Importance of Class 100 Air in a CO_2 Incubator

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Class 100 Air White Paper

Key Words
- Class 100 air
- Contamination control
- HEPA filtration
- Incubator

Abstract

Federal Standard 209E defines the classifications of air quality as Class 1, 100, 1,000, 10,000, and 100,000. The class number (e.g., 100) is the maximum allowable number of particles 0.5 microns and larger per cubic foot of air; the lower the number, the cleaner the air. Our Thermo Scienitifc Forma® Series II Water Jacketed CO_2 Incubators, Steri-Cycle® CO_2 Incubators, Steri-Cult® CO_2 Incubators, Steri-Cult® R Automated CO_2 Incubator, Biological Safety Cabinets, Console Shakers, and Laminar Airflow Workstations include a HEPA filter to maintain a high quality environment. Each Series II Water Jacketed, Steri-Cycle, Steri-Cult, and Steri-Cult R Incubator comes equipped with our patented HEPA Filter Airflow System. The HEPA filter used is rated a minimum 99.97% efficient for 0.3 micron particulates with greater efficiency for particles larger than 0.3 microns. HEPA filter efficiency does not decrease greatly for particle sizes below 0.3 microns. The system continuously filters the entire chamber volume every 60 seconds. Class 100 air quality is achieved within 5 minutes of the door closing.

Introduction

Concern about incubator contamination led us to develop and patent a HEPA (High Efficiency Particulate Air) filter method designed to handle primary sources of contamination (biological contaminants and airborne particulates) found in most laboratory settings. Common visible and invisible airborne contaminants include metal ions, inside dust, pyrogens (fever-producing substances), tobacco smoke, hair, plant spores, carbon black, bacteria, yeast cells, viruses, and pollen.

Requirements for a clean environment are as diverse as the types of applications implemented. For example, semi-conductor producers require an ultra-clean environment when applying thousands of circuits to a miniature chip. Pharmaceutical manufacturers must control airborne contamination to protect the buyers of their products. Some manufacturers depend on cleanrooms to provide high quality air. Most laboratory professionals rely on their controlled environment laboratory equipment, such as cell culture incubators and biological safety cabinets, to provide clean air and control many of the variables required for experiments, cell growth, etc.

Why Should I Care about Air Quality?

Air quality is an important factor if you are working in an environment where you want to achieve and maintain process integrity. Product yields, product reliability, and protection of people can be affected by airborne contamination in a room or inside an incubator chamber. When an incubator door is opened, laboratory room air enters the chamber. Reducing airborne particulates inside the chamber helps prevent or minimize the potential damage to your product. Industries such as aerospace, food, pharmaceuticals, medical devices, research, and healthcare understand the process and product benefits of controlling airborne contamination.

How Air Quality is Measured

Air cleanliness is classified by the number and size of particles within a sample of air. The level of cleanliness can be classified by the maximum allowable number of particles per cubic foot or cubic meter of air. The basic unit of measurement is the micron. Typically, the source or type of particle indicates the particle's size range. The human eye is capable of seeing particles down to approximately 25 microns, the size of a dust particle. A human hair is approximately 100 microns.
Two standards used to test and categorize the class of air include the United States Federal Standard 209E and the International Standard ISO 14644-1. Both standards define terms, identify procedures for collecting and testing the air, and provide the statistical analysis required to interpret the data. Federal Standard 209E classifications of air are Class 1, Class 10, Class 100, Class 1,000, Class 10,000, and Class 100,000. The ISO

Air Classification and Typical Environments

Examples of typical environments and the associated air classification follow.

Air Classification	Typical Environment
Class 1/Class 10	Semiconductor production facilities (Abuzeid, S., 1993)
Class 100	Pharmaceutical production/filling operations, biological safety cabinets, HEPA filtered air in our Series II Water Jacketed, Steri-Cycle, Steri-Cult, and Steri-Cult R Incubators
Class 10,000	Toothbrush bristle manufacturing, aircraft component manufacturing (Matthews, Richard A., 1999)
Class 100,000	Drug preparation areas, such as IV and below rooms (Chandler, S. W., 1993) and hospitals, hospital indoor sites
Class 100,000	Offices, laboratories without air filtering and above systems, general manufacturing

The Biosafety Cabinet–Incubator Connection

The importance of directed airflow and effective HEPA filtration is realized by laboratory professionals worldwide who use biological safety cabinets and/or laminar airflow workstations to protect their product, themselves, and their environment. Proper product design, effective HEPA filtration, and steady, directed airflow are the keys to success.

The principles of gentle, directed airflow and complete HEPA filtration have been incorporated into the design of our Water Jacketed, Steri-Cycle, Steri-Cult, and Steri-Cult R CO_2 Incubators for many years. This innovation addresses the following key issues:

- Concern about the quality of air that the product is continuously exposed to while under incubation
- Awareness that the air entering your incubator during door openings often is heavily contaminated by airborne particulates
- Knowledge that the principles governing the reliability and dependability of high quality air can be applied to incubator design
- Desire to help establish an ideal culturing environment for products to incubate

Our Unique HEPA Filter Airflow System

Class 100 air is achieved and maintained within the Series II Water Jacketed, Steri-Cycle, Steri-Cult, and Steri-Cult R CO_2 Incubators by way of our advanced incubator design and HEPA Filter Airflow System.*

figure 1–Steri-Cult CO_2 Incubator with Class 100 Air

The HEPA Filter Airflow System, which is located inside the incubator chamber, ensures directed, continuous, gentle airflow throughout the incubator by **filtering the entire chamber volume every 60 seconds.**

The HEPA filter's performance is rated a minimum 99.97% efficient for 0.3 micron particulates with greater efficiency for particles larger than 0.3 microns. HEPA filter efficiency does not decrease greatly for particle sizes below 0.3 microns. The filter entraps the particulate air contaminants and prevents their escape. Filter efficiency increases as particulates and micro-organisms are entrapped.

