

COVID-19 Disaster Mitigation Efforts

Title: DIY Ventilator from locally procured parts and tradesman talent – Distributed Construction

COVID-19 has exposed a critical shortage in our medical care capabilities, and supply chain. Throwing money at the vendors to produce more and faster is unlikely to work in serious worldwide pandemic where supply-chains are shut down, the need for ventilators vastly outstrips the manufacturing capability, or quarantine simply shuts down transportation.

The total number of available ventilators in the US is around 600-800k¹. Of the total ventilators 80% are currently in use for car accidents, surgery recovery, etc. Even if we had 1M and 20% avail that only leave 200k avail. Some models from the CDC are predicting over 1M dead. Some of these people may live if a rudimentary Ventilator existed and could be put into use prior to the major manufacturers getting to full production and distribution.

In Italy, Doctors and Nurses are already having to triage who lives and dies based on available Ventilators. That does not need to happen here. Americans are the most helpful people on the planet during a crisis, they just need a little direction. The same way in an emergency, a first responder needs to point at a person and say, “You there! Call 911!”

Theory

The concept of a ventilator is pretty simple. The first ventilators were developed during WW2 to provide Pilots with O2. The basic design is not complicated. A manual ambu+ bag works on the following theory. Figure 1 shows the basic operation of a 2 step Ventilator.

- Step 1: The accumulator is isolated from the air source and pushed into the patient.
- Step 2: The accumulator is filled to max pressure and volume isolated from the patient while the patient exhales.

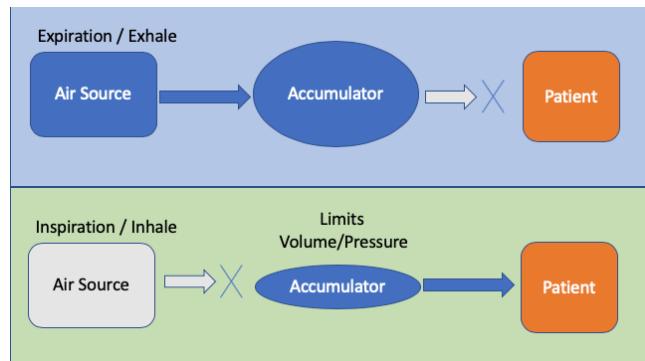


Figure 1: Basic Theory

¹ Based on off the record conversations with USG officials

Concept & Motivation

Discussions of shortages across the planet of ventilators are occurring hourly on the news. Retooling industrial plant to build and ship massive numbers of ventilators will take time. We undertook the task of investigating if locally accessible parts could be used to build a ventilator using local tradespeople in a timely fashion. We have found that answer to YES!

Other teams are motorizing breathing bags (Ambu+ etc..). We initially used an Ambu+ bag to test. It is not a requirement. Nearly everything one needs to build a functional prototype can be found out a sports store and a hardware store. Our overall design shown in Figure 2, with our prototyped parts highlighted in figure 3.

