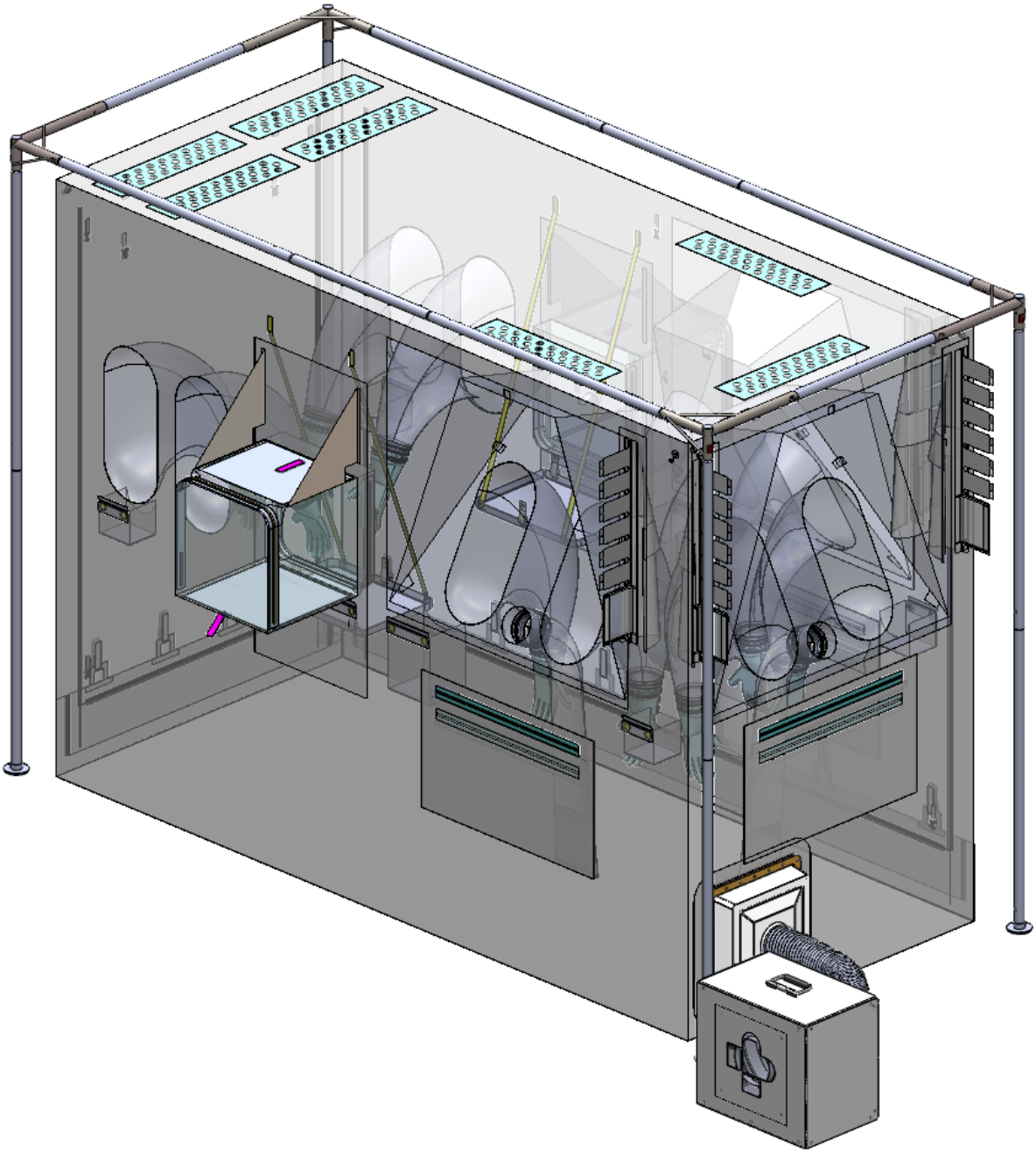
Carecube Negative Pressure Isolation Chamber



Carecube

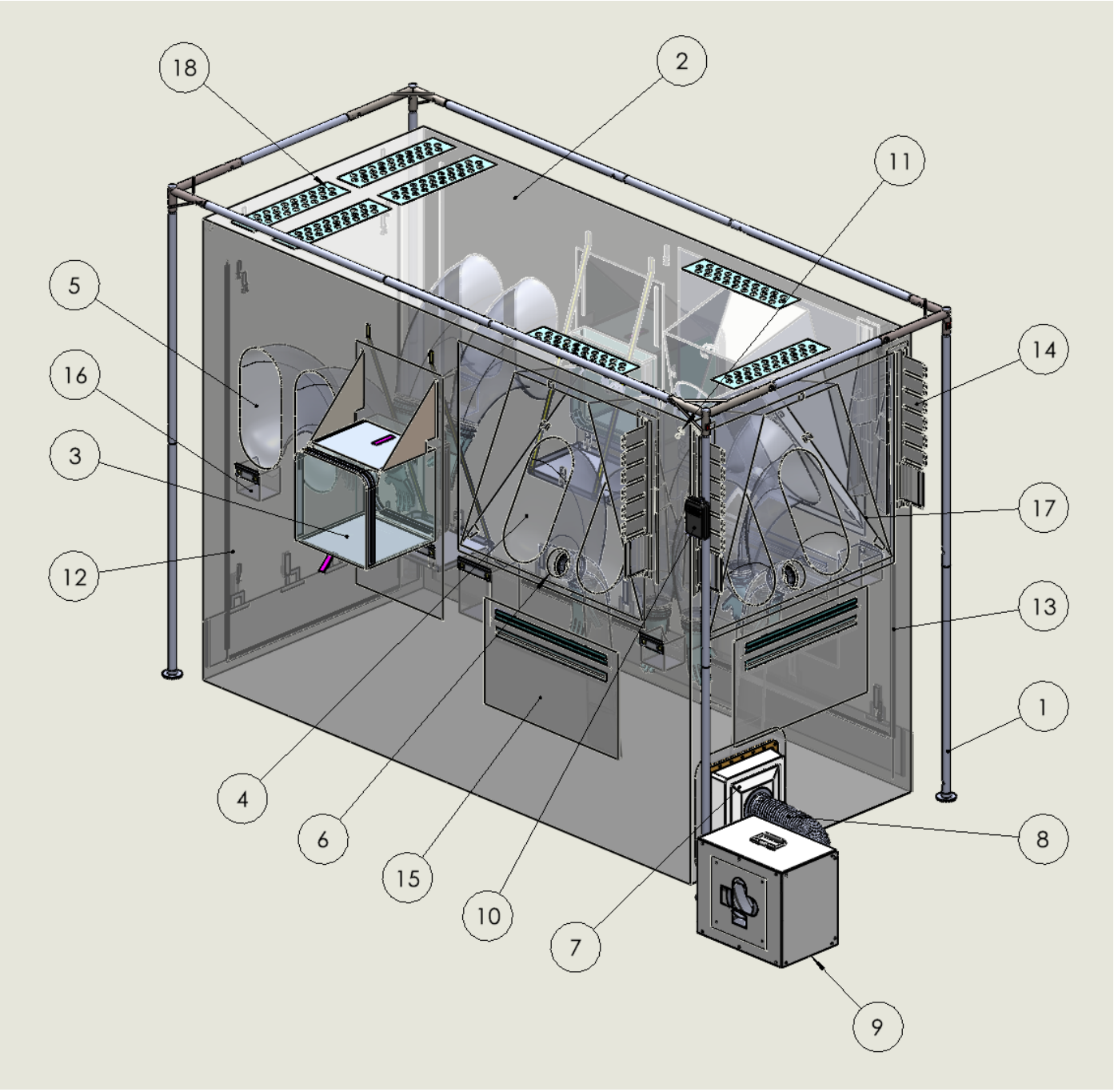


Image 1. Carecube Negative Pressure Isolation Chamber, Model 1BX, With Assembly Callouts

1	External Frame	11	Manometer Ports (4)
2	Canopy	12	Footwall Entry/Exit Roll-up Door
3	Airlock pass-through	13	Sidewall Entry/Exit Roll-up Door
4	Glove Ports (3)	14	Conduit Panels (4)
5	Auxiliary Glove Ports (2)	15	Folio Pockets (2)
6	Stethoscope Trunk Ports (3)	16	Interior Storage Pockets (8)
7	HEPA Filter	17	Lean-In Window (3)
8	Duct	18	Intake Filters (7)
9	Main Exhaust Fan		
10	Manometer		

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INTRODUCTION

Device Information

The Carecube Negative Pressure Isolation Chamber (“Carecube”) device is a modular, negative pressure patient isolation unit for the isolation and treatment of patients with suspected or confirmed airborne infectious diseases. The device is assembled on-site in a controlled healthcare environment. It is constructed of a hollow metal tubing frame (“Frame”) and a clear thermoplastic polyurethane (TPU) outer shell (“Canopy”), allowing visual monitoring of the patient and an unrestricted view of the patient's surroundings. Negative pressure is achieved using an externally placed main exhaust fan (“Main Fan”) and monitored with a manometer (“Manometer”). Exchanged air is filtered through a high efficiency HEPA filter. The unit contains Lean-In Windows with Glove Ports, allowing treatment of the isolated patient. Conduit Panels distributed throughout the device facilitate the introduction of medical tubing and instrumentation leads of various sizes. Airlock Passthroughs (“Passthrough”) enable providers to safely transfer equipment and materials in and out of the enclosure. The unit is designed to be used with the required personal protective equipment (PPE).

