INSTRUCTIONS FOR HEALTHCARE FACILITIES:

Assembly, Use, Disassembly, and Cleaning/Disinfection of the Individual Biocontainment Unit (hereafter IBU)

HCP must follow these instructions and the procedures at their healthcare facility when using the IBU.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the IBU, to be used by healthcare providers (HCP) as an additional layer of barrier protection 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 medical procedures, or during transport of such patients during the COVID-19 pandemic. It is for use in addition to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE. The IBU has neither been FDA cleared or approved, but has been authorized by FDA under an EUA. The IBU is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use during the COVID-19 outbreak, 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.

The IBU is a negative pressure, rigid chamber made of transparent materials (e.g., transparent polycarbonate sheet) with aluminum framing and is designed to cover a patient's head and upper body. The IBU attaches to a standard hospital or surgical bed. A single sealable access window is built into the rear of the isolation chamber, which allows for isolated patient access. The negative pressure environment is generated within the Biocontainment Unit via 510(k)-cleared smoke evacuator device. Regardless of the negative pressure source, an in-line ultra-low particulate air/high-efficiency particulate air (ULPA/HEPA) filter is present to filter particulates ≥ 99.99% with respect to the isolation patient chamber. This product should be removed if they impede ability to care for or perform a medical procedure on a patient, or impede the communication between HCP and patients.

The device is for use in addition to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

Authorized use of the IBU during patient transport is 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 EKG, Pulse Oxygen Saturation (SpO2), End-Tidal CO_2 monitoring, if available throughout transport and patient should always have supplemental oxygen during use of the IBU. To transport patients, the IBU must maintain negative pressure via negative pressure source connected to the isolation chamber, all being transported in tandem with the patient.

Authorized non-transport use of IBU is only for airway management (e.g., intubation, extubation, and suctioning airways), or when performing any aerosol-generating 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).

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

<u>Inspect the IBU prior to use.</u> Any wear/tear of the chamber or other signs of degradation on the IBU must promptly be reported to Dr. J. Peter Rubin (the Product Sponsor/EUA holder and distributor) and Innovative Electronics Corporation (the manufacturer and distributor). The healthcare facility must not use on patients and must dispose of such IBU.

All connections should be tightly secured and checked frequently. Anytime anyone is within the IBU, direct observation is required.

Caution: Federal law restricts this device to sale by or on the order of a physician

Please note that all Cautions and Warnings should be reviewed and understood prior to any use of this equipment.

CONTRAINDICATIONS:

The IBU is not authorized for the following uses:

- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with communication disorders that might interfere with clinical care
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On children under 45 pounds (lbs.)

WARNINGS:

- Please read this manual thoroughly. Familiarize yourself, your staff, and any other personnel responsible for use and/or maintenance of this system with the contents of this manual prior to using this equipment.
- Inspect each component, set up, and then test the equipment prior patient use. Disconnect the unit from the electrical outlet prior to inspecting system components.
- The IBU is intended and suitable only for the applications that are mentioned in the operating instructions. **This device does not replace standard PPE.** Always wear appropriate PPE when using this device with a patient. To maximize HCP safety, the Translucent Drape should remain affixed to the Biocontainment Box and be securely tucked under the patient.
- Flammability of the IBU has not been tested. No interventions that could create a spark or be a flammable source must be used within the IBU. The IBU must not be operated in the presence of flammable or explosive gases. Remove the IBU and use standard of care if there is difficulty visualizing or identifying anatomic landmarks or inability to intubate.
- Prolonged use of the IBU may induce hypercarbia in a spontaneously breathing patient. The IBU must only be used with a spontaneously breathing patient with medical air flow and suction both on and 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 IBU must be limited to no more than a short duration of time with medical air flow and suction both on and under direct observation.

