THE NEW BUREAU
NYC

# MEMORANDUM

**Date:** April 9, 2020

**To:** EUA Review Team for Ventilators, Connectors, and Accessories
Center for Devices and Radiological Health
U.S. Food and Drug Administration

**From:** Peter E. Raymond

**Re:** Request for Emergency Use Authorization for the Sparrow COVID-19 Co-Ventilator Assist Device: Pre-Submission

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On behalf of The New Bureau, an innovation incubator and global network of experts focused on healthcare, climate change, education, and Smart Cities,[1] I respectfully submit the attached preliminary information to initiate a request for Emergency Use Authorization ("EUA") pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 USC § 360bbb-3, for the Sparrow COVID-19 Co-Ventilator Assist Device, an open-label, modular ventilator circuit adapter[2] intended for use to co-ventilate up to three patients on a single, continuous use ventilator in a healthcare facility. The product is not currently marketed in the US or in any other jurisdiction.

I am a population health and technology professional and have helped develop innovative and lifesaving solutions for global healthcare organizations and health systems, including nonprofit foundations, health insurance providers, and biopharmaceutical and medical device manufacturers for more than 15 years.

In January 2020, I watched as China's healthcare providers were forced to deal with an increasingly critical deficit of ventilators and respiratory support systems by reverting to "on-the-spot" solutions, including cut up ventilator circuit tubing, garden hoses, plumbing supplies, and even saran wrap and duct tape to co-ventilate multiple patients from one ventilator. In response to this troubling observation, we started to design and test a more reliable solution that could be rapidly tooled and distributed. We cannot allow our own healthcare workers in the US to be put in a similar position to keep our citizens alive.

We have prepared this submission to offer another alternative to U.S. healthcare providers who may be forced to make the difficult choice to co-ventilate their patients in an emergency. Our proposed product has been rigorously developed and tested to allow providers to co-ventilate COVID-19 patients as safely and effectively as possible. We have taken into account the clinical workflow of an emergency and critical care provider to help facilitate crisis management by reducing the need to improvise solutions and the stress this causes clinicians, patients, and their families by offering a device that can reduce technical limitations that might otherwise complicate the difficult choice to co-ventilate.

This document presents preliminary information that we are prepared to augment in coordination with FDA to demonstrate that the Sparrow COVID-19 Co-Ventilator Assist Device meets FDA criteria for safety, performance and labeling as set forth in Section II and Appendix B of FDA's Public Health

[1] *See*: www.newbureau.com.

[2] 21 CFR 868.5975, product code BZO: Set, tubing and support, ventilator; 21 CFR 868.5895, ventilator, continuous, facility use.

Emergency Guidance: Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19).[3] It is our intention to make the design documentation and other technical information available to any entity that wishes to manufacture and distribute the product for use during a public health emergency in any jurisdiction.

Please contact me directly at your convenience. My team and I would welcome the opportunity to engage FDA staff in discussion to identify any specific additional documentation or materials that may be required to satisfy criteria for Emergency Use Authorization.

We are prepared to initiate manufacturing of the product immediately and are developing a distribution channel to deliver the product quickly to states, hospitals, health systems and other entities to help address the acute need for ventilator capacity caused by the COVID-19 pandemic.

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[3] *See*: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus.

## I. ADDRESSING A CRITICAL UNMET PUBLIC HEALTH NEED

SARS-CoV-2, the virus that causes COVID-19, has been observed to cause severe respiratory illness in certain infected individuals who subsequently require mechanical ventilation to provide sufficient oxygen to maintain their lungs, heart, and body, and ultimately, to sustain their lives. Because of the rapid infection rate of the SARS-CoV-2 virus and the severe respiratory distress requiring mechanical ventilation that many patients appear to experience, ventilators are in limited supply. As the rate of infection continues to grow over the coming weeks and months, the available supply is unlikely to be able to keep up with critical patient demand in many parts of the country.

We understand that the current standard of care for emergency respiratory support is to use one ventilator with one patient under the supervision of a respiratory therapist or other qualified clinical professional.[4] However, our preliminary testing, described below, suggests that more than one patient can receive adequate respiratory support from a single ventilator when it is not possible for an overburdened facility to provide one ventilator for each individual patient.

FDA has already indicated that it does not object to the creation and use of certain T-connectors for co-ventilation, and has granted Emergency Use Authorization for the VESper Ventilation Expansion Splitter (Prisma Health, Greenville, SC) for use when the number of patients who need invasive mechanical ventilation exceeds the supply of available ventilators, and the usual medical standard of care has been changed to "crisis care" in the interest of preserving life.[5]

Through this Memorandum, we respectfully submit a design and associated documentation for FDA's review of our Sparrow COVID-19 Co-Ventilator Assist Device. The product is adaptable and intended to be easy for the clinical decision maker to use in a crisis or emergency management situation. This is an alternative ventilator circuit adapter to connect more than one patient to a single ventilator during a public health emergency. The device can be 3D printed or mass produced through a surgical grade injection molding process.

### A. Acknowledged risks associated with multi-patient use of a single ventilator

The Centers for Disease Control and Prevention ("CDC") have recommended that clinicians not attempt to ventilate more than one patient with a single ventilator while any clinically proven, safe, and reliable alternative therapy remains available. However, it further noted that, in a dire emergency, the additional health risk associated with using a single ventilator for more than one patient would likely be small, assuming that the established infection control interventions were in place.

We agree with these recommendations and would propose to label the Sparrow COVID-19 Co-Ventilator Assist Device for use only when there is an insufficient supply of ventilators available for mechanical ventilation according to standard protocols.

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[4] Washington DC COVID-19 Co-Ventilation Task force. Co-Ventilating Patients During a Critical Ventilator Shortage: A Method for Implementation. March 31, 2020. *Available at*: https://www.hhs.gov/sites/default/files/optimizing-ventilator-use-during-covid19-pandemic.pdf

"Using one ventilator for a single patient is the only established method to safely and reliably provide mechanical ventilation for patients with acute respiratory failure. The use of 1 ventilator to support 2 patients simultaneously (Co-Venting) is technically possible and has been tested only in controlled, experimental models using test lungs or animals for brief periods. The reliability and safety of Co-Venting in critically ill patients remains unknown. Identifying and managing the complexities of critically ill patients are among the most challenging and unpredictable aspects of Co-Venting. Therefore, the use of Co-Venting should only be considered if a hospital cannot provide clinically proven, reliable, and safe methods to manage acute respiratory failure, including manual bagging. Co-Venting should be performed for the briefest time required with rapid transition to 1:1 patient-ventilator support when additional ventilators become available."

[5] Giroir BP. Optimizing Ventilator Use during the COVID-19 Pandemic. US Public Health Service. March 31, 2020. *Available at*: https://www.hhs.gov/sites/default/files/optimizing-ventilator-use-during-covid19-pandemic.pdf.

## II. EMERGENCY USE AUTHORIZATION FOR THE SPARROW COVID-19 CO-VENTILATOR ASSIST DEVICE

The **S**ingle **P**ath **A**irway **R**apid **R**etrofit **O**ptional **W**orkflow ("Sparrow") COVID-19 Co-Ventilator Assist Device is intended for use during a public health emergency to allow more than one patient to be connected to a single ventilator when a sufficient number of mechanical ventilators are not available for individual respiratory support. Sparrow is intended to allow clinicians to adapt a single ventilator for simultaneous use by multiple patients with similar clinical needs, according to applicable emergency protocols at each facility.

