

Background and personal position

On Monday, March 23rd, I read from Heise (a German tech news channel) of a tender from McGill University in which the development of easily replicable ventilators is stimulated. The background to this is that ventilators will be the critical resource if the Covid19 pandemic wave continues to roll through the world without significant slowdown.

My understanding of this call for tenders is that of a demanding medical project with admissibility, almost at pre-production level, is required as a condition for participation. **To fulfil this requirement I am far too late, but on the otherhand, I am convinced that it is clearly too late for requesting such an elaborate design to make a difference.** If you want to make a difference with a development, you have to make optimal use of existing resources.

I myself have started to think of possible implementations of a simple ventilator that can be replicated essentially anywhere (one of the important basic ideas of the McGill tender), but which use widely available resources as far as possible. I have no economic interests in this project, I would be happy, if it takes longer, to contribute to my livelihood and keep my back clean to any rights holders.

Currently I lack some knowledge of the details of clinical ventilation, so I will quickly need to find a technically interested specialist as a sparring partner. I'm convinced I'll find one in the bubble I'm living in.

Assumptions made

Resuscitators with patient valve (and possibly PEEP valve), intubation tube and possibly as an emergency aid mouthpieces will be available in sufficient quantities worldwide. In critical times, a used intubation tube is boiled out and reused, the patients all have Covid19 anyway. Hopefully the industry is already producing these items 24/7.

Compressed air (car workshops, petrol stations, etc.) and electricity (at least 12V from automobiles, possibly with cyclical battery replacement) are available worldwide. Oily compressed air can be filtered in a tube using locally built filters from layers of fabric. The fabric is changed every day. The air is only control air, not patient air.

Small controllers (here ESP8266 / ESP32 etc) are available in large quantities.

Standard solenoid valves for compressed air are IMHO available in bulk quantities, whether 3/2, 5/2, 2/2, 12 or 24V, together with connection nipples and possibly cable ties to secure the lines, at least much more readily available than geared motors on which other designs are based.

Android smartphones are ubiquitous. People can handle them too.

All over the world, even in poor areas, there are skillful car and bicycle mechanics who can start with an explanation and a drawing and possibly modify them according to the locally available components. The global maker community might assemble the more complicated controllers and maintain them by testing and updating firmware.

Security guidelines

Something will certainly break, it only has to be recognized. As far as possible, failures should be survivable for the patient

Ventilator design

A resuscitator is enclosed in a pressure vessel. Here in Europe I would take HT pipe duct components (used for ducts in housing), which are available immediately in large quantities. Adapters may have to be produced for the respiratory bags in order to realize the passage through the pressure vessel wall, this is done quickly on CNC automatic lathes. Nuts for this are on sale in huge quantities in the warehouse in the electrical installation - they are used in fixing electrical ducts.

The respiratory bag inlet and outlet are both led out of the pressure vessel and provide breathing air and eventually pure oxygen to the patient.

The pressure vessels may be prepared with large or small breathing bags - to industry standards - as required. Breathing bags (resuscitators) come in different sizes. We also have small patients.

The pressure vessel gets a compressed air-controlled ReliefValve with a large cross-section, 50..75mm, in order to quickly release the excess pressure in the vessel.

Pressure relief of the control line opens the pressure vessel to the outside. The seals for the ReliefValve may be bought here(EU) from the manufacturers of sink drains, in Africa we might make them out of cut bicycle tubes. The pressure vessel also has a filling connection for the compressed air with hose nipple and a built-in pressure sensor (e.g. Bosch BMP280, BME280)

At the outlet of the solenoid valve, both a hose to the large pressure relief valve and - via a throttle - to the above filling connection is placed. The throttle can be a 'luxury' part of Festo (the local DE pneumatics specialist), in the simplest case the hose (maybe 3..4mm lumen) is clamped between two pieces of wood and the throttle is adjusted with the connecting screws.

Operating pressure : as low as possible - some solenoid valves need a certain minimum pressure, perhaps 1 bar at the outlet, or less, depending on the locally available throttle. I'd prefer a design where the big ReleaseValve doubles as a security valve against excess pressure on the patient lung.

A tube goes from the resuscitator bag - a standard resuscitation hose, otherwise reinforced garden hose - to the patient valve (where switching between breathe in/breathe out occurs) with optional PEEP (pressure maintenance valve for pneumonia patients). An intermediate ring containing a patient lung pressure sensor is set into the tube / mask connection. The intermediate ring might be constructed from an emptied HEPA ventilation filter and adhesive, it is important that the pressure supplied to the patient can be measured. This can also be a simple turned/lathed part with a glued-in sensor.

