TERRA UNIVERSAL.COM
Critical Environment Solutions

Quick-Start Operating Guide *Document No. 1800-90*

USP 797 Modular Cleanroom

 Rev. August 2022

Your Comprehensive Equipment Source

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Proprietary Notice

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Safety Notice

A thorough familiarity with all operating guidelines is essential to safe operation of the product. Failure to observe safety precautions could result in poor performance, damage to the system or other property, or serious bodily injury or death.

The following symbols are intended to call your attention to two levels of hazard involved in operation:

CAUTION

Cautions are used when failure to observe instructions could result in significant damage to equipment.

WARNING

Warnings are used when failure to observe instructions or precautions could result in injury or death.

USP 797 Compliant Cleanrooms

Installation and operating instructions in this manual pertain to Terra Modular Cleanrooms designed to comply with the provisions of USP 797 for sterile compounding. It is recommended that you review this manual in its entirety prior to installation.

These cleanrooms feature Terra's standard hardwall construction configured in two standard sizes: 6' x 8' and 6' x 10'. Refer to attached system drawings for details on any custom features specified in your order, including custom dimensions. Standard designs include a "buffer" area (main processing room) and anteroom (staging/gowning area). These spaces are divided by a swing door mounted to an internal wall, which maintains the required pressure differential between the two areas.

Modular Hardwall Cleanrooms designed to the requirements of USP 797 feature three Fan Filter Units, which are factory set at medium speed. At this setting, these systems meet the requirements for internal pressure, air displacement, and cleanliness specified by USP 797 for both the ISO 7 "buffer room" (main processing room) and ISO 8 ante room (see "Compliance Testing Protocol" for more information).

Users are typically required to undergo on-site testing and certification by an independent testing company authorized by the relevant regulating agency. Any data furnished by Terra, including information published in Terra literature or web pages, do not constitute formal certification to USP 797 or any other specification or regulation.

1.0 Description

Terra Universal's Modular Cleanroom provides an economical alternative to high-cost, fixed-installation cleanrooms while providing the rigidity and durability of a freestanding room.

Designed to combine economy and versatility, this system features ceiling HEPA Fan Filter Units (FFUs) that direct a continuous flow of HEPA or ULPA-filtered air through the enclosure. The continuous positive pressure created by this laminar airflow helps to control particles generated inside the enclosure by sweeping them downward through the room and out the air vents. This design also helps to prevent contaminants from entering the cleanroom when an access door is opened.

ISO 7 Buffer Room of Terra Universal's USP 797 Cleanroom. Depending on specified dimensions, your cleanroom may be configured differently. Glovebox, hood and other furnishings not included.

The Modular Hardwall Cleanroom is supported by a rigid frame structure consisting of powder-coated 2"- square steel upright members and horizontal cross members. Support braces along the horizontal cross members form 2-foot x 4-foot ceiling grids that accommodate FFUs, lights and ceiling panels.

Cleanroom walls consist of 5/8"-thick fire-resistant wallboard attached to the support frame, with fiberglass-reinforced plastic (FRP) panels laminated to the inside wallboard to create a smooth, clean, sealed surface that can be easily washed and sterilized. ***Terra does not provide a finish for the exterior wallboard. When installation is completed, however, this surface can be finished and painted relatively easily and inexpensively to match your facility.***

IMPORTANT SAFETY NOTICE
Terra Universal cleanrooms are not designed to support more weight than the blower modules and lighting fixtures originally installed. Ceiling grid beams are not load-bearing and will not support personnel or other additional loads. Placing added weight on the ceiling grid may result in serious damage to the cleanroom and its occupants.
Yellow safety notice supplied by Terra Universal must be affixed prominently to the cleanroom grid.

Fan Filter Units (FFUs)

Fan Filter Units (FFUs) direct a vertical laminar flow of filtered air downward through the enclosed cleanroom area.

Each includes a 3-speed impeller blower (average flow: 650 CFM, operating at medium speed under filter load) mounted in a powder-coated steel housing with a plenum design that optimizes uniform air velocity across the entire face of the filter. A HEPA (high efficiency particulate air) filter installed inside the housing is rated 99.99% efficient at 0.3 um particles. The filtration medium consists of micro porous polyurethane minipleats held in place by strong, rigid plastic separators that keep the medium from nesting. This design channels airflow with optimal efficiency to reduce resistance. The filter is sealed into the sturdy steel frame with a fire-retardant, non-outgassing adhesive. On an optional basis, an ULPA (ultra-low penetration air) filter, rated 99.999% efficient at 0.12 um particles, may be substituted for the HEPA filter. Power to the Fan Filter Units is controlled by a master ON/OFF switch located on the cleanroom control panel.

All 120VAC units and 220VAC, 60Hz units are UL listed. CE-marked models are available for 220VAC, 50Hz operations. FFU quantity in USP 797 Cleanroom: three (3).

Fan / Filter Units (HS: high speed; MS: medium speed; LS: low speed)										
Model	Nominal Dimensions Inches (mm)	Wt. Lbs. (Kg)	Avg. CFM @ MS	Airflow ft/min (m/s)			Run Amps (Watts) @ 60Hz			Power
				HS	MS	LS	HS	MS	LS	
2 x 4	23.63 x 47.63 x 13	71	717	115	102	93	4.3A	3.5A	3.3A	120VAC, 60 Hz
	(600 x 1210 x 332)	-32	-1218	-0.58	-0.51	-0.47	(512W)	(416W)	(393W)	220VAC, 60 Hz
2 x 3	23.63 x 35.63 x 13	53	602	121	116	106	4.1A	3.1A	2.7A	120VAC, 60 Hz
	(600 x 905 x 332)	-24	-1023	-0.61	-0.59	-0.54	(500W)	(378W)	(329W)	220VAC, 60 Hz
2 x 2	23.63 x 23.63 x 13	44	558	172	166	162	3.9W	2.8A	2.4A	120VAC, 60 Hz
	(600 x 600 x 332)	-20	-948	-0.87	-0.84	-0.82	(472W)	(339W)	(290W)	220VAC, 60 Hz

Recommended Fan Filter Configurations (based on ceiling height of 8 feet or less)

Recommended Fan Filter Configurations							
Nominal Dimensions	No. of Ceiling Bays	No. of Filter Modules to meet ISO Cleanliness Standards					
		ISO 3	ISO 4	ISO 5	ISO 6	ISO 7	ISO 8
8' x 8'	8	5 -8	4 - 8	3 - 6	2 - 3	1 - 2	1
8' x 12'	12	7 - 12	6 - 12	4 - 8	3 - 5	2 - 3	1 - 2
8' x 16'	16	10 - 16	8 - 16	6 - 11	4 - 6	2 - 4	1 - 3
12' x 12'	18	11 - 18	9 - 18	6 - 13	5 - 7	3 - 5	1 - 3
12' x 16'	24	14 - 24	12 - 24	8 - 17	6 - 10	4 - 6	2 - 4

Fluorescent Illuminator Module

Each fluorescent light fixture is externally mounted to ensure effective illumination of the work area without interfering with the controlled air stream. Each module contains four 40W fluorescent T8 light tubes controlled by a master switch mounted on the main Cleanroom Control Panel. The housing is made of epoxy-finished aluminum.

Power Requirements: 115VAC/60Hz, 1.50A Each (US)
277VAC/50Hz, 0.65A Each (International)
Quantity: Two, one in Buffer room, one in Antechamber

Blank Ceiling Panels

All remaining ceiling grids are covered with blank panels, which can be removed to allow installation of additional fan filter units or illuminator modules. Panels are made of white polypropylene. All of these ceiling modules rest against the ceiling grid frame to form a tight seal along the ceiling grid perimeters.

Walls

IMPORTANT SAFETY NOTICE
All personnel should wear eye protection and respirators in addition to gloves and appropriate clothing while cutting, drilling or sanding FRP panels in accordance with local state safety laws.

Structural support is provided by powder-coated steel framing, consisting of 1.75" square steel upright and horizontal members. Steel frames ensure a rigid, free-standing support structure that requires no external bracing. Walls are finished with Fiberglass-Reinforced Plastic (FRP) panels applied to fire-resistant wallboard. FRP panels are available in Class A and Class C material.

Both Classes of FRP panels are applied with a unique advanced polymer non-outgassing adhesive, allowing installation on porous and nonporous surfaces. A specialized seam sealant provides trim-free seams that expand and contract to accommodate temperature-induced dimensional changes without creating cracks or gaps. Finally, a patented surfacing technology seals panels uniformly to enhance durability and prevent particle emission and microbial growth. The result: smooth, chemical-resistant, sealed, cleanroom-compatible walls that won't shed particles or outgas.

Class A BioSafe interior panels are the only FRP wall panels certified to ISO 5 standards for added cleanliness.

BioSafe® FRP Wall Panel Specifications

Composition: Random chopped fiberglass in a modified polyester copolymer resin mix, with smooth finish and proprietary surface seal
Thickness: 0.075" (1.9 mm)
Total VOC: 22.16 ppb (Methyl methacrylate): 1.66 ppb (ISO 16000-9) - FDA and USDA approved
Color: White

BioSafe FRP Wall Panel Certifications*

- Particle emission ISO Class 5 – 8 per ISO 14644-1
- Meets USDA/FSIS (US Dept of Agriculture/Food Safety Inspection Service) requirements
- Does not support mold or mildew (per ASTM D3273 and ASTM D3274)
- Meets minimum requirements of major model building codes for Class A interior wall and ceiling finishes of flame spread ≤ 25, smoke developed 450 or less (per ASTM E-84)
- Meets requirements of ASTM D5319 for Classification Class A / Grade 5 (refers to standard specifications for materials, workmanship and physical requirements)
- Biological Resistance rating of 0 – Excellence per ISO 846

** ISO 5 rating apply to Class A FRP panels.*

Entrances

1. **Access Door:** An access door, made of rigid static-dissipative PVC or polycarbonate mounted in an aluminum frame, affords entrance to the enclosure. The door is 36"W x 80"H and includes inside and outside handles and a pneumatic self-closing damper. The door opens inward, allowing hands-free entry as required by cleanliness protocol.

   Note: This room is not sealed airtight. Because it is designed to operate under positive pressure, small gaps around the doors or in the panel structure will not compromise clean conditions.

2. **Antechamber/Gowning Area:** The USP 797 modular cleanroom includes an antechamber, which can function as a gowning or staging area. It includes one Fan Filter Unit to meet ISO 8 cleanliness classification. It is separated from the main "buffer" area by a second swing door, as described above.

Control Panel

The Control Panel, mounted to the right of the access door, includes a power switch for the fluorescent light and ON/OFF pushbuttons to control operation of the FFUs. When FFUs are in operation, the Operation Status Indicator lights (blue TUI logos at each corner of the top exterior trim) glow to indicate that the room is operational. When the FFU power switch is off, the Operation Status Indicator lights flash intermittently to call attention to the inoperability of the room.

Control Panel showing ON/OFF switch for Fan Filter Units, light switch, and Magnehelic pressure gauges for antechamber (top) and buffer area (bottom). A lock-out cage can be installed to prevent tampering with fan operation.

The Control Panel also includes two Magnehelic® differential pressure gauges that monitor air pressure. These gauges measure differential between the buffer room and antechamber, as well as antechamber and outside room (general lab or pharmacy area): scale range is - 0.25 to + 0.25" WC.

The Control Panel is factory installed/wired, prior to shipping.

Duplex Power Outlet

The USP 797 Cleanroom includes a 120VAC, 60Hz duplex power outlet mounted along the rear wall of the Buffer Room, providing a convenient power source for equipment installed inside the cleanroom (220VAC, 60Hz duplex outlet also available).

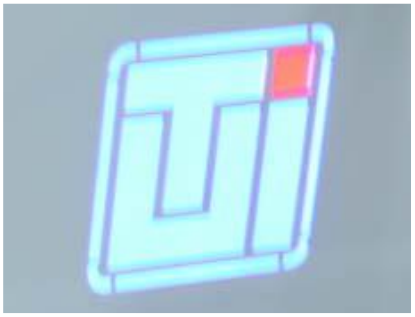
The outlet is factory-installed prior to shipping.

Stainless Steel Window

The USP 797 includes a 0.25"-thick, 44.5"W x 34"H tempered glass viewing window installed in a stainless steel frame on the buffer room wall.

Operation Status Indicator

Mounted to the top trim strip above each corner, these LED indicators glow to show that Fan Filter Units (FFUs) are turned on, and flash if they are turned off. They thus provide a convenient visual indication of proper room operation.



2.0 Installation

Component Inspection: Unpack all system components and check for damaged or missing parts (refer to component list/chart on the next page as well as the sales order to determine correct quantity of parts). Any damage should be reported to the shipping company immediately. Contact Terra Universal if any parts are missing.

Site Preparation

Refer to Terra installation contract for details of work to be performed by Terra Universal technicians.

A. Site preparation requirements should be observed for any installation performed by Terra Universal technicians.
B. Customer facility area where the cleanroom is to be installed must provide a minimum clearance of 18" (including fixtures, ducts and pipes) on all sides and at least 24" of vertical clearance between the FFU inlet and ceiling. Refer to drawing for Fan Filter Unit system inlet height.
C. Customers must provide permanent electrical connection from facility supply panel to Terra Cleanroom Power Distribution Modules (typically, one power line with 40A circuit breaker for a USP 797 room) in conformance with

local electrical code, as well as any vacuum, air, H20, sprinkler, or nitrogen connections required for the cleanroom.

D. Customers must give advance notice of dates and times for Terra personnel to perform the installation. Short notice may result in higher fees for travel and accommodations.

E. Customers are to provide utilities, installation power, and removal of any packing material.

F. Because installation requires unpacking and assembling components, customers are to ensure an adequate staging area for parts and equipment adjacent to the assembly area, clear and ready for work.

G. Customers are to inform Terra Universal in advance of any requirements for security, escorts, special training, badges, work hours, parking areas or special identification and how to obtain all such required permissions and related items.

