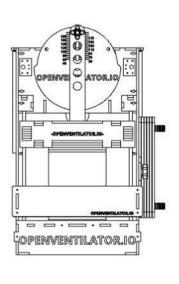
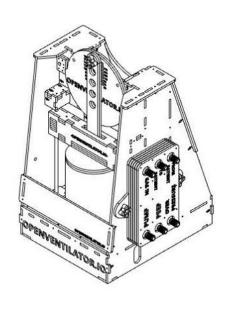
OpenVentilator.io Spartan Model Mk1 Documentation





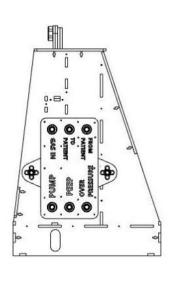




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DISCLAIMER

WARNING GRAPHIC

THIS PROJECT IS NOT YET INTENDED FOR MEDICAL USE. THIS DOCUMENT IS AN ENGINEERING DOCUMENT DESIGNED FOR MEDICAL DEVICE ENGINEERS TO REPLICATE THE MACHINE AND TEST AND VALIDATE ITS FUNCTIONS, RELIABILITY AND SUITABILITY FOR MEDICAL USE.

DO NOT USE THIS MACHINE FOR MEDICAL PURPOSES. THIS IS A PROTOTYPE, NOT A MEDICAL DEVICE.

THIS PRODUCT MAY CAUSE SERIOUS INJURY OR DEATH IF USED AS A MEDICAL DEVICE

WARNING GRAPHIC

Note to Engineers and Medical Testers

If you are an Engineer or Medical tester and have built this system and tested it, we would appreciate your thoughts, results and suggestions. OR, if you have technical questions, Please contact us at lab@openventilator.io

DESCRIPTION OF THE PROJECT

The OpenVentilator.io Spartan Model Mk1 is an open source mechanical ventilator designed to be manufactured with a minimum of commonly available components.

There are no microcontrollers or off the shelf electromechanical valves which may be hard to source in remote or low income locations, or in the event of supply chain slowdown or stoppage in heavily developed locations.

The machine system is designed to be component agnostic where possible, allowing manufacturers of the device to swap component types depending on their manufacturing process capabilities. One of the future goals of the project is to design individual components and component sets that can be manufactured using different manufacturing processes, including: 3D printing, injection molding, laser cutting, die cutting, hand cutting with a jigsaw or coping saw. Not all components are currently manufacturable with all processes, we are still working on this step of the project as of the publishing date of this document.

The machine is designed to use components that can be used in other designs. The Spartan Model Mk1 is designed to work with a minimum of off the shelf medical supplies, and to be component agnostic. There may be more well suited solutions in different parts of the world, or from different manufacturers. We hope that if and when a manufacturer of another ventilator design cannot source a component for their design, that they will be able to use components from the OpenVentilator Spartan Model Component Library in place of their original components, or as stopgap measures during supply chain delays or stoppages.

The OpenVentilator.io Spartan Model Mk1 is designed to give an end user the following operating controls:

- 1. Tidal volume control
- 2. Inhale vs. Exhale timing ratio as well as control over BPM (Breaths Per Minute)
- 3. Overpressure regulation
- 4. PEEP (Positive End Exhalation Pressure) regulation
- 5. O2 Mix ratio

The machine is designed to modularly:

- 1. Filter and sterilize intake air supply
- 2. Filter and sterilize outtake air supply
- 3. Allow for Autonomic Inhale initiated by the patient during an Exhale Cycle

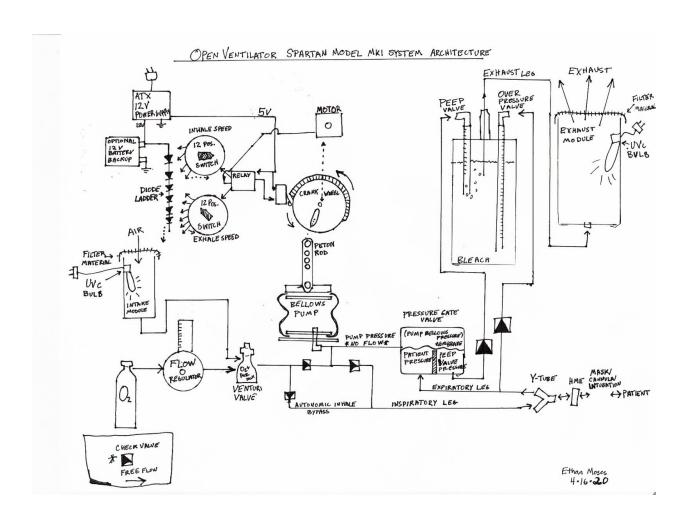
Functional Description

In this section we will show functional diagrams of the system architecture for assembly and in use in each of 3 states:

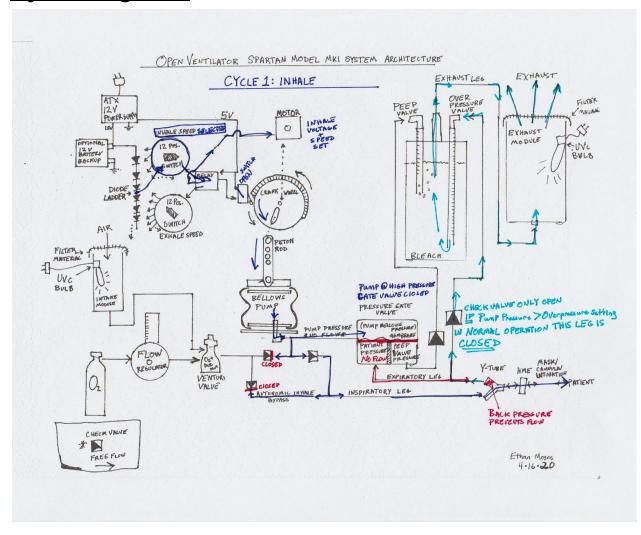
- 1. Cycle 1: Inhale;
- 2. Cycle 2: Exhale;
- 3. Cycle 2a: Autonomic inhale initiated by patient during Exhalation Cycle (Cycle 2).

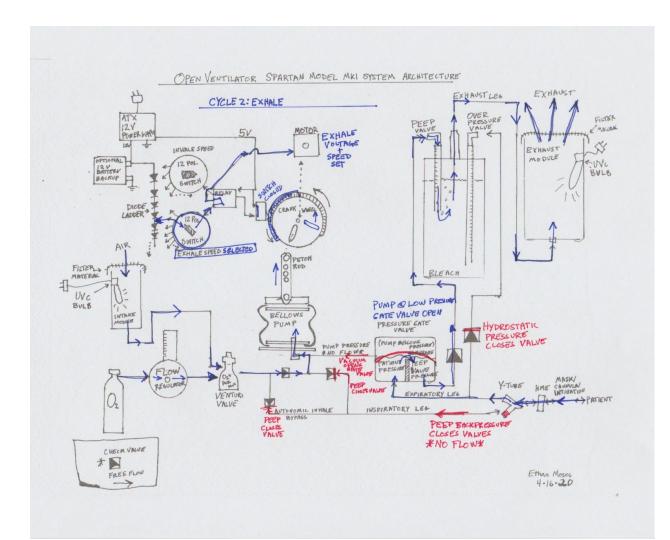
We will show these diagrams both for the system architecture, and the main Diverter valve in all three states.

