



BSI Standards Publication

Determination of particle size distribution — Single particle light interaction methods

Part 1: Light scattering aerosol spectrometer

National foreword

This British Standard is the UK implementation of ISO 21501-1:2025. It supersedes BS ISO 21501-1:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/37, Particle characterization including sieving.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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**Determination of particle size
distribution — Single particle light
interaction methods —**

**Part 1:
Light scattering aerosol
spectrometer**

*Détermination de la distribution granulométrique — Méthodes
d'interaction lumineuse de particules uniques —*

Partie 1: Spectromètre d'aérosol en lumière dispersée

**Second edition
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 24, *Particle characterization including sieving*, Subcommittee SC 4, *Particle characterization*.

This second edition cancels and replaces the first edition (ISO 21501-1:2009), which has been technically revised.

The main changes are as follows:

- alignment with ISO 21501-4;
- addition of [Annex F](#) addressing counting efficiency.

A list of all parts in the ISO 21501 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Particle size distributions and particle number concentrations must be monitored in various fields, e.g. in filter manufacturing, in the electronic industry, in the pharmaceutical industry, in the chemical industry, in the manufacture of precision machines and in medical operations. The aerosol spectrometer is a useful instrument for the determination of the size distribution and number concentration of particles suspended in a gas.

The purpose of this document is to provide the calibration procedure and the validation method for aerosol spectrometers, so as to improve the accuracy of the measurement result by aerosol spectrometers in general, and to minimize the difference in the results measured by different instruments.

The light scattering technique described in this document is based upon single particle measurements. The size range of particles measured by this method is between approximately 0,06 μm to 45 μm in diameter.

Instruments that conform to this document are used for the determination of the particle size distribution and particle number concentration at relatively high concentrations of up to 10^{11} particles/ m^3 .

Determination of particle size distribution — Single particle light interaction methods —

Part 1: Light scattering aerosol spectrometer

1 Scope

This document specifies characteristics of a light scattering aerosol spectrometer (LSAS) which is used for measuring the size, number concentration and number-based size distribution of particles suspended in a gas. This document provide the calibration procedure and the validation method for aerosol spectrometers.

This document applies to:

- characterization of metered dose inhalers (MDI), dry powder inhalers (DPI) and nebulizers in pharmacy;
- production control of active agents;
- cut-off determination: impactors, cyclones and impingers;
- atmospheric aerosols: bio-aerosols, stables or composting facilities, nebulized droplets, measurements in street tunnels;
- fractional separation efficiency determination of filters.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

particle

discrete element of the material regardless of its size

[SOURCE: ISO 2395:1990, 3.1.1]

3.2

aerosol

airborne particles and the gas (and vapour) mixture in which they are suspended

Note 1 to entry: In general, one divides the atmospheric aerosol into three size categories: the ultrafine range $x < 0,1 \mu\text{m}$, the sub-micrometre range $0,1 \mu\text{m} < x < 1 \mu\text{m}$ and the super-micrometre range $x > 1 \mu\text{m}$, where x is the particle diameter.

[SOURCE: ISO 4225:2020, 3.1.3.1, modified — Note 1 to entry added.]

3.3

particle size

diameter of a spherical particle determined by a specified measurement method and under specified measurement conditions

Note 1 to entry: See also [3.4](#).

Note 2 to entry: There is no single definition of particle size. Different methods of analysis are based on the measurement of different physical properties. The physical property to which the equivalent particle diameter refers shall be indicated using a suitable subscript or reference to the documentary measurement standard according to which the particle size was measured.

Note 3 to entry: In the whole series of ISO 9276, the symbol x is used to denote the particle size or the diameter of a sphere. However, it is recognized there that the symbol d is also widely used to designate these values. Therefore, the symbol x may be replaced by d where it appears.