- All patients within the device enclosure must receive supplemental oxygen.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety.
- The Access Window at the rear of the Biocontainment Unit must *not* be opened when the Biocontainment Unit is pitched at an angle.
- To stabilize the Biocontainment Unit and prevent it from motion during a procedure, it must be securely fastened to a bed, gurney, or other stable structure that is nearby.
- To maximize patient safety, the vacuum tubing should not come into direct contact with the patient.
- Care must be taken to route the power cord, evacuation tubing, and any other accessories as to not cause a tripping hazard or crimping of cords.
- The vacuum source should not be used adjacent to or stacked with other equipment.
- Observe patient monitoring devices and wearable or implantable patient devices for interference from the vacuum source motors frequently while the unit motors are operating and after any significant change in distance of devices and cables from vacuum source motors.
- 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 must be receiving supplemental oxygen. Patients must have continuous monitoring of SpO2, vital signs, EKG, and End-tidal CO2 if available during transport.
- Please dispose of any components of this system according to your local codes or regulations and hospital policy. The filters may be disposed of or incinerated, whichever is appropriate for your institution.

When using with Buffalo Smoke Evacuators:

- If the smoke evacuator produces a strong vacuum, adjust the airflow to prevent suction of materials and specimens.
- The BUFFALO FILTER ViroSafe® filters and single-use accessories are completely disposable.
- The use of ACCESSORIES other than those specified by BUFFALO FILTER or sold by BUFFALO FILTER as replacement parts for internal components, may result in increased emissions or decreased immunity of the Turbo Auto-Sense™.

1. Declarations of Conformity

The IBU is a novel product. Therefore, the product is manufactured in conformance with the design in IBU Drawing Number IBU-BB-001.

