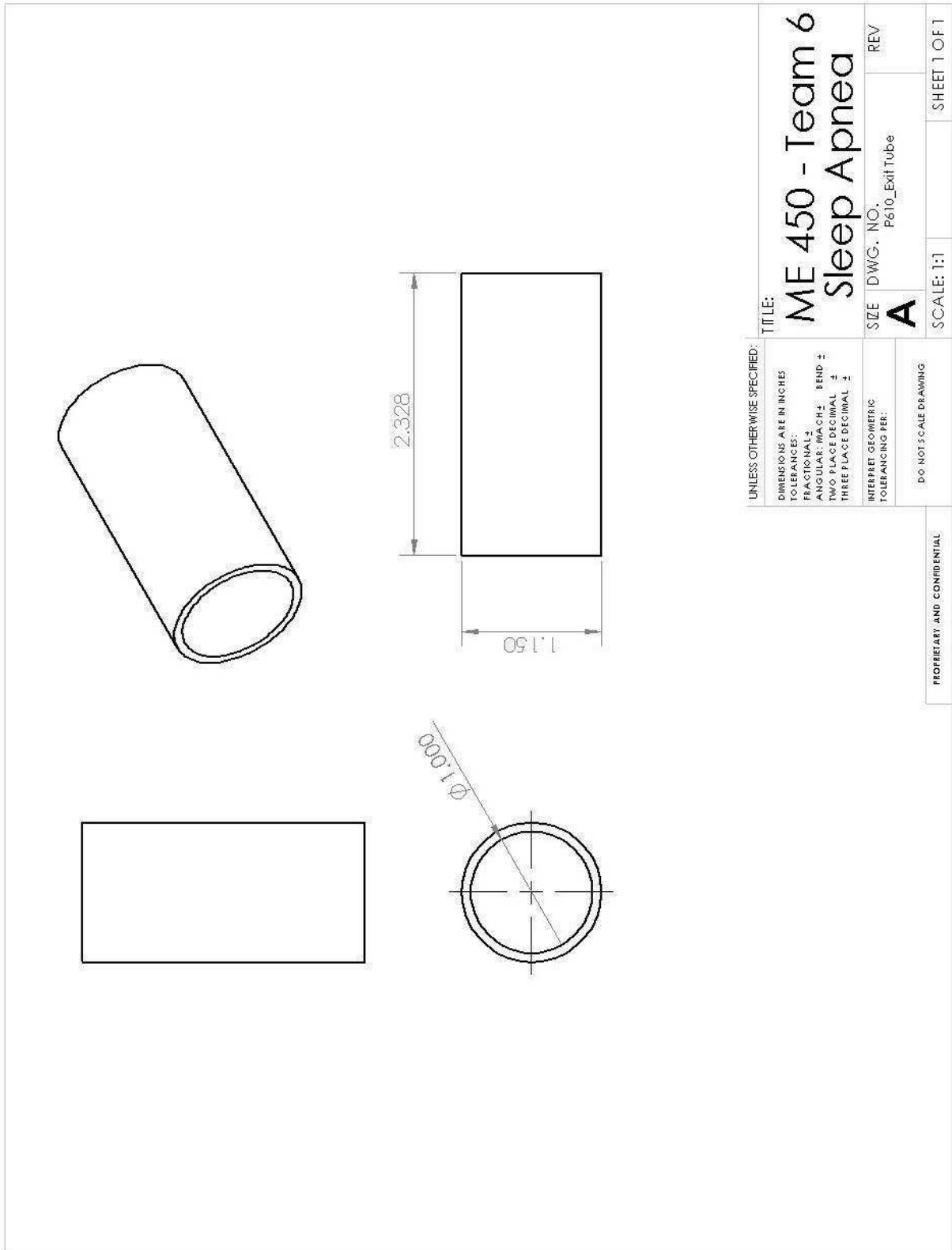
Safety valve Rod Pusher



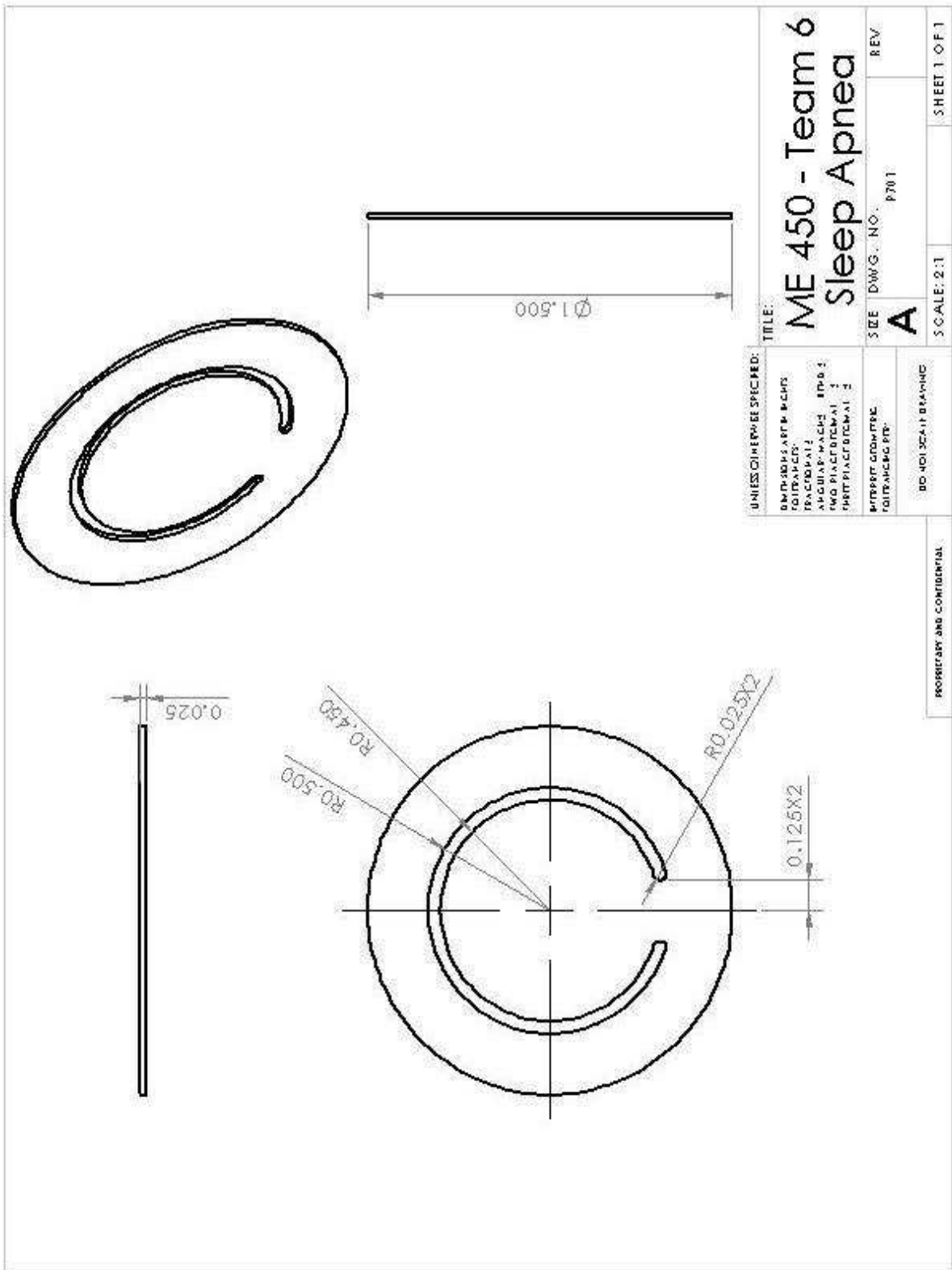
UNLESS OTHERWISE SPECIFIED:	TITLE:
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TOLERANCES:	Sleep Apnea
FRACTIONAL: 1/16	SIZE DWG. NO. P609_Rod - Safety
ANGLES: WAGON 1/2 BEND 1/2	REV
TWO PLACE DECIMAL 1/32	A
THREE PLACE DECIMAL 1/64	SCALE: 1:1
INTERPRET GEOMETRIC TO LEADING PER:	SHEET 1 OF 1
DO NOT SCALE DRAWING	

PROPRIETARY AND CONFIDENTIAL

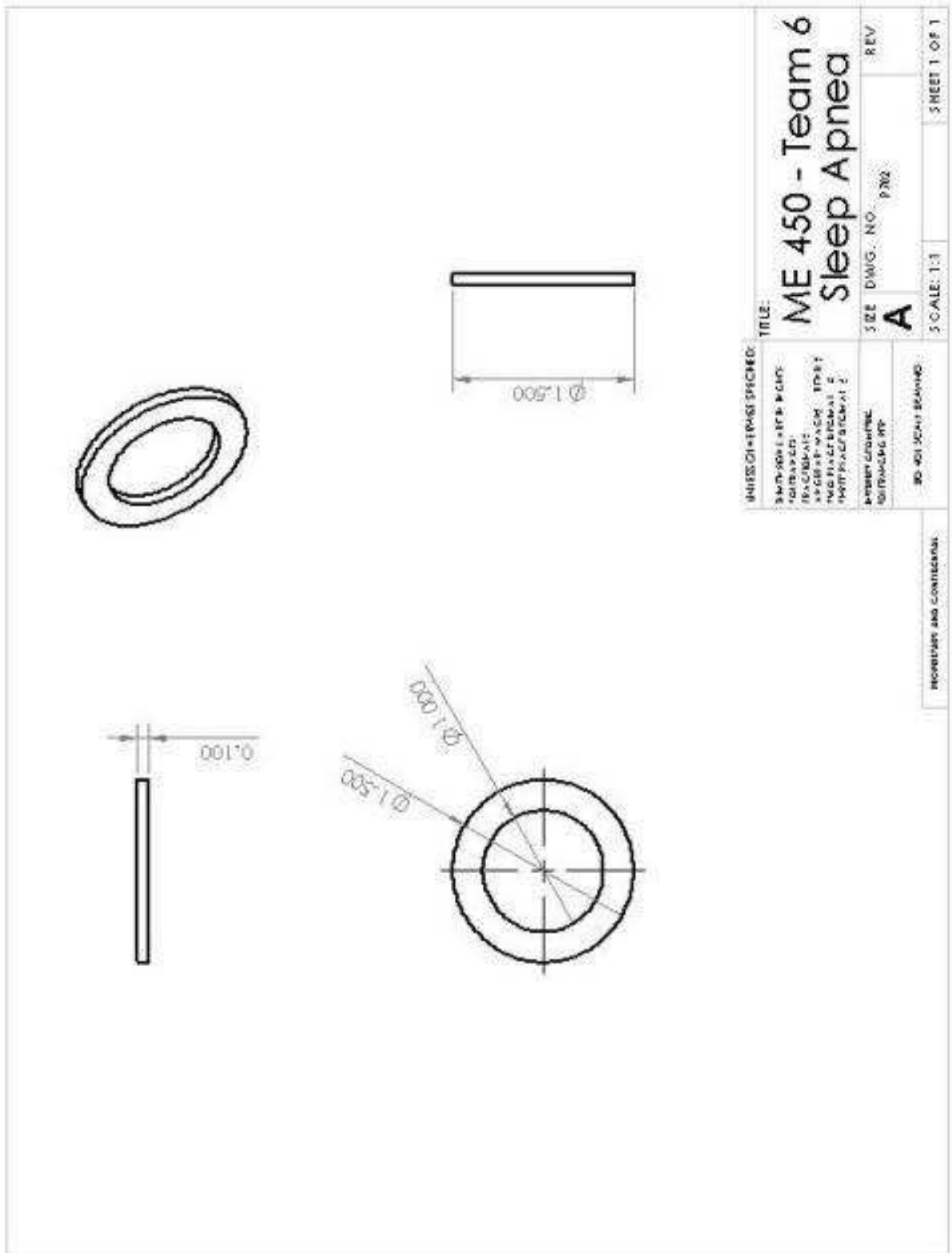
Exit Tube



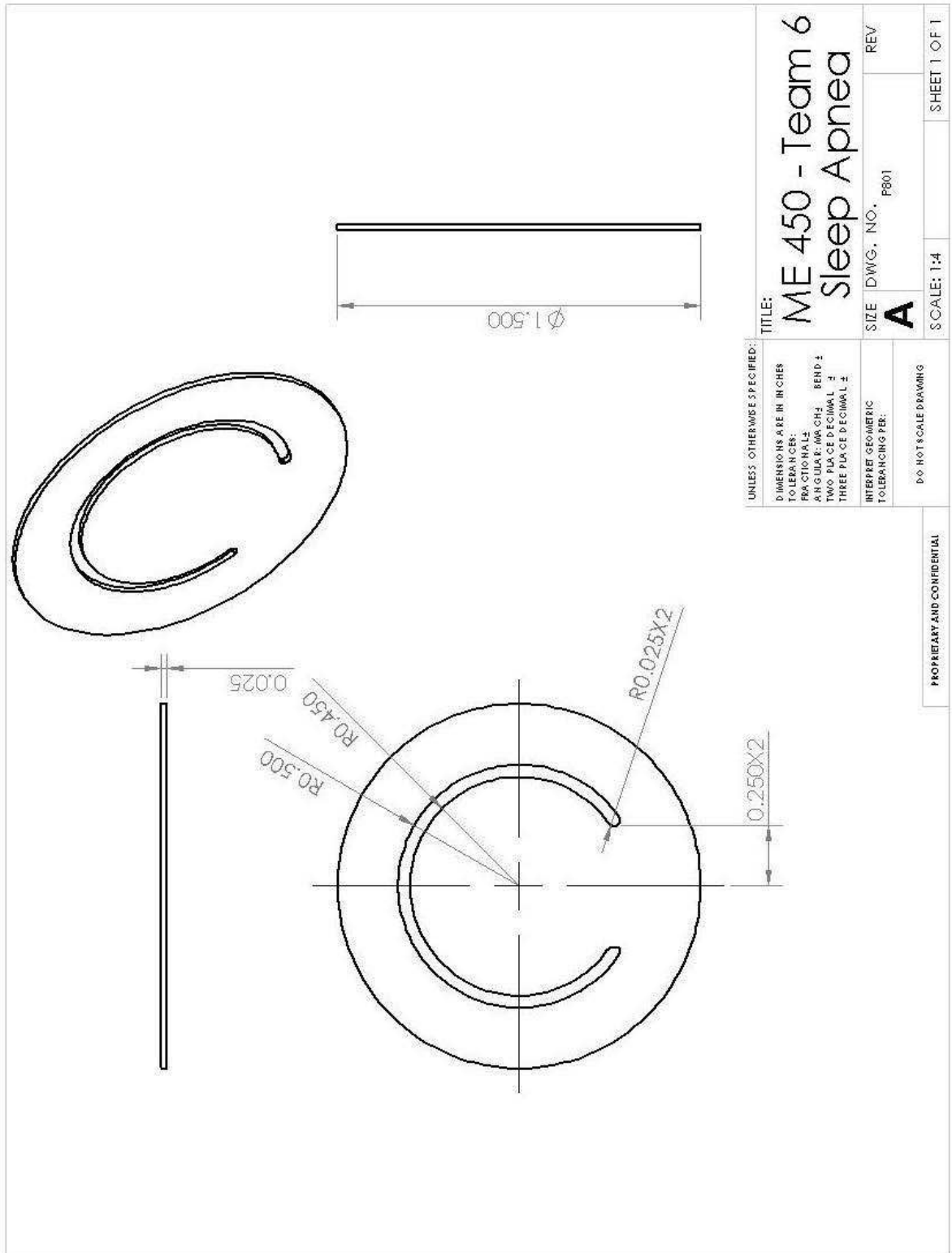
Rubber Flap with Round Perimeter 1



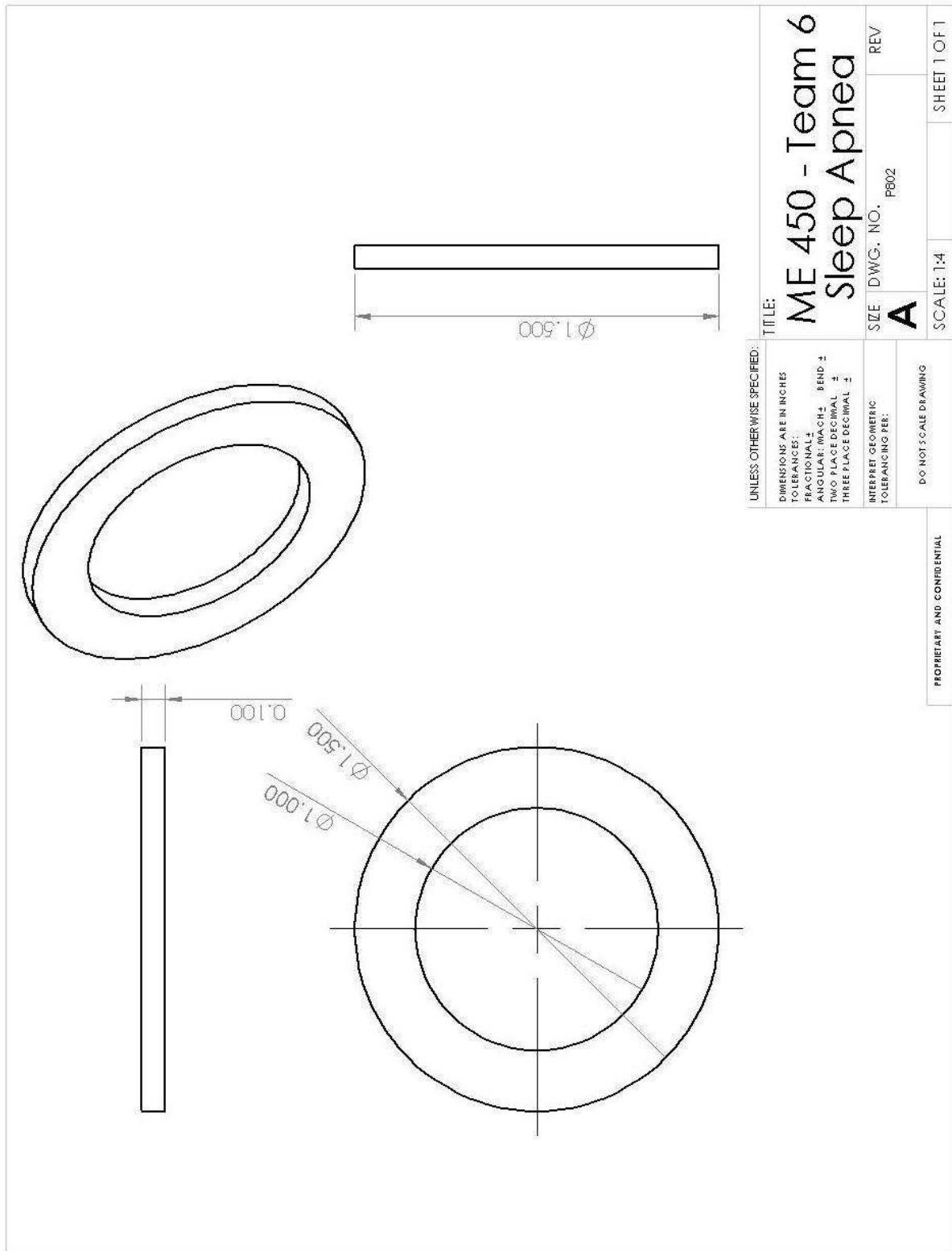
Round Rubber Flap Holder 2



Round Rubber Flap Holder 2



Round Rubber Flap Holder 3



5. **Manufacturing**. Provide a list of all fabrication or manufacturing activities you will perform. Where will these activities take place? Why are these processes necessary?
- CAD drawings for parts to be manufactured are required (per #4 above).
 - For machining or forming processes, list special setup requirements and the operational conditions that will be employed (e.g., speeds, feeds, etc.).

