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## Cleanroom FAQs

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### How does a cleanroom work?

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A cleanroom provides a controlled, isolated environment for handling contamination-sensitive substances or for protecting the exterior environment from dangerous substances in the controlled area. The density of sub-micron and larger airborne particle contamination inside a cleanroom is kept within tightly controlled limits by forcing clean, filtered air into the cleanroom.

Controlling particulate contamination is a process, not an event. Contaminants are generated continuously by people, processes, facilities and equipment and must be continuously removed from the cleanroom. The allowable level of contamination is dictated by specifications for the operations being performed. In the US, particle counts per cubic foot are commonly given as "class ratings," such as "Class 1000" specifying fewer than 1,000 particles, with a size greater than .5  $\mu\text{m}$  per cubic foot. ISO standard 14644-1, however, provides more precise standards but is often used interchangeably in the US.

Contamination control requires controlling the total environment. Air flow rate and direction, pressurization, temperature, humidity and specialized filtration all need to be tightly maintained to remove particles from the cleanroom. Particle sources must be eliminated whenever possible.

**Positive pressure modular cleanrooms** provided by Terra Universal typically use ceiling-mounted self-powered Fan-Filter Units (FFUs) to force HEPA- or ULPA-filtered air into the cleanroom. This creates an internal air pressure greater than ambient pressure, which reduces particulate intrusion around doors, and minor un-sealed areas in walls, ceilings, etc. Wall venting near floor level exhausts cleanroom air with the particles it carries into the external environment and promotes laminar flow of incoming air. The ability to remove particles and thus create a particulate-controlled environment inside the cleanroom is measured by the number of air changes per hour; the more clean air, the cleaner the cleanroom. Basically, a positive pressure cleanroom protects the internal environment.

In a given cleanroom, cleanliness can generally be increased by simply adding more FFUs, and thus filtered air, in the correct locations. Positive pressure can be built with hard walls made of solid plastic or steel, or soft walls made from flexible plastic strips and curtains. In hardwall cleanrooms, temperature and humidity can be controlled to provide human comfort, protect processes and prevent static charges by adding air conditioners, humidifiers and dehumidifiers.

**Negative-pressure modular cleanrooms** provided by Terra Universal

are designed to keep contaminants from entering the external environment. A common design uses exhausting FFUs, or air handlers, and HEPA filters to remove internal air. The cleanroom's in-room processes contaminate the air, that is then exhausted to a safe location. This exhaust system creates a negative pressure inside the cleanroom that draws external air into the cleanroom either directly or through filters. A common application for this design is a powder filling operation. A negative pressure cleanroom, then, protects the external environment but not necessarily the internal area.

**Positive/negative pressure modular cleanrooms** provided by Terra Universal, a more complex design, typically use FFUs to inject clean air into the cleanroom and exhaust contaminated cleanroom air into a buffer area. An air-handling system then removes slightly more air from the buffer area than is supplied by the FFUs, thus creating a negative pressure with respect to both the cleanroom and the external environment. This negative pressure prevents cleanroom contaminants from entering the external environment and also prevents external particulates from entering the cleanroom. A positive/negative pressure cleanroom, then, protects both the cleanroom and external environments.

## [Design Examples](#)

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### **What are the big differences between hardwall cleanrooms and softwall cleanrooms?**

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**Hardwall modular cleanrooms** provide a rigid wall structure and a completely enclosed cleanroom with air vents to exhaust air. These cleanrooms hold higher pressure differentials, which is important to provide differing cleanliness levels in different areas (and which is required to meet FDA 797 requirements). Negative and positive/negative pressure cleanroom designs require hardwall cleanrooms, as do A/C and humidity control cleanrooms.

Terra Universal fabricates hardwall cleanroom walls from acrylic, static-dissipative PVC, polycarbonate, and polypropylene (all in various colors) with frames of powder-coated steel. In addition, Terra offers BioSafe hardwall cleanrooms fabricated from 304 or 316 stainless steel.

