Vol 2: Hardware

(Volume 2 of 4 in "<u>A brief for engineers, by a doctor, on hacking a ventilator for surge</u> <u>capacity in Covid19 patients</u>")

Feedback is welcome. @ErichSchulz

(return	to	Volume	<u>1</u>)	

Introduction	3
Overall architecture	3
Blender	3
Inspiratory flow regulator or pump	4
Alternatives	4
High pressure approach	5
Low pressure approach	5
Pumps	6
High pressure regulators	6
Standard hospital regulators	6
Solenoid valves	7
Motorised valves	7
Hybrid approach	7
Fluidics	7
Valve and Sensor Packaging	8
Combined units	8
Gender of connections	8
22mm medical connectors	8
Plumbing connectors	9
Luer lock connectors	9
Pressure and flow sensors	10
Pressure sensors	10
Flow sensors	10
Inspiratory manifold	11
Non-return valve	11
Overpressure valve	11
Underpressure valve	12
Gravity based valves	12
Circuit and airway device	12
Expiratory manifold	13

Pneumatic patient inflating valves	13
PEEP valve	15
Disposable	15
Electronic	15
Hydrostatic	15
Weighted pop-open valve	15
3D printed prototype	15
Scavenging System	15
Electronics	16
Software and control	16
External connector hardware	16
Housing	16
Appendix 1 - Notes on tubes and hoses	17

Introduction

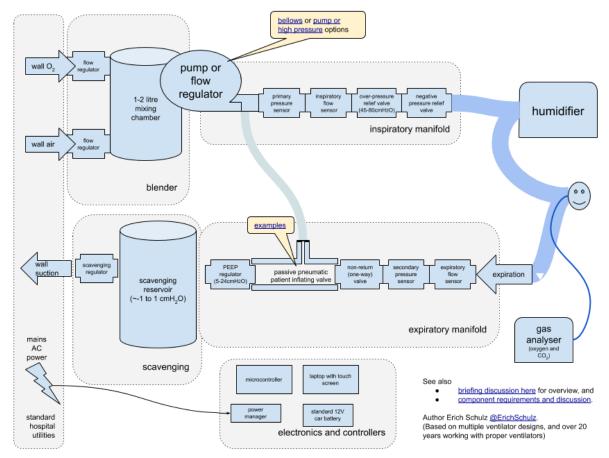
I would like to expand this volume to provide links to more detailed discussion on each component and to catalog potential readily available solutions. Assistance is very welcome.

The documents are very much living so I welcome review and contributions (for example links to resources and discussion around individual components).

I am particularly hoping that the document I've started on components may be useful for facilitating sharing of knowledge between groups.

Overall architecture

Broadly using this generic architecture, I discuss some of the reasonable alternative approaches to the components below, starting at the gas inflow and ending with the exhaust.



Blender

Requirements:

- Mixes high-pressure hospital air (containing 21% oxygen) and oxygen to produce a mixed gas containing between 30% and 100% oxygen (in at a minimum of 10% steps).
- Pressure rated to at least 5bar if using high pressure option for inspiratory flow regulator. Could be rated to 10-40cmH2O if using a low-pressure approach (for example just a garbage bag).
- Ideally should have volume under 1-2I so that, in an emergency, users can rapidly increase FiO2.
- it MUST be impossible to accidentally swap oxygen or air hoses

Components:

- High pressure oxygen connector (ideally comes with a hose with a standard fitting to connect to wall supply)
- High pressure air connector (ideally comes with a hose with a standard fitting to connect to wall supply)
- Electronically controlled flow regulators x 2
- High pressure mixing chamber
- Outlet to connect to inspiratory flow regulator
- Ideally has back up connectors of portable O₂ and air cylinders with automatic crossover in event of pipeline supply failure

Inspiratory flow regulator or pump

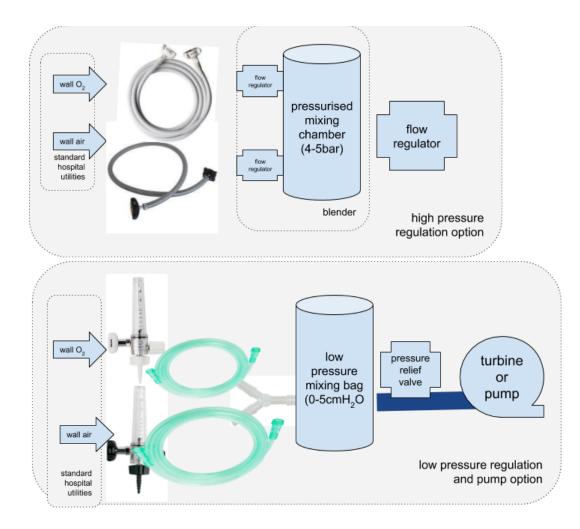
This is a critical component. It could be integrated into the inspiratory manifold.