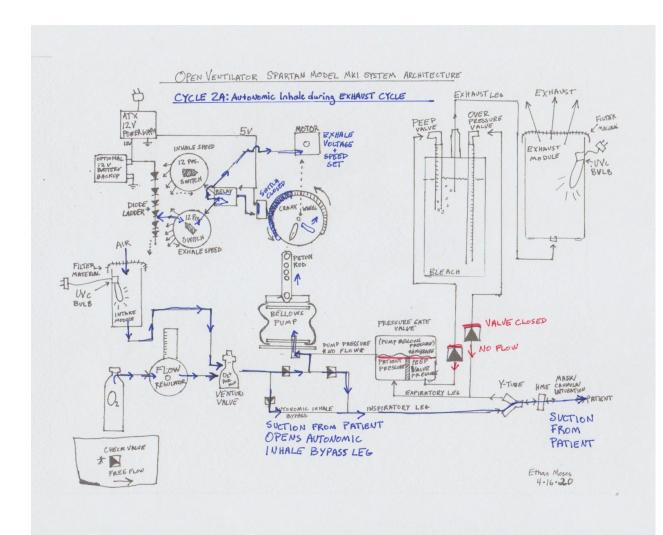
System Diagram



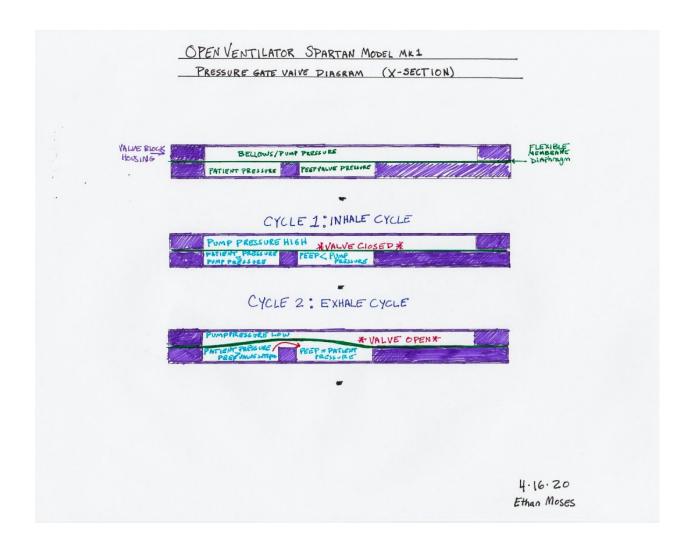
Cycle Diagrams

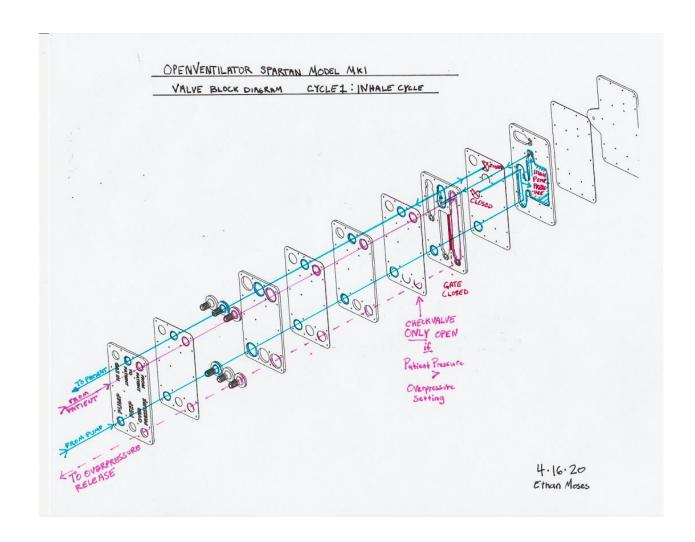


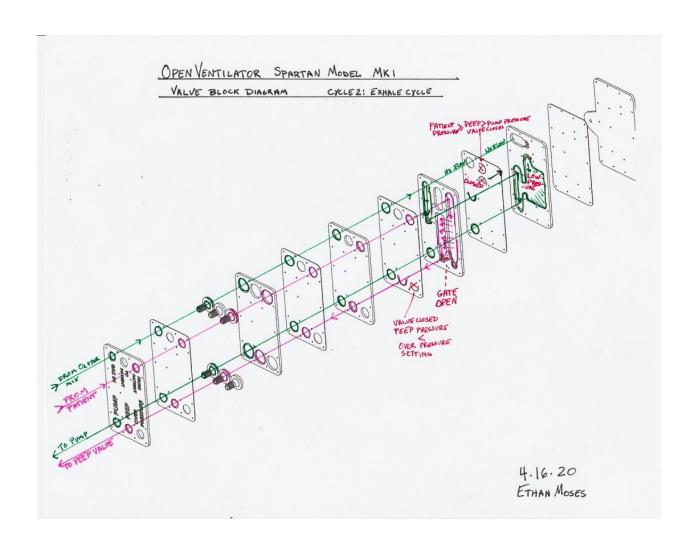


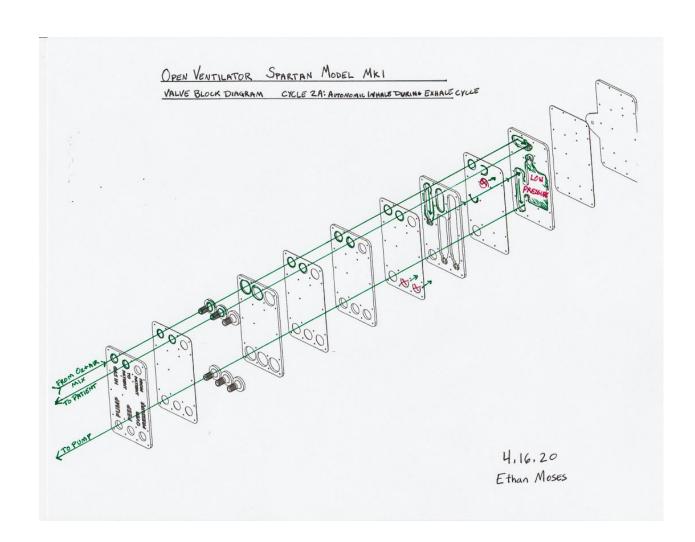


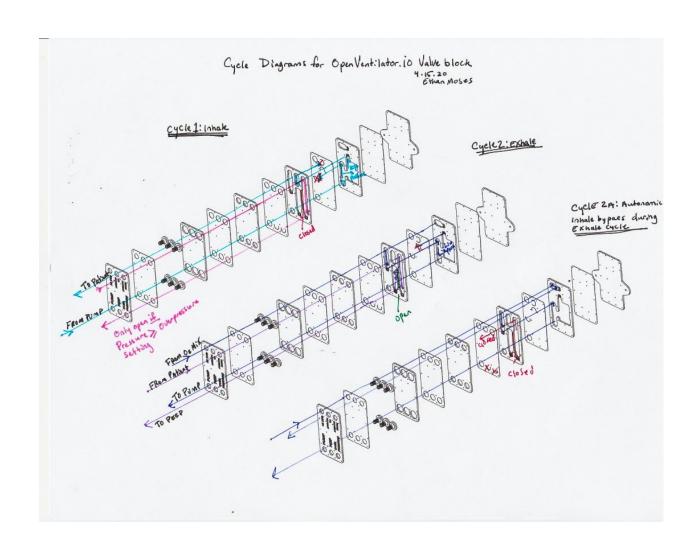
Functional Schematics of Parts











Functional Description of the System

**NOTE: INHALE CYCLE refers to the PATIENT inhaling, NOT the PUMP INHALING.

The system works as follows:

A 12 volt power supply (optional inline battery backup) is connected to multiple diodes in series (10A10 diodes, commonly found in alternators and off the shelf). We will refer to this as a 'Diode Ladder.' Two rotary 12 position switches are connected at each of their positions to different points in the diode ladder. Their center taps are each connected to one side of a relay. In this manner, each switch provides a voltage setting output to the relay by turning each switch. One of the position switches corresponds to Inhale Cycle voltage, and thus Inhale Cycle motor speed, and the other corresponds to Exhale Cycle voltage and thus Exhale Cycle motor speed.