**Softwall modular cleanrooms** use a simpler steel frame structure to support flexible PVC (or non-out-gassing Polysym) curtains cut a few inches above the floor to provide an exhaust vent. Softwall cleanrooms provide only the lowest of positive pressures and are typically used only in lower cleanliness ratings such as Class 1000, 10,000 and 100,000. Because these cleanrooms offer less control over air flows, temperature and humidity control are normally not provided.

Smaller softwall cleanrooms can be fitted with casters. Softwall cleanrooms are generally not suitable for complex, multi-room designs

and long spans.

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### **Which is cleaner, a hardwall cleanroom or a softwall cleanroom?**

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Although both types of cleanroom can be built to meet the same air-change-per-hour standards, hardwall cleanrooms offer a more complete barrier to particle intrusion and more control over atmospheric temperature and humidity than is possible with softwall cleanrooms.

Probably the most important difference in many applications, is that a hardwall cleanroom can hold a significant positive pressure, which prevents particulate intrusion. Since softwall cleanrooms generally have a perimeter air gap, they can maintain very little positive pressure and no negative pressure differentials.

Hardwall cleanrooms offer somewhat less turbulent air flow since the walls are fixed and do not move as is possible with softwall cleanrooms. Plus, it is definitely easier to clean hard walls than curtains and strips.

Up to a reasonable size, softwall cleanrooms can be mounted on casters, which makes them mobile. Hardwall cleanrooms are fixed in place but can be disassembled, moved and reassembled. Finally, softwall cleanrooms cannot be secured against unauthorized entry.

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### **How is cleanliness measured? If I buy one class now, can I make the cleanroom cleaner later?**

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Achieving a specific cleanroom class requires not only clean physical design (non-particulating materials, etc.) but also a flow of clean, filtered air sufficient to both dilute existing particulates and to drive "dirty" air out of the controlled space.

Fan-filter units (FFUs) are generally used in Terra Universal modular cleanrooms to provide HEPA- or ULPA-filtered air. FFUs provide air flow at velocities of about 90 to 110 feet per minute, fast enough to generate laminar flow but slow enough to prevent excessive turbulence.

Assuming a clean physical design, air flow determines the design cleanliness of a cleanroom. Cleanroom classes, ISO standards and Terra's general recommendations in terms of air-changes-per-hour are:

<b>Class</b>	<b>ISO Average</b>	<b>Air changes/hour</b>
100,000	ISO Level 8	5 to 48
10,000	ISO Level 7	60-90
1,000	ISO Level 6	150-240
100	ISO Level 5	240-480
10	ISO Level 4	300-540

The cleanroom class is the number of particles  $\geq 0.5 \mu\text{m}$  in diameter

per cubic foot. For instance, a Class 1,000 cleanroom could contain an average of up to 1,000 particles per cubic foot of space.

The good news is that simply adding FFUs can generally lower the cleanroom class (make it cleaner). That assumes, of course, that the cleanroom has ceiling grid spaces not occupied by lights, FFUs or Power Distribution Modules.

Actual particulate levels are measured by taking a panel of readings with a particle counter at various points throughout the cleanroom. Terra Universal sells such counters.

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### **How clean do I need the cleanroom to be?**

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The cleanroom classification needed depends on specifications for operations to be conducted within. Research in your specific field will probably provide a specification or at least a general guideline.

FDA requirements cover several types of clean facilities, the most generally known being USP 797, specifying conditions for pharmaceutical compounding facilities.

Very generally speaking, simply keeping products "clean," as in dust-free to the human senses during packaging and similar processes, probably fits within Class 10,000 or even Class 100,000. "Clean" storage of previously-packaged products usually fits in Class 100,000. Basically, if the operating staff wear frocks and possibly hairnets but not masks, bunny suits, booties and the like, these two classes probably fit.

If full suiting is required for more contamination-sensitive products or difficult contaminants, a Class 1,000 environment or cleaner will generally be required.

If your application requires a Class 100 or Class 10 environment, you already know it, or certainly should.

An important cost reduction potential is to design areas with different cleanliness levels for different operations. For instance, a gowning room for a Class 1,000 cleanroom could be effective at Class 10,000. This reduces the number of FFUs and lowers operating costs.

