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Open Source Breathing Assistance (Basic Ventilator) Project, with rough plans. Version 3.1 4/1/2020

Problem: There are not enough mechanical ventilators – or breathing assistance devices - available for the expected wave of sick people who will need them.

A potential partial solution: Develop an *open source design* for a DIY therapeutic respiratory device consisting of a modified CPAP machine that is robust, effective, easy to use and maintain and that will swiftly pass emergency standards issued by regulatory agencies. A largely DIY design would entail offering production instructions, a bill of materials with alternates, an online training program, and elements of a mutual-support community to solve problems that arise. A clear use case and abbreviated validation protocol may help provide a device that can help people in dire need. This is not a money-making project. It is about saving lives.

Preliminary versions already work. A version of a device suitable for patients with low to intermediate respiratory distress has already been built from inexpensive and easily found hardware store parts, as demonstrated in this video, with more detailed instructions soon to come online. Key to our approach is a simplified, easily built method of applying lung back-pressure (PEEP) and adding oxygen while simultaneously capturing and reducing the virus in the patient's exhalations.
https://tinyurl.com/breathassist1

Even this basic version might enable thousands of sufferers to reduce the burden on already overwhelmed intensive care units. More advanced versions would incorporate accessible, off-the-shelf sensors, plus access to supplementary oxygen and some degree of control via a cellphone app.

What is needed: *Time is of the essence!* Racing against the clock, we believe we can take this vital project further and more quickly with an initial grant for parts and supplies, say $20K, with maybe another $60-200K as we refine and simplify… then simplify again to reach an optimized design that almost anyone could build. Additional money will be needed – or else partnership with an agency or major corporation – for clinical testing, legal etc.

Flometrics – A San Diego County company with decades of experience in fluid and gas flow systems, and a designer of blowers, valves and flow sensors for local medical ventilator companies, would seem an ideal place to attempt this. We don't make ventilators, but we have the skill and equipment to design, build and test them. *An advisory board that includes medical doctors, design experts and elements of the DIY Maker community is being assembled.*

What we are working on:

- Optimizing the design to be maximally effective, inexpensive, simple, easily constructed by semi-skilled persons, and (frankly) "idiot-resistant."

- Supply chain, making sure enough parts are available fast enough.
- Acceptance: Doctors, respiratory therapists and nurses will justifiably be skeptical. But urgent times demand agility and flexibility.
- Testing: We are developing a test plan for work of breathing and mask leakage.

What is a "ventilator" and what crucial traits must an open source unit have? A true ICU ventilator - assists patients who have difficulty breathing on their own, a notable symptom of severe respiratory distress exhibited by 5% or so of those infected with the COVID-19 virus. Especially affected are the elderly and those with pre-existing medical problems. By providing extra pressure in the lungs, these devices force more oxygen into the bloodstream for someone who has compromised lungs to hopefully give them more time to build antibodies. They must be capable of taking ambient air, increasing delivery pressure, and helping the patient inhale air augmented with oxygen. (See footnote.)

We are not currently developing an ICU ventilator. Patients needing this level of attention are generally intubated – a tube is sent down the trachea – requiring attention of a respiratory therapist. *We are not claiming to replace that level of care.*[1]

Rather, a Do It Yourself modified CPAP is meant to help those who are otherwise healthy and conscious enough to inhale and exhale on their own volition, receiving to overcome somewhat or moderately labored breathing and – perhaps – stay out of the hospital altogether or get out of the ICU faster.

The device must provide some resistance to exhalation to keep the lungs inflated. For the COVID-19 patient, doctors in Italy report that a fast breath rate of 20-40 breaths per minute with 20 cm of water inhalation pressure and 5 cm of water exhalation pressure (PEEP) is best.

Can all of these traits be achieved with a system that's built according to downloaded, open-source instructions, from parts bought at a major hardware store, perhaps augmented with 3D printable components?

We believe they can. In fact, *with perhaps half a million victims possibly needing help within the month*… they must.

