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March 31, 2020

Dear Sirs,

This letter is in support of work being done by RespiraWorks to increase production of mechanical ventilators worldwide. I am an Emergency Department Physician Board Certified in both Emergency Medicine and Clinical Informatics. The use of ventilators is part of my routine practice. I have had many international medical experiences, including countries already lacking sufficient supply of ventilators.

The COVID-19 outbreak has created an overwhelming need for more ventilators and will continue to do so. Mechanical ventilators are needed to optimize chances for recovery and survival from COVID-19. Innovative solutions are needed for alternative ventilator designs that are effective, safe, and affordable. Supporting this effort is crucial and will save lives. I have discussed the medical needs of ventilation with the RespiraWorks team, and reviewed the specifications provided. If they can produce something to these specifications it would fulfill a critical medical need.

Sincerely,

A handwritten signature in black ink that reads "Mark Baker". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark Baker, MD, FACEP, FAMIA

	Item	Needed for	Included	Ordered	In Oakland	Edwin Has	Each Vent	Price @ 1	Price @ 200	Price @ 1k	Description	Prototype analog	Source	Source Bulk Order	Additional	Likely to Change?
E1.1	Blower	1.00	Y	0.00	11.00	12.00	1.00	\$46.00	\$40.0	\$33.0	DANIU WM7040 DC 12V/24V High Pressure Blower 7.5Kpa	submarine parts	https://www.aliexpress.com/item/33025679738.html			No
E1.2	Driver	1.00	Y	0.00	10.00											
E1.3	Wiring	1.00		0.00	11.00											
E2.1	Inlet Differential pressure (flow) sensor	2.00	Y	0.00	8.00	5.00	1.00	\$18.00	\$6.6	\$10.0	PRESSURE SENSOR Differential ±0.29PSI (±2kPa) Analog Voltage 0.5 V ~ 4.5 V 8-B SOP (0.475", 12.06mm Width) Dual Ports, Same Side Temperature Compensated	Burny dP sensor?	https://www.digikey.com/product-detail/en/ntp-usa-inc/MPXV7002DP/MPXV7002DP-ND/1168436			No
E2.2	2.5mm tubing, 12"	5.00		16.00	5.00						2.5 mm x 5 mm Silicone Translucent Tube Water Air Pump Hose Pipe, 16' Long, 0.1 inches ID		https://www.amazon.com/gp/product/B01F4B7JP1			
E2.3	Patient Pressure sensor	1.00	Y	0.00	9.00	10.00	1.00	\$3.50	\$8.6	\$10.0	SENSOR GAUGE PRESS 0.57PSI (3.92kPa) Analog Voltage 1 V ~ 4.9 V Male - 0.13" (3.3mm) Tube, Dual Barbed Temperature Compensated 8-B SOP (0.475", 12.06mm Width) Dual Ports, Same Side		https://www.digikey.com/product-detail/en/bosch-sensortec/BMP280/828-1064-1-ND/6138315			No
E5	Mixing Volume	N/A	Y*	N/A	N/A	N/A	N/A	\$10.00		\$10.0	Gallon Water Bottle Portable Water Jug	Can prototype with Elizabeth's Platy water reservoir, which has compatible tubing and hose clips	https://www.amazon.com/dp/B07VD62FR7/	Need reqts		Yes
E6	Battery Charger	1.00			1.00			\$20.00		\$13.0	intelligent digital display 12V 24V ac dc 10A automatic fast car battery charger for lead acid battery		https://www.alibaba.com/product-detail/Sunchonglic-intelligent-digital-display-12V-24V_60610614113.html	Local sourcing		Yes/source locally
E6(alt)	Wall Charger, 12V, 5.5/2.1	1.00		3.00	0.00											
E6.2	5.5/2.1 barrel pigtail adapter	1.00		10.00	1.00											
E7.1	CPAP Hoses	2.00		2.00	2.00	5.00	3.00	\$17.00		\$17.0	Premium Universal CPAP Tubing Hose 96" - 8 Foot - by MARS WELLNESS - 2 Pack		https://www.amazon.com/gp/product/B01N14F1MV/	Casa Medica?		Yes/source locally
E7.2	CPAP Hose cut up	1.00			1.00											
E8	Oxygen control regulator	N/A		N/A	N/A	N/A	N/A	\$26.00		\$17.0	The Aftermarket Group Oxygen Cylinder Regulator, Green Anodized Aluminum, 0-8 LPM 870 CGA, TAGTR8-8B		https://www.amazon.com/Aftermarket-Group-Cylinder-Regulator-TAGTR8-8B/dp/B07RMBYNPZ	Need better search terms f		Yes/source locally
