PARTICLE MEASURING SYSTEMS
www.pmeasuring.com
5475 Airport Boulevard, Boulder, Colorado 80301-2339
303.443.7100 1.800.238.1801 Fax: 303.546.7380
Customer Service Center 1.877.475.3317
Instrument Service 1.800.557.6363

How to Select a Portable Airborne-Particle Counter for ISO Certification of Cleanrooms

Basics

Certain factors are routinely considered for any particle counter purchase, such as price, warranty, quality, and expected laser lifetime. When selecting a particle counter for cleanroom certification it is important to consider additional factors. Of these, sensitivity and flowrate are the most important parameters, both of which determine the sampling time required to complete certification at the desired level of cleanliness. Particle counter saturation also must be considered.

The *sensitivity* of an airborne particle counter is the size of the smallest particle the unit can detect. Particle counters available today that are appropriate for cleanroom certification typically have sensitivities of 0.1, 0.3, or 0.5 µm.

The *flowrate* of a particle counter is simply the rate at which its pump draws the sample air through the sample chamber. The flowrates of the particle counters commonly used in cleanroom certification traditionally have been 0.1 CFM and 1.0 CFM.

However, the growing recognition in pharmaceuticals both of the critical importance of large particles and of how difficult large particles can be to sample has greatly reduced the utility of 0.1 CFM units for certification. These factors, combined with the need to minimize labor costs, are driving the increased acceptance and use of 3.53 CFM (100 LPM) counters.

Cleanliness Levels

ISO 14644-1 is the accepted worldwide standard for classifying the cleanliness of the air in cleanrooms and clean zones. **Table 1** gives the maximum number of particles allowed (per cubic meter) if the zone is to meet a specified ISO class of cleanliness.

From this table one can observe how the particle concentration allowed for one size of particle differs from that of another size. For 0.3 µm, for example, Class 6 allows 10 times as many particles as Class 7. In fact, note that the ISO classes have been constructed such that *this 10:1 ratio is true for all vertically adjacent ISO classes, regardless of particle size*.

Table 1: ISO Classification vs. Maximum Particle Concentration Allowed

ISO Class	Approx. FS209 Class	<---------- Certification Particle Size (um) ---------->					
		0.1	0.2	0.3	0.5	1.0	5.0
1	---	10	2	---	---	---	---
2	---	100	24	10	4	---	---
3	1	1,000	237	102	35	8	---
4	10	10,000	2,370	1,020	352	83	---
5	100	100,000	23,700	10,200	3,520	832	29
6	1,000	1,000,000	237,000	102,000	35,200	8,320	293
7	10,000	---	---	---	352,000	83,200	2,930
8	100,000	---	---	---	3,520,000	832,000	29,300
9	---	---	---	---	35,200,000	8,320,000	293,000

Comparing Particle Counters

Particle counters with greater sensitivity can count smaller particles. For example, a particle sensor with a sensitivity of 0.1 µm collects 28 times as many particles as a 0.5 µm instrument with the same flowrate. Thus, for ISO Class 4 the concentration of 0.1 µm particles can reach 10,000, but for 0.5 µm particles only 352 particles are allowed (10,000 / 352 = 28.4).

The higher the flowrate, the more data the counter collects per time period — or the faster it can collect a specified volume. An instrument that samples 3.53

CFM (100 LPM) can sample 1.0 M^3 (1,000 L) in only 10 minutes, where a 1.0 CFM (28.3 LPM) particle counter takes over 35 minutes.

Similarly, a portable particle counter with a flowrate of 1.0 CFM will sample at ten times the rate of a handheld monitor with a flowrate of 0.1 CFM. Thus, it takes a 0.1 CFM handheld counter 353 minutes to sample 1.0 M^3.

Sample Volume

To determine what sensitivity and flowrate are needed for certifying a set of cleanrooms you also must consider the sample volume required and the resulting sampling time. **Table 2** presents the minimum required sample volume per sample location to meet ISO 14644-1. Values for each ISO class have been derived from the following equation.

