



Ventilator Supply Mitigation Strategies: Letter to Professional Societies

March 24, 2020

Dear Colleagues:

The U.S. Food and Drug Administration (FDA) recognizes that the need for ventilators, ventilator accessories, and other respiratory devices may outpace the supply available to health care facilities during the Coronavirus Disease 2019 (COVID-19) outbreak. We are sending this letter to you because we believe that your professional society membership will be directly impacted by any shortage of ventilators, related respiratory devices, and accessories due to the outbreak.

Below we provide recommendations for health care providers and facilities, based on a recently issued [guidance](#). This guidance outlines a policy intended to help increase the availability of ventilators and their accessories as well as other respiratory devices during the COVID-19 pandemic. Specifically, the policy fosters the continued availability of certain safe and effective medical devices while being flexible regarding manufacturer modifications made to ventilators, anesthesia gas machines and other respiratory devices, and their accessories, in response to the COVID-19 public health emergency.

In choosing the best ventilation option for your patient, you should consider your patient's condition, the available technology, and the respiratory care expertise and experience present in your institution.

The FDA's recommendations are intended to augment, not replace, specific controls and procedures developed by health care organizations and the [Centers for Disease Control and Prevention](#) (CDC).

Recommendations

Under the policy described in the [guidance](#), manufacturers may make certain modifications to FDA-cleared indications, claims, or functionality of these devices, without submission to the FDA for evaluation of the modification, where the modification will not create an undue risk in light of the public health emergency. In these circumstances, the FDA recommends:

- Health care providers and facilities use FDA-cleared conventional or standard full-featured ventilators wherever possible.
- Health care providers using devices with these modified indications, claims, or functionality, contact the manufacturer (or review the manufacturer's website) for updated labeling, including information on the features and limitations of the modified

device. The [guidance](#) outlines the information that the FDA expects manufacturers include in labeling for the modifications discussed.

Additionally, if the number of ventilators in your facility is running low, consider alternative devices capable of delivering breaths or pressure support to satisfy medically necessary treatment practices for patients requiring ventilatory support. Examples of potential alternative uses of respiratory devices to address shortages include:

- Continuous ventilators labeled for home use used in a medical facility setting
- Emergency transport ventilators used for prolonged ventilation in a medical facility setting.
- Anesthesia gas machines capable of providing controlled ventilation or assisted ventilation used outside of the traditional anesthetic indication. **CAUTION:** Because of significant differences between the anesthesia gas machine and traditional critical care ventilators, refer to the manufacturers' websites for specific instructions on safe use of anesthesia gas machines for this indication.
- Noninvasive Ventilation (NIV) Patient Interfaces capable of prescribed breath used for patients requiring ventilatory support, including NIV Patient Interfaces labeled for sleep apnea.
- Continuous Positive Airway Pressure (CPAP), auto-CPAP, and bilevel positive airway pressure (BiPAP or BPAP) machines indicated for treatment of sleep apnea (either in the home or facility setting) used to support patients with respiratory insufficiency.

Conservation Strategies for Ventilator Accessories

Given the potential for extensive use of ventilators and anesthesia gas machines in response to the COVID-19 pandemic, to help avoid depletion of breathing circuit supplies, i.e., ventilator accessories such as filters, humidifiers and tubing, health care facilities may consider:

- Using ventilator accessories beyond the labeled shelf-life
- Extending the duration of use of accessories in an individual patient depending on the availability of resources
- Extending the duration of use of passive humidifiers (heat-moisture exchangers) for up to one week, depending on a patient's condition and available resources.

Examples of circumstances where FDA currently believes a change would not create an undue risk in light of the public health emergency include devices used according to healthcare institutional protocols, or useful life is limited to the occurrence of malfunction or visible soiling.

Risk of Room Air Contamination

Take appropriate precautions with environmental control (for example, negative pressure) or use additional filtration where feasible. Ventilating patients with communicable diseases using devices that are single limb or noninvasive without a filtered seal from atmosphere may contaminate the room air and increase risk of transmission. This risk may be exacerbated by high-flow nasal cannula systems or CPAP machines.

Additional Resources

Anesthesia Patient Safety Foundation (APSF): [FAQ on Anesthesia Machine Use, Protection, and Decontamination During the COVID-19 Pandemic](#)
[External Link Disclaimer](#)

American Society of Anesthesiologists: [COVID-19 Information for Health Care Professionals](#)
[External Link Disclaimer](#)

Society of Critical Care Medicine: Emergency Resources: COVID-19 <https://www.sccm.org/disaster>

Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.

SARS-CoV-2 has demonstrated the capability to spread rapidly, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. To respond effectively to the COVID-19 outbreak, appropriate clinical management and infection control and implementation of community mitigation efforts are critical.

The FDA is aware that patients suffering from respiratory complications as a result of COVID-19 may require ventilatory support. These patients may require assistance via mechanical ventilation through the controlled delivery of gases, including the delivery of oxygen during inhalation and/or the removal carbon dioxide during exhalation.

FDA Actions

The FDA is collaborating with manufacturers of ventilators, ventilator accessories, and other respiratory devices to better understand the current supply chain issues related to the COVID-19 outbreak and to help mitigate any widespread shortages of these devices.

The FDA is also working with the [Strategic National Stockpile \(SNS\)](#) to develop strategies for the use of ventilators and ventilator accessories in the SNS. For more information, refer to HHS's [Assistant](#)

[Secretary for Preparedness and Response \(ASPR\)](#) and [Biomedical Advanced Research and Development Authority \(BARDA\)](#).

The FDA will continue to keep health care providers, manufacturers, and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

For potential or actual supply issues, email information to the FDA at deviceshortages@fda.hhs.gov. Any one – user, patient, manufacturer, or organization within the supply chain – who is aware of a delay in distribution of a product, or anticipates a potential or actual shortage, can notify us.

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with ventilators.

- Voluntary reports can be submitted through [MedWatch, the FDA Safety Information and Adverse Event Reporting program](#).
- Device manufacturers and user organizations must comply with the applicable [Medical Device Reporting \(MDR\) regulations](#).
- Health care personnel employed by organizations that are subject to the [FDA's user facility reporting requirements](#) should follow the reporting procedures established by their organizations.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact deviceshortages@fda.hhs.gov or, for general questions, the [Division of Industry and Consumer Education \(DICE\)](#).

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Director

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