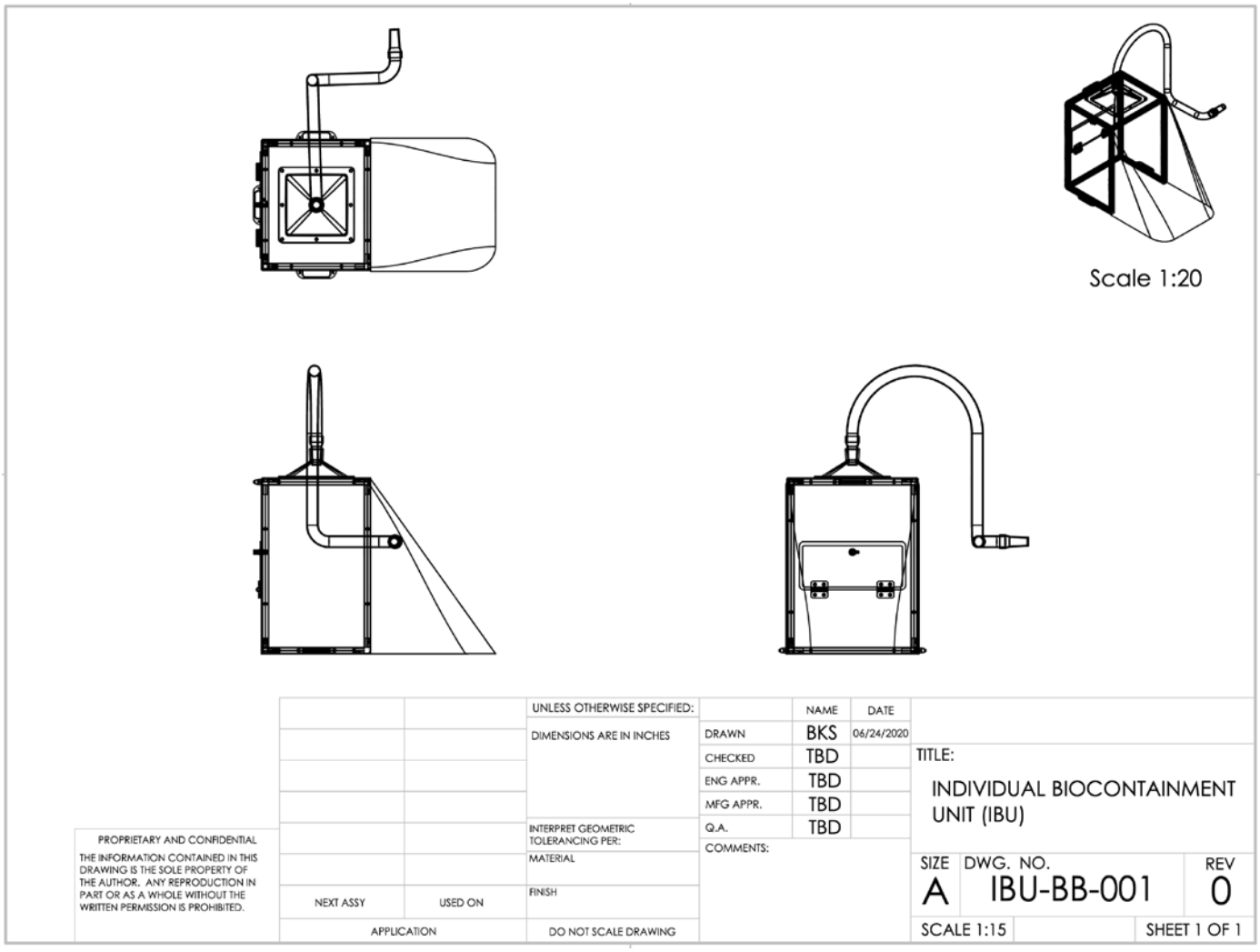


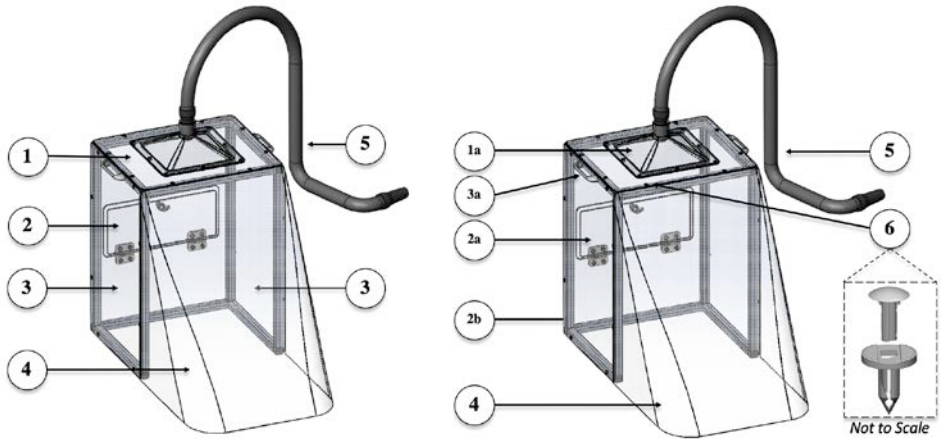
Figure 1. IBU General Assembly Drawing.

2. Facility Requirements (as applicable)

Standard electrical outlet conforming to applicable US Federal, State, and Local codes for healthcare systems. Environmental controls to reduce transmission: Device provides a localized negative pressure environment around the patient head/airway and containment.

3. Protocol for Cleaning the IBU

Please check each component, assemble, and test the unit before using it to ensure that no damage has occurred in transit.



1. Top Panel Assembly
   a. Pyramidal Collector
2. Rear Panel Assembly
   a. Access Window
   b. Rear Handle
3. Side Panel Assembly
   a. Side Handle
4. Translucent Drape
5. Pre-Filter Tubing
6. Fasteners

Figure 2. IBU images with callouts of subassemblies and key functional components.

DO NOT AUTOCLAVE

1. **Put on clean gloves and appropriate PPE** before beginning the cleaning and disinfection procedure.
2. Ensure the negative pressure source is turned off and unplugged.
3. Ensure patient and any suction hoses are removed from the device.
4. Remove and discard the pre-filter tubing from the collector and the negative pressure source. **NOTE**: This component is potentially biohazardous and should be disposed of accordingly.
5. Remove and discard the translucent drape. **NOTE**: This component is potentially biohazardous and should be disposed of accordingly.
6. If the device needs to be moved prior to cleaning,
   a. Close and secure the access window at the rear of the IBU,
   b. Remove any straps and/or tie-downs that are affixed to the IBU,
   c. Pick up device with handles on the lateral side and move to the final cleaning location.
   d. **Handle the IBU with care.** Do not drop, strike, or place heavy objects onto the IBU.
   e. Continue cleaning procedure.
7. Establish a checklist to track the cleaning of the individual components and subassemblies of the IBU.