H. Prior to shipping, all frame and ceiling members are labeled at each end. Refer to the "Installation" section and Appendix for detailed information on how your cleanroom is numbered.

I. Before you start assembly, it is mandatory that the floor is level to assure the completed room will fit properly and be rectangular. Failure to level the floor may result in the inability to complete the assembly of the room or the insertion of the blowers, lights or ceiling. For vertical alignment, measure with the leveler before assembly.

Required Installation Equipment (not included)

A. Handling cleanroom shipping crates, which generally measure over 300 inches long and weigh well over 1,000 pounds, requires at least one forklift or pallet jack. If crates must be moved through narrow aisles or entrances, two forklifts or pallet jacks are recommended, one to support each end.

B. Unloading crates from the truck is much easier if you have a truck-high loading dock. Without such a dock, you will need at least one forklift and a support to brace one end while the forklift is positioned beneath the center of each crate. Several people are required to unload individual components from the crates.

C. **Frame Installation:** You'll need heavy rubber hammers, good portable drills/screwdrivers, measuring tapes (to make sure everything's square) and six to ten 11" locking C-Clamps used to hold beams in place as you insert fasteners. Another tool that will be needed is an 8" – 12" shaft extension for the screwdriver bits (to drive screws in narrow gaps between parts).

D. **Drywall and FRP Installation:** You will also need 2 inch wide thin painter's tape (3.5mil or 0.09mm – the red or green kind), various drywall cutting tools, Grip-Rite 25-lb. #6 x 1-5/8 in Bugle-Head Philips drywall screws, a laminate roller, a 3/16" x ¼" x 5/16" v-notched trowel, your FRP cutting tools (typically a circular saw and a sheet metal "nibbler" cutter), a router with carbide bit for cutouts or corner radius cuts, a handsaw/hacksaw for small cuts, protective gear (gloves, respirator mask, eyewear), a caulking gun (pneumatic is recommended), and mixing tips.

E. **Ceiling Joists Installation:** You will need a rivet gun to install the ceiling joists with Terra-provided rivets.

Component List (included)

This list includes the basic cleanroom components and may not be complete. Quantities vary based on the specifications of each particular unit:

NOTE: Refer to "Hardware Sheet" and "Crate Pages" included with your delivery for complete information specific to your order.

Room structure:
Upright Frame Supports
Horizontal Frame Members
Long and Short Ceiling "T" Joists numbered to facilitate installation (see system drawings)
SS Window Frames (interior and exterior)
0.25" thick x 46"W x 36"H tempered glass window
Polypropylene Air Exhaust Vents
2' x 4' Polypropylene Ceiling Panels
FRP Side Panels (Fiberglass Reinforced Plastic): (12) 4' x 8' sheets (includes one extra)
Advanced Polymer FRP Adhesive
Sealant for FRP Seams
Powder-coated Steel Trim Strips (top horizontal)
Operation Status Indicators (4), installed in top trim corner pieces
U-brackets (provide mounting support for dry wall installation)
.25" and .125" plastic spacers (for mounting FRP panels)
Outlet template (guide for FRP cut-out to accommodate duplex outlet)
Yellow warning stickers, instructing personnel not to stand or walk on cleanroom ceiling

Hardware:
See list on following two pages

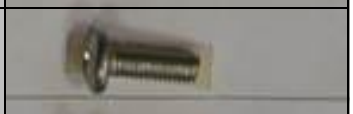
Tubing/Cords:
Polyethylene tubing
Yellow cord (with 3- and 4 pin-connections) to connect blowers and lights
Mini Yellow cord (with 4- and 5-pin connections) to connect control panel and Power Distribution Module (PDM)
White telephone cable for Status Indicator Lights
Warning Labels to attach to Ceiling Trim

Electrical:
Electrical Service Equipment, including
- One (1) master light toggle switch, mounted on control panel
- One (1) master blower switch (ON/OFF pushbuttons), mounted on control panel
- Power Distribution Module (controls up to 5 lights and 4 Fan Filter Units)
- 115 or 230 VAC yellow power cables (for connection to FFUs and lights).
- Duplex Power Outlet, installed on upright frame support in Buffer Room
- Operation Status Indicators: mounted on each exterior corner

Component Descriptions only

USED FOR *(shaded items not standard with USP 797 rooms)*	***DESCRIPTION***	***PICTURE***
Door Stopper Sliding	**Screw SS ¼ - 20 x 5/8 Phillip Pan**	
Air Conditioning	**Bolt SS ¼ - 20 x 1" Slotted Hex Wash**	
Air Conditioning	**Washer SS ¼" Split Lock**	
Air Conditioning	**Washer SS ¼ Flat**	
Air Conditioning	**Nut SS ¼ - 20 Cap**	
Cover Control Switch	**Screw SS 6/32 x ½ Philip Pan**	
Anchor: for slotted anchor bracket (2 per door; floor anchor bolts not included)	**Screw SS # 14 x ¾" Hex Washer**	
Pass-Through Frame	**Bolt SS 5/16 x ¾" Hex**	
Sliding Door Bracket	**Bolt SS 5/16 x ¾" Hex**	
Sliding Door Bracket	**Washer SS 5/16 Flat**	
Sliding Door Bracket	**Washer SS 5/16 Split Lock**	
Swing Door Frame Stopper	**Screw SS 6-32 x ½ Phillip Pan**	

Component Descriptions only

USED FOR *(shaded items not standard with USP 797 rooms)*	***DESCRIPTION***	***PICTURE***
Ceiling Joists, Trim, Internal Support Bar	**SS #12 x ¾ Hex Head Sheet Metal Screws**	
Trimming	**Screw SS # 12 x ¾ "Sheet Metal Phillip"**	
Frame	**Plastic Push-In Fastener**	
Top Fascia Trim Connectors	**Screw SS 8/32 x 5/8" Phillip Pan**	
Top Door Stop	**Screw SS 10/32 x 1/2" Phillip Pan**	
Top Fascia Trim Connectors	**Washer SS # 8, Flat**	
Top Fascia Trim Connectors	**Washer SS # 8, Split Lock**	
Door/Hinge	**Screw SS ¼ - 20 x 1" Phillip Flat**	
External Support Bar	**Screw SS # 12 x ¼ Self Tapping**	
Plenum	**Screw SS 10/32 x ¾ Phillip Pan**	
Door Closer Holder	**Screw ¼ - 20 x 1" Flat Head** **Screw ¼-20 x 3/8 Phillip Pan**	

Ceiling Joists	**Rivet**	
Ceiling Panels	**Ceiling Panel Clips**	
Drywall	**Screw Phillips Drywall #6 x 1-5/8" Bugle-Head Black Phosphate**	

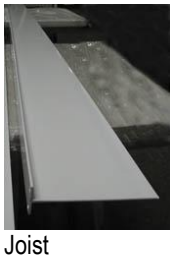
Frame Components


Support Bar (not used in USP 797 clean rooms)

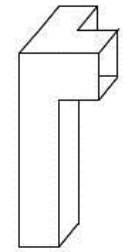

Center Post

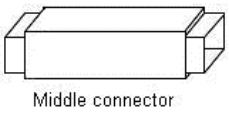

Middle Connector

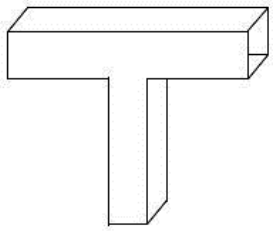

Corner Post

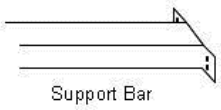

Joist

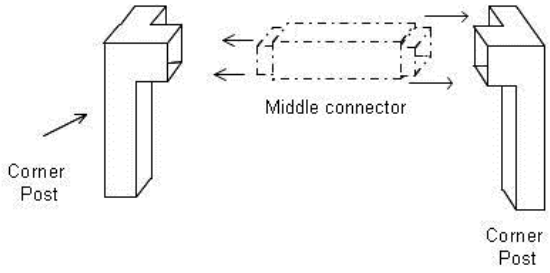

Joist Divider

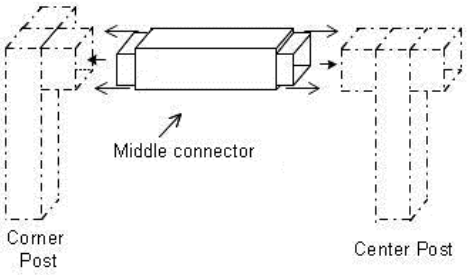

Corner Post

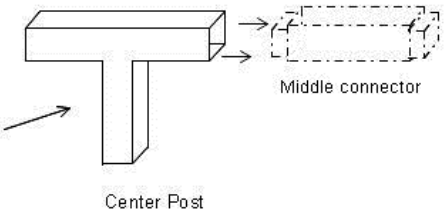

Middle connector

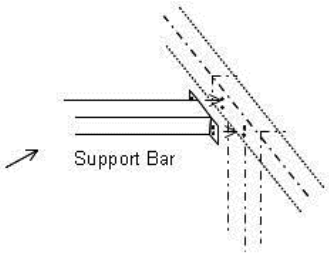

Center Post


Support Bar









Installation Notes:

Plan on following this order of assembly for successful installation of the USP 797 Modular Cleanroom. Instructions in this manual present each section in this order:

1) Frame, Ceiling and Control Panel
2) Power Distribution Module
3) FFUs, lights, and ceiling panels
4) Wallboard
5) Air Exhaust vents, Control Panel
6) Viewing Window
7) FRP Application to Wallboard
8) Access Doors
9) Top Trim

Review all of the steps and drawings below before beginning installation.

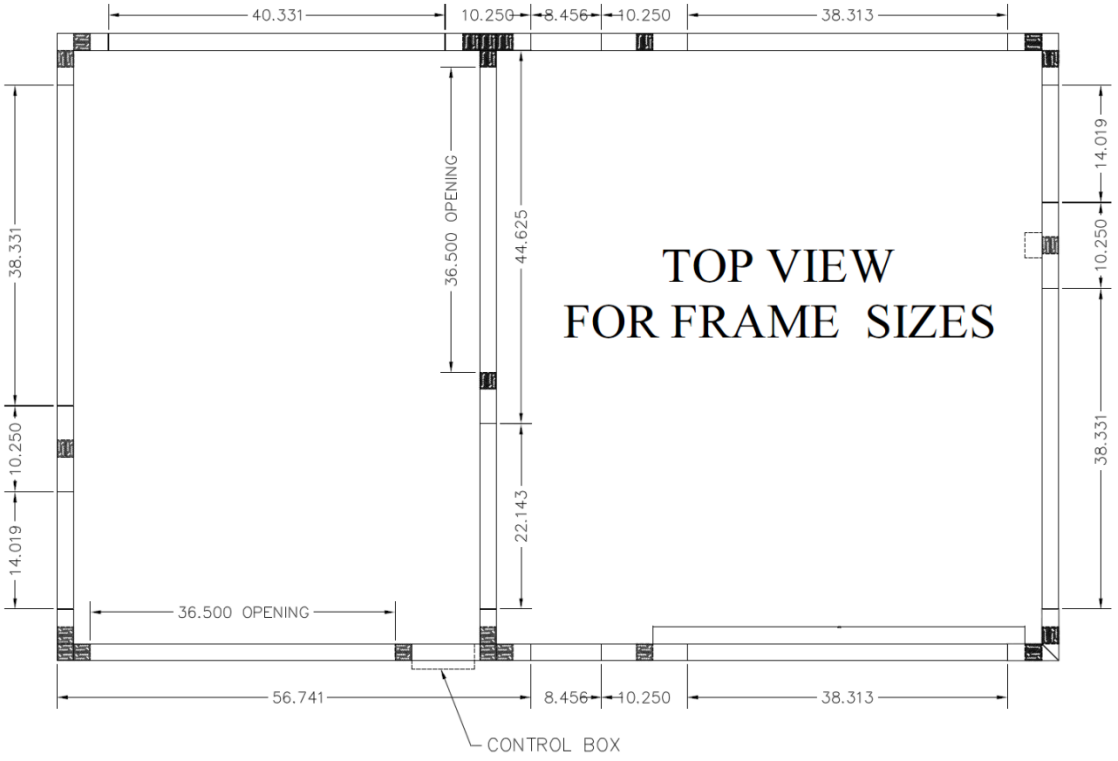
IMPORTANT SAFETY NOTICES

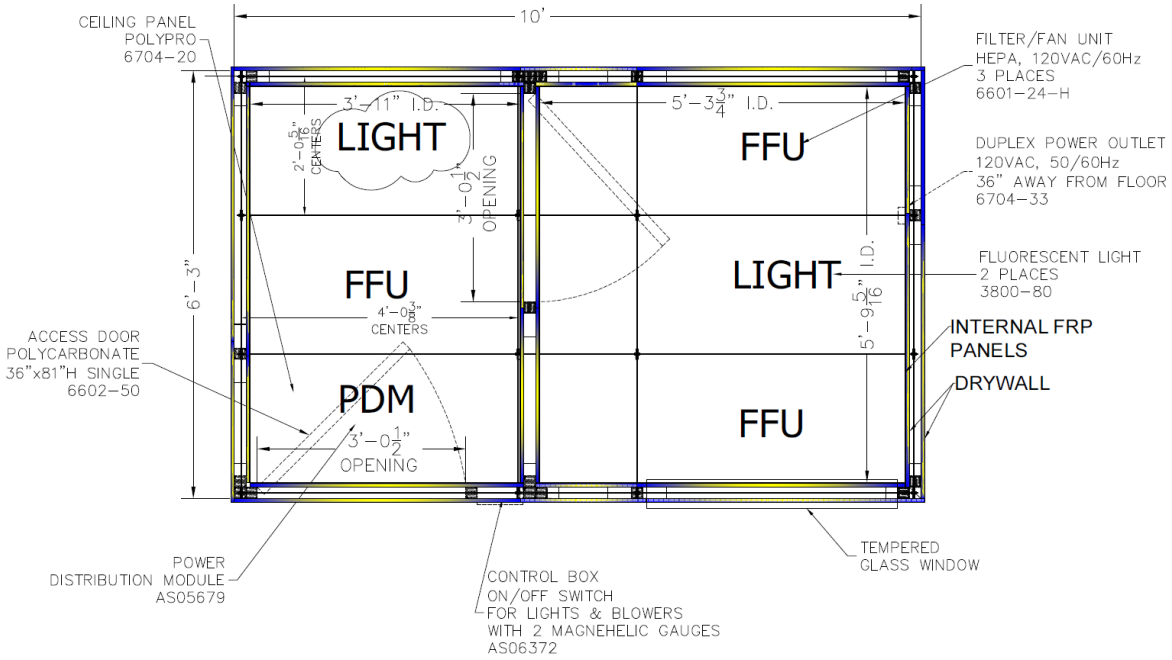
1) Terra Universal Cleanrooms are not designed to support more weight than the blower modules and lighting fixtures originally installed. In particular, the ceiling grid beams are not load bearing and will not support personnel or other additional loads. Placing added weight on the ceiling grid may result in serious damage to the room and occupants. The yellow safety notice supplied by Terra Universal must be affixed to the cleanroom grid.

