



## **Ventilator, Ventilator Tubing Connectors, and Ventilator Accessories Pre-Emergency Use Authorization (EUA)/EUA Interactive Review Template**

This interactive review template (the “template”) was designed to capture the data/information needed by FDA to support inclusion of an eligible product under the Ventilator, Ventilator Tubing Connectors, and Ventilator Accessories EUA (the “Ventilator EUA” or “EUA”), as set forth in the EUA. This template is intended to help companies provide the information to FDA, but alternative approaches can be used. For more information about EUAs in general, please see the FDA Guidance document: *Emergency Use Authorization of Medical Products and Related Authorities*. **For more information on the Ventilator EUA, see the Ventilator section of the [COVID-19 EUA website](#). Once completed, please send this interactive review memo to [CDRH-COVID19-Ventilators@fda.hhs.gov](mailto:CDRH-COVID19-Ventilators@fda.hhs.gov).**

### **GENERAL INFORMATION ABOUT THIS TEMPLATE**

- Text highlighted in yellow [text] should be completed by the medical device product developer (sponsor) as applicable to its specific device. If any of the sections are not applicable, please indicate such and provide an explanation (if one is necessary).
- This is a template for Pre-EUA/EUA submissions and not a guidance document. It includes the information that should be included in such submissions, as outlined in the *Emergency Use Authorization of Medical Products and Related Authorities* Guidance document as well as the Ventilator EUA. This Template is subject to change including because of revisions to the Ventilator EUA as we learn more about COVID-19 generally and these devices’ risk-benefit profiles.
- Any proprietary information provided within the template and during the interactive review process will remain confidential.
- Feedback provided by FDA during the interactive review of a pre-EUA/EUA submission is subject to change as FDA gains experience during an emergency, as FDA learns more about the disease/condition this device addresses, and as the device’s risk-benefit profile may evolve to address the unmet public health need.
- Please remember that if your product is added to this specific EUA, the authorization would be only for the use specified in the EUA and subject to the conditions in the EUA. This device must not be introduced into interstate commerce for uses outside the authorized use without obtaining marketing clearance, approval, an approved IDE, or another EUA by the FDA.

- If added to this specific EUA, the product would be authorized for use until the declaration of public health emergency is terminated, the EUA is revoked by the FDA or the product is removed from the EUA.
- ***The EUA is not a pathway to permanent marketing of your device.*** For information on premarket submissions, please refer to FDA’s website on “How to Study and Market Your Device” at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device>. For information on FDA’s enforcement policy for ventilators, see FDA guidance [\*Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency\*](#). For guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to FDA guidance [\*Deciding When to Submit a 510\(k\) for a Change to an Existing Device\*](#).

**Pre-EUA/EUA INTERACTIVE REVIEW TEMPLATE  
for Ventilator, Ventilator Tubing Connectors, and Ventilator Accessories**

**A. Basic Information**

**1. Purpose of Submission**

Request for the addition of the [include device name] device to the Ventilator EUA.

**2. Applicant**

Include the following applicant information:

Contact name/phone/address/email:

Contact information for a U.S. agent:

Manufacturer name/address:

**3. Device proprietary or brand name, model number:**

**4. Indication for use:**

**5. Regulatory information (Approval/Clearance status in US):**

[Please indicate whether the device is legally marketed in the US. If applicable, please include a description of any modifications made to the legally marketed device.]

**6. Marketing authorizations in any other country:**

[Please indicate whether the device currently has marketing authorization in another regulatory jurisdiction, such as the European CE Mark, Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion, Health Canada License, or Japan Pharmaceuticals and Medical Device (PMDA) approval (including certification number, if available).]

**7. Unmet Need**

The [Ventilator Emergency Use Authorization \(EUA\)](#) was issued in response to concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in healthcare settings to treat patients during the Coronavirus Disease 2019 (COVID-19) pandemic.

**B. EUA Section II Information**

As stated in the EUA, the information below should be provided to ensure the criteria described in Section II of the EUA have been met.

### 1. Product Labeling

Please provide a copy of the product labeling, including the instructions for use.

### 2. Applicable Standards

Please indicate whether the device has been designed, evaluated, and validated in accordance with the applicable FDA-recognized standards identified in [Appendix A of the EUA](#).

### 3. Quality System

Please indicate whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, or an equivalent quality system, and the manufacturer or importer has documentation of such.

### 4. Other Quality Management Standards

Please indicate whether the device is manufactured in compliance with other internationally recognized quality management systems.

### 5. Power Supply

Please indicate whether the device is designed with a power supply that is compatible with United States voltage, frequency, and plug type standards or is accompanied by an appropriate power supply adapter for use in the United States.

### 6. Authorized Labeling

Authorized products must be accompanied by the following information pertaining to the emergency use (also described in [Appendix A](#) of the EUA) which are authorized to be made available to healthcare providers and patients:

- [Fact Sheet for Healthcare Providers](#): Emergency Use of Ventilators During the COVID-19 Pandemic
- [Fact Sheet for Patients](#): Emergency Use of Ventilators During the COVID-19 Pandemic

The sponsor’s developed instructions for use and the two fact sheets are referred to in the EUA as “authorized labeling.”

