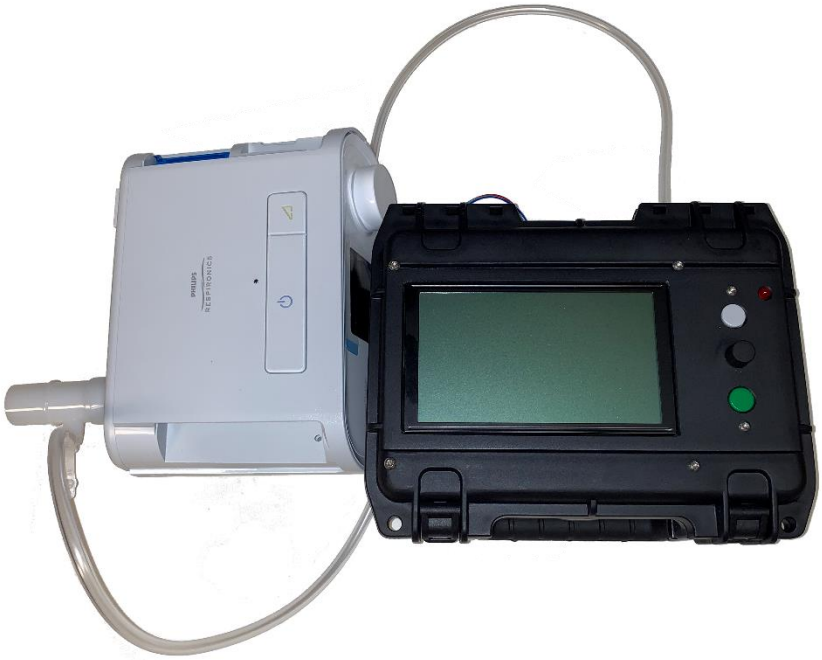

COVID-19 PCV VENTILATOR

User Guide and Reference Manual

AES Covid Rapid Response Team

AES Concinnity 4:3 CEO connection

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Contents

Introduction

Foreword & Motivation

The AES Technologies COVID-19 PCV Ventilator device was designed specifically to help address the dire ventilator shortage due to the COVID-19 Pandemic. As of this writing, on April 1, 2020, New York City is the current epicenter of this virus, and over 900 deaths were reported in the US within a 24-hour period. This indicates that the death rate in the US is currently doubling every three days - on par to quickly outpace even Italy, who was hit extremely hard a couple of weeks prior to the US.

It appears that the aside from the obvious calamity and complete lack of preparedness for such a widespread catastrophe, the primary mechanisms of death in the COVID-19 Pandemic will likely be due to:

- ARDS
- Lack of respiratory support (ventilators, respiratory therapists) to combat the influx of ARDS patients to the ICU
    - Lack of PPE contributing to dwindling personnel

The shortage of ventilators is a massive dilemma that boils down to a lack of parts/components, and an inability of the supply chain to address the shortage quickly enough - especially for New York.

Our device was designed to address these shortages. There is a massive supply and supply chain for CPAP/BiPAP machines prescribed for Sleep Apnea. These machines in their stock form do not have the capability of functioning as PCV Ventilators (aside from hospital-grade units), but they do have the necessary electromechanical components to function as such - and are already FDA approved medical devices. Our conversion kit utilizes the electromechanical components of the existing CPAP/BiPAP machines, and adds in a closed-loop pressure regulating control system, combined with a therapist-programmable interface to control ventilator mode (control or support mode), peak pressure, PEEP, breathing rate (b/min), and Inspiratory:Expiratory ratio (I:E). This converts the device into a PCV Ventilator capable of supporting up to 35 cmH2O of pressure, and a programmable PEEP with a high settable limit - with the understanding that ARDS patients need substantial PEEP to maintain alveoli recruitment and to prevent pneumothorax.

Another chief concern with such a conversion - especially in the case of non-invasive ventilation (NIV) - is the spread of aerosol or droplets from the open-loop circuits present in these CPAP/BiPAP machines. We have designed an anti-aerosolization system that utilizes existing standard parts, including exhalation ports and inline antibacterial/antiviral filters. This ensures that minimal droplets/aerosol escape the closed-loop system, even in NIV cases (of course, we recommend the added precaution of a surgical mask over the NIV mask in any case).

