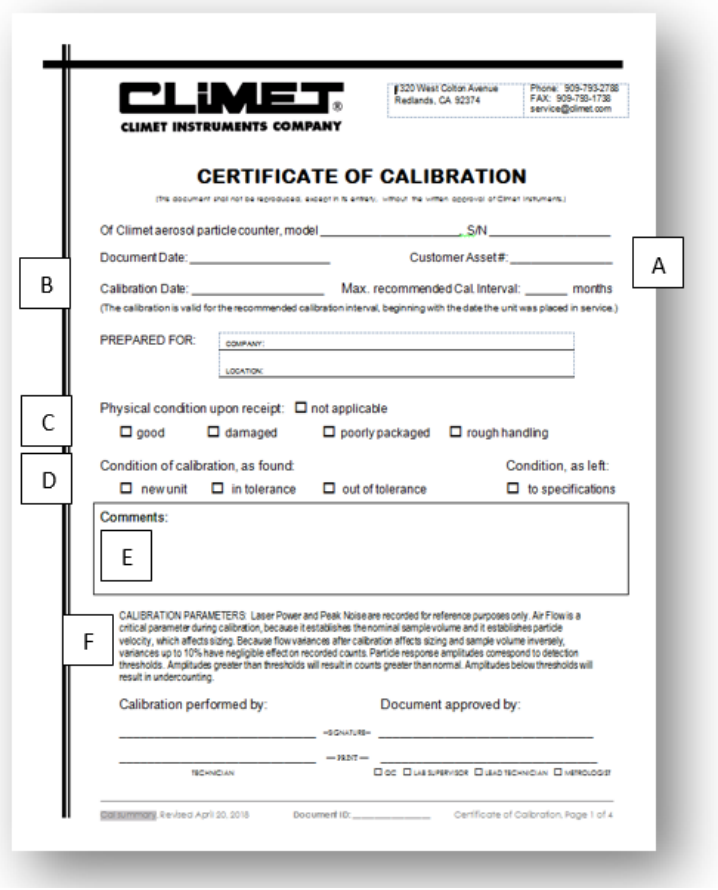
A Division of Venturedyne Ltd.
1320 West Colton Avenue ♦ Redlands, California 92374

UNDERSTANDING CALIBRATION DOCUMENTS

Application Note: 20210609A

Revision 1.0 (June 2021)

The Calibration Summary Page



The summary page contains information required by calibration standards, including identification of the instrument, model number, serial number, and the company for whom the instrument was calibrated.

A place is provided [A] for the customer's asset number. This is filled in if we know what the asset number is. (Some companies have more than one asset number on their equipment.)

The date the document was created and the date that the instrument was calibrated is recorded at [B].

The physical condition of the instrument [C] is provided as feedback, since poor packaging can lead to damage in shipment.

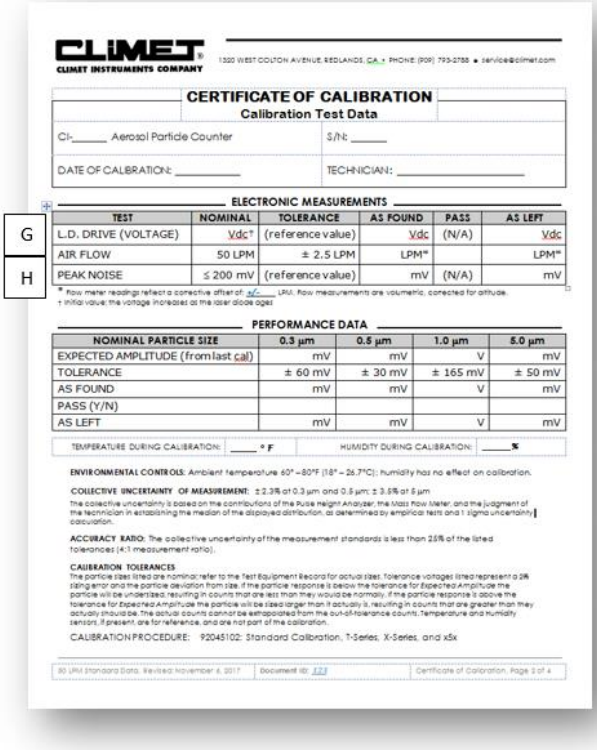
The *as found* calibration status [D] is recorded, and the *as left* status: *To specifications*, is checked to provide quick affirmation that the unit met specifications after the calibration was completed.

