

Proof-of-concept of a minimalist pressure-controlled emergency ventilator for COVID-19

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Abstract

This study concerns the proof-of-concept of a simple ventilator implementing the pressure-controlled continuous mandatory ventilation mode (PC-CMV) with settable breathing rates and expiration/inspiration time ratios, intended as a last resort to ventilate COVID-19 patients.

The design tries to minimize the use of technical components and those used are common in industry, so its construction may be possible in times of logistical disruption or in areas with reduced access to technical materials and at a moderate cost. Most of the device can be manufactured by modest technical means.

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Introduction

Coronavirus disease 2019 (COVID-19) is the result of an infection caused by severe acute respiratory syndrome-related coronavirus-2 (SARS-CoV-2). Clinical presentation ranges from mild respiratory tract symptoms to acute respiratory distress syndrome and sepsis, which can be lethal. Of those infected, there is an important percentage of patients that develops severe SARS-CoV-2 pneumonia and require early mechanical ventilation.

Further than the individual impact, COVID-19 has major consequences for national healthcare systems. The evolution and extent of the outbreak causes enormous pressure and increasing demand for ventilation equipment that may reduce mortality. Most countries will not be able to provide such mechanical respiratory support for all those patients that will need it, as the supply of this equipment by existing manufacturers is notoriously insufficient to meet the demand.

Additionally, the international procurement of the technical materials and components necessary to produce ventilators locally within the relevant timeframe and in the quantities required is likely to be difficult or impossible. For this reason our design emphasizes simplicity and local availability of components and manufacture.

There are many similar initiatives in progress all around the world at this moment. This particular work is rooted in a previous online publication by one of the authors [1], and shares several common ideas with Galbiati's work [2] but with emphasis on reducing the number and specificity of components.

This paper describes a quantitative proof-of-concept test of a PC-CMV mode emergency ventilator that implements the following main characteristics, considered by us as minimal but sufficient for the critical care of COVID-19 patients:

- Positive Inspiratory Pressure (PIP) adjustable in the range 10 to 40 cmH₂O
- Positive End Expiratory Pressure (PEEP) adjustable in the range 0 to 20 cmH₂O
- Pure oxygen operation
- Safety pressure relief valve in the inspiration tube adjustable in the range 0 to 45 cmH₂O
- Breathing rate adjustable in the range 12 to 25 breaths per minute (bpm)
- Inspiration/expiration time ratio (I/E) adjustable in the range 1:1 to 1:3
- Low and high PIP and PEEP alarms can be implemented

Two devices were independently developed for cross-checking purposes, using only locally-sourced components that are likely to be available in large quantities in many parts of the world.

It should be clear that the devices presented below are meant to be for proof-of-concept only and it is not implied that they may be suitable as bedside instruments. Further engineering will be required for that purpose, adapted to the local conditions.

As the components proposed are not medical-grade, the use of a ventilator made on this basis should be considered only as a last resort solution.

Principle of operation

The schematic representation of the proposed emergency ventilator is shown in Figure 1.

Pure oxygen at the standard pressure of 4 bar (400 kPa) is fed from the hospital supply to an adjustable pressure regulator with output range of 10 to 40 mbar, allowing the PIP pressure to be set by just turning a knob.

The regulator output is fed to the inspiration electrovalve V1. This valve should have enough of an aperture for the air to pass through easily at normal breathing flows.

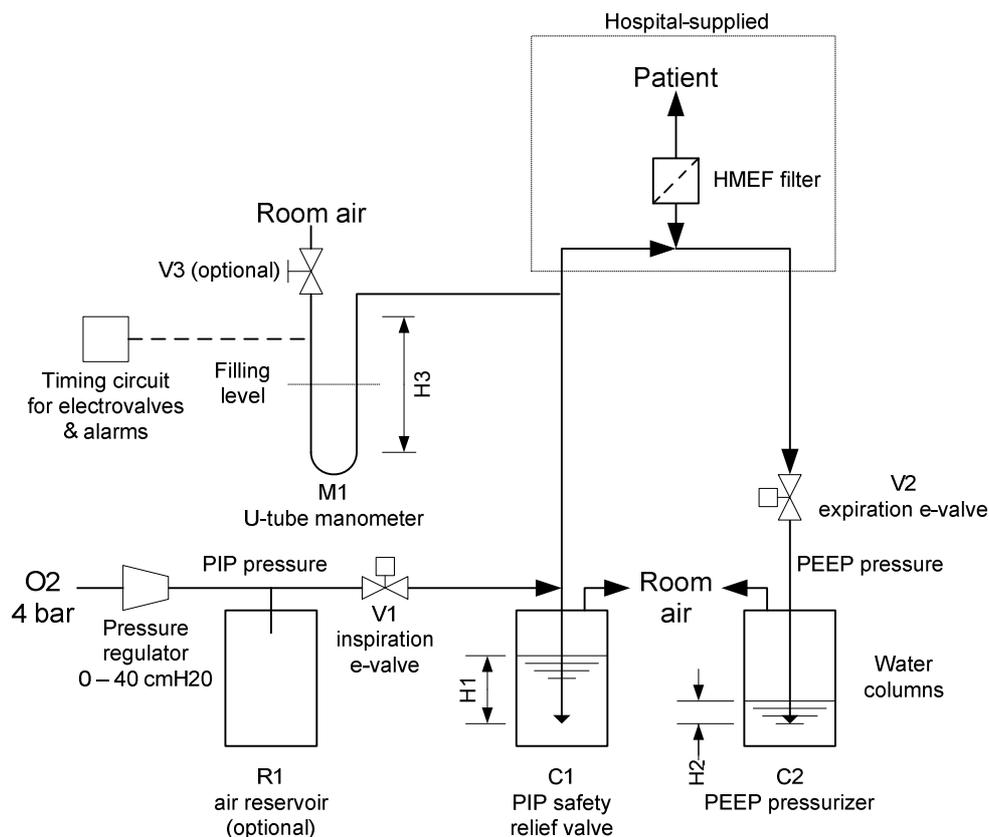


Figure 1 – Schematic representation of the proposed emergency ventilator.