Min. Volume (M3) ≥ 20 particles / Max. Concentration.

In other words, to certify that a cleanroom meets the standard, ISO requires you to collect a large enough volume that you expect to sample at least 20 particles (i.e., a statistically-adequate sample) when the room holds the maximum acceptable number of particles.

Thus, you can collect a modest sample volume and still get valid readings in a relatively dirty room, but it takes a much larger sample to characterize a room maintaining at an extremely clean classification level.

Table 2: Sample Volume Required per ISO Class

ISO Class	<--------- Certification Particle Size (um) ---------->					
	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 minimum of 1.0 minute sample, which for the standard 1.0 CFM counter = 0.0283 m^3

Sampling Time

Upon determining the sample volumes you must collect, you next calculate the time required for a specific counter to collect the sample data.

Table 3A gives these calculations for a 1.0 CFM instrument, while **Table 3B** gives the time requirements for a 1.78 CFM (50 LPM) unit.

Table 3A: Sampling Time Required @ 1.0 CFM

	Minutes @ 1.0 CFM to Collect Min. Sample Volume					
ISO Class	**<---------- Certification Particle Size (um) ----------->**					
	0.1 um	**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

Table 3B: ISO Minimum Sampling Time @ 1.78 CFM

	Minutes @ 1.78 CFM to Collect Min. Sample Volume					
ISO Class	**<--------- Certification Particle Size (um) ----------->**					
	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
	Where 1.77 CFM = 50 LPM					

Table 3C: ISO Minimum Sampling Time @ 0.1 CFM

	Minutes @ 0.1 CFM to Collect Min. Sample Volume					
ISO Class	**<-------- Certification Particle Size (um) ---------->**					
	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

A statistically adequate sample can be collected relatively quickly in a dirty room; it takes much longer to certify an extremely clean zone. A statistically adequate sample can also be collected more quickly with a high sensitivity particle counter than with a low sensitivity counter.

It only takes one minute per location for a 0.1 µm, 1.0 CFM counter to sample the required volume of 0.1 µm particles to certify an ISO Class 3 area. It takes the same unit 7.1 minutes for ISO Class 2, and a lengthy 70.7 minutes for ISO Class 1 (see **Table 3A**).

A 0.5 µm, 1.0 CFM unit takes 20.2 minutes per location for ISO Class 3, and 176.7 for ISO Class 2; it is unable to certify a room for ISO Class 1. Considering the impact of different flowrates, a 0.5 µm, 0.1 CFM handheld counter requires 201.9 minutes to certify ISO Class 3 (see **Table 3C**).

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.

Once again, you can collect an adequate sample relatively quickly in a dirty room, but it takes much longer to certify an extremely clean room. Thus, for a 1.0 CFM instrument the required volume of 0.1 µm particles can be collected in 1.0 minute for Classes 3-6, but requires 7.1 min. for Class 2 and a lengthy 70.7 minutes for Class 1.

Further, you can collect an adequate sample more quickly with a high-sensitivity particle counter than with a low-sensitivity counter. For example, again with a 1.0 CFM flowrate, for ISO Class 3 a particle counter with 0.1 µm sensitivity can certify the area in 1.0 minute, where a particle counter with 0.5 µm sensitivity would require 20.2 minutes to certify the same area.

If you now include the impact of a lower flowrate, a

0.1 CFM handheld counter requires 200+ minutes to certify ISO 3 at 0.5 µm. On the other hand, from **Table 3B** the 1.78 CFM instrument counting 0.5 µm particles now completes sampling in 11.4 minutes, instead of the 20.2 minutes at 1.0 CFM.

Collection Efficiency

The user now has enough information to choose between alternative particle counters. However, some users prefer to go one extra step to achieve a single, simple measurement value that is independent of ISO Class. Collection efficiency describes the combined effects of sensitivity and flowrate on the ability of the particle counter to gather data. Specifically, it is the product of the expected particle concentration (relative to that at 0.5 µm) and the flowrate (relative to 0.1 CFM).