Please confirm that the product will be accompanied by the Fact Sheets identified above and labeling/instructions for use.

**C. EUA Section IV Conditions of Authorization**

Please provide a written confirmation that you will be meeting the conditions for sponsors set forth in [Section IV](#) of the Ventilator EUA.

**D. Criteria for Safety, Performance and Labeling (from [Appendix A](#) of the EUA)**

To be authorized and added to [Appendix B](#) of the Ventilator EUA, the product must be determined to meet the applicable criteria for safety, performance and labeling set forth in Appendix A of the EUA and outlined below.

**1. Declarations of Conformity**

Please provide declarations of conformance with the following standards as applicable. In addition, please provide an explanation of how conformance to the standards identified adequately ensures the safety and performance of the device:

- IEC 60601-1: 2012: *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2: 2014: *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- IEC 60601-1-11: 2015: *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- Any other applicable collateral/particular standards in the IEC 60601-1: 2012 family
- IEC 62304: 2015: *Medical Device Software – Software Life Cycle Processes*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017: *American National Standard for Evaluation of Wireless Coexistence*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ISO 10993: Fifth Edition 2018-08: *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process*
- ISO 18562-1 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process*

- ISO 18562-2 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter*
- ISO 18562-3 First Edition 2017: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds*
- ISO 18562-4 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 4: Tests for Leachables in Condensate*
- ISO 10651-5 First Edition 2006-02-01: *Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance - Part 5: Gas-Powered Emergency Resuscitators*
- ISO 17510 First Edition 2015-08-01: *Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories*
- ISO 80601-2-12 First Edition 2011-04-15: *Medical Electrical Equipment - Part 2-12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators [Including: Technical Corrigendum 1 (2011)]*
- ISO 80601-2-13 First Edition 2011-08-11: *Medical Electrical Equipment -- Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]*
- ISO 80601-2-69 First Edition 2014-07-15: *Medical Electrical Equipment - Part 2-69: Particular Requirements for Basic Safety and Essential Performance of Oxygen Concentrator Equipment*
- ISO 80601-2-70 First Edition 2015-01-15: *Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnoea Breathing Therapy Equipment*
- ISO 80601-2-74 First Edition 2017-05: *Medical Electrical Equipment - Part 2-74: Particular Requirements for Basic Safety and Essential Performance of Respiratory Humidifying Equipment*
- ISO 80601-2-79 First Edition 2018-07: *Medical electrical equipment - Part 2-79: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Impairment*
- ISO 80601-2-80 First Edition 2018-07: *Medical Electrical Equipment - Part 2-80: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency*

## **2. Device Specifications and Instructions for Ventilators and Accessories**

Please provide the following specification information for your device, as well as any other relevant device specification information that may not be covered by the items below.

For devices for delivering ventilatory support, sponsors should provide specific information and instructions regarding the device's:

- Available ventilation modes, patient interfaces, ventilatory parameter ranges (e.g., maximum inspiratory pressure, positive end-expiratory pressure, respiration rate, flow, delivered tidal volume, triggering, etc.)
- Battery specifications (if applicable), including runtime, how users are notified of device battery status (e.g., alarms), and expected use life that is supported by testing. For devices with external or replaceable internal batteries, the sponsor should provide information regarding chemistry, including information regarding design, capacity, and software and/or hardware risk mitigations for overcharging, alarms, and information regarding conformance to applicable standards (e.g., IEC62311 for rechargeable batteries or IEC 60086-4 for non-rechargeable batteries for lithium-ion technology)
- Alarm functionality, including a listing of all alarm conditions and the associated default settings and limits
- Sensors and monitored parameters (including device parameters or patient parameters, as applicable)

For ventilator accessories please provide specific information and instructions (as applicable), regarding the device's:

- Connection dimensional characteristics (i.e., per ISO 5356-1) types (e.g. single limb with active exhalation, dual limb)
- Compensating control

### 3. Reprocessing and Shelf-life Information

Please provide the following information and instructions regarding device reprocessing:

- Instructions on how to reprocess reusable accessories, including filters and sensors
- A list of all components—both internal and external to the ventilator—that can contact patient-expired gases or may become contaminated with patient bodily fluids. Such components may include, but are not limited to: the expiratory module, flow sensors, pressure sensors, humidifier, patient circuit, carbon dioxide module sensor. The list should specify whether the device components are intended for single use or are reusable. This applies to both patient-contacting components, as well as components that may otherwise come in contact or be contaminated with patient-expired gases or bodily fluids
- Information regarding device shelf-life

### 4. Facility Requirements (as applicable)

As applicable, please provide the following information and instructions regarding the gas input and gas source of the device manufacturing facility:

- Gas input connection type (e.g., Diameter Index Safety System (DISS), NIST)

- Gas type (e.g., air, oxygen), including information regarding input pressures and flow rates
- Gas source (e.g., internal blower, wall-source)
- Environmental controls to reduce transmission (e.g., negative pressure)

## 5. Labeling Requirements for Conditions of Use

Please confirm that the device's labeling includes the device's specifications (including ventilatory parameters), information regarding alarms (e.g., disconnect, EtCO<sub>2</sub> alarms, etc.), device reprocessing instructions, and other instructions described above as applicable.