5.1 Air Chambers

The air chambers will be cut to length from vinyl ventilation duct tubing (Figure 1) using wire cutters and scissors. Scissors are sufficient to cut through the vinyl duct as the duct itself is made out of thin plastic sheet material. The spring-shaped wire that guides the shape of the duct can also be cut easily using wire cutters instead of using other elaborate cutting methods.



Figure 1: Vinyl ventilation duct to be cut into sections to make air chambers

5.2 Box/plates

The box and plates will be made from .22" thick acrylic cut using the laser cutter in the ME machine workshop. To optimize our usage of the material, we arranged the shapes to be cut as shown in the CAD drawing in Figure 2a and 2b. The lines and curves on each acrylic sheet (rectangular boxes) are the contours to be cut out. The small holes in Figure 2b will be cut using the laser cutter as well. The holes where the rods are to be put in have dimensions of 0.1". Some of these holes will be enlarged to the desired size using 1/8" and #23 drill bits and a mill in the workshop. This is done so that we could get a more accurate center cut on the small holes before using the drill.

The rods are to be inserted into the holes that will be the guide for a moving part in the device. It is important that these holes have tight tolerances and be located in the right place on the acrylic sheet. It is difficult to center the drill bit correctly due to parallax and human errors. The laser cutter is very accurate and could give us a high precision so that parts could fit on properly to one another. Some of our plates are circular and it is very difficult to do that using manual cutting methods. Furthermore, if we were to use other cutting methods such as band or hand saw, the cut edge will not be as smooth as when using laser cutter. No threading of the holes are necessary since there will be no parts to be fastened using screws.

The laser cutter will also be used to cut the shapes on Figure 2c. These shapes are components to the one-way and L-shaped valves that we will be manufacturing for the device.

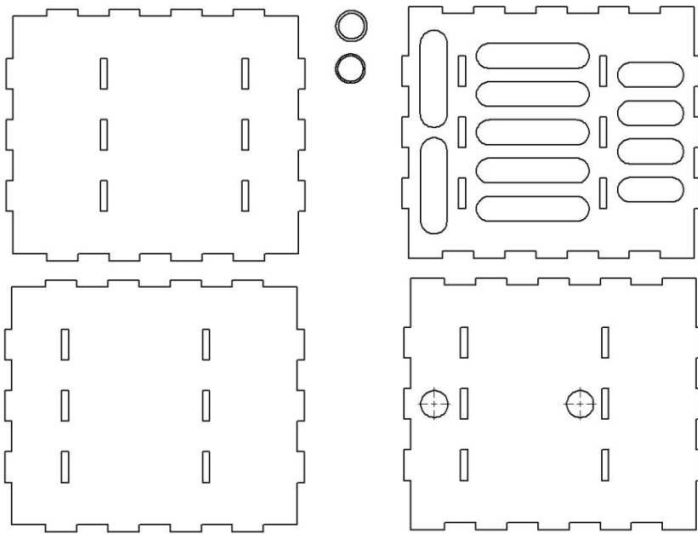


Figure 2a: The shapes to be cut out of 0.22" thick acrylic sheets. The shapes are for device box.

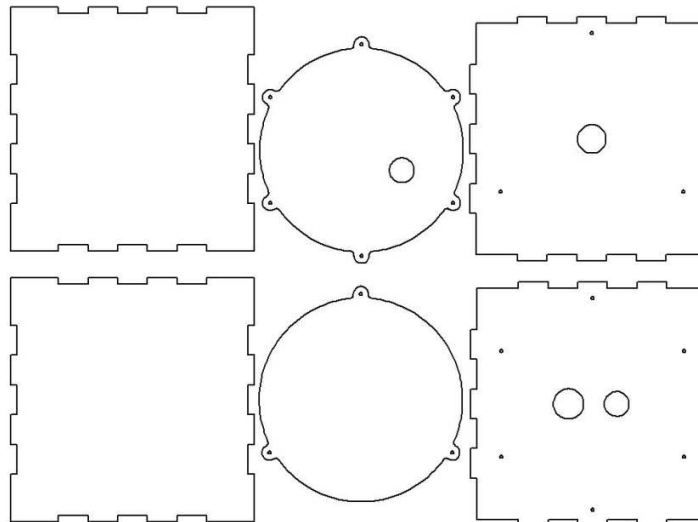


Figure 2b: The shapes to be cut out of 0.22" thick acrylic sheets. The shapes are for the fixed and moving plates of the device.

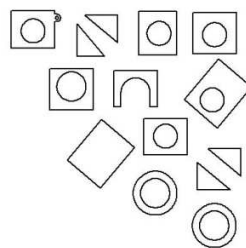


Figure 2c: The shapes to be cut out of 0.1" thick acrylic sheets. The shapes are for the components of the valves.

5.3 Valves

The valves will be made by cutting rubber sheets to size with scissors as shown in Figure 3. The outer area of the cut rubber pieces will be glued onto the plates as shown in Figure 4. The pivoting edge of the rubber piece will be the functional portion of the one-way valve. For the back-flow stopping valve, an acrylic Y-shaped tubing connector shown in Figure 5 will be cut using the plastic band saw in the ME undergraduate workshop. A rubber piece will be glued to two plates; the Y-shaped connector will be glued back together with epoxy.

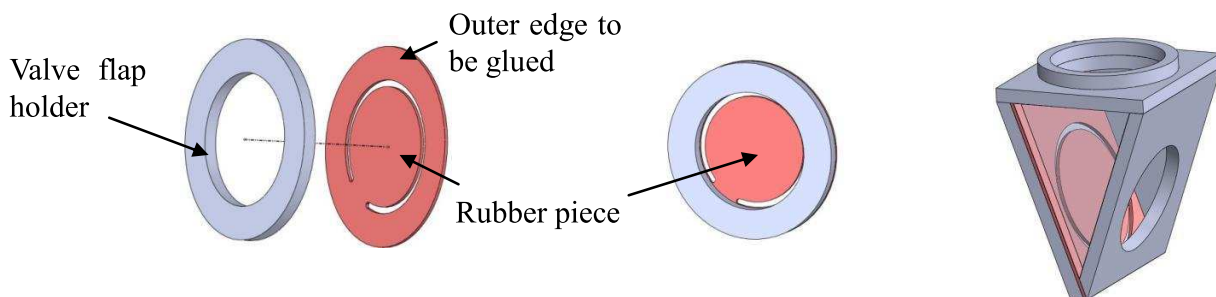


Figure 3: Valve plate and rubber piece Figure 4: One-way valve Figure 5: Y-shaped valve

The L-shaped valves are to be manufactured as shown in the Figure 6. The ring top of the L-shaped valves of the device will be attached to the holes on the fixed square plates using epoxy. The difference of the L-shaped valves for the fresh air chamber and the used air chamber is shown in Figure 7a and 7b respectively.

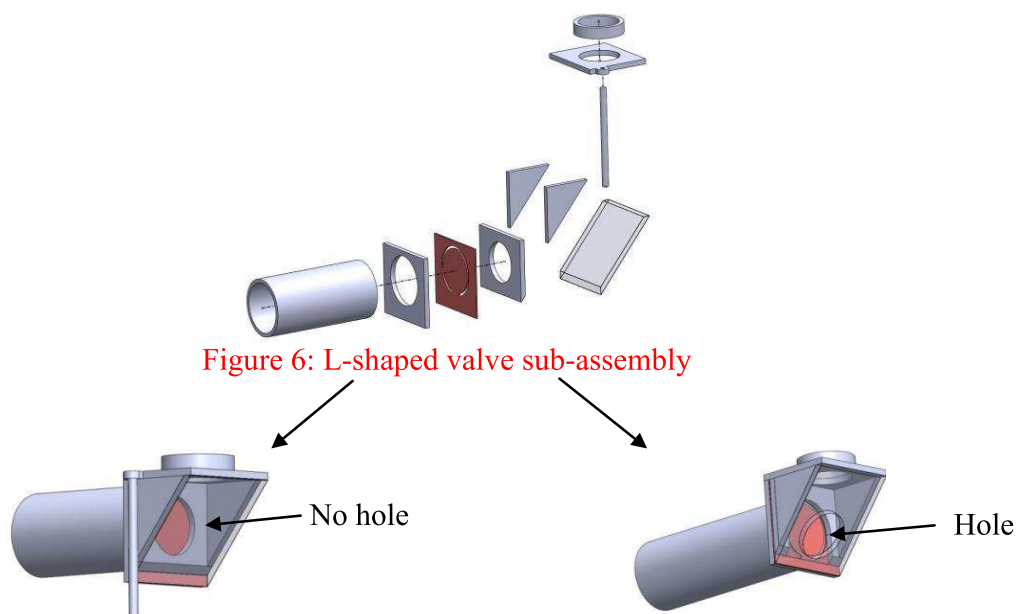


Figure 7a: Fresh Air Chamber L-shape valve without a hole on the other side as its only function is to let fresh air flow into a patient's breathing passage.

Figure 7b: Used Air Chamber L-shape valve with a hole on the other side to let used air out when air chamber is deflated.

5.4 Linkage Rods

The linkage rods are made from 1/8" steel rod cut to length using a hack saw in the workshop, six 7" rods and one 2" rod will be required. The ends will be smoothed using a file. A hack saw is used in this process because tight tolerances are not needed.

6. **Assembly**. How and where will your components be assembled? On what basis do you conclude that the assembly will not fail before use, during use, or after use?

The components are going to be assembled in the University of Michigan Mechanical Engineering (ME) machine shop under the supervision of Mr. Bob Coury and Mr. Dan Johnson.

Used Air Chamber (bottom) Sub-Assembly

The used air chamber sub-assembly consists of the system that will receive exhaled air from the patient/user and be the platform for the moving plates to be supported. Figure 8 below shows a CAD model of the used air chamber sub-assembly.

The used air chamber sub-assembly was constructed using the following steps:

4. Adhere a cut vinyl air chamber onto the square base plate with one valve hole.
5. Place three 7" linkage rods onto the holes on the square base plates such that the top parts of the rods are exposed.
6. Position the bottom round plate such that the three exposed rods are slid into three holes which are not next to each other. This is done while the rods are perpendicular to the square base plate.
7. Adhere the opposite side of the vinyl air chamber onto the round plate.

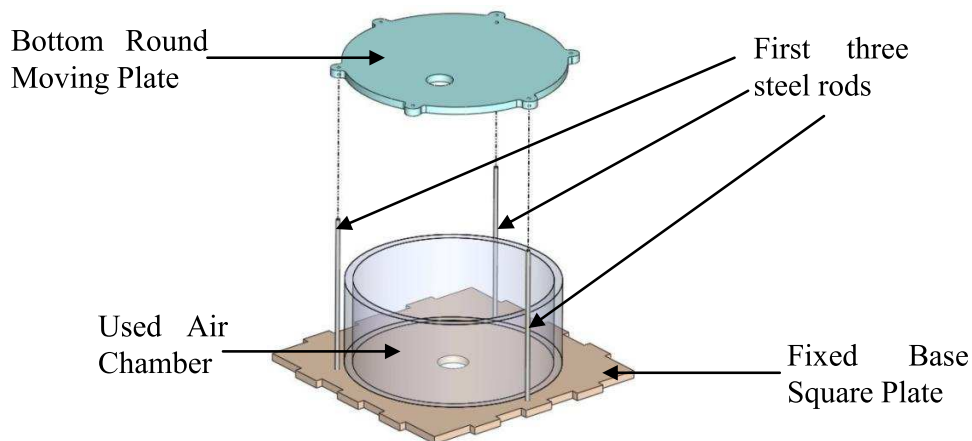


Figure 8. Used air chamber sub-assembly CAD model

Fresh Air Chamber (top) Sub- Assembly

The fresh air chamber sub-assembly consists of the system that will be inflated as the used air chamber is being filled with exhaled air through the motion of the linked moving plates. The fresh air chamber will also provide the continuous air pressure to treat sleep apnea.

The fresh air chamber sub-assembly was constructed using the following steps as shown in Figure 9a and 9b:

5. Slide in the square base plate with two valve holes onto the first three rods exposed from the used air chamber assembly.
6. Insert the remaining three rods into the rest of the three holes on the first round plate.
7. Adhere the other vinyl air chamber onto the top part of the square base plates.
8. Position the remaining round plate such that the top three rods slide into the remaining holes then adhere the opposite side of the vinyl air chamber onto the round plate as in Figure 9b.

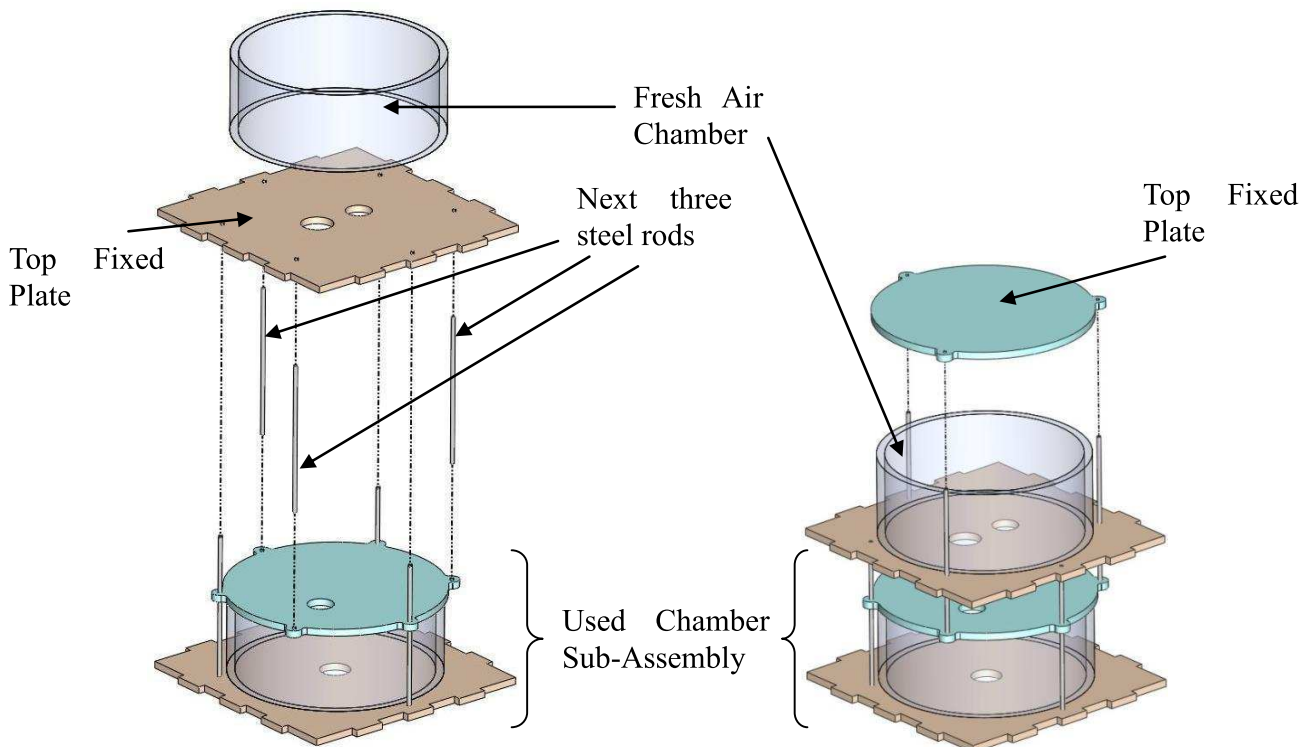


Figure 9a: Step 1, 2 and 3

Figure 9b: Step 4

Valve Sub-Assembly

The next step of the assembly is to attach the L-shaped valves and the one-way valve onto their respective holes as shown in Figure 10a and 10b and 10c. The valves are to be connected to the holes using epoxy.

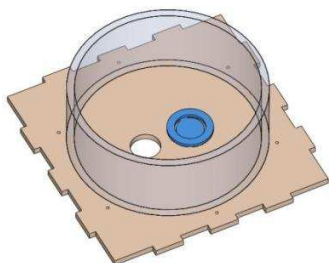


Figure 10a: Used Air Chamber one-way valve attached to the one hole on the top fixed plate.

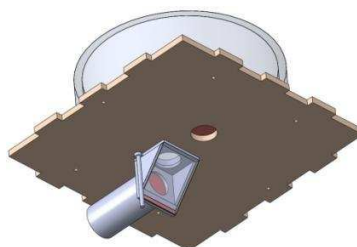


Figure 10b: Fresh Air Chamber L-shape valve without a hole on the other side attached to the other hole on the top fixed plate.

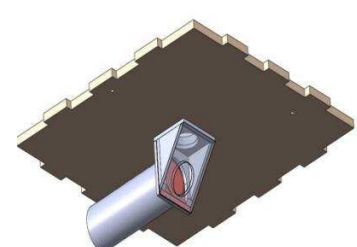


Figure 10c: Used Air Chamber L-shape valve with a hole on the other side attached to the hole on the bottom fixed plate.

