

INSTRUCTIONS FOR USE

AerosolVE Device

Portable Negative Pressure Isolation & Procedural Tent System

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the AerosolVE Device, for use by healthcare providers (HCP) as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

Authorized non-transport use of the AerosolVE Device is only for airway management (e.g., intubation, extubation and airway suctioning), when performing any airway-related procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or continuous positive airway pressure/bi-level positive airway pressure (CPAP/BiPAP) mask use, airway suctioning, percussion and postural drainage). Authorized use of the AerosolVE Device is only within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), oxygen saturation (SpO₂%), end-tidal carbon dioxide (EtCO₂), if available throughout transport. The AerosolVE Device should only be used with a spontaneously breathing patient with air flow fan working, under direct observation, and with end-tidal CO₂ monitoring, if available. If end-tidal CO₂ monitoring is not available, then the use of the AerosolVE Device is limited to no longer than 30 minutes. For all authorized uses, the patient should always have supplemental oxygen during use of the AerosolVE Device. If intermittent use is needed, total duration of use is limited to up to fourteen (14) days.

The AerosolVE Device has not been FDA-approved or cleared for this use; the AerosolVE Device has been authorized for emergency use by FDA under an EUA. The AerosolVE Device has been authorized only for the duration of the COVID-19 public health emergency declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

HCP should follow these instructions, as well as procedures at their healthcare facility, to use the AerosolVE Device.



The instructions below are to assist in using the AerosolVE Device. The AerosolVE Device is an adjunctive protective barrier designed to mitigate risk to HCP. The AerosolVE Device is not meant to be a stand-alone unit of PPE. The AerosolVE Device should always be used with appropriate PPE and pursuant to the guidance of your institution.

All connections should be secured and checked frequently. Any time anyone is within the AerosolVE Device tent, direct observation is required. Inspect all of the AerosolVE Device components prior to use, to ensure they are working properly. Any signs of degradation or wear and tear of the AerosolVE Device must be promptly reported to Inspire Rx, LLC. In such case, the healthcare facility must not use the product on patients and must properly dispose of the AerosolVE Device.

WARNINGS

- When the AerosolVE Device is in use, patients should always receive supplemental oxygen.
- Remove the AerosolVE Device and use standard of care if there is difficulty visualizing or identifying anatomic landmarks or inability to intubate after the first try.
- Prolonged use of the AerosolVE Device may induce hypercarbia in a spontaneously breathing patient. The AerosolVE Device should only be used with a spontaneously breathing patient with air flow fan working, under direct observation, and with EtCO₂ monitoring, if available. If EtCO₂ monitoring is not available, then the use of the AerosolVE™ Device should be limited to no longer than 30 minutes with air flow fan on and under direct observation.
- Patient transport must only occur within a hospital setting for temporary transport with direct admission within the hospital in the presence of a registered nurse or physician. Maintenance of negative pressure with

adequate air flow must be assured. Patients must have continuous monitoring of SpO₂, vital signs, electrocardiogram (EKG), and EtCO₂, if available throughout transport.

- Patients with diminished hearing may have difficulty understanding the provider while inside the AerosolVE Device tent.
- When the device is accidentally folded, or the airflow inlets are blocked, this may result in patient injury.
- The system should be connected to an uninterruptible power supply to mitigate instances of power loss.
- The AerosolVE Device is not to be sealed around the patient and requires air flow into the tent to provide air flow through the high-efficiency particulate air (HEPA) filter.
- Do not exceed eight (8) 406 mm/16-inch-long direct patient access slits or four (4) 100 mm/4 inch holes, per tent.
- The AerosolVE Device fan should be frequently checked, to confirm airflow. When the fan is on, the fan outlet air flow indicator strips will flutter to provide a visual means to confirm air flow, which indicates the system is under negative pressure, and functioning as intended.
- If loss of negative pressure occurs during use, the AerosolVE Device tent should be removed.
- After use, the tent kit components should be disposed of following the hospital's biohazardous waste disposal procedures.
- The reusable fan and fan base should be cleaned and disinfected per the hospital's infection control protocols, in preparation for reuse.
- Components should not be heated above 130°F.

