FDA-Authorized for Emergency Use Only VentMI™ Ventilator Splitter Instructions for Use

Contents

Contact

MakeMedical LLC

Email: contact@makemedical.net
Telephone: +1 (248) 956-0377
Website: www.makemedical.net/ventmifeedback

INTENDED USE

A single ventilator fitted with the VentMI Ventilator Splitter can be used for two adult patients with the same pathology for ventilatory support for up to fourteen (14) days during the COVID-19 pandemic when individual ventilators are not available.

CONTRAINDICATIONS

The VentMI is NOT to be used with patients who:

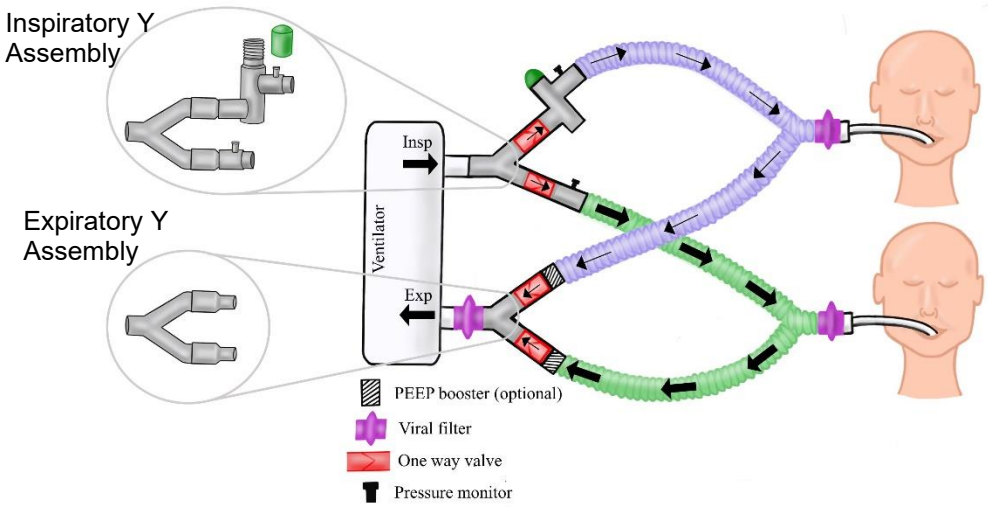
- Exhibit symptoms of **acute asthma** or who have been diagnosed with **chronic obstructive pulmonary disease** (COPD), as these conditions substantially complicate respiratory parameter assessment and joint patient management.
- Are under **18 years of age**
- Are capable of **spontaneous ventilation**

The device may NOT be used without heat and moisture exchange filters (HMEF), as indicated in the instructions

DEVICE SPECIFICATIONS

OVERVIEW

The VentMI consists of two primary assemblies: an Inspiratory Y Assembly with an attached regulator for the inspiratory outlet on the ventilator, and an Expiratory Y Assembly for the expiratory inlet on the ventilator. The device is used with standard ventilator tubing circuits and viral/bacterial filters, which connect to the patients' endotracheal or tracheostomy tubes, as shown in the figure below:



One way valves are part of each assembly to prevent backflow and mixing of gases between the two patients. A luer connector is present on each arm of the Inspiratory Y Assembly to allow pressure measurement and alarms for each patient. Viral/bacterial filters (not included) help prevent cross-contamination and contamination of the ventilator. Optionally, an in-line PEEP modifier (PEEP booster in image) may be used to regulate the PEEP for each patient.

PRINCIPLE OF OPERATION

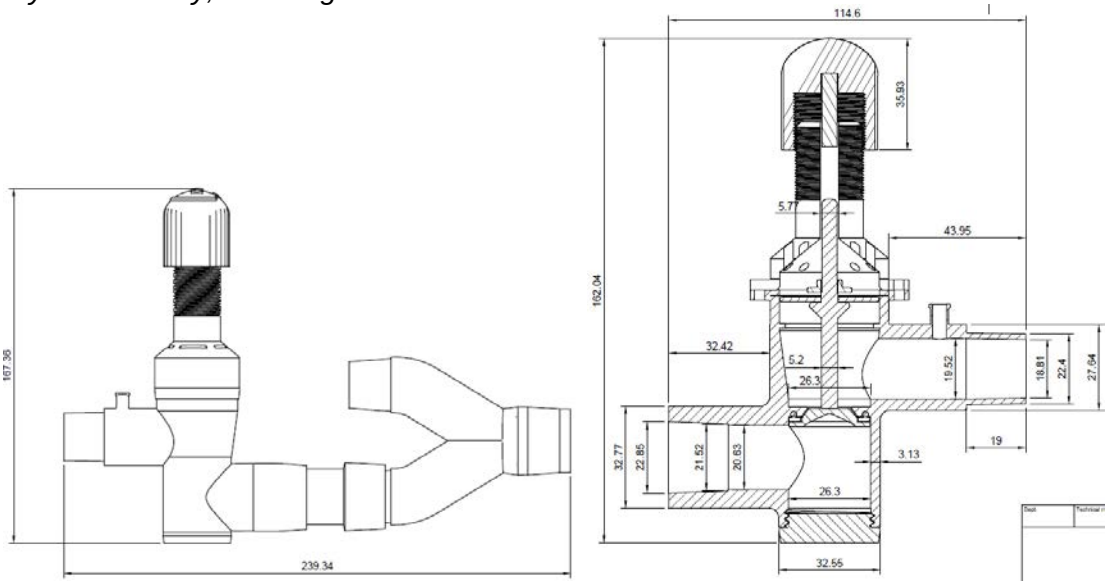
The device uses a regulator to modify downward the pressure delivered to the second patient. The principle at work is similar to scuba gear, where a diver cannot breathe the gas under pressure directly, but must use a regulator to prevent lung injury.

The ventilator pressure is set for the primary patient (Patient A in the instructions). In the inspiratory limb of the circuit for the second patient (Patient B), airflow from the ventilator enters the regulator through the inlet port. The gas then passes through the normally open pressure control valve orifice and the downstream pressure rises until the valve-actuating diaphragm is deflected sufficiently to restrict the valve, limiting any more gas from entering the circuit above the pressure set for the second patient. A fully “open” valve allows the same pressure to be delivered to Patient B as is delivered to Patient A. Twisting the cap of the regulator as indicated in the instructions for use changes the amount of pressure needed to actuate the restricting valve.

