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HOW TO GAS SAMPLE USING A PARTICLE COUNTER

Lighthouse Worldwide Solutions

Overview

Particle counters are powerful tools in a cleanroom – and they can be dual use with the right equipment. High pressure gas is common in cleanrooms, but can present a contamination risk. Using a particle counter and High Pressure Diffuser, you can test the gas for contamination.

Cleanroom Gas Sampling Using a Particle Counter

GMP requires you test compressed gases in cleanroom applications. This testing is critical because product process zones in ISO 5 cleanrooms require tight contamination control. Compressed gases, if not correctly properly checked, can be an avenue for particle contamination. This can impact the quality and safety of sterile products. Testing gas lines mitigates against adding another source of cleanroom contamination that may impact the cleanroom's set classification based on operating conditions.

ISO 14644-1 states the required air cleanliness for different classes of cleanrooms based on a cubic meter sample of air taken at given locations. The result is compared to a table, which validates the cleanroom ISO class. For example, ISO 14644-1 requires a cleanroom to have the following limits per cubic meter of air sampled.

ISO 14644-1:2015 Classification of air cleanliness by particle concentration

ISO CLASS (N)	Maximum allowable concentrations (particles/m³) for particles equal to and greater than the considered sizes, shown below					
	≥0.1 (m³)	≥0.2 (m³)	≥0.3 (m³)	≥0.5 (m³)	≥1.0 (m³)	≥5.0 (m³)
ISO 1	10	d	d	d	d	e
ISO 2	100	24	10	d	d	e
ISO 3	1,000	237	102	35	d	e
ISO 4	10,000	2,370	1,020	352	83	e
ISO 5	100,000	23,700	10,200	3,520	832	d,e,f
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7	c	c	c	352,000	83,200	2,930
ISO 8	c	c	c	3,520,000	832,000	29,300
ISO 9	c	c	c	35,200,000	8,320,000	293,000

Table 1. ISO 14644-1:2015 Classification of Air Cleanliness by Particle Concentration

In the pharmaceutical industry, sterile processing mainly occurs in cleanrooms with an ISO 5 classification. Therefore, the particle concentration should be below the limits for the sizes tested. If 0.5µm and 1.0µm particles were tested using a particle counter, then the limit for each size would be 3,520 and 832, respectively, per location.

The number of locations is based on a lookup table (outlined in ISO 14644-1:2015) and the size of the cleanroom. If all sample locations are below the particle sizes per cubic meter at each sample, then the cleanroom would be classified as an ISO 5 cleanroom.

If there was a contaminated gas line, there is potential for the introduction of the gas to contaminate the room further and potentially fail the ISO 5 classification. This could lead to a risk of product safety and quality. ISO 8573 is a standard to follow when testing gas lines. There are several parts to ISO 8573, but parts 4 and 7 refer to particulate contamination. ISO 8573-1:2010 outlines the maximum number of particulates per m3 which is the same concept as ISO 14644-1:2015.

ISO 8573 – Part 4:

1. **Provides a method for sampling compressed air.**
2. **A guide for choosing suitable measuring equipment to determine its particle size and concentration by number.**
3. **Establishes a minimum sampling volume of 1000L (1m³).**
4. **Use of Optical Particle Counter for testing sizes from ≥ 0.1 to ≤ 10µm.**

ISO 8573-1: 2010 Table for Solid Particle Classes

For example, a Class 5 cleanroom with particle diameter 0.5 < d ≤ 5.0µm would have an expected maximum number of particles per m³ sample less than 100,000. For Class 4, that value would be ≤10,000. Class 3 would be ≤1000, Class 2 would be ≤100, and Class10 would be ≤10.