The *Comments* box [E] is used to note anything relevant to the calibration.

The paragraph below [F] briefly explains parameters calibrated.

This page is signed by the calibration technician and the person that reviews the procedure.

The Calibration Data Page



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CERTIFICATE OF CALIBRATION
Calibration Test Data

CI-_____ Aerosol Particle Counter — S/N: _____
DATE OF CALIBRATION: _____ — TECHNICIAN: _____

ELECTRONIC MEASUREMENTS

	TEST	NOMINAL	TOLERANCE	AS FOUND	PASS	AS LEFT
G	L.D. DRIVE (VOLTAGE)	Vdc†	(reference value)	Vdc	(N/A)	Vdc
	AIR FLOW	50 LPM	± 2.5 LPM	LPM*		LPM*
H	PEAK NOISE	≤ 200 mV	(reference value)	mV	(N/A)	mV

* Flow meter readings reflect a corrective offset of +/- ___ LPM. Flow measurements are volumetric, corrected for altitude.
† Initial value; the voltage increases as the laser diode ages

PERFORMANCE DATA

NOMINAL PARTICLE SIZE	0.3 µm	0.5 µm	1.0 µm	5.0 µm
EXPECTED AMPLITUDE (from last cal)	mV	mV	V	mV
TOLERANCE	± 60 mV	± 30 mV	± 165 mV	± 50 mV
AS FOUND	mV	mV	V	mV
PASS (Y/N)				
AS LEFT	mV	mV	V	mV

TEMPERATURE DURING CALIBRATION: ____ ° F — HUMIDITY DURING CALIBRATION: ____%

ENVIRONMENTAL CONTROLS: Ambient temperature 60° – 80°F (18° – 26.7°C); humidity has no effect on calibration.

COLLECTIVE UNCERTAINTY OF MEASUREMENT: ± 2.3% at 0.3 µm and 0.5 µm; ± 3.5% at 5 µm
The collective uncertainty is based on the contributions of the Pulse Height Analyzer, the Mass Flow Meter, and the judgment of the technician in establishing the median of the displayed distribution, as determined by empirical tests and 1 sigma uncertainty calculation.

ACCURACY RATIO: The collective uncertainty of the measurement standards is less than 25% of the listed tolerances (4:1 measurement ratio).

CALIBRATION TOLERANCES
The particle sizes listed are nominal; refer to the Test Equipment Record for actual sizes. Tolerance voltages listed represent a 2X sizing error and the particle deviation from size. If the particle response is below the tolerance for Expected Amplitude the particle will be undersized, resulting in counts that are less than they would be normally. If the particle response is above the tolerance for Expected Amplitude the particle will be sized larger than it actually is, resulting in counts that are greater than they actually should be. The actual counts cannot be extrapolated from the out-of-tolerance counts. Temperature and humidity sensors, if present, are for reference, and are not part of the calibration.

CALIBRATION PROCEDURE: 92045102: Standard Calibration, T-Series, X-Series, and x5x

90 LPM Standard Data, Revised November 6, 2017 | Document ID: 123 | Certificate of Calibration, Page 2 of 4

The calibration data page records the '*as found'* and '*as left'* measurements made during the calibration. The '*expected values'* are the '*as left'* threshold values from the last calibration.