These classes refer to environments with reduced particulate contamination, not to creating sterile environments. Consult your industry standards for sterile environments. Terra Universal's BioSafe stainless steel cleanrooms may be ideal for sterile applications since they are not affected by harsh wash-down chemicals.

The cleanroom is only part of the equation for a successful clean operation. Cleanroom garments such as frocks, coveralls, gloves, face masks, booties and head covers are often used because people are a

major source of contamination. These supply items are available from Terra Universal.

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### **How are Terra Universal's ValuLine and standard softwall cleanrooms different? Is the standard line cleaner?**

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Both softwall cleanroom lines meet the same quality standards for design and materials. Within a class rating, both offer the same cleanliness. However, since Terra Universal's standard line softwall cleanrooms offer higher power for additional FFUs and teardrop lighting, they can be configured to Class 10, which is not available in ValuLine cleanrooms.

Each standard line softwall cleanroom is built to order, a process that takes generally four weeks or more. Standard line cleanrooms, then, can be made in virtually any reasonable size and can feature unusual materials such as stainless steel frames. Standard line softwall cleanrooms use Terra-designed Power Distribution Modules (PDMs) that are hard-wired to the building's electrical system in order to support larger numbers of FFUs, lights and in-room power outlets with higher power ratings.

ValuLine softwall cleanrooms are preconfigured from standard components to produce ten standard sizes from 6' x 6' up to 12' x 12' in each of two heights (7' and 8'). In place of PDMs, ValuLine softwall cleanrooms are powered by a simple Power Supply Unit (PSU) that plugs into your standard wall outlet (20 amp free circuit required). The PSU switches a fused outlet box on the ceiling into which FFUs and lights are plugged, using standard 120V plugs. The PSU also provides one non-switched, light-duty outlet for in-room instrumentation.

ValuLine softwall cleanrooms generally ship in a few days. The ValuLine cleanroom arrives in one (large) crate that rolls on its own casters through 36" doors to the assembly area. Each ValuLine cleanroom comes complete with all tools needed for assembly.

ValuLine softwall cleanrooms do not include the decorative top trim included on standard line cleanrooms, which makes assembling the ValuLine cleanroom easier. ValuLine softwall cleanrooms do not include the flashing status indicators optionally provided on standard line cleanrooms.

ValuLine softwall cleanrooms are significantly less expensive yet offer full cleanliness for operations that fit their sizes and power ratings.

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### **What sizes and class ratings are available in Terra's softwall cleanrooms?**

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Terra Universal's standard line softwall cleanrooms can be built in virtually any size or configuration in heights up to 15 feet.

Terra Universal's ValuLine softwall cleanrooms are assembled from

standard components and can be obtained in the following standard nominal sizes:

12' x 12'	12' x 10'	12' x 8'	12' x 6'
	10' x 10'	10' x 8'	10' x 6'
	8' x 6'	8' x 8'	8' x 6'
			6' x 6'

Standard heights for ValuLine softwall cleanrooms are 7' and 8'. Custom heights are easily available. All actual sizes are slightly larger than the stated nominal sizes – by an inch or two – to fit standard components. ValuLine cleanrooms can generally be custom sized at additional cost and with longer lead-times.

ValuLine softwall cleanrooms offer class ratings from 100 to 100,000. Standard line softwall cleanrooms provide class ratings from 10 to 100,000.

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#### **Why can't I get exactly the sizes I want in ValuLine?**

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#### **Why can't I get a class 10 rating?**

ValuLine softwall cleanrooms are assembled from off-the-shelf components and ship in a few days. In order to achieve this rapid service, only standard sizes can be offered. ValuLine cleanrooms can generally be custom sized at additional cost and with longer lead-times.

Class 10 requirements are generally provided by hardwall cleanrooms since they offer more complete airflow control and sealed cleanrooms. In addition, Class 10 airflow requirements usually require nearly continuous FFUs, more power than can be supplied by wall circuits and sometimes teardrop lights, none of which can be supplied in ValuLine softwall cleanrooms. Terra's standard line softwall cleanrooms may provide Class 10 in some configurations.

