

ICU Ventilator Tech Primer

Disclaimer

The information contained in this document is for educational purposes only. It is a primer for engineers to get an overview of the technical problem at hand. It may not be 100% accurate and should not be used in any medical capacity without being peer reviewed, tested by experts and the appropriate authorities.

For any information about COVID-19 please refer to your government health advisory.

Treatment of chronic illnesses should be done in a controlled medical setting by trained staff. Using untested medical devices on yourself or others can cause permanent injury or death.

Introduction

Due to the global COVID-19 pandemic many popup clinics around the world will need access to a large quantity of mechanical ventilators. These clinics will have varying local conditions - many will not have reliable electricity supplies or sufficiently trained staff. Modern hospitals will also face equipment shortages and the demand may rapidly outpace supply for ICU grade ventilators familiar to doctors and nurses around the world.

Additionally, with border closures, the global supply chain has been significantly interrupted. As such, multiple design solutions should be considered to cater for local material and human resources and anticipated shortages.

ICU Ventilator Outline

- Off the shelf parts where possible
- Some 3d printed parts if needed until injection moulding manufacturers are online
- Plastic moulded body with ICU compatible stand.
- High grade microcontroller design with multiple redundancies and failsafes.
- Simple control panel with potentiometers, buttons and LEDs.
- Audible and visual alarm.
- Mass producible by local factories

Concept Design

This concept design spec outlines a modern ICU mechanical ventilator. The values are a guide only. For reference the pressures that the lung is operating at are under 1psi - compared to 100psi for typical industrial pneumatic systems.

Design Specs

The UK Government has released a design spec which now supersedes this one. I have left it in for reference only. *Upon further review the UK Govt model should be a bare minimum. The below and Johns Hopkins specs are ideal*

These specs are based on commercial models that medical personnel are familiar with.

- Familiar interface and controls for clinically trained operators
- Central control input for stable and fine adjustment of parameters
- Central display/led signals for clear readout of status
- System to check for failure of the main system and sound alarm
- Run off mains power (240V)
- Battery backup (4 hours)
- Safe to handle and touch (spill proof, shock proof, no sharp edges to tear PPE)
- Easy to wipe clean
- Easy to change between patients
- Attaches to standard ET medical tubing
- Scalable manufacturing
- HEPA filter on exfiltration
- Bacteria filter
- Can be overridden or disconnected in case of emergency (manual intervention)
- Failsafes - alarm, battery, manual intervention
- O2 sensor to record fraction of oxygen - alternatively this can be measured using blood tests.

These specs have been given by doctors using the equipment for ARDS.

- Provides 100cmH2O pressure
- Provides up to 3L/s flow rate
- Outlet pressure - 50cmH2O
- Pressure sensor spec - 100cmH2O @ 10Hz min. Ideally 100Hz
- Flow sensor - 0-3L/min @ 10Hz min. Ideally 100Hz
- Maximal breath capacity - 900mL in 0.4s
- Standard bag valve on exhaust with PEEP valve - off the shelf
- PEEP pressure 0-30cmH2O (5-15 setting)
- Inspiratory hold maneuver feature - press button on machine to activate

Detail Design

This paper goes into great detail on the design and function of mechanical ventilators. The following section outlines the system design and function of the basic components. Additional resources can be found online.

https://www.researchgate.net/publication/13113699_A_new_system_for_understanding_mechanical_ventilators

System Overview

A ventilator pushes air into the patient's lungs to help them breathe and has sensors to detect pressure on the inlet and outlet of the device. Modern ventilators use hospital supplied pressurised air and oxygen at 4-6bar. They are very similar to industrial pneumatic control systems. Oxygen and air are mixed to provide the desired ratio for treatment.

The supply and regulation of pressurised gases is outside of the scope of this project - hospital air and oxygen comes out a port in the wall, or bottles can be used.

A mechanical ventilator has many modes of operation. To avoid confusion with operators, the modes and interface of the machine should match currently used commercial models.

A microcontroller is used to control the volume, pressure and flow rate of the system. Commercial devices have dual controllers for redundancy.

Usually only pressure or volume is measured and then the other can be calculated.

Medical equipment should not cause further harm to the patient. The design should be defensive and have multiple failsafes and redundancies. The design must be more conservative if components of lesser quality than usual are used (or available).

Equipment Failure Mitigation

The design of life saving equipment should protect the patient from the event of equipment failure.

Audible and Visual Alarms

Carers should be alerted to any issues with an audible and visual alarm (LEDs on top of the unit). These signals and alarms should match current commercial ventilators to ensure clear communication with carers. These alarms must also be able to be silenced by carers (clear alarm button).

Hazards

Potential hazards in electronic equipment are shock and static electricity. Best practices for insulating mains voltage equipment should be followed. The plug that connects to the mains powerpoint should be a standard size and design to allow for connection to a standard hospital wall outlet, alongside other equipment.

It is common for hospitals to use liquids and gases near electrical equipment. These liquids could be medication, water, salt water (corrosion hazard) and there are biohazards such as blood and bodily fluids. Oxygen is used and presents a spark and fire hazard.

MRIs also present a significant magnetic hazard but are outside the scope of this design. Eliminate this hazard by keeping the unit away from large magnetic fields.

Radio signals such as those from mobile phones could cause interference. Consider electrical shielding.

