PATIENT ISOLATION TRANSPORTATION UNIT (PITU)

Patient Information

What is the PITU?

The PITU is a protective enclosure that you are being placed into that allows doctors and nurses to attend to you while providing an additional level of barrier protection against the COVID-19 virus. It also allows healthcare personnel to move you safely while minimizing risk of exposing other patients, visitors and staff.

Why do I need to be inside the PITU?

Because of your symptoms, it is possible that you have the COVID-19 virus infection. The virus is spread from droplets created when you cough, sneeze or talk and when you touch surfaces with your hands if your hands have the virus on them. To help prevent healthcare workers from being exposed to the virus, you have been placed inside a specially made see through enclosure. The enclosure will allow you to be comfortable on your hospital bed while healthcare personnel can take care of you from outside the enclosure using the gloves that are attached to the enclosure walls. You will be able to lie down, sit up, eat, read, watch TV and do other things that you would normally do while in a hospital bed or gurney.

How does the PITU work?

The PITU has three ventilation motors that draw in fresh air from outside the enclosure and exhaust air through special filters that remove bacteria and virus particles. By drawing air out of the enclosure, a negative pressure is created inside the tent that keeps particles from sneezes, coughs and talking inside the enclosure and then trapped in the exhaust filters. This may help protect healthcare workers from becoming infected.

What will I be able to do while inside the enclosure?

You will be able to lie down, sit up, eat, read, watch TV and do other things that you would normally do while in a hospital bed or gurney.

PATIENT ISOLATION TRANSPORTATION UNIT (PITU)

Information for Healthcare personnel:

Intended Use: Comunale Patient Isolation Transport Unit (hereafter “PITU”) is intended to be used by healthcare providers (HCPs) for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19 requiring airborne or droplet isolation precautions in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment.

What is the PITU?

The PITU is a negative pressure enclosure that functions in a similar manner to a hospital negative pressure, Airborne Infection Isolation Room (AIIR). The PITU is not intended to replace personal protective equipment (PPE), room sanitation and disinfection procedures. The enclosure is constructed of a flame retardant, clear, medical grade vinyl material that is single patient use and disposable as medical waste. The enclosure is suspended from a reusable, adjustable aluminum frame that fits most hospital beds or gurneys. Negative pressure is created inside the enclosure by three reusable battery powered ventilation blower motors mounted at the top of the foot wall of the enclosure. The motors draw air in through vents at the foot of the tent and exhaust air to the environment at the head of the tent after passing through NIOSH approved disposable High Efficiency Particulate Air (HEPA) filters. In addition, air is exhausted from the enclosure through disposable HEPA filters attached to the intake side of the blower motors. Each blower motor has its own battery with a nominal 8 hour life. For operation beyond nominal battery life, maintain a set of three freshly charged batteries (see Warnings and Instructions Section IV – I, Section V – H, and Section VI - B and D). Medical personnel can attend to the patient inside the PITU by using the glove ports located along the walls of the enclosure. It is recommended that a gown and gloves be used when using the glove ports.

Equipment, food, drink, reading material, and other items can be passed into (and out of) the enclosure without opening the enclosure entrance through the use of the zippered pass through compartment on the side of the enclosure.

Cable and tubing ports are located on the walls at the head of the enclosure (refer to set up instructions).

When the unit is operating properly and creating negative pressure, the enclosure appears taut and has concave (bowing inward slightly) walls. Actual pressure inside the enclosure can be measured by unzipping the entrance approximately one half of an inch and inserting a digital manometer’s tubing through the opening. When operating correctly, a reading of negative 0.03 inches of water column or less should be obtained.

Airflow from the blower exhaust can be assessed for proper functioning using the supplied flow meter on each blower exhaust port (refer to set up instructions).

The unit generates negative pressures and hourly room air exchanges in excess of hospital room AIIR requirements as defined by the American Society for Healthcare Engineering (ASHE).