CONTRAINDICATIONS

The AerosolVE Device is contraindicated for use:

- On patients needing emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On patients with anticipated or known history of claustrophobia
- On patients with communication disorders that might interfere with clinical care
- On patients under the age of 18
- On bariatric patients
- On patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure
- On patients requiring procedures that involve exceeding the maximum direct access slits or holes as stated in this IFU
- In elderly care centers – it is only for use in a hospital environment
- In ambulance transport

The AerosolVE Device System includes the following Key Components:

AerosolVE Device Disposable Kit: P/N IN-200001 – For Non-Sterile, Single Patient Use Only

- ☐ **Tent:** Provides a fire retardant, clear vinyl covering over the patient, which allows for direct access patient access points and fresh air intake through openings.
- ☐ **Tent Base:** provides tent structure, interfaces to patient bed, and houses the HEPA filter/manifold; includes Patient ID label.
- ☐ **Exhaust Tubing:** carries HEPA-filtered air away from the patient
- ☐ **2 Tape Strips:** to secure exhaust tubing inlet/outlet
- ☐ **1 Airflow Indicator Strip:** attached to HEPA filter manifold

AerosolVE Device Fan Unit Kit: P/N IN-200002 - Reusable

- ☐ **Fan with Integral Base:** Creates negative pressure, high volume air flow within the system
- ☐ **2 Airflow Indicator Strips:** attached to Fan outlet



Aerosolve Device: Instructions for Use (IFU): P/N IN-110001

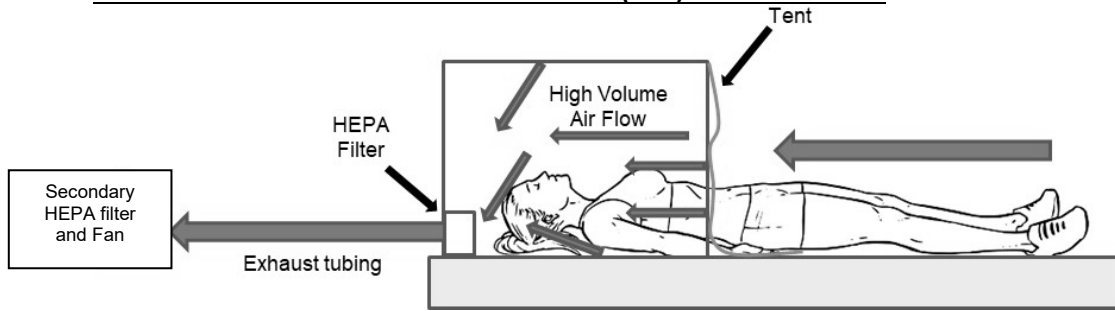


Figure 1: Aerosolve™ Device System Overview Schematic

A diagram of the airflow is shown in below:

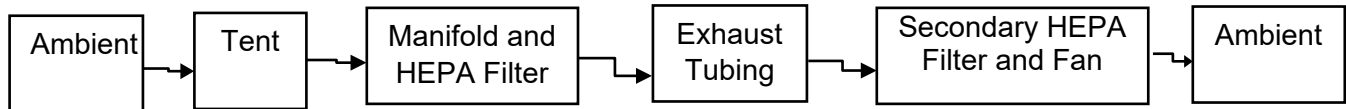


Figure 2: Aerosolve™ Device Airflow schema

INSTRUCTIONS FOR USE



Aerosolve™ Device System

CAUTION:

The disposable Aerosolve Device tent kit with integral HEPA filter is for non-sterile, single-patient use only, for intermittent use, as needed, for up to fourteen (14) days. The Aerosolve Device is to be used on patients with suspected or confirmed COVID-19 ONLY AFTER they have begun receiving medical care at the hospital. The patient's body temperature, CO₂ level and oxygen levels are to be monitored by HCP caring for the patient with suspected or confirmed COVID-19 prior to and during clinical use of the Aerosolve Device. The HCP should wait at least 2 minutes after the patient coughs or sneezes, or after performing airway management procedures before removing the Aerosolve Device tent from the patient. This 2-minute waiting period helps to ensure aerosols are cleared prior to opening the Aerosolve Device tent.

