INSTRUCTIONS FOR USE

O2Ventilate

Manual Emergency Ventilator

Definitions

Warning: **Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.**

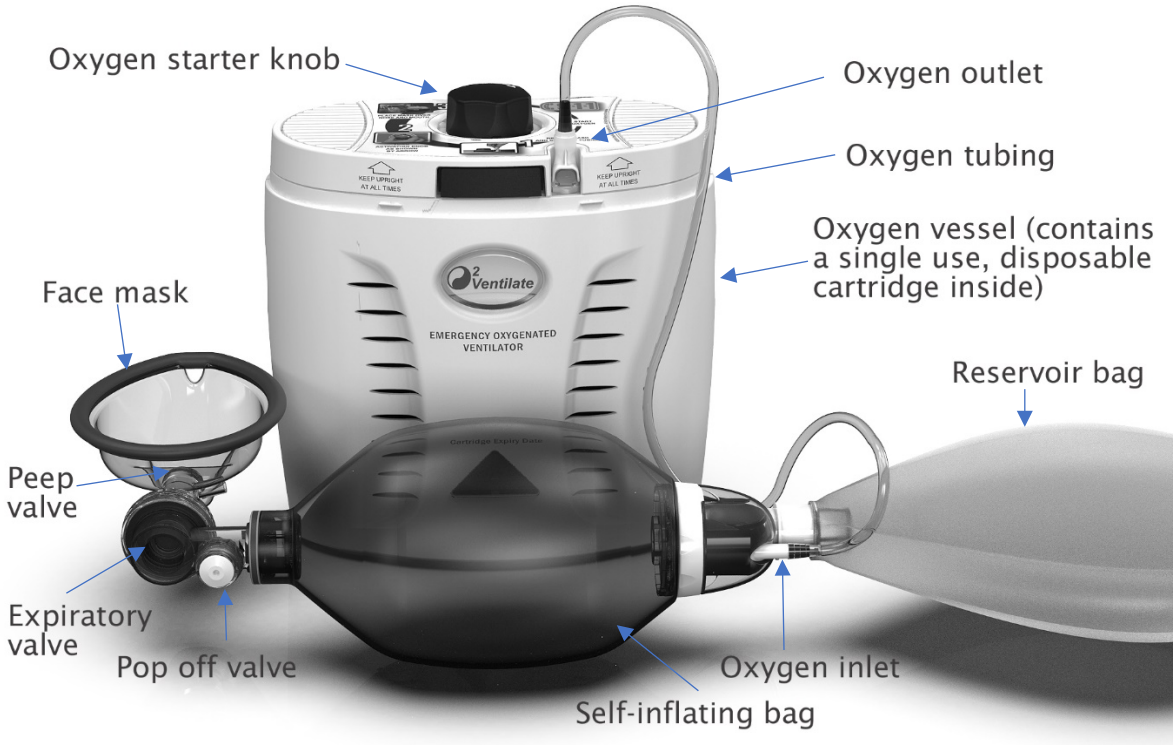
Caution: **Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or may result in property damage.**

O2Ventilate, Manual Emergency Ventilator
INSTRUCTIONS FOR USE

Intended Use

The O2Ventilate System is intended for the emergency, non-invasive ventilation of children and adults.

The O2Ventilate device is intended for use by trained responders to manually provide emergency ventilation to a patient when an FDA cleared ventilator is not available due to COVID-19 pandemic.



