

AmboVent
1690.108

Emergency ventilation alternative system



**Open-Source Code Mentality Initiative
Global Partnership for the Greater-good**



Automatic, Controlled Mechanical Ventilator for Operation in Emergency

I Introduction

1. Coronavirus COVID-19 brought up unique global health challenges and implications, among them is the challenge of manually ventilating masses of patients. Most countries, including Israel, is now in a race to find solutions for shortage in ventilators.
2. The AmboVent 1690.108 automatic controlled ventilator device is being developed as a solution capable of automatically and repeatedly squeeze A bag valve mask (BVM), sometimes known by the proprietary name Ambu bag or generically as a manual resuscitator or "self-inflating bag", to generate a simple but effective alternative ventilator, for use in extreme situations.
3. The R&D task was initiated by the Israeli Air Force Electronics and Teleprocessing Base (Unit 108) and others, such as, First Israel Robotics, and various experts and mentors who joined the endeavor on a voluntary basis. This Ad hoc team work together as an open organization aiming at providing in an ultra-short time a viable, usable, simple and intuitive to use mechanical ventilator. The device is being developed in open code, on a non-profit basis to enable free and simple mass production by anyone, anywhere in the world.
4. The system can operate with any Ambu (or other manufacturers) BVM, sizes 1100 – 1475 cm³ volume.
5. Link to the project website - <https://1nn0v8ter.rocks/AmboVent-1690-108>
6. Joint partners in this project includes MDA Israel, Ichilov medical center, Tel Aviv, IAF, MASHA 7000, and other Israeli experts and mentors, coming from various disciplines, to collectively advance the project on voluntary basis.
7. About the project
 - a. This initiative is an open code, non-profit project
 - b. Estimated cost per unit: \$500

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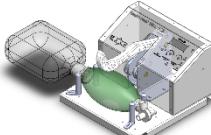
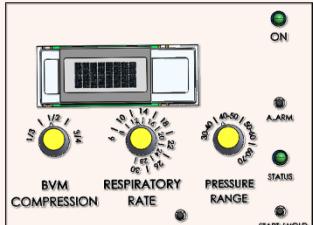
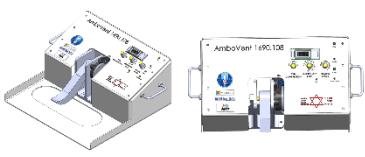
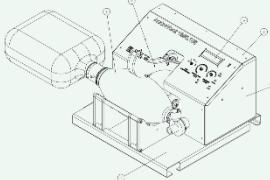
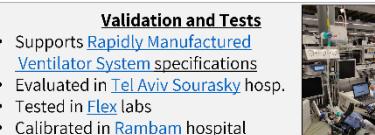


8. We intend to continue putting our best efforts in the device development and testing. However, it is clear to all, including the Israeli Regulatory Authority AMAR, that the ultrashort time from project initiation to the time the device might be needed and in use, makes full regulatory approval pathway unrealistic. We look at our device as a last resort life saver, aiming to be used in catastrophic occasions, when people are dying simply because of shortage in technology that could keep them alive. We already witness such situation, for example in Italy, where people are dying due to lack of regulatory approved ventilators.
9. Despite of the ultrashort time, with the help and work around the clock of the talented and committed teams and individuals who joined the effort, the device became real and went through various tests, to examine its performances and safety characteristics. Tests we done so far include performances using medical equipment uses for testing ventilators. We plan safety of medical electrical equipment tests complying with ISO 60601 EMC standard. We also plan animal (pig) study shortly.
10. We hope that in case of need, our efforts will support live saving.

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General specification – one pager

<p>Specifications</p> <ul style="list-style-type: none"> Volume control ventilation (VCV) machine 3 tidal-volume respective to (33%, 50%, 75%) of the bag total volume 11 ventilation rates ranging from 6 to 24 cycles per minute 5 ventilation steps between 30-70 cmH2O, of not-to-exceed inspirium pressure Electrical Source 110/220V Batteries Backup (2 hours duration) Visual and Vocal Alerts: Batt. On Low Batt Hose disc. Vent. rate fail. Extreme Pressure Ventilation pressure continuous monitoring IOT-based system, to monitor multiple patients 	<p>Emergency ventilation initiative coming out of Israel</p> <p>Who is behind it? Lead by the CTO & innovation leader of the Israeli Air-Force 108 Electronic Depot and backed by a large community of innovators behind him</p> <p>To include: 40 Professional Volunteers - Israel's national EMS, Physicians from leading Israeli hospitals such as Tel Aviv Sourasky and Hadassah JLM as well as other medical centers, Engineers, First Israel mentors and students, The Haifa Technological Center Rafael and Israel Aerospace Industries, IAF Unit 108, The garage program by Microsoft Israel and others..</p>	 <p>Analysis of Open Source COVID-19 Pandemic Ventilator Projects</p> <p>Project of Robert Lee Reed</p> <p>Rated by Robert Lee Reed as the leading solution in this category, among 40 other initiatives</p>
<p>UI-UX Specifications</p> 	<p>AmboVent 1690.108</p> <p>Automatic, Controlled Resuscitator Device</p> 	<p>Documentation</p> <ul style="list-style-type: none"> Files are available in an ANSI-metric standard Mechanical model design source-code files are provided in a Parasolid format (.X_T) 
<p>Off the Shelf Components</p> <ul style="list-style-type: none"> Hex Shaft Snowblower motors Spark mini Motor Controller ArduinoNano SparkFun Pressure Sensor 	<p>Emergency ventilation alternative system</p> <p>Global Partnership for the Greater good Leading Open Source Code Mentality Initiative</p> 	<p>Getting Ready for Production</p> <ul style="list-style-type: none"> Materials: Aluminum, Akylon-nylon6 Metallic painting capacities FDM based 3D printing machines Factory assembling capacities CNC, Punch, Bend manufacturing Capabilities Printing on Lexan  <p>Maj. Dr. David Alkaher Dalkaher@gmail.com</p>

To contact the project leader Dr. David Alkaher

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Lead by Dr. David Alkaher CTO & Innovation Leader

II AmboVent 1690.108 capabilities

General requirements

1. Manual selection of tidal volume, by choosing % of squeeze from full (100%) bag squeeze. For example, choosing 60% means the device pushes out every cycle, 60% of its full (100%) capacity.
2. Enable selection of 9 different respiratory rates, from 6-24 cycles per minute, increasing by steps of 2.
3. Compatible with Ambu (and other manufacturers) commonly used self-inflating bags, ranging between 1100 to 1475 cc.
4. Maximum inhalation pressure setting, ranging between 30 to 70 cmH₂O, increasing by steps of 10.
5. Works with standard Positive End-Expiratory Pressure (PEEP) valves.
6. Standard 110-220V Powerline feed + two-hours battery backup.
7. In events of resistance during inhalation (abnormal rise in air pressure), the bag squeezing process stops and regains inhalation in the following cycle.
8. Insulation of electrical and electronic parts to prevent the chance of sparking (in a pure oxygen-rich ventilation environment).
9. The ventilation bellows and piping connected to it are not part of the product and shall be provided by the hospital / MDA.

Functionality

1. Compliance with the use, connection, parts and integration of ventilation piping available in medical facilities.
2. Compact and lightweight. Can be positioned with flexibility around the patient's bed, up to 1.5 meters away with no fear of increasing the dead space.
3. Wide options of tidal volume selection, ranging from 30% to 100% of full squeezing capacity.
4. Nine different respiratory rates, ranging between 6 to 24 cycles per minute.
5. A predetermined I:E time ratio of 1:2. Can be changed in the program.
6. Positive End-Expiratory Pressure (PEEP) control, using a standard PEEP valve.
7. 110-220V power supply
8. Two hours of continuous operation on backup batteries in case of external power supply failure.
9. Simple, durable and intuitive structure and operation.
10. Capable of choosing Peak Inspiratory Pressure (PIP) sensing threshold, ranging between 30-70 cmH₂O.
11. Compatible with standard ventilation oxygen bags.
12. Can be connected to hospital's clean air supply. Useful for ventilating fresh and clean air in crowded rooms.

