A brief for engineers, by a doctor, on hacking a ventilator for surge capacity in Covid19 patients (Vol. 1)

Dr Erich Schulz, MBBS, FANZCA, Brisbane, Australia.
(feedback welcome: @ErichSchulz)

(See Volume 2: Hardware, Volume 3: Software, Volume 4: How to help)

Acknowledgments

This document is written in first person, but it is a team effort. Thanks notably to:

- Dr. Ron Tsur, retired senior engineer and engineering consultant at Intel Corp. and many other companies (AKA *Dr. Flywheel*)
- Jonas Wahlfrid
- Dr. Robert Read
- Engineering students at the University of Queensland

Preface

In late March 2020, things started looking pretty grim, and severe ventilator shortages were being predicted around the world. At this time multiple teams started exploring how to fill the predicted short-fall in ventilators. Sadly many teams started work without obtaining an adequate understanding of how and why an ICU ventilator function. I started this briefing in early April 2020 in order to fill in the gaps.

Thankfully, in late April 2020, it now appears that strong public health measures have slowed the pandemic faster than most had predicted. Therefore, it thankfully appears unlikely that many of the projects will actually need to provide emergency ventilators. While the urgent need appears to have evaporated, the work that has been done can still add value in the future.

Good quality, high performance ventilators can still save lives. By extracting the best designs we can still offer under-resourced health services access to high-quality, robust and powerful ventilators at a greatly reduced cost.

The challenge right now is how to extract the usable designs from all the projects and get them tested and published.

Introduction

Are we having fun yet?

Before you get going, just want to remind everyone to look after themselves. This pandemic sucks, and people are literally dying like flies. Not my fault. Not your fault. But you want to help, right? Well that's great. I hope you give it red-hot go and maybe, you never know, you might even save a life. But remember that's a two edged dream. You may find yourself having all kinds of thinks as a result. If it starts to get to you, have a chat with someone who can talk you down. And look after each other. You might find this paper helpful to help you navigate what you may be feeling: Extraordinary times: coping psychologically through the impact of covid-19.

About me

I'm an anaesthetist (in America you'd call me anesthesiologist) and a bit of a geek. Not a ventilator expert but I have a few thousand hours as a user. I now know a lot more ventilators than I did when I started writing this document!

I've written this brief cognisant of the latest treatment guidelines for Covid19 respiratory failure (eg April 3 National Taskforce, and other more recent documents).

I'm lucky enough to live in Queensland, Australia, where we have many very good anaesthetists (and me), and so far we have very few Covid19 patients. During around eight weeks from mid-March to mid-May 2020, we were in a moderately strict lock-down and lots of elective surgery was cancelled. So I wouldn't say I was ever bored per se, but I had plenty of free time. I grew my best ever tomatoes in this period!

About this document

These are living documents and I welcome feedback, either here, or on twitter.

This is a four volume document:

1. Overview (this current document)
2. Hardware
3. Software
4. How to help (just starting this)

I try to summarise the key requirements in a way accessible to non-medical engineers in order to allow the simplest, fastest solution for delivering fit-for-purpose rapidly manufactured ventilator systems (RMVSs in UK) or emergency use ventilators (EUSs in USA).

Where possible I link to resources as I find them.

They omit a lot of the important context, and much of the "how" and the "why", but the UK, American and Australian Governments have also produced specifications covering some aspects more deeply than I have. I suggest reading their documents after this one, or read their's first, or both at the same time. Whatever you like, but you probably want both.

The importance of teamwork, and inter-team teamwork

This is a fascinating challenge and will need a collaborative effort. A rapidly growing set of groups have formed already. The single biggest challenge for most of these groups is to stop working in isolation on inadequate solutions and to pool their efforts.

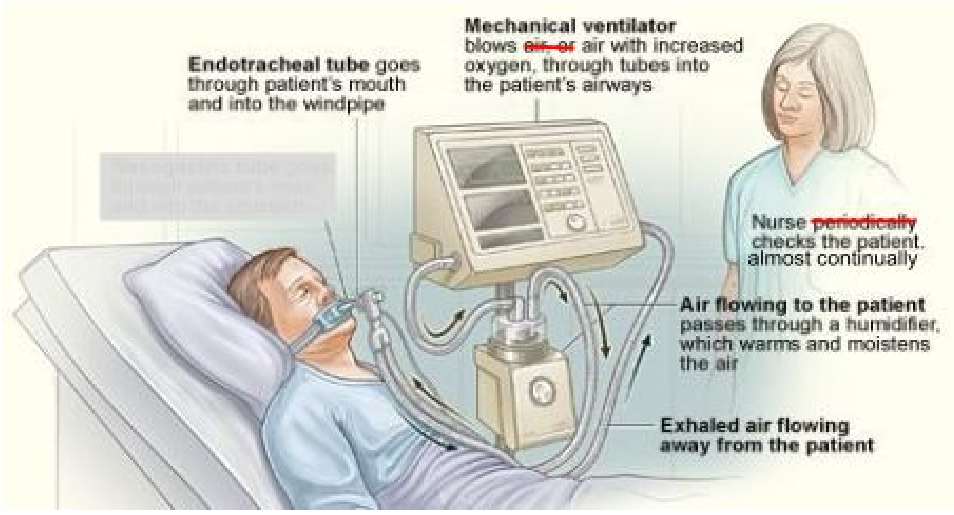
This is a big job people. People need to work in multidisciplinary teams for software (Volume 3), and plumbing, fabrication, sensors, actuators (Volume 2). Working on a complete solution by yourself is unlikely to be useful. As a team, you are all amazing and you can do this, but there is a lot to do. **Also it is vitally important that the teams collaborate with each other.** (So important I had a rant on twitter on the topic, and I started Volume 4.) There are many teams out there who are reinventing wheels and failing to come up with a workable solution.

Yes I'm looking at you Oxford, and you MIT, and even you University of Florida. Stop thinking you have all the solutions and start pooling your efforts. You have weeks to do this. Pick a component, release the design. Help others find the components (design and hardware) they need.

The groups are being collated by Robert Read [here](). More recently Robert, and team, have started collating individual components. I encourage you strongly to assist the team.

The job at hand

The following picture illustrates the general environment and plumbing external to the ventilator. Many of the other diagrams mess up some features that this picture captures well. Note that there are two hoses going to the patient. You can't see it, but the Y junction at the other end is simply that. All the valves and whatnot are tucked away in the ventilator box. Also notice that there is a seperate humidification unit that sits in the inspiratory line. What is missing in this picture is a bunch of other hoses and wires attached to the patient which connect to a collection of electronic monitors and pumps, which is fine because they are out of scope.



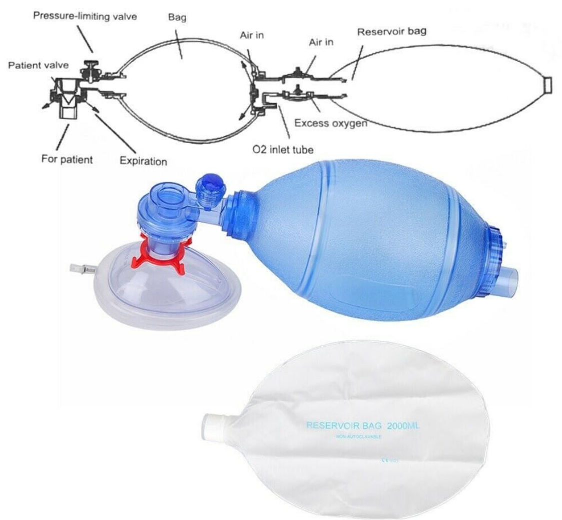
[source]()

The case against bag squeezers

Designed to be cheap, light, portable, and hand powered, self-inflating bag-valve-masks (BVMs, eg "ambubags™") are everywhere:

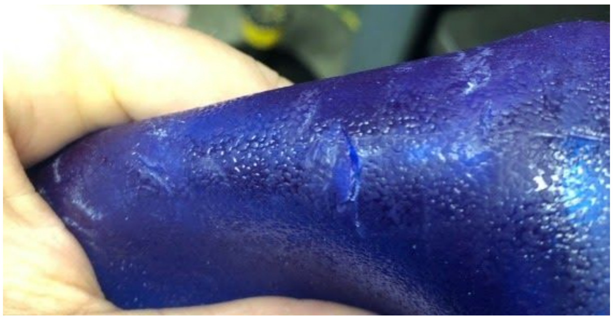
There are scores of teams working on designs based on squeezing a self-inflating bag. One of the seminal [2010 MIT papers is here]().

A dumb bag-squeezer simply won't do the job we need doing in this pandemic. Sorry. [Others agree](). I fear many people (you are far from alone) are working on machines that simply won't manage a COVID19 ARDS patients and allow them to "wean." Listen, even if I fail to convince you and you still want to make a bag squeezer, keep reading. The topics covered in this document can still help you make a better ventilator.



We need the electronic controls to synchronise with the patient (see section on importance of smart ventilation below). If our current crisis was something like polio (where the lungs were healthy but the muscles were not), or a mass neurotoxin poisoning, then it would be different. If ICUs have to heavily sedate (or even paralyse) a patient to keep them ventilated then we'll drastically increase the number of ventilated days we need to wean. Then we will rapidly run out of staff. We're better off with a smart ventilator that gets people in and out of ICU as fast as we can.