Indications for Use

The Carecube is a patient isolation unit (PIU) designed for the temporary isolation of patients within a hospital setting to prevent particulate (biological) cross-contamination between user and patient, while enclosing the contaminated patient from the external environment. Device should only be used in a hospital setting. This is for temporary housing of a patient prior to transfer to an appropriate hospital destination. Transfer to a more permanent hospital setting should occur as soon as possible. The Carecube is designed with features that enable low-moderate complexity medical interventions. This includes the following procedures: blood draw, medication administration, palpating abdomen, cardiac auscultation, and connection to IV line/monitoring cables.

Intended Use

The Carecube is intended to be used by a single patient for up to 24 hours of continuous use. The Carecube Negative Pressure Isolation Chamber Canopy is intended for multi-patient use with a maximum of ten (10) patients. The Glove portion of the Glove and Auxiliary Glove ports and the Trunk port of the Carecube are intended for single patient use only.

Contraindications

- Do not use the Carecube in an oxygen rich environment.
- The Carecube is not intended for use with morbidly obese patients.
- The Carecube is not intended for use in patients weighing less than 45 pounds or for pediatric use.
- The Carecube is not intended for the performance of minimally invasive non-surgical endoscopic, diagnostic or surgical procedures.
- The Carecube is not intended for airway management, intubation, or placement of central venous access.

Storage

- Store at room temperature.
- Do not store in direct sunlight.

WARNINGS, PRECAUTIONS AND LIMITATIONS

General Warnings

A. **Warning:** Once assembled, do not transport or move the unit.
B. **Warning:** Do not use highly acidic and alkaline cleaners, or solvents to wipe down or clean the Canopy.
C. **Warning:** The HEPA filter cannot be replaced. Do not attempt to replace the filter or use the device beyond the labeled expiration.
D. **Warning:** Avoid touching the screen in front of the HEPA Filter with cleaning and disinfecting materials so as not to damage or impede the performance of the HEPA Filter.
E. **Warning**: This device is not intended for use during surgical procedures.
F. **Warning:** The Carecube is not intended for use with patients who are not medically stabilized.
G. **Warning:** In the event of an emergency, access the patient through zipper doors.
H. **Warning**: In the event that the Main Exhaust Fan stops during use, airflow in the Carecube will cease, resulting in a loss of negative pressure.
I. **Warning**: The Carecube should be operated only in temperature-controlled environments to prevent temperature fluctuations that could interfere with patient thermal regulation. Monitor patient temperature at frequent intervals while the patient is in the unit.
J. **Warning:** After removing the patient, the entire Carecube (the Canopy, and all single patient use and reusable components) MUST be cleaned, before reuse, disposal or storage. (Note: Only reusable components are able to be stored.)
K. **Warning:** Canopy cannot be stored after being set up and used with patients.

Electrical & EMC Warnings

- **Note:** The Carecube device is IEC 60601-1 Medical Device Safety Testing compliant.
- **Note:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- **Warning:** Do not modify in any way the electrical equipment supplied with the Carecube as this could result in user and/or patient harm.
- **Warning:** To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- **Warning:** To isolate the device from wall power during disassembly or service, unplug the main exhaust fan.
- **Warning:** Use of the fan adjacent to or stacked with other equipment should be avoided because it may result in improper operation. If such use is necessary, this equipment and the adjacent equipment should be observed to verify that they are operating normally.
- **Warning:** Use of electrical accessories, cables, or equipment other than those specified or provided by Carecubes could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- **Warning:** Portable RF communications should be used no closer than 12 inches away from the Main Exhaust Fan, Manometer, and power cords. Otherwise, degradation of the performance of this equipment could result.
- **Warning:** The manometer display may be impacted if exposed to electrostatic discharge or in the presence of radiated

RF EM fields of 236-269 MHz. If display is impacted, reset the manometer by removing and reinserting the power cord.

- **CAUTION:** Never repair a damaged Main Exhaust Fan. Contact Carecubes, Inc. Customer Service for a replacement. See the *FREQUENTLY ASKED QUESTIONS (FAQ)* section for contact information.

Warnings Prior to Use

A. **Warning**: Visually inspect the Main Fan enclosure, power cord wires and power cord pins for damage or tears prior to use. Do not use Carecube if there is any identified damage.
B. **Warning:** The Manometer should be checked frequently to confirm negative pressure is being maintained at min of -2.5 pascals.
C. **Warning:** Failure to snap poles into Corner Pole Fittings securely can cause External Frame to collapse.
D. **Warning:** Check that the duct is securely fastened to filter housing and free of cracks or damage.
E. **Warning:** Ensure Access Doors, Glove Ports and Airlock Pass Throughs are fully sealed.
F. **Warning:** Do not open both zippers to Airlock Passthrough at the same time.
G. **Warning:** All materials being removed from Carecube are considered waste.
H. **Warning:** Do not place the patient inside the Carecube unless the Main Fan is running, and -2.5 pascals of pressure has been achieved. Five (5) minutes after all access doors have been closed, check the Manometer to verify that the patient enclosure is under negative pressure.
I. **Warning:** Cables must be secured to Conduit Panels with zip ties at all times.

ASSEMBLY and INSTALLATION

Unpacking the Carecube

NOTE: Unit comes un-assembled, packaged in 3 packages.

External Frame
Canopy with optional reload kits for additional patient use
Main Exhaust Fan with manometer

Reusable Components	Limited Reuse (Not to exceed 10 patients)	Single Patient Use Components
External Frame	Canopy with HEPA Filter	Lean-in Window Glove Ports
Main Exhaust Fan	Manometer Tubing	Auxiliary Glove Ports
Manometer		Stethoscope Trunks

Assembly Instructions

Inspect the packaging contents for shipping damage and ensure all components are present. The product should be inspected before use. The device can be stored for up to one (1) year.

- Inspect for damage or missing parts throughout the assembly process and before use. Never use if parts are missing or damaged. Contact Carecubes, Inc. Customer Service for replacements. See the *FREQUENTLY ASKED QUESTIONS (FAQ)* section for contact information.
- **WARNING: Never repair a damaged unit** (reference *Troubleshooting* section).
- Assemble in or near the location where the Carecube will be used.

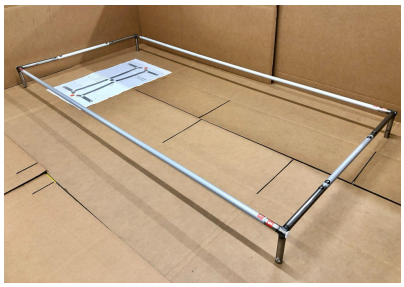
Frame Assembly

A. ***NOTE:*** Carecubes recommends two operators for frame assembly.
B. **Inspect for damage or missing parts throughout the assembly** (reference *Unpacking the Carecube* section).
C. **READ ALL LABELS!**
D. **DANGER! METAL CONDUCTS ELECTRICITY! Use care when using near electrical lines and circuits.**
E. Erect the Frame on a firm, level surface.
F. Make sure all poles snap together securely before advancing to the next step.

Step 1: Remove four corner fittings and arrange as shown above.

Step 2: Connect poles labeled "2" to the matching arm of each fitting, as shown. .

Step 3: Connect poles labeled "1", which are connected by internal cord, to the corner fittings.



Step 4: Attach all poles to corner fittings by depressing the pin and inserting to secure.

WARNING: FAILURE TO SNAP POLES INTO CORNER POLE FITTINGS SECURELY CAN CAUSE EXTERNAL FRAME COLLAPSE AND SERIOUS INJURY

Step 7: Remove poles labeled “3” with no foot label from packaging and attach the first two legs to fittings.

Step 8: Attach remaining two legs labeled “3” with no foot label to the opposite end.

Step 9: Pause! Set Pole Set #4 aside and continue to Canopy Installation.

Canopy Installation

NOTE: Assembly requires two operators for completion

Step 1: Determine the head and foot end of the Frame in accordance with the preferred orientation of the patient.

Step 2: Remove the Canopy from packaging and place it under the Frame.

Step 3: Unfold Canopy as shown in image above.
Note: The small cardboard box corresponds with the head-end.

Step 4: Open the Canopy and align under the Frame and identify the top corners of the Canopy. (The top corners are identified by the group of 3 orange clips)

Step 5: Find and attach the corners of the Canopy.