Technical details: The key spec for an open source device is that it must be made of parts that are available everywhere already. Almost all parts should be things that you can buy at Home Depot or Wal-Mart, with only a few requiring use of a local machine shop, vacuum former or 3D printing shop, or (if unavoidable) shipped from a regional distributor. The design needs to be developed in coordination with medical experts along with a training program, so that a mechanical design, cell phone app, 3D models of printable fittings and training video can be prepared.

Also, FDA Regulations and legal liability will need to be waived. (See the FDA website on emergency approvals[2]). Flometrics will get the ball rolling. We can do the mechanical design, first build and lab

[1] For full background, see a 5 part tutorial on ventilation and breathing assistance, at: https://www.youtube.com/watch?v=gk_Qf-JAL84#t=4m25s

[2] FDA website on emergency approvals: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus

testing. We will be happy to share the design with other manufacturers and engineering service organizations. We are connecting with some local engineering service providers, such as NOVO engineering now.

Modified CPAP Our first concept (see a working model in the cited video) is a modified CPAP machine that may help people at home or to get out of the ICU. The inhalation and exhalation circuits are separate. Check valves are used to prevent mixing of the fresh and exhaled air. It uses an oxygen fortified CPAP or Bipap machine with a pipe in a bucket filled with water for exhalation resistance (positive expiratory ending pressure aka PEEP) Capture of the exhaled breath under water prevents the virus from escaping into the room. Dishwasher soap and/or bleach in the bucket kills the virus without foaming up. This needs a source for masks (maybe thermoformed or 3d printed, or adapted from painting respirators. (See figure 1.) This system could be used:

- At home so that a patient can perhaps avoid an ICU visit, particularly if they cannot be seen
- To delay admission to the ICU and the need for a ventilator
- In the kind of "MASH-type" expansion urgent triage centers some cities are setting up.
- To help them recover so that they can leave the ICU earlier.

A number of these modified CPAP systems could be used with a single premixed air and oxygen source in a field hospital setting. In the event that oxygen sensors are not available, the oxygen flow could be controlled indirectly by referring to a pulse oximeter. If a CPAP machine is not available, a shop vac with a dimmer switch for an adjustable pressure air supply can be used.

This type of device could be tested immediately. Some doctors are recommending using NIV (noninvasive ventilation) now because of a lack of ventilators. It has already been done in Italy. We will need to do this in the USA, so this device is a way to get ahead of the problem. We are also working on 3d printed fittings to adapt CPAP masks so that they can capture the exhalation. We are working on testing it now. We will publish the results. Detailed instructions are attached.

The second concept (working on next) is a time cycle pressure limit mechanical ventilator. The pressure could be supplied by a shop vac or CPAP machine with modified sprinkler valves or 3 D printed valves for inhalation and exhalation valves, all controlled by a cell phone via the audio output or some other adjustable timer. A stereo can be used to amplify the signals from the cell phone. (These parts have been tested).This could be used in a MASH tent in the hospital parking lot in case they run out of ventilators. This would provide a peak pressure of 20-50 cm H2O for inhalation and 5-20 cm exhalation pressure (PEEP) The oxygen level would be 40-60%. (See figure 2.)

In either case, the patient may need an oxygen supply, which might be supplied via a pipe from the tank at the hospital, or from a tank or Dewar from a welding supply store. If there is an issue with oxygen distribution, clean fiberglass insulated steel drums could be used for Liquid Oxygen distribution. (See figure 3.)

These ventilation methods may atomize the virus in the patient, leading to the need to 100% capture of the exhalation into a filter, exhausting outdoors or bubbling through bleach or detergent. A bathroom exhaust fan sucking air from over the patient's head and blowing it outdoors could help reduce contamination, particularly if the mask leaks during coughing.

Plan: We met with senior engineers, CTOs, clinicians & managers each who have worked in the medical respiratory business for 10-30 years. (One of us (SH) is co-inventor of the Philips/Respironics Espirit US6,543,449, and the other engineers have many patents as well.) We have several concepts that we have shown to front line doctors working with patients. These are the major steps that need to be done: (some are underway*)

- Build a prototype. Make videos showing function assembly and test instructions.
- Engage with pulmonologists, respiratory therapists etc. about what is needed and what is acceptable in an emergency*.
- Work with public health officials to determine how/when to use the DIY ventilator systems and get appropriate regulatory permissions or waivers.
- Validate design, measure basic performance against limited ventilator specifications.