The second issue with bags squeezers is the durability. A mechanical squeezer will hit a bag in exactly the same pattern 12-20 times a minute for weeks. Furthermore, if you are going to cope with diseased lungs then you want to be generating something close to a square wave of pressure, not a sine wave. (see here for why).They simply aren't designed for this.


(Photo courtesy of Jeffrey Ebin, MD)

Most groups seem to be underappreciating the power and forces within a modern ICU ventilator. These machines are capable of delivering pulses of gas at upto 120 litres/min. In fact, the Australian TGA specification requests 150 litre/min peak flow. Achieving this kind of power isn't hard with simple off the shelf components, but not with flimsy light-weight plastic components in a standard self-inflating BVM.

Finally, using a mass produced bag probably isn't even the cheapest option. The right design should be able to sacrifice lightness and portability, to come up with a design that is both cheaper and far more robust.

One of the obvious attractions of incorporating BVM is the ability to use the clever (but flimsy) valves within it. However it is easy enough to simply fabricate all these valves, and I lay out the requirements and alternatives in the volume 2.

Notes on reliability

Ventilators should be easy to turn on, but harder to turn off (for obvious reasons).

In this pandemic crisis situation, a solution that is only 99% reliable may be far better than nothing. Doing better than 99% up-time would obviously be better and would aid uptake. Suddenly, and unpredictably needing a busy nurse to abandon their current task and take over ventilation obviously comes with a cost. But if the choice is nothing or something that works pretty well 99% of the time, it will be an interesting call.

It is critical that if the device fails, then it fails in a way that is obvious. Healthcare workers have become used to modern, extremely reliable ventilators. In the 5 minutes before a patient develops irreversible brain damage, the busy, stressed, inexperienced staff may completely fail to realise that it is the ventilator that has failed, not one of the 20 other potential causes of cardiac arrest that is going through their heads. **It is possible that a gradually failing machine that continues to make appropriate noise is overlooked with fatal consequences.**

Finally, it is vital that the ventilator continue to work in the event of mains power outage. Every single ventilator in a hospital failing at the same time would be disastrous.

Risk analysis, or what kills people on ventilators

There's not much we can do about these:

- the patient's condition gets worse despite best care (generally their lungs, heart or other organs fail, leading ultimately to multi-organ failure, often associated with some other complication such as infection.)
- hospital personnel make a mistake that has nothing to do with the ventilator itself - this is quite common under normal circumstances and will likely to be more common during the pandemic.

However, the risks listed in the table below are understood ahead of time and must be mitigated through good design, clear, unambiguous and appropriate warnings, as well as staff training. Any emergency ventilator is going to be compromised by the nature of rushed design and manufacture, together with the stressed situations in which they are deployed. The probable use by inexperienced staff escalates and alters the pattern of usual operational risks.

Awareness of the risks listed below has formed this document as well as the associated discussion of both proposed hardware and software. Many of the aspects of the following table are dealt with in detail the various sections on hardware and software. Ventilators do not normally offer a diagnosis, but will merely report which alarm conditions have triggered. In a pandemic ventilator, some user guidance could potentially be helpful. The below notes on warnings would require further review before implementing.

Source	Risk	Signs	Mechanical Mitigation	Alarm level	Operator Warning*
circuit	circuit or ETT tube disconnects	prolonged low pressure, but pulsing flow detected in attempted inspiration, large difference between inspiratory and expiratory volumes		moderate, but escalating	"Check circuit for leak or disconnect"
circuit	circuit occlusion	high peak and plateau pressure, almost no low flows		severe and escalating	
patient	breath-holding	high pressure,	over-pressure relief	depending on pressure and volume	

		almost no low flows		alarms	
patient	mucous plugging	high peak and plateau pressure, lower tidal volumes			
patient	tension pneumothorax	high peak and plateau pressure, low compliance, **rapid** expiration (see below)		moderate-severe (depending on severity)	"Check tube position. Listen to chest, confirm bilateral breath sounds"
patient	bronchospasm	high peak pressure, normal plateau pressure, low compliance, **slow** expiration		moderate-severe (depending on severity)	"Listen to the patient's chest. Consider bronchodilation"
patient and ventilator	dyssynchrony or coughing (see section on importance of smart ventilator)	erratic pressure wave, flows in reverse direction to expected		mild-severe (depending on severity)	
patient and ventilator	ventilator induced lung injury	gradual deterioration	accurate pressure and flow controls, avoiding dyssynchrony, good user interface		
ventilator or user	oxygen toxicity	gradual deterioration	accurate controls	low-moderate	"Consider reducing FiO_2"
ventilator or user	inadequate minute volume	hypercapnia (excess blood co_2)	minute volume measured on expiratory limb, external capnography (co_2) monitor	low-moderate	"minute volume low"
hospital facilities	oxygen supply failure	low pressure, low flows,	reserve tank with automatic cut-over, pressure sensor on oxygen line to detect low pressure	critical	"low oxygen" or "pump failure, check supply"
ventilator	insp valve stuck open/exp valve stuck closed leading to uncontrolled high pressure	high continuous pressure	over-pressure relief valve	critical	"machine fault - replace ventilator immediately"
ventilator	valve stuck	low (and	under-pressure	moderate (for 15	"negative circuit

	closed (or open if in expiration manifold) leading to uncontrolled low pressure	potentially negative pressure), simultaneous flow through inspiratory and expiratory manifolds	relief valve	seconds as maybe due to big breath in by patient) then critical if sustained	pressure" -> "machine fault - replace ventilator immediately"
ventilator	pump failure	low pressure and low flow as above		critical	"machine fault - replace ventilator immediately"
ventilator	inspiratory valve failure or non-return valve failure	low flow detected in expiratory manifold	two flow meters are required to detect this.	critical	"machine fault - replace ventilator immediately"
ventilator	miscalibration of flow sensors	large discrepancy b/t insp and exp flow sensors assuming only one fails	test and calibration on start-up, and then ongoing comparison during operation	moderate	"sensor fault in flow sensors"
ventilator	miscalibration of pressure sensors		test and calibration on start-up, and then ongoing comparison during operation	moderate	"sensor fault in pressure sensors"
hospital facilities	hypoxic gas mixture (due to the plumber diverting the wrong gas into the pipe, or putting wrong gas in cylinder)	not detectable by ventilator ? is there a plan for an oxygen sensor	external oxygen concentration monitor		
doctor	oesophageal (esophageal) intubation (medical error)	low flow, high peak and plateau pressuresnot detectable by ventilator	external capnography (CO_2) monitor		

* It may be desirable to provide additional operational tips in addition to reporting the actual abnormal sensor readings

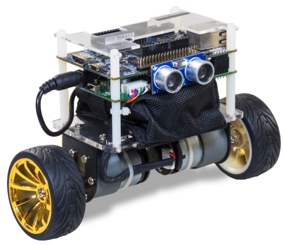
High pressure, low compliance states are explained below in the section on respiratory mechanics.

The importance of making a smart ventilator

Implementing a dumb bellows pump, governed only by rate of squeezing per time interval is relatively easy to achieve (well it would take me a few days, but I'm sure you'd be quicker). The challenge is to sense a patient's own respiratory effort and support that effort.

Simple "dumb" ventilators used for transport purposes are in adequate supply for patient transport, but because these ventilators require the patient to be either paralysed or heavily sedated they are not suitable for prolonged ventilation as the patient will lose muscle mass and become too weak to ever get off the ventilator.

Patient's level of consciousness and respiratory drive will fluctuate randomly during an ICU stay (due to changes to medication and patient physical status). Ideally a ventilator should seamlessly transition from breathing purely on a preset and repetitive timing interval, to sensing the patient's initiated breathing pattern (sensing the exact patient's transition from inspiration to expiration). The control part of the ventilator must be capable of rapidly characterizing the patient's breathing phase and consequently, rapidly transition into a new compliant, assisted breathing mode of operation. Using modern micro-mechanical pressure sensors and proper software running on microcontrollers is likely the key to implementing a closed-loop control system to govern the dynamics of the proposed mechanical ventilator behavior.



To illustrate the proportional response principle, ventilators should exhibit the agility of a balancing robot toy that is programmed to gently roll backward and forward until bumped to reverse direction. In our case, rather than rolling backwards and forwards, the ventilator is breathing in and out, changing airflow direction to closely track and assist the patient's intrinsic respiratory efforts.

The most succinct paper I've encountered that explores the issues in detail is this excellent review by Subirà et al in 2018. That said Subirà et al describe all the difficulties in getting the final 5-10% of breaths synchronised. Getting your ventilator to synchronise with the vast majority of breaths is relatively simple: just wait until the pressure in the circuit falls and then initiate inspiration, then wait for the flow to decrease before ending inspiration. It's not that hard to get right most of the time.

