Oxygen Concentrators for Neonates in Low Resource Environments

ME 450 Fall 2020 Semester

Final Report

Team 17

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Executive Summary

The goal of this project was to develop a portable, reliable, and robust oxygen provision device. The device must be appropriate to treat neonates experiencing RDS and hypoxia in low-resource clinical settings, specifically in Nepal. Using the target product profile (TPP) developed by UNICEF and NEST360°, we created a list of stakeholder requirements and engineering specifications that are the foundation of the problem definition.

With detailed research and stakeholder interviews, we furthered our understanding of the maintenance, training materials, and use of such a device. The method of oxygen concentration is the most vital component of the proposed solution, so concept generation focused on this. Concept generation strategies including a morphological chart and TRIZ triggers produced five unique designs based around five different. Through an evaluation process supported by a pugh chart comparison, vacuum swing adsorption (VSA) was selected as our final oxygen concentration method. The final design was built around a vacuum swing adsorption system, with a simple user interface in portable housing. The design was modeled in SolidWorks.

Theoretical analyses were run on the VSA system to determine the necessary number of sieve beds and identify ways to simplify the user interface. Through research and meetings with subject matter experts we determined that there was no obvious barrier to a small scale VSA portable oxygen concentration. In detail we performed five engineering analyses: expert interviews, sieve bed analysis, cost analysis, risk analysis, and user interface analysis. The five analyses supported the theoretical feasibility of the VSA design.

To verify the solution, a prototype made of a retrofitted pressure swing adsorption (PSA) oxygen concentrator was planned. However, due to the coronavirus pandemic, the team was unable to meet in person and safely modify the PSA concentrator. Instead, solution verification consisted of updates to the theoretical usability and cost analysis, along with test plans detailing the PSA retrofit and testing. To better understand next steps that would have to be considered after a working prototype is developed, the team met with Randy Schwemmin from the Center for Socially Engaged Design to understand the overhead costs of obtaining a CE mark or FDA approval and bringing devices to low resource settings. In the case that a prototype proved to have a cheaper component cost than current PSA systems with the same functionality, it would be worthwhile to pursue a CE mark or FDA approval to make this device available in low resource markets, including Nepal.

When designing medical devices for low-resource settings, it is especially important that health solutions are evaluated critically as individuals cannot afford to invest in ineffective treatments [3]. Therefore, there should be high importance placed on both the safety and efficiency of proposed oxygen concentration devices. Because of the low-resource target demographic of the solution, medical and health claims will be appraised critically through the design process. The CE mark or FDA approval would indicate to low resource buyers that this device will meet high

safety standards and serve their patients effectively. The solution verification indicates that it may be possible to create a VSA system at a cheaper cost than a PSA system. Physical testing will be necessary to substantiate this theory and push the design on towards validation.

Problem Description and Background

Approximately 1 in 10 newborns require immediate assistance breathing after birth due to improper formation of lungs [5]. In the womb, a fluid called surfactant is built up in the fetus's lungs. This surfactant is responsible for reducing surface tension in the lungs, allowing for the lungs to be inflated more easily. A diagram of this is illustrated in *Figure 1* below. After birth, this fluid is absorbed into the neonate's lungs as they begin to breathe with their fully expanded lungs. This process is reflexive and must occur directly after birth, i.e. the "baby's first breath". If the amount of surfactant in the lungs is insufficient and the lungs are not fully expanded, then neonate may struggle to take the first breath, leading to Respiratory Distress Syndrome (RDS).Surfactant production begins in week 24 of pregnancy. Neonates born before 24 weeks gestational age all have RDS [5]. By 34 weeks gestation age, most neonates have produced enough surfactant to survive on their own. Despite this, some neonates born after 34 weeks and even full term neonates can suffer from RDS. If the RDS remains untreated, it can lead to hypoxia, or oxygen deprivation in organs and tissues, causing further complications. Nepal, with a neonatal mortality rate of 27.9 per 1000, is ranked 17th in the world for neonatal mortality [37]. Of all neonatal deaths in Nepal, the largest sector of deaths are complications from preterm birth, including respiratory distress syndrome [38].

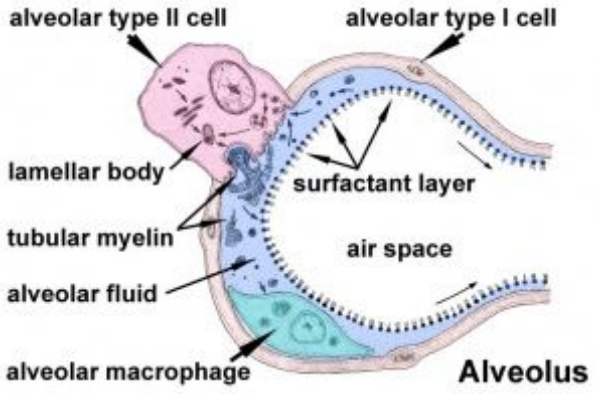


Figure 1: *Fetal respiratory system development, and surfactant build up. [5]*

Current Solutions

Newborns with Respiratory Distress Syndrome can be treated with artificial surfactant or with supplemental oxygen. These artificial treatments of surfactant for one patient can range in cost from $800 to $1200 [34]. In Nepal, many hospitals, including that of our main stakeholder Dr. Stephen John, do not have wall oxygen. Dr. John's hospital uses portable oxygen concentrators to provide relief for respiratory distress [16]. These are often a practical way to provide oxygen,

they do however have some obstacles. Portable oxygen concentrators cost above $1500 and only treat one patient [16]. If such a concentrator could take more patients, or cost half as much, a hospital could double its capacity to treat infants in respiratory distress. It is our goal to create an effective and low cost oxygen concentration device to treat neonates experiencing RDS and hypoxia in low-resource settings such as Nepal. The currents standard in portable oxygen concentration are pressure swing adsorption oxygen concentrators.

Pressure Swing Adsorption

Overview

Current oxygen concentrators operate on a Pressure Swing Adsorption (PSA) system. When gasses are pressurized, different gasses are attracted to solids more or less than others. PSA systems utilize this and pressurize air to attract gasses to the molecular sieve beds in the system [31]. This process can be seen in oil refineries for carbon dioxide removal in hydrogen gas production, methane concentration to produce biogas similar to natural gas, and in hospitals for oxygen concentration as a substitute for oxygen tanks.

Portable Oxygen Concentrators

Portable oxygen concentrators (POC) are similar to the systems that can be found in hospitals for bulk oxygen generation but on a smaller scale. POCs work by intaking ambient air and filtering it through a two stage filter. The first stage is a Cyclone High Efficiency filter meant to remove large dust particles and other contaminants while the second stage is a High Efficiency Particulate filter which is responsible for eliminating the smaller sized contaminants [31].

The filtered air is then pushed into a compressor and a dryer to produce pressurized air without any excess moisture generated from the change in temperature and pressure. This clean air is now ready to enter the molecular sieve beds. For oxygen concentration, zeolite is often used because of its strong attraction to nitrogen at high pressures. These beds adsorb the nitrogen resulting in air that has higher oxygen concentration than atmospheric air. The air is removed from the beds and placed into tanks for further processing. A simplified diagram of this entire process can be seen in *Figure 2* below.

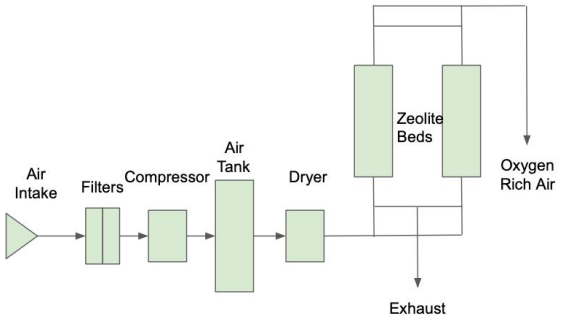


Figure 2: This diagram depicts the major components of the PSA system

For the process to begin again, the beds are depressurized allowing for the nitrogen to detach from the zeolite. Some of this air is removed as exhaust back into the environment while the rest of it is used to pressurize the other molecular bed in a process known as pressure equalization. The usage of more than one bed allows for the continuous production of oxygen concentrated air.

Benchmarking

Current solutions for newborns with RDS are similar for both high and low resource settings. As part of the design process, we compared current portable oxygen concentrators in the market and other projects that either tried to serve low resource settings or tried to serve a need for portable oxygen. To better illustrate why these solutions do not meet the requirements of our stakeholders, we selected a few high and medium priority specifications from our project and marked whether or not these alternatives are viable options. All benchmarks found used pressure swing adsorption as described above to achieve oxygen concentration. The table can be seen below in *Table 1.*

Table 1: *Comparison of current oxygen concentrator solutions. Details regarding the requirements can be found under "Requirements and Specifications" on page 6*

Green: *Optimal requirement is satisfied*
Yellow: *Minimal Requirement is satisfied*
Red: *Neither requirement is satisfied*

	Lightweight	Number of patients	Cost	Portable	Oxygen concentration	Flow Rate
Inogen One G4 POC with Pulse Dose Flow [14]						
Inogen at Home [31]						
O2 Concepts Oxlife Independence POC [15]						
OxCart (Rice University) [3]						
OGSI (OG-15 and OG-20) [8]						

Inogen One G4's portable oxygen concentrator claims to be the most portable POC available; however, its lightweight components make for a more expensive unit, exceeding the required $1,600.00 limit. Its size also limits the number of users per device which is not ideal pricewise.

Inogen at Home provides sufficient oxygen at proper concentrations, but it is meant for stationary use only. This limitation may make it difficult to deliver to the hospitals in Nepal and will not allow for users to continue oxygen treatment in their homes.

O2 Concepts' portable oxygen concentrator is similar to that of *Inogen One G4's* product. Their product boasts extended battery life but at the cost of expense which is a higher priority requirement. was not designed with our specific stakeholders in mind.

OGSI's oxygen concentrator is another device that is catered more for communities outside of the one we were tasked with designing for. Although it generates the proper oxygen concentration and can be used on multiple users at a time, it is not portable.

No benchmarked concepts meet all the listed requirements. Inogen and O2 Concepts achieved all technical requirements without achieving the cost. Therefore we know that the technical requirements are achievable, and our primary goal will be to decrease cost.

Stakeholders

There are multiple stakeholders for this project. Dr. Stephen John, is one of the most important stakeholders and sponsors. He serves as a technical mentor for our team, is the co-founder and CEO of Aim Tech and a pediatrics resident for internal medicine. He has helped make NeoVent, an ultra-low cost, easy to use, energy efficient respiratory device for infants in respiratory distress. Stephen is especially invested in this project due to the applications that it can have with NeoVent and in Nepal. The University of Michigan, as well as Caroline Soyars, a global health sponsor, are also stakeholders and sponsors, as this project is not only applicable to low-resource settings, but can also be applied to more developed countries. The World Health Organization (WHO), as well as the United Nations Children's Fund (UNICEF) are stakeholders, as the need for oxygen treatments are at an all time high, especially during the COVID-19 pandemic. Parents of newborns with RDS are also stakeholders, as this project aims to create a more affordable treatment. The Kwame Nkrumah University of Science and Technology (KNUST) in Ghana is also a stakeholder. The student team at KNUST is also working on a similar project with connections to local research hospitals there in Ghana. This is very important to them because Ghana is one of the low-resource environments where a viable solution is needed most.

Subject Matter Experts

In addition to our stakeholders, meeting with subject matter experts from a variety of fields and backgrounds will help us broaden our knowledge on low resource settings, infant care and RDS, and device manufacturing, cost structure, and training.

From the Clinical Simulation Center (CSC) at the University of Michigan School of Nursing, Ms. Debra Yake, Training Specialist; Dr. Deb Rooney, PhD; and Mr. Ed Lockett III, Simulation Technician, have helped us understand how doctors, nurses, and clinicians are trained on new devices. Deb Rooney is the CSC's Director of Education and Research where she has over 25 years of medical education experience, with the last 12 being in simulation. Debra Yates is a training specialist and course director with the CSC.

From the Center for Socially Engaged Design at the University of Michigan, Mr. Randy Schwemmin has knowledge on medical device manufacturing and costs associated with that. We hope to gain understanding on the current costs associated with oxygen concentrators, and where in the manufacturing and distribution those costs lie.

From the Chemical Engineering department, Mr. J.T. Anyanwu is the graduate student of Dr. Ralph T. Yang who has done research on cyclic adsorption processes such as PSA as well as adsorbents and diffusion in zeolites. From Mr. Anyanwu, we gained valuable insight on vacuum swing adsorption and its feasibility on a small-scale.

Dr. Jeff Plot is the Associate Director of Engineering and Development, Biomedical Engineering, at the University of Michigan. We plan to use his experience with medical device product development to validate our current design.

Throughout the project, we will continue to seek advice from subject matter experts, especially as we seek to delve deeper into low resource design and constraints specific to hospitals in Nepal.

Requirements and Specifications

Overview

A report [3] summarizing the consensus achieved at a meeting regarding Target Product Profiles(TPP) for newborn care in low income settings was written by a professor from Northwestern. The meetings held for this TPP involved individuals from UNICEF, NEST360° and other stakeholders. Many of the requirements and specifications from the TPP were adopted and applied to our project.

The current list of requirements will grow as meetings with stakeholders provide further information. Dr. John [16] will also be a valuable source of information given his experience in the medical field in Nepal. These meetings will include individuals from the Kwame Nkrumah University of Science and Technology (KNUST) who are working on a similar project and have access to a hospital in Ghana, giving them greater insight on the needs of hospitals in these lower resource settings..

To cater our work towards low resource hospitals in Nepal, we have reconsidered all requirements from the Target Product Profile, refined them, made them more specific to Nepal, and prioritized them based on the input of our stakeholders.

High Priority

From stakeholder feedback and the target product profile, we have identified the requirements and specifications with the greatest priority, listed in Table 2 on page 6.