2) Fiberglass is a known irritant. Personnel working with FRP sheets should wear protective coveralls, eye protection, and respirators when cutting FRP sheets, as required by local safety code.

Assembly Drawings

Details about each step are discussed on subsequent pages. These drawings can be used as references during assembly.





1. Installing the Support Frame and Control Panel

All frame and ceiling members are stamped and then labeled at each end prior to shipping, according to the concept illustration below. Numbering begins immediately to the right of the access door and continues counter clockwise (viewed from above) around the perimeter of the enclosure. Refer to system drawings.

Frame/Ceiling Labels: Example of numbered members; these identify the components and guide the installation

Before beginning installation of the support frame, familiarize yourself with the placement of the frame members and ceiling "T" joists.

NOTE: it is mandatory that the floor is level to assure the completed room will fit properly and be rectangular. Failure to level the floor may result in the inability to complete the assembly of the room or the insertion of the blowers, lights or ceiling. For vertical alignment, measure with a level before assembly.

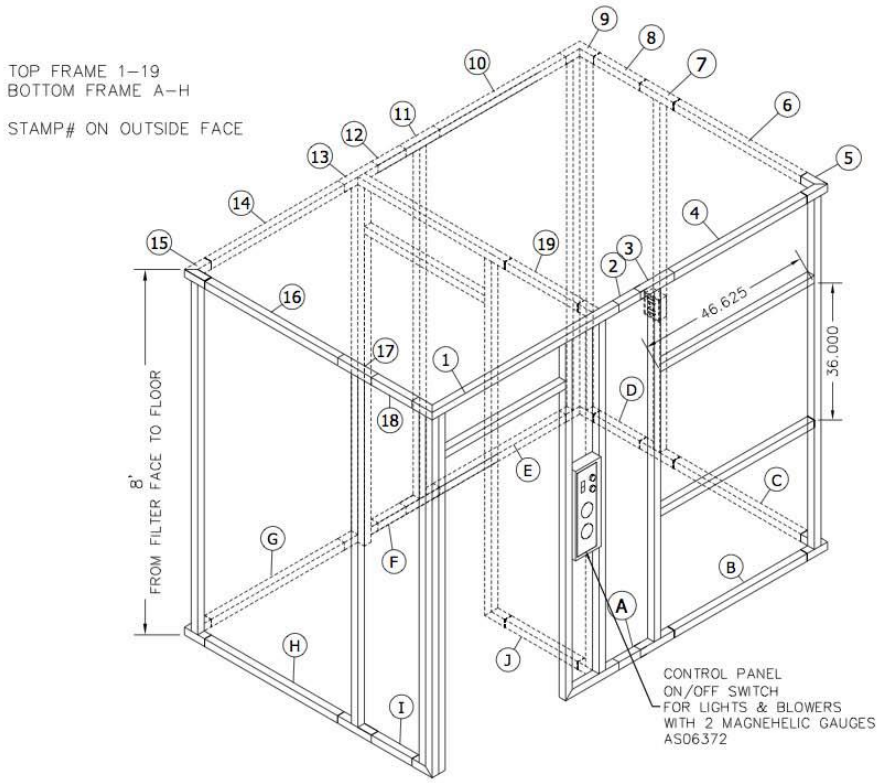


Figure 1: Frame Assembly - Position vertical and horizontal members as shown, matching-up numbered components. Fasten loosely with plastic fasteners as shown. **Do not fully insert fasteners until frame is complete.**

A. Beginning with the frame members labeled "1," insert each horizontal frame member into the appropriate opening of the corresponding upright frame support. As you position each horizontal member, fasten it loosely in place with a white plastic push-in fastener (pre-drilled holes are located on the inside of the upright support). Do not insert these fasteners completely until you have all horizontal supports correctly in position.

B. When the frame members have been completely attached, square the structure to ensure that ceiling modules will slide easily into place. To do this, measure the two diagonals (corner-to-corner distances). If they are not equal, adjust the frame (by pushing on the appropriate corner) until they are.

C. Two horizontal frame members provide the top and bottom support for the viewing window (see location in Fig. 1). These pieces attach to pre-drilled holes on the uprights on either side of the window. Make sure that the mounting flange on each support bar attaches outside the window opening, so that the bars leave a 36"H opening.

D. Once the frame is complete, you will install the ceiling "T" joists: Before beginning ceiling installation, make sure that you identify the ceiling perimeter members; these are pre-drilled for fastening to the cleanroom uprights. Refer to system drawings to determine precise location (all members are labeled prior to shipping). The long "T" joists span dimension of the cleanroom parallel to the entry door, and the short "T" joists slide in place to complete the 2 x 4 ceiling grid (see page 17). Position the joists on top of the frame, as shown, and loosely fasten the end of each joist in position with two SS #12 x ¾ hex screws. Do NOT tighten the hex screws until all joists are in place and the room is square

E. **Control Panel Installation:** The Control Panel mounts to pre-drilled holes on the side of the upright next to the main access door. Remove the front panel of the Control Panel, align the drilled holes inside to those on the frame, and secure using sheet metal screws. Replace the front panel.

F. **Magnehelic Gauges and Control Panel Cable:** Each Magnehelic Gauge has a bulkhead fitting on top of the Control Panel that connects to 0.25" poly tubing, which provides the reference pressure for the Anteroom and the Buffer Room. Two shorter lengths of tubing are pre-plumbed to obtain the reference ambient pressure from two fittings on the front of the Control Panel. The longer tubes, along with the yellow Control Panel power cable, pass through the hole pre-drilled in the side of the steel frame upright and exit through the hole at the top. Make sure the power cable is securely attached to the connector on top of the Control Panel. The other end of this cable will attach to the Power Distribution Module on the ceiling, and the two poly tubes will attach to bulkhead fittings in the Anteroom and Buffer Room ceiling panels (see Step Two). Mark the tubes to keep this reference clear: the tube attached to the top gauge connects to the Buffer Room, and the tube attached to the bottom gauge connects to the Anteroom. Ensure that these gauges are appropriately labeled.

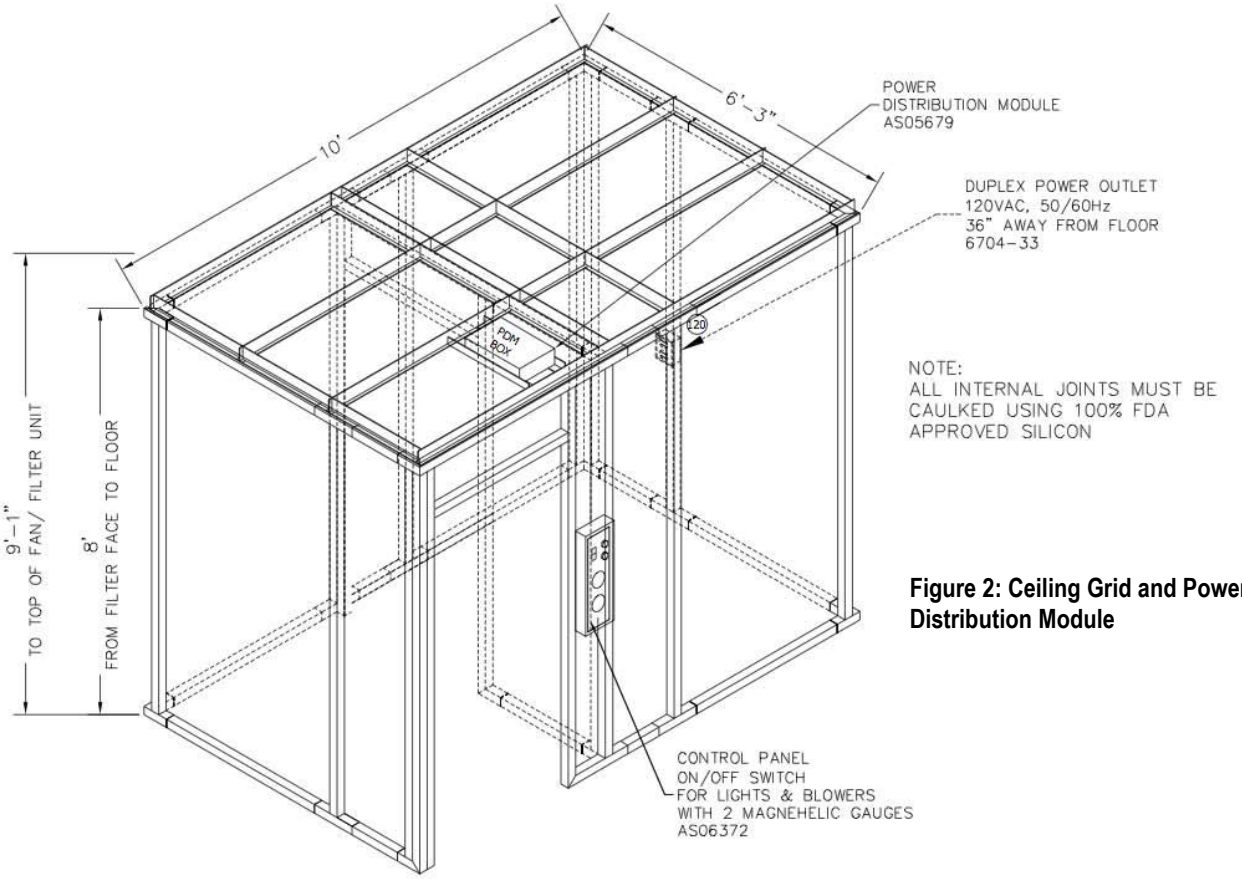
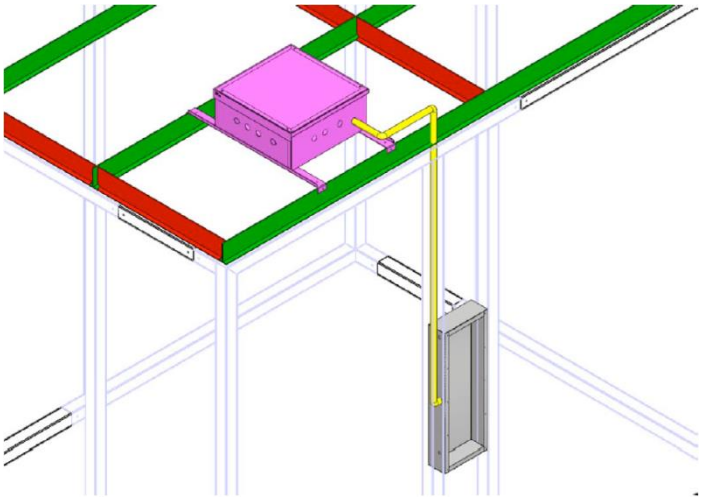