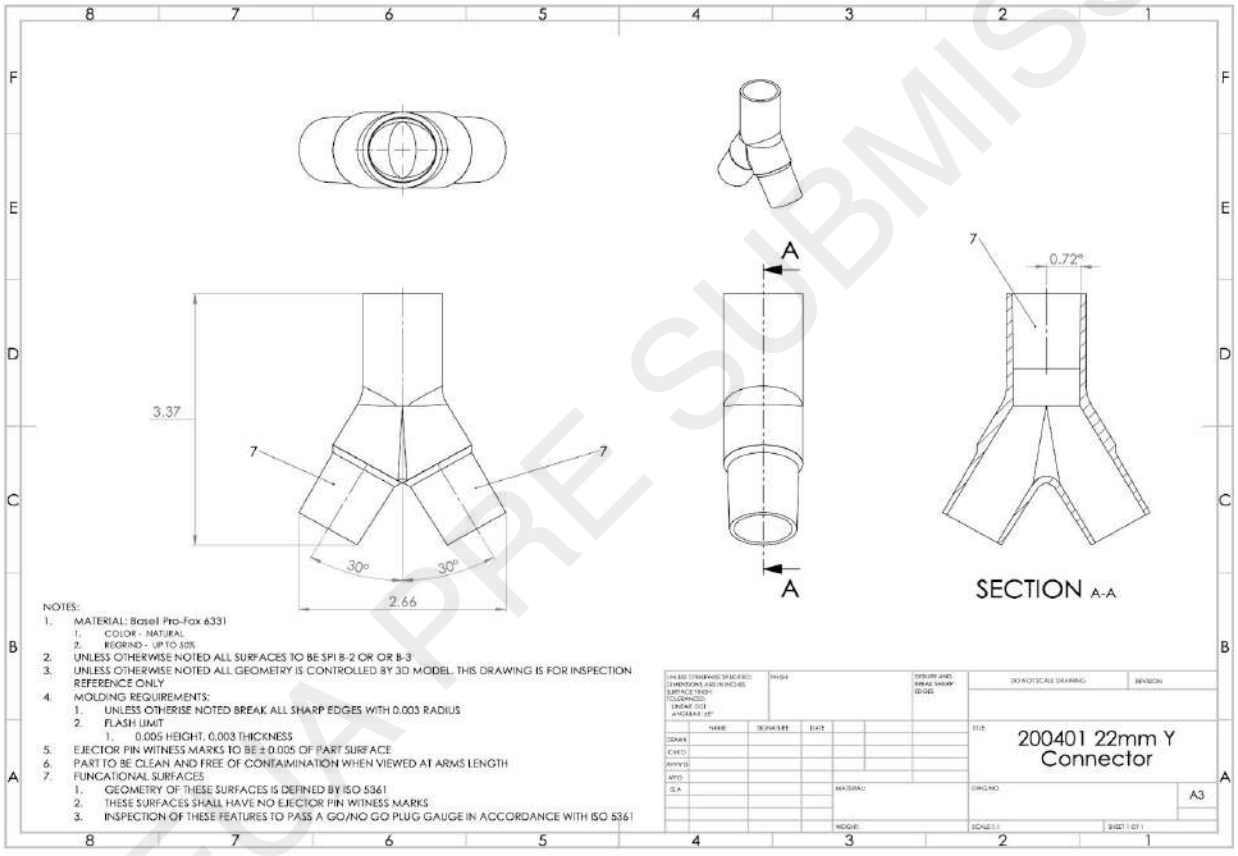



***Figure 1: Sparrow COVID-19 Co-Ventilator Assist Device***

## III. TECHNICAL DOCUMENTATION AND DESIGN SPECIFICATIONS

The Sparrow design and protocol for use are intended to allow clinicians to expand ventilator availability immediately in an emergency situation. The manifold has been designed and tested to support up to three patients, each having access to both inspiratory and expiratory airway circuits.

It is modular in design to allow for fluid/safe transition of ventilator distribution to patients - from one to three patients at the same time.

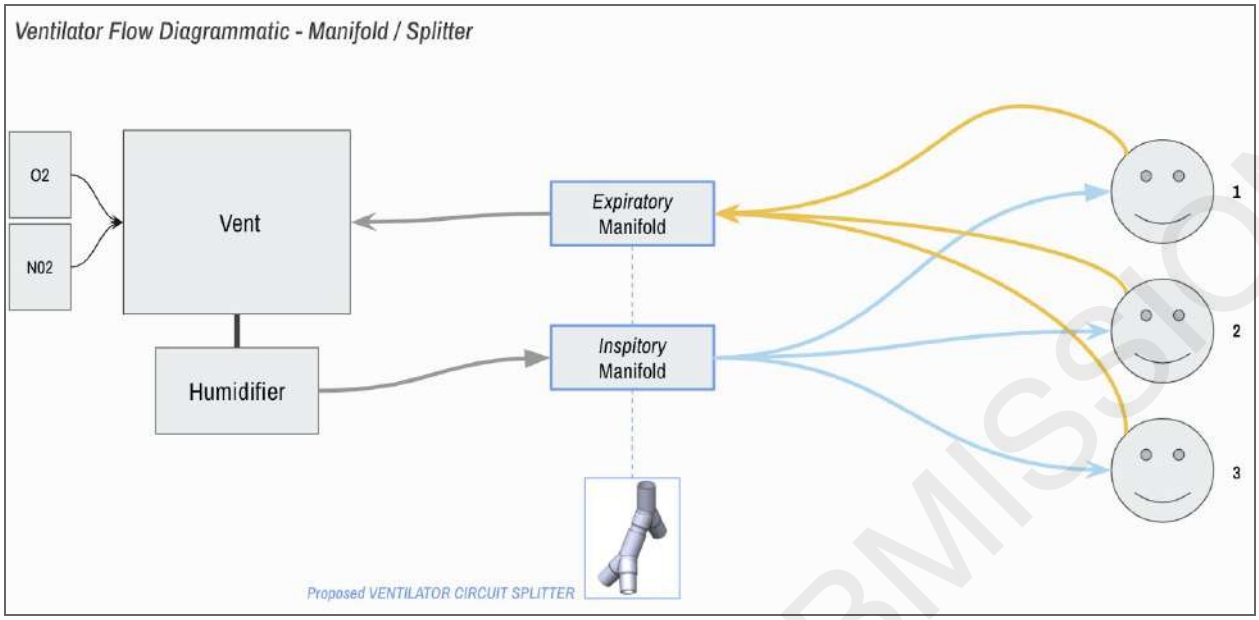



***Figure 2: Design Specifications - Ventilator Flow Diagram***

## A. Design

- One input, into either 2 or 3 output channels
- Modular design to allow for fluid/safe transition of ventilator distribution to patients -- from one to three patients at the same time
- Reversible; the same single-part object is used for inspiratory + expiratory

