Fundamentals of particle counting

Selecting an airborne-particle counter for ISO 14644-1 certification

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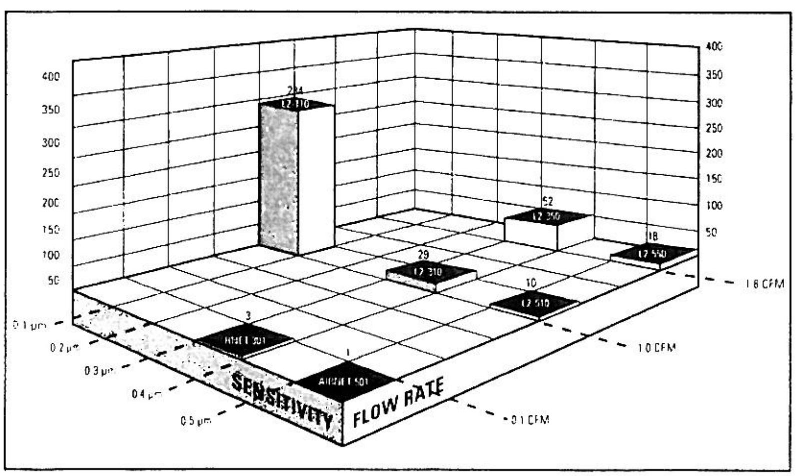
When considering the purchase of a particle counter, the user typically evaluates factors such as price, quality, laser lifetime, warranty, and service. However, performance-related factors also must be considered if the particle counter will be used for certifying a cleanroom to ISO 14644-1. Of these, sensitivity and flow rate are the most important parameters, since both impact the collection efficiency, which, in turn, determines the required sampling time. In the less-clean zones, particle counter saturation also must be considered. (This article, however, does not discuss the critical importance of the certification software. Software from various manufacturers often differs significantly in interpretation of how ISO and EC GMP regulations should be implemented.)

The sensitivity of an airborne-particle counter is determined by the size of the smallest particle the unit can detect. Modern particle counters used for cleanroom certification typically have sensitivities of 0.1, 0.3, or 0.5 micron (µm). Particle counters with greater sensitivity can count smaller particles and, therefore, many more particles. For example, under ISO conditions, a particle sensor with a sensitivity of 0.1 µm can count 28 times more particles greater than or equal in size to 0.1 µm than a 0.5 µm instrument can count particles greater than or equal in size to 0.5 µm. (There are many more small, rather than large, particles.)

Recent particle counting and regulatory trends have increased the utility of 1.78 and 1.0 CFM counters, while reducing the value of 0.1 CFM particle counters.

Figure 1: Collection efficiencies (relative to 0.5 µm at 0.1 CFM)



The flow rate of a particle counter is simply the rate at which its pump draws the sample air through the sample chamber. The higher the flow rate, the more data the counter collects per time period—or the faster it can collect a specified volume. Historically, the flow rates of the particle counters used in cleanroom certification were 0.1 CFM and 1.0 CFM. However, recent particle counting and regulatory trends have increased the utility of 1.78 CFM (50 LPM) and 1.0 CFM counters, while reducing the value of 0.1 CFM particle counters.

For instance, an instrument that samples 1.78 CFM (50 LPM) can sample 1.0 m^3 (1000 liters) in only 20 minutes, whereas a 1.0 CFM (28.3 LPM) particle counter takes 35.3 minutes to complete the same 1.0 m^3 sample size A handheld monitor with a flow rate of 0.1 CFM takes 353 minutes to sample 1.0 m^3.

The collection efficiency of a particle counter describes the combined effects of sensitivity and flow rate on the counter's ability to collect data. It is

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defined as the product of the expected particle concentration multiplied by the flow rate for the selected particle counter, as compared to a 0.5 μm, 0.1 CFM particle counter.

No matter the ISO classification, the higher the collection efficiency, the lower the sampling time. Figure 1 displays the collection efficiencies of several PMS air-particle counters and sensors as a function of sensitivity and flow rate.