Step 6: Secure the remaining roof Canopy clips to the Frame.
Note: Leave leg clips unattached for now.

Final Frame Assembly

NOTE: Assembly requires two operators for completion.

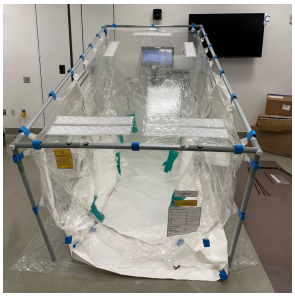
DANGER! METAL CONDUCTS ELECTRICITY! Use care when using near electrical lines and circuits.

A. Erect the Frame on a firm, level surface.
B. Make sure all poles snap together securely before advancing to the next step.

Step 1: Locate remaining poles and grey pole feet and remove from packaging.

Step 2: Align the foot-labeled end of pole into the grey foot and press to assemble.

Note: Properly seating the pole completely into the grey foot will require adequate pressure.



Step 3: Attach remaining poles labeled "3" with foot label to rest of Frame then attach remaining two poles to the foot end of Frame.

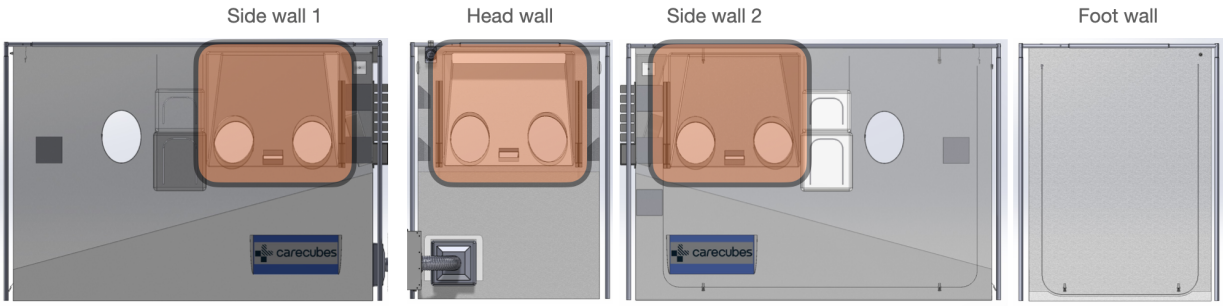
Step 4: Secure remaining Canopy Clips to the frame.

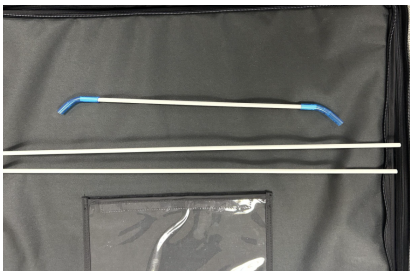
Step 5: Make any final location adjustments to the frame now. *Note: We recommend choosing a location with proximity to a power source for the Main Fan and Manometer.*

Step 6: Check all sides and panels of the Canopy for any visible tears or punctures. **WARNING: If any punctures or tears are identified, do not use the damaged Canopy.** Contact Carecubes, Inc. Customer Service for a replacement. See the *FREQUENTLY ASKED QUESTIONS (FAQ)* section for contact information.

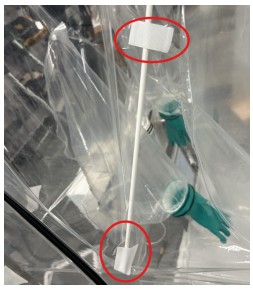
Lean-In Window Poles Installation

There are three (3) Lean-In Windows, one (1) on each side wall and one (1) on the head wall in the Carecube Canopy highlighted in orange below. Each Lean-In Window requires installation of a pole set. Lean-In Window pole sets are packaged with the Canopy.

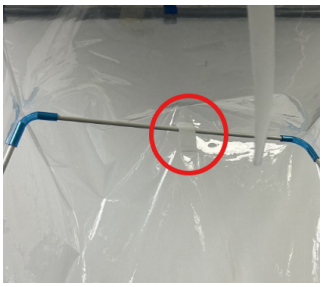




Step 1: Locate Lean-In Window pole sets that were placed aside during the prior Canopy Installation steps. Each poleset contains a small top pole with blue connectors, as well as two longer legs.

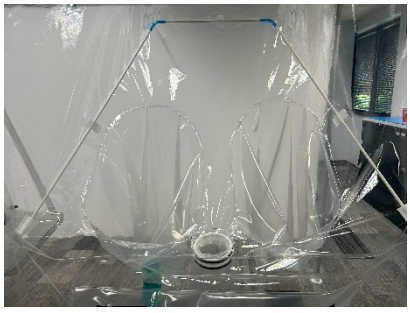


Step 2: Go to the Lean-In Window, and locate the pole pockets and pole loops on the outside (highlighted above). Slide the legs of the Lean-In Window poles through the pole loops and into the pole pockets.



Step 3: Locate the top pole loop (highlighted above), and slide the top pole through the loop.

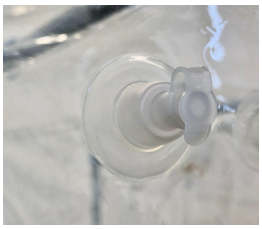
Step 4: Connect the top pole to the pole legs on each side by gently inserting the pole legs into the blue connector. Repeat installation for two remaining Lean-In Window pole sets.

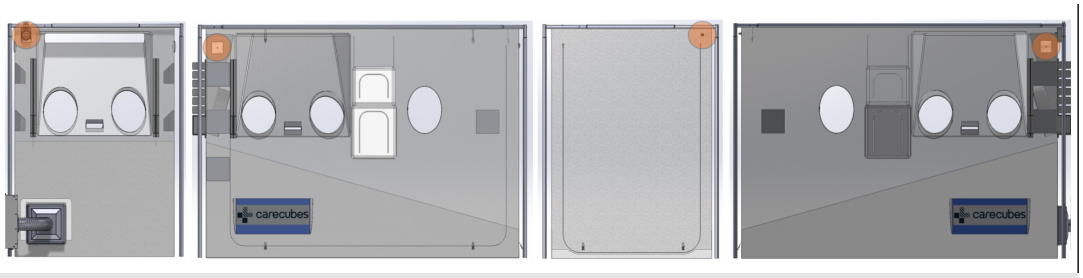


Note: Lean-In Window Pole should seat securely at the deepest location possible as shown in image above.

Manometer Installation

The Manometer assembly includes the manometer (with digital pressure reading display) and a light beacon as an additional visual indicator for pressure performance. The Manometer must be installed near one of the four Manometer Access Ports and may be clipped onto the nearest vertical pole.





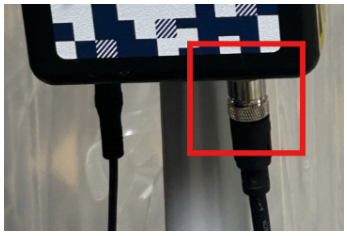
Step 1: Identify all four (4) locations of the Manometer Access Ports on the Canopy (highlighted in orange above).
Step 2: Choose which one of the four Access Port locations provides the highest visibility and an unobstructed view for healthcare providers to see the Port location (this will ultimately be the Manometer location).
Step 3: Once you have chosen the Carecube final location, if needed adjust the Manometer's power source as well.

Step 4: Use the flexible strap to clip the Manometer to the frame pole closest to the Access Port you identified in Step 2.

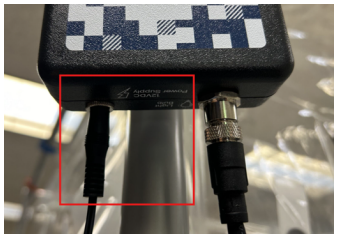
Step 5: Connect the manometer tube to the port on the back of the Manometer.

Step 6: Connect the manometer tube to the port on the back of the Manometer. Feed ½ inch of the tube through the port to ensure the tube is not easily pulled out.

Step 7: Using the attached clamp (highlighted) connect the beacon light to an easily visible spot on the frame roof.



Step 8: Connect the beacon light to the manometer by attaching the cord as shown.



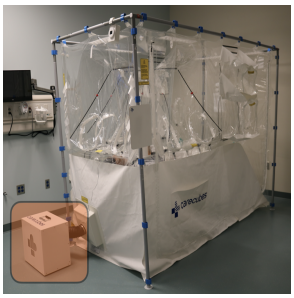
Step 9: Plug the power cord into the manometer, ensuring the power cord is connected to a power source.

A. The Manometer is pre-configured for the Carecube pressure requirement of negative 2.5 Pascals (displayed as -2.50 Pa).
B. Under normal operation when negative pressure requirement is being met, the beacon light will glow green.
C. If negative pressure is not at the required level, the beacon light will glow red. Reference *Troubleshooting* section for options if this occurs.

Main Exhaust Fan Installation

The Main Exhaust Fan is packaged in Box 4.

