TECHNICAL DESCRIPTION

Low-cost, easy-to-build non-invasive pressure support ventilator for under-resourced regions: open source hardware description, performance and feasibility testing

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LISENCE:

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Content:

0. Ventilator description summary

The ventilator was designed to be affordable and easy-to-build, providing an open-source hardware description to allow free replication. The prototype was built using off-the-shelf materials available via e-commerce: a high-pressure blower and its driver (WM7040, Ning Bo Feng Hua Wei Cheng Motor Factory, Zhejiang, China), two pressure transducers (XGZP6847005KPG, CFSensor, Wuhu, Anhui, China) and an Arduino Nano controller with a digital display. Pressure and flow were continuously measured at the outlet of the ventilator and fed into the controller which was provided with a custom-made code to detect inspirations and expirations and to accordingly trigger the inspiratory and expiratory pressures generated by the blower. The ventilator can operate in timed or spontaneous timed (ST) mode (spontaneous breaths of patients are assisted and if the patient's effort is not detected a timed breath is triggered according to a rescue frequency). The retail cost of this ventilator prototype was below 75 US$, and includes all required electronic circuits and power source. Noteworthy, this cost could be considerably reduced by wholesale purchasing. The figure shows external and internal images of the prototype:
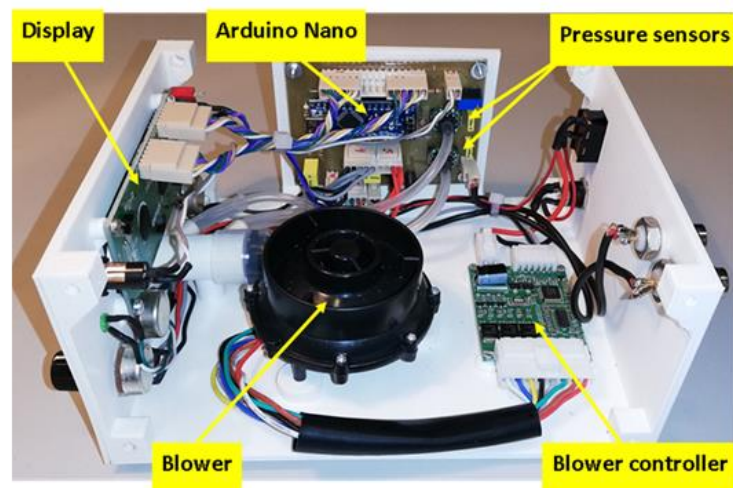
1. __Description of the device algorithm__

General description of the ventilator algorithm (a file with the detailed code to drive the Arduino Nano is also open access provided):

1. Initial offset adjustment:
   a. After switching on, the blower is not activated, zero pressure transducer signals are read and any offset is digitally corrected. The device is ready to use.
2. Reading ventilation parameters in the front panel:
   a. The parameter values set at the front panel of the device are continuously read: Inspiratory pressure (P_{ins}), expiratory pressure (P_{exp}), and flow percentage for cycling (%cycle). These values, which are shown in the front panel display, can be modified by the user during ventilator operation.
3. Pressure and flow measurement:
   a. The downstream (close to the patient) pressure transducer (calibrated in cmH_2O), which is measuring nasal pressure, is continuously acquired and digitally low-pass filtered to reduce noise.
   b. The upstream pressure transducer signal (calibrated in cmH_2O) signal is also continuously acquired and digitally low-pass filtered.
   c. The difference between both pressures is a surrogate signal of flow since it corresponds to the pressure drop across a resistor (pneumotachograph). The flow signal is high pass filtered to eliminate the constant flow component corresponding to the air flow through the intended leak in the patient's mask. Hence, the flow signal corresponds to the patient's breathing flow. As the pressure-flow relationship in the non-linear resistor is quadratic, the flow signal is linearized by computing the square root of its absolute value (keeping positive values for inspiration and negative values for expiration).
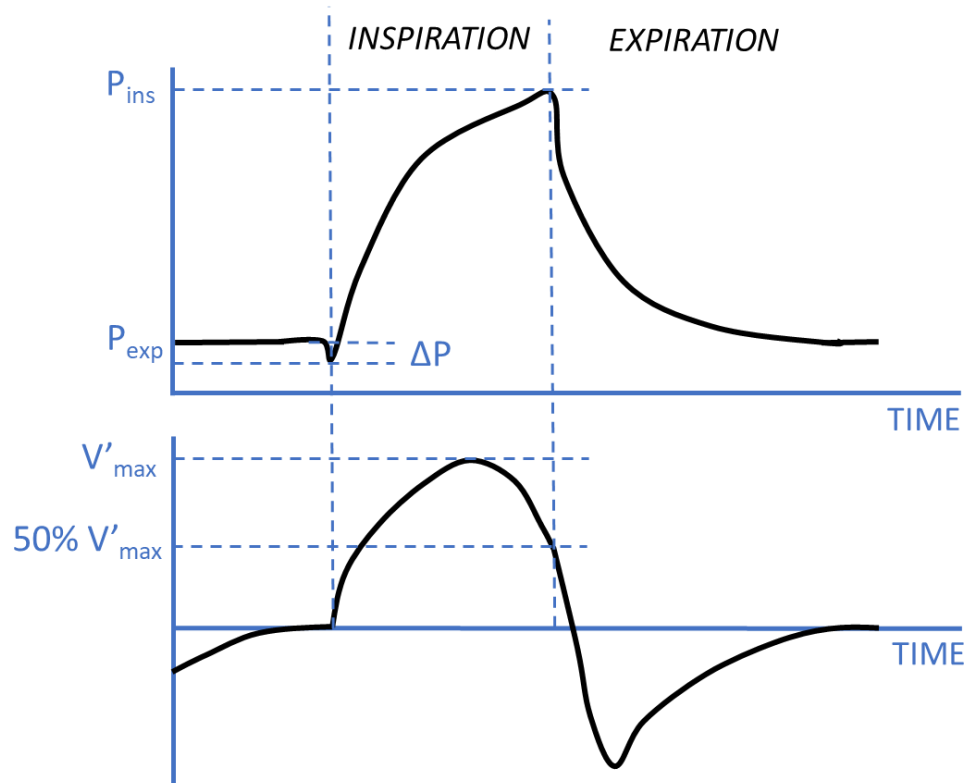
4. Ventilation start:
   a. When a pressure greater than a threshold is detected, indicating that the patient is connected, the blower is driven to generate P_{exp}.
5. Trigger inspiration:
   a. When a negative deflection in nasal pressure (ΔP in the Figure) is greater than a set threshold, the ventilation status is changed to inspiration and the blower is commanded to generate Pins. The inspiratory phase is kept until the expiratory phase is reached as explained in point 6).
6. Cycling to expiration:
   a. After inspiration is triggered, maximum inspiratory flow is detected (Figure) and when inspiratory flow decreases to a value corresponding to %Cycling (set at the front panel) of maximum inspiration, the ventilator status changes to expiration (Figure; as an example here %cycle is 50%) and the blower is commander to generate P_{exp} until a new inspiration is detected according to point 5).
7. Backup inspiration triggering:
   a. In case that after 5 s of the previous inspiration is triggered, no new inspiration is detected according to point 5), a backup inspiration is mandatory triggered (i.e. 12 resp/min rescue frequency).