Table 2: *Highest Priority Requirements and Specifications*
Green: *High Understanding*
Yellow: *Growing Understanding*
Red: *Incomplete Understanding*

Requirement	**Specifications**
Be able to provide sufficient oxygen [31]	The concentrator must provide 93% FiO2 with a 3% contingency [31]
Be safe [31]	The device must meet either approval guidelines for USFDA or other stringent regulatory body of a founding member of IMDRF [31]
Be cost-effective [31] [32]	Optimally, the device should cost less than 500 USD Minimally, the device must cost less than 1,600 USD [31]
Be able to maintain a low flow rate [31][16]	The concentrator's minimal flow rate must not be higher than 0.5 LPM (optimal)/2 LPM (minimal requirement) [31]
Be modular [31] [23]	The device must use a standard ribbed conical connector to interface with a variety of oxygen delivery methods [31] Compatible with standard outlet/inlet connectors (22 mm outer diameter) and flex adapters [23]
Be usable by a minimally trained user [31][16] [15]	To show current state of oxygen concentration and warnings pertinent to patient condition and device condition: ● The visual display should be at contrast ratio >7:1 and luminance >35 cd/m^2 with a font size >16 to make it easily visible at a distance of 3 ft. The visual warning/indicator lights should be red or green. [15] ● The auditory warning should be approximately 89 dB and 127 sones. [15] No specialized tools may be required for day to day operation [31] The device should be usable after a 5 minute training video. [16] Alarms and communications on the device should be

	understandable to hospital staff as well as parents with no training time, so that they know when to alert a hospital staff member.
Be able to operate in a variety of extreme environments common to Nepal [31]	The device should not need more than quarter-annual preventive maintenance. The device must operate up to 2000m above sea level. 10°C < Operating Temp < 40°C 15% < Operating Relative Humidity < 95% The device must meet ISO 13485:2015 (Quality Standard) [31]

Provide Sufficient Oxygen

Of high priority, the oxygen concentrator solution must be able to provide sufficient oxygen for the neonates. This specification is 93% FiO2 ±3%, that is 93% pure oxygen, as defined by the Target Product Profile [31].

Be Safe

In designing medical devices, safety of the users is of the utmost importance and high priority. Thus, adequate safety of the solution is defined as meeting either approval guidelines for USFDA or other stringent regulatory body of a founding member of IMDRF [31].

Be Cost-Effective

Of similar high priority, the cost of the oxygen concentrator solution should be lower than current oxygen concentrators to ensure its affordability in low-resource settings. Optimally, the device should cost no more than 500 USD; however, at minimum the device should cost less than 1600 USD [31]. As mentioned earlier in benchmarking, the existing solutions that are able to provide sufficient oxygen concentration are currently above this price level. The Inogen at home meets our minimum cost requirement but is not an optimal solution.

Be Able to Maintain a Low Flow Rate

When delivering oxygen to an infant, doctors decide the percentage of oxygen and the flow rate at which the oxygen is delivered to the infant based on the infant's specific situation. Doctors can modulate the percentage of oxygen by diluting the 93% oxygen directly from the concentrator with room air. To achieve the desired oxygen percentage at a proper flow rate, it is important to have precise control over the flow rate at which the 93% oxygen is delivered. Optimally, the oxygen can be delivered at a rate of 0.5 LPM, at the lowest [31]. Minimally, the oxygen will be able to be delivered at 2 LPM [31]. Through stakeholder input, we have determined that one user will be treated by each device [16].

Be Modular

In order to get the most use out of the oxygen concentrator, it should be modular, meaning it should be able to work with a variety of ventilators, masks, and nasal cannulas [31]. According to guidelines from the WHO on ventilator design, this means the concentrator should be compatible with standard inlet/outlet adaptors of 22 mm outer diameter [23]. This requirement is still developing as we learn more about the ventilation devices available at the location we are designing the concentrator for.

Be Usable by a Minimally Trained User

To maximize the accessibility of the concentrator, it should be usable by a minimally trained user. This means the device should require minimal training time and no specialized tools for day to day operation [3]. The training time is defined as being usable after a 5 minute training video which is an acceptable time target given to us by Dr. Stephen John [16]. The device should also have clear visual and auditory warnings and displays. Through research on human factors we found this means the visual display should be at contrast ratio >7:1 and luminance >35 cd/m2 with a font size >16. The visual warning/indicator lights should be red or green and the auditory warning should be approximately 89 dB and 127 sones [15]. The visual display requirements were made to be easily visible at a distance of about 3 ft which is appropriate for a bedside device. Any alerts on the device should be able to be interpreted by hospital staff as well as an untrained person so parents are able to understand and notify hospital staff when there are warnings.

Operational in Extreme Environments

In general, low resource hospitals face more extreme environmental stressors because they may not have climate control or reliable climate control. In addition, part of the Himalayan mountain range falls in Nepal and has major population centers as high as 1700m above sea level. Given Nepal's geography and climate, it is critical that our device operate in temperatures between 10°C and 40°C, relative humidity ranging between 15% and 95%, and function at elevations up to 2000 m [31]. Based on further research, there are no hospitals above 2000m in Nepal. In specific, the hospital of our stakeholder Dr. John lies at 1500m above sea level.

Medium Priority

There are quite a few requirements and specifications that are not ranked quite as highly in terms of importance by our stakeholders. These requirements are listed below in Table 3.

Table 3: *Medium Priority Level Requirements and Stakeholders*
Green: *High Understanding*
Yellow: *Growing Understanding*
Red: *Incomplete Understanding*

Requirement	Specifications
Be able to start working quickly [31]	The concentrator must be able to reach 95% of 93% FiO2 and 10 LPM flow rate in less than five minutes [31]
Be transportable by a single hospital staff member [31] [16]	Weight < 30 kg [16] The unit must be movable with at least two wheels [31]
Device maintenance should be simple [31]	No specialized tools required. Fixable by a biomedical technician after a 5 minute training video. Filters are easy to wash and replace. Attachments must be removable so the device is simple to sanitize between patients. The device must not require preventative maintenance more than four times per year. [31]

Begin Operation Quickly

The oxygen concentrator is meant to provide oxygen to newborns in cases when they cannot breathe on their own. This means every second it takes to start up the device, the newborn has to survive longer with improperly formed lungs. Although it is essential for the device to start up quickly in the scenario mentioned above, it is expected for the device to be set up and ready to provide oxygen at any given time. Hardly ever should the device setup begin at a moment's notice of the newborn's condition.

Be Transportable

It is ideal for the device to be set up and ready to go in the room it will be needed; however, if the device needs to be moved to another part of the hospital, it is ideal for the oxygen concentrator to be moveable by one person. Since we are designing for a hospital setting, we do not have to factor in any potential rough terrain. In a setting such as the hospital, it is essential to reduce the number of staff members required per operation.

Simple Maintenance

To perform its life saving function, the oxygen concentrator must be reliable. In order to avoid burdening staff at low resource hospitals, it must be easy to maintain. No specialized tools should be needed for both regular operation and maintenance - all tools required should be already owned by the hospital for maintenance on other equipment. Thus, we can assume the use of phillips and flathead screwdrivers along with basic hand tools. No specialized torque screws may be required [16]. Procedures should be simple so that preventive and emergency maintenance can be communicated in a 5 minute video. This time target was also provided by

Dr. Stephen John [16]. While the device should be very durable and rarely need emergency maintenance, it is important that it also only needs preventative maintenance four times a year or less as stated by the TPP [13]. The filters, which will need to be regularly switched, should be reusable and simple to wash and change.

Low Priority

There are two lower priority requirements as prioritized by our stakeholders and the Target Product Profile, shown in *Table 4*.

Table 4: *Low Priority Requirements and Specifications*
Green: *High Understanding*
Yellow: *Growing Understanding*
Red: *Incomplete Understanding*

Requirement	Specifications
Be quiet [31]	Ambient operating noise < 50 dB [31]
Be operable in Nepal [31] [16] [15]	The device uses mains power. Power consumption <275W at 5 LPM The Voltage model must match the voltage and frequency of the purchasing country's local power grid. Nepal operates on a 230V supply voltage and 50Hz [15] Type C, Type M, Type D connectors

Be Quiet

In order to create a product that is pleasant to the senses, the device must be quiet. The specification for this is that the ambient operating noise be less than 50 dB. The noise of the device does not affect the functionality, it is strictly for customer satisfaction.

Be Operable in Nepal

Given that our main stakeholder, Stephen John, is primarily focused on working with neonates in Nepal, we have decided to focus our efforts there. In order for the device to function properly, the specifications are that it must consume less than 275 W at 5 LPM. The device also has to operate properly on Nepal's power grid. Which means it must operate on a 230V supply voltage at 50Hz, and have a type C, type M, or type D connector.

Solution Neutral Considerations

Since the oxygen concentrator will be used in a low-resource setting for the purposes of healthcare, there are some environmental and ethical factors we have to consider. These aren't requirements that can be described with quantified specifications but considerations that will influence our design space. There is a possibility that the device will be used in patient homes so we must consider various backgrounds and levels of education to maximize the accessibility of the concentrator. The device will be used for the purpose of healthcare so we want it to abide by the principle of "Do No Harm" which in this case would mean to avoid disease transfer via the oxygen concentrator, both synchronously if more than one patient were to be receiving oxygen, and asynchronously between patients. We'll have to consider emotional stressors between the carer and infant as well environmental stressors such as patient density within the hospital. We mentioned cost above from the perspective of the hospital being the purchaser but we should also consider what the patients at the hospital can afford for healthcare.

Concept Exploration

Concept Generation and Development

Methods and Rationale

Three design tools were used to generate solution concepts: a design space map, a morphological chart, and TRIZ triggers. The design space map was chosen to give us a physical representation that might allow us to recognize unexplored aspects of oxygen concentrator designs. A morph chart, with its organization of concepts by function, allowed us to view the oxygen concentrator as four smaller problems based on individual functions. Because an oxygen concentrator can include complex chemical, mechanical, and electrical subsystems, our generation approach needed to be research based. The TRIZ effects database allows users to search general solutions by function, parameter, or transform. Having broken down the oxygen concentrator into four basic functions for the morph chart, we ran a generalized restatement of each function though the TRIZ effects database and focused our research on promising ideas listed there for each function [36].

Results

The design space map was of limited use to us, we were unable to imagine much outside the confines of the current oxygen concentration method, PSA. The morph chart allowed us to expand more by function, and we were able to brainstorm creative ideas for the following four functions: Raw Material Intake, Oxygen Purification, Air Formatting, and Air Delivery. After brainstorming for each function, we used the TRIZ triggers to find more ideas for each function as shown below in *Table 5*.

Table 5: *Morphological Chart showing solution concepts for the four subproblems*

Morphological Chart: Subproblem Solution Concepts				
	Raw Material Intake	**Oxygen Purification**	**Air Formatting**	**Air Delivery**
1	Air through compressor	Liquify air and use fractional distillation to separate oxygen and nitrogen	Constricting a flexible pipe	Modular hose with attachment kit
2	Air into balloon vacuum	Zeolite/ Pressure swing adsorption system	Mechanical valve	Face Mask
3	Air via corona discharge	Use selective permeation to separate oxygen molecules from pressurized air	Variable density filter	Helmet/bubble
4	Fan pushing air	Electrolysis of water	Layering filters	Cannula
5	Gravity differential with water	Carbon Molecular Sieve	Reintroduce ambient air through a pump and valve	External pump to imitate lungs (NeoVent)
6	Pump with water			

Some ideas were mutually exclusive to ideas in other categories, meaning they could be applied to any solution from a different category. For example, a mechanical valve for air formatting can be applied to any oxygen filtration solution. Other ideas were less so: using water as the raw material for intake only works with the electrolysis oxygen concentration concept. In general, the raw material intake is dependent on the oxygen purification method and cannot be varied.

Using these constraints and significant research, we identified five unique solutions from the morphological chart as shown below in *Table 6*. Oxygen concentration was determined to be the key design function, so the team focused on this function for concept selection, prioritized over the other solution sub-functions. This led us to center our solutions around the five different methods for oxygen purification: Semi-Permeable Membrane, Electrolysis, PSA, VSA, and VPSA. *Table 6* shows the raw material intake associated with each oxygen purification method. After the oxygen is purified, the next step is to format the air for delivery. This part of the solution is independent of the oxygen purification method. For this step, we plan on having a mechanical valve which will allow ambient air to be reintroduced to the system. This gives us control of the exact oxygen concentration of air that is being delivered to the patient. When the air is being delivered out, we want the solution to be compatible with as many ventilation devices as possible. To achieve this, we decided the delivery method would take the form of a universal standard adapter.

Table 6: *Solution Concepts*

	Solution Concepts				
Function:	**Semi-permeable membrane**	**Electrolysis**	**Oxygen Generator**	**Oxygen Generator**	**Oxygen Generator**
Raw Material Intake	Ambient air via compressor	Water via pump	Ambient air via compressor	Ambient air via blower	Ambient air
Oxygen Purification	Uses membrane and molecule structure to filter nitrogen from air	Water electrolysis	Pressure Swing Adsorption (PSA)	Vacuum Swing Absorption (VSA)	Vacuum-Pressure Swing Absorption (VPSA)
Air Formatting	Air-Oxygen Blender: 2 input, 1 output system				
Delivery	Hose with conical universal connector				

Electrolysis

Overview

Electrolysis is a process in which water undergoes decomposition into hydrogen and oxygen gas via an electric current as shown in the simplified diagram in *Figure 3* below[39]. Currently, electrolysis is used mainly for hydrogen generation in appliance sized electrolyzers for lower-scale hydrogen production and large-scale, centralized hydrogen production facilities for energy production[39]. Using electrolysis for oxygen generation, especially on a portable scale, has not been commercialized. One of the few industries engaging with this technology is the aerospace sector, where oxygen generation via electrolysis has been used to supply space stations with necessary oxygen levels[20].

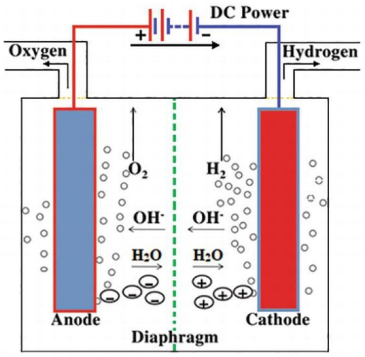


Figure 3: *Electrolysis Overview [21]*

Oxygen Concentration

In the proposed electrolysis design water will be pumped into the device from an external source. Oxygen is generated when electricity is run through the water, decomposing water into hydrogen and oxygen gas. The resulting concentration of oxygen is extremely high, greater than 97%[20].

Benefits of Electrolysis

The high concentration of oxygen produced via electrolysis is a major benefit to the system, surpassing the requirement of 93% oxygen. However, electrolysis is expensive, especially in terms of the electricity required to run it. Additionally, the system does not lend itself well to portability as it must be connected to both a power supply and a water source. The oxygen concentration system also raises safety concerns, as the produced hydrogen gas potentially could lead to explosions[20].

Semipermeable Membrane

Overview

Semipermeable membranes employ the physical differences between molecules in the air to filter out undesirable molecules by size as shown in *Figure 4*. Currently, semipermeable membranes are used for nitrogen concentration, shunting oxygen, argon, and all other air components off while allowing nitrogen molecules through. This method provides nitrogen for a variety of industries such a metallurgy, oil and gas, electronics, and medicine, and allows these industries to operate independently of the liquid nitrogen supply chain [25]. In general, membrane based gas separation methods are lower fidelity than zeolite based methods, however very successful air to concentrated nitrogen solutions exist, so it is possible that this method could be reversed to leave nitrogen as the byproduct and filter for oxygen [25, 33].