Automatic alerting upon malfunctioning

1. Electrical power supply failure (Audio alert (sound alarm) + visual indication by LED).

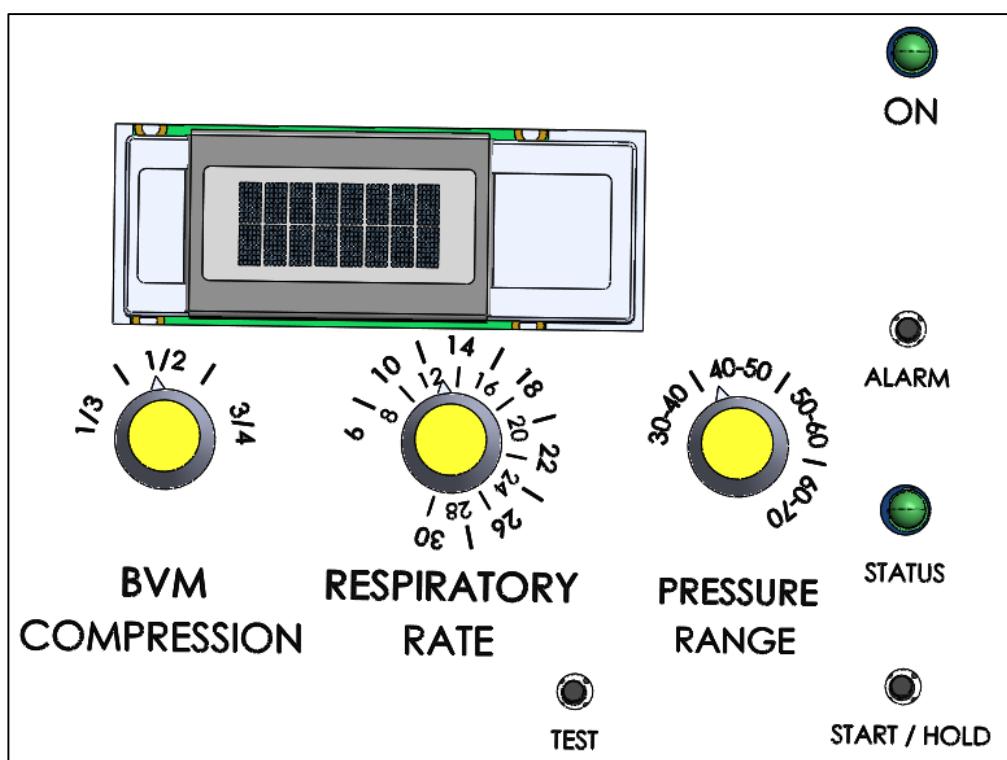
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2. Internal battery voltage drop (a continuous sound alarm that cannot be dismissed before reconnecting to an external power source + a visible led indication).
3. Alerting in case someone tries to turn off the device during active ventilation (will cause a one-minute continuous sound alarm + a visible led indication).
4. Pressure rise above the PIP threshold (one-time sound alarm. In case it continues (repeating events) – (continuous sound alarm with a prominent light indicator).
5. Sudden, unexpected pressure drops (may indicate air tubes disconnect) (continuous sound alarm that stops if pressure is build back to normal within two ventilation cycles. Otherwise, the alarm continues until operator active intervention.
6. Deviation from the user respiration rate setting (continuous sound alarm + a visible led indication).

User Interface and Operation

Device user interface



Functionality

Display	Type	Remarks
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BVM Compression	Potentiometer 	Pick values ranging from 30% - 100% of full bag squeeze
Respiratory Rate	Potentiometer	Pick values between 6 to 24 (increments of 2).
PIP Range	Potentiometer	Pick values between 30 to 70 cmH ₂ O (increments of 10).
Start / Hold	Button	Single short press turns the device on / 5 seconds continued press turns the device off.
Test	Button 	Pressing the button runs a one time cycle of 75% bag squeeze.
Alarm	Button	Turns off screen alerts and LED Status
Status	LED 	<p>LED Indications</p> <p>The device is on in Hold mode - Green</p> <p>Ventilation is on - Blinking green, synchronized with the respiration rate</p> <p>Malfunction - Blinking orange, synchronized with the respiration rate (error type will be listed on screen)</p> <p>Critical malfunction - Red</p> <p>Transitioning to battery mode (power disconnected) - blinking red in synchrony with the respiration rate</p>
On	LED	Indication of turning on the device - green in operating mode

UI: Feedback for User

Display	Type	Display	Remarks
Low pressure	Number	Value of minimum pressure as measured	Check the system

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		by the system	
Ventilation pattern differs from operator settings	Number	Value of maximum pressure as measured by the system	Reenter value of preferred ventilation rate
Alert when working on battery power	Potentiometer	“Batt On” Indication after disconnecting power source	LED - blinking red
Alert when continually working on battery for 2 hours	Button	“Low Batt” Indication of reaching 2 hrs of continuous operation on batteries	LED - malfunction blinking orange
Alert when ventilation hose disconnects	Button	“Hose Disconnect” Indication pressure hose disconnected	LED - malfunction blinking orange
Critical malfunction alert	Button	“Vent. Rate fail”	LED - malfunction red
Pressure reaching the PIP threshold	Number	Extreme Pressure	Alarm

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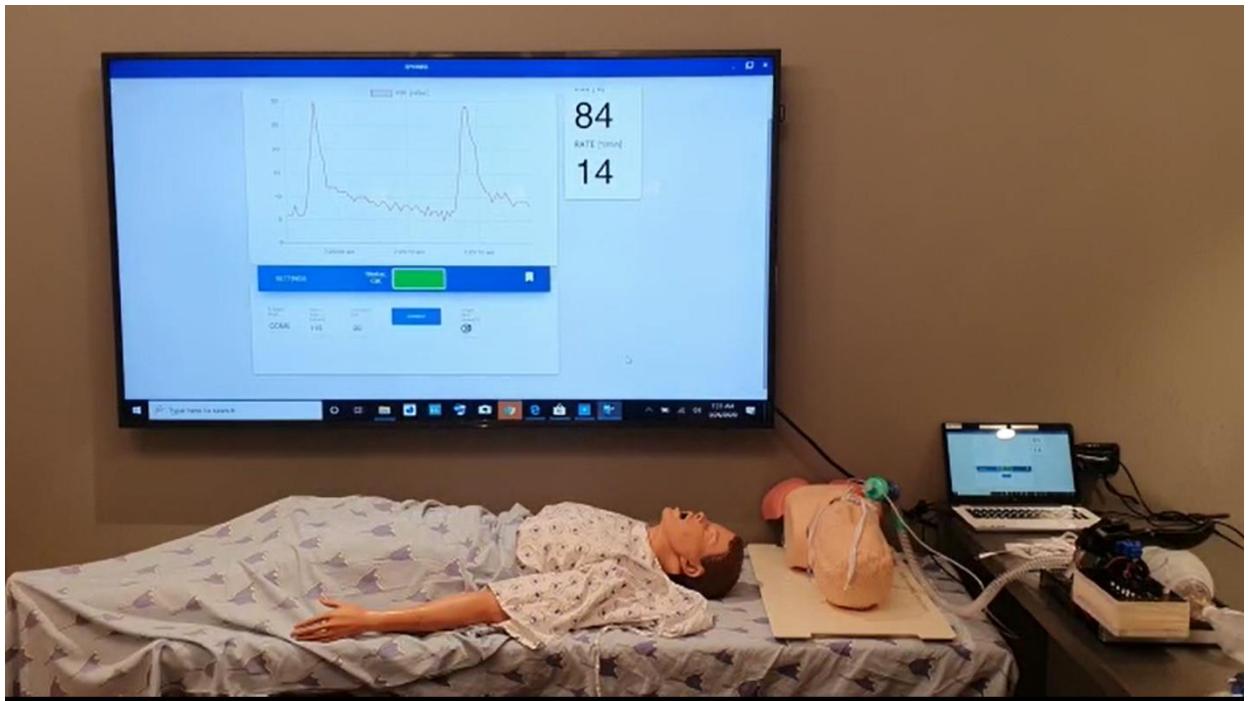
1. General scheme for use of system