Lastly, this design was established to address this need in HIGH VOLUME. Using a small Bill of Materials (BOM) of very easily obtainable parts (and parts that do not overlap with the existing invasive ventilator (IV) supply chain), virtually any existing supply of CPAP/BiPAP machines can be converted for immediate use as a PCV Ventilator.

About the AES Technologies COVID-19 PCV Ventilator device

The AES Technologies COVID-19 PCV Ventilator device provides mechanical ventilation to both ventilation dependent and non-dependent patients. It delivers pressure ventilation through a single-limb circuit, and is compatible with a range of accessories to support specific use cases

⚠ WARNING

- Read the entire manual before using the COVID-19 PCV Ventilator device.
- Use the COVID-19 PCV Ventilator device only as directed by a physician or healthcare provider
- Use COVID-19 PCV Ventilator device only for the intended use as described in this manual. Advice contained in this manual does not supersede instructions given by a physician.
- Install and configure the COVID-19 PCV Ventilator device in accordance with the instructions provided in this guide.

Indications for use

The AES Technologies COVID-19 PCV Ventilator device provides continuous ventilatory support for patients who require mechanical ventilation. The COVID-19 PCV Ventilator device is intended to be used in home and institution/hospital applications for both invasive and non-invasive ventilation.

General warnings and cautions

The following are general warnings and cautions. Further specific warnings, cautions, and notes may appear next to the relevant instruction(s) in the manual.

A **warning** alerts you to possible injury.

⚠ WARNING

- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if the device or the power supply are dropped or mishandled discontinue use and contact your healthcare provider.
- For ventilator-dependent patients, always have alternate ventilation equipment available, such as a back-up ventilator, manual resuscitator or similar device. Failure to do so may result in patient injury or death.
- The COVID-19 PCV Ventilator device is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Clinical supervision is required in critical care/intensive care unit environments.
- Ventilator-dependent patients should be continuously monitored by qualified personnel or adequately trained caregivers. These personnel and caregivers must be capable of taking the necessary corrective action in the event of a ventilator alarm or malfunction.

- The COVID-19 PCV Ventilator device is not intended to be operated by persons (including children) with reduced physical, sensory or mental capabilities without adequate supervision by a person responsible for the patient's safety.
- The COVID-19 PCV Ventilator device is not intended to be operated by patients unless they have been given adequate instruction concerning the operation of the device by a person responsible for the patient's safety.
- The COVID-19 PCV Ventilator device must not be used in the vicinity of an MRI or diathermy device.
- The effectiveness of ventilation and alarms should be verified including after any ventilation or alarm setting change, any change in circuit configuration, or after a change to co-therapy (i.e. nebulization, oxygen flow, et al.).
- The COVID-19 PCV Ventilator device and AC Power Supply can get hot during operation. To prevent possible skin damage do not leave the device or AC Power Supply in direct contact with the patient for extended periods of time.
- The device must not be used at an altitude above 9842 ft (3000 m) or outside the temperature range of 32–104°F (0–40°C). Using the device outside these conditions can affect device performance which can result in patient injury or death.

A **caution** explains special measures for the safe and effective use of the device.

 CAUTION

- Repairs and servicing of the device should only be performed by an authorized AES Technologies service representative.
- The temperature of the airflow for breathing produced by the device can be as much as 43F° (6°C) higher than the temperature of the room. Caution should be exercised if the room temperature is warmer than 95°F (35°C).
- Do not expose the device to excessive force, dropping or shaking.
- Dusty environments may affect device performance.

For assistance and reporting of issues associated with the COVID-19 PCV Ventilator device, contact your Health Care Provider or authorized AES Technologies representative.

