User Requirement Specification (URS)

For

Particle Counter

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Date	1403.02.01	1403.02.01	1403.02.01	1403.02.02	1403.02.02

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1. Purpose and Scope

This standard establishes a test procedure for evaluating the performance of air cleaning devices as a function of particle size. This document is applicable on testing for spot-checking real-time cleanliness during operation, root out contamination and creating standardized testing routine for long-term monitoring and data logging.

2. Responsibility

1. The expert of IPQC unit is responsible for preparing URS.
2. The manager and head of the QC are responsible for the approval of this document.
3. The quality assurance manager and technical officer are responsible for approving this document.

3. Overview

Optical particle counters (OPC) or spectrometers employ a small sensing volume, either by a focused incandescent lamp or by a laser source. In such instruments it is important to avoid coincidence errors resulting from more than one particle in the sensing volume. The instrument manufacturer specifies the maximum number concentration which can be handled. Generally, commercial instruments handle concentrations of up to ~10^6 particles/litre. Beyond this concentration limit, sample dilution is usually used, which decreases the accuracy of the determination of the concentration. The range of particle diameter that single-particle instruments are capable of handling is ~0.1 μm. Optical particle counters have found wide use, first in cleanroom monitoring and more recently in community air pollution and industrial hygiene studies. A number of laboratory instruments employing single-particle scattering have been constructed. A critical review of such instruments is given by Chigier and Stewart.

Based on previous light scattering experiments, the development of airborne particle counters and sizers started in the middle of the twentieth century and accelerated in the 1960s after the invention of lasers.

The particle size distribution in single-particle counters is determined by comparing the detected pulse heights of the optical signals that correspond to the single particle flow through a small illuminated zone with a standard calibration curve, obtained from a set of uniform particles of known diameter. For determination of the concentration, the flow rate (the volume to be tested) is also measured simultaneously. The different light detection geometries applied in different particle counters yield a wide range of instrument designs and constructions. As the dependence of the scattered intensity on the refractive index of

the particles is less pronounced around 90° of scattering angle, in most airborne particle counters perpendicular scattering geometry is implemented.

4. Operational Requirements

4.1 Function specification

Mass Ranges	PM1, PM2.5, PM4, PM7, PM10, TSP
Concentration Range	0-3000000 particles per cubic foot (105900 particlrs/L)
Accuracy	± 10% to calibration aerosol
Sensitivity	High = 0.3 µm, Low= 0.5 µm
Flow Rate	0.1 CFM (2.83 L/min)
Sampling Time:	60 seconds
Hold Time	Adjustable_ 0 to 999 seconds
Electrical	
Light Source	Laser Diode, 90 mV, 780 nm
AC Adapter/Charger	Li-ion battery charger, 100-240 VAC, 50/60 Hz, 0.2 A
Battery	7.4 v Li-ion battery pack
Battery Life	24 hours intermittent operation, 10 hours continues operating
Battery charge Time	Fully changed in 2.5 hours
Communication	USB, RS-232 or RS-485 Mini B Type
Interface	
Display	16 character × 4 line LCD
Keyboard	7 key membrane type
Physical	
Height:	6.25" (15.9 cm)

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4.2 Capacity

N.A

4.3 Process Requirements

N.A

4.4 Process Control

N.A

4.5 User Interface

N.A

4.6 Data and Security

N.A

5. Environment

This device is placed in cleanroom where you'll find particle counters.

6. Constraints

6.1 Milestones and Timelines

N.A.

6.2 Equipment Constraints

N.A

6.3 Compatibility and Support

N.A

6.4 Availability/Maintenance

N.A

6.5 Access Level

N.A

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6.6 Procedural Constraints

- Since the handheld particle counter is small, it does not force airflow. Thus, due to the

lower airflow, it can take longer than other particle counter options to produce reading.

- A handheld particle counter is designed for spot checks, so it does not integrate well into a real time system.

7. Lifecycle

7.1 Development

N.A

7.2 Testing

- Verify that all aspects of the cleanroom system which contribute to its operational integrity (air handling, filtration systems, walls, ceilings, floors, etc.) are complete and functioning. The following primary tests shall be completed prior to performing the cleanliness classification tests:
  - Airflow test
  - Filter leak test
  - Room pressurization test
- The Cleanroom has been purged for at least 12 hours before testing commences.
- The rooms are divided into test grids as per minimum sampling locations requirement by ISO 14644-1:2015.
- The counter's sample rate is set to 1 m^3/min and the sampling time set to 1 minute or as required.
- A minimum of 1 sample is taken at each grid, at a height of 1 meter above the floor.
- When an obstruction is encountered, the sample is to be taken at 300 mm above the obstruction.

7.3 Delivery/ Documentation

The manufacturer must comply with good documentation practice and deliver the necessary documentation to prove that the facility, system and equipment is constructed according to GMP guidelines and in line with our URS. Thus, it must be documented that the materials used are compliant with GMP guidelines and the appropriate validation tests have been performed. Checklists should be used to validate that all parts of construction, equipment and systems are in concordance with GMP guidelines. These should include,

but not be limited to: the material used, quality specification, certificates, test methods/protocols, responsible test person, number of tests performed, test results, transfer plans and reports, IQ, OQ, PQ, Certificate of Analyses (CoA) /Compliance (CoC), validation and documentation

7.4 Support and training

Training course should be performed by manufacturer on the site.

8. References

- ISO 14644-1:2015(E) Cleanrooms and associated controlled environments-Part 1: Classification of Air Cleanliness by Particle Concentration.
- ISO 21501-4:2018 Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces

9. Attachments

N.A

10. Definitions, Acronyms and Abbreviations

N.A

11. Document Distribution

Department	Version
Original version	QA
Copy No. 1	QC

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