

# FACT SHEET FOR PATIENTS

Emergency Use of Ventilators During the COVID-19 Pandemic

March 24, 2020

Coronavirus  
Disease 2019  
(COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you treatment using a ventilator, anesthesia gas machine modified for use as a ventilator, or positive pressure breathing device modified for use as a ventilator (collectively referred to as “ventilators” in this Fact Sheet), ventilator tubing connectors, and/or ventilator accessory.

This Fact Sheet contains information to help you understand the benefits and risks of using ventilators, ventilator tubing connectors, and ventilator accessories for the treatment of patients during the COVID-19 pandemic. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

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- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
  - <https://www.cdc.gov/COVID19>
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## What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19, but it likely spreads to others when a person shows signs or

symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

## 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 under an Emergency Use Authorization (EUA) for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider.

A healthcare provider may choose to treat you with a ventilator if you have difficulty breathing, or other respiratory symptoms. During the COVID-19 pandemic, certain authorized ventilators may be used to support multiple patients using a continuous ventilator splitter when individual ventilators are not available, or preemptively to increase the potential of single-use ventilators for multiple patients simultaneously.

## 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 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 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

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- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
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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).

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

Potential benefits of ventilators include:

- Ventilator support may be effective in treating you if you have difficulty breathing, or other respiratory symptoms
- The use of a ventilator may help your condition improve and allow you to recover
- Life-supporting and potentially life-saving treatment

Potential risks of ventilators include:

- Modified ventilator devices and techniques may have new risks associated with them that have not been studied

## 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 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:

- The device may be effective in treating you if you have difficulty breathing, or other respiratory symptoms
- The device may help your condition improve and allow you to recover
- Life-supporting and potentially life-saving treatment

Potential risks of using alternatives to traditional ventilators include:

- A positive pressure breathing device cannot offer all the support a traditional mechanical ventilator can offer
- A positive pressure breathing device may expose others to aerosols that could be contagious
- Healthcare providers may not be familiar with the operation of the modified devices that are authorized under this EUA, which could lead to use error

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