Box and Final Sub-Assembly

The assembly of the device box is quite simple as there are puzzle-like ridges on the edge of each cut acrylic sheet to form clean connections amongst the parts. The concave portions of the edges are to have epoxy applied before being attached to its complementary sheet. The acrylic sheets are transparent and have the same texture all over such that confusion on the symmetric portions of the box will not be a big issue to the functionality of the device. The cylindrical hose attachment interfaces are to be epoxied onto the holes on the left side of the box. The final sub-assembly consists of putting all the other sub-assemblies together in an organized fashion as shown in Figure 11. The final product will look like Figure 12.

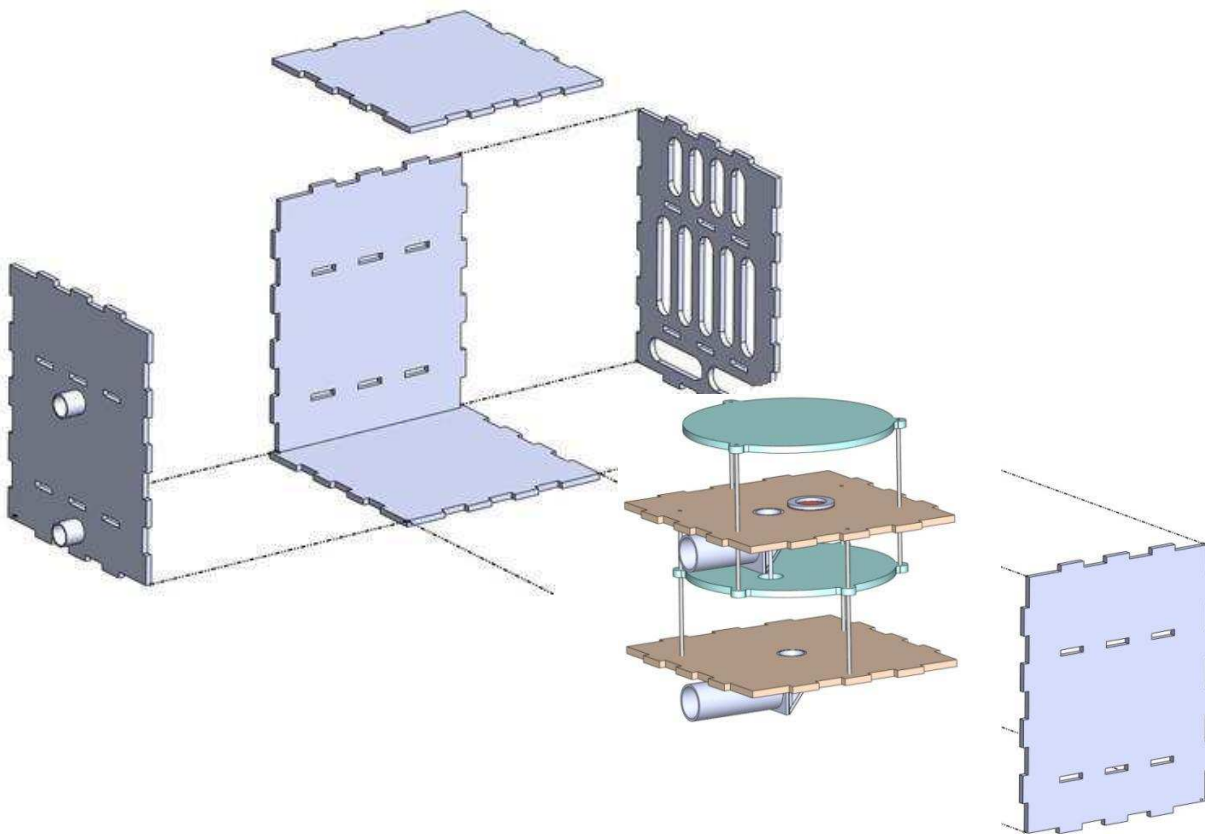


Figure 11: Box and Final sub-assembly

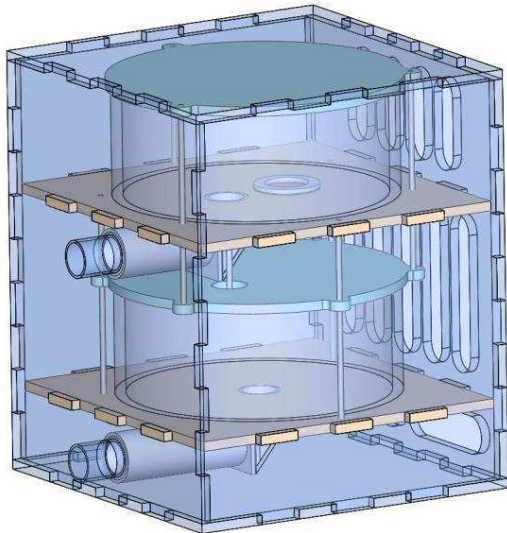


Figure 12: Final Assembly of the Device

7. **Design Testing and Validation.** How and where will your final design be tested? Which design specifications are being validated through the testing? Do you plan to test aspects of your design as you manufacture your prototype, or are you going to be validating a finished prototype after most/all manufacturing has been completed?
 - a. What would you consider to be your first major test of the design?
 - b. Have you arranged with your Section Instructor to have a cognizant individual present at your first major test? Who will this be? When do you expect this first test to take place?

The ultimate goal of this project is to determine if the mechanical device could be used to provide continuous positive airway pressure to a sleep apnea patient and be used comfortably without any safety issues. Validation of the system depends on whether the goal of the project can be achieved. To validate the system, we obtained a manometer and filled it with water. The fresh air outlet hose is then attached onto the manometer and ensured to be airtight using tape. This is meant to measure the air pressure that will be delivered to the patient when a given pressure of breath is exhaled into the used air chamber. The used air outlet hose is attached to the electrical CPAP machine.

Brass weights are placed on the top moving plate during “inhalation.”

The Procedure

1. Attach one hose to the used air chamber inlet valve and one hose to the fresh air chamber outlet valve.
2. Connect the other ends of these hoses to the Y-valve as shown in Figure 13.
3. Connect the mask to the 3rd hole of the Y-valve as shown in Figure 14
4. Check that every edge is smooth and not a hazard.
5. Measure the dead volume existing in the system—likely located in hose/mask
6. Measure the maximum and minimum size of the device with a tape measurer
7. Check that the device is compatible with hoses and masks in the market
8. Measure the weight of the device with a scale

9. The tester should be sitting or lying down. Then, place the mask on the tester's face and the tester should begin to breathe. Check:
 - a. The moving plates are rising and falling without any binding issues
 - b. For leaks in the seals or valves by listening and visually inspecting
 If the tester cannot breathe or is feeling lightheaded, remove the mask immediately.
10. Continue use for 5 minutes—use stopwatch and determine if the tester can comfortably use it throughout time period. Also, listen for how loud the device is.
11. Now place the device sideways as the tester continues to use it and determine if the device continues to function smoothly and appropriately.
12. Determine at what range of supplied and provided pressure the device runs at.
13. Tester should breathe into device with moving plates locked into position and determine if breathing is possible
14. Determine the time it takes to remove the mask from the user's face

Interpreting Results

We can be certain that the device could provide positive airway pressure, however, perhaps not continuous but rather in a cyclical manner such that the average air pressure delivered is high enough to keep breathing passage opened during sleep. Some initial findings we found was that for a given pressure (measured in cm H₂O) provided to the used air chamber, there is a constant decrease of 1 cm H₂O to the pressure supplied to the patient. This is quite promising as there is not much loss of pressure in the system.

8. Additional Appendices:

- c. For every chemical (powder, liquid, gas – distinguished from a “material” defined in step 2 above as a solid) you propose for use in testing or design, you must supply a complete MSDS as an appendix.
- d. If relevant safety documentation is provided with a purchased component, include it as an appendix.

See Appendix C for the MSDS for the Acrylic Sheet and Appendix D for the MSDS of the epoxy adhesive.

9. Submission. After addressing points 1-8 above, please do the following:

- e. Submit this report to your Section Instructor for signature. Please check with your Section Instructor to learn if a hard copy or an electronic copy is preferred for signature. Regardless, please create an electronic copy for filing and email to Bob Coury and Dan Johnson (below).
- f. After the report is signed, email a copy to Bob Coury (hornet@umich.edu) and our course GSI Dan Johnson (danijohn@umich.edu)
 - i. Both Bob and Dan are expected to raise additional safety concerns that will be shared with the students and the Section Instructor. They have the authority to stop any activity they deem unsafe, regardless of whether a safety report has been signed. If this happens, the safety report will be revised and re-signed by the Section Instructor, then emailed with revisions to Bob Coury and Dan Johnson.

Appendix I-1: FMEA Table

Part Number, Name & Functions	Potential Failure Mode	Potential Effect(s) of Failure	Severity (S)	Potential Cause(s) Mechanism(s) of Failure	/Occurrence of (O)	Current Controls / Tests (D)	Design Detection	Recommended Actions(s)	RPN (=S×O×D)
Used Air Chamber Sub-Assembly	Incomplete seal	Air leak, Pressure loss	8	Manufacturing Defects, Improper Assembly	4	Visual inspection to ensure tight seal of epoxy, 4 Manual tightness testing		Inspect each sealed joint, Test assembly with slowly increasing pressures underwater. Watch for bubbles coming out if there is leak.	128
Fresh Air Chamber Sub-Assembly	Fracture / Parts separate	Breakdown, air leak	7	Manufacturing Defects	1	Built to withstand related pressure in the system.		Inspect each purchased products and manufactured parts to ensure 7 no defects before assembling.	7
Valves Sub-Assembly	Incomplete seal	Air leak, Pressure loss	8	Manufacturing Defects, Improper Assembly	4	Visual inspection to ensure tight seal of epoxy, 4 Manual tightness testing		Inspect each sealed joint, Test assembly with slowly increasing pressures underwater. Watch for bubbles coming out if there is leak.	128
Box Sub-Assembly	Fracture / Parts separate	Breakdown, air leak	7	Manufacturing Defects	1	Built to withstand related pressure in the system.		Inspect each purchased products and manufactured parts to ensure 7 no defects before assembling.	7
Valves Sub-Assembly	Loose fittings, Valve flap stuck on holders	Air leak / blocked	8	Manufacturing Defects	4	Visual inspection to ensure correct alignment of valve components.		Inspect each purchased products and manufactured parts to ensure no defects before assembling. 96 Inspect functionality of valves by blow air into the valve flap and see if it goes to the right direction.	96
Box Sub-Assembly	Fracture / Parts separate	Breakdown, air leak	7	Manufacturing Defects, Improper Assembly	1	Built to withstand related pressure in the system and the weight it will carry.		Inspect each purchased products and manufactured parts to ensure 7 no defects before assembling.	7

Appendix I-2: DesignSafe Report

Application: Mechanical CPAP Device

Analyst Name(s):

ME450 Team 6:
Katya Christenson
Steven Fannon
Joseph Jacquemin
Davina Widjaja
University of Michigan – Ann Arbor
Sleep Disorders Center.

Description: This report is meant to assess the task-based

(safety usage, manufacturing, assembling and experimentation) safety of the mechanical CPAP device which is designed by ME450 Project Team 6 and planned to be outsourced for manufacture for the medical industry.

Product Identifier: Facility Location:

Assessment Type: Detailed

Limits:

Sources:

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

User / Task	Hazard Hazard Cause/Failure Mode	Severity Exposure Probability	Risk Level	Risk Methods / Comments	Reduction Severity Exposure Probability	Risk Level	Person Responsible	Status
Patients / Normal Operation	mechanical / cutting / severing / The machine may have sharp edges that could hurt the user when the user knocks onto it.	Serious Remote Possible	Moderate	File down sharp edges to eliminate such risks. Or Remote injection blow parts to give a smooth surface. /Before presentation to user, team will ensure thorough filing or proper blow molding processes to reduce sharp edges.	Minimal Or Remote Negligible	Low	Team	In-process
Patients / Normal Operation	mechanical / fatigue / The machine is going to be used as often as a person breathes when sleeping. The air bags are to inflate and deflate continuously with the cyclic rod movements. Rods may be fatigued in the long run affecting the machine and the	Serious Remote Possible	Moderate	Pick a material that will withstand fatigue for this function.	Slight Remote Unlikely	Low	Team	Complete [11/12/2009]

Patients / Normal Operation	breathing passage. slips / trips / falls / fall hazard from elevated work / The machine is to have flat surfaces to accommodate tabletop mounting but there are hoses coming out of one side that may affect stability depending on the size of the tabletop. The machine may fall from the table, be damaged and hurt someone.	Serious Remote Possible	Moderate	Ensure that the moments created by the extruding hoses could be countered by different placements of hoses.	Moderate	Team	Complete [11/12/2009]
Patients / Normal Operation	ergonomics / human factors / human errors / behaviors / The machine is to function with the assumption that the volume of exhaled air is fixed at every exhalation. However, that may not be the case and the machine may not provide enough pressure to the airway if not supplied with enough exhaled air.	Slight Occasional Possible	Moderate	This could be because the machine is designed to inflate and deflate easily.	Low	Team	Complete [11/12/2009]
Patients / Normal Operation	environmental / industrial hygiene / asphyxiants / The air holes on the machine is to the environment and if any asphyxiants may be present in the atmosphere, the sleeping patient may be in danger of being choked at night.	Serious Remote Negligible	Low	Put filters at the air inlet. /This will be ready to be used by user as a medical device. Else conditions of air do not matter too much.	Low	Team	In-process
Patients / Normal Operation	ventilation / loss of exhaust / The one-way valve mechanism may fail and air from outside is blocked and may choke the user.	Serious Remote Possible	Moderate	The fresh air chamber is designed to be exposed to the atmosphere when valves malfunction.	Low	Team	Complete [11/12/2009]
Patients / Normal Operation	ventilation / concentration / The carbon dioxide from the chamber may leak and disrupt the fresh air concentration from the fresh air.	Slight Occasional Possible	Moderate	Ensure clean seal on the air chamber bags and other joints.	Low	Team	Complete [11/12/2009]
Patients / Normal Operation	ventilation / lack of fresh air / The machine is designed such that patient could get access to fresh air even if the machine malfunctions. This does not pose much safety issues unless the	Slight Occasional Possible	Moderate	To be used in a fresh air atmosphere.	Low	Team	Complete [11/12/2009]

environment they live in lacks fresh air in the first place.						
Patients / Normal Operation	ventilation / air contaminants / There may air contaminants in the air that could contaminated the fresh air being breathed in.	Serious Remote Possible	Moderate	Put filters at the air inlet. /This will be done when it is ready to be used by user as a medical device. Else conditions of air do not matter too much.	Slight Remote	Low Team In-process
Patients / Normal Operation	ventilation / airflow direction / The backdraft from the common hose to the used air chamber may be greater than expected incoming fresh air.	Slight Occasional Possible	Moderate	Ensure manufactured valves to backdrafts. /This will be manufactured after DR3.	well- Slight Remote Unlikely	Low Team In-process
Patients / Normal Operation	chemical / failure at key points and trouble spots / There is a Y-valve in between the out hoses. The Y-valve is important to separate the used air from fresh air chamber. It is important that the plates railings kept lubricated to ensure movement.	Slight Occasional Possible	Moderate	Ensure holes are enough for the rods to move through.	big Minimal Remote Possible	Low Team Complete [11/12/2009]
Patients / Normal Operation	chemicals and gases / carbon dioxide / If the used air chamber leaked and mixed with the fresh air, too much carbon dioxide is breathed in may be toxic to the user.	Serious Occasional Unlikely	Moderate	Ensure clean seal on the air chamber other joints.	Minimal Occasional Unlikely	Low Team Complete [11/12/2009]
Patients / Normal Operation	chemicals and gases / oxygen / Too much oxygen can be toxic.	Serious Occasional Unlikely	Moderate	The machine is designed such breathing atmosphere is possible even when the valves malfunction.	to be Slight that Remote the Unlikely is still possible when the	Low Team Complete [11/12/2009]
Patients / Normal Operation	biological / health / unsanitary conditions / Moisture is exhaled along with the air. In the long run and maybe air chambers contaminated with them.	Serious Occasional Possible	High	Periodic maintenance/cleaning are necessary to reduce this risk. /To be done by user after usage period.	Miminal Occasional Unlikely	Low Team On-going
Patients / Normal Operation	biological / health / bacterial /	Serious Occasional	High	Periodic maintenance/cleaning	Miminal Occasional	Low Team On-going

	The moist condition in the hoses or bags is ideal for growth of bacteria or other microorganisms.	Possible	High	are necessary to reduce this risk. /To be done by user after usage period.	Unlikely		
Patients / Normal Operation	biological / health / mold / Mold may grow in the hoses or bags due to moist conditions.	Serious Occasional Possible	High	Periodic maintenance/cleaning are necessary to reduce this risk. /To be done by user after usage period.	Minimal Occasional Unlikely	Low	Team On-going
Patients / Normal Operation	fluid / pressure / fluid leakage / ejection / Leakage of air pressure will make machine to function less properly.	Serious Remote Possible	Moderate	Ensure clean seal on the air chamber bags and other joints.	Minimal Occasional Unlikely	Low	Team Complete [11/12/2009]
Patients / Periodic Maintenance	ergonomics / human factors / lifting / bending / twisting / The hoses need to be removed from the machine and this requires quite a bit of effort. Pulling too hard could damage the valves interface, etc.	Slight Remote Unlikely	Low	Use snap-fit designs for easy attachment and removal of parts. /This will be achieved using injection blow molding not for prototype.	Minimal and Remote Unlikely	Low	Team In-process
Patients / Periodic Maintenance	chemicals and gases / chlorine / Chlorine may be required to sanitize parts in the machine. Inhaling too much chlorine could have harmful effects on the body or breathing passage.	Serious Remote Unlikely	Moderate	Gloves /To be done by user after usage period.	Slight Remote Unlikely	Low	Team In-process
Patients / Periodic Maintenance	chemicals and gases / methanol / Methanol may be required to sanitize parts in the machine. Inhaling too much chlorine could have harmful effects on the body or breathing passage.	Serious Remote Unlikely	Moderate	Gloves /To be done by user after usage period.	Slight Remote Unlikely	Low	Team In-process
Patients / Periodic Maintenance	biological / health / unsanitary conditions / Microorganisms may be harmful to health when exposed to them during periodic cleaning.	Serious Occasional Unlikely	Moderate	gloves, respiratory protection /To be done by user after usage period.	Slight Remote Unlikely	Low	Team In-process
Manufacturer / Engineer / Manufacturing	mechanical / cutting / severing / Cutting using saw, wire-cutter scissors, wire-cutter involve a certain risk of getting manufacturers injured.	Serious Occasional Possible	High	supervision, two hand controls, slow down energy release	hand Serious down Remote Possible	Moderate	Team Complete [11/12/2009]

Manufacturing Engineer / Manufacturing	mechanical / drawing-in / trapping / entanglement / A drill is used to drill some holes. Injury is viable when it is not used carefully. Debris could fly and hurt the eyes.	Serious Remote Possible	Moderate	Safety glasses, two hand controls, special tools or acrylic plates in place while drilling.	Serious Remote Unlikely	Moderate	Team	Complete [11/12/2009]
Manufacturing Engineer / Manufacturing	lasers / eye exposure / Laser-cutting will be used to cut some parts and exposure of the beams to any parts of the body could be potentially dangerous to the health.	Catastrophic Remote Possible	High	safety glasses	Slight Remote Unlikely	Low	Team	Complete [11/12/2009]
Manufacturing Engineer / Assembly	mechanical / crushing / Use of hammer could pose a danger of being crushed when using it.	Serious Occasional Possible	High	Ensure that hands are away from the holes where the rods are going through and use slow tapping motions to hammer the rods/plates down.	Serious Remote Unlikely	Moderate	Team	Complete [11/12/2009]
Manufacturing Engineer / Assembly	mechanical / cutting / severing / Some parts of the machine could have sharp edges on the outside of the machine that could potentially cut the manufacturer.	Serious Occasional Possible	High	File down sharp edges to eliminate such risks. /Before presentation to user, team will ensure thorough filing or proper blow molding processes to reduce sharp edges.	Minimal Remote Negligible	Low	Team	In-process
Manufacturing Engineer / Assembly	mechanical / pinch point / The moving plates could pinch fingers of assemblers.	Slight Occasional Possible	Moderate	two hand special tools or fixtures to keep moving plates stationary when it is being worked on.	Minimal Remote Negligible	Low	Team	Complete [11/12/2009]
Manufacturing Engineer / Assembly	mechanical / stabbing / puncture / Long thin rods are going to be hammered down into the round acrylic plates. Puncturing of the hands by the rods could occur if hammering is not done properly.	Catastrophic Occasional Possible	High	Preferably have snap-fit designs for the rods to fit in the holes. /This will be achieved using injection blow molding not for prototype.	Minimal Occasional Negligible	Low		TBD
Manufacturing Engineer / Assembly	chemical / reaction to / with chemicals / For most of the joining parts, we are using epoxy to glue things together. Epoxy could be harmful to the body since it reacts with the body when the	Serious Occasional Possible	High	substitute less hazardous material / respiratory protection, gloves	Slight Occasional Unlikely	Moderate	Team	Complete [11/12/2009]

vapor is inhaled.						
Manufacturing Engineer / Assembly	chemical / skin exposed to toxic chemical / Getting epoxy on the skin could be harmful too in the long run.	Serious Occasional Possible	High	substitute less hazardous material / respiratory protection, Unlikely gloves	Moderate	Team Complete [11/12/2009]
Manufacturing Engineer / Conducting Tests	mechanical / cutting / severing / Sharp edges on the box may cause cuts and injuries to the person using or conducting tests.	Serious Remote Possible	Moderate	File down sharp edges to eliminate such risks. Or Remote injection blow mold parts to give a smooth surface.	Low	Team Complete [11/13/2009]
Manufacturing Engineer / Conducting Tests	mechanical / pinch point / Since the device has moving and fixed plates, fingers may be pinched in between this moving and fixed plates and cause injuries.	Slight Remote Possible	Moderate	Ensure any body parts are not anywhere near moving objects while conducting tests.	Low	Team Complete [11/13/2009]
Manufacturing Engineer / Conducting Tests	slips / trips / falls / object falling onto / The machine is to have flat surfaces to accommodate tabletop mounting but there are hoses coming out of one side that may affect stability depending on the size of the tabletop. The machine may fall from the table, be damaged and hurt someone.	Slight Remote Possible	Moderate	Tests should be done in a wide table to prevent the device from imbalance and falling down.	Low	Team Complete [11/13/2009]
Manufacturing Engineer / Conducting Tests	noise / vibration / equipment damage / This is similar to pinch point but if device is damaged, eg: bag leaks, the moving plates may go down too fast and pinch the handlers' hands if he/she happens to be touching there.	Slight Remote Possible	Moderate	Ensure any body parts are not anywhere near moving objects while conducting tests.	Low	Team Complete [11/13/2009]
Manufacturing Engineer / Conducting Tests	chemical / reaction to / with chemicals / Device handlers may be exposed to epoxy (touch or smell) and the harmful effects it may entail.	Serious Remote Unlikely	Moderate	Wear gloves and try to not get too close to epoxy to prevent exposure to the respiratory system.	Low	Team Complete [11/13/2009]

Appendix I-3: MSDS – Plaskolite Optix® Acrylic Sheet

[ref: http://www.plaskolite.com/products/flat_sheet/optix/index.cfm]

PLASKOLITE, INC. EMERGENCY HOTLINE:

1770 Joyce Avenue (614) 294-3281

Columbus, OH 43219

Date Issued: 1/4/2000

Date Revised: 3/23/2006

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MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

Material: Plaskolite OPTIX Acrylic Plastic

(includes OPTIX Acrylic Sheet, Run-to-Size OPTIX Acrylic Sheet, OPTIX Acrylic (PMMA) Resin, Roll Stock OPTIX Acrylic Sheet, OPTIX TemperElite Green Edged Acrylic Sheet, OPTIX Colored Acrylic Sheet, OPTIX Non-Glare Acrylic Sheet, OPTIX Patterned Acrylic Sheet, Acrylic Lighting Sheet, ARmadillo AR Scratch-Resistant Acrylic Sheet, OPTIX Frost Acrylic Sheet)

Chemical Name

or Synonyms: Polymethyl methacrylate

2. PRODUCT COMPONENTS

COMPONENTS CAS REG. NO. WEIGHT (%)

1. Polymethyl methacrylate (PMMA) 9010-88-2 99.5 (MIN)

2. Methyl methacrylate (MMA) 80-62-6 0.5 (MAX)

3. PHYSICAL PROPERTIES

Appearance: Clear to opaque solid

Odor: N/A

Viscosity: N/A

Melting Point: 150°C/300°F

Boiling Point: N/A

Vapor Pressure: N/A

Vapor Density: N/A (Air =1)

Specific Gravity: 1.19 (Water =1)

pH: N/A

Solubility in Water: Negligible

Volatility: Negligible (Weight %)

Evaporation Rate: Negligible (Butyl Acetate = 1)

4. FIRE AND EXPLOSION HAZARD INFORMATION

Flash Point: N/A

Auto Ignition Temperature: 445°C/833°F

Upper Explosion Limit (%): N/A

Lower Explosion Limit (%): N/A

Extinguishing Media: Carbon dioxide, dry chemical, or water.

PLASKOLITE, INC. EMERGENCY HOTLINE:

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Columbus, OH 43219

Date Issued: 1/4/2000

Date Revised: 3/23/2006

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Fire Protection Equipment: Wear self-contained, positive pressure breathing apparatus (MSHA/NIOSH approved, or equivalent) and full protective gear.

Unusual Fire and

Explosion Hazard: Product is combustible thermoplastic material that burns vigorously with intense heat.

5. WORKPLACE EXPOSURE LIMITS

OSHA ACGIH

COMPONENTS PEL STEL TLV STEL

1. PMMA None None None None

2. MMA 100 ppm None 50 ppm 100 ppm

3. Nuisance dusts 5 mg/m³ None 10 mg/m³ None

(as inhalable particles
not otherwise specified)

MMA: 100 ppm = 410 mg/m³

6. HAZARD INFORMATION

Hazard Scale: 0 = Insignificant, 1 = Slight, 2 = Moderate, 3 = High, 4 = Extreme

Health Designation: 1

Fire Designation: 1

Reactivity Designation: 0

Inhalation: Inhalation of vapors from heated product can cause nausea, headache, dizziness as well as irritation of lungs, nose, and throat.

Eye Contact: Vapors from heated product can irritate the eyes.

Ingestion: Low hazard associated with normal conditions.

Skin Contact: Possible skin irritation. Contact with molten material can result in burns.

Carcinogenicity: N/A

7. EMERGENCY AND FIRST AID PROCEDURES

Inhalation: Move subject to fresh air.

Eye Contact: Flush eyes with plenty of water for at least 15 minutes. Call a physician.

Ingestion: This material is not expected to be absorbed within the gastrointestinal tract, so induction of vomiting should not be necessary.

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Skin Contact: If molten material contacts skin, cool rapidly with cold water and obtain medical attention for thermal burn.

8. REACTIVITY INFORMATION

Stability: Stable

Conditions to Avoid: Temperatures over 300°C/570°F.

Hazardous Decomposition

Products: Thermal decomposition or combustion may emit vapors, carbon monoxide, or carbon dioxide.

Incompatible Compounds: Acids, bases, and strong oxidizing agents.

9. SPILL OR LEAK INFORMATION

Sweep or scoop up and remove.

10. WASTE DISPOSAL

Landfill or incinerate at a facility that complies with local, state and federal regulations.

11. EXPOSURE CONTROLS/PERSONAL PROTECTION MEASURES

Respiratory Protection: None required under normal conditions. See Section 12.

Hand Protection: Canvas or cotton gloves.

Eye Protection: Safety glasses with side shields (ANSI Z87.1 equivalent).

Other Protection: N/A

Ventilation: Local exhaust ventilation systems should be constructed and installed in accordance with ANSI Z9.2 or ACGIH guidelines to control potential emissions near the source.

12. STORAGE AND HANDLING INFORMATION

Maximum Storage

Temperature: 99°C/210°F (softening temperature).

Storage Measures: If material is stored under ambient temperature conditions, it is not hazardous. However, extensive storing at higher than the maximum temperature will emit vapors, carbon monoxide or carbon dioxide.

Handling Measures: Processing of the material under high temperatures will cause hazardous emissions of vapors, carbon monoxide or carbon dioxide. Blower collecting and local exhaust ventilation systems should be installed to prevent contaminant dispersion into the air.

Sawing of this product generates particulates regulated as “inert”

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or “nuisance” dusts. To minimize dust emissions, engineering controls should be employed, such as baghouse filters and cyclone separators.

13. REGULATORY INFORMATION

Environment

Comprehensive

Environmental Response,

Compensation, and

Liability Act (CERCLA):

Under section 102(a) of the Act, this product is NOT designated as hazardous. In addition, no reportable quantities and no

notification requirements to the National Response Center in Washington, DC are set forth for its release from a vessel, an offshore or an onshore facility (40 CFR Part 302).

Resource Conservation and Recovery Act (RCRA):

When this product becomes a waste, it is identified as solid but NOT hazardous waste under RCRA criteria (40 CFR Part 261).

Toxic Substances Control

Act (TSCA):

The components of this product are on the TSCA inventory list. Any impurities present in this product are exempt from listing.

Superfund Amendment and

Reauthorization Act

of 1986 (SARA) Title III:

This product may be considered an immediate (acute) health hazard due to potential MMA emissions. However, reporting of thresholds for the material is not required because the concentration of its MMA component is below the de minimis concentration (40 CFR Part 370).

Transportation

DOT Hazard Class: Not regulated.

DOT Shipping Name: N/A

Labor Awareness

This product as supplied is non-hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200). However, under processing conditions it may become a health hazard to employees because vapors and/or particulates could be released. See Section 12 for Storage and Handling Information.

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14. GLOSSARY

ACGIH American Conference of Governmental Industrial Hygienists

CFR Code of Federal Regulations

DOT United States Department of Transportation

mg/m³ milligrams per cubic meter (concentration)

MMA Methyl methacrylate

MSHA Mine Safety and Health Administration

N/A Not Applicable or Not Available

NIOSH National Institute for Occupational Safety and Health

OSHA Occupational Safety and Health Administration (Department of Labor)

PEL Permissible Exposure Limit (time-weighted average)

PMMA Polymethyl methacrylate

ppm parts per million (concentration)

STEL Short-Term Exposure Limit (15-minute)

TLV Threshold Limit Value (time-weighted average)

The information presented herein is believed to be factual and reliable. It is offered in good faith, but without guarantee, since conditions and methods for the use of our products are beyond our control. We recommend that the prospective user determine the suitability of our products and these suggestions before adopting them on a commercial scale.

Please direct comments and questions to Plaskolite Environmental, Health and Safety

Filename: MSDS - Optix Acrylic Plastic.doc

Appendix I-4: MSDS – DEVCON® Epoxy

[ref: http://www.devcon.com/profiles/pdfs/sku_msd_93.pdf]

MSDS Name: **DEVCON® 5 Minute® Epoxy amber**

[1:1]

Manufacturer Name: ITW Devcon

Stock No.: 14200

Components:

5-MINUTE EPOXY HARDENER

5-MINUTE EPOXY RESIN

ITW Performance Polymers (Finished Goods) Product Code : 14200

View Section :

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: **5-MINUTE EPOXY RESIN**

Manufacturer Name: ITW Devcon

Address: 30 Endicott Street

Danvers, MA 01923

MSDS Revision Date: 10/10/2006

Emergency telephone number (800) 424-9300

HMIS

*** Chronic Health**

Effects:

Health Hazard 2*

Fire Hazard 1

REACTIVITY 1

Personal

Protection x

In the US, call CHEMTREC: (800) 424-9300

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SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name CAS#

Bisphenol A diglycidyl ether resin 25068-38-6 60 - 100 by Weight

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SECTION 3: HAZARDS IDENTIFICATION

Emergency Overview: WARNING! Potential Sensitizer. Irritant.

Primary Routes of Exposure: Eyes. Skin. Inhalation. Ingestion.

Potential Health Effects:

Eye Contact: Can cause moderate irritation, burning sensation, tearing, redness, and swelling. Overexposure may cause lacrimation, conjunctivitis, corneal damage and permanent injury..

Skin Contact: Can cause skin irritation; itching, redness, rashes, hives, burning, and swelling. Allergic reactions are possible.

May cause skin sensitization, an allergic reaction, which becomes evident on reexposure to this material.

Inhalation: Respiratory tract irritant. High concentration may cause dizziness, headache, and

anesthetic effects. May cause respiratory sensitization with asthma-like symptoms in susceptible individuals.

Ingestion: Causes irritation, a burning sensation of the mouth, throat and gastrointestinal tract and abdominal pain.

Chronic Health Effects: Prolonged skin contact may lead to burning associated with severe reddening, swelling, and possible tissue destruction

Signs/Symptoms: Overexposure can cause headaches, dizziness, nausea, and vomiting.

Target Organs: Eyes. Skin. Respiratory system. Digestive system.

Aggravation of Pre-Existing

Conditions:

Individuals with pre-existing skin disorders, asthma, allergies or known sensitization may be more susceptible to the effects of this product.

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SECTION 4: FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If swallowed, do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

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SECTION 5: FIRE FIGHTING MEASURES

Auto Ignition Temp : Not determined.

Flash Point: >400°F (204.4°C)

Flash Point Method: Pensky-Martens Closed Cup

Lower Explosive Limit (LEL) Not determined.

Upper Explosive Limit (UEL) Not determined.

Extinguishing Media: Use carbon dioxide (CO₂) or dry chemical when fighting fires involving this material.

Protective Equipment: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire

exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Unsuitable Media: Water or foam may cause frothing.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering

the spill area.

Spill Cleanup Measures: Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical

waste container. Provide ventilation. Clean up spills immediately observing precautions in the protective equipment section. After removal, flush spill area with soap and water to remove trace residue.

Avoid personal contact and breathing vapors or mists. Ventilate area. Use proper personal protective equipment as listed in section 8.

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Other Precautions: Pump or shovel to storage/salvage vessels.

To Top of page

SECTION 7: HANDLING AND STORAGE

Handling: Use with adequate ventilation. Avoid breathing vapor, aerosol or mist.

Storage: Store in a cool, dry, well ventilated area away from sources of heat and incompatible materials. Keep container tightly closed when not in use.

Hygiene Practices: Wash thoroughly after handling.

Special Handling Procedures: Provide appropriate ventilation/respiratory protection against decomposition

products (see Section 10) during welding/flame cutting operations and to protect against dust during sanding/grinding of cured product.

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SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls: Use appropriate engineering control such as process enclosures, local exhaust

ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Good general ventilation should be sufficient to control airborne levels. Where such systems are not effective wear suitable personal protective equipment, which performs satisfactorily and meets OSHA or other recognized standards. Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

Skin Protection Description: Wear appropriate protective gloves and other protective apparel to prevent skin

contact. Consult manufacturer's data for permeability data.

Eye/Face Protection: Wear appropriate protective glasses or splash goggles as described by 29 CFR

1910.133, OSHA eye and face protection regulation, or the European standard EN 166.

Respiratory Protection: A NIOSH approved air-purifying respirator with an organic vapor cartridge or

canister may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits. Protection provided by air purifying respirators is limited. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection.

Other Protective: Facilities storing or utilizing this material should be equipped with an eyewash

and a deluge shower safety station.

Notes : Only established PEL and TLV values for the ingredients are listed below.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Appearance: Viscous Liquid.

Color: Clear.

Odor: slight odor

Boiling Point: >500°F (260°C)

Melting / Freezing Point : Not determined.

Solubility: negligible

Specific Gravity: 1.17

pH: Neutral.

Vapor Density: >1 (air = 1)

Vapor Pressure: 0.03 mmHg @171°F

Molecular Formula: Mixture

Molecular Weight: Mixture

Percent Volatile: 0

VOC Data : 0 g/L

Percent Solids by Weight 100

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SECTION 10: STABILITY AND REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.

Conditions to Avoid: Extreme heat, sparks, and open flame. Incompatible materials, oxidizers and

oxidizing conditions. Heating resin above 300 F in the presence of air may cause slow oxidative decomposition.

Incompatibilities with Other

Materials:

Strong Lewis or mineral acids, strong oxidizing agents, strong mineral and organic bases (especially primary and secondary aliphatic amines).

Hazardous Polymerization: Not reported.

