

Cleanroom Gas Sampling Using an Active Air Sampler

by Jason Kelly

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Testing of compressed gases is a GMP requirement when such gases are used in cleanroom applications. It is critical for such testing to occur since product process zones in ISO 5 cleanrooms and zones require tight control on contamination and compressed gases used may also if not checked correctly be an avenue for particulate contamination that may affect the quality and safety of sterile products.

ISO 8573-Part 7:2003 Test method for viable microbiological contaminant content defines the testing methods for microbial particulates in compressed gas samples. ISO 8473-1:2010 defines the acceptable limits of microbial particulate concentrations, see table 1 below. Overall the goal is to achieve no microbial or viable particulates in compressed gases to align with GMP standards shown below in table 2.

ISO8573-1:2010 CLASS	Solid Particulate			
	Maximum number of particles per m ³			Mass Concentration mg/m ³
	0.1 - 0.5 micron	0.5 - 1 micron	1 - 5 micron	
0	As specified by the equipment user or sup			
1	≤ 20,000	≤ 400	≤ 10	-
2	≤ 400,000	≤ 6,000	≤ 100	-
3	-	≤ 90,000	≤ 1,000	-
4	-	-	≤ 10,000	-
5	-	-	≤ 100,000	-
6	-	-	-	≤ 5
7	-	-	-	5 - 10
8	-	-	-	-
9	-	-	-	-
X	-	-	-	> 10

Table 1. ISO 8573-1: 2010 table for Solid Particle Classes

ISO 8573 – Part 7;

- Using an Air Sampler and agar sample plate
- Isokinetic sampling should be maintained (High Pressure Diffuser)
- Pressure reduction to atmospheric or to maintain isokinetic
- After sample taken the CFU/m³ count should be observed
- Sample Report to include;
 - o Sterile or non-sterile statement
 - o Date of sampling
 - o Date of measurements
 - o Location

FDA microbial Active Air guidelines summarize microbial contamination based on air classification similar to GMP requirements. Samples from ISO 5 or Class 100 environments should normally yield no microbiological contaminants. Tables below indicate FDA and current GMP microbial limits. Overall the objective for controlling microbial contamination in Class 100, ISO 5 or Grade A sterile environments is to have no CFU's.

Clean Area Classification (0.5 um particles/ft3)	Microbiological Active Air Action Levels (cfu/m3)		Grade	Microbiological Active Air Action Levels (cfu/m3)
100	1		A	1
1000	7		B	10
10000	10		C	100
100000	100		D	200

Table 2 FDA and GMP Microbial CFU limits for Active Air Sample at 1m³

Using a Lighthouse Active Count Air Sampler to sample compressed gas lines

Using a Lighthouse Active Count air sampler to take compressed gas samples is extremely easy compared to other instruments and adaptors available on today's market and economical too. The Active Count has a build in test system that walks the operator through the testing process. The gas sampler adaptor is also small and easy to connect.

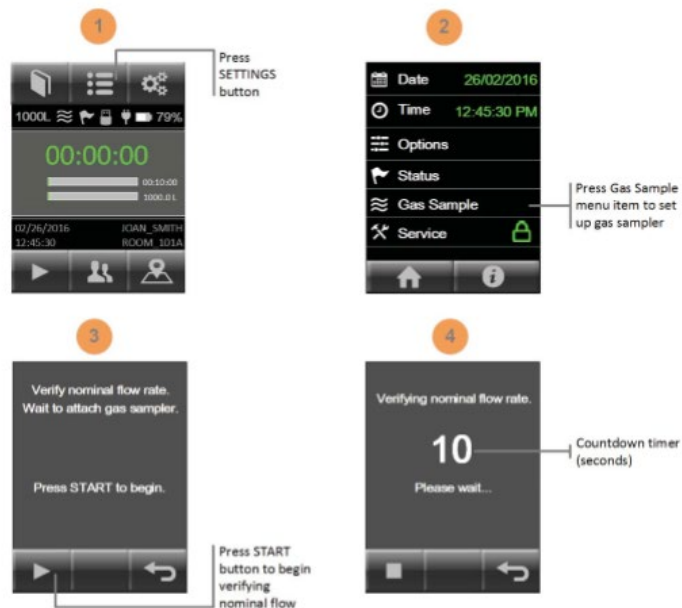
Verify Nominal Flow before Gas Sampling

Before using the optional compressed gas sampler, first verify nominal flow of ActiveCount100H without the gas sampler.



Front of ActiveCount100H

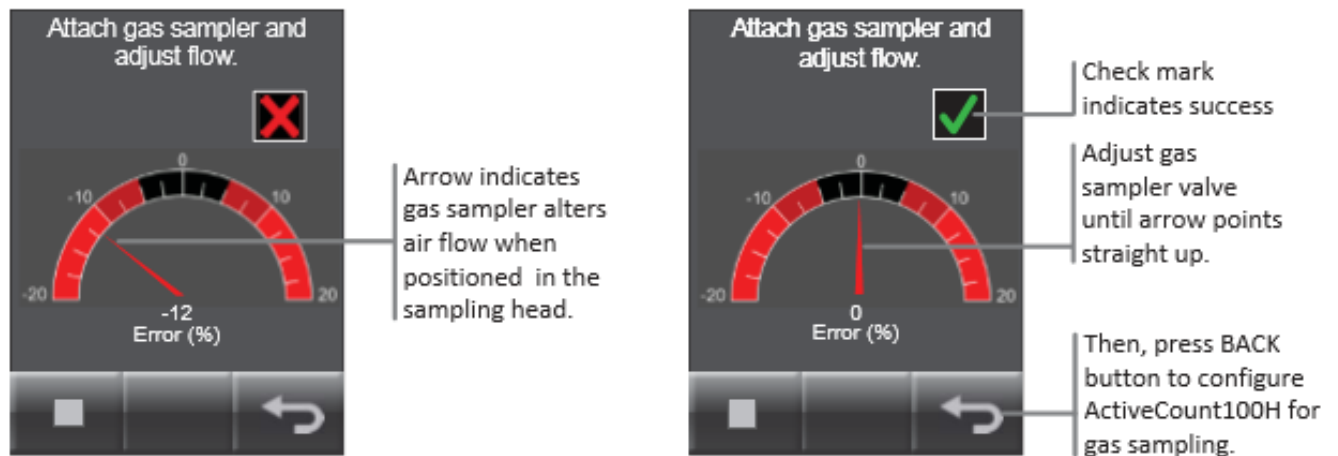
To verify ActiveCount100H nominal flow rate, follow the steps below.



When ActiveCount100H displays the following screen, position gas sampler snugly in the sampling head while ActiveCount100H blower is running.



Then, adjust gas sampler valve until the arrow in the display screen points straight up, indicating ActiveCount100H has nominal flow for gas sampling. You're now ready to sample compressed air!



Do not sample explosive nor corrosive gases. ActiveCount100H gas sampler is designed to sample compressed air only, and is not designed for sampling of explosive nor corrosive gases.