Basic way of working

The controller opens the solenoid valve for one ventilation cycle. The large valve (release valve) closes, air flows into the pressure vessel through the filling connection and the throttle, the pressure rises and compresses the respiratory bag, the patient valve switches to inhalation, the air from the bag flows into the patient. The pressure curve on the patient and in the pressure vessel is monitored; if the patient pressure exceeds a threshold, the solenoid valve is closed immediately, thus opening the release valve. If everything is running normally, the device is ventilated until the pre-configured time and then the pressure is released, the release valve opens and empties the pressure vessel, the

patient valve switches to exhalation, the resuscitator bag fills up again while the patient exhales. After a preconfigured time, the next cycle starts. If anything does not run normally, the controller alarms and, depending on the malfunction, goes into a malfunction pattern to be determined.

Controller and operation

The controller measures the pressures, controls the solenoid valve, checks the plausibility of the measurement data and triggers an alarm if necessary.

As an interaction with the configuration, I am currently imagining that the controller connects to the strongest visible WLAN access point that accepts the specified password. If you take the AccessPoint to every patient bed during set-up of the ventilation station, you should be able to easily capture all the controllers. New controllers are then taught in next to the relevant access point on the current WLAN and then brought to the patient's bed.

It must be expected that the controller firmware will have to be updated according to new findings. Then new controllers are issued to replace the old ones. The old ones are brought to the local MakerPoint, where they are updated, tested and kept available for new use.

The smartphones of the operators / carers are also logged into the above AccessPoint, possibly 2..3 smartphones per department, so that there is redundancy. In every smartphone, you can locally decide which controllers are to be monitored, as some controllers of the neighboring department may be logged in on the same AP. The controllers send Alive messages at shorter intervals, the smartphones read them. If the Alivemessages go missing for over 30..40 seconds, the smartphone alerts. The controllers are also configured via the smartphones. If the controllers detect critical conditions, they actively alert them via the smartphones. The controller keepalives contain the respective alarm status.

Configuration of a breather

The doctor decides which tidal volume, in what time and at what frequency the patient receives. For this purpose, the configuration is carried out when the patient is disconnected from (tube / mask not connected). The device determines how much time it takes to completely compress the resuscitator bag (when completely compressed the internal pressure in the pressure vessel increases) . The device is calibrated by changing the throttle, i.e. the time that the system needs to completely compress the resuscitator (need not be very precise) is then determined for the patient, which filling he gets (eg bag volume 1600ml, total compression measured in 20 sec, therefore 400 ml are transferred in 5 .. 6 seconds, the additional second due to the initial pressure of the partially collapsed lungs). After connecting the patient, ventilation start and end pressure are measured, quantities corrected if necessary and alarm thresholds are set. The controller determines and saves the resulting pressure profiles in this human-monitored phase.

Monitoring

During operation, the device monitors the pressure profiles, so a pinched breathing tube would cause the pressure in the pressure vessel to rise early (because nothing is flowing out) without patient pressure being present -> alarm. If the patient valve has gone off the hose or the intubation hose off the patient valve, the pressure rise in the pressure vessel is unexpectedly low and there is no pressure at the patient connection -> alarm. If the cable to the solenoid valve is broken, no pressure builds up when the cycle starts -> alarm. If the intubation tube is blocked, the pressure vessel and patient pressure rise synchronously

and clearly too fast -> ALARM. If the solenoid valve remains open, the patient unfortunately gets the full bag volume (hopefully the patient valve has a pressure relief valve, this is AFAIK obligation in the EU), then the pressure vessel pressure increases -> ALARM.

A welcome extension would be to monitor the breathing pressure at the patient connection for spontaneous breathing and to support this. I definitely need help here.

Still open

With a suitable design with regard to compressed air pressure, cross-section of the ReleaseValve etc. one could ensure that the ReleaseValve pressure relief valve doubles as a security valve: max. Internal pressure pressure vessel = working piston area * control pressure / valve area
ReleaseValve <= 65mBar

It would be a luxury to monitor the CO2 content of the exhaled air with infrared sensors in the exhaust air duct: as soon as the CO2 boost at the end of exhalation is missing, something is wrong. The infrared sensors I found in a quick search do not like any condensing water, thus one could mix the exhaled flow in a venturi mixer with compressed air, the relative air humidity will drop IMHO far enough - but also the CO2 concentration in the same direction, which is no problem due to the sensitivity window of the sensors. Most of the sensors available are probably sufficiently sensitive to allow this 'mixing down' without serious loss of information.

A second solenoid valve would also be a luxury to separate the 'ReleaseValve' and 'Fill' functions for greater security, but this could cut the number of buildable devices in half if solenoid valves are the critical component.

Local knowledge of available building materials in different corners of the world would be helpful once the project picks up speed. If the principle is understood, the valves and pressure vessels can be made from a wide variety of ingredients. Also in quantities.