## Cleanroom and Controlled Environments

FOOD | PHARMA | BIOTECH | ELECTRONICS | MEDICAL



## Cleanroom and Controlled Environments

The terms "Cleanroom" and "Controlled Environment" can be often used synonymously, but there is a difference in how these spaces are regulated for environmental factors. Controlled Environments typically control the temperature, pressure, humidity and location, while cleanrooms require these environmental controls plus decontamination and filtration.

#### **Controlled Environments**

A controlled environment, also referred to as a critical environment, is a designated area that must have stringently controlled parameters such as, pressure, temperature, electrical classification and segregation. Many laboratories are considered controlled environments, as they have controlled temperature and pressure and are separated from other manufacturing and operations. Unlike cleanrooms, controlled environments do not measure the level or control the particle contamination and therefore do not have the same level of decontamination standards as cleanrooms.

#### Cleanrooms

A cleanroom is a form of a controlled environment with stringent requirements, requiring temperature and pressure control from the outside environment and other operations. All of these controls need to be controlled to very specific standards. Cleanrooms are classified by the maximum acceptable numbers of particles (by size) in the air per cubic meter, and must be regularly tested to ensure compliance to that standard.

Federal Standard 209E has long been the only definition of cleanroom classification levels available from a standards organization. This standard was created by the United States General Services Administration in 1963 and was often used as the global standard until it was canceled in 2001 in favor of a new international global standard created by the International Standards Administration (ISO).

As of November 29th, 2001, the Federal Standard 209E (FS209E) has been replaced with ISO 14644-1. This method is simple; the number assigned to the class is the classification that the room must be designed to. In the Federal Standard 209E, Class 1 was the cleanest. In the new ISO 14644-1 Standard, Class 3 is the cleanest. The difference? Generally speaking, the Federal Standards were measured in cubic feet and the ISO standards are measured in cubic meters. Below you will find a chart comparing the FS209E to ISO.

#### Cleanroom Class Comparison Chart

Cleanliness Level	ISO	Fed. Std. 209E Equivalent	Maximum Particles / Cubic Meter					
			0.1 Micron	0.2 Micron	0.3 Micron	0.5 Micron	1 Micron	5 Microns
Extremely Clean	ISO 1	n/a	10	2	n/a	n/a	n/a	n/a
	ISO 2	n/a	100	24	10	4	n/a	n/a
	ISO 3	Class 1	1,000	237	102	35	8	n/a
	ISO 4	Class 10	10,000	2,370	1,020	352	83	n/a
	ISO 5	Class 100	100,000	23,700	10,200	3,520	832	29
	ISO 6	Class 1,000	1,000,000	237,000	102,000	35,200	8,320	293
	ISO 7	Class 10,000	n/a	n/a	n/a	352,000	83,200	2,930
	ISO 8	Class 100,000	n/a	n/a	n/a	3,520,000	832,000	29,300
Clean	ISO 9	n/a	n/a	n/a	n/a	35,320,000	8,320,000	293,000



CR-1200D

WATTAG

AMPERAGE

120 V

60 Hz

Single

1000 V

8.5 A



#### 5 STAGE FILTRATION SYSTEM

- · ULPA Filter
- · HEPA Filter
- · PTFE Laminated Main Cloth Filter
- · Safety filter
- · Disposable Filter Bags

**EMI·RFI** SHIELDED

STATIC FREE AND ESD SAFE

#### Cleanrooms running efficiently

Tiger-Vac offers the largest range of portable industrial vacuum systems for use in cleanroom and contamination controlled environments. Our systems are designed specifically for the Pharmaceutical, Food, Medical Biotech, Semiconductor and Microelectronics industries. Compatible with ISO Class 4 cleanroom conditions as defined in ISO 14644-1 (Class 10 as per FED STD 209E) and helps to comply with GMP standards. Tiger-Vac Cleanroom Industrial Vacuum Systems are

equipped with H14 HEPA Filters and U15 ULPA Filters as per EN 1822. Our HEPA and ULPA filters are individually laser tested and every cleanroom vacuum system that leaves our factory is aerosol leak tested.