ISO 8537-1:2010 CLASS	Solid Particulate			
	Maximum number of particles per m³			Mass Concentration mg/m³
	0.1 - 0.5µm	0.5 - 1µm	1 - 5µm	
ISO 0	As specified by the equipment, user, or supplier, and more stringent than Class 1			
ISO 1	≤ 20,000	≤ 400	≤ 10	-
ISO 2	≤ 400,000	≤ 6,000	≤ 100	-
ISO 3	-	≤ 90,000	≤ 1,000	-
ISO 4	-	-	≤ 10,000	-
ISO 5	-	-	≤ 100,000	-
ISO 6	-	-	-	≤ 5
ISO 7	-	-	-	5 - 10
ISO 8	-	-	-	-
ISO 9	-	-	-	-
ISO X	-	-	-	> 10

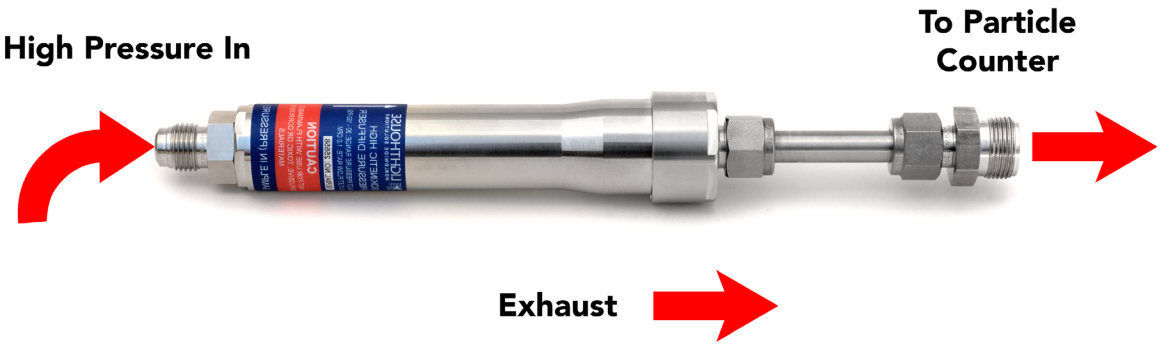
Table 2. ISO 8537-1:2010 Classes

- **Isokinetic sampling should be maintained (If particle diameter is > 1µm, use High Pressure Diffuser)**
- **OPC Particle size range 0.1µm to 5µm**
- **Sample Report to include;**
  - **Sterile or non-sterile statement**
  - **Date of sampling**
  - **Date of measurements**
  - **Location**

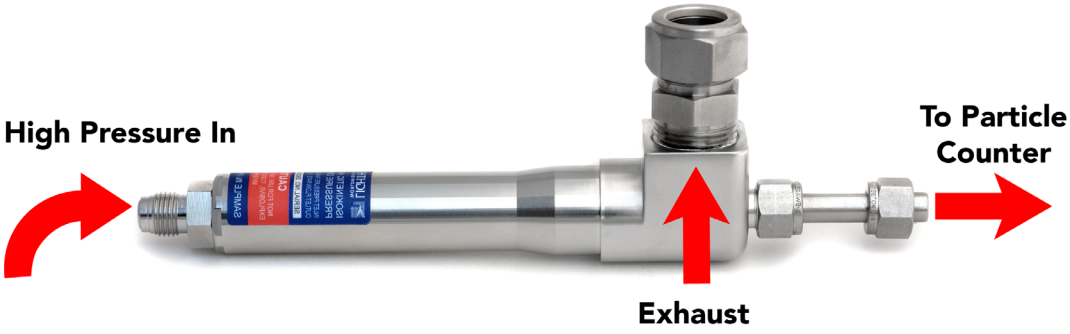
Choosing The Right HPD

To sample compressed gas, a particle counter will need an accessory called a High Pressure Diffuser (HPD). The HPD connects the particle counter and the compressed gas line and diffuses the gas as is enters the particle counter sample inlet. If the high-pressured gas enters the particle counter sample inlet without the HPD, the sensor inside the particle counter can be damaged and the results of the testing will not be accurate.

There are two types of HDPs offered by Lighthouse Worldwide Solutions: Vented Return HPD and Ported Exhaust HPD. Vented Return HPD vents the gas into the environment and is best suited for gases such as air. If the gas should not be in the environment, you should use a Ported Exhaust HPD, which will safely vent the gas outside the environment.