Figure 2: Ceiling Grid and Power Distribution Module

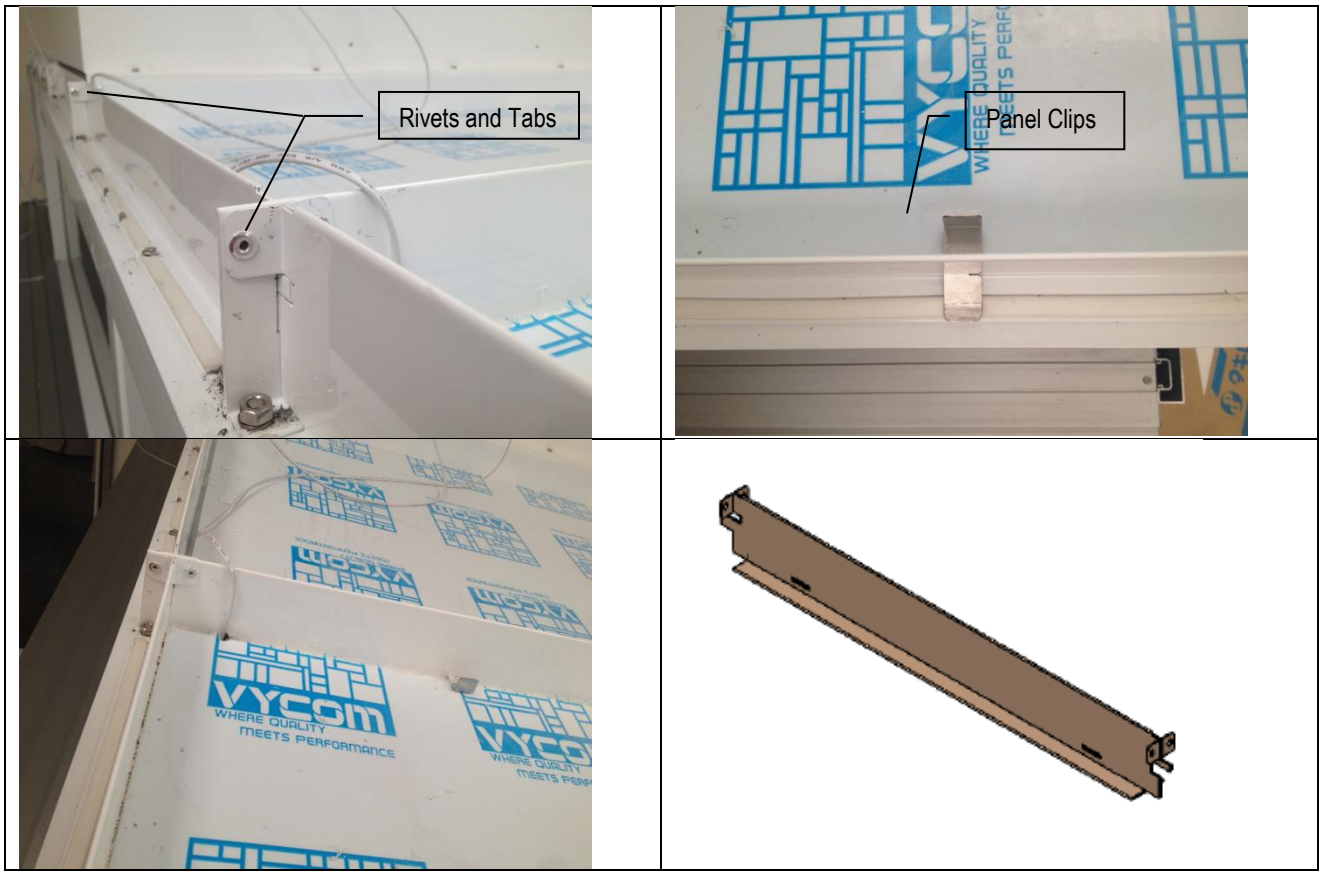
2. Power Distribution Module

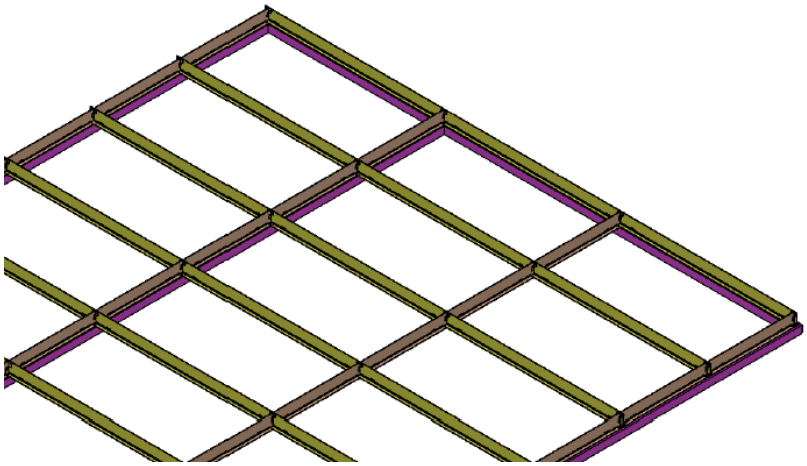


A. Identify the two long "T" joists that support the Power Distribution Module (electrical control box). These will have two pairs of opposing screw holes for fastening the mounting straps. They should be installed so that the control box will be positioned in the correct ceiling grid.

B. **Power Distribution Module (PDM) Assembly:** Mount Power Distribution Module box to ceiling joists with opposing tapped screw holes, using Control Box Mounting Straps. To complete the switch circuit, attach the yellow cable from the Control Panel (extending from the vertical fame: see yellow cord in diagram above), to the connector labeled "To Switch Connection" on the PDM.

C. Recheck the frame to ensure that the structure is square. Then tighten all set screws.





Installing the Ceiling Grid

Use pre-drilled holes to fasten the ceiling joists with Terra-provided rivets. The tabs on the T-bars should overlap. Use Terra-provided ceiling panel clips to secure the ceiling panels in place at the cut-outs along the joists.

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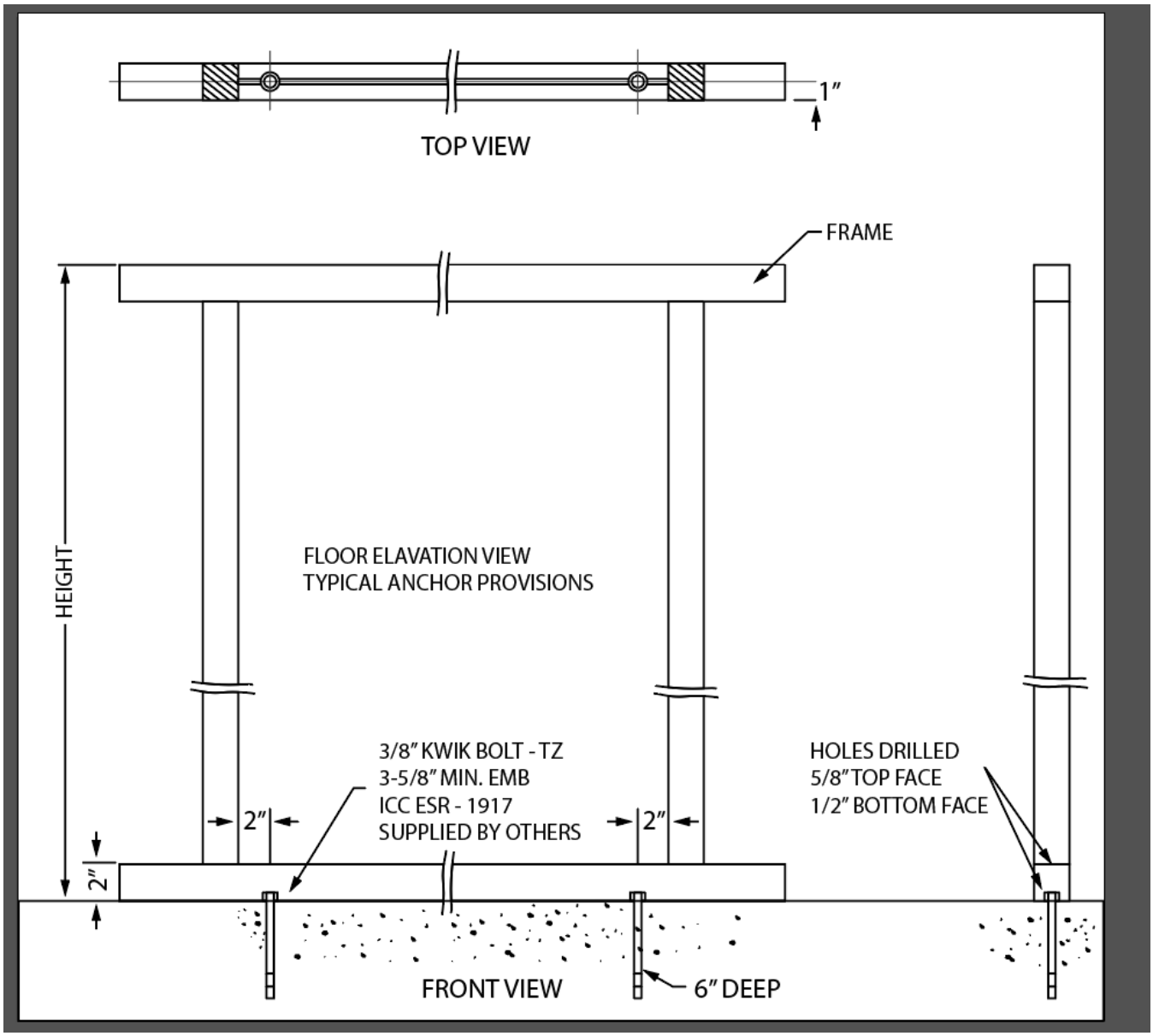
NOTE

If your cleanroom requires seismic anchoring, be sure to adhere to local seismic codes.

For example:
Prior to installing wall panels, drill and install an anchor every 4' along the base frame about 2" from the vertical frame, and one into the base of the door frame underneath the control panel. The holes should be drilled into the base frame approximately 2" away from the vertical frame posts. Avoid drilling through the corner inserts or through the connector pieces; drill only through the H-frames. For the top face of the base frame, drill a 5/8" hole to fit the anchor. Directly beneath it, drill a ½" hole. The concrete should be a minimum of 6" deep and field verified. Use 3/8" Kwik Bolt TZ (not included) for a minimum embedment of 3-5/8". The diagram below is an example, local seismic codes may vary.



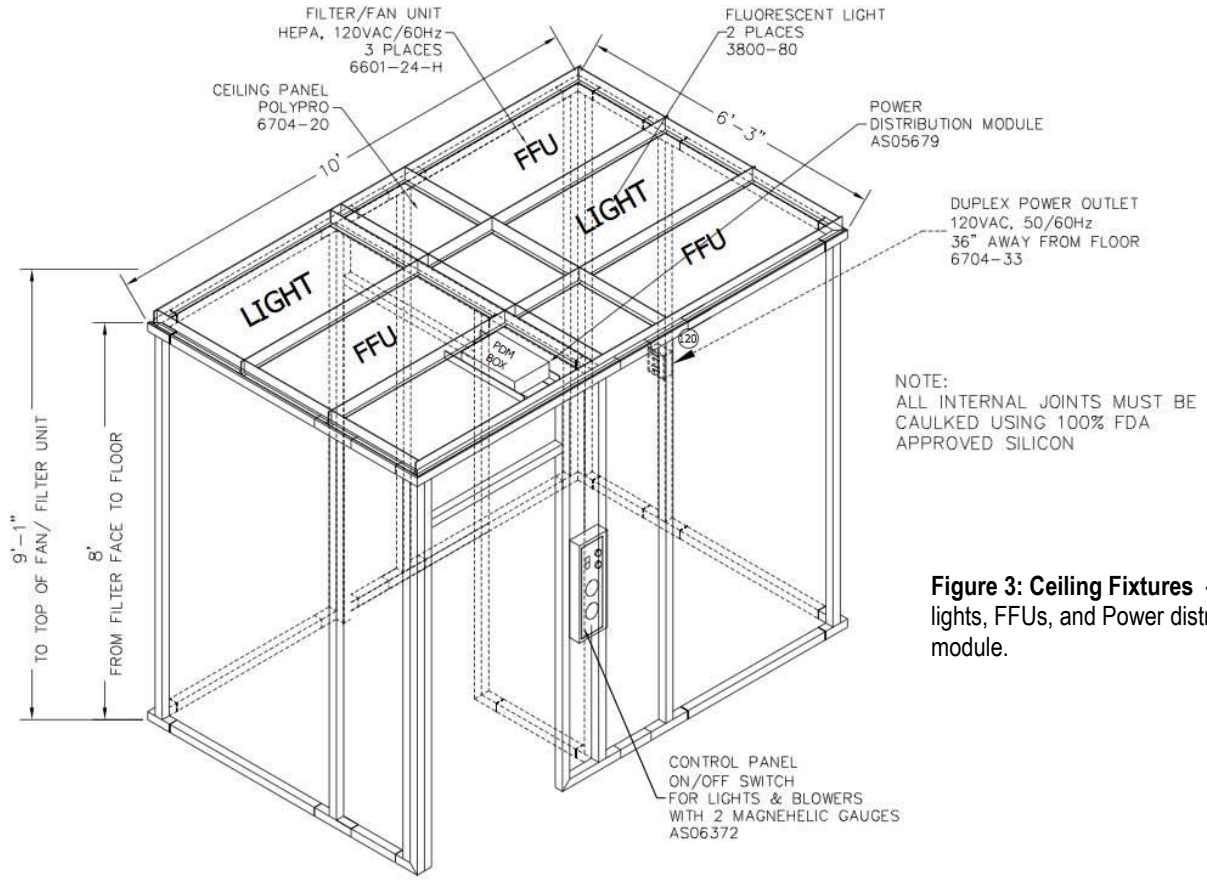


Figure 3: Ceiling Fixtures – Including lights, FFUs, and Power distribution module.

3. Installing the Ceiling Components: FFUs, Light, Duplex Cable, and Ceiling Panels

CAUTION

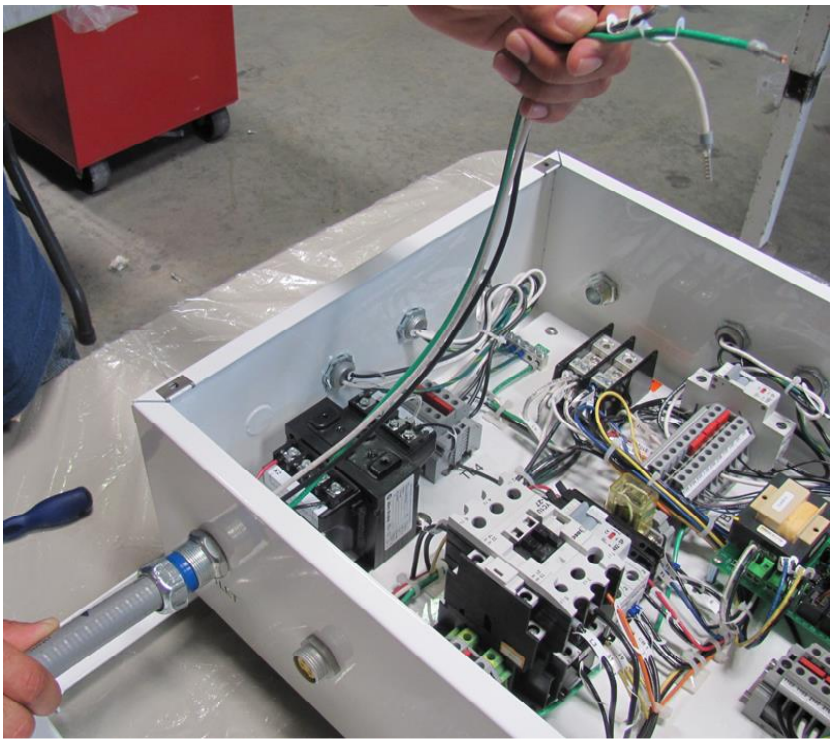
To prevent damage to the delicate filter medium, always exercise care when handling Fan Filter Units! Handle FFUs by the frame only; do NOT apply pressure to the filter face.

