

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:



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



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

1.0 Introduction



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. **Do not attempt to stand on ceiling joists while performing maintenance or cleaning.**

These guidelines below are intended as general recommendations for cleanroom cleaning, not strict cleaning or sterilization protocol. They should be integrated into a formal cleaning protocol based on specific requirements.

The aim of a formal cleaning protocol is to ensure reproducible cleaning and sterilizing results. Every facility should develop its own cleaning protocol based on a number of application-specific considerations.

Cleaning Frequency

In some industries, frequency is regulated by government agencies and may depend on specific operations being performed. For example, the U.S. Pharmacopeia bases cleaning protocol on types of sterile preparations that may be performed inside the cleanroom (high, medium, and low risk compounds). In other cases, cleaning frequency depends on the amount of foot traffic and number of particles emitted by process equipment.

Consult with an expert familiar with your own certification or compliance requirements as you determine a cleaning/sterilization schedule.

Sterilization Requirements

In one facility, cleaning may be strictly a matter of removing contaminants that settle on the floor or other surfaces. In another, it may require regular sterilization of all cleanroom features to specific germicidal standards (e.g., D99 dosage), including seams, cracks and crevices where microbial contaminants can grow. Depending on sterilization requirements, use of a biocidal fog (such as hydrogen peroxide vapor) may be indicated. See attached document "Ultraviolet Disinfection" for more information on sterilization efficiency.

Guidelines below address noninvasive cleaning and disinfecting methods: mechanical wipe-down and UVC germicidal sanitation. For more thorough sterilization requirements, contact Terra Universal.

Chemical Vapors

These guidelines make no specific recommendation regarding cleaning or disinfecting agents. A solution of 70% IPA / 30% DI water is common, but many facilities require other solutions, depending on specific cleaning requirements and sensitivity of parts and processes to the chemical vapors ("outgassing") that emanate from various cleaning agents.



Composition of Wipers, Mops and Other Cleaning Products

These products vary widely with respect to critical physical characteristics: basis weight, particle shedding, absorbency, softness, and purity (ionic extractables). In general, you should select cleaning products made of a non-linting material.

In the cleanest environments (ISO 3 - 5 / Class 10 - 100), you should select knitted polyester wipers or spun-lace, nonwoven blends of cellulose and polyester manufactured and packaged specifically for cleanroom use. These products are manufactured under tightly controlled conditions that restrict the use of binders or chemical treatments that can outgas, and cleanroom packaging and strict lot control ensures optimal cleanliness.

Less critical cleanliness classifications (ISO 6 – 8 / Class 1000 – 100,000) generally tolerate more absorbent materials made of 100% cotton twill or cellulose.

Don't forget that related cleanroom supplies, such as paper and pens, must also comply with cleanroom conditions. Terra provides a comprehensive range of these products at TerraUniversal.com.

Use of Vacuum Cleaners

Vacuums designed for use in a cleanroom incorporate exit filtration to trap particles from the exhaust flow. Exit filters may be either High-Efficiency Particulate Air (HEPA) filters, rated to contain 99.99% of all particles down to 0.5 microns in diameter, or Ultra-Low Penetration Air (ULPA) filters, rated o contain 99.999% of all particles down to 0.12 microns in diameter.

If vacuum cleaning is permissible, Terra recommends vacuuming the floor and all accessible surfaces of the facility before and after mechanical cleaning with wipers, mops or other hand tools. Thorough vacuum cleaning before and after wiping/mopping will remove particles initially present on surfaces as well as particles that may become dislodged during mechanical wiping.

Training and Documentation

As you develop your protocol, be sure to incorporate appropriate written documentation of how cleaning personnel are trained, as well as a written schedule of all cleaning and sterilizing procedures conducted. This documentation may be critical to certification and/or quality assurance requirements.

To minimize the contamination load on your cleanroom, be sure to follow proper gowning and entry protocol, including placement and maintenance of shoe cleaners, whether motorized systems or adhesive mats.