See text for details

A closed deposit (R1) may be placed on this line to provide a reserve of pressurized air for faster pressurization of the lungs upon inspiration. This helps to make the pressure profile more rectangular in shape, which is clinically desirable.

The output of V1 connects to the C1 water column, to the M1 water manometer and to the patient inspiration tube, which is a consumable item normally provided by the hospital.

The C1 water column provides a safety purge to the atmosphere in case of any malfunction that may cause a dangerous overpressure of oxygen to the patient. It can be set by adjusting the water level H1 to be slightly above the maximum intended PIP. In normal operation there should be no gas flowing through this column. To fulfill its safety purpose, the connecting and inner tubes should have sufficient diameter for a considerable gas flow to pass through without overpressure.

The M1 U-tube water manometer measures the PIP and PEEP pressures directly in cmH₂O by mere observation of the water height difference H3. The tube length should comfortably exceed the intended maximum PIP. Optionally, for more precise measurement, near critical damping of the water column oscillations can be achieved by adjusting the needle valve V3. Even then, it was observed that the column only reached a stationary state in each breathing stage for the 12 bpm rate, so the absolute pressure adjustments should be made at such rate or lower. A more viscous liquid would probably also improve this characteristic.

If filled with a conductive liquid (e.g. salted water), the sustained presence or absence of the liquid at certain levels is perceptible (with the help of simple electronics) by electrodes placed across the tube. Both high and low PIP and PEEP alarms can be implemented.

From the patient "Y-piece" the expiration tube connects to the expiration electrovalve V2, similar to V1.

Finally, the expiration air is vented to the atmosphere through the water column C2. The water level H2 directly determines the PEEP pressure.

The valves must be electrically commanded with adjustable rate and duty-cycle in the ranges stated in the introduction. There are several electrical solutions for this functionality, adjustable to the availability of components.

A note is in order here to justify the extensive use of water columns in this design.

The water column is a device with many interesting flow-control characteristics: (a) it has no moving parts except the water itself, so it is very reliable and easy to build; (b) it regulates air pressure in the tens of cmH₂O range accurately, adjustably, and quite independently of the flow; (c) if made of transparent materials the observation of the difference in water levels between the two vessels provides direct information of the differential pressure; and (d) it provides check-valve functionality up to a certain reverse pressure.

Besides being bulky, the main drawback of the water column is the water itself, as its level must be adjusted/monitored and may become bacterially contaminated, requiring anti-bacterial treatment. The water may be replaced by other suitable substances such as low viscosity oils.

It is clear that the functionality provided by the water columns can be performed more conveniently by traditional pneumatic components, if available.

Experimental setup

Two slightly different devices were built independently for cross-check purposes.

Device 1

For the regulator we used an adjustable type normally used as the final regulator in gas distribution installations in buildings, with nominal output pressure of 37 mbar (Figure 2). It was found to be adjustable quite precisely from 10 to 40 mbar and that it could accept input pressures as low as 1 bar without perceivable loss of flow.

For both the V1 and V2 electrovalves we used components normally used for safety reasons in gas distribution installations for buildings and industry (Figure 3). Other

low-pressure valves (e.g. water valves) may be suitable for the purpose, provided they have enough aperture for the air to pass through easily at normal breathing flows.



Figure 2 – Pressure regulator.



Figure 3 – Inspiration (yellow) and expiration (gray) valves

High-pressure valves, such as those used for water intake in domestic appliances, may be unsuited as they are often commanded via an internal servomechanism that requires a few bars of pressure to operate. Eventually, such high-pressure valves could be used on

the oxygen line before the regulator (removing R1), but this was not explored. Electrovalves for pneumatics would also certainly work, if ones with sufficient aperture can be found.

For the R1 deposit we tested two alternatives, both made of common plastics. For most results an 8 L rigid cylindrical deposit was used (Figure 5 – lower left). In Figure 13 it is shown the effect of using instead a 20 L parallelepipedic reservoir with some lateral elasticity.

The M1 U-tube water manometer was made with a flexible 6 mm external diameter tube filled with slightly salted and colored water (Figure 4). The dye was found to reduce the adhesion of water to the tube walls, which is important for its function as a pressure-activated alarm. Some further investigation is needed for optimization of this characteristic. For the V3 valve a small plastic air-flow regulating valve normally used in aquariums was used. Merely squeezing the tube in a controlled way might work as well.

The C1 water column was manufactured with polycarbonate pipes, glued to a base of the same material (Figure 4).