The two 12 position switches will be used to control the DC motor speed in the inhale and exhale cycle independently, so that BPM as well as Inhale/Exhale timing ratio can be set by adjusting the two rotary switches.

The center tap of the relay is connected to the positive terminal of a DC motor that will turn a crank wheel.

The control side of the relay is connected to either a limit switch in the case of a 360 degree continuously rotating motor, or a Toggle switch in the case of a reciprocating geared motor that moves in two directions. This will be explained shortly.

The DC motor we are using is a windshield wiper motor from a car, this part can be swapped for other motors, with suitable adjustments made to the rotary switches, the motor mount on the pump frame, and the mounting hole in the crank wheel.

The DC motor is affixed to the top of the pump frame and a Crank wheel is affixed to the motor shaft.

The current design can take a 360 degree continuously rotating motor, or a motor with a reciprocating gear drive that moves back and forth in both directions. Each type of motor will require a different type of Crank, and either a toggle switch for a reciprocating motor assembly, or a limit switch for a continuously rotating motor assembly.

In the case of a continuously rotating motor assembly: The Crank wheel has a 180 degree cam along half of its circumference. (the difference between cam arcs will be explained later). During one half of the rotational cycle, the cam depresses the limit switch, which in turn triggers the relay, which toggles the motor voltage supply to the INHALE speed setting rotary switch, thus setting the motor voltage supply and thus crank wheel rotational speed. This will determine

the speed of the INHALE cycle. During the EXHALE half of the rotational cycle, the cam on the circumference of the crank wheel is not in contact with the limit switch, which does NOT toggle the relay, causing the motor power to be supplied through the OTHER rotary position switch, setting the crank speed and thusly the cycle time for the EXHALE stroke, opposed to the first half of the crank's rotational cycle.

*NOTE it is better to have the motor and crank wheel rotate Counterclockwise if possible, which will resist loosening the bolt and nut that form the pivot between the crank wheel and piston rod.

In the case of a reciprocating motor assembly: The Crank wheel will move back and forth, so a simple cam will not work, as the cam would pass the limit switch in both directions, and therefore depress the switch on both inhale and exhale cycles. In this case we use two pawls or tabs that extend from the crank wheel at an arc angle equal to the reciprocation angle of the motor (minus the arclength of the throw of a toggle switch) that will toggle a toggle switch at the end of each cycle, thereby toggling the relay which determines the power path to the motor through one of the two rotary position switches that sets the voltage to the motor, and thereby the crank speed and cycle times of each of the inhale and exhale cycles.

The crank wheel, in addition to the mounting hole for the motor shaft and either a cam or set of pawls on its radius, has a radial mounting slot for one end of a piston rod. By moving the pivot connection of the piston rod towards or away from the axis of the crank wheel, we can vary the throw of the piston arm, and thereby control the vertical displacement of the piston, which will set a tidal volume pumped to the patient.

The bottom of the piston rod is connected to the top of the piston on a pivot joint, and the piston is held by a gantry that allows the piston to only move up and down.

The piston we are using consists of a section of a truck inner tube, clamped on both ends (top and bottom) between two cut pieces. These can be wood, metal, acrylic, or injection molded or 3D printed plastic. We are using laser cut acrylic in the prototype, but these can be manufactured in many different ways with equal effectiveness.

The bottom of the piston has a hose port which is connected at the other end to the 'PUMP' port on the valve block assembly.

The Valve block assembly allows the stacking and folding of valves into one single assembly of alternating acrylic or metal plates, and silicone or rubber gasket/membrane material. For simplicity, in this section we will describe the individual valves in the system as if they were in circuits of pipes, as they are depicted in the system architecture and cycle diagrams. In actuality, these valves and circuits are nested and folded together into the valve block

assembly. You can see the actual physical flow paths through the valve block assembly in valve block assembly cycle diagrams.

The GAS port is connected to a Venturi mixing valve designed by other crowdsourced and open sourced groups, which mixes O2 and air in proportion before it enters the piston. This is 3D printable, and possibly available as a pre-existing injection molded part from medical supply manufacturers.

The Venturi mixing valve is connected to a filtered air supply, and an O2 supply.

The O2 supply is provided by a high pressure tank (or in the case of hospital use, a wall port) and runs through a commercially available flow regulator before entering the venturi valve.

The air supply can run through the best particle filter available, as well as a UV C light chamber for sterilization. NOTE: It is VERY IMPORTANT that if a UV C sterilization lamp is used, that it is of the type that DOES NOT PRODUCE OZONE. There are UV C lamps that produce ozone, and filtered lights that do not produce ozone. Ozone gas is extremely dangerous if created at the ventilation air source.

The Gas in port leads to two check valves, one which leads directly to the patient inspiratory leg of the circuit, which forms an autonomic inhale bypass, allowing the patient to inhale autonomously while the pump is in the exhale cycle. If the Patient inhales during this cycle, the check valve opens, and allows the patient to breathe mixed air and O2 around the pump, even while the suction of the pump pulls the check valve on the normal inspiratory circuit pathway closed. In normal operation of the ventilator, there is always a positive pressure from the patient side on this bypass check valve, and it remains closed.

The second check valve on the leg of the circuit connected to the venturi air mixer is connected to the bellows or piston inlet. This allows air to flow into the piston during the exhale cycle when the piston is being expanded, and will close during the inhale cycle, while the piston is being compressed, preventing gas flow back towards the venturi valve.

The Piston port is connected to: the previously described check valve coming from the venturi mixing valve, that allows flow into the piston; a pressure chamber that forms the gate of a pressure gate valve which we will see in function later; and then to a check valve which allows flow to the patient, and prevents flow back into the pump. During the inhale cycle, the bellows compresses, pushing air through this last check valve towards the patient, through a Y tube, HME (Heat and Moisture Exchanger), and patient side mask, nasal cannula, or intubation setup.

The Y tube, located close to the patient, is connected on one side to the pump, through the aforementioned inspiratory leg of the pneumatic circuit. On the other side of the Y tube, forming the Expiratory leg of the circuit, there are connected two valves in parallel. First, a check valve, which leads to a long tube placed vertically in a liquid tank, with its end at a known depth in the liquid. This check valve and tube form the overpressure valve of the ventilator. If at any point, a patient coughs, or some malfunction of the device induces a pressure in the circuit above the known hydrostatic pressure at the end of the overpressure tube, any excess pressure above that hydrostatic pressure will be released through this valve.

If a clear tube and tank are used, the overpressure tube can be marked at known intervals, and the check valve on the overpressure section of the system will stop flow back into the system from the overpressure valve, causing the water level in the tube to be displaced to a set depth below the water level at the top of the tank, which will indicate to the operator the peak pressure of the inhale cycle. If a clear tank cannot be sourced, another Tee in this system, after the check valve, but before the overpressure exhaust tube, may be connected to a U-Tube Manometer, so that peak pressure can be read by the operator.

The second valve on the expiratory leg of the circuit is a pressure gate valve. The pressure gate valve is composed of three chambers. A patient pressure chamber, a PEEP valve pressure chamber, and Pump pressure chamber. We will now discuss the function of this valve.

In the pressure gate valve, the patient pressure and PEEP valve pressure chamber are located side by side, with one side of their chamber covered by a flexible membrane or diaphragm. They are separated by a wall, that can seal to the membrane, or un-seal from the membrane, depending on the differential pressures inside the valve. Above the membrane is a third chamber, which leads directly to the bellows pump.

The PEEP valve pressure chamber is connected, much like the overpressure leg of the circuit, through a check valve and to the top of a tube placed vertically in a tank of liquid, whose end is at a known depth, and therefore known hydrostatic pressure on the end of the tube.