A. ***Verify that each FFU speed control is set at "Medium."*** Install the FFUs by carefully lowering each into the appropriate opening in the ceiling support frame (see following page for location). Each module should fit snugly against the ceiling grid frame to form a tight seal. No fasteners are necessary to hold these modules in place.

B. Install the light modules by carefully lowering each into the appropriate opening in the ceiling support frame. The light fixture should fit snugly against the ceiling grid frame to form a tight seal. No fasteners are necessary to hold it in place.

C. Control Panel Switchbox is installed to the right of the access door. The power cable extends from the switch box, through the vertical upright and out at the top of the ceiling joist. Verify that this cable is attached to the connector labeled "To Switch Connection" on the Power Distribution Module.

D. The duplex power outlet is installed inside the buffer room. To complete the electrical connection, run the power cable that extends above the duplex receptacle to the Power Distribution Module, and complete the connections as shown below and on the following page.



Duplex Connections:

Thread wires into outlet connection port of Power Distribution Module and tighten fitting.

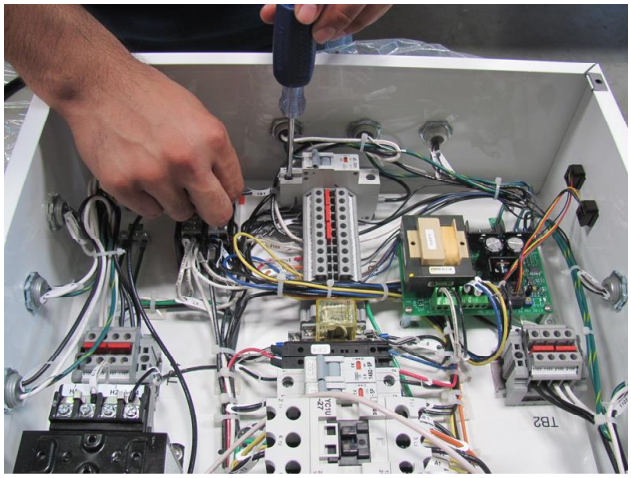
E. Using the yellow power cables provided, plug in the Fan Filter Unit (which use 4-pin connectors) and the light modules (which use 3-pin connectors) to the control box.

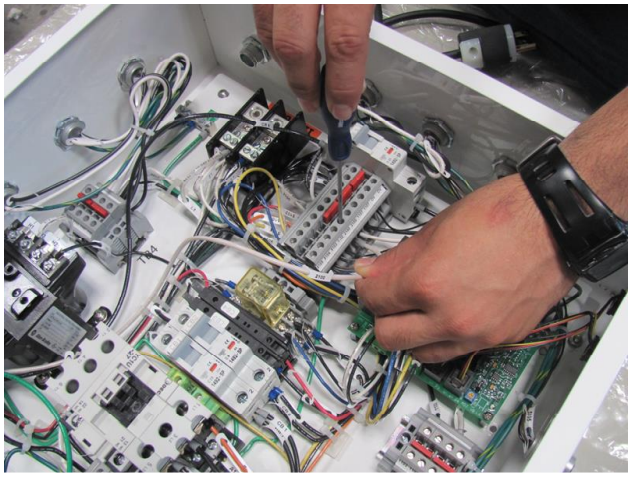
F. To preserve the UL listing of Terra Fan Filter Units, Terra must configure them for hard-wiring. If your FFUs are shipped without cable connections, refer to wiring procedure below.

G. To test for proper operation, hard wire the unit to a grounded 115VAC/60Hz (or 220VAC/50Hz, where applicable), 40A power source. ***The power connection should be made by a licensed electrical contractor, in conformance with local code.*** Turn on the light by flipping the light switch. Turn on the FFUs by pressing the green ON switch.

H. To install the remaining ceiling panels, remove the protective plastic from each panel and drop it in place. The panel below the Power Distribution Module can be inserted up into the grid from inside the room.

I. Connect the 0.25”-diameter poly tubing from the Magnehelic gauges to the two ceiling panels with QuickConnect bulkhead fittings. The tube from the top Magnehelic Gauge should connect to the panel above the Buffer Room, and the tube from the bottom Magnehelic Gauge should connect to the panel above the Anteroom.



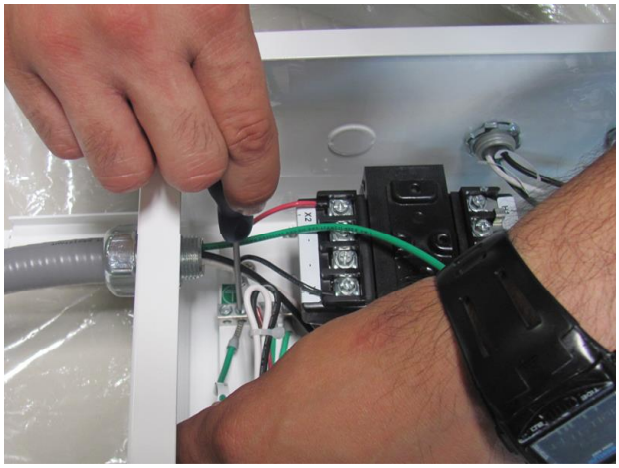


Duplex Connections

Black Wire ("CB 5") connects to main circuit breaker (above)

White Wire ("2100") connects to corresponding terminal (above right)

Green Wire (ground) connects to ground terminal (right)



Fan Filter Unit (FFU) Locations
Refer to connection instructions below.

Fan Filter Unit Hard Wiring

WARNING: Disconnect the unit from the electrical power source before attempting any service.

To preserve the UL listing of Terra Fan Filter Units, Terra must configure them for hard-wiring. Cords are dressed to simplify this operation, which typically does not require an electrician.

1. Remove the blue prefilter, which rests on top of the fan filter unit (Figure 1)
2. Unscrew metal top panel of the electrical housing (Figure 2) to expose wiring junction (Figure 3).
3. Install cord grip as shown (Figures 4, 5) into appropriate opening.
4. Thread the AC power cord through the cord grip and connect to wire port as shown (Figure 6). Strip wires and match the colors of the wiring; green to green, black to black and white to white. Tighten retaining screws to fasten wires.
5. Tighten cord grip to secure AC power cord.
6. Replace the metal panel on top of the electrical housing.
7. Replace the blue prefilter.


Fig 1


Fig 2

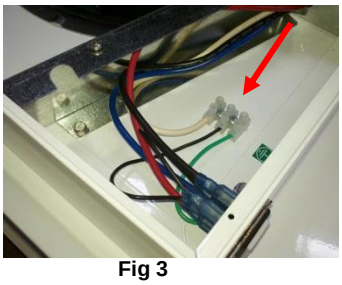


Fig 3


Fig 4

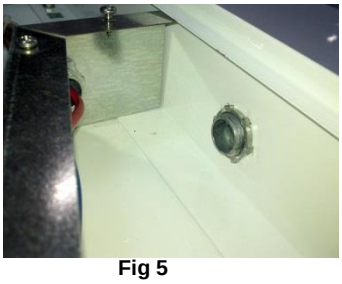


Fig 5

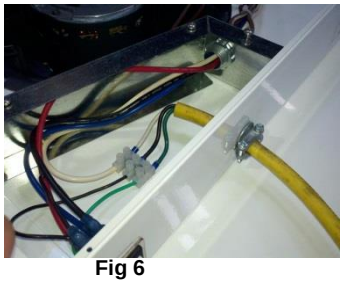


Fig 6

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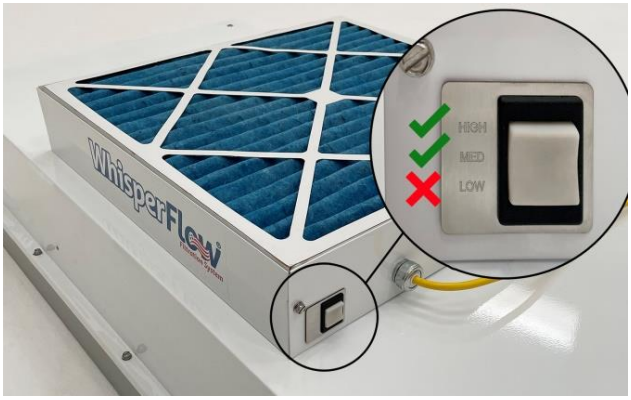
Fan Filter Unit Speed Configuration with PDM

WARNING

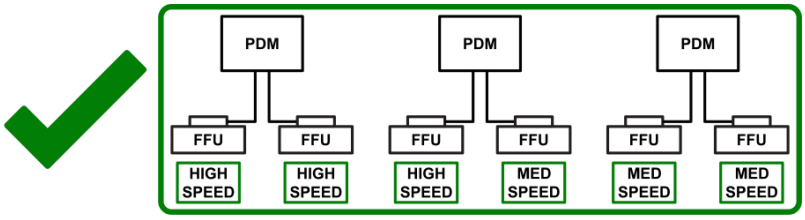
To avoid thermal overload on FFU's with Permanent Split Capacitor (PSC) motors, do not use LOW speed switch when the FFU is connected to a PDM.

The electric circuit design of the PDM limits speed configurations of FFU's with PSC motors. All FFU's with PSC motors should be switched to MEDIUM or HIGH speed setting when connected to a PDM. Thermal overload can occur when one FFU is set to LOW, and the others are set to MEDIUM or HIGH speed settings. The FFU motor set to LOW can draw excess current from the PDM which can lead to thermal overload on the motor, motor failure, and/or electrical hazards.

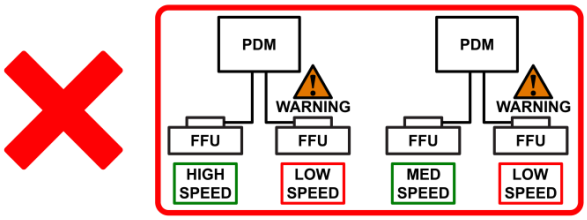


NOTES:

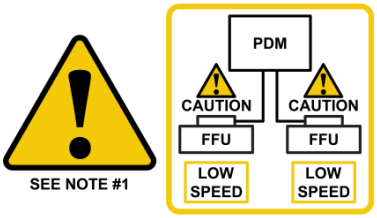
1. Setting all FFU's with PSC motors to LOW does not cause an immediate problem. However, it is not advised as there is a risk of accidently adjusting one FFU's speed setting to HIGH or MEDIUM, which could lead to thermal overload on a FFU motor that is still on LOW speed.



2. "Night service" mode from the control panel is unaffected and operates correctly when all individual FFU's are switched to HIGH or MEDIUM speed settings.



3. This limitation does not apply if the FFU with PSC motor is used individually without a PDM, and powered directly from a standard wall outlet.



SEE NOTE #1

4. This limitation does not apply to Smart® FFU's with Electronically Commutated (EC) motors. Smart® FFU's do not use PSC motors.

4. Installing the Wallboard

Wallboard should be attached to the inside and outside of the steel frame, using Grip-Rite 25-lb #6 x 1-5/8" Bugle-Head Black Phosphate Phillips drywall screws. Cut-outs are needed on the interior wall to accommodate the duplex outlet, and on the exterior wall to accommodate the Control Panel.

Terra furnishes U-Channel brackets that provide a mounting support for locations where a wallboard panel does not extend all the way to an upright support member. These brackets screw to the nearest upright, approximately midway between the bottom and top of the panel.

Note: Before installing the wallboard over the window support frame, mark it to indicate the window cutout location: the distance between the two support bars and the two vertical bars they attach to (approx. 46-5/8"W x 36"H).

Note: For seismic anchoring, drill through the cleanroom frame to anchor it to the floor in accordance with local seismic code.

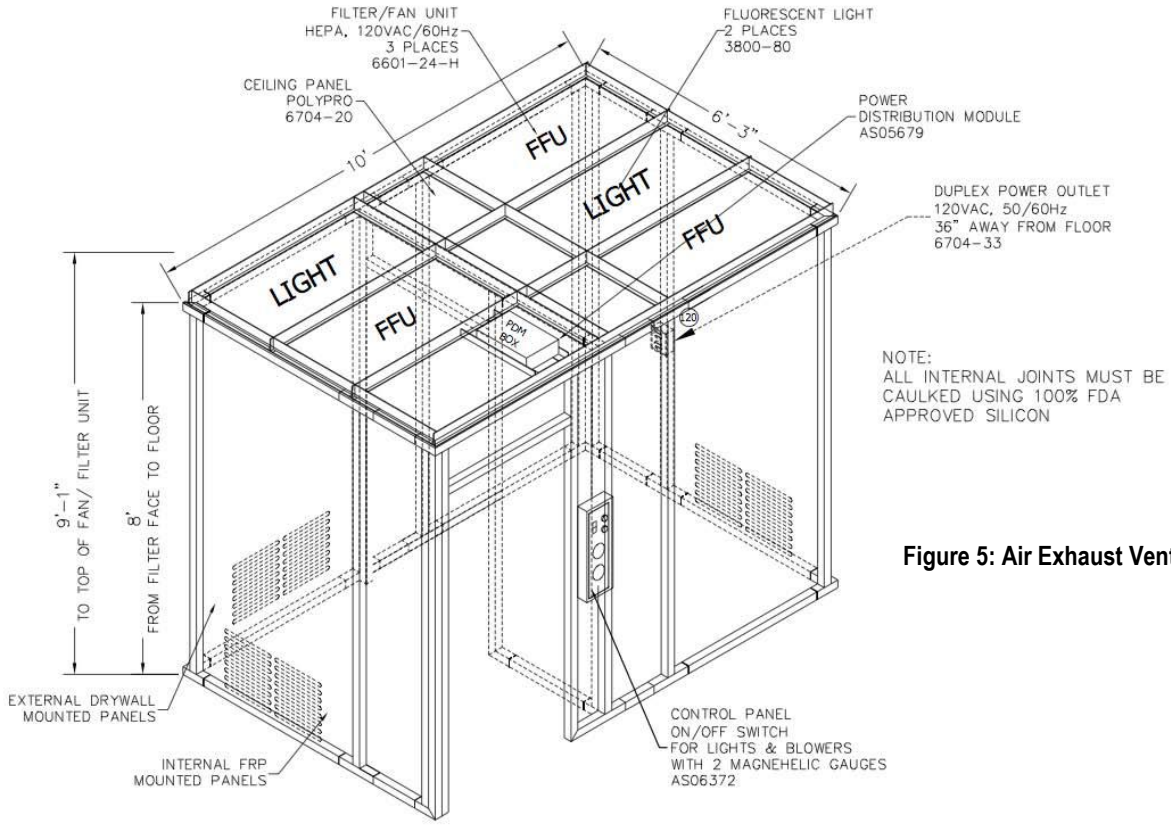


Figure 5: Air Exhaust Vent Locations

5. Installing Air Exhaust Vents

Create cut-outs in locations indicated above for two air exhaust vents in the Anteroom and one in the Buffer Room (see Figure 5). Each cut-out should be large enough to hold the vent snugly in place, and to allow the polypropylene weld bead to seat inside the wall, so that the flange fits flush against the drywall.