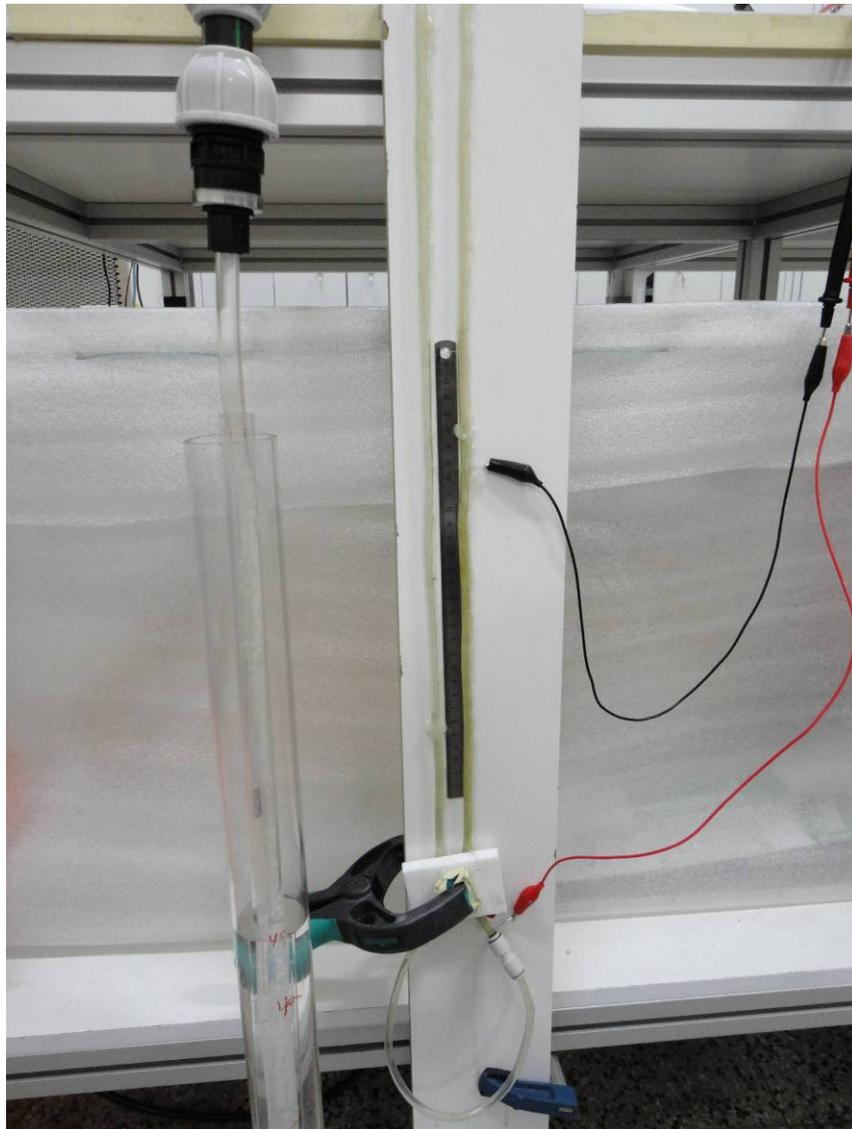


Figure 4 – Safety column (C2) and M1 water manometer, with attached electrodes for low PIP alarm.

The C2 water column was made of the same kind of deposit as R1 (Figure 5 – lower left). The flow of air through C2 was somewhat turbulent and it reduced the PEEP pressure by 2 cmH₂O with respect to the water height. The use of some kind of diffuser would be advisable here; for instance tamponing the end of the inner pipe and opening several lateral orifices in the pipe close to its end.

We used 25 mm out-diameter plastic tubes and accessories normally meant for permanent water sprinkling systems for the tubing. The tubes connecting to the test "lung" were the actual tubes used in hospitals for this purpose.

A test "lung" was made from two sturdy plastic bags meant for urine collection in bedridden patients, each with 1.5 L capacity (Figure 5 – right hand side). The bags were squeezed between two plates forced together by long elastic ropes. The compliance of the "lung" could be adjusted by varying the strength of the ropes.

All components were sourced from local (Coimbra, Portugal) retailers.

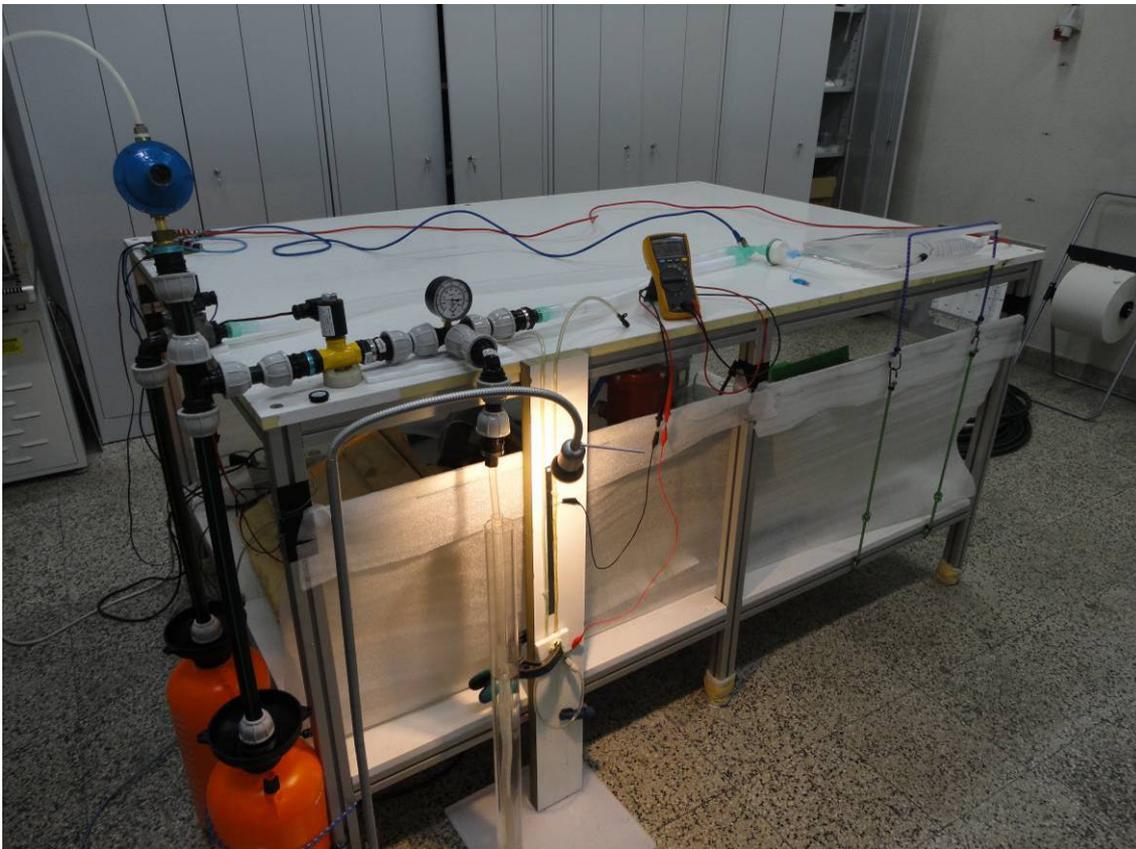


Figure 5 – A view of the complete setup. The mechanical and electrical manometers were added for test purposes.