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#### **How do I get electricity to the ValuLine cleanroom? How is power controlled? Are lights and FFUs separately switched?**

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Lights and FFUs on a ValuLine cleanroom are plugged into a ceiling-mounted outlet strip that is part of the Power Supply Unit (PSU). The PSU, in turn, is plugged into a wall outlet on a free 20 amp circuit. One switch on the PSU controls both lights and FFUs.

The PSU also supplies one non-switched outlet for light-duty applications in the cleanroom.

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#### **How fast can I get a ValuLine softwall cleanroom? How fast can I get a standard cleanroom?**

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Terra Universal ValuLine softwall cleanrooms generally carry a lead time of three business days, meaning that an order released on Monday will probably ship Wednesday or Thursday, depending on how early in the

day it is released.

An order can be released when Terra has received either the payment and a firm order or, for organizations with pre-cleared credit terms, a Terra-approved purchase order.

Terra Universal's standard softwall cleanrooms are made-to-order, generally in four to five weeks. Terra's hardwall cleanrooms carry a six- to eight-week lead time, or more, depending on complexity and workloads.

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### **How hard is it to assemble a ValuLine cleanroom? What tools are required?**

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Most ValuLine softwall cleanrooms can be erected in less than a day from crate to operation with two assemblers.

That time assumes that the assemblers read the assembly instructions included in the crate and are generally familiar with operating common hand tools such as electric screwdrivers, hammers and measuring tapes. A third person can be helpful to lift the FFUs, and assist on larger cleanrooms.

ValuLine cleanrooms generally arrive in one large crate with casters and roll through 36" doors to the assembly site.

You will need a way to get the crate off the truck, however. Dock-high facilities generally let the crate just roll off. Without a dock, a forklift or tail gate delivery will be required.

All tools required to assemble a ValuLine softwall cleanroom are included in the crate – electric screwdriver, hammer, etc.

***You will need a step stool for each assembler and one six foot tall ladder.***

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### **What maintenance is required on a ValuLine softwall cleanroom? How often must the filters be changed?**

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Your ValuLine softwall cleanroom from Terra Universal will be beautifully and ruggedly constructed with chip resistant powder coated steel uprights and a powder coated steel ceiling grid.\* Simply follow standard cleanroom wipe down protocols. IPA and mild bleach solutions will not harm components including the chemically resistant soft wall material. Other than cleaning, the only normal maintenance is changing FFU filters and light bulbs.

The HEPA filter on the FFU can last two to five years, or more, in a standard cleanroom environment. Life of the HEPA filter depends on ambient conditions and on prefilter cleanliness. Terra Universal sells replacement HEPA filters.

FFUs include prefilters similar to those in home air conditioners that should be changed as needed – check annually. DIY stores and Terra Universal sell replacement prefilters.

If you plug a high-current device into the Power Supply Unit, you will have to reset push-type circuit breakers.

\*Aluminum? Never in a Terra-manufactured cleanroom! Terra's all-steel frames mean that you can disassemble, move and reassemble your room with confidence.

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### **Can ValuLine softwall cleanrooms be certified?**

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Yes, Terra Universal ValuLine cleanrooms can be certified. Terra does not issue certifications on its own cleanrooms, naturally, but can usually refer you to a third-party certifier.

Please note that since users' operating specifications, individual certifier's protocols and, where invoked, local building code requirements often differ radically, Terra does not guarantee certification and code compliance on a general basis. Terra does guarantee that the cleanroom and all Terra-provided accessories will operate to specifications that are explicitly listed in all product descriptions.

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### **Can ValuLine softwall cleanrooms be equipped with temperature and humidity control?**

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Due to the nature of all softwall cleanrooms, humidity and temperature control require custom engineering. Generally, these options will require a standard line softwall cleanroom, not a ValuLine cleanroom.

Since FFUs draw air from the surrounding room, an HVAC system in that room can often keep the cleanroom comfortable.

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### **What are softwall curtains made of? Does Terra offer alternate softwall curtain materials?**

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All Terra Universal's standard softwall curtains and strips – ValuLine or standard line – are made of anti-static PVC. Panels are 40 mil (.040") thick; door strips are 60 mil (.060") thick.

