

The Airborne Isolation Hood

Instructions for Health Care Facilities

Product Name: The Airborne Isolation Hood

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for Airborne Isolation Hood, for use by healthcare provider (HCP) as an additional 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, when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

Authorized non-transport use of Airborne Isolation Hood is only for definitive airway management (e.g., intubation, extubation and suctioning airways), or when performing any airway-related medical 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 Airborne Isolation Hood during patient transport 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), SpO₂% (oxygen saturation), End-tidal carbon dioxide (EtCO₂) if available throughout transport. For all authorized uses, the patient should always have supplemental oxygen during use of the Airborne Isolation Hood. Limit the duration of transport to 30 minutes if End-Tidal CO₂ monitoring is not available with inline blower fan on and under direct observation.

Airborne Isolation Hood has not been FDA-approved or cleared for this use; Airborne Isolation Hood has been authorized for emergency use by FDA under an EUA. Airborne Isolation Hood 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 authorization is terminated or revoked sooner.

HCP should follow these instructions, as well as procedures at their healthcare facility to use the Airborne Isolation Hood.



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

All connections should be tightly secured and checked frequently. Any time anyone is within

Manufactured for and Distributed by:

Aspire Air, Inc.

Minneapolis, MN 55442

612-518-7064

Airborne Isolation Hood, **direct observation is required. Inspect** Airborne Isolation Hood **prior to use. Any wear/tear of the chamber or other signs of degradation on** Airborne Isolation Hood **must promptly be reported to** Airborne Isolation Hood **Medical Solutions Inc. The healthcare facility must not use on patients and must dispose of such an** Airborne Isolation Hood. **Rx Only**

WARNINGS:

- Flammability of Airborne Isolation Hood has not been tested. No interventions that could create a spark or be a flammable source should be used within Airborne Isolation Hood.
- Remove Airborne Isolation Hood 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 Airborne Isolation Hood may induce hypercarbia in a spontaneously breathing patient. Airborne Isolation Hood should be used with medical air flow and suction both on and working, under direct observation, and with EtCO₂ monitoring if available.
- Patient transport must only occur within a hospital setting for temporary transfer 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. All patients should be on supplemental oxygen. Patients must have continuous monitoring of Sp-O₂, vital signs, EKG, and EtCO₂ if available during transport.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety.
- When using Airborne Isolation Hood, patients should always be receiving supplemental oxygen.
- Patients with diminished hearing may have difficulty understanding the provider while inside Airborne Isolation Hood.
- Airborne Isolation Hood is a single-use device and should be disposed of following the disposal instructions after use.

CONTRAINDICATIONS:

Airborne Isolation Hood is not authorized:

- 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 and/or confined space anxiety
- 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

Manufactured for and Distributed by:

Aspire Air, Inc.

Minneapolis, MN 55442

612-518-7064

- On patients in elderly care centers (non-hospital environment)
- On patients in ambulance transport
- Patients who are morbidly obese
- Pregnant women in the 2nd or 3rd trimester
- Individuals with certain communication disorders
- Patients with other anatomical abnormalities
- Children under 45 pounds (lbs.)

The Airborne Isolation Hood Instructions for Use

Device Description:

The Airborne Isolation Hood provides respiratory isolation of patients to decrease risk of spread of COVID-19 to healthcare personnel (HCP) and visiting family.

The Airborne Isolation Hood is a clear, rigid chamber made of transparent plastic that covers a patient's head and upper body and uses negative pressure airflow to filter respiratory particles from the chamber, through a high-efficiency particulate air (HEPA) filter, to isolate those outside the hood from the exhalation and respiratory secretions of the patient inside the hood. The hood is a protective barrier enclosure, with negative pressure and sealed ports, utilizing silicon gaskets, through which HCP hands are passed to perform medical procedures, for isolated access to the patient. There is also a small cutout at the bottom of the hood with a silicone barrier that acts as a cord feedthrough so that the hood can be removed without tangling cords attached to the patient. The hood has four tie-down points mounted to the polycarbonate panels and is attached to the bed with two black rubber elastic cords with metallic "S" hooks on each end. All components are disposable. During transport, the hood must be used with a battery pack adequate to power the blower.

System Components

- Respiratory Isolation Hood
- Exhaust hose-Clear Blo-R-Vac Duct Hose 4" ID; aluminum coated flexible hosing
- Blower Fan, 8-speed setting blower (AC Infinity CLOUDLINE S8)
- Levoit Air Purifier Filter; LV-H132XR
- Electrical Outlet/Power Source
- Cleaning supplies (Isopropyl Alcohol or similar) per hospital protocol
- Transport after use on a hospital owned cart and securement devices (e.g., bungee cords or nylon rope)
- Optional plastic drape for covering for duct

Note: The AC Infinity CLOUDLINE S8 Blower has an 8-speed setting, and the speed can be controlled currently by a connected remote.

Storage Instructions

- It is recommended that the Airborne Isolation Hood be stored on a hospital transport cart in a storage area near the location of its intended use.

Manufactured for and Distributed by:

Aspire Air, Inc.

Minneapolis, MN 55442

612-518-7064

- Transport per local policies for prescribed sanitation and reuse.
- The Airborne Isolation Hood should be cleaned in the patient room after use, following hospital instructions.
- The blower fan, exhaust hose and HEPA filter may remain connected to the Airborne Isolation Hood when it is not in use. These can be placed on a shelf on the cart below the hood, or inside the hood, during transport to storage, and while being stored.

