Met One Instruments

POWERED BY ACOEM

Portable Particle Counters for Cleanroom Compliance

FDA validation GMP
requirements ISO
14644
Filter Testing
Compliance Testing
Emission Sourcing
QA Programs Indoor
Air Quality Process
Controls HVAC
Applications

Manufacturing & Research
Semiconductor
Biotechnology
Life Science
Pharmaceutical
Electronic
Optics
Military/Aerospace
Medical
Packaging

Met One Particle Counters for Cleanroom Operations

GT-324

DR-528

BT-610

BT-620

Particle Counters are used to quantify the discrete number of airborne particles in the environment. Samples are taken from an environment during a specific measurement period or continuously. They typically count and size each particle individually but simultaneously in real time. Particle Counters are typically used for classification and monitoring. Classification is the process of qualifying an environment for certain tasks by determining the number of particles and sizes using a standard method. Classification focuses primarily on the ambient or controlled environment. Monitoring focuses primarily on processes and people, as well as the environment. Environmental monitoring is performed on a scheduled basis to determine the stability of an area over time to develop trend data. Process monitoring is performed where relevant activities occur to determine the readiness of a room to carry out a designated task. Particle Counters are deployed extensively as a quality control and yield maximization tool in a wide variety of manufacturing and industrial processes.

Producers of a variety of sensitive goods are required by regulatory bodies to comply with various standards such as ISO 14644. Additionally, many require clean environments as a matter of best practices to achieve certain internal quality and/or yield objectives. Particle Counters are a key tool for organizations to certify themselves to the ISO 14644 or other international standards.

Businesses that classify themselves as ISO Class 5 and below must demonstrate their compliance every 6 months, and businesses that classify themselves as greater than ISO Class 5 must demonstrate their compliance every 12 months. Properly calibrated and tested (per ISO 21501-4) Particle Counters are used to demonstrate and certify compliance. These same Particle Counters are also used extensively during non-certification events to periodically or continually monitor cleanrooms to verify compliance with regulatory or internal standards.

All models meet ISO 14644-1:2015 criteria and can be used in Class 3 through Class 9 cleanrooms. All models can also meet the calibration requirements of ISO 21501-4. Met One Instruments Particle Counters also meet the requirements for the Manufacture of Sterile Medicinal Products per EU GMP Annex I (EMEA) by meeting Grade A through D size and count requirements.

FED STD 209E CLASS	ISO CLASS	0.1 um	0.2 um	0.3 um	0.5 um	1 um	5 um
	ISO 1	10					
	ISO 2	100	24	10			
1	ISO 3	1,000	237	102	35		
10	ISO 4	10,000	2,370	1,020	352	83	
100	ISO 5	100,000	23,700	10,200	3,520	832	
1,000	ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
10,000	ISO 7				352,000	83,200	2,930
100,000	ISO 8				3,520,000	832,000	29,300
	ISO 9				35,200,000	8,320,000	293,000

Number of Particles per Cubic Meter

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Description of a Cleanroom

A cleanroom has a top to bottom laminar air flow at ISO Class 3 and below. These cleanrooms are normally on raised flooring such that air penetrates holes of the flooring. The idea is that any particles generated in the cleanroom are being pushed straight downwards such that they are flushed out through the raised flooring in the shortest possible path to contamination. This laminar flow of particle free air is generated via HEPA filters.

Humans are the largest particle generators in a clean room. 100,000 particles can be generated just by the act of sitting. People must wear a clean room suit (aka bunny suit) to minimize contamination. The suit covers the wearer to prevent skin and hair being shed into a clean room environment.

Most cleanrooms are held in positive pressure. This means that the air will flow out of the room instead of in, preventing unfiltered air or air particulates from entering the cleanroom.