COMPONENTS

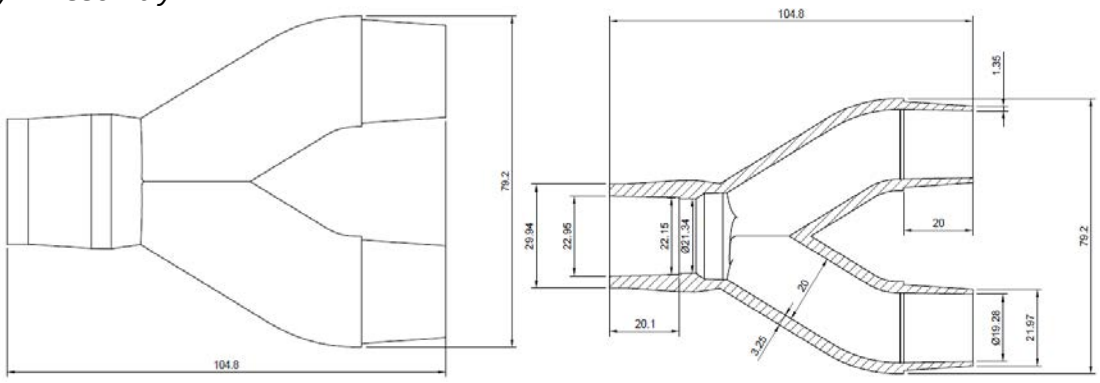
The Inspiratory Y Assembly is 239 mm long, 167 mm tall and 32 mm wide. The two cone (male) connectors are parallel to each other with openings 22 mm in diameter. Wall thickness varies from 3 to 5 mm. The housing is machined from aluminum; other materials of construction include Radel® polyphenylsulfone, polypropylene and silicone. The Inspiratory Y Assembly is preassembled, with the regulator body joined to a Y piece.

Inspiratory Y Assembly, with Regulator Detail



The Expiratory Y Assembly is 105 mm long, 79 mm high and 30 mm wide. The two cone (male) connectors are parallel to each other with openings 22 mm in diameter. Wall thickness ranges from 3.25 mm to 3.49 mm.

Epiratory Y Assembly



PACKAGING

The VentMI comes packaged in three ways:

1. Simple Kit: one Inspiratory Y Assembly, one Expiratory Y Assembly
2. Simple Kit + PEEP Booster: one Inspiratory Y Assembly, one Expiratory Y Assembly, one PEEP Booster set
3. Full Kit + PEEP Booster: one Inspiratory Y Assembly, one Expiratory Y Assembly, one PEEP Booster set, three viral/bacterial filters, two T pieces and the ventilator tubing.

The PEEP booster is an optional component that may be used to regulate the PEEP for each patient.

The device was disinfected in 70% isopropyl alcohol prior to packaging, but is NOT sterile.

The figure on the next page will be affixed to the exterior of the device packaging.

Package Label

<table>
<tr>
<td>

VentMI™ Circuit
Ventilator Splitting Device

FOR USE WITH VENTILATORS and ANESTHESIA MACHINES

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Non-sterile

Single use, do not re-use

This device has been disinfected in 70% isopropyl alcohol, but is NOT sterile

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This device is only to be used under the FDA Emergency Use Authorization during times of public health emergency, when approved ventilators are not available for standard of care use.

A single ventilator fitted with the VentMI Ventilator Splitter can be used for two adult patients with the same pathology for ventilatory support for up to fourteen (14) days during the COVID-19 pandemic when individual ventilators are not available.

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WARNINGS 

- **DO NOT** attempt this without full knowledge and understanding of pressure control settings on a ventilator. Failure to observe this could result in injury to a patient's lungs or death.
- **DO NOT** try this with volume control settings. A change in compliance or resistance with one patient on the multiplex can have serious consequences with other patients on the multiplex with volume control ventilation.

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SYMBOLS

Symbol	Meaning
	Caution
	Non-sterile
	Single use, do not re-use
	Warning

DEFINITIONS AND ABBREVIATIONS

Abbreviation	Meaning
INSP	Inspiration port
EXP	Expiration port

WARNINGS

- **DO NOT** attempt this without full knowledge and understanding of pressure control settings on a ventilator. Failure to observe this could result in injury to a patient's lungs or death.
- **DO NOT** try this with volume control settings. A change in compliance or resistance with one patient on the multiplex can have serious consequences with other patients on the multiplex with volume control ventilation.
- This is a **single use** FDA authorized device for emergency use. Re-use could result in pathogenic exposure to the patient or contamination of the ventilator.
- **DO NOT** use this device for more than 14 days, as it has not been tested for durability in excess of the number of cycles during a 14 day period.

CAUTIONS

Cautions in general

1. This product should only be used by a trained healthcare professional.
2. This product should be used immediately after opening the package.
3. Do not use if the packing is wet or damaged.
4. Do not use if there is mold on the product.

Cautions and considerations for using a single ventilator on more than one patient:

1. Use of the Vent-MI circuit allows an additional patient to be added to a single ventilator. The second patient's circuit should have lower or equal PIP requirements. The PIP can be controlled for each patient. Monitoring ports are present that can be attached to an arterial line monitor to enable remote monitoring or to be sampled to determine actual pressure. Viral filters and one way valves may decrease the risk of cross contamination.

2. Airflow of 40 liters/minute per patient free gas flow (FGF) for oxygen is recommended when the ventilator is used for multiple patients.

3. **The pressure control mode should be used when more than one circuit is added to the ventilator. Failure to do so will result in differing pressures delivered to each patient, which can result in lung injury or death.**

4. While the VentMI circuit allows for differing levels of pressure support, a single ventilator fitted with the VentMI will provide each patient with the same rate of respiration, the same inspiratory/expiratory ratio and the same FiO2. PEEP boosters allow differential in the delivered PEEP for one patient.

   While the sampling port can be used to allow the FiO2 to be increased in one line while the delivered pressure is still being monitored, this has not been tested in patients.

5. Caution: paralysis and sedation, and additional infusion pumps to administer these agents, may be needed to avoid dyssynchronous breathing and system alarming from Valsalva, bucking and coughing.

6. Caution: additional infusions pumps may be needed.

7. Caution: Special precautions should be taken when proning a patient. (1) Do not attempt to prone both patients at the same time. (2) Reassess both patients after one patient is proned. (3) The use of specialty beds for prone positioning is discouraged due to a potential risk of iatrogenic harm. (4) There is an increased risk of aerosolization if the ventilator circuit becomes disconnected during proning. (5) There can be increased exposure to staff during proning due to the number of individuals required to prone a patient.

8. Caution: Any intervention that could result in respiratory compromise in one patient should not be done to both patients simultaneously. This includes suctioning, patient repositioning, endotracheal tube repositioning, tracheostomy tube changes and upper body central venous catheter insertion. If possible, twenty minutes to assure stabilization is recommended before moving on to the next patient.