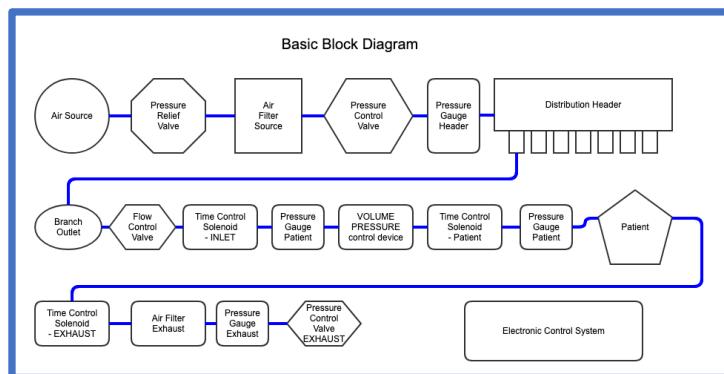


Figure 2: Simple Open Ventilator Block Diagram

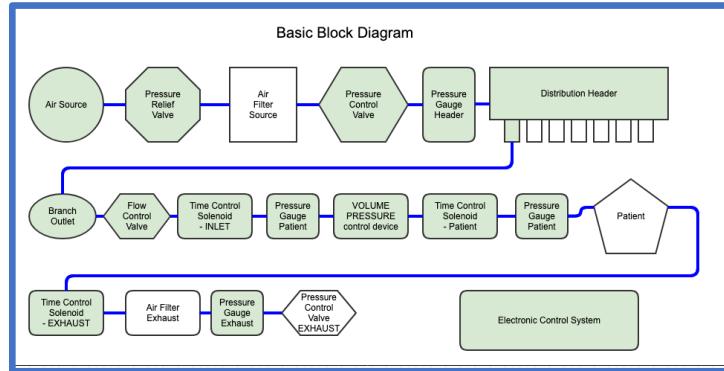


Figure 3: Actual Prototyped & Tested in Green

Over the last week, we have been learning and constructing the framework for the DIY ventilator <https://github.com/MakerSeldon/SimpleOpenVentilator>. Our overarching mission is that local tradespeople need to be able to construct the system with locally procurable parts. Each assembly is sufficiently designed and documented so a local tradesperson can make field changes based on what parts they have available. Below is where we are on a shoestring budget. We will identify each of the major parts in the diagram 1 block at a time. The section under discussion is highlighted in blue.

Air Source

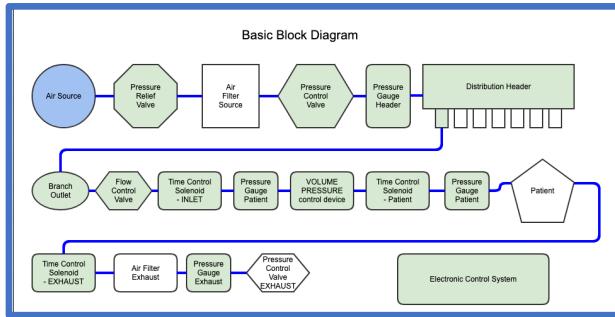


Figure 4: Air Source and Hookup

We used a standard Rigid Shop Vac [Model ____]. We connected to the blower output of the shop vac with a HEPA filter installed. The main lines for operation are 2" PVC piping. The shop vac does not directly hook up. We used a 2" screw together type coupler, as shown in figure 5. This provided a robust connection over the last several weeks without any issue.



Figure 5: Shop Vac to 2" PVC hookup

Pressure Relief Valve:

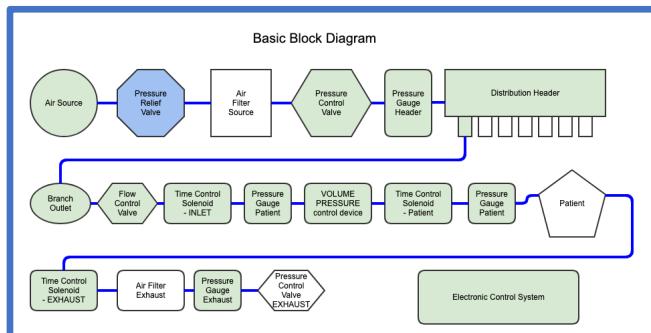


Figure 6: Pressure Relief Valve

The pressure relief valve acts as an overall safety valve. The fitting has a cap and a weight that is designed to fall off at 65mmHg. Once the valve is activated, all the pressurized air is dumped out the large port. The untested theory is a book placed on top of the valve with it at a 10 degree angle is sufficient to fall off with the correct weight placed. **REWORD and Test**



Figure 7: Prototype Pressure Relief Valve

Pressure Control Valve:

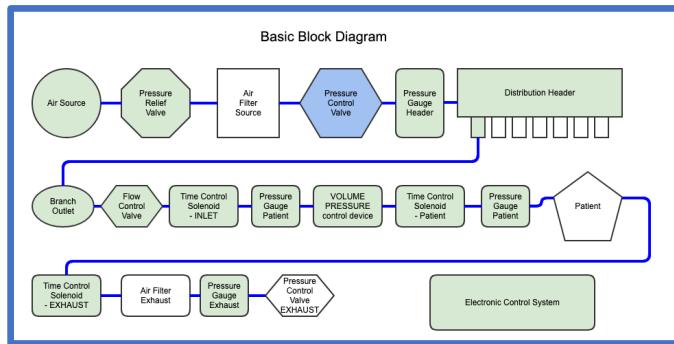


Figure 8: Pressure Control Valve

The pressure relief valve is critical to the proper operation of the system and safety of the patient. The valve is similar to a linear voltage regulator, ensuring constant pressure under varying loads. This system was tested with all ports closed and one $\frac{3}{4}$ " port wide open with no restrictions successfully. We monitored the pressure with a large water manometer – details covered in a later section. The pressure control valve consists of a 1-1/2" vertical standpipe with a factory finished edge at the top, and Pressure Control Valve Cap. The Theory and Math will be discussed in an Appendix. It is designed to be leaky no seal is required.