> ***Disclaimer and cautionary notice:*** *It is vital that this kind of system only be viewed as an urgent-situation backup that's for otherwise healthy patients whose apparently mild-to-intermediate respiratory distress seems stable, with no sign of deterioration. It is not a substitute for professional medical care, but a backup for when those resources are strained or unavailable. It is for those able to breathe on their own, but wanting help to maintain lung pressure while successfully fighting off the infection. It is also, of course, for places where professional machinery is simply unavailable*

We at Flometrics stand ready to set aside other priorities and jump at this project, which might empower folks in even the smallest town or isolated community to adapt and save lives.

We need painting respirators and CPAP machines and masks to test so we can publish instructions and develop adapters for common types.

Thanks for your time and consideration.

Steve Harrington, Steve Duquette, Paul Edwards, Carl Tedesco, David Brin, Paul Breed+ others

For further information or to help facilitate contacts, get in touch with:

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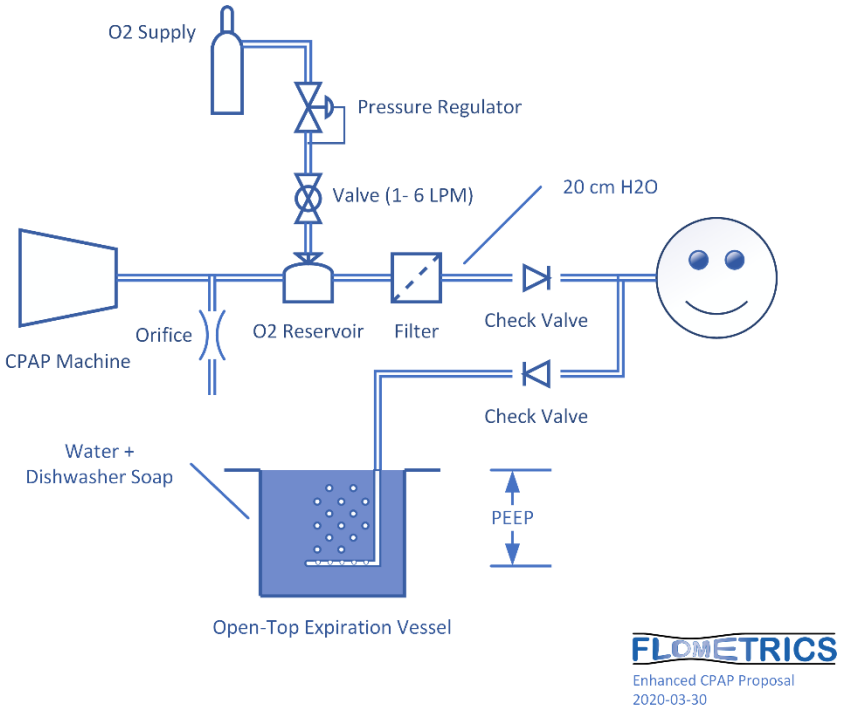