A. CAUTION! Inspect for damage or missing parts before each use and read all labels.



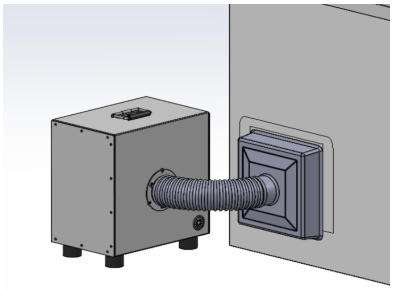
Step 1: Place the Main Exhaust Fan directly outside the HEPA Filter Housing at the head of the enclosure, as highlighted above.

Step 2: Visually verify that the HEPA Filter, Filter Housing and Duct are secure and in good condition.

CAUTION: Never repair a damaged Main Exhaust Fan. Contact Carecubes, Inc. Customer Service for a replacement. See the *FREQUENTLY ASKED QUESTIONS (FAQ)* section for contact information

Step 3: Expand the duct and securely fasten onto the Main Exhaust Fan by connecting the duct docks and twisting clockwise to snap together.

Step 4: Ensure that the duct is securely attached at both ends. Plug the power cord into a nearby power source to turn the Main Exhaust Fan on.



Note: The Main Exhaust Fan can be placed directly in front of HEPA housing with duct compact, extended, or slightly angled as needed. Significant kinking/twisting of ducting may reduce optimal negative pressure.

B. **Negative Pressure Check:** Using the Manometer, check that the Carecube internal pressure is meeting the negative pressure requirement of -2.5 pascals (i.e. -2.5 Pa on manometer screen). **Repeat the Negative Pressure Check at least once every 24 hours during use.**

C. 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, in addition to Manometer checks, by

visually inspecting the Carecube Canopy for presence of taut and concave walls or ceiling to confirm the unit is generating negative pressure.

D. Follow all applicable infection control and containment requirements. **Ensure that proper procedure is followed when entering and exiting the isolation area including the opening and closing of the Carecube's zippered doors.**

Upon completion of installation of all Carecube components, the Carecube is now ready for operation.

OPERATING INSTRUCTIONS

Preparing the Carecube for Use

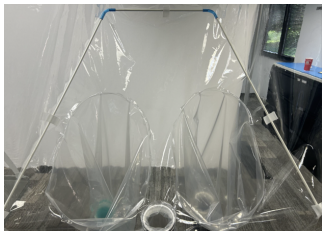
If there is visible film or residue on the Canopy, wipe down the Canopy and Lean-In Windows with bleach wipes to remove (see the *Cleaning and Disinfecting the Carecube - Detailed Procedure* section).

Prior to placing patient into the enclosure ensure the following steps are completed:

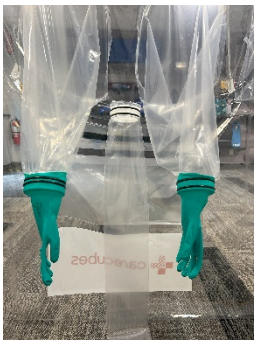
Step 1: Ensure the Canopy, Glove, Auxiliary Glove and Trunk Ports are free of tears and/or punctures.
Step 2: Airlock Passthrough must have both inner and outer zippers fully closed.
Step 3: Manometer Ports not in use must be sealed.
Step 4: Canopy Access Doors should be zipped fully closed and anchored with the t-bar.
Step 5: Duct is secured to HEPA Housing on Canopy and Main Exhaust Fan.
Step 6: Main Exhaust Fan is plugged in and unobstructed.
Step 7: Lean-In Window Poles are installed correctly (pushed all the way in) and retracted.
Step 8: Manometer pressure reading is less than or equal to -2.5 pascals.

Carecube Features

Healthcare providers can access the patient and equipment inside the Carecube to enable appropriate medical interventions through the use of various features of the Carecube.



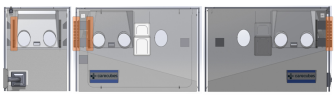
Lean-In Windows (3)
Lean-In Windows provide greater visibility to the patient by allowing the provider to lean in closer during standard medical interventions with the patient and/or medical equipment while maintaining an isolation barrier between the patient and provider.



Glove Ports (3)
Glove Ports are located in three locations, within the Lean-In Windows. These provide access to the patient for standard medical interventions, allowing the use of medical equipment as needed, while maintaining digital dexterity.

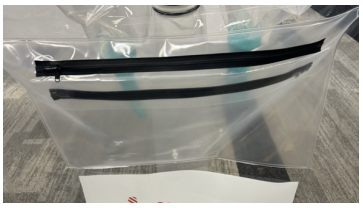
Auxiliary Glove Ports (2)
Additional Glove ports are provided next to the Airlock Passthroughs. Auxiliary Glove Ports are used to provide access to the feet of the patient for standard medical interventions as well as the Airlock Passthroughs.

Trunk Ports (3)
Trunk Ports are located at the center of each Lean-In Window and are available for the utilization of medical equipment, such as a stethoscope, while maintaining a barrier between patient and provider.



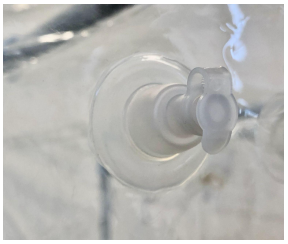
Conduit Panels (4)
Conduit Panel allows the healthcare provider the ability to introduce necessary cords and cables, needed for operation of standard medical equipment, into the Carecube.

Airlock Passthroughs
Airlock Passthroughs allow for the passage of materials (i.e., food, medications, blankets, etc.) into and out from the Carecube interior. **CAUTION!** All materials being passed from inside the Carecube are considered waste.



Flat Airlock Passthroughs
Flat Passthroughs also allow for the passage of materials into and out from the Carecube interior. **CAUTION!** All materials being passed from inside the Carecube are considered waste.

Manometer
Manometer is used to verify that the patient enclosure is under the required level of negative pressure.
Note: pressure must be less than or equal to **NEGATIVE** 2.5 pascals (displayed as -2.50 Pa). e.g. -3.50 Pa is acceptable, but -1.50 Pa is NOT acceptable. Beacon light will be green when pressure is meeting this requirement.

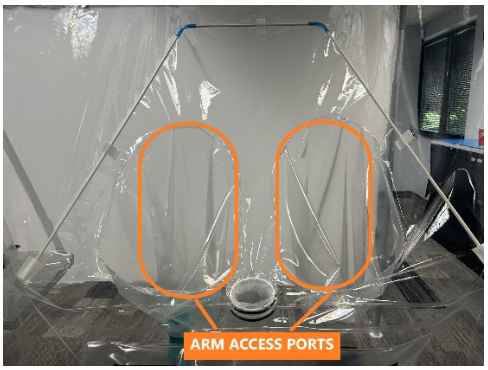


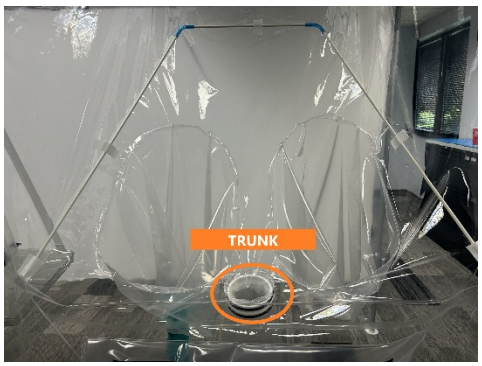
Manometer Port
There are four (4) Manometer Port locations around the Carecube, one on each wall to provide maximum flexibility for easy visual identification of the Manometer indicator beacon light.

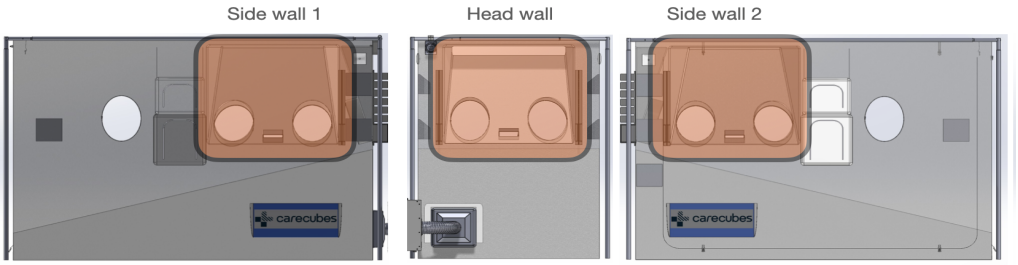
Main Exhaust Fan
Negative pressure is achieved using the externally placed Main Exhaust Fan.

Lean-In Window Operation

Use the Lean-In Windows to access the patient for the performance of standard medical interventions. There are three (3) Lean-In Window locations in the Canopy.







Step 1: Expand the Lean-In Window by releasing the velcro tab in the top center of the window and gently push in towards the patient.