Once the effects of sensitivity and flowrate are combined, the user can compare different instruments with respect to collection efficiencies. Regardless of ISO class, *the higher the collection efficiency, the lower the sampling time*.

For example, the PMS LASAIR-II-110 (with a sensitivity of 0.1 µm and a flowrate of 1.0 CFM) has a collection efficiency of about 284 times that of the Airnet II-501 (with a sensitivity of 0.5 µm and a flowrate of 0.1 CFM). Thus, 10,000 / 352 x 10 = 284.

Figure 1 displays the collection efficiencies of a number of PMS air particle counters and sensors as a function of sensitivity and flowrate.

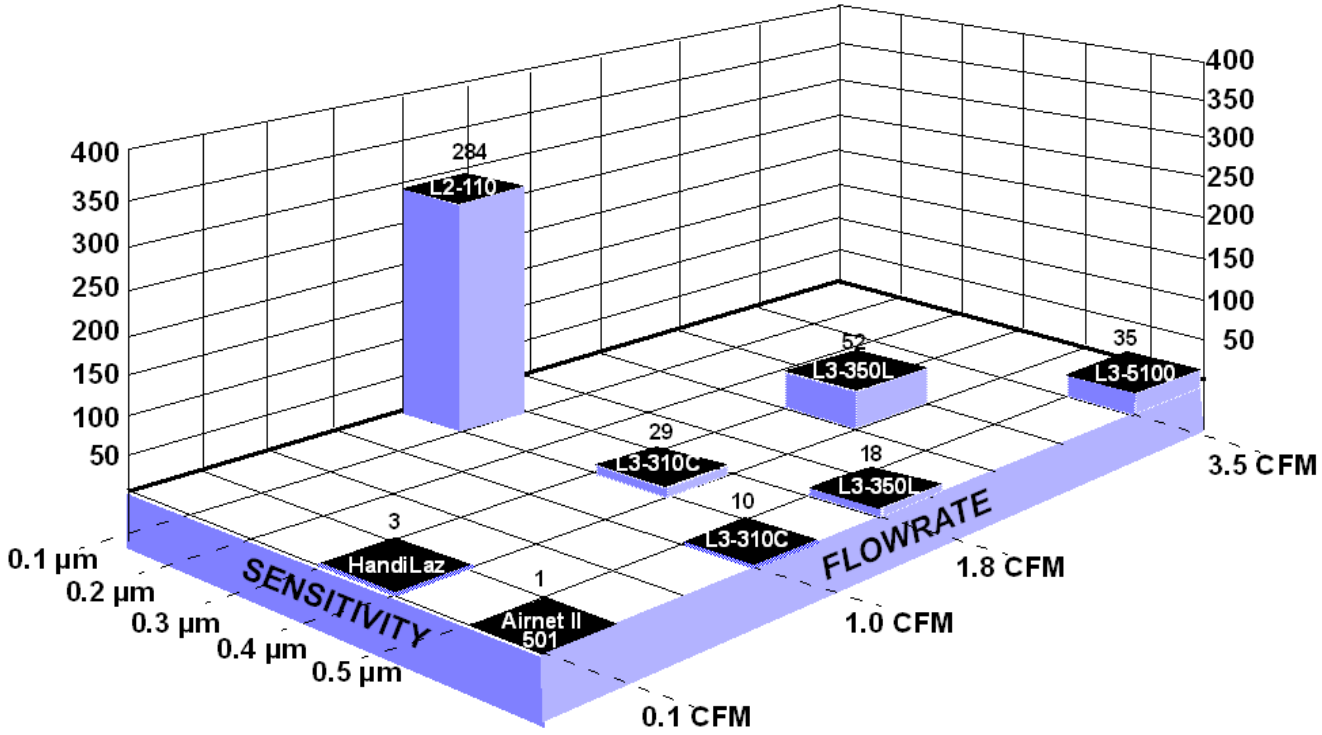

Figure 1: Collection Efficiency of Various Particle Counters
(Relative to 0.5 µm at 0.1 CFM)