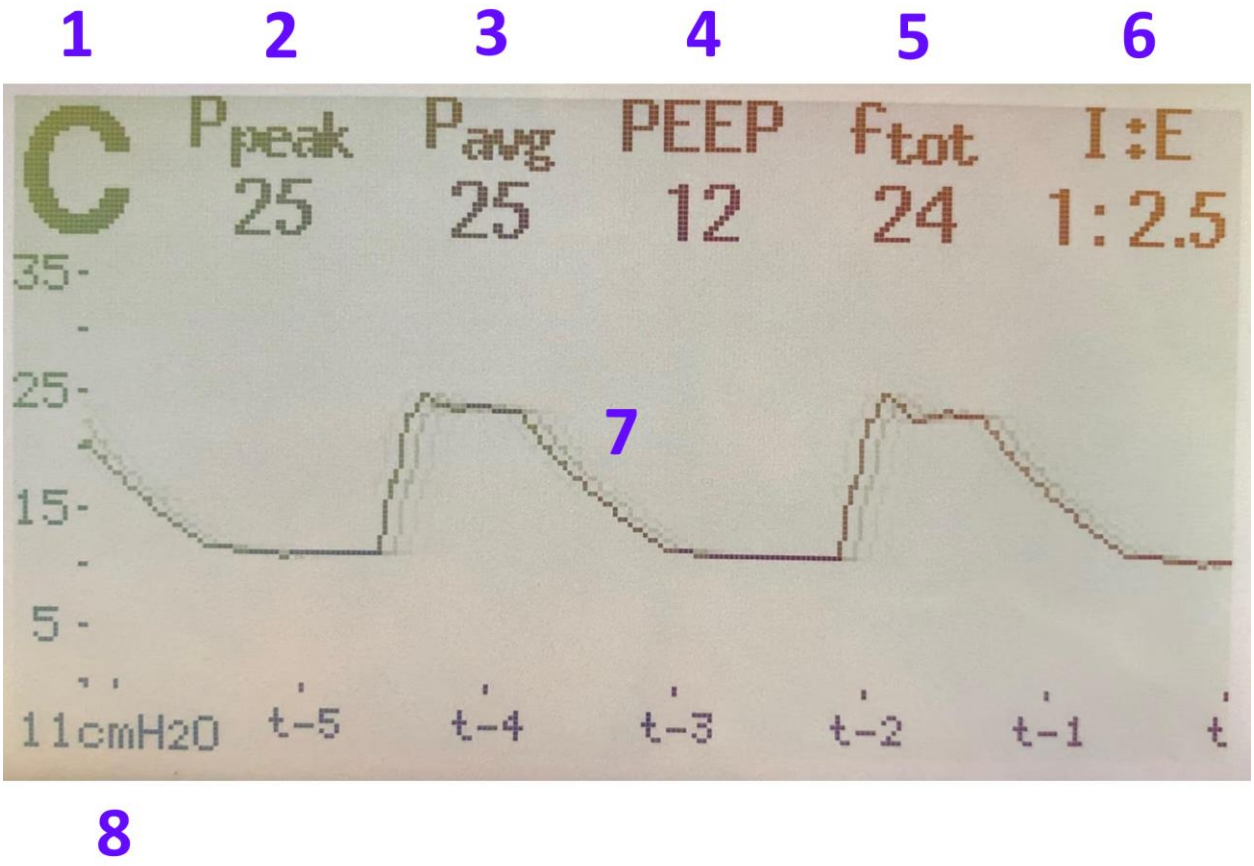
The COVID-19 PCV Ventilator device

The following images describe the components of the COVID-19 PCV Ventilator device.

	Description
1	System MODE button
2	Rotary dial & button for user input
3	System MENU button
4	Fault Indicator Light
5	System Display
6	Power supply connection (24V, 10A)
7	Pressure sensing port – connect to patient breathing circuit
8	Ambient sensing port – DO NOT CONNECT
9	RESERVED FOR FUTURE USE
10	RESERVED FOR FUTURE USE
11	Connection terminal to CPAP/BiPAP machine blower motor

