Waters™

Andrew+ Pod

Vertical Laminar Flow (with HEPA H14 filter) Performance Document

INTRODUCTION

This report is based on a study done by SKAN AG[1] called: "SKAN Containment Testing (Conttest) on a newly developed Biderectional Filtration Cabinet in 13 situations". This report summarizes the performance testing of the Andrew+™ Pod configured as a Downflow Cabinet, using certified HEPA filters (H14 type). The objective was to evaluate its compliance with ISO 14644 standards, focusing on cleanliness level and airflow dynamics.

Downflow cabinets, also known as Vertical Laminar Flow (VLF) cabinets, function by drawing environmental air through a high-efficiency particulate air (HEPA) filter and directing it downward in a smooth, laminar flow over the work surface. This continuous stream of filtered air blocks airborne contaminants from encountering sensitive samples by creating a clean and controlled workspace.

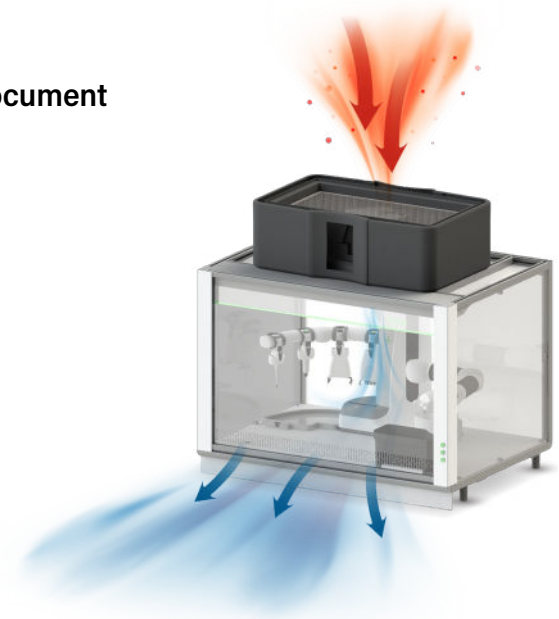


Figure 1. The Andrew+ Pod can be configured as a Downflow Cabinet. By creating a vertical laminar flow of HEPA-filtered air, the enclosure protects samples from exterior contaminations.

ISO 14644 STANDARDS

WHAT ARE THEY?

ISO 14644 is an international set of standards that define the requirements for cleanrooms and controlled environments, including the testing and monitoring of air cleanliness. The standards are critical in industries such as pharmaceuticals, biotechnology, electronics, and medical device manufacturing, where airborne contamination must be strictly controlled. The Andrew+ Pod is a cleanroom-adjacent solution specifically designed for applications requiring these controlled environments. As of such, it falls under ISO 14644 and has been tested against these norms to determine its performance.

KEY COMPONENTS

1. ISO 14644-1: Specifies the classification of air cleanliness based on particle concentration. Cleanrooms are categorized according to both the size and the number of particles present per volume of air. ISO 14644-1 standards specify the decimal logarithm of the number of particles 0.1 µm or larger present per cubic meter of air[2]. Cleanliness classes of this norm range from ISO Class 1 (most stringent) to ISO Class 9 (least stringent). ISO Class 5 permits a maximum of 3,520 particles (≥0.5 µm) per cubic meter for example.
2. ISO 14644-3: Covers test methods for verifying cleanroom performance, including airflow, filter integrity, and particle concentration.

