

The Sparrow COVID-19 Co-Ventilator Assist Device

A. INDICATIONS FOR USE

The Sparrow COVID-19 Co-Ventilator Assist Device is a ventilator circuit splitter used to adapt a single mechanical ventilator for use by more than one patient when individual ventilators are not available. It is not intended to be used when the supply of available ventilators is sufficient to provide individual mechanical ventilation.

For use with adult patients only during the COVID-19 pandemic.

The US Food and Drug Administration (“FDA”) has provided Emergency Use Authorization for the Sparrow COVID-19 Co-Ventilator Assist Device during the COVID-19 pandemic.

**FDA has not approved or cleared this product for use
outside of the COVID-19 pandemic.**

B. INSTRUCTIONS FOR USE

DO NOT USE if the supply of available ventilators is sufficient to provide individual ventilation.

ONLY USE according to facility-specific protocols for crisis care when a clinician determines that it is appropriate to co-ventilate rescuable patients because the available supply of ventilators is insufficient to provide standard mechanical ventilation support.



The Sparrow COVID-19 Co-Ventilator Assist Device is a **single use (disposable) device**. Do not reprocess. Follow facility protocol for disposal of hazardous waste.

C. SETUP FOR USE

The Sparrow COVID-19 Co-Ventilator Assist Device is compatible with ICU ventilators and anesthesia gas machines with standard 22mm size ports to adapt them for use by more than one patient at the same time. Each ventilatory circuit can be fitted with in-line bacterial/viral filters.

Remove the Sparrow COVID-19 Co-Ventilator Assist Device from its shipping container and place it in Cidex® or similar disinfectant solution for 15 minutes or per your institution protocol. Rinse thoroughly with water and then let air dry.

The device can be used for both inspiratory and expiratory circuits. It is modular and interchangeable, and can be configured as depicted in the Figure, below:

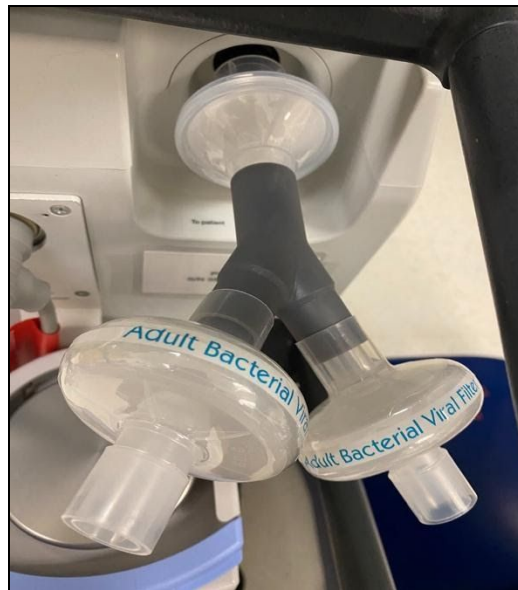
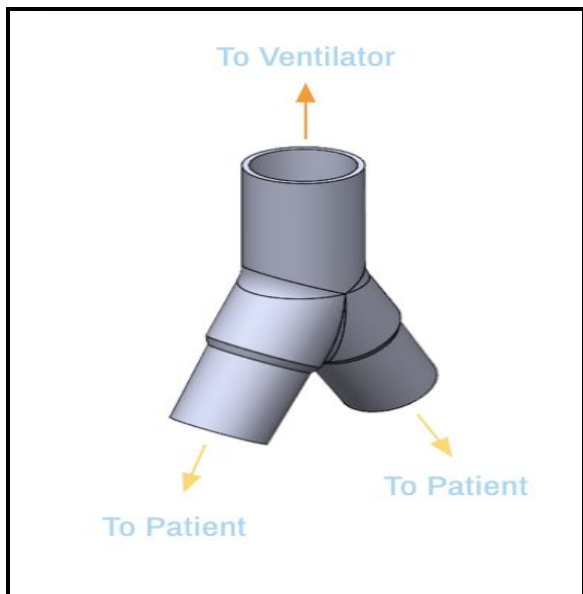


Figure: Sparrow COVID-19 Co-Ventilator Assist Device
In this Figure, one (1) modular splitter is used to create 2
separate ventilatory circuits.

This configuration is used to adapt a single ventilator for use by 2 patients simultaneously.

NOTE

- Consider a color-coding system or similar approach to be certain of which device connects to which patient to avoid iatrogenic harm.
- Extra-long tubing may be needed to position patients in a manner that allows appropriate access to patients and to the ventilator. Use approved anesthesia tubing only, per facility protocol.
- **Only** setup on a ventilator **NOT currently supporting a patient.**



WARNING - AN OPERATIONAL SELF-TEST CANNOT BE RUN ON A MULTIPLEXED DEVICE. (SELF-TEST FAILS)

D. SELECTING PATIENTS FOR CO-VENTILATION

Use the checklist below to confirm that two patients are compatible for co-ventilation (be paired to use the same ventilator).