WARNINGS:

A. Do not place patients inside the enclosure unless blower motors are on and blower exhaust air flow has been tested with a manometer.
B. Do not keep patients in the PITU in direct sunlight.
C. The PITU should be operated only in temperature-controlled environments to prevent temperature fluctuations that could interfere with patient thermal regulation.
D. The PITU should be checked for generation of negative pressure regularly (refer to WARNING in Section VI - PERFORMANCE CHECK).
E. This device is not approved for operation in an oxygen enriched environment.
F. The PITU is not intended for use during surgical procedures. (only used in outpatient wards and for patient examinations and transport).
G. The PITU is for PRESCRIPTION USE ONLY.
H. For loss of blower motor function while in operation, perform check as indicated in Section VII TROUBLESHOOTING table and Section VII- A: Blower Motor Failure.

WARNING AND INSTRUCTIONS

UNPACKING AND ASSEMBLY

NOTE: Unit comes un-assembled

WARNING: Inspect the packaging contents for shipping damage and ensure all components are present. The product should be inspected before each use.

I- UNPACKING:

A. Unpack the Patient Isolation & Transport Unit (PITU) from shipping packaging.
B. Identify the square frame portion—this is the top of the PITU unit.
C. Check all sides and panels for any tears or punctures. If any punctures or tears are identified, do not use the damaged enclosure. Obtain a new enclosure before proceeding. Clean and disinfect undamaged, reusable components of the PITU and obtain new disposable components before proceeding.

II- EVALUATION & PREPPING OF PATIENT GURNEY:

A. Identify the patient transport gurney to be used with the PITU device and remove the mattress.
B. In this example is a commonly used Emergency Department Gurney manufactured by Stryker.
C. At the head and foot of the Stryker Gurney is a right and left equipment port.
D. Identify each equipment port and ensure that they are free from blockage and not in use.
E. Next identify the equipment ports at the foot of the Stryker gurney.
F. Again, ensure both these equipment ports are free from blockage and not in use.

III- PITU ASSEMBLY

A. Slide long small diameter tube into the long big diameter tube. (2)
B. Slide the short small diameter tube into the short big diameter tube. (2)
C. Assemble (4) 3way corner receivers to each end of the long sections.
D. Attach the (2) short sections to the 3way receivers to make a rectangle and so that the open end of the corner receivers are faced up when laying on the floor.
E. Take the 4 legs and insert them into the 3-way receivers at each corner.
F. Tighten set screw with the 5/32 hex Allen key provided in hardware pack
G. Insert feet into the end of the legs
H. Take out barrel and screw provided in your hardware pack and insert through both the leg and feet on all 4 legs.
I. Tighten with 5/32 hex Allen key provided in hardware pack.
J. Turn the frame over so that the rectangular portion is at the top and legs are projecting from the rectangular frame downward.
K. Spread the enclosure out lengthwise under the frame such that the rectangular shape of the tent is aligned under the rectangular shape of the top of the frame.
L. Make sure the enclosure is correct side up by observing the Velcro fasteners located on the top edges of the enclosure (the bottom of the enclosure does not have any).
M. Attach the enclosure to the frame using the Velcro fasteners starting at the top of the enclosure and the top of the frame and working downwards.
N. Ensure the device is sitting upright with the patient enclosure freely hanging from the frame.
O. Attach a motor mount/vent bracket to the top of the frame at each end of the PITU (head and foot end).
P. Ensure the patient enclosure is stretched over the gurney.
Q. Place the gurney mattress into the patient enclosure so that it rests on top of the PITU enclosure's sealed bottom section.

IV- BLOWER MOTOR SETUP AND ATTACHMENT OF MOTORS AND FILTERS

A. In the packaging you will find 6 P100 filters, 3 motors and 3 rechargeable batteries.
B. Attached the batteries to each blower motor.
C. Secure the battery to the holder below the motor.
D. Turn on the motor and check the airflow with the airflow indicator (See Section: Performance Check).
E. The motor is electrically isolated from the motor bracket by the plastic motor casing. Attach each motor to the motor mount bracket at the foot of the enclosure by placing the motor intake manifold through the motor mount and corresponding hole in the enclosure from the outside and then screw the threaded male end of the P100 Filter into the female threaded motor intake manifold on each blower motor from inside the enclosure. Remove the filter cap covers. Save caps/covers.
F. Attach the P100 Filters to other inlet vents at the head of the PITU by placing the threaded portion of the filter through the vent bracket and corresponding holes in the enclosure. Secure the filters in place by threading the plastic nut onto the threaded portion of the filter from inside the enclosure and hand tighten. Remove the filter cap covers. Save caps/covers.
G. Negative Pressure Check: The enclosure walls become taut and bowed inward (slightly concave) when the unit is generating negative pressure. Healthcare personnel can easily monitor the function of the unit by visually inspecting the enclosure for presence of taut and concavity of the walls or ceiling to know that the unit is generating negative pressure.