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SECTION 11: TOXICOLOGICAL INFORMATION

Bisphenol A diglycidyl ether resin:

Skin Effects: Skin - rat LD: >2 gm/kg - [Nutritional and Gross Metabolic - other changes] (RTECS)

Ingestion Effects: Oral - Rat LD: >5 gm/kg - [Nutritional and Gross Metabolic - other changes] (RTECS)

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SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Fate: No environmental information found for this product.

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SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal: Consult with the US EPA Guidelines listed in 40 CFR Part 261.3 for the
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classifications of hazardous waste prior to disposal. Furthermore, consult with your state and local waste requirements or guidelines, if applicable, to ensure compliance. Arrange disposal in accordance to the EPA and/or state and local guidelines.

RCRA Number : None

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SECTION 14: TRANSPORT INFORMATION

DOT Shipping Name: Non regulated.

DOT UN Number: N/A

DOT Hazard Class: Not applicable.

DOT Packing Group: Not applicable.

IATA Shipping Name: Non regulated.

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SECTION 15: REGULATORY INFORMATION

Bisphenol A diglycidyl ether resin:

TSCA Inventory Status Listed

EC Num : 603-074-00-8

Canadian Regulations. WHMIS Hazard Class(es): D2B

All components of this product are on the Canadian Domestic Substances List.

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SECTION 16: ADDITIONAL INFORMATION

HMIS Health Hazard: 2*

HMIS Fire Hazard: 1

HMIS Reactivity: 1

HMIS Personal Protection: x

MSDS Revision Date: 10/10/2006

Disclaimer: "This Health and Safety Information is correct to the best of our knowledge and belief at the date of its publication but we cannot accept liability for any loss, injury or damage which may result from its use. The information given in the Data Sheet is designed only as a guidance for safe handling, storage and the use of the substance. It is not a specification nor does it guarantee any specific properties. All chemicals should be handled only by competent personnel, within a controlled environment."

View Section :

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: **5-MINUTE EPOXY HARDENER**

Manufacturer Name: ITW Devcon

Address: 30 Endicott Street

Danvers, MA 01923

MSDS Revision Date: 10/10/2006

Emergency telephone number (800) 424-9300

HMIS

*** Chronic Health**

Effects:

Health Hazard 3*

Fire Hazard 1

REACTIVITY 1

Personal

Protection x

In the US, call CHEMTREC: (800) 424-9300

To Top of page

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name CAS#

Trade secret. N/A 60 - 100 by Weight

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SECTION 3: HAZARDS IDENTIFICATION

Emergency Overview: **WARNING!** Potential Sensitizer. Irritant.

Primary Routes of Exposure: Eyes. Skin. Inhalation. Ingestion.

Potential Health Effects:

Eye Contact: Can cause severe eye irritation and burns. Eye contact may cause permanent damage or blindness.

Skin Contact: Causes severe skin irritation. May cause permanent skin damage. Allergic reactions are possible.

May cause skin sensitization, an allergic reaction, which becomes evident on reexposure to this material.

Inhalation: Vapor or mist may cause severe respiratory system irritation. May cause respiratory sensitization with asthma-like symptoms in susceptible individuals.

Ingestion: Causes irritation, a burning sensation of the mouth, throat and gastrointestinal tract and abdominal pain.

Chronic Health Effects: Prolonged skin contact may lead to burning associated with severe reddening, swelling, and possible tissue destruction

Signs/Symptoms: Overexposure may cause eye watering or discomfort, redness and swelling.

Target Organs: Eyes. Skin. Respiratory system. Digestive system.

Aggravation of Pre-Existing

Conditions:

Individuals with pre-existing skin disorders, asthma, allergies or known sensitization may be more susceptible to the effects of this product.

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SECTION 4: FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If swallowed, do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

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SECTION 5: FIRE FIGHTING MEASURES

Flammable Properties : Class III B.

Auto Ignition Temp : Not determined.

Flash Point: >200°F (93.3°C)

Flash Point Method: Pensky-Martens Closed Cup

Lower Explosive Limit (LEL) Not determined.

Upper Explosive Limit (UEL) Not determined.

Extinguishing Media: Use carbon dioxide (CO₂) or dry chemical when fighting fires involving this material.

Protective Equipment: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire

exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Unsuitable Media: Water or foam may cause frothing.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.

Spill Cleanup Measures: Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical

waste container. Provide ventilation. Clean up spills immediately observing precautions in the protective equipment section. After removal, flush spill area with soap and water to remove trace residue.

Avoid personal contact and breathing vapors or mists. Ventilate area. Use proper personal protective equipment as listed in section 8.

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Other Precautions: Pump or shovel to storage/salvage vessels.

To Top of page

SECTION 7: HANDLING AND STORAGE

Handling: Use with adequate ventilation. Avoid breathing vapor, aerosol or mist.

Storage: Store in a cool, dry, well ventilated area away from sources of heat and incompatible materials. Keep container tightly closed when not in use. Do not store in reactive metal containers. Keep away from acids, oxidizers.

Hygiene Practices: Wash thoroughly after handling.

Special Handling Procedures: Provide appropriate ventilation/respiratory protection against decomposition

products (see Section 10) during welding/flame cutting operations and to protect against dust during sanding/grinding of cured product.

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SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls: Use appropriate engineering control such as process enclosures, local exhaust

ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Good general ventilation should be sufficient to control airborne levels. Where such systems are not effective wear suitable personal protective equipment, which performs satisfactorily and meets OSHA or other recognized standards. Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

Skin Protection Description: Wear appropriate protective gloves and other protective apparel to prevent skin

contact. Consult manufacturer's data for permeability data.

Eye/Face Protection: Wear appropriate protective glasses or splash goggles as described by 29 CFR

1910.133, OSHA eye and face protection regulation, or the European standard EN 166.

Respiratory Protection: A NIOSH approved air-purifying respirator with an organic vapor cartridge or

canister may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits. Protection provided by air purifying respirators is limited. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection.

Other Protective: Facilities storing or utilizing this material should be equipped with an eyewash and a deluge shower safety station.

Notes : Only established PEL and TLV values for the ingredients are listed below.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Appearance: Liquid.

Color: Clear to slight Yellow.

Odor: Mercaptan.

Boiling Point: Not determined.

Melting / Freezing Point : Not determined.

Solubility: negligible

Specific Gravity: 1.13

pH: 9.5 @ 5 Percent Solution

Vapor Density: Not determined.

Vapor Pressure: <<<1 mmHg @70°F

Molecular Formula: Mixture

Molecular Weight: Mixture

Percent Volatile: 0

VOC Data : 0 g/L

Percent Solids by Weight 100

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SECTION 10: STABILITY AND REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.

Conditions to Avoid: Extreme heat, sparks, and open flame. Incompatible materials, oxidizers and

oxidizing conditions.

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Incompatibilities with Other

Materials:

Oxidizers, acids, and chlorinated organic compounds. Reactive metals (e.g. sodium, calcium, zinc). Sodium/calcium hypochlorite. Nitrous acid/ oxide, nitrites. Peroxides. Materials reactive with hydroxyl compounds.

Hazardous Polymerization: Not reported.

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SECTION 11: TOXICOLOGICAL INFORMATION

To Top of page

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Fate: No environmental information found for this product.

To Top of page

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal: Consult with the US EPA Guidelines listed in 40 CFR Part 261.3 for the classifications of hazardous waste prior to disposal. Furthermore, consult with your state and local waste requirements or guidelines, if applicable, to ensure compliance. Arrange disposal in accordance to the EPA and/or state and local guidelines.

RCRA Number : None

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SECTION 14: TRANSPORT INFORMATION

DOT Shipping Name: Non regulated.

DOT UN Number: N/A

DOT Hazard Class: Not applicable.

DOT Packing Group: Not applicable.

IATA Shipping Name: Non regulated.

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SECTION 15: REGULATORY INFORMATION

Canadian Regulations. WHMIS Hazard Class(es): D2B

All components of this product are on the Canadian Domestic Substances List.

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SECTION 16: ADDITIONAL INFORMATION

HMIS Health Hazard: 3*

HMIS Fire Hazard: 1

HMIS Reactivity: 1

HMIS Personal Protection: x

MSDS Revision Date: 10/10/2006

Disclaimer: "This Health and Safety Information is correct to the best of our knowledge and belief at the date of its publication but we cannot accept liability for any loss, injury or damage which may result from its use. The information given in the Data Sheet is designed only as a guidance for safe handling, storage and the use of the substance. It is not a specification nor does it guarantee any specific properties. All chemicals should be handled only by competent personnel, within a controlled environment."

APPENDIX J: Design Analysis Assignments

1. Material Selection Assignment (Functional Performance)

The two major components chosen are the bag and the housing/plates, which are discussed separately below.

A. Bag

i. Function

Contain air

ii. Objective

The bags need to hold air well, keep their form in the radial direction, but allow easy extension and compression in the axial direction with very little force—if force is required, it is as constant as possible—and allow washing with alcohol/soap/water.

iii. Constraints

Not spring-like

Easy to extend and compress

Easy to clean

Do not block valves

Durable—can undergo a large number of loading cycles

Low forces and pressure values—so probably of low concern

Cheap material (less than \$2/lb)

Air tight—very limited air permeability

Seals well

Easy to attach and unattach to plates-- It can undergo a manufacturing process that produces threads for large mouthed containers (unlike pop bottles, which can small closures)

Absorbs limited water (max 1%)

Not biodegradable

Not susceptible to UV radiation

Not susceptible to fresh water or salt water

Won't expand or bulge outward—retain shape

Not flammable

Not brittle

Homogenous material structure

iv. Appropriate Material Indices

Percent filled

Filler type

Low

Cost/pound

Low Young's Modulus (less than 1×10^{-6} psi)

Yield Strength

High % Elongation—if <2% then it is considered brittle

Fatigue Strength

Low % Water Absorption (less than 1%)

Zero Air Permeability—volume of oxygen through unit thickness of material per unit area per unit time per unit barometric pressure ($\text{cm}^3 \cdot \text{mm}/\text{m}^2 \cdot \text{day} \cdot \text{atm}$)

Non-flammable

Good or excellent resistance to Fresh Water

Good or excellent resistance to UV Radiation

Non-biodegradable

Can be injection blow molded

v. Top Five Material Choices

When we originally specified constraints, 9 materials came up: ECTFE, FEP, PCTFE, PFA, PI, PTFE, PVDC (plasticized), PVDC (unplasticized), and PVDC (injection molded). These were easily narrowed down to the top 3 for the following reasons:

--PI is a thermoset and it has a very low percent elongation, so it is considered a brittle material

--PCTFE is very costly (\$55-60.5/pound) especially compared to the other options

--PFA and PTFE were also costly, but more importantly the amount of oxygen permeability it has was much higher than the others (a minimum of $227 \text{ cm}^3 \cdot \text{mm}/\text{m}^2 \cdot \text{day} \cdot \text{atm}$)

--FEP and ECTFE were quite good in all indices, but the PVDC options were all much cheaper and provided even lower permeability.

vi. Explanation

Finally, choosing between the three PVDC options was difficult. Their material indices only vary slightly in the yield strength, percent elongation, and fatigue strength (although their densities vary slightly as well).

Instead of just focusing on the material indices required, we also constantly kept the component production in mind. We need to shape a hollow 3D component with a large open closure at a low cost, with high tolerances, and that can have threaded ends. The PVDC (plasticized) and PVDC (unplasticized) cannot be injection molded. The best way to make something like we described was determined to be injection blow molding. However, this did not actually limit any of the three options as all three materials can be used for this process.

If a material is plasticized, then it is more soft and flexible, so the PVDC (unplasticized) was eliminated. And, the PDVC (injection molded) has a lower percent elongation, so it was also eliminated, which left us with the PVDC (plasticized). In addition, this choice fulfilled the middle material indice for all three indices (it did not have the highest or lowest yield strength, percent elongation, or fatigue strength).

vii. Summary

Currently, the prototype utilizes vinyl air duct bags (Figure 1), but a number of issues result from this. The bags are difficult to attach to the plates as they use epoxy, they cannot be removed once attached, and they cannot be cleaned after attachment. The accordion-style bags will be manufactured with threaded ends, which will allow the bags to be just as flexible, but will also allow them to be unscrewed from the plates and washed. The bags will also have threads at each end for easier attachment and removal and a gasket at each end to provide a good seal. For example, common water bottles function on this same concept, but seal liquid instead of gas.



Figure 1: Accordion-style bag design example

To determine the material the chambers will be manufactured from, we knew the material needed to be a thermoplastic, not an elastomer or thermoset, as the material needs to be very flexible but still retain its shape. Secondly, if the material was 0% filled, or unfilled, then the material would be homogeneous and isotropic. Thirdly, the material must be as impermeable to oxygen and absorb very minimal amounts of water, as it will be used as an air tight breathing chamber for moist air and potentially be washed often. The material should also be non-flammable, have excellent durability in fresh water, be good or excellent under UV radiation, and not be biodegradable. So, as long as it met these conditions, the yield strength, the fatigue strength and the cost needed to also be appropriate. Using these 10 parameters in CES, we were able to narrow our search to a total of 9 materials. We then selected PVDC (copolymer, barrier film resin, plasticized) to be injection blow molded. According to CES, injection blow molding provides high tolerances and small wall thicknesses. Although injection blow molding has slightly higher capital costs than extrusion blow molding, it is capable of producing hollow 3D-objects with wide-mouthed containers, where the neck areas can be threaded.

B. Housing/Plates

i. Function

The plates must hold air, not bulge with pressure, and be rigid (for the rods)

The housing must be rigid to provide the device protection.

ii. Objective

The plates will be connected to rigid rods and the chamber bags. They will need to be manufactured with threads to allow for easy assembly and cleaning. They will need to hold air effectively and allow for easy cleaning with soap, water, or alcohol.

The housing will also need to be rigid to protect the entire device and allow it to stand up and hold its shape. They will also need to be manufactured with threads to allow for easy assembly and cleaning. They will not need to hold air but must allow for easy cleaning with soap, water, or alcohol.

iii. Constraints

Air tight--plates

Cheap

Rigid—high young's modulus

Lightweight –low density
 Manufactured using a precise enough process that threads could be created.
 Cannot bulge—minimum yield strength of 0.3 psi
 Cannot be brittle—above 10% elongation
 Less than 1% water absorption
 Not flammable
 Not biodegradable
 Good under fresh water, salt water, and UV radiation

iv. Appropriate Material Indices

Percent filled
 Filler type
 Low Cost/pound
 High Young’s Modulus
 High Yield Strength
 Percent Elongation (more than 10% so that it isn’t brittle)
 Low % Water Absorption (less than 1%)
 Zero Air Permeability—volume of oxygen through unit thickness of material per unit area per unit time per unit barometric pressure ($\text{cm}^3 \cdot \text{mm}/\text{m}^2 \cdot \text{day} \cdot \text{atm}$)
 Non-flammable or self-extinguishable
 Good or excellent resistance to Fresh Water
 Good or excellent resistance to Salt Water
 Good or excellent resistance to UV Radiation
 Non-biodegradable

v. Top Five Material Choices

Through our CES material search, we narrowed the material down to a type of PVC: PVC(rigid, molding, extrusion), PVC (rigid, lead stabilized), PVC /PMMA, ASA/PVC, PVC (rigid, high-impact, molding, extrusion), PVC (chlorinated, molding, extrusion), and PBT (general purpose, flame retardant). But the PVC (rigid, lead stabilized) has health risks, and the PBT(general purpose, flame retardant) has a high permeability. See Table 1 for results of comparing the density versus the price.

We wanted to use the same material for the both the plates and the housing to provide simplicity in the design. Many of the material indices for the housing and the plate are the same except the housing does not need to be air tight. The material permeability index was not a factor in the material decision, because the same material could be used for both the housing and the plates.

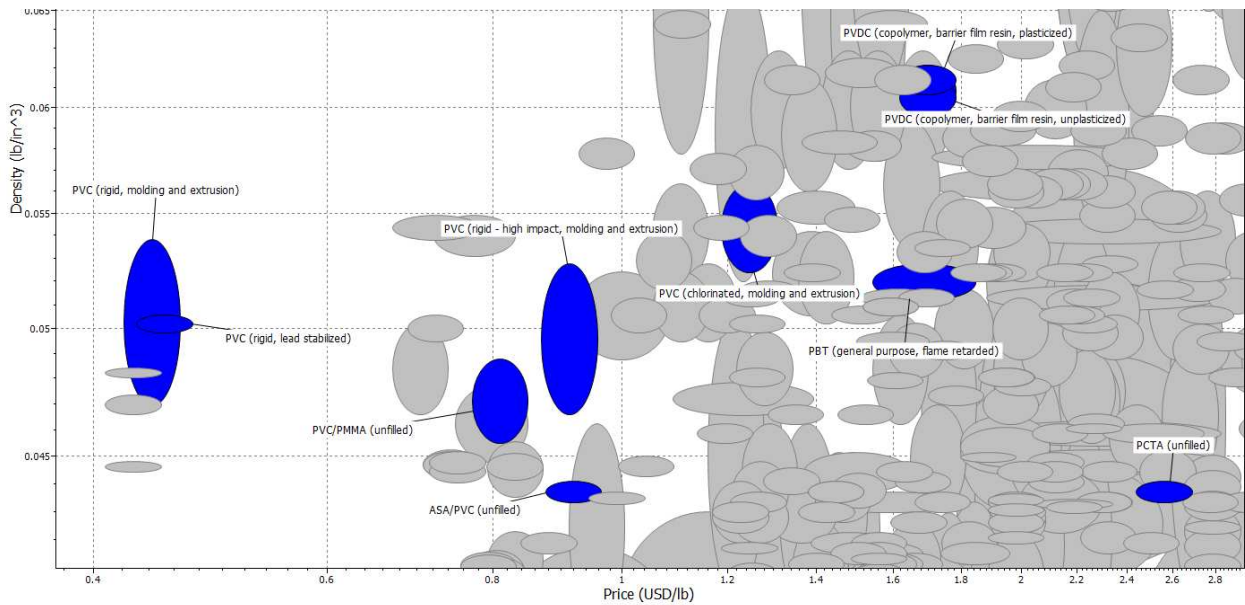


Table 1: CES Results

vi. Explanation

During our prototyping, we used PVC/PMMA, or acrylic, which worked very well. It actually also ended up being one of our top five material choices. The PVC/PMMA, ASA/PVC, PVC (rigid, high-impact, molding, extrusion), PVC (chlorinated, molding, extrusion), and PVC (rigid, molding, extrusion) all have very similar material characteristics including density, except the PVC (rigid, molding, extrusion) is a lot cheaper. Thus, we chose this material for the housing and plates.

vii. Summary

Housing

The housing will consist of a cylinder with a one end closed and an open end with a threaded outside. It will have lightening holes that serve as air intake/outtake holes and hose outlet/inlet holes. The entire assembly will be inserted inside the cylindrical housing and screwed into place. The hose outlet/inlet holes will be aligned with the hard tubing extending from the elbow valves from the fresh and used air chambers when the assembly is fully screwed into position. This is shown below in Figure 2 and again with the housing removed in Figure 3.