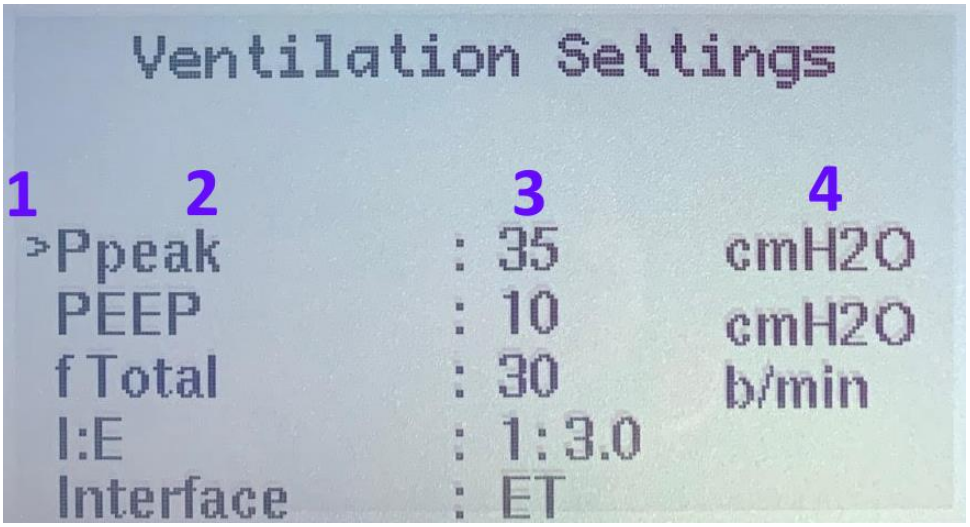
The COVID-19 PCV Ventilator device interface

The interface of the COVID-19 PCV Ventilator device comprises several different features described in the following images.



	Description
1	Current System Mode indicator
2	Peak inspiratory pressure setpoint indicator
3	Average tidal pressure indicator
4	PEEP setpoint indicator
5	Breathing rate setpoint indicator
6	I:E ratio setpoint indicator
7	Realtime pressure plot
8	Realtime pressure indicator

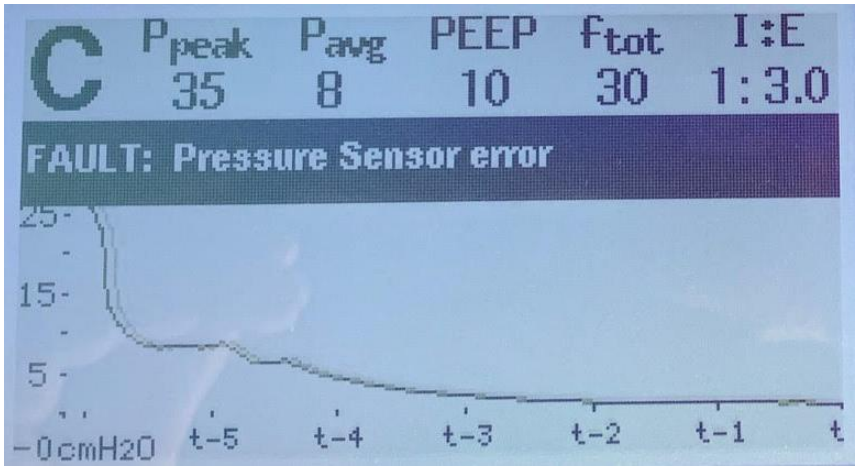
Ventilation settings menu



	Description
1	Menu selection indicator
2	Menu selection item description
3	Menu selection current parameter value
4	Menu selection parameter unit(s), if applicable

Device setting	Unit	Description
Ppeak	cmH2O	Peak inspiratory pressure
PEEP	cmH2O	Positive end expiratory pressure
f total	b/min	Breathing rate
I:E	ratio	Ratio of inspiratory time to expiratory time
Interface	N/A	Patient interface selection – MASK or ET

Ventilator Fault display



Using the COVID-19 PCV Ventilator device

⚠ WARNING

Make sure the area around the device is dry, clean and clear of bedding or clothes or other objects that could block the air inlet. Blocking the air inlet could lead to patient injury.

⚠ CAUTION

- To prevent possible damage to the ventilator, always secure it to its stand or place it on a flat, stable surface.
- Ensure the device is protected against water if used outdoors

Using the COVID-19 PCV Ventilator device for the first time

When using the COVID-19 PCV Ventilator device for the first time, AES Technologies recommends you first perform a functional test. A functional test will ensure the device is in proper working order before starting therapy. Information to assist you in resolving any issues is available in the section.

⚠ CAUTION

If any of the following checks fail, contact your Healthcare provider or AES Technologies for assistance.

To perform a functional test:

1. Turn off the device by unplugging the power source from the back of the device.
2. Check the condition of the device and accessories. *Inspect the device and all accessories. Damaged components should not be used.*
3. Check the patient circuit setup. *Check the integrity of the patient circuit (device and accessories) and that all connections are secure.*
4. Turn on the device and test alarms.