3.4

equivalent particle diameter

diameter of the sphere with defined characteristics which behaves under defined conditions in exactly the same way as the particle being described

3.5

light scattering equivalent particle diameter

x_{sca}

diameter of a homogeneous sphere of a reference substance (e.g. latex) which scatters defined incident light with the same radiation efficiency into a defined solid angle element

3.6

particle concentration

indication of, e.g. particle numbers, particle mass, particle surface related to the unit volume of the carrier gas

Note 1 to entry: For the exact concentration indication, information on the gaseous condition (temperature and pressure) or the reference to a standard volume indication is required.

3.7

coincidence error

probability of the presence of more than one particle inside the sensing volume simultaneously

Note 1 to entry: Coincidence error is related to particle number concentration and size of sensing volume.

3.8

counting efficiency

relation of the concentration determined from the counting rate of the measuring instrument and the real concentration of the aerosol at the inlet of the instrument, or ratio of the particle number measured by an LSAS to that introduced to the LSAS for a given sampling time

3.9

border zone error

particle sizing error that occurs when particles pass through the optical border of the sensing volume

3.10

light scattering aerosol spectrometer

LSAS

instrument that measures airborne particle numbers by counting the pulses as the particles pass through the sensing volume, and also particle size by scattered light intensity

Note 1 to entry: The optical particle size measured by the LSAS is the light scattering equivalent particle size and not a geometrical size.

Note 2 to entry: The principle of the instrument is described in [Annex A](#).

3.11**lower size limit**

smallest particle diameter with which the counting efficiency is $0,5 \pm 0,15$

3.12**upper size limit**

largest diameter with which the counting efficiency is $0,5 \pm 0,2$

3.13**size range**

distance between lower and upper size limit of quantification

3.14**reference instrument**

reference particle counter is a counter that exhibits no particle losses or, if losses occur, these are small (e.g. below 5 %), well characterized and taken into account during data evaluation

4 Requirements**4.1 Introduction**

Aerosol spectrometers should determine the particle size distribution and particle number concentration as accurately as necessary. For this purpose, they should have appropriate size resolution, sizing accuracy, counting efficiency and flowrate accuracy. These aerosol spectrometers are not suitable for the classification of clean rooms.

The effects of LSAS parameters are described in [Annex C](#). The representative samplings are described in [Annex D](#).

4.2 Counting efficiency

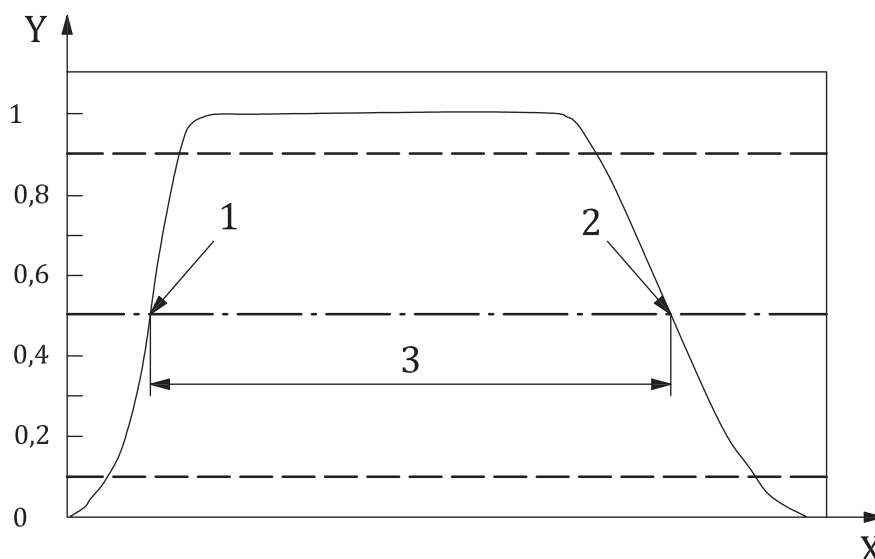
The counting efficiency is the relation of the particle number concentration $C_{N, \text{measured}}$ — determined from the counting rate of a device and corrected for possible coincidence errors — to the real particle number concentration $C_{N, \text{actual}}$ of the aerosol at the inlet of the device. The counting efficiency $[\eta(x)]$ is a function of the particle size and is expressed as the ratio shown in [Formula \(1\)](#).

$$\eta(x) = \frac{C_{N, \text{measured}}(x)}{C_{N, \text{actual}}(x)} \quad (1)$$

The counting efficiency is also a function of signal processing, the homogeneous illumination of the sensing volume and the extent to which the particles enter the sensing volume and flow rate.