Figure 2: Final Design Housing

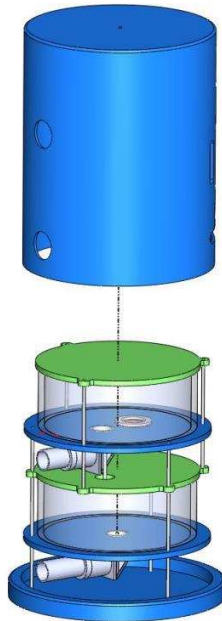


Figure 3: Final Design with housing removed

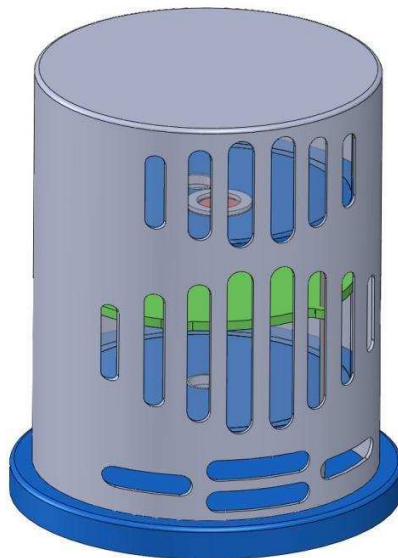


Figure 4: Back view of Final Design

To determine the material the housing will be manufactured from, we knew the material we wanted needed to be a cheap, rigid, lightweight plastic that could be manufactured using a precise enough process that threads could be created. Through our CES material search, we narrowed the material down to a type of PVC. We then selected PVC (rigid, molding, extrusion). This PVC can be injection molded using any color plastic desired to make the device more esthetically pleasing. We validated that this material would be sufficient as PVC/PMMA, or

acrylic, has very similar material characteristics including density, except the acrylic is twice as expensive and is transparent. A view of the back of the housing can be seen in Figure 4.

Plates

Currently, the prototype utilizes acrylic plates, which provides a light-weight, transparent material, as it was an accessible material at the prototype manufacturing stage. The final design of the plates will be manufactured from PVC (rigid, molding, extrusion) using injection molding, just like the housing. It provides a rigid attachment for the chambers, is lightweight, and it can have threads engraved. In the final design, all of the fixed plates will be made to be circular so that the entire assembly can be inserted into the cylindrical housing.

2. Material Selection Assignment (Environmental Performance)

A. Chamber—PVDC(plasticized)

i. Mass

Two chambers of $\frac{1}{4}$ mm = 0.09 inches thickness
 6.5 inches in diameter
 2.5 inches in height
 So, total of 1.36 in³
 Density = 0.06 lb/in³ for PVDC (plasticized)
 SO, mass = **0.0816 pounds**

ii. Closest Material Available in SimaPro

The closest materials available in SimaPro are PVDC B250 or PVDC I.

iii. Calculate total mass of air emissions, water emissions, and solid waste (shown in Figure 5).

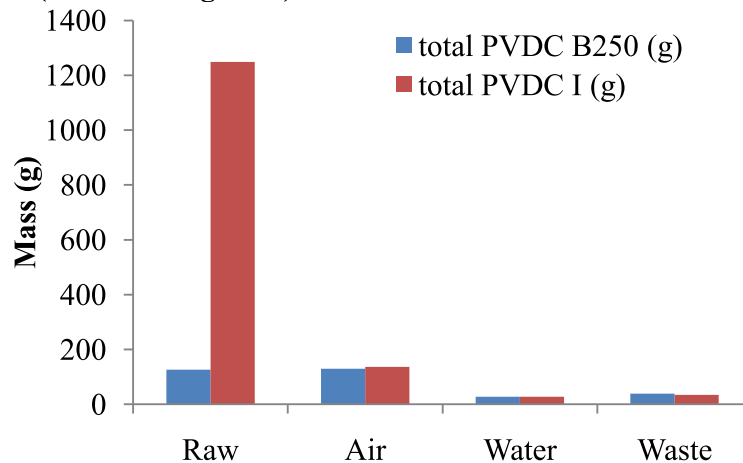


Figure 5: Bar chart comparing masses of wastes produced by PVDC B250 or PVDC I

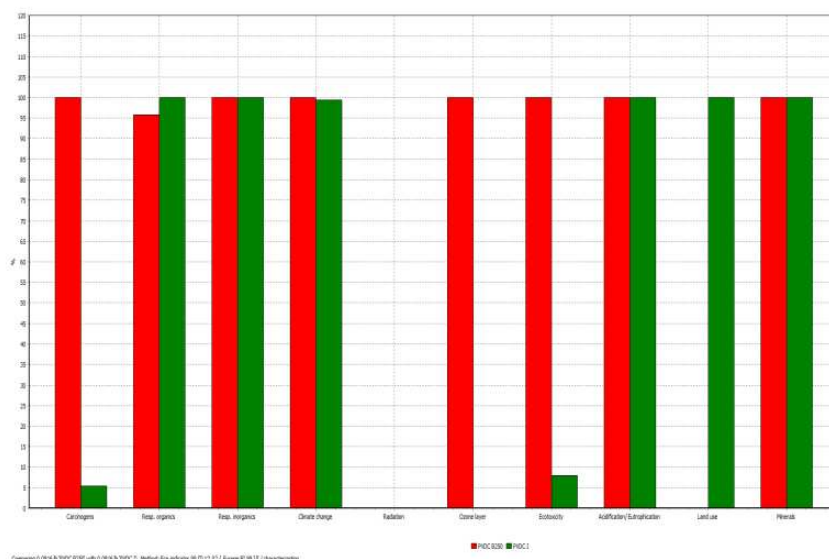


Figure 6: Impact Assessment – Characterization (Red=PVDC B250, Green=PVDC I)

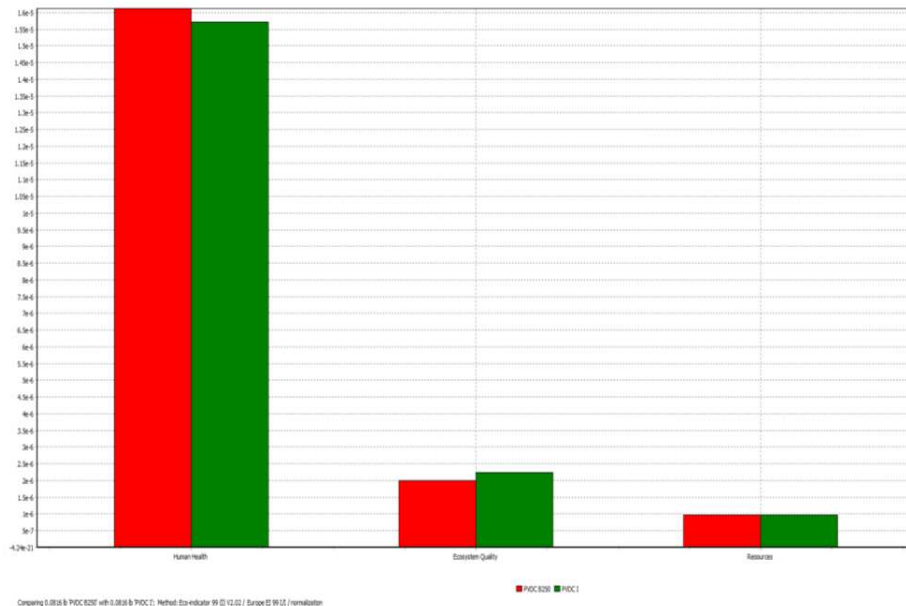


Figure 7: Impact Assessment – Normalization

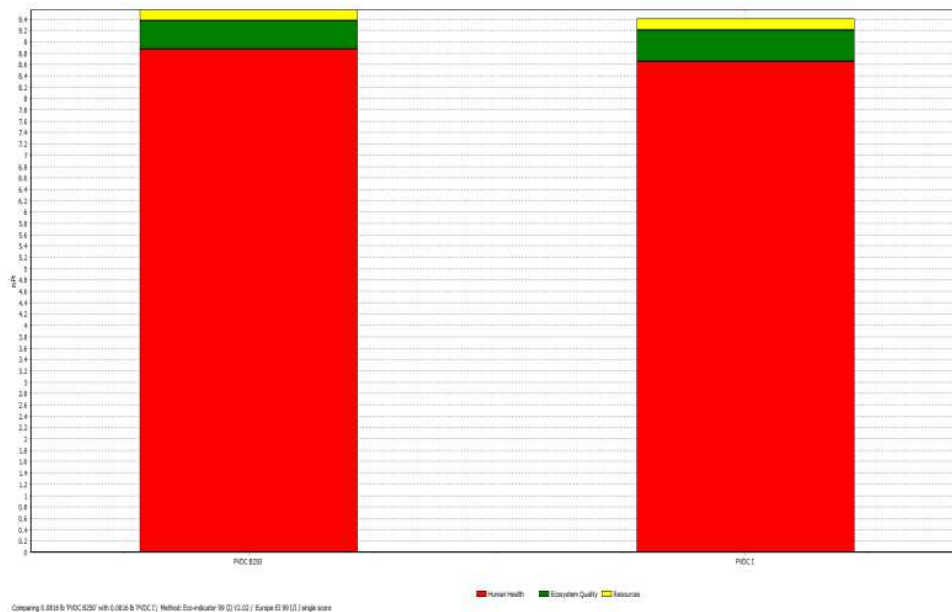


Figure 8: Impact Assessment – Single Score

Determine which material choice has a bigger impact on the environment within each of the EcoIndicator 99 damage classifications.

Within the EcoIndicator99 damage classifications, there are different effects. The use of PVDC I as a raw material seem to be the most popular at about 1250 g, while PVDC B250 is less used. Even though PVDC I is used more often, the air, water and solid waste emissions are about the same level as that of PVDC B250. PVDC I contains 5% carcinogens and 7% ecotoxicity compared with PVDC B250 containing 100% carcinogens and 100% ecotoxicity. PVDC B250

also has an ozone layer impact risk of 100% compared with PVDC I which has an impact risk of 0%. For all of the other damage classifications both materials are almost identical.

Discuss which of the damage meta-categories are most likely to be important based on the EI99 point values.

The meta category of Resources is the most important based on the EI99 point values. This is because the risk associated within each damage classification is minimal compared with the waste produced during production of each material.

Determine which material (on its own) has a higher EcoIndicator 99 “point value” and discuss which material is likely to have a bigger impact when the life cycle of the whole product is considered.

PVDC I will have a much bigger environmental impact when considering the life cycle of the product. This is shown in Figure 5, where we see that the mass of raw material waste produced in the production of PVDC I is roughly 12 times the raw waste produced in manufacturing PVDC B250.

B. Housing/Plates—PVC (rigid, molding, extrusion)

i. Mass

*based on our CAD models in SolidWorks

Housing: 22.267 in³

Plate E (bottom plate): 21.871 in³

Plate D(fixed palte-lower): 9.95 in³

Plate B (fixed plate-upper): 9.81 in³

Plate A (moving plate-upper): 7.98 in³

Plate C (moving plate-upper): 7.97 in³

So, total of 79.848 in³

Density = 0.05 lb/in³

SO, mass = **3.9924 pounds**

ii. Closest Material Available in SimaPro

The closest materials available in SimaPro are PVC B250, PVC I and PVC injection molding E.

iii. Calculate total mass of air emissions, water emissions, use of raw materials, and solid waste (shown in Figure 9)

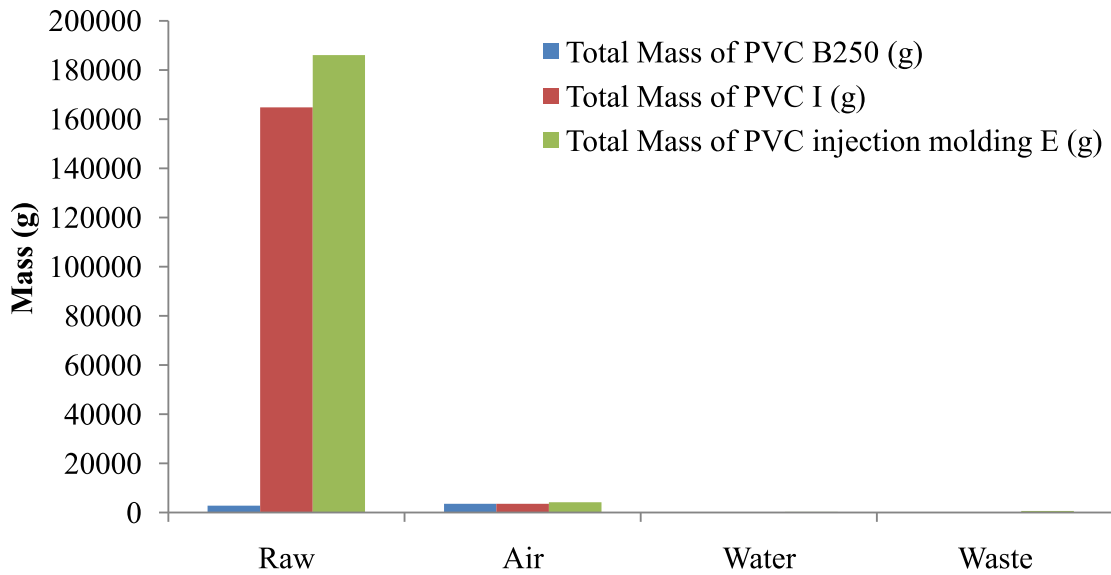


Figure 9: Bar chart comparing masses of wastes produced by PVC B250, PVC I or PVC injection molding E

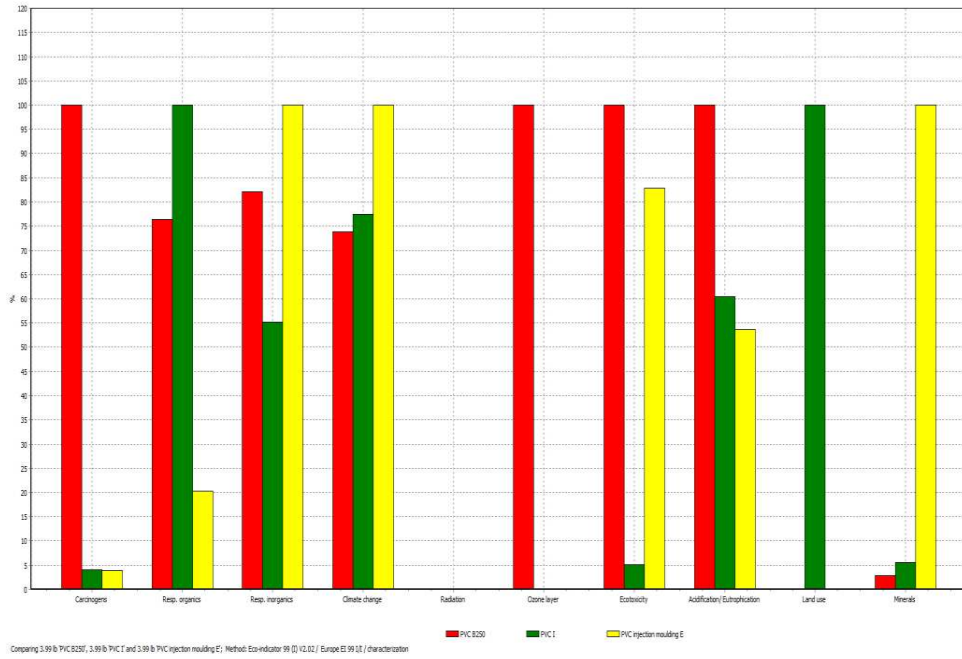


Figure 10: Impact Assessment – Characterization

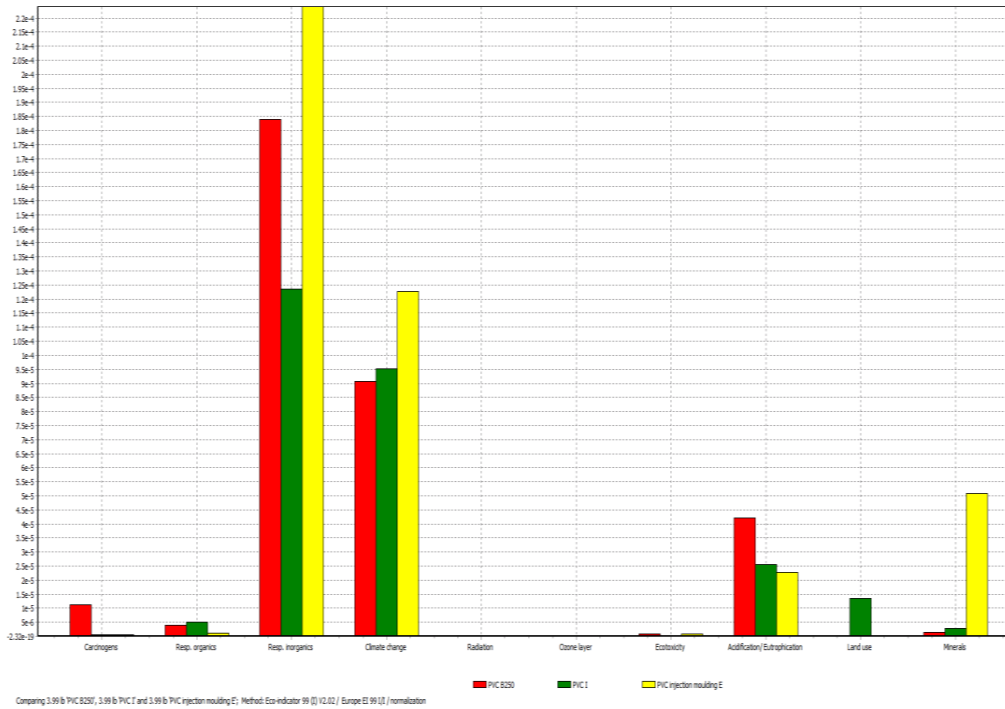


Figure 11: Impact Assessment - Normalization

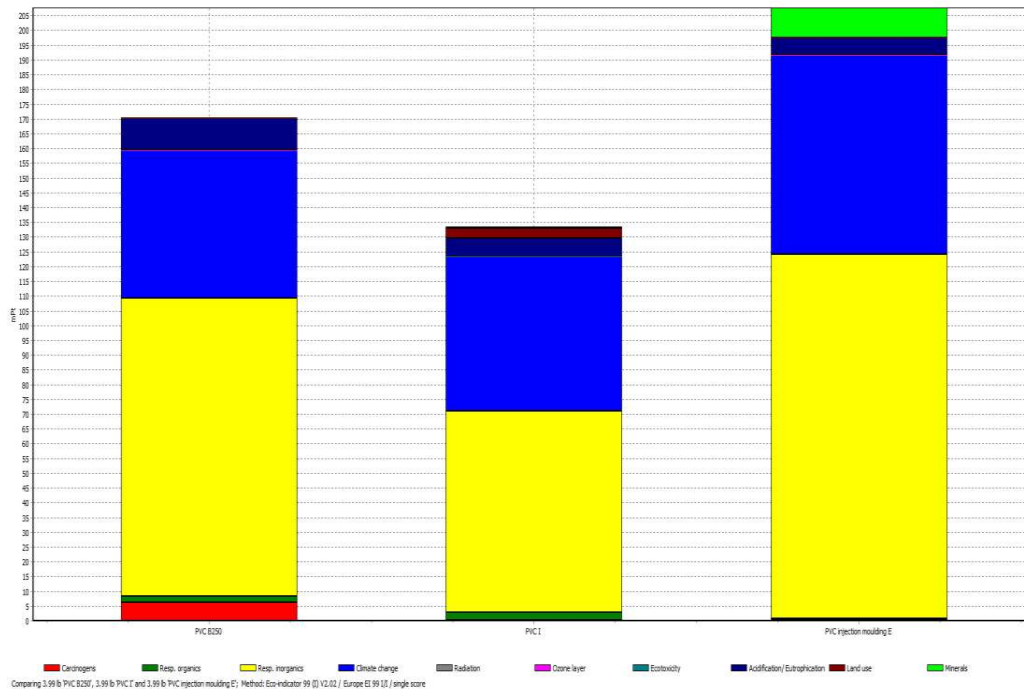


Figure 12: Impact Assessment – Single Score

Determine which material choice has a bigger impact on the environment within each of the EcoIndicator 99 damage classifications.