⚠ WARNING

If no alarm sounds, do not use the ventilator.

Plug the power source into the back of the device to turn on the device. Check that the alarm sounds the tri-tone test beeps and the LED for the alarm signal flashes. The device is ready for use when the Home screen is displayed.

Powering on the device

To power on the COVID-19 PCV Ventilator device, simply plug the power source into the back of the device. The device will perform a system check while the logo and splash screen are displayed, followed by the Home screen.

Powering off the device

The COVID-19 PCV Ventilator device must only be powered off when ventilation is stopped!

To power off the COVID-19 PCV Ventilator device, simply unplug the power source from the back of the device.

Starting and stopping ventilation

Note: If using the device for the first time, AES Technologies recommends performing a functional test before starting ventilation. Refer to Using the COVID-19 PCV Ventilator device for the first time.

To start ventilation:

1. Power on the device by plugging the power source into the back of the device (if power is not already on).
2. Press and hold the **green** MODE button for at least half a second (500ms). Ventilation is started. The Mode indicator in the upper-left portion of the screen should now show “C” for control.
3. Add oxygen if required.

To stop ventilation:

Ventilation can be stopped at any time and from any screen.

1. If oxygen is connected, turn off the oxygen.
2. Press and hold the **green** MODE button for at least half a second (500ms). Ventilation is stopped. The mode indicator in the upper-left portion of the screen should now show “OFF”.

Navigating the user interface

The COVID-19 PCV Ventilator device features a mode indicator and current ventilation parameter display as well as real-time pressure waveform on the Home screen, and a ventilation settings menu for setting ventilator parameters.

To access the ventilation settings menu, press the **grey** MENU button.

To toggle between active menu selections, press the round dial button. The indicator (“**>**”) indicates the current selection.

To toggle between values for the active menu selection, rotate the dial to the left or right to increase or decrease the value, respectively.

To leave the ventilation settings menu and return to the home screen press the **grey** MENU button again.

Connecting a single limb circuit with exhalation port

Works with either distal or proximal pressure port sensing.

⚠ WARNING

- At low pressures, the flow through the mask vents may be inadequate to clear all exhaled gases, and some rebreathing may occur when using a single limb circuit with exhalation port.
- Ensure that all vent holes at the exhalation port are unobstructed. Ensure the area around the vent holes is clear of bedding, clothes, or other objects and that the vents holes are not directed towards the patient.

To connect a single limb circuit with exhalation port:

1. Connect the inspiratory limb to the inspiratory port.
2. Attach any required circuit accessories (i.e., humidifier or filter). **Note: Due to the COVID-19 Pandemic, it is HIGHLY recommended to ALWAYS use inline viral/bacterial filters to protect against virus droplet/aerosol transmission. In the case of Non-invasive masks, it is also recommended to place a surgical mask over the outside of the mask to provide additional protection against stray droplets.**
3. If using a non-vented mask or tracheostomy connector, attach an exhalation port to the free end of the air tubing ensuring that the exhalation port is as close as possible to the patient.
4. Attach the patient interface (i.e. mask) to the exhalation port or the free end of the air tubing as appropriate.

Connecting a single limb circuit for invasive use

For invasive ventilation, since the patient's upper respiratory system is bypassed by an artificial airway device (for example endotracheal or tracheostomy tube) humidification of the inspired gas is required to prevent lung injury. It is recommended to use a Heat Moisture Exchange (HME) filter.

Attaching a Heat Moisture Exchange (HME)

HME's are passive humidification systems that retain heat and moisture from the patient's exhaled gases via an internal membrane. An HME should not be used with active humidification.

⚠ WARNING

Only use HMEs that comply with the relevant safety standards, including ISO 9360-1 and ISO 9360-2.

Place the HME between the patient end of the circuit and the patient interface.

Attaching an antibacterial filter

⚠ WARNING

- Regularly check the antibacterial filter and expiratory valve for signs of moisture or other contaminants, particularly during nebulization or humidification. Failure to do so could result in increased breathing system resistance and/or inaccuracies in sensor measurements.

- Only use antibacterial filters that comply with the relevant safety standards, including ISO 23328-1 and ISO 23328-2.

⚠ CAUTION

The antibacterial filter must be used and replaced according to the manufacturer's specifications.