Figure 9: Image - Exploded View PCV cap

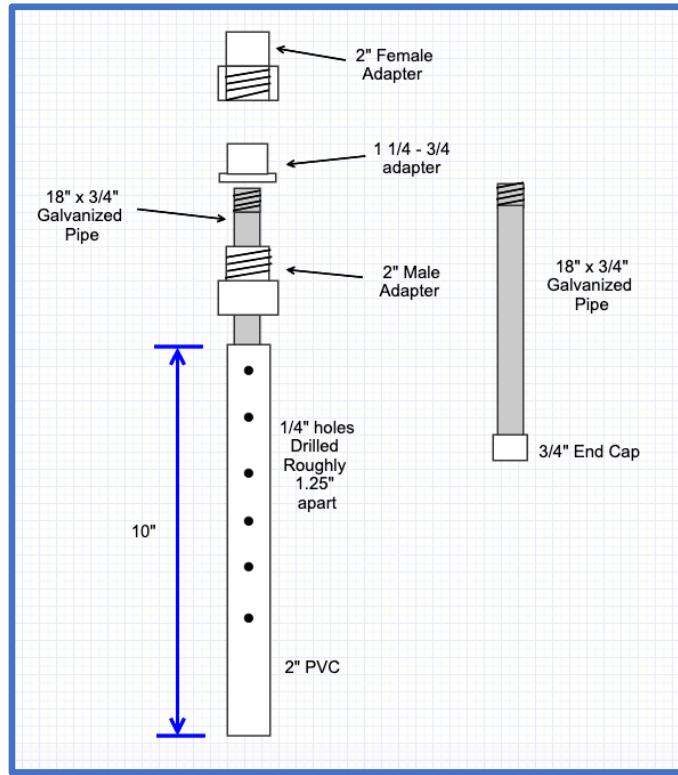


Figure 10: Detail View PCV Cap

Pressure Gauge

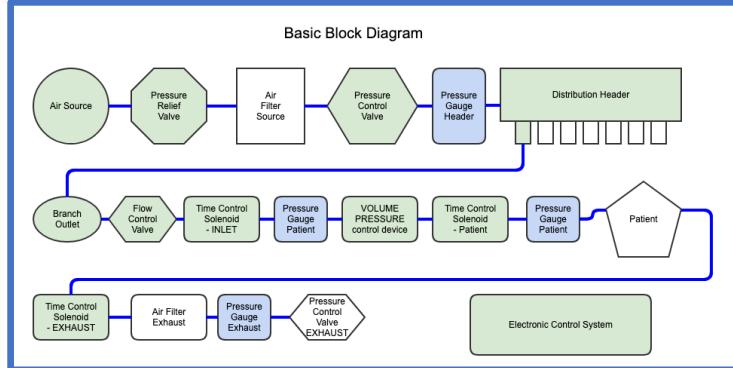


Figure 11: Locations of Manometers

Accurate low-pressure gauges are simply not readily available at hardware stores, or even auto-supply shops. Constructing one is the only option. Most medical measurements are measured in mmHg. We needed to transform from mmHg to inH₂O. The conversion factor is 1mmHg to 0.535776 inH₂O. We need to measure 40-60mmHg. This means we need a height of 21" – 32" when we build our manometer. The detailed theory is in the appendix. A manometer measures pressure difference. If you have a U-shaped column of water with ambient on one side and the other side hooked to a manifold. You can measure positive and negative pressures based on the differences in the height of the two sides assuming the water covers the U at the bottom. Our plans to make these devices are very inexpensive and easy to make. Adding food coloring to the water makes them easy to read and with the ratio of 1mmHg to .53 inH₂O using a yardstick should be plenty resolution.

