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# What to Expect From an ISO/IEC 17025 Calibration

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July 2019

## What to expect from your ISO/IEC 17025 Calibration?

ISO/IEC 17025 is a quality standard, developed jointly by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) that defines requirements for laboratories to ensure quality, reliability, and repeatability of performed tests or calibrations. With regards to particle counting, this holds manufacturers to maintain the standard set forth by ISO 21501-4.

Calibration certificates issued by ISO/IEC 17025 accredited laboratories will cover the following parameters:

- **Size Setting Error-** The size setting error is the deviation from the particle counters programmed sizes. The pass/ fail criteria as per ISO 21501-4:2018 is  $\pm 10\%$  of the particle size. The Uncertainty of each particle size is stated in  $\mu\text{m}$ .
- **Counting Efficiency-** The counting efficiency is determined by comparing a unit to a NIST (National Institute of Standards and Technology) traceable unit with a higher sensitivity. The ISO 21501-4 standard dictates a tolerance of 50% ( $\pm 20\%$ ) of the minimum detectable size, and 100% ( $\pm 10\%$ ) of a size 1.5 – 2 times larger than the minimum. The uncertainty is stated in percent counting efficiency.
- **Sampling Flow Rate Error-** The sampling flow rate tolerance is  $\pm 5\%$  of the stated rate for the unit. The flow value uncertainty is stated in LPM.
- **Size Resolution-** The size resolution will be stated with the particle size used in  $\mu\text{m}$  and the criteria of less than 15% as stated per ISO 21501-4. The uncertainty will be stated in percent size resolution.
- **False Count-** The false count (also known as a zero-count test) is the number of particles detected on the minimum detectable channel in a certain volume of air stated at a 95% upper confidence level. We also state the false count rate in accordance with JIS B 9921, which gives a limit of one count per five minutes. Both values are stated as observed counts per five minutes.

## What is uncertainty regarding ISO 21501-4?

Uncertainty of measurement is the doubt that exists about the results of any measurement. It is important to remember that with any device that yields a measurement there always will be some measurement of doubt. The uncertainties stated on our calibration certificates are all traceable. The uncertainties stated rely on the accuracy and specifications of our test equipment and reference particles. The formulas for calculating the uncertainty for the five parameters can be found in 21501-4:2018 Annex A:E.

## Why is an ISO/IEC 17025 Calibration important?

ISO 21501-4 is the standard that has been used by most particle counter manufacturers to develop and produce their instruments. By being accredited ISO/IEC 17025, we have demonstrated to an accrediting body of auditors that we do more than just claim ISO 21501-4 compliance – we prove our technical competence and document it. The audit process evaluated our calibration and intermediate testing of reference equipment, calibration of customer equipment, proficiency testing between laboratories, and a wide range of other technical applications outlined in the ISO 21501-4 standard. With an ISO/IEC 17025 accredited calibration, you are guaranteed a fully documented chain of ISO-compliant calibration data tracing back to appropriate-stated references.