Pharmaceuticals USP 797

The purpose of U.S. Pharmacopeia (USP) 797 is to provide the practice standards to help ensure that compounded sterile preparations are of high quality and sets the standards that apply to all settings in which sterile preparations are compounded. The USP 797 cleanroom requirements are general in nature but refer to ISO-14644-1 standards for cleanroom requirements. To achieve USP 797 compliance, producers must perform sterile drug compounding within an ISO Class 5, hood environment, enclosed within a larger compounding "Buffer Zone" of ISO Class 7 positive pressure controlled-air environment. In addition, areas where personnel perform hand hygiene and garbing procedures, staging of components, and other high particulate generating activities must be ISO Class 8.

Electronics Manufacturing

Particle Counters play a crucial role in monitoring, classifying, and diagnosing the source and complexion of contaminants in cleanroom operations. Electronics manufacturing relies on this information to monitor facility functions such as air filters and pass throughs. They can be used to validate engineering and process controls. It is critical to reduce the number of airborne particles in this industry because yields drop dramatically when components interact with dust, airborne microbes, aerosol particles, and trace moisture. Due to the small pitch of modern electronics, particle laden devices will fail yield due to contamination.

Healthcare Facilities and Other Sensitive Locations

According to guidelines for Environmental Infection Control in Health-Care Facilities, Recommendations of the Center for Disease Control (CDC) and the Healthcare Infection Control Practices Advisory Committee (HICPAC): "Particulate sampling (i.e., total numbers and size range of particulates) is a practical method for evaluating the infection-control performance of the HVAC system, with an emphasis on filter efficiency in removing respirable particles <5 μm in diameter or larger particles from the air". Particle Counters can monitor this by documenting a count baseline of an area, detect when airborne particulate levels diverge from normal levels, and give an early warning of underlying issues such as changes in operating procedures and equipment malfunctions.

Hvac and Filter Performance ISO 16890

Met One Particle counters can be used to classify ISO 16890 and ASHRAE 52.2

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Particle Counters & Dust Monitors