CO-VENTILATION COMPATIBILITY CHECK-LIST

PATIENT A & PATIENT B PARAMETERS	DIFFERENCE BETWEEN PATIENTS	YES	NO
(1) Anticipated time needing invasive ventilation \geq 72 hours			
(2) COVID-19+ lab confirmed			
(3) Associated bacterial infection(s): same	List if known		
(4) FiO ₂ : 21% to 60%	\pm 10%		
(5) Respiratory rate: 12-30 breaths/min	0-8 breaths/min		
(6) PEEP: 5-18 cm H ₂ O	0-5 cm H ₂ O		
(7) Ideal Body Weight*	\pm 10%		
(8) Lung Compliance	\pm 10%		
(9) Expected Tidal Volume: 6-8 mL/Kg PBW**			
(10) pH: \geq 7.30			
(11) Driving Pressure (Δ P=Plateau – PEEP) between 5-16 cm/ H ₂ O	0-6 cm/ H ₂ O		
(12) O ₂ Saturation: 92% - 100%			
(13) Hemodynamic stability	Physician Clinical Evaluation		

*IBW-Ideal Body Weight

IBW (lbs) males = 106 + 6*[height (inches) – 60]

IBW (lbs) females = 100 + 5*[height (inches) – 60]

**PBW-Predicted Body Weight

PBW (lbs) males = 50 + 2.3*[height (inches) – 60]

PBW (lbs) females = 45.5 + 2.3*[height (inches) – 60]

If you checked “NO” for any question above, patients are not compatible. DO NOT CO-VENTILATE.



WARNING - USE IN-LINE FILTERS TO REDUCE THE RISK OF INFECTION AND VENTILATOR CONTAMINATION.

E. INITIATING DUAL-PATIENT VENTILATION



WARNING – DISCONNECTING VENTILATOR CIRCUITS IS AN AEROSOL-GENERATING PROCEDURE. ANYONE PRESENT SHOULD WEAR APPROPRIATE PPE, INCLUDING EYE PROTECTION AND AN N95 OR EQUIVALENT RESPIRATOR.

F. PRESSURE CONTROL MODE

Use the Pressure Limited and Time Cycled Modes for ventilation whenever more than one circuit is attached to the same ventilator.

Follow facility-specific protocols for assigning more than one patient to a single ventilator (“co-ventilation” or “multiplexing”).

Each patient on the same ventilator will receive the same level of inspiratory pressure, the same rate of respiration, the same inspiratory/expiratory ratio, the same FiO₂, the same level of PEEP, etc.

NOTE

- Co-vented patients cannot be managed individually for clinical deterioration or weaning.
- Follow standard protocol for paralysis and sedation. Use additional infusion pumps to administer these agents to avoid dyssynchronous breathing and system alarming from bucking and coughing.

G. PATIENT MONITORING

Continuous cardiopulmonary physiological monitoring should be conducted according to standard ICU protocol.

Clinical assessment of each patient should be frequent, at least as frequent, if not more frequent than monitoring a single patient on a ventilator, including vital signs, oxygen saturation level, end tidal Co₂, examinations of the chest for bilateral air movement, and, if indicated,

assessments of arterial blood gas findings to assure clinical stability on the shared system. Manual ventilation (Ambu/Bag Valve Mask) should be available for each patient.

Conduct ABG testing as clinically appropriate, especially if using extra-long tubing.

Close monitoring of all patients is critical since they will likely be paralyzed and sedated.

Recommended clinical monitoring includes:

- Ventilator alarms are carefully set
- Continuous neuromuscular blockade (paralysis) for entire time patients are paired
- Continuous pulse-oximetry for both patients
- Continuous telemetry for both patients
- Frequent blood pressure checks for both patients
- End-tidal CO₂ for both patients (if available)
- pH and pCO₂ via arterial or venous blood gas in both patients at 2 hours, 4 hours, and then q8 hours
- pH and pCO₂ via arterial or venous blood gas 20 minutes after every change in ventilator support except FiO₂
- Independent tidal volume monitoring

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.



WARNING - MONITOR CO-VENTED PATIENTS BEFORE AND AFTER PRONING USING ABG's, ETCO₂, SpO₂, AND AVAILABLE VENT INFORMATION TO AVOID DISCONNECTION AND CHANGES TO VENT PARAMETERS.

H. ALARMS

Whenever a shared ventilator alarms for any reason, **conduct clinical assessments of each patient immediately** to identify which patient is triggering the alarm.

CAUTION - The ventilator cannot identify which co-ventilated patient has triggered an alarm.

Follow facility protocols for:

- Assessing, suctioning, and proper tube placement
- Disconnecting unstable patients

- Mechanical bagging

RECOMMENDED INITIAL VENTILATOR ALARM SETTINGS

Parameter	Lower Alarm	Upper Alarm
Tidal volume	$(V_T \text{ in Patient A + Patient B}) - 100\text{mL}$	250mL above lower alarm
Respiratory rate	5 breaths/min below preset value	5 breaths/min above preset value
Peak pressure	5 cmH ₂ O below preset value	5 cmH ₂ O above preset value
PEEP	2 cmH ₂ O below preset value	5 cmH ₂ O above preset value
Minute-volume	$(\text{MinVol in Patient A + Patient B}) - 1 \text{ liter/min}$	$(\text{MinVol in Patient A + Patient B}) + 1 \text{ liter/min}$

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

I. CARING FOR CO-VENTILATED PATIENTS

SHIFT CHANGES: Each time staff change for patients undergoing co-ventilation, the team should meet to review key safety elements, including the following:

- Paralysis of both patients with no spontaneous respiratory effort
- Circuit configuration, including how to replace if ever dislodged or disconnected
- Availability of acute airway and respiratory backup support devices, including bag valve mask and rescue ventilator nearby.

INFECTION CONSIDERATION: 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.

ROUTINE CARE: 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.

J. ADVERSE EVENTS

Monitor patients frequently. In the event of cardiac arrest, accidental self-extubation, or other adverse events, follow facility-specific protocols for Emergency Care.

- [Fact Sheet for Healthcare Providers](#): Emergency Use of Ventilators During the COVID-19 Pandemic -- **FDA STANDARD FACT SHEET TO BE ATTACHED**
- [Fact Sheet for Patients](#): Emergency Use of Ventilators During the COVID-19 Pandemic -- **FDA STANDARD FACT SHEET TO BE ATTACHED**