

Competitive Advantages

Cleanroom Test Equipment



Topas instrument package for cleanroom applications: aerosol generator ATM 226, dilution system DIL 554, particle counter LAP 340, sampling probe SYS 529

More and more clean room equipment and facilities are required by an increasing number of industrial applications and research fields. This equipment must be tested and validated on a regular basis. Apart from technical expertise, testing requires suitable instrumentation, which is itself verified and in compliance with existing standards and guidelines. Topas offers aerosol generators, dilution systems and rectangular sampling probes which have been especially developed to comply with the requirements as specified in current standards and regulations. During the development phase, great emphasis was put on the design of instruments to make them suitable for mobile use. During manufacture each device has to pass a series of defined testing procedures. This guarantees the consistently high quality of each unit which is documented by an official certificate of instrument testing. Cleanroom validation according to ISO 14644 requires:

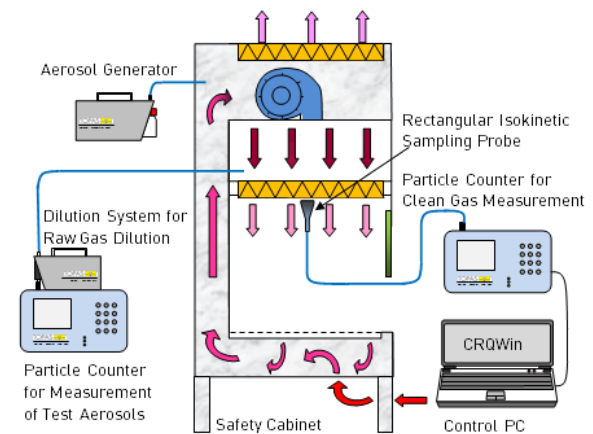
- Measurement of cleanroom class (particle counter)

Optionally included:

- Filter leak test, which alternatively uses a photometer instead of a particle counter
- Recovery test measurement using particle counter

Special Advantages

- Optimized for mobile use
- Fast start-up
- Easy handling
- Lowest maintenance
- Suitability for long-term measurements
- Fast service (equipment inspection, new calibration, repair)
- Rugged stainless steel housing



Arrangement for the validation of a safety cabinet

Testing a laminar flow box is done, for example, by means of an aerosol generator of the ATM 226 series which creates a challenge aerosol that is introduced into the intake air stream.

The raw gas side concentration of the challenge aerosol is reduced using a Topas dilution system of the DIL 554 series and determined with a particle counter of the LAP 340 series. Scanning the downstream side of the filter is carried out with the rectangular sampling probe SYS 529 and a particle counter, e. g. the LAP 340. In case of determining leakage tests of sensitive product groups only particle counters and no photometers are allowed for validation according to ISO 14644. Due to the higher detection sensitivity of particle counters a significantly lower filter loading can be guaranteed.

Atomizer Aerosol Generator ATM 226 and Dilution Systems DIL

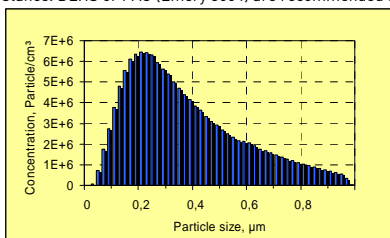


Atomizer aerosol generator ATM 226: adjustable particle production rate, stainless steel casing, integrated mains adapter

For the reliable testing of the performance parameters of the filters, aerosol generators are used producing a liquid aerosol at a sufficiently high concentration with a peak particle size in the range of the most penetrating particle size (MPPS) ($>10^7$ Particles/cm³). The Atomizer Aerosol Generators of the series ATM especially developed for this purpose by Topas atomize a suitable liquid by means of a patented two-substance nozzle assembly.

DEHS (Di-Ethyl-Hexyl-Sebacate) has widely been favored across Europe for validation of clean rooms. The colorless low volatile liquid is characterized by an exceptionally long-term stability of the droplets produced. The particle size distribution of the DEHS aerosol is in the range of MPPS and has proved ideal for testing the efficiency of HEPA and ULPA filters. Apart from the above-mentioned liquid other liquids, such as PAO (Emery 3004), DOP¹⁾, paraffin oil or PSL can be atomized with Topas aerosol generators.

¹⁾In the Globally Harmonised System (GHS), DOP is classified as a hazardous substance. DEHS or PAO (Emery 3004) are recommended as a replacement for DOP.



Particle size distribution of a DEHS aerosol, generated by an aerosol generator series ATM



Dilution system DIL 554, power supply via battery, stainless steel casing

A reliable detection of filter leaks in clean room environments is only possible if the filter is challenged with a sufficiently high number of particles on its upstream side.

In VDI guideline 2083 this concentration is defined as 1 million particles/cf.

As clean room particle counters are limited to a certain concentration range, the challenge aerosol must be diluted on the basis of a certain factor. This way both upstream and downstream concentrations can be measured with only one particle counter.

The dilution systems DIL 554 are available for 28.3, 50 and 56.6 l/min and a dilution factor of 100. The pressure loss in these devices is minimal, compressed air is not needed.

Specifications	DIL 554	DIL 550
Total flow rate	1 cf/min (28.3 l/min), 1.77 cf/min (50 lpm) or 2 cf/min (56.6 l/min) ^{*)}	0.1 cf/min (2.83 l/min) or 1 cf/min (28.3 l/min) ^{*)}
Dilution factor	1:100	1:10; 1:100 ^{*)}
Power supply	9 V battery	9...15 V DC DC adapter

^{*)} customization possible on request



Cleanroom Particle Counter LAP340 and Sampling Probe SYS 529



Clean Room Particle Counter LAP 340

The LAP 340 is an airborne particle counter for mobile use to measure the number and size of particles in accordance with ISO 14644, VDI 2083, DIN 1946, EN 12469 / DIN 12980, ISO 21501-4. Other gases can thus be verified.