E9	Outlet Ball Valve	1.00		2.00	2.00	3.00	1.00	\$13.00		\$13	2-Pack in-Line Barbed Ball Valve 13mm for 1/2 Inch Tubing .520 ID - Regulate and Shut-Off/On Water Flow		https://www.amazon.com/gp/product/B07C5B4S1S	https://www.aliexpress.com	Wrong size on AliEx	Yes
E10	Arduino for control	1.00	Y	2.00	2.00	6.00	1.00	\$5.00	\$2.8	\$5	AFVIN Nano V3.0, Nano Board ATmega328P 5V 16M Micro-Controller Board Compatible with Arduino IDE (Nano x 3 with USB Cable)		https://www.amazon.com/LAFVIN-Board-ATmega328P-Micro-Controller-Arduino/dp/B07G99NNXL/	https://www.aliexpress.com		No
E11	High current switch for Arduino	1.00		0.00	3.00	2.00	1.00	\$13.00		\$13	NOYITO DC Control 4-Channel FET Module MOS Electronic Switch Control Board Output Controlled Voltage 5V-36V 5A Input Output Completely Isolated		https://www.amazon.com/NOYITO-4-Channel-Electronic-Controlled-Completely/dp/B07P52C4YP		Prototype only; Will be integrated onto custom PCB	Yes
E12	Outlet solenoid valve	1.00		2.00	2.00	1.00	1.00	\$10.00		\$10	Brass Low Pressure Solenoid Valve Normally open DC12-24V		https://www.alibaba.com/product-detail/HOYAN-PU-M03K-Brass-Low-Pressure_62063241728.html			Yes
E13.1	User Interface Raspberry Pi	1.00	Y	2.00	1.00	2.00	1.00	\$35.00		\$35	Raspberry Pi 3 B+		https://www.alliedelec.com/product/raspberry-pi/raspberry-pi-3-model-b-/71131895/			No
E13.2	Raspi SD Card, UHS-1 C10	1.00		3.00	0.00											
E14	User Interface Touchscreen	1.00	Y	2.00	1.00	2.00	1.00	\$63.00	\$45.0	\$37	LCD Capacitive Touch Screen 7 inch Raspberry Pi 3 Display		https://www.alibaba.com/product-detail/Hot-Sale-LCD-Capacitive-Touch-Screen_60672720017.html	https://www.aliexpress.com	https://www.aliexpress.com	Yes
E15	Inline Humidifier	1.00		2.00	1.00	1.00	1.00	\$16.00		\$16	Fisher & Paykel H Inc Fphc385S Humidification Chamber For Use With Hc200,Fisher & Paykel H Inc - Box 1		https://www.amazon.com/gp/product/B0181W999M/			No
E16	Heater for Humidifier	1.00		2.00	1.00	2.00	1.00	\$5.00		\$5	12V 10W 51mm Diameter Gold Round Polyimide Silica Gel Flexible Adhesive Hot Foil Heater Heating Film Automotive Parts		https://www.amazon.com/gp/product/B07G1896YS OR https://www.amazon.com/12V-Flexible-Polyimide-Heater-Plate/dp/B07P2RJDPL			No
E17.1	HEPA filters	2.00	Y	0.00	9.00	12.00	2.00	\$1.20		\$1.20	12 Pack Hepa Filter Filters Replacement for irobot Roomba 800 900 Series		https://www.amazon.com/gp/product/B00K7DMEJ0			No
E17.2	Filter Housings	2.00	Y		0.00	0.00	2.00									
E17.3	Mounting, filter to enclosure	2.00	Y		0.00											
E17.4	Intake filter to fan assembly	1.00	Y		0.00											
E18.1	3/4" elbowed hose barb	2.00		10.00	2.00											
E18.2	3/4" T hose barb	1.00		0.00	1.00											
E18.15	HOSE CLAMPS	20.00		10.00	0.00						improves pressfit tolerance					
E19	MEasurement Chamber for pressure/flow (formerly Volume Sensor)	2.00			2.00			\$15.00		\$15	open item for experimentation, see #flow-measurement	Currently a custom, 3D printed part				
E21	Patient Filter	2.00	Y	0.00	6.00	10.00	2.00	\$1.90			CPAP/BIPAP Inline Bacteria Filter Filters Out Moisture and Unwanted Particles to Purify Your CPAP Experience Available in 5 & 10 Packs Effectively		no longer available on amazon			
E22	Alarm Speaker	0.00		0.00	4.00	4.00	1.00									
E23	Alarm Buzzer	0.00		0.00	0.00	2.00	1.00									
E24	Enclosure	1.00	Y	0.00	5.00											
E24.1	Lid for Enclosure	1.00	Y	0.00	5.00											
E25	Wiring for RPI/Arduino	1.00			0.00											
E25alt	Level shifters for RPI/Arduino	1.00		10.00	0.00											
E26.1	DC/DC Converter (12->5 V)	1.00		3.00	0.00											
E26.2	Wiring for DC Converter	1.00		3.00	0.00											
	TOTAL							\$377.70		\$291.7						