Cleanliness levels

ISO 14644-1 has become the dominant, worldwide standard for classifying the cleanliness of the air in clean areas. Figure 2 lists the maximum number of particles allowed (per cubic meter) if the zone is to meet a specified ISO class of cleanliness. It is important to note that each successively higher classification allows approximately 10 times as many particles as the previous class. Also, the ratio of particles of Size A to Size B remains nearly constant for all classes. For example:

- Class 4 allows 10,200 particles of ≥0.3 μm, or 3520 of ≥0.5 μm.
- Class 5 allows 102,000 particles of ≥0.3 μm, or 35,200 of ≥0.5 μm.

Figure 2: ISO classification versus maximum particle concentration allowed.

Maximum allowable cumulative particles/m³ to meet ISO

ISO class	Approx. FS209 class	Certification particle size (μm) 0.1	0.2	0.3	0.5	1.0	5.0
1	---	10	2	---	---	---	---
2	---	100	24	10	4	---	---
3	1	1000	237	102	35	8	---
4	10	10,000	2370	1020	352	83	---
5	100	100,000	23,700	10,200	3520	832	29
6	1000	1,000,000	237,000	102,000	35,200	8320	293
7	10,000	---	---	---	352,000	83,200	2930
8	100,000	---	---	---	3,520,000	832,000	29,300
9	---	---	---	---	35,200,000	8,320,000	293,000

Sample volume

To determine the sensitivity and flow rate your particle counter needs in order to certify a set of cleanrooms, you also must consider the sample volume required and the resulting sampling time. Figure 3 presents the minimum required sample volume per sample location necessary to meet ISO 14644-1. Values for each ISO class have been derived from the equation:

Min. volume (m³) ≥ 20 particles/ Max. particle concentration allowed (from Figure 2)

In other words, to certify that a cleanroom meets the standard, ISO requires you to collect a large enough volume at each location that you should expect to sample at least 20 particles (that is, a statistically adequate sample) when the room holds the maximum acceptable particle concentration.

Sampling time

Upon determining the minimum required sample volume to collect at each location, you can calculate the minimum time required for a specific counter to collect the sample data. Figures 4A through 4C give these calculations for a 1.0 CFM, 1.78 CFM, or 0.1 CFM sampling rate. Note that in the figures, many conditions require a sample of 1 minute; this is driven by the ISO requirement of an absolute minimum sampling time of 1 minute per location.

A statistically adequate sample can be collected relatively quickly in a dirty room; it takes much longer to certify an extremely clean zone. Moreover, a statistically adequate sample can be collected much quicker with a high-sensitivity particle counter than with a low-sensitivity counter. For instance:

- It only takes 1 minute per location for a 0.1 µm, 1.0 CFM counter to sample the required volume of 0.1 µm particles to certify a Class 3 area. It takes the same unit 7.1 minutes for Class 2, and a lengthy 70.7 minutes for Class 1 (see Figure 4A).
- A 0.5 µm, 1.0 CFM unit takes 20.2 minutes per location for Class 3, and 176.7 for Class 2; it is unable to certify a room for Class 1. Considering the impact of different flow rates, a 0.5 µm, 0.1 CFM handheld counter requires 201.9 minutes to certify Class 3 (see Figure 4C).
- In pharmaceutical cleanrooms requiring a sample volume of 1.0 m^3, a 1.78 CFM unit can sample one location in 20 minutes, while a 1.0 CFM unit requires 35.3 minutes.

Dirty rooms

If an airborne-particle counter is used in a dirty environment, eventually enough dirt particles will collect on the optics so that the unit will no longer function correctly; this is referred to as the particle counter reaching saturation. At this point, the unit will begin displaying coincidence errors until the counts eventually become unreliable.