The use of PVC I and Injection molding E as a raw material seem to be the most popular at about 16,000 g and 19,000 g respectively, while PVC Injection Molding E is the most popular, followed by PVC I and PVC B250 being the least popular. Even though PVC Injection molding E and PVC I are highly popular, the air, water and solid waste emissions are about the same level amongst the three thermoplastics.

Discuss which of the damage meta-categories are most likely to be important based on the EI99 point values.

The meta category of Resources is the most important based on the EI99 point values. This is because the risk associated within each damage classification is minimal compared with the waste produced during production of each material.

Determine which material (on its own) has a higher EcoIndicator 99 “point value” and discuss which material is likely to have a bigger impact when the life cycle of the whole product is considered.

PVC I and PVC Injection molding E will have a much bigger environmental impact when considering the life cycle of the product. This is shown in Figure 5, where we see that the mass of raw material waste produced in the production of PVC I and Injection molding E are more than 10 times the raw waste produced in manufacturing PVDC B250.

3. Manufacturing Process Assignment

i.

People are becoming increasingly aware of their lack of sleep and the affect this has on their everyday lives. “Of a total population of 305 million Americans, 58% are estimated to experience insomnia symptoms or sleep disorders.” It is estimated that approximately 80% of people suffering from OSA are undiagnosed or untreated. This is partially due to their ignorance that they suffer from OSA, but more likely because they cannot afford the time or money to be treated. The standard way to be treated is through a PAP machine. The wide variety of machines can range from \$250-\$1500, but they all struggle to be smaller, lighter-weight (~5 lbs), quieter (~30 dB), and more electrically portable [AA]. While to even be diagnosed requires long hours in doctors’ offices participating in sleep studies, which also requires time and money. And, if the patient has a difficulty with their machine or needs to change the pressure, they need to schedule a doctor’s appointment to do so. They do not have the ability to alter the pressure supplied by their own machine.

Our innovative device not only does not require a battery pack or any other electrical source (thus it is appropriate in any location globally), but it is significantly quieter, less than 4 lbs, between \$50-\$100, and the patient can alter the pressure supplied by their machine without the hassle of doctor visits. With this device, we could increase the availability of treatment to low-income families and developing nations. However, it is useful to note that physicians could potentially not like this device as it allows the patient to control their treatment, nor does it provide historical compliance information like current machine provide. Our device tends to push treatment toward the patient and away from the physician.

In 2008, Marketdata Enterprises determined that the PAP market is a \$2.4 billion market that is growing 18% a year up to 2012 [BB]. Secondly, they estimate there are over 3,000 sleep labs, which each individually have revenues of \$1.33 million per year [BB]. These values only include people who are diagnosed with OSA, but do not include the untreated and undiagnosed. The major competitors in the market are ResMed, Respironics, SleepMed, AEIomed, and Probasics. If we approximate the price of our product in the market to be \$75, and we wanted to capture 1% of this known market, we would sell over 300,000 items. But, this could easily increase to 5% of the market share, and thus over 1 million items would need to be produced.

ii.

To manufacture the *bags* from *PVDC (copolymer, barrier film resin, plasticized)*, many molding processes could be used including injection blow molding, extrusion blow molding, calendaring, injection molding, polymer extrusion, polymer forging, rotational, and thermoforming. However, keeping in mind that the bags qualify as a Hollow 3D shape, a high production rate is required, small tolerances are imperative, and thin wall thicknesses essential, we were able to narrow it down to extrusion blow molding and injection blow molding. However, because the bags qualify as a wide-mouthed container and that the bags need to have threads at each end, injection blow molding was the obvious choice. *Injection blow molding* is described by CES to be used for thin-walled hollow shapes, with wide mouthed containers that require high control over finished part weight and wall thickness. And, most importantly, CES mentions it “is capable of high tolerances in the unblown, injection molded neck area, and hence it is useful to screw closures, etc.” Injection blow molding has the capability of meeting our batch size requires of 300,000 parts, as

it can produce a range of 1×10^5 – 1×10^7 units, with a low capital cost of no more than \$56,000 and low tooling costs of no more than \$19,000. In addition, the mass range of the process is applicable. One potential issue could be the required thickness and tolerances of the bag. No other shaping process provides a better section thickness and only 1 other process provides a slightly better tolerance— injection molding. So, the abilities of the capabilities of the material may be tested depending on the performance provided.

To manufacture the housing and the plates from PVC (rigid, molding, extrusion), many molding processes could be used including extrusion blow molding, injection blow molding, calendaring, compression, injection molding, polymer extrusion, polymer forging, rotational, thermoforming, and transfer molding. However, keeping in mind that the chambers are likely a circular prismatic and/or a hollow 3D shape with a complex wall design, only polymer casting, injection molding and transfer molding are feasible options. Polymer casting is immediately eliminated based on its small economic batch size abilities. But, choosing between injection molded and transfer molding was much more difficult. Injection molding has a higher capital cost, higher production rate, slightly higher batch size, and slightly smaller tolerances and section thickness abilities. But, transfer molding has high tooling costs and a lower production rate. In the end, we chose injection molding, because it is a very well know, established process, we are confident it will function as needed, and the machines are applicable to a wide range of materials and shapes (so if we decide to expand our business or change the design, we could easily do so). Most importantly however, we chose injection molding because we expect that we will be producing a large number of products on the injection molding machine such that the capital cost will be quickly paid off, while the tooling costs of transfer molding will be a significant cost to our process for the lifetime of production.

[AA] CPAP.com (2009). *CPAP.com Consumer Preferences Report*. Retrieved 6 December 2009 from <http://www.cpap.com/cpap-user-preference.php>

[BB] LaRosa, John (2008). *U.S. Sleep Aids Market Grows To \$23 Billion, As Americans Battle Insomnia, Sleep Disorder*. Marketdata Enterprises, Inc. Retrieved 6 December 2009 from <http://tired.ws/a316951-u-s-sleep-aids-market-grows-to.cfm>

PVDC (copolymer, barrier film resin, plasticized)

General properties

Designation

Polyvinylidene Chloride (Copolymer, Barrier Film Resin, Plasticized)

Density	0.0607	-	0.0621	lb/in ³
Price	* 1.62	-	1.78	USD/lb

Tradenames

Anjaflor; Diofan; Dyflor; Ensikem; Foraflon; Hylar; Ixan; Krehalon; Kynar; Murinyl; Solef; Sustatec

Composition overview

Composition (summary)

(CH₂-CCl₂)_n

Base	Polymer
Polymer class	Thermoplastic : semi-crystalline
Polymer type	PVDC
% filler	0 %

Filler type	Unfilled		
Composition detail			
Polymer	* 90	- 95	%
Plasticizer/oil	* 5	- 10	%
Mechanical properties			
Young's modulus	0.05	- 0.0801	10 ⁶ psi
Compressive modulus	* 0.05	- 0.0801	10 ⁶ psi
Flexural modulus	* 0.05	- 0.0801	10 ⁶ psi
Shear modulus	* 0.0174	- 0.0279	10 ⁶ psi
Bulk modulus	* 0.162	- 0.17	10 ⁶ psi
Poisson's ratio	* 0.428	- 0.445	
Shape factor	3.6		
Yield strength (elastic limit)	* 2.61	- 3.19	ksi
Tensile strength	3.34	- 3.67	ksi
Compressive strength	* 5.6	- 6.18	ksi
Flexural strength (modulus of rupture)	* 4.67	- 5.14	ksi
Elongation	250	- 300	%
Hardness - Vickers	* 9.7	- 10.7	HV
Hardness - Rockwell M	* 62	- 68	
Hardness - Rockwell R	98	- 106	
Fatigue strength at 10 ⁷ cycles	* 1.23	- 1.6	ksi
Fracture toughness	* 0.915	- 2.75	ksi.in ^{1/2}
Mechanical loss coefficient (tan delta)	* 0.0725	- 0.116	
Impact properties			
Impact strength, notched 23 °C	0.761	- 2.52	ft.lbf/in ²
Thermal properties			
Melting point	325	- 358	°F
Glass temperature	-4	- 14	°F
Heat deflection temperature 0.45MPa	* 165	- 217	°F
Heat deflection temperature 1.8MPa	129	- 151	°F
Maximum service temperature	* 149	- 174	°F
Minimum service temperature	* -23.8	- 12.2	°F
Thermal conductivity	0.0699	- 0.0757	BTU.ft/h.ft ² .F
Specific heat capacity	* 0.287	- 0.299	BTU/lb.F
Thermal expansion coefficient	186	- 194	µstrain/°F
Processing properties			
Linear mold shrinkage	0.5	- 2.5	%
Melt temperature	340	- 399	°F
Molding pressure range	4.99	- 29.9	ksi
Electrical properties			
Electrical resistivity	* 1e20	- 1e22	µohm.cm
Dielectric constant (relative permittivity)	* 3.5	- 4.5	
Dissipation factor (dielectric loss tangent)	* 0.03	- 0.15	
Dielectric strength (dielectric breakdown)	399	- 599	V/mil
Optical properties			
Refractive index	1.59	- 1.61	
Transparency	Translucent		
Absorption, permeability			
Water absorption @ 24 hrs	0.091	- 0.11	%
Water vapor transmission	0.0963	- 0.125	g.mm/(m ² .day)
Permeability (O2)	0.0254	- 0.254	cm ³ .mm/(m ² .day.atm)
Durability: flammability			
Flammability	Non-flammable		
Durability: fluids and sunlight			

Water (fresh)	Excellent
Water (salt)	Excellent
Weak acids	Excellent
Strong acids	Acceptable
Weak alkalis	Excellent
Strong alkalis	Limited use
Organic solvents	Limited use
UV radiation (sunlight)	Good
Oxidation at 500C	Unacceptable

Primary material production: energy, CO2 and water

Embodied energy, primary production	* 1.07e4	-	1.18e4	kcal/lb
CO2 footprint, primary production	* 3.75	-	4.15	lb/lb
Water usage	* 6.95e3	-	7.7e3	in^3/lb

Material processing: energy

Polymer molding energy	* 805	-	889	kcal/lb
Polymer extrusion energy	* 314	-	348	kcal/lb
Polymer machining energy (per unit wt removed)	* 209	-	232	kcal/lb

Material processing: CO2 footprint

Polymer molding CO2	* 0.594	-	0.657	lb/lb
Polymer extrusion CO2	* 0.232	-	0.257	lb/lb
Polymer machining CO2 (per unit wt removed)	* 0.154	-	0.171	lb/lb

Material recycling: energy, CO2 and recycle fraction

Recycle	True			
Embodied energy, recycling	* 4.49e3	-	4.96e3	kcal/lb
CO2 footprint, recycling	* 1.57	-	1.74	lb/lb
Recycle fraction in current supply	0.0475	-	0.0525	%
Downcycle	True			
Combust for energy recovery	True			
Heat of combustion (net)	* 1.07e3	-	1.12e3	kcal/lb
Combustion CO2	* 0.886	-	0.931	lb/lb
Landfill	True			
Biodegrade	False			
A renewable resource?	False			

Notes

Typical uses

Piping; fittings and parts in the chemical industry; packaging.

Reference sources

Data compiled from multiple sources. See links to the References table.

Links

- ProcessUniverse
- Producers
- Reference
- Shape

No warranty is given for the accuracy of this data. Values marked * are estimates.

PVC (rigid, molding and extrusion)

General properties

Designation

Poly Vinyl Chloride (Rigid, Molding); Type I

Density	0.047	-	0.0538	lb/in^3
Price	0.422	-	0.464	USD/lb

Tradenames

Acvitron; Advex; Alphacan; Apex; Apiflex; Arlanyl; Asnil; Benvic; Boltaron; Celtec; Certavin; Clealite; Crossvinil; Crylac; Decelith; Dural; Duromix; Ecolvin; Ecovil; Epivyl; EslonPlate; Etinox; Evicom; Eviron; Fiberloc; Formolon; Geon; GeonFiberloc; Hishiplate; Hy-Vin; Indovin; Kaneka; Lacovyl; Lajavinyl; Lucalor; Marvelate; Marvylan; Mazpound; Mecian; Mron; Nakan; NanYa; Neralit; Nipolit; Nordvil; Norvinyl; Novablend; Novacycle; Novatemp; Nuvin; Oxyclear; OxyVinyls; Palvinyl; Petvinil; Pevikon; Polanvil-S; Polyvin; Reon; Rimtec; Simona; Sinvicomp; Sinvoprene; Slovanyl; SolVin; Sumilite; Sunprene; Superkleen; Suvyl; Sylvil; Tanegum; Tarvinyl-S; Tecavinyl; Tefanyl; Treglum; Trocal; Tygon; Unichem; Vinidur; Vinika; Vinnolit; Vinoflex; Vintec; Vinuran; Vinycel; Vynychlon; Vinyfoil; Vistel

Composition overview

Composition (summary)

Compound of PVC, (CH₂CHCl)_n, with stabilizer (commonly tin-based)

Base	Polymer		
Polymer class	Thermoplastic : amorphous		
Polymer type	PVC-rigid		
% filler	0		%
Filler type	Unfilled		

Composition detail

Polymer	100		%
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Mechanical properties

Young's modulus	0.36	-	0.479	10 ⁶ psi
Compressive modulus	* 0.35	-	0.479	10 ⁶ psi
Flexural modulus	0.392	-	0.493	10 ⁶ psi
Shear modulus	* 0.128	-	0.172	10 ⁶ psi
Poisson's ratio	* 0.395	-	0.405	
Shape factor	6.7			
Yield strength (elastic limit)	6	-	7.64	ksi
Tensile strength	6	-	7.64	ksi
Compressive strength	* 5.37	-	6.42	ksi
Flexural strength (modulus of rupture)	12	-	13.3	ksi
Elongation	40	-	80	%
Hardness - Vickers	* 12.4	-	15.8	HV
Hardness - Rockwell M	* 72	-	90	
Hardness - Rockwell R	105	-	130	
Hardness - Shore D	80	-	85	
Fatigue strength at 10 ⁷ cycles	* 2.4	-	3.06	ksi
Fracture toughness	* 3.3	-	3.5	ksi.in ^{1/2}
Mechanical loss coefficient (tan delta)	* 0.00966	-	0.0166	

Impact properties

Impact strength, notched 23 °C	1.81	-	2.57	ft.lbf/in ²
Impact strength, notched -30 °C	* 0.476	-	0.952	ft.lbf/in ²
Impact strength, unnotched 23 °C	90.4	-	95.2	ft.lbf/in ²

Thermal properties

Glass temperature	176	-	190	°F
Heat deflection temperature 0.45MPa	154	-	169	°F
Heat deflection temperature 1.8MPa	149	-	163	°F
Maximum service temperature	122	-	149	°F
Minimum service temperature	14	-	32	°F
Thermal conductivity	0.0849	-	0.121	BTU.ft/h.ft ² .F
Specific heat capacity	0.239	-	0.263	BTU/lb.F
Thermal expansion coefficient	50	-	100	µstrain/°F

Processing properties

Linear mold shrinkage	0.2	-	0.6	%
Melt temperature	351	-	390	°F
Mold temperature	68	-	104	°F

Molding pressure range	9.98	-	39.9	ksi
Electrical properties				
Electrical resistivity	1e20	-	1e22	μohm.cm
Dielectric constant (relative permittivity)	3	-	3.2	
Dissipation factor (dielectric loss tangent)	0.02	-	0.03	
Dielectric strength (dielectric breakdown)	351	-	500	V/mil
Comparative tracking index	400	-	600	V
Optical properties				
Refractive index	1.53	-	1.54	
Transparency	Transparent			
Absorption, permeability				
Water absorption @ 24 hrs	0.04	-	0.4	%
Water vapor transmission	0.836	-	0.924	g.mm/(m ² .day)
Permeability (O ₂)	3.49	-	6.96	cm ³ .mm/(m ² .day.atm)
Durability: flammability				
Flammability	Self-extinguishing			
Durability: fluids and sunlight				
Water (fresh)	Excellent			
Water (salt)	Excellent			
Weak acids	Excellent			
Strong acids	Excellent			
Weak alkalis	Excellent			
Strong alkalis	Excellent			
Organic solvents	Limited use			
UV radiation (sunlight)	Good			
Oxidation at 500C	Unacceptable			
Primary material production: energy, CO₂ and water				
Embodied energy, primary production	6.88e3	-	7.61e3	kcal/lb
CO ₂ footprint, primary production	1.85	-	2.04	lb/lb
Water usage	* 1.68e3	-	1.86e3	in ³ /lb
Material processing: energy				
Polymer molding energy	* 949	-	1.05e3	kcal/lb
Polymer extrusion energy	* 368	-	407	kcal/lb
Polymer machining energy (per unit wt removed)	* 217	-	239	kcal/lb
Material processing: CO₂ footprint				
Polymer molding CO ₂	* 0.701	-	0.774	lb/lb
Polymer extrusion CO ₂	* 0.272	-	0.301	lb/lb
Polymer machining CO ₂ (per unit wt removed)	* 0.16	-	0.177	lb/lb
Material recycling: energy, CO₂ and recycle fraction				
Recycle	True			
Embodied energy, recycling	* 2.88e3	-	3.19e3	kcal/lb
CO ₂ footprint, recycling	* 0.775	-	0.857	lb/lb
Recycle fraction in current supply	1.43	-	1.58	%
Downcycle	True			
Combust for energy recovery	True			
Heat of combustion (net)	* 1.9e3	-	1.99e3	kcal/lb
Combustion CO ₂	* 1.37	-	1.44	lb/lb
Landfill	True			
Biodegrade	False			
A renewable resource?	False			

Notes

Typical uses

Pipe and pipe fittings; building products; bottles; film; records; floor tiling.