Particle Counter Saturation

If an airborne-particle counter is used in a dirty environment, eventually enough dirt particles will collect inside the optics that the unit will no longer function correctly. At this point the user is sometimes able to clean the unit out 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 (e.g., ISO 9), you can avoid this problem by selecting a particle counter with a high *maximum concentration*. This means the unit can sample from a high concentration without incurring over 5% coincidence errors. (*Coincidence errors* occur when the unit mistakes two small particles for one large particle.)

Table 4 includes this data, plus goes on to include the impact of sensitivity and, thus, to specify the dirtiest ISO classification a unit can be used in without requiring the addition of an aerosol diluter. For example, the high sensitivity of the Lasair II-110 makes it the best option for sampling ISO 1-3 rooms. However, this same sensitivity means it counts so many particles that it cannot be used in ISO 8-9 rooms without an aerosol diluter.

Comparison of Particle Counters

Reducing sampling time provides significant cost savings when certification (or daily monitoring) is done frequently or at many locations. **Table 4** 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, 0.1 µm counter can certify effectively for ISO Class 1-3, but almost any counter can certify for ISO Class 6.

Table 5 specifies the maximum concentration limit for a number of particle counters, plus the dirtiest ISO classification in which a unit can be used without requiring the addition of an aerosol diluter.

For example, the high sensitivity of a 1.0 CFM, 0.1 µm particle counter makes it the best possible option for sampling ISO Class 1-3 rooms. However, this same sensitivity means it counts so many particles that it cannot be used in ISO Class 8-9 rooms without an aerosol diluter.

Table 4: Characteristics of PMS Airborne-Particle Counters

ISO Class			**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
FS209D Equivalent			**NA**	**NA**	**1**	**10**	**100**	**1,000**	**10,000**	**100,000**	**NA***
Particle Counter	**Flow Rate**	**Sensitivity**									
Lasair® II 110	1.00 CFM	0.1 µm	71	7	1	1	1	1	NA*	NA*,**	NA**
Lasair III 350L	1.78 CFM	0.3 µm	NA*	40	4	1	1	1	NA*	NA*	NA**
Lasair III 310C	1.00 CFM	0.3 µm	NA*	71	7	1	1	1	NA*	NA*	NA**
Lasair III 350L	1.78 CFM	0.5 µm	NA*	100	11	1	1	1	1	1	NA**
Lasair III 5100	3.53 CFM	0.5 µm	NA	50	6	1	1	1	1	1	NA
HandiLaz Mini	0.10 CFM	0.5 µm	NA*	1767	202	20	2	1	1	1	NA**

* NA = ISO does not provide for certification of this room classification using this size particle.

