

FDA-Authorized for Emergency Use Only Ventilator Expansion Splitter (VESper): Instructions for Use

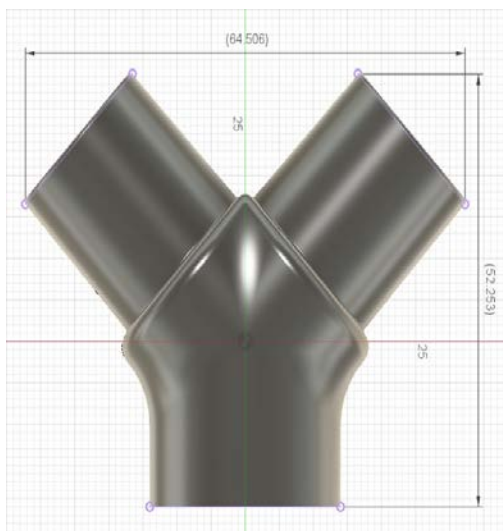
Intended Use

A single ventilator fitted with the Vent Splitter can be used for two patients for ventilatory support during the COVID-19 pandemic when individual ventilators are not available.

Device Specifications

The device is a Y-connector that is 65mm wide, 53mm tall, and 25mm wide, and weighs approximately 20g. The two cone (male) connectors are angled 90 degrees from each other to allow clearance for connected filters. The interior of the part is smooth walls with no shoulders or other discontinuities. The connector openings are 22 mm in diameter.

Wall thickness varies from 2.4mm on the female socket (attaches to ventilator) to 1.4mm on the male cone connectors. Future revisions of the part may have slightly increased thickness on the male cone connectors to support producing the part in more readily available materials and color may vary.



- **DO NOT** attempt this without full knowledge and understanding of pressure control settings on a ventilator.
- **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.
- The **pressure control mode is recommended** when more than one circuit is added to the ventilator
- This is a **single use** FDA authorized device for emergency use

A. EQUIPMENT & SUPPLIES

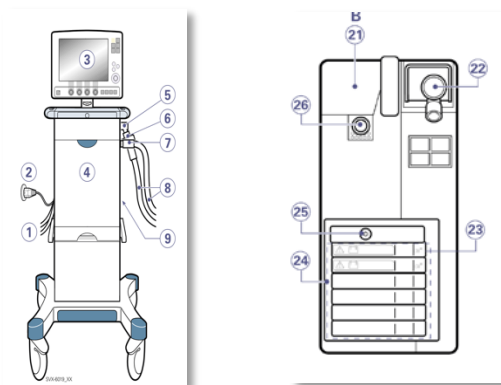
Specific equipment required may vary depending on supplies and equipment available.

1. One ventilator
2. Two Ventilation Expansion Splitter (VESper)
3. HEPA filter for each arm (4 total)
4. Ventilator circuit for each patient with a designated color or labelling pattern
5. Ensure that the caps of the ventilator circuit are **SAVED**
6. Test lungs for ventilator circuit set up and testing

B. SETTING UP SHARED VENTILATOR

IMPORTANT: Setup should be done **ONLY** on a ventilator **NOT CURRENTLY SUPPORTING A PATIENT**

1. After removing the VESper device from its shipping container, place the device in Cidex® for 15 minutes or per your institution protocol. Rinse thoroughly with water and then let air dry.
2. Place one VESper device on the inspiratory outlet #7 and #26 in diagram below. The VESper needs to be well connected to the outlet
3. Place one VESper device on the expiratory inlet # 5 and #22 in diagram below



Taken from Servo I manual.

4. A universal bacterial/viral filter (such as the HEPA box) needs to be placed on each of the limbs of the VESper devices. Once the filters have been placed, standard ventilator tubing should be attached. Ensure that there is a good connection between the VESper device and the filters. Tubing for each of the 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.



5. Turn on ventilator and set alarms as recommended prior to initiating ventilator sharing.
6. Please see the clinical protocol for the remaining recommendations (Appendix A).