Respiratory mechanics, physiology and pathophysiology

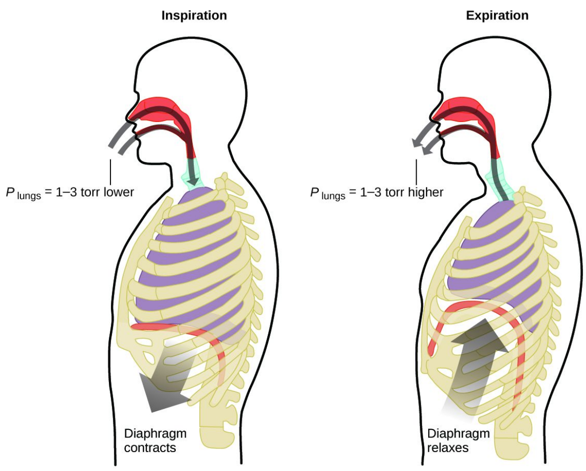
Overall this is a wide field, well covered in many papers and textbooks. You do not need to become an expert, however, if you are interested in the subject matter then search for "West's respiratory physiology" which is readable over a day or two. You probably don't have time for that, and I attempt to give you all you need to know about the topic, possibly more than you need to know.

Importance of fine control

Lungs are very delicate sponge-like structures. High levels of oxygen, excess pressure and shear forces can lead to a cycle of trauma, inflammation, swelling and loss of compliance. The loss of compliance and swelling result in the need for higher oxygen concentrations and higher inspired gas pressures, driving the downwards-leaning process escalation, towards death. This is especially the case in diseased lungs.

Work of breathing

Ventilators do most of their work during the inspiration phase of breathing. The passive elastic recoil of the lungs and chest wall perform the necessary expiration work. (Induction of negative pressures were tried in the early days and it didn't go well. The little air sacs, called *alveoli*, get sucked closed under negative pressure induction and then tend to stay that way due to surface tension within the alveoli tissue.)



This diagram above is a simplification of normal breathing at rest, omitting the role of the muscles between the ribs (intercostal muscles) that normally assist breathing by rotating outwards and tilting up. When straining, coughing or breathing hard the other intercostal muscles, combined with the abdominal muscles can tighten to squeeze air from the lungs.

Peak flows and volumes in healthy patients

A tall (eg 190cm) man can potentially achieve peak expiratory flow rates (PEFR) of up to 660 litres/minute. If such a patient is capable of maximal breath in and out, they can breathe a total gas volume of 5 litres (vital capacity) in a single breath. Patients who unexpectedly wake up while undergoing mechanical ventilation may exhibit such behavior. This is one of the reasons for needing fail-safe pressure relief valves in any type of ventilator, to cope with unanticipated high negative and positive pressures.

When lungs go bad

High pressure, low compliance states can be for a variety of causes. Progression of ARDS will lead to gradual worsening over days, whereas the "not to be missed" tension pneumothorax will come on more rapidly (over less than a minute, or possibly over days). Patient breath-holding can also mimic this state. (Yes, it's true, sometimes patients make it hard for you to help them, even when semiconscious.) Doctors can identify two seperate patterns, "restrictive" and "obstructive", by examining the shape of the expiratory flow. Restrive patterns (eg ARDS, pulmonary oedema, pneumothorax, straining) lead to difficulty inflating the lungs, but then rapid exhalation. Obstructive states are typically due to narrowing in the small breathing tubes in the lungs (asthma, chronic smoking, severe allergic reaction). In this case the real problem is emptying the lungs, as a result the lungs become over-inflated, and the expiration is prolonged.

Scope

In scope

Things a ventilator can and should be able to control are:

- the pressure waveform: (as described via settings such as respiratory rate, tidal volume, PEEP, I:E ratio, slope. More on this later)
- synchronisation with patients' own respiratory efforts (as detected by pressure/flow sensors)
- information on pressures and volumes available to the clinicians (potentially a sensor housing could connect to an external monitor, but that is probably suboptimal)
- inspired oxygen concentration (FiO_2) (potentially this could be adjusted by an external blender)

Out of scope

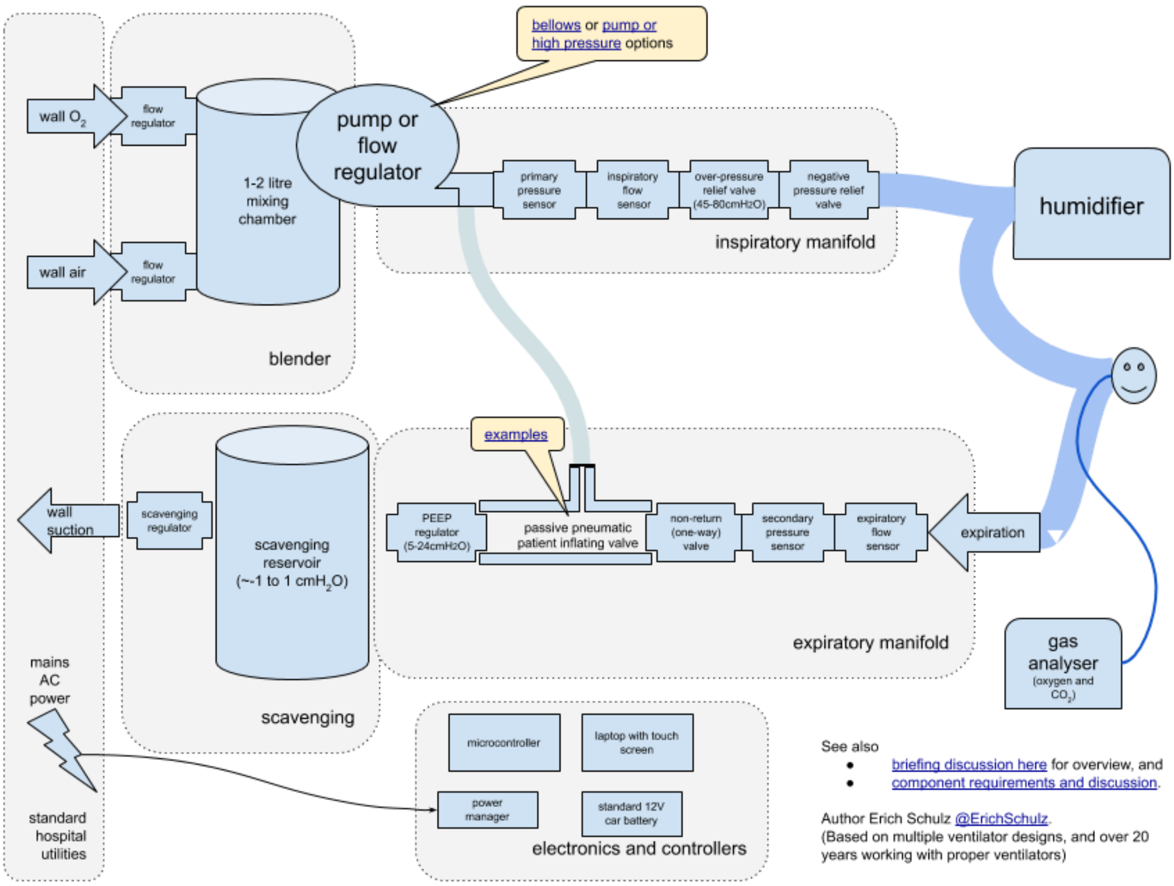
Standard attachments exist that will allow any ventilator to interface with mechanisms that:

- control temperature and humidity of inspired gas (via a standard OSA CPAP humidifier)
- display gas analysis (capnography and confirming actual FiO_2)
- attach to the patient's airway (typically an endotracheal tube, more rarely a tight fitting face mask)

Standard hospital monitors will allow monitoring of patients' vital signs (eg ECG, pulse oximetry, blood pressure). The one monitor that could be in short supply is the real-time gas monitors that measure FiO2 and carbon dioxide waves, typically via a thin hose continually aspirating gas from the patient Y connector. These monitors are very important but out of scope for this document.

Overall system architecture

This diagram illustrates the overall system components. I systematically step through each hardware component in Volume 2 and control in Volume 3.



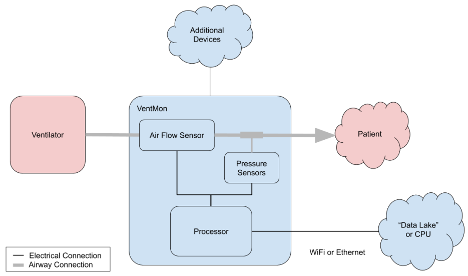
The figure is intended to be deliberately generic. (Hint: to read the details of this and my other diagrams click on them and open the source document so you can pan and zoom). Most ventilator proposals (certainly, dare I say, the ones consistent with a fully specified machine) conform roughly to this pattern.

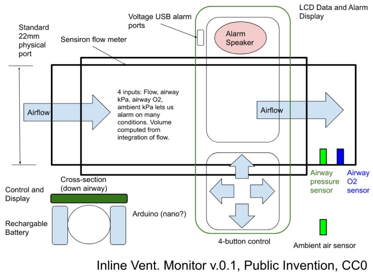
Some example proposals

Here's a couple of schematics I've encountered that help illustrate some of the approaches. Each one of these, to my thinking, has serious limitations, but they are worth considering and each has some features worth cherry-picking.

Standalone pressure flow monitor

Watching so many teams start working on ventilator designs, Robert Read and the Public Invention team have decided that the best way they can contribute is to make an in-line monitoring device. This would be a tube that connected near the patient and would track the flow and pressure of gases as they entered and left the patient. Much of the rest of the document discusses flow and pressure sensing, but it worth noting that such a simple device like this is extraordinarily valuable and most definitely life-saving.