** Requires aerosol diluter.

Table 5: Appropriate Airborne-Particle Counters for Each ISO Class

ISO Class	**FS209D Class**	**Particle Counter**	**Sensitivity**	**Flow Rate**	**Collection Efficiency**	**Time (Min/ Location)**	***ISO Classes**	****Max. Concentration**	****ISO Class**
1	NA	Lasair II 110	0.1 µm	1.0 CFM (28.3 LPM)	284	71	1-7	500,000	7
2	NA	Lasair II 110	0.1 µm	1.0 CFM (28.3 LPM)	284	7	1-7	500,000	7
3	1	Lasair II 110	0.1 µm	1.0 CFM (28.3 LPM)	284	1	1-7	500,000	7
		Lasair II 350L	0.3 µm	1.78 CFM (50 LPM)	52	4	3-8	350,000	8
		Lasair III 310C	0.3 µm	1.0 CFM (28.3 LPM)	29	7	3-8	375,000	8
4	10	Lasair III 110	0.1 µm	1.0 CFM (28.3 LPM)	284	1	1-7	500,000	7
		Lasair III 350L	0.3 µm	1.78 CFM (50 LPM)	52	1	3-8	350,000	8
		Lasair III 310C	0.3 µm	1.0 CFM (28.3 LPM)	29	1	3-8	375,000	8
5	100	Lasair II 110	0.1 µm	1.0 CFM (28.3 LPM)	284	1	1-7	500,000	7
		Lasair II 350L	0.3 µm	1.78 CFM (50 LPM)	52	1	3-8	350,000	8
		Lasair II 310	0.3 µm	1.0 CFM (28.3 LPM)	29	1	3-8	375,000	8
		Lasair II 550L	0.5 µm	1.78 CFM (50 LPM)	18	1	4-8	250,000	8
		Lasair II 510	0.5 µm	1.0 CFM (28.3 LPM)	10	1	4-8	425,000	8
		HandiLaz Mini	0.3 µm	0.1 CFM (2.83 LPM)	3	1	N/A*,**	2,000,000	8
		HandiLaz ®Mini	0.5 µm	0.1 CFM (2.83 LPM)	1	2	5-8	2,000,000	8
6	1,000	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 0.1 µm , 1.0 CFM unit requires aerosol diluter							
9	1,000,000	All of above particle counters can be used, but an aerosol diluter is also required							

* With max. 5% coincidence loss.

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

Frequently Asked Questions

Q. Which particle counter should you choose to primarily monitor ISO Class 3 & 4 cleanrooms?

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

A-1. Which particle counters can complete sampling in the least time?

Many 1.0 CFM counters can sample an ISO Class 4 location in only one minute. ISO Class 3, however, is much more demanding, clearly demonstrating the importance of counting efficiency. Thus, a 1.00 CFM, 0.1 µm particle counter can sample an ISO Class 3 location in one minute, while a 1.78 CFM, 0.3 µm particle counter takes 4 minutes per location (see **Table 4**). Other particle counters just take too long for sampling ISO Class 3.

A-2. How much will you use this particle counter to certify other rooms?

If you will use this same unit to certify ISO 1 & 2 rooms, the time savings from using a 1.00 CFM, 0.1 µm are so substantial that the extra cost generally will be justified. But if you use it for ISO Class ≥ 5 certification, a 0.1 µm particle counter may be over-kill.

A-3. How frequently will you use this particle counter for trouble-shooting, real-time monitoring, etc.?

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?

A-4. Do you need to worry about saturation?

Because ISO Classes 3 & 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 Class 8 & 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 **Table 5** for information on individual particle counters.

A-5. All things considered, which particle counter should you choose?

Since a 1.00 CFM, 01 µm particle counters costs 2-3 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 4 times longer; this could be outweighed if the ISO Class 3 measurements are only a small portion of the total particle counting activity. Thus, you need to estimate:

- 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 & all other uses)

and where: *Cost/Sample for Class N is proportionate to Sample time per location, etc*.

plus: 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 6 months — plus perform a minimal amount of trouble-shooting?

A. Almost any particle counter can perform ISO Class 6-8 certification in 1.0 minute per location (see **Table 4**). With infrequent usage, you should place a relatively high weight on low equipment cost. For example, a handheld particle counter offers a combination of high quality and low cost that makes 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 5-8 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 min. volume of 1.0 m3 (35.3 CFM). For this case many users are now selecting a 1.78 CFM particle counter instead of a 1.0 CFM; this increase in sample flowrate reduces the sample time from 35.3 to 20 minutes per location.

Q. Are there additional considerations when selecting a particle counter?

A. Consideration should be given to how the particle counter will be used. Physical size, weight, and materials of construction should be all taken into account when selecting a particle counter. If sterilization chemicals are to be used on the particle counter make sure to check the materials of compatibility prior to purchase.

Authors: Paul Hartigan and Mark Hallworth, Particle Measuring Systems