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Fundamentals of Particle Counting: Selecting a Particle Counter for ISO 14644-1 Certification of Cleanrooms

When considering the purchase of a particle counter the user typically evaluates factors such as price, quality, laser lifetime, warranty, and service. This paper discusses the performance-related factors which also must be considered if the particle counter will be used for certifying a cleanroom to ISO 14644-1. Of these, sensitivity and flowrate are the most important parameters, both of which impact the collection efficiency, which in turn determines the required sampling time. In the less-clean zones particle counter saturation also must be considered[1].

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 microns (µm). Particle counters with greater sensitivity can count smaller particles, thus many more particles.

For example, under ISO conditions a particle sensor with a sensitivity of 0.1 µm can count 28 times more particles of size ≥0.1 µm than a 0.5 µm instrument can count of particles of size ≥0.5 µm. (There are many more smaller particles than larger ones.)

The *flowrate* of a particle counter is simply the rate at which its pump draws the sample air through the sample chamber. The higher the flowrate, the more data the counter collects per time period - or the faster it can collect a specified volume. Historically, the flowrates 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.

An instrument that samples 1.78 CFM (50 LPM) can sample 1.0 m^3 (1,000 L) in only 20 minutes, where a 1.0 CFM (28.3 LPM) particle counter takes 35.3 minutes to sample the same 1.0 m^3. A handheld monitor with a flowrate 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 flowrate on the counter's ability to collect data. It is defined as the product of the expected particle concentration times the flowrate for the selected particle counter, as compared to a 0.5 µm, 0.1 CFM particle counter.

No matter which 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 flowrate.

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[1] This paper does not discuss the critical importance of the certification software. Different particle counter manufacturers often have significantly different interpretations of the way the ISO and EC GMP Annex #1 regulations should be implemented in software.