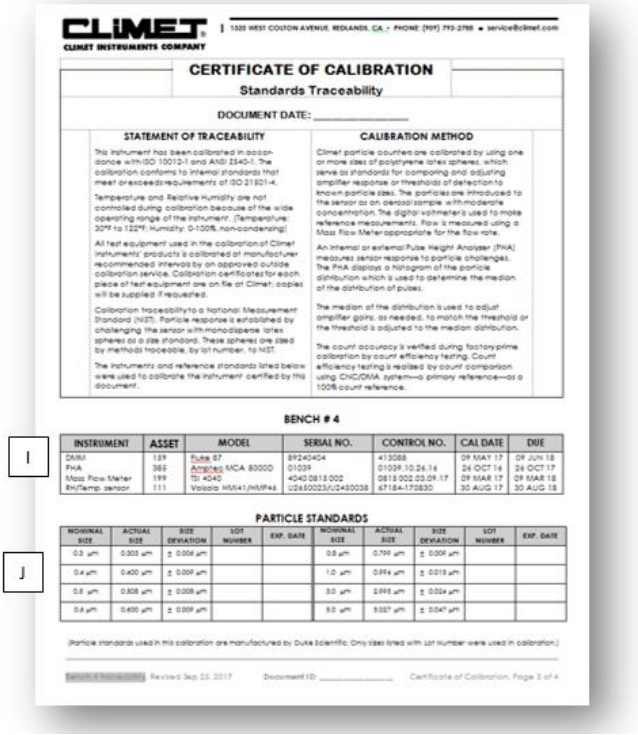
The '*Tolerances'* provided in the **Performance Data Table** are in mV (millivolts) and reflect a 10% count variance. These tolerances are specified by ISO 21501-4:2018 §6.1.

Preventative Maintenance: **Laser Diode drive current** [G] is a reference value with no tolerance because the tolerance is in the signal response. It is used by the technician to evaluate the condition of the laser diode. The technician looks for a value that is 20% above the value first reported when the laser diode was installed, but the technician also compares the values recorded during the last two calibrations to spot a high rate of increase that would predict a laser failure. Laser drive that is within 20% of the original value is still in regulation, and thus does not affect the calibration.

Preventative Maintenance: **Peak Noise** [H] has no tolerance, but it is recorded for as a reference when evaluating whether the sensor needs cleaning as a preventive maintenance. Increased background noise may make it harder to provide consistent calibrations, and contamination build-up on the mirror (the collection optic) can decrease the amplitude of the signal response, resulting in undercounting.

Below the tables are reports on the limits for environmental factors and the uncertainty of measurement. Since measurements are based on particle sizing, rather than on counts, measurement uncertainty does not translate to counts, and has less effect than count efficiency. Count Efficiency should be used to determine the instrument's count bias and to evaluate counts reported by the instrument.

The Traceability Page



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CERTIFICATE OF CALIBRATION

Standards Traceability

DOCUMENT DATE: _____

STATEMENT OF TRACEABILITY

This instrument has been calibrated in accordance with ISO 10012-1 and ANSI Z540-1. The calibration conforms to internal standards that meet or exceeds requirements of ISO 21501-4.

Temperature and Relative Humidity are not controlled during calibration because of the wide operating range of the instrument. (Temperature: 30°F to 122°F; Humidity: 0-100%, non-condensing)

All test equipment used in the calibration of Climet instruments' products is calibrated at manufacturer recommended intervals by an approved outside calibration service. Calibration certificates for each piece of test equipment are on file at Climet; copies will be supplied if requested.

Calibration traceability to a National Measurement Standard (NIST). Particle response is established by challenging the sensor with monodisperse latex spheres as a size standard. These spheres are sized by methods traceable, by lot number, to NIST.

The instruments and reference standards listed below were used to calibrate the instrument certified by this document.

CALIBRATION METHOD

Climet particle counters are calibrated by using one or more sizes of polystyrene latex spheres, which serve as standards for comparing and adjusting amplifier response or thresholds of detection to known particle sizes. The particles are introduced to the sensor as an aerosol sample with moderate concentration. The digital voltmeter is used to make reference measurements. Flow is measured using a Mass Flow Meter appropriate for the flow rate.

An internal or external Pulse Height Analyser (PHA) measures sensor response to particle challenges. The PHA displays a histogram of the particle distribution which is used to determine the median of the distribution of pulses.