Step 2: Use the Glove Ports on either side of the Lean-In Window to access the patient and the Trunk Port at the center of the Lean-In Window for utilization of medical equipment, e.g. a stethoscope.

Step 3: Retract the Lean-In Window back to its original position by securing the velcro tab to the velcro strip at the top center of the Lean-In Window.

Donning Gloves in Glove Ports and Auxiliary Glove Ports

Internal pockets located near the Lean-In Windows are designed to accommodate boxed medical gloves. Carecubes, Inc. recommends that healthcare providers don a pair of medical gloves prior to using the Carecube.

Glove Port Operation

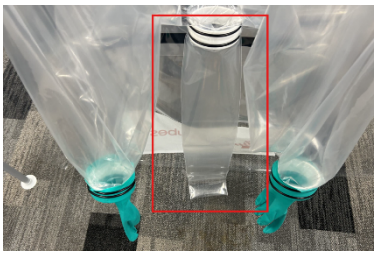
A. A pair of Glove Ports are located within each of the three Lean-In Windows.
B. Glove Ports are used to provide access to the patient for standard medical interventions. Provider may don medical gloves before inserting hands into the Glove Ports as shown in the photo above.

Auxiliary Glove Port Operation

A. Auxiliary Glove Ports are located in two (2) locations, one on each side wall, next to Airlock Passthroughs.
B. Auxiliary Glove Ports are used to provide access to the foot of the patient for standard medical interventions as well as the Airlock Passthrough.
C. Provider may don medical gloves under the Auxiliary Glove Ports as shown in the photo above.

Stethoscope Trunk Port Operation

A. Stethoscope Trunk Ports are located at the center of each Lean-In Window and are available for the utilization of medical equipment, such as a stethoscope, while maintaining a barrier between patient and provider.

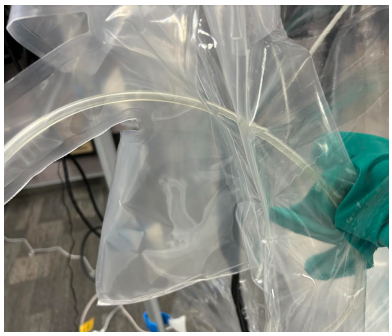


Conduit Panel Operation

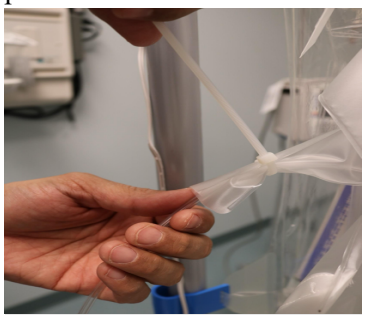
The Conduit Panel allows the healthcare provider the ability to introduce the tubing, cords and cables needed for operation of standard medical equipment into the Carecube.

Step 1: Locate the Conduit Panels at the head of the bed or gurney and on either side of the bed or gurney, Select the most convenient or functional position relative to the patient's monitoring lines or IV placement.

Step 2: Insert the necessary tubing, cords or cables through the Conduit Panel slots on the outside.



Step 3: Once lines are inserted through the slots, thread the lines downward through the conduit panel barrier shield on the interior of the canopy. The gloves can be used to access the lines inside the barrier shield and pull them down.

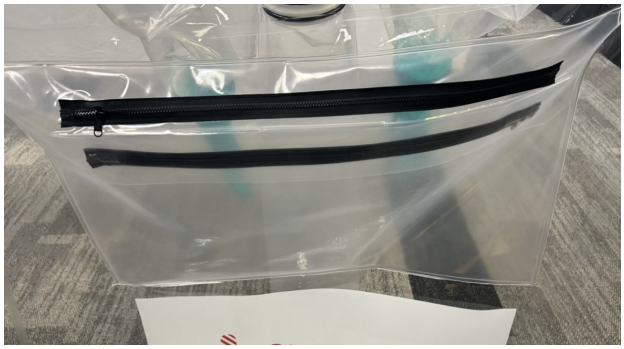


Step 4: Ensure all tubing, cords or cables are connected and cinched securely using the provided releasable zip ties.

WARNING: Follow facility disinfection and cleaning protocols prior to removing tubing, cords or cables from the Conduit Panel to ensure safety.

Passing Objects In and Out of the Carecube

There are Airlock Passthrough and Flat Passthrough chambers ("chamber"), which can be used to add or remove materials (medicines, waste, etc.) to/from the patient in the Carecube.

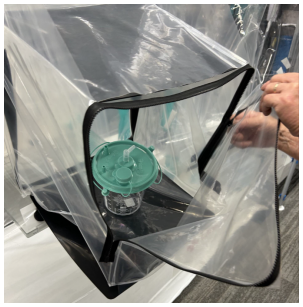


Passing Materials INTO the Carecube:

Use the chamber to pass materials (i.e., food, medications, blankets, etc.) to the patient inside the Carecube.

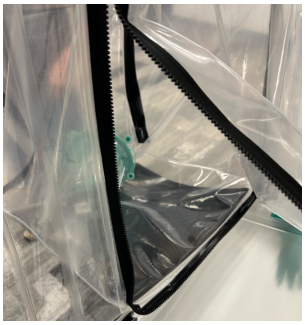
WARNING: Do not open both zippers to Passthrough at the same time.

Step 1: Unzip the chamber and place items inside.



Step 2: Zip the chamber closed.

To get the materials to the patient, you need to access them from the inside of the cube by unzipping the chamber from the inside. The Airlock Passthrough can be accessed via the glove ports on either side of the airlock. It is generally easiest to reach items in the Airlock Passthrough with the Auxiliary Glove Ports. However, the Lean-In Window Glove Ports can also be used. *Note: To use this approach, you need to put the opposite arm in the port (e.g., right arm in left glove) which may feel odd but will facilitate zipping and unzipping.*



Step 3: Unzip the chamber.

Step 4: Remove the materials.

Step 5: Zip the chamber after the materials have been passed inside the Carecube.

CAUTION: All zippers must be fully zipped once Passthrough procedures are complete.

Removing Materials FROM the Carecube:

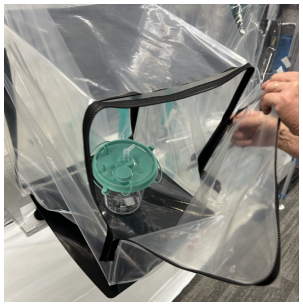
Use the chamber to remove materials (i.e., waste, etc.) from inside the Carecube.

CAUTION! All materials being removed are considered waste.
WARNING: Do not open both zippers to an Airlock Passthrough at the same time.

To remove materials, you will reverse the above steps with the chamber.

Step 1: Unzip the inner zipper chamber and place materials inside.

Step 2: Zip the inner zipper chamber closed.



Step 3: Face the outer chamber and unzip the outer chamber.

Step 4: Remove the materials from the outer chamber. Re-zip the outer chamber, and dispose of any waste.

CAUTION: All zippers must be fully zipped once Passthrough procedures are complete to prevent cross contamination.

Emergency Access

Emergency access allows the healthcare provider to open the Carecube to gain complete and immediate access to the patient in the event of a medical emergency.

Healthcare providers can gain direct access to the patient by breaching the containment chamber through the Footwall Entry/Exit Roll-up Door or Sidewall Entry/Exit Roll-up Door. See Image 1 page 2 for location reference.

Follow institutional protocols for use of PPE when entering and exiting the negative pressure containment chamber.

Manometer

Reading the Manometer

The manometer is pre-configured for the Carecube so that the visible beacon light indicator will be green when the -2.5 Pa pressure requirement is reached.

Ensure the appropriate pressure (≤-2.5Pa) has been achieved prior to placing a patient into the Carecube by reading the visual display on the Manometer.

Under normal operation, when pressure is at the required level, the beacon will glow green.

If negative pressure does not reach the -2.5 Pa requirement, the beacon will glow red.

Reference Troubleshooting section for options if the system is unable to achieve the required pressure.

Moving the Manometer

A. Manometer is ready to be moved after cleaning procedure has been completed.
B. Unclip Manometer and move to one of the other three (3) Manometer Port locations on the Carecube.

PATIENT CARE

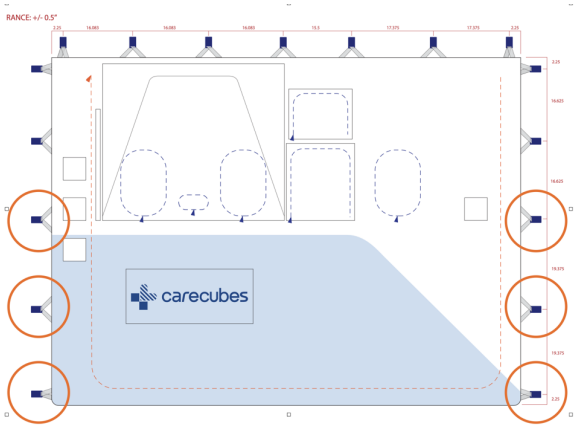
Placing Patient into Carecube

CAUTION: Ensure the Carecube pressure has reached -2.5 Pa before placing a patient into the Carecube.