2.0 Mechanical Cleaning of Cleanroom Surfaces

All cleaning procedures below should be performed while a cleanroom is in operation, with air passing through ceiling Fan Filter Units (FFUs). In order not to compromise cleanroom validation, all cleaning staff should follow standard protocol for garbing and cleanroom etiquette (i.e., no gum or tobacco, avoid abrupt or fast movements).

• Always check chemical compatibility before cleaning plastic surfaces. Although polycarbonate and staticdissipative PVC withstand exposure to a wide range of common cleaning agents, repeated exposure to strong chemicals can cause damage. Acrylic surfaces can be damaged by repeated exposure to alcohol and other strong cleaning agents.

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

Vacuum Cleaning

If vacuum cleaning is permissible in your facility, Terra recommends thorough, systematic vacuum cleaning both before and after the cleaning procedures described below. Use only a vacuum cleaner compatible with your cleanroom facility, generally, a multi-filter cleaner that uses ULPA final filtration and incorporates cleanroom-compatible components: a stainless steel housing, non-shedding hoses and other attachments, and non-marking wheels. Hand-held vacuum cleaners can be used to clean horizontal surfaces (see "Cleaning Accessories").

As in most cleaning procedures, begin vacuuming at the ceiling, using a soft brush attachment, and work your way down to the floor. By using a hand-held vacuum with the appropriate attachments and cleanroom stepladder, you can remove particles from shelving and other horizontal surfaces, even intricate benchtop setups. When you have cleaned ceiling and wall panels, use a floor vacuum to remove particles from the cleanroom floor, beginning in the area furthest from the entrance and working your way to the access door.

Because the vacuum discharge generates turbulence that makes particle difficult to capture, keep the vacuum canister behind you, trailing your motion forward through the cleanroom.

Surface Cleaning

All surfaces of the cleanroom should be wiped down thoroughly at regular intervals. Cleaning frequency and materials should be determined based on regulatory requirements and use (see introductory comments).

Whether you're cleaning an enclosure or an entire cleanroom, cleaning should be performed from the ceiling to the floor.

Ceiling Cleaning

Cleanroom ceilings typically require minimal cleaning as long as the ceiling FFUs are operational. If ceiling cleaning is necessary, use a soft brush attachment of a cleanroom vacuum cleaner, if permissible.

Open each light unit and gently wipe the bulbs with a wiper dampened with DI water, as well as the inside of the diffuser. Close the fixture. Then, gently wipe the external light diffuser panels, blank ceiling panels, and the ceiling T-bar with a dampened wiper to disinfect the surfaces.





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. Use only a vacuum soft brush attachment to clean FFU surfaces.



For uniform, repeatable results, avoid circular motion when wiping surfaces. Wipe in one direction, from top to bottom or left to right, using slightly overlapping strokes. Fold the wiper between strokes.

Cleanroom Walls, Windows, Doors and Work Surfaces

Cleaning of walls depends on cleanroom type. Terra's BioSafe™ Cleanrooms feature smooth, all-stainless steel panels that typically will not accumulate particles. The conductive panel material does not support static surface charges, so particles generally will not cling, as they do to non-conductive surfaces. As long as panel seams are caulked with silicone, they should inhibit microbial growth.

If the room has been inoperative, Terra recommends cleaning with a cleanroom-compatible adhesive roller to remove loose particles. Roll in a single direction, using overlapping strokes (refer to "Cleaning Accessories" below).

To remove contact stains, walls can be cleaned with a saturated wiper. Begin cleaning from the top of each panel, working to the very bottom (see Caution above on unidirectional wiping). Doors and windows should be cleaned, using this same unidirectional motion, once the portion of the wall above them has been cleaned.

If your cleanroom uses a steel frame with plastic panels, wipe down the vertical and horizontal frame members when all panels are clean.

After wiping walls, vacuum with a soft brush attachment to remove particles that may have been loosened.