The command of the (220 VAC) electrovalves was made via a computer-controlled relay, to be replaced in a more realistic setup by simpler electronics, for instance, of the kind described in the next section.

A video of the device in action can be seen in [3] and one of the action of the low PIP alarm in [4].

Device 2

This implementation is depicted in Figure 6, with indication of its main constitutive components.

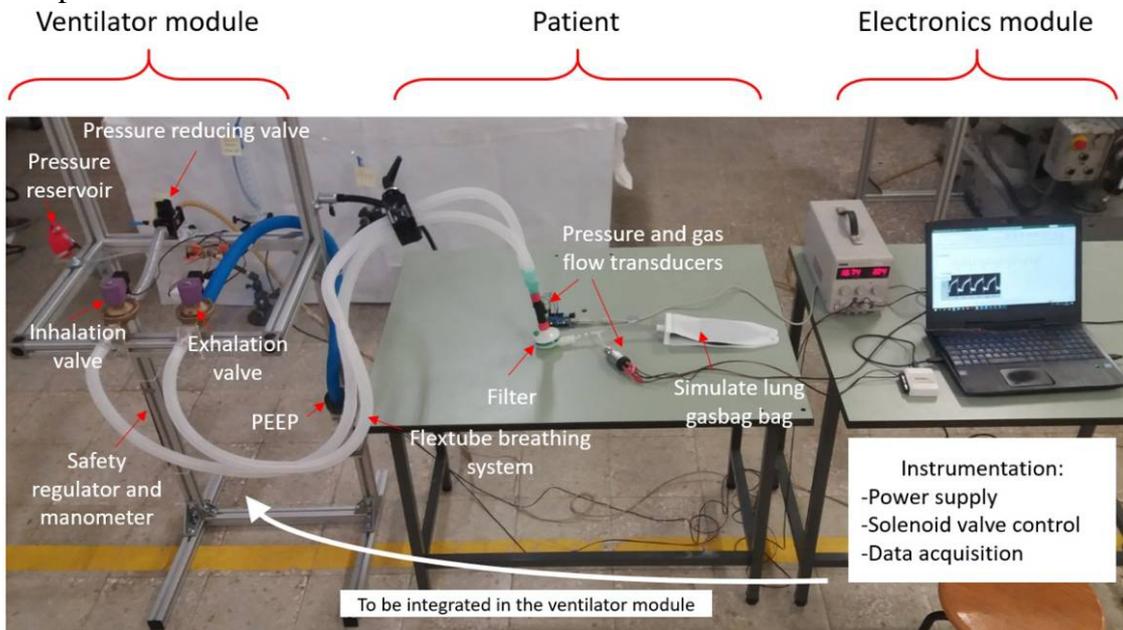


Figure 6 - A view of the complete setup of the Device 2.

A video of the device in action with explanation of the mechanism can be seen in [5].

A customized PEEP valve was produced in PLA by FDM 3D printing (Figure 7). It has 6 independent flow exits to minimize the turbulence in water during the expiration period, assuring a pressure condition similar to the hydrostatic conditions.

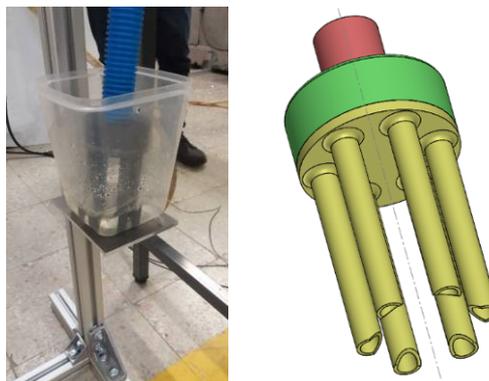


Figure 7 - The PEEP valve.

The required and complete electronic circuit necessary to drive the two electrovalves is shown in Figure 8. It comprises a 555 highly stable device for generating accurate square signals. In the astable mode, as an oscillator, the free running frequency and the duty-cycle can be independently controlled and adjusted by means of external resistors (R4, R5, R6) and one capacitor (C3). Two cascaded inverters (74HC04) are used to buffer the 'DISCHARGE' output of the 555 IC and control the two power transistors (BD243) that will drive the two electro-valves (#1 and #2). Adjustable resistors R6 and

R4 allow varying the duty cycle (over a small range) and the operating frequency, F_{osc} , respectively.

Expiration/inspiration time ratio (E/I) adjustable in the range of 2:1 up to 3:1, corresponding to an adjustable *duty-cycle* between 75-to-66% and 25-to-33%, for the valves controlling the expiration and the inspiration, respectively. The main reason is because expiration is always a passive phenomenon and it basically depends on the time-constant defined by the pneumatic air duct resistance *versus* lung compliance. In a lung primarily with this type of restrictive pathology, it will be roughly around 0.3-to-0.4 seconds. Thus, it will be necessary to have between 0.9 and 1.2 seconds of expiratory time to let out about 96-to-97 % of the tidal volume comes out. If this timing is not carefully respected, there will be a risk of inducing an air-trapping phenomenon that will constrain the next inspiration. Moreover, the breathing rate is adjustable in the range 12 to 25 bpm and, consequently, the oscillating frequency, F_{osc} , of the 555 timer should be set in the adjustable range of 0.40-to-0.83 Hz.