Position each so that the bottom of the vent is at least 4" above the floor, to allow space for FRP lamination and floor coving (if desired). The portion of each vent that includes the adjustable baffle plate goes on the outside of the room.

If required, use tape or adhesive to hold the vent in place while the FRP panels are attached and sealed (see below).

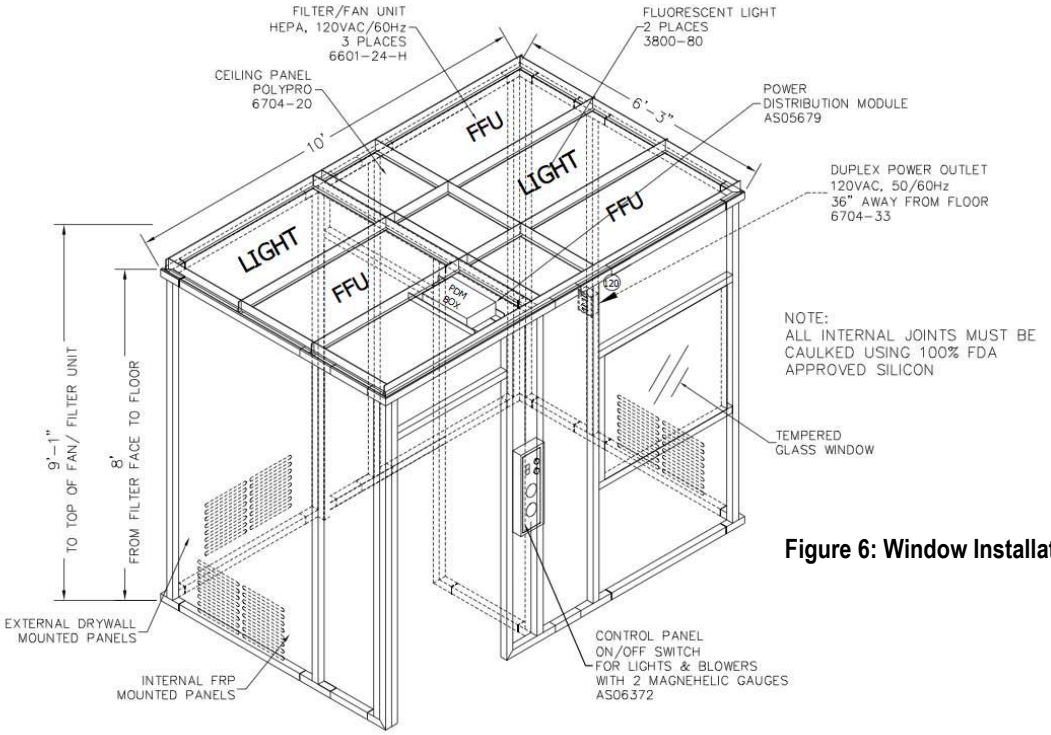


Figure 6: Window Installation

6. Window Retaining Frames: Outside frame (left), with predrilled holes for fastening to inside frame (right) with glass securely positioned in between.

Installing the Viewing Window

The viewing window is sandwiched between two stainless steel retaining frames. To install,

A. From inside the room, insert the interior stainless steel retaining frame (the portion with no pre-drilled holes along the window ledge) through the wallboard cut-out.

B. Place the tempered glass window flush against the frame from outside the room.

C. From outside the room, insert the exterior stainless steel retaining frame into the wallboard cut-out, so that it slides inside the interior frame and securely sandwiches the glass between the two stainless steel retaining plates. No gasket is required.

D. The outside retaining frame is pre-drilled along the ledge to allow secure attachment to the inside frame and the side support frame. Use self-tapping screws along the side to secure the frame to the steel wall frame. Threaded screws along the front ledge engage in the threads pre-drilled to the interior window frame.

7. Installing the FRP Panels

Required Tools and Materials		
4' x 8' FRP Panel (Type A or C)	**FRP Cutting Tools:** circular saw, sheet metal "nibbler" (for trimming), router with carbide bit (for cut-outs)	2" wide thin painter's tape (3.5mil or 0.09mm), e.g., Shercon PC21 series
Advanced Polymer Adhesive	400ml Pneumatic Dispenser	Laminate roller
Cleanroom Wall Seam Sealant	Inline seam finisher (for smoothing)	3/16" x ¼" x 5/16" v-notched trowel
Protective gear (mask/respirator, glasses, coveralls)	Mixing tips, sandpaper, utility knife, plastic spacers	A flat cutting surface (e.g., 6' x 10' plywood on sawhorses)

Storage
Panels should be stored on a flat dry surface. Do not stack on concrete floor or any surface that emits moisture. Lay panels flat. Do not stand on edge. Store between 60° to 75° at 35% to 55% relative humidity. Allow 24 hours to acclimate to the room temperature and humidity before installation.

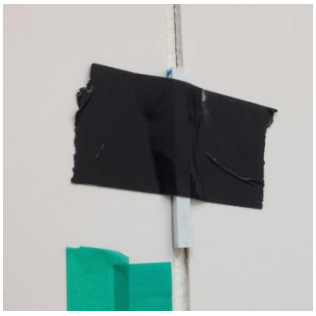
Installation Planning and Guidelines
Each FRP panel is held in place on a drywall substrate by means of the Cleanroom Recommended FRP Polymer Adhesive, which is effective on porous or nonporous surfaces. Make sure all drywall applications (window, outlet and any other drywall penetrations) are installed. The drywall surface must be free of any material that may deter adhesion, including severe and thick amounts of drywall join compound. Patch holes and depressions and remove any bumps, high spots, dust, oil or grease.

Pre-fit each panel for all fixtures, trim, doors and molding. All cutting and drilling should be done prior to the application of adhesive. Make sure to measure and mark for all cut-outs, leaving a 0.25" gap between panel and other surfaces (windows, air vents, ceiling panels, etc.) and 0.125" gap between adjacent panels. Use Terra-supplied templates to mark cut-outs for outlets.

Preplan for cove or base molding. FRP panels should be installed so that the base molding will not restrict normal panel movement during expansion and contraction. Cut panels 0.25" short of where the base molding will extend. Poured acrylic flooring with built in base cove should be in place prior to installation.

Spacing and Expansion
All FRP panels have expansion characteristics due to changes in humidity and temperature that must be accounted for during installation with proper spacing around panel edges and around fixtures attached to the panel/wall. Failure to provide adequate space could result in cracking or buckling due to expansion and contraction. See chart below for FRP expansion joint guidelines. An appropriately sized plastic (provided) or wood spacer or screws can be used to check spacing along the sides and bottom when applying the panels with adhesive. The spacers should remain for an hour before being removed.

FRP Expansion Joint Guidelines	



Plastic spacer, held in place by black tape

PANEL SIZE	4’ x 8’	4’ x 10’
Gap at ceiling	3/8”	3/8”
Gap at floor	3/8”	3/8”
Gap between panels at the inside corner	3/8”	3/8”
Gap between panels at the outside corner	3/8”	3/8”
Gap between panels at the center lines	1/8”	1/4”
Gap between panels and fixtures	1/8”	1/4”

Cutting and Drilling Instructions
Position panel face down on a covered work area. When cutting with a circular saw, position the panel so that the saw blade enters the back side of the panel first to avoid chipping damage. Trim panel to fit. Cut out any fixture openings with a router. The inside corners of all cut-outs must have a radius of at least 1/8”. Failure to radius corners may result in stress cracking. For pilot holes a 1/4” diameter router bit or drill bit may be used. Use a jig saw to complete the radius cut out. Allow 1/8” clearance around all fixtures, electric boxes, piping, etc.

Applying Adhesive
The drywall and FRP surface must be free of any material that may deter adhesion, including thick amounts of drywall join compound. Patch holes and depression and remove any bumps, high spots, dust, oil or grease.

Spread adhesive over entire back of FRP panel using the v-notched trowel. Keep the trowel notches clean and free of adhesive build-up to insure proper application. Spread no more adhesive than can be installed in 20 minutes or less.

Place panel against surface and press firmly over entire surface, working from the edge of the panel where molding is installed outwards to the open edge. Using a roller over entire installed wall panel is also strongly recommended. An appropriately sized plastic or wood spacer or the correct diameter screws can be used to check spacing when applying the panels with adhesive. Allow one hour for the adhesive to cure before removing spacers.

Applying and smoothing FRP panel

Adhesive residue should be thoroughly cleaned prior to leaving the job site. Remove latex-based adhesive with warm water and a clean non-abrasive cotton cloth. If necessary, use a mild, non-abrasive detergent. For best results, change water and cleaning rags frequently. For cleanup with solvent based adhesives, use mineral spirits or acetone to remove residue.

Sealant Application

Surfaces must be free of any dust, oil or grease. Clean seams as necessary with a dry lint free rag or a rag dampened with solvent if necessary. Prior to dispensing urethane sealant each seam will need to receive thin painter's tape (3.5mil or 0.09mm, typically red or green) on each side of the seam. If the panel has a pre-applied tack film, that can be left in place.

A minimum of two operators is recommended. If one operator is used then each seam will have to processed individually (filled and then smoothed by the same operator before moving on to the next seam); a new mix tip will likely be needed for each seam in this case. With multiple operators, one operator can dispense while a second can follow and smooth seams. Care will need to be taken to ensure the open time of the material is not exceeded in either scenario. Smoothing must occur within the open time of the sealant. After smoothing remove painter's tape. Any excess adhesive on panels can be cleaned using a solvent dampened rag.

Open time is the amount of time from when the sealant begins to travel down the mix tip until dispensed. It is important to note that open time begins at initial mix, not at time of dispense on to the surface of the application. Product needs to be completely worked in the seam. Operators will also need to be aware of the timing in regards to the material remaining in the mix tip after each application. Material will either need to be purged every 2-3 minutes between uses or a new mix tip applied at the re-start of a partial cartridge.

Sealant Workability Time (Open Time)

Time (minutes)	Temperature (°F)			
	°70	°80	°90	°100
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Workable
Suspect
Not Workable

Ensure that there is enough sealant to complete the current seam. Sealant should be dispensed into each seam at a rate such that the seam is completely filled with adhesive but completed within the open time. Allow vertical seams time to cure before completing horizontal seams.

If a seam cannot be filled by sealant in one pass, an initial filler can be applied, then a secondary application over the top of the initial application once the initial application has dried. Weather-strip putty may also be used for larger gaps prior to finishing the seam with sealant. After smoothing remove painters tap before the sealant fully cures. Any excess adhesive on panels can be cleaned using a solvent dampened rag.

Preparation of Applicator

- Remove the plastic nut from the outlet end of the sealant cartridge
- Remove the metal retaining clip and the plastic plug in the outlet ports of the cartridge and discard
- Load the cartridge into the dispense gun, ensuring that the plungers are lined up properly
- The plungers need to be level at the start of each new cartridge prior to use
- Prior to installing the mix tip, slowly advance the plungers until a small amount of material is equally dispensed from each port
- After leveling the plungers fit the plastic mix tip onto the outlet end of the cartridge and secure with the plastic nut that removed previously ensure the a proper mix ratio is being dispensed

After all panels have been seamed, apply seam sealant to any other cracks, such as gaps within the window frame, along the perimeter of air vents and outlets, or joints between the FRP panel and the ceiling frame.