Figure 1: Enhanced CPAP with PEEP and Oxygen

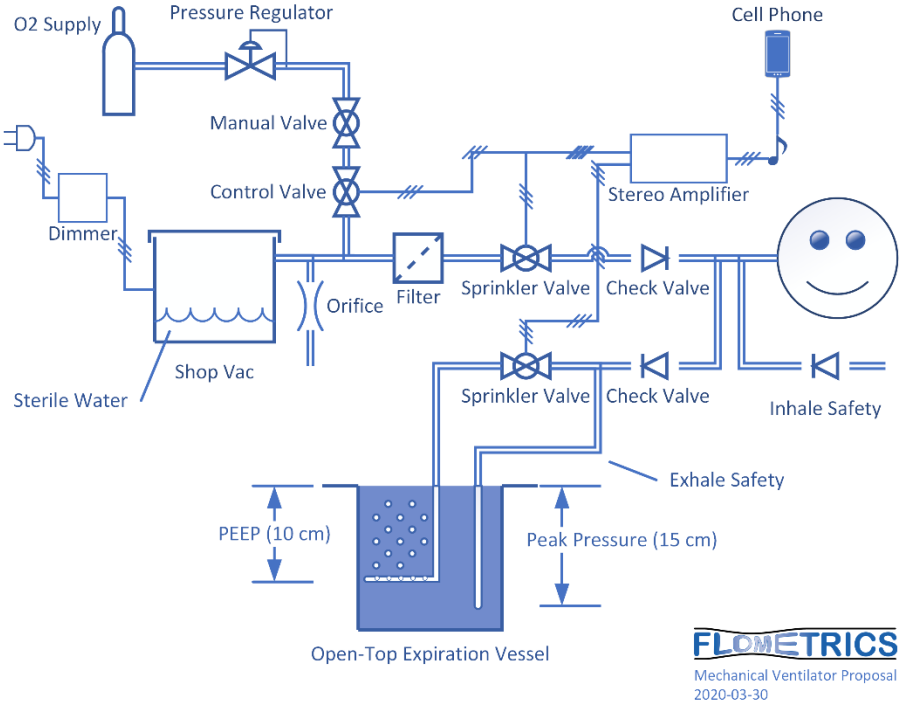

Figure 2: Simple Ventilator

Concept 1 prototype

Detailed description:

The CPAP machine provides a constant pressure over a range of flow rates. The orifice in the tube from the CPAP machine to the Oxygen reservoir keeps the CPAP pressure constant as the patient inhales and exhales. The CPAP leak can be a single 3.5mm (1/8 or 5/32 inch) drilled hole. This hole should provide leak flow of 12 l/min at 3cmH20, and 35 l/min at 25 cm H20. The flow of oxygen should be in the range of 8-10 lpm. This flow can be provided with a medical oxygen tank but if one is not available, a welding torch can be used. The flow can be adjusted by filling a measuring cup with water, holding it upside down 4inches underwater, putting the flowing torch under the cup under the water and measuring the time for the cup to fill. 9 liters/min is 3.1 secs to fill up a 2-cup container

$$\frac{1}{9.\frac{\text{liter}}{\text{min}}} = 3.155\frac{\text{sec}}{2\text{cup}}$$

If you have access to medical devices, you can use a wye at the patient and two check valves and these can be connected to a non-vented CPAP mask. If these are not available, fittings can be added to the inlet and outlet of a painting respirator as shown in the videos. The PEEP valve can be a PVC pipe clamped to the side of a bucket, and the bucket filled so that the pipe is 4 inches (10 cm) deep. A lid placed on the buck can collect the output and set up to flow outdoors through a dryer duct.

Introductory video at **https://tinyurl.com/breathassist1.**

Assembly video at **https://tinyurl.com/breathassist2.**

If you don't have the CPAP parts, start with a painters' respirator. (Ask your local painter, or contractor for a used one, as they are likely sold out. Industrial suppliers such as McMaster-Carr, Grainger or Zoro may have them) I was able to get this one: https://www.mcmaster.com/5541T14

Remove the cartridge or the activated charcoal from the cartridge, to reduce flow resistance. Blow out all the fragments with compressed air. Find a PVC pipe adapter and hose barb that goes to whatever hose you use, a CPAP hose or a dishwasher drain hose will work (make sure it is clean and sterile). This could also be a 3D printed adapter for less weight. I used a ¾ inch barb x NPT fitting and then a ¾ NPT x 1 in slip PVC fitting. The filer should be a bacterial filter, if one is not available, a CPAP filter or a house filter could be used.