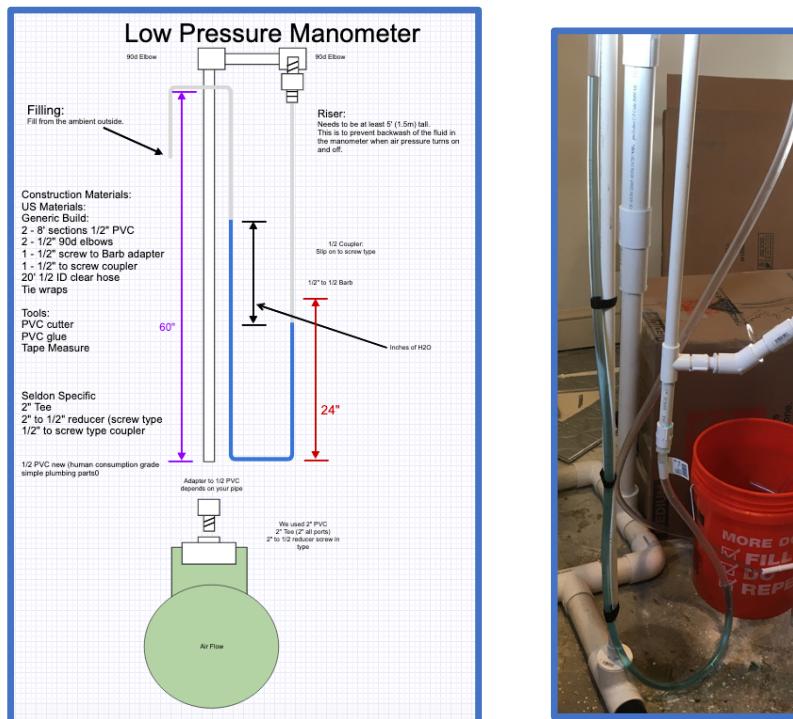


Figure 13: Manometer

Distribution Header

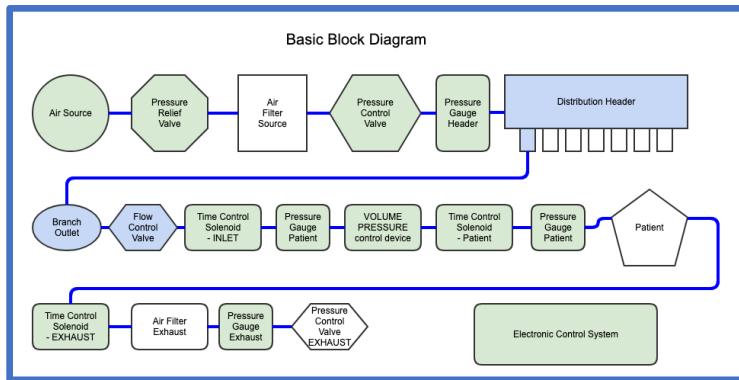


Figure 14: Distribution Header and Valves

The distribution header is simply 2" PVC with 2" Tees and $\frac{3}{4}$ " tap offs with a valve.



Figure 15: Distribution and Valve

Time Control Solenoid Input / Output

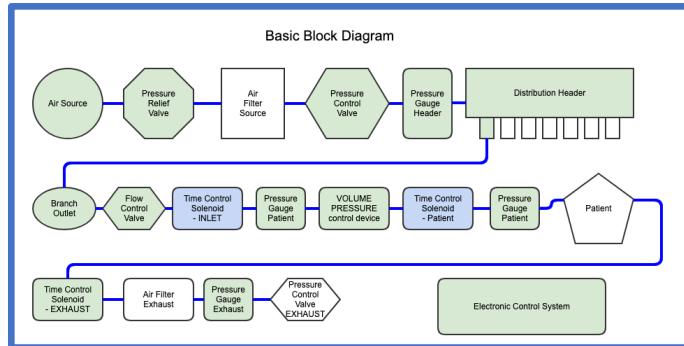


Figure 16: Solenoid valves

Finding electrically activated valves in home improvement stores was the most challenging part of all this effort to date. The normal valves are gear driven ball valves for irrigation. These have two challenges. The valves are slow, and they are not rated for safe for humans. Through a little bit of luck, we found a repair shop that had used and new washing machine valves. These are poppet type valves, are electrically activated (120V). They are designed to be underload for long periods of time. We are still not clear on the number of cycles, but with our design a little leaky is ok.