Requirements:

• Takes gas from the blender at 3-5 bar and regulates flow up to 120 litres per minute. Should have fast response time, ideally cutting off flow from full open to full closed with hopefully less than 10ml of gas allowed through before closure. (I've plucked the 10ml figure out of the air so if it is not achievable then need further consideration, and testing with a test lung to see how smooth the pressure in the entire system is in the event of a simulated patient cough.)

Alternatives

There's a couple of ways of doing this that could be workable. One approach is to keep the pressure high and use a high pressure regulator to produce inspiratory pressure. The other approach is to use standard hospital flow regulators to fill a low pressure chamber and then use a pumping mechanism, or a bellows.



High pressure approach

Components:

- coupling to blender rated at 5bar
- coupling to inspiratory manifold rated to 80cmH₂0
- electronic connectors
- some kind of actuator and valve assembly (for example a moderately powerful stepper motor attached to a valve)

Low pressure approach

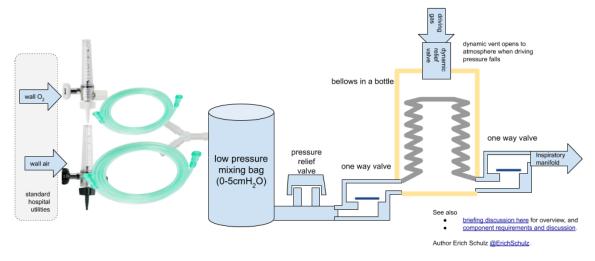
- Low pressure collapsible reservoir with two input connectors that will take standard hospital oxygen tubing and a large diameter (?25-50mm) outflow connector that will connect to the pump
- low pressure pop-open valve the low pressure reservoir does not pop
- pump capable of pulsing gas at 60-120 litres/minute with minimal momentum (ie when the patient coughs then this thing needs to shut off quickly).

Pump

Only needed if using a "low pressure" approach. Alternatives include:

- linear diaphragm compressor (LDC)
- some kind of turbine based pump.
- belows in bottle with a compressed air (or oxygen) source used to squeeze the bellow

The bellows in a bottle looks like this:



The Openventilator team are using a bellows made from car tyre inner tube.

High pressure regulators

These are needed for both "high pressure" and "low pressure" approaches, although the requirements will differ depending on the exact role. In a low pressure approach a relatively slow response is adequate. The high pressure approach requires a very dynamic and robust mechanism.

Standard hospital regulators

Hospitals are full of manually adjusted regulators that screw directly onto the wall gas outlets. These are accurate enough, reliable and well understood by staff. There's a ball floating in a glass column that displays the flow (typically 0-12 litres per minute. I guess it would be possible to hack these to electronically turn the knob and sense the ball location. Feels a bit weird to me.



Solenoid valves

The team at <u>CSSALT at University of Florida</u>, uses an electric sprinkler valve as a high pressure on-off valve - I'd be a bit concerned these are probably only designed to activate several times a day, not 12 times a minute. So durability could be an issue with some models, although this team is performing rigorous testing, with over a million test cycles of their chosen "Rainbird" valves.

I imagine the response time could be quite quick, and that could be useful.

Motorised valves

The <u>MUR team</u> is using a model aircraft RC servo geared onto a valve. This could work, if the valves can be opened and closed very quickly. Servos of this type can rotate up to speeds of 60 degrees in 0.1 seconds. A high speed stepper motor, with the speed possibility controllable by software for finer control, would be another good choice.



Hybrid approach

For some designs it could be useful to have a motor driven valve and a solenoid in series. This would allow a gradual ramp up of pressure (potentially a useful "feature") but would allow the inspiration to be cut off rapidly when the patient started to breath out. This could be excessively complicated, but would allow use of a slightly less powerful stepper at the cost of added complexity.

Fluidics

The <u>world wide ventialor team</u> and <u>ARMEE team</u> are using fluidics, which is used in some modern advanced ICU ventilators. This is clever, and the right design could maybe work and be made out of CNCed aluminium, but the idea makes me dizzy, and it's likely to waste a lot of gas.