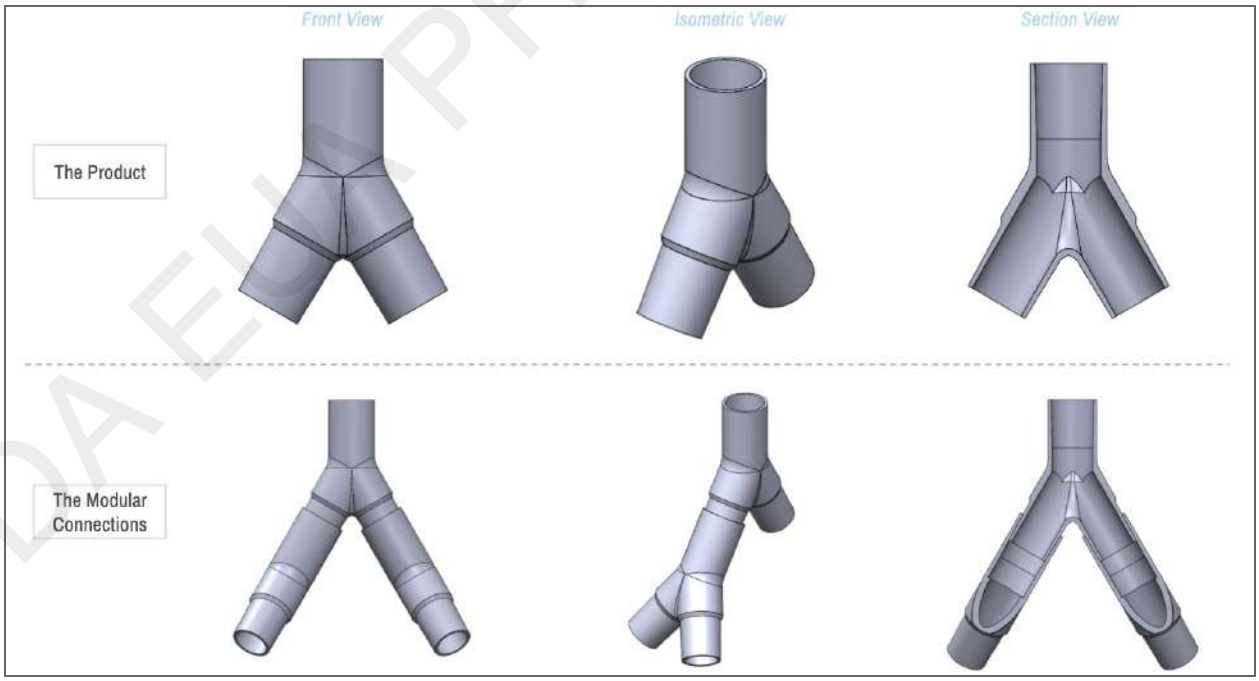



***Figure 3: Sparrow Modular Connections***

- Single use, disposable
- Modular; allowing the manifolds to be inter-connected to each other to increase capacity
- Universal 22 mm standard female connection to ventilator sizing

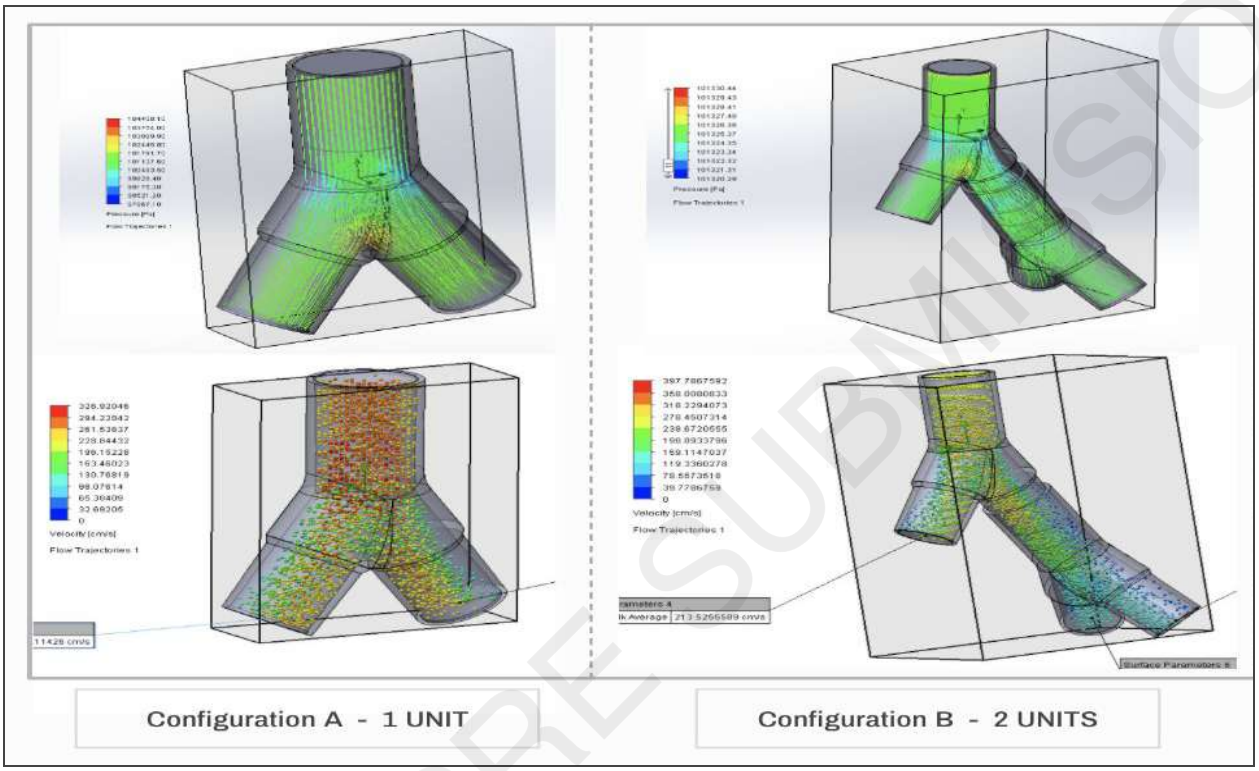



***Figure 4: Design Optimization***

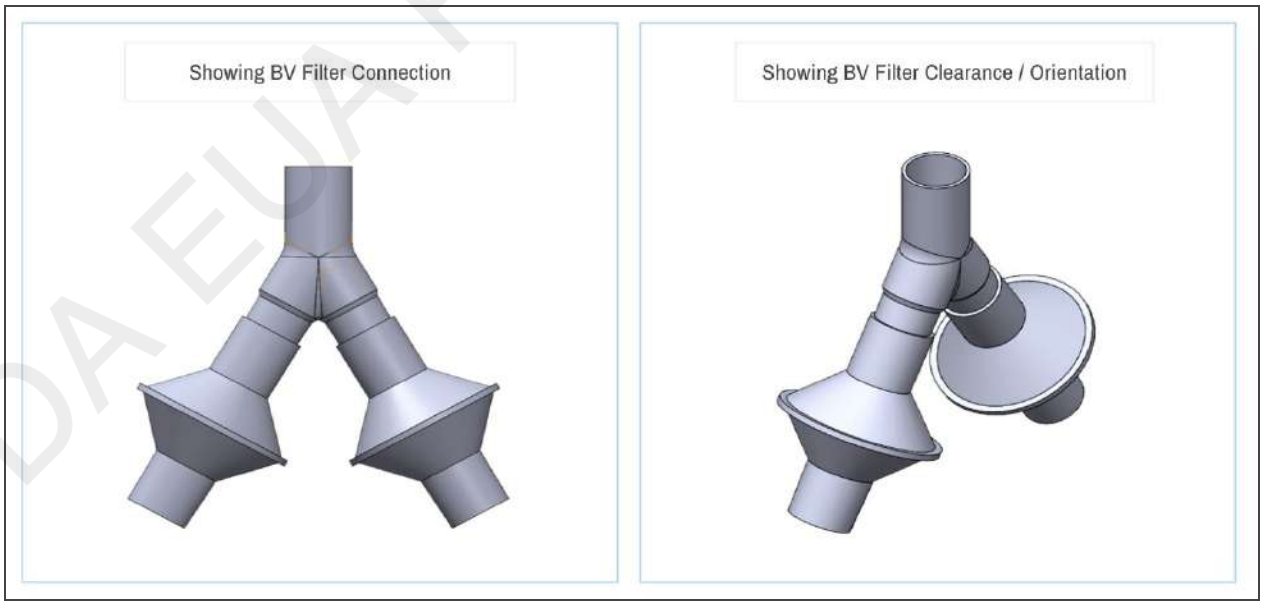



***Figure 5: Design Allows for In-Line Bacterial/Viral Filter Placement***

- Conical design to allow for tension/compression fit and ventilator machine brand variability
- Optimized laminar flow; maximizing the air flow rate
- Design allows for use of in-line bacterial/viral filters fitted in each ventilatory circuit