9. Caution: Ensure that there are enough healthcare professionals to monitor each individual patient. Procedures to be used in emergency situations should be reviewed during each shift change.

10. Caution: Even though two patients can have initially similar lung compliance, they may progress differently and thus need continuous assessment. The greatest risks are with acute deterioration of one patient with balance of ventilation distributed to other patients, especially if device used in VC mode.

11. Caution: In Two Patient Mode, ventilator's operational self-test may fail and could add to errors in measurement.

12. Because the single ventilator provides similar ventilatory support to two patients, it is preferable to size match patients.

13. Because the single ventilator provides similar ventilatory support to both patients, it is also preferable to select, to the extent possible, patients with similar underlying lung physiology, lung compliance, and ventilatory requirements, so that one system can generally meet each patient's needs, as they await individualized ventilators; ideally the circuit is placed on standby for a patient with high but stable settings. This will allow a second patient to piggy-back onto that support with a setting lower than the more stable patient.

14. Close monitoring of all patients will be critical since they may need to be paralyzed and sedated. Each patient should be assessed frequently clinically, at a minimum of 15-30 minute intervals, including vital signs, oxygen saturation level, end tidal CO2, examinations of the chest for bilateral air movement, and, if indicated, chest x-ray or assessments of arterial blood gas findings to assure clinical stability on the shared system.

15. If the shared ventilator alarms for any reason, clinical assessments of each patient are indicated immediately in order to determine which patient is triggering the alarm. *The ventilator cannot indicate which patient is triggering the alarm.* Providers need to assess all patients, consider suctioning and proper tube placement, and disconnect any unstable patient, considering mechanical bagging if necessary;

16. ⚠ Potential infectious complications from sharing one ventilator have not been studied, and therefore caution is advised. A COVID-19 positive patient should NOT share the same ventilator as a non-COVID- 19 positive patient. If patients share the same infection, the single ventilator for multiple patients is a viable short-term management option. Each patient's circuit should contain in-line filters designed to filter out viruses and/or bacteria and to protect the ventilator from contamination. **Failure to do so could result in cross contamination.**

EQUIPMENT & SUPPLIES

Specific equipment required may vary depending on supplies and equipment available.

1	One ventilator
2	One VentMI Circuit device (two components: Expiratory Y assembly, Inspiratory Y Assembly with Regulator)
3	Three (3) viral/bacterial filters, one for each patient and the expiratory gas inlet
4	Ventilator circuit for each patient with a designated color or labeling pattern
5	Test lungs for ventilator circuit set up and testing

INSTRUCTIONS

SET UP STANDBY MODE

CAUTION: Setup is typically done on a ventilator supporting a patient that is stable with higher inspiratory requirements than the patient to be added. **If a patient is not stable, they are not a good candidate to be put in STANDBY MODE.**

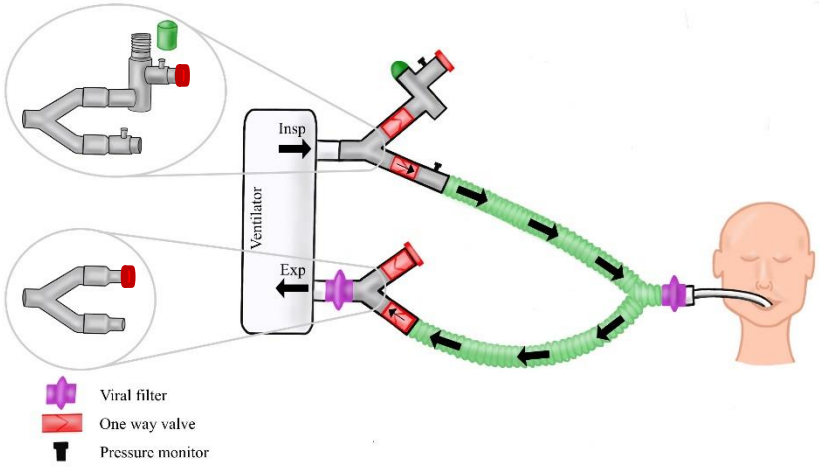
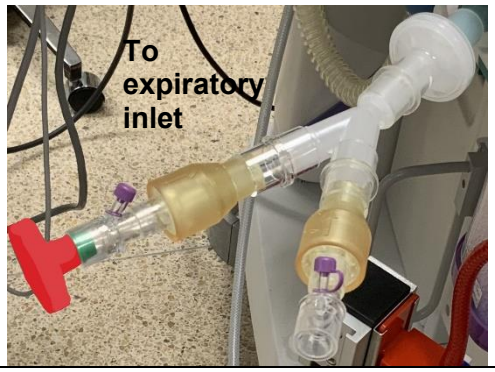


Diagram of Standby Mode (single patient)

1	Remove the VentMI device components from their package. The device is not sterile, but has been subject to a 70% alcohol wash prior to packaging.  Each assembly has a red cap on one arm. **LEAVE THIS IN PLACE.**	
2	Firmly attach a viral/bacterial filter to the leg of the Expiratory Y Assembly.	
3	Firmly attach the filter on the Expiratory Y Assembly to the expiratory inlet of the ventilator. **LEAVE THE RED CAP IN PLACE.**	

4	Firmly attach the Inspiratory Y Assembly to the inspiratory outlet of the ventilator.	
5	Connect standard ventilator tubing to the Expiratory Y Assembly and the short leg of the Inspiratory Y Assembly. **LEAVE THE RED CAP IN PLACE.**	
6	Connect a viral/bacterial filter to the circuit connector that connects to the endotracheal tube, proximal to the patient.	
7	Test operation of ventilator as indicated in instructions for use of ventilator. Check stability of the system for a minimum of 15 minutes.	