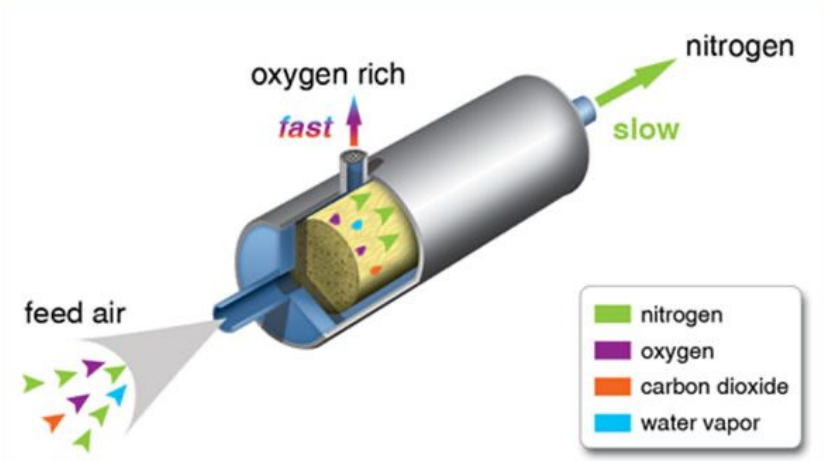


Figure 4: *Current nitrogen concentration via a semipermeable membrane [25]*

Oxygen Concentration

The Semi-permeable membrane method requires ambient air be taken in via a compressor. The ambient air is filtered before entering the system and goes through heating and cooling to remove excess moisture from the air before it is ready to be separated. Directional filters directional filters should select for oxygen molecules along the grain and shunt all other molecules, especially nitrogen molecules, off into the byproduct stream [25].

Benefits of Semipermeable Membrane

The semipermeable membrane is a physical solution that does not rely on a chemical reaction or, therefore, the chemical reactants needed for that reaction. Air must be very clean before passing through the membrane, but given this condition, it may be possible to develop a membrane with a very long lifetime [25, 33].

Vacuum Swing Adsorption System

Overview

Vacuum swing adsorption systems (VSA) are similar to pressure swing adsorption systems in that they use molecular sieve beds, more specifically zeolite, to filter out the unwanted molecules in air to concentrate oxygen. VSA systems are currently used to generate oxygen, treat wastewater, combustion, and mining [18]; however, there have been very few applications of VSA systems in portable oxygen concentrator technology.

Oxygen Concentration

VSA systems differ from PSA in that there is no compressor. The air is taken into the system using a blower and filtered through the same two-stage filter as before. Once the air is pushed through the zeolite, the system swings to a vacuum using a pump to remove the nitrogen from the bed and force out the exhaust. A simplified diagram of the process can be seen in *Figure 5*.

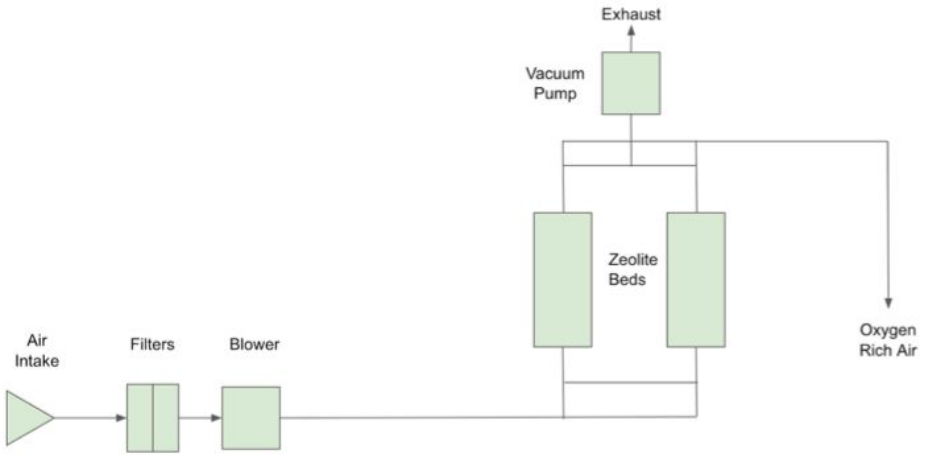


Figure 5: *Portable Oxygen Concentration*

Benefits of VSA

As mentioned before, this system does not use a compressor. This means the energy requirement compared to that of PSA is lower by as much as 50% [18]. The absence of a compressor also means the operating temperatures and pressures are much closer to that of ambient air. This makes for a safer system that is minimally affected by atmospheric pressures and a system that requires fewer parts because of the lack of pressurization. These benefits satisfy the requirements regarding operation in extreme environments and simple maintenance.

The molecular sieve beds in a VSA system last much longer than that of a PSA system for several reasons. There is no additional moisture added to the air because there is no compression. This reduces the amount of contaminants that enter the beds, meaning they do not have to be replaced as often. Vacuum pumps are also more efficient at removing the

nitrogen from these beds which allows for more nitrogen to be adsorbed in the next cycle and for more oxygen to enter the system. This more efficient cleaning procedure means VSA systems produce more oxygen in the long run than PSA systems do.

Hybrid Vacuum Pressure Swing Adsorption System

Overview

Hybrid vacuum pressure swing adsorption systems (VPSA) are a combination of the PSA and VSA systems mentioned above. They operate using both a vacuum pump and compressor. Because of the compressor, VPSA systems are best suited for applications that require pressures higher than ambient. Otherwise, the additional cost has no real benefit in a portable oxygen concentrator [30]. This is the reason why VPSA systems are not commonly applied to these devices.

Benefits of VPSA

This system combines processes for clearing beds which means more efficient oxygen concentration and longer lasting materials. Although there is a higher initial cost because of the additional components in the system, operating costs in a VPSA operated POC is lower than that of PSA. This, however, does not include maintenance costs which is higher than the previously mentioned systems because of the complexity of the device. A simplified version of the process is shown in *Figure 6* below.

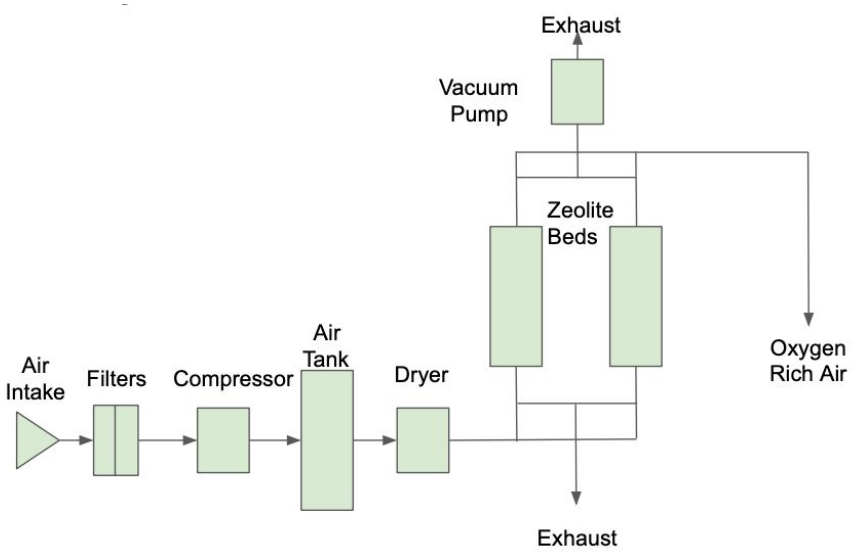


Figure 6: *Portable Oxygen Concentration*

Concept Selection

Method and Rationale

A Pugh Chart was used to evaluate the five possible solutions. Pugh Charts evaluate concepts in relation to a baseline concept based on specified criteria. Criteria are weighted, and concepts are ranked as being either better or worse than the baseline [35]. This format lent itself well to evaluation of the five solutions proposed; it allowed for evaluation of the four novel solution concepts in relation to the current solution. In this way, all ideas were compared to the current standard solution: pressure swing adsorption. This allowed for both identification of the best idea and whether or not it improves on the current solution.

Six criteria were used in the Pugh Chart to evaluate the four novel ideas in relation to pressure swing adsorption. The weighted criteria were designed to simply reflect the requirements and specifications in the context process performance, and are as explained below in *Table 7.*

Table 7: *Pugh Chart criteria weights*

Criteria	**Weight**
Cost	6 (highest weight)
Oxygen Concentration	5
Maintenance	4
Energy Efficiency	3
Safety	2
Raw Material Intake	1 (lowest weight)

Cost falls in the category of highest importance in the requirements and specifications. In Nepal and other low resource settings, affording sufficient oxygen concentrators is a significant barrier to a hospital. In achieving the $500 - $1200 cost goal set by the World Health Organization in the Target Product Profile, we would enable low resource hospitals to purchase more concentrators with the same budget, or reduce their budget and send that money elsewhere, depending on hospital needs.

We cannot lose functionality as we bring down cost. Oxygen concentration is also a high importance requirement. Any proposed solution must be able to concentrate oxygen to 93% ± 3%. This requirement comes second only to cost because solutions with proper oxygen concentration rates do exist while solutions at affordable cost do not.

Simple maintenance is a medium importance requirement defined in the Requirements and Specifications. Maintenance schedules will greatly impact how useful the device is to the hospital: its reliability is paramount. Once the device works and is aquireable at reasonable cost, it should require no more than yearly preventative maintenance.

Energy efficiency refers to the ability of the device to concentrate oxygen efficiently so as to not require frequent filter replacement and not consume high power. While this does fall under the medium importance maintenance requirement, it has been separated into a separate criteria here in light of significant differences between the process. That is to say, one proposed process may be robust enough not to require frequent preventative maintenance but is inefficient in that it requires a large amount of energy or dirties the filters frequently.

Safety is a high priority requirement in the requirements and specifications. It is weighted below cost, oxygen concentration, and maintenance on the Pugh Chart because we have observed that safety does not change heavily between the proposed processes, with the possible exception of the electrolysis process. Our largest effort in safety will not be with the differences between the four novel solutions, but with a scope decision under consideration: if the oxygen concentrator, regardless of concentration method, is used to support more than one patient, then disease transfer must be impossible. Since the most important aspect of the safety requirement is not directly applicable to the Pugh Chart, we have chosen to prioritize the other differentiators for concept selection.

Raw material intake is listed as a criteria because each process directly influences the possible intake methods, so the intake is inseparable from the process. It is weighted least of all criteria as it is not heavily tied to any requirement. Certainly, the raw material used and the intake method must be accessible in environments common to Nepal (a high priority requirement), and must allow for a quick start-up time (a medium priority requirement), but there is no indication that any method won't meet either of these two requirements. This criteria exists more so to compare the intakes than to eliminate one.

Results

Criteria	Oxygen Concentrator - PSA	Weight	Semi-permeable Membrane	Electrolysis	Oxygen Concentrator - VSA	Oxygen Concentrator - VPSA
Cost	0	6	-6	-6	6	-6
Oxygen Concentration	0	5	5	5	0	0
Maintenance	0	4	0	-4	4	4
Energy Efficiency	0	3	3	-3	3	3
Safety	0	2	0	-2	2	0
Raw Material Intake	0	1	0	-1	0	0
Score			2	-11	15	1

Figure 7: *Pugh Chart showing selection of VSA Solution Concept*

Vacuum Swing Adsorption was shown to be the most promising solution across the six criteria using the Pugh Chart, outperforming the current solution baseline by 15 points. This is quite a large win, with the closest solution, semi-permeable membrane scoring 14 points lower. This result is due to VSA's low cost and greater than or equal to performance to PSA in all other metrics. We have chosen to agree with the Pugh Chart results and select VSA as our final

concept, as the Pugh chart accurately represents the priorities of the stakeholders to solutions that are both low cost and effective.

Proposed Solution Concept

The vacuum swing adsorption portable oxygen concentrator solution concept will be modeled after current pressure swing adsorption portable oxygen concentrators to help determine general size and process flow. The system will be housed in a mobile box no heavier than 5 lbs per current Inogen PSA benchmarks [13, 14] with a pair of wheels and a handle for easy transportation. Ambient air will be brought into the system via a blower, purified to 93% oxygen concentration via vacuum swing adsorption, formatted using an air-oxygen blower, and output via the conical universal connector. The external clinical interface will include sensors, warnings, and user inputs for ambient air and oxygen levels as shown in *Figure 8* below The model will follow the schematic detailed in *Figure 5* on page 19.

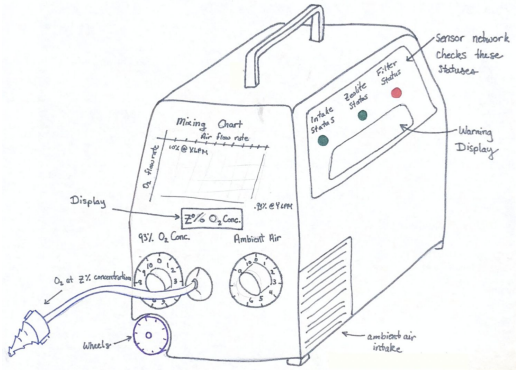


Figure 8: *VSA Portable Oxygen Concentrator Concept*

Solution Development and Verification

Engineering Analysis

Eight different engineering analyses were used to evaluate whether the proposed vacuum swing adsorption system meets specific stakeholder requirements and engineering specifications. The analyses include expert interviews, sieve bed analysis, cost analysis, risk analysis, usability analysis, filter system, air formatting, and surge tank necessity. The first five modes of analysis have been completed and are described in detail. The last three analyses are completed as a form of solution verification.

Expert Interviews

Expert Interview 1

Question: What are the important features of the concentrator and interface for clinicians?

Requirement: “The device should be usable after a 5-minute training video.”

The University of Michigan Clinical Simulation Center (CSC) is a learning laboratory that allows nurses, physicians and clinicians in training the opportunity to practice skills in simulated ICU and hospital environments. In this in person, semi structured interview, Sarah spoke with three experts affiliated with the Clinical Simulation Center at the Towsley Center in the UM Hospital. Debra Yake, a training specialist, Deb Rooney, PhD, the CSC director of Education and Research, and Ed Locket III, Simulation Technician, shared information on medical procedures for infants with respiratory distress syndrome and demonstrated the features they use on related equipment. Because of their firsthand experience with oxygen concentrators and infants in respiratory distress, their input was invaluable to us, and because their experience is so much greater than ours, an expert interview to understand the important features medical professionals need was warranted. They emphasized the following two things:

1. Although infants with hypoxia are typically delivered as high an oxygen percentage as possible. Ability to vary oxygen concentration is important so that clinicians may use the device flexibly for hypoxia as well as other common neonatal respiratory issues, as the reason for respiratory distress is not always immediately clear.
2. Respiratory distress requires very quick reaction time. Ability to set both oxygen concentration and flow rate quickly, and to switch delivery devices quickly is of critical importance because of the time sensitive nature of hypoxia.