### B. Technical features

- One 22mm female connection, into two 22mm male connections
- Optimization; via computational simulations; for fluid dynamics / flow rate / laminar flow
- Equally distributed air flow through each channel, to each patient

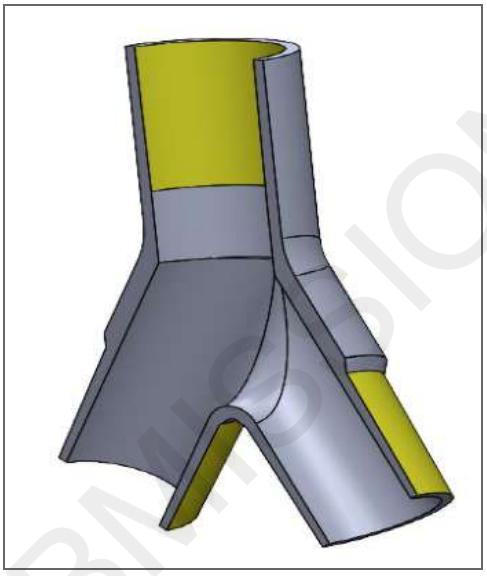


***Figure 6: Surface Finish***

### C. Material composition & finish

- Surgical / medical grade Polypropylene Homopolymer; Pro-fax 6331 (see Appendix A)
- Material will be clear & colorless, non-textured surface
- The finish (see Figure 6, at right) will be b-2 / b-3 on the non-critical surfaces [indicated in gray], and a-1 / a-2 on the critical surfaces [indicated in yellow].

### D. Manufacturing

- Can be 3D printed or mass produced through a surgical grade injection molding process

***Figure 7: 3D Printed Prototype - formZ, 25 µm***

## IV. SAFETY AND PERFORMANCE TESTING

Safety and Performance testing of the Sparrow COVID-19 Co-Ventilator Assist Device ("Sparrow") was conducted between March 28, 2020 and April 6, 2020. Based on the testing described below, the consultants concluded that the Sparrow:

- Does not appear to introduce resistance that would compromise a traditional ventilator circuit;
- Passes standard safety tests, and;
- Should allow an even distribution of gases to adequately ventilate properly selected patients.

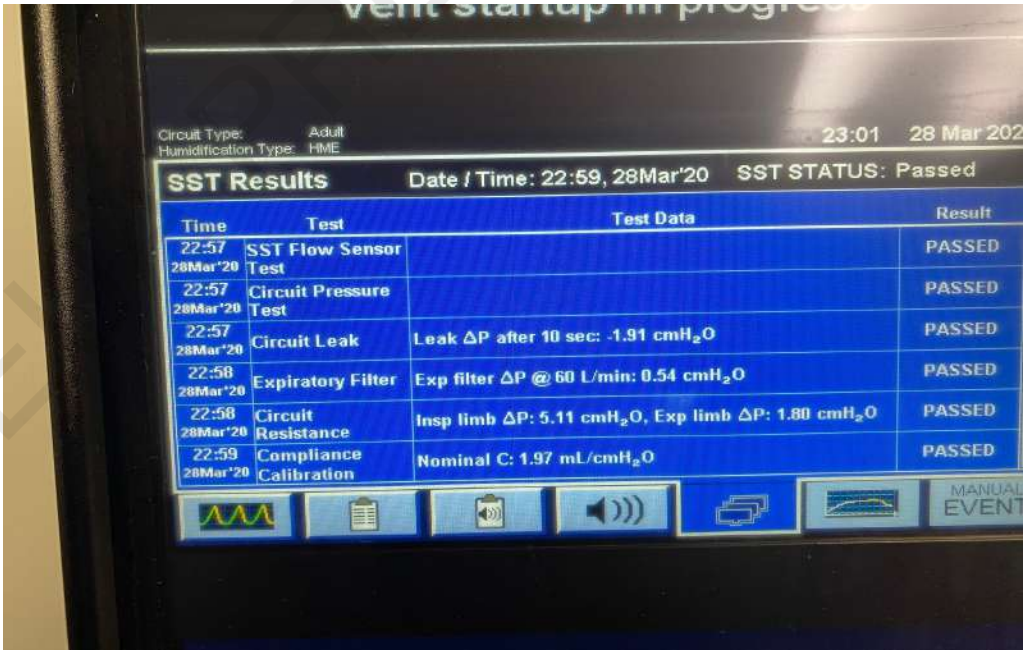
### A. Evaluators

Daniel Stemen BS, RCP, RRT-ACCS, ECMOS was Team Leader. Other participants included two surgeons, four respiratory care practitioners, and one engineer.

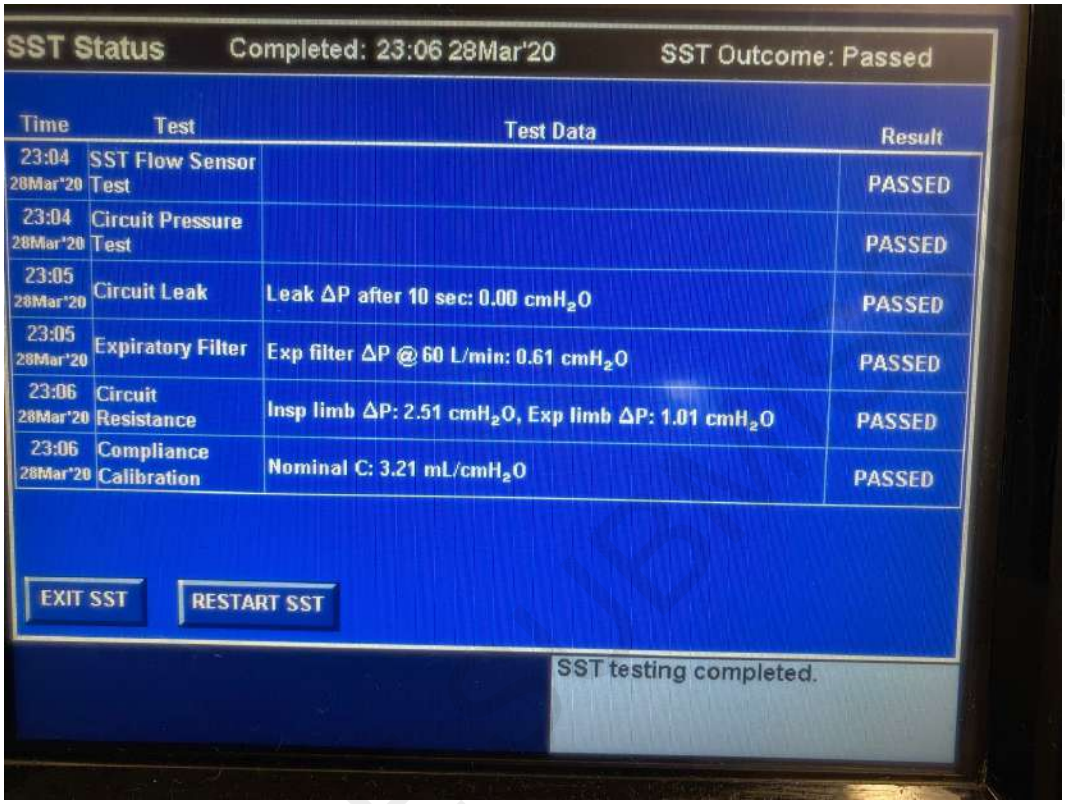
### B. Testing Protocols

The testing team conducted repeatable safety and simple performance testing to establish basic levels of safety and efficacy. The Sparrow is a manifold that splits one 22mm standard ventilator connection into two male 22mm connections. These can be set in sequence to provide additional branches for additional circuits to be attached.