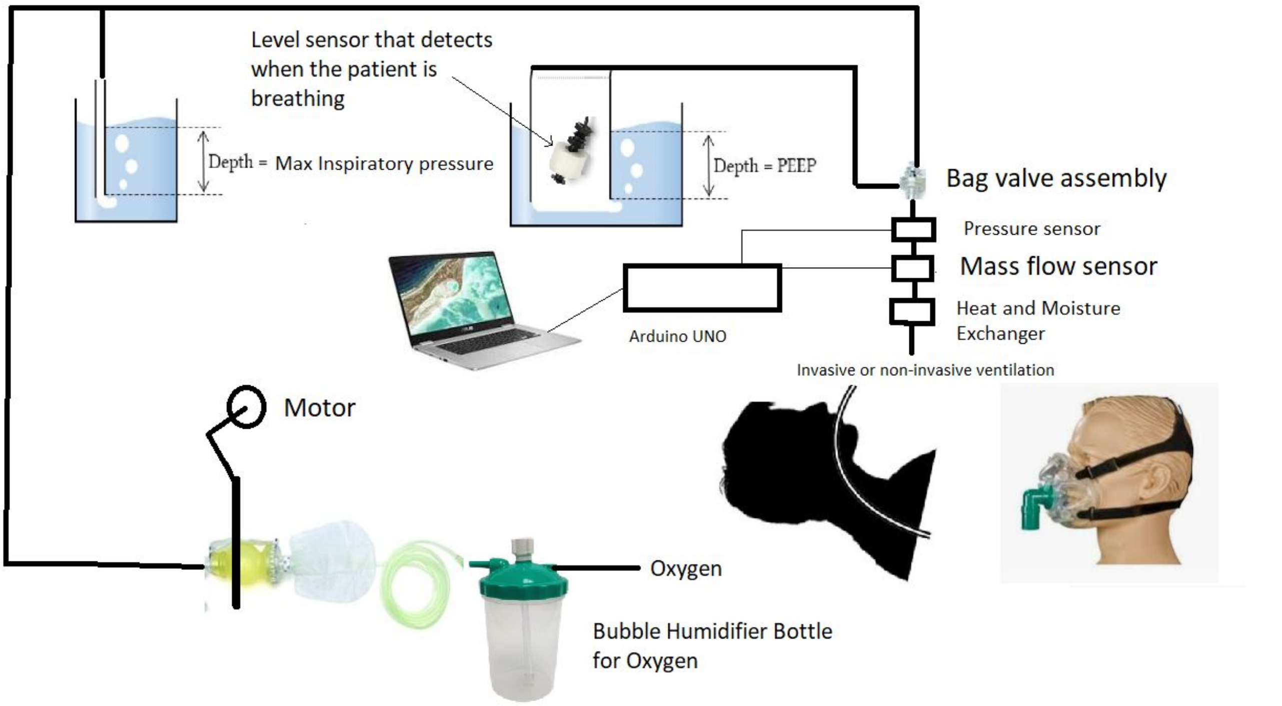


(source)

In a perfect world each ventilator has two sensor packages, located in each manifold. The benefits extend beyond simple redundancy, but also allow semi-automated start up validation of actuators and sensors, but even more important breath by breath monitoring of the proper functioning of the ventilator. The start-up self checking section in Volume 3 explores this in more detail.

Jonas' simple bag squeezer

This is the simplest, and safest dumb bag squeezer approach I've seen (from Jonas on facebook). Setting the pressure limits using literal cm of water is great for a safe operation, providing aerosols are properly managed with scavenging or HEPA filters. It's important that the plumbing is configured to prevent the patient entraining water if they unexpectedly take a big breath in. The water bottles regulate the air pressure in and out to X cm H2O completely according to the laws of physics without mechanics or software. Since the water level in the tube that is inserted in the PEEP water bottle rises x cm, when the patient is inhaling, it is possible to detect this using a level sensor. Even if a project is not using a manual resuscitator bag, the water bottles may add to the functionality. The manual resuscitator bag, allows the patient to breathe through the bag valves and valve assembly, even if the bag is not squashed. It is also possible for the patient to exhale through the valve assembly. The worst case in terms of pressure is when the patient's lungs are filled with air, and the motor squeezes the bag. However, the water pressure in the driving pressure bottle, will limit the pressure to, for example 25 cm H2O, depending on the water level. In a third world country you could probably make this for under $20 (minus the electronics). It's good to see the problem reduced to its simplest. See here for tests and details. There are quite a few groups working on related designs.



UF Open Source Ventilator

Another clever approach from the team at CSSALT at University of Florida, uses an electric sprinkler valve and an "exhalation bulb" (made from a segment of bicycle tyre inner tube) to occlude the expiratory limb during inhalation. This team is close to seeking FDA approval.

The expiratory valve requires a high pressure side (1400 cmH_2O) and a low pressure side (<40 cmH_2O), with the patient obviously on the low side. The bicycle tyre inner tube valve gets air from the high side. Flow is restricted enough by the D2 orifice plate with a small hole, that when the solenoid closes the sprinkler valve, pressure slowly equalizes and gas continues to flow to the patient. Eventually enough pressure is bled off to allow the bicycle tyre inner tube valve to deflate enough to allow exhalation. Since the design has a big pressure difference and a patient safety valve, it is not possible to over pressure, so that it becomes impossible to open the expiratory valve. In the original paper for the valve type they used a bellows. With a bellows the valve can not get stuck in the closed position, since the bellow will reduce the pressure in the next cycle.

(source)

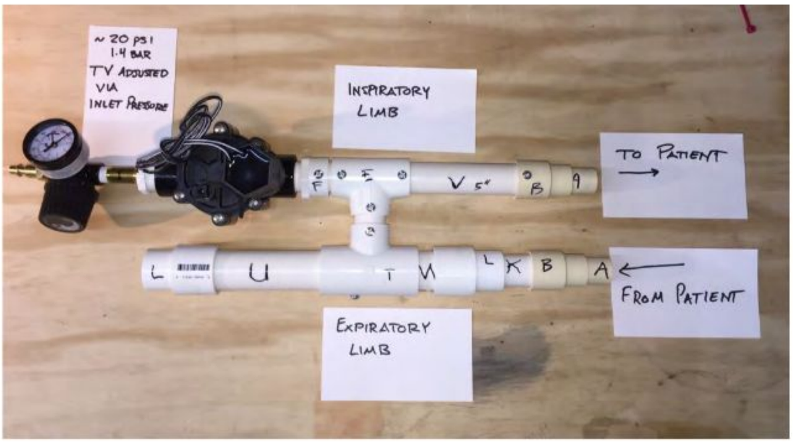


Fig 1. Assembled Ventilator V1.2

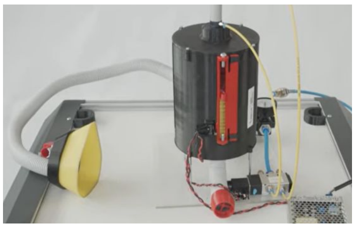
Fig2. Exploded Assembly

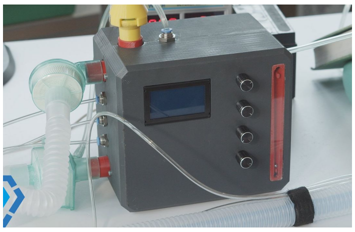
Tesla

Worthwhile watching Tesla's quick video on their efforts. This is the closest I have seen to something I would want to use on myself or a loved one. Personally I'd be happy to fly to the USA to help out this team but they haven't responded to my offer on twitter! The thing that impresses me is that it does not look like they have under-specified the hardware.

Ventilaid

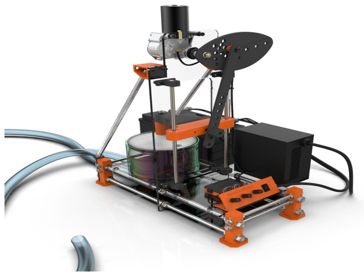
This group, based in Poland, initially worked on an open source pneumatic bellows device using 3D printed parts, but they have now moved on to turbine design.





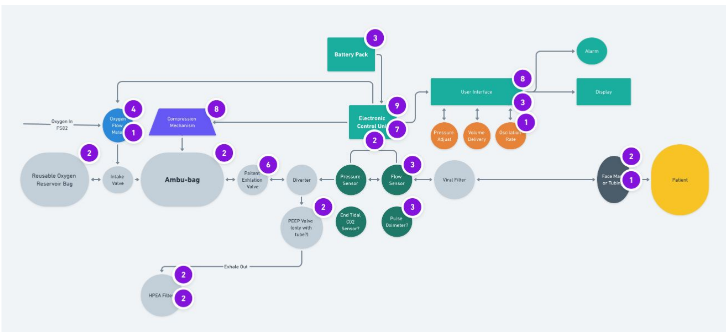
Openventilator Bellows

This Brazillian group is doing a variation on the bag squeezer, but using a bellows made from car tyre inner tube along with a windscreen wiper motor. They have a video too.