Softwall Panels

Begin by vacuuming panels, using a soft brush attachment, or by cleaning with an adhesive roller. Then, wipe surfaces with a dampened wiper. Use vertical strokes, from top to bottom, when cleaning flexible softwall panels. For best results, an assistant should support the wiper on the opposing side of the curtain, using a clean panel as backing as the wiper moves from top to bottom.

After wiping the panel, vacuum or roller-clean it once more.

Floors

If permissible, use a cleanroom vacuum cleaner on the floors after walls are cleaned (see vacuuming guidelines above). If vacuuming is not permissible, use an adhesive roller to remove loose particles.

Next, clean floors thoroughly using a cleanroom-compatible mop and appropriate cleaning agent and mop bucket. A divided bucket is ideal since it provides one receptacle for mop rinsing and particle removal, and a separate receptacle to for saturating the mop with cleaning agent. Mop in straight, overlapping paths, rather than circular motions, to optimize



contaminant removal. *Replace the rinse water after mopping every 10 to 15 square feet of cleanroom floor.* Mop heads should be replaced or autoclaved after each use. In aseptic environments, disposal after each use is recommended.

After the floor dries, clean it once more using a vacuum cleaner or adhesive roller to remove any particles that may have been dislodged.



3.0 UVC Sanitation

Sanitizing a room with Ultraviolet C (UVC) radiation provides additional control of microbes, including MRSA and similar pathogens. See attached document "Ultraviolet Disinfection" for more details on UVC germicidal efficacy with common microorganisms.

UVC sanitation is recommended for aseptic environments as a supplement to – but not replacement for - conventional cleaning operations described above. The critical considerations in UVC sanitation include exposure duration and exposure intensity. If a surface is very close to the radiation source, it will receive a sufficient germicidal dosage (often defined as a D99 dosage: a 2-log reduction of all microbes present) much more quickly than if it is located further away.

UVC offers several advantages over more invasive sterilization techniques like hydrogen peroxide vapor. Most importantly, it does not require absolute containment to meet safety standards. As long as people are not present during the UVC cycle, which typically lasts only for several minutes, it poses no residual danger. Because most window materials, including glass and most plastics, provide effective UVC barriers, personnel outside the room are at minimal risk. UVC equipment is also typically much less expensive and easier to use than other sterilization systems. (See "Cleaning Accessories" for more information.)

The principle disadvantage is the line-of-sight requirements: Surfaces not in direct contact with the UVC source may not experience any significant germicidal effects. Thus, UVC may have little effect on microorganisms lodged in cracks or crevices that don't receive direct exposure to the UVC radiation.

A variety of portable UVC systems are available for use cleanroom use. UVC lights can be installed inside air return ducts to kill microorganisms in the air stream. As long as air speed is below 100 ft./minute, these systems are typically effective. Portable UVC systems can be positioned inside a cleanroom for sanitizing cycles when personnel are not present. These systems are ideal for sanitizing walls and ceilings that might not be accessible to standard mechanical disinfection. Safety features include kill-switch motion detectors and cycle timers and alarms.

See attached document "Ultraviolet Disinfection" for additional information.



Vacuum Cleaners

TerraUniversal.com

4.0 Cleaning Accessories



MicroVac No. 5100-00

VALUTER

SS Floor Vacuum No. 1764-36

Wipers

Pre-Saturated Nonwoven Spunlace Wipers TUI # 5605-55

Pre-Saturated Laundered Polyester Wipers TUI # 5605-17 Other styles at TerraUniversal.com

MicroVac –Vacuum Cleaner (ULPA Filtered) Includes mine-tool kit for cramped spaces. TUI # 5100-00 SS Floor Vacuum (ULPA Filtered) Available with biohazard containment unit. TUI # 1764-36 Other models and complete specifications at

Sticky Roller Cleanroom-compatible cleaning system available with handle extensions and foam or poly film rollers. Ordering information at TerraUniversal.com.



Hydrogen Peroxide Vapor Decontamination System

Services rooms up to 9000 cu. feet. Call Terra to discuss your application.