(1) Vented Return HPD

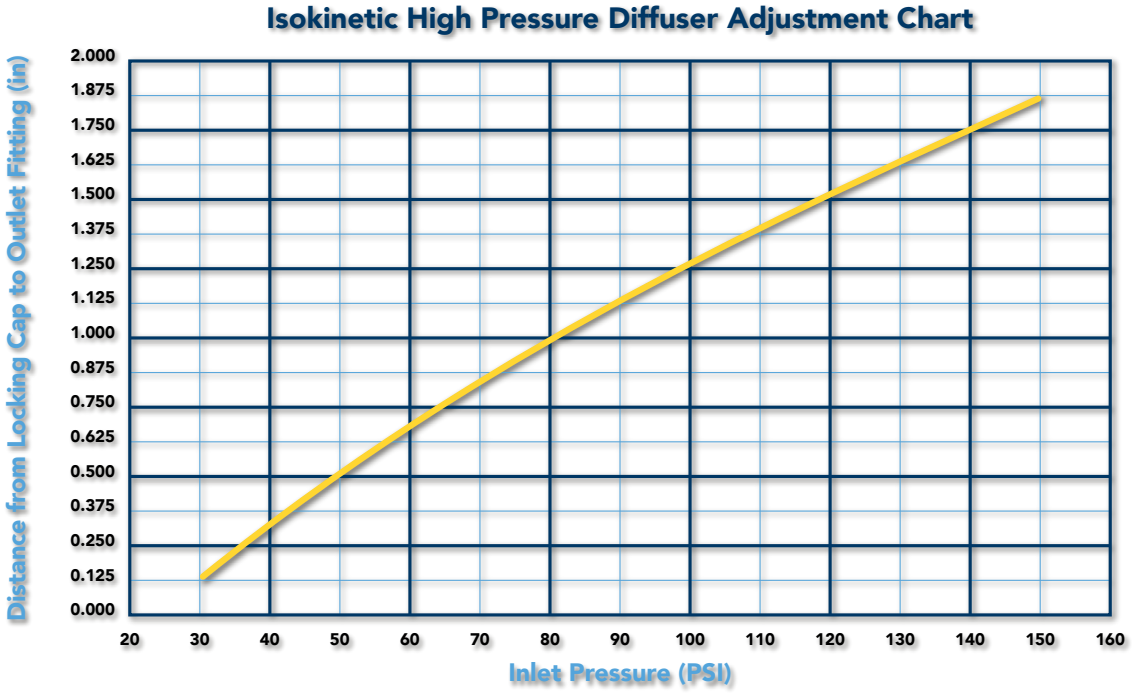


(2) Ported Exhaust HPD

Setting Up The HPD Flow Rate

When using an HPD, it is critical to match the flow rate of the particle counter used to test the compressed gas.

Depending on the HDP and particle counter model, setting the proper airflow is necessary in order to verify the system is setup correctly and the results are as accurate as they can be based on iso-kinetic sampling. Iso-kinetic sampling maintains the correct airstream and, with the right pressure, enables the particle counter to sustain the right flow rate as the flow rate is critical to the accuracy of the sample results. The table below outlines the correct HPD adaptor adjustment based on the inlet pressure of the compressed gas to be sampled to maintain ideal flow into the particle counter for accurate sampling.



Graph 1. Isokinetic High Pressure Diffuser Adjustment Chart

Setting Up The Particle Counter and HPD For Compressed Air Sampling

The HPD connects between the compressed gas line and the particle counter based on the diagram below. Take care to ensure the adaptor fittings are tight, the gas line is free from any leakage, and the air is flowing in the correct direction.

With the correct set-up and team on your side, the process is seamless and smooth. Particle counters should be powerful, multi-use tools and the Lighthouse team is dedicated to ensuring you get the most out of your particle counter as possible. When working with one of our particle counters, such as the ApexZ50, our team will stand alongside you to ensure proper training and maximization of the application.