Initially we only had one of the two valves hooked up on each side². Our initial experiments that showed we could not get enough flow (current) through the valves with safe pressures. The choice was to increase the pressure or increase the aperture size for the air to flow through. Initial results with 2 ports open on input and output may work. But we may need to move to two valves on the input and output ports to get the desired mmHg / inH2O for operation.

In later designs if we can find different sized ports, we can a combination of valves to adjust the tidal volume and inspiration speed without having to change the mass on the pac-man.



Figure 17: Cutaway View of Valve

² See Appendix for first iteration that failed.

Volume and Pressure Control Device PAC-MAN

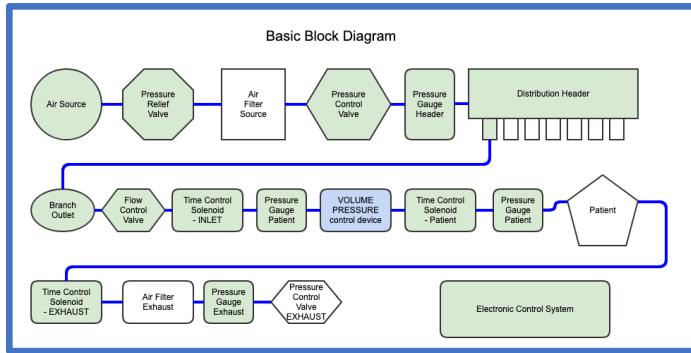


Figure 18: Volume and Pressure Control Device - PAC-MAN

At the heart of the system is the device that controls and delivers the correct pressure and volume of air to the patient. Like with the rest of our system, gravity and basic mechanics is what delivers the answer. It depended on an accumulator placed between two boards that squished the bag to the proper pressure with weights on the top.



Figure 19: PAC-MAN with accumulator

The Accumulator is just a bag that holds air. Our current version is made out of a turkey basting bag. It has an input and output port. The ports use 2" couplers and 2" to $\frac{3}{4}$ " adapters with 1/2 " PVC adapter to $\frac{1}{2}$ pipe. In our next design, we will move to a collapsible water bottle with one port. These bottles are nearly indestructible and have a screw-on port. Adapting the pop-top port to PVC or MIP fitting will not be a challenge as epoxy is always an option.



Figure 20: Accumulator Version 2.0, Turkey Bag

Squishing the bag is accomplished by a hinged mechanism. We used a piece of left over laminate flooring 48"x 10" cut in half. With a piece of 2x4 keeping them apart so the door hinge worked perfectly.



Figure 21: PAC-MAN Hinge

For the weights, we used 1lb bags of beans. 1lb bags give sufficient resolution for our initial testing, and can be found readily anywhere, and can be fine-tuned easy enough.

Patient

We don't have our patient model fabricated yet. The basic design is 2 each 2L jugs with latex gloves put in them. Put a hole in the bottom part of the 2L bottle, put the amount of water in the glove that you want to displace. Then seal the hole. Now you have a mockup set of lungs with a negative pressure where it belongs. The natural spring of the gloves will set an equilibrium with the vacuum in the 2L bottle. Hook up two of these and a set of lungs to watch. Once the system is running well-enough live tissue testing will be in order.

Exhaust Air Filter and PEEP control

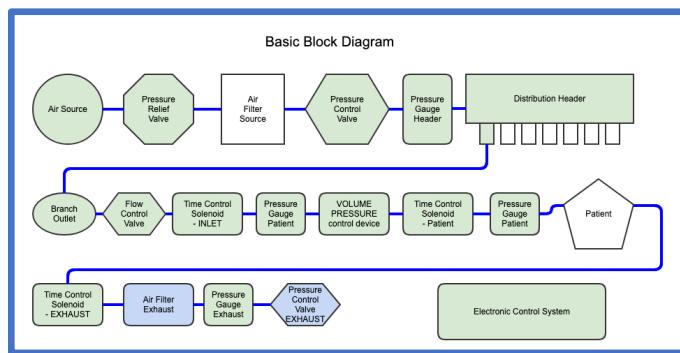


Figure 22: Exhaust and PEEP

As we have the three main control valves, redirecting the expiration / exhaust is pretty trivial. Our exhaust box is designed to be a sealed metal box with a very low pressure gravity PCV valve. On the output. Inside the box will be a HEPA filter and UV lights. We expect to need a check-valve for leaking. If the box leaks too much, we can just direct a pressure regulated flow into the box providing positive pressure at the desired value inH2O.