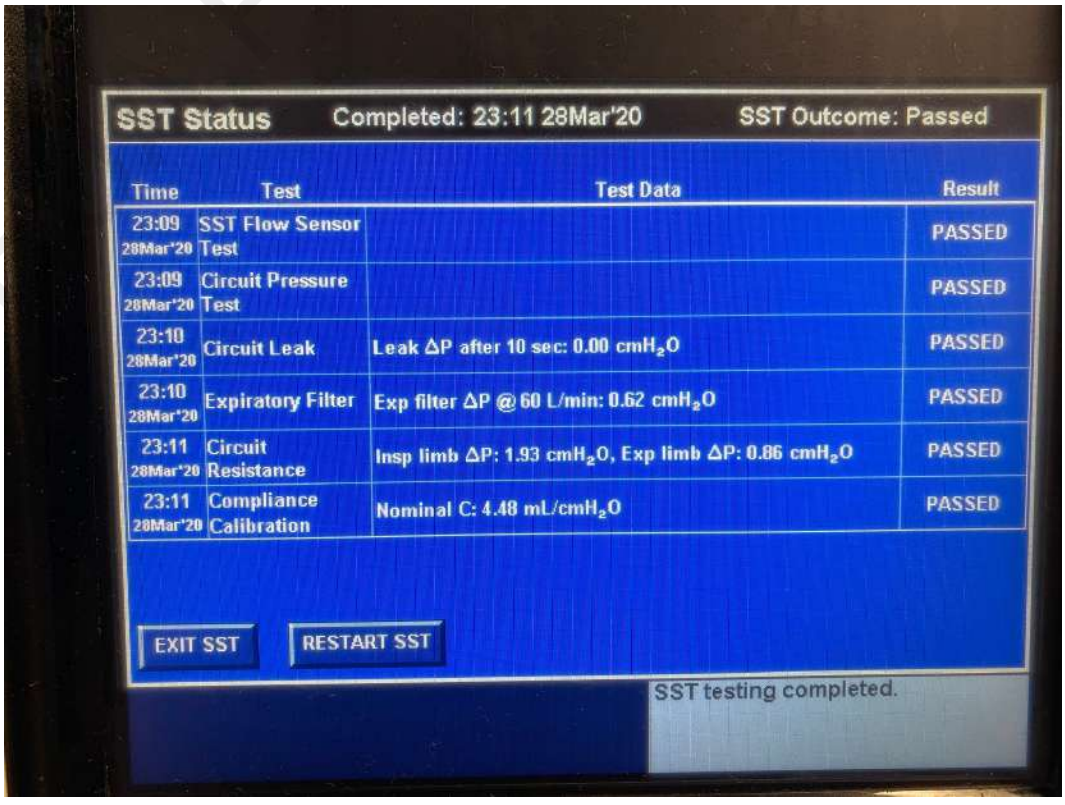
1. **Puritan Bennett 840 ICU ventilator:** Five standard safety tests were conducted.
    - **Test 1:** 22:57 March 28, 2020 at Keck Hospital of USC Department of Respiratory Care
        - 1 ADULT CIRCUIT FISHER & PAYKEL RT-380 Evaqua 2



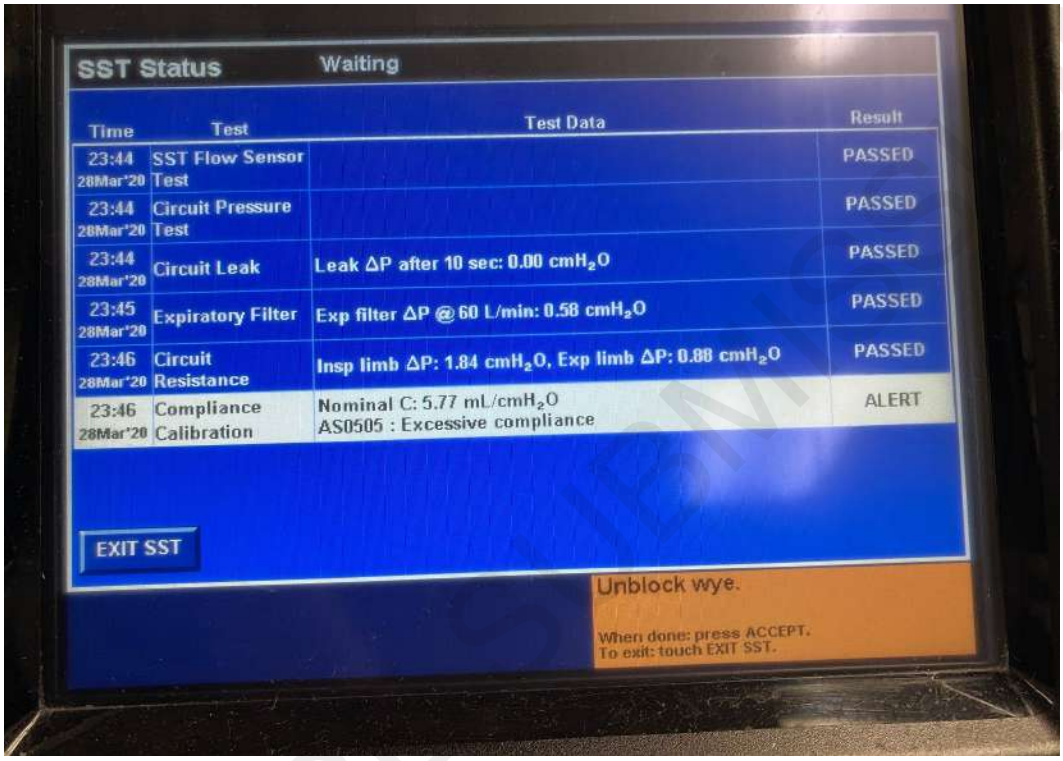
- **Test 2**: 23:04 March 28, 2020 at Keck Hospital of USC Department of Respiratory Care
    - 2 ADULT CIRCUIT FISHER & PAYKEL RT-380 Evaqua 2