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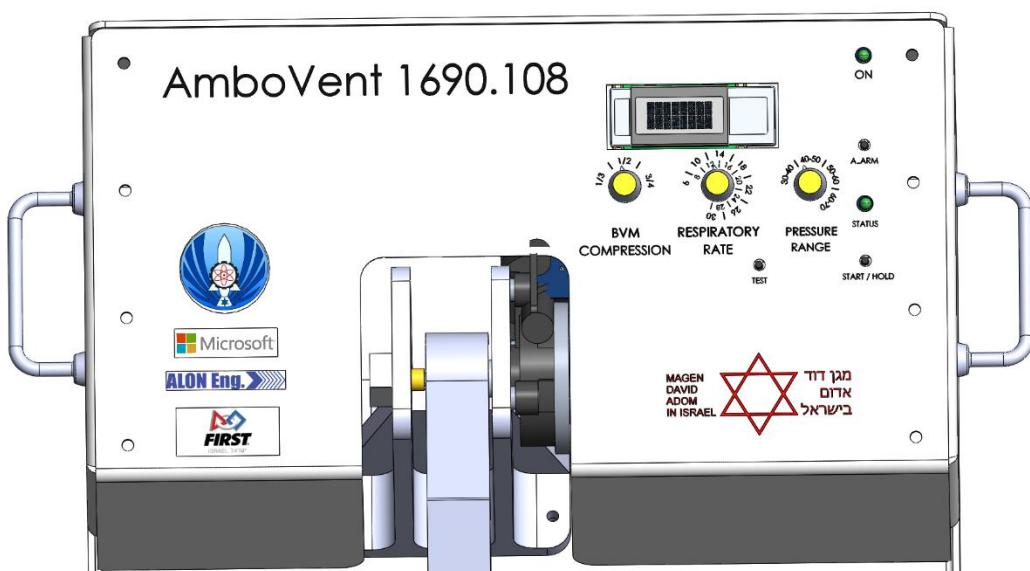
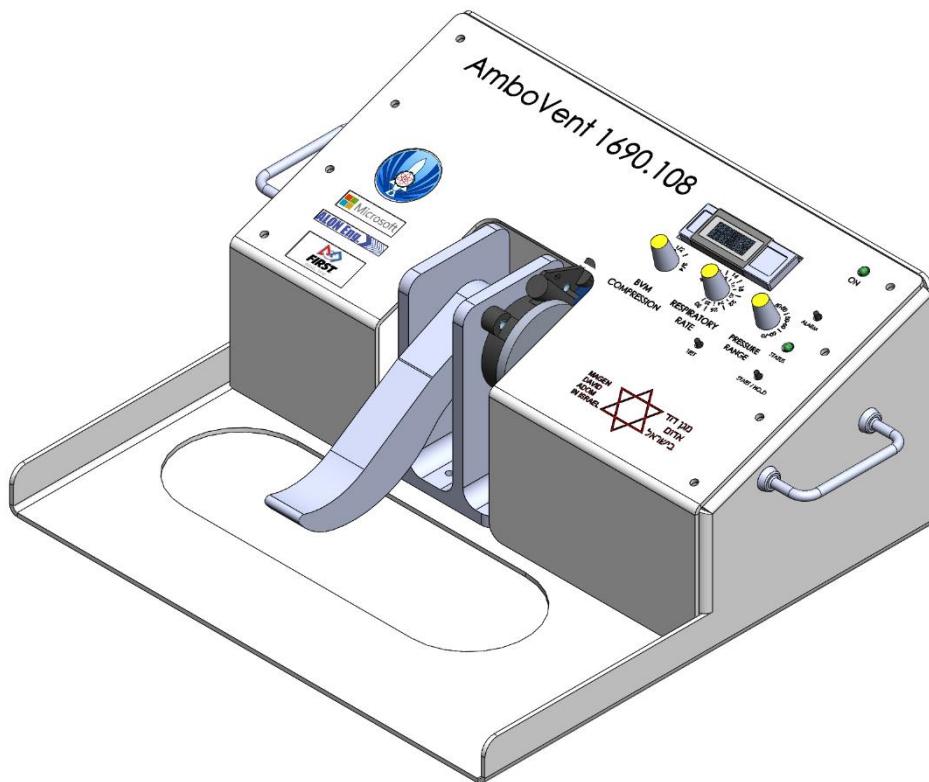
2. Monitor indication



Method of monitor connection – to laptop computer with USB connection

III Mechanical design

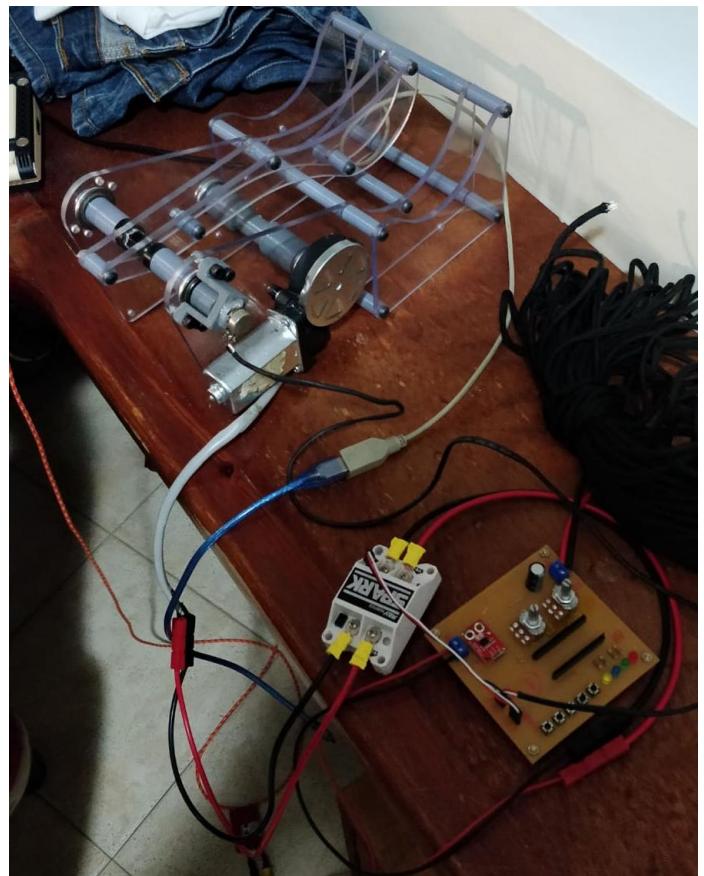
1. Packaging



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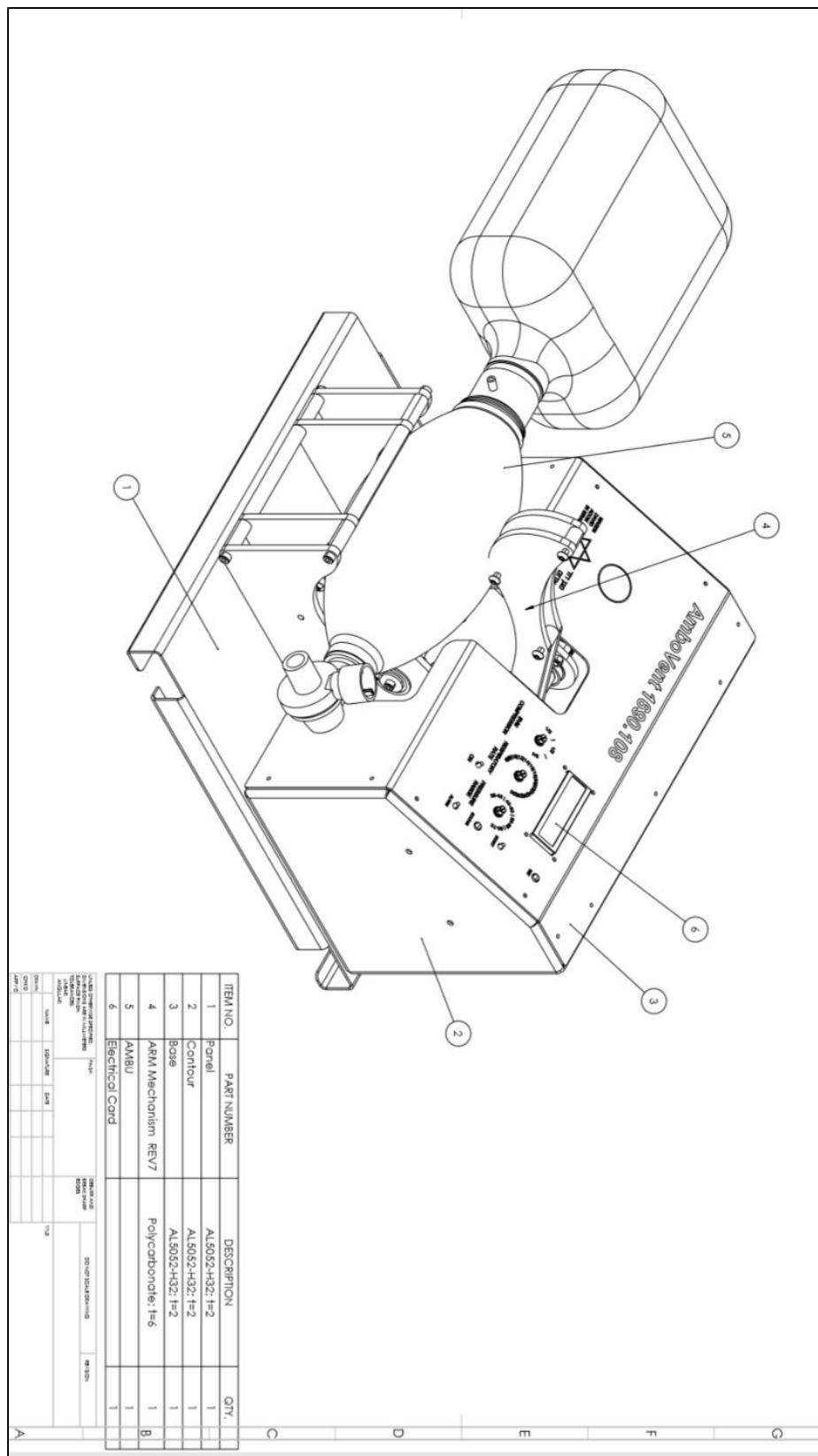
2. Illustration of parts of pressing system mechanics, before and after assembly