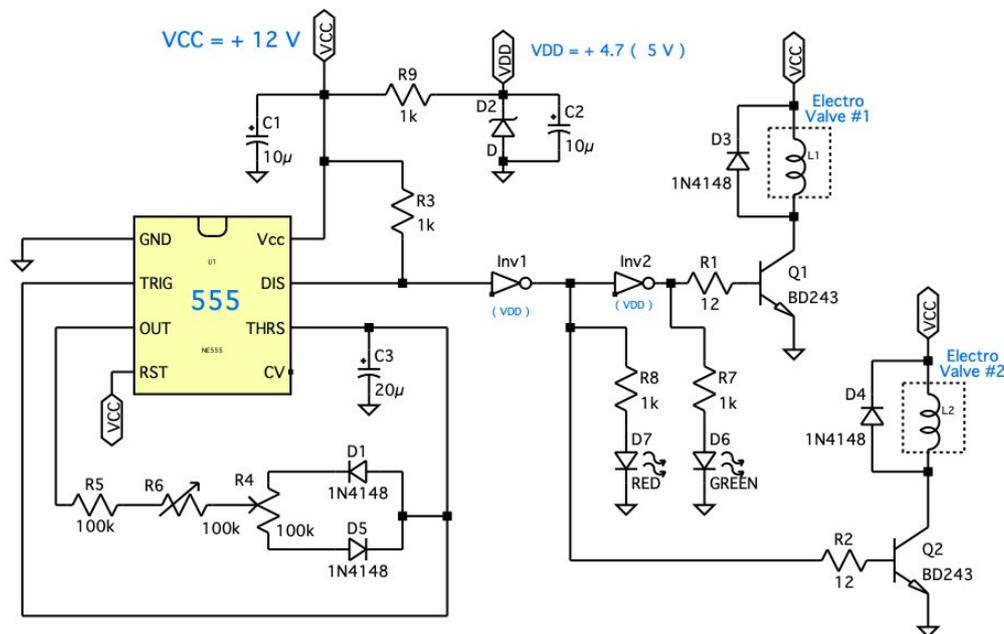


Figure 8 - Complete schematic of the electronic circuitry to control the proposed emergency ventilator.

When the potentiometer/adjustable resistor R4 is centred, operation is obvious and the duty-cycle is 50%. However, as R4 is rotated in either direction, the charge time and discharge times vary accordingly. The two sides of R1 have independent switching diodes (D1, D5). Capacitor C3 is the timing capacitor and it sets the operating frequency, F_{osc} , which can be adjusted by means of the potentiometer/adjustable resistor R6. Pins 2 & 6 of the 555 are the upper and lower thresholds of the input comparators. The charge/discharge voltage is taken from pin 3 instead, since it has a rail-to-rail voltage swing. The rectangular waveform output is taken from the open collector output (pin 7) instead and R3 is mainly a pull-up resistor. In Figure 9 and Figure 10 are shown the two measured outputs of the inverter buffers (connected to the base terminals of transistors Q1 and Q2) in two different operating conditions.

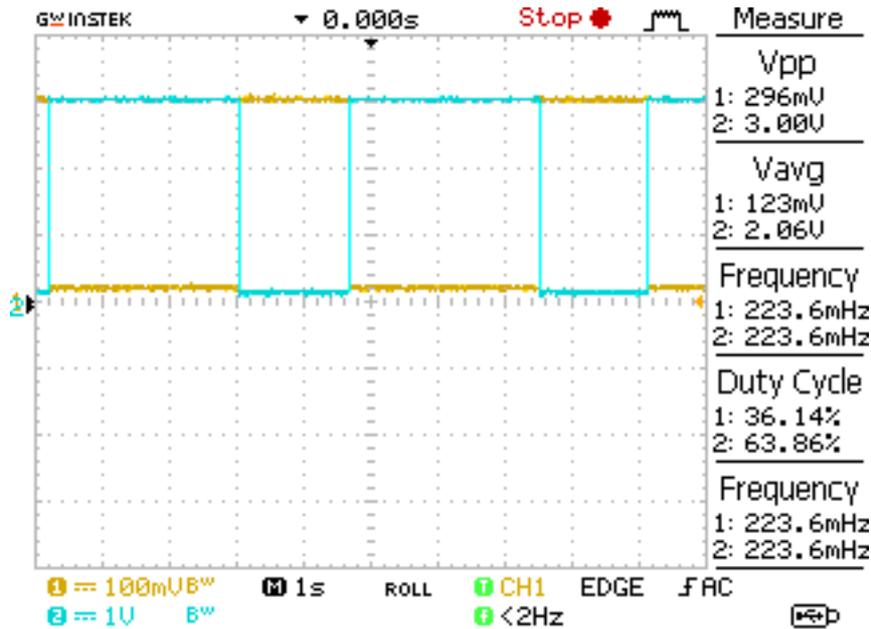


Figure 9 - measured outputs driving the devices Q1 and Q2 having a F_{osc} of 223.6 mHz and duty-cycles of 36.1 and 63.9 % by properly setting adjustable resistors R4 and R6.

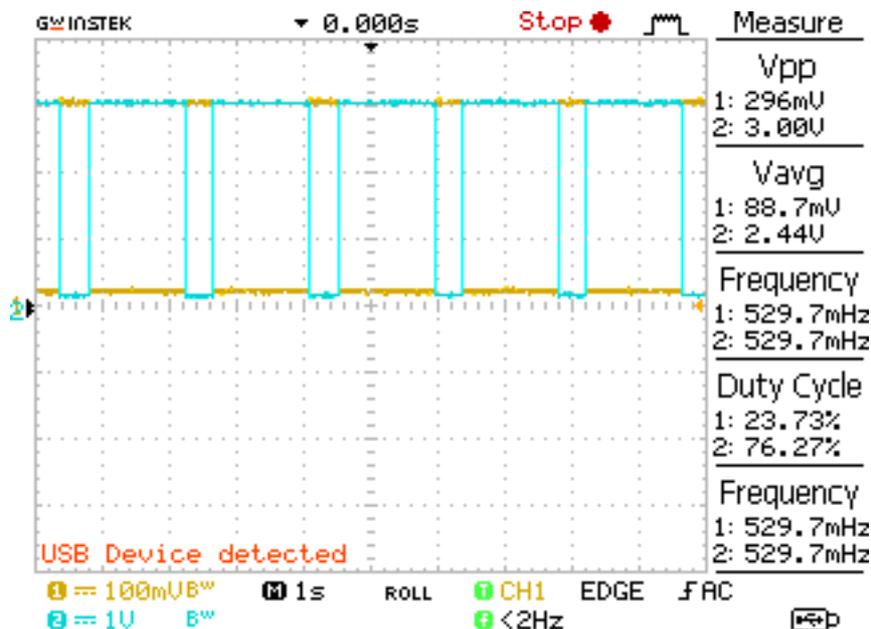


Figure 10 - measured outputs driving the devices Q1 and Q2 having a F_{osc} of 529.7 mHz and duty-cycles of 23.7 and 76.3% by properly setting adjustable resistors R4 and R6.