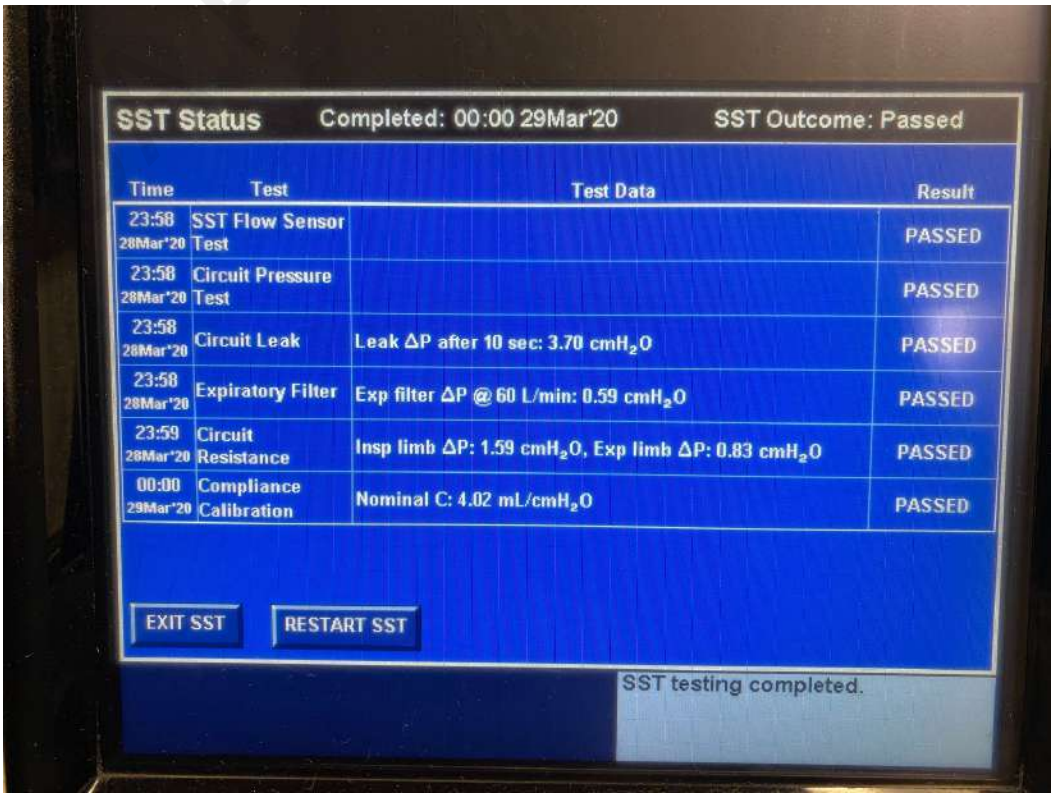

- **Test 3**: 23:09 March 28, 2020 at Keck Hospital of USC Department of Respiratory Care
    - 3 ADULT CIRCUIT FISHER & PAYKEL RT-380 Evaqua 2



- **Test 4**: 23:44 March 28, 2020 at Keck Hospital of USC Department of Respiratory Care
    - 4 ADULT CIRCUIT FISHER & PAYKEL RT-380 Evaqua 2

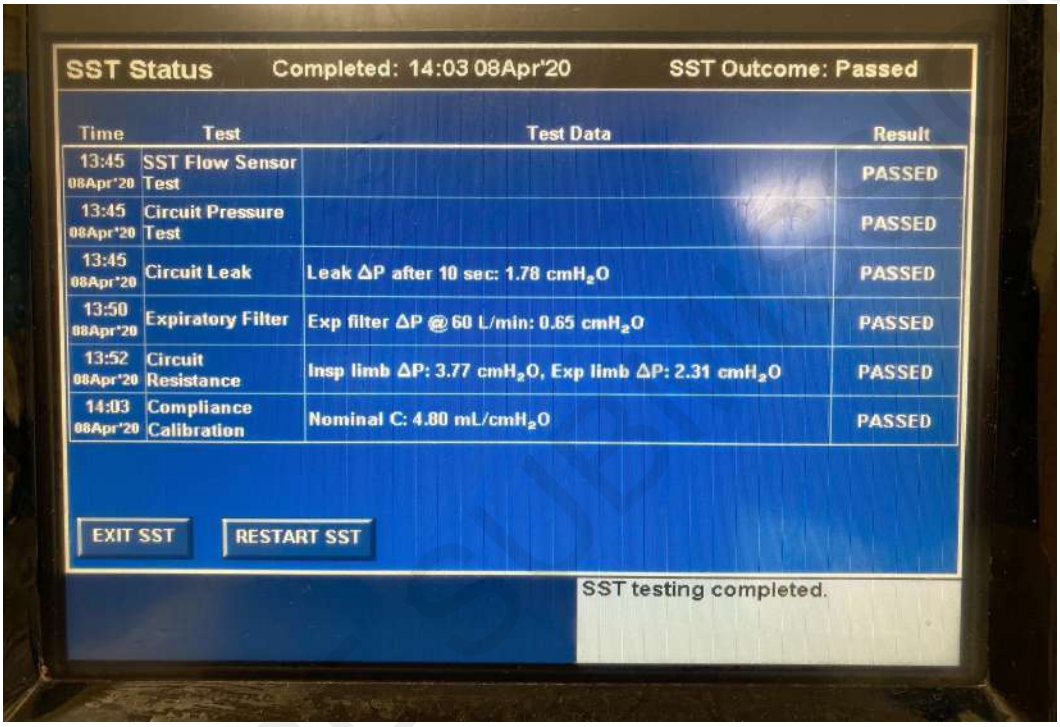



- **Test 5**: 23:58 March 28, 2020 at Keck Hospital of USC Department of Respiratory Care
    - 4 Flexi-Care Adult Expandable Circuit 96” with Y piece Luer elbow, 038-01-852U

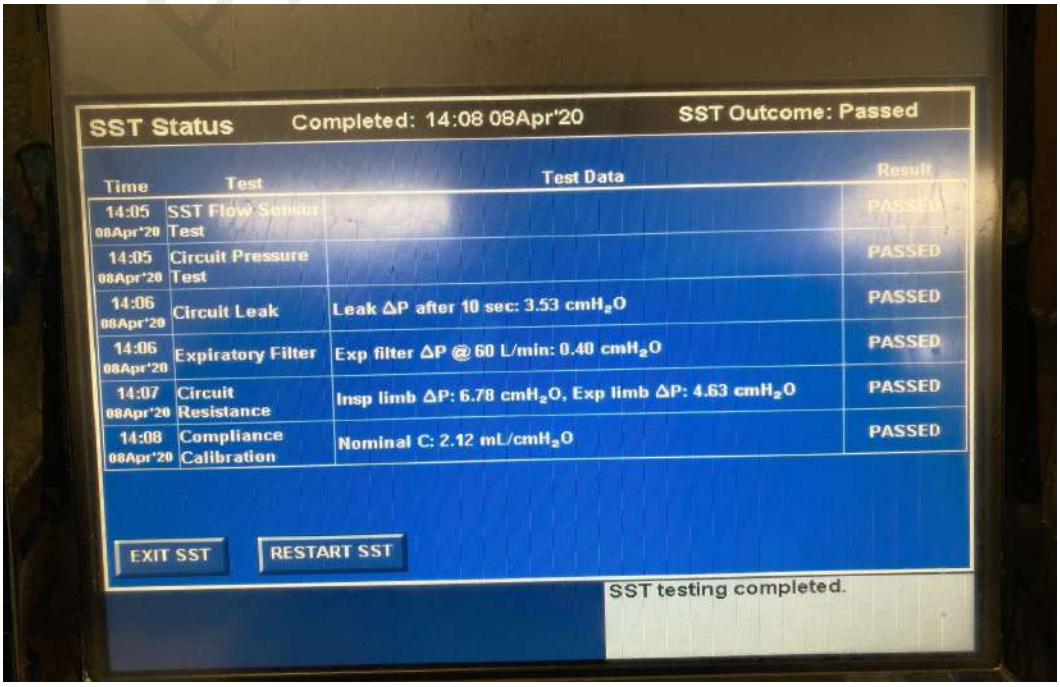


**2. Additional safety testing -**

- **Test 1**: 13:45 April 8, 2020 at Keck Hospital of USC Department of Respiratory Care
  - 2 Flexi-Care Adult Expandable Circuit 96" with Y piece Luer elbow, 038-01-852U




- **Test 2**: 14:05 April 8, 2020 at Keck Hospital of USC Department of Respiratory Care
  - 1 Flexi-Care Adult Expandable Circuit 96" with Y piece Luer elbow, 038-01-852U



3. **Avea ICU ventilator:** Three performance tests

Three circuits were constructed using a Flexi-Care Adult Expandable Circuit 96" with Y piece Luer elbow, 038-01-852U. The circuits were connected to the COVID-19 Ventilator Circuit Splitter, and then connected to the AVEA ICU ventilator. A Wright Spirometer was calibrated using a BD 60ml syringe.

Maquet 190 test lungs were used. Tidal Volume max 1 liter, 60 06 832 E037E, times 3. The test lungs were new, out of the box from Maquet.