The median of the distribution is used to adjust amplifier gains, as needed, to match the threshold or the threshold is adjusted to the median distribution.

The count accuracy is verified during factory prime calibration by count efficiency testing. Count efficiency testing is realized by count comparison using CNC/OMA system—a primary reference—as a 100% count reference.

BENCH # 4

I

INSTRUMENT	ASSET	MODEL	SERIAL NO.	CONTROL NO.	CAL DATE	DUE
DMM	159	Fluke 87	89240404	413088	09 MAY 17	09 JUN 18
PHA	388	Amptek MCA 8000D	01039	01039.10.26.16	26 OCT 16	26 OCT 17
Mass Flow Meter	199	TSI 4040	4040.0815.002	0815.002.03.09.17	09 MAR 17	09 MAR 18
RH/Temp sensor	111	Vaisala HMI41/HMP46	U2650023/U2450038	67184-170830	30 AUG 17	30 AUG 18

PARTICLE STANDARDS

J

NOMINAL SIZE	ACTUAL SIZE	SIZE DEVIATION	LOT NUMBER	EXP. DATE	NOMINAL SIZE	ACTUAL SIZE	SIZE DEVIATION	LOT NUMBER	EXP. DATE
0.3 µm	0.303 µm	± 0.006 µm			0.8 µm	0.799 µm	± 0.009 µm		
0.4 µm	0.400 µm	± 0.009 µm			1.0 µm	0.994 µm	± 0.015 µm		
0.5 µm	0.508 µm	± 0.008 µm			5.0 µm	5.995 µm	± 0.024 µm		
0.6 µm	0.600 µm	± 0.009 µm			8.0 µm	8.027 µm	± 0.047 µm		

(Particle standards used in this calibration are manufactured by Duke Scientific. Only sizes listed with Lot Number were used in calibration.)

Revised Sep 25, 2017 Document ID: _____ Certificate of Calibration, Page 3 of 4

The traceability page contains the traceability statement and a brief description of the calibration method. Each technician's bench has its own traceability page.

It contains tables listing the *test equipment* [I] assigned to the bench, and the *test particles* [J] used as part of the calibration.

Test equipment is defined by type of instrument, the asset number and serial number of the instrument, and the model number. The last calibration date and the calibration due date are included, along with the control number of the calibration certificate.

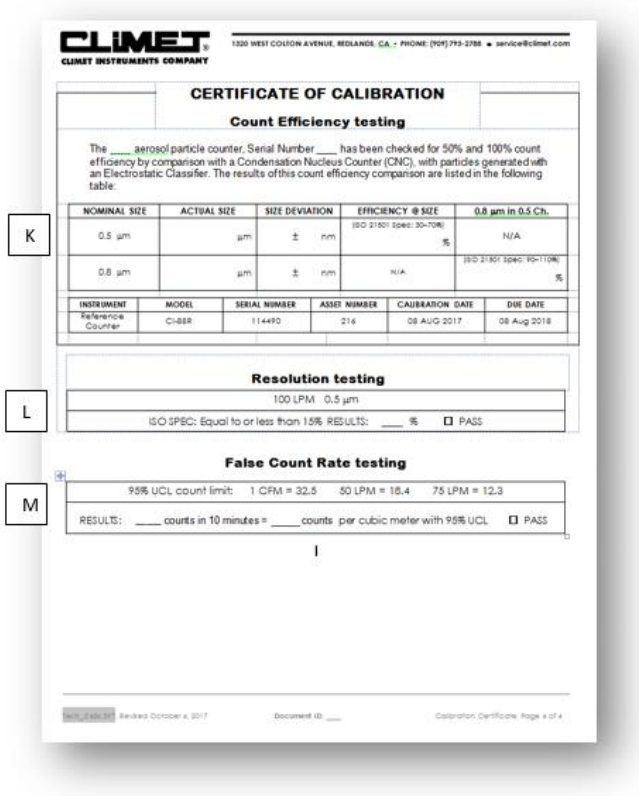
The **particle standards** are identified by nominal size, the actual size, the standard deviation of size, the lot number for traceability, and the expiration date for the particle standards.