A. Prior to placing the patient, the zippered doors of the Carecube may remain open while placing 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 Conduit Panels located around the Lean-In Windows of the Carecube. Cinch lines in the conduit panel fingers with zip-tie after placement, to avoid migration of contaminated lines to the outside of the Carecube.

C. Once all necessary equipment is placed inside the enclosure, unclip the lowest three blue canopy clips (indicated below) on either side of the door being utilized and transfer the patient into the Carecube.



Exit the Carecube, reattach the lowest three blue clips to frame legs, and zip all access doors completely closed.

D. The patient is now ready to be connected to monitoring cords and instrumentation leads using the Glove Ports in the Lean-In Windows.
E. Devices incorporating wireless connectivity are recommended for use in the Carecube.
F. Any additional equipment needed can be safely transferred using the Airlock Passthroughs on the patient's left or right side of the Carecube.
G. Add patient record number to Patient Tracker Label on the foot of the Canopy to ensure patient maximum does not exceed ten (10).

Removing Patient from Carecube

WARNING: All equipment and patient linens inside the Carecube should be considered waste and be cleaned according to institutional cleaning protocol.

A. Ensure the main fan is ON.
B. Supply the patient with an appropriate face covering per institutional protocol using the airlock pass through.

*With all Pass Throughs closed, and the Main Fan ON, allow the patient to be **masked for 5 minutes** before opening doors for removal. This reduces the aerosolized infectious agent inside the Carecube.*

1. Using the Lean-in Windows and Glove Ports, disconnect all patient monitoring lines/IV tubing. Once disconnected, **all lines should be PULLED INTO the Canopy** via the Conduit Panels, using the glove ports. **Do NOT pull any lines OUT of the Canopy** through the Conduit Panels.
2. While remaining outside the Canopy, remove waste from inside the Canopy utilizing the glove ports and Flat Pass Throughs.
    a. Remove as much waste as possible prior to opening the Carecube.
    b. Use the Lean-In Window to bag waste as per institutional protocol (tie and secure inner and outer bag).
    c. Remove waste from the Carecube per *Removing Materials from the Carecube* section.
3. From outside of the Canopy, using the Lean-in Windows and Glove Ports, clean the accessible inside surfaces of the Canopy (including the floor) and all single patient surfaces: perform cleaning of the inside surfaces of the Canopy, including Glove Ports, Lean-In Windows and Trunks.
    a. Wipe down including the single patient use surfaces: Glove Ports, Lean-In Windows, Gloves, Trunks and equipment.
    b. Pay attention to the corners and folds.
    c. Invert the Glove by pushing the fingers into the cuff. This minimizes contact with used gloves.
    d. Roll the bottom half of the Trunk and push it into the port to invert.
4. Ensure you have cleaned visible waste and highest touch surfaces like gloves, windows and trunks.
5. **Patient is now ready to be moved out of the Carecube.**
6. Utilize institutional protocol for use of PPE for patient removal and entry into the Carecube.
7. Prepare the patient for transport per institutional protocol (PPE, gurney, reconnect relevant connections/lines)
    a. If equipment remains that will move with the patient, use institutional protocol for cleaning before moving the patient.

After removing the patient, close the Canopy by zipping access wall(s), leaving the Main Fan running until cleaning steps are completed.

Removing Patient from Carecube if Patient is Deceased

If the patient is deceased, patient removal should be conducted per institutional protocol. Refer to *Removing Patient from Carecube* section for guidance. *Carecubes recommends **waiting 5 minutes before opening doors** for removal. This reduces the aerosolized infectious agent inside the Carecube.*

WARNING:
After removing the patient, the Carecube system MUST be cleaned before reuse, disposal, or storage per the *Cleaning and Disinfecting the Carecube Interior - Detailed Procedure* section.

Cleaning & Disinfecting the Carecube - Summary

Cleaning and Disinfection of the Carecube MUST be performed at the following times:

- in between patients
- before disposing of single patient use components
- before replacing single patient use components
- before disposing of the Canopy

Cleaning and Disinfection should be performed as per institutional protocol and the detailed instructions below.

After cleaning and disinfection, the Carecube is ready for the following:

- Canopy usage with the next patient
- Canopy disposal prior to or at the end of its usable life
- Reusable parts storage (Frame, Main Fan, Manometer, Lean-In Window Pole Sets)
- Disposal of single-patient use components (Gloves and Trunks)

Regarding cleaning, parts should be considered as follows:

- Single patient use/replace after cleaning and disinfecting: Gloves, Trunks
- Limited reuse after cleaning Canopy, Manometer Tubing
- Reusable after cleaning: Main Fan, Frame, Manometer, Lean-In Window Pole Sets

WARNING: Canopy cannot be stored after initial set up and use with patients.

Cleaning & Disinfecting the Carecube Interior - Detailed Procedure

Materials inside the Carecube should be handled as waste and handled as per institutional protocol.

1. Follow instructions for removing the patient from the Carecube.
2. Ensure the Main Fan remains ON.
3. Pull all lines INTO the Canopy using the Glove Ports.
4. Pull the Manometer Tubing INTO the Canopy using the Glove Ports. If it cannot be reached, PUSH it in from the outside of the Canopy.
5. Entering the Canopy:
    a. Now that the patient and waste have been removed, follow institutional protocol for the use of PPE before entering the Canopy.
    b. Open the Canopy using either the zippered foot wall or zippered side wall.
    c. Fold the wall inward in half and secure using the buckles located at the top of the wall.
    d. Enter the Canopy, unclip the wall, and zip it closed from the inside.

WARNING: Avoid touching the screen in front of the HEPA Filter with cleaning and disinfecting materials so as not to damage or impede the performance of the HEPA Filter.

6. **Cleaning:**
    a. For cleaning and disinfection steps below, a bleach wipe with a minimum of 0.55% Sodium Hypochlorite (NaOCl) should be used. For steps utilizing a spray, a bleach spray with a minimum of 0.65% Sodium Hypochlorite (NaOCl) should be used. Note: Clorox Healthcare Bleach Germicidal Cleaner wipes and spray meet the concentration requirements above and were used in validation testing.
    b. Thoroughly wipe down all interior surfaces (including the floor) using bleach wipes and in accordance with institutional high-touch cleaning protocols. Clean all surfaces, whether soil is visible or not. Inspect

all surfaces after cleaning and if any visible soil is observed, repeat cleaning steps.

c. Thoroughly wipe down all exterior surfaces using the same procedure as the interior surfaces.

7. **Disinfecting:**
    a. Zipper Disinfection:
        i. For each zipper, spray bleach liberally along the zipper track. After spraying, thoroughly wipe down the entire length of the zipper track with a bleach wipe and allow the solution to remain on the track for 3 minutes before removing.
    b. Canopy Disinfection (all surfaces):
        i. Wipe down all interior surfaces a second time using fresh bleach wipes. Ensure that the cleaning solution covers all surfaces, including corners, and hard to reach small spaces.
        ii. Allow cleaning solution to remain on surfaces for a minimum of 3 minutes, then wipe down all surfaces with a clean, lint-free cloth to remove the cleaning solution.
        iii. Disinfect the exterior surfaces using the same disinfection procedure as the interior surfaces.
8. Prepare the single patient use components (gloves and trunks) for removal by inverting them into the cuff. This will minimize contact with highest touch surfaces on these components.
9. Remove all O-rings, Gloves, Trunks and dispose of them all per institutional protocol.

NOTE: The Carecube Canopy can safely withstand cleaning and disinfection (using the instructions listed above) up to 10 times using Sodium Hypochlorite (Bleach) at a 0.65% concentration.

Carecubes, Inc. recommends using institutional protocol where referenced above. Please refer to the CDC's Guidelines for "Cleaning procedure summaries for specialized patient areas" subsection "Transmission-based precautions/Isolation Wards." CDC Reference.

Cleaning the Carecube Exterior

As needed, wipe down any reusable equipment that is OUTSIDE the Canopy (Main Fan, Frame, Manometer, Lean-In Window Pole Sets) as per institutional protocol.

Replacing Gloves After Cleaning

WARNING: All Gloves in the Carecube must be replaced between patients and disposed of according to institutional protocol. Gloves should not be replaced while a patient is inside the Carecube. During cleaning, you should have removed and disposed of the used Gloves and O-rings.

Step 1: From inside the Canopy, remove the existing Gloves from each of the Cuffs by removing each of the black o-rings (2) from the Glove. Discard the used o-rings.

Step 2: Pull the Glove off of the Glove Port, exposing the plastic cuff and discard the used Glove.

Step 3: Roll the new Glove over the white plastic cuff of the Glove port. It may take two hands to stretch the base of the glove wide enough to fit. Once one side of the glove is over the cuff, it is easier to stretch the other side over.