Electronic Control System

The electrically controlled valves that direct the air flow are the on things that need controlled. The control circuit only needs to generate a PWM signal. The states are described in Figure 23.

	Valve	INLET	Patient	Exhaust
State				
Start		N/C	N/C	N/C
Fill / Exhaust		OPEN / ON	CLOSED / OFF	OPEN/ON
Inspiration		CLOSED/OFF	OPEN / ON	CLOSED/OFF

Figure 23: State Values for Solenoids

The circuit only toggles between 2 states and only 2 outputs the Q and not Q values. The breathing rate is determined by the overall period of the PWM signal. The inspiration speed is determined by the width of the pulse.

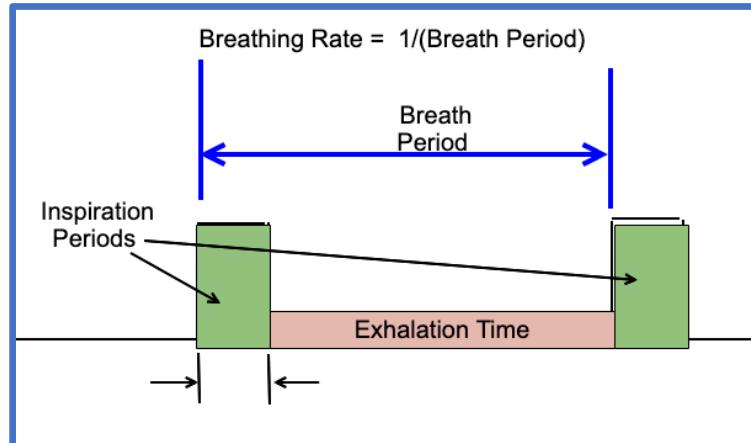


Figure 24: PWM Signal Control Elements

The current control circuit is a simple Arduino with two relays and an LED, running a simple program. See Appendix for .ico file.