NOTE: Triggering and cycling (previous points 5-7) are operating in the bilevel pressure mode. In case that CPAP mode is selected in the front panel, P_{exp} and %cycle are not active and the blower is set to generate a continuous pressure corresponding with the value set for P_{ins}.

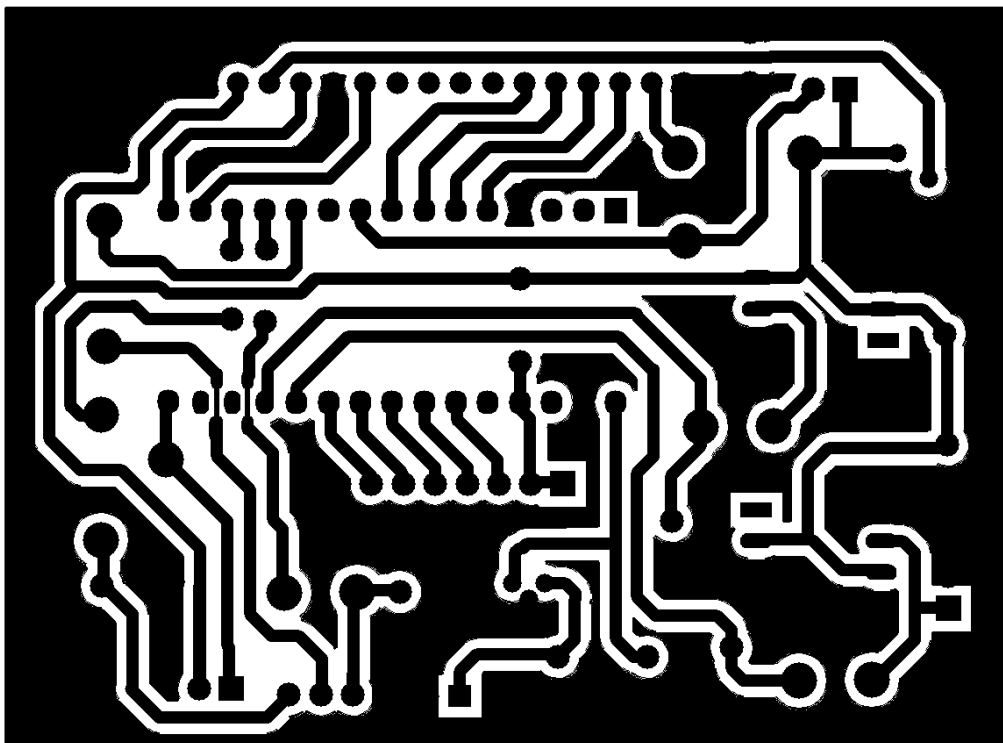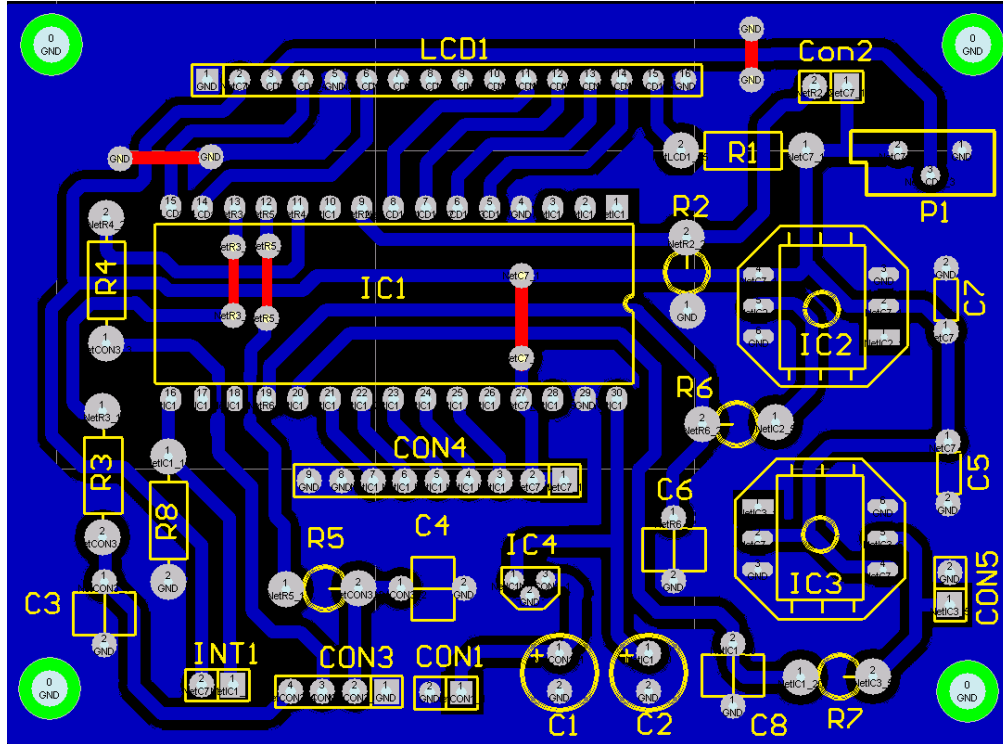## Implementation in Arduino: code diagram
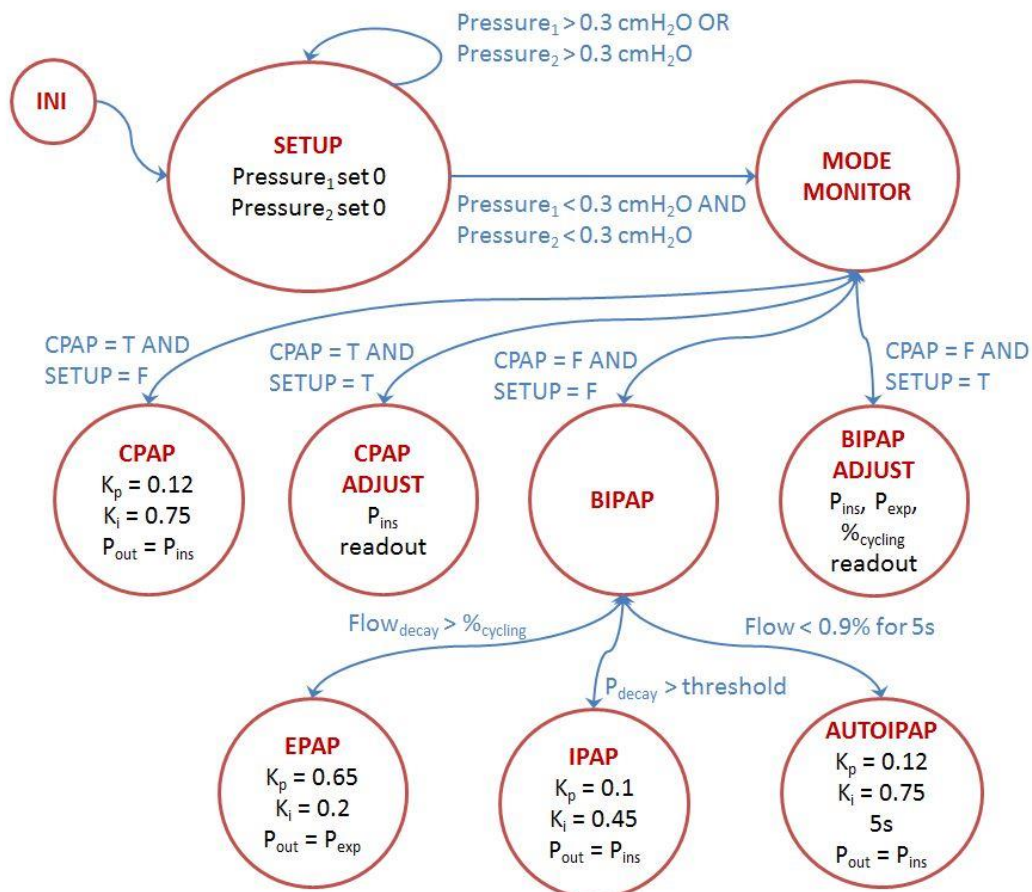
2. Schematics of the circuit