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Figure 3: Minimum sample volume required per ISO class (at a sample flow rate of 1.0 CFM)

ISO class	<------------------ Certification particle size (µm) ------------------------------>					
	0.1	0.2	0.3	0.5	1.0	5.0
1	2.000	10.000	NA	NA	NA	NA
2	0.200	0.834	2.000	5.000	NA	NA
3	0.028	0.085	0.196	0.572	2.500	NA
4	0.028	0.028	0.028	0.057	0.241	NA
5	0.028	0.028	0.028	0.028	0.028	0.690
6	0.028	0.028	0.028	0.028	0.028	0.068
7	NA	NA	NA	0.028	0.028	0.028
8	NA	NA	NA	0.028	0.028	0.028
9	NA	NA	NA	0.028	0.028	0.028

ISO requires a minimum of a 1.0-minute sample, which for the standard 1.0 CFM counter equals 0.0283 m^3.

Comparing particle counters

Reducing sampling time provides significant cost savings when certification (or daily monitoring) is done frequently or at many locations. Figure 5 provides the time required by various particle counters to complete a single ISO sample for one location in a cleanroom of designated cleanliness. Note that only a 1.00 CFM, 01 µm counter can certify effectively for ISO 1 through 3, but almost any counter can certify for ISO 6.

Ultra-clean rooms

ISO Class 1 through 3 rooms are extraordinarily clean, allowing only 10 to 1000 particles/m^3. At this level of cleanliness, it is important to verify that the particle counter itself is not generating particles.

Most particle counters include a HEPA filter on the output of the pump; in ultra-clean rooms, this is not enough. The rotary action of pumps and fans can generate a significant number of particles that are inside the particle counter chassis; these particles are not drawn down the sample path, so they are missed by the HEPA filter. Thus, the particle counter may require a second, high-efficiency filter that scrubs the output of particles emitted from the chassis.

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Figure 4A: ISO minimum sampling time.

Minutes at a sample flow rate of 1.0 CFM to collect min. sample volume

ISO class	<--------- Certification particle size (µm) ------------> 0.1	0.2	0.3	0.5	1.0	5.0
1	70.7	353.4	NA	NA	NA	NA
2	7.1	29.5	70.7	176.7	NA	NA
3	1	3.0	6.9	20.2	88.4	NA
4	1	1	1	2.0	8.5	NA
5	1	1	1	1	1	24.4
6	1	1	1	1	1	2.4
7	NA	NA	NA	1	1	1
8	NA	NA	NA	1	1	1
9	NA	NA	NA	1	1	1

Figure 4B: ISO minimum sampling time.

Minutes at a sample flow rate of 1.78 CFM to collect min. sample volume

ISO class	<--------- Certification particle size (µm) ------------> 0.1	0.2	0.3	0.5	1.0	5.0
1	40.0	200.0	NA	NA	NA	NA
2	4.0	16.7	40.0	100.0	NA	NA
3	1	1.7	3.9	11.4	50.0	NA
4	1	1	1	1.1	4.8	NA
5	1	1	1	1	1	13.8
6	1	1	1	1	1	1.4
7	NA	NA	NA	1	1	1
8	NA	NA	NA	1	1	1
9	NA	NA	NA	1	1	1

1.77 CFM = 50 LPM

Figure 4C: ISO minimum sampling time.

Minutes at a sample flow rate of 0.1 CFM to collect min. sample volume

ISO class	<--------- Certification particle size (µm) ------------> 0.1	0.2	0.3	0.5	1.0	5.0
1	706.7	3533.6	NA	NA	NA	NA
2	70.7	294.5	706.7	1766.8	NA	NA
3	7.1	29.8	69.3	201.9	883.4	NA
4	1	3	6.9	20.1	85.1	NA
5	1	1	1	2	8.5	243.7
6	1	1	1	1	1	24.1
7	NA	NA	NA	1	1	2.4
8	NA	NA	NA	1	1	1
9	NA	NA	NA	1	1	1

Coincidence errors occur when the unit mistakes multiple small particles for one large particle. Thus, the counts for large particles become too high, while the counts for smaller particles become too low. When this occurs, sometimes the user is able to clean out the unit by running it for 24 hours with a zero filter. Often, however, the user will need to have the unit cleaned by a certified service representative.

If you perform ISO certification in relatively dirty rooms (for example, ISO Class 7 or 8), you can minimize this problem by selecting a particle counter with a high maximum concentration. This means the unit can sample from a higher particle concentration without incurring greater than 5 percent coincidence errors. ISO Class 9 is so dirty that most particle counters will require the addition of an aerosol diluter so it can measure without saturation.