Results

Device 1

The test "lung" was calibrated by filling it with a volumetric pump with a displacement of 150 mL. The resulting curves can be seen in Figure 11. By counting the number of steps in the interesting pressure range and the corresponding pressure variation two

compliance values were defined, 17 and 36 mL/cmH₂O, close to the observed limits for COVID-19 patients.

Figure 12 shows the pressure profiles measured at the entrance of the "Y piece", measured as a function of time for breathing rates of 12, 18 and 25 bpm, fixed I/E ratio of 1/2, and the two calibrated lung compliance values of 17 or 36 mL/cmH₂O. The limit PIP (achievable in long inspirations) was set to 40, 30 or 20 cmH₂O. The corresponding intake volume estimated from the calibration can be read on the right hand side

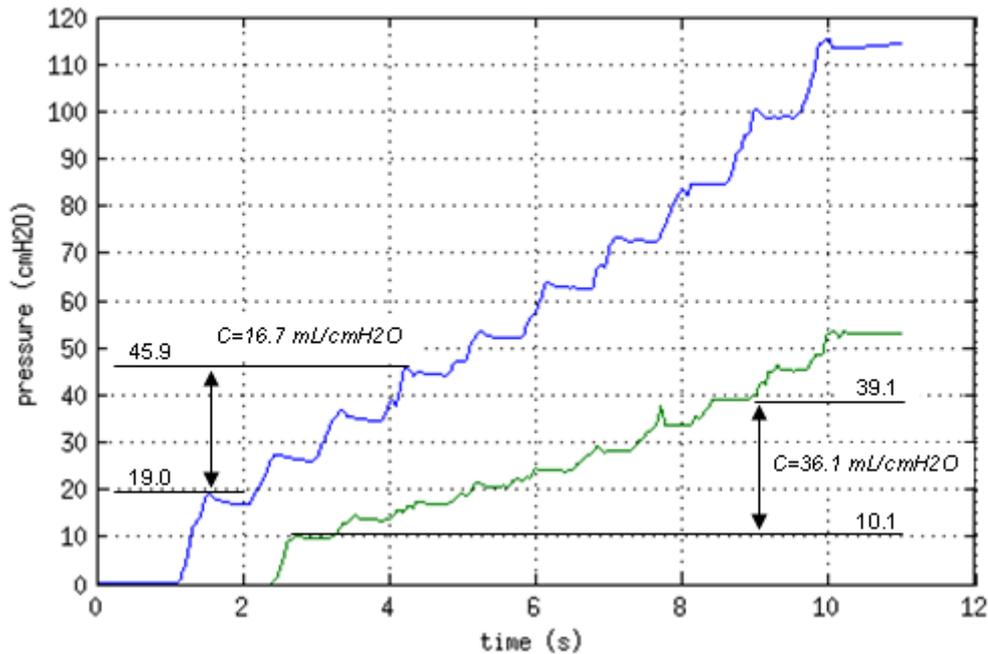


Figure 11 – Calibration of the lung models. Air was injected in the "lung" by a volumetric pump in steps of 150 mL.

PEEP was set to 12 cmH₂O for all measurements, which is in the range of advisable values for COVID-19.

A slow downward trend is visible in the post-expiratory pressure, which is likely owed to small leaks in the many tube junctions, which are not fully adequate for this purpose. In this region are also visible some pressure oscillations caused by turbulence of the air flow in the C2 water column. A diffuser would likely mitigate this phenomenon.

All curves show a fast initial pressure step and then a slower convergence to the set PIP. This effect is stronger in the more compliant "lung", which accepts a larger tidal volume[†] for the same pressure. The initial step is likely owed to the air reservoir R1, which, upon opening of V1, suddenly fills the tubing until the pressure is equalized. The slower convergence to the set PIP is clearly caused by the flow-limited regulator.

It should be noted that in normal clinical practice PIP is not set above 30 cmH₂O in the majority of the patients for safety reasons and that the tidal volume doesn't exceed 6 mL/kg of ideal body weight.

For the most complacent "lung" a tidal volume of 0.6 L requires only 17 cmH₂O above the PEEP pressure, so only the two lower curves (20 and 30 cmH₂O) should be considered as of practical interest.

[†] Inhaled volume in each inspiration.

The relevant curves, highlighted by thicker lines, are of acceptable shape for all cases, reaching the set PIP, except for the 30 cmH₂O PIP at 25 bpm in the most compliant "lung". This case is explored in Figure 13.