Fig 3 Ref Number	Description	Quantity	Material
1	Top panel assembly	1	Polycarbonate; aluminum
2	Rear panel assembly	1	Polycarbonate; aluminum
3	Side panel assembly	2	Polycarbonate; aluminum
4	Screws	8	Stainless steel

5	Fasteners	17	Nylon

8. Disassemble each of the panel assemblies by removing the fasteners from their insertions into the frame. Consult the Parts List to ensure all parts are cleaned.
    a. Remove the thirty-two (32) fasteners from the each of the Panel Assemblies. This may be done by wedging a flathead screwdriver in between the two nylon components and applying a gentle force to remove the inner nylon fastening piece. Once the inner-most piece of the fastener is removed, the outer spike of the fastener that contacts the polycarbonate can then be pulled out.
    b. Remove the polycarbonate panels from the aluminum scaffold and disassemble the scaffold connector pieces.
    c. Remove the eight (8) screws securing the Pyramidal collector to the Top Panel Assembly using a screwdriver.
9. For cleaning, dispense a towelette of Cavicide wipe or other hospital-approved EPA-registered quaternary ammonium compound/isopropyl alcohol-based hospital disinfectant wipe. Wipe clean the inner and outer surfaces of each of the Assemblies and their respective components to remove soiling. Use at least one wipe per inner and outer surfaces.
10. If visible soiling 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.
11. For disinfection, spray all disassembled parts with a hospital-approved EPA-registered isopropyl alcohol-based disinfectant, such as Cavicide. **Let all parts sit visibly wet for at least the contact time indicated on the disinfectant labeling** (i.e., 2 minutes for Cavicide) before allowing all parts to air dry. See List N: Disinfectants for Use Against SARS-CoV-2 https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.
12. If visible soiling remains, repeat the cleaning and disinfection procedures.
13. Reassemble the IBU and inspect it as described below under System Maintenance and Routine Inspection.
14. Do not use harsh chemicals or abrasives to clean. Do not apply heat. Do not use high concentrations of ammonium in excess of 20% as this may degrade components.
15. Store device at room temperature and a relative humidity between 40-60%. Store in a container, if possible, to avoid foreign contaminants (e.g., dust, grease) from accumulating on the device.
16. **All external surfaces of the negative pressure-generating source should be cleaned and disinfected. If the negative pressure-generating sources require cleaning and/or disinfection (i.e., if the negative pressure source is suspected of collecting liquids):**
    a. For cleaning and/disinfection of the Buffalo PlumeSafe, Buffalo ViroVac, and the Stryker Neptune, refer to their respective instructional information for appropriate procedures.

    For cleaning the *outer surfaces* of the vacuum source and/or the Atrix ULPA filter, repeat the cleaning and disinfection steps listed above. **NOTE: DO NOT expose any internal compartments of either the vacuum source or the Atrix Filter to chemical cleaners or disinfectants.**

4. Parts, Maintenance, and Shelf-Life Information

Parts List:
When totally assembled *without* a negative pressure-generating source, the IBU Assembly consists of 107 individual parts.

Fig 3 Ref Number	Description	Quantity	Material
1	Top Panel Assembly		
	Top Panel	1	Polycarbonate
1a	Pyramidal Collector	1	Polycarbonate
	Fastening Bolt (Pyramidal Collector)	8	Stainless Steel
	Fastening Nut (Pyramidal Collector)	8	Stainless Steel
	Scaffolding Parts	4	Aluminum
2	Rear Panel Assembly		Polycarbonate; aluminum
	Rear Panel	1	Polycarbonate
	3-Way Connector	4	Nylon
2b	Handle	1	(ABS) Acrylonitrile butadiene styrene
	Handle Bolt	2	Stainless Steel
	Scaffolding Parts	4	Aluminum
	Access Window	1	Polycarbonate
	Window Hinge	2	Stainless Steel
	Fastening Bolts (for Window Hinge)	8	Stainless Steel
	Acorn Nuts (for Window Hinge)	4	Stainless Steel
	Window Hinge Spacer	2	Polycarbonate
	Window Latch	1	Stainless Steel
3	Side panel assembly		Polycarbonate; aluminum
	Side Panel	2	Polycarbonate
	3-Way Connector	2	Nylon
	2-Way Connector	2	Nylon
3b	Handle	2	(ABS) Acrylonitrile butadiene styrene
	Handle Bolt	4	Stainless Steel
	Scaffolding Parts	8	Aluminum
4	Translucent Drape	1	Polyethylene
5	Pre-Filter Tubing	1	PVC (polyvinyl chloride)
	Tubing Adapter, (for 7/8” tubing)	1	Polycarbonate
6	Fasteners	17	Nylon