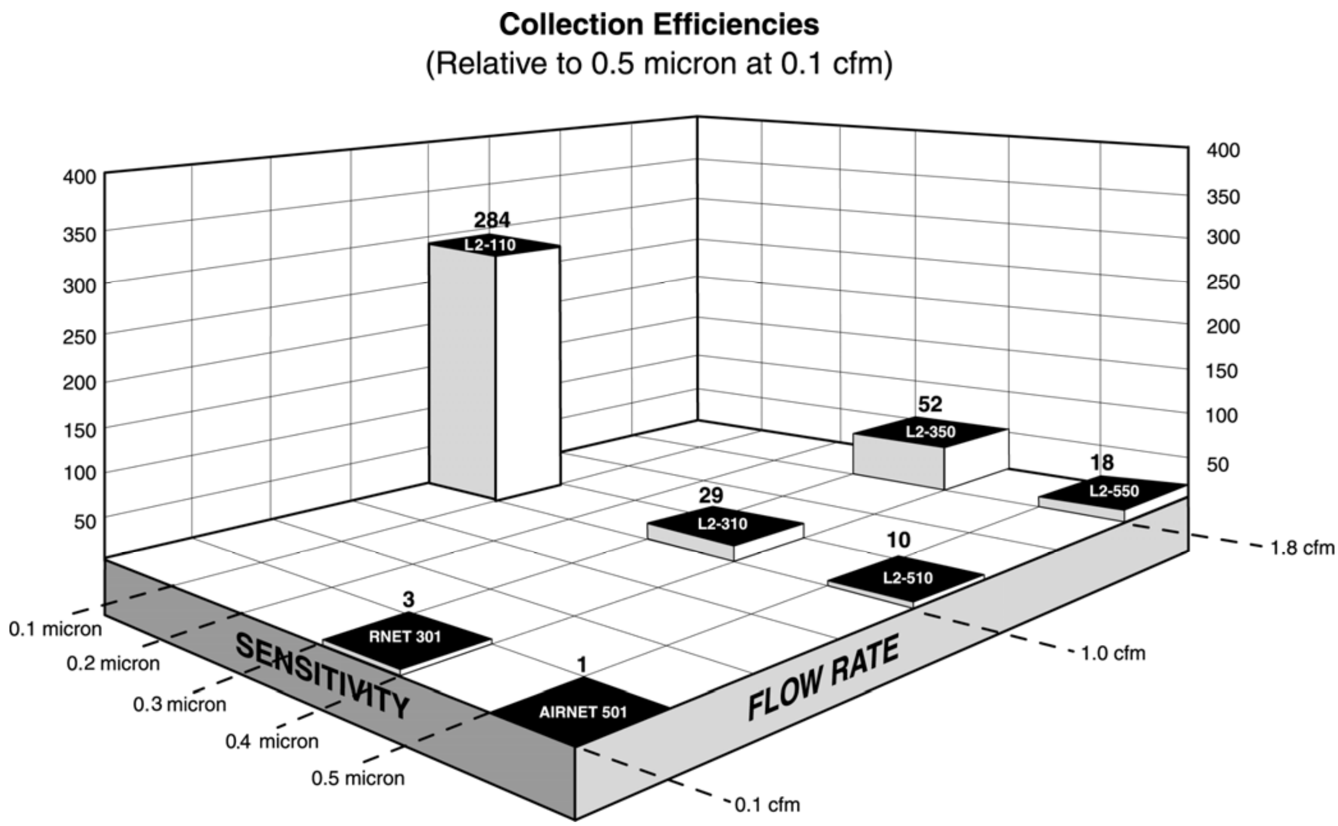

Figure 1: Collection Efficiency of Select Particle Counters

Cleanliness Levels

ISO 14644-1 has become the dominant, worldwide standard for classifying the cleanliness of the air in clean areas. Table 1 gives the maximum number of particles allowed (per cubic meter) if the zone is to meet a specified ISO class of cleanliness. Please note:

- Each successively higher classification allows approximately 10 times as many particles as the previous class.
- The ratio of particles of size A to size B remains approximately constant for all classes. For example:
  - Class 4 allows 1,020 particles of ≥0.3 μm, or 352 of ≥0.5 μm.
  - Class 5 allows 10,200 particles of ≥0.3 μm, or 3,520 of ≥0.5 μm.
- FS209 is for reference purposes only. This standard has been withdrawn

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

Table 1: ISO Classification vs. Maximum Particle Concentration Allowed

Sample Volume

To determine the sensitivity and flowrate your particle counter needs to certify 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 equation:

Min. Volume (m^3) $\geq$ *20 particles / Max. Particle Concentration Allowed (from Table 1)*

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 expect to sample at least 20 particles (i.e., a statistically-adequate sample) when the room holds the maximum acceptable particle concentration.

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 min. of 1.0 minute sample, which for the standard 1.0 CFM counter = 0.0283 m^3,

Table 2: Minimum Sample Volume Required per ISO Class (@1.0 CFM)

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. Table 3 gives these calculations for a 1.0 CFM, 1.78 CFM, or 0.1 CFM sampling rate. Note in the Table that many conditions require a sample of one minute; this is driven by the ISO requirement of an absolute minimum sampling time of one minute per location.

Table 3A: ISO Minimum Sampling Time

	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

	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

ISO Class	Minutes @ 0.1 CFM to Collect Min. Sample Volume <-------- 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

Table 3: Minimum Sampling Time Required

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 be collected much quicker 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.

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.

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 II 350L	1.78 cfm	0.3 µm	NA*	40	4	1	1	1	NA*	NA*	NA**
Lasair II 310	1.00 cfm	0.3 µm	NA*	71	7	1	1	1	NA*	NA*	NA**
Lasair II 350L	1.78 cfm	0.5 µm	NA*	100	11	1	1	1	1	1	NA**
Lasair II 510	1.00 cfm	0.5 µm	NA*	177	20	2	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 4: Minutes Required to Sample One Location

Ultra-Clean Rooms: High-Efficiency Filtering of Chassis Particles

ISO Class 1-3 rooms are extraordinarily clean, allowing only as few as 10 and as many as 1,000 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 exhaust of the particle counter; 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 are missed by the HEPA filter. Thus, the particle counter may well require a second, high- efficiency filter that scrubs the output of particles emitted from the chassis.

Dirty Rooms: Particle Counter Saturation

If an airborne-particle counter is used in a dirty environment, eventually enough dirt particles will collect on the optics 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.

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 (e.g., 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 >5%

coincidence errors. ISO Class 9 is so dirty that most particle counters will require the addition of an aerosol diluter to be able to measure without saturation.

Table 5 specifies the maximum concentration limit for a number of particle counters, plus the dirtiest ISO classification in which a unit can be without requiring the addition of an aerosol diluter.
For example, the high sensitivity of a 1.0 cfm, .01 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.

Particle Counters Appropriate for Each ISO Class

Table 5 also lists the types of particle counter appropriate for monitoring each ISO classification, plus , as an example, provides data including the sensitivity, flowrate, and collection efficiency for several Particle Measuring Systems particle counters.

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 II 310	0.3 µm	1.0 cfm (28.3 lpm)	29	7	3-8	375,000	8
4	10	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	2	4-8	425,000	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 dilutor

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

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 a 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 Class 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 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?

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?

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 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; 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?

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.

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