Source file for Altium Designer in file: ventilator_circuit.SchDoc (included in the same zip folder where this pdf file is located).
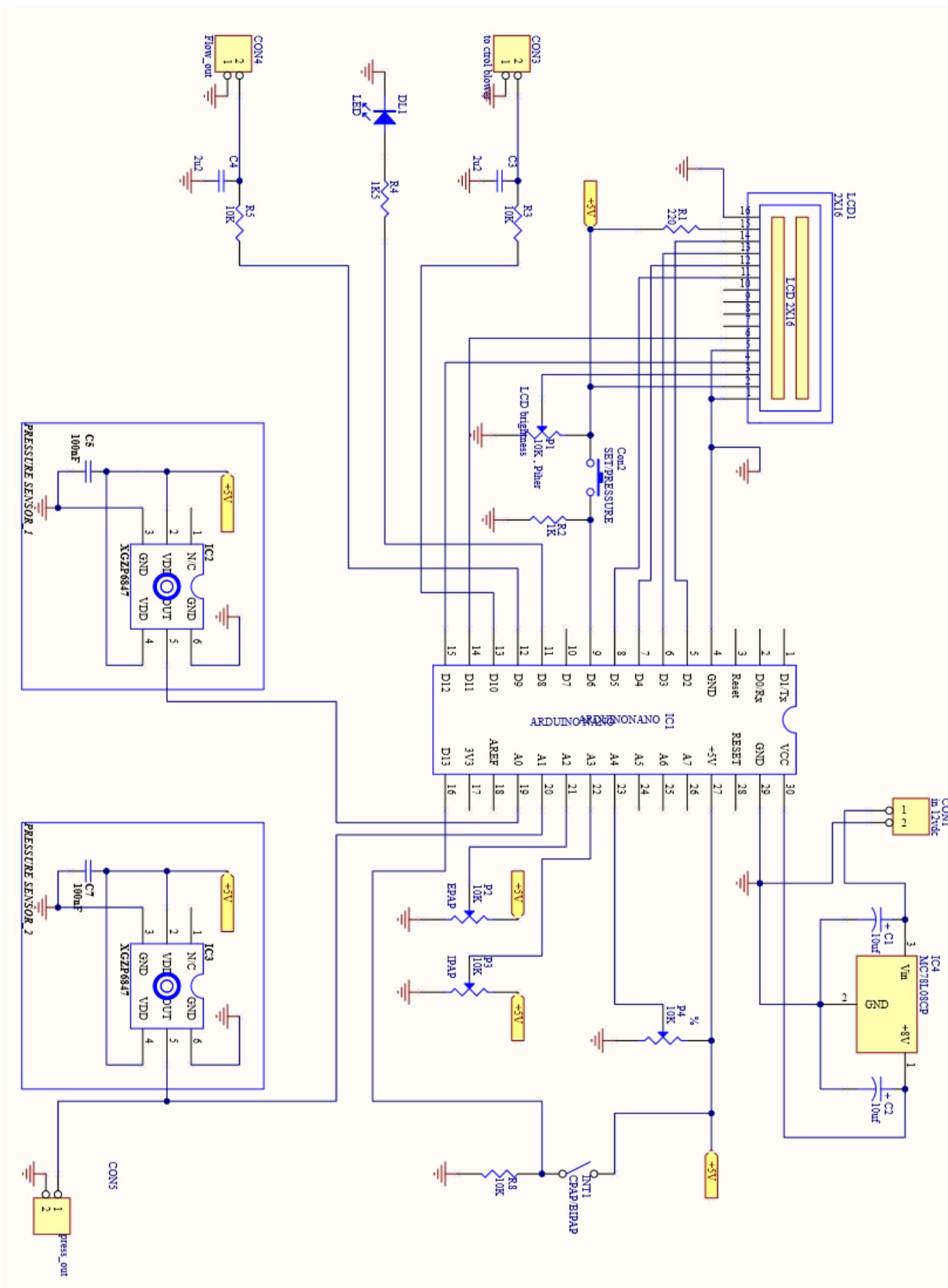
3. PCB board layout

Source file for Altium Designer in file: ventilator_layout.PcbDoc (included in the same zip folder where this pdf file is located).

4. **List of components**

<u>PCB:</u>

- Resistors: 3x10kΩ, 1x1.5kΩ, 1x1kΩ, 1x220Ω, 1x10kΩ potentiometer
- Capacitors 2x10µF (electrolitic), 2x2.2µF, 2x100nF
- 2xXGZP6847 pressure sensor
- MC78L08CP low-current voltage regulator
- DIP32 Arduino Nano controller
- DIP32 Socket
- Connectors: 1x16pin,1x9pin, 1x4pin, 4x2pin

<u>External:</u>

- WM7040-12/24V-65W blower + 7040 driver
- 1xSODIAL(R) LCD display (model 015085) with HD44780 controller + 2x6pin connectors
- 3xHSEAMALL HB20 10kΩ potentiometers (16x7mm)
- 3pin switch 1.3x0.8x3.3 cm
- Button switch 16mm
- ON/OFF switch 22mm
- LED 5mm head
- 2xBNC connector
- 1x15V source connector

<u>Conventional external power source (15 V DC; 4A):</u>

Note: The power source can be 12 V-DC, but in that case the maximum (inspiratory pressure) could be slightly limited to 16-18 cmH2O (see 6. Blower and blower-controller).