TRANSITION FROM STANDY TO TWO-PATIENT MODE

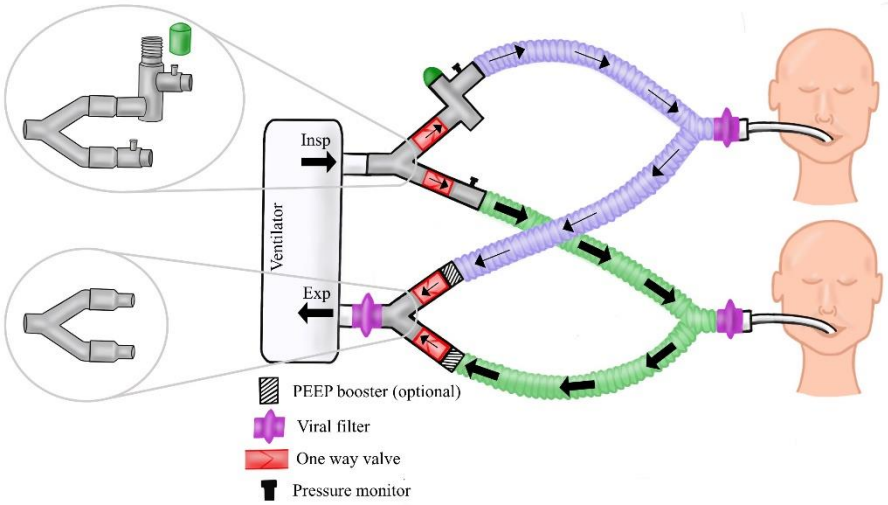


Diagram of Two Patient Mode

1	Setup tubing for second patient. Connect a viral/bacterial filter to the circuit connector that attaches to the endotracheal tube, proximal to the patient. Tubing for the second patient MUST be distinguished in some manner, either with colored tape or a different colored tubing. The inspiratory tubing runs to the patient and then back to the expiratory inlet as would be standard with any ventilator circuit.	
2	Remove the red caps from the Expiratory Y Assembly and the Inspiratory Y Assembly of the VentMI.	

3	Connect second circuit to the VentMI Assemblies.	
4	Turn valve on the Inspiratory Y Assembly clockwise to open position and adjust pressure on the second patient. Adjust alarms as necessary.	
	Please see the clinical protocol for the remaining recommendations (**Appendix A**).	

TROUBLESHOOTING

General approach: A single patient with relatively high but stable settings is the preferred primary patient (Patient A). **Observe that the Patient A is stable in Standby Mode for at least 15 minutes to demonstrate stability.**

⚠CAUTION: If a patient is unable to maintain adequate support in Standby Mode, they are unsuitable for use of the VentMI.

If a secondary patient (Patient B) is unable to be placed successfully on the circuit in Two-Patient Mode, remove Patient B from the circuit, reassess the circuit as indicated in the table below.

Ventilator/circuit problems can be distinguished from endotracheal tube/patient problems by taking the patient off the ventilator and manually bag-mask ventilating the patient with a self-inflating resuscitator.

PROBLEM	IMMEDIATE ACTION	POTENTIAL CAUSE(S)	POTENTIAL SOLUTION
Patient A unable to enter standby mode	Remove Inspiratory Y Assembly Remove Expiratory Y Assembly	Red piggyback caps for second circuit are dislodged.	Confirm that red caps are in place, in the correct position and tight.
		Inspiratory Y Assembly and Expiratory Y Assembly are reversed	Confirm that the trunk of the Inspiratory Y Assembly is connected to inspiratory (outflow) outlet of the ventilator. Confirm that the trunk of the Expiratory Y Assembly is connected to the expiratory (return flow) inlet of the ventilator.
		Loose connection of Inspiratory Y Assembly or Expiratory Y Assembly to the ventilator	Check each connection individually
		Patient deterioration unrelated to the VentMI circuit	Patient will continue to have difficulties after circuit removal. Standard resuscitation algorithms.
		Excessive leak from sampling port	Confirm that sampling ports are tightly capped.
Secondary Patient B unable to connect	Remove Patient B from circuit. Close circuit. Replace cap.	Ventilator is inadequate	Check performance
		Valve was not opened, reassess valve position	Valve opens by screwing clockwise

PROBLEM	IMMEDIATE ACTION	POTENTIAL CAUSE(S)	POTENTIAL SOLUTION
Excessive pressures in secondary Patient B	Close pressure-valve: Turn screw cap away from open (counterclockwise)	Pressure-Valve is allowing too much pressure (too open)	1. Partially close pressure-valve by turning screw cap away from open (counterclockwise). 2. Check pressure in Patient B circuit. 3. If pressure remains too high, repeat steps 1 and 2.
Worsening disease of secondary Patient B makes them no longer suitable to be paired with primary Patient A.	Disconnect secondary Patient B by removing circuit. Replace caps, close valve.	Patient B patient is unsuitable to be supported by Patient A.	Look for a suitable new primary Patient A in Standby Mode requiring higher support. Consider alternative ways of supporting ventilation.
Inadequate PEEP in either primary Patient A or secondary Patient B			Place PEEP booster in patient's circuit, just ahead of the expiratory inlet Y. Check pressure. Increase the PEEP booster limit by changing out PEEP boosters or stacking as necessary to achieve desired PEEP.
Alarms after PEEP booster placed	Remove PEEP booster	PEEP booster not placed correctly.	Check that PEEP booster is vertical, in the correct location, on the correct circuit and in the correct direction.
Unintentional loss of pressure difference between patients	Close pressure-valve by turning screw cap away from open (counterclockwise)	Failure of one-way valves	Replace Inspiratory Y Assembly.
		Failure of regulator pressure valve	Replace Inspiratory Y Assembly if closing pressure-valve does not affect pressures.
Overpressure alarm		Airflow obstruction may result from airway secretions, bronchospasm, endotracheal tube migration, kinking of the ventilator circuit, and biting on the endotracheal tube. Decreased pulmonary compliance may be as a result of atelectasis,	Check complete circuit for any kinking, fluid pooling secretions or obstruction. Assess patient. Return to Standby Mode by removing Secondary Patient B from circuit. Close circuit. Replace cap. Assess each patient individually.

PROBLEM	IMMEDIATE ACTION	POTENTIAL CAUSE(S)	POTENTIAL SOLUTION
		pulmonary edema, pneumonia, pneumothorax, or pulmonary fibrosis. Check ventilator settings: excessive tidal volume; excessive flow; excessively short inspiratory time; high airway pressure; alarm limit too low.	Disconnect primary Patient A from ventilator and manually ventilate using self-inflating resuscitator. If the patient is difficult to ventilate the problem, the problem is with the endotracheal tube or respiratory system. If the patient is not difficult to hand ventilate, assess the ventilator and the circuit for obstruction or kinking. For ventilator and circuit problems check ventilator settings and function, and check circuit for obstruction or kinking.
Ventilator alarms due to sensed obstruction, may pulse to attempt to dislodge	Evaluate patient for obstruction	Ventilator sensitive to pressure restriction in Patient B; this was found during testing in ICU ventilator (Puritan Bennett model 840)	Remove VentMI Assemblies from ventilator. Add two additional Y pieces at ventilator inlet/outlet ports and connect one arm of each piece to the other via tubing. Connect other arm to VentMI device components.
Monitored pressure does not match		Monitor has not been zeroed correctly	Check with hand manometer
Need to manually ventilate secondary Patient B	Return to Standy Mode by removing secondary patient B from circuit. Close pressure valve by rotating away from open position (counterclockwise) Replace caps on assemblies.	Accidental extubation, worsening hypoxia	n/a
Need to manually bag primary Patient A	Remove primary Patient A from the circuit. Place cap over Inspiratory Y	Accidental extubation, worsening hypoxia	n/a