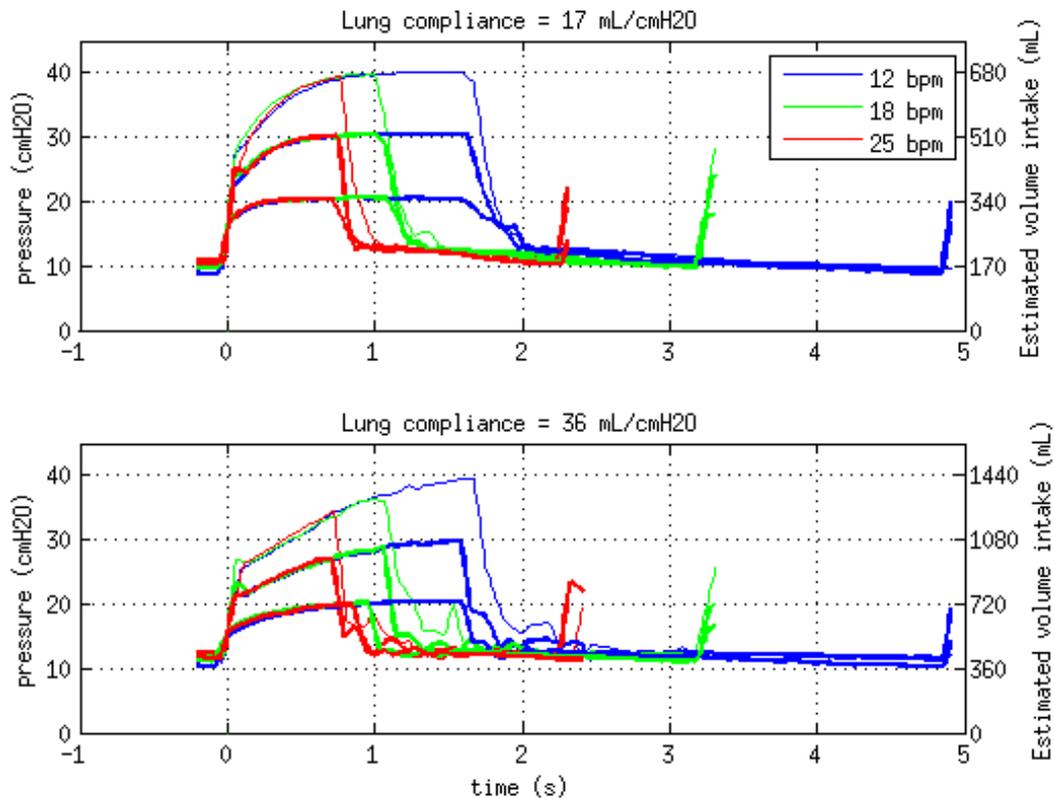


Figure 12 – Pressure profiles measured at the entrance of the "Y piece" as a function of time for breathing rates of 12, 18 and 25 bpm, I/E ratio of 1/2, and lung compliance values of 17 or 36 mL/cmH₂O. The PIP was set to (upper to lower curves in each plot) 40, 30 or 20 cmH₂O and PEEP was set to 12 cmH₂O in all cases. The corresponding intake volume estimated from the calibration can be read on right hand side. The thicker lines correspond to the clinically interesting range (see text).

In Figure 13 several parameter variations were explored around the clinically relevant most difficult case: 30 cmH₂O PIP at 25 bpm.

The I/E ratio was changed to 1/1, which actually improves the curve shape, as more time is available for inspiration.

The 8 L rigid R1 reservoir was replaced by a larger (20 L) and more flexible one. In the least complacent "lung" there is no visible difference in the curves, but in the most complacent "lung" this, as expected, heightens the initial pressure step, improving the shape of the curve. However the pressure remains below the set PIP and the end pressure remains about the same, close to 27 cmH₂O, corresponding to a tidal volume of $C \times (\text{actual_PIP} - \text{PEEP}) = 36 \times (27 - 12) = 540 \text{ mL}$.

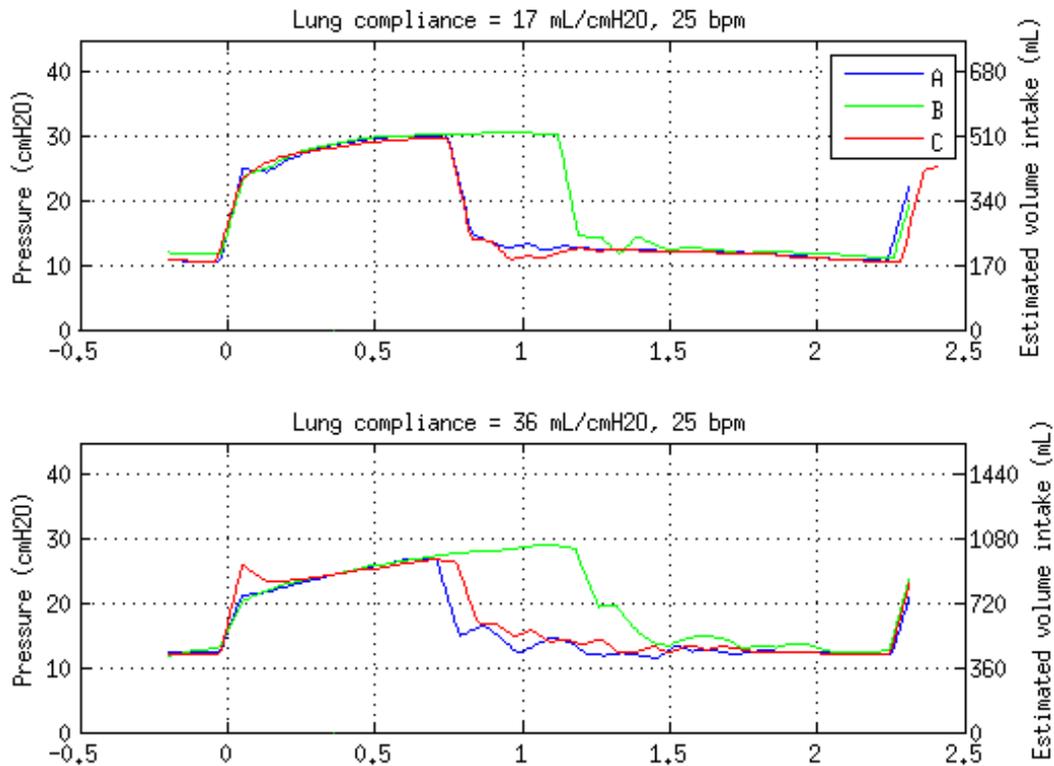


Figure 13 - Pressure profiles measured at the entrance of the "Y piece" as a function of time for a breathing rate of 25 bpm and lung compliance values of 17 or 36 mL/cmH₂O. Except when mentioned, the I/E was set to 1/2. PIP was set to 30 cmH₂O and PEEP to 12 cmH₂O. The corresponding intake volume estimated from the calibration can be read on right hand side. Curve A: baseline conditions, as represented in Figure 11. Curve B: I/E ratio of 1/1. Curve C: larger and more flexible air deposit added before the inspiration valve.

