TECHNICAL PAPER

The Impact of Low Counting Efficiency Explained

by Jason Kelly

LIGHTHOUSE WORLDWIDE SOLUTIONS

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What is Counting Efficiency?

According to ISO 21501-4 “Counting Efficiency (CE) is the ration of the number concentration by a light scattering particle counter (LSAPC) to that measured by a reference instrument for the same test aerosol”.

In context it means that the counting efficiency is the ratio of particles measured by two particle detection instruments. One a particle counter and the other a reference instrument which could be another particle counter with a higher resolution or a Condensation Particle Counter (CPC). CPC’s are widely used to calibrate particle counters.

ISO 21501 requires the counting efficiency shall be within 0.30 to 0.70 [corresponding to (50 ± 20) %] for calibration particles with a size close to the minimum detectable size (let’s call that the smallest channel on your particle counter). CE shall be within 0.90 to 1.10 (100% +/-10%) for calibration particles with a size 1.5 to 2 times larger than the minimum detectable particle size.

In a mathematical formula Counting Efficiency is determined by the following equation;

$$\eta = \frac{C_1}{C_0}$$

Where;

η is the counting efficiency;

C0 is the particle number concentration measured by reference particle counter

C1 is the particle number concentration measured by the particle counter under test

In context this means that the CE for a channel 1.5 to 2 times larger than the smallest channel has a CE of 100% with an accepted tolerance of +/-10% or between 90-110% when compared to a reference standard. Really what this statement means is that it is acceptable for a particle counter to see 10% less or 10% more than a reference standard. This has been an accepted norm in the particle counting industry far longer than 2007 when ISO 21501-4 was introduced to the world.

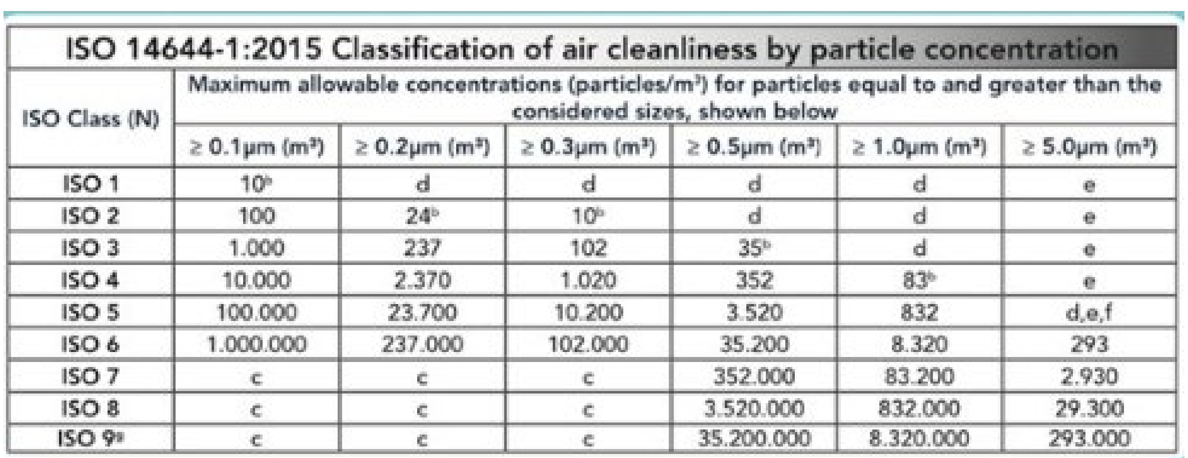
How does CE impact on Particle Counts?

What impact does a lower CE have than the ideal 100% CE that the particle counter under test is calibrated to? In reality the impact of a particle counter with a lower CE than expected depends on how the data is used and the magnitude of the data in terms of statistical relevance. You also need to understand that a 100% CE is near impossible as there are many factors to consider in particle counter calibrations ranging from coincidence error to probabilities and uncertainty of measurement. Particle counter calibrations also us spherical spheres with the same reflective indices so the references used to calibrate do not mimic real life particles that the particle counters actually count. Therefore tolerance levels in particle counter calibrations are much larger than say an micro balance calibration tolerance as a mass calibration is more simple than a particle counter calibration and the references are better defined based on mass. Particle counters in essence take a physical sample and optically convert this sample into a digital signal. Microbalances take a mass sample and convert the mass into a digital reading based on analog strain gauge technology so there is a simpler measurement method using analog to analog conversion whereas particle counters use an analog to digital conversion based on light energy.

Let's look at the low CE impact from a practical point of view. With a particle counter when it has a CE of 95% and 100 particles are passed through the sensor and converted to counts and sized based on the light energy magnitude scattered we would expect to see 95 of the 100 particles. Even with the ISO 21501-4 lower threshold limit of 90% it is acceptable that the loss could be 10 particles out of the 100 particles. So how does this impact on real time data? Again the impact is really based on how the data is used.