Figure 3: Hot glue the parts together as shown in the video. Make sure they are clean. Then hot glue the exhalation valve in the front together so it doesn't fall apart from the weight of the hose and hot glue or tape on another PVC adapter for the exhalation

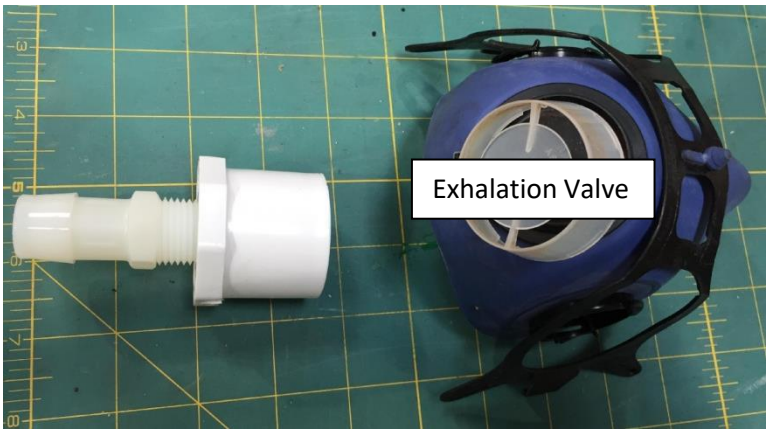

Figure 4: Here is the respirator before taping on the exhalation fitting. The plastic ring on the exhalation valve may need to be glued to the mask, otherwise it may fall off with the extra weight.

Figure 5: Here is the complete hacked together painting respirator with PVC fittings glued and or taped to the inlet and exhaust. The head gear may need to be reinforced for the extra pressure. The mask may be reinforced so that is doesn't leak along the sides of the nose or under the chine by using a piece of sheet metal, such as a metal binder prong. It can be glued onto a silicone rubber mask with silicone adhesive.

Figure 6: Here is another one, made from a Honeywell North® 770030 Mask.

Figure 7: Here is the bubbler, aka back pressure regulator. It uses 1/8" holes to expel exhaled air underwater to provide a back pressure according to the depth. This is placed in a top-vented container. It could also be clamped to the side of a bucket. Adding bleach or dish soap should destroy viruses. Smaller holes lead to smaller bubbles and less chance of the virus making it out of the bucket inside of a large bubble.