Valve and Sensor Packaging

The sections on the two manifolds below steps through all the components. However, there are a few common aspects of all the valve and sensor elements. Ideally the manifolds fit together in a way that is moderately robust and facilitates easy service and replacement of faulty parts. Given the operating pressure of the ventilator is nearly always under 40cmH2O then often snug push fitting (as opposed to glue) may be adequate, especially if it is possible to clamp the manifold pipes down onto a rigid frame.



(credit Gordon Gibby, showing early CSSALT prototype)

Combined units

It would work well to have the pressure and flow sensors combined, but separate components could also work. Similarly it could be OK to have valve units combined into single packages.

Gender of connections

For maximum flexibility, it is probably best to have a male and female end with a reversible sensor, but as long as male-male and female-female fittings are reality available this is not critical.

22mm medical connectors

This is the standard for circuit components. This random commercial product nicely illustrates packaging of a sensor with male and female 22mm connectors:



Plumbing connectors

Rather than using standard 22mm medical connectors, using standard plumbing or irrigation fittings could also be a good option (at least internally). I did a Google image search and this array of options came up (conveniently with indicative pricing in Australian dollars).



Luer lock connectors

These are abundant in hospitals and very cheap due to volume manufacturing. Obviously these are unsuitable for ventilating through. However, they do allow sampling and potentially cappable access points, as many standard fittings are available that combine anaesthetic 22/15mm circuit fittings with Luer ports.



You can rely on the availability of

- syringes (1,3,5,10,20,60 ml)
- taps (two female and one male connector)
- occluding caps
- extension tubes (either in minimum volume or standard bore)

Female-female, and male-male connectors are available but use is very limited. The standard 3-way tap provides a ready mechanism for making a female-female adapter.

Pressure and flow sensors

Having sensors in both inspiratory and expiratory manifolds greatly improves safety by enabling validation of the sensors, both on start-up and while the ventilator is operational (discussed in more detail in Volume 3). Dual monitoring also improves diagnostic information available to clinicians.

There have been concerns raised about supply chain issues for certain off-the-shelf components.

Pressure sensors

A common suggestion here is to use a <u>BMP280</u> module.

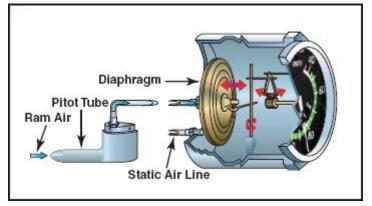
Hospitals use many pressure transducers with Luer-lock plumbing for arterial blood pressure monitoring. These are common commodities and familiar to staff.

A water manometer is potentially a solution in impoverished situations but really isn't fast enough to accurately measure peak pressures.

Flow sensors

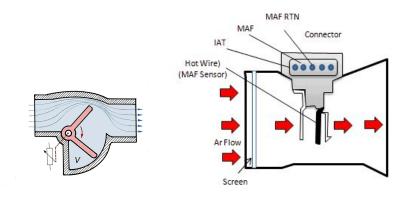
Need a good solution for this in terms of reliability, speed, accuracy and supply (or manufacturability).

The <u>Ventilator Inline Sensor Package</u> (VISP) project is working on incorporating bidirectional flow, pressure, and temperature sensing in a single inexpensive I2C/SPI package. This looks very promising.



A variation on an aircraft air-speed indicator could be possible.

Mass flow sensors could potentially work, either a flap based sensor, or a more modern heated wire.



Inspiratory manifold

Requirements

- Rated to at least 80cmH₂O
- Tolerant to 100% oxygen (should be dry and cool gas)

Components

- connector to the inspiratory flow regulator (if not incorporated)
- outlet to connect low-compliance hose to passive pneumatic patient inflating valve on expiratory manifold
- electronic pressure sensor (ideally covering -20 to 100 cmH₂O)
- flow sensor (ideally covering 0 to 150 litres per minute)
- overpressure relief valve venting to the atmosphere if pressure exceeds specified range (I've seen numbers quoted for 40-80cmH₂O, personally I'd like 50, it would be good to have a simple plan for technicians to customise the emergency threshold for each hospital). This valve only ever opens if there is some kind of fault. (See the section on PEEP valves below for thoughts.) It is possible that a simple cheap pressure driving system could rely on a valve like this to help moderate pressure. However, ideally this valve only functions as a fail-safe and only needs adjustment at the factory to set to the optimal level, with potentially technicians adjusting with a screwdriver if requirements change)
- under-pressure relief valve to allow atmospheric air into the circuit.
- standard 22mm connector to standard ventilator circuit

Non-return valve

This valve must offer low resistance and be robust over millions of cycles. I don't know what material is lightweight and strong, but that is what you want for your valve disk. It will either be some kind of spring loaded or gravity based valve. Springs are common in portable devices because the orientation changes. However, you can plan for your ventilator to be mounted on a stable heavy trolley. Gravity driven mechanisms are common in anaesthetic ventilators and are highly regarded as simple and reliable.