**Third-party tested/independently verified; test results are available on request for Water Jacketed Incubators. Testing protocol is available for Steri-Cycle and Steri-Cult CO_2 Incubators and the Steri-Cult R Automated CO_2 Incubator. U.S. Patent 5,792,427 (Water Jacketed and Steri-Cycle Incubators).*

Not All HEPA Filter Systems are Created Equal

Figure 2, Particulate Count Reduction in a Forma Series II Water Jacketed, Steri-Cycle, and Steri-Cult CO_2 Incubator versus Competitive Units, illustrates major differences. Class 100 air quality is achieved in our incubators **within 5 minutes** of the door closing. Competitive designs do not perform as well and do not reach the air classification level of our units.*

Primary Benefits of the HEPA Filter Airflow System

- Efficiency and long term effectiveness of our HEPA Filter System minimizes the need to remove your product for frequent, lengthy decontamination cycles.
- HEPA filtration does not interfere with the incubator's functioning or with your product.
- Incubator down time is diminished.
- Quickly achieved Class 100 air quality contributes to an ideal culturing environment.

Our HEPA Filter Airflow System allows you to attain and maintain process integrity within your incubator at a Class 100 air quality or better.

Contact us, your international distributor, or your local account manager for additional information about our unique HEPA Filter Airflow System, Steri-Cycle and Steri-Cult CO_2 Incubators, Series II Water Jacketed Incubators (510K number K991408), and Steri-Cult R Automated CO_2 Incubator.

Common Definitions

airborne particulate cleanliness class. Level of cleanliness specified by the maximum allowable number of particles 0.5 microns or larger per cubic meter of air (or cubic foot of air)

Class 100. Particle count does not exceed 100 particles per cubic foot of a size 0.5 micron and larger

cleanroom. Room in which the concentration of airborne particles is controlled and which contains one or more clean zones

clean zone. Defined space in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class micron. One millionth of a meter or 39 millionths of an inch

particle. Solid or liquid object which, for air classification purposes, falls between the 0.001 micron and 1,000 micron range

particle size. Maximum linear dimension of the diameter of a particle

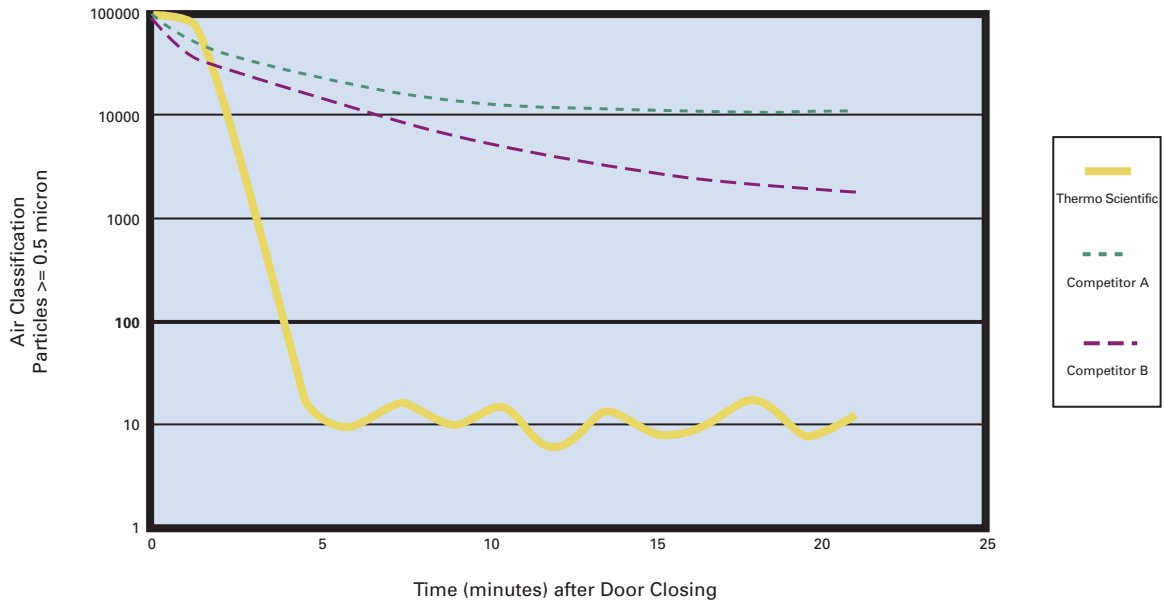

figure 2–Particulate Count Reduction in a Forma Series II Water Jacketed, Steri-Cycle, and Steri-Cult CO_2 Incubator versus Competitive Units

**Third party tested/independently verified; test results are available on request for Water Jacketed Incubators. Testing protocol is available for Steri-Cycle and Steri-Cult CO_2 Incubators and the Steri-Cult R Automated CO_2 Incubator.*

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