	Assembly arm (short) that goes to Patient A. Place cap over Expiratory Y Assembly arm that goes to center patient. Fully open the pressure valve by turning it clockwise.		
Desaturation	Increase FIO2 to 1.0 Examine chest wall motion. If cause is not obvious, manually ventilate patient with 100% oxygen to exclude ventilator malfunction.	Mainstem or too distal intubation Accidental extubation Pneumothorax Pulmonary embolus Intrapulmonary shunt Hypoxic respiratory failure Ventilator malfunction	Check ventilator settings to improve oxygenation. Obtain chest x-ray to diagnose.
Patient-ventilator dysynchrony	Return to Standy Mode by removing secondary Patient B from circuit. Close circuit. Replace caps.		Search for other causes before sedating the patients.
Pain, anxiety, agitation, and delirium			Search for other causes before sedating the patients
Minute ventilation, tidal volume, and apnea alarms			Check respiratory and tidal volume. Patients may be unable to be paired.
Auto-PEEP and patient triggering inappropriate inspiratory/expiratory times			Check that vent is triggering appropriately. Check inspiratory/expiratory times, adequacy of flow, lung compliance, and airway resistance.
Circuit leaks			Check circuit for loose connection. It may be possible to continue to ventilate both patients if leak is small.

Appendix A: VentMI Clinical Protocol

(Based on the "Ventilator Sharing Protocol: Dual-Patient Ventilation with a Single Mechanical Ventilator for Use during Critical Ventilator Shortages" developed by NewYork-Presbyterian Hospital and supported by the GNYHA member hospitals

NOTE: The VentMI device has not been endorsed by NewYork-Presbyterian Hospital or the GNYHA

Version Date: March 27, 2020, 8:23AM (version 4)

For most current version of this protocol, please reference

https://www.gnyha.org/news/working-protocol-for-supporting-two-patients-with-a-single-ventilator/

A. SUMMARY OF KEY PROTOCOL RISKS & SAFETY FEATURES

Supporting two patients with a single ventilator poses real risks to patients, including the following:

1. *One patient causing accidental extubation in the other*. This risk is mitigated by neuromuscular blockade. Any extubation or tube dislodgement causing air leak would be detected by PEEP alarm immediately, even during dual-patient ventilation.
2. *One patient infecting the other*. This risk is mitigated by the antimicrobial filter placed between airflow of the two patients, by the one way valves preventing backflow. In spite of these mitigating steps, patients sharing the same ventilator should have the same underlying infectious agent or prior testing ruling out positive COVID status.
3. *Delayed detection of hypo/hyperventilation*. This risk is mitigated by rigorous safety check before initiation, careful selection of patients with similar mechanical support needs for pairing, use of capnography where available, use of pressure monitoring through the sampling ports where available, and frequent blood gases.
4. *Detrimental patient-ventilator interactions from respiratory muscle effort (breathing, hiccup, cough)*. This risk is mitigated by use of neuromuscular blockade.
5. *Delayed weaning*. This risk is mitigated by the ventilator allocation schema, reserving some ventilators for weaning.

This protocol was developed with focus on ensuring that events in one patient will not harm the other, with several safety features to that end:

1. *Neuromuscular blockade (paralysis)* ensures neither patient triggers the ventilator and helps mitigate risk of pendelluft in the patient not breathing spontaneously.
2. *Pressure-control mode* ensures that if airway blockage, endotracheal tube obstruction, pneumothorax, or other acute change occurs in one patient, the other patient will continue to receive the same tidal ventilatory support because driving pressure is unchanged. In contrast, with volume-control, if one patient experiences any of the above acute changes, the unaffected patient would receive a much higher tidal volume and/or the peak inspiratory pressure limit would be exceeded, canceling the inspiratory cycle & risking hypoventilation.
3. *Pressure-control mode* also ensures that if one patient occultly makes spontaneous inspiratory efforts despite paralysis, the patient effort does not "steal" tidal volume from the other patient as would occur in volume-control.
4. *Similar mechanical support needs* for patients considering to be paired together to minimize risk of deleterious ventilation-induced lung injury or hypo/hyperventilation.
5. *Ventilator alarms* are tightly adjusted to detect changes that would warrant bedside evaluation. Because tidal volume and minute-volume reflect the additive values from both

patients combined, it is essential that ventilator alarms be adjusted expertly to detect small deviations in either of these parameters.

6. *Independent patient-specific monitoring and alarms* for tidal volume, minute-volume, end-tidal carbon dioxide, airway pressure, and airflow ensure the same individual patient information is available as during single-patient ventilation.
7. *Redundant safety checks* throughout the protocol ensure any error in key steps is identified and corrected before proceeding.
8. *Ventilator sharing is restricted to two patients on one ventilator* to minimize risk of harm to either patient. Ventilator titration to ensure appropriate full support already is challenging with two patients and would become prohibitive with additional patients sharing one ventilator. Adding more patients markedly decreases likelihood of good matching and increases likelihood that at least one patient's course will diverge from others, creating a barrier to sharing. Technical complexity for trouble-shooting during acute events further compromises safety. These factors collectively necessitate no more than two patients for ventilator sharing in severe acute respiratory failure to ensure safety.
9. *Multiple antimicrobial filters, one-way valves and patient matching by respiratory pathogen* minimize risk of one patient infecting the other. Despite this, patients with positive known pathogen should not be paired with patients other than known positive for the same pathogen.

B. VENTILATOR CIRCUIT SAFETY TEST

***Step 1*:** Turn on new ventilator to be used for dual-patient ventilation. Run the system checks as you normally would per local institutional practice

Note: If the system check is performed with two circuits connected to the ventilator (two-patient setup), many ventilators give an error. If such error occurs during leak test, double-check all connections to ensure they are snug. Consider repeating leak test with a single circuit attached as done in usual practice. Testing by the developers of this protocol at New York-Presbyterian Hospital found that ventilators were able to support two patients despite this anticipated warning during the safety test, although the tidal volume may be misestimated by 50-80 mL. Use of independent tidal volume monitoring overcomes this issue.

***Step 2*:** Connect a “test lung” to each circuit where the endotracheal tube would normally attach. The two test lungs should have identical mechanics (e.g. same manufacturer and model).

***Step 3*:** Initiate ventilation in **pressure control mode** with standard settings for this mode.

***Step 4:* SAFETY CHECK:** Observe the following.

1. No ventilator alarms or errors occur.
2. Both test lungs inflate and deflate at the same time with each tidal breath.
3. As available equipment permits, independently measure tidal volume in each test lung simultaneously to confirm they are similar.