Our full range of both Intermittent and Continuous Duty Vacuum Systems are third party legally certified to meet the requirements of your environment. We offer dry and wet-dry units, explosion proof, and dust ignition protected systems, scrap recovery systems for trim, scrap on a packaging line, and containment vacuum systems for potent compounds. If you are mixing and blending powders, Tiger-Vac offers a range of Portable Dust Collection Systems to capture any dust plume generated by the process. With over 150 years of combined industry and application knowledge Tiger-Vac will help keep you and your employees stay safe!



#### CR-1000 (CV)

VOLTAGE	120 V
HERTZ	60 Hz
PHASE	Single
WATTAGE	1000 W
AMPERAGE	8.3 A
AIR FLOW	96 CFM
VAC DDECCLIDE	00 in H20

#### Potent Powder

Safe Containment Canister for Potent Carcinogenic Powders



### Preventing contamination and handling chemical spills

From time to time, chemical spills will occur in the laboratory and if handled properly, they will be nothing more than a nuisance. However, chemical spills can be seriously disruptive and in the worse cases can cause damage or injury. Most spills will involve small amounts of known material and cleaning these up will involve a low level of risk if proper precautions are taken. Users of the lab are best positioned to clean these spills as they will know the substance and be able to respond quickly. A proper response to spills should include thorough planning and the availability and use of necessary clean up equipment and appropriate vacuum system. In turn, this will reduce costs, in terms of both injuries and money. Tiger-Vac has been manufacturing cleanroom vacuum systems for over 30 years. Let us guide you in choosing the right vacuum system for your application.



Having a cleanroom cleaning process in place is incredibly important. After all, it's not much of a cleanroom if it isn't clean! Beyond that, the state of your working environment impacts all facets of business operations. From your employees to your consumers, from your reputation to your bottom line, proper cleanroom cleaning is of paramount importance for any company that produces products in a controlled environment.

like needles, scalpels, and other tools that cut or go into the skin.

to handle and recover sharps.

Prevent accidental needlesticks and cuts using a Needle Trap

The bottom line is, regardless of your business's revenue, you can't afford to have anything short of meticulous cleanroom cleaning processes in place.

#### Preventing contamination from combustible or explosive Airborne Dust

Dust explosions remain an under-reported issue, but a real concern in the pharmaceutical and chemical manufacturing industry. Combustible or explosive dust can be described as any finely divided particulate solid, which presents a fire or explosion hazard when dispersed in the air.

The powdered and granulated ingredients, central to pharmaceutical and chemical manufacturing processes, are naturally prone to creating dust, which can become airborne. Once the airborne dust is captured at its source, it must be effectively contained so to reduce the risks of a further, more devastating dust explosion. It also reduces the risk of cross-contamination in sensitive products.

#### Tiger-Vac has the Solution!

EXP1-10/15 CR CWR-10 EX (4W) WET & DRY RECOVE VOLTAGE 60 Hz HERTZ 60 Hz Sinale PHASE Sinale 1000 W 1200 W 132 CFM AIR FLOW 110 CFM VAC PRESSURE 69 in HoO VAC. PRESSURE 107 in.H20

VOLTAGE

Combustible |

Dust

HERTZ

Although combustible dust is prevalent in pharmaceutical plants, combustible dust incidents are preventable. The secret is simply to not let the dust accumulate to hazardous levels. The recommended approach is using a vacuum system designed for a specific purpose and location. Trust Tiger-Vac to help you choose the right vacuum cleaner system.



HERTZ

PHASE

In summary, your bottom line is directly related to your cleanroom cleaning. Incorrect procedures that cause wasted products is money straight out of your pocket. An effective maintenance plan ensures the seamless functionning of the entire production cycle.

60 Hz

Single or Three Phas

120 in. H<sub>2</sub>0 to 130 in. H<sub>2</sub>0

1110 W to 1480 W

2.1 A to 15 A 125 CFM to 158 CFM

Includes a True Cyclone Separator System located at the suction intake to enhance suction performance



## Effectively addressing the issue of accumulated Dust by capturing it at the source of generation

With Pharmaceutical manufacturing there are a wide range of non-active and active ingredients that may be blended to create the final blend used for the solid dose form being produced. During the manufacturing process the powders often require milling to properly size it into a drug powder. Mixing, batching and blending are also areas that dust can easily be liberated and if not controlled create a dust hazard. There is a wide range of equipment used in the Pharmaceutical Industry where dust can easily be liberated during the manufacturing process.