V- BATTERY PACK CHARGING

WARNING: The Battery Pack BP-17IS can be used in environments that require intrinsically safe equipment ONLY when the clothing clip and screw are in place. If the clothing clip and screw are not in place, DO NOT USE in environments that require intrinsically safe equipment. The batteries supplied with the unit cannot be charged while in use. The user should not attempt to charge the batteries while in use.

A. Unplug the motor power cord from discharged batteries. Return discharged batteries to the battery charger and follow instructions for recharging the battery in the instruction manual.
B. Connect a freshly charged battery to the motor power cord. Follow instructions for turning the motor in the instruction manual.
C. 3M batteries provide up to 500 charge/discharge cycles. The service life of the batteries will be significantly reduced when they are exposed to high temperatures over an extended period of time.
D. To properly dispose of the battery pack, follow local solid waste disposal regulations or call the RBRC Battery Recycling information Helpline at 1-800-8-BATTERY (1-800-822-8837).
E. Charging battery pack with standard charger (521-01-43):
    - Plug the charger into a regulated 120v-60Hz outlet and then insert charging lead into the battery pack.
    - The LED light will turn on, indicating that the battery pack is connected.
    - A new or completely exhausted battery pack should be charged for 16 to 24 hours. After this time, the battery pack should be removed from the charger.

    NOTE: The standard charger does not switch to a trickle rate mode. It is important to avoid leaving the battery pack connected to the charger longer than necessary.
F. Charging battery pack with smart charger (520-03-73, 520-03-72, and 520-01-61):
    Charge in an area free of combustible material and readily monitored.
    - A new of completely exhausted battery pack should be charged for 16 to 24 hours.
    - Place the charging station horizontally on a flat surface and plug the station AC power cord into a regulated 120v-60Hz outlet. The green LED light will turn on.
    - Insert the charging lead into the battery pack.
    - The LED will turn off, indicating that the battery pack attached in being charged in a high rate mode.
    - After approximately eight hours (depending on the amount of charging required) the LED will turn back on, indicating that the charger has switched to trickle rate mode. For Canadian chargers, when in trickle mode, the LED light will cycle on and off every 3-5 seconds.
G. To Maximize battery pack life, these guidelines should be followed:
    - Charge battery packs before they are completely discharged. Damage may occur if the battery pack is completely discharged (“deep discharged”) frequently.
    - Battery packs may be charged any time during the discharge cycle. Unlike some NiCad batteries, 3M battery packs do not develop a “memory”.
    - Do not allow water to enter the battery pack.
    - Always charge batteries at a temperature between 50 and 80F. At higher temperatures, the battery pack may not accept a full charge. If a battery pack feels hot, let it cool for ½ hour before charging.
    - Batteries may be left on trickle rate mode to maintain optimum capacity for up to 30 days. Batteries should not be stored long term connected to the charger. Without periodic charging, a NiCad battery pack in storage loses approximately 1% of its charge each day. Infrequently used battery packs should be fully charged, initially, then charged overnight once per week or one hour each day to maintain a full charge. Batteries subjected to prolonged storage (longer than 6 months) may lose their capacity to hold a full charge.
    - For infrequently used batteries, battery pack capacity should be checked regularly by running the PAPR motor blower unit and noting how long the required airflow is maintained at or above the proper level using the air flow indicator. Several charge/run-down cycles may restore battery pack capacity.
    - Do not charge multiple battery packs in an enclosed cabinet without ventilation.
H. Battery Pack run time is approximately 8 hours.
I. For uses beyond nominal battery life (8 hours), have an additional three (3) batteries charged and ready to go.

VI- PERFORMANCE CHECK

WARNING: The PITU should be checked for generation of negative pressure frequently. When the unit is generating negative pressure, the enclosure walls will have a concave appearance (bowed inward). If concave walls are not observed, the user should:

A. Check all blower motors are turned on.

B. If blower motors are functioning, check airflow of each blower motor exhaust outlet using the provided airflow indicator, See user instructions: Initial Device Inspection and Performance Check. Ensure the airflow indicator float is at or above the two horizontal arrows (4CFM) on the airflow indicator. If the float fails to reach this mark, substitute a freshly charged battery pack and or install a new filter. Replace the plug and screw cap on the old filter and dispose of it in accordance with federal, state, and local laws and regulations.