1. Remove disposable tent unit and reusable fan unit from the packaging.
2. Carefully place tent base over patient on bed.
3. Lift hoops and rotate stand brackets to support hoops on the base, creating the canopy.



4. Insert exhaust hose end through canopy.
5. Then, insert into HEPA filter outlet duct.

NOTE: An airtight seal is not necessary.



6. Remove the white fan inlet cover (it is attached to the fan unit with a tether), insert the other end of the exhaust hose into the fan inlet on the top of the fan unit.

NOTE: An airtight seal is not necessary.

7. Plug the fan into a standard 120 VAC power main.



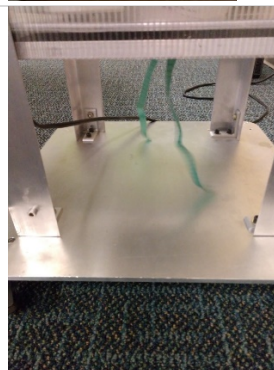
8. When fan is OFF, the airflow indicator strip will drape loosely over the face of the HEPA filter inlet



9. When the fan is ON, the HEPA filter air flow indicator is drawn tight against the HEPA filter inlet. This allows the user to confirm the Aerosolve Device's negative pressure environment is operational.



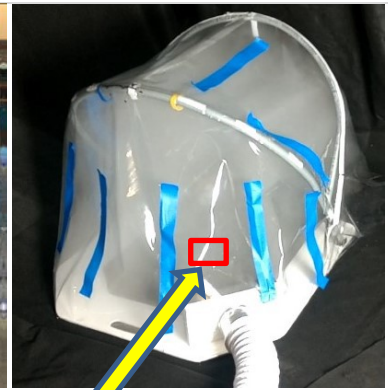
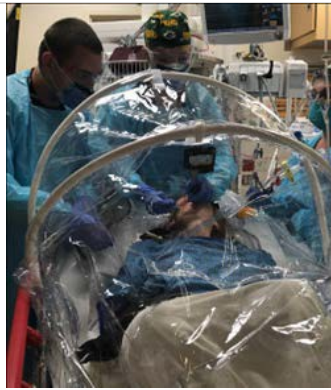
10. When the fan is ON, the Fan Unit air flow indicators will flutter at the bottom of the Fan Unit



11. The health care provider can then cut slits* into the vinyl material of the tent, where desired, to provide full and direct patient access.

Direct patient access may alternatively be provided by creating a 100 mm/4-inch diameter hole in place of 2 each, 406 mm/16 inch slits.

Write the patient's *Name/ID*, *Date of First Use* and *Replace by Date* on the label located on the outside of the tent, near the HEPA filter manifold.



PATIENT NAME / ID: _____
DATE of FIRST USE: _____
REPLACE BY DATE: _____
(On or before day 14)

NOTE: Each tent can accommodate up to eight (8), 408 mm/16-inch-long slits or four (4) 100 mm/4-inch diameter holes. The blue strips on the tent image (above, to the right), depicts example slit location / size configurations chosen by HCP.

12. For Transport within the Hospital: The AerosolVE Device can be used to transport patients when used in conjunction with a hospital grade uninterrupted power supply (UPS).
13. To prepare the AerosolVE Device for patient transport:
- Verify that the UPS is attached to the patient transport gurney
 - Verify that the UPS is turned on and in a fully charged state
 - Unplug the Fan from the wall outlet
 - Plug the Fan into the UPS
 - Note the time
- f. If an outlet is available at the destination, note the time and plug the UPS in for the duration of the procedure
- g. Ensure that the UPS is only in use for a predetermined amount of time - based on the hospital's UPS - typically, not more than 50 minutes.
14. When use of the AerosolVE Device is complete (not more than 14 days of intermittent use), the disposable tent kit component should be disposed of following the hospital's biohazardous waste disposal procedures.
15. The exterior of the reusable fan should be cleaned and disinfected per the hospital's infection control protocols, and the white cap should be placed on the fan inlet opening in preparation for reuse.

Emergency Patient Access Instructions:

1. Emergency access to the patient can be achieved quickly by lifting the distal tent curtain from the patient's waist (Figure 1) and rotating the smaller hoop proximally, toward the head of the bed (Figure 2). Patient may then easily exit bed, if needed (Figure 3).