5. Connections
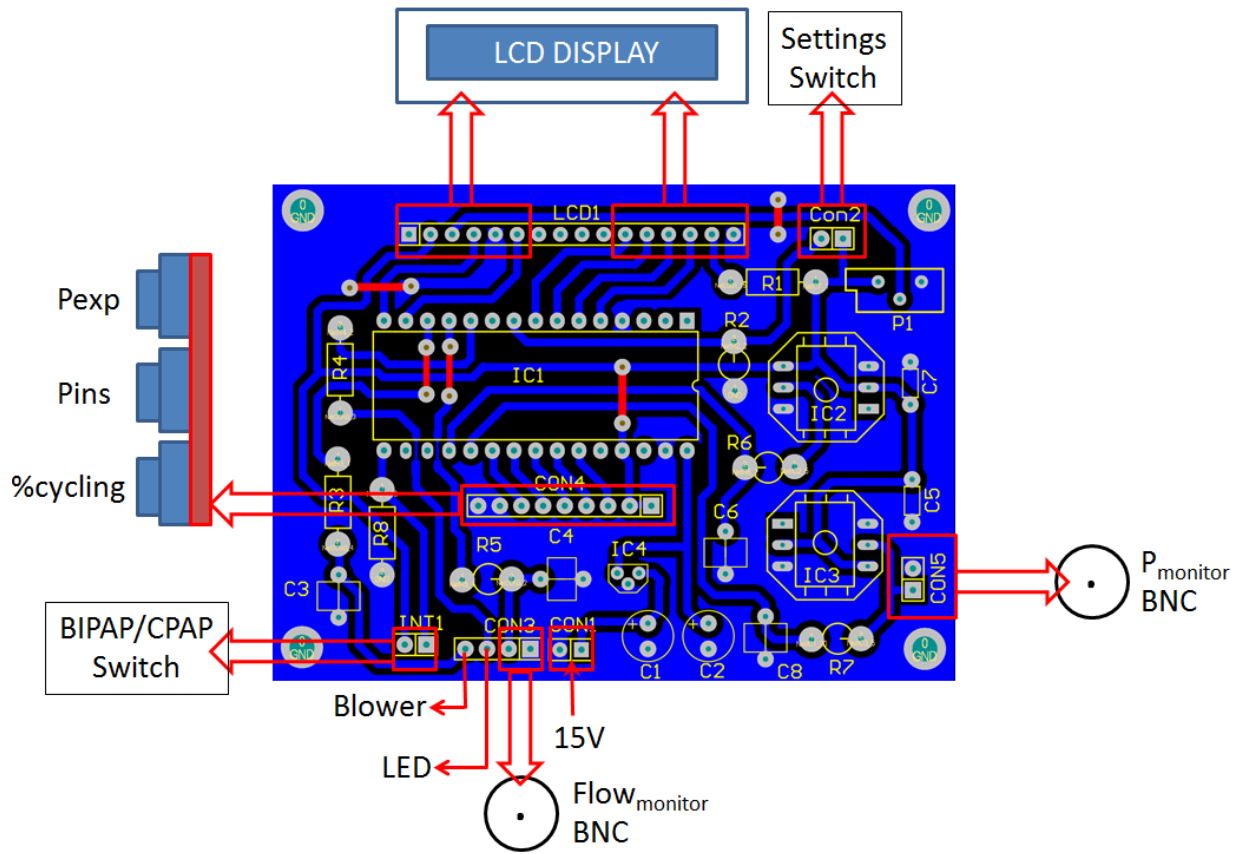
6. Blower and blower-controller:

These figures/tables were obtained from the provider website (December 12, 2018):

WM7040-12/24V-65W
7.5Kpa-240L/min-45dB
70 mm

Brushless 12/24V dc silent blower for auto CPAP to cure Sleep Apnea			
Voltage and Current		12V (4.5A±0.1A) , 24V (2.7A±0.1A)	
Max Air Flow (Air pressure=0)	240L/min, 14m³/h, 8.5 CFM	Max Pressure （Air flow=0)	7.5 Kpa, 75 cm H2O
Size	70mm*40mm	Noise	45dB(1Kpa-1M) 73dB(7Kpa-1M)
Power	65 W	Warranty	12 months
Speed	35000±5% rpm	MOQ	100 pcs
Material	PA66+GF	Price	$17.39-$35
Certification	CE	Port	Ningbo/Shanghai

WM7040-24V 风量风压变化关系图:
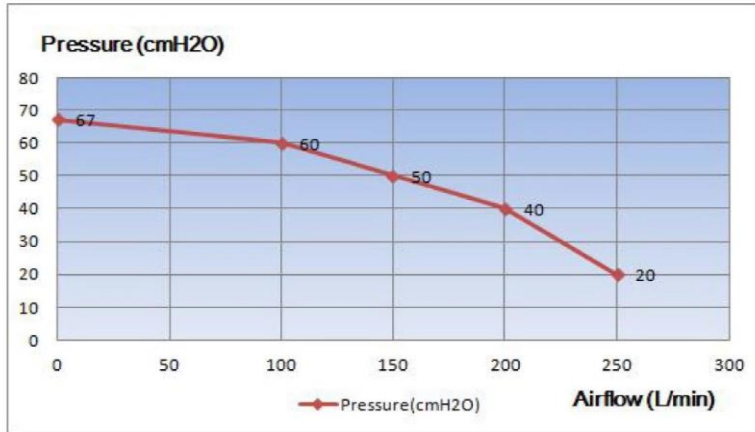
Technical parameters:

+5V	Voltage supply to Hall	+5V	5V voltage supply
HU	Hall U	VSR	0-5 voltage or PWM to adjust speed
HV	Hall V	GND	GND
HW	Hall W	EN	Running Or Stop
GND	GND	FR	CCW or CW
U	Phase U	FG	Speed Pulse Output
V	Phase V	GND	24V Power -
W	Phase W	+	24VPower +

Product model	Unit	Driver Of 7040-24V
Rated voltage	V	24
Allowable operating voltage	V	7-26
Maximum continuous current	A	3
Holzer electrical angle	Degree	60
Weight	Gram	18

The following figures correspond to the pressure-flow (P-V) relationship measured in the specific blower unit used in this setting for different power supply: 12 V, 15 V and 24 V. A 15 V power supply ensure a maximum pressure of 30 cmH₂O.