Figure 6 specifies the maximum concentration limit for a number of particle counters, plus the dirtiest ISO classification for a unit before requiring the addition of an aerosol diluter. For

Figure 5: Minutes required to sample one location.

ISO class		1	2	3	4	5	6	7	8	9
FS209D equivalent		NA	NA	1	10	100	1000	10.000	100,000	NA
Flow rate	Sensitivity									
1.00 CFM	0.1 µm	71	7	1	1	1	1	NA[1]	NA[1,2]	NA[1,2]
1.78 CFM	0.3 µm	NA[1]	40	4	1	1	1	NA[1]	NA[1]	NA[1,2]
1.00 CFM	0.3 µm	NA[1]	71	7	1	1	1	NA[1]	NA[1]	NA[1,2]
1.78 CFM	0.5 µm	NA[1]	100	11	1	1	1	1	1	NA[2]
1.00 CFM	0.5 µm	NA[1]	177	20	2	1	1	1	1	NA[2]
0.10 CFM	0.5 µm	NA[1]	1767	202	20	2	1	1	1	NA[2]

[1] ISO does not provide for certification of this room classification using this size particle.

[2] Requires aerosol diluter.

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Figure 6. Appropriate airborne-particle counters for each ISO class.

ISO class	FS209D class	Instrument	Sensitivity	Flow rate	Collection efficiency	Time (min./ location)	ISO classes*	Max. concentration**
1	NA	LASAIR-II-110	0.1 µm	1.0 CFM (28.3 LPM)	284	71	1-7	500,000
2	NA	LASAIR-II-110	0.1 µm	1.0 CFM (28.3 LPM)	284	7	1-7	500,000
3	1	LASAIR-II-110	0.1 µm	1.0 CFM (28.3 LPM)	284	1	1-7	500,000
		LASAIR-II-350L	0.3 µm	1.78 CFM (50 LPM)	52	4	3-8	350,000
		LASAIR-II-310	0.3 µm	1.0 CFM (28.3 LPM)	29	7	3-8	375,000
4	10	LASAIR-II-110	0.1 µm	1.0 CFM (28.3 LPM)	284	1	1-7	500,000
		LASAIR-II-350L	0.3 µm	1.78 CFM (50 LPM)	52	1	3-8	350,000
		LASAIR-II-310	0.3 µm	1.0 CFM (28.3 LPM)	29	1	3-8	375,000
		LASAIR-II-550L	0.5 µm	1.78 CFM (50 LPM)	18	1	4-8	250,000
		LASAIR-II-510	0.5 µm	1.0 CFM (28.3 LPM)	10	2	4-8	425,000
5	100	LASAIR-II-110	0.1 µm	1.0 CFM (28.3 LPM)	284	1	1-7	500,000
		LASAIR-II-350L	0.3 µm	1.78 CFM (50 LPM)	52	1	3-8	350,000
		LASAIR-II-310	0.3 µm	1.0 CFM (28.3 LPM)	29	1	3-8	375,000
		LASAIR-II-550L	0.5 µm	1.78 CFM (50 LPM)	18	1	4-8	250,000
		LASAIR-II-510	0.5 µm	1.0 CFM (28.3 LPM)	10	1	4-8	425,000
		HandiLaz Mini-301	0.3 µm	0.1 CFM (2.83 LPM)	3	1	NA	2,000,000
		HandiLaz Mini-301	0.5 µm	0.1 CFM (2.83 LPM)	1	2	5-8	2,000,000
6	1000	All of above counters can be used						
7	10,000	All of above counters can be used						
8	100,000	All of above counters can be used, except L2-110 requires aerosol diluter						
9	1,000,000	All of above particle counters can be used, but an aerosol diluter is also required						

* Can certify these ISO classes in the minimum possible time without requiring a diluter.