Pharmaceutical GMP regulations

In the world of Pharmaceutical GMP and controlling the cleanroom environment to prevent contamination of products there are certain standards followed using a particle counter to monitor a cleanroom environment to validate the environment at a certain classification based on the number of particles found at a given volume of air sampled. ISO 14644-1:2015 is the most widely used standard and has a look up table to determine the cleanroom cleanliness based on the particle concentration sampled. For example ISO 9 to ISO 1 represents the cleanliness of the cleanroom from less clean to ultra clean. An ISO 1 cleanroom has an extremely low concentration of airborne particles compared to an ISO 9 cleanroom. Therefore certain cleanroom processes and operations are performed based on the product being manufactured and the cleanliness level of the cleanroom. Even in today's operating theatres in hospitals the operating room must maintain a cleanliness level to reduce the risk of the patient from contamination of microbes that could be fatal to them if there were exposed to them during the operating procedure.



ISO 14644-1:2015 Classification of air cleanliness by particle concentration						
ISO Class (N)	Maximum allowable concentrations (particles/m³) for particles equal to and greater than the considered sizes, shown below					
	≥ 0.1µm (m³)	≥ 0.2µm (m³)	≥ 0.3µm (m³)	≥ 0.5µm (m³)	≥ 1.0µm (m³)	≥ 5.0µm (m³)
ISO 1	10[b]	d	d	d	d	e
ISO 2	100	24[b]	10[b]	d	d	e
ISO 3	1.000	237	102	35[b]	d	e
ISO 4	10.000	2.370	1.020	352	83[b]	e
ISO 5	100.000	23.700	10.200	3.520	832	d,e,f
ISO 6	1.000.000	237.000	102.000	35.200	8.320	293
ISO 7	c	c	c	352.000	83.200	2.930
ISO 8	c	c	c	3.520.000	832.000	29.300
ISO 9[g]	c	c	c	35.200.000	8.320.000	293.000

The table above represents the particle concentrations per cubic meter of air sampled. For example an ISO 5 class cleanroom when considering 0.5µm particles must have below 3,520 particles at a determined sample location in order for that cleanroom to be classified as an ISO Class 5 cleanroom. In reality most cleanrooms are classified by more than one particle size. Let's look at the impact of a lower than accepted CE on the results of an ISO 5 cleanroom being classified or tested at 0.5µm.

If the particle counter has a 100% counting efficiency then if 3520 0.5µm particles passed through the sensor then 3,520 particles would be counted. As explained in reality a CE of 100% would never exist based on uncertainty of measurement being applied or coincidence error factors applied at the concentration of particles sampled during the time of calibration. Therefore taking the lower threshold of the accepted tolerance of 90% then a particle counter with a CE of 90% would see 3,168 and miss 352 of the 0.5µm particles and according to the international standard for airborne particle counter calibrations this 10% loss of particles is acceptable. If we were dealing with a micro balance and it was reading 352µg lower than the expected mass this would be a major deviation. Yet in the analog to digital world of particle counters this 10% loss is acceptable.

What if the CE was lower than 90%? The same would apply if the CE was lower than 90% let's say it was 5% lower at 85% and out of the 3520 particles 528 would not be seen.

The reality of using Particle Counters

When using particle counters as absolute measuring devices as outlined in the case above the end user must be aware of the limitations of the accuracy of particle counting technology. Compared to a micro balance where mass is absolute based on small uncertainties and mass is converted to a measurement using an analog to analog technique you can never expect the same level of accuracy from a Particle Counter.

Therefore understanding the limitations of particle counters is a good start and applying measurement uncertainty to any data and good science will enable better data management. In the above example a CE with a 5% (85%) lower value than the lower limit of the CE threshold (90%) yields a difference of 176 particles over a potential 3,168 which represents a 5.5% difference in missed counts compared to the potential at 90% (3,168). Now apply the uncertainty of measurement to this 5.5% and the uncertainty of measurement would wipe out this 5.5% error and the impact of the 85% versus lower threshold level of 90% is not that much.

In the real world and when using particle count data to follow certification tables if your count results are approaching the upper limits of acceptable established limits for classification then applying uncertainty of measurement analysis is good practice but not widely used based on the lack of knowledge around the accuracy of particle counter technology.

Particle Counting data for Real Time Systems

When taking the above example an applying to particle monitoring during ISO 5 processing applications when particle counters are monitoring continuously during the process duration and looking at 5µm data the update rate and flow rate of the sensor should be considered and remote particle counters with 1.ocfm flow rates are widely used for this application. Taking the ISO 5 particle concentration for 5µm we see the limit is 20 particles per cubic meter. With the volume sampled at 35.3 times less than the required cubic meter (for certification and remember we are not certifying but monitoring for a trend) if you use this 20 particle limit and divide by the 35.3 factor the limit per cubic foot sample is 0.56 particles however particle counts are never less than 1 they are either a 1 or above of a zero so we put the limit as 1 particle per cubic foot but there would have to be 20 consecutive counts out of 36 with 1 5µm particle to say that the environment is not meeting the ISO 14644-1 table limit of 20/m3. In 2015 the 5µm size was removed from ISO 5 and higher ISO classes because of limitations surrounding the statistical relevance of such low counts to establish any sound mathematical trending. Since the fact the particle limit at 1 cubic foot was rounded up from 0.56 to 1 does a lower CE really have a big impact on the results? The actual rounding off skews that argument to one side and the rounding factor alone would by far compensate for a 5% lower CE below the lower threshold of 90%. This all sounds reasonable when we consider that particle counting real time systems used for critical process applications in a “continuous” setting (continuous meaning during the critical process run) is based on seeking trends that would alert management that the trend could have a negative impact on product safety and quality or yield.