C. Inspect the enclosure to make sure that:

- The patient entry is completely closed
- There are no tears or punctures in the enclosure or glove ports.
- The pass-through compartment on the side of the enclosure is zippered closed.
- The cable ports have been sealed with tape. See user instructions: Placement of cords.
- Constant observation of negative pressurization. See user instructions: Blower motor setup (IV-G)

D. Changing batteries during PITU operation.

When the battery pack of each independent blower motor must be exchanged for a fresh battery pack.

1. Obtain freshly charged batteries from the battery chargers.
2. Turn off one blower motor at a time while leaving the other two motors running.
3. Replace the battery on the motor that is turned off with a fresh battery and turn the motor on again.
4. Repeat step 3 with each of the other two motors as needed.
5. Check airflow of each motor using the airflow indicator as described in VI-B above.
6. Clean (see Section XVI) and return used battery packs to the charger.

VII- TROUBLESHOOTING

Problem	Possible Cause	Corrective Action
Low airflow	Battery pack needs charging Filter is loaded Blower motor malfunction	Switch to fully charged battery pack Replace filter Switch to a different blower unit
Motor operates sporadically or not at all	Motor is broken Power cord wires are broken Power cord pins too narrow	AR TECH, DIV OF AR TARPAULINS, INC. MAIL@ARTECH2000.COM 909-829-4444 16246 VALLEY BLVD FONTANA, CA 92335

A. Blower Motor Failure

Should a blower motor fail, turn off the power to the motor and unplug the battery pack.
-Visually inspect the motor and motor casing, power cord wires and power cord pins for damage (see section VII TROUBLESHOOTING table above).
-Check for a dead battery pack by connecting a freshly charged battery and turning on the power.

B. Tears and Punctures in the Enclosure.

Should tears or punctures develop in the enclosure during PITU operation, a new complete PITU must be substituted. While the new PITU is being set up, the patient should be moved out of the PITU into an appropriate bio-secure environment. Please contact the distributer for more information on obtaining a new PITU.

VIII- PITU IS READY FOR PATIENT CARE

A. Prior to a patient being placed in the PITU, place necessary supplies in the enclosure based on each patient's condition and needs.

B. If EKG monitoring, respiratory support, IV lines, etc. are needed they can be pre-placed through the additional port located on the patient's right upper region of the PITU device. When doing so, ensure cables are placed as far as possible from the unit blower motors.

C. Any additional equipment needed can be safely passed through the compartment on the patient's left side of the PITU.

IX- PLACEMENT OF CORDS

A. Open the port located at the head of the gurney
B. Pull the lining outward
C. Place monitoring cords through the port
D. Twist the PITU fabric port around the cords
E. Tape the PITU fabric port to the cords forming a seal
F. Push the cords and PITU fabric port inward
G. Ensure all monitoring probes are connected to cords
H. Repeat this process for Oxygen and IV tubing on the second port

X- OPENING OF THE PITU ENCLOSURE

A. Each zipper located on the zipper ring should be used to fully open the PITU patient entry flap.
B. The zipper is two-sided. It can be opened from outside and inside of the tent as well.
C. Once each zipper is moved to the right and left lower portion of the zipper ring, drop the PITU flap straight down.
D. Ensure that there is no PITU flap that may obstruct the patient's path to placement into the device.
E. If needed fold the flap under the gurney to facilitate the gurney being placed in a lower position for patient transfer.
F. PITU is now ready for the placement of the patient.

XI- PLACING PATIENT INTO PITU

WARNINGS:

- Do not place patients in the unit unless the unit blower motors are operating and blower motor exhaust airflow has been tested with the manometer
- Monitor patient temperature at frequent intervals while the patient is in the unit
- Do not keep patients in the PITU in the direct sunlight.

- The PITU should be operated only in temperature- controlled environments to prevent temperature fluctuations that could interfere with patient thermal regulation.
- Place patient monitoring cables such as EKG, pulse oximetry cables as far as possible from the unit blower motors.
- Place patient monitoring devices as far as possible from the unit blower motors.
- Observe patient monitoring devices and wearable or implantable patient devices for interference from the unit blower motors frequently while the unit motors are operating and after any significant change in distance of devices and cables from PITU motors.

