

# **INSTRUCTIONS FOR HEALTHCARE PERSONNEL (HCP):** **Use 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. 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 IBU via 510(k)-cleared smoke evacuator device. Regardless of the negative pressure source, an in-line ultra-low particulate air/high-efficiency particulate air (UPLA/HEPA) filter is present to filter particulates  $\geq 99.99\%$  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.

Authorized use of the IBU during patient transport is for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. 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. A registered nurse or physician should be in constant attendance during this time. Adequate oxygen flow and maintenance of negative pressure with adequate air flow should be assured. Patients should have continuous monitoring of SAT-O<sub>2</sub> levels, vital signs, and End-tidal CO<sub>2</sub> if available during transport. If end-tidal CO<sub>2</sub> monitoring is not available during transport, duration of use is limited to 30 minutes with medical air flow and suction both on and under direct observation.

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 use of the IBU. The IBU is an additional 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 in conjunction with appropriate PPE and pursuant to the guidance of your institution.**

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Dr. J. Peter Rubin  
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**Proprietary Information**

**Inspect the IBU prior to use. 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), at the University of Pittsburgh, Department of Plastic Surgery, (the manufacturer and distributor). You must not use such IBU on patients and it must be disposed of.**

**All connections should be tightly secured and checked frequently. Anytime a patient 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:**

- 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
- 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 Unit 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 land marks or inability to intubate.

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- 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 CO<sub>2</sub> monitoring if available. If end-tidal CO<sub>2</sub> monitoring is not available, then the use of the IBU must be limited to no more than 30 minutes with medical air flow and suction both on and under direct observation.
- All patients within the device enclosure must be receiving 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 Box 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 must not come into direct contact with a 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 pulse oxygen saturation (SpO<sub>2</sub>), vital signs, EKG, and End-tidal CO<sub>2</sub> monitoring, 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™.

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**Unboxing, Initial Set-Up, and Inspection**

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

In preclinical testing, four unique installations of this system have been tested and verified to achieve four-log reduction (i.e., ≥ 99.99%) of airborne particulates. The function of the Biocontainment Box is the same regardless of the vacuum source used.

<b>Model</b>	<b>Required components (vacuum source supplied separately)</b>
IBU-BB <i>Biocontainment Box Only</i>	Operator’s Manual Biocontainment Box Clear drape Filter-Tubing Adapter
IBU-ADW	Operator’s Manual Biocontainment Box Clear drape Pre-Filter Tubing 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). Atrix ULPA Filter (99.999% efficient at 0.12 micron) Filter-Tubing Adapter
IBU-BVV <i>For use with the Buffalo ViroVac® Smoke Plume Evacuation System</i>	Operator’s Manual Biocontainment Box Clear drape Filter-Tubing Adapter Buffalo ViroVac® Smoke Plume Evacuation System
IBU-BPS <i>For use with the Buffalo PlumeSafe® Turbo Surgical Smoke Plume Evacuator</i>	Operator’s Manual Biocontainment Box Clear drape Filter-Tubing Adapter Buffalo PlumeSafe® Turbo Surgical Smoke Plume Evacuator
IBU-SNT <i>Stryker Neptune Waste Management System</i>	Operator’s Manual Biocontainment Box Clear drape Filter-Tubing Adapter Stryker Neptune Waste Management System

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

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- Hoses, Tubing, Laparoscopic Kits, Adapters, Wands & Other Accessories

Please contact STRYKER Customer Service to purchase the following accessories:

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

### **Emergency Removal Instructions**

If the IBU needs to be opened emergently, remove any straps or tiedowns securing the Biocontainment Unit and then lift the device away from the patient. The negative pressure source does not need to be turned off to remove the device.

NOTE: Emergency removal of the Biocontainment Unit may expose the operator and nearby personnel to airborne or aerosolized particulates from the patient. The operator and nearby personnel should be wearing appropriate maximal PPE including an appropriately fitting N95 respirator in case of potential airborne exposure or leave the area immediately if without appropriate PPE.

### **Instructions for Use**

The information here is a summary of the pertinent Operational Information, which is given in additional detail in the User's Manuals and Instructions for Use (IFU) for each negative pressure source.

**Review the appropriate User's Manuals and Instructions for Use (IFU) based the specific IBU installation that is being used.**

1. All exterior surfaces of the IBU should be set up, tested, and cleaned/disinfected prior to use with a patient. See "Instructions for Healthcare Facilities : Assembly, Use, Disassembly and Cleaning/Disinfection of the Individual Biocontainment Unit"
2. The vacuum sources and vacuum tubing are *not* intended for contact with patients.