Appendix A: VESper 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 VESper 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 ventilator sharing.
2. *One patient infecting the other.* This risk is mitigated by antimicrobial filters and matching for respiratory pathogen.
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 patient-specific capnography and tidal volume measures, 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 between patients.
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.
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 and patient matching by respiratory pathogen* minimize risk of one patient infecting the other.

B. VENTILATOR CIRCUIT SAFETY TEST

Step 1: Turn on new ventilator to be used for ventilator sharing. 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 (dual-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. All ventilators we tested work fine to support two patients despite this anticipated warning during the 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. **Independently measure tidal volume in each test lung simultaneously to confirm they are similar**, using a respiratory monitor with inline flow measurement (e.g. Philips NM3). Note the combined tidal volume for test lung A+B. The combined tidal volume for A+B should be similar to the tidal volume on the ventilator; in our experience, they may differ by 50-80 mL due to measurement and calibration imprecision across devices.

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 (tiP = plateau pressure – PEEP)	5-16 cmH ₂ O	0-6 cmH ₂ O
Respiratory rate	12-30 breaths/min	0-8 breaths/min
PEEP	5-18 cmH ₂ O	0-5 cmH ₂ O
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 (tiP = 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 FiO₂:** 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 (tiP = 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 FiO₂:** 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. **FiO₂:** titrate to be the same in both patients while maintaining SpO₂ ≥ 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.
4. **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 & pCO₂ 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. INITIATING VENTILATOR SHARING

*****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 FiO₂ 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 & pCO₂** on matched ventilator settings is in acceptable range.
 - c. Both patients remain **paralyzed** and not making any spontaneous breathing effort.
3. Shared ventilator circuit is powered on, operational and insufflates both test lungs per **Section D**.

Step 4: 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 5: Complete following procedures to transition the patients to the new circuit:

1. Remove one test lung from one circuit of the new shared ventilator and cap that circuit.
2. Remove the other test lung from the shared ventilator circuit.
3. 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.
4. Repeat for Patient B, connecting to the other circuit on the shared ventilator.

Step 6: SAFETY CHECK after initiating ventilator sharing:

1. **Patient-specific tidal volume** is within ± 50 mL of tidal volumes just prior to shared ventilation.
2. **SpO₂ > 95%** in each patient. Wean FiO₂ as tolerated.
3. After 20 minutes, check **arterial or venous blood gas** in both patients to confirm pH & pCO₂ 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.

I. MONITORING & SUPPORT DURING VENTILATOR SHARING

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 CO₂** for both patients (if available)
7. **pH and pCO₂** via arterial or venous blood gas in both patients **at 2 hours, 4 hours, and then q8 hours.**
8. **pH and pCO₂** via arterial or venous blood gas **20 minutes after every change** in ventilator support except FiO₂.
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 and mandatory for our institutional protocol. For example, we use 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.

*****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.

J. CARING FOR PATIENTS ON SHARED VENTILATOR

1. **Managing shift changes:** Each time staff changes for patients undergoing ventilator sharing, the team should huddle to review key safety elements, detailed in **Appendix 1**.
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

K. VENTILATOR MANAGEMENT ON SHARED VENTILATOR

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

Table 3. Recommended Range for Ventilator Settings during Ventilator Sharing ^a	
Parameter	Recommended Range
Ventilator mode	Pressure control
Tidal volume	6-8 mL/kg PBW in each patient
Peak inspiratory pressure	30 cmH ₂ O or less ^b
Driving pressure	5-18 cmH ₂ O ^b
Respiratory rate	12-36 breaths/min
Inspiratory time	0.6-1.0 seconds
PEEP	5-18 cmH ₂ O
FiO ₂	21-100% (lowest tolerated) ^c
SpO ₂	92-100%
pH	7.20-7.45 ^d If one patient is markedly acidemic and other alkalemic: <ul style="list-style-type: none"> • 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 Higher peak and driving pressures may be considered with expert consultation. Higher pressures may be required to maintain tidal ventilation as moisture buildup in the filters over time adds resistance to the circuit.

^c If one patient cannot tolerate FiO₂ below 100% but other can, consider transition to single-patient ventilator for dedicated support.

L. 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 cmH₂O, PEEP ≤ 10 cmH₂O, and FiO₂ $\leq 40\%$, 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.