These pressure-flow figures characterize the performance of the blower as a pressure source. The maximum pressure that the blower can generate is when its output is occluded (zero flow). As the output is progressively open and hence the generated flow increases, the pressure generated by the blower is decreases. For instance, when the blower is powered at 15 V, the maximum pressure it can generate (for zero flow is 30 cmH₂O). Interestingly, for flows up to 100 ml/min (which could account for inspiratory flow plus leak flows) pressure decreases to only 25 cmH₂O. For the same generated flow, pressures are 17 and 66 cmH₂O when powered at 12 and 24 V, respectively. These data indicate that the same blower (if powered up to 24 V) could produce much higher pressures (similar to the ones required for intubated mechanically ventilated patients).
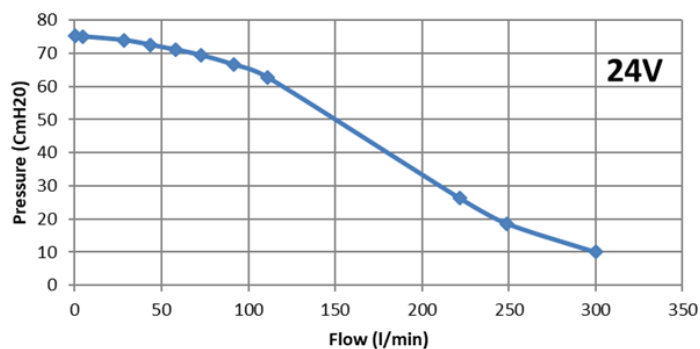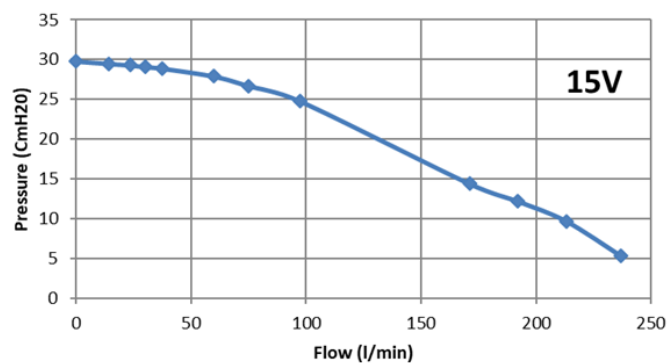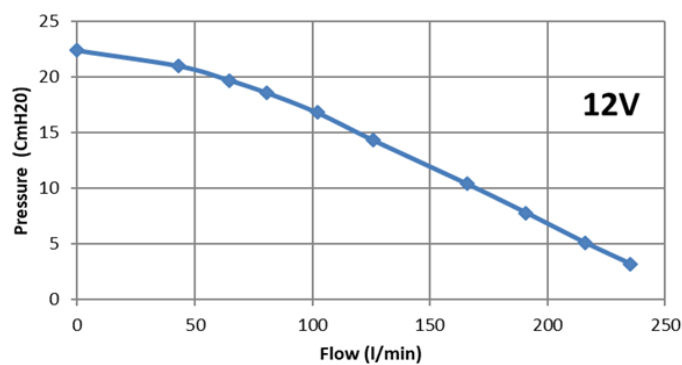
7. Pressure transducer:

These figures/tables were obtained from the provider website (December 12, 2018):

CFSensor — *Always Perfect Under Pressure*

XGZP6847 Pressure Sensor Module

Features

- Ranges: -100kPa～0kPa…1000kPa(-15PSI～0PSI…150PSI)
- Perfect Accuracy(±1.0%) of full scale
- Gage,Vacuum Type
- For Non-corrosive gas or dry air
- Calibrated,Amplified analog output
- Temp. Compensated:0°C～+85°C(32°F～+185°F)
- Direct application,Low Cost.
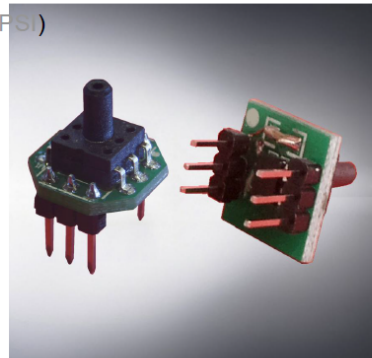
Performance Parameter

Unless otherwise specified, measurements were taken with a supply voltage of 5 Vdc at a temperature of 25±1°C and humidity ranging from 25％～85

| Item	Data	Unit
Power Supply	5(or 3.3v by custom)	V
Output Signal	0.5-4.5(or by custom)	V
Accuracy	±1.0	%Span
TSO(Temp. Coefficient of Offset)	±0.03	%FS/°C
TCS(Temp. Coefficient of Span)	±0.03	%FS/°C
Long Term Stability(1year)	±2	%Span
Over Pressure	2X (≤500kPa)	Rated
	1.5X(≥500kPa)	
Compensation Temp.	0 ～ 85/32 ～ 176	°C/°F
Ambient Temp.	-20 ～ 100/-4 ～ 212	°C/°F
Storage Temp.	-40 ～ 125/-40 ～ 257	°C/°F

8. **Enclosure by 3D printer**

STL files for 3D printing in: ventilator_enclosure.zip (included in the same zip folder where this pdf file is located).