Terra Universal offers Polysim curtains on a custom basis. The cost for this change is \$250 plus the difference in cost for the material itself.

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### **How much vertical space above the cleanroom ceiling is required? Why?**

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Normally, the facility should provide 24" clearance above the cleanroom height. For example, an 8' cleanroom usually requires a 10' high surrounding room.

The cleanroom height (8' in the example) is measured from floor to the filter face. The FFU extends 11" or so above that. Terra generally recommends an additional 12" of clearance to allow easier FFU

installation and maintenance and to assure unobstructed air flow to the FFU. If your facility does not provide the full 24", the cleanroom could be shortened or, depending on configuration, a few inches could be squeezed out of the clearance. If a tight clearance is necessary, discuss your room configuration with your Sales Associate who will design alternatives with Terra Universal's engineering staff.

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### **Is flooring included with the cleanroom? Does Terra offer flooring options?**

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Flooring cannot be included in the standard cleanroom price since Terra Universal is not a locally-licensed contractor and cannot make facility modifications. (Terra can, of course, install modular cleanrooms.)

Terra partners with Staticworx, a manufacturer of cleanroom floors with a nation-wide network of installers. Terra can provide a quote for a standard or ESD cleanroom floor through Staticworx.

Local flooring contractors can often provide cleanroom flooring. Depending on your operating and cleanliness specifications, a simple epoxy painted floor or even a sealed concrete floor may be acceptable. Epoxy floor paints and concrete floor sealers are available at DIY stores.

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### **Can I expand the cleanroom in the future?**

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Yes, you can generally extend or reconfigure a Terra Universal cleanroom. Based on the original order number and your new specifications, your Sales Associate will work with Terra's engineering staff to design changes and manufacture the additional parts and modifications.

If you think the chance of future modifications is high, discuss potential changes with your Sales Associate when the initial cleanroom is ordered. If parts can be designed to accommodate future expansion, the transition will be easier.

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### **Can modular cleanrooms be placed against existing walls?**

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#### **Why is this restricted?**

Yes, modular cleanrooms can generally be installed against existing walls, provided that sufficient space is allowed to erect the cleanroom and adequate provisions are made for exhausting air. Discuss spacing to existing walls with your Terra Universal Sales Associate when ordering the cleanroom.

Both hardwall and softwall cleanrooms generally depend on exhausting air through vents or open spaces at or near the bottoms of walls or curtains. Blocking this exhaust in large areas may create more turbulent airflow in the cleanroom or limit exhausting air. To prevent this, Terra recommends leaving a one- to two-foot clearance space between the modular cleanroom and existing room walls.

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**Does the cleanroom cost include installation and freight?**[Top](#)

Costs quoted for the cleanroom and related accessories do not include installation and freight. Your Sales Associate can provide a detailed installation quote and freight cost estimate on either an FOB destination or FOB Terra basis.

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**What is Terra's warranty for ValuLine and other cleanrooms?**[Top](#)

Terra Universal's standard warranty for all cleanrooms is one year parts and 90 days labor after shipment of order. For specific warranty provisions, please see Terra's [warranty](#).

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**Can top trim be purchased for a ValuLine softwall cleanroom after installation?**[Top](#)

Although top trim can be purchased later as a custom item, it is not possible to assure that custom parts manufactured later will fit perfectly. It is FAR better to order top trim when the cleanroom is ordered!

Top trim is included on standard hardwall and softwall cleanrooms. Top trim can be ordered custom on ValuLine softwall cleanrooms for a \$250 custom charge plus cost of the trim itself.

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**What are the maximum dimensions for Terra's ValuLine softwall cleanrooms?**[Top](#)

On a custom basis, ValuLine cleanrooms can be manufactured to the usual sizes permitted for standard line softwall cleanrooms.

Generally, this means about 16' on a side and 15' tall. Note that ValuLine PSUs will not power the number of FFUs and lights required on larger cleanrooms with low class levels.

Basically, if the cleanroom is over 150 square feet, it's best to obtain standard line.

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