

Information on Use of Ventilators and Other Respiratory Devices

Protecting Against COVID-19

The U.S. Food and Drug Administration (FDA) has provided [guidance](#) to expand the availability of ventilators and other respiratory devices and accessories.

Some highlights:

- Wherever possible, healthcare facilities should use FDA-cleared conventional/standard full featured ventilators when necessary to support patients with respiratory failure.
 - To expand availability, the FDA will not object to limited modifications to the indications, claims, or functionality, or to the hardware, software, or materials of FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency.
 - The policy applies only during the public health emergency.
- Possible changes to indications could include significant change/modification in design, material, chemical composition, energy source, or manufacturing process. Specific examples of products FDA will allow:
 - Use of powered emergency ventilators and anesthesia gas machines for patients needing mechanical ventilation.
 - Use of ventilators outside of their cleared environment for use. (Use of a ventilator in a healthcare facility when it is only cleared for use at home or during transport.)
 - Use of devices indicated for sleep apnea — including continuous positive airway pressure (CPAP) and Bilevel Positive Airway Pressure (BiPAP) devices — provided that appropriate design mitigations are in place to minimize aerosolization.
 - Use of oxygen concentrators for primary supply when medically necessary and clinically appropriate.
- Possible changes to indications, claims, or functionality of devices could be made without prior submission of a premarket notification. Examples of circumstances in which the FDA believes a modification would be allowed include:
 - Modifications to motors, batteries, or other electrical components.

- Material changes to components in the gas pathway or with other patient tissue contact.
 - Introduction of filtration to minimize aerosolization.
 - Software modifications intended to modify the ventilation parameters, including inspiratory pressure, tidal volumes, flow rates, positive end-expiratory pressure (PEEP), in accordance with an applicable device standard.
 - Software modifications implementing physiological closed loop (automated) algorithms for oxygen titration, when the algorithms/devices are the subject of an FDA-approved Investigational Device Exemption (IDE).
 - Hardware and/or software modifications allowing for remote monitoring and remote adjustment of ventilator parameters (such as adjustment of parameters from outside an isolation unit to avoid unnecessary exposures).
- The FDA will consider use of manufacturers of ventilatory support devices that are not currently legally marketed in the U.S. as well as manufacturers who have not previously manufactured medical devices. FDA will work with these manufacturers through its Emergency Use Authorization (EUA) process. The guidance includes specific information to send to the FDA, and all information and questions can be sent to: CDRH-COVID19-Ventilators@fda.hhs.gov.

For additional information, visit coronavirus.ohio.gov.

For answers to your COVID-19 questions, call 1-833-4-ASK-ODH (1-833-427-5634).

If you or a loved one are experiencing anxiety related to the coronavirus pandemic, help is available. Call the Disaster Distress Helpline at 1-800-985-5990 (1-800-846-8517 TTY); connect with a trained counselor through the Ohio Crisis Text Line by texting the keyword "4HOPE" to 741 741; or call the Ohio Department of Mental Health and Addiction Services help line at 1-877-275-6364 to find resources in your community.

CORONAVIRUS DISEASE 2019 Ohio

Department
of Health

Protect yourself and others from
COVID-19 by taking these precautions.

PREVENTION

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STAY HOME



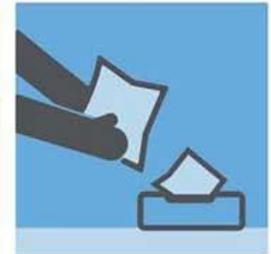
PRACTICE
SOCIAL
DISTANCING



GET ADEQUATE SLEEP
AND EAT WELL-
BALANCED
MEALS



WASH HANDS OFTEN
WITH WATER AND SOAP
(20 SECONDS
OR LONGER)



DRY HANDS WITH
A CLEAN TOWEL
OR AIR DRY
YOUR HANDS



COVER YOUR MOUTH
WITH A TISSUE OR
SLEEVE WHEN
COUGHING OR SNEEZING



AVOID TOUCHING
YOUR EYES, NOSE,
OR MOUTH WITH
UNWASHED HANDS
OR AFTER
TOUCHING SURFACES



CLEAN AND DISINFECT
"HIGH-TOUCH"
SURFACES OFTEN



CALL BEFORE VISITING
YOUR DOCTOR



PRACTICE GOOD
HYGIENE HABITS

For more information, visit: coronavirus.ohio.gov