Ventilator settings for performance testing were:

- Pressure Control Mode
- Inspiratory Pressure 25 cmH2O
- Positive End Expiratory Pressure 5 cmH2O
- I-Time 1.0 seconds
- Rate of Respiration 12 breaths per minute

- **Test 1**: 16:02 March 29, 2020 - at the USC Surgical Skills Simulation and Education Center

Measurements of 10 breath cycles per lung were taken using the calibrated Wright Spirometer.

The test showed even distribution of gases between the three test lungs in the circuit.

- **Test 2**: 16:41 March 29, 2020 - at the USC Surgical Skills Simulation and Education Center

A rubber band was added to decrease compliance of one test lung. Test lung compliance was decreased from 18 ml/cm$H^2O$ of driving pressure to 9 ml/cm$H^2O$ using the calculator on the ICU ventilator. (This is effectively a 50% decrease in compliance.) The same 10 cycle breath measurements were run and results using the calibrated Wright Spirometer were recorded.

The test showed uneven distribution of gases between patients with differing lung compliance.

- **Test 3**: 17:03 March 29, 2020 - at the USC Surgical Skills Simulation and Education Center

Finally, two more sets of 10 breath cycles were measured on the test lung with the highest compliance characteristics. The Wright Spirometer was placed on all three sections of the circuits.

This test showed that varying positions in the circuit did not yield changes to distribution of gases.

4. **Conclusion**

The COVID Ventilator Circuit Splitter does not appear to introduce resistance that would compromise a traditional ventilator circuit. It also passes the standard safety tests as shown above. This vent splitter should allow an even distribution of gases to adequately ventilate properly selected patients.

***Table 1: Summary of Results of Performance Testing of the Sparrow COVID-19 Co-Ventilator Assist***

| | Lung 1 | Lung 2 | Lung 3 | Observation |
|---|---|---|---|---|
| **Test 1** | 2969 ml | 2924 ml | 2886 ml | All three patients received similar volume. |
| **Test 2** | 3448 ml | 2998 ml | 1247 ml | One patient had 50% the compliance of the other two and volume distribution was noted as uneven. |
| **Test 3** | 3468 ml | | | The highest compliance lung was tested on all circuits and yielded consistent results. |
| | 3468 ml | | | |
| | 3448 ml | | | |

## V. PROPOSED LABELING

The Sparrow COVID-19 Co-Ventilator Assist Device is a modular ventilator circuit adapter intended for use only during a public health emergency to adapt a single ventilator for use by multiple patients ("co-ventilate") with similar clinical and respiratory needs simultaneously. It is not intended to be used when the supply of available ventilators is sufficient to provide individual mechanical ventilation.

The Sparrow COVID-19 Co-Ventilator Assist Device should be used according to facility-specific emergency protocols.

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**. It has not been tested for use by patients younger than 18 years of age.

### A. Directions 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 compatible with any model of ventilator to adapt it for use by multiple patients at the same time. It can be used for both inspiratory and expiratory circuits. It is modular and interchangeable, and can be configured in different ways, as depicted in Figure 8, below:

- In **Configuration A**, 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.
- In **Configuration B**, two (2) modular splitters are used to create 3 separate ventilatory circuits. This configuration is used to adapt a single ventilator for use by 3 patients simultaneously.

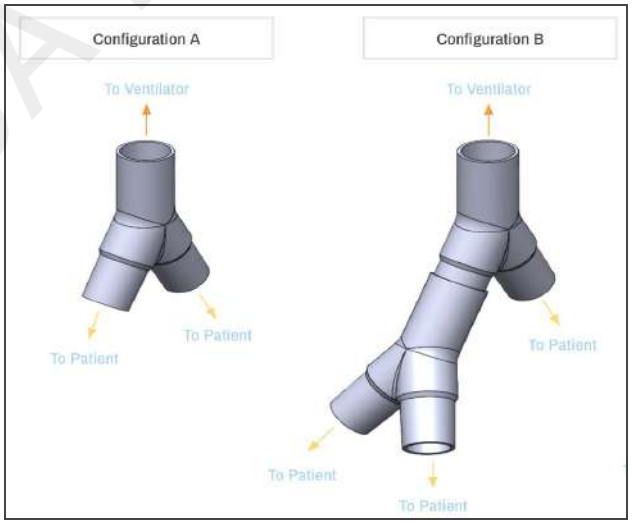



***Figure 8: Sparrow COVID-19 Co-Ventilator Assist Device Configurations***

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

### 1. Assigning more than one patient to a single ventilator

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

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. Only add patients with similar underlying lung physiology, lung compliance, ideal body weight, and clinical condition to the same ventilator.

Each ventilatory circuit can be fitted with in-line bacterial/viral filters.

**WARNING - PATIENTS WITH CONFIRMED OR SUSPECTED COVID-19 SHOULD ONLY BE PAIRED ON THE SAME VENTILATOR WITH OTHER COVID-19 PATIENTS.**

### 2. Use pressure control mode

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

**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.

### 3. Alarms

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

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

Follow facility protocols for:

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

**CAUTION** - **Potential infectious complications from sharing one ventilator have not been studied.**

### B. Fact Sheet for Healthcare Providers - Preliminary Draft

The Sparrow COVID-19 Co-Ventilator Assist Device is a modular ventilator circuit adapter intended for use during a public health emergency to adapt a single ventilator for use by multiple patients (co-ventilate) with similar clinical and respiratory needs simultaneously.

The Sparrow COVID-19 Co-Ventilator Assist Device has received authorization for emergency use (Emergency Use Authorization) during the COVID-19 pandemic by the US Food and Drug Administration ("FDA"). FDA has not approved or cleared the device for use outside of the COVID-19 public health emergency.

Using one ventilator for a single patient is the only established method to safely and reliably provide mechanical ventilation for patients with acute respiratory failure.[6]

The reliability and safety of "co-venting" (the use of 1 ventilator to support 2 patients simultaneously) in critically ill patients remains unknown.

Identifying and managing the complexities of critically ill patients are among the most challenging and unpredictable aspects of Co-Venting.

Co-Venting **should only be considered if** clinically proven, reliable, and safe methods to manage acute respiratory failure cannot be provided. Co-Venting **should only be used until** 1:1 patient-ventilator support using additional ventilators becomes available.

**CAUTION:** The Sparrow COVID-19 Co-Ventilator Assist Device has not been tested for use by patients younger than 18 years of age. Potential complications associated with sharing one ventilator have not been studied.

### C. Fact Sheet for Patients - Preliminary Draft

The Sparrow COVID-19 Co-Ventilator Assist Device is intended to be used to connect more than one patient to a single ventilator at the same time. This is sometimes called "co-venting" or "co-ventilation." Co-ventilation should only be considered during a health emergency when a hospital does not have enough ventilators for each individual patient.

The Sparrow COVID-19 Co-Ventilator Assist Device has received authorization for emergency use (Emergency Use Authorization) during the COVID-19 pandemic by the US Food and Drug Administration ("FDA"). It has not been approved or cleared by FDA for use outside of the COVID-19 pandemic.

**RISKS**:

There are risks associated with co-ventilation. If you agree to allow your doctor to connect you to a ventilator that is being used by another patient at the same time, you may not receive mechanical breathing support that has been optimized for you. Using one ventilator for one patient is the only established method to safely and reliably provide mechanical ventilation for patients with acute respiratory failure.

If you share one ventilator with another patient, it is possible that you could share health complications, such as an infection with that patient, but this has not been studied.

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[6] Washington DC COVID-19 Co-Ventilation Task force. Co-Ventilating Patients During a Critical Ventilator Shortage: A Method for Implementation. March 31, 2020. *Available at*: https://www.hhs.gov/sites/default/files/optimizing-ventilator-use-during-covid19-pandemic.pdf.