Device 2

The pressure was measured at the entrance of the lung simulator via a *WIKAS10* electronic manometer, as shown in Figure 14. In the inhaling phase, a preset pressure is reached with two different visible slopes: first quickly at the beginning of the breath, which then decelerates. The pressure keeps increasing until the end of the inspiration phase. This may be due to the pressure reservoir (balloon), indicating that a bigger reservoir is needed. After inspiration, the pressure drops to the PEEP set pressure. As the pressure reaches the PEEP value, an instable pressure value is visible, which is caused by water bubbling inside the PEEP valve.

The gas flow rate was measured with an *SFM3000* electronic flowmeter, capable of acquiring both inhalation and exhalation gas flow values, up to a maximum of 200 L/min, and an accuracy of 1.5 L/min. In Figure 14 four respiration cycles are visible, where the flow is delivered quickly at the beginning of each cycle. Then it decelerates to 8 L/min and is kept constant until exhalation starts. As the exhalation occurs the values in the flow rate tend to decrease. It is desirable that before inhalations starts, the exhalation cycle is fully complete. An adjustment of the breathing frequency is necessary, as the flow rate should reach zero before inhalation.

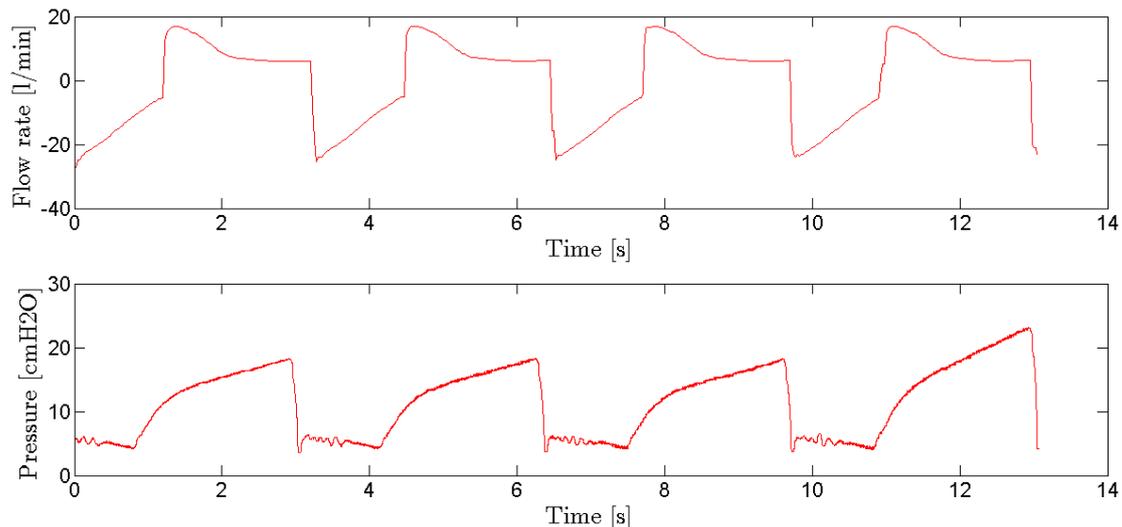


Figure 14 - Pressure profile measured at the entrance of the simulated lung gas bag and air flow rate as a function of time for a breathing rate of 18 bpm.

Discussion

The results should be evaluated against the ventilation parameters relevant for the majority of COVID-19 patients:

- PIP not exceeding 30 cmH₂O;
- PEEP around 12 cmH₂O;
- tidal volume not exceeding 6 mL/kg of ideal body weight;
- breathing rates up to 25 bpm;
- I/E ratio down to 1:3;
- Lung compliance from 20 to 40 mL/cmH₂O.

Device 1 reaches the set PIP for all conditions tested except one, typically with an initial pressure step corresponding to at least 50% of the tidal volume. The deviation from the desirable rectangular pressure curve shape seems to be caused by the limited flow capability of the regulator. Higher I/E ratios or lower bpm improve the curve shape by providing more time for inspiration.

In the non-conforming case, PIP of 30 cmH₂O, 25 bpm at I/E of 1:2 and lung compliance close to 40 mL/cmH₂O, the achievable tidal volume seems to be limited to about 500 mL.

The results are therefore conditioned by the flow characteristics of the pressure regulator, of which we have only tested one model. It may be that, if a selection of models will be available, some models will perform better than others.

Some engineering concerns for fabrication

Several issues come to mind that may require attention if the present concept is to be engineered into a patient-care instrument.

Although certainly a thorough ultrasonic cleaning of all components will be mandatory, some materials may spontaneously emit noxious gases.

The use of pure O₂ raises safety concerns in terms of fire hazard and also of accelerated degradation of materials and components.

The use of water in the columns may raise bacteriologic concerns.

All components, but particularly the electromechanical ones, should be subject to a rapid on/off cycling test in pure O₂ at least equivalent to several weeks of operation before being approved for this application.

Some consideration should be given to what should be the behavior of the instrument in case of power loss. Desirably it should continue to operate for some time, or, at least, an auditory alarm should sound.

At a minimum a "no PIP" alarm should be included, indicating the failure to raise pressure. Probably a "no PEEP" alarm should also be present, indicating a permanent PIP pressure.

Further useful indications may be found in the UK's "Rapidly manufactured ventilator system specification" [6].

Conclusion

The proposed emergency ventilator concept, implemented with a small number of common industrial components, reasonably fulfills the clinical requirements for pressure-controlled continuous mandatory ventilation mode (PC-CMV) and may prove to be helpful on severe COVID-19 patients in conditions in which normal ventilators are unavailable.

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- [4] Video of the low PIP alarm action in device 1: https://drive.google.com/open?id=1Q_fvv6UmcpfgErn6s8AYHPxFCB8A_Vfr
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