FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of Ventilators During the COVID-19 Pandemic **March 24, 2020**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators" in this Fact Sheet), ventilator tubing connectors, and ventilator accessories.

Certain ventilators, ventilator tubing connectors, and ventilator accessories are authorized for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.

All patients who are treated with authorized ventilators during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of Ventilators During the COVID-19 Pandemic

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of ventilators?

- Certain ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling have been authorized for emergency use.
- Ventilators found in the list of authorized products are authorized for use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.
- For each device, healthcare providers should review the instructions for use, including device specifications, reprocessing instructions (if applicable), and other labeling information.
- During the COVID-19 pandemic, certain authorized ventilators may be used to support multiple patients using a continuous ventilator splitter. Healthcare providers should review additional device specifications, labeling, and patient monitoring recommendations in these circumstances.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of ventilators?

Potential benefits of ventilators include:
- Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
- Life-supporting and potentially life-saving treatment

Potential risks of ventilators include:
- Device malfunctions or adverse events
- Potential infectious and mechanical complications from sharing one ventilator through the use of multiplexing adapters have not been studied, and therefore caution is advised
- Risks of modified ventilator devices have not been studied, and therefore caution is advised

- Risks associated with the potential reduced requirements for alarms and monitoring of patients
- Reduced familiarity of healthcare providers with novel technologies used to treat patients

What are the alternatives to traditional ventilators, and the known and potential benefits and risks of such products?

Alternatives to traditional ventilators that are authorized under this Emergency Use Authorization (EUA) include anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators.

Potential benefits of using alternatives to traditional ventilators include:

- Improved oxygenation and ventilation in the treatment of acute respiratory illness or difficulty breathing
- Life-supporting and potentially life-saving treatment

Potential risks of using alternatives to traditional ventilators include:

- A positive pressure breathing device cannot offer all of the support that a traditional mechanical ventilator can
- A positive pressure breathing device may expose others to aerosols that could be contagious
- Healthcare providers other than trained anesthesia providers may not be familiar with the operation of anesthesia equipment, and therefore should pay careful attention to the instructions for use to avoid use error

What is an EUA?

The United States FDA has made certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

Ventilators, ventilator tubing connectors, and ventilator accessories made available under an EUA have not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance, and labeling may be effective in treatment of patients during the COVID-19 pandemic.

The EUA for ventilators, ventilator tubing connectors, and ventilator accessories is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations