

MET ONE ISO 21501 Certified Air Particle Counter Calibration

Ensure count accuracy and reproducibility

Features and Benefits

ISO 21501 is a new family of standards describing the instruments and calibration requirements for determining particle size distribution using light interaction methods. It represents the culmination of work by instrumentation manufacturers and industry leaders and comes at a critical time for the industry with the increasing trend for real-time air particle monitoring in cleanrooms.

Air Particle Counters and ISO 21501

The calibration of an air particle counter presents challenges due to the need to generate air samples containing sub-microscopic particles of homogenous size and distribution. Although the technology of air particle counting is well understood, the ability to calibrate any two air particle counters so that they produce the same results when sampling the same air sample has proven to be difficult, bringing into question the accuracy of these instruments. ISO 21501 now delivers a calibration method that can significantly improve the repeatability and reproducibility of these air particle counters.

CoreCal 3 Calibration

Hach's MET ONE brand is the global leader in particle counting and has the largest installed base of air particle counters in the world. To support this base, Hach's calibration system, CoreCal 3, was designed and developed to perform full ISO 21501 compliant calibrations. The CoreCal 3 system, backed by globally deployed calibration tools, procedures and technician training, has enabled all of Hach's worldwide service teams to provide ISO 21501 compliant calibrations at your site or at the company's local service depots.



The International Standards Organization (ISO) has introduced a new standard for the calibration of air and liquid particle counters. This new standard, ISO 21501, incorporates a number of new tests that are designed to reduce count variability between different instruments.

Specifically, the standard specifies new counting resolution and counting efficiency tests be performed at routine calibration cycles, typically every six or twelve months. ISO 21501 compliant calibrations for air particle counters will become mandatory for aseptic filling under EU-GMP Annex 1 and FDA cGMP Guidance.



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Specifications

From the ISO 21501 Standard:

"The purpose of ISO 21501 is to provide a calibration procedure and verification method for particle counters, so as to minimize the inaccuracy in the measurement result by a counter, as well as the differences in the results measured by different instruments."

The full list of elements that ISO 21501 requires to be tested are as follows:

Size calibration: The error in the detectable minimum particle size and other sizes specified by the manufacturer of an air particle counter shall be equal to or less than $\pm 10\%$.

Counting efficiency: The counting efficiency shall be $(50 \pm 20)\%$ for calibration particles with a size close to the minimum detectable size, and it shall be $(100 \pm 10)\%$ for calibration particles with a size of 1.5 times to 2 times larger than the minimum detectable particle size.

Size resolution: The size resolution shall be equal to or less than 15% for calibration particles of a size specified by the manufacturer.

False count rate: The false count rate is determined by measuring the particle number concentration in the unit of counts per cubic meter at the minimum reported size range when sampling clean air.

Concentration limit: The coincidence loss is determined by the flow rate, the time required for particles to pass through the sensing zone and the electrical signal processing time. These values are determined by the design of the air particle counter.

Sampling flow rate: The standard uncertainty of volumetric flow rate shall be equal to or less than $\pm 5\%$. An external flow meter is used to measure the volumetric flow rate of the sample being taken. Volumetric flow measurements allow for greater accuracy by removing the variance due to altitude.

Sampling time: The standard uncertainty in the duration of sampling time shall be equal to or less than $\pm 1\%$ of the preset value. Sampling time is measured by comparing the sample time as directed by the instrument under test to a calibrated stopwatch or timing device.

Calibration interval: It is recommended that the calibration interval of an air particle counter be one year or less. Calibration at the calibration interval should include at least size calibration, size resolution, counting efficiency and sampling volume uncertainty.

Current instruments designed to comply with ISO 21501 Calibration:

MET ONE 3400 Series, MET ONE 6000 Series and MET ONE 7000 Series
Other legacy instruments may comply. Please contact Hach technical support for further information.

Only Hach certified and trained Field Service Engineers and agents with the Hach CoreCal 3 calibration tool and reference instrument are able to perform fully ISO 21501 compliant calibrations on MET ONE air particle counters.

For more information and to receive a copy of the ISO 21501 Sourcebook:
www.hach.com/iso21501



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In the interest of improving and updating its equipment, Hach Company reserves the right to alter specifications to equipment at any time.

At Hach, it's about learning from our customers and providing the right answers. When it comes to the things that touch our lives...

***Keep it pure.
Make it simple.
Be right.***

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