During the inhale cycle, the bellows pump exerts a pressure both on the upper pump pressure chamber, and an equal pressure on the patient pressure chamber, since the pump pressure will cause the check valve leading to the patient to open, and is connected after that check valve, unvalved to both the patient and the expiratory leg of the circuit. This pressure in both the patient pressure chamber and the pump pressure chamber will be higher than the hydrostatic pressure exerted on the PEEP valve pressure chamber, through the PEEP valve leg of the circuit. This will cause the membrane to seal to the peep valve pressure chamber, thus blocking any flow from the patient to the PEEP valve. This allows the pump to pump a pressure higher than the set PEEP into the patient, without gas escaping through the PEEP valve.

During the exhale cycle, the pump exerts a suction on the pump pressure chamber in the pressure gate valve. The patient exerts an expiratory pressure on the patient pressure chamber of the valve, which is a higher pressure than the PEEP valve pressure chamber. The flexible membrane moves away from the wall between the patient pressure chamber and the PEEP pressure chamber, thus allowing air to flow from the patient to the PEEP valve and out of the system.

A note for electronics engineers: It is interesting that so often we explain electronics concepts by using the analogy of water through a pipe. Voltage being a physical height difference in piping, and thus hydrostatic pressure, resistors being strictures in the pipe, amperage being a flow rate, and so on. I wish to point out that there is a good digital electronics analog to the pressure gate valve, and explain in reverse here. This pressure gate valve works something like a transistor, where the gate is pressure driven rather than voltage driven, and the flow of gas from one of the lower chambers to the other is analogous to the flow of current through a transistor's emitter and collector legs.

The top of the liquid tank containing the PEEP and Overpressure valves has a third port, which is connected by pipe or hose, to the lower inlet of an exhaust module. This module is constructed in exactly the same manner as the intake module, out of a large tank containing a port on the bottom, a UV C bulb for sterilization of the exhaust gasses. Again, this light should be filtered such that it does not create ozone gas, which is harmful to the patients and operators of the device. Finally, there is an exhaust port in the top of this module that is covered ideally with a HEPA filter, or the best filter material available.

A note about the construction of the PEEP and Overpressure valve tank:

There are multiple methods of controlling the liquid level in the tube. Earlier designs used a float to control the level of the PEEP and Overpressure ports in the liquid, but maintaining float height with stiff tubing or maintaining seal and flow with very flexible tubing were difficult to achieve. Instead we use one of multiple methods for controlling the liquid level in the tank.

- 1. An attendant can manually check and refill the tank to a set height. This is the simplest solution to build, but adds one additional task for a clinician using the machine.
- 2. A U shaped tank, with a floating ball sealed against a top orifice, leading to a shallow reservoir will seal the port to the reservoir when the liquid is up to the correct level, and when the level decreases, the floating ball will fall, thereby opening the port to the reservoir until the water level is replenished to a level where the floating ball once again seals the reservoir.
- 3. A mechanism similar to a toilet tank float valve, or an off the shelf toilet tank float valve may be used, connected to a separate reservoir, such that when the liquid level is correct, the valve will be closed, and if the liquid level drops, the float will drop, opening the valve until the liquid level and thusly the float move back into position, and close the valve.

ASSEMBLY INSTRUCTIONS

The OpenVentilator Spartan Model Mk1 is a component agnostic system, and because of that there are many configurations that can be built, depending on the tools and resources at hand. This section will document the assembly of the Mk1.0.0 as we have built our first prototypes. It is possible to swap out an increasing number of components for assembly and testing by following the GitHub organizational chart. Individual component assembly files are being updated continuously. What follows is first a note about the organization of the Github files, and then the assembly and manufacture instructions for our current core build, the Spartan Model Mk1.0.0

ORGANIZATION OF THE GITHUB FILES

The GitHub repository for building any version of the Spartan Model Mk1 is organized as follows:

MASTER LEVEL: This level contains a functional system description; a list of component groups necessary to complete the system; and a list of completed builds lists of individual components, materials, and tools used for that particular build.

COMPONENT GROUP LEVEL: This level contains folders for each component group: The Pump; Valves; Electronic Controls; Exhaust Systems; Intake Systems.

Each Component Group folder will have a Readme file that contains a list of all the possible ways fo build a component group, along with the list of necessary materials and tools needed to complete that component. The component group level will have folders containing specific files for individual components.

INDIVIDUAL COMPONENT LEVEL: This level will comprise individual components necessary to complete the system.

Each folder will contain: a read me file that contains a description of the component, tools and materials necessary to complete the component; assembly and manufacturing instructions. This document will link to the source files (as in CAD files) when possible, so that builders and designers can make their own modifications to individual components, and suggest improvements. The folder will also contain any necessary design files: STL files; DXF files; PDF dimension files, Electrical and wiring diagrams; etc.

PARTS LIST

This section will cover all necessary parts to build the OpenVentilator Spartan Model Mk1. build 1.0.0. Please note, once again, that it is possible to build a Mk1 system with different tools, methods, and components by substituting component files within the system, increasingly available on the Github page. This component list and assembly manual are for ONE particular build, as an example.

LIST OF COMPONENTS

NECESSARY COMPONENTS OF A VENTILATOR SYSTEM NOT INCLUDED IN THE SCOPE OF THIS PROJECT:

- 1. An oxygen supply or tank
- 2. An oxygen flow regulator
- 3. A Venturi O2 + Air Mixing Valve (commercially available and 3D printable from other projects SPECIFY SOURCE)
- 4. An HME (Heat and Moisture Exchanger)
- 5. A Mask, Cannula, or Intubation set

PARTS LIST

We currently have no designs for the manufacturing of many of the following components. If you would like to add component files that could replace any of these part in the event of scarcity, please let us know and we may add them to the part libraries.

- 1. 12V Motor Car Windshield Wiper Motor (360 degree continuous, or reciprocating gearbox type)
- 2. 2 way relay
- 3. 12V power supply
- 4. 12V battery (optional more stable machine in the case of power outages)
- 5. 2x 12 position rotary switches
- 6. 14x 10A10 Diodes (commonly available off the shelf or in automotive alternators)
- 7. Wire
- 8. Solder (Preferable to only mechanical wire bonding)
- 9. Shrink wrap tubing
- 10. 1 piece of Proto-Board (perf-board or soldering prototyping board)
- 11. Limit Switch or Toggle Switch
- 12. ~5 meters Vinyl Tubing (minimum ½" diameter, but 1" is suggested. If you can get proper Ventilation tubing, all the better. There will be valve files with all possible connection nipples available, and currently they are open source files which can be easily modified to fit your available tubing.

- 13. 2x to 3x Hose Barb Tees in the correct size diameter to fit the tubing in item 9. These can be swapped for regular Tee's with hose barb connectors at their ports. We will also soon have 3D printable Tee files that can replace these off the shelf items.
- 14. A large tank ~1+ M deep, to hold the PEEP and overpressure tubes, a float, and sanitary liquid. We recommend a section of 4" PVC pipe with an end cap on the bottom, and hose clamps, duct tape, or zip ties to affix to something that will prevent it from tipping over.
- 15. 2x electrical conduit glands to fit the PEEP and Overpressure Tubing
- 16. 2X Pipe cap for the liquid tank, which will accommodate 2 glands and a hose barb or pipe nipple port.
- 17. 2x hose nipples or pipe connectors to connect from the top of the liquid tank to a hose or pipe, and then from that pipe to the bottom of the exhaust module
- 18. A PVC pipe with end cap, and hose nipple fitting long enough to enclose an intake UV light when possible. We recommend 4" PVC when possible.
- 19. 2x 90 degree pvc elbows (male threads on one side with retaining nut and seal gasket; hose barb or pvc female fitting on the other) these will connect to the bottom of the bellows pump.
- 20. 1 or 2 Ozone Free UV C sterilization Light Bulbs, and the appropriate Ballast to drive them. If you have 1 UV light, we recommend using it on the exhaust port. If you have access to 2 lamps, we recommend using them on both the intake and exhaust ports of the machine.
- 21. Enough filter material to cover your Intake and Exhaust ports.
- 22. A Truck Inner Tube, R13 or R14 are common sizes that will fit our currently manufactureable parts. (We also have alternate DXF and CAD files that will fit an R15/16 tube currently)
- 23. 2x 608 roller skate style bearings