PRODUCT		APPLICATIONS	FEATURES	Count Channels	Particle Sizes (μm)	Flow Rate	Concentration Limit	Data Memory	Computer Interface	Power Supply/Charger	Cont. Operating Time	Recharge Time	Software	Dimensions	Carrying Case
804	PARTICLE COUNTER	• Indoor Air Quality • Process Control • HVAC Applications • Filter Testing • Hospital & Clinics • Laboratory Environments • Controlled Environments	• Fast Sampling • Simple Operation • Selectable Sizes with Available Favorites (2); Sizes Displayed • Low Cost with Data Logging • Self Contained	4 (SELECTABLE)	0.3, 0.5, 0.7, 1.0, 2.5, 5.0, 10.0	0.1 cfm (2.83 lpm)	3,000,000 / cf	2,500 records	USB	Yes	8 hours	2.5 hours	YES	6.73" x 3.75" x 2.0"	Optional
GT-324	PARTICLE COUNTER	• Indoor Air Quality • Controlled Environments • QA Programs • HVAC Applications • Process Control • Filter Testing • Compliance Testing • Emission Sourcing	• 2200 Stored Data Samples • Simple Operation • Fast Sampling • Battery or AC Powered • Integrated Temp. & RH Sensor • Select Between 7 Particle Sizes	4 (SELECTABLE)	0.3, 0.5, 0.7, 1.0, 2.0, 5.0, 10.0	0.1 cfm (2.83 lpm)	3,000,000 / cf	2,200 records	USB	Yes	8 hours	2.5 hours	YES	6.25" x 2.0" x 3.65"	Included
DR-528	PARTICLE COUNTER	• Process Controls • HVAC Applications • Filter Testing • Compliance Testing • Emission Sourcing • QA Programs • Controlled Environments • Indoor Air Quality	• 8 channels counted & recorded at one time • User Selectable Sizes • Large Color LCD Display • Menu-Drive Multi-Function Rotary Scroll Wheel • Alpha Numeric Locations IDs • Integrated RH/Temp Sensor • Flexible Data Interfaces	8 (SELECTABLE)	0.3 - 10.0	0.1 cfm (2.83 lpm)	3,000,000 / cf	15,000 records	USB; WiFi, Ethernet & RS-485 w/docking station	Yes	8 hours	3 hours	YES	8.8" x 2.25" x 3.75"	Included
BT610	PARTICLE COUNTER BENCH TOP	• Cleanroom Monitoring • Medical Device Mfg./ Pkg. • Filter Testing • Hospital & Pharmacy • Food/Beverage • Paint Booths • Aerospace Assembly • Cosmetic Mfg./ Pkg.	• Compact • Built in Printer • Volumetric Flow Control • Large Display • Improved Software • 2-Year Warranty	6 (SELECTABLE)	0.3 - 10.0	0.1 cfm (2.83 lpm)	3,000,000 / cf	8,000 records	RS232 / RS485 / Analog (0-5V) / USB / Memory Stick	Yes	8 hours	3 hours	YES	8.75" x 6.75" x 85"	No
BT620	PARTICLE COUNTER BENCH TOP	• Cleanroom Monitoring • Medical Device Mfg./ Pkg. • Filter Testing • Hospital Surgery Suites/ Pharmacy • Food/Beverage • Cosmetic Mfg. / Pkg.	• Compact • Built in Printer • Volumetric Flow Control • Large Display • Improved Software • 2-year Warranty • CE Certified	6 (SELECTABLE)	0.3 - 10.0	1.0 cfm (28.3 lpm)	600,000 / cf	8,000 records	RS232 /RS485/Analog (0-5V)/USB/Memory Stick Ethernet	Yes	4 hours	3 hours	YES	10.1" x 8.0" x 9.5"	No
AEROCET 380	DUST MONITOR	• Indoor Air Quality • Industrial Monitoring • Occupational Hygiene • Public Monitoring • Workplace Monitoring	• Real Time Monitoring • Simple Operation • Rugged Design • Built-in Datalogger • Purge Air System • Low Power Consumption	N/A	TSP	2 LPM	100 mg/m3	15,000	RS-485, USB-C, WiFi	Yes	10 hours	2.5 hours	YES	8.52" x 6.0" x 8.25"	N/A
AEROCET 831S	PARTICLE COUNTER/ DUST MONITOR	• Indoor Air Quality • HVAC Applications • Industrial Monitoring • Occupational Hygiene	• Five Mass Ranges • Extremely Portable • 2500 Data Sample Storage • 2-Line by 16-Character LCD • 2 Button Keypad With Rotary Dial	4 (SELECTABLE)	1.0, 2.5, 4.0, 10.0	0.1 cfm (2.83 lpm)	Counter = 3,000,000 / cf Mass = 1mg/m3	2,500 records	USB mini B Type	Yes	8 hours	2.5 hours	YES	6.25" x 3.63" x 2.0"	Optional
AEROCET 532	PARTICLE COUNTER/ DUST MONITOR	• Controlled Environments • Process Control • Filter Testing • Indoor AQ • Industrial Hygiene • Schools, & Medical • Public & Workplace Monitoring • HVAC Applications	• 2-in-1 Performance • Particle Counting & Mass Monitoring Modes • Large Color LCD Display • Menu-Driven Multi-Function Rotary Scroll Wheel • Alpha-Numeric Location ID's • Integrated RH/Temp Sensor • Flexible Data Interfaces	8 (Fixed)	Count: 0.3, 0.5, 1.0, 2.5, 4.0, 5.0, 7.0, & 10 Mass: PM1, PM2.5, PM7, PM10, TSP	0.1 cfm (2.83 lpm)	Counter = 3,000,000 / cf Mass = 1mg/m3	15,000 records	USB; WiFi, Ethernet, & RS-485 w/docking station	Yes	8 hours	3 hours	YES	8.8" x 2.25" x 3.75"	Included

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