Our main stakeholder, Dr. Stephen John, confirmed that the ability to vary oxygen would be necessary for the Nepalese Clinicians for the same reason. Based on this feedback, our design will incorporate a method to vary oxygen concentration in addition to being able to provide 93% oxygen concentration, and we will use a Usability Analysis to seek out ways to minimize human response times and human error when interfacing with the oxygen concentrator.

Expert Interview 2

Question: Are there size limits on cyclic adsorption processes that prevent downsizing?

Requirement: “The device must be transportable by a single staff member”

Portable Oxygen Concentrators have been the subject of study in university labs. At the University of Michigan, Dr. Ralph T. Yang in the Department of Chemical Engineering studied zeolite-based cyclic adsorption processes in the late 1990s and early 2000s before pivoting to research on carbon capture. In a virtual, semi-structured interview with Dr. Yang’s PhD students John-Timothy Anyanwu and Yiren Wang, we asked questions about zeolite, the chemical

processes involved in adsorption, and the field of portable oxygen concentrators research. Because there are so few labs currently affiliated with research in cyclic adsorption processes, it was very useful for us to be able to talk to John-Timothy and Yiren. Since this information was not readily available on the internet and we were not able to gather in person to experiment, speaking with somebody who had first had experience helped fill those gaps. We learned many things from the interview, including:

1. Research into cyclic adsorption processes is largely experimental. Simulations are complicated and inaccurate, and so most research relies on experiments with a high volume of cycles.
2. Since pressure swing adsorption portable oxygen concentrators were commercialized in the 1990s, there has been little to no university research related to different portable oxygen concentrator concepts.
3. The same way that pressure swing adsorption was scaled down to achieve portable oxygen concentrators in the 1990s, there is no constraint on the chemical processes that prevent a scale-down of vacuum swing adsorption.

Because of this interview, we pivoted our engineering analysis methods to be primarily experimental, using zeolite purification cycle data published online and planning to retrofit parts to an existing pressure swing adsorption system.

Sieve Bed Analysis

Question: How much zeolite is needed to provide the required amount of oxygen?

Requirement: “The device must provide 10L of oxygen per minute”

There are different forms of zeolite used to absorb different molecules in the air. Most commonly used in a portable oxygen concentrator is 13x zeolite. For these calculations, we used LiAgx zeolite which is lithium and silver ion exchanged zeolite. We chose this zeolite because it is best for nitrogen removal with 96% oxygen purity and 62% recovery. After the amount of zeolite was determined, we can calculate the volume of the molecular sieve beds needed and make adjustments as needed. The following table shows the important calculations used to find the amount of zeolite needed in kilograms:

Table 7: Sieve Bed Analysis Summary

Target Oxygen Concentration (%)	93
Total Recovery of Oxygen LiAgX (%)	62.7
Cycle Time (sec)	5
Outlet oxygen needed for 1 user at 10 LPM	10
Inlet Oxygen (L/min)	15.95
Inlet Air Mixture (L/min)	79.74
Inlet Air Feed to each column (L/min)	39.87

Flow rate Air (L/sec)	1.33
Product Throughput kg O2/h/kg adsorbent	0.1
Total Pure Oxygen from LiAgX	10
Mass of LiAgX Zeolites Needed (kg)	11

The mass of LiAgx zeolite needed is low enough to allow the weight of the entire device to fall below the required maximum weight. However, most portable oxygen concentrators use molecular sieve beds with a length of 18in and a diameter of 3in which would not be large enough to hold the amount of LiAgx zeolite needed.

These calculations will be repeated for a zeolite that is more dense than LiAgx so that the size of the beds can remain unchanged and interchangeable with other existing beds. Possible zeolites to test include 13x and AgA zeolite. The design goal is to fit the proper amount of zeolite in two 18in X 3in cylinders and produce the required amount of oxygen.

Cost Analysis

Question: Is current design affordable for low resource, clinical settings in Nepal?

Requirement: “Optimally, the device should cost less than 500 USD. Minimally, the device must cost less than 1,600 USD”

The design driver “Is current design affordable for low resource, clinical settings in Nepal?” was developed to ensure that design decisions aligned with the high priority requirement that the solution should be cost-effective. Specifically, the device should cost less than 500 USD, optimally, and the device must cost less than 1,600 USD at a minimum. To address this design driver, cost analysis was performed on the ideal, current oxygen concentrator design as shown below in *Figure 18* on page 27. The cost analysis displayed in the bill of materials operates on the assumption that sourced components direct from suppliers and in the consumer after-market are similar in price to what they would be if we were to produce our design at a large scale. This assumption is not entirely accurate, however, meaning our final calculated cost for the design will be higher than if we were to mass-manufacture our design (as costs would fall with larger production quantities and more components being sourced either directly from manufacturers or manufactured in house).

Part	Quantity	Weight (lb)	Price	Cost
Air Feed Blower				
Blower	1	1.00	$4.99	$4.99
VPSA Bed				
Sieve Bed	2	25.35	$100.00	$200.00
Silica Gel (Drying)		0.18	$0.02	$4.00
Pneumatic Actuator				
Pneumatic Actuator	1	0.50	$48.11	$48.11
Oxygen Surge Tank				
Surge Tank	1	1.50	$29.99	$29.99
Air Mixer				
Air Mixer	1	2.29	$350.00	$350.00
Connections				
Hosing	2	0.60	$8.99	$17.98
Valves	8	0.36	$4.95	$39.60
Packaging				$0.00
Frame (Aluminum)	1	5.00	$50.00	$50.00
Casing (Plastic)	1	5.55	$1.50	$8.33
Interface				
Interface		1.00	$30.00	$30.00
Power				
Control Computer	1	0.09	$100.00	$100.00
Electric		0.10	$50.00	$50.00
Total Weight (kg)		**43.5169948**	**Total Cost**	**$932.99**

Figure 18: *Cost Analysis of Current Design*

A cost analysis was performed on the ideal, current design, sourcing the most important and expensive components. Estimates were also driven by benchmarking components and materials to find the least expensive part estimates. The resulting total cost estimate is $932.99 USD, failing the ideal specification of less than 500 USD, but meeting our minimum cost requirement of 1600 USD. We expect this total cost to be lower in reality, due to many components not being sourced directly from suppliers. This mode of analysis is effective in proving whether we hit our cost requirement, taking into account all major system components as well as lower priority parts. The emphasis on internal component costs and detail in the cost analysis was chosen to illustrate both the most essential pieces of the design and their respective weight of the total product cost. The most important system components tend to be the most expensive, as shown in the cost analysis.

The consequences of this cost analysis are varied. We estimate that we are in the middle of our two cost goals- meeting the minimum requirement but falling short of the ideal. We plan to move our estimate closer to the ideal price of 500 USD by taking a closer look at the materials and whether there are less expensive options, finding more information on other sources of components, and verifying the amount of zeolite necessary for effective oxygen concentration. Because the sieve beds and the blower are the most expensive components, more benchmarking of these products will be done to look for less expensive options. Further detail will be added to the cost analysis by estimating reduction in cost of the product because of either direct purchase from manufacturers or mass production.

A weight analysis was performed synchronously to the cost analysis, providing an estimated weight of 43.5 lbs. This estimate is lower than the specified <30 kg (~66 lb), meeting the ‘transportable by a single person’ requirement for the design. The bulk of this weight estimate stems from the large weight estimate of the zeolite beds. Our estimate for the weight of these beds is driven by the quantity required to effectively purify the air derived in the sieve bed analysis. Our next steps include verifying our sieve bed calculations to ensure the current zeolite quantity is correct and that our resulting weight estimate is reasonable. The current weight estimate leaves wiggle room in the design in terms of materials and extra components (ie. adding more user interface components). We will use this information in addition to the cost estimate to tweak our design within the bounds of the required cost and weight to be the most efficient in both oxygen performance, safety, and usability.

Risk Analysis

Question: What are the risks associated with a portable VSA oxygen concentrator?

Requirement: Solution Neutral Considerations

The next analysis that was performed for the oxygen concentrator was the risk analysis. The risk analysis was performed in order to address the question of what risks are associated with a VSA oxygen concentrator. In order to analyse the risks, a FMEA model, or failure modes and effects analysis, was used as shown in *Figure 19*. A hazard analysis was also done in order to review some of the potential hazards associated with the oxygen concentrator shown in *Figure 20*. The FMEA was used because it helps to review as many components, assemblies, and subsystems as possible in order to help identify potential failure modes in a system, as well as analysing their causes and effects. This is the appropriate mode of analysis because it goes into great detail and analyses individual components where failure might occur. This level of detail was chosen so that we can find out which individual components are actually in a failure mode, and focus on those. With this information from the FMEA analysis, we can then recommend actions that can be taken to to combat and prevent that failure mode. These analyses are theoretical at the moment as we do not have a prototype yet. The following figures show the results of these analyses.

Item	Function	Potential Failure Mode	Effect of Failure	Severity	Potential Causes of Failure	Recommended Action
Air Feed Blower	Inlet Feed Compressor	Leakage	High flow rate is unachievable	7	Physical damage to blades Motor failure	Protective vent around compressor
VSA Bed	Remove nitrogen from air	Beds do not regenerate fully	93% oxygen concentration is not reached so that output and mixture calculations are wrong and deliver incorrect concentration to infant	9	Insufficient cycle time Expired zeolite	Oxygen purity sensor Nitrogen sensor in beds
Surge Tank	Store concentrated oxygen	Leakage	High flow rate is unachievable	7	Physical damage High pressures in tank	Protected location in concentrator Protected by aluminum frame
Valve Connectors	Output concentrated oxygen and exhaust	Leakage Sticky valve	Nitrogen rich air is delivered to patient	10	Mechanical failures Motor failure Dirty components	Regular cleaning maintenance Oxygen purity sensor at output
Aluminium Frame	Protect device	Structural damage	Mobility is impeded Zeolite tanks are damaged	4	Physical damage during transport	Structural test for frame Guidelines for transport
Control Computer	Detect errors and transmit warnings, report on operation	Disconnect from screen, short circuit	Warnings are not communicated	8	Device losing power Physical damage	Audio notification for screen malfunction Computer malfunction
Power Supply	Supply power to unit	Power loss, overload	Device does not opperate	10	Loss of local power, device overload	Use circuit breaker to prevent overloads, backup power supply (battery)

Table 8: *FMEA Analysis*

Hazard	Hazardous Situations	Likelihood	Impact	Level	Technical Performance	Schedule	Cost	Action to Minimize Hazard
Electric Shock	Under extreme conditions, user could be shocked due to high voltage and wattage from power source	Low	Serious	4	Significant degradation in performance, supportability, and sustainability	Able to meet key dates	Budget increase 1% or less	Ensure constant current, circuit breakers and proper insulation
Overheating	Device can overheat as result of overuse	Medium	Medium	2	Reduction in technical performance expected from high temperature	Able to meet key dates	Budget stays same	Open ventilation for heat dissipation and fans
Fire	Device may be fire hazard because of stored, concentrated oxygen	Low	Serious	5	Device would shut down and no longer work under these conditions	Able to meet key dates	Budget increase 2% or less	Use properly insulated tanks, flow regulators, and insulating wires
Leaks	Device may leak oxygen if valves are not secured properly	Medium	Medium	2	Device will still work, with lower performance, outputting lower oxygen concentrations at lower pressure	Able to meet key dates	Budget stays same	Flow rate and oxygen concentration warning system and regular maintenance

Table 9: *FMEA Hazard Analysis*

The two tables above show the FMEA analysis for the VSA oxygen concentrator. These tables illustrate the fail states of the individual components within the concentrator, as well their functions, and actions that can be taken to prevent failure. Potential hazards associated with the oxygen concentrator are also shown. The severity of the failures are also shown, ranging from 1 to 10, 1 being the lease sever and 10 being the most.

The results from the risk analysis indicate that we have to focus heavily on the valve connectors and the oxygen tank, the VSA bed, and making sure that the device is powered properly. This is extremely important in order to avoid a fire hazard. The device contains concentrated oxygen which is highly flammable, so we need to take the proper precautions in order to avoid this. The results of these analyses will impact the design by having us focus on protecting the oxygen tank as well as protecting the compressor. Also, based on our risk analysis, we should include oxygen sensors as well as nitrogen sensors and incorporate circuit breakers and insulation for the tank and wiring. The next steps that we plan to take for the risk assessment is to benchmark with an oxygen concentrator and see where failure modes are, and what improvements can be made to better the design. The overall risk associated with our design is now at an acceptable level.

Usability Analysis

Question: What errors does an untrained user make interacting with the user interface?

Requirement: *"The device should be usable after a 5-minute training video"*

As a result of Expert Interview 1 with experts from the clinical simulation center at the University of Michigan, we determined that a physical usability analysis would be necessary to find ways to minimize user response time and user error.

To do a physical usability analysis, we created a cardboard mock-up of the concentrator. The mockup featured two moveable sliders for adjusting oxygen concentration and flow rate, as well as an imitation of the warning lights and display *Figure 21*.

