

CLIMET CHRONICAL

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INSTRUMENTS COMPANY

Celebrating Over 50 Years in Business!



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Regulatory Corner

Climet Instruments Company

This section of our newsletter is dedicated to the answering or discussing any regulatory questions or pertinent issues.

Climet User Authenticator for CI-x5x Series Particle Counters

By Dave Chandler, Engineering Manager
Climet Instruments Company

The FDA regulation 21 CFR Part 11 defines the requirements for electronic records to be considered reliable in a regulated industry.

Most of our customers are in regulated industries which include pharmaceutical manufacturers, medical device manufacturers and biotech companies. In order for electronic records to be considered reliable, the company must implement controls to insure that only authorized users can have access to the data and that the data cannot be altered. IT departments in regulated industries utilize strong security

policies such as password aging, strong passwords, prevention of duplicate users, control of file access, and control of program access. Administrators can quickly add and remove users and change their permissions. Users can change their password once and it is good for any device on the network that they are authorized to use. If only the particle counters could have the same user authentication policies as the network! Now there is a way.



A customer recently asked that we enable our particle counter to connect to the company network and load the user name and security level into the counter after the user was successfully authenticated by the network policies. This resulted in the

development of a custom program we are calling the Climet User Authenticator. It works with CI-x5x counters with firmware version 3.60 or later.



The User Authenticator consists of two parts. A Supervisor program enables a supervisor to set up each particle counter user (analyst) according to his/her computer log in name. There is no practical limit to the number of users that can be set up. An encrypted file with the user names and security levels is stored on the network. The second part is the Workstation program. The analyst logs into a workstation that is connected to the network and runs the program. The program reads the log in name of the analyst. The particle counter is

connected to the workstation. It detects the counter and reads the user name and security level of the analyst from the network and loads them onto the counter. The analyst then disconnects the counter and proceeds to take the samples for the controlled environment according to the SOP.

When the analyst has completed their rounds, they return to the workstation and run the program again. This time they use the program to transfer the records from the stored data memory to a folder on the network designated by the supervisor. The contents of the records are timestamped and contain the authenticated user name. Access to the folder is controlled by permissions established by the network policies. The data would then typically be transferred to a secure data base such as a LIMS and archived.

Contact Climet if you know of a customer we can help with similar requirements.

When to Use Sample Probes

By Randy Grater, Service Manager
Climet Instruments Company



It has been called the *horn*, the *megaphone*, the *funnel*, and even the *big sucky thing*.

Occasionally it is called a sample probe.

Officially, it is an *isokinetic sample probe*.

Isokinetic means that in a laminar flow area, the air flows in and around the probe without creating any turbulence.

To understand why this is important, we need to understand a fundamental difference between micro and macro particles. While 5

μm particles may seem infinitely small when we consider that our hair is 70 μm to 100 μm in diameter, 5 μm particles exhibit surprising inertia compared to submicron particles. If one were to sample without a sample probe, 5 μm and larger particles would have to be very close to the inlet before they could be pulled over to the inlet. However, the inlet would be surrounded by turbulence, and the turbulent air would repel particles that were being pulled over to the inlet. So, without an isokinetic sample probe, we lose 5 μm particles that should be counted, whether we are sampling in laminar flow or turbulent flow.

The isokinetic sample probe has a wide opening that captures air that belongs to the sample without creating turbulence. The 5 micron particles flow into the opening and are then funneled down into the tubing that connects the probe to the particle counter's inlet. Particles belonging to the sample are thus drawn in.



However, due to the inertia of 5 μm and larger particles, there is significant loss of 5 μm particles in the transport tubing. Some have tried sampling without a probe, but they are just exchanging loss of 5 μm particles in the transport tubing for a loss of 5 μm particles for lack of a wide enough opening to entrain the 5 μm particles; only 5 μm particles in a narrow cone above the inlet will enter the particle counter.

Some have used a couple of inches of tubing to place the probe directly over the inlet. While this entrains particles into the sensor, it raises another, more noticeable problem. Whether sampling with a bare inlet or

sampling with only a couple of inches of tubing to support the sample probe, light has a direct path to enter the sensor cavity if the sensor is directly under a fluorescent light fixture while sampling. This is a problem, because modern ballasts turn the light off and on in the kilohertz range, producing a pulse with a width that is about the same that a particle produces when it passes through the laser beam. This makes it impossible to filter electronically. But we have a solution for that.



Climet gives the customer the choice between the default standard stainless steel probe with transport tubing or a light blocking isokinetic probe that fits directly over the inlet. The probe has an aerodynamic light blocking element that

allows air to flow around it, and has been verified against a probe without a light blocking element to verify that the light blocking element does not take out 5 µm particles by impaction. The probe with transport tubing is needed in applications where the particle counter cannot go, such as sampling in a clean hood. (The particle counter's exhaust would produce turbulence, resulting in high counts, if placed in the hood.) For applications where sampling is made from a cart, the light blocking probe is a better choice. For customers with both applications, a second probe can be purchased for half price when the particle counter is purchased.