C. INITIAL PATIENT COMPATIBILITY ASSESSMENT

Recommended initial requirements for identifying patients to pair together are presented in **Table 1**. Values were selected to mitigate risk to either patient and allow room for ventilator titration if needed.

Table 1: Recommended initial patient compatibility criteria. If patients do not meet all of these criteria, pairing them on a single ventilator is not recommended.

Parameter	**Acceptable Limit in Either Patient**	**Acceptable Difference *Between* Patients (patient A – patient B)**
Anticipated time needing invasive ventilation	72 hours or higher	
Tidal volume	6-8 mL/kg PBW	
Driving pressure (ΔP = plateau pressure – PEEP)	5-16 cmH_2O	0-6 cmH_2O
Respiratory rate	12-30 breaths/min	0-8 breaths/min
PEEP	5-18 cmH_2O	0-5 cmH_2O
FiO_2	21-60%	
pH	7.30 or higher	
Oxygen saturation	92-100%	
Ventilator titration	No recent major changes as judged clinically	
Neuromuscular blockade	No contraindication to initiation if not already receiving	
Respiratory infectious status	Both patients have same infectious organism	None
Asthma or COPD	No severe baseline disease nor current exacerbation	
Hemodynamic stability	No rapid vasopressor increase	

Abbreviations: PBW = predicted body weight, calculated as follows:
PBW males = 50 + 2.3 [height (inches) – 60]
PBW females = 45.5 + 2.3 [height (inches) – 60]

D. STEPWISE APPROACH TO MATCHING VENTILATOR SETTINGS

Step 1*:** In ***both patients: Respiratory effort must be completely eliminated as follows.

1. Titrate sedation to RASS -5 (unresponsive)
2. Initiate continuous neuromuscular blockade (paralysis) with **Cisatracurium 15mg bolus followed by continuous infusion of 37.5 mg/hour (typically 6-8 mcg/kg/min)** (Papazian et al NEJM 2010).
    a. **Do *NOT* check train of four (TOF)**. Goal is to minimize unnecessary entry into room, and TOF is irrelevant to protocol where explicit goal is to ensure passive ventilation.
3. Reconfirm initial patient compatibility in Table 1

Step 2*:** In ***patient A:

1. Make note of the following baseline values:
    a. baseline driving pressure (ΔP = plateau pressure – PEEP)
    b. baseline tidal volume
    c. baseline respiratory rate
2. Initiate **pressure control ventilation (PCV)** mode with:
    a. **Driving pressure** (inspiratory pressure above PEEP): set to match measured baseline driving pressure.
    b. **Inspiratory time**: adjust between 0.6 to 1.0 seconds to achieve tidal volume approximating baseline
    c. **Respiratory rate, PEEP, and FiO_2**: Unchanged from baseline unless adjustment needed for safety

Step 3*:** In ***patient B:

1. Make note of the following baseline values:
    a. baseline driving pressure (ΔP = plateau pressure – PEEP)
    b. baseline tidal volume
    c. baseline respiratory rate
2. Initiate **pressure control ventilation (PCV)** mode with:
    a. **Driving pressure** (inspiratory pressure above PEEP): set to match measured baseline driving pressure.
    b. **Inspiratory time**: adjust between 0.6 to 1.0 seconds to achieve tidal volume near baseline
    c. **Respiratory rate, PEEP, and FiO_2**: Unchanged from baseline unless change needed for safety

Step 4*:** In ***both patients:

1. **PEEP**: titrate to be the same in both patients.
    a. Use clinical judgement on the appropriate PEEP that both patients can tolerate.
    b. Consider initial PEEP adjustment set to average of the two patients.
2. **FiO_2**: titrate to be the same in both patients while maintaining $SpO_2 \geq 95\%$.
3. **SAFETY CHECK:** Confirm tidal volume has not decreased more than 50 mL after PEEP change.
    a. Tidal volume decrease by more than 50 mL strongly suggests either overdistension (if PEEP was increased in patient) or de-recruitment (if PEEP was decreased in patient).

Step 5*:** In ***both patients:

1. **Driving pressure**: titrate to be the same in both patients.
    a. Consider initial driving pressure adjustment set to average of the two patients.
2. **Inspiratory time**: titrate to be the same in both patients.
    a. Consider initial inspiratory time adjustment set to average of the two patients.
3. **Respiratory rate**: titrate to be the same in both patients.
   SAFETY CHECK
    a. Confirm **minute-volume** remains **within ± 2 liters/min baseline in each patient**.
    b. After 20 minutes, check **arterial or venous blood gas** in both patients to confirm pH & pCO_2 in acceptable range.
    c. Confirm both patients remain **paralyzed** and not making any spontaneous breathing effort.
    d. Confirm both patients now are tolerating **identical ventilator settings**.
    e. Note these values for use in setting initial ventilator alarms (Table 2)

E. RECOMMENDED INITIAL VENTILATOR ALARM SETTINGS

Table 2. Recommended Initial Ventilator Alarm Settings

Parameter	Lower Alarm	Upper Alarm
Tidal volume (V_T)[a]	(V_T in patients A+B) – 100 mL	250 mL above minimum alarm
Respiratory rate	5 breaths/min below preset value	5 breaths/min above preset value
Peak pressure	5 cmH_2O below preset value (preset = driving pressure + PEEP	5 cmH_2O above preset value (preset = driving pressure + PEEP
PEEP	2 cmH_2O below preset value	5 cmH_2O above preset value
Minute-volume[a]	(minvol in patients A+B) – 1 liter/min	(minvol in patients A+B) + 1 liter/min

[a] Values for V_T and minvol are to be taken on identical ventilator settings at final safety check while both patients are still on their own ventilator just prior to pairing on one ventilator (page 6, Step 5).

***IMPORTANT:** During dual-patient ventilation, ventilator may misestimate compressible gas volume in circuit. As a result, V_T may be incorrect by ~80 mL, with similar misestimation of minute-volume. V_T alarm may need to be adjusted, but then blood gas must be done to confirm adequate ventilation.

F. INITIATING TWO-PATIENT VENTILATION

IMPORTANT:** Disconnecting ventilator circuit is an ***aerosol-generating procedure. Anyone present should wear appropriate PPE, including eye protection and an N95 or equivalent respirator**.**

Step 1*:** In ***both patients:

1. **Increase FiO_2 to 100%** for preoxygenation prior to transfer.
2. Position patients sufficiently close to each other so that they can be connected to same ventilator ***with NO addition* of deadspace extension tubing**.