Step 4: Once the glove is fully covering the cuff, secure the glove in place by rolling each (2) of the black O-ring into the selected grooves. It may take two hands to stretch the o-ring over the cuff. Once one side of the o-ring is in place, the other end can be stretched over the cuff. Repeat for the second o-ring.

Replacing Trunk Ports in the Lean-in Windows, After Cleaning

During cleaning, you should have removed and disposed of the used Trunk Ports and O-rings.

Step 1: From inside the Canopy, remove the existing Trunks from each of the Cuffs by removing each of the black o-rings (2) from the Glove. Discard the used o-rings.

Step 2: Pull the Trunk off the Glove Port, exposing the plastic cuff and discard the used Trunk.

Step 3: Roll the new Trunk over the white plastic cuff of the Glove port. It may take two hands to stretch the base of the glove wide enough to fit. Once one side of the glove is over the cuff, it is easier to stretch the other side over.

Step 4: Once the trunk is fully covering the cuff, secure the trunk in place by rolling each (2) of the black O-ring into the selected grooves. It may take two hands to stretch the o-ring over the cuff. Once one side of the o-ring is in place, the other end can be stretched over the cuff. Repeat for the second o-ring.

Carecube Disassembly, Storage, and Disposal

If you are NOT intending to use the Carecube with another patient, ensure the following steps are followed.

WARNING: The Canopy itself cannot be stored after use; it must be disposed of as per institutional protocol.

Summary Procedure

1. Properly clean and disinfect the Canopy and all parts (see *Cleaning and Disinfecting the Carecube Interior* section).
2. Disassemble the Carecube.
3. Dispose of the Canopy and all single patient use components per institutional protocol.
4. Store remaining reusable components.

Detailed Procedure: This process is easiest with two persons working together.

1. Ensure the Canopy and all parts have been properly cleaned (see *Cleaning and Disinfecting the Carecube Interior* section), including all external reusable components (Main Fan, Frame, Manometer).
2. Disassemble the Carecube.
    a. Remove Lean-in Window Poles and dispose.
    b. Uninstall Manometer and store in dedicated packaging.
    c. Main Fan should remain on until the Canopy is completely collapsed to avoid creating a positive pressure event during disassembly.
    d. Remove the lower Canopy Clips from the Frame Legs.
        i. Work from the foot of the Canopy towards the head.
        ii. Starting with the first leg, unclip the Canopy from the lowest three (3) blue Canopy Clips.
        iii. Remove lower section of each frame leg until the device is at half-height.
        iv. Repeat steps **ii-iii** for the other leg at the FOOT of the Canopy.
        v. Repeat steps **ii-iii** for both legs at the HEAD of the Canopy.
    e. The entire Frame is now lowered to half-height.
    f. Move Canopy material as needed to ensure the HEPA filter is unobstructed so air can flow through it.
    g. Starting from the foot end, remove the remaining clips and the corner clip on the legs on the foot end, one at a time.
    h. SLOWLY, remove one clip at a time on each side of the top frame (alternate sides if you're working alone). The Canopy should slowly lower to the floor.
    i. As sections of the Canopy lower to the floor, roll Canopy up (like a sleeping bag) as you go, forcing the air towards the head/filter end of the Carecube.
    j. Continue removing the roof frame clips, alternating sides and moving towards the head.
    k. Work slowly to maintain the negative pressure inside the Carecube.
    l. **Canopy Disposal:** Continue rolling towards the head of the Carecube/Main Fan until all Canopy Clips are released from the External Frame and the Canopy has been folded to meet the size desired to dispose of as per institutional protocol (e.g. will fit in a 96 Gallon Medical Waste Bin).
    m. Detach the Duct from the Main Fan.
    n. Turn off the Main Fan, and store in its dedicated packaging
    o. Dispose of Canopy and HEPA Filter/Housing, and Duct as per institutional protocol.
    p. Break down Manometer and store in dedicated packaging.

q. Break down the External Frame and store in dedicated packaging.
r. Clean area where the Carecube was installed, as per institutional protocol.

WARNING: The Canopy itself cannot be stored after use; it must be disposed of as per institutional protocol.

TROUBLESHOOTING

Problem	Possible Cause	Corrective Action
Negative air pressure cannot be maintained	**Manometer** • Manometer and canopy are not properly connected with tubing.	• Reference *Manometer Installation* section Contact Carecubes, Inc. Customer Service if the issue is not resolved.
	Canopy • Opening in the Canopy • Tear in the Canopy	• Check if all zippers are fully sealed • Check if Gloves (10) and Trunks (3) are all securely fastened • Check for tears • Do not attempt to repair Canopy. Contact Carecubes, Inc. Customer Service for replacement. See the *FREQUENTLY ASKED QUESTIONS (FAQ)* section for contact information.

	Main Fan & Filter
	• Exhaust Filter is blocked
	• Duct is not connected
	• Duct is torn/damaged
	• Duct is bent >90 degrees, or twisted
	• Fan malfunction
	  • Fan is not plugged in
	  • Fan is not functional
		• Check if HEPA filter is blocked from inside Canopy
		• Check Duct is damage free and fully connected
		• Straighten Duct to maximize airflow, and confirm ducting is not twisted or kinked
		• Contact Carecubes, Inc. Customer Service for a replacement if
		  • Main Fan is malfunctioning
		  • Duct is torn
		See the *FREQUENTLY ASKED QUESTIONS (FAQ)* section for contact information.

Zipper is stuck	• Something is caught in the zipper	• Reverse zipper direction and check if debris

	• Zipper is kinked	is present, clear out and reattempt zipping • Reverse zipper direction and check if zipper teeth are kinked and need to be realigned • Do not force the zipper closed, this may cause permanent damage • If unable to seal the enclosure, *Contact Carecubes, Inc. Customer Service* for replacement

Preventive Maintenance

A. There is no preventive maintenance required for the Carecube.

DEVICE SPECIFICATIONS

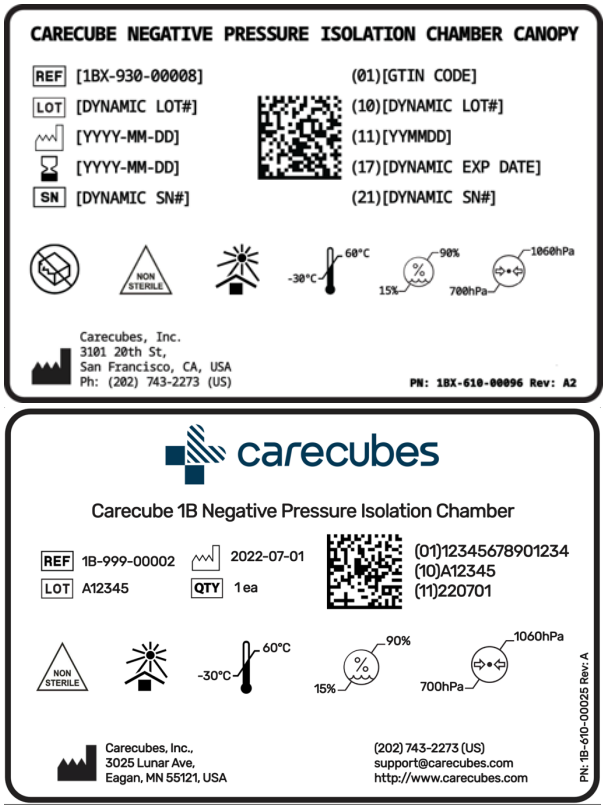
Size of assembled device	54”W x 118”L x 82” H
Weight	175 lb
Shelf life / storage life	1 year
Air filtration rate	HEPA (99.97% particulates @ 0.3μ)
Negative pressure under operating conditions	≤ -2.5 Pascals
Manometer Accuracy	Accuracy: ±0.5%, Range ± 500Pa
Transportation / Storage Temperature	-30 – 60°C / -22 – 140°F
Transportation / Storage Humidity	15 – 90% condensing humidity
Transportation / Storage Atmospheric Pressure	700hPa – 1060hPa
Operating Temperature	15 – 30ºC / 59-86ºF
Operating Humidity	15 – 90% condensing humidity
Operating Atmospheric Pressure	Sea level to 3,000m above sea level
Fuse Rating	3AG 1.6A 250V

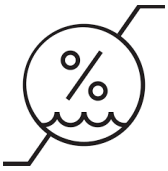
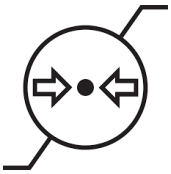
FREQUENTLY ASKED QUESTIONS (FAQ)