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3. Mechanical assembly drawing of entire system



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Panel	Al.5052-H32; I=2	1
2	Contour	Al.5052-H32; I=2	1
3	Base	Al.5052-H32; I=2	1
4	ARM Mechanism REV7	Polycarbonate; I=6	1 B
5	AMB		1
6	Electrical Card		1

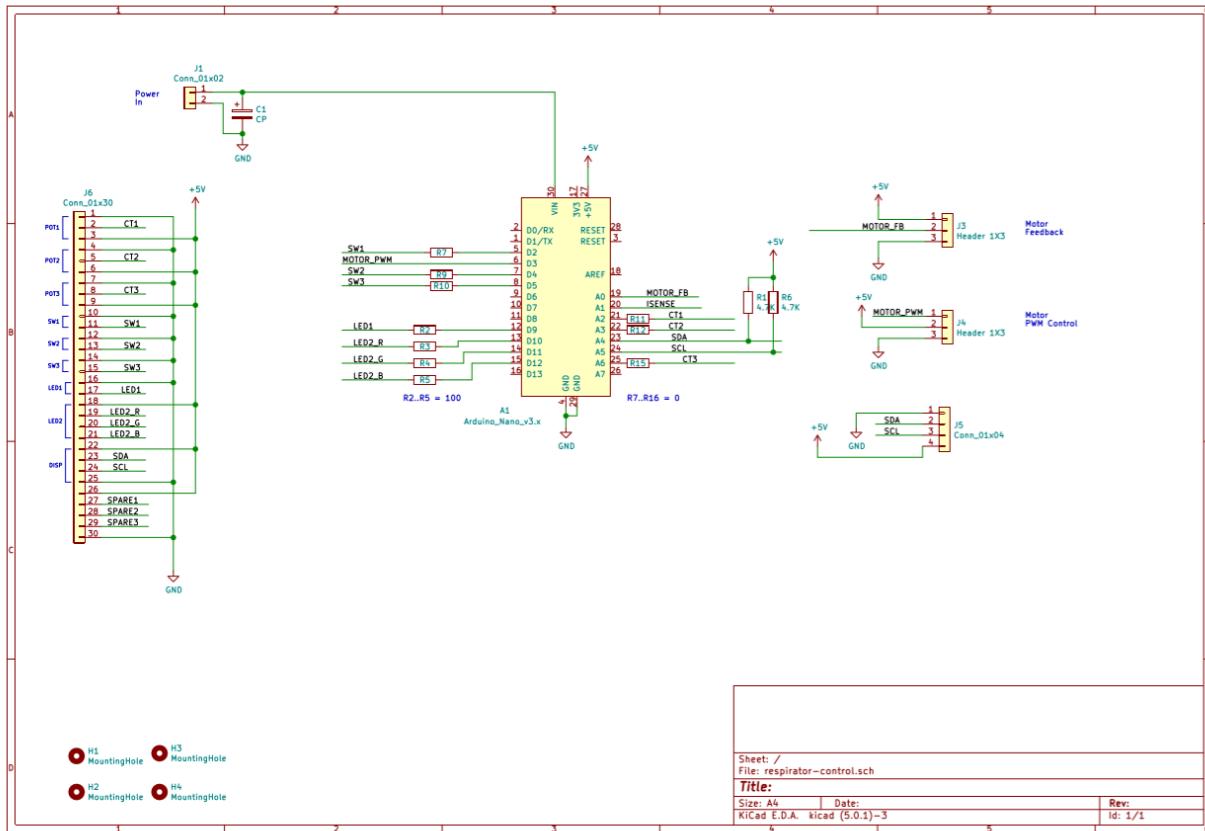
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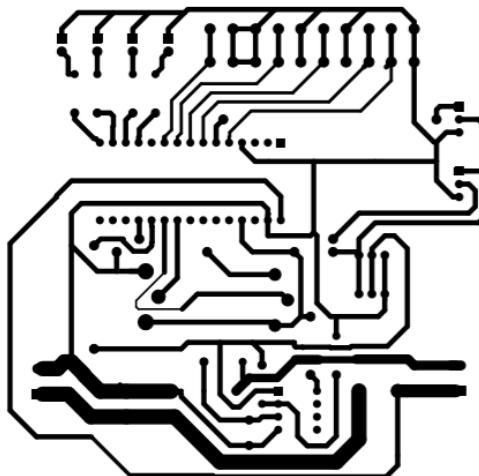
IV Electronics specification