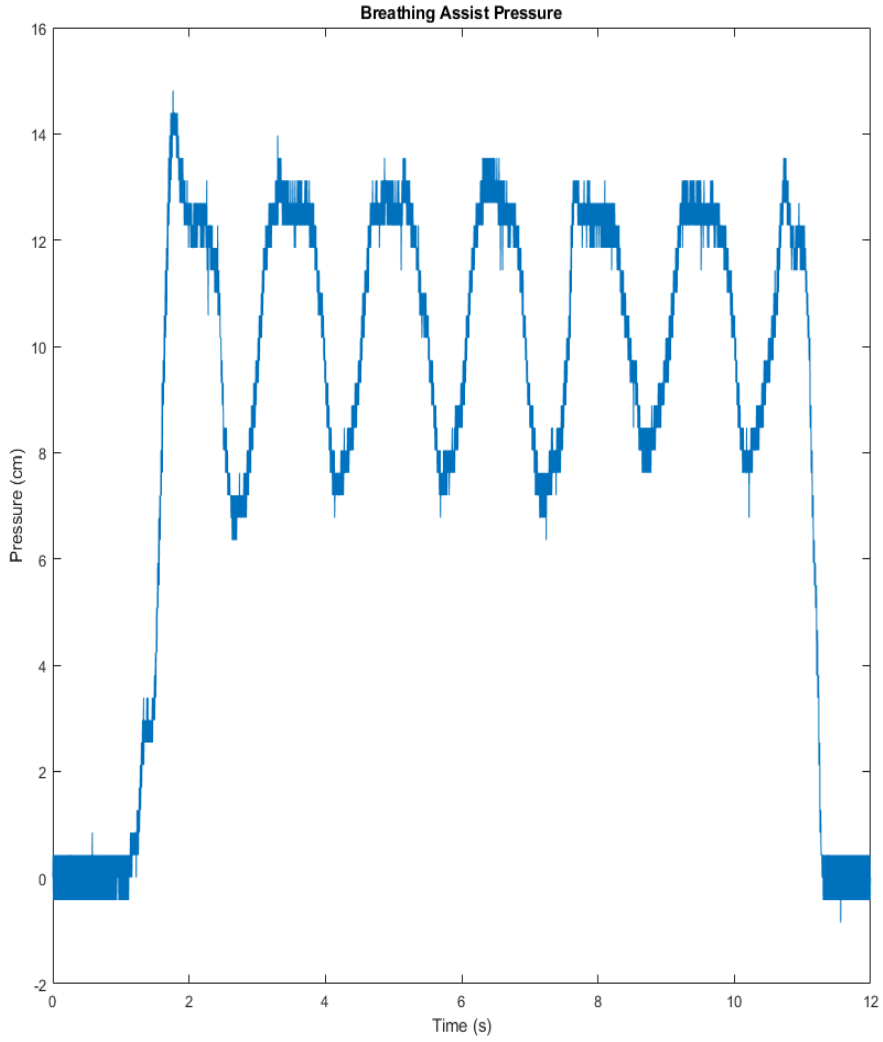

Figure 8: Here's a pressure plot. I put the mask on, took 8 breaths and then took the mask off. This was set up using a shop vac with a dimmer switch and a 3/8-inch orifice on the output of the shop vac so that it holds pressure better during inhalation. The pressure is adjusted by placing the mask on the face and holding your breath and increasing the speed of the shop vac until the bubbler starts to let a little air out. Then breathe normally. This chart shows a back pressure of 10+/- 3 cm H2O.

Figure 9: Here is a kit of all the parts that you can get at your local hardware store to make one of these. We need to conduct some longer-term tests to check for mask leakage, long term comfort etc.

Parts list

Painting respirator (Honeywell North® 770030 Mask or equivalent

Mask reinforcement. Binder prong from Office supplies or other piece of sheet metal.

CPAP machine or

Shop vac, brand new, clean and never used. Must have blower output

Dimmer switch 600 watts

Extension cord

Electrical box

Water container, such as a bucket.

Bleach or Peroxide

3x 1-inch slip female by ¾ inch NPT PVC fittings

3x ¾ inch PVC NPT couplers

4 x ¾ NPT barb fittings

Hot glue

Electrical tape

2x CPAP hose or Dishwasher drain hoses

Oxygen system from hobbyist Oxy-Acetylene welding rig such as:

https://www.homedepot.com/p/Forney-Medium-Duty-Oxygen-Acetylene-Shop-Flame-Victor-Type-Torch-Kit-1705/205694683

And oxygen tanks from your local welding supply, you can assume 20 ft^3/hr, so a 125 ft^3 tank will last for 5 hours, you will need 4- 5 per day. Or you can get a Dewar, that holds 4500 ft^3, lasts 9 days but harder to get, must be a business to order it.

Also, a bacterial filter, available from a CPAP supply house.

Notes on the Simple ventilator.

This design is a pressure limited time cycle ventilator. The pressure is generated by the shop vac (A CPAP machine can be used as well.) The shop vac speed and therefore the pressure is controlled via a dimmer switch. The outlet of the shop vac it reduced to the correct size for the CPAP hose, a ¾ inch barb connected to a PVC pipe reducer taped to the end of the shop vac hose works well. At the shop vac blower outlet fitting there is a small hole 3/8 inch in diameter and it allows some of the air out so the pressure won't drop too much when the patient inhales. If you are using a CPAP machine then the holes must be smaller: 1/8 or 5/32 inch. After the ventilation hole then there is an oxygen supply. The oxygen is supplied by a cylinder with a regulator. There is a needle valve to control the flow rate and then there is a control valve to turn it on during inhalation and off during exhalation. After that we have an inhalation valve which is a modified sprinkler valve which lets the air into the patient and there is another modified sprinkler valve that lets air out of the patient and into a pipe in a bucket that maintains the back pressure on the patient. In addition to the inhalation and exhalation valves there is also a safety valve in case the ventilator stops working the patient can still breathe. That includes a one-way valve that allows the patient to inhale even if the valves are shut. It includes a pipe in a bucket that is deeper than the normal exhalation pipe so that in case the patient coughs they won't have too much pressure in their lungs, it also allows the patient to exhale if the valves are shut. The valves are sprinkler valves. These run on 24 V AC. The sprinkler valves are connected to the output of a stereo amplifier with about 100 W capacity. The input of the stereo amplifier is connected to a cell phone where the right and left channels are used to control the inhalation and exhalation valves via a 60 HZ signal. In addition, the inhalation valve circuit also controls the oxygen valve. The user can program the cell phone for the time of inhalation, whatever pause there may be, the time of exhalation and whatever pause there may be before the next inhalation. This way the entire system is made from common parts. There may be some special valve components, as the standard pilot operated diaphragm valve for a sprinkler system is designed for 20 psi minimum pressure. In the ventilator application, the delta pressure needs to be 2 cm of water or .03 psi. https://instrumentationtools.com/pilot-operated-solenoid-valve-works/
This means the spring must have less force. Large quantities of springs can be quickly manufactured, and if necessary, a thinner diagram could be molded. These valve modifications need to be designed and tested. Alternative valve designs can be developed as needed.