Question	Answer
How many unique patients (in total) can you treat using the Carecube?	The Carecube Canopy is intended for multi-patient use with a maximum of ten (10) patients, one patient at a time.
How long may a single patient remain inside a Carecube?	The Carecube is intended to be used by a single patient for up to 24 hours of continuous use. Note: Physiologically stable and normal healthy patient values were achieved for the duration of a 4-hour patient study as a basis for 24-hour single patient use.
Under what conditions should the Carecube **not** be used?	The Carecube is not intended for use with morbidly obese patients, patients weighing less than 45 pounds, for pediatric use, or in oxygen-rich environments.
How can you determine if the Carecube is operating at the appropriate negative pressure?	The Carecube is maintaining a minimum of -2.5pa pressure when the Manometer beacon light is glowing green. If the beacon light changes color to red, the minimum -2.5pa pressure is not being maintained and troubleshooting is recommended.
What actions can be taken to improve dexterity?	Donning a pair of medical gloves over the Lean-in Window Gloves can help improve dexterity. Internal pockets located near the Lean-In Windows are designed to accommodate boxed medical gloves.
How should the Carecube be cleaned and disinfected?	The Carecube must be cleaned between patients and before disposal as per your institution's protocol and according to the instructions in the *Cleaning & Disinfecting the Carecube - Detailed Procedure* section.
For how long can the Carecube be stored?	The Carecube has a shelf life of one (1) year. The Canopy, Gloves utilized in the Glove Ports and Auxiliary Glove Ports and Trunks cannot be stored after use, they must be disposed of per the healthcare facility's waste disposal policy. Reusable components such as the Frame, Main Fan and Manometer can be cleaned and stored away for the remaining shelf life of the Carecube.
Should PPE be used with the Carecube?	Follow institutional protocols for use of PPE.
The canopy material seems thin and perhaps easily tearable – how strong is the material?	The Carecube is constructed from a tear-resistant clear thermoplastic polyurethane (TPU), for which material usage has been validated.
Who should I contact for questions or issues with the Carecube?	*Contact Carecubes, Inc. Customer Service* 202-743-2273 (US only) support@carecubes.com

Question	Answer
	Replacement parts can be ordered by contacting Carecubes at the same number/email. For all inquiries regarding returns, please contact Carecubes at the email or phone number above.

GLOSSARY OF SYMBOLS

	Packaging label
	Consult instructions for use
	Warning
	Manufacturer
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Serial number

	Manufacturing date
	Use by date
	IEC-60601
	Non-sterile
	Do not use if package is damaged
	Keep away from sunlight
	Temperature limit
	Humidity limit
	Atmospheric pressure limit
	Manufacturer logo
	Pause

	Prescription only

EMC Test Compliance

Electromagnetic Conformity Declaration

The Carecube Negative Pressure Isolation Chamber has been built and tested according to IEC 60601-1 (3rd Edition) and IEC 60601-1-2 (4th Edition) standards. The Carecube is intended for use in the electromagnetic environment specified below. The user of the Carecube should assure that it is such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Carecube is intended for use in the electromagnetic environment specified below. The customer or the user of the Carecube should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR11	Group 1	The Carecube emissions are very low and are not likely to cause any interference in nearby electronic equipment in a typical hospital environment.
RF Emissions CISPR11	Class B	The Carecube is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Carecube is intended for use in the electromagnetic environment specified below. The customer or the user of the Carecube should assure that it is used in such an environment.			
Immunity Test	**Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electro-Static Discharge Immunity Test IEC 61000-4-2 ed 2.0 (2008-12)	±8 kV contact ±15 kV air	When discharging on the various metallic surfaces, insulated surfaces, and coupling planes, the Manometer's screen blanks out and sometimes requires reboot for screen to return to normal functionality. All other functions of the Manometer remain unaffected.	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical Fast Transient/Burst Immunity Test IEC 61000-4-4 ed 3.0 (2012-04)	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power should be that of a typical hospital environment.
Immunity to Surges IEC 61000-4-5 ed 2.0 (2005)	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power should be that of a typical hospital environment.
Power Frequency Magnetic Field Immunity Test IEC 61000-4-8 ed 2.0 (2009-09)	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips/Interruptions Immunity Test IEC 61000-4-11 ed 2.0 (2004-03)	**Voltage Dips @ 60 Hz** 30% reduction, 30 periods @ 0° 100% reduction, 0.5 period @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 100% reduction, 1 periods @ 0°	**Voltage Dips @ 60 Hz** 30% reduction, 30 periods @ 0° 100% reduction, 0.5 period @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 100% reduction, 1 periods @ 0°	Mains power should be that of a typical hospital environment.

	100% reduction, 300 periods @ 0°	100% reduction, 300 periods @ 0°	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	**Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted, Radio-Frequency, Electromagnetic Immunity Test IEC 61000-4-6 ed 4.0 (2013) IEC 61000-4-2 ed 2.0 (2008-12)	3 Vrms (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Carecube, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]
Radiated, Radio-Frequency, Electromagnetic Immunity IEC 61000-4-3 ed 3.0 (with A1:2007+A2:2010)	10 V/m 80 MHz to 2.7 GHz	Manometer: From 236-269 MHz at Vertical Polarity, Pa readings on the Manometer display abnormally. All other functions of the Manometer remain unaffected.	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Carecube is used exceeds the applicable RF compliance level above, the Carecube should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Carecube. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Carecube			
The Carecube is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Carecube can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Carecube as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity to RF Wireless Communications Equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

No Deviations from 60601-1-2 Ed. 4 were used.

CARECUBES, INC. CONTACT INFORMATION

Contact Carecubes, Inc. Technical Support Monday - Friday from 9AM to 5PM PST

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Email: support@carecubes.com
Website: carecubes.com
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3101 20th Street
San Francisco, CA 94110

LIMITED EQUIPMENT WARRANTY

1. Under this Warranty, Carecubes, Inc. warrants to Purchaser that the delivered equipment and parts (collectively, the Equipment) are free from significant defects in material or workmanship for a period of 180 days from the date of shipment of the Equipment (the Warranty Period). This Warranty contains Purchaser's exclusive remedy for defective Equipment (notwithstanding any conflicting document).

2. This Warranty does not apply to any Equipment that has been (a) misused, abused, neglected, tampered with, or damaged by accident, flood, water, fire, or other act of God or hazard, (b) subjected to abnormal or unusual physical stress or environmental conditions, (c) improperly installed, maintained, stored, altered, used, or operated (which includes an installation, maintenance, storage, alteration, use, or operation that is not in accordance with Carecubes Inc.'s instructions, including its Instructions for Use). This Warranty does not apply to any single use Equipment.

3. Purchaser's remedy under this Warranty is conditioned upon Purchaser's compliance with its obligations under Sections 3(a) and 3(b) below. During the Warranty Period, with respect to any allegedly defective Equipment the following shall apply.

    (a) Purchaser shall promptly notify Carecubes, Inc., in writing and in reasonable detail, of any alleged claim or defect within ten (10) business days from the date Purchaser discovers, or upon reasonable inspection should have discovered, such alleged claim or defect. Such notification shall include the Equipment's serial number and either a purchase order number, invoice number, or order number under which the Equipment was originally purchased.

    (b) Purchaser shall, at its expense, make the allegedly defective Equipment available to Carecubes, Inc. for inspection (either in person or virtually) and shall cooperate with Carecubes, Inc. in connection with such inspection.

    (c) If Carecubes Inc.'s inspection reveals, to Carecubes Inc.'s reasonable satisfaction, that the Equipment is significantly defective in materials or workmanship (per Section 1) and any such defect has not been caused or contributed to by any of the factors described under Section 2, Carecubes shall, in its sole discretion, and at its expense, (i) repair or replace such defective Equipment using new or reconditioned parts and/or subassemblies or (ii) credit or refund the price of such defective Equipment less any applicable discounts, rebates, or credits.

    (d) Purchaser shall ship the defective Equipment to a location designated by Carecubes Inc., and Carecubes Inc shall be responsible for all costs incurred in connection with such shipment. If Carecubes Inc. exercises its option to repair or replace and determines that the defect does not impact the Equipment's negative pressure or any other critical component of the Equipment, Carecubes Inc. shall ship the applicable replacement

Equipment to Purchaser at Carecubes Inc.'s cost, and Purchaser shall be responsible for installing such Equipment. This Warranty will be applicable to such newly installed Equipment starting from the date of shipment of such Equipment.

THIS SECTION 3 SETS FORTH THE PURCHASER'S SOLE AND EXCLUSIVE REMEDY AND CARECUBES'S ENTIRE LIABILITY FOR ANY BREACH OF THIS WARRANTY. This Warranty does not provide any compensation during the period that the Equipment is inoperative.

4. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTION 1, CARECUBES MAKES NO WARRANTY WHATSOEVER WITH RESPECT TO THE EQUIPMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD PARTY, WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE, OR OTHERWISE.

5. In no event shall Carecubes be liable or responsible for direct, indirect, special, incidental, punitive, exemplary, or consequential damages of any kind, including, without limitation, revenues or profits lost, even if Carecubes has been advised of, or could reasonably foresee, the possibility of such damages.

Patent Pending: ISOLATION ROOM SYSTEMS AND METHODS: U.S. Provisional Application No. 63/071,830