1. Circuit electronics for prototype

a. Circuit diagram for prototype

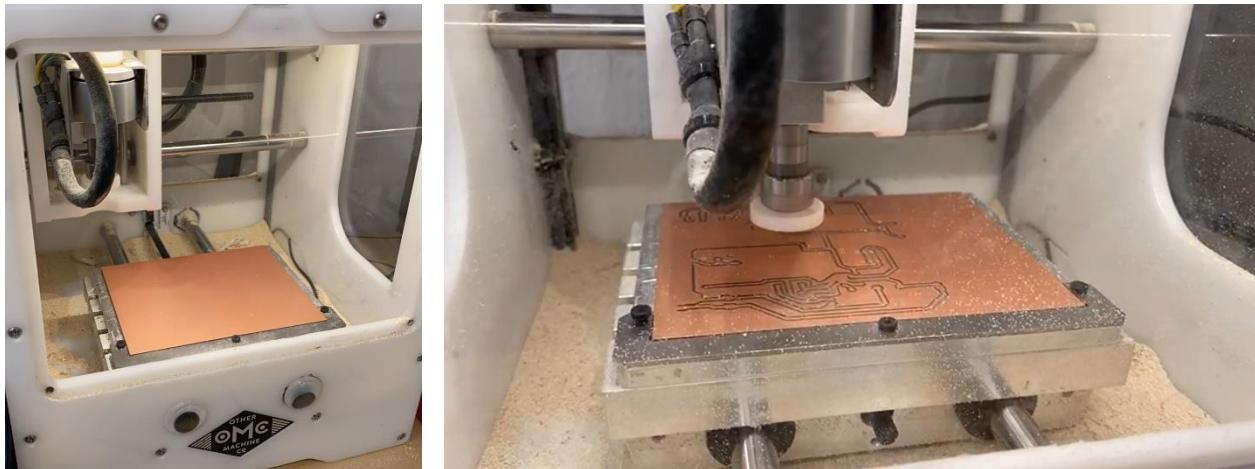


b. PCB diagram

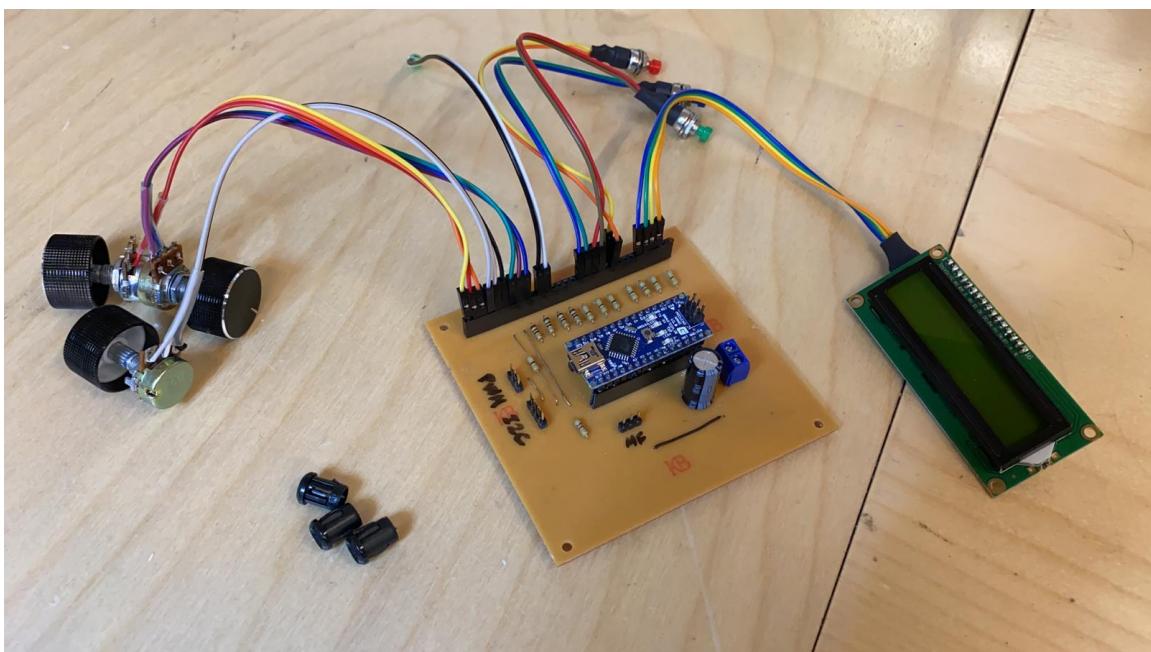


c. Method of production of electronic PCB for prototype – copper etching

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d. PCB after production



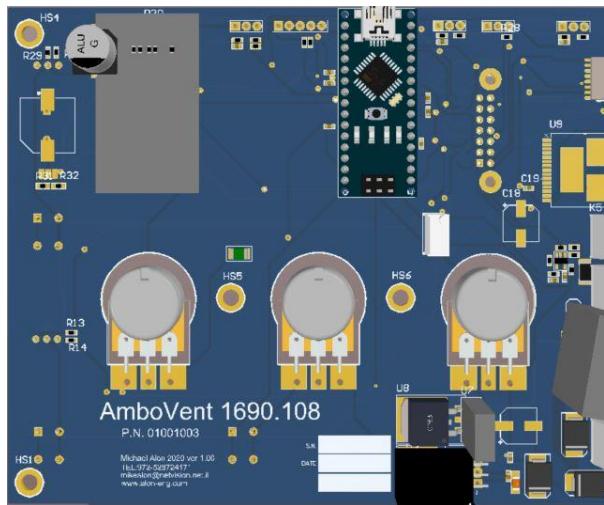
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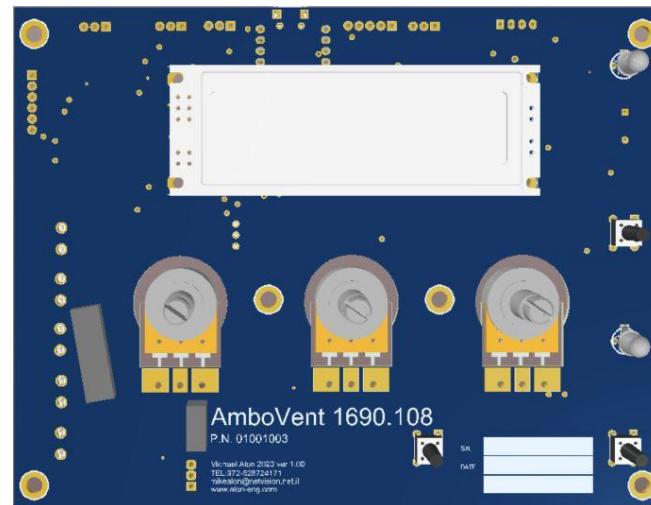
2. PCB for serial production

a. Illustration of PCB for serial production

Top view



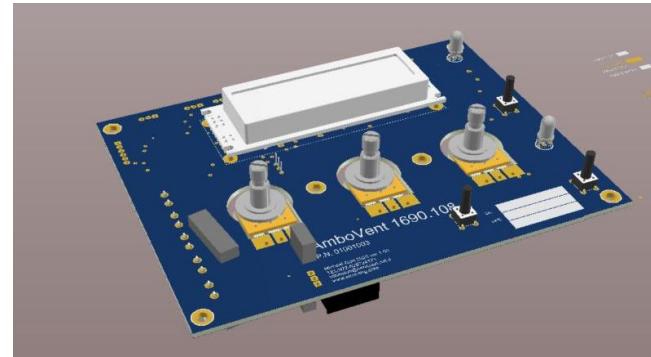
Bottom view



Upper side view



Bottom side view



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Annex – Manual Automatic Ventilation Bellows – Regulatory Specification

I Introduction

1. This annex constitutes a minimal specification for a system of converting manual ventilation bellows to autonomous operation according to Code Life Ventilator Challenge, McGill University. <https://www.agorize.com>. Solutions for conversion of such bellows should be introduced by various medical emergency bodies as a last resort, for use in cases where the number of COVID-19 virus patients requiring ventilation treatment exceeds the number of available standard ventilation devices. Simple devices that replace human hands shall enable treatment of many patients, if needed. The device also substitutes supervision by a medical staff member.
2. Ventilation at positive pressure based on a ventilation bellows – mandatory criteria we comply with, based on [Rapidly Manufactured Ventilator System MHRA](#).

*Marked in parentheses at the end of each section, the section referred to according to the MHRA standard.

II Ventilation

1. The relevant ventilation mechanism is a VCV (Volume Control Ventilation) type mechanism ([Ventilation 1B](#)).
2. Ventilation according to volume and rate, as indicated by the caregiver ([Ventilation 1D](#)).
3. The machine shall ventilate continuously from the moment it's turned on, until turned off ([Ventilation 2](#)).
4. Ventilation pressure – at present, current-based closed loop control. Later an external sensor will be included for pressure control. Calibration shall be based on standard pressure of 40cm H₂O with option of change by caregiver's requirement for

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values in the range of 30 to 70 cm H₂O – to be performed only after matching a control screen (Ventilation 3C).

5. Mechanical pressure relief valve for pressure above 80cm H₂O – based on standard, existing medical equipment (Ventilation 3D).
6. Installation of external PEEP valve, based on standard PEEP valve compatible with the ventilation bellows to be used (Ventilation 4).
7. I:E ratio of 1:2, i.e., it takes the bellows twice as long to perform expirium than inspirium. It should be verified that this measure is maintained throughout all ventilation volumes and rates (Ventilation 5A).
8. The ventilation rate shall vary in the range of 10 to 30 ventilations per minute, at increments of 2 (there is room for flexibility with several intermediate steps within the range) (Ventilation 6A)
9. The default state of ventilation volume (Tidal Volume) shall be 400cm³ with a range of 300-800cm (Ventilation 7).



III Electricity and electronics

1. Wall transformer shall be capable of receiving an output voltage of 220V (Gas and electricity 2A).
2. Battery sufficient for at least two hours of operation (g&e 2D).
3. Recommendation for capability of battery replacement if needed, to extend device's operation time in case of power outage. (g&e 2D)

IV Casing

1. The device's casing shall be made of material that is easily cleaned, and remains undamaged from commonly used disinfectant equipment used in the medical field. (Infection control 2)
2. The device's casing shall be resistant to staining by blood and other body fluids. (Infection control 2)

V Alerts and alarms

1. Power outage of output voltage (alarm that may be muted with indicator lamp that stays on) (Monitoring and Alarms 1A).
2. Decrease in voltage of internal battery (continuous alarm that cannot be canceled without reconnecting to external power source; prominent indicator lamp (Monitoring and Alarms 1A).
3. Attempt to turn off device while ventilating (continuous alarm of one minute with prominent indicator lamp) (Monitoring and Alarms 1B).
4. Dangerous pressure rise in the system (one-time alarm and change of ventilation pattern; if incident recurs then a continuous alarm with prominent indicator lamp (requires installation of pressure sensor) (Monitoring and Alarms 1C).
5. Sudden drop in pressure that could indicate a disconnection of tubing (continuous alarm that cannot be muted until ventilation stopped or device turned off) (Monitoring and Alarms 1D)
6. Inability to achieve ventilation volume defined in user's selector (prominent indicator lamp, and if incident recurs then alarm may be canceled) (Monitoring and Alarms 1E).