System Maintenance and Routine Inspection:
Routine inspection and preventative maintenance should be performed in between patient usages. It is recommended that periodic inspection and performance testing be performed by a qualified Biomedical Technician to ensure the continued safe and effective operation of the IBU and its respective negative pressure-generating source.

The IBU should be visually inspected after each patient use. This inspection should include checks for:

- Proper mating, cleanliness and absence of damage to Biocontainment Unit fasteners, including the latch of the Access Window.
- Proper mating, cleanliness, and absence of damage to the filter.
- Structural integrity of all tubing and absence of punctures, gaps, or holes.
- Presence of debris within inlet of tubing.
- Obvious external or internal damage to any component of the system.
- Damage to the power plug or power inlet module.
- Damage to the power cord.

For additional details on maintenance of the respective negative pressure-generating source, refer to the appropriate manufacturer.

Please contact Atrix Customer Service to purchase the following accessories:

- ULPA Filters

Please contact BUFFALO FILTER Customer Service to purchase the following accessories:

- Replacement Filters
- EZ Link® Remote Activator
- Hoses, Tubing, Laparoscopic Kits, Adapters, Wands & Other Accessories

Please contact Stryker Customer Service to purchase the required accessories

- Replacement Filters
- Hoses, Tubing, Adapters & Other Accessories

System Repair

All repairs should be performed by technical personnel designated by the healthcare system or by an authorized manufacturer.

Maintenance by Manufacturer

All assemblies have been designed to be replaced if necessary – contact Innovative Electronics Corporation, the IBU Manufacturer, for replacements. The IBU, if no longer useable or serviceable, should be disposed of as biohazardous waste.

Consumable and Replacement Parts

The Pre-Filter Tubing and the Translucent Drape are designed for single use only.

Any fastening components (e.g., bolts, screws, nylon fasteners) should be replaced immediately if lost or worn. The paneling or scaffolding should be immediately replaced if lost, worn, damaged or warped. **NOTE: A lack of seal due to panel or scaffold damage may compromise the negative pressure environment.** All assemblies have been designed to be replaced, if necessary – contact an approved IBU Manufacturer for replacements.

5. CAUTIONS

Cautions regarding the device:

- Handle device with care. Do not drop. Do not strike or impact. Do not place heavy objects on device.
- Negative pressure sources compatible with this system are exclusive to those listed here.
- The device is rigid. Care should be taken when placing of the pre-filter tubing and when negative pressure is being generated such that the tube does not become blocked.
- The Access Window at the rear of the Biocontainment Box should be kept closed as much as is reasonably possible to maximize the vacuum pressure.
- The installation of the vacuum component must be performed such that the exhaust vent is not obstructed. Failure to properly install the unit may cause reduced performance, damage and/or cause the system to be inoperable and may void the warranty.
    - *For Buffalo Smoke Evacuators*: the exhaust vent is located on the bottom of the system.
    - *For Stryker Neptune Smoke Evacuators*: the exhaust vent is located on the bottom of the system.
    - *For Other Vacuum Sources*: identify location of the exhaust vent from the labeling.
- Do not block either the tubing or the filter. If either becomes occluded or significantly restricted, the motor/blower may overheat and cause the unit to fail.
- Failure to change the filter may result in decreased efficiency and contamination of the electric motor, vacuum pump, and sound absorbing media within the unit. *For Buffalo Smoke Evacuators*, the ViroSafe® Filter should be changed according to the life of the filter, and should not be used for more than the time specified for each filter.
- This device is not intended for evacuation of fluid. Attempting to evacuate fluid may cause filter blockage and electrical damage.
- The ambient temperature during operation must be kept between 50°F to 104°F (10°C to 40°C).
- The relative humidity during operation must be kept between 10% to 75%.
- An atmospheric pressure range of 700 hPa to 1,060 hPa. Storage environmental ambient temperature 14°F to140°F (-10°C to 60°C). Storage environmental relative humidity: 10% to 75%.
- Use only with the power cord provided and always plug into a grounded outlet.
- Do not use harsh chemicals or abrasives to clean. Please use chemicals from the list of List N: Disinfectants for Use Against SARS-CoV-2 https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.
- **Do not apply heat. Do not autoclave.**