24. NUTS AND BOLTS

- 25. Liquid Silicone or Teflon Sealant (Plumbers Pipe Dope)
- 26. Silicone or lithium or other bearing grease
- 27. Acrylic Cement / Wood Glue (We are using acrylic cement with laser cut acrylic panels, we would use wood glue if we were forced to use wood or mdf panels to form the pump chassis.
- 28. XXXX square meters of 6mm thick acrylic. This can be swapped for double the area of 3mm thick acrylic by doubling up the panels.
- 29. XXX square meters of (0.5-1mm thick??) Silicone or other gasket material
- 30. About 2 meters of pvc pipe at ½". ¾ or even 1" pvc pipe can be easily substituted with minimal modifications to the design by changing the intake and exhaust port hole diameters on the pump, and choosing a larger port diverter valve listed on the github page.
- 31. Pvc glue

- 32. 2x 330mm x8mm in diameter steel rods. These will form the linear slides for the pump gantry. The diameter and length can easily be adjusted with only two dimensional changes in the source files of the pump chassis.
- 33. About 500g of 3D printing filament PLA or PETG is recommended
- 34. Silicone caulk or epoxy resin
- 35. Large rubber bands

TOOLS necessary for this build

- 1. Laser cutter and optional hand saw
- 2. FDM 3D printer
- 3. Screwdriver or hex wrench (screw type dependant)
- 4. Adjustable crescent wrench
- 5. Tubing cutter / hand saw
- 6. Razor / sharp knife
- 7. Ruler
- 8. Sharpie Marker
- 9. Soldering Iron
- 10. Acrylic Cement Needle Applicator
- 11. Furniture clamps (optional, but recommended)
- 12. Multimeter (optional, but recommended)
- 13. Drill power drill or drill press.

ASSEMBLY:

This Assembly guide will be broken into multiple parts: first component assembly, then system assembly. The component assembly guides will comprise:

- 1. Valve assembly
- 2. Intake Module Assembly
- 3. Exhaust module assembly
- 4. PEEP and Overpressure tank assembly
- 5. Pump Frame assembly
- 6. Motor and Speed Control Assemby
- 7. System assembly.

Valve assembly

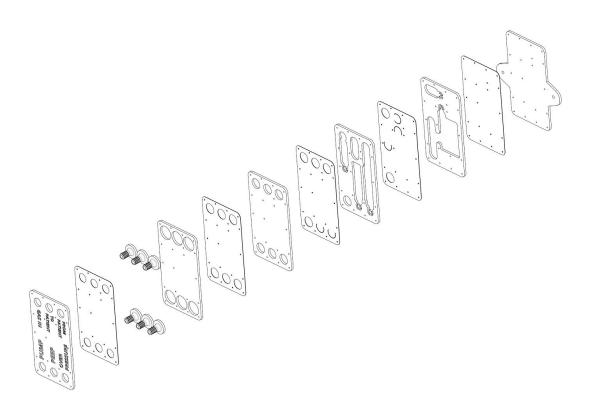
First 3D print 6X port nozzles for the valve block. We are currently working on a version of this assembly that will not require printed nozzles, but instead will use common off the shelf hose barb fittings. These will be updated to github when the design becomes available

Laser cut all acrylic panels for the valve block assembly.

Laser cut all Silicone or rubber gasket sheets for the valve block assembly.

Once the pieces are cut, assemble the acrylic and silicone plates, along with the port nozzles in the order shown in the diagram below. Where there are small holes, insert M3 hex screws and fasten with M3 nuts. First loosely hand tighten all of the nuts, then move in a star shaped pattern, tightening each screw one turn at a time until the valve block assembly is sealed tight. This is the same procedure as tightening engine head bolts, or lug nuts on a car. You don't want to tighten any one bolt much more than any other bolt at any one time, which could cause poor seating of the gaskets and diaphragms inside the block.

ASSEMBLY ORDER DIAGRAM:



Intake Module Assembly

Cut a section of 4" PVC pipe, long enough to mount a UV C bulb inside.

Drill a hole through the sidewall of the pipe just large enough to thread the wires for the lamp through.

Drill a hole through a 4" PVC end cap and mount a hose barb through the hole. Seal the threads or connection with silicone caulk or silicone pipe dope.

Glue the endcap to the bottom of the pipe.

Install the UV C lamp inside of the pipe.

Seal the wires into the hole with silicone caulk, or epoxy resin.

Use a piece of Hepa filter or the best filter material available to cover the top of the pipe and hold it in place with a rubber band.

Exhaust module assembly

The Assembly of the Exhaust module is exactly the same as the intake module.

PEEP and Overpressure tank assembly

Cut a 4" PVC pipe a little more than 1 meter long

In the case of a manually maintained water level, cap the bottom with a pipe cap and glue.

Drill 3 holes in a 4" PVC end cap.

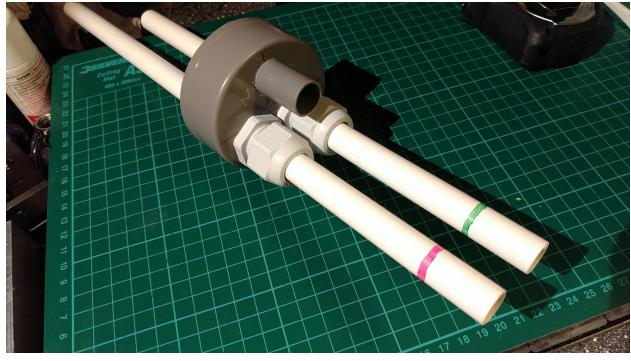
Mount 2 electrical conduit glands and one hose or pipe nipple in the top of the cap with pipe dope or silicone sealant.

Place one piece of PVC pipe through each one of the glands. One pipe will be about 750mm long, the other about 250mm long.

Glue a hose barb fitting to the top end of each of these pipes.

Mark a water level inside and outside of the 4" pipe with a sharpie marker Mark distances in 1-2cm increments on both the PEEP and the Overpressure pipes starting above the glands on the top of the pipe cap. Start with a distance of 0 cm marked at the top of the gland, when the bottom of each pipe is at the exact level of the water mark. Add horizontal marks upwards of this "0" mark, to indicate how far below the liquid surface the end of the tube is located, and thereby, how much hydrostatic pressure in cm H2O is exerted on the Overpressure and PEEP valve systems.

With a section of vinyl tubing, connect the exhaust nipple on this tank assembly with the intake port nipple on the bottom of the exhaust assembly.





Pump Frame assembly

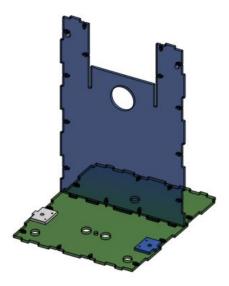
First cut all the DXF files from the pump chassis folder on github, out of 6mm thick acrylic. You will need to 3D print one knob for ease of use. Print the STL in this same

folder at 30% infill, 4 shell walls top, bottom, and sides, 0.4mm nozzle, 0.3mm layer height. PLA or PETG.