NOTE: For better electromagnetic compatibility (if needed) it is recommended to use a grounded metalic enclosure.
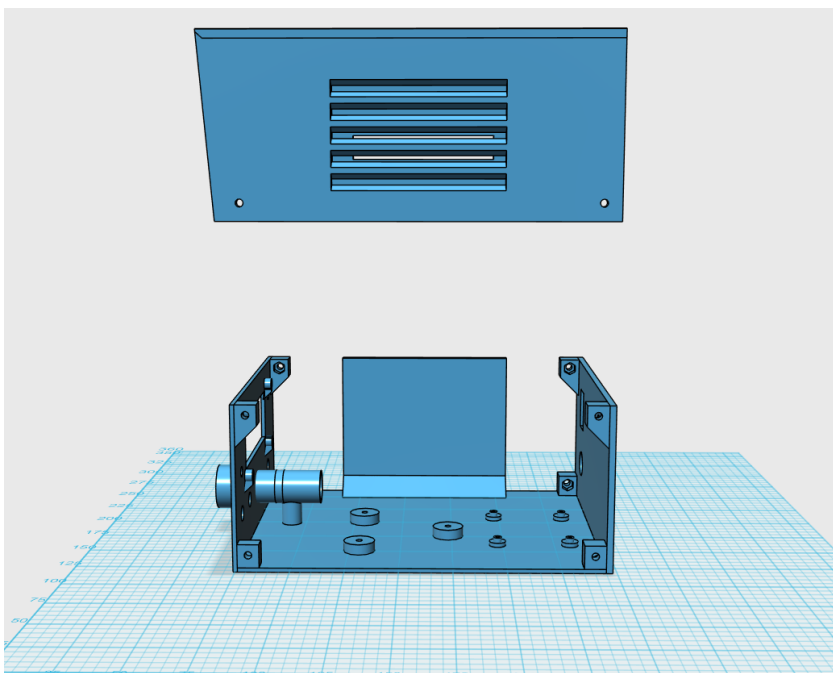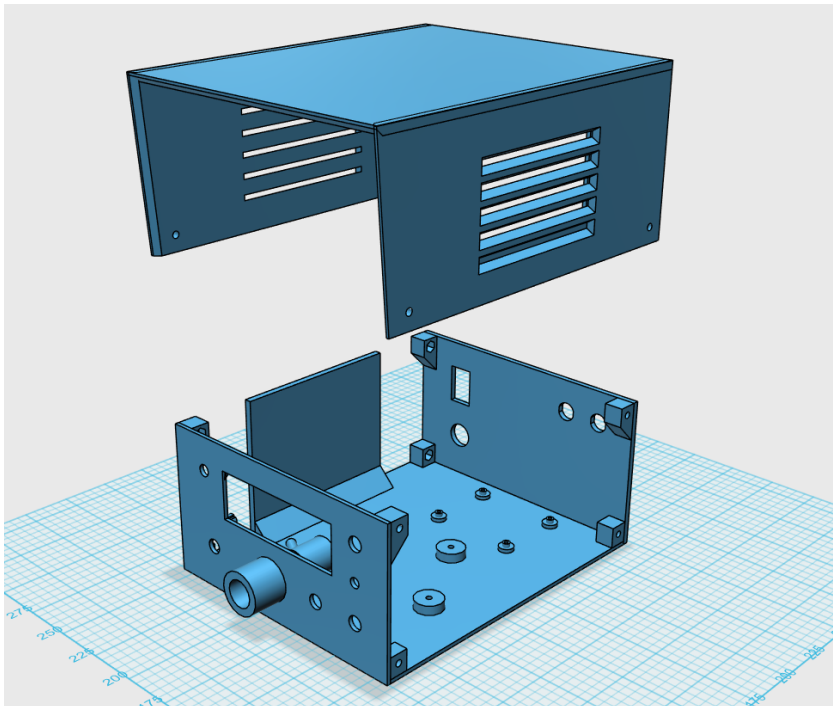
9. Brief user manual

# NON-INVASIVE BILEVEL MECHANICAL VENTILATOR PROTOTYPE

SETTING DESCRIPTION

IMPORTANT NOTE:

1) **Non-invasive ventilation must be applied under the supervision of a health care professional legally qualified to provide this medical treatment.**

2) The ventilator prototype **must be connected to a conventional patient's interface** consisting of a flexible tubing and a nasal mask including the corresponding **intended air leak orifice to avoid rebreathing.** A suitable protecting **air filter** at the interface should be used as required.

Front view:
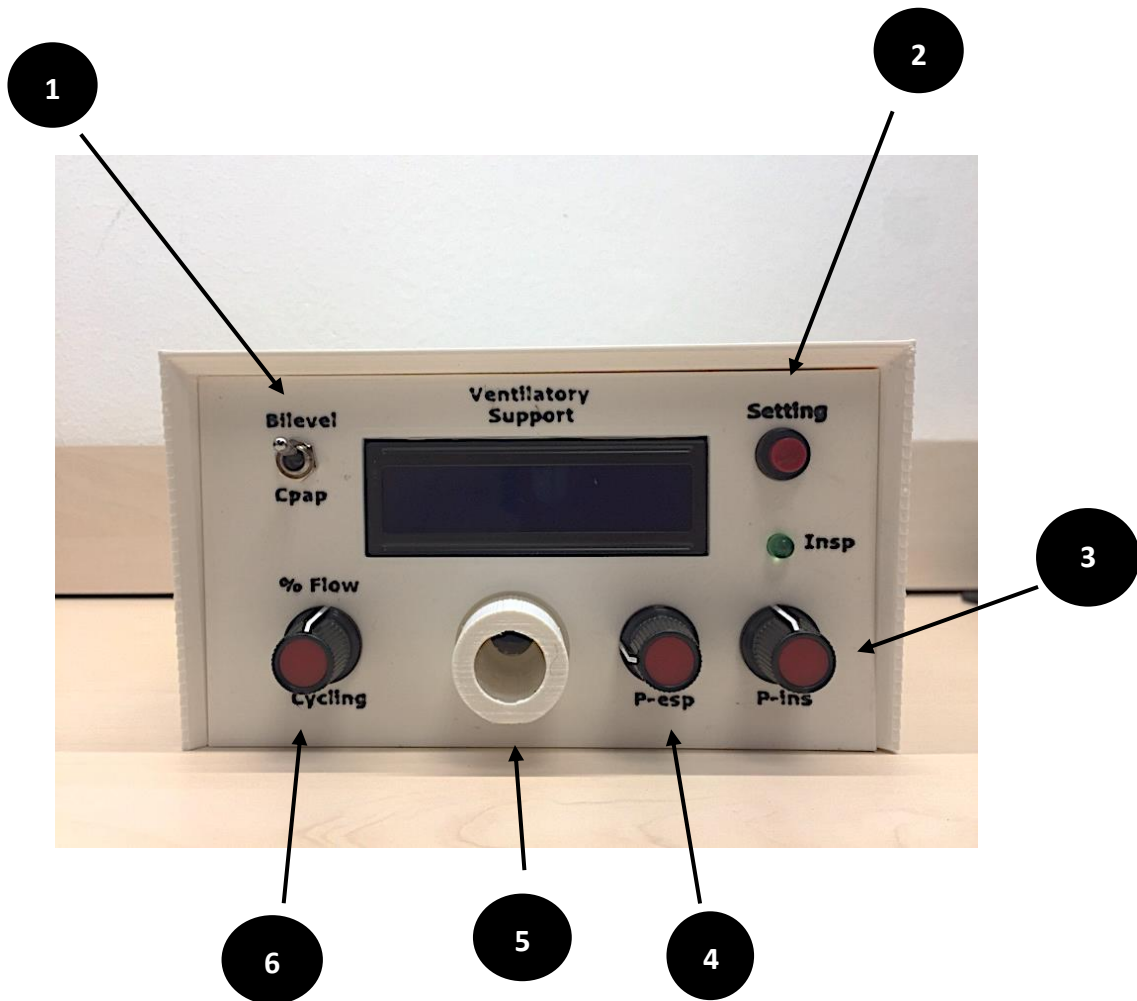
Number	Device Feature	Description
1	BiPAP/CPAP selector	To select BIPAP or CPAP mode
2	Button for pressure setting	Pressing this button allows to modify inspiratory or expiratory pressures. See explanation for buttons 3 and 4.
3	Button for inspiratory pressure (P-ins) setting	Turning this button (while button 2 is pressed) sets inspiratory pressure.
4	Button for expiratory pressure (P-esp) setting	Turning this button (while button 2 is pressed) sets expiratory pressure.
5	Air Outlet Port	To connect the tubing to nasal mask
6	Button for % flow cycling setting	Turning the button allows to set the % of maximum inspiratory flow at which the device cycles to start expiration