A. Once the patient is placed in the PITU device, run all additional support lines through the port on the right.
B. Ensure all EKG leads, IV lines and oxygen are connected prior to closing the PITU unit.
C. Once patient and all support lines, leads, and oxygen is secured, then close the flap by zipping both sides until they meet at the top of the PITU unit.
D. Turn on the blower motors; you should see the sides "bow" inward as negative pressure builds up.

XII- PASSING OBJECTS INTO THE ENCLOSURE

A. Transfer Pocket is available in the event a patient needs additional supplies
B. Open the outside zipper to the transfer pocket
C. Place the object inside the pocket
D. Zip up the pocket
E. Place your hands into the premade glove ports next to the transfer pocket.
F. Unzip the inside pocket and obtain the item
G. Zip the inside pocket closed after obtaining the items in the pocket.

XIII- DISASSEMBLE PITU

A. After the patient has been removed from the unit, reseal the entry door using the zippers.
B. Allow the PITU blower motors to run for at least 20 minutes.
C. At the end of 20 minutes shut off the blower motors.
D. Remove cables and tubing from the equipment ports.
E. Reusable patient cables and tubing should be cleaned per the facility cleaning and disinfection policies and the equipment manufacturer's instructions for cleaning and disinfection.
F. Using gloves and gown open the patient entry and remove the mattress from the enclosure.
G. Clean and disinfect the mattress per hospital policy of cleaning and disinfecting mattresses.

XIV- DEVICE DISPOSAL

WARNING: PITU IS A SINGLE USE ENCLOSURE. PITU'S FABRIC AND FILTERS CONSTITUTE THE DISPOSABLE AND NON-REUSABLE COMPONENTS AND SHOULD BE PLACED INSIDE A BIOHAZARD BAG FOR DISPOSAL PER THE HEALTHCARE FAILITY'S MEDICAL WASTE DISPOSAL POLICY.

A. Using gloves, partially unzip the entry door, reach in and replace the filter plugs on the blower motor intake filters.
B. Remove the filters by unscrewing them from the blower motor and replace the screw on caps. Cap and unscrew the vent filters on the outside of the enclosure and replace the screw on caps. Dispose of used filters in accordance with federal, state and local laws and regulations.
C. Close the zippered patient entry.
D. After removing the filters, close the patient entry using the zippers.
E. Unfasten the enclosure from the frame beginning at the top of the enclosure and proceeding along the sides downward.
F. Allow the enclosure to collapse.
G. Roll the enclosure up from head to foot.
H. Place rolled enclosure inside a biohazard bag and dispose of the bag per facility policy on disposal of medical waste

XV- REUSABLE COMPONENTS

NOTE: The reusable portions of the unit (tent frame, blower motors, motor mounts, batteries and vent stabilization plates) can be disinfected as per facility disinfection or decontamination policies.

XVI- CLEANING AND STORAGE

WARNING: THE <u>ONLY</u> REUSABLE PITU COMPONENTS ARE THE FRAME, MOTORS, RECHARGABLE BATTERIES, AND BRACKETS. CLEANING OF THESE COMPONENTS IS MANDATORY AFTER EACH USE. DO NOT ALLOW WATER OR CLEANING SOLUTION TO ENTER THE BATTERY PACK AS IT CAN DAMAGE THE BATTERY ASSEMBLY. WEAR GLOVES, GOWNS AND OTHER REQUIRED PPE WHILE CLEANING AND DISINFECTING.

I. Remove blower motors from motor and filter brackets.
J. Remove power cord plug from each battery pack.
K. Reusable aluminum frame, motors, aluminum motor mounts, and battery packs can be cleaned by wiping down with a quaternary ammonia disinfectant or sodium hypochlorite (1oz household bleach in 2 gallons of water), or other disinfectant. Follow the manufacturer's instruction for use.
L. The vinyl enclosure is single patient use. Should exterior cleaning be necessary, do not use solvent or abrasive products.
M. Do not allow cleaning solution, water, or mist to enter the blower motors.
N. Cleaned components should be stored away from contaminated areas when not in use.