The device has especially been designed for monitoring ventilation installations with high purity requirements, monitoring and verification of clean rooms, safety cabinets, filter systems in operating rooms or filling systems in the pharmaceutical industry.

During a measurement, the LCD panel displays the summary of the particle size channels, date, time and number of the current measurement. Measurement results are tabulated. After measuring, the data can be printed together with exceedances and the sample code with the device's internal printer.

Using the PASWin software developed by Topas it is possible to transfer the measurement results to the PC for further processing. Measurement procedures can be specified with start/pause/stop.

Specifications	LAP 340
Particle size measuring range	0.3-10 μm^{-1}
Channels	max. 16
Measuring flow rate	28.3 l/min ⁻¹

*) Other configurations available on request



Isokinetic sampling probe SYS 529, rectangular shaped, with antistatic tube for connection to cleanroom particle counter

Considering the isokinetics, sampling probes have usually been produced and used in round design. But the international standard ISO 14644 recommends probes with rectangular cross section, as these have a number of advantages compared to the round design model. The Topas sampling probes have a rectangular cross-section at the suction site, which merges into a circular cross-section for the hose connection. The design of the probe is based on the ISO 14644. Thereafter, a maximum permissible width to length ratio of 1:6 is required.

Advantages of the rectangular shape:

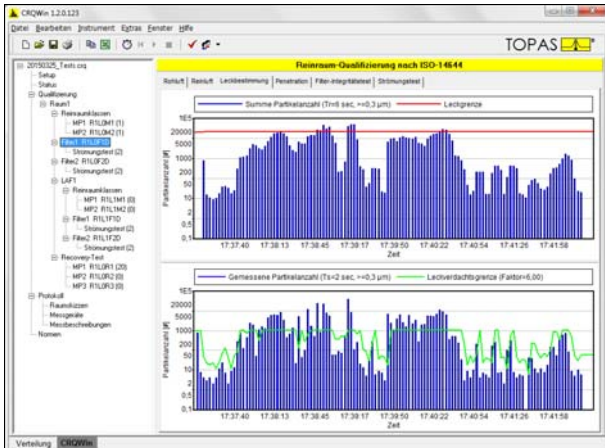
- Reliable sampling
- Precise scanning into the filter corners
- Design in accordance with ISO 14644-3
- Shorter scan times due to larger probe width (perpendicular to the scan direction)

The described Topas devices have been developed according to the following standards:

- VDI 2083:** Cleanroom technology -Metrology and test methods
- VDI 3491:** Particulate matter measurement – production and dilution of test aerosols
- ISO 21501-4:** Verification and calibration of Light scattering airborne particle counters for clean spaces
- EN 1822-4:** High efficiency air filters (EPA/HEPA/ULPA) - Determining leakage of filter elements (scan method)
- ISO 14644-3:** Cleanroom classification – Test methods
- EN 12469:** Performance criteria for safety cabinets and verification
- DIN 12980:** Testing of safety cabinets for handling cytotoxic substances
- EN 1946-4:** Ventilation and air-conditioning technology - et al. qualification of operating rooms



Software for Cleanroom Validation CRQWin



Cleanroom Qualification Software CRQWin 1.2

Principle

CRQWin has been developed according to the standards ISO 14644 and GMP (*Goods manufacturing practice*) as an extension of the Particle Analysis Software PASWin. The software enables the structured acquisition, storage, presentation and analysis of all required measurements for cleanroom classification.

Supported qualification measurements

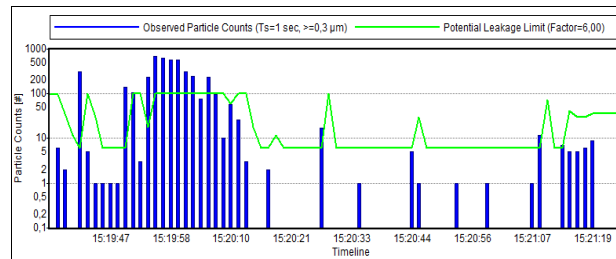
- Classification of the cleanliness class
- Recovery Test
- Data acquisition for filter performance
- Filter Integrity Test / Leakage Test
- Air flow test for non-unidirectional flow
- Data acquisition for difference pressure test of adjacent rooms

Clean Room Qualification according to ISO					
Clean Room Classes	Filter Integrity	Recovery	Airflow Test		
Room/System	Norm Class	Norm Class	Status	Status	
	Target	Measured	Code	Text	
Room1	GMP C	GMP -	NOM	Not measured	
Demo-Room	ISO 8	ISO 8	PAS	Passed	
Demo-Room LAF1	ISO 9	ISO -	NOM	Not measured	

Status tables as a result overview

Special Advantages

- Significant time saving and error prevention
- Supports simultaneous measurement with multiple particle counters
- Support for other tests such as Flow test, temperature and humidity
- Free configurable time intervals
- Realtime measurement and data recording, analysis and reporting
- Multitasking capable Windows-application



Counting-Statistic versus time

Applications

- In all cleanroom areas
- Evaluation of laminar flow boxes and cytostatic work benches

QMS certified to DIN EN
ISO 9001



12 100 11908 TMS

For more information please
visit our website at
www.topas-gmbh.de

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