Rear view:
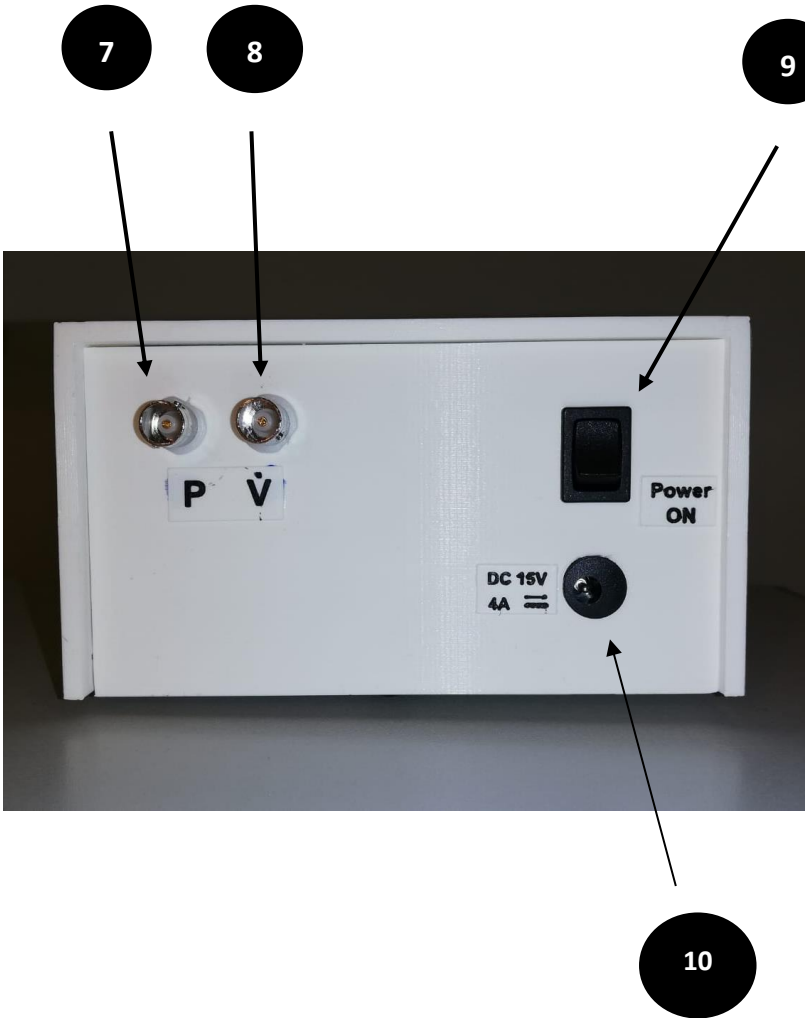
Number	Device Feature	Description
7	Pressure output	Real time analog pressure signal
8	Flow output	Real time analog flow signal
9	ON/OFF	General power connection
10	Power inlet	Input connector for the external power source (15 V-DC)

Setting for bilevel pressure ventilation:

- Connect the device using the external power source (10, rear).
- Switch the ventilator on (9, rear)
- The device will take a few seconds to auto-check and auto-correct any zero drift in the sensors. Note: Do not touch or use the device during this initial stage:

- When auto-check is finished this screen appears:

- Choose Bilevel mode (1, front). Note: Please see comments on CPAP mode in the Appendix 1).
- Select Inspiratory pressure: Keep pushing button Setting (2, front) and simultaneously turn the knob P-ins (3, front) until the desired inspiratory pressure appears as IPAP in the display. Range available: 4-25 cmH2O. Inspiratory pressure can be modified during patient use for better adaptation to his/her breathing pattern.
- Select Expiratory pressure: Keep pushing button Setting (2, front) and simultaneously turn the knob P-esp, (4, front) until the desired expiratory pressure appears as EPAP in the display. Range available: 4-25 cmH2O, but the device does not allow than expiratory pressure is higher than inspiratory pressure. Expiratory pressure can be modified during patient use for better adaptation to his/her breathing pattern.
- Set cycling: typically a value of 30%-50% is advisable. This value can be modified (by simply turning button 6, front) during patient use for better adaptation to his/her breathing pattern.
- The device is now ready to use. At any moment you can check what are the pressure settings in the ventilator by just pushing Setting button (2, front). The display will show:
-

Use in patients:

- Once the settings (inspiratory and expiratory pressures and % cycling) are established, the ventilator can be connected to a patient wearing a nasal mask with intended airleak orifice.
- When a patient is connected, the device detects pressure in the mask and the device starts ventilating.
- When the device detects inspiratory effort from the patient, inspiration is automatically triggered, as it is indicated by the green led light labeled "Insp" (front).
- In case that no inspiratory effort is detected a back-up inspiration is automatically triggered (back-up frequency of 12 breaths/min).