***Step 2*:** Review and confirm:

1. Ventilator settings for each patient are identical while on pressure-control mode.
2. Patient compatibility assessment:
    a. **Minute-volume remains within ± 2 liters/min baseline in each patient.**
    b. **pH & pCO_2** on matched ventilator settings is in acceptable range.
    c. Both patients remain **paralyzed** and not making any spontaneous breathing effort.
3. Two-patient ventilation circuit is operational and insufflates both test lungs as per **Section D**.

***Step 3*:** Set initial ventilator settings on the new ventilator to match what both patients already are receiving. The patients already should be receiving identical ventilator settings per protocol.

Step 4: Complete following procedures to transition the patients to the new circuit:

1. New dual-patient ventilator is on with circuit connected and insufflating the two test lungs (**Section D**).
2. Remove one test lung from one circuit of the new dual-patient ventilator and cap the circuit
3. Remove the other test lung from the dual-patient ventilator circuit.
4. Transfer Patient A in following steps in *immediate* succession:
    a. **Clamp endotracheal tube** of Patient A (minimizes aerosols and derecruitment).
    b. Disconnect Patient A from old (single-patient) ventilator circuit
    c. Connect Patient A to new circuit
    d. Immediately unclamp endotracheal tube after patient on new circuit.
5. Repeat for Patient B, connecting to the other circuit on the dual-patient ventilator.

Step 5: **SAFETY CHECK** after initiating dual-patient ventilation

1. **Dual-patient tidal volume** (on pressure control) is within ±100 mL of tidal volumes for patients A+B added together from just prior to dual-patient ventilation
2. **SpO2 > 95%** in each patient. Wean FiO_2 as tolerated.
3. After 20 minutes, check **arterial or venous blood gas** in both patients to confirm pH & pCO_2 in acceptable range.
4. Both patients remain **paralyzed** and not making any spontaneous breathing effort.
5. Maintain old ventilators at bedside until 20-minute blood gas results returned and deemed acceptable.

G. MONITORING & SUPPORT DURING DUAL-PATIENT VENTILATION

Recommended clinical monitoring includes:

1. Ventilator alarms carefully set (Table 2)
2. Continuous neuromuscular blockade (paralysis) for duration of time that patients are paired
3. Continuous pulse-oximetry for both patients
4. Continuous telemetry for both patients
5. Frequent blood pressure check for both patients, either continuous (preferred) or otherwise checked every 5-15 minutes
6. **End-tidal CO_2** for both patients (if available)
7. **pH and pCO_2** via arterial or venous blood gas in both patients **at 2 hours, 4 hours, and then q8 hours**
8. **pH and pCO_2** via arterial or venous blood gas **20 minutes after every change** in ventilator support except FiO_2.
9. **Independent tidal volume monitoring:** Freestanding respiratory monitors to independently monitor each patient's individual tidal volume and minute-volume are strongly advised for safety. For example, we have used the Philips NICO, NICO2, or NM3 monitor for this purpose during ventilator-sharing, which includes an inline flow sensor that can be used to track tidal volume and minute-volume.
10. **Viral/bacterial filter on the Expiratory Y Assembly should be changed twice as often as indicated by the manufacturer.**
11. CO2 scrubber of the ventilator should be changed out twice as frequently as indicated by the manufacturer.

    ***IMPORTANT:** Ventilator-reported "tidal volume" and "minute-volume" reflect additive value for both patients combined. What each individual patient is receiving is unknown. Therefore, capnography or blood gases are essential to ensure both patients have adequate ventilation.

H. CARING FOR PATIENTS RECEIVING DUAL-PATIENT VENTILATION

1. *Managing shift changes*: Each time staff change for patients undergoing dual-patient ventilation, the team should huddle to review key safety elements, including the following:
    a. Availability of this protocol at bedside at all times
    b. Paralysis of both patients with no spontaneous respiratory effort
    c. Circuit configuration, including how to replace if ever dislodged or disconnected.
    d. Availability of acute airway and respiratory backup support devices, including bag valve mask and rescue ventilator nearby.
2. *Culture results and infection considerations*: Despite use of antibacterial/antiviral filters, there is no guarantee they are universally protective. Therefore, **all respiratory and blood culture results from one patient should be viewed as potentially applying to both patients**.
3. *Routine care procedures*: Any procedure that could contribute to respiratory compromise in one patient should not be done in both patients simultaneously. Such procedures include but are not limited to the following: suctioning, patient repositioning, endotracheal tube repositioning, or upper body central venous catheter insertion.

I. VENTILATOR MANAGEMENT DURING DUAL-PATIENT VENTILATION

The ventilator should be adjusted as needed to maintain both patients in the following parameter ranges:

Table 3. Recommended Range of Ventilator Settings during Dual-Patient Ventilation[a]

Parameter	Recommended Range
Ventilator mode	Pressure control
Tidal volume	6-8 mL/kg PBW
Peak inspiratory pressure	30 cmH_2O or less
Driving pressure	5-18 cmH_2O
Respiratory rate	12-30 breaths/min
Inspiratory time	0.6-1.0 seconds
PEEP	5-16 cmH_2O
FiO_2	21-100% (lowest tolerated)[b]
SpO_2	92-100%
pH	7.25-7.45[c] *If one patient is markedly acidemic and other alkalemic*: • *Treat **acidemic** patient with **ventilator changes** as normally would do.* • *Treat **alkalemic** patient by adding deadspace to ventilator circuit of affected patient to induce hypercapnia.*
Neuromuscular blockade	Mandatory for both patients while paired

[a] Patients who cannot be maintained within this range should be considered for their own ventilator where feasible.
[b] If one patient cannot tolerate FiO_2 below 100% but other can, consider transition to single-patient ventilator for dedicated support.
[c] Permissive hypercapnia tolerating pH as low as 7.20 may be considered where clinically appropriate.

J. WEANING STRATEGY

Recommended weaning strategy:

1. Ventilator settings in Table 3 should be weaned as tolerated.
2. Consider unpairing patients (single-patient ventilation) if:
    a. If one patient seems to be improving but weaning is prohibited by other patient's condition
    b. If one patient acutely worsens disproportionately to other
3. Once a patient tolerates driving pressure ≤ 10, PEEP ≤ 10, and FiO_2 ≤ 40%, consider transitioning that patient to single-patient ventilator for further weaning and screen for extubation.
4. Paralytics and sedation should not be stopped until patient is on single-patient ventilator.

K. TRANSITION TO SINGLE-PATIENT VENTILATION

***Step 1*:** Prepare a new ventilator and circuit for single patient ventilation as per local protocol.

***Step 2*:** Confirm availability of red caps, or obtain two circuit caps that fit on end of the Inspiratory and Expiratory assemblies. In most circumstances, the cap can be obtained from the new circuit being set up.

***Step 3*:** Transition Patient B from dual-patient to single-patient ventilator, clamping endotracheal tube during transfer to minimize aerosol and derecruitment.