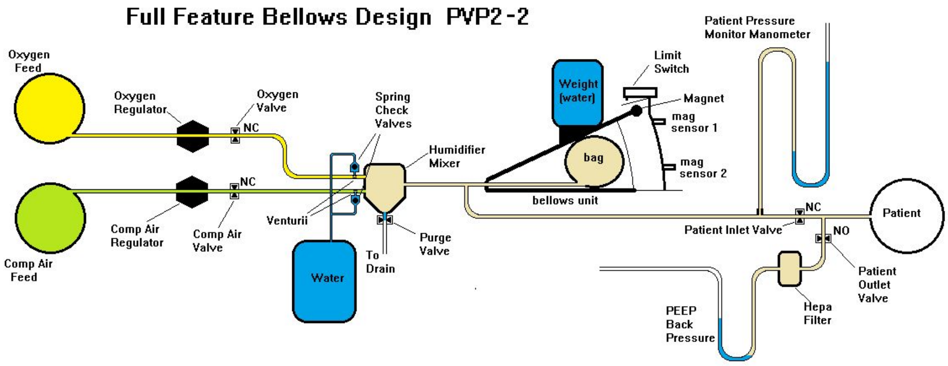
Open Lung

This diagram from OpenLung starts to add in some sensors and control of the inflow (but they've fudged the plumbing quite a bit)



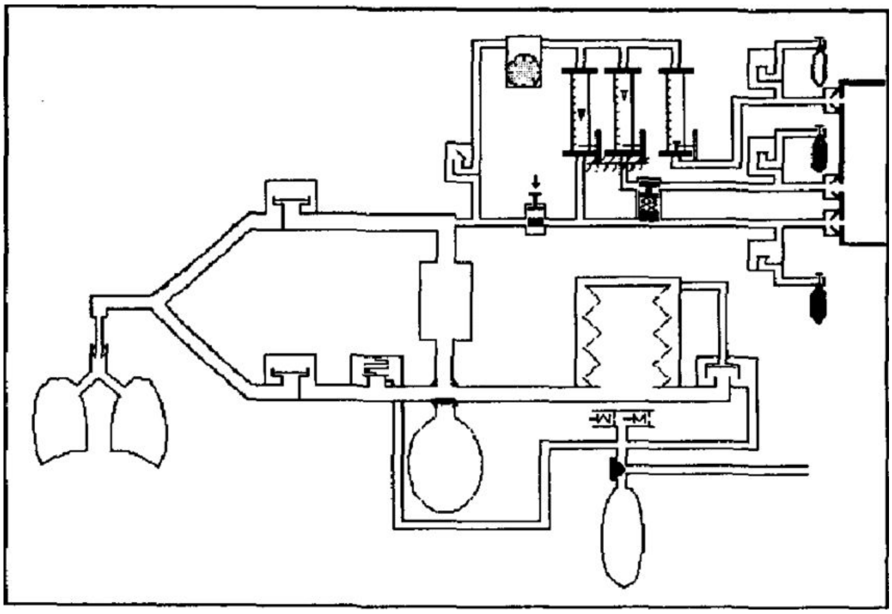
Panvent

This diagram from PanVent is a more complicated version of Jonas' simple solution. It starts to think about humidification, but normally humidifiers are placed directly onto the inspiratory pressure outlet (between the ventilator and the hose leading to the patient). The HEPA filter on the expiratory limb is not required if using normal hospital suction for scavenging. I'm not sure if the team is aware of patient inflation valve mechanisms as they are using a pair of solenoids.



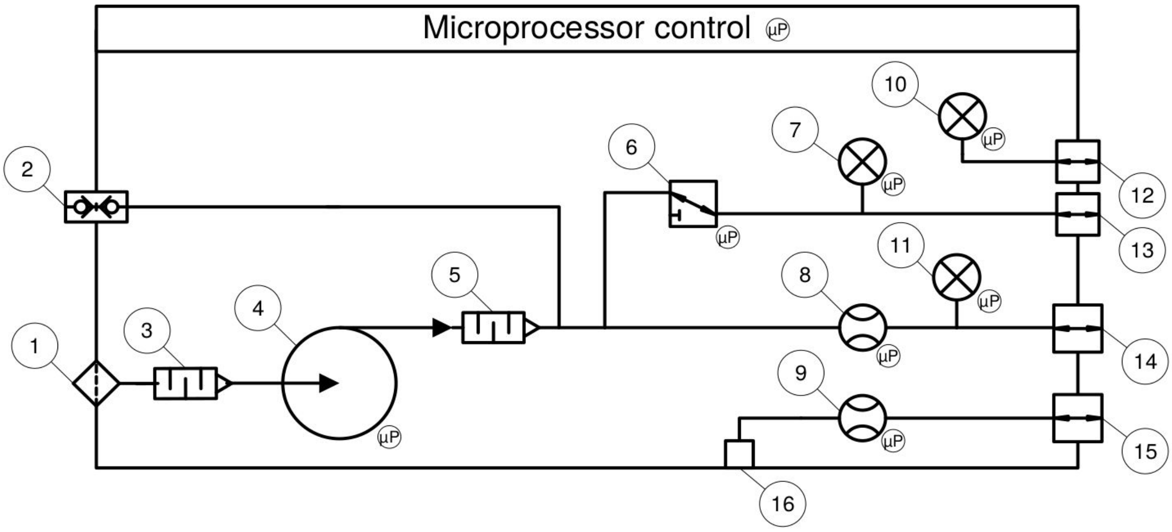
Traditional anaesthesia machines

These things are fantastic workhorses. Simple and reliable. Unfortunately they are far more complicated (in some ways) than they need to be, notably including piped nitrous oxide and fittings for volatile anaesthetic vaporisers. These machines also include soda lime canisters for carbon dioxide scrubbing to allow rebreathing which helps reduce consumption of nitrous oxide and anaesthetic vapours. However, neither nitrous oxide nor volatile anaesthetic are needed for an ARDs ventilator. The automated cut over valves to cylinder back-up gas is worth noting.


(source)

Medtronic 2009

This is Medtronic's schematic from here for their PB560. It draws air (1) through a high speed low-inertia turbine (4) via some mufflers (3 and 5). Inspiratory gas is blended with low-pressure oxygen via a one way valve in (2) before passing through both flow (8) and pressure sensors (11). Exhaled gas returns via (15) and passes another flow sensor before being released (16). Pressure at the patient-side Y connector is monitored via (12) and (10). Some kind of control valve (6) and back-up pressure sensor (7) control the patient "exhalation valve" (I haven't seen this style of plumbing with an external exhalation valve in some years.) This turbine system also includes continual oxygen concentration monitoring.

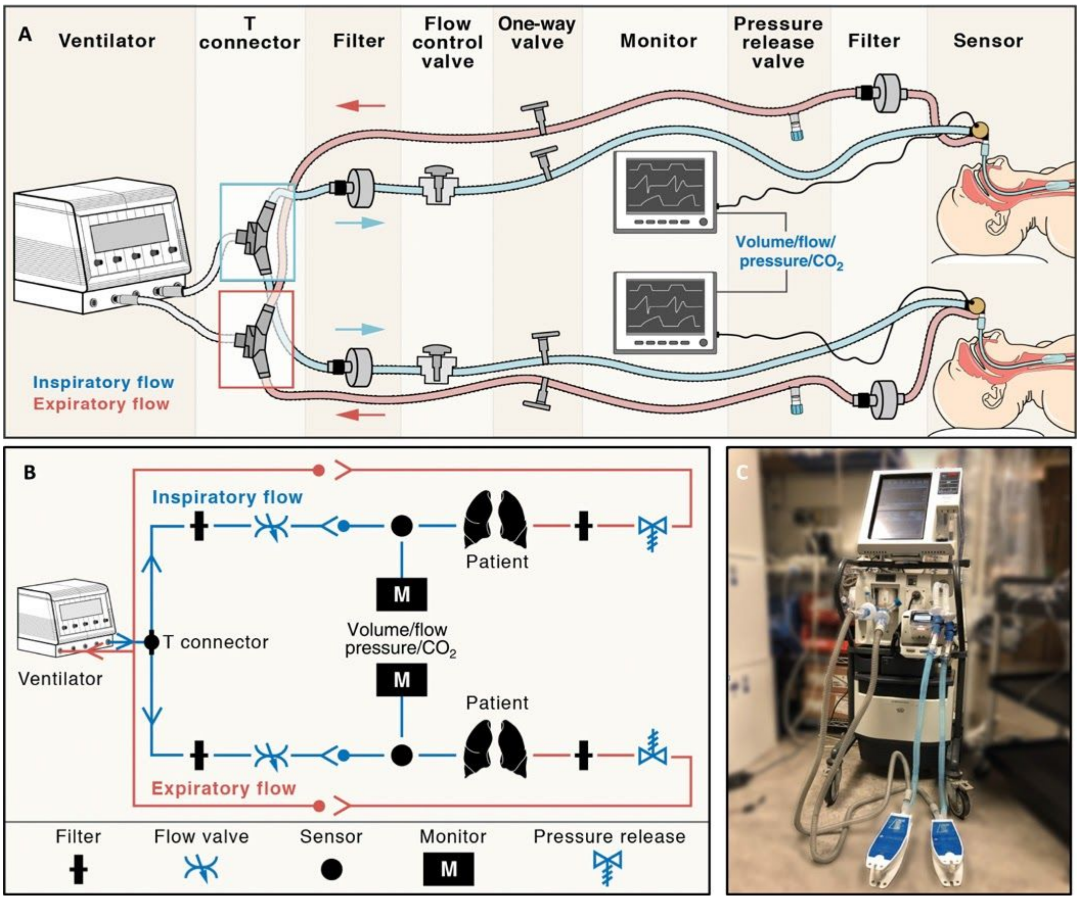


Fluidic approaches

The world wide ventialor and ARMEE teams are using what I believe is a fascinating, and very clever, old US military design. I'm not convinced these could be modified to be a fully functional ventilator. I could be wrong. They would make sense as emergency portable ventilators, if they didn't use 30 litres of pressured air/O_2 mix to run.