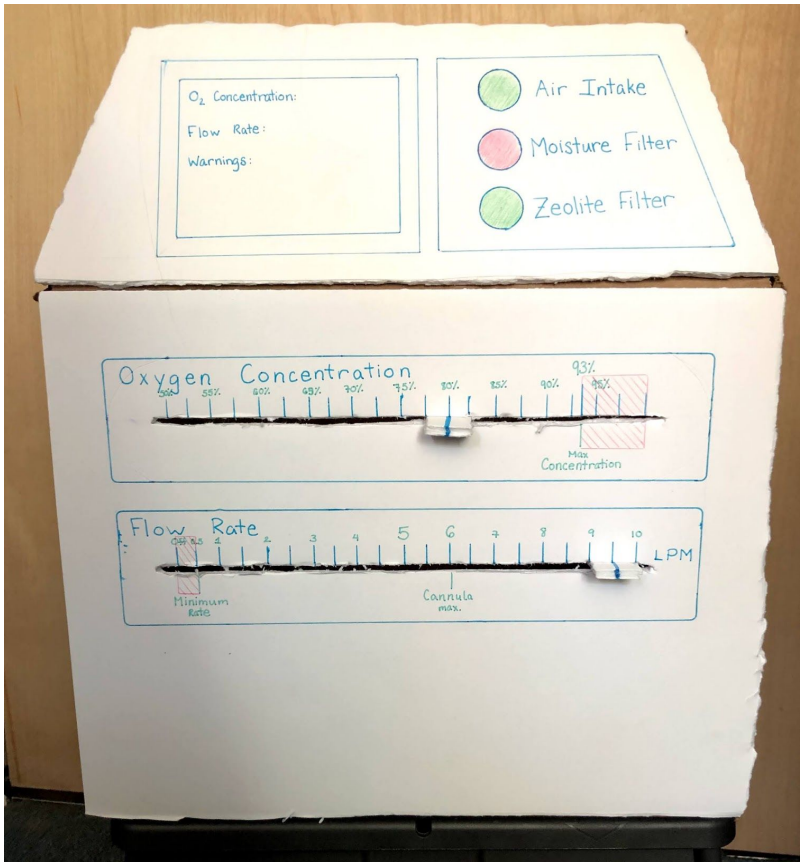


Figure 19: Usability Analysis Mock Interface

Seven untrained students between the ages of 18 and 22 were asked to complete four tasks with the interactive interface. This is a strong feasibility analysis because students with less experience than the clinicians who will eventually be using the design. If we are able to proof the device for mistakes with inexperienced and young students, we will also have streamlined its use for people more knowledgeable. Additionally, this will mean that clinicians can ask parents to help operate the device and instruct parents on device operation, should the hospital be

understaffed. Users were prompted using the following script:

1. The patient needs to be switched to a nasal cannula. Can you adjust the flow rate?
2. Set the oxygen concentration to the maximum concentration value.
3. Does the zeolite filter need to be replaced?
4. Set the device to the lowest achievable flow rate.

The results are listed in *Figure 22*:

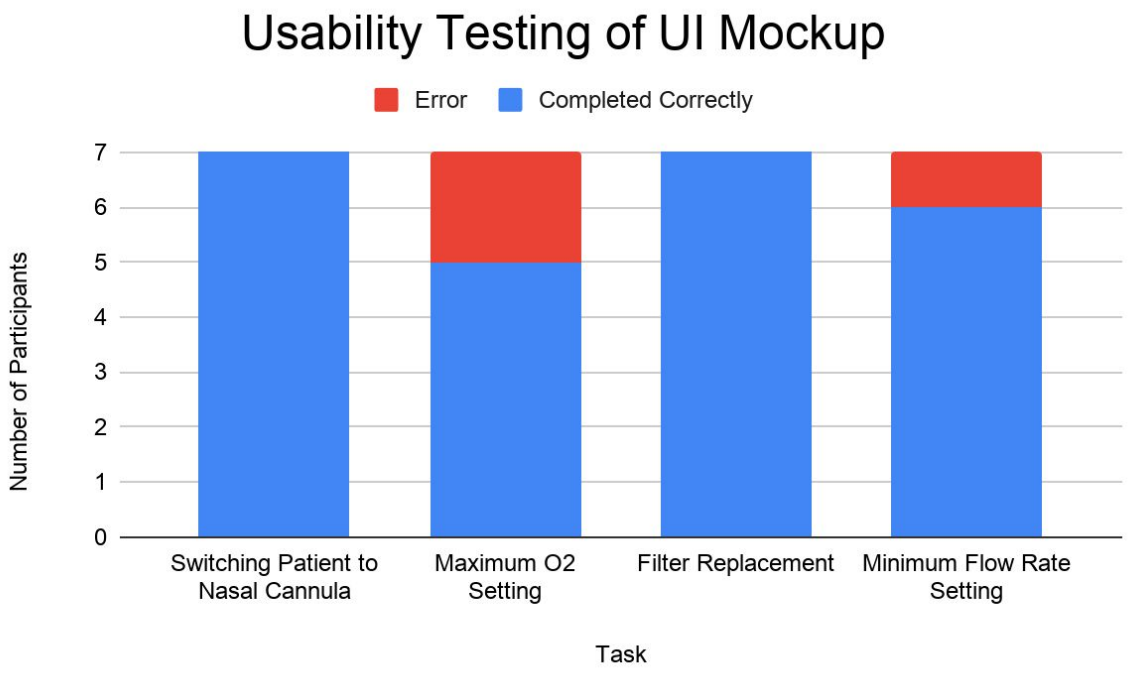


Figure 20: Usability Testing Results

Participants only made errors in setting minimum and maximum settings. They found the interface otherwise clear and easy to react to. Based on participant feedback and the results presented in *Figure 22*, four changes will be made to the final design:

1. There will be no unachievable values on the slider scales
    a. O2 Conc. Max Slider Value will be: 93%
    b. Flow Rate Min Slider Value will be: 0.5 LPM
2. There will be a flow on/off switch.
3. Arrows will be added to the flow rate sliders scale to indicate acceptable use ranges for devices including a nasal cannula and an infant CPAP

Detailed Design Solution

The detailed design solution has been developed in CAD, including dimensions, internal components, and user interface design in *Figures 9-12*. This design builds off of the selected VSA concept.

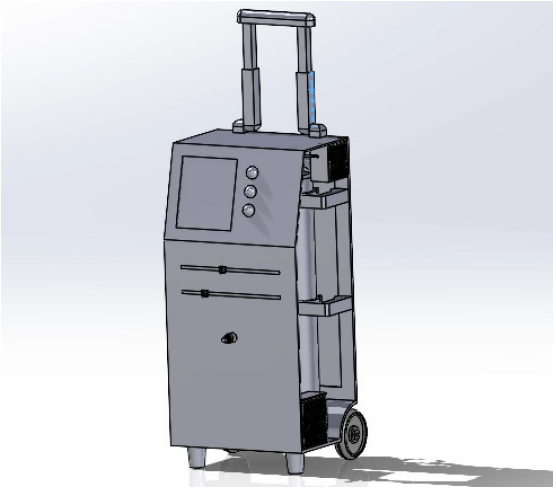


Figure 21: Front view of Oxygen Concentrator

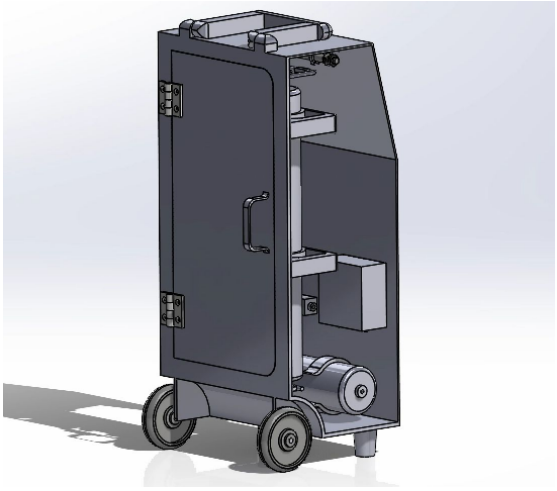
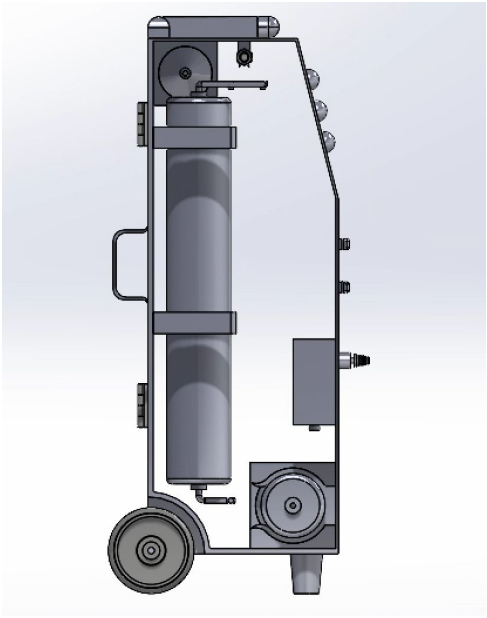
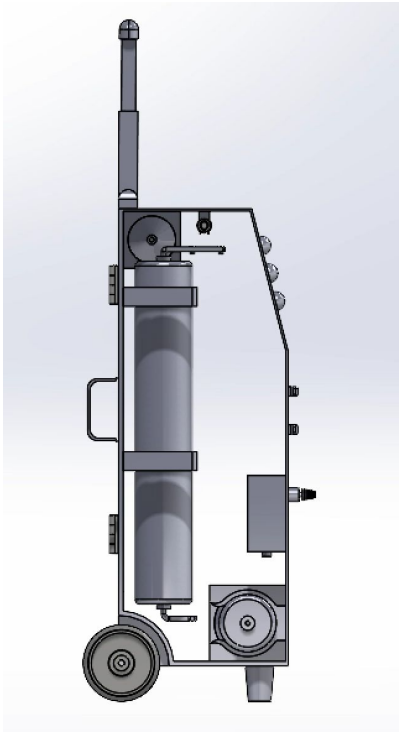


Figure 22: Rear view of Oxygen Concentrator





Figures 23-24: Side Views of Oxygen Concentrator (Handle down and Handle up)

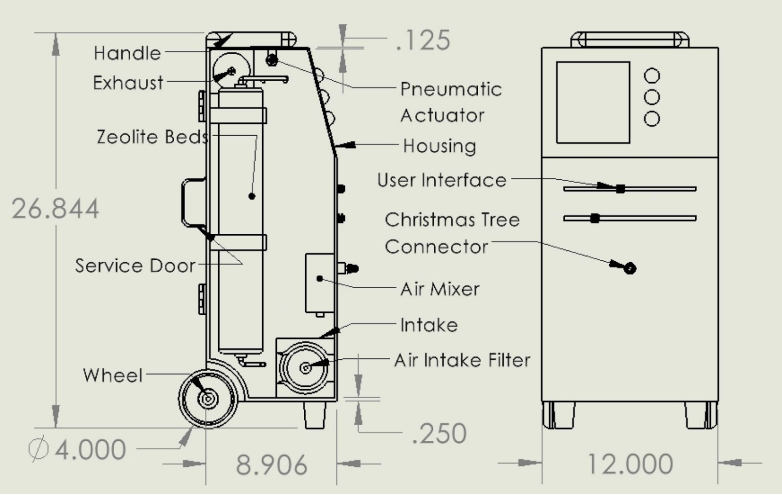


Figure 25: Oxygen Concentrator Dimensions (Handle Down)

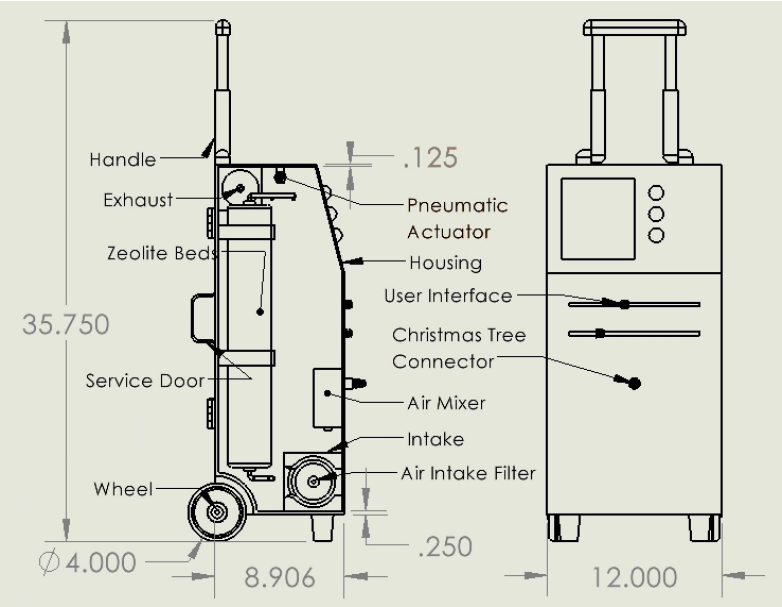


Figure 26: Oxygen Concentrator Dimensions (Handle Up)

In *Figures 21-26*, a 3D model of the current portable oxygen concentrator design is presented. This model mainly focuses on the internal components and how they fit together inside the transportable device's packaging. The sides of the device are left transparent to allow visibility of the components inside the device, however these sides do exist in the current design with the same material as the rest of the external packaging. The air enters the system via the air intake and blower shown in Figure 25. The air is then filtered through a parallel system of zeolite beds and nitrogen is absorbed and removed from the air. The nitrogen exits the device via the pneumatic actuator and exhaust located at the top of the design. The now concentrated oxygen continues throughout the system to an air mixer, then through to the output in the form of a christmas tree connector. In Figure 21, shown on the right hand side are the intake and

exhaust vents, and at the front of the device, there is a christmas tree connector which will be used to connect the oxygen to the ventilation device. The christmas tree connector allows air to be delivered to a variety of devices that will distribute air to the patients. There is also a mock-up of the current user interface design included in front of the device. Sliders are included for control of the flow rate and the oxygen purity level exiting the device. Sliders were chosen after feedback from a concept generation activity with our peers. Sliders allow the user to quickly move to the desired setting and with a slider there is no uncertainty of which way to increase/decrease, a problem using a knob may present. A digital screen is also included for additional user feedback, including alarms and system diagnostics. In Figure 22, we can see there is a door at the back of the device to allow easy access when servicing the device. The zeolite beds are in the back of the device so they can be replaced easily via the door. This design decision was made as zeolite beds must be replaced annually, as the filters degrade over time. Figure 23 shows a side view of the device. This view shows how all the parts of the VSA system fit into the device while at the same time keeping it transportable. The empty space is left open for the controls/user interface and the power supply. In the figures, the device is presented multiple times with either the handle up or down. This shows the retractable functionality of the handle and in Figures 25 and 26 a size comparison is made of the device when the handle is down as opposed to up. The dimensions of the device are 26.8 inches x 8.9 inches x 12 inches, just over 2 feet in height allowing portability. Fully extending the handle brings the height of the device to about 36 inches.

