

March 23, 2020

FDA Releases Guidance to Mitigate Ventilator Supply Disruptions

In response to the novel coronavirus (COVID-19) outbreak, the Food and Drug Administration (FDA) March 22 published additional information focused on mitigating disruptions to or shortages in the ventilator supply chain.

First, the agency released [updated guidance](#) to provide flexibility around and expand the availability of ventilators and other respiratory devices to treat patients during the public health emergency. The FDA also released a [letter](#) to health care providers in an effort to supplement the updated guidance and provide recommendations directed at providers. Due to the urgency of this issue, the guidance was issued without public comment and will remain in effect only for the duration of the public health emergency.

The guidance provides information for modifications to FDA-cleared ventilators, as well as information for emergency use authorization (EUA) for those ventilators that are not FDA-cleared. While the FDA expects providers to use FDA-cleared ventilators when possible, it will not object to limited modifications without premarket notification for and approval of those devices. Specifically, the guidance aims to create more flexibility for manufacturers of FDA-cleared ventilators. Examples of those flexibilities include:

- Changes to the ventilator motor to allow an alternate supplier to meet the required design specifications; and
- Changes to the material in the ventilator tubing to allow for more flexible material sourcing.

For manufacturers of devices not cleared by FDA, the agency will consider authorizing EUAs if the device meets the necessary requirements. Specific information pertaining to the EUA application process can be found in the guidance.

As a complement to the guidance, FDA's letter to health care providers shares additional recommendations for hospitals and health systems. Among other information, the letter offers options for those hospitals who are at or nearing ventilator capacity. In those instances, hospitals are permitted to use alternative devices capable of delivering breaths or pressure support to satisfy medically necessary treatment processes to care for patients. Examples of alternative options include:

- Utilization of certain home use ventilators in a medical facility;
- Using emergency transport ventilators in a medical facility;
- Utilization of anesthesia gas machines capable of providing controlled or assisted ventilation;
- Use of Noninvasive Ventilation (NIV) Patient Interfaces capable of prescribed breath; and
- Utilization of machines typically used for sleep apnea, such as Continuous Positive Airway Pressure (CPAP), auto-CPAP, and bilevel positive airway pressure (BiPAP or BPAP) in certain situations.