RespiraWorks Ventilator End User Guide

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1.0 Overview

The RespiraWorks ventilator is a mechanical ventilator providing respiratory support to patients. It was designed in response to the COVID-19 pandemic crisis with a goal of being sourced from and manufactured within resource constrained communities. It is not intended to replace all features of a traditional ICU ventilator, but still to provide the necessary respiratory support for patients suffering from COVID-19, with a particular focus on ARDS.

1.1 Indications for Use

This device should not be a front-line ventilator, such as when hospitals are operating under normal resource constraints with functional full-feature ventilators in capacity.

The RespiraWorks Ventilator is indicated for up to 14 days or intermittent mechanical ventilatory support of patients weighing at least 75 lb (35 kg) IBW who require mechanical ventilation.

The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a doctor. It is essential to read, understand, and follow these instructions before using the RespiraWorks Ventilator.

1.2 Contraindications

This device cannot be safely used with infants, pediatric patients, or patients weighing less than 75 lb (35 kg) IBW. It cannot stably support the low flow rates and high frequency required for those patients.

1.3 Target Environment

This product is intended to be used in a clinical environment for patients with patients under continuous monitoring.

1.4 Target User

The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a doctor.

1.5 Warnings

Misuse of this device could end in serious injury to the patient. This device should only be used under careful medical supervision.

2.0 Device Operation

2.1 Device Installation and Setup

Prior to connection to patient the device should go through the test procedure outlined in the *RW-003 RespiraWorks Ventilator Validation Test Procedure*.

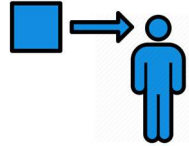
2.1.1 Power Connection

The device must be connected to a 12 V power supply. This can be through the 110-240 V 50 Hz/60 Hz power supply or directly through a 12V source. The device has no internal battery and will start up once connected to a power supply. Ideally, the unit should be connected to a standard Group 24 car battery or similar which is continuously charged by a mains-powered battery charger with a capacity of at least 5A. This will provide an uninterruptable power supply with an endurance of at least 20hrs.