When using with Buffalo Smoke Evacuators:

- Using any other filter or accessory not supplied by BUFFALO FILTER may cause damage and/or cause the system to be inoperable and may void the warranty.
- There are no user serviceable components in the Turbo Auto-Sense™ Smoke Evacuation System(s).
- Refer service to qualified service personnel.

When using with Stryker Neptune Smoke Evacuators:

- Using any other filter or accessory not supplied by Stryker may cause damage and/or cause the system to be inoperable and may void the warranty.
- Refer service to qualified service personnel.

When using with other vacuum sources:

- A vacuum source with an affixed ULPA filter, such as a surgical smoke evacuator, where the vacuum source generates a minimum flow rate of 25 cubic feet per minute (CFM) through a hose of at least 7/8" internal diameter (ID).
- The vacuum source should not be operated with a filter within the wet/dry container.
- The vacuum source can be operated under battery power. Ensure the battery is fully charged in between usages.

Cautions related to patients:

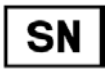
- Patients shall be monitored at all times if left in the device to verify air flow into the device, thermoregulation, and shall be monitored for discomfort, irritation, or other medical conditions.
- Patients in the device should be checked regularly to look for potential areas where the device may be providing discomfort, restricting blood flow, or creating an area of irritation. The device body shroud can be placed over clothing, fabric, towels, or sheets to increase comfort to the patient.
- When moving the device with a patient inside, negative pressure should be activated at all times and the Access Window at the rear of the Biocontainment Unit should be kept closed to maximize the vacuum pressure within the Biocontainment Unit.
- When under negative pressure, any surgical barriers may potentially inhibit the flow of air into the device.
- Once the patient is intubated or the airway of the patient no longer presents and infectious risk, the negative pressure may be turned off and the IBU removed.
- The device should only be used for patients over 45 pounds (lbs.)
- All patients inside the device should receive supplemental oxygen.

Cautions for HCP:

- Emergency removal of a patient under negative pressure will potentially expose the area outside of the device to contaminates. HCP shall use appropriate universal precautions and wear appropriate maximal PPE at all times.
- The device may be used in the Emergency Room, Intensive Care Units, or during patient transport. Only the negative pressure source tested and listed here should be used. The suction provides the air flow and filtered exhaust to create the negative pressure environment.
- The device is equipped with handles at the top and at the base on three sides to facilitate securing the IBU to hospital beds and gurneys. Take care to ensure any component is securely fastened.

6. Labeling and Symbols:

Symbol	Label information
	*Manufacturer*: Symbol will be followed by the name and address of the manufacture at the rear of the device and on sterility barrier of components and solutions
	*Date of Manufacture*: Symbol indicates the date (day, month, year) of the device was manufactured.

	*Serial Number*: Symbol will be followed by the serial number of the device at the rear of the device and on sterility barrier of components and solutions.
	*Not for General Waste*: Symbol indicates that the device can be reused, and must be disposed of in accordance with local, state, and federal regulations.
	*Alternating Current*: Symbol indicates that each installation of vacuum component operates with alternating current.
	*Radio Frequency Transmission:* Symbol indicates emission of non-ionizing radiation.
	*Grounding (Earth)*: Symbol indicates electrical grounding.
	*Water Ingress*: Symbol indicates that the vacuum source is protected against vertically falling water drops *(Buffalo Smoke Evacuators only).*
	*Biohazard*: Symbol indicates potentially biohazardous material after usage, which will be placed on the vacuum, the vacuum tubing, and the filter.
	*Non-Sterile*: Symbol indicates that the device is *not* provided sterile.
	*Consult Instructions*: Symbol will be placed on physical interface of the filter housing. Instructions will detail the setup, use, and clearing of the device.