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7. Consecutive recurring incidents of ventilation volume greater than that set with user's selector (continuous cancellable alarm with prominent indicator lamp) (Monitoring and Alarms 1E).
8. Deviation from ventilation rate set by user (continuous cancellable alarm with prominent indicator lamp).

VI Output for user

1. The following parameters shall be presented to the user in a clear and intuitive display:
 - a. Ventilation volume (Monitoring and Alarms 2A)
 - b. Ventilation rate (Monitoring and Alarms 2A)
 - c. PEEP pressure if defined on system level or clear direction to disposable mechanical valve (shall be based on PEEP valve from manufacturer of tubing used at the hospital) (Monitoring and Alarms 2A).
2. In addition:
 - a. Must be reliable, with ability of continuous operation according to instructions of manufacturer of motor used, and manufacturer's guidelines for number of squeezes of ventilation bellows. (Miscellaneous 1)
 - b. Must have option of placing the device on the floor (Miscellaneous 3).
 - c. Size and weight must be small and light enough in order to move the product and place it on the patient's bed while moving his bed (Miscellaneous 4).
 - d. Reasonably high resistance to mechanical shock. For example, should the device fall from the bed to the floor (Miscellaneous 5).
 - e. Intuitive operation to a reasonable degree, in order that a medical staff member from that field may use the product with no need for in-depth instruction. (Miscellaneous 6)
 - f. Training time of less than 30 minutes with little previous experience in use of ventilators (Miscellaneous 6A).
 - g. Must attach operating instructions and quick operation cards to place adjacent to device including explanation of all alerts, alarms, and their implications. (Miscellaneous 6C+6D)

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- h. All operating instructions or additional material must be in language compatible with area of distribution.
 - i. Device must be light and easily portable, in order not to disrupt orderly functioning of the hospital. (Miscellaneous 8)
 - j. It should be clearly noted that the device is intended for use in times of crisis, emergencies and extreme cases only, and is not suited for use under normal circumstances and over time. (Testing 3)
3. User interface:
- a. It should be assumed that in extreme cases the user shall be wearing an impenetrable apron, a pair of double gloves, face protection, and N95 mask and a hat. Therefore, the device must be easy to use even by a caregiver wearing all of this or other protective equipment. (Testing 4)
 - b. It is desired that the device should be usable even when wearing stringent and cumbersome protective equipment and clothing.

VII Table of Ambo 1690.108 comparison with MHRA

Chapter	Section	Is it relevant for discussion?	Does it comply with the section?
Ventilation	1.a Must have mandatory ventilation.		
	1.b Mandatory mode must be either (ideally) Pressure Regulated Volume Control, or a pressure controlled ventilation (PCV) or a volume controlled ventilation (VCV).	+	+
	1.c PRVC/Pressure Controlled - a set pressure is delivered for the period of inspiration and the volume achieved is measured and displayed. Ideally, PRVC, an adaptive mode where the tidal volume is set and the lowest possible pressure is delivered to achieve this volume. Pressure Control Ventilation where the user has to provide the adaptive control to achieve tidal volume is only acceptable if the tidal volume delivered is clearly displayed and the user can set patient specific upper and lower tidal volume alarms to alert to the need to adjust the pressure.		
	1.d Volume Control – the user sets a tidal volume and respiratory rate. The tidal volume is delivered during the inspiratory period. Acceptable only if additional pressure limiting controls are available, see Inspiratory Pressure section.	+	+
	1.e Optional pressure support mode for those patients breathing to some extent themselves, e.g. BIPAP or SIMV-PC. The user sets an inspiratory pressure and an expiratory pressure. The ventilator can sense when a patient starts to breathe in and apply the inspiratory pressure, then sense when the patient starts to breathe out and apply the expiratory pressure (this pressure is still positive but lower than the inspiratory pressure).		
	2. If the patient stops breathing in a spontaneous mode it must failsafe automatically onto mandatory ventilation.	+	+
	3.a Plateau pressure should be adjusted to achieve volume and be limited to 35 cmH ₂ O by default. It is acceptable if an option to increase this to 70 cmH ₂ O in exceptional circumstances is provided.		
	3.b Peak pressure should be no more than 2 cmH ₂ O greater than plateau pressure.		

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	3.c If volume control ventilation is used, the user must be able to set inspiratory airway pressure limit in the range at least 15 – 40 cmH ₂ O in at least increments of 5 cmH ₂ O.	+	+
	3.d There must be a mechanical failsafe valve that opens at 80 cmH ₂ O.		
	4. Positive End Expiratory Pressure (PEEP). The pressure maintained in the breathing system during expiration.	+	+
	4.a Range 5-20 cm H ₂ O adjustable in 5 cmH ₂ O increments.	+	+
	4.b Patient breathing system must remain pressurised to at least the PEEP level setting at all times.	+	+
	5. Inspiratory:Expiratory ratio (I:E). The proportion of each breathing cycle that is spent breathing in compared to breathing out.		
	5.a 1:2.0 (i.e. expiration lasts twice as long as inspiration).	+	+
	5.b Optionally adjustable in the range 1:1 – 1:3.		
	6. Respiratory Rate. The number of breathing cycles every minute.		
	6.a Range 10 – 30 breaths per minute in increments of 2 (only in mandatory mode) can be set by the user.	+	+
	7. Tidal Volume (V _t) setting, if provided. The volume of gas flowing into the lungs during one inspiratory cycle	+	+
	7.a Must have at least one setting of 400ml +/- 10 ml.	+	+
	7.b Ideally 350ml and 450 ml options.	+	+
	7.c Optionally Range 250 – 600 ml in steps of 50ml.	+	+
	7.d Even more optionally up to 800 ml.	+	+
	7.e Optionally the ability to input body weight and have volume calculated as e.g. 6ml/kg of ideal body weight.	+	+
Gas and electricity	1. Incoming Gas Supply.		
	1.a All gas connectors and hoses must comply with BS EN ISO 5359:2014+A1:2017, ISO 5359:2014/AMD 1:2017 and BS 2050: 1978 Electrical Conductivity.	-	-

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	1.b Must connect to wall pipeline oxygen supply via BS 5682:2015 compatible probes (Schrader). If hose not permanently fixed to machine, then must connect with NIST (Non-Interchangeable Screw Thread to ISO 18082:2014/AMD 1:2017). Oxygen pipeline pressure is approximately 3.7 – 4.5 bar.		
	1.c Oxygen supply from wall outlets outside of ICU and theatres is limited to approximately 6-10 lpm (HTM_02-01_Part_A) and so provision for a gas reservoir will be required to manage peak inspiratory flow rates of up to 100 lpm		
	1.d Average oxygen consumption must be no more than 3 lpm. This may be allowed to increase as greater certainty is gained over oxygen supply.		
	1.e Optionally can connect to wall pipeline Medical Air (MA4, NOT SA7) via BS 5682:2015 compatible probes.		
	1.f Optionally can connect to ISO 7396-2:2007 compatible Anaesthetic Gas Scavenging System or an external activated charcoal absorber (If inhaled anaesthetic agents are being used).		
	1.g Optionally can operate using an oxygen concentrator device for input oxygen, these will typically be limited to 10 lpm.		
	2. Electricity Supply.		
	2.a Should connect to 240V mains.	+	+
	2.b Should be PAT tested to the adapted IEC 60601, IEC 62353 standards		
	2.c Battery backup – see Unknown issues section. Must have 20 minutes back up battery in case of mains electricity failure.		
	2.d Optionally hot swappable batteries so that it can be run on battery supply for an extended period, e.g. 2 hours for within hospital transfer.	+	+
	2.e Must avoid harmful RF or EM emissions that could interfere with other critical machinery.		
	3. Gas supply to patient.		