Splitting ventilators

A few teams, e.g. https://www.differentialmultivent.org, have looked at this (and there are a few papers on the topic too). The approach has advocates, (etc) but I'm not a huge fan, primarily because you lose the ability to synchronise with patients' own respiratory efforts. Others, such as Society of Critical Care Medicine (SCCM), American Association for Respiratory Care (AARC), American Society of Anesthesiologists (ASA), Anesthesia Patient Safety Foundation (APSF), American Association of Critical-Care Nurses (AACN), and American College of Chest Physicians (CHEST) have raised their own concerns. You also have challenges managing cross-infection (a really nightmare in ICU patients), and regulating FiO_2 and inspiratory pressures. Flow restrictors can help adjust inspiratory pressures but they are going to be quite finicky and need constant tuning. PEEP is the one element that should be relatively easy to control.



source

Components

You've noticed, I am not an engineer, but I've had a few thoughts about what will work better for different components.

I discuss each hardware component in detail in a Volume 2 around a couple of specific design approaches. Below are a few notes about the broad components.

Pressure generator

People seem to be underestimating the power required to run a proper ICU ventilator. Many solution developers, even universities, are making "bag squeezers". I can understand the attraction however I'm quite certain that this is not the best approach to the challenge that we are facing. (see "The case against bag squeezers" in the introduction). We need a solution that can exhibit dynamic behavior and be able to interact cooperatively with the patient’s own respiratory efforts and actions. Such a solution can take advantage of cheap modern off the shelf electronic parts and widely available microprocessors and electronic sensors.

Commercial ICU ventilators can deliver flows as high as **60-120l/min and achieve pressures of 40cmH$_2$0 or more**, operating in a tight control loop, capable of adjusting air delivery flow to maintain a pressure deviation of no more than 2cmH$_2$O from set value, in response to changes in patient state. The Australian government has requested 150litre/min. I believe surge ventilators need to aim for this level of peak performance.

The two broad strategies are either to pulse high pressure gas, or to decompress the gas before repressurising with a pump of some type. Both strategies are used effectively in high-performance modern ICU ventilators.

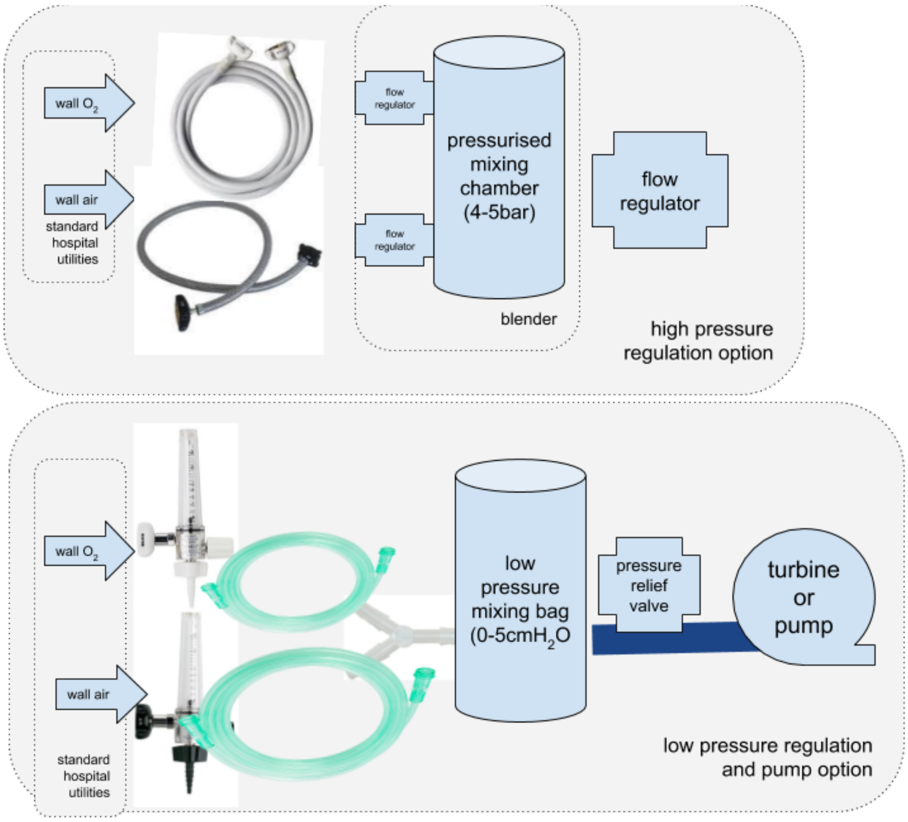
I think, but I'm not sure, that the best solution is the former, using a high pressure blending chamber for air and oxygen, as in the Tesla ventilator.

Alternatives for pumps include:

- linear diaphragm compressor (LDC)s,
- a turbine based pump or
- squeezing a bellows with a pneumatic or motorised driver.

Whatever you use it must be responsive to signals from the microcontroller.

This doodle illustrates two broad approaches that I explore in more detail in the component document:



Valves

There are so many valves! See Volume 2.

The case for redundant flow and pressure sensors

You must include two flow meters (or sensors) in your design, and probably in addition, two pressure sensors as well. Even if your product is a simple bag squeezer.

This allows testing of both non-return valves and importantly the patient inspiration valve. Failure of these valves is very dangerous as it may not be recognised by the care team and as a result it may be fatal. This would be true even in a well resource ICU with experienced staff as this is not something they are trained to look-out for as modern ICU ventilators come with dual flow meters. Simply flashing a warning "Leak detected" or "Sensor Fault" or "No expiratory flow" may be enough of a clue to prompt the care team to disconnect the malfunctioning unit and replace it with a temporary solution like a back-up Ambu-bag from the nurses station. Otherwise in the panic of a “blue patient”, the inexperienced doctors may simply crank up the FiO2 to 100%, air delivery pressures, rate and volumes, reacting to a bunch of alarm sounds. Medical staff may even misdiagnose a pneumothorax condition and place an intercostal catheter.

By performing a start-up test sequence each time that the machine starts it is possible to validate the operation and accuracy of both flow and pressure meters before the ventilator goes into service, as well as the critical valves. During the test sequence, and in real time, it is possible to validate that both flow meters are measuring roughly equal values when averaged over a minute. Also the pattern of flow should be, to state the obvious, recorded in the inspiratory manifold during inspiration, and then in the expiratory valve during expiration.

Finally, having accurate flow meters helps to cross validate the performance of the pressure valve.

How much does a second flow meter cost?

Notably it was this pattern of vulnerability that contributed to the grounding of the Boeing 737-MAX. In the 737-MAX that crashed, although there were two angle of attack sensors present, only one sensor was connected to the control system. Unlike in aeroplane, the timely recognition of a fault is all that is required to enable lifesaving intervention by the treating team.

Context and operating environment

Hospital Context

For ventilator design, it is safe to assume that:

- There will be "medical air" and "medical oxygen" available at 4-5bar (generally from a wall gas outlet, occasionally from a cylinder.) If that's not the case then maybe rewind a step and address that first.
- Compressed air should be in plentiful supply, but try to conserve oxygen (aim for less than 10l/min or less).
- There are generally dedicated wall suction outlets that can be plumbed in to provide scavenging of exhaust gases
- There will be a 99% reliable power supply at the normal national standard voltage.
- There are likely to be very smart people around, but they may be tired, busy or asleep.
- Leaks of expired air introduce the risk of contaminating the environment with viral particles, similar to a patient coughing. So it would be nice if things didn't leak, especially into places where a technician may need to go (it's not the end of the world, but ick?)
- Leaks of high oxygen gas into housing with electronics could be a fire/explosion hazard

Moisture and humidity

Gases leaving the ventilator are typically cold and dry due to sudden expansion, until warmed and humidified in an external humidifying device. The gases returning from the patient air exhaust circuit (even if there is no external humidifier), will be warm and humid.

Moisture condensing in the expiratory manifold could short electronics and risks build up of mold or legionella organisms over time. So ideally electronics will be water resistant and the thermal properties of the ventilator will passively cool the expired gas and trap the expired moisture before it enters the hard to clean expiratory manifold.

Scope and Operational Assumptions

Maintaining a patient on the ventilator requires much more than the ventilator machine itself. These other equipment, consumables, and staff, should be addressed in separate projects. In the order of resource scarcity, ventilators are currently seen as the most precious resource and a major bottleneck. This is followed by the availability of trained staff and PPE. Most hospitals will be able to stretch out existing resources to cover monitoring (except integrated ventilation pressure and volume monitoring) as well as relevant drugs (hopefully).

OpenSourceVentilator identified the following reasonable assumptions:

- Regulatory bodies may waive clearance or reduce regulatory barriers for medical devices to be deployed for emergency interventions.
- Traditional certified medical components and supplies used in ventilators will be in short supply.
- Supply chain and local logistics will be impaired or disrupted.
- Non-medical supplies, manufacturing systems and components will be readily available globally.