Overpressure valve

This vents to the atmosphere if pressure exceeds specified range. I've seen numbers quoted for 40-80cm H_2O , personally I'd like 50, it would be good to have a simple plan for technicians

to customise the emergency threshold for each hospital. This valve only ever opens if there is some kind of fault, or during test cycles.

See the section on PEEP valves below for thoughts.

Note that a simple cheap pressure driving system could rely on a valve like this to help moderate pressure. However, ideally this valve only functions as a fail-safe and only needs adjustment at the factory to set to the optimal level, with potentially technicians adjusting with a screwdriver if requirements change.

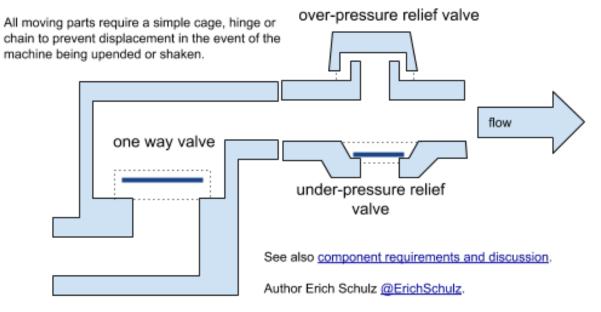
Underpressure valve

Like the overpressure valve, this valve should only open if there is some kind of fault or gas outage. Patients can damage their lungs by attempting to inspire against a closed pipe, leading to a condition called negative pressure pulmonary oedema.

Gravity based valves

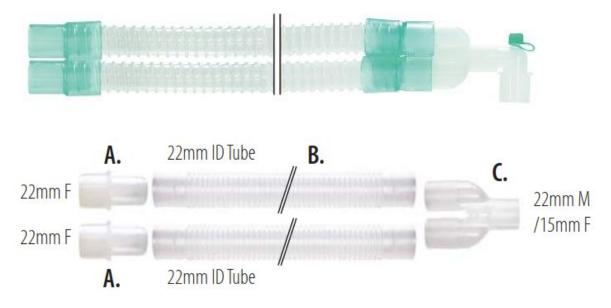
Personally I like the idea of making these three valves simple gravity driven mechanisms. Note that the ventilator (which should be bolted onto a trolley with a car battery strapped low close to the wheels) is unlikely to ever be toppled over in operation. However each of these moving parts should be held down in some kind of simple light cage to prevent them floating off. In a portable device you could use these approaches and use springs, but I think this style based purely on weight is reliable and simple to make.

Don't take my doodle as gospel for the shape. I'm a doctor, remember, not an engineer.



Circuit and airway device

This is out of scope. Hospitals have lots of these, as well as all the endotracheal tubes they need:



Expiratory manifold

Requirements

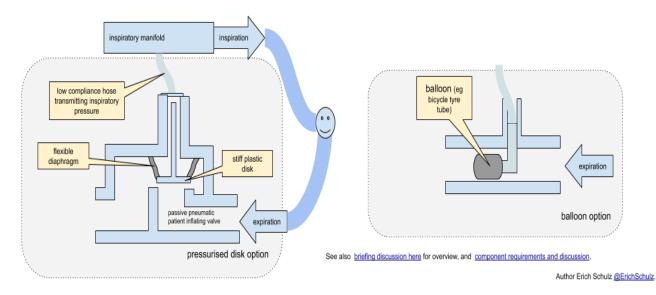
- Rated to at least 80cmH₂O pressure
- Able to tolerate moist oxygen rich gases

Components

- standard 22mm connector to standard ventilator circuit
- non-return valve
- patient inflating valve (or, alternatively, an electronic cut-off valve)
- PEEP valve (ideally covering the range 0 to 24cmH₂O), The simplest case is hose suspended in a bucket of water.
- large diameter (ie low resistance) connector to scavenging

Pneumatic patient inflating valves

Obviously during the inspiration cycle you do not want the gas blowing out the PEEP valve. This is the role of the "patient inflating valve". <u>This 2010 article</u> covers the topic in detail, and has useful illustrations.