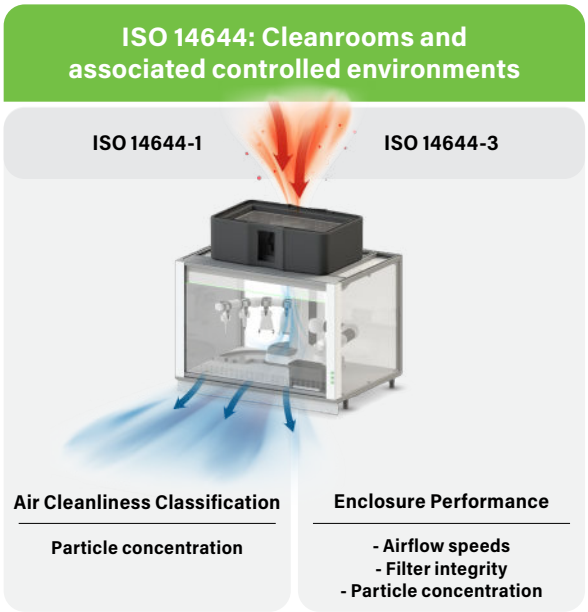


Figure 2. Andrew+ Pod was tested against ISO 14644 norms to determine enclosure performance and evaluate air cleanliness levels when in use.

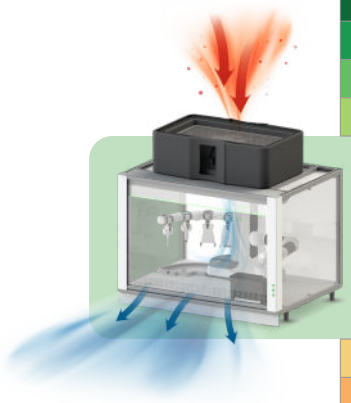
[1] *SKAN AG is a third-party company based in Switzerland. SKAN AG is a global market and technological leader for isolators, cleanroom devices, and decontamination processes for the aseptic production of biopharmaceutical substances.*

[2] *https://alliedcleanrooms.comwhat-are-iso-14644-1-cleanroom-classifications/*

TEST RESULTS

1. The Andrew+ Pod complies with Class 5 Cleanliness Standards of ISO 14644-1.

√ By sitting in this class, the Andrew+ Pod is suitable for precision tasks like automated pipetting in labs working with sensitive materials, making it an ideal solution for labs that need ISO Class 5 levels of containment without needing to build a full-scale cleanroom. This way, the Pod bridges the gap between standard lab enclosures and cleanroom-grade equipment.



	Maximum concentration limits (particles/m3 of air) for particles ≥ the sizes shown below					
ISO Class	**0.1 µm**	**0.2 µm**	**0.3 µm**	**0.5 µm**	**1 µm**	**5 µm**
Class 1	10	2	–	–	–	–
Class 2	100	24	10	4	–	–
Class 3	1000	237	102	35	8	–
Class 4	10000	2370	1020	352	83	–
Min. Requirements **Class 5**	100000	23700	10200	3520	830	29
Andrew+ Pod	Not measured		1068	84	12	0
Class 6	1000000	237000	102000	35200	8320	293
Class 7	–	–	–	352000	83200	2930
Class 8	–	–	–	3520000	832000	29300
Class 9	–	–	–	35200000	8320000	293000

Figure 3. The Andrew+ Pod easily passed Class 5 standards under ISO norm 14644-1, with actual readings well-below the maximum allowed measurements to fall within this class.

2. The Andrew+ Pod underwent and passed air velocity, filter integrity, and airflow visualization tests, all key components of ISO 14644-3 standards.

√ The average Air Velocity created by the Andrew+ Pod is of 0.20m/s (downflow of 202 m3/h) when the onboard ventilation module is set at 2000 rpm (rotations per minute) with a sash opening of 540 mm (fully opened). This remained true even with the Andrew+ pipetting robot in motion inside it, demonstrating robust airflow under challenging conditions. The 8 different measurements constituting this average were taken in 8 different positions within the enclosure, all 30cm below the surface of the HEPA H14 filter.

√ The Airflow Visualization tests of the Andrew+ Pod demonstrated consistent unidirectional flow without dead zones, backflows or eddies, meeting the standard's guidelines for cleanroom airflow – again confirming its classification as a Class 5 device.

√ The HEPA (H-14) filter used passed filter integrity checks with no leaks or damage detected during operation.

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