Covid19

Covid19 is caused by the SARS-Cov-2 virus. It primarily affects adults.

A common cause of death is *acute respiratory distress syndrome* (ARDS), which will often respond to 7-14 days of mechanical ventilation. Early guidance was that higher PEEP values were needed relative to normal ICU patients, but this guidance is still fluid, changing almost daily.

The overwhelming demand for mechanical ventilators will be to cover the typical 7-14 days of ARDS treatment.

From a session hosted on 3 April 2020, 10:30 to 11:30 am, by the Intensive Care Society as part of the National Emergency Critical Care Committee:

- COVID-19 appears to have several phases. Management should be guided by timing of the onset of symptoms to understand where in the trajectory of the disease the patient is.

- Early phase of respiratory failure primarily affects the vasculature. Pro-coagulation leading to micro-vascular pulmonary thrombosis has been observed. Lung compliance is generally good.
- Later respiratory failure can involve ARDS and bacterial pneumonia

Mechanical Ventilation

- Aggressive ventilation in the early phases of treatment may adversely affect later outcomes. The starting PEEP and tidal volumes should be lower than previously recommended – PEEP of 10cmH_2O appears satisfactory for many.

Patient states

From a ventilator's perspective, patients can be in one of the following states:

- Actively breathing in
- Actively breathing out
- Coughing (rapid explosive inspiratory and expiratory effort at around 2Hz cycles) - ideally the ventilator will sense the rapid transitions from inhaling to exhaling and respond accordingly - many commercial ventilators struggle to do this effectively but some manage better. This is one of the reasons why ventilators must include various pressure relief valves.
- Sighing - have an unexpected big breath in then out
- Breath holding (imagine being on the toilet and straining). Essentially all the muscles in the ribs and abdomen contract and this leads to almost complete loss of compliance. This state can actually be difficult to manage and need medical intervention to paralyse the patient or to sedate. From the ventilator device perspective this can be impossible to differentiate from obstruction, pneumothorax, or asthmatic bronchospasm. Younger people, smokers, and those with sleep apnoea tend to exhibit such behavior more often. In practical terms, there is not much that the ventilator can do, except trigger an alarm indicating that the circuit pressure is too high or that the volume set by the device operator has not been fully delivered to the respiratory system.)
- Apnoeic (pronounce "app-knee-ick") (that is floppy and passive - usually due to heavy sedation) - this state might persist for only 10-15 seconds, or alternatively, last for days. Note that the simple ventilator proposal generally assumes, and could briefly work effectively, for a patient in this state. The problem is that shuffling patients from a dumb ventilator to a smart one whenever they wake up and breath on their own would be logistically impractical in an already stretched ICU. Keeping patients deliberately apnoeic leads to wasting of the respiratory muscles that the patient will need to wean.
- Disconnected - the gas leaves the ventilator but nothing comes back in the expiratory manifold - Yes, this actually happens and it is potentially a fatal condition! If the ventilator device ever observes this condition it must produce a distinct, attention grabbing alarm.

Don't panic - all of things are manageable. Hopefully being aware of what the patient may be doing helps to explain the motivation of various requirements.

Ventilator control modes (pressure or volume)

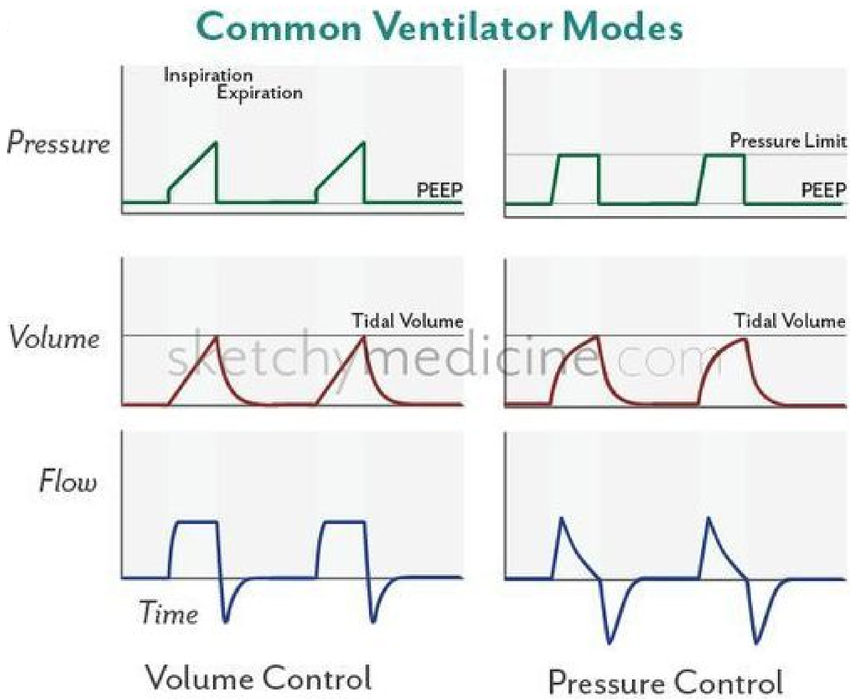
tldr: The simplest option is to make a ventilator that delivers air at a set pressure (pressure control) and reports the actual volume delivered. Then either the user (as in PCV) or, better yet, the software (as in PRVC) can tune the pressure to achieve the desired volumes.

There are two broad patterns of ventilation "volume control" and "pressure control". Both are used commonly and there are quite a few hybrid modes in modern full-feature ventilators.

In **volume control ventilation** (VCV) modes the user sets the volume to be delivered (ie 500ml), and the ventilator calculates the flow rate using the inspiratory time. For example at a RR of 12, and Inspiratory to expiratory ratio (I:E) of 1:2, then the ventilator knows that it has 60/12=5 seconds for the entire breath cycle, and only a third of 5 seconds for inspiration (~1.7 seconds). In this mode the inspiratory flow remains constant but the pressure gradually increases. This is the oldest, simplest method of mechanical ventilation. I use it most days, but for ARDS patients I would generally choose a different mode.

In **pressure control ventilation** (PCV) the user sets the inspiratory pressure (or the ΔP, which is the inspiratory pressure minus PEEP). So in this mode the inspiratory pressure is constant but the flow tends to decrease as the lungs expand and become less compliant.

The preferred[ref] control approach is one of the hybrid approaches: **pressure regulated volume control** (PRVC): In this mode the user sets a set tidal volume while an electronic control system tunes the ventilator to the lowest pressure possible in the airway. The key difference from VCV, is that once the ventilator is tuned, the pressure waveform is similar to that of PCV.



In both pressure and volume control modes the compression of the gas and the compliance of the flimsy, flexible plastic circuit introduce some error, that may not be awfully significant.

In volume control modes the ventilator will usually alarm if a certain pressure is reached (eg 35cmH_2O, and will limit pressure to 40cmH_2O in order to prevent lung damage.

In pressure control modes the ventilator will alarm if it senses that the delivered volume is out of bounds (eg <200ml, or > 1000ml).

The "high pressure right from the start" in pressure control is slightly more efficient than the gentle ramp up of the pressure in volume control. In most patients the overall impact is small, but particularly in patients with airway disease (not a feature of Covid19) this extra efficiency is important.

In terms of evidence of which one (VCV or PCV) is better, there is actually not a lot:

> "Studies have been published since the early 1990's comparing VC-CMV and PC-CMV. An article by Rittayami et al., published in 2015, was a comprehensive review of published studies comparing VC-CMV to PC-CMV. According to Rittayami, there were no differences in physiologic or clinical outcomes between the two modes and that adjusting the ventilator settings based upon the patient's individual characteristics may help to reduce lung damage, minimize work of breathing, and improve patient comfort [3]. Findings from a 2015 Cochrane Review by Chacko, et al., stated that there was insufficient evidence that PC-CMV improved outcomes for people with acute lung injury when compared to VC-CMV. The authors suggested that not only more, but larger studies may provide evidence as to whether PC-CMV improves outcomes when compared to VC-CMV [4]." (source)

Read more on cycling here.

Software and control aspects

April 11: This section has moved to a new volume 3, covering best practice, human factors and usability, ventilator states, start-up test sequence, triggering and timing, display and alarms.

Vol 3: Software and control

Ideal features of a "surge ventilator"

- Short time to availability
- Ideally, the ventilator must be able to run for 15 minutes or longer if there is a power outage (ability to work from off-line independent power source, such as regular car battery would be reasonable)
- Should conserve oxygen (ideally, 90% of gas entering the machine should be delivered to the patient's lungs)
- Modular, well documented and easy to service
- Operating software must be field upgradable and easy to acquire
- Optionally allow connection to medical oxygen and air cylinders for backup operation. Alarms and automatic switch-over from facilities gas supply to bottled oxygen in event of pipeline failure is a very desirable safety feature
- Accept data specific to the patient to be manually entered by an operator. For example, entering the patients' height and sex. Patient height and sex are used to calculate ideal body weight. **Note**: Ideal body weight is computed in men as 50 + (0.91 × [height in centimeters −

152.4]) and in women as 45.5 + (0.91 × [height in centimeters − 152.4]). The display can then show tidal volume in ml/kg_{ideal}.

- Manage removal of expired moisture in the expiratory manifold.