=== Appendix 1:

Notes on the version shown in the "how to build" video at **https://tinyurl.com/breathassist2.**

(1) A clinician pointed out that at least some exhaled breath will escape around the edges of the mask. Rather than attempt to seal this off, a likely-effective palliative would be a Plexiglas or plastic *face shield*, either the kind that dentists use or something makeshift. Covid-19 virus is carried in droplets which will settle on the inside surface, which can be (carefully) cleaned. A UV lamp might be helpful. It should also be noted that many at-home or emergency caregivers will be among those already past their own benign infection.

(2) The earlier (first) video (https://tinyurl.com/breathassist1) shows some pressure gauges included which would improve monitoring, but may not be available at a local hardware store. The correct pressure may be created by adjusting the CPAP pressure or blower speed until a bubbler located 4 inches below the water surface just starts to leak air. Once the patient starts breathing, the bubbles will only be present during exhalation.

(3) Other teams are welcome to add to this baseline unit, e.g. with oxygen-level sensors controlling oxygen augmentation, as well as links to potential cell-phone based warning and control Apps. Please contact the Flometrics team with info on your variant, so everyone can increment together.

=== Appendix 2: Other projects and resources

We are all in this together. So here is a list (as of March 24, 2020) of *alternative projects* pertinent to this breathless era:

-- A 5-part tutorial on ventilators: https://www.youtube.com/watch?v=gk_Qf-JAL84#t=4m25s

-- Extant DIY ventilator projects: https://makezine.com/2020/03/17/covid-19-a-collection-of-resources-from-our-community/

-- The re-insurance company *MunichRE* is said to be pushing a ventilator project.

-- -Montreal hospitals launch global challenge offering a $200,000 prize to design a new low-cost and easy-to-use ventilator to help with the COVID-19 outbreak. https://www.3dprintingmedia.network/montreal-hospitals-launch-global-challenge-design-ventilators/

-- Replacing missing parts for disused ventilators in northern Italian hospitals, plus makeshift respirators based on hacked scuba gear. https://dgiluz.wordpress.com/2020/03/17/innovation-without-permission-saving-life-in-emergency/

-- A UK centered contest to develop cheap devices (no prize money.) https://medium.com/frontier-technology-livestreaming/frontier-tech-4-covid-action-emerging-market-ventilation-systems-9c818cb46189

-- An Italian company used 3D printing to produce a special valve needed for ventilators. Got sued by company that holds the patent. https://www.commondreams.org/news/2020/03/18/italians-found-way-3-d-print-key-ventilator-piece-1-help-battle-coronavirus-so

-- Designing a low-cost, open source ventilator with Arduino. https://blog.arduino.cc/2020/03/17/designing-a-low-cost-open-source-ventilator-with-arduino/?fbclid=IwAR0KXY4tx61X7w7zphWRrgYNKoTMfLNgeE72xVU2OfEys_CxFHYRm5ehApI

-- "Can a CPAP fan become a ventilator"? https://hackaday.com/2020/03/18/can-a-cpap-fan-become-a-ventilator/

-- BioCurious biohackerspace in Silicon Valley, helping coordinate hacker/maker efforts around COVID-19. https://covidbase.com,https://covidaccelerator.com