[Figure 1](#) shows a graphical representation of counting efficiency. In an ideal case, the counting efficiency in the middle of the measuring range (as represented in [Figure 1](#)) has the value one. If an experimental examination results in a value deviating from one, then this is to be accounted for as a correction to the measurement result. For a proper evaluation of a measuring instrument, it is useful to determine the complete counting efficiency curve, or to indicate the particle diameters corresponding to values of the counting efficiency (e.g. at 0,1 and 0,9) besides those corresponding to a counting efficiency value of 0,5 at lower size limit.

The counting efficiency shall be within 0,30 to 0,70 [corresponding to $(50 \pm 20) \%$] for calibration particles with a diameter close to the lower size limit. It shall also be within 0,90 to 1,10 [$(100 \pm 10) \%$] for calibration particles with diameter ranging from twice the lower size limit up to 10 μm or up to the maximum diameter of the plateau region stated for the instrument if this is smaller. The counting efficiency can be determined according to [4.5](#).

**Key**

X	particle size
Y	counting efficiency $\eta(x)$
1	lower size limit
2	upper size limit
3	size range

NOTE [Figure 1](#) shows a graphical representation of the counting efficiency.^[5]

Figure 1 — Counting efficiency

4.3 Size resolution

The size resolution indicates which neighbouring particle sizes a particle measuring instrument can still differentiate between and record separately. Aerosol spectrometers should determine the particle size distribution and the particle number concentration as accurately as possible with high size resolution and good sizing accuracy. The size resolution depends on particle size.

Almost all measuring instruments determine the particle number concentration in a limited number of size classes which are firmly specified by the instrument design (e.g. instrument geometry, evaluation electronics, evaluation software). In practical operation, the size resolution of an LSAS cannot be better than the width of its size classes.

The size resolution shall be less than or equal to 0,15 (corresponding to 15 % of the specified particle size), when it is evaluated using calibration particles of a certified average size specified by the manufacturer. The size resolution can be determined according to [4.4](#).

4.4 Sizing accuracy

The sizing accuracy depends on the particle size. Therefore, the sizing accuracy can be evaluated for any particle size as shown in [Formula \(2\)](#).

$$\varepsilon(x) = \frac{x_s - x_r}{x_r} \times 100 \quad (2)$$

where

$\varepsilon(x)$	is the ratio of particle size difference, in %;
x_r	is the particle size of the size certified traceable particles, in μm ;
x_s	is the particle size indicated by the LSAS, in μm .

The sizing accuracy of an LSAS describes the difference between the actual calibration particle size and the particle size indicated by the instrument. The correlation between the particle size and size class stated by the manufacturer (channel number) is normally based upon a calibration of the instrument with a known test aerosol [mostly polystyrene latex (PSL) particles]. Refer to [Annex E](#).

4.5 Sampling flow rate

The sampling flow rate is the volumetric flow rate entering the LSAS and the error in the sampling flow rate shall be within 5 %. Typical sampling flow rate is about 0,5 l/min to 5 l/min.

4.6 Effective flow rate through the sensing volume

The effective flow rate through the sensing volume is the volumetric flow rate through either the optically or aerodynamically, or both, limited sensing volume. For particle number concentration measurements, the effective flow rate through the sensing volume shall be evaluated. If the geometrical dimensions of the sensing volume are exactly known, the effective flow rate through the sensing volume can be determined by measuring the transit time of the particles through the sensing volume. Otherwise, the effective flow rate through the sensing volume shall be determined by a calibration experiment according to [4.2](#).