The three pages above are included for the ISO 21501-4 compliant calibration.

The Standard calibration is the *size calibration* specified as the calibration method in ISO 21501-4.

This standard also specifies tests to be made following the calibration itself. These tests are reported on a fourth page when the calibration requested is the *ISO calibration*.

The Test Page



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CERTIFICATE OF CALIBRATION

Count Efficiency testing

The ____ aerosol particle counter, Serial Number ____ has been checked for 50% and 100% count efficiency by comparison with a Condensation Nucleus Counter (CNC), with particles generated with an Electrostatic Classifier. The results of this count efficiency comparison are listed in the following table:

NOMINAL SIZE	ACTUAL SIZE	SIZE DEVIATION	EFFICIENCY @ SIZE	0.8 µm in 0.5 Ch.
0.5 µm	µm	± nm	(ISO 21501 Spec: 30–70%) %	N/A
0.8 µm	µm	± nm	N/A	(ISO 21501 Spec: 90–110%) %

INSTRUMENT	MODEL	SERIAL NUMBER	ASSET NUMBER	CALIBRATION DATE	DUE DATE
Reference Counter	CI-8BR	114490	216	08 AUG 2017	08 Aug 2018

K

Resolution testing

100 LPM 0.5 µm	
ISO SPEC: Equal to or less than 15% RESULTS: ____ %	☐ PASS

L

False Count Rate testing

95% UCL count limit: 1 CFM = 32.5	50 LPM = 18.4	75 LPM = 12.3
RESULTS: ____ counts in 10 minutes = ____ counts per cubic meter with 95% UCL		☐ PASS

M

Revised October x, 2017 Document ID: ____ Calibration Certificate Page x of x

The test page is supplied with ISO 21501-4 compliant calibrations.

The count efficiency table lists the results of the 50% count efficiency test and the 100% count efficiency test.

The **50% Count Efficiency** test is based on the smallest channel. The threshold for a given channel represents the median of the particle distribution. Under the JIS 9921 standard, this was important, because it assured that 0.1 µm particle counters used in the semiconductor industry were true 0.1 µm instruments, at least within 20 percentage points. ISO 21501-4 sets the acceptable tolerance to 50% ± 20%. Climet finds this much too loose, and has established our own standard of ± 10% for new production particle counters.

The **100% Count Efficiency** test is the important test, because it reports the bias of the instrument, that is, to what degree the instrument undercounts or overcounts. For example, if an instrument has 95% count efficiency, multiplying the counts reported for a given sample by 1.05 will correct for the bias of the instrument, and correcting for the bias of other instruments will provide counts that are more consistent between instruments. The standard allows a variance of ±10% from 100%.

There are no adjustments for fine-tuning count efficiency. The test only verifies that the count efficiency of the instrument meets ISO 21501-4 specifications. While it provide no performance improvement, auditors are increasingly expecting to see evidence of count efficiency testing.

Table [L] reports the results of resolution testing. The limit for resolution is 15%. Resolution is a product of the flow rate of the instrument and the laser diode installed. There is no way to fine tune resolution. Passing resolution assures that particles corresponding to the size of one channel do not overlap the threshold of the next channel and add to the counts in that channel. Because of design choices, it is virtually assured that a Climet particle counter will pass the resolution test.

The False Count Rate (FCR) indicates the potential false counts, with 95% Upper Confidence, that might be reported in a cubic meter sample. ISO 21501-4 does not specify an acceptance criterion. Climet uses ten 1-cubic meter samples during manufacturing to define the FCR. In analyzing the cost benefit of this test in terms of value of the data versus time and expense, Climet has limited this test to 10 minutes for interval calibrations. This keeps costs to the customer down and does not add to delays in returning equipment to the

customer because of the time added to the calibration if longer tests were implemented.