8. Door Installation

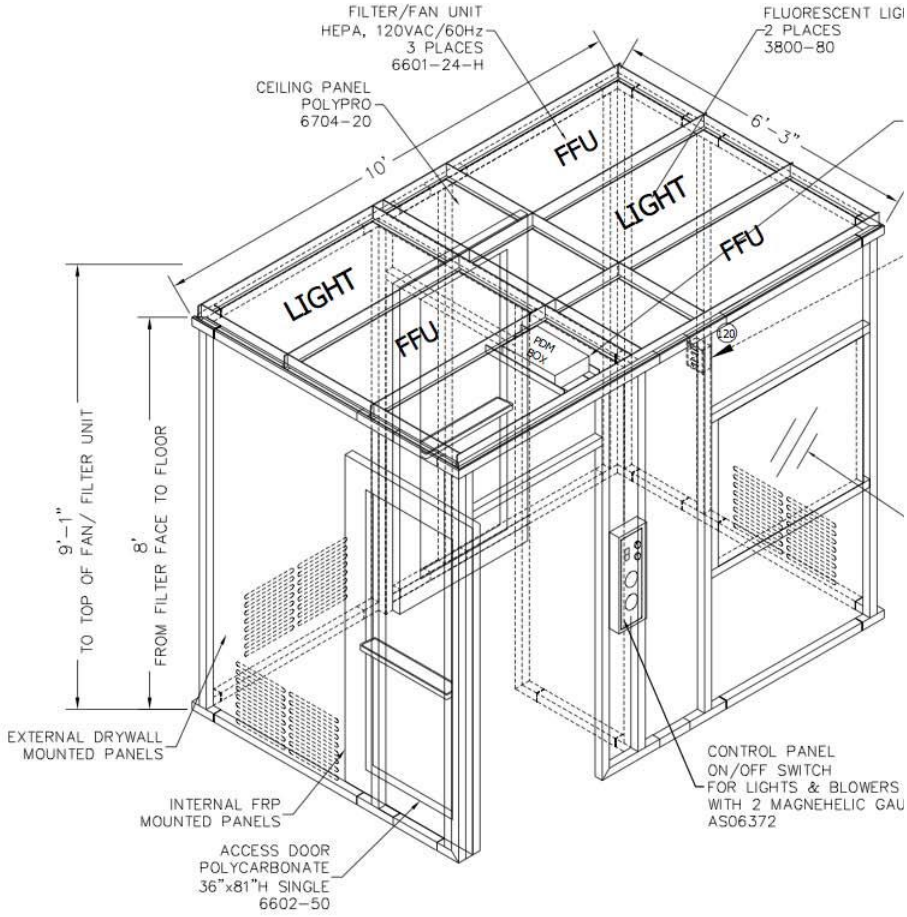


Figure 6: Door Installation

To install the two swing doors,

A. Screw the door frames to the steel uprights. Pre-drilled holes along the steel uprights indicate proper position. Doors open inward, so verify that the door closer (the ridge along the frame) is positioned near the outside edge, allowing the door to seat flush with the inside frame.

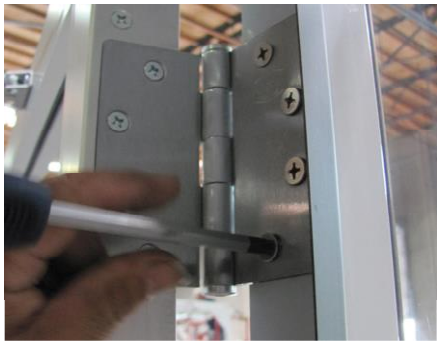
B. Install the door hinges, using self-tapping 1-5/8" screws.

C. Door closures mount on the outside of each door.

D. Apply Seam Sealant to all cracks and gaps to ensure a sealed finish.

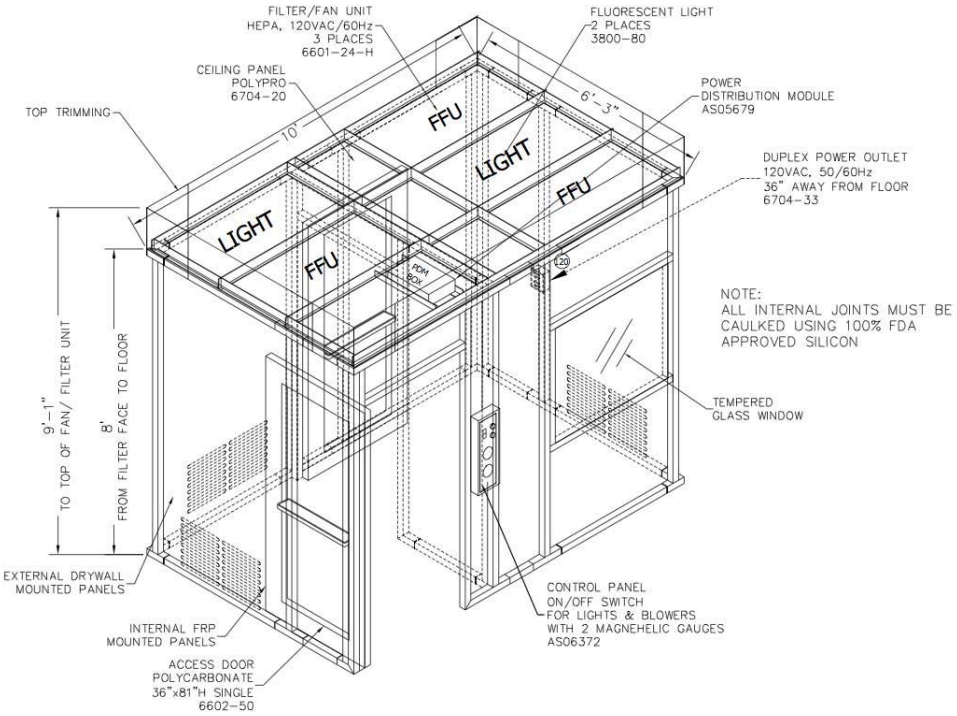
Door Frame (inside view)

Door Frame (outside view)



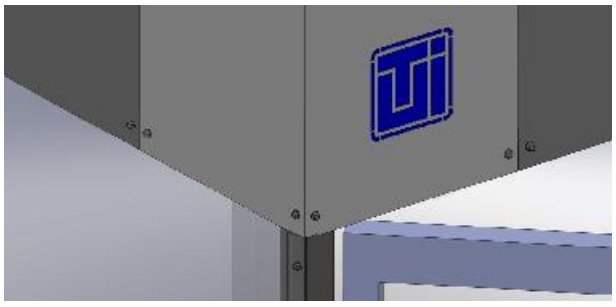
Hinge Installation

9. Installing Top Corners, Operation Status Indicators, and Side Trim Fascia



A. Begin by positioning the corner trim with Operation Status Indicator (TUI Logo) on the top corner posts so that all holes are aligned. The corner trim should fall over the wallboard installed earlier. Loosely fasten #6 x 1-5/8" Bugle-Head self-tapping drywall screws through the wallboard and into the steel frame.

B. Install the top fascia trim strips next to the corner trim. Each piece attaches to the adjacent piece by means of two screw holes on the mounting plates, which bend 90 degrees inward. For each connection, use one 8/32 Phillips screw, two flat washers, one lock washers and one acorn nut. Do not tighten.



Installing the top trim fascia: use #6 x 1-5/8" Bugle-Head self-tapping drywall screws to attach pieces to frame (using pre-drilled holes) and 8/32 screws with washers and acorn nuts to connect adjoining pieces. **Operation Status Indicator lights** connect to the PDM by means of low-voltage telephone cable. When connected, they should glow continuously as long as FFUs are ON, and flash intermittently when they are turned OFF.

Ceiling Panel Caulking

To meet USP 797 requirements for a sterile environment, seams along the edges of the cleanroom ceiling panels must typically be caulked. Terra provides 100% silicone sealant for this purpose. Prior to caulking, carefully clean all panel-to-frame seams with a clean, non-woven wiper saturated with appropriate cleaning agent (such as 70% IPA / 30% DI water). Allow cleaned surfaces to dry before applying sealant with a caulking gun (not provided). Apply a

uniform, ¼"-wide bead of silicone along all ceiling panel seams, including cracks where the perimeter frame meets polypropylene ceiling panels. Typically, caulking is not required along the perimeter of FFUs or lights.

3.0 Operation and Maintenance

Recommended Operation Guidelines

The guidelines below are intended as general recommendations for cleanroom operation, not strict operation protocol. Always confirm your operation protocol with the appropriate certification agency before you place the cleanroom into service.

Environmental Monitoring
UPS 797 and other regulations stipulate monitoring of environment conditions, including positive pressure inside the antechamber and the buffer room, particle counts, and air change rates. Measurements of these environmental conditions should be taken and recorded at intervals appropriate to your application.

To assist in environmental monitoring, Terra's USP 797 cleanrooms include two Magnehelic differential pressure gauges (mounted on the control panel) with a range of -0.25" to +0.25"WG. Recommended pressures: ≥ 0.025"WG in Anteroom; ≥ 0.05"WG in Buffer Room (minimum difference of 0.025"WG between Anteroom and Buffer Room). External baffles on the Air Exhaust Vents can be adjusted to attain these recommended values.

Cleaning/Sterilizing
Before initial use, clean the side panels and uprights thoroughly with appropriate cleaning or sterilizing agent. See "Recommended Cleaning Protocol" below.

Initial Start-Up
Once installation has been completed and electrical connections checked, turn ON fan filter units by pressing the green ON button***. When the cleanroom is initially commissioned, FFUs should be set in the "Medium" power setting, as specified in the installation procedures above.*** Turn on the light by pushing up on the 2-position switch.

At initial start-up, allow the cleanroom to operate for several minutes before entering the room. This allows the sweeping action of the airflow to remove any loose particles inside the room and for the room to fully pressurize. Always verify that the Magnehelic gauge indicates a positive pressure (generally, > 0.02"WC) before entering the room.

Operating Tips
For optimal cleanliness in the Buffer Room (main processing area), always allow the main entry door to close fully before opening the swing door that separates the Anteroom from the Buffer Room.

USP 797 stipulates that an ISO 5 PEC (Primary Engineering Control, generally a laminar flow hood) be installed inside the buffer room. All sterile preparations should be made inside the PEC. The buffer room is configured to allow installation of a PEC on a bench up to 6-ft. wide inside the buffer room. A duplex outlet, positioned on the vertical upright on the rear wall of the cleanroom, provides power for the PEC and additional process equipment that may be required.

Continuous Cleanroom Operation
Once a cleanroom is certified for operation, Fan Filter Units (FFUs) should be allowed to operate continuously. Turning off the FFUs eliminates the positive pressure inside the room that sweeps away particles and prevents contaminant influx. Interrupting this positive pressure may require extensive cleaning and revalidation, depending on application.

Maintenance

The Modular Cleanroom typically requires minimal maintenance. The filters provide effective operation for years under typical operating conditions. In fact, filter efficiency increases as the filter captures more and more particles. The filter does not require replacement until the backpressure it generates increases to the point that the system can no longer provide an adequate air velocity to maintain required particle counts and positive pressure.

WARNING: Never attempt to service or replace the filter/blower without first disconnecting system power.

FFU Speed Adjustment
Initially, FFUs are operated in the "Medium" power setting. As filters capture particles and backpressure increases, airflow will decrease. When the airflow is no longer adequate to maintain required environmental conditions, the simplest remedy is to turn up the FFU operating speed to "High." As filters continue to retain particles and backpressure grows, it will eventually become necessary to replace the filter.

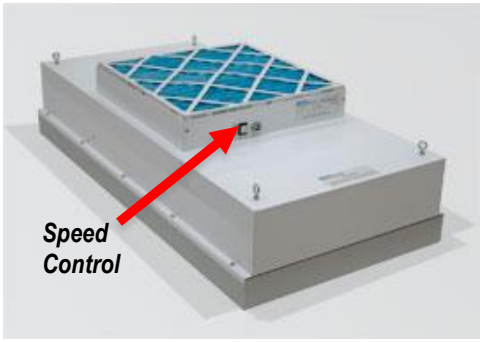
It is recommended that this adjustment be performed from a ladder or skyjack outside the room. Turn OFF FFU power; then rotate the speed control dial on the top of each FFU to the desired position (see photo below).

Generally, FFUs should operate at the same speed setting, If the air pressure between the buffer room and the anteroom falls below 0.025"WG, you can adjust the baffles on the air vents or increase the speed setting of the two FFUs in the buffer room to increase the pressure differential.

Filter Replacement

To replace the filter, turn OFF system power and disconnect the yellow FFU power cable from the Power Distribution Module (see Section 2 above). Then position it to come through the 2' x 4' opening and into the cleanroom. See chart below for ordering information. Detailed replacement instructions on the next page.

Replacement Filters for Terra WhisperFlow™ Fan Filter Units		
Type	Size	TUI Part #
HEPA	2 X 2	6601-27
	2 X 3	6601-26
	2 X 4	6601-25
ULPA	2 X 2	6601-30
	2 X 3	6601-29
	2 X 4	6601-28



Removal and Replacement of the HEPA/ULPA Filter (Standard Unit)

Warning: Disconnect the unit from the electrical power source before attempting any service.

Warning: The Standard Filter is protected with an expanded metal face screen. This is never to be used to handle the filter. It is only for protection against an accidental touch of the filter. Handle filter only by the frame.

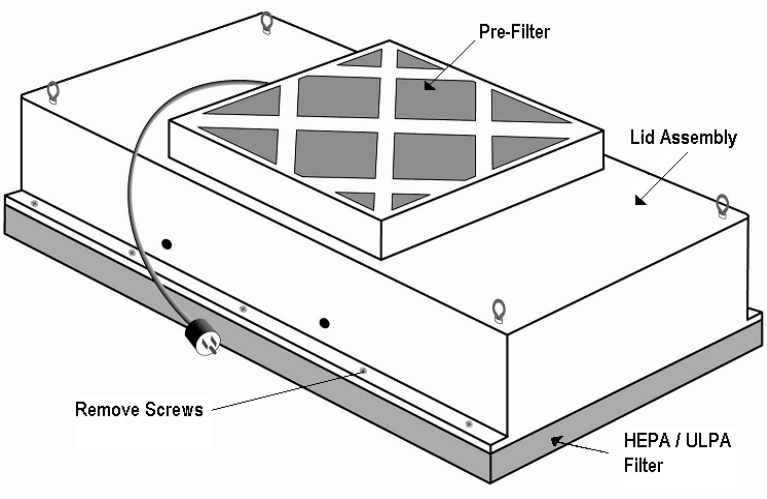
Tools Required: Phillips Head Driver

Step 1: Disconnect yellow power cable and remove unit from ceiling (see next page for recommended procedure).

Step 2: Remove the 10 screws holding the HEPA/ULPA filter to the lid assembly.

Step 3: Lift the lid assembly off the HEPA/ULPA filter (see figure below). Discard the used filter as per applicable regulations.

Note: Before replacing with a new HEPA/ULPA filter, carefully inspect the new filter for any visible damage.