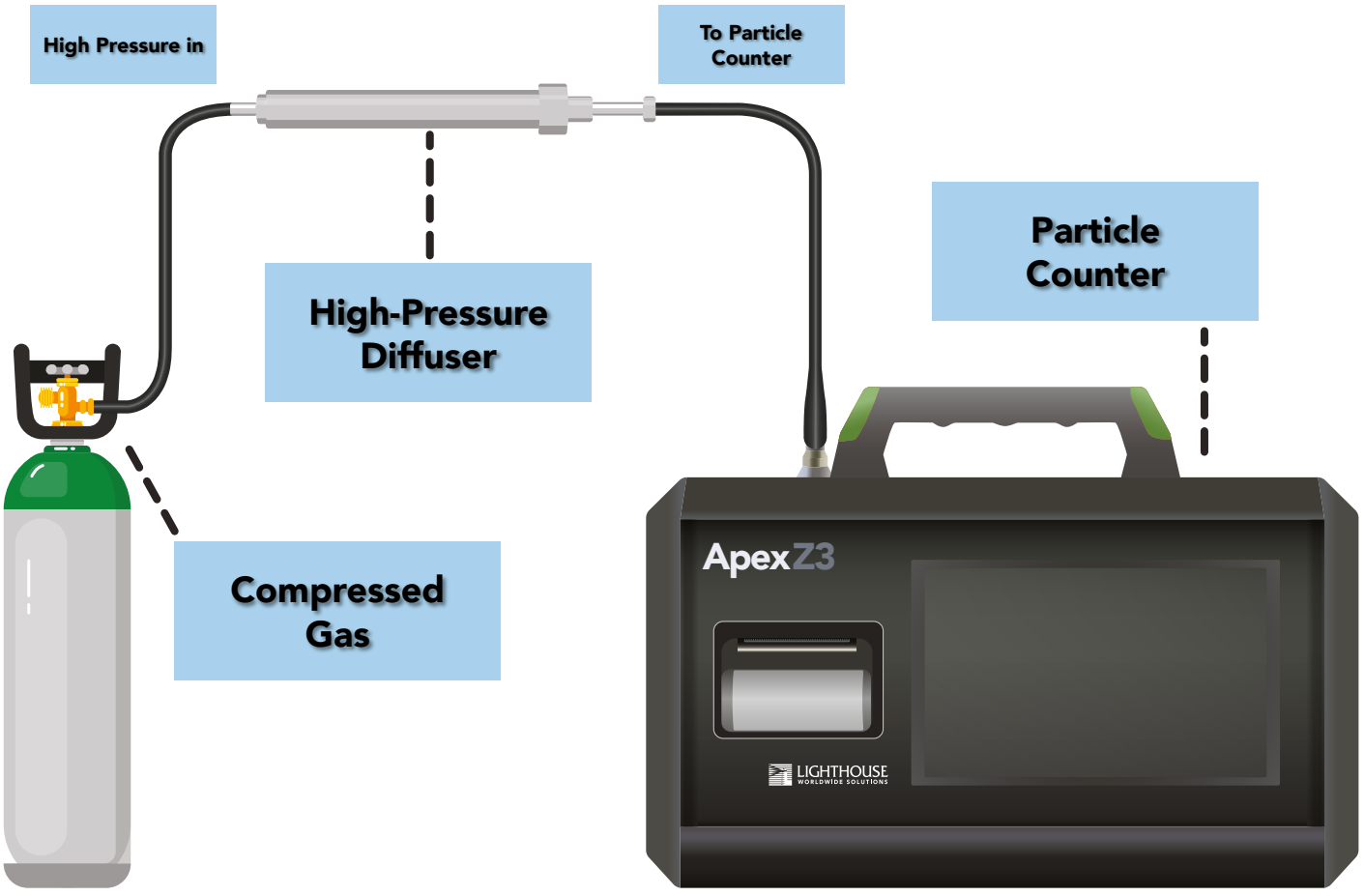


Figure 1. Compressed Gas to Remote Particle Counter Flow

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