

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the Individual Biocontainment Unit during the COVID-19 Pandemic

April 1, 2021

**Coronavirus
Disease 2019
(COVID-19)**

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Individual Biocontainment Unit (hereafter referred to as the "IBU"). This device is authorized for use by healthcare provider (HCP) as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent 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 on such patients during the COVID-19 pandemic.

All patients who are treated with IBU will receive the Fact Sheet for Patients: Emergency Use of an Individual Biocontainment Unit During the COVID-19 Pandemic

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the Center for Disease Control and Prevention (CDC) webpage for the most up to date information (<https://www.cdc.gov/COVID19>).

What do I need to know about the emergency use of an IBU?

- The IBU is authorized for emergency use by HCP when caring for or performing medical procedures on patients with suspected or confirmed diagnosis of COVID-19, in healthcare settings, to prevent HCP exposure to pathogenic biological airborne

particulates by providing an extra layer of protection in addition to standard PPE.

- The IBU is not intended to replace standard PPE.
- The IBU is authorized for patient transport within a hospital setting for temporary transfer only with direct admission within the hospital, in the presence of a registered nurse or physician.
- Authorized non-transport use of the 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 CPAP/BiPAP (continuous positive airway pressure /bi-level positive airway pressure) mask use, airway suctioning, percussion and postural drainage).
- HCP should review the IBU labeling before use on a patient and follow the instructions for use.
- Inspect IBU upon receipt. Any wear/tear of the Biocontainment Unit or other signs of degradation on the IBU must promptly be reported to Dr. J. Peter Rubin (the product sponsor/EUA holder and distributor); the healthcare facility (HCF) must not use any compromised IBU on patients and must dispose of such IBU.
- When using the IBU on a patient, the following are required:
 - Direct observation at all times.
 - Use of continuous pulse oximetry and End-tidal CO₂ monitoring if available.
 - Ensure all connections are tightly secured and checked frequently.
 - All patients should have supplemental oxygen in place at all times while IBU is in use.
 - Position the patient in a temperature-controlled environment to avoid hyper- and hypothermia.
- Ensure the suction is connected to vacuum source that has either a ultra-low particulate air (ULPA)/high-efficiency particulate air (HEPA) filter that evacuates the vacuumed air safely to the environment.

Use appropriate PPE when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control*

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Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings or on the CDC webpage on Infection Control.

Current information on COVID-19 for HCP is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What is the IBU?

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. A 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 (UPLA/HEPA) filter is present to filter particulates \geq 99.99% with respect to the isolation patient chamber. This product should be removed if it impedes ability to care for a patient or impede the ability to perform a medical procedure on a patient, or impedes 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.

When should an IBU be used?

The virus that causes COVID-19 is highly contagious and the IBU provides an additional layer of protection when exposure to contaminated droplets or aerosolized particles are expected. During use with aerosol generating procedures, the risk of virus transmission is extremely high, and these products can provide an additional layer of protection for the HCP. The patient's respiratory status and airway should be assessed prior to use of the IBU.

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 (lbs.)

Warnings and Precautions

- 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 should be used within the IBU.
- Remove the IBU 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 IBU may induce hypercarbia in a spontaneously breathing patient. The IBU should only be used with medical air or oxygen 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 should be limited to no more than a short duration of time with medical air flow and suction both on and under direct observation.
- 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 IBU should not be opened when the IBU is pitched at an angle.
- Observe patient monitoring devices and wearable or implantable patient devices for interference from the vacuum source motors frequently while the unit

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motors are operating and after any significant change in distance of devices and cables from vacuum source motors.

What are the known and potential benefits and risks of the IBU?

Known and Potential Benefits

- Prevent/minimize risk of HCP exposure to the virus.
- Provide an extra layer of barrier protection in addition to PPE.
- Allow safer method for HCP to perform standard, non-invasive respiratory treatments by containing and evacuating pathogenic biological airborne particulates

Known and Potential Risks

- Device malfunction may lead to hypoxia of the patient, patient injury and possible contamination of HCP, or increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of personnel.
- Device prolonged use may lead to hypercarbia in a spontaneously breathing patient.
- Device may interfere with procedures conducted on the patient.
- Allergic reaction to non-biocompatible materials
- Inadequate disinfection to the IBU between patients uses may result in increased risk of disease transmission from contamination.
- Electromagnetic interference of the electrical parts of the device on patient's monitoring cables and devices, patient's implantable or wearable medical devices.

What is an Emergency Use Authorization (EUA)?

The United States Food and Drug Administration (FDA) has made the IBU available under an emergency access mechanism called an EUA. The EUA is supported by a

Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

The IBU made available under an EUA has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the IBU may be effective for use by HCP as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates during transport of patients with suspected or confirmed diagnosis of COVID-19 or at the time of definitive airway management and performing medical procedures related to airway management and breathing treatments during the COVID-19 pandemic.

This EUA is in effect for this device is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless the declaration is terminated or authorization is revoked (after which the device may no longer be used).

Manufacturer & Distributor Information:

Innovative Electronics Corporation
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Pittsburgh, PA 15205
(412) 276-0711

Product Sponsor/EUA Holder & Distributor:

Dr. J. Peter Rubin
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Suite 6B Scaife Hall, Room 690
3550 Terrace Street, Pittsburgh, PA 15261
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How can I learn more?

CDC websites:

General: <https://www.cdc.gov/COVID19>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Infection Prevention and Control Recommendations in

Healthcare Settings: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

FAQ on Personal Protective Equipment:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

FDA websites:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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