A beautifully simple and quick approach based on a bicycle tyre inner tube is illustrated in <u>this pdf</u> from <u>CSSALT at UF</u>. Some of the team are also <u>modifying commercial solenoid</u> <u>products</u> to create a disk-based alternative.

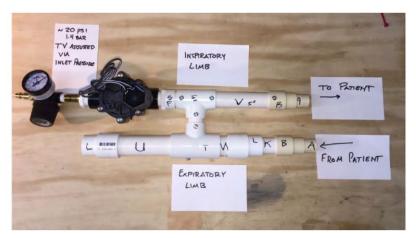


Fig 1. Assembled Ventilator V1.2



Fig2. Exploded Assembly

PEEP valve

Disposable

I don't know what supplies and durability of these is like, but they are common. Most only go to 20 or 24 cmH2O so will work for PEEP but not as over-pressure valve.



Electronic

Some kind of spring loaded wide down valve that had a stepper motor attached would be perfect. This could be calibrated against a sensor in the start up test cycle (or "factory calibrated" initially. A pretty small stepper would be more than adequate if it can adjust the valve by a minimum of 1cmH₂O per second. Rapid changes in PEEP are not required.

Hydrostatic

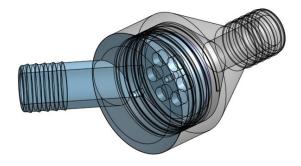
Putting the outlet hose in a bucket of water to the appropriate depth is a very simple solution and doable in the most resource poor situations. In the Covid19 pandemic it is critical that any generated aerosol is safely managed and not allowed to bubble into the room.

Weighted pop-open valve

This would be a pretty simple design and could use a standard weight, like coins to allow adjustment. See the section in the inspiratory manifold section on gravity based valves.

3D printed prototype

There's this 3D printable option: (video)



Scavenging System

Suction Requirements

- Able to regulate suction to direct exhaled gases (and any possibly infectious agents) out the hospital suction
- •

Components

- large diameter (ie low resistance) connector to the expiratory manifold
- a reservoir to hold gases
- some kind of regulator that apply adequate suction to empty reservoir without risking application of negative pressure to the breathing circuit
- connection for a standard hospital suction hose (needs to be robust enough not to collapse under negative pressure).

Filter requirements

- Commercial disposable in-line filters
- In resource poor environments this system could be a hose directed through a filter material.



Electronics

Components

- mains power connector
- battery with charger
- microcontroller (don't skimp on this, crashes won't be fatal, but users will *hate* you).
 Some informed discussion <u>here</u>, and <u>here</u>)
- laptop (ideally with touch screen)

One of the benefits of having both a laptop and a microcontroller, is that if one fails the other can raise the alarm.

Software and control

I cover this in detail in <u>Volume 3</u>. Having quality hardware will make the software easier.

External connector hardware

Requirements:

• should be robust and comply with standards that exist for all these things covered well in UK specification.

Possibly useful 3d model here of a sensor housing.

Housing

Requirements

- Should securely hold internal components and external interfaces
- Should be cleanable (ie splashproof at minimum)
- Entire thing should be on lockable wheels with a low centre of gravity, but control at working height for a standing user

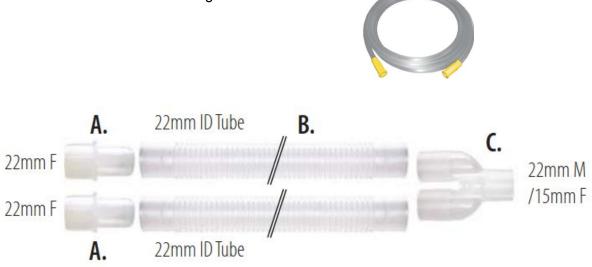
Appendix 1 - Notes on tubes and hoses

These are not relevant to ventilator requirements, but in your design it is useful to consider the many tubes and hoses users may have access to. In richer countries they are normally available in large numbers as disposable items. The following varieties are especially common:

- various intravenous drip "giving sets"
- thin "minimum volume" extension tubs with male and female luer connectors (10-3000mm long), mainly used for intravenous infusions, but also (the longer ones) for gas analysis in ventilated patients



- 6mm ID "oxygen tubing" typically ~2m
- 6mm ID suction tubing
- 22mm flexible "circuit tubing"



High pressure air and oxygen hoses with standard non-swappable threads are not disposable, and supply is likely to be limited.



(advance to Volume 3: Software)