Probes with transport tubing should be pointed towards the filter when in a laminar flow area. In not laminar areas, the probe should be placed at work height and pointed upwards. Pointing the probe upwards allows the particles to float down into the probe. If the probe were in a horizontal position, 5

µm and larger particles will float past the probe due to their inertia and never become a part of the sample.

The Meaning of Particle Counts and their Representation

**By Randy Grater, Service Manager
Climet Instruments Company**

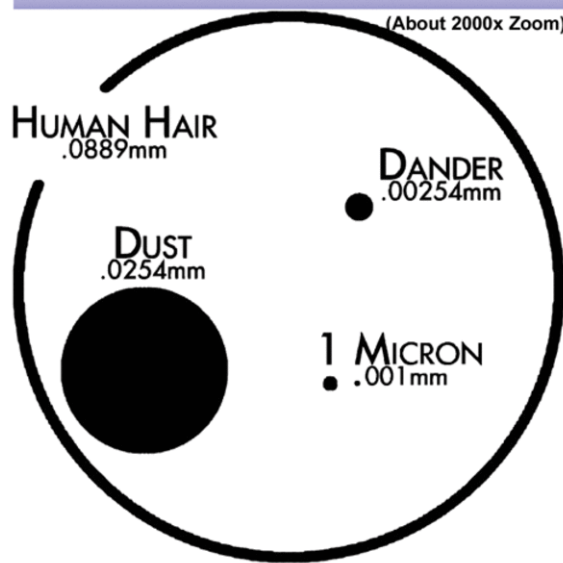
Particle counts are displayed in channels, and the channels are labeled for specific sizes. While it is clear to those who have worked with particle counters for years what these counts represent, it is not always clear what the numbers mean to those new to particle counting.

What is the largest particle size that gets counted?

This is a question that is frequently asked, and it is part of the explanation of what the counts for each channel represent. Essentially, anything that can fit through the inlet nozzle will pass through the sensor, and anything that passes through the laser beam will be counted.

HOW BIG IS A MICRON?

(About 2000x Zoom)



The nozzle on the inlet is several millimeters wide, and in terms of particles, it can accommodate a really large particle. Human hair is much smaller than the nozzle inlet, and it is around 70 to 80 microns in diameter. The human eye can discriminate particles down to 50 microns. But in a typical cleanroom, we monitor for particles in the 0.3 micron to 5.0 micron range. As we continue to go up in size, the number of particles becomes smaller and smaller, because larger particles tend to fall out rapidly, compared with submicron particles. Particles above 5 micron are relatively few and far between, so they have to fall into the inlet to

be detected. So, even though a BB might fit through the inlet, it is highly unlikely (in a cleanroom) that the particle counter will ever detect a particle visible to the human eye (particles 50 micron and larger).

How is the particle detected?

Particles are converted into light energy as they pass through a laser beam, scattering light, and the light that is scattered is proportional to the size of the particle. The light is then collected by optics and focused onto a photodetector, which then converts the light into electrical current. The current is then filtered electronically, producing a voltage pulse with an amplitude that is proportional to the collected light scatter. These pulses are then applied to circuits that compare the particle pulse amplitude to a fixed voltage threshold. Any particle large enough to exceed the voltage threshold will be counted by that channel.

What do the counts in each channel represent?

So, a particle that exceeds the threshold for the 0.3 micron channel will produce a count in that channel. If it is large enough to exceed the threshold voltage for the 0.5 micron channel, it will also count in the 0.5 micron channel. And, as is hopefully obvious at this time, a BB would produce a voltage pulse that is large enough to clear the 0.3 micron channel, the 0.5 micron channel, the 5.0 micron channel, and any other channel offered by the particle counter.

And this is what the standards for cleanrooms are based on: how many particle that are equal to or greater than the size of consideration are detected by the particle counter. If we are monitoring 0.5 micron particles, we want to know how many particles there are (of any size) that are equal to or greater than 0.5 micron (in a given volume of air).

Particle Counts Conclusion

The counts in any given channel represent all particles that are equal to or greater than the particle size represented by that channel. For example, counts in the 0.5 micron channel will include 5.0 micron counts, and any larger particles that might drop into the inlet. This is consistent with what the limits represent in Fed. Std. 209E, ISO 14644-1, and the European GMP standard for particle monitoring.

For more information and additional resources regarding particle counts and channel representation, please feel free to reach out to us at sales@climet.com.