To attach an antibacterial filter:

1. Fit the antibacterial filter to the inspiratory port of the patient interface (NIV Mask or ET).
2. Connect the air tubing to the other side of the filter.
3. Attach the free end of the air tubing to the device.

⚠ WARNING

To prevent the risk of cross-contamination, an antibacterial filter is mandatory if the device is to be used on multiple patients.

Adding supplemental oxygen

At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration will vary depending on the Ventilation mode and settings, patient breathing pattern, mask selection, and leak rate.

⚠ WARNING

- Use only medical grade oxygen sources.
- Always ensure that the device is ventilating before the oxygen supply is turned on.
- Oxygen flow must be turned off when the device is not ventilating so that oxygen does not accumulate within the device enclosure. Explanation: Accumulation of oxygen presents a risk of fire. This applies to most types of ventilators.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well-ventilated rooms.
- The patient circuit and the oxygen source must be kept at a minimum distance of 2 meters away from any sources of ignition.
- Monitoring of supplemental oxygen requires the use of an external O2 monitor compliant with ISO 80601-2-55.

To add supplemental oxygen:

1. Insert one end of the oxygen supply tubing into the supplemental oxygen inlet port connector (typically located on or near non-invasive mask or endotracheal tube). Be sure oxygen tubing is securely attached to port fitting.
2. Attach the other end of the oxygen supply tubing to the oxygen supply.
3. Start ventilation
4. Turn on oxygen and adjust (at the oxygen supply) to the prescribed flow rate.

To remove supplemental oxygen:

1. Remove the oxygen port connector from the supplemental oxygen inlet port connector (typically located on or near non-invasive mask or endotracheal tube).

Connecting the device to mains power

⚠ WARNING

Ensure that the power cord does not pose a tripping or choking hazard.

To connect to mains power:

1. Connect the DC plug of the supplied external power supply unit to the rear of the COVID-19 PCV Ventilator device.
2. Before connecting the power cord to the external power supply unit, ensure the end of the connector of the power cord is correctly aligned with the input socket on the power supply unit.
3. Plug the other end of the power cord into the power outlet.

Note: The power cord is equipped with a locking connector. To remove, grasp the power cord housing and gently press down the retaining tab while pulling the connector from the device. Do not twist its outer housing or pull on the cord.

Alarms

The COVID-19 PCV Ventilator device activates alarms to alert you to conditions that require attention to ensure patient safety. When an alarm is activated, the COVID-19 PCV Ventilator device provides both audible and visual alerts and displays an alarm message in the Alarm display on the Information bar.

As soon as the activation condition is met, the device provides both audible and visual alerts without delay.

The following list of alarms is ordered by relative importance within priority:

- Total power failure*
- High pressure protection
- Circuit disconnection
- Low Pressure
- Obstruction
- High Pressure
- High leak
- High pressure
- Low PEEP
- High PEEP
- Device overcurrent

* No LED will flash, and no buzzer will sound, during a Total power failure alarm

Resetting Alarms

Resetting an alarm removes that alarm from the Alarm display and the Active alarms screen and turns off the visual and audible alerts. An active alarm should only be reset after the situation that caused the alarm has been attended to. If the alarm condition has not been corrected, the alarm will activate again.

To reset alarms:

Once an alarm event has been raised, power to the blower motor is cut off until the device is placed into the OFF mode by pressing and holding the **green** MODE button for about half a second (~500ms) and then ventilation is resumed normally by placing the device into run mode by once again pressing and holding the **green** MODE button for about half a second (~500ms).

Testing the alarms

⚠ WARNING

Do not perform alarm tests while the patient is connected to the ventilator.

This section describes functional tests to allow the user to understand the conditions that can trigger common alarms.

Alarm	**Test procedure**
Low pressure	Disconnect patient interface
Obstruction	Obstruct breathing circuit
High leak	Disconnect patient interface
Pressure sensor error	Block ambient pressure sensor port

Troubleshooting

If there is a problem, contact your care provider or AES Technologies.

Liability Statement

The AES Technologies COVID-19 PCV Ventilator device is covered under the FDA Emergency Use Authorization (EUA) for ventilators. More information can be found at the FDA website: https://www.fda.gov/media/136318/download