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	3.a User must be able to control inspired oxygen proportion (FiO2). The percentage of oxygen in the gas being breathed in by the patient. Room air is 21% oxygen.		
	3.b At least (50% or 60%) and 100% options		
	3.c Ideally variable between 30 – 100 % in 10% steps.		
	3.d Patient breathing system connections: the ventilator must present 22mm outside diameter (OD) 'male' standard connectors to ISO 5356-1:2015 on both outlet and inlet ports for connection to user supplied 22mm 'female' connectors on the breathing system. These must be rigid and robust (not plastic) and separated by a minimum of 10 cm between centers to accommodate filter HMEs.		
	4. All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimise risk of fire or contamination of the patient's airway.		
Infection control	1. All parts coming into contact with the patient's breath must be either disposable or able to be decontaminated between patients.		
	2. All external surfaces must be cleanable in the likely event that they get respiratory secretions or blood splatter on them. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid.	+	+
	3. There will be a separately sourced HMEF-bacterial-viral filter between the machine and patient which may impact on resistance within the system, which may need to be accounted for with some designs. The pressure being delivered to the patient is the specified pressure. If the filter has a resistance of, say 2 cmH2O at 30 lpm, the ventilator needs to output 37 cmH2O to achieve a set 35 cmH2O at the patient. This will need further detailed consideration. Viral filtering filters may have much higher resistance that may be clinically relevant.		
	4. Optionally include facility for hot water humidifier to be included in breathing system.		
Monitoring and Alarms	1. Must alarm at:		

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	1.a Gas or electricity supply failure.	+	+
	1.b Machine switched off while in mandatory ventilation mode.	+	+
	1.c Inspiratory airway pressure exceeded.	+	+
	1.d Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm).	+	+
	1.e Tidal volume not achieved or exceeded.	+	+
	2. Monitoring – the following should be continuously displayed so the user can verify.	+	+
	2.a Current settings of tidal volume, frequency, PEEP, FiO ₂ , ventilation mode.	+	+
	2.b Actual achieved rates of tidal volume, breathing rate, PEEP, plateau pressure, FiO ₂ .		
	2.c If it exists, in pressure support mode there must be real time confirmation of each patient's breath and an alarm if below acceptable range.		
	2.d Optionally CO ₂ monitoring included.		
Miscellaneous	1. Must be reliable. It must have 100% duty cycle for up to 14 days.	+	+
	2. Optionally it can be used beyond 14 days, the expected durability must be specified.		
	3. Can be floor standing.	+	+
	4. Ideally small and light enough to mount on patient bed and orientation independent functioning.	+	+
	5. Should be as robust as possible. For example, it may be dropped from bed height to floor.	+	+
	6. It must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use.	+	+
	6.a Must not require more than 30 minutes training for a doctor with some experience of ventilator use.	+	+

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	6.b Must include Instructions for Use.		
	6.c Ideally instructions for use should be built into the labelling of the ventilator, e.g. with 'connect this to wall' etc.	+	+
	6.d Must include clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognized by UK healthcare staff.	+	+
	7. Must have transparent design, supply chain, manufacture, quality assurance and testing processes that are of sufficient quality to enable MHRA officials to deem appropriate for usage in exceptional circumstances.		
	8. Must not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospital premises.	+	+
	9. Must be made from materials and parts readily available in the UK supply chain (anticipating increasing global restrictions on freight movement).		
	10. Standards – there are many standards that exist in this area. Below is a list of the most relevant ones. They are not formal regulatory requirements, but many are harmonized against regulatory requirements. Consider them as helpful advisory standards for now. MHRA will lead an exercise to define which can be 'safely' relaxed for this emergency		
	10.a BS EN 794-3:1998 +A2:2009 Particular requirements for emergency and transport ventilators		
	10.b ISO 10651-3:1997 Lung Ventilators for Medical Use - Emergency and Transport		
	10.c BS ISO 80601-2-84:2018 Medical electrical equipment. Part 2-84. Particular requirements for basic safety and essential performance of emergency and transport ventilators – especially the parts on 'patient gas pathway' safety (very similar to IEC 60601)		
	10.d ISO 80601-2-12:2020 Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators		
	10.e BS ISO 19223:2019 Lung ventilators and related equipment. Vocabulary and semantics		

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Testing	1. It is accepted that full demonstration of compliance to ISO 80601-2-12:2020 is unrealistic in the timeframe required for development. Nevertheless, compliance with the essential safety standards must be demonstrated for patient safety.		
	2. It is not anticipated that devices will be CE marked and approval by the MHRA will be through the “Exceptional use of non-CE marked medical devices” route.		
	3. When the current emergency has passed these devices will NOT be usable for routine care unless they have been CE marked through the Medical Device Regulations. The device must display a prominent indelible label to this effect.	+	+
	4. Usability testing at both prototype and final production stages will be required. This should be done as a short Formative Usability Test to ISO62366 (this can be done in a day) in a realistic environment if possible. The user will be wearing complex protective clothing which includes: Eye goggles (in addition to spectacles if worn), Face shield, Plastic apron, Surgical gown, Two layers of gloves, usually nitrile non-handed small, medium, large variants, Gloves are donned in layers and sticky taped onto sleeves of gown in between layers.	+	+
	5. The user must be able to instantly see the settings selected and be able to easily operate all controls while dressed in protective gear. They may be required to remain so clothed and operating the ventilator for a number of hours without breaks.		



Literature review and comparison to other similar solutions

Evaluating Open Source Ventilator Projects

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I propose we use a 5-point scale for each attribute, but we give a precise definition of what it means to be at a certain level for each scale. Then we can add footnotes, but the overall table will be short and understandable.

Attributes are:

1. Openness
2. Buildability
3. Community Support
4. Functionally Tested
5. Reliability Tested
6. COVID-19 Suitability
7. Clinician Friendly

Openness

1. Not Open
2. Declared to be open, but no plans published
3. Have a repo with at least some plans
4. Has a clear license strategy, regular updates to plans
5. Fully open, everything documented, responsive community, clear license

Buildability

1. Unbuildable
2. Documents available but they require guesswork
3. All software and hardware transparent and documented. Some manufacturing instructions, such as a build video
4. Complete documentations suggested reproducibility
5. Has been successfully reproduced by another team purely from documentation

Community Support

1. Inactive; not point of contact
2. Point of contact, but unresponsive
3. Responsive leader or manager, more than one volunteer
4. Active community, weekly activity and reports, git repo or other shared documents
5. Large, active, open community

Functional Testing

0. In Design Phase, Not listed/tested

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1. Makes a bag move
2. Tested with a test lung
3. Tested for pressure and volume limits, with breath rate control
4. Tested for alarms, multiple modes, O2 mixing
5. All test green (if asserted as a feature)

Reliability Testing

0. Not Listed

1. Operates for one hour
2. Operates for 12 hours
3. Operates for 12 hours passing all functional test acceptably (low exception rate)
4. Independent team operates for 48 hours passing all functional tests, data logs reviewed
5. Mean time between failure data starting to become meaningful

COVID-19 Suitability

1. Operates with supplemental oxygen
2. Pressure or volume control or both
3. PEEP
4. Sophisticated alarm capability and stabilizability of all patient contact points
5. Meets British [RVMSv1 standards](#)

Clinician Friendly

0. Unknown controls

1. No controls
2. Breath rate and volume control, standard ports
3. Breath rate, volume and pressure control easy to set, standard ports, clear external labeling graphically and in the language of choice
4. Alarms easy to set and understand, wholesale replication of an existing UI or conformance to a TBD UI standard
5. Data logging, informative, easy control, battery backup for moving. No training needed in normal operation due to similarity with familiar designs.

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VIII Comparison (1/4/20)

Project Name	Project Link	Openness	Buildability	Community Support	Functional Testing	Reliability Testing	COVID-19 Suitability	Clinician Friendly	Average	Notes
Ambovent	https://members.smugme.in/view.aspx?messegeid=447982&listid=3581502196540127397&msgid=1009	2	1	3	4	3	5	4	3.14	
Low-Cost Open Source	https://github.com/jcl5m1/ventilator	5	4	4	3	0	2	2	2.86	Has a good repo and community behind it with active projects
VentilAid	https://www.ventilaid.org/	5	4	4	3	0	2	2	2.86	Great open source project that has amazing documentation that could be built to completion
Open Source Ventilator Project	https://simulation.hettich.edu/technology_development/open_source-ventilator-project/	3.5	2.5	4	2	2	3.5	2.5	2.86	Best evidence of reliability. Seems very open, but has no license. Requires close watching!
DIY-Beatmungsgerät [Respirator]	https://devpost.com/software/diy-beatmungsgeraet	5	4	3	1	0	3	3	2.71	In German, may be misreading. May not have PEEP, but mentions good alarm monitoring, so 3.5 on functional tests.
Rice OEDK Design: ApolloBVM	https://docs.google.com/document/d/1DRXnVkJ0fXmV2hDgWfIwvS7IBVvHnpzv8NA/edit	3	3	2	3	3	2	3	2.71	Good documented solution created for senior design in university.
Jeff Ebin's Prototype	https://www.ebcore.io/?fbclid=IwAR3_S0qJsohI4rmP3tQfYS26_8Npx61nakv8kNPnPj4KS4i0L_aR0U	5	4	3	1	0	2	3	2.57	Created by MD, Worth a look
A low oxygen consumption pneumatic ventilator for emergency construction	https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2009.06207.x	4	3	2	4	1.5	1	2	2.5	Very good research topic with layed out plans for pressure controls
Protofy Team OxyGEN	https://oxygen.protofy.xyz/	4	4	4	1	0	2	1	2.29	Easy mechanical build
Electric Blower Based Portable Emergency Ventilator	https://digitalcommons.sjsu.edu/cpj/viewcontent.cgi?referer=https://www.google.com/search&hl=en&ct=&cd=&rq=1&hlid=1wR1f1VxXm82Pj0WFCa07H_MN7Vuse4Pf6N0REs9h47Qj09sNdQjxhc	3	3	2	3	1	2	1	2.14	
MIT E-Vent	https://e-vent.mit.edu/	2	1	2.5	3	1	3	1	1.93	Apparently tested on a live porcine model
Saving Babies' Lives Starts With Aquarium Pumps And Ingenuity	https://www.npr.org/sections/health-shots/2014/01/03/259436944/saving-babies-lives-starts-with-aquarium-pumps-and-ingenuity	1	1	2	5	0	0	4	1.86	CPAP for infants
The Pandemic Ventilator	https://docs.google.com/document/d/1H7zMeXnufPbBA_OPkfXwHnIMhGtAxPshCj2V4/edit?usp=sharing	4	2	3	0	0	4	0	1.86	Good document for design, not finished, a work in progress
VentilatorPAL	https://freerethinking.org/	2	1	3	1.5	1	1.5	2	1.71	Pre-orderable. Large but somewhat opaque team, little test information.