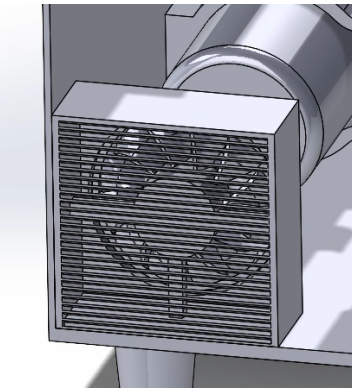


Figure 27: Air Intake

Figure 28: Zeolite Beds

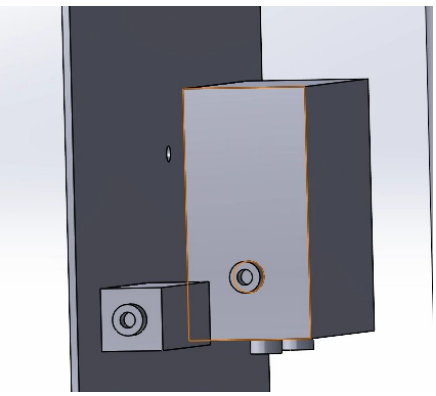


Figure 29: Air Mixer

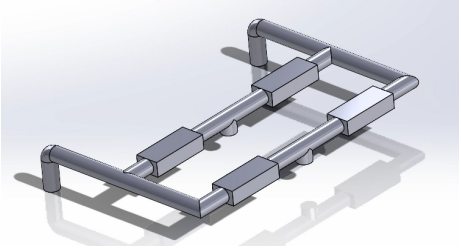


Figure 30: Valve Assembly

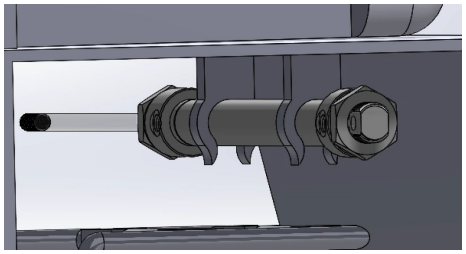


Figure 31: Pneumatic Actuator

The figures shown above present a close up of some of the individual components of the VSA system. Figure 27 shows our air intake and behind it there is a silica gel bed which is a filter that removes moisture from the air as it enters the system to increase efficiency of the zeolite. In Figure 28, shown are the zeolite beds and in Figure 30 we show a close up of the valve assembly at the top of the beds, which allows us to control which bed provides oxygen to the patient and which one is being emptied using the pneumatic actuator shown in Figure 31. The actuator creates a vacuum which will create an airflow out of the bed into the exhaust. Before reaching the patient the oxygen rich air will go through an air mixer that allows us to control the concentration of oxygen by reintroducing ambient air if the concentration needs to be lowered. The air then goes through a flow regulator that lets us control the flow rate.

Verification

The overall compliance of our design solution with respect to the requirements and specifications was tested with a series of expanded engineering analyses and new verification tests and plans as shown below in *Table 8*. Overall, the majority of our high priority requirements have been met. The requirement “Be able to provide sufficient oxygen” is not fully verified as the amount of zeolite necessary to filter the air sufficiently has been determined, but the resulting cycle time from this amount of zeolite has not been verified. Test plans have been developed to further validate the flow rate and sufficient oxygen levels of the design as well as cycle time of the VSA system. The medium level and lower level requirements have not been fully verified, as we spent most of our time focusing on the higher level priority requirements. These requirements could be verified easily with a working prototype and corresponding experimental tests with the device. Overall, we have a medium level of confidence in our design, as our high priority requirements are at high levels of verification, making up for the requirements that have been less defined. Additionally, through our research and stakeholder meetings, we have not run into significant pushback or criticisms of the important components of our design. Our verification processes and potential future test plans are outlined in the following sections.

Table 10. Verification of Final Design

Requirement	Specification	Analysis	Result	Verification
Be able to provide sufficient oxygen	Provide 93% Oxygen	Calculation of zeolite needed to purify to 93% at 10 LPM flow rate	11 kg of LiAgX needed, 2 3”x18” cylinders Validation of cycle time needed	
Be cost-effective	Cost: < $500; < $1600 (Min.)	Cost analysis	System Cost: $1400	
Be able to maintain a low flow rate	Flow Rate between 0.5 and 10 LPM	Expert interview direction: adopt current solution	Adoption of current mixer and blower	

Be modular	Modular Interface for CPAP, cannula	Expert interview direction: adopt current solution	Adoption of current 'christmas tree' connector	
Be usable by a minimally trained user	Simple to use and maintain	Usability Study	Sliders for input Screen for output R/G Warning lights and sounds	
Be Safe	Meets approval guidelines for USFDA	Planned: FDA Clinical Testing	---	
Be able to operate in a variety of extreme environments common to Nepa	The device must operate up to 2000m above sea level. 10°C < Operating Temp < 40°C	Planned: Environmental Testing at 90 kPa, 10°C < T < 40°C	---	
Be able to start working quickly	Reach 95% of 93% FiO2 and 10 LPM flow rate in less than five minutes	Planned: Prototype testing	Removal of pressurized air results in a startup time similar to that of existing devices	
Be transportable by a single hospital staff member	Weighing < 30 kg	CAD, Component Analysis	Weight 22 kg < 30 kg	
Device maintenance should be simple	Fixable after 5 minute training video	Usability Study	Easily accessible Zeolite Beds using service door	
Be quiet	Operating noise <50dB	Planned: Prototype run test	---	
Be operable in Nepal	Device uses mains power	Planned: Electrical Testing at 230V, 50Hz	---	

Usability Verification

Requirement: *"Be usable by a minimally trained user" and "Device maintenance should be simple"*

The original user interface of the final design solution had three main features:

1. Two sliders to control the oxygen concentration and flow rate of delivered oxygen
2. Three red/green light indicators sharing intake, silica gel filter, and zeolite filter status
3. A screen to show current oxygen concentration and flow rate

In the usability analysis, the users tested made errors related to the two sliders.

The oxygen concentration slider scaled from 50% to 100% oxygen, although 93% was the max achievable concentration. The range between 93% and 100% was marked unusable by red hatching. Users still mistakenly used this area, so the oxygen concentration slider was changed so that its range was 50% to 93% oxygen.

The flow rate slider scaled from 0 LPM to 10 LPM, although 0.5 LPM is the lowest achievable flow rate. The range between 0 LPM and 0.5 LPM was marked unusable by red hatching, but the 0 LPM setting was intended to turn the flow off. This was confusing for users. Therefore, the flow rate slider was changed so that its range was 0.5 LPM to 10 LPM, and an on/off switch was added next to the flow rate slider.

With these changes, five untrained users were asked to complete the four tasks of the usability analysis study. None of these untrained users were in the original study pool so as to avoid the factor of previous experience. No users repeated the errors of users in the original study. All users performed all for tasks without error, because the errors made previously were no longer possible with the new design. Thus, the previous user interface enabled errors, but the updated design addressed and eliminated these errors as shown below in *Figure 34.*

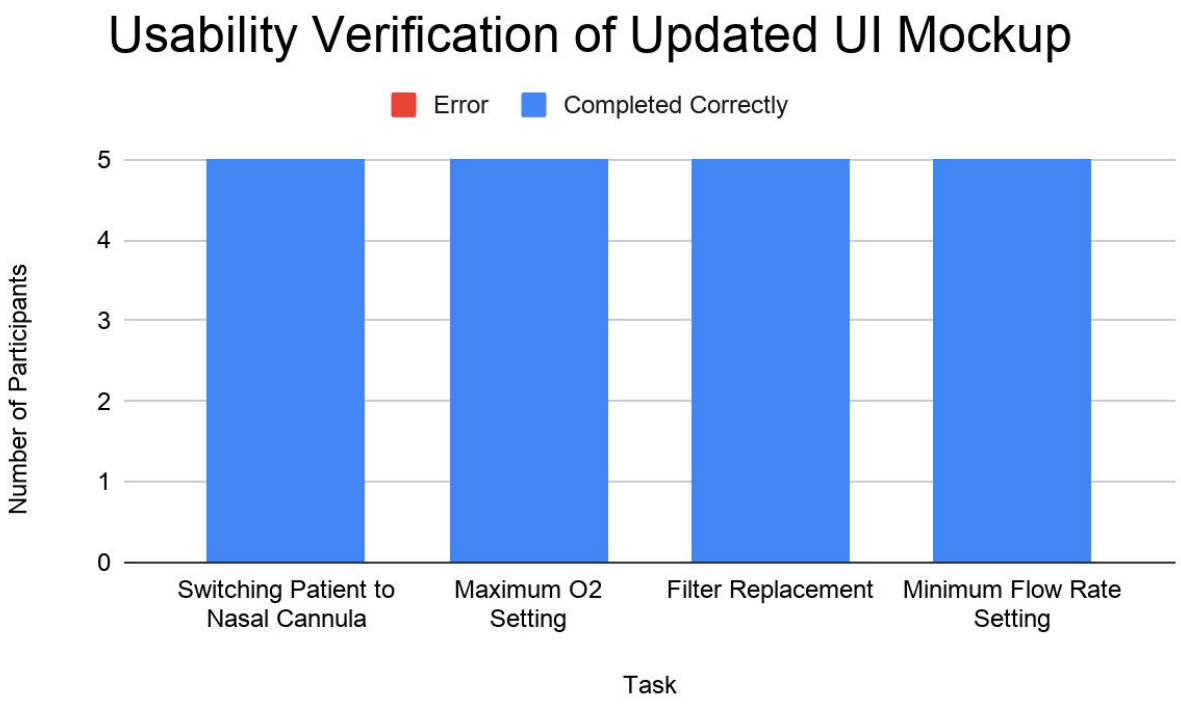


Figure 32: Usability Verification of Updated UI

Due to the coronavirus pandemic, the conditions of both the usability analysis study and the usability verification were not ideal. Under ideal conditions where gathering and travel are allowed, there are several things that would be done differently for these two studies. The

Handbook of Human Factors in Medical Device Design, Chapter 6: Testing and Evaluation was referenced to define ideal testing conditions [41].

1. The user interface prototype would be higher fidelity, a working early horizontal prototype with that would show the full range of the interface
2. The study participants would have been representative of the mostly likely users of the device. The study would have included clinicians with license to practice in Nepal and parents of children under 6 months old in Nepal.
3. To comply with the second change, the study would have been completed in Nepal.
4. The study would have included at least 10 participants, as there should be no less than 5 users per user group. Ideally, the study would have included at least 8 users per user group.

Cost Analysis

Requirement: *"Be cost-effective"*

One of the high priority requirements of the design is to 'be cost-effective'; specifically, the device should cost less than 500 USD, optimally, and the device must cost less than 1,600 USD at a minimum. To verify this requirement, a cost analysis was performed on the ideal, current oxygen concentrator design as shown below in *Figure 35*. This bottom-up cost analysis includes the materials cost identified in the previous engineering analysis as well as external costs such as assembly/labor and transportation. This cost estimate is about $1400 USD, meeting our minimal cost requirement of $1500 USD. The labor estimate was created using the assumption of US Labor and international shipping costs for a unit less than 40 kg.

Part	Cost
Air Feed Blower	$4.99
VPSA Bed	$204.00
Pneumatic Actuator	$48.11
Oxygen Surge Tank	$29.99
Air Mixer	$350.00
Connections	$57.58
Packaging	$58.33
Interface	$30.00
Power	$150.00
Assembly + Labor	$250.00
Transportation	$200.00
Total Cost	**$1,382.99**

Figure 33: Final Design Cost Estimate

The team met with subject expert, Randy Schwemmin of C-SED to validate our cost analysis. Through this interview, we determined that the bottom up approach is not wholly indicative of the predicted final product cost. The benchmarked, commercially-available PSA oxygen concentrator's cost includes mark-up for profit by its manufacturer. Thus, comparing the bare-bones VSA design cost analysis does not make the most sense, as the two numbers describe different things. To resolve this, a similar materials, labor, and transportation cost analysis was created for the PSA system, resulting in a cost estimate of about $1900 , a relative cost comparable to the VSA cost analysis. This cost was used to create a ratio of 1.05 of the PSA concentrator's bottom-up cost estimate to its advertised cost of roughly $2000 USD. Assuming, this ratio holds true for similar oxygen concentrators, our VSA design is estimated to cost $1475. This total cost is still less than the minimal cost requirement of $1500 USD, thus the cost-effective requirement has been verified.

The cost-analysis has posed many important questions not outlined explicitly in the requirements and specifications. Further research into potential cost-saving actions, especially regarding the front heavy costs associated receiving certification and validation from reputable medical device agencies would be beneficial. A market size analysis of Nepal taking into account the lifetime of the device and number of beds in Nepal would provide additional context on cost reduction of materials from mass production. A deeper look at the location of production is also necessary. Nepal borders both India and China, and production in either of these companies would significantly lower both assembly and transportation costs.

Verification Test Plans

In an ideal situation, the team would have had enough time and resources to fully validate our final design. However, due to the complexity of the project's subject matter, a compressed timeline, and Covid-19 complications, the desired testing and verification were not able to be completed. The plans for these projected tests include testing of a PSA portable oxygen concentrator, of that POC retrofitted to a VSA system, and testing maintenance of the system. These testing plans would create a more complete verification of the final design, and, thus, higher confidence in the final design.

PSA Test Plan

Requirements: *"Be able to maintain a low flow rate" and "Be able to provide sufficient oxygen"*
We had planned to test the performance of the acquired PSA portable oxygen concentrator, the *Oxygen Concentrator MAF015AW* from TTLIFE, to create a benchmark to compare the retrofitted VSA system to. The test plan is outlined below and includes testing of the device 'as is' from the supplier.

I. **Objective**: Test Flow Rate of the POC
    a. Procedure
        1. Turn on the device, and set flow rate to 1L/min.

2. Wait ten minutes for the machine to reach full performance, then measure the flow rate of oxygen output with the flowmeter tool.
3. Repeat steps 1 and 2 for flow rates 1-6 L/min.

b. Data Analysis
1. The measured flow rate with the flowmeter will be compared to the displayed flow rate on the user interface to verify the system's internal measurement accuracy

II. **Objective**: Test Oxygen Purification Levels of the PSA portable oxygen concentrator

a. Procedure
1. Turn on the device, setting flow rate to 1L/min.
2. Record the oxygen purity level of the device's output every 15 seconds for the first ten minutes of operation via oxygen concentration content tester meter.
3. Turn off device, waiting at least ten minutes between trials, and repeat steps 1 and 2 until three trials have been completed.
4. Repeat steps 1-3 for flow rate settings of 1-6L/min.

b. Data Analysis
1. The data collected in the above test will be compared to the machines given operating oxygen concentration levels (30-90%) and, eventually, similar data taken from the VSA prototype.

VSA Test Plan

Requirements: *"Be able to maintain a low flow rate" and "Be able to provide sufficient oxygen"*
Ideally, the team would have had sufficient time and resources to fully complete verification with the build of a working VSA portable oxygen concentrator prototype. The compressor of the purchased PSA concentrator would be removed, and a pneumatic actuator would be added to generate the cycling of air through the zeolite beds. The VSA prototype would then be tested similarly to the original PSA system, and its performance would be analyzed to verify flow rate and oxygen purification requirements.