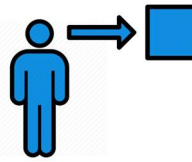
2.1.2 Patient Connection

The device is intended to be used with a dual limb patient connector. The patient inspiration tube and filter should be connected to the connector “to patient –

inhale” marking above the port (to the left side of the display screen). The port also shows the following symbol:



The exhaust tube should be connected to the port on the right side of the screen with the text “from patient – exhale”. The port shows the following symbol:



2.2 Modes of Operation

2.2.1 ACV P Mode (Assist Control Ventilation - Pressure)

This mode is used for patients who can provide some level of inspiratory effort or are not totally paralyzed/sedated. The provider sets a minimum respiratory rate, and an assist and PEEP pressure. The device synchronizes itself to the patient respiratory effort and supplies additional pressure support on inspiratory effort. The device will alarm if the patient is consistently not initiating breaths.

2.2.1.1 Parameters

The following parameters are adjustable in ACV P mode.

- Assist pressure. Variable in increments of 5 cm H₂O from 0 to 30 cm H₂O. This value is displayed on the interface and is the target pressure the device will attempt to support during the inspiratory phase.
- PEEP. Variable in increments of 2 cm H₂O from 0 to 20 cm H₂O. The device will maintain a minimum pressure throughout the cycle based on this value.
- Minimum Respiratory Rate. This is the minimum rate (full I/E cycles) that the device will enforce. The device will initiate a breath if the patient has not initiated by the following breath. This is available from 10-30 bpm.
- I:E Ratio. This is the ratio of time spent in inspiration to exhalation in each respiratory cycle. The device will split the respiratory period set by the Command Respiratory rate according to this ratio and command the PIP pressure during the Inspiration time and PEEP pressure during the Exhalation time.
- FiO₂. This is the fraction of inhaled oxygen delivered to the patient. The device will command the oxygen source valve, which, mixed with

ambient air drawn from the inlet, delivers the required oxygen mix from 21-100% oxygen.

2.2.2 PRVC (Pressure-Regulated Volume Control) Mode

This mode is used for patients who are fully paralyzed/sedated. The provider sets a command respiratory rate, peak inspiratory pressure and positive expiratory pressure. The device will display a target MV based on the above information. The device enforces a respiratory effort by controlling pressure through the cycle. The device will calculate TV and MV and check it against the initial MV target. If TV is lower than that required to reach the required MV at the respiratory rate, the device will increase the rate by up to 10% while alerting medical personnel to the change in lung characteristics.

2.2.2.1 Parameters

The following parameters are adjustable in PRVC mode.

- PIP. Variable in increments of 5 cm H₂O from 20 to 40 cm H₂O. This value is displayed on the interface and is the target pressure the device will attempt to support during the inspiratory phase.
- PEEP. Variable in increments of 2 cm H₂O from 0 to 20 cm H₂O. The device will maintain a minimum pressure throughout the cycle based on this value.
- Command Respiratory Rate. This is the minimum rate (full I/E cycles) that the device will enforce. The device will initiate a breath if the patient has not initiated by the following breath. This is available from 10-30 bpm.
- Target MV. Target Minute Volume. If the observed patient MV drops below this setting, the device will automatically increase PIP up to +10% of the initial setting to meet the target MV, while displaying a warning. If the target MV is not met, an alarm will be triggered.
- I:E Ratio. This is the ratio of time spent in inspiration to exhalation in each respiratory cycle. The device will split the respiratory period set by the Command Respiratory rate according to this ratio and command the PIP pressure during the Inspiration time and PEEP pressure during the Exhalation time.
- FiO₂. This is the fraction of inhaled oxygen delivered to the patient. The device will command the oxygen source valve, which, mixed with ambient air drawn from the inlet, delivers the required oxygen mix from 21-100% oxygen.

2.2.3 CPAP (Constant Positive Airway Pressure) Mode

This mode is used for patients who are not intubated. The device supplies a constant positive airway pressure to the patient.