**With questions or for reporting problems contact:**

J. Peter Rubin, MD, MBA, FACS at the University of Pittsburgh  
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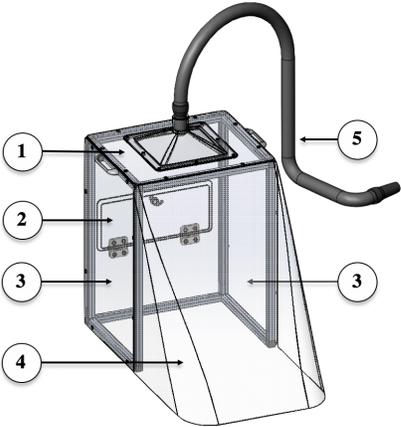
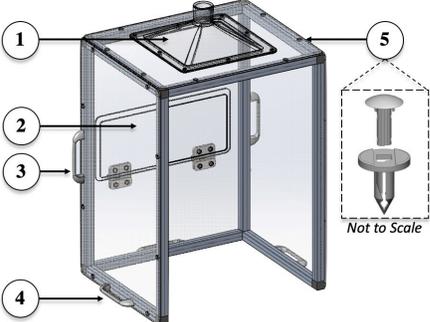
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**Operating Instructions:**

**Setup**

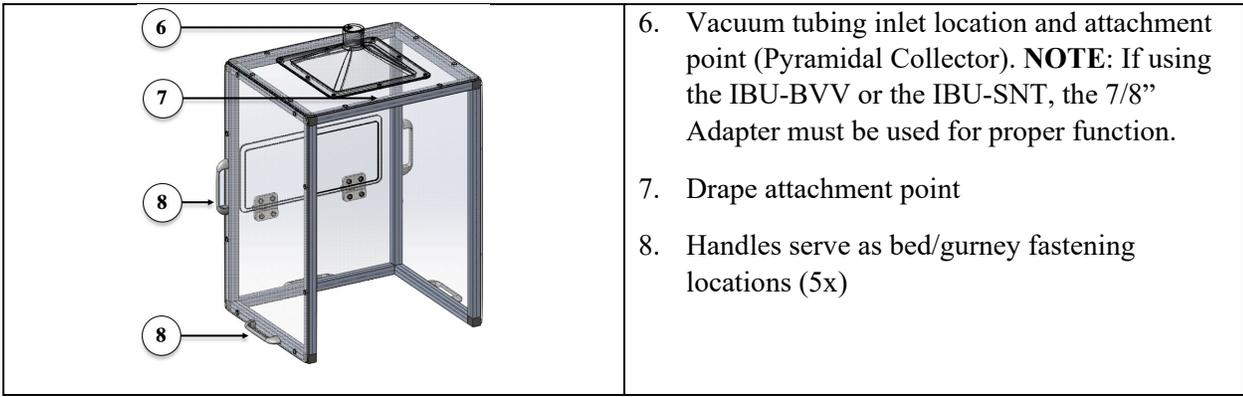
The following images display the assemblies and key features of the Biocontainment Unit of the IBU. The Biocontainment Unit may be shipped assembled or partially assembled. If assembly is required, press the black corner junctions together and align the translucent siding with the pre-drilled holes in the framing. Fasten all components using the two-piece fasteners provided.

	<ol style="list-style-type: none"> <li>1. Top Panel Assembly</li> <li>2. Rear Panel Assembly</li> <li>3. Side Panel Assembly</li> <li>4. Translucent Drape</li> <li>5. Pre-Filter Tubing</li> </ol>
	<ol style="list-style-type: none"> <li>1. Pyramidal Collector</li> <li>2. Patient Access Window (located at rear of Biocontainment Box)</li> <li>3. Side Handles (2x)</li> <li>4. Base Handles (3x)</li> <li>5. Fasteners (32x)</li> </ol>