Potential extra specific features

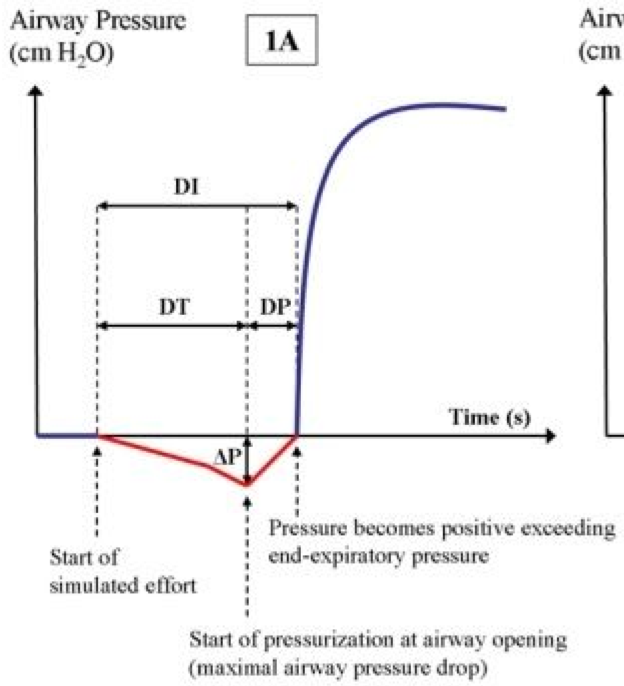
- **If oxygen is in critically short supply** it could be possible to use a closed loop gas recycling circuit with CO_2 scrubbing, or "circle" circuit. This capability is standard in ventilators used in operating theatres because, up until about 10 years ago, nearly all anaesthesia involved use of inhaled CFCs (eg sevoflurane) and nitrous oxide (a potent greenhouse gas). In recent times we've started using less CFCs and have started using intravenous anaesthetics (generally propofol), but as anaesthetists, we're all used to these "circle" circuits now. Patients typically consume about 3ml/kg/minute of oxygen gas, and exhale almost as much carbon dioxide (CO_2) gas. Most ventilation in healthy patients is aimed at clearing carbon dioxide from the lungs rather than supplying oxygen. In diseased lungs however, oxygen delivery via the lungs and then to blood and then the brain, becomes the critical issue. To be honest I do not think oxygen shortage is likely to be the critical shortage. You can do a web search on circle circuits if you are curious.
- **Portability** is a potentially useful feature in a perfect ventilator, but is not essential. Generally if a patient needs to be transferred between hospitals or to have a scan performed, the treating team will sedate and paralyse the patient and change them over to a simpler portable device. Very few commercial ICU ventilators are "portable", although most will have a battery for back-up and ability to connect to cylinders.

Testing and performance evaluation

The UK government, again, has spelt out quite a thorough test plan.

As a way of benchmark the French Groupe de Travail sur les Respirateurs evaluated ICU thoroughly evaluated ICU ventilators. In order to test spontaneous respiration they used a commercial "double lung" device where one ventilator could be used to simulate patient effort.

This device enables evaluation of a key performance characteristics of the ventilators as a ventilator senses that the patient is attempting to breath and then starts to provide pressure.



The best ventilators can achieve a DI under 70ms in most conditions, and under 100ms in the most taxing.

Volume 3 covers pre-use test protocols, and Volume 4 touches on this topic too.

Resources and open source projects

Other people have laid out specifications:

- UK Coronavirus (COVID-19): RMVS ventilator specification
- Australian TGA specification
- USA FDA Authorisation, and Association for the Advancement of Medical Instrumentation AAMI Emergency Use Ventilator Design Guidance
- Medrontic's 2009 specification is also potentially useful
- Surge Capacity Mechanical Ventilation (2008 Respiratory Care journal paper)
- Specifications for a Pandemic Ventilator for Coronaviris COVID-19 (by the Panvent team)
- Mexican government (Spanish)

Reviews of existing options

- A review of open source ventilators for COVID-19... https://doi.org/10.12688/F1000RESEARCH.22942.1

For a catalog of open source projects you should use Robert Read's comprehensive list here. This is very incomplete, semi-random list of the many projects I've discovered is here:

- Open Source Ventilator Project (University of Florida) - using a sprinkler valve and inflation balloon valve.
- MIT E-vent - a bag squeezer
- VentilAid - an cool open source 3D printable project with a piston bellows and laudable goals
- Panvent - https://panvent.blogspot.com/
- OxVent (@OxVent): - bag squeezer
- Open Lung - bag squeezer
- Mark-19 based on the bird ventilator
- Un-named Italian? group
- Open Source CoVid-19 Ventilator Canada - using a Linear Diaphragm Compressor (LDC)
- Openvent Pakistan and facebook post - bag squeezer
- many others

Other

- Reference chart for 3d printed material and sterilisation
- Paper The basics of respiratory mechanics: ventilator-derived parameters
- Paper Clinical management of pressure control ventilation: An algorithmic method of patient ventilatory management to address “forgotten but important variables”
- Get yourself published: Special Issue on Open-Source COVID19 Medical Hardware - Call for Papers
- How to Improve Your Arduino Ventilators: Intro to RTSs and SCSs for Makeshift COVID-19 Ventilator Designs
- Catalog of potential manifold components by UQ Engineering students
- Catalog of plastic bits and pieces common in hospitals
- History: The Mechanical Ventilator: Past, Present, and Future

Glossary and typical values

- airway device - normally an endotracheal tube. There are other options, including facemasks. They are out of scope. Note some devices are prone to leaking, which means that sometimes a ventilator may not get back as much gas as it puts into the patient.
- apnoea - not breathing
- asynchrony - the patient wants to do one thing, but the ventilator wants to do another
- circuit - in this context we're talking about the 22mm flexible hoses and associated fittings that connect the ventilator to the patients' airway device.
- compliance - $\Delta V/\Delta P$
- dead space - this is part of the tidal volume that doesn’t reach the alveoli, but that serves merely to push gas to alveoli. It's about 2ml/kg in adults ("anatomical dead space", including pharynx, trachea, bronchi etc). Using a ventilator always increases daapspace a bit ("equipment dead space"), but the splitting of the breathing tubes into expiratory and inspiratory limbs keeps this to a minimum.
- expiration or exhalation- breathing out
- FiO_2 - fraction of oxygen in inspired gas, ranging from 0.3 to 1.0
- I:E ratio - ratio of time spent in inspiration to time spent in expiration. Typically 1:2 but anywhere from 1:4 to 2:1

- Ideal body weight - how much you would weigh if you were a healthy weight. In men it is 50 + (0.91 × [height in centimeters − 152.4]) and in women it is 45.5 + (0.91 × [height in centimeters − 152.4]).
- inspiration or inhalation - breathing in
- humidifier - both warms and humidifies inspiratory gases, normally an external unit with its own power supply and a little water reservoir. (As far a know, the units used by CPAP patients are adequate)
- minute volume - roughly actual mean tidal volume times respiratory rate (around 6l/minute)
- paralysis - means the muscles do not work - in the context of a COVID pandemic this is most likely because the ICU doctors are giving drugs that block nerve signals to the muscle (NMJ blockers, such as rocuronium and many other related drugs). The problem with paralysing someone for more than a few hours is that the muscles begin to weaken, and this makes it harder for the patient to ever get off the ventilator). - see also "sedation"
- PEEP - "positive end expiratory pressure" - simply pressure during expiration, or "back pressure" (normally $5cmH_20$ in a healthy patient, but as high as $24cmH_20$ is severe Covid19 pneumonia)
- PCV –Pressure Controlled Ventilation
- VCV –Volume Controlled Ventilation
- PRVC–Pressure Regulated Volume Controlled: A hybrid mode of ventilation where a set tidal volume is delivered to the patient while an electronic control system tunes the ventilator to the lowest pressure possible in the airway. This is the preferred control approach [ref].
- plateau pressure - the pressure observed in the circuit at the end of inspiration after the flow has ceased. This pressure reflects the pressure that the lung tissue is exposed to and should be kept <= 30 cm H2O to avoid damaging the lungs.
- recruitment - briefly increasing the pressure to open up the little air sacs in the lungs. This can do more harm that good. Well covered here. Australian Covid19 specific guidelines currently recommend against staircase style recruitment.
- respiratory rate - breaths per minute - normally ~10-15, but potentially up to 30/min, or even 60/m in some protocols (more likely to use fast rate in children, so 30 is a reasonable maximum, but if your hardware can support 60/min let the user do it if they want - you just never know)
- sedation - this can mean anywhere from just a bit sleepy to deeply unconscious. ICU doctors try to use the least sedation they can, because patients will wean better. A frequent reason patients need sedation is that they are fighting against the ventilators. (There are many sedative drugs including midazolam, ketamine, opioids, propofol).
- tidal volume - volume of gas inspired during a breath (typically this is around 350-600ml (rarely as high as 800ml). This is useful to know in terms of ml/kg of ideal body weight.
- triggering - the act starting inspiration, often the patient starting to breath in causing a pressure drop in the circuit.
- weaning - the important process of gradually allowing the patient to do more of the breathing for themselves. The more respiratory work a patient has been able to do while on a ventilator the more rapidly this will occur.

Continue on to Volume 2.