Sanitization Instructions

1. For cleaning/disinfection, the sponsor referred to the CDC's recommendation for hospitals/facilities - <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>. The disinfectant used should be from the CDC's list of disinfectants for COVID19 found here: <https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19>
2. For cleaning, after each patient use, recommend spraying all inner and outer surfaces with approved disinfectant for surfaces per local guidelines (e.g. isopropyl alcohol-based disinfectant, such as Cavicide or Peroxide Multi Surface Cleaner and Disinfectant). Follow instructions per hospital requirements on disinfectant specific contact times.
3. Alternatively, after each patient use, wear gloves and wipe down the plastic outside surfaces, inside surfaces, and iris ports with disinfecting wipes or isopropyl alcohol such as Cavicide as used by the institution. All materials are isopropyl alcohol and disinfecting wipe compatible.
4. If possible, soil remains, repeat the procedure. Let all parts sit visibly wet for at least 2 minutes. Allow all parts to air dry. Remove and discard gloves.
5. For disinfection, spray all disassembled parts with a hospital approved EPA-registered isopropyl alcohol-based disinfectant, such as Cavicide or Peroxide Multi Surface Cleaner and Disinfectant. Let all parts sit visibly wet for at least the contact time indicated in the labeling (2 minutes for Cavicide) before allowing all parts to air dry. See List N: Disinfectants for Use Against COVID-19: <https://www.epa.gov/pesticide-registration/list-n-advanced-search-page-disinfectants-coronavirus-covid-19>.
6. Do not use harsh chemicals or abrasives to clean. Do not apply heat. Do not use high concentrations of cleaning agents than recommended as this may degrade components.
7. Store device at room temperature and a relative humidity between 40-60%. Store in a container, if possible, to avoid dust and grease build up on the device.
 - The blower fan, exhaust hose (duct) and HEPA filter may remain connected to the Airborne Isolation Hood when it is not in use. These can be placed on a shelf on the cart below the hood, or inside the hood, during transport to storage, and while being stored.
8. The exposed surfaces on the blower may be wiped down (same wipes) after each use. There is no need to take anything apart in the blower.
9. It is recommended that the connections remain intact unless changing out filter or tubing. Do not put hands in the interior space of the tubing or open the filter housing, to reduce the risk of contaminating this space.
10. It is recommended the filter and exhaust hose (duct) be replaced every 3 months.

Use Instructions

To use this portable Isolation hood, have the patient positioned appropriately and place all supplies on

Manufactured for and Distributed by:

Aspire Air, Inc.

Minneapolis, MN 55442

612-518-7064

the bed next to the patient within the area of the enclosure. Initial installation of the system above a patient should be done with adequate PPE.

1. Place the enclosure on the bed over the patient.
2. Ensure all lines pass through cord feedthroughs or the open face of the box (towards patient's feet).
3. *Note: Please do not insert wires/tubing through the iris ports to avoid tethering (to allow easy emergency removal of the protective hood if required)*
4. Plug into electrical outlet and turn on blower system. (Fan power setting of 4 for efficacy)
5. Ensure bed attachments are in place if there is a need to elevate the head of the bed.

Removal Instructions

1. While wearing adequate PPE, wait 30 seconds after treatment before removing the hood. Aerosol will be cleared at a 99.9% reduction at 27.19 seconds when blower is at level 4 and 12.11 seconds at when blower is at level 8.
2. Turn off the blower system, unplug the device from the electrical outlet, disconnect the in-line blower.
3. Detach the bed attachments from the bed
4. Ensure all wires/tubing are free of the unit
5. Lift and raise the unit straight up off the bed
6. Place on transport cart for in-room cleaning and then transport per local policies for prescribed sanitation and reuse

Disassembly and Removal of Blower Motor and Duct

If the Blower Motor and/or duct need to be detached from the Airborne Isolation Hood:

1. Loosen clamp at each end of the exhaust hose (duct) with a screwdriver.
2. Gently separate the exhaust hose (duct) from the blower motor and the hood.
3. Wipe the blower duct at the connection point with disinfecting wipes or isopropyl alcohol.
4. Wipe the exterior of the tubing with disinfecting wipes or isopropyl alcohol. The interior of the tubing does not need to be cleaned. It is recommended that the tubing be replaced every 3 months.
5. Wipe the exterior of the blower with disinfecting wipes or isopropyl alcohol.
6. If the filter housing is detached from the hood, wipe the exterior and exposed interior of the filter housing with disinfecting wipes or isopropyl alcohol. The filter housing and interior filter should not be opened unless to change the filter. It is recommended that the filter be changed every 3 months.

Replacement of Filter and Duct

- It is recommended the filter and exhaust hose (duct) be replaced every 3 months.
- The replacement for the HEPA filter is a Levoit Air Purifier Replacement Filter; LV-H132XR. The filter can be removed from the filter housing by pulling on the side tabs of the filter, which are visible upon opening the housing thumb screws and opening the housing. Be sure to orient the

Manufactured for and Distributed by:

Aspire Air, Inc.

Minneapolis, MN 55442

612-518-7064

replacement filter in the proper direction. The filter can be directly installed without modification needed.

- The replacement for the exhaust hose is a 6-foot length of Clear Blo-R-Vac Duct Hose 4" ID.
- Replacement components are commercially available, and can be sourced directly from Aspire Air, Inc, or from a commercial supplier.