Warnings

1. Do not use O2Ventilate in toxic atmospheres.
2. The device is intended for use by qualified medical and emergency personnel trained in pulmonary ventilation and advanced cardiac life support techniques.
3. Proficiency in the assembly, disassembly and use of this device should be demonstrated before use on a patient.
4. Always monitor airway pressure with a manometer when ventilating a patient.
5. Only qualified personnel trained in the use of Positive End Expiratory Pressure (PEEP) should set the PEEP level and the function of the resuscitator before using on a patient.
6. Always verify PEEP level and the function of the resuscitator before using on a patient.
7. Monitor airway pressure with a manometer when ventilating a patient.
8. O2Ventilate is provided with a non-compressed oxygen source. Oxygen will increase the rate and intensity of a flame. There should be no open flames, including lit cigarettes in the vicinity of the O2Ventilate system while it is in use. Do not use oil or grease in conjunction with the O2Ventilate System. Failure to comply may cause acceleration of flames and serious injury.
9. If the O2Ventilate System is used in conjunction with an Automated External Defibrillator (AED), care should be taken to strictly follow the defibrillator instructions regarding avoidance of sparks or flame ignition.
10. Do not obstruct the flow of oxygen. Obstruction of the oxygen flow may cause a potentially dangerous buildup of excessive pressure in the oxygen generating vessel. Do not kink the hose. Do not insert objects or material of any kind in the oxygen delivery port or the mask or hose, as this may inhibit the oxygen flow.
11. The O2Ventilate system is not intended for use under water.

Cautions

1. If overriding the pressure relief valve on the resuscitation bag, great caution must be taken not to allow the pressure in the patient's airways to become too high.
2. Do not attempt to disassemble the pressure relief valve assembly. Disassembly will damage the component.
3. The O2Ventilate oxygen vessel must maintain an upright position for the proper flow of oxygen. Upon activation and during active oxygen generation the unit should remain in an upright position. If the unit is tilted beyond 45°, residue may clog the filtration system and impede the proper flow of oxygen. If the unit exceeds a tilt beyond 45°, immediately restore the unit to the upright position. Oxygen flow can be confirmed by an audible bubbling sound. If oxygen flow is sustained you may continue use.
4. Avoid excessive shaking of the unit before and especially during use. Prior to use, excessive shaking of the unit should be avoided as it could cause inadvertent activation of the system. If excessively shaken while in use, it may cause an increase in the rate of the reaction (that creates the oxygen flow) and affect the flow rate and duration of oxygen delivery.

5. If the user sees residue in the tubing while the system is in use, the resuscitator mask should be removed immediately to avoid ingestion of any residue. If any residue is ingested, wash out mouth with water, provided the person is conscious. Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the patient is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.
6. Under no circumstances should anyone attempt to open the disposable cartridge of the oxygen prior to, during, or after its use. Do not unplug the mask/tubing during or after use.
7. The O2Ventilate unit may become warm to the touch due to the exothermic reaction within the disposable cartridge.
8. The disposable cartridge, tubing and mask are single use items only and should be disposed of after each use.

The mask/tubing/bag assembly is custom designed for use with the O2Ventilate system. Do not use a mask or other accessories not specified for use with the O2Ventilate System under any circumstances. Use only approved O2Ventilate components.

Supplies and Materials

No special tools or materials are needed to activate or maintain the O2Ventilate System.