III. **Objective**: Test Flow Rate of the POC

a. Procedure
1. Turn on the device, and set flow rate to 1L/min.
2. Wait ten minutes for the machine to reach full performance, then measure the flow rate of oxygen output with the flowmeter tool.
3. Repeat steps 1 and 2 for flow rates 1-6 L/min.

b. Data Analysis
1. The measured flow rate with the flowmeter will be compared to the displayed flow rate on the user interface to verify the system's internal measurement accuracy. Discrepancies between these two measurements will be compared to those recorded in the PSA system previously. If the prototype successfully operates at 1L/min, the 'Be able to maintain a low flow rate' minimal requirement will be satisfied.

IV. **Objective**: Test Oxygen Purification Levels of the PSA portable oxygen concentrator

a. Procedure

1. Turn on the device, setting flow rate to 1L/min.
2. Record the oxygen purity level of the device's output every 15 seconds for the first ten minutes of operation via oxygen concentration content tester meter.
3. Turn off device, waiting at least ten minutes between trials, and repeat steps 1 and 2 until three trials have been completed.
4. Repeat steps 1-3 for flow rate settings of 1-6L/min.

b. Data Analysis

1. The data collected in the above test will be compared to the data taken from the original PSA concentrator. If the prototype reaches 90%+ oxygen purity, the 'Be able to provide sufficient oxygen' requirement will be verified. However, if this value is not reached by either the PSA or VSA concentrator, and the two devices' oxygen outputs are similar, the requirement will be partially verified under the assumption that the max concentration is reached by both of these systems, and thus the VSA system is capable of performing to the researched 93% oxygen levels of PSA systems.

V. **Objective**: Test Cycle Times of the POC

a. Test the cycle time of the POC by removing one of the beds to create a view of when flow is entering and exiting the remaining bed. The timing of this cycle would be recorded to further validate the oxygen concentration requirement, as well as the 'Be able to start working quickly' requirement.

Maintenance Test Plan

Requirements: *"Device maintenance should be simple"*

In order to meet this requirement, the oxygen concentrator must be able to be maintenanced with no specialized tools and by a technician after a five minute training video . The simplicity of the maintenance can be tested by conducting tests changing the filters and zeolite beds and recording technician performance.

VII. **Objective**: Test Simplicity of the Maintenance

b. Procedure

1. Have a group of biomedical technicians, clinicians, and other relevant users watch a five minute training video on routine device maintenance.
2. Rate the performance of each user in the completion of two tasks: filter removal and replacement and zeolite bed replacement of prototype based on number of errors and time taken to complete tasks.

c. Data Analysis

1. Analyze performance of users and ease of tasks to fully verify the device maintenance requirement.

Clinician Critique

The oxygen concentrator is designed to use it in a clinical setting. Under ideal conditions, we would have set up interviews with clinicians at the University of Michigan (and potentially low resource hospitals) to gain their input on the final input of the design. These interviews would include a structured, repeatable agenda with specific questions on parts of the design such as the user interface and exterior shape and features to facilitate design changes.

IX. **Objective**: Improve the design with clinician feedback

d. Procedure
    1. Allow clinicians to review the design and use a potential prototype.
    2. Structure a meeting with clinicians and present them with our design idea and have a prototype for them to test.
    3. Have them fill out a survey or short report on what they liked about the interface and the concentrator and what can be improved.

e. Data Analysis
    1. Examine the feedback that the clinicians gave and incorporate them into the design or modify the concentrator for ease of use.

Discussion and Recommendations

Design Critique

The theoretical design was modeled on existing pressure swing adsorption systems, with the intention to take an existing system and retrofit a vacuum swing adsorption system to develop a working prototype. Because existing systems work so well and are available in Nepal, the design was conceived mainly to lower cost in an effort to increase accessibility. Using this redesign of current systems approach, the effect of any cost reduction can be understood by researching existing systems. The cost of components can be directly compared with components in current systems while operating under the assumption that testing and supply chain costs would likely match that of other systems. This way, any reduction in the cost of components acts as a good indicator that the new design reduces the overall cost of the concentrator, which must include all overhead and shipping costs.

While this redesign approach gives increased clarity in cost analysis, the fully theoretical nature of the design makes a critique of the design difficult. In a practical scenario, problems and insufficiencies would be able to be found and traced, and testing the output of the system would make it easily clear what updates the system needs. If the oxygen output were too moist, it would be evident that more silica gel would be necessary to maintain that flow rate. If measurements showed the oxygen concentration was too low, more zeolite could be added.

With a fully theoretical design, none of the calculations done are verifiable in practice. It is hard to identify inefficiencies (like the use of too much zeolite) or insufficiencies. While a computer simulation may often help validate theoretical designs, expert interviews with PhD candidates in the UM Chemical Engineering department shared that modeling of zeolite adsorption processes is extremely difficult and highly imprecise, so all previous research on these processes has been experimental.

To best create a portable oxygen concentrator design, it would have been necessary to create a working prototype of the device and a prototype of the zeolite adsorption process alone and heavily vet these prototypes to ensure device performance and oxygen concentrations match or exceed theoretical calculations. It would also be helpful to fully break down the cost and components of current systems, as current systems fully meet the medical needs of patience, just at too high of a cost. Such a full breakdown might help identify inefficiencies in current systems and allow more targeted redesigns of the inefficient subsystems, which must be where the cost reduction will come from, as the costs of obtaining FDA approval or a CE mark and shipping costs will not be able to be different between systems.

Future Modifications

The team's priority when designing the oxygen concentrator was largely focused on cost. As a result, the design is very minimal and does not contain all of the components that may have been necessary to ensure performance comparable to that of existing concentrators.

For example, the design does not include an oxygen surge tank. Although it is not necessary for the concentration of oxygen, it is useful in providing a continuous flow of air. While the system switches between active sieve beds, the tank is essential in preventing fluctuations in flow rate. Similarly, a feed buffer tank may also improve performance as it provides a constant supply of air to the beds in case of an unexpected reduction in air supply.

Future modification may also include changes in zeolite type. Our calculations are based on LiAgX zeolite because that was the compound with the most data we had access to. However, the most common carbon molecular sieve on the market today is 13X zeolite. Although the performance of our concentrator depends largely on the type of zeolite used, it may prove to be more cost efficient to use a zeolite type currently accessible to hospitals in Nepal.

Another possible modification involves the filtering system placed before the sieve beds. The current design only has a silicon filter which is useful for removing moisture from the intake flow. The removal of water is critical to extending the life of the beds and the system as a whole; however, there is no system in place to remove particulate matter. The addition of a High Efficiency Cyclone filter followed by a High Efficiency Particulate filter, although more costly, may be useful in reducing the frequency of maintenance repairs.

These suggested modifications to our vacuum swing adsorption system operated portable oxygen concentrator are not necessary for the device to function but may be added to improve efficiency, performance, and possibly cost.

Recommendations

Given the theoretical nature of the project completed by a fully remote team, there are several recommendations that apply to the design presented.

An operational prototype of the vacuum swing adsorption system should be built and tested to verify that the full range of oxygen concentrations can be maintained at all flow rates between 0.5 LPM and 10 LPM. The prototype could be tested with all five potential modifications listed above to compare for improved performance. A separate operational prototype of the user interface should be tested per the explanation of the ideal usability verification on page 37: in the environment of a controlled study with clinicians and parents. Once both of these systems are optimized and functional, a high fidelity prototype should be made and tested according to the procedures listed in solution verification.

With a working prototype presentable as the design solution, cost analysis should be repeated with the goal of understanding the cost of manufacturing and getting a CE mark or FDA approval. Any reduction here with respect to location of the manufacturer or funding to undergo FDA testing would have a significant cost impact on the oxygen concentrator.

Finally, in order to ensure that the fully working prototype meets all requirements, including ease of use and maintenance, it would be best to take the device to Nepal and work with clinicians and parents in low resource hospitals.

Conclusion

Creating a portable oxygen concentrator for a clinical, low resource setting is a unique and difficult problem that addresses a worldwide need for effective, affordable solutions, especially during the Covid-19 pandemic. To address this we have created a robust problem definition, and in the interest of capitalizing on our technical mentor's experience with low resource hospitals in Nepal, we have written our requirements and specifications with the more narrow use case of neonates in a clinical setting in Nepal. We have identified the oxygen concentration method as the most vital component of the proposed solution; and, we have employed concept generation strategies such as a morphological chart and TRIZ triggers to produce five unique concepts. Through an evaluation process supported by a Pugh chart, vacuum swing adsorption (VSA) was selected as our final oxygen concentration method. The concept has been analyzed through five distinct engineering analyses including meetings with subject matter experts, sieve

bed analysis, cost analysis, risk analysis, and usability testing and analysis. From the results of these analyses, the design of the portable oxygen concentrator has shifted to include a more robust design composed of distinct internal system components and a comprehensive user interface design. The current design is illustrated by a detailed CAD model. We completed a theoretical concept validation with a focus on vacuum swing adsorption feasibility for our application, subject matter input and feedback, and expansion of our engineering analyses. The final design has been validated to a medium confidence with verification of most of the high priority requirements and less verification of the lower priority requirements and specifications. A continuation of this project would require construction of physical prototype, physical validation, and more extensive theoretical verification, especially in regards to the cost analysis.

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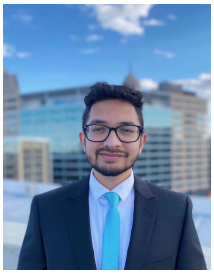

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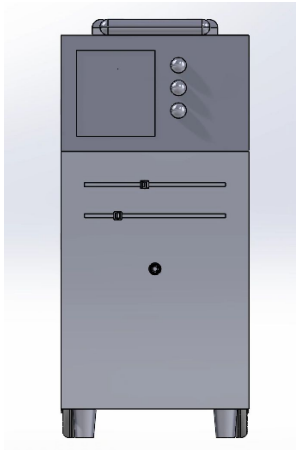
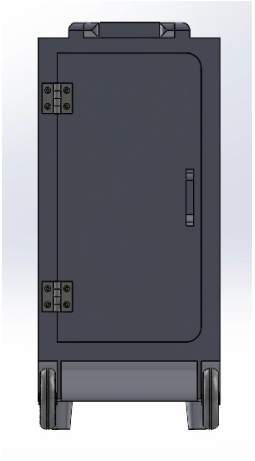
Appendix A - Design Detail

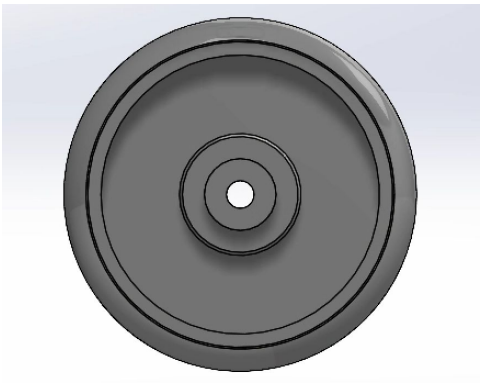
Close Up Of CAD Components



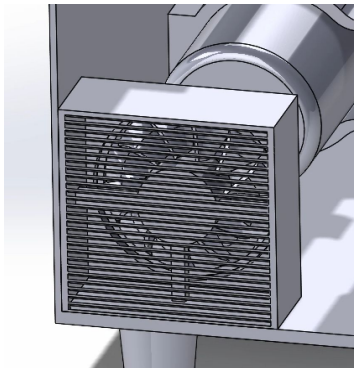
Device Housing



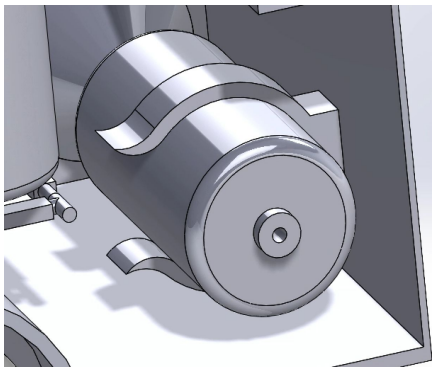
Rear Service Door



4 inch Rubber Wheel

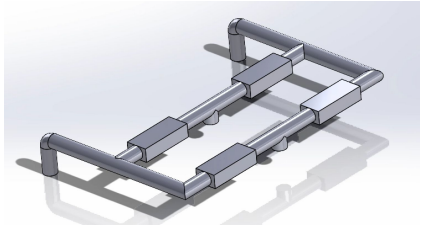


Air Intake

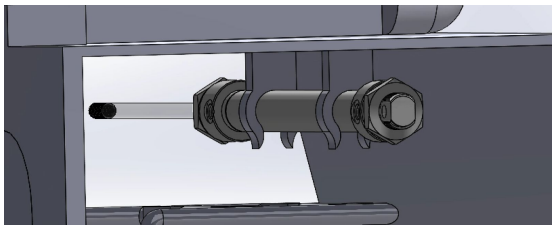


Air Filter (Moisture Removal)

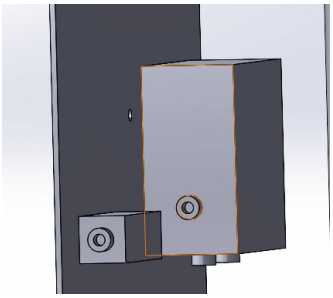
Zeolite Beds



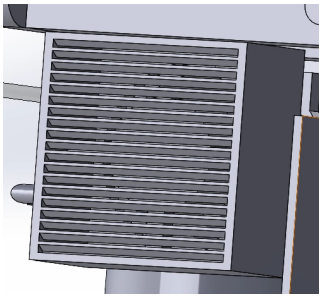
Valve Assembly



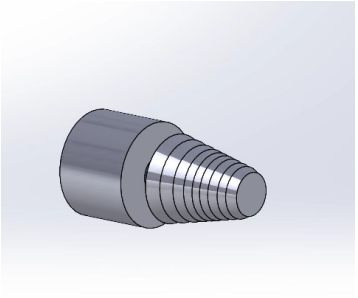
Pneumatic Actuator



Air Mixer and Flow Regulator



Exhaust



Christmas Tree Connector

FMEA Risk Analysis

Item	Function	Potential Failure Mode	Effect of Failure	Severity	Potential Causes of Failure	Recommended Action
Air Feed Blower	Inlet Feed Compressor	Leakage	High flow rate is unachievable	7	Physical damage to blades Motor failure	Protective vent around compressor
VSA Bed	Remove nitrogen from air	Beds do not regenerate fully	93% oxygen concentration is not reached so that output and mixture calculations are wrong and deliver incorrect concentration to infant	9	Insufficient cycle time Expired zeolite	Oxygen purity sensor Nitrogen sensor in beds
Surge Tank	Store concentrated oxygen	Leakage	High flow rate is unachievable	7	Physical damage High pressures in tank	Protected location in concentrator Protected by aluminum frame
Valve Connectors	Output concentrated oxygen and exhaust	Leakage Sticky valve	Nitrogen rich air is delivered to patient	10	Mechanical failures Motor failure Dirty components	Regular cleaning maintenance Oxygen purity sensor at output
Aluminium Frame	Protect device	Structural damage	Mobility is impeded Zeolite tanks are damaged	4	Physical damage during transport	Structural test for frame Guidelines for transport
Control Computer	Detect errors and transmit warnings, report on operation	Disconnect from screen, short circuit	Warnings are not communicated	8	Device losing power Physical damage	Audio notification for screen malfunction Computer malfunction
Power Supply	Supply power to unit	Power loss, overload	Device does not opperate	10	Loss of local power, device overload	Use circuit breaker to prevent overloads, backup power supply (battery)