Figure 1



Figure 2



Figure 3



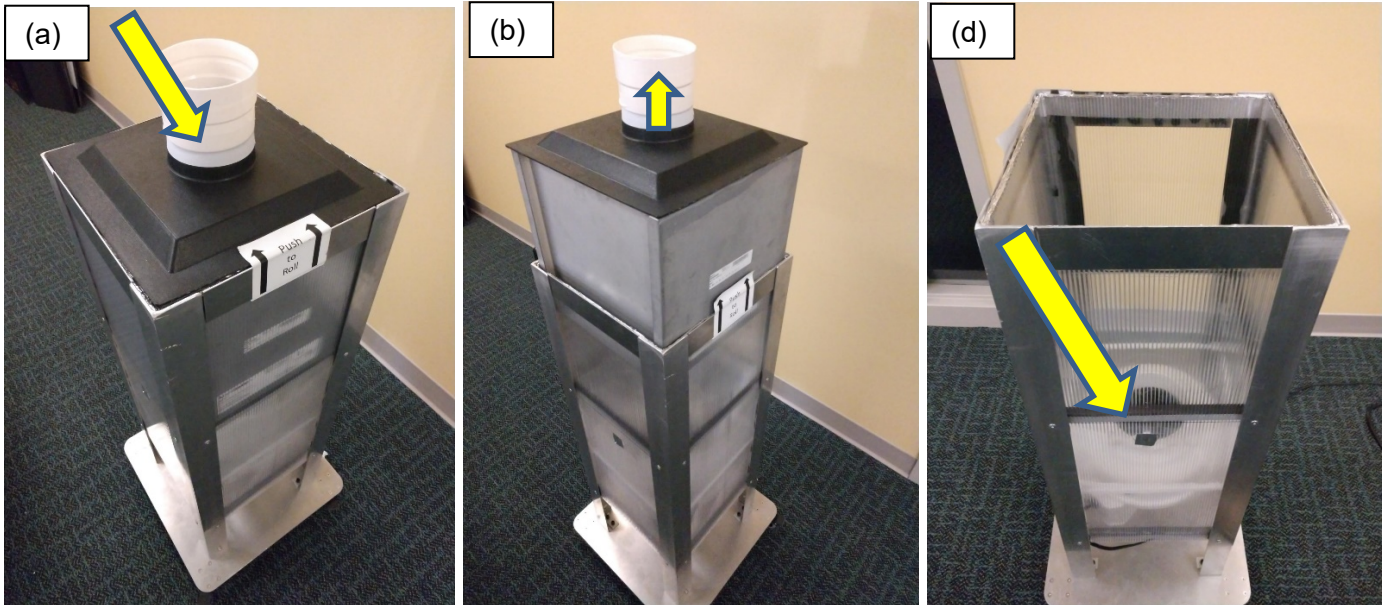
Emergency AerosolVE Device Removal Instructions:

1. In the event that emergency removal of the AerosolVE Device is required, verify that no lines or hoses run through the tent cover or above the tent base (all lines and hoses should run between the base and the bed mattress in normal use)
2. Disconnect the airflow duct hose from the HEPA filter manifold, with a gentle tug
3. Grasp the base of the tent by the hand-hold near the patient's head, and pull the tent away from the patient toward the proximal end of the bed, until clear of the patient
4. Place the AerosolVE Device tent aside for further proper disposal (see step 15 of these instructions) and unplug the fan.

AerosOLVE Device System Maintenance Requirements:

1. The Fan Unit high-flow HEPA filter is to be replaced on a yearly basis if the system has been in use
2. If not in use the Fan Unit and HEPA filter can be placed in storage for up to 5 years without replacing filter
3. The Fan Unit high-flow HEPA filter is permanently attached to the intake manifold and will be replaced as a unit
4. To replace the filter:
 - a. While wearing personal protective equipment, remove the white cap and grasp the black plastic manifold
 - b. Gently pull the filter up and out of the fan unit
 - c. Dispose of the filter following the hospital's biohazardous waste disposal procedures.
 - d. Insert the new filter and manifold into the top of the fan unit so it rests against the bottom seal in the Fan Unit

NOTE: An airtight seal is not necessary.



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Patents Pending