## 6. Continuous Ventilator Splitters (Adapters for Multiplexing)

### a. Engineering and Manufacturing Considerations:

Please provide the engineering and manufacturing considerations for a ventilator circuit adapter for multiplexing certain continuous ventilators intended for use in a healthcare facility (21 CFR 868.5895 and product code CBK (ventilator, continuous, facility use)) are set forth below.

These safety and performance considerations highlight the technical application of creating and testing this type of component and are not intended to be inclusive of all considerations. Please provide a description or discussion demonstrating an assessment of these considerations.

- 1) Material properties and high polymeric crosslinking/conversion
- 2) Material strength and durability
- 3) Gas pathway biocompatibility
  - a. Dry gas validation would include:
    - i. Testing for volatile organic compounds
    - ii. Particulate matter sampling
- 4) Leak tests on finished product
- 5) Design for use of disconnect alarms that are on multiple circuit paths
- 6) Compliance with guidelines regarding standard for ventilator circuitry
  - a. ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
  - b. ISO 5366 First edition 2016-10-01 Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors
  - c. ISO 18190 First edition 2016-11-01 Anaesthetic and respiratory equipment - General requirements for airways and related equipment
  - d. ISO 18562-1 First Edition 2017-03: Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process



- e. ISO 18562-2 First Edition 2017-03: Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter
  - f. ISO 18562-3 First Edition 2017: Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds
- 7) Appropriate labeling providing instructions for use and cautionary statements regarding the device use and recommended monitoring activities

**b. Labeling Considerations:**

Please confirm that the product labeling conveys the following information:

- 1) A single ventilator fitted with the Vent Splitter can be used for multiple patients for ventilatory support during the COVID-19 pandemic when individual ventilators are not available or preemptively to increase the potential of single-use ventilators permitting mechanical ventilation for multiple patients simultaneously;
- 2) A description of the recommended use options/configuration (e.g. 2 splitters that can provide 2 ventilatory circuits (2 patients), 4 splitters that can provide 3 ventilatory circuits (3 patients) or 6 splitters that can provide 4 ventilatory circuits (4 patients); recommendations regarding the need for extra long tubing if needed to position patients in a manner that allows access to the patients and the ventilator; recommendations regarding free gas flow (FGF) requirements for oxygen when the ventilator used for multiple patients.
- 3) The pressure control mode is recommended when more than one circuit is added to the ventilator
- 4) The single ventilator fitted with the Vent Splitters will provide each patient with the same level of pressure support, the same rate of respiration, the same inspiratory/expiratory ratio, the same FiO<sub>2</sub>, the same level of PEEP, etc.
- 5) Because the single ventilator provides similar ventilatory support to all patients, it is important to size match patients
- 6) Cautionary statement regarding the need for paralysis and sedation, and the need for additional infusion pumps to administer these agents, to avoid dyssynchronous breathing and system alarming from bucking and coughing;
- 7) Cautionary statement regarding the need for additional infusions pumps
- 8) Because the single ventilator provides similar ventilatory support to all patients, it is also important 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;
- 9) A description of recommended approach to patient monitoring, e.g. 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, assessments of arterial blood gas findings to assure clinical stability on the shared system; close monitoring of all patients will be critical since they will likely be paralyzed and sedated.

- 10) 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;
- 11) Potential infectious complications from sharing one ventilator have not been studied, and therefore caution is advised. If patients share the same infection, the single ventilator for multiple patients is a viable short-term management option. Each patient's is individualized with in-line filters designed to filter out viruses and/or bacteria and to protect the ventilator from contamination.

**E. Benefit/Risk Assessment**

This is a key section of the EUA Interactive Review Template that outlines the risk benefit analysis. The section should be filled out by the sponsor based on the risk-benefit analysis for the product.

**F. FDA Summary of Documentation and Review [for FDA Internal Use Only]**

FDA reviewers will include a brief summary of the documentation provided and their conclusion of whether the product meets the criteria and conditions identified in Sections II, IV, and Appendix A of the EUA.

**G. Interaction Review Log**

Please use the table below to document interactive review with FDA, include interactions initiated by either FDA or the sponsor.

Date	Type of Interaction (phone/ email/ formal submission-DCC)	Brief Description (e.g., questions asked/ feedback from FDA received / any word documents included)
[X]	[X]	[X]

**H. Next Steps**

Once FDA review is completed, if the eligible product has been confirmed to meet the safety, performance, and labeling criteria in Appendix A of the EUA, then you will receive an email notification with that information and your product will be added to Appendix B of the Ventilator EUA. If the product is not eligible for addition to or fails to meet the safety, performance or labeling criteria in Appendix A of the EUA, then you will be receive an email notification with that information. Please note that, as set forth in FDA's guidance *Emergency Use Authorization of Medical Products and Related Authorities*, FDA intends to prioritize its review of EUA requests during a declared emergency based on various factors, including the extent to which the product would serve a significant unmet medical need.