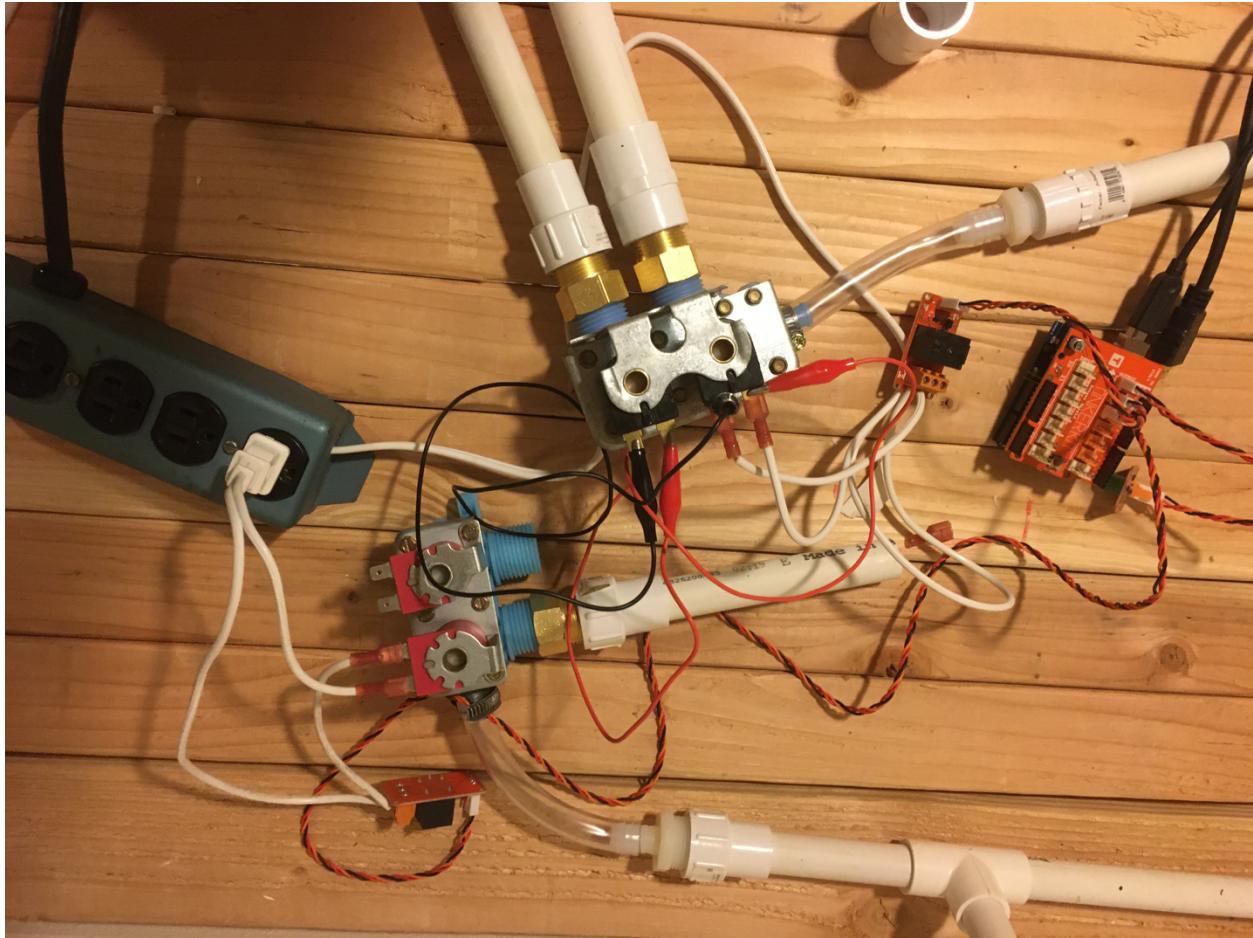


Figure 25: Control Circuit as with 3/4 solenoids hooked up

<add circuit Diagram here>
<add source code to appendix>

Vulcan-SOF

SOW: Study Ad-Hoc Distributed Manufacturing of un-approved ventilators

Introduction:

COVID-19 has exposed a critical shortage in our medical care capabilities, and supply chain. Throwing money at the vendors to produce more and faster is unlikely to work in serious world-wide pandemic where supply-chains are shut down, the need for ventilators vastly outstrips the manufacturing capability, or quarantine simply shuts down transportation.

Motivation:

The total number of ventilators available is around 600-800k. Of the total ventilators, 80% are currently in use for car accidents, surgery recovery, etc. Even if we had 1M and 20% avail that only leave 200k avail. The CDC is predicting over 1M dead in one model.

Question:

Can a ventilator be produced from locally procured parts by local tradespeople with no skills in the medical industry in an emergency.

Outcome: Proof of Concept for Quick Reactionary Capability with distributed production for medical or other emergency requirements.

Deliverable:

Attempt to produce a design spec, instructions, guides, and test procedures enabling local tradespeople to assemble and test the system.

Test design for reproducibility.

Generate after action report.

Expectations:

This is an impossible task.

- Traditional FDA approved ventilators are complex pieces of machinery.
- Innovating a design and a functioning prototype over a 2-week period
- of time is a near impossible task. It is unlikely that an ideal system can be developed that meets all the desired specifications and requirements.
- However, it IS possible to get close!

- Impossible Specifications:
- In order of **descending **importance, the ideal desired specifications of a Do-It-Yourself mechanical ventilator are:

1. Total Cost of all parts <\$300
2. Able to be assembled and operated by low-skill levels
3. Assembled from readily available, consumer off-the-shelf parts and capabilities (Home 3D printers acceptable)
4. Capable of functioning for at least 48 hours
5. Needs to accommodate a standard 22 mm size hose that is 5 feet long (Hose design not necessary)
6. Have a connection method to allow an adjustable O₂ source to be connected
7. Capable of providing a Respiratory Rate of 12-40 breaths per minute
8. Capable of Providing 5-24 cm H₂O of PEEP (Positive End Expiratory Pressure)
9. Capable of Delivering Tidal Volumes of at least 500cc (range 160-1500cc) with every breath
10. Capable of limiting the Peak Inspiratory Pressure to 18-40 cm H₂O
11. Has a method to humidify the air being delivered (in line Passive humidifiers or alternative)
12. Powered using 120V or lower (12 V car battery)
13. Inspiratory Time of 0.4 seconds
14. Gauges or instruments to visualize delivered values and settings

Super Long shots:

- A. Provide ability to control Flow during inspiration, but if fixed: able to deliver 60L/min
- B. Pressure Support—a breath triggers either a set pressure or volume of air; and
- C. maintains a continuous PEEP (Positive End Expiratory Pressure)
- D. Expired air scrubbing--method of absorbing or filtering the expired air

Ventilator Basics:

At the basic level a ventilator provides the means to push air into the lungs and allow the air to escape via the natural force of the patient's chest cavity. This has to be accomplished without injuring the patient.