Climet has established a specification of 4 counts in ten minutes in the 0.5 µm channel. Based on a 10-minute sample for a 1 CFM particle counter, the 95% UCL value for 4 counts is 32.5 counts. To put this in perspective, the ISO Class 5 limit for 0.5 µm particles is 3,520 counts, so 32.5 counts represents only 0.92% of the room limit. Even if typical counts were around 1,000, this would only represent a 3% increase in counts.

It is highly unlikely that false counts as high a 4 counts in 10 minutes would violate a room, and if it did, the false count rate should not be the focus of a deviation investigation. A longer test would produce lower 95% UCL counts, but given the limited value of this test, a longer test during the interval calibration would not add value to the calibration.

Testing not included

ISO 21501-4 specifies requirements for the calibration report, but elsewhere it lists requirements for a particle counter that are not tests or are not appropriate at the interval calibration.

- **Maximum particle number concentration**
  ISO 21501-4:2018, §6.5

  The concentration limit is a mathematical calculation made during design. It is a product of the flow rate and the inlet nozzle dimensions. It is not a test. The concentration limit is reported in the User's Manual, not on the calibration report.

- **Sample Time Error**
  ISO 21501-4:2018, §6.7

  In a Climet particle counter, the ***sample time*** is controlled by the real time clock chip. The chip has an accuracy of at least 1 second in 7 hours. These chips are extremely reliable, and a failure would be obvious and would not require test measurements to detect. Testing the clock circuit is a board level test performed with a frequency counter. This is not a test, but a statement of 'sampling time control system.'

Preventative Maintenance

Climet calibration technicians conduct a number of preventative maintenance tests on each interval calibration:

- **Laser Diode Power**
  (Ref. Calibration Data Page)

  Climet measures the output current to the laser diode, which is a critical test. This test helps identify Catastrophic Optical Damage, or COD, before it occurs. A COD occurs when high output levels cause a short, melting part of the laser diode edge, and causing a laser diode failure. Please, refer to Application Note 20210226A. A non-authorized 3rd Party Calibration Service Provider does not have access to initial factory values of the instrument, does not have Climet calibration procedures or test points, and cannot perform this test.

- **Peak Noise**
  (Ref. Calibration Data Page)

  Climet checks the Peak Noise to ensure there's no sensor contamination. High peak noise is a leading indicator of sensor contamination. A non-authorized 3rd Party Calibration Service Provider does not have access to Climet software, and cannot conduct this test.

- **Battery Test**

  Climet conducts a capacitive test on battery powered portables to ensure reliable life. Regardless, we recommend customers implement their own preventative maintenance program and replace batteries every 3-5 years.

- **Memory Battery Replacement Interval**

  Depending on the model, Climet will replace the internal coin cell battery at regular intervals.

- **Verification of time and date stamp**

  Each calibration includes validation of the time and date stamp for the location where the instrument is received from.

- **Readjustments**

  This is the second half of a calibration. Here, the instrument is readjusted annually to ensure high accuracy, high assurance, and high reliability. A non-authorized 3rd Party Calibration Service Provider does not have access to Climet calibration procedures, Climet software, test points, or adjustment values.

- **Validation of Communication Protocols**

  Climet validate all Ethernet, RS-232, WiFi, USB, 4-20 mA output signals to ensure proper communication with LIMS equipment.

- **Printer Validation**

  Climet technicians test and validate internal printers to identify early or actual failures.

Other Services You May Want To Order

- **Exhaust Emissions Test**

  This ensure the HEPA filtered exhaust has no leaks, and is doing its job. Climet is the only manufacturers that tests and certifies new production instruments to ISO Class 3 cleanrooms. We recommend you re-test the HEPA filter after 5 years.

- **High Pressure Diffuser Cleaning Maintenance and Testing**

  The high pressure diffuser is commonly used in conjunction with particle counters and microbial air samplers to measure inert and viable contamination in high pressure gases. It has no moving parts and does not need a calibration. However, we do recommend a routine cleaning every two years. Please, refer to the User Manual if you wish to clean these instruments yourself.

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