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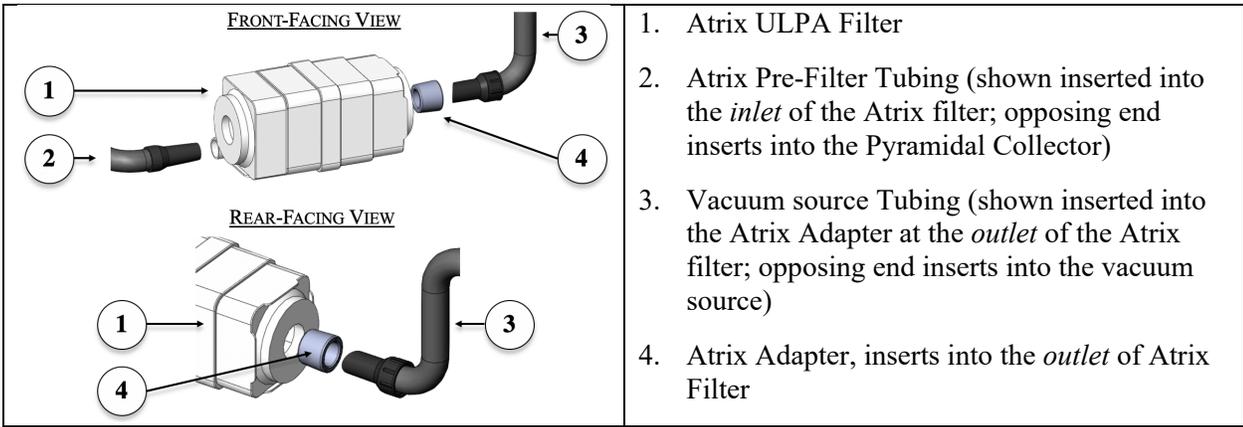
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**Proprietary Information**



*For the IBU-ADW:*

After the Biocontainment Unit is assembled, insert the Atrix vacuum tubing into the Pyramidal Collector (6); the tubing will fit snugly into the inlet. After the Atrix tubing is inserted into the Pyramidal Collector, inset the opposing end into the Atrix UPLA filter. The inlet of the Atrix ULPA filter is offset from the center. Affix the vacuum source tubing into the outlet of the Atrix filter. The vacuum source should generate a minimum flow rate of 25 cubic feet per minute (CFM) through a hose of at least 7/8" internal diameter (ID). The Atrix ULPA filter will be furnished with the Atrix Adapter so that the vacuum source tubing can be tightly press-fitted into the filter outlet.

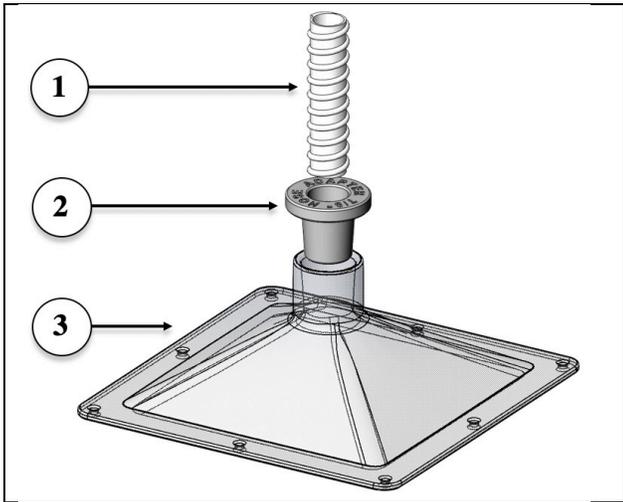


*For the IBU-BVV:*

The maximum Pre-Filter Tubing size for this model is 7/8" and requires an adaptor for the Pyramidal Collector, which has been supplied with the device. Firmly press the Pyramidal Collector Adaptor into the Pyramidal Collector. Then, insert the appropriate size Pre-Filter Tubing into the Pyramidal Collector Adaptor. After the Pre-Filter Tubing is inserted into the Pyramidal Collector Adaptor, insert the opposing end into the appropriate fitting of the smoke evacuator.

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5. Pre-Filter Tubing, 7/8"
6. Pyramidal Collector Adaptor. **NOTE:** This adapter configuration is necessary *only* when using the Buffalo ViroVac and 7/8" Pre-Filter Tubing.
7. Pyramidal Collector

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**Proprietary Information**

*For the IBU-BPS:*

After the Biocontainment Unit is assembled, insert the appropriate size Pre-Filter Tubing into the Pyramidal Collector (6); the tubing will fit snugly into the inlet. After the Pre-Filter Tubing is inserted into the Pyramidal Collector, inset the opposing end into the appropriate fitting of the smoke evacuator.



Figure 1 demonstrates a patient in the IBU using the Buffalo ViroVac as the negative pressure generating source.