** With maximum 5% coincidence loss.

example, the high sensitivity of a 1.0 CFM, 01 µm particle counter makes it the best possible option for sampling ISO 1 through 3 rooms. However, this same sensitivity means it counts so many particles that it cannot be used in ISO 8 and 9 rooms without an aerosol diluter.

Figure 6 also lists the types of particle counters appropriate for monitoring each ISO classification, plus, as an example, provides data, including the sensitivity, flow rate, and collection efficiency for several PMS particle counters. C

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Frequently asked questions concerning airborne-particle counters

Q: Which particle counter should you choose if you will need to monitor primarily ISO Class 3 and 4 cleanrooms?

A: Answering this question first requires answering a series of preliminary questions:

Which particle counters can complete sampling in the least time?
Many 1.0 CFM counters can sample an ISO Class 4 location in only 1 minute. Class 3, however, is much more demanding, clearly demonstrating the importance of counting efficiency. Thus, a 1.00 CFM, 01 µm particle counter can sample a Class 3 location in 1 minute, while a 1.78 CFM, 0.3 µm particle counter takes 4 minutes per location (see Figure 5). Other particle counters just take too long for sampling Class 3.

How much will you use this particle counter to certify other rooms?
If you will use this same unit to certify ISO 1 and 2 rooms, the timesavings from using a 1.00 CFM, 01 µm are so substantial that the extra cost generally will be justified. But if you use it for Class 5 or greater certification, a 0.1 µm particle counter may be overkill.

How much will you use this particle counter for troubleshooting, real-time monitoring, and so forth?
You need to define particle counter requirements for these applications, and then calculate the costs and number of samples per year that will be required in these efforts. For example, how portable must the unit be? If it will be placed on a mobile cart, then the size and weight are not nearly as important, but the cost of the cart should be included. If the counter is used for real-time monitoring, what are the data downloading requirements and costs?

Do you need to worry about saturation?
Because ISO 3 and 4 are extremely clean areas, you do not need to consider the potential saturation of the particle counter. However, if you also will be using this unit to sample in ISO 8 and 9 cleanrooms, it will be important to consider the maximum concentration the particle counter could allow. It might even prove necessary to use the particle counter in conjunction with an aerosol diluter. (See Figure 6 for information on individual particle counters.)

All things considered, which particle counter should you choose?
Since a 1.00 CFM, 01 µm particle counters costs two to three times as much as a 1.78 CFM, 0.3 µm particle counter, it is important to evaluate the cost trade-offs between various particle counters and requirements. While a 1.78 CFM, 0.3 µm particle counter's sampling time may be four times longer, this could be outweighed if the Class 3 measurements are only a small portion of the total particle counting activity. Thus, you need to estimate the following:

- What are the sampling costs per location if the sample lasts 1.0 minutes? 4.0 minutes?
- How many samples per year will be taken in ISO Class 3 cleanrooms or zones? In ISO Class 4?
- What are the frequencies and sampling costs of other uses of this equipment?

The choice between units then can be expressed as a financial comparison. For each particle counter under consideration, calculate:

Estimated total costs = Initial purchase costs + sampling costs + maintenance costs

Where:
Sampling costs = Sum (# Samples of Class N x Cost/Sample for Class N), (summed over all classes and all other uses)
Cost/Sample for Class N is proportionate to sample time per location, etc.
Time period (over which costs are projected) is defined by appropriate payback criteria

Q: Which counter should you consider if you are certifying only ISO Class 6 cleanrooms—and only certify every six months—plus perform a minimal amount of troubleshooting?

A: Almost any particle counter can perform ISO 6 through 8 certification in 1.0 minute per location (see Figure 5). With infrequent usage, you should place a relatively high weight on low equipment costs. For example, a handheld particle counter offers a combination of high quality and low cost, making it a very compelling choice if you are only certifying occasionally. However, no handheld units are adequate long term for frequent usage; the handheld's lower pump lifetime, minimal data management, and much longer sampling times all combine to make a full-sized particle counter more cost-effective than any handheld.

Q: If you will be certifying that ISO Class 5 through 8 pharmaceutical cleanrooms also meet the CE GMP Annex #1 standards, which particle counters should you consider?