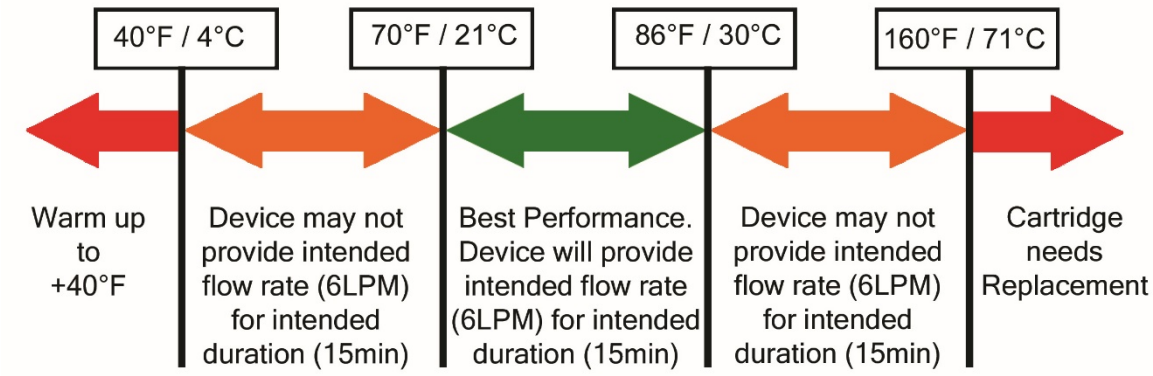
Conditions of Device Use

- The O2Ventilate System MUST be stored at room temperature because this device operates via a chemical reaction which can be greatly affected by the temperature of the reactants.
  Best Operating Temperature Range: 70°F to 86°F (21°C-30°C)
  If this device is operated immediately after being exposed to temperatures outside of the Best Operating Temperature Range indicated above, the device may not provide the intended flow rate of oxygen (6LPM) for the intended duration (15min).
- The O2Ventilate System should not be exposed to temperatures above 160°F/71°C at any time (including during shipping and storage) because the device operates via a chemical reaction whose reactants may be damaged if exposed to temperatures of 160°F/71°C or above. If the device is exposed to temperatures above 160°F/71°C, the disposable cartridge MUST be replaced to ensure proper operation.
  The O2Ventilate System should not be used if currently below 40°F/4°C. If the disposable cartridge is below 40°F/4°C, it should be returned to room temperature prior to activation. Each device has an indicator located on the bottom of the disposable cartridge which shows if the cartridge needs to be replaced and/or returned to room temperature. The indicator will also indicate if the system has been inadvertently activated and therefore needs to be replaced. The following details the color changes of the indicator:
  From WHITE (ready to use) to BLUE (proper function cannot be guaranteed), if exposed to a temperature BELOW 40°F (4°C). The system must be returned to

room temperature prior to activation. Once returned to room temperature, the BLUE dot will disappear letting you know that the system is ready for use.
From WHITE (ready to use) to RED (proper function cannot be guaranteed), if exposed to a temperature ABOVE 160°F (71°C). The disposable cartridge must be replaced to guarantee proper operation.

*Note: The O2Ventilate System should not be stored in an environment where drastic temperature fluctuations can occur, such as a motor vehicle. For example, it has been shown that parts of a vehicle interior can heat up to more than 190°F (87.8°C) when an enclosed car is left in 89°F (31.7°C) heat. This type of temperature fluctuation could compromise the proper function of the O2Ventilate System.

The following diagram summarizes the temperature range indications for the O2Ventilate System:



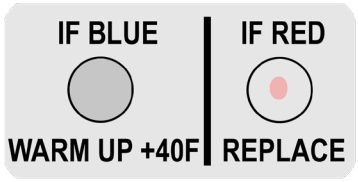
- Once cool, expended single use O2Ventilate disposable cartridges can be discarded along with standard household or public waste. Under no circumstance should anyone attempt to open or cut the disposable cartridge prior to, during, or after its use. In the event that the disposable cartridge is compromised and the contents are exposed, both the reactants and the residue are completely environmentally friendly. If the contents come in contact with the skin, wash immediately with running water and non-abrasive soap. If the skin becomes irritated apply an emollient. If irritation persists seek medical attention.
- If the system requires cleaning after use, we recommend a warm damp cloth to wipe down the exterior and interior of the housing.
- Do not use lubrication agents with the O2Ventilate System.
- The disposable cartridge, tubing and mask are single use items only and should be disposed of after each use.
- Using a mask or other accessories not specified for use with the O2Ventilate System may impair its performance and is strongly discouraged. Use only approved O2Ventilate components.

Supplies and Materials

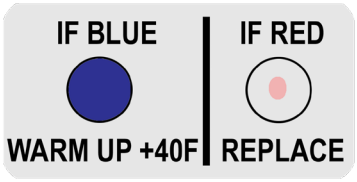
No special tools or materials are needed to activate or maintain the O2Ventilate System.

User Preparation

1. Prior to use, read the Instructions, cautions and warnings, and check the function of the resuscitator, by confirming that the intake, reservoir and patient valves are allowing all phases of the ventilatory cycle to occur.
2. New systems are delivered pre-assembled and should be visually inspected prior to usage or placing the unit into service. Check the temperature indicator on the bottom of the disposable cartridge (inside the oxygen vessel) and confirm that both indicator windows are "WHITE" (meaning ready-to-use). The indicator serves to notify you if the system was exposed to temperatures outside the Acceptable Temperature Exposure Range of 40°F / 4°C to 160°F / 71°C at any point during shipment. Exposure to the high and low temperature correlates to a change in color from white to blue and white to red (respectively), see Figure 2. If there is moisture or residue within the housing, it may be an indication that the system has inadvertently activated. If you receive a disposable cartridge that is compromised or expended, please contact Kwivik Therapeutics, Inc. If both indicators are WHITE, the system is ready for use and/or can be placed into service (Figure 2).