While the patient is in ICU and on mechanical ventilation, they are sedated but not lifeless. The patient is breathing with assistance and may even cough or sneeze (high pressure spike). Additionally, with ARDS and COVID-19 it has been recommended that the patient must also be rolled onto their stomach for 12 hours a day. This movement could damage hoses over time or suddenly and cause leaks in the system.

Automatic Triggering by the Patients Inhalation

When the patient starts to breathe in, it should trigger the system to deliver air to the patient (assisted delivery). This is triggered by a detection of pressure drop.

Electronic Controller

The electronic controller has 2 identical microcontrollers both running the same software. These are purely for system control.

Due to time constraints, these should be off the shelf commercial controllers such as those used in industrial automation.

If possible, a parallel team should work on a circuit board to be designed and manufactured using available local manufacturers to prepare for supply line interruptions. Secondary systems such as the display (if any) should run off a separate controller.

The microcontroller and electronic board should be reliable above all else. The microcontroller should be simple and slow, not fast and fancy.

System Validation

A test rig will be needed to validate the performance of the ventilator falls within required specs.

The device should have self calibration and self testing modes similar to current systems.

Manufacturing and Assembly

This should ideally be done under clean room conditions. The ventilator should be clean and sterile upon delivery.

Educational Resources

Mechanical Ventilator History

- 1850 Early designs.
- 1900 Negative pressure designs - iron lung and polio. Positive pressure design problems.
- 1950 Positive pressure mechanical design problems solved.
- 1970 Microcontrollers replace mechanical systems and extend treatment options.
- 2010 Complex automated systems, touchscreen displays, connectivity.

Operating Ventilators vs ICU Ventilators

Mechanical ventilators were originally designed for operation under anesthesia. These patients have healthy lungs, are only ventilated for a short period of time and are monitored closely by highly trained staff. Therefore these ventilators don't need to be too complex. For many decades simple mechanical and pneumatic ventilators worked well for this purpose. Modern ventilators are now completely digitally controlled with many parameters that can be adjusted depending on the respiratory therapists needs.

For ICU use, ventilators are required to operate uninterrupted for long periods of time (weeks to months) and with only occasional checkups. Patients with damaged lungs require very careful treatment as to not cause further harm to the patient. Modern ICU ventilators can automatically adjust to varying patient conditions or alert carers.

Additional complications due to the length of treatment with a ventilator - drying of the patient's throat, further infection or death can occur.

Using a ventilator while the patient also has an infectious disease, such as COVID-19, requires filtering at key points to prevent contamination of the machine and the room. Poor setup or failure can result in ejection of the infectious disease into the air, creating a significant hazard for carers.

Other problems can occur over the patient's treatment period, such as operator complacency and fatigue, errors in patient data management, risk of power outages, sudden systems failure and material fatigue failure. These can be managed with staff protocols, backup batteries and generators and preventative maintenance.

Lung Function and Care

Lungs are biological gas exchangers that allow oxygen to enter the body and carbon dioxide to exit it. Breathing is usually done using your diaphragm muscle. When lungs are very damaged a ventilator is used to assist or completely breathe for the patient.

Lungs are commonly compared to balloons but in reality, simply inflating and deflating the lungs does not treat ARDS. In fact, it can make things worse!

The treatment of ARDS requires great care that the lungs are not fully inflated or fully deflated. Fully inflating the lungs (or worse, overinflating) can cause further irritation, severe lung damage or death. Fully deflating the lungs can cause part of the lung to collapse and fail to reinflate, resulting in reduced oxygen intake and therefore eventual death.

Treatment of ARDS and COVID-19

What is ARDS?

Acute Respiratory Distress Syndrome (ARDS) is a severe respiratory illness that requires careful and prolonged treatment of the patient's lungs.

What about COVID-19?

COVID-19 is a highly contagious disease that can cause ARDS in acute cases. Patients must be isolated and strict PPE protocols must be followed to prevent the spread of the disease to carers while the patient is ventilated.

Why do we need a ventilator?

In acute cases a ventilator is needed to help the patient breathe while their lungs recover. A tube must be placed down the patient's throat (intubation) so this is an invasive procedure that must be done by trained staff in a clinical setting.

Current data suggests that with COVID-19 it can take 2-4 weeks until the patient can breathe on their own again. During this period patients need continuous care and monitoring. Adjustments are made to the ventilator settings by trained operators to accommodate different patients, and are continuously adjusted over the course of a patient's treatment.

What are the risks of ventilation?

Ventilation can worsen symptoms, create new complications or cause death. Lungs are sensitive and complex biological gas exchangers and can be easily damaged by overpressure, lack of oxygen, mechanical system failure or operator error.

COVID-19 is highly infectious and leaks or disconnection of the tubing can cause the virus to spread further. It can also contaminate the ventilators themselves.

Modern ICU Mechanical Ventilators

This information outlines the specs of modern ventilators. The details vary between manufacturers. See manufacturer's websites for detailed documentation.

Features

- Full pressure and volume measurement in and out of patients lungs.
- Oxygen monitoring and variable oxygen mixing

- Bacteria and HEPA filters
- Overpressure failsafe
- Electronic control with dual controllers for redundancy
- Battery backup (4 hours)
- Mains power supplied
- Compatible with hospital procedures and setups
- Easy to override the ventilator with a manual bag without removing the intubation tube
- Easy to transport
- Easy to clean and maintain
- Many adjustable settings
- Digital touch screen display
- Advanced features: advanced automated detection tools, connection to other machines, online connectivity tools for patient monitoring, online training integration, one product that can be customised to suit needs around the hospital.

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