- Although not necessary, it is possible to monitor the pressure and flow signals in real time from the BNC connectors in the rear part. To compute pressure (P, in cmH2O) from voltage (V, in Volt): $P = (V - 0.5) \cdot 25$. Flow is a non-calibrated voltage signal.
- Just as example some signals recorded during ventilation of a voluntary subject are shown:
-
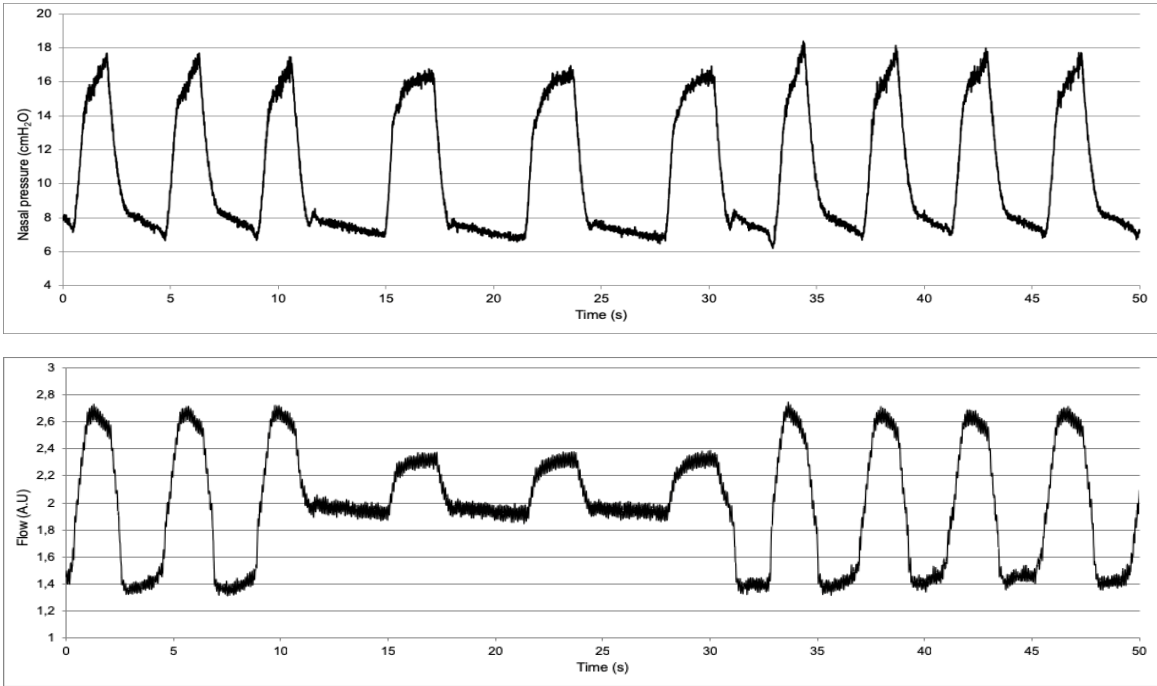
Example of the nasal pressure and breathing flow signals recorded in a volunteer. From second ≈12 to ≈30, the volunteer was asked to perform an end-inspiratory apnea with glottis closure to test that the ventilator automatically triggered mandatory inspirations at the 12 breath/min backup frequency. Both the pressure (in cmH2O) and flow (uncalibrated arbitrary units (a.u.)) recording correspond to the signals from the sensors within the ventilator. The flow observed during the apnea corresponds to the flow though the intended leak corresponding to the inspiratory and expiratory pressure.
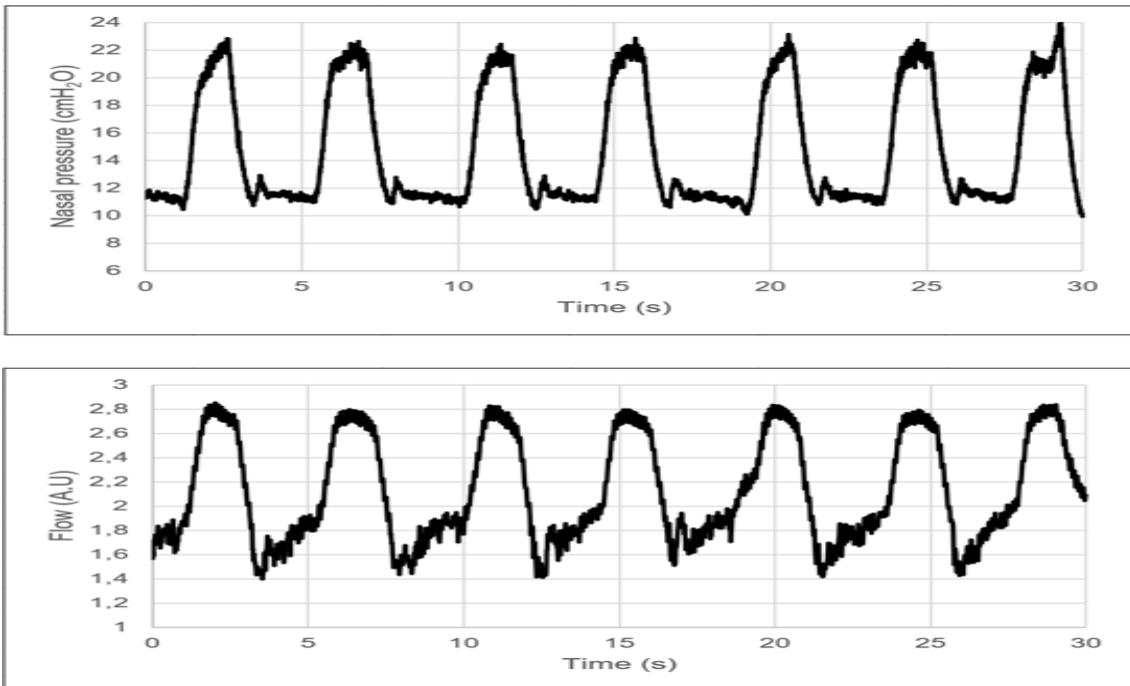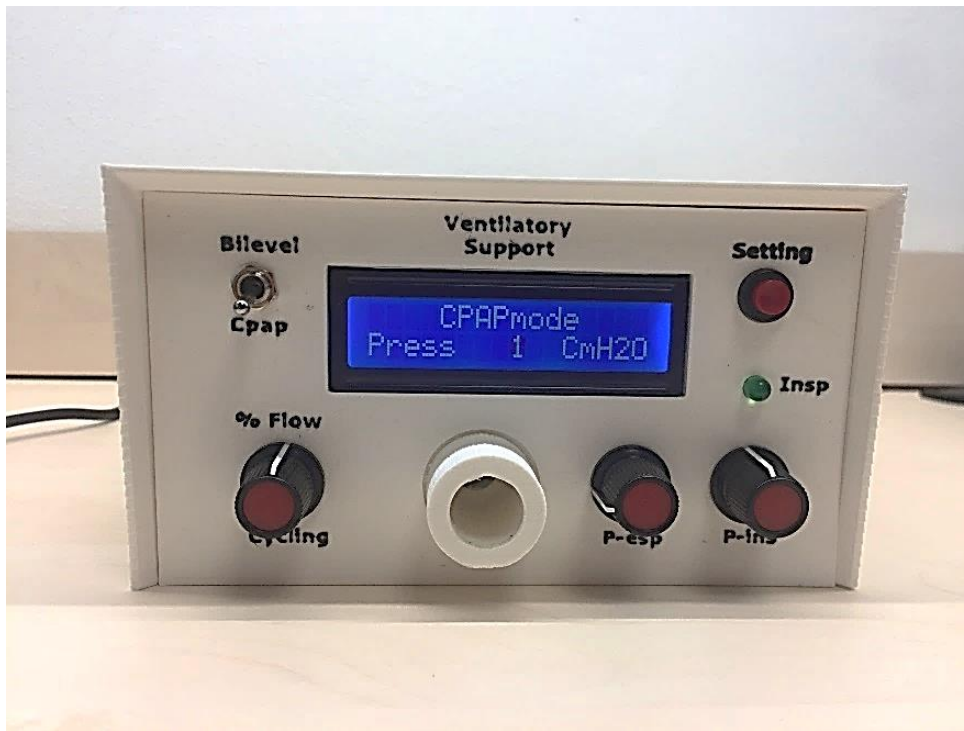

A volunteer breathing with the prototype ventilators support. Ventilator is set at inspiratory pressure of 10 cmH2O and expiratory pressure of 20 cmH2O.

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APPENDIX 1: CPAP mode

The ventilator prototype con be used in CPAP mode instead of bilevel pressure ventilation.

To this end, selector 1 (front) should be switched to CPAP.

In this mode the Cycling function (6, front) and expiratory pressure (4, front) are internally disabled. Inspiratory triggering and back-up frequency also disabled. Only inspiratory pressure selection (to set the CPAP value) is active (2 and 3, front).