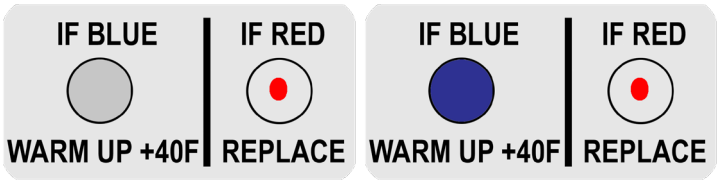


System is Ready-To-Use
(Both Indicators are "WHITE")



Cartridge MUST be Returned to Room Temperature Prior to Activation

(Left Circle Dark Blue)



Cartridge MUST be REPLACED
(Left Circle Dark Blue –OR– Right Circle has Bright Red Dot)

Figure 2

Expended O2Ventilate disposable cartridges and mask/tubing/bag assemblies are single use items and **must be replaced after each use before the system can be redeployed** (Figure 3).

Replacing the oxygen cartridge

1. Press the black button on the edge of the lid to open the lid.

2. Remove the expended cartridge by pulling up on the handle as indicated. Discard the used cartridge in a trash bin, along with the single use resuscitator bag, mask and tubing.
3. Insert a new cartridge into the housing and remove the two red safety tabs. Close the lid and press down until the latch is secured.
4. Remove the mask/tray component from the bag, keeping the mask on the tray. Insert it, mask first, inside the top of the dust cover until secure. Put the dust cover back on the unit.

Instructions for use

User must carefully read all instructions immediately upon receipt of the O2Ventilate System. If you have any questions regarding usage, maintenance, and/or disposal, please contact O2Ventilate Customer Service at:

Kwivik Therapeutics, Inc.
Attn: O2Ventilate Customer Service
207 King Rd #203
Frisco, Texas 75036-9204 USA
info@kwivikmedical.com
Tel: (+1) 972.752.3400 / Toll free: (+1) 844.636.6454
www.kwivikmedical.com

The O2Ventilate System is intended for the emergency, non-invasive ventilation of children and adults. The O2Ventilate device is intended for use by trained responders to manually provide emergency ventilation to a patient when an FDA cleared ventilator is not available due to COVID-19 pandemic.

Step-by-Step Instructions for Use

1. Prior to use, read the Instructions, cautions and warnings, and check the function of the resuscitator, by confirming that the intake, reservoir and patient valves are allowing all phases of the ventilatory cycle to occur.
2. Connect the self inflating resuscitator bag to the oxygen vessel, by: (a) connecting the oxygen tubing provided to the oxygen outlet port on the one end, making sure it is fully seated (a click sound will indicate that the connector is fully seated); and (b) connecting the other end of the oxygen tubing provided to the oxygen inlet.
3. Confirm that there is no obstruction of the oxygen flow through the tubing caused by a twist or kink in the tubing.
4. Ensure that the reservoir expands completely during inspiration and nearly collapses as the bag refills during exhalation.
5. Turn the oxygen starter knob in the direction indicated (clockwise) to commence the flow of oxygen (a quarter turn). Once activated, the O2Ventilate system delivers medically pure [USP] oxygen into the self inflating bag throughout the entire delivery process. Once activated, the oxygen flow cannot be stopped.
6. Place the face mask over the patient's mouth and nose.
7. Follow accepted Advance Cardiac Life Support (ACLS) or Institution-approved protocol for ventilation. For example, the self inflating resuscitator bag should be compressed at a rate of 12-20 times per minute (every 3-5 seconds) to deliver

oxygen to the patient, if that comports with current ACLS protocol. For each cycle, compress the bag to deliver a breath. Observe the chest rise to confirm inspiration. Then, release pressure on the bag to allow exhalation. Observe the chest fall to confirm exhalation.