***Step 4*:** Immediately place red circuit caps on both the Inspiratory and Expiratory assemblies of now-disconnected dual-patient circuit. This allows the former dual-patient circuit to continue to support Patient A on that circuit.

L. VENTILATOR ALLOCATION SCHEMA FOR HOSPITAL

Ventilator Cluster	**Use**
Transport ventilators (single-patient)	• Transport patients throughout hospital • Emergency department
Rescue ventilators (single-patient)	• Rescue a patient undergoing dual-patient ventilation who needs to be urgently placed back on single ventilator
Dual-patient ventilators	Only when deemed appropriate & necessary due to exhausted ventilator supply
Single-patient ventilators	Need for individualized support: 1. Patient's ventilator needs must be individualized (Table 1) 2. Patient ready for active weaning from ventilator

At least one rescue ventilator should be placed near each cluster of patients that are supported by dual-patient ventilation. Any hospital applying this protocol should determine the appropriate ratio of paired patients to backup ventilators for their facility.

It is *NOT* appropriate to support all patients with dual-patient ventilation. Patient selection must be carefully considered, and some ventilators must be reserved for patients who need individualized support or are ready to wean.

M. ADMINISTRATIVE AND ETHICAL CONSIDERATIONS

Hospital administration should approve the protocol before use, acknowledging the unique ethical considerations. This protocol is only appropriate for consideration when (i) crisis standards have been instituted, (ii) there are not enough ventilators to meet demand for single-patient ventilation, and (iii) multiple patients are present for whom invasive ventilation has a reasonable probability of being life-saving.

Ethically, it must be recognized that dual-patient ventilation is not the usual standard of care. However, in the setting of a mass crisis, such as the COVID19 pandemic, the number of potentially rescuable patients may exceed the number of ventilators to support them. With the above safety measures, we believe this approach offers the best chance at saving the most lives. The use of dual-patient ventilation should be discontinued as soon as a sufficient supply of ventilators becomes available.

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of Ventilators During the COVID-19 Pandemic **March 24, 2020**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators" in this Fact Sheet), ventilator tubing connectors, and ventilator accessories.

Certain ventilators, ventilator tubing connectors, and ventilator accessories are authorized for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.

All patients who are treated with authorized ventilators during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of ventilators?

- Certain ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling have been authorized for emergency use.
- Ventilators found in the list of authorized products are authorized for use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.
- For each device, healthcare providers should review the instructions for use, including device specifications, reprocessing instructions (if applicable), and other labeling information.
- During the COVID-19 pandemic, certain authorized ventilators may be used to support multiple patients using a continuous ventilator splitter. Healthcare providers should review additional device specifications, labeling, and patient monitoring recommendations in these circumstances.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of ventilators?

Potential benefits of ventilators include:
- Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
- Life-supporting and potentially life-saving treatment

Potential risks of ventilators include:
- Device malfunctions or adverse events
- Potential infectious and mechanical complications from sharing one ventilator through the use of multiplexing adapters have not been studied, and therefore caution is advised
- Risks of modified ventilator devices have not been studied, and therefore caution is advised

- Risks associated with the potential reduced requirements for alarms and monitoring of patients
- Reduced familiarity of healthcare providers with novel technologies used to treat patients

What are the alternatives to traditional ventilators, and the known and potential benefits and risks of such products?

Alternatives to traditional ventilators that are authorized under this Emergency Use Authorization (EUA) include anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators.

Potential benefits of using alternatives to traditional ventilators include:

- Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
- Life-supporting and potentially life-saving treatment

Potential risks of using alternatives to traditional ventilators include:

- A positive pressure breathing device cannot offer all of the support that a traditional mechanical ventilator can
- A positive pressure breathing device may expose others to aerosols that could be contagious
- Healthcare providers other than trained anesthesia providers may not be familiar with the operation of anesthesia equipment, and therefore should pay careful attention to the instructions for use to avoid use error

What is an EUA?

The United States FDA has made certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

Ventilators, ventilator tubing connectors, and ventilator accessories made available under an EUA have not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling may be effective in treatment of patients during the COVID-19 pandemic.

The EUA for ventilators, ventilator tubing connectors, and ventilator accessories is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

FACT SHEET FOR PATIENTS

Emergency Use of Ventilators During the COVID-19 Pandemic **March 24, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you treatment using a ventilator, anesthesia gas machine modified for use as a ventilator, or positive pressure breathing device modified for use as a ventilator (collectively referred to as "ventilators" in this Fact Sheet), ventilator tubing connectors, and/or ventilator accessory.

This Fact Sheet contains information to help you understand the benefits and risks of using ventilators, ventilator tubing connectors, and ventilator accessories for the treatment of patients during the COVID-19 pandemic. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
- **https://www.cdc.gov/COVID19**

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19, but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What do I need to know about the emergency use of ventilators?

Certain ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling have been authorized under an Emergency Use Authorization (EUA) for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.

A healthcare provider may choose to treat you with a ventilator if you have difficulty breathing, or other respiratory symptoms. During the COVID-19 pandemic, certain authorized ventilators may be used to support multiple patients using a continuous ventilator splitter when individual ventilators are not available, or preemptively to increase the potential of single-use ventilators for multiple patients simultaneously.

What is an EUA?

The United States FDA has made certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

Ventilators, ventilator tubing connectors, and ventilator accessories made available under an EUA have not undergone the same type of review as an FDA-approved

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling may be effective in treatment of patients during the COVID-19 pandemic.

The EUA for ventilators, ventilator tubing connectors, and ventilator accessories is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

What are the known and potential benefits and risks of ventilators?

Potential benefits of ventilators include:
- Ventilator support may be effective in treating you if you have difficulty breathing, or other respiratory symptoms
- The use of a ventilator may help your condition improve and allow you to recover
- Life-supporting and potentially life-saving treatment

Potential risks of ventilators include:
- Modified ventilator devices and techniques may have new risks associated with them that have not been studied

What are the alternatives to traditional ventilators, and the known and potential benefits and risks of such products?

Alternatives to traditional ventilators that are authorized under this EUA include anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators.

Potential benefits of using alternatives to traditional ventilators include:
- The device may be effective in treating you if you have difficulty breathing, or other respiratory symptoms
- The device may help your condition improve and allow you to recover
- Life-supporting and potentially life-saving treatment

Potential risks of using alternatives to traditional ventilators include:
- A positive pressure breathing device cannot offer all the support a traditional mechanical ventilator can offer
- A positive pressure breathing device may expose others to aerosols that could be contagious
- Healthcare providers may not be familiar with the operation of the modified devices that are authorized under this EUA, which could lead to use error

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.