Instructions for removing the Fan Filter Unit from the cleanroom ceiling grid

2 installers minimum
2 ladders or step stools

1. Disconnect the fan/filter unit from the PDM.
2. Attach double stick tape to a polypropylene panel – place on all four sides. The panel protects the HEPA filter from damage (See Figure 1).
3. Place the polypropylene panel over the filter screen, making sure that it only adheres to the screen without overlapping the edges (See Figure 2).
4. Push one side of the FFU up (See Figure 3), rotate it 90° (See Figures 5 and 6) and lower through the ceiling grid.
5. Place the unit on a flat work surface and remove the 10 sheet metal screws that hold the HEPA/ULPA filter to the case (See Figure 7).
6. Replace with a new HEPA/ULPA filter carefully handling edges only.
7. Secure filter to the case with the same screws used previously.
8. Place unit back onto the ceiling grid.

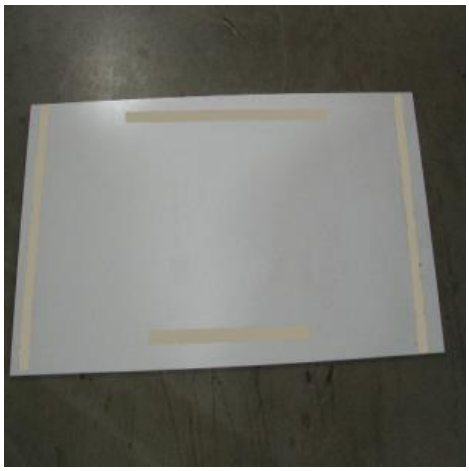


Figure 1: Polypropylene panel with tape


Figure 2: Panel attaching to exposed HEPA filter


Figure 3: Panel fully attached to filter screen without overlapping edges


Figure 4: FFU pushed up on one side for removal

Figure 5: Personnel rotating FFU to remove from ceiling grid

Figure 6: FFU rotated 90° and lowered completely from ceiling grid

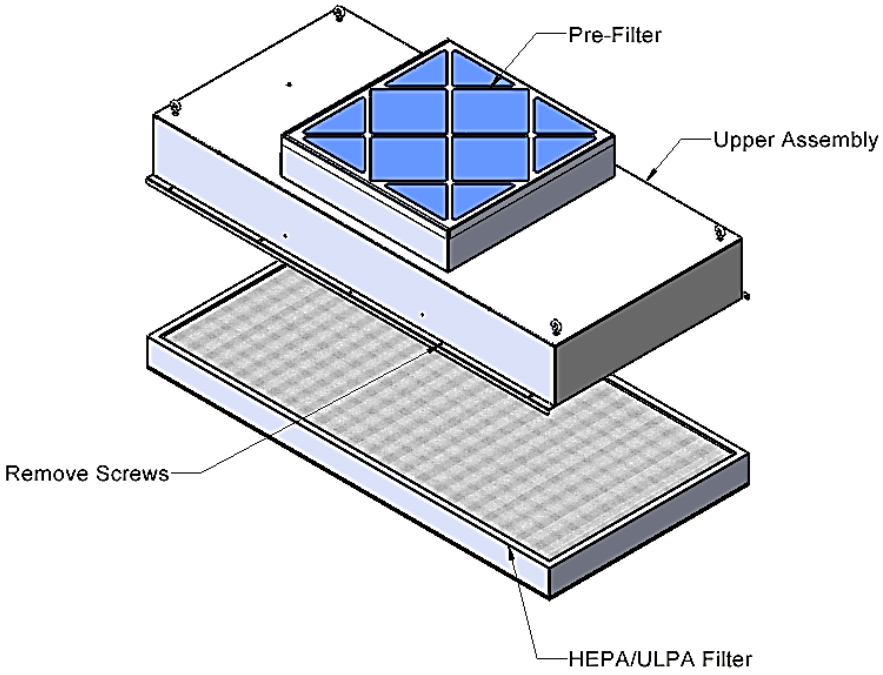


Figure 7: Diagram of FFU assembly

Cleaning

All surfaces of the cleanroom should be wiped down thoroughly at regular intervals. Cleaning frequency should be determined based on regulatory requirements and use, including types of sterile preparations performed (e.g., "high risk" vs. "low risk").

Cleaning begins with the selection of an appropriate cleanroom wiper and cleaning agent. When selecting wipers, consider such characteristics as particle-shedding properties, chemical residue of the wiper content, static properties, absorbency and size. Nonwoven, polyester wipers generally produce the cleanest results. If cleaning with isopropyl alcohol or a similar cleaning agent, perform a full wipe-down of the sanitized area with deionized water.

Select a cleaning agent based on requirements for sterilization. The FRP, static-dissipative PVC and polycarbonate panels used in Terra's USP <97 cleanrooms, as well as power-coated steel surfaces, are compatible with most disinfecting agents, including a 70% IPA/30% DI water solution. Pre-saturated wipers provide a convenient way to ensure optimal wiper saturation and minimize solvent evaporation and surface residue (many varieties available at TerraUniversal.com).

Cavicide, Caviwipes, and similar products contain ethylene glycol and benzethonium chloride, which are caustic chemicals that corrode stainless steel if not rinsed with water. After disinfecting with ethylene glycol or benzethonium chloride products, the affected area must be fully wiped down with deionized water and dried.

To maximize cleaning uniformity, wipe in one direction, from top to bottom or left to right. Use only slight overlapping strokes, and fold the wiper between strokes. Do NOT use circular motion, which moves but does not remove surface particles and produces non-uniform results. Begin cleaning from the top of each panel, working to the very bottom, and then wipe down the vertical and horizontal frame members when all panels are clean.

WARNING:

• Always check chemical compatibility before cleaning plastic surfaces. Although polycarbonate and static-dissipative PVC withstand exposure to a wide range of common cleaning agents, repeated exposure to strong chemicals can cause damage

• Always wear protective gloves and safety glasses or goggles when handling saturated wipers.

Floors should be cleaned with a cleanroom-compatible mop and appropriate cleaning agent. Mop in straight, overlapping paths, rather than circular motions, to optimize contaminant removal.

CAUTION

To prevent damage to the Fan Filter Units (FFUs), do NOT attempt to wipe the protective screen on the filter face. Applying pressure to this screen can damage the delicate filter pleats.

Vacuums

Terra offers a variety of portable, hand-held vacuum cleaners with Ultra-Low Penetration Air (ULPA) final filtration, including models with mini-tools designed for irregular surfaces.

4.0 Warranty

Products Manufactured by Terra: Terra Universal, Inc., warrants products that it manufactures to be free from defects for a period of 12 months for parts and 90 days for labor, commencing from the date of shipment. Terra's sole responsibility is to repair or replace, at its option, any part of the product that proves defective or malfunctioning during this time limit. In some cases, components incorporated in Terra Universal products are covered by additional warranties from component manufacturers; obtain specific information from Terra sales representatives. This warranty is void if the equipment is abused or modified by the customer, is operated outside Terra's operating instructions or specifications, or is used in any application other than that for which it is specified. This warranty does not include routine maintenance or service procedures, breakage of quartz baths after 60 days, shipping damage, nor damage from misuse, intentional or unintentional abuse, neglect, natural disasters, or acts of God.

Products Manufactured by Others: Terra Universal, Inc., warrants that, to the best of its ability, Terra's representations of products that are manufactured by others reflect the manufacturer's representations, subject to change without notice. Sole warranty for these products is the original manufacturer's warranty that is passed forward to the purchaser and constitutes the customer's sole remedy for these products. Detailed warranties for distributed products are available through Terra sales representatives.

Freight Shortage or Damage: Upon receipt of any equipment from Terra Universal, Inc., customer shall immediately unpack and inspect for damage or shortage. The customer shall not accept a damaged package or a short shipment until the carrier makes a "damage or shortage" notation on both the carrier's and customer's copy of the freight bill or delivery receipt. Service title passes when the shipment is loaded, so customer is responsible for filing and collecting a freight claim. Any replacement products must be ordered and paid for separately. For Terra's "Policy and Procedures for Returning Goods," see Terra's Internet site: www.TerraUniversal.com.

Generally, customers can improve the chance of collecting on a freight claim by following these procedures: 1) formally requesting that the carrier inspect the shipment immediately upon suspecting damage or shortage to verify condition; 2) notifying the carrier upon discovery of concealed damage and requesting an inspection within 15 days of receipt, both in person or phone and following up via mail; 3) keeping the shipment as intact as possible, including retaining original packaging materials and keeping the product as close to the original receiving location as possible; 4) holding salvage for disposition by the carrier.

All Claims: Terra Universal expressly disclaims all other warranties, expressed or implied or implied by statute, including the warranties of merchantability or fitness for intended use. Terra Universal is not responsible for consequential or incidental damages arising out of the purchase or use of the products supplied by Terra Universal. Terra Universal is not liable for damage to facilities, other equipment, products, property or personnel of others, or of their agents, suppliers, or affiliated parties, which is caused or alleged to have been caused by products supplied by Terra Universal. In any event or series of events, Terra Universal's total liability for any and all damages whatsoever is limited to the lesser of the actual damages or the original invoice cost of the items alleged to have caused the damage. The customer's sole and exclusive remedy for any cause of action whatsoever is repair or replacement of the non-conforming products or refund of the actual purchase price, at the sole option of Terra Universal. All claims must be made in writing within 90 days of the date the product was shipped. Any claims not made within this time limit shall be deemed waived by the customer. Terra Universal is not responsible for any additional costs of repair caused by poor packaging or in-shipment damage during return.

Warranty Returns: All warranty returns must be authorized in advance by Terra Universal and approved under an RMA. Unless approved in advance for good reason, all returns must be in original condition, including all manuals, and must be packaged in original packaging materials. All returned goods are to be shipped to Terra Universal, freight prepaid at customer's expense. See Terra's "Policy and Procedure for Returned Goods."

5.0 Spare Parts & Accessories

For replacement parts and accessories for your cleanroom order at Terra Universal.com

Filter Replacement

Replacement Filters for Terra WhisperFlow™ Fan Filter Units		
Type	Size	TUI Part #
HEPA	2 X 2	6601-27
	2 X 3	6601-26
	2 X 4	6601-25
ULPA	2 X 2	6601-30
	2 X 3	6601-29
	2 X 4	6601-28

Fluorescent Illuminator

2 X 4 Ceiling Module115VAC / 60Hz	TUI # 3800-80	Replacement Ballast: TUI #6704-12
2 X 4 Flow – Through Module 115VAC / 60Hz	TUI # 6704-77	
2 X 4 Ceiling Module 277 VAC / 60Hz	TUI # 3800-80-277	
2 X 4 Flow - Through Module 277 VAC / 60Hz	TUI # 6704-77-277	

Yellow 12-foot Power Cables

For connection of light or fan filter unit to Power Distribution Module (electrical box)

No. EL04962: for Fan Filter Units
4 Pin – up to 600 VAC

No. EL01297: for Fluorescent Illuminator
3 Pin – Up to 600 VAC

Vacuums

MicroVac – Portable Vacuum Cleaner — TUI # 5100-00
TUI # 5100-00-220 (220 VAC)

HEPA – Filtered Vacuum Cleaner — TUI # 1001-00
ULPA – Filtered Vacuum Cleaner — TUI # 1764-00
TUI # 1764-00-220 (220 VAC)

Wipers

Pre-Saturated Nonwoven Spunlace Wipers — TUI # 5605-55
Pre-Saturated Laundered Polyester Wipers — TUI # 5605-17
Many other styles at TerraUniversal.com

Appendix I:
Terra Universal USP 797 Compliance Testing for Compounding Clean Rooms

Terra Part Numbers: 2900-52A, 2900-53A, 2900-54A, 2900-55A

Terra's Compounding Cleanroom has been compliance-tested by an independent certifier to the environmental requirements specified by USP 797. Sample test protocol and data are furnished below. Factory testing is intended to demonstrate compliance with USP 797; however, it does not constitute certification, which must be conducted on-site by an authorized testing company.

Unless otherwise noted, all testing is performed with FFUs in the "Medium" speed setting. As filters clog or other operating conditions change, FFU speeds can be adjusted upward to "High" settings in order to increase air change rate, internal pressure level, and air displacement rate between buffer and anterooms.

1.0 Buffer Room Pressure Test

Purpose:
Verifies: pressure > 0.04"WC

Apparatus:
Magnehelic gauge installed inside Buffer Room (Terra P/N 6600-86; Mfgr: Dwyer No. 2300-0; 0.25 – 0 - 0.25"WC bidirectional scale range)

Results:
Meets pressure requirement with FFUs on medium speed and exhaust vents open (unobstructed), at a pressure value of ≥ 0.02"WC.

2.0 Ante Chamber Pressure Test

Purpose:
Verifies: pressure > 0.02"WC

Apparatus:
Magnehelic gauge installed inside Ante Chamber (Terra P/N 6600-86; Mfgr: Dwyer No. 2300-0; 0.25 – 0 - 0.25"WC bidirectional scale range)

Results:
Meets pressure requirement with FFUs on medium speed and exhaust vents open (unobstructed), at a pressure value of ≥ 0.02"WC.

3.0 Airflow Testing – Turbulent Airflow

Purpose:
Verifies: air change rate > 150 ACH

Apparatus:
Mfgr.: Shortridge Instruments: Series 8400 Flow Hood with Airdata Multimeter Model ADM-860C

Results:
Meets Airflow Requirement: Average FFU airflow = 620 CFM at medium speed; Average air change rate = 300

4.0 Particle Count

Purpose:
Verifies: particle count < 352,000/m^3 in buffer area (ISO 7); <3,520,000/m^3 in ante area (ISO 8) @ 0.3 microns

Apparatus:
Terra P/N 1510-30 Hand-Held Particle Counter (Hal Technology Model HPC600)

Results:
Meets ISO Particle Count Requirement. Average particle measurements for both Buffer Room and Ante-Room: < 352,000 /m^3 @ 0.3 microns