2.2.3.1 Parameters

The following parameters are adjustable in CPAP mode.

- CPAP pressure. Variable in increments of 2 cm H₂O from 2 to 20 cm H₂O. The device will maintain a minimum pressure throughout the cycle based on this value.

3.0 Alarms

The alarms or faults generated by the ventilator are classified into two categories.

- Technical alarms: These relate to the device mechanical function. These are visible alert UI on the screen.
- Patient alarms. These relate to the patient condition.

3.1 Alarm Levels – Priority

- High – Alarms which indicate a situation which could result in inability for the system to ventilate which needs to be immediately addressed.
- Med – Alarms which indicate a that the system that do not compromise ventilation in short term but could potentially result in harm if situation persists
- Low – Alarms which indicated events that warrant attention of the clinician in the short term but may result in harm or discomfort in the long term.

3.2 Deactivating Alarms

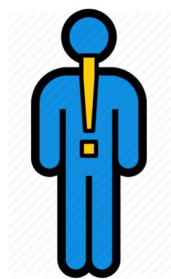
Alarms may be deactivated by selecting alarm notification on the user interface. A popup window will allow the alarm to be dismissed.

3.3 Technical Alarms

Technical alarms are self-monitored to the extent possible by the device. It is always possible that a device malfunction could disable self-monitoring features. Patient condition should always be monitored independent from the ventilator. To the degree possible, the device will supply the following alarms in decreasing order of priority.

3.4 Patient Alarms

Patient alarms are indicated by a blue light on the device and the following icon on the user interface.



Alarm	Probable Cause	Priority
Battery Level Low (audible, visual)	Low charge on battery, low voltage on power supply, battery connections loose.	Low – if device loses power it will not be able to ventilate patient.
Mechanical Malfunction	Device cannot control output or read sensor as designed. Many possible causes; blocked patient supply or exhaust tubing, hardware failure, electrical failure.	High - If this alert sounds the device should be disconnected from patient and alternate ventilation applied immediately; the device is not reliably supplying ventilation.
Low MV	Increased lung resistance/decreased lung compliance. Device not hitting targeting MV at current PIP/RR. Device is attempting to compensate but has reached the limit of its thresholds. Increase RR or PIP, check patient parameters.	High – check patient
Volume Sensor Mismatch	If there is a mismatch, it indicates one of the volume estimate sensors is out of range and may indicate a fault. The system will supply ventilation without correcting for TV. Patient condition should be monitored and moved to an additional ventilator if available.	Medium – consider alternate ventilation if available. Monitor patient if not.
PEEP not met	This sensor indicates the respiratory pressure is not plateauing at the PEEP level set (above). This could indicate resistance in the system (exhaust blockage)	Medium – indicates potential patient condition change and insufficient respiratory diffusion

	or that the respiratory rate is too high. Decrease RR or PIP and monitor patient.	
High Airway Pressure	Paw sensor above thresholds on inhale or exhale.	Medium – check patient condition and device settings
No Respiratory Effort Detected - I	Device is in A/CP mode. Patient has not triggered a breath cycle in 20 seconds.	Low – alert displayed on screen. Check patient condition and ventilator settings.
No Respiratory Effort Detected - II	Device is in A/CP mode. Patient has not triggered a breath cycle in 120 seconds.	Medium – Alert on screen
No Respiratory Effort Detected - III	Device is in A/CP mode. Patient has not triggered a breath cycle in 5 minutes.	Medium High – Alert on screen audible alarm.

4.0 Acronyms and Abbreviations

ACV	Assist Control Ventilation
CMV	Continuous Mandatory Ventilation
PCV	Pressure Controlled Ventilation
PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure
TV	Tidal Volume
PRVC	Pressure-Regulated Volume Control (Ventilation)
I:E	Inspiration: Exhalation (Time Ratio)
RR	Respiration Rate
CPAP	Continuous Positive Airway Pressure
MV	Minute Ventilation