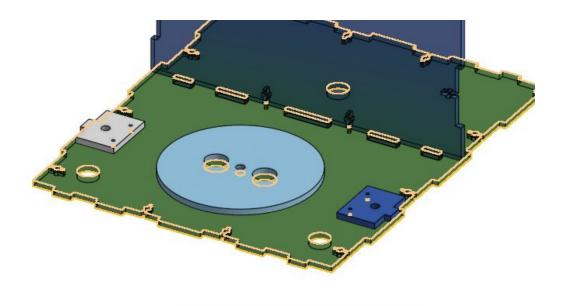
This assembly will be done first with 15mm M3 Hex bolts and nuts, then glue/ acrylic cement may be added to all joints using a needle applicator once the machine is fully assembled. The assembly instructions will not specifically denote when to add a screw and nut, it is assumed that every joint assembled that has a screw hole and nutsert cutout will be fastened with a 15mm M3 Hex Screw and nut.

Make sure to read the instructions thoroughly. For the sake of expediency we have omitted modeling off the shelf components like motors and switches in this set of released files. We do note in the instructions where a component other than fully modeled parts must be placed.

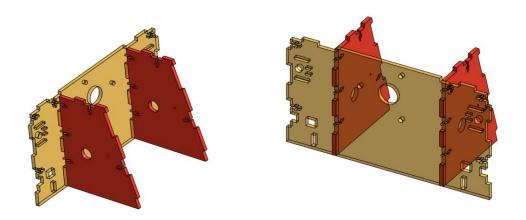
1. Assemble the Base Plate, Lower Rod Mounts, and Center Plate



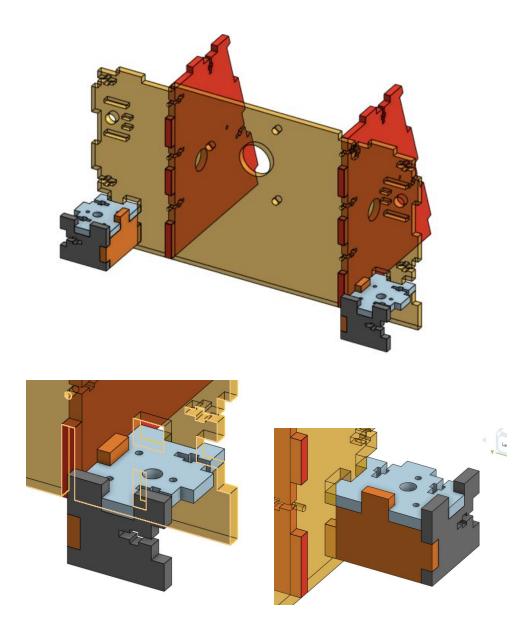
2. Place the lower bellows clamping plate in the bottom end of the section of R13/15 inner tube cut to form the bellows. Place this plate on top of the baseplate, and clamp these two plates together with an M8 bolt and nut, using a rubber sealing washer, or a small piece of inner tube cut in the shape of a washer. Then place two pvc threaded ports through the port holes, seal with pipe dope or silicone sealant, and thread the locking nut down tight from above. This will complete the piston port assembly. (PVC fittings and Inner Tube not pictured.)



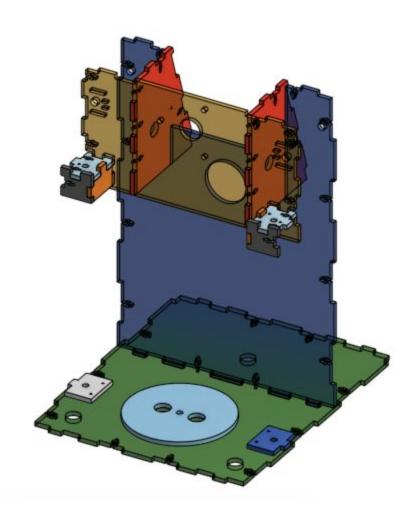
3. Connect Motor Mounting Plate to Motor Mount Braces:

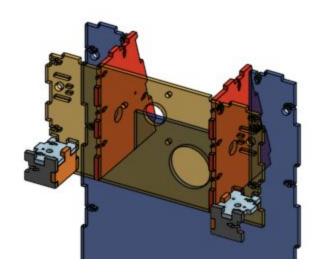


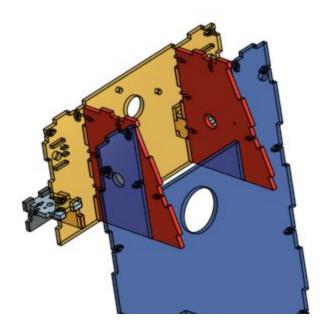
4. Add Rod mounts to Motor mount assembly (these may need either gluing or tape to hold in place betore they are screwed in in a later step) DO NOT add the top plate to this part of the assembly. The top plate will come later once we have installed the rods



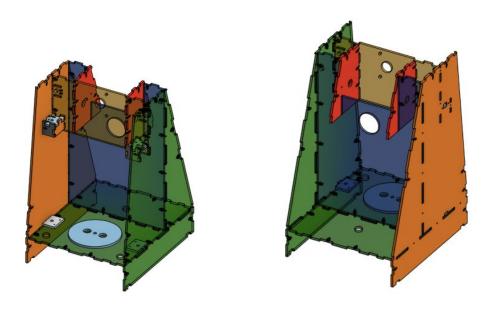
5. Install the Motor Mount Assembly on the top of the center plate:



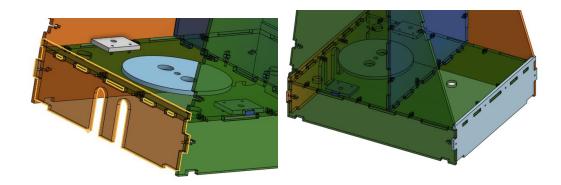




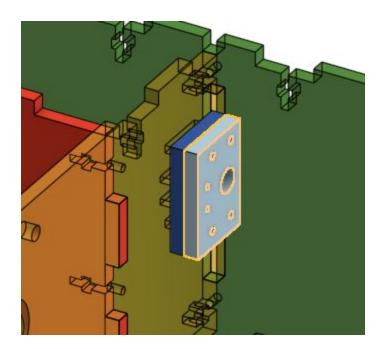
6. Install the side plates on the frame:



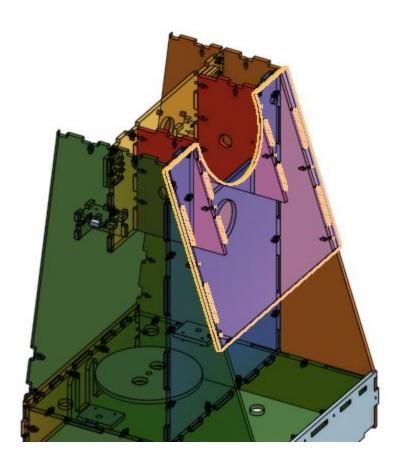
7. Add front and rear plates to the base of the machine:



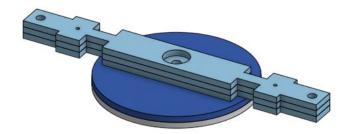
8. Add limit switch mounting plates to the machine. There are mounts for Two limit switches, one on either side of this machine for future expansion, however only one side is required for this build. Note that there are 2 plates that mount in front of the motor mounting plate, to achieve proper alignment between the limit switch and the cam on the crank wheel. Now is a good time to mount the limit switch to the switch mount (not pictured) Don't fully tighten the nuts on these screws, you will have to snake your hand inside to hold these nuts and tighten these screws into position once you have mounted the motor and crank wheel, so that the switch and crank cam are in propper alignment.