After assembly of the vacuum source, affix the translucent drape to the front of the Biocontainment Unit. The Translucent Drape should be securely tucked under the patient when the device is in use to best prevent any leakage of aerosolized particulates. **The vacuum source *should remain ON and at the maximum vacuum setting at all times regardless of the vacuum source being used* during any procedure(s).**

#### **Disassembly:**

Please refer to “Instructions for Healthcare Facilities: Assembly, Use, Disassembly and Cleaning / Disinfection of the Individual Biocontainment Unit”.

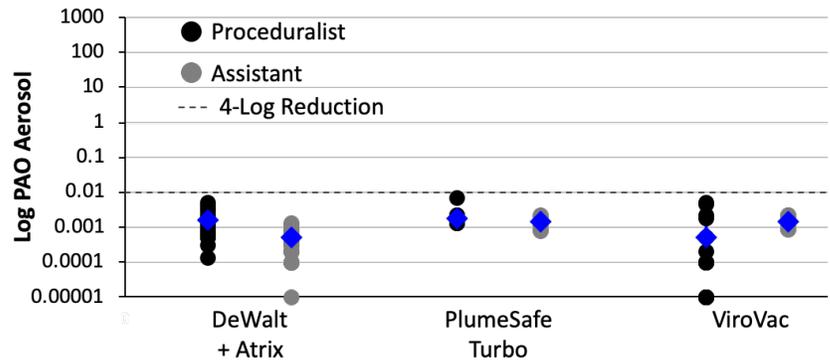
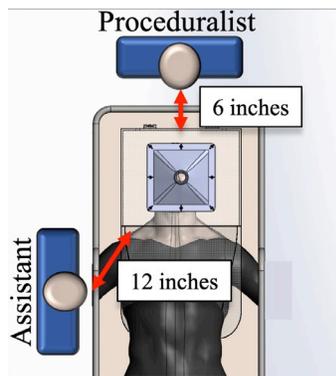
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**Proprietary Information**

**Performance References:**



Measurements of aerosolized particulates concentration are plotted from testing at two locations. The “Proceduralist” position (black circles) was located 6 inches from the Access Window. The “Assistant” position (gray circles) was located 12 inches from the Translucent Drape. The blue diamonds represent the mean of all measurements for a given configuration. The horizontal dotted line represents the acceptable standard for aerosol concentration (<0.01%) based on a 4-log reduction per FDA’s Emergency Use Guidance, “Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency” (March 2020).

MODEL	Filtration Efficiency	Mean Penetration (Proceduralist)	Mean Penetration (Assistant)	Maximum Penetration (Proceduralist)	Maximum Penetration (Assistant)	Window Mean Face Velocity (FPM)
IBU-ADW	99.9988%	0.002%	0.001%	0.005%	0.001%	69
IBU-BVV	99.9883%	0.001%	0.001%	0.005%	0.002%	52
IBU-BPS	99.9936%	0.002%	0.001%	0.007%	0.002%	127

*NOTE: For reference purposes only. Assumes use of clean components and a new filter.*

**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 Unit should be kept closed as much as is reasonably possible to maximize the vacuum pressure.

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- 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 to 140°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.

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- 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 contaminants. 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 sources 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.

**Labeling and Symbols:**

Symbol	Label information
	<i>Manufacturer:</i> 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
	<i>Date of Manufacture:</i> Symbol indicates the date (day, month, year) of the device was manufactured.
	<i>Serial Number:</i> 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.
	<i>Not for General Waste:</i> Symbol indicates that the device can be reused, and must be disposed of in accordance with local, state, and federal regulations.

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	<p><i>Alternating Current:</i> Symbol indicates that the each installation of vacuum component operates with alternating current.</p>
	<p><i>Radio Frequency Transmission:</i> Symbol indicates emission of non-ionizing radiation.</p>
	<p><i>Grounding (Earth):</i> Symbol indicates electrical grounding.</p>
<p><b>IPX1</b></p>	<p><i>Water Ingress:</i> Symbol indicates that the vacuum source is protected against vertically falling water drops (<i>Buffalo Smoke Evacuators only</i>).</p>
	<p><i>Biohazard:</i> Symbol indicates potentially biohazardous material after usage, which will be placed on the vacuum, the vacuum tubing, and the filter.</p>
	<p><i>Non-Sterile:</i> Symbol indicates that the device is <i>not</i> provided sterile.</p>
	<p><i>Consult Instructions:</i> Symbol will be placed on physical interface of the filter housing. Instructions will detail the setup, use, and clearing of the device.</p>

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