8. Manometer Port: If using a manometer, remove the tethered blue cap from pressure monitoring port, securely connect manometer or monitoring line to the port.
9. The Child and Infant resuscitators are fitted with a pressure relief valve. These valves open when the pressure is in excess of 40 +/- 5 cmH20. It is also possible to lock the pressure relief valve in this position with the lock type Non-rebreathing Valve by twisting or turning the valve clockwise (to the right side) (as show by the arrow).
10. During ventilation, check for:
    - -signs of cyanosis
    - -proper function of all valves
    - -adequacy of ventilation
    - -airway pressure
    - -proper function of reservoir, and oxygen supply and oxygen tubing
11. The O2Ventilate system produces oxygen that is slightly humidified. Moisture or condensation in the tubing and in the self inflating bag is normal and should not be a cause for concern.
12. Should the non-rebreathing valve become contaminated with vomitus, blood or secretions during ventilation, disconnect the device from the patient and clear the non-rebreathing valve as follows:
    - Rapidly compress the squeeze bag to deliver several sharp breaths through the non-rebreathing valve to expel the contaminate.
    - If the contaminate does not clear. Rinse the non-rebreathing valve in water and then rapidly compress the squeeze bag to deliver several sharp breaths through the non-rebreathing valve to expel the contaminate.
    - If the contaminate still does not clear, discard the resuscitator.
13. If the patient requires additional ventilation or oxygen upon expiration of the disposable cartridge (15 minutes or more), replace the disposable cartridge, along with the single use tubing, mask and bag and repeat the process starting with step two. **Caution: Handle with care. The used oxygen cartridge may be hot to the touch.**

Oxygen is not flowing

If the O2Ventilate system has been started but oxygen is not flowing:

1. Check the oxygen tubing and resuscitator bag connections and confirm they are secure.
2. Check the oxygen tubing and confirm that there are no kinks or twists causing the flow of oxygen to be obstructed.

**Note: Oxygen flow can be confirmed by listening for a bubbling sound.*

Resuscitator Volumes:

Non-rebreathing Valve:	7ml
Child Mask:	95ml
Adult Mask:	150ml
Infant Mask:	28ml

	Bag Volume	Stroke Volume	Reservoir Volume	Situation Body Valve
Adult Model	1600ml	700ml	2500ml	>30kg
Small Adult	1000ml	540ml	2500ml	>30kg
Child Model	500ml	300ml	2500ml	7-30kg
Infant Model	280ml	150ml	1000ml	<7kg

Size	**Minimum Cycle Rate**	**Oxygen Concentration**
Adult	20bpm with reservoir	90%
Small Adult	20bpm with reservoir	90%
Child	20bpm with reservoir	95%
Infant	40bpm with reservoir	85%

The performance characteristics for Manual Resuscitators will vary from user to user depending on a variety of factors; ambient temperature, patient lung compliance, ventilatory frequency, size of operator's hands.

	CYCLE RATE		
	-18°C (0°F)	22°C (72°F)	50°C (122°F)
Adult	20	20	20
Small Adult	20	20	20
Child A	30	30	30
Infant A	60	60	60

The Results were obtained under the following conditions:

- Adult: V 600ml, Compliance 0.02L/cmH2O, Resistance 20cm H2O/L/s
- Small Adult: V 600ml, Compliance 0.02L/cmH2O, Resistance 20cm H2O/L/s
- Child A: V70ml, Compliance 0.01L/cmH2O, Resistance 20cm H2O/L/s
- Infant A: V20ml, Compliance 0.01L/cmH2O, Resistance 20cm H2O/L/s

The correct ventilation frequency may vary, please follow the current ventilation frequencies as recommended by the American Heart Association (AHA).

STROKE VOLUME RANGE

	Using one hand	Using two hands
Adult	700ml	900ml
Small Adult	540ml	650ml
Child A	300ml	350ml
Infant A	150ml	225ml

Kwivik Therapeutics, Inc.
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