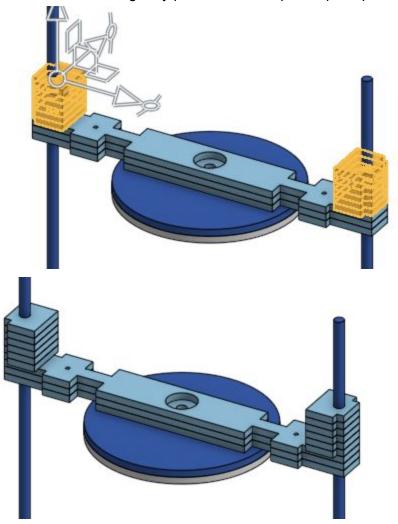
9. Add Rear Support Plate (This may be a good place to mount electronics externally for testing purposes later)



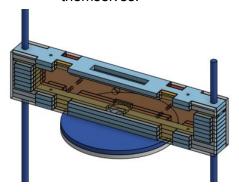
10. Stack the Three Bottom Plates of the Gantry with the center hole cut facing up, place the lower of the two upper bellows plates into the end of the inner tube and clamp the edges of the tube between the upper and lower plates, by inserting an 8mm Hex bolt up from the bottom, and clamp down tightly with an M8 hex nut from the top of the gantry plates:



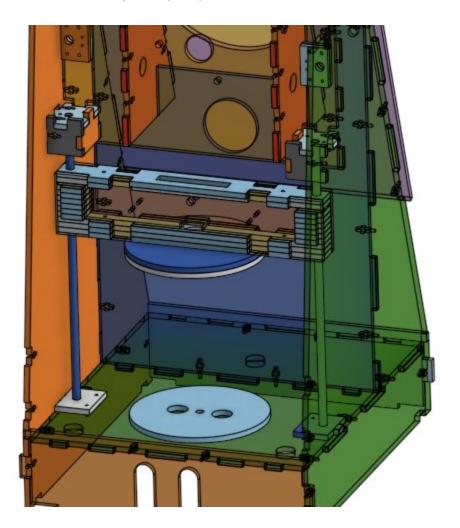
11. Use the two 330mm x 8mm diameter rails to align the bearing plates on top of the bottom gantry plates, and clamp, or tape in place, then glue.



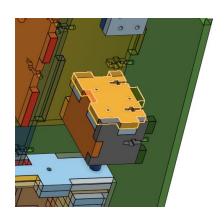
12. Now add the side plates, and top plates to the gantry, and screw them together with 4 long m3 hex bolts and 4 nuts. Use the rails for alignment, but make sure that the glue from the bearing plates is dry and that you don't glue the rails themselves.



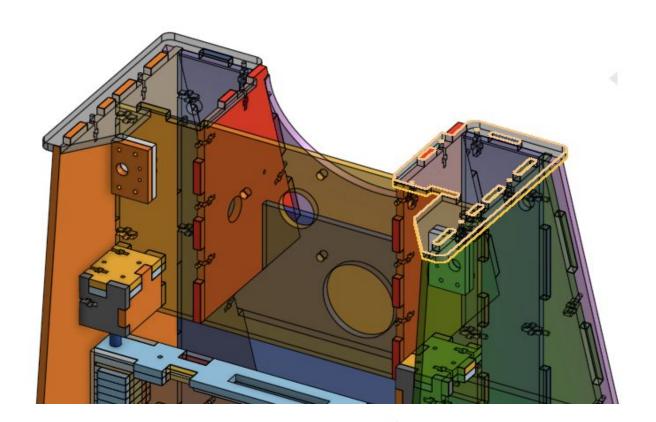
13. Remove the rails, put the gantry into place, and slide the rails through their top mount, through the gantry, and into their lower mounts.

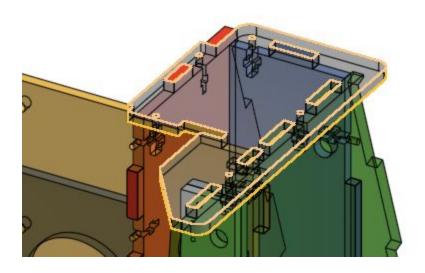


14. Add the Top retaining plates to the upper rod mounts:

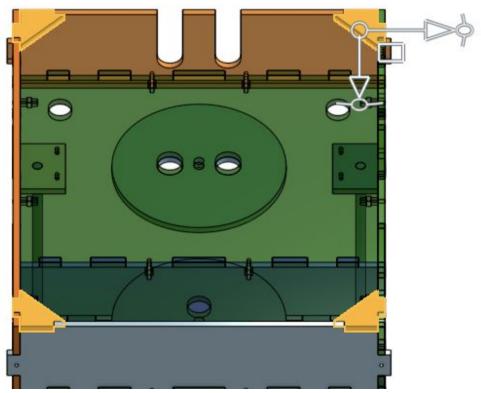


15. Add Top Corner gussets on both sides of the top of the machine.

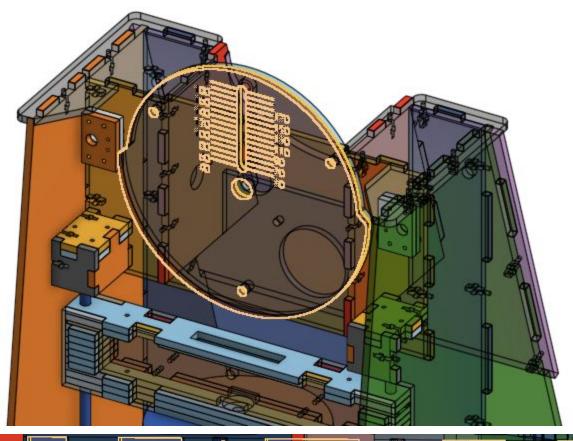


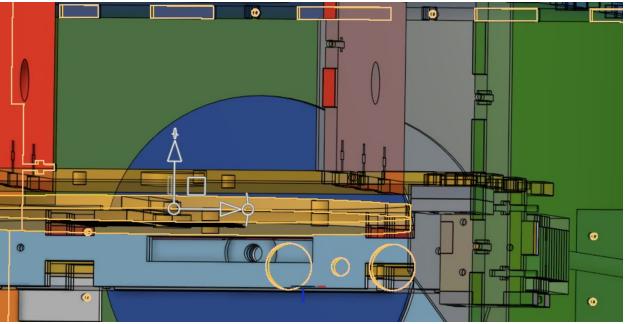


16. Add foot corners to the bottom of the machine with Acrylic Cement.

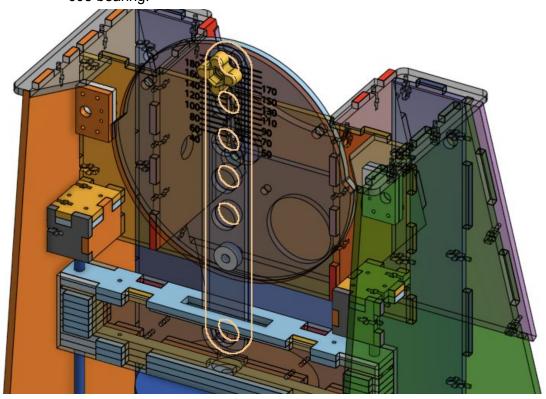


17. Mount the motor to the motor mounting plate. The mounting holes in the plate are easily modified in the onshape source files, to a bolt pattern for many available motors. Mount the Front and Rear Crank wheels to the end of the motor shaft, and use washers to space the motor behind the plate, such that the space between the crank wheel and the front of the motor mount plate is exactly 8mm.

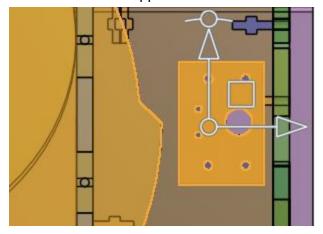




18. Push an M8 hex bolt through the 3D printed knob, until the head bottoms out on the recess in the face of the knob. Mount a 608 roller skate bearing in each end of the two piston rods, and mount one end to the gantry, and one end to the slot in the crank wheel. The end at the crank wheel will have a captured hex nut in the rear crank wheel, and the bolt and knob entering from the front, through the 608 bearing.