Whether you are filling or compressing powders, polishing capsules or dedusting tablets Tiger-Vac has an Industrial Vacuum System or portable Dust Collector can play a significant role in complying with good manufacturing practices.

CD-2600 CR	DESIGNED TO BE INTEGRATED
DRY RECOVERY	TO PROCESS MACHINES

DITT TIEGOTETT	
VOLTAGE	230 V to 575 V
HERTZ	60 Hz
PHASE	Single or Three Phase
WATTAGE	1900 W to 2600 W
AMPERAGE	2.6 A to 9.4 A
AIR FLOW	140 CFM to 219 CFM
VAC. PRESSURE	111 in.H20 to 145 in.H20
VRV SETTING	110 in.H20





D-1500 CF	3	DESIGNED TO BE INTEGRAT
	•	TO DESCRIPTION AND STREET

DRT RECOVERT	1011100200 11810	
VOLTAGE	120 V to 460 V	
HERTZ	60 Hz	
PHASE	Single or Three Phase	
WATTAGE	850 W	
	1.1 HP	
AMPERAGE	2.1 A to 14 A	
AIR FLOW	95 CFM	
VAC. PRESSURE	110 in.H20	
VRV SETTING	70 in.H <sub>2</sub> 0	





Strict rules and procedures are followed to prevent contamination of the product. Without effective control, contamination can wreak havoc on products and processes.

The higher the level of cleanliness, the lower the likeliness of particles or microbes damaging or corrupting production processes by tainting sterile and non-sterile products.











FILTER CONDUCTIVE STAR-SHAPED

DT DETACHABLE RECOVERY TANK

MFS MANUAL FILTER SHAKER

TCSS TRUE CYCLONE SEPARATOR SYSTEM

TEFC TOTALLY ENGLOSED FAN-GOOLED MOTOR

CD-100L (DT) EX

DITT HEGOVERT		
VOLTAGE	230 V to 575 V	
HERTZ	60 Hz	
PHASE	Three	
WATTAGE	3700 W to 5550 W	
POWER		
AMPERAGE	5 A to 12 A	
AIR FLOW	225 CFM to 324 CFM	
VAC. PRESSURE	155 in. H <sub>2</sub> 0	
VRV SETTING	95 in.H20 to 100 in.H20	

Larger Speed

Capsule Machine

Continuous Duty =

## Manufacturing safe and quality products

In manufacturing facilities that generate or handle dust, it's an important responsibility to manage combustion risks. When a combustible dust encounters an ignition source, there is the potential for a fire or explosion. It's essential to have a comprehensive plan to manage and mitigate that potential risk.

**Prevent and Protect Against Combustible Dust**Once you have determined the combustibility of your dust, you can develop a plan to mitigate the risks in your process.

However, housekeeping is only a partial solution.

Also, consider the design of your dust collection system; for example, the physical location of the dust collector will depend on the process hazards and risk assessment. Additionally, consider adding mitigation devices to your system, such as ignition controls or explosion vents.

A dust collection system is an integral part of your effort to comply with proper standards and regulations.

Tiger-Vac® can assist you in choosing the right vacuum system for the specific needs of your facility.





Div.1 or Div.2

**SRV-55** 

DRY RECOVERY VOLTAGE

HERTZ

PHASE

WATTAGE

AMPERAGE

**Duty** 

Blister Pack and Trim

Thus-Vas'

CD-600 EX HEPA

DUST COLLECTOR	{ 	
VOLTAGE	120 V to 460 V	
HERTZ	60 Hz	
PHASE	Single or Three Phase	
WATTAGE	1150 W to 1725 W	
POWER		
AMPERAGE	3 A to 15 A	
AIR FLOW	600-700 CFM	
SUCTION INLET	6 in.	
CORD LENGTH	50 ft.	

Duty 24.7

# Experience the Tiger-Vac difference tiger-vac.com

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