**You do not have to agree** to allow your doctor to connect you to a ventilator that is being used by another patient at the same time (co-ventilation). If you do not agree to share a ventilator, your doctors will continue to do everything they can to provide you appropriate care. However, you may have to wait until another ventilator becomes available for you to use on your own. It may be difficult for your doctors to predict how long you might have to wait for a single ventilator during a health emergency.

**CAUTION:** This product has not been tested in patients younger than 18 years of age.

## VI. MANUFACTURING

To provide for maximum flexibility and rapid availability, the Sparrow COVID-19 Co-Ventilator Assist Device was designed so that it can be 3D printed or manufactured through a surgical grade injection molding process.

Our contract manufacturer, Tessy Plastics Corporation (Skaneateles, NY)[7] will use surgical grade polypropylene homopolymer (see Appendix A) to manufacture the product. Tessy's manufacturing facility is GMP-registered and ISO 13485:2016 certified.

### A. Tooling

Full engineering for tooling the COVID-19 Ventilator Circuit Splitter has been completed, as summarized below:

- The tooling will be made steel-safe on the functional surfaces (see EUA; Figure 1 (note 7), Page 4, above)
- Once the parts are molded, they are measured and any steel adjustments are made (if necessary) so that the parts meet design specification.
- Test rings and plugs are made in accordance with standards set forth in ISO 5361:2016, Anaesthetic and respiratory equipment — Tracheal tubes and connectors.
- The parts are then tested for axial and radial removal force, according to the Standard.
- If parts fail standard testing, the core and cavity are polished to make the surface tackier, and tests are rerun and results documented.
- Once the surface finish meets the specified standards, *note 7* is updated to denote a standard SPI surface finish.

### B. Supply chain

Materials have been assessed for quantity and no extended supply chain dependencies have been identified.

## VII. DISTRIBUTION

A process for inventory control and distribution is being developed.

## VIII. ADVERSE EVENT REPORTING

The New Bureau will identify to FDA a qualified Third Party to track and investigate product complaints and report device-related adverse events according to standard operating procedures ("SOPs") and timelines applicable to emergency use authorization and consistent with the requirements set forth at 21 CFR Part 803 and 21 CFR Part 820. That Party will also be tasked with records retention according to 21 CFR 820.180. We intend to execute a Supplier Agreement with the Party and make copies of the executed Supplier Agreement and relevant SOPs available for FDA inspection.

[7] Tessy (Owner/Operator No 1317202) currently manufactures two non-metal vaginal specula (K120743, K022948) and blood bank supplies (BK950026).

**APPENDIX A - Material Composition**

INDELPRO

# PROFAX

## 6331

## PRODUCT DATA SHEET

### Polypropylene Homopolymer, General Purpose and Fiber

Pro-fax 6331 is general purpose and fiber polypropylene homopolymer, designed for extrusion and injection molding.

The base resin in this product meets the requirements of the FDA contained in the Code of Federal Regulations in 21 CFR 177.1520.

Features:

- High rigidity
- Ease of processing.
- High dimensional stability

Typical Applications:

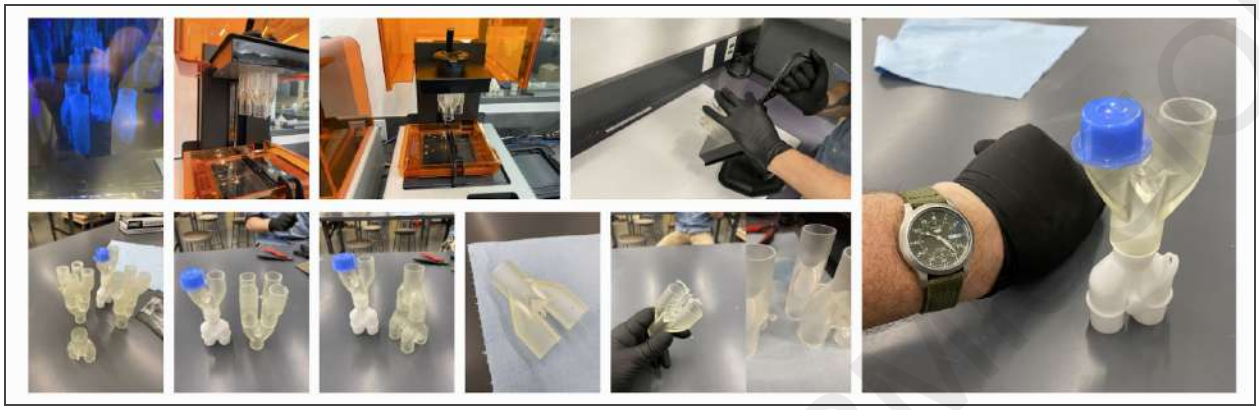
- Monofilament and mulifilament
- Housewares
- Injection
- Fiber extrusion
- OPP film, cast film

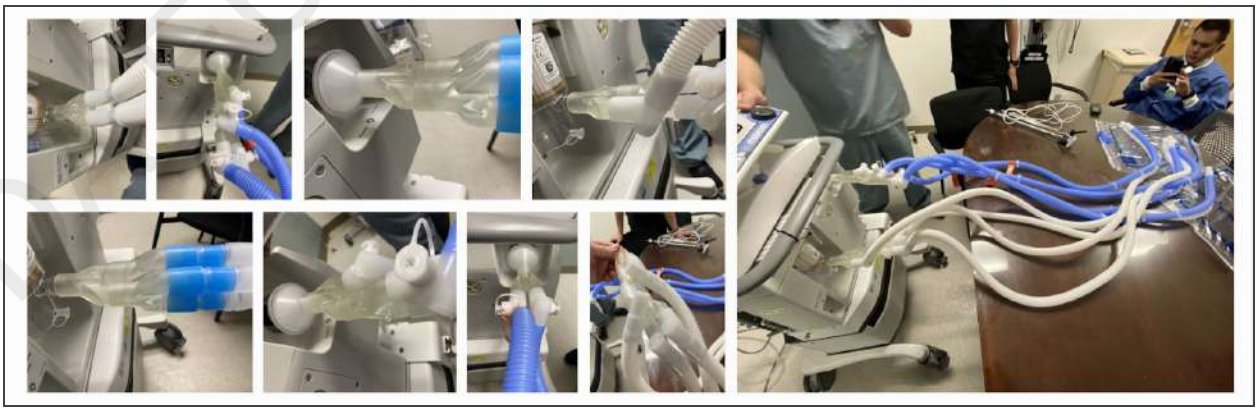
PRO-FAX 6331: PROPYLENE HOMOPOLYMER, GENERAL PURPOSE AND FIBER.

| TYPICAL PROPERTIES (a) | TYPICAL VALUE | ASTM METHOD (b) |
|---|---|---|
| - Melt Flow Rate (MFR), dg/min | 12 | D1238 |
| - Tensile strength at yield, psi ($N/mm^2$) | 5,220 (36) | D638 |
| - Izod impact strength (notched) at 73°F, ft-lb/in (J/m) | 0.67 (33) | D256A |
| - Elongation at yield, % | 11 | D638 |
| - Flexural Modulus, psi ($N/mm^2$) | 220,400 (1,520) | D790B |
| - Density, $g/cm^3$ | 0.9 | D792A |
| - HDT 0.46 $N/mm^2$ (66 psi), °F (°C) | 207 (97) | D648 |
| - VICAT softening point (2kg/$mm^2$),°F (°C) | 304 (151) | D1525 |

(a) Values shown are averages not to be construed as product specifications. These values may sift as additional data are accumulated.
(b) ASTM methods are the latest under the Society's current procedures. All specimens are prepared by injection molding.

## APPENDIX B - Testing the Sparrow COVID-19 Co-Ventilator Assist Device






Viral Filter


Adult Bacterial Viral Filter