M. TRANSITION FROM SHARED TO SINGLE-PATIENT VENTILATOR

Step 1: Preoxygenate using the shared ventilator.

Step 2: Prepare a new ventilator and circuit for single patient ventilation as per local protocol.

Step 3: Confirm a circuit cap is available that fits on end of Y-connector. In most circumstances, the cap can be obtained from the new circuit being set up.

Step 4: Transition Patient A to single-patient ventilator via following steps in **immediate succession**.

1. Perform breath hold on ventilator (minimizes aerosols)
2. **Clamp endotracheal tube** of Patient A (minimizes aerosols and derecruitment).
3. Disconnect Patient A from shared ventilator circuit.
4. Connect Patient A to new circuit.
5. **Immediately unclamp endotracheal tube after patient on new circuit.**
Immediately place circuit cap on Y-piece of the now-disconnected shared circuit that was occupied by Patient A. This cap will allow the former shared circuit to continue to support Patient B on that circuit.

N. VENTILATOR ALLOCATION SCHEMA FOR HOSPITAL

Ventilator Cluster	Use
Transport ventilators (single-patient)	<ul style="list-style-type: none"> Transport patients throughout hospital Emergency department
Rescue ventilators (single-patient)	<ul style="list-style-type: none"> Rescue a patient undergoing ventilator sharing who needs to be urgently placed back on single ventilator
Shared ventilators	Only when deemed appropriate & necessary due to exhausted ventilator supply for well-paired patients
Single-patient ventilators	Need for individualized support: <ol style="list-style-type: none"> Patient's ventilator needs must be individualized (Table 1) Patient ready for active weaning from ventilator

At least one rescue ventilator should be placed near each cluster of patients that are supported by shared ventilators. 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 ventilator sharing. Patient selection must be carefully considered, and some ventilators must be reserved for patients who need individualized support or are ready to wean.

Ventilator sharing is most safely performed at centers with advanced expertise in invasive mechanical ventilation. A regional referral model may be appropriate to maximize the number of patients who may benefit while maintaining safety standards.

o. 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 a shared ventilator strategy 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 a shared ventilator strategy should be discontinued as soon as a sufficient supply of ventilators becomes available.**

APPENDIX 1

Ventilator-Sharing Shift Change Checklist	
Protocol	A copy of the full ventilator sharing protocol is at bedside
Power	Ventilator and NM3 A/C power are connected to emergency red outlets
Ventilator Settings	Acknowledge FiO ₂
	Acknowledge PEEP
	Acknowledge respiratory rate (RR)
	Acknowledge driving pressure
	Acknowledge inspiratory time
	Acknowledge combined tidal volume (Vt) on ventilator (patient A+B)
NM3	Acknowledge <i>patient-specific</i> tidal volume (Vt)
	Acknowledge <i>patient-specific</i> end-tidal CO ₂
Ventilator Alarms	Vt in pts A+B: Lower (A+B - 100 mL). Upper 250 mL > min
	RR: Lower 5 bpm < preset. Upper 5 bpm > preset
	Peak Pressure: Lower 5 cm H ₂ O < preset. Upper 5 cm H ₂ O > preset
	Minute ventilation: Lower (A+B) - 1 L/min. Upper (A+B) + 1 L/min
Emergency	2 clamps available
	2 ventilator circuit caps available
	2 extra ventilator circuits available
	2 T-pieces and 2 cuff connectors available
	Ambu bag available
	Back-up ventilator available in cluster
Circuit	Ensure patient wristband located on personal circuit for BOTH patients
	Circuit tubing lines free of tension
	Ensure T-piece and filters secure and well-positioned
	Inspect HEPA filter for soiling or saturation in BOTH patients
	Ensure back-up HEPA filter available for BOTH patients

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

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

FACT SHEET FOR HEALTHCARE PROVIDERS

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- 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>

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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.

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- **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>
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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

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- **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.
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FACT SHEET FOR PATIENTS

Emergency Use of Ventilators During the COVID-19 Pandemic

March 24, 2020

Coronavirus
Disease 2019
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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

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