

Appendix A. Criteria for Safety, Performance and Labeling

To be added to Appendix B, ventilators, ventilator tubing connectors, and ventilator accessories must be determined to meet the applicable criteria for safety, performance and labeling set forth below. FDA will add a ventilator, ventilator tubing connector, or ventilator accessory to the list of authorized products in 0 upon submission of a request from the sponsor as described in Section II and after confirmation that the applicable safety, performance and labeling criteria have been met, and pursuant to the Conditions of Authorization in this EUA.

Declarations of Conformity

Sponsors should provide declarations of conformance with the following standards as applicable:

- 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*

In addition, sponsors should provide declarations of conformance with the following particular standards as applicable to the device:

- 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*

Device Specifications and Instructions for Ventilators and Accessories

Sponsors of ventilators, ventilator tubing connectors, and ventilator accessories should provide the following specification information.

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)

- Description of the device’s alarm functionality, including a listing of all alarm conditions and the associated default settings and limits
- Description of the device’s sensors and monitored parameters (including device parameters or patient parameters, as applicable)

For ventilator accessories sponsors should 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 controls

Reprocessing and Shelf-life Information

Sponsors of ventilators, ventilator tubing connectors, and ventilator accessories should provide the following information and instructions regarding device reprocessing.

- Instructions on how to reprocess reusable accessories, including filters and sensors¹
- 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

Facility Requirements (as applicable)

As applicable, sponsors of ventilators, ventilator tubing connectors, and ventilator accessories should 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)

¹ Such information is critical to ensuring that a device is appropriately prepared for its initial and subsequent uses. For recommendations regarding the development and validation of reprocessing instructions in your proposed device labeling, refer to FDA’s guidance [Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

- Environmental controls to reduce transmission (e.g., negative pressure)

Labeling Requirements for Conditions of Use

The device's labeling includes the device's specifications (including ventilatory parameters), information regarding alarms (e.g., disconnect, EtCO₂ alarms, etc.), device reprocessing instructions, and other instructions described above as applicable.

The Fact Sheet for Healthcare Providers administering the device includes the following:

- A statement that FDA has authorized the emergency use of the device;
- A description of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
- Information regarding the available alternatives to the device, including benefits and risks of the available alternatives.

The Fact Sheet for Patients to whom the device is administered includes the following:

- A statement that FDA has authorized the emergency use of the device;
- A description of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
- Information regarding the individual's option to accept or refuse administration of the device; of the consequence, if any, of refusing administration of the device; and of the available alternatives to the device, including the benefits and risks of the available alternatives.

Continuous Ventilator Splitters (Adapters for Multiplexing)

A. Engineering and Manufacturing Considerations:

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.

Sponsors should provide a description or discussion demonstrating their 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:

The 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 FiO₂, 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.