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Project Name	Link	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
Open source ventilator Pakistan	https://docs.google.com/spreadsheets/d/1nBFyHlItev0hWGIISzr_yQkhYF2OCy8RPaI1zIWFMy/edit#gid=1040995025	3	1	2	0	0	3	3	1.71	Well documented, large community, but in design phase																																																																																											
CoronavirusMakers	https://github.com/coronavirusmakers	3	2	3	0	0	2	1	1.57	In Spanish, can only read a little, may have more																																																																																											
The Pandemic Ventilator (older)	https://www.instructables.com/id/The-Pandemic-Ventilator/	3	4	1	1	0	1	1	1.57																																																																																												
Open Source Ventilator - OpenLung BVM Ventilator	https://github.com/OpenLungVentilator/OpenLungVentilator	5	1	4	0	0	0	1	1.57																																																																																												
MIT Low Cost Ventilator	https://github.com/JulianSpain/openventilator	3	2	2	1	0	0	2	1.43																																																																																												
Dr. Mujeeb ur Rahman design	http://www.technologreview.pk/pakistan-engineer-haves-tragedy-to-develop-low-cost-ventilator/	1	1	2	1	0	2	3	1.43																																																																																												
Hackaday Rex Ventilator V1	https://github.com/hackadayrex/ventilator	2.5	2	2.5	1	0	1	1	1.43	Great photos and video but no reproducible plans.																																																																																											
Pandemic Ventilator	https://www.facebook.com/groups/670932272050560/permalink/67564606617268/	1	1	2	2	0	0	1	1.29	Inventor says may open source																																																																																											
Simple device from www.POMO.cl	https://www.facebook.com/groups/670932272050560/permalink/67564606617268/	1	2	3	1	0	0	1	1.14																																																																																												
Cuirass Ventilator the DIY way	https://www.youtube.com/watch?v=pw7QcMa3a8&feature=youtu.be	2	2	1	1	0	0	1	1																																																																																												
Pandemic Ventilator Project	https://pavent.blogspot.com/2008/02/test-of-pandemic-ventilatorwith.html	2	1	1	2	0	0	0	0.86																																																																																												
Mechanical Ventilator Milano (MVM)	https://arxiv.org/pdf/1003.1040.pdf	1	2	1	1	0	0	1	0.86																																																																																												
OxVent	https://oxvent.org/	1	1	1	3	0	0	0	0.86	Could be great, but almost no information																																																																																											
Low-Cost Ventilator Wins Sloan Health Care Prize	https://www.medicaldesignandoutsourcing.com/low-cost-ventilator-wins-sloan-healthcare-prize/	1	1	1	0	0	2	0	0.71	Very little information																																																																																											
Open Breath Italy	https://www.openbreath.it/en/	1	1	2	0	0	1	0	0.71	Not enough information to evaluate well																																																																																											
YACoVV - Yet Another (SARS-) CoV(-2)Ventilator	https://github.com/auenkind/YACoVV	2	1	2.5	1	0	3	1	1.5	Fluid pressure based solution																																																																																											



Emergency Ventilation Initiative Coming Out of Israel



Israel Society of Resuscitation

Within Hospital Outline

Written and validated by:

Prof. Sharon Einav – Chairman, Israel Society of Resuscitation

Deganit Kobliner-Friedman, Institutional Resuscitation Coordinator, Sha'arei Tzedek

1. Hospital outline:

Preliminary guidelines

1. Suspected or confirmed COVID 19 patient shall be treated by the **team of the caregiving department**, in the event of cardiac arrest as well.
2. If an anesthetist is needed for intubation, it should be noted **at time of call** that the patient is suspected of or confirmed for COVID 19.
3. Every team member treating airway must be **fully protected** with the designated protective equipment for treatment of COVID 19 patients.
4. **Due to fear of aerosol spread**, the procedure of resuscitation for these patients shall be as follows:
 - 4.1. Patient ventilated through ET tube: do not disconnect from respirator.
 - 4.2. Patients assisted by artificial ventilation (Vapotherm, Optiflow or CPAP): **close the flow of oxygen** immediately at start of resuscitation, before treating the patient.
 - 4.3. Patient with BIPAP: **do not remove the mask** before turning off the device.
 - 4.4. Non-ventilated patient: **do not give oxygen in oxygen glasses or oxygen mask, and do not ventilate in mask with Ambu.**

Resuscitation

1. Begin high-quality massaging ASAP.
2. Connect to defibrillator and give a shock within two minutes if dealing with VT/VF.
3. If the patient is still breathing, injection of anesthesia and **paralyzing drug. Paralysis is intended to prevent coughing and spread of aerosol (a gasping patient is considered breathing)**.
4. **Do not insert airway.**
5. Tracheal intubation should be done by the most highly skilled team member **present on-site**.
 - 5.1. If there is a video laryngoscope, **cover the patient's upper body with a transparent surgical sheet** and perform the tracheal intubation with the hands of the intubator are under him and his head above him with minimum recess in massaging.

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- 5.2. If there is no video laryngoscope, **contrary to the usual practice, massaging should be stopped during laryngoscopy**, and cover the patient's upper body with a transparent surgical sheet immediately after tracheal intubation.
- 5.3. Use of a disposable blade should be preferred + guide (Bougie).
6. **After spreading the sheet, all actions connected with ventilation and airway should be performed only under the transparent sheet.**
 - 6.1. If a respirator is available, after tracheal intubation immediately inflate the balloon, connect the viral filter to the ET/tube, and on that a Capnograph/CO2 detector.
 - 6.2. If no respirator is available, ventilate with an Ambu connected to a viral filter at a rate not in excess of 6-8 breaths per minute, with one hand. Oxygen flow should be adjusted to the minimum required (8 liters per minute).
7. Avoid (as far as possible) opening the tubing.
 - 7.1. Use of a Capnograph is preferred (a CO2 detector requires an additional opening of the tubing in order to remove it).
 - 7.2. The closed suction system should be connected at the next opening of the tubing. Do not open specially.

**** After ventilating, it is important not to disconnect the filter from the tube at any stage! Furthermore, do not disconnect the ventilating machine from the filter! If needed, first turn off the respirator. Then place the clamp on the tube, and only then may the filter be disconnected or replaced.**

Instructions for replenishing cart equipment after resuscitation

1. The resuscitation cart shall not be removed from the contaminated department / unit.
2. Replacement of required equipment / materials shall be done according to the resuscitation cart equipment list. Do not add more equipment than required!!!
3. The resuscitation medication tray **shall not** be returned to the pharmacy. Replenishment of the tray shall be done by department nurses and **double checked**. Make sure expiration date of medications is not sooner than the expiration date marked on the tray.

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The following has volunteered & contributed to the success of this project

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The success of this project is also attributed to

[Israel's national EMS](#), [Tel Aviv Sourasky](#), [Hadassah JLM](#), [First Israel](#), [Haifa Technological Center](#), [Israel Aerospace Industries](#), [The garage program by Microsoft Israel](#), [IDC](#), [lichi](#), and others