Hazard	Hazardous Situations	Likelihood	Impact	Level	Technical Performance	Schedule	Cost	Action to Minimize Hazard
Electric Shock	Under extreme conditions, user could be shocked due to high voltage and wattage from power source	Low	Serious	4	Significant degradation in performance, supportability, and sustainability	Able to meet key dates	Budget increase 1% or less	Ensure constant current, circuit breakers and proper insulation
Overheating	Device can overheat as result of overuse	Medium	Medium	2	Reduction in technical performance expected from high temperature	Able to meet key dates	Budget stays same	Open ventilation for heat dissipation and fans
Fire	Device may be fire hazard because of stored, concentrated oxygen	Low	Serious	5	Device would shut down and no longer work under these conditions	Able to meet key dates	Budget increase 2% or less	Use properly insulated tanks, flow regulators, and insulating wires
Leaks	Device may leak oxygen if valves are not secured properly	Medium	Medium	2	Device will still work, with lower performance, outputting lower oxygen concentrations at lower pressure	Able to meet key dates	Budget stays same	Flow rate and oxygen concentration warning system and regular maintenance

Appendix B - Project History

DR1 Project Plan

Project Plan				
Day	**Date**	**Events**	**Team Members Responsible**	**Status**
T	**9/22**	Research: Oximeter Probes and Equipment Donations	Sarah	Complete
		Research: Durability	Maddie	Complete
		DR1 Presentation	All Members	Complete
Th	**9/24**	Meeting w/Caroline Soyars	All Members	Complete
		~~Meeting w/ Stephen John (Review Requirements and Specifications)~~	~~Thanvir~~	Cancelled
		Research: Human Factors and Ghanian Hospital Requirements	Abdul and Maddie	Complete
M	**9/28**	~~Meetings w/ Nursing + Medical Simulation Centers (Debra Yake, Niles Marand, and/or Dr. Michelle Aebersold)~~	~~Sarah~~	Cancelled due to COVID-19
T	**9/29**	DR1 Report	All Members	Complete
		Initial Concept Exploration Plan Set	Sarah, Maddie, and Abdul	Complete
Th	**10/1**	Meetings w/ Nursing + Medical Simulation Centers (Debra Yake, Niles Marand, and/or Dr. Michelle Aebersold)	Maddie	
		Meeting w/ Stephen John (Review Requirements and Specifications)	Thanvir	
		Brainstorming Session + Decomposition Analysis	All Members	
		PATH Live Forum—access to lifesaving oxygen during COVID-19.	Sarah and Maddie	
		Research: Design for Low-resource Settings and Human Factors	Abdul	
Fri	**10/2**	Meeting w/ Joanna Thielen (Engineering Librarian)	Sarah and Ulises	
Sun	**10/4**	Concept Development Meeting	All Members	
T	**10/6**	Research: Healthcare Tech in Low-resource Settings	Maddie	
		Meeting w/ Randy Schwemmin	Thanvir	
		Meeting w/ KNUST team	Ulises	
Th	**10/8**	Meeting w/Caroline Soyars	All Members	
		Meeting w/ Stephen John (Concept Exploration Check-in)	Thanvir	
		Concept Selection Meeting	All Members	
T	**10/13**	DR2 Presentation	All Members	
Th	**10/15**	Research: Human Factors	Abdul	
T	**10/20**	DR2 Report	All Members	

Project Plan from 09/22 to 10/20

DR2 Project Plan

T	10/13	~~DR2 Presentation~~	All Members
		~~Research: Vacuum Swing Adsorption~~	Ulises and Sarah
W	10/14	~~Meeting w/ Nursing Simulation Center (Debra Yake, Niles Marand, and Dr. Deb Rooney)~~	Sarah
Th	10/15	~~Meeting w/ Dr. Stephen John (Concept Selection Check-In)~~	Thanvir
		~~Research: Human Factors~~	Abdul
		~~Research Pressure Swing Adsorption~~	Maddie and Ulises
T	10/20	~~DR2 Report~~	All Members
		~~Research: Vacuum Pressure Swing Adsorption~~	Thanvir
Th	10/22	Meeting w/ Caroline Soyars	All Members
T	10/27	Meeting w/ Chemical Engineering Professors (on Potential Modeling Software)	Sarah
		Meeting w/ Dr. Ralph T. Yang (on Vacuum Swing Adsorption)	Ulises and Maddie
		Research: Maintenance and Manufacturing Costs	Abdul
Th	10/29	Meeting w/ Joanna Thielen (Engineering Librarian)	Maddie
		Meeting w/ Dr. Stephen John	Thanvir
		Determine Modeling/Simulation Software	All Members
		Research: System Component Analysis	Abdul and Ulises
T	11/3	Meeting w/ Randy Schwemmin	Maddie, Abdul, and Sarah
		Determine Feasabilty of VSA system	All Members
Th	11/5	Meeting w/ Caroline Soyars (Solution Development Check-In)	All Members
T	11/10	DR3 Presentation	All Members
Th	11/12	Meeting w/ Dr. Stephen John (Solution Development Check-In)	Thanvir
T	11/17	DR3 Report	All Members

Project Plan from 10/13 to 11/17

DR3 Project Plan

Day	Date	Events	Team Members Responsible
T	11/10	~~DR3 Presentation~~	~~All Members~~
Th	11/12	~~Research: Usability Testing of Medical Devices~~	~~Sarah~~
T	11/17	~~DR3 Report~~	~~All Members~~
Th	11/19	Research: Manufacturing in Low Resource Areas	Ulises
		Meeting w/ Dr. Stephen John (Solution Development and Verification Check-In)	Thanvir
		Meeting w/ Caroline Soyars	All Members
		Meeting w/ Mr. JT Anyanwu to Verify Computational Analysis	Sarah
		Sieve Bed Analysis Update	Ulises
		Initial Testing on Purchased PSA System	Abdul and Sarah
T	11/24	Meeting w/ Randy Schwemmin	Thanvir and Maddie
		Meeting with Mr. Ed Lockett III of the CSC to Verify Computational and Cost Analysis	Ulises
		Retrofitting of Purchased PSA System to VSA	Abdul, Sarah, and Maddie
Th	11/26	Meeting w/ Dr. Tim Johnson on Potential Clinician Contacts	Ulises
		Updated Cost Analysis	Maddie
T	12/1	Meeting w/ Dr. Jeff Plot to review current design	Thanvir and Abdul
		Final Design Usability Testing	Sarah
Th	12/3	Design Exp	All Members
		Meeting w/ Caroline Soyars	All Members
		Testing of Retrofitted VSA system	Sarah and Maddie
T	12/8	Final Report, Final Budget	All Members
Th	12/10	Meeting w/ Dr. Stephen John (Final Project Check-In)	All Members
T	12/15	Final Project Archive to Sponsors	All Members

Figure 23: *Current Project Plan from 11/10 to 12/15*

DR1 Requirements and Specifications

Key:
High Confidence
Medium Confidence
Low Confidence

Stakeholder Requirement	**Engineering Specification**	**Priority**	**Source**
Be able to provide sufficient oxygen	The concentrator must provide 93% FiO2 with a 3% contingency.	High	31, pg 7
Be able to maintain a low flow rate.	The concentrator's minimal flow rate must not be higher than 2 LPM	High	31, pg 7
Modular	The device must easily and modularly interface with a broad variety of ventilators and pumps, nasal cannulas, masks, etc, used in-country	High	
Be usable by a minimally trained user	The concentrator must clearly visually and auditorily share the current state of oxygen concentration and warnings pertaining to patient health and device condition. No specialized tools may be required for day to day operation. The device should be usable after minimal training time.	High	31, pgs 7 & 8
Be safe.	The device must meet either approval guidelines for USFDA or other stringent regulatory body of a founding member of IMDRF	High	31, pg 7
Be durable.	The device should need maintenance less than 1 time a year. The device must operate above 2000m above sea level. 10°C < Operating Temp < 40°C 15% < Operating Relative Humidity < 95% The device must meet ISO 13485:2015 (Quality Standard)	High	31, pgs 7 & 8
Be able to start working quickly.	The concentrator must be able to reach 95% of 93% FiO2 and 10 LPM flow rate in less than five minutes.	Medium	31, pg 7
Be transportable by a single hospital staff	Weight < 30 kg	Medium	31, pg 7

member.	The unit must be movable with at least 2 wheels		
Be cost-effective.	Optimally, the device should cost less than USD 500. Minimally, the device must cost less than USD 1600.	Medium	31, pg 8
Device maintenance should be simple.	No specialized tools required. Fixable by a minimally trained technician. Filters are easy to wash and replace. The device must not require preventative maintenance more than one time per year.	Medium	31, pg 8
Be quiet	Ambient operating noise < 50 dB	Low	31, pg 7
The device must be operable in most countries.	The device uses Mains Power. Power Consumption <275W at 5 LPM The Voltage Model must match the voltage and frequency of the purchasing country's local power grid.	Low	31, pg 8

Appendix C- Supplemental Appendix

Engineering Standards

Engineering standards were only used indirectly on this project, and were not heavily referenced.

One of our set requirements directly references a standard: ISO 13485. This standard speaks on the quality management of medical devices. Because we did not bring the project to the point of usable prototype with a manufacturing and maintenance plan, we did not actively apply this standard.

Despite the lack of progress to reach application of this quality standard listed in our requirements, we did apply information from the American Standards Association's standards on human noise exposure to set the appropriate decibel level of device warning system to meet our requirement "Be usable by a minimally trained user".

Aside from these two instances, our project did not use standards for two reasons. First, standards provide engineers a common language across stakeholders for a project. We were already provided this common language by the Target Product Profile [31] created by the World Health Organization and NEST 360, and so we did not end up needing the language of standards to create our requirements. We chose instead to stay within the bounds of the Target Product Profile referenced by our stakeholders to set requirements. Second, in our initial research it became clear that many existing portable oxygen concentrators are either CE or FDA approved and meet a variety of standards, as well as most of the requirements of the Target Product Profile [31]. Despite considering more drastic designs that would have required a ground up approach, we settled on a design that was based on modifications to current pressure swing adsorption oxygen concentrators. Therefore, rather than identifying standards from the ground up, it would be necessary to consider parts of the concentrator that changed, and examine the standards that apply to them. Once the project had reached a point where all necessary modifications were clear, we would have moved on to studying the applicable standards.

Engineering Inclusivity

Specific steps were taken to promote inclusive stakeholder engagement and make inclusive design decisions through the length of the project. An active effort was put forth to realize that interviews with more qualified and knowledgeable experts does not need to be intimidating. Meetings with doctors, nurses, and Ph.D level candidates were approached with the intent of the team being vocal in voicing their questions and opinions. Additionally, as our project centered on low-resource settings the team acknowledged that our social identity provided

power over decisions with real impacts for these people. We ensured that we would take responsibility for the safety that the decisions I make afford these people. This is evident in our ‘solution-neutral design considerations’ outlined in the problem definition and requirements and specifications. Our requirements also included certification by high power medical device agencies, providing guidelines for our design to responsibly aid people using our design in Nepal. These inclusions of our project were especially important to include, as our device is a life-saving device with potentially severe consequences of failure.

Our team practiced inclusive design to a fair extent. We considered several of the key aspects of social identities of our teammates, including that each of us have multiple identities, that we have flexible identities, and that our identities can be both visible and invisible. With our identities considered, we were able to fully identify the social power that our actions and design decisions had and the inherent biases that we each had that potentially could persuade important decisions. To make our design more inclusive we could have reached out to a greater sphere of stakeholders including those who are not necessarily experts. This greater range of representation would provide the team with a better perspective on problem definition and more inclusive requirements, leading to an overall more inclusive final design.

Environmental Context Assessment

When making design decisions, thinking environmentally should be a top priority. Our design incorporates to the best that it could be done. The components are packed into the device housing as tightly as possible to reduce waste in packaging and conserve material used by the device. When it comes to sustainability, our device does meet the first two necessary conditions required for sustainable technologies. The first requirement is that the solution should make progress towards a social or environmental goal. Our solution was made for low resource settings so we were meeting a social goal by making a necessary technology more accessible to a group of people. Our solution does this by reducing the cost of the device as much as possible and takes into consideration the usability of the device by the people in these settings. The second requirement is that the device should not have the potential to lead to undesirable consequences in its lifecycle that would outweigh the benefits. Our device does not have that potential. It is a scale down of an already existing oxygen purification method and does not use any novel components. This oxygen purification method is already in use at larger scales and provides a longer life to the device. The device can be easily serviced which also increases the life of the device which in the long run reduces waste.

Social Context Assessment

Designers should consider the social and economic context of technologies when doing design work. This is true for our design as well. Our system is likely to be adopted and self sustaining in the market given that a working model can be produced. The final design is significantly more

affordable than anything that is currently out in the market for portable oxygen concentration. This will have a major social impact, especially in low income and low resource countries.

This oxygen concentrator design will help many people, as one of the main goals is to minimize cost. At the end of the day, this design is for the common good.This will allow a lot of impoverished families and low income hospitals to have access to better quality healthcare, ultimately leading to a better quality of life for these people.

Ethical Decision Making

Ethical decision making is when designers consider the ethical responsibilities of their design work and evaluate the potential ethical impacts of their designs. The engineering Code of Ethics was followed when creating this design. The main goal with this design was creating a low cost oxygen concentrator for low income environments. This goal held the fundamental principle of human welfare at its core.

These ethics were incorporated into the major design decisions for this project. The usability, affordability, and overall accessibility of this oxygen concentrator were prioritized for all aspects of the design process. It is our duty as engineers to put the safety and needs of the people using our designs first. We approached our space with these ethical values in mind. We also prioritized the environmental impact of our device and tried to make it as safe as possible, not only to the environment but the user as well. The components are packed into the device housing to reduce waste in packaging and conserve material used by the device. Our solution minimizes the cost associated with producing such a device, these savings are then passed on to the consumer, creating a low cost and easily available solution to portable oxygen concentration.