Reference sources

Data compiled from multiple sources. See links to the References table.

Links

[ProcessUniverse](#)

[Producers](#)

[Reference](#)

[Shape](#)

No warranty is given for the accuracy of this data. Values marked * are estimates.

Ethics and the Environment

Before discussing the broad ethical issues of our design project in the real-world and in-class settings, it is important to define our spectrum of discussion. One definition of “ethics” derived from the Webster’s Dictionary is the discipline dealing with what is good and bad, and with moral duty and obligation. From the time we are children, we are always taught between right and wrong. Yet real-life situations are not always as clear-cut as they seem. Decisions made based on the judgment and interest of one person may be conflicting with another person’s judgment and interest. This essay will explore the effects of various decisions made in our product development that could pose ethical problems to the people handling the product and to the environment by illustrating hypothetical case studies specific to our design project. These case studies will profile a problem that could otherwise be too broad to be discussed. We will also discuss how each of our resolutions will be in line with the ASME Code of Ethics for Engineers’ Fundamental Canons.

First, let us introduce the design project we are working on. The product is a mechanical Continuous Positive Airway Pressure (CPAP) device that is designed to help treat obstructive sleep apnea. The device that we manufactured supplies positive airway pressure that will open up the airway by lifting up the tongue and soft palate that blocks the airway. This device operates without the use of an electrical outlet and thus is more portable and travel-friendly for sleep apnea sufferers who travel frequently, low income users, and people in developing nations. The device is estimated to be much cheaper than the current electrical CPAP machine and could almost replace them entirely. The use of this device will treat a wide range of sleep apnea severity and cost less than \$100, which is cheaper than electrical CPAP products that range from \$250-1300. This could be a big breakthrough in the sleep medicine industry.

However, the device will be in contact with patients and their vital breathing passage. And, it will not be in a professionally-controlled environment such as a hospital. Therefore, it is the utmost important that the device is manufactured safely and correctly with the right materials before it reaches the user. There could be ethical issues such as downgrading the material and overall quality of the product to increase profit margin, where we must consider both sides of the story. Overall, the device could be harmful to society if it is not manufactured correctly, such that its desired functionality is not achieved when the device reaches the end user.

We will discuss the ethical issues specific to this product according to the five topics laid out in the OnlineEthics.org website: (1) Safety and the Environment, (2) Professional Practice, (3) Employment and Legal Issues, (4) Responsible Research and (5) Computers and New Technology.

Safety and the Environment

Case 1: As a design engineer and creator of the mechanical CPAP device, you are opening a starting venture company, Mecha-PAP, to manufacture the device. Due to limited funds, you have the option to either adopt the Occupational Safety and Health Administration (OSHA) regulations or continue with the operations as per normal, reminding workers to be safe in whatever they do. The OSHA regulations can be expensive and the current economic situation does not deem it favorable for you to invest in those safety regulations. Furthermore, the device

is small and its manufacturing process is very manageable without the use of large machinery or a high-skilled operator. You decide not to follow the OSHA regulations for the time being until you are able to break even in your investments. Besides, even if the OSHA Administrators decide to conduct safety inspections, you doubt that they will find too many things that would violate the rules. While interviewing potential employees, you turned away an interviewee because they expect more pay that you could afford. He also happened to mention, during his interview, that he will not want to work in the non-OSHA-compliant workplace even though the manufacturing processes are not that risky to begin with. Instead, you hire other interviewees who are willing to work for a lower pay and does not mind working in a non-OSHA-compliant workplace.

Discussion Questions

- Are you breaching the moral ethics code by doing this?
- How would you have done things differently?

Case 1 Resolution: This boils down to your own conscience about whether you turned the potential worker away due to him wanting to be in an OSHA-compliant workplace and thus could lodge complaints if he encounters OSHA violations during the job; or, did you turn him away purely because you cannot afford to pay him his demanded wage. Nevertheless, although the manufacturing processes involved in the product development are not risky to begin with, you are still violating the moral ethics code by not implementing the OSHA regulations in the first place. Furthermore, you are going against one of the first Fundamental Canons: “Engineers shall hold paramount the safety, health and welfare of the public in the performance of their professional duties.” Although you may be reminding workers to be safe, each individual may have different standards and definitions of safety. It is important that a standard is set so that problems encountered could be easily identified and resolved. Safety is the utmost importance in anything especially for this product as it is for medical purposes. Not only is it important to keep the workplace safe for employees, it is almost important to follow FDA regulations when manufacturing medical equipment. If the device being manufactured does not follow these rules, then the device is not safe for the public either. If we are short in monetary funding, you need to find other ways to raise the money without compromising safety standards. After all, investment in safety is an investment for life, literally speaking.

Case 2: While developing the product, as a design engineer, you have the option to either use Material A or B to make the air chamber bags of the mechanical CPAP device. Both materials fit the bill in terms of functionality and essential mechanical properties. However, material A is far more expensive than material B due to its convenient recyclability. However, its recyclability also limits the life of the material such that if material A is made to make the air chamber bags, the device will fail in a matter of months. Material B is cheaper than material A and could provide a longer life for the device but has very poor recyclable properties.

Discussion Questions

- Which material would you choose to make the device and why?
- If you choose material A due to its recyclability, you would have sacrificed the expected life of the device, which in turn does not give value for the customers’ money. Which is more important, the customers or the environment?

Case 2 Resolution:

If both materials are offered, then you allow the customer to choose based on their need. For example, customers in the US have reliable access to stores to allow them to purchase the bag made of Material A. This would allow the customer to be environmentally friendly, but would require them to have a consumable part as part of their device that they must change frequently. However, developing nations do not have this reliable access, nor the monetary ability to continually purchase new bags. They need their bags to last as long as possible and be made of Material B—in this case, the customer needs to be placed in front of the environment. The company could also choose to only offer Material A only to certain customers or in certain markets, and offer Material B on a limited basis—this places the environment in front of the customer.

Professional Practice / Computers and New Technology

Case 3: As a recent engineering graduate, you approach your graduate school professor and ask him for a temporary research job opening. Your professor then recommends you to Dr. Z.Z. from the University of Michigan Sleep Medicine Center who hires you to work on developing a patent-pending mechanical CPAP device that he would like to develop. He is having significant trouble with the working mechanism of the device and has asked you to design it. You worked hard for the project and six months later, you presented your proposal to the doctor. After reviewing it, Dr. Z.Z. decided that the idea was not feasible. He thanked you, paid you for the service, and asked you to sign what he claims to be an intellectual property confidentiality form. You felt uneasy about it but signed it anyway thinking that this is just a temp job and you should not be worried about it.

A few months later, you read an article in the Journal of Medicine and see that Dr. Z.Z. is featured in the article. Other medical magazines commentators mention that the device could be a marketable product in the future. You read through it and realized that the working principle of the mechanical CPAP device he is featured for is the same working principle that you had proposed before. In fact, as a fresh graduate then, you were convinced by Dr. Z.Z. (the expert in the field) that your idea would not work, so you decided to apply for a patent for your research work. You approached the doctor and requested that your name be included as a co-creator of the device. However, the doctor claimed that his device is totally of different functionality from what you had been working on and you had signed a typical invention form giving up your rights to the invention. He refused to put your name in as a creator but offered to credit you as a fellow researcher instead and include you in the acknowledgements.

When you approached your graduate school professor, he refused to partake in the situation, claiming that the conflict is between you and the doctor, although he subtly advised that you take a step back. Furthermore, Dr. Z.Z. has been working in the field for many years, such that it is hard for you to have a case against him. Knowing your rights as the primary creator of this product you decided to pursue this case with the patent office, causing tensions between you, the doctor and other researchers who have recommended you to the doctor in the beginning.

Discussion Questions

- Are you being professional? Is there a conflict of interest?

- Should you have forgone the rights to being a creator and accepted the offer to be a fellow researcher?
- What could the doctor have done differently to appease the situation?

Case 3 Resolution:

In this case, it is unclear if the doctor has other agendas to keep you from being co-creator of the device. It may be that if you fight for your right, it is going to be a tough fight because Dr. Z.Z. has started patenting the device already. However, Dr. Z.Z. should have recognized that you indeed contributed a big portion of the idea. The first thing you should likely do is find a mentor to provide assistance in this scenario. As a young graduate, you could likely be walking into a lion's den aware. The business world can be overwhelming, but continually acting professional and never being viewed as a petulant child can be difficult at times if you do not handle the situations accordingly. If you have enough proof of your intensive involvement in the project, you could have a chance to convince Dr. Z.Z. with a more formal presentation of your proof that you were involved and eloquently imply you are unwilling to let this slide. However, from the professional point of view, you could seem unprofessional and you may be violating the fundamental canon number 4 which says "Engineers shall act in professional matters for each employer or client as faithful agents or trustees, and shall avoid conflict of interest." You should have properly read the "confidentiality" form that you signed earlier before committing to it. Because you have signed the form, you could be seen as being unprofessional if you decide to act against the confidentiality agreement between you and the doctor. In addition, there is also conflict of interest because you played a part in the development of the device. You either breach the confidentiality agreement you signed or go ahead with the struggle. However, the doctor may sue you for letting confidential information of the project out even though you may have been the co-creator. Overall, this is a complicated situation. You, the doctor, your graduate school professor, as well as, a third party who would be neutral to the case should come together and discuss the problem. Preferably, the third party could be an engineer or a scientist who could impartially determine if the working principle that the doctor used in his mechanical CPAP device is the same or completely different from what you had proposed earlier. That way the next steps of actions could be taken accordingly. If this does not resolve things, and you still feel strongly about the situation, then you might have to file a lawsuit against him.

Employment and Legal Issues

Case 4: This mechanical CPAP product has the potential to grow into the global market and therefore it is feasible for Mecha-PAP to have manufacturing plants in developing countries where labor is cheaper, thus lowering the production cost even more. You could sell the mechanical CPAP for cheaper, open-up a door to new markets and you could also be increasing the profit margins that could be beneficial for future research and development of the device. However, it should be noted that investments in other countries are cheaper also because of the lack of enforcement in workplace safety standards. In fact, while there, you, as a manufacturing engineer, notice the lack of safety standards when you see there are workers walking around the factory grounds in open-toe footwear, machining parts without safety goggles, etc. When you informally approach management, who also happened to be the major investors in this foreign firm, with this information, you are sternly rebuffed and told that the regulations in that country does not dictate the same measures as those in the United States and that they are economically

inconceivable at the moment. You feel uncomfortable at the lack of safety standards but are aware of the management's reaction toward your feeling.

Discussion Questions

- How should you address this concern?
- Is it morally acceptable for management to adopt different safety standards for the plant than for the American plant based on legal grounds?

Case 4 Resolution: Based on legal grounds of that country, the management of this plant is not doing anything wrong. However, this does not exclude them from the moral obligation to keep their workers safe in the workplace. This situation is very hard to resolve as the law in that particular country does not mandate the high safety standards that the American plant may have. Even though the plant manufacturing processes do not involve dangerous machinery, as an engineer, you are bound by the first Fundamental Canon to ensure safety. If mentioning the problem to top management does not work, then we should start at the bottom. One way to address this is to commend workers who exemplify high safety standards by rewarding him or her. This could encourage other workers to strive for safety in the workplace and start safe practices while working without management implementing it. As a manufacturing engineer, you could try and develop a safer production line without hindering production—this is not outside your job scope.

Responsible Research

Case 5: You are an engineering analyst hired by Mecha-PAP to collect and analyze data of a new and upcoming device, called ZZZ-5000, which could treat sleep apnea and aid in sleeping. It is designed and manufactured by Mecha-PAP. After significant testing, not only do you discover that the ZZZ-5000 device disrupts sleep at night, the device could actually worsen the patients' apnea in the long-run. You reported back to Mecha-PAP of these findings. Management thanked and paid you for your efforts. They also ask that you signed a confidentiality form as the company's "normal" procedure for newly-developed products.

A few months later, you saw that ZZZ-5000 has been sold in the market and its "success" was confirmed by an external private research company QQQ. QQQ claims that the device works to treat sleep apnea and aids in sleeping. You read their published papers of experiments conducted and realized that they seem to have "left out" an ultimate test that would deem the product unfit for market use. When you approached Mecha-PAP and expressed your concerns, the management does not seem surprised when you mentioned that QQQ "left out" that essential information. They explained that due to the large amount of time and money invested into making the ZZZ-5000, management decided to seek a second opinion not wanting the development of ZZZ-5000 to go down the drain. They deemed the ultimate test to be too extreme for the scope of the device and thus instructed QQQ to not include that in their findings. You knew that the ultimate test should not be left out and mentioned that you are worried of the future outcome if the problem is not resolved. The management told you not worry too much and to be on your way, reminding you that you have signed a confidentiality agreement.

Discussion Questions

- As a responsible engineer, what should you do? If you were to make a public announcement of the failure of ZZZ-5000, are you doing the right thing?
- Does their major investment in developing ZZZ-5000 justify Mecha-PAP decision to leave out the ultimate test?
- Imagine you decided to go public with your findings but Mecha-PAP threatened to fire you from the job. What would you do?

Case 5 Resolution:

As a responsible engineer, you are obligated to announce your discovery to the public as the product will indeed provide more harm to society than its benefits would. As the Fundamental Canon 3 says, “Engineers shall issue public statements only in an objective and truthful manner.” You will be breaching the confidentiality agreement, however, safety of the public is paramount and its integrity should be protected. However, you do need to be aware of libel as you could be unaware of further product developments that make this product safe and usable. Due to your extenuating circumstances, even the judge in a court would regard your action to be right as Mecha-PAP is trying to hide a serious fact from the public that could be harmful. Mecha-PAP may be a private company but they have a moral obligation to not even market ZZZ-5000 as it is not a functional product no matter how much investment of time and money are spent developing the product. In fact, they are technically committing fraud if they try to sell the non-functional product for a profit, which is something they seem to care about. They should have included the ultimate test in the report and perhaps improved the design of ZZZ-5000 instead of hiding it. Engineering Canon 6 says, “Engineers shall act in such a manner as to uphold and enhance the honor, integrity, and dignity of the engineering profession and shall act with zero-tolerance for bribery, fraud and corruption.” Therefore, doing the right thing and going public is the only option, even if it costs you your job.

To tackle environmental considerations in our design, we used the SimaPro program that calculates for us the overall impact of the materials used in many aspects. The program is able to assess the impact of the materials used by characterizing its impact, normalizing the results as well as giving it individual scores in terms of its impact on the environment. Usually the higher the impact of the materials on the environment, the more we should strive to use alternatives so that we will not be damaging the environment with our product. We feel that the resources calculations that indicate the amount of waste produced by each material is the most useful than all because it shows us clearly which material produces the most waste (raw materials, air and water emissions, as well as waste material produced). This provides us with a guide to which materials we should consider to reduce waste. In our case study 2, we managed to resolve the customer vs. environment issue considering customer needs and their purchase power. Designing products for sustainability is very important but not everyone can afford it. For now, those who could afford it should be encouraged to buy recyclable products while those who cannot be given either option. That way, we are “sowing our seeds” by educating and promoting the act of sustainability and hope that in the future, we will be able to “reap the harvest.”

While working in this project we were lucky enough not to encounter major ethical dilemmas with our teammates, instructors or sponsor. Perhaps the only ethical issue we encountered was related to the questions we asked in the survey. We are not professionals in the medical field and if we were to ask sleep apnea patients some questions regarding their disorder and treatments, it

could pose some confidentiality boundaries of the patients. For this purpose, we were very careful in our construction of the survey questions so that the patients would not feel as if we are invading their privacy and convincing them that we are trying to help. This seems to work out perfectly as we received tremendous response for our survey. Some people even wrote back to us that they are grateful that we are trying to see into the problem. One of them wished us luck with the project and thanked us for the effort. Another also recommended us other sleep apnea patient support groups that we could get more feedback from. Therefore, we know that we must have done something right.

Overall, the workload of this class has been tremendous and at times stressful. However, we never gave up and we were continually involved and working hard on the project. We were very professional in the undertaking of our assigned tasks and everyone was able to complete them on time without any problems of the classic “parasitic” teammates. This, we felt, is a great strength of our group as everyone contributes, big or small, to the best of their ability. Everyone was respectful of each other at all times and we were able to communicate quite effectively and ask (and/or provide) help as needed. The fact that our whole team took this class and project seriously really facilitated a worry free semester in terms of ethical dilemmas or team dynamics problems. Our instructors and all other individuals that we seek guidance from over the span of the project this semester have been very helpful. They kept us on track and provided invaluable resources that are beneficial for the project. In fact, unlike the project-ownership issues we discussed above (case 3), our instructors are extremely helpful and supportive with regards of patenting issues and including the whole team as co-inventors of the device. Without them, we could not have gotten this far.