4.7 Maximum particle number concentration

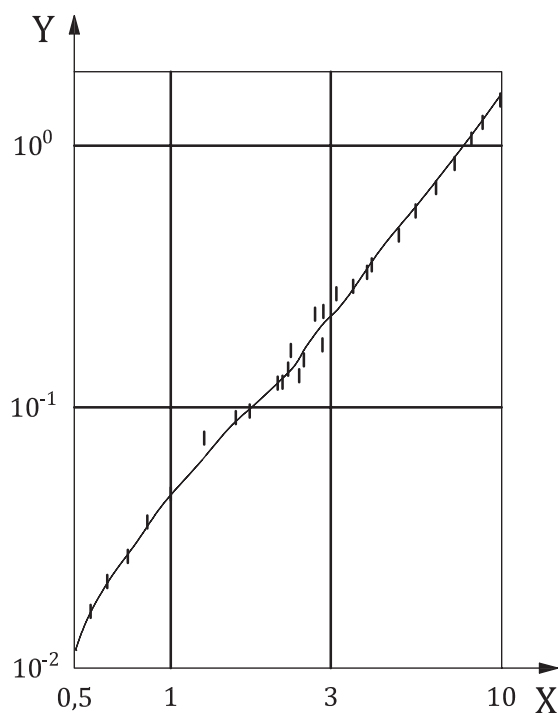
The LSAS must be able to measure in high particle number concentrations up to 10^5 particles/cm³ and the maximum particle number concentration shall be specified by the manufacturer. According to [4.3](#), the coincidence loss at the maximum particle number concentration of an LSAS shall be equal to or less than 10 %.

5 Test method

5.1 Size calibration

The light scattered by the individual particles is detected and transformed into a voltage pulse. These pulses are classified according to their height in a multi-channel analyser (MCA). The result is a count rate histogram. This histogram is transferred into a particle size distribution by applying the calibration curve. This calibration curve, which is instrument specific, shall be determined either experimentally or theoretically. Normally, aerosol spectrometers are calibrated with monodisperse test aerosols of known (traceable) size and refractive index. [Figure 2](#) shows a theoretical calibration curve.

For the production of monodisperse test aerosols, several generation principles can be used. The size distribution of test aerosols with small variances are obtained if aqueous suspensions of PSL particles are nebulized, dried and drawn through the instrument. Dry powder monodisperse PSL particles are also useful for calibration.

**Key**

X particle size, in μm
 Y relative scattered light intensity

NOTE Vertical bars are monodisperse particle experimental data.[\[14\]](#)

Figure 2 — Theoretical calibration curve

Other techniques of providing narrow distributed aerosols are the vibrating-orifice generator, the Sinclair and La Mer aerosol generator (SLG) or passing a polydisperse aerosol through a differential electrical mobility classifier (DEMC) or aerodynamic aerosol classifier (AAC), which extracts particles within a narrow size range according to their electrical mobility or aerodynamic relaxation time, respectively.

5.2 Effective flow rate through the sensing volume

The flow rate through the sensing volume is obtained by relating the instrument particle count rate to a reference particle number concentration measurement using an instrument with a higher particle number concentration range than the instrument to be calibrated and that is traceable to internationally accepted standards. [Figure 3](#) shows an effective flow rate and counting efficiency test set up.

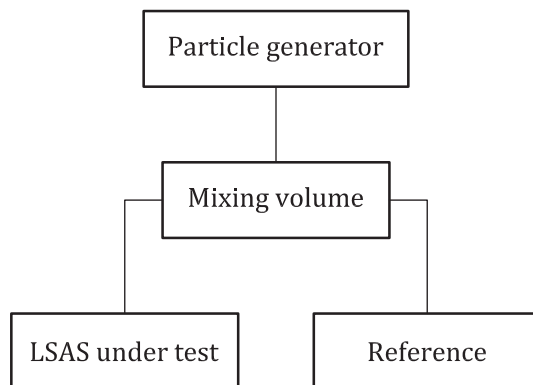


Figure 3 — Effective flow rate and counting efficiency test set-up