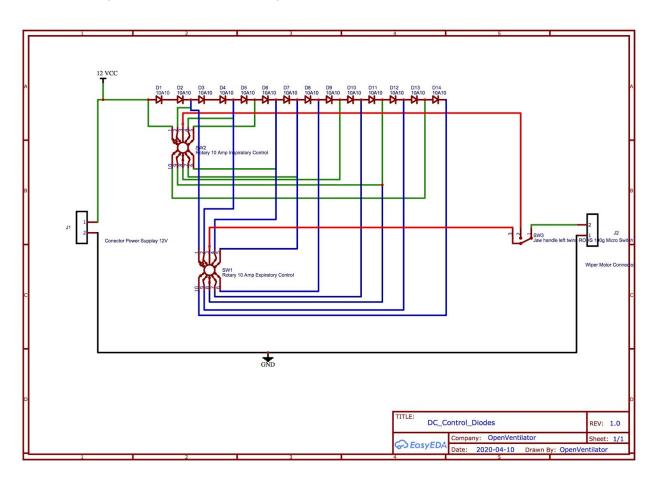


19. Align and tighten limit switch mounting plates, such that the limit switch is tripped when passed by the 180 degree cam on the outer radius of the crank wheel, and not tripped when the cam is on the alternate side of the stroke.



Motor and Speed Control Assembly

Connect the following circuit to the machine. The Limit Switch will be mounted on one side of the pump frame, the Two Speed Control Rotary position switches will be mounted on the lower front panel of the pump chassis. The motor must mount to the motor mount plate. It is preferable that the diode ladder is mounted inside the frame of the machine, behind the center plate and away from the moving parts of the bellows and gantry. The Power supply and optional battery may be affixed to the side of the machine for stability, or placed away from the machine entirely.



System assembly.

- Mount the electronics on the pump frame. We recommend using a piece of proto-board to solder all electrical components securely. We may release a PCB containing surface and through hole mounting points that would speed up the assembly for a manufacturing process. For now, follow the schematic in the motor and speed control assembly diagram in the previous section.
- 2. Connect the valve block assembly to the frame of the machine. This is done, to finger tightness with two %" hex bolts with optional 3D printed bolt knobs. The system is designed so that the valve block assembly can be easily removed for sterilization.
- 3. Connect a piece of vinyl tubing from the piston port below the machine, to the port labeled 'PUMP' on the valve block assembly.
- 4. Connect the venturi valve to the air intake module, and the oxygen source and flow regulator on one side, and then to the 'GAS IN' port on the valve block.
- 5. Connect the 'TO PATIENT' and 'FROM PATIENT' ports via a long enough tube to the Y or Tee connector at the patient.
- 6. Connect this Y connector to an HME, then to a patient side mask/cannula/intubation setup
- 7. Connect the 'PEEP' and 'OVER PRESSURE' ports on the valve block to their respective ports on the top of each tube in the liquid tank.
- 8. Secure liquid tank to something sturdy so it cannot tip over, and fill to set height with sterile liquid.
- 9. Connect the liquid tank to the bottom port of the exhaust module

User Manual

This manual is designed for medical, scientific and testing labs, not for clinical use.

This manual will cover settings for:

- 1. Inhale and Exhale cycle speed settings and thus BPM (breaths per minute)
- 2. Tidal volume setting
- 3. PEEP setting
- 4. Overpressure Setting
- 1. By setting the two 12 position switches you can set the inhale cycle speed and the exhale cycle speed. Use a chronometer to determine the ratio of the two cycle times, and total BPM. We recommend timing 10 cycles and dividing the time by 10 for a more accurate BPM setting measurement.
- 2. Tidal volume can be adjusted by loosening the end of the piston rod at its pivot in the slot of the crank wheel, adjusting the crank length, and re tightening the pivot of the piston rod on the crank wheel. The 'pump volume' will be roughly the cross sectional area of the bellows, times the crank length setting. The patient side induced tidal volume will be a function of 'pump volume' and peak pressure on the system, which can be read either from the liquid level in a clear overpressure tube and liquid tank, or from a U tube or other manometer placed on the circuit leg of the overpressure tube, between the tube, and the check valve leading to it from the patient. We have not yet fully charted this function in our prototypes, and suspect that it will vary between builds. This is one of the important questions that we have in the Clinical; Engineering; and Testing questions section.
- 3. PEEP (Positive End Expiratory Pressure) can be set by loosening the gland at the top of the liquid tank and adjusting the height of the PEEP tube, so that the bottom end of the tube is at a known depth below the waters surface, and therefore a known hydrostatic back pressure. Tighten the gland once this adjustment is made, to once again seal the tank, and keep the PEEP tube in place.
- 4. Overpressure setting can be made in exactly the same way as the PEEP setting above.

The Spartan model was designed for use in VCV (Volume Control Ventilation) mode, however, we suspect that it can also be used in PCV (Pressure Control Ventilation) mode as well, buy using the same adjustments in a different manner. For use in PCV, We suspect that a user could set the overpressure setting to the desired peak plateau pressure, and then set the crank wheel pivot radius such that the 'pumped volume' is enough that gas escapes the overpressure valve during the entirety of the pressure plateau, which is to say, that we pump more volume than necessary, and release excess pressure and flow through the overpressure tube.

Clinical; Engineering; and Testing Questions

The OpenVentilator Spartan Model Mk1 is an ongoing project, and we could use your help in answering some questions, making modification suggestions, and posing questions that we might not have thought of yet, or described here. In this section, we will address some questions that we have that we are hoping that will be answered by another group in a research or lab setting. If you have something to add along these lines, please contact us at Lab@openventilator.io

- We suspect that you could control O2 mixture by knowing the flow rate pumped by the Spartan model, and the flow rate from the regulator on the input oxygen tank. We would like clinical confirmation that this is the case, and thoughts on factors affecting the O2 concentration that we have not considered should this be the case.
 - a. We also suspect that using the calculation of O2 concentration from #1, along with either a pulse oximeter, or other method of oximetry, a clinician could control and adjust patient side oxygenation with some useful accuracy. We would like a clinician or test facility to suggest a methodology for controlling patient oxygenation with this hardware system.
- 2. The tidal volume induced in the patient is a function of the 'pumped volume' and the peak pressure induced in the system. We would like to empirically test a formula for calculating patient side tidal volume from peak pressure and 'pumped volume' We are unsure if this function will be fairly straightforward, or have some nonlinearities caused by flow and compression inside the circuit. We would like to connect the ventilator to a test lung, and measure peak pressure and tidal volume in the test lung, while varying the 'pump volume' by changing the crank pivot length on the pump, to better understand the patient side induced volume as a function of 'pumped volume' and peak pressure.
- 3. We have not yet tested the method described in the previous section for PCV (Pressure Control Ventilation), but suspect that it would be a useful mode of use by clinicians. A detailed strategy and methodology as well as testing data for a PCV operation mode would be very helpful to the project.
- 4. We think thiat this machine will be very useful in some, but not all clinical cases of COVID-19. We would like suggestions for a methodology for determining, or endpoint conditions that determine necessary functions of the hardware, that would determine the clinical situations where this machine WOULD and WOULD NOT be appropriate.
- 5. We recognize that this machine, as it is built now, does not use standard sterile medical materials, or manufacturing techniques. We would like suggestions pertaining to:

- a. Methods of sterilization of the machine
- Manufacturing methods, and materials that might be more easily sterilizable, keeping in mind the ethos of the Spartan Model, being something that is still EASILY, CHEAPLY, and UBIQUITOUSLY manufactured.

Testing Data

Contact information

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Appendix