This simplest case is mouth-to-mouth rescue breathing. This method has been taught and successfully used many times. It is typically taught in CPR classes by the Red Cross to the general public.

Next in line is "bagging" a patient. An Amub+ bag or equivalent is used to push air into the lungs and let it escape. The bag has a maximum size limiting the possibility of over-inflation and injury. It also has a wide set of simple one-way valves ensuring safety. The breathing rate, pressure, volume, is all limited by the human squishing the bag.

If we automate the human with a mechanical device to squish the bag you can create a large number of tunable simple ventilators. These devices can be produced locally but depend on having an Ambu+ bag or equivalent present.

Next we have the traditional ventilators, these come in many different configurations and options, but the minimal functionality is the same as the mouth-to-mouth or motorized bagging.

From our testing, we have determined to achieve basic functionality, you need the following:

1. Deliver Air to the patient with the following parameters
2. Determine/control the volume of air per breath (Inspiration / Tidal Volume)
3. Control how fast the breaths come (Respiration Rate)
4. Control how much pressure the patient sees during Inspiration
5. Control the speed of Inhalation (How long inspiration Takes)
6. Using 1-5 use values that will keep patient alive and uninjured

To accomplish this we believe you need the following.

1. A means to fill an accumulator
 - a. Pressurized air
 - b. Vac creating structure – Ambu+ bag
2. Accumulator Pressure Isolation
3. Patient Pressure Isolation
4. Safety measurement tools
5. Means to repeat filling lungs repeatedly

The Ambu+ bag accomplishes 1,2,3, and 4 is accomplished by a human or machine. If a Ambu+ bag is not used. The block Diagram looks like the following:

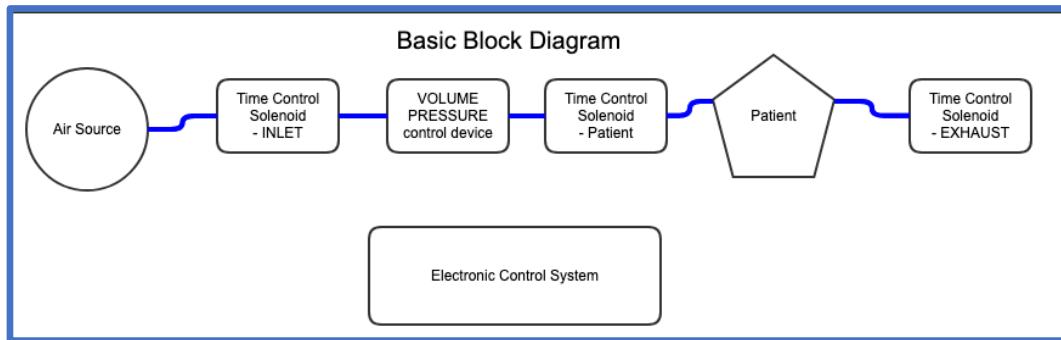


Figure 26 Simplified Block Diagram

From our testing, 3/8 WOG poppet valves should suffice at a working pressure of 40-60mmHg. The controller circuit for the valving is a trivial PWM circuit with a duty cycle of less than 50% for any value. With proper valving and driver design, a single control signal could control all three valves. These values can be trivially changed with potentiometers. A fully analog circuit could easily drive this design. The BOM cost below assumes an external air source and a greatly simplifies the problem.

Estimated Professional BOM cost

EACH	DESCRIPTION	COST EST
3	High end Valves. 200 USD each	600 USD
1	Driver Circuit	50 USD
1	accumulator	50 USD
1	Tablet for display (optional)	400 USD
1	Push on hosing and fittings	100 USD
1	Box	50 USD
TOTAL		1250 USD