A: If the pharmaceutical drugs are to be shipped only to the US, then the ISO formulas all apply, and a 1.0 CFM, 0.3, or 0.5 µm counter would be appropriate. However, if the drugs are to be shipped to the European Union, additional regulatory requirements call for samples from Class A and B rooms to have a minimum volume of 1.0 m^3 (35.3 CFM). For this case, many users are now selecting a 1.78 CFM particle counter instead of a 1.0 CFM unit; this increase in sample flow rate reduces the sample time from 35.3 to 20 minutes per location.

A Comparison of ISO 14644-1 and Federal Standard 209E

In the United States, there are two major documents used quantify air cleanliness relative to particulate levels. These are Federal Standard 209E and ISO 14664-1. Federal Standard 209 was developed by the US government to facilitate development and use of clean air equipment by providing standard ways of describing clean air. FS209 provided the definitions for Class 100 and Class 100,000. It described how to count particles in the air and how to use the data to describe air cleanliness in an area. The current version of the standard is FS209E. ISO 14664 is produced by an international organization whose purpose is to develop international standards. ISO 14644 contains a family of standards related to clean air and cleanrooms and includes ISO 14644-1 which is an international version of FS 209.

In Cleanrooms Magazine, Dick Matthews said, "With the creation of ISO 14644-1 and ISO 14644-2, U.S. Federal Standard 209E essentially becomes obsolete." Only time will tell how fast that will happen, but we still need to understand this new standard and the easiest way to start is by comparing it to Federal Standard 209E.

Particulate Limits

While 209E has both metric and English requirements, 14644-1 only has metric requirements. Both documents have a table of particulate limits and a formula to calculate intermediate classes. Both documents require that the 95% Upper Confidence Limit be calculated for situations where there are less than ten locations. The table below shows the particulate limits for some of the ISO classes for 0.5 micrometers and larger.

ISO Class	Particles per cubic meter	Particles per cubic foot	Comparable FS209E Classification	Particles for cubic foot
4	352	10	10	10
5	3,517	100	100	100
6	35,168	996	1,000	1,000
7	351,676	9,960	10,000	10,000
8	3,516,758	99,597	100,000	100,000
9	35,167,573	995,967	1,000,000	1,000,000

ISO Class 5 is roughly equivalent to FS209E's Class 100. The ISO Class 6 goes up an order of magnitude in FS209E to approximately Class 1,000. ISO Class 7 moves up another order of magnitude in FS209E to approximately Class 10,000. The table below illustrates the comparison of the metric particulate limits in FS 209E and ISO14644-1 over three different particle sizes.

	0.3 µm		0.5 µm		5.0 µm	
	FS 209E	ISO14644-1	FS 209E	ISO14644-1	FS 209E	ISO14644-1
Class 10/ISO 4	1,060	1,020	353	352	-	-
Class 100/ISO 5	10,600	10,200	3,530	3,520	-	29
Class 1,000/ISO 6	106,000	102,000	35,300	35,200	247	293
Class 10,000/ISO 7	-	-	353,000	352,000	2,470	2,930
Class 100,000/ISO 8	-	-	3,530,000	3,520,000	24,700	29,300

The limits vary slightly between the two standards depending on the particle size. The 0.3µm and 0.5µm particulate limits are slightly greater under FS 209E than the equivalent ISO class. The 5.0 µm particulate limits are slightly greater under ISO 14644-1 than the equivalent FS 209E class.

Sample Location Requirements

FS209E requires that at least five samples be taken in at least two locations to class any area. In FS209E there are two methods of determining the number of sample locations needed for a certain area. First, the area (in square feet) is divided by the square root of the air cleanliness class. This yields the number of sample locations for nonunidirectional airflow areas. For example, a 600 square foot Class 10,000 nonunidirectional room would require six sample locations or one location for every 100 square feet. If the same area were Class 1,000, it would require 19 locations or one location every 31.67 square feet. If the room were Class 100, it would need 60 locations. For areas with unidirectional airflow, the area in square feet is divided by 25 and the lesser of either this value or the value reached using the nonunidirectional method is used.