Climet Introduces NextGen™ CI-x70 Series Portable Particle Counter

By Benjamin Yuem, Marketing Associate
Climet Instruments Company

On September 15, 2017, Climet announced the introduction of our NextGen portable particle counter, the **CI-x70 Series**. This NextGen™ model compliments Climet's current CI-x5x Series of portable particle counters.



The CI-x70 NextGen particle counter is the smallest and lightest pharmaceutical / industrial grade portable particle counter on

the market today. The design is extremely rugged, having been successfully calibrated after being both drop and vibration tested.

The CI-x70 Series introduces many new options not available in previous generations, and includes several innovations not available elsewhere. It comes standard with six-channels, and varies by flow rate (1 CFM, 50 LPM, 75 LPM, and 100 LPM).

New features include a capacitive touch screen, similar to smart devices allowing users to pinch-to-zoom and swipe-to-scroll. This is of particular benefit when reviewing pdf reports (ISO 14644, EU GMP, or FS 209e), which are fully compliant with 21 CFR Part 11.

The extremely energy efficient design offers users the longest run time on a single battery confirmation, even when compared to competitors' dual battery design. This offers users a substantial savings in consumables,

and contributes to Climet's unparalleled lowest Total Cost of Ownership (TCO).

The new CI-x70 has onboard memory for up to a million or more samples, and factory expandable User ID's, Location ID's, and Programs (default of 100 each).

Its unique user-configurable light ring provides for 360 degree viewing, 5-colors, and several alert patterns.

The CI-x70 NextGen particle counter has a stainless steel enclosure, is only 9.4 pounds with the battery installed, and is only 587.9 cubic inches in size. Climet's new patent pending (or patented) ultra-quiet / ultra-clean blower technology makes the CI-x70 Series the world's smallest, lightest, quietest, and cleanest portable particle counter on the market.

According to Jim Strachan, Climet's General Manager, "The CI-x70 Series incorporates disruptive technology providing not only innovative features and

benefits today, but also it provides a platform for future expansion and development."

"The CI-x70 NextGen particle counter incorporates the highest quality material, and with over 55 years in business it is designed with the highest level of engineering acumen," says Dave Chandler, Climet's Engineering Manager. "This provides the lowest interval calibration out-of-tolerance rates in the industry, and helps to mitigate user deviation reports and failure investigations."

Climet is the only manufacturer of particle counters to both test and certify the HEPA filtered exhaust to ISO Class 3.

Climet is currently accepting customer pre-orders and production is slated to begin on or before December 2017. Additional features and enhancement will be announced in the future.

To view the press release in its original form, click the following link:

[CI-x70 Series Announcement](#)

For more information, to request a quote, datasheets or manuals on the CI-x70 Series click the following link:

[CI-x70 Series Information](#)

Climet Announces Brand New and Improved Website

**By Benjamin Yuem, Marketing Associate
Climet Instruments Company**

After many months of hard work, we are excited to officially announce the launch of our brand new and revamped website as of September 15th, 2017. You can still find us at www.climet.com but with a more user friendly and easy to use interface.



Our goal with our new and improved website is to provide our visitors more user friendly methods of learning about the products and services Climet provides. This also will allow the visitor the ability to use specific searches to more easily find which of our solutions best meets each specific need or needs. The new website is now more interactive and provides better access when conducting research in regards to particle counters, microbial samplers and other customized solutions in environmental monitoring. Our current and prospective customers will find helpful information about our products and services as well as access to our technical library.

Amongst the newest features of the website contains integrated, easy-to-use tablet and

mobile friendly access. We will be constantly updating our content with helpful information, articles, application notes, newsletters, company announcements and other premium content in our technical library section.

We hope you find the new website refresh more modern and easy to use. We have worked very hard to make sure it contains valuable information to assist you with every one of your environmental monitoring needs.



For any questions, suggestions, feedback or comments, please e-mail us at

byuem@climet.com.

Product and Service Updates

To stay up to date on the latest Climet Products and Services continue checking our website on new additions or contact us using the information below:

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Firmware and Software Revision Updates

**By Dave Chandler, Engineering Manager
Climet Instruments Company**

As of 14 January 2016, DataPro 3 supports reporting for the new ISO 14644-1:2015 standard. DataPro 3 is monitoring software used with Climet CI-3100 Ethernet OPT continuous monitoring particle counters.

For customers who require information on previous firmware or software versions, please create a login to our website at

www.climet.com/partners/join/

Informative Articles, Technical and Application Notes

For more info about materials contained in this newsletter, technical information, or other informative environmental monitoring tips from leading experts please visit:

<http://www.climet.com/library/index.htm>

Suggestions, Comments and Recommendations

We are always looking for relevant topics, and welcome your comments, suggestions, and feedback.

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