New real time technique for visualization and counting of fine airborne particles

Gordon Farquharson

gjf@critical-systems.co.uk

Critical Systems Ltd, Guildford, United Kingdom

Abstract

This paper explores the potential of a new laser-sheet airborne particle visualization and counting technology that analyses the cleanliness of real space. Historically, visualization of airflow and dissemination of particles has been limited to "smoke pattern" testing and observation. Also, particle counting has been limited to sampling at specific locations, transporting the sample to an instrument for counting. A new technique, has been developed [(1)] to investigate particle generation, dissemination, and concentration (counting) using a laser light sheet and image visualization and analysis. The technology was developed initially to observe equipment generated particles in order to prevent damage to products and processes. The technology is now well developed, and can be used to visualize actual contamination events, visualize airflow using a seeded particle source, and most interestingly count particles in real-time as they pass through a critical process plane. This paper explores the science of this novel technique, discusses examples of its application, and explores the potential benefits for design and monitoring of critically controlled clean process environments.

Key words: Cleanroom, Airflow Visualization, Smoke Patterns, Vectors, Contamination Control, Particle Counting, Simulation, Industrial Ventilation, Occupational Health, CFD, Validation, Qualification, Detective work.

1. Introduction to the technology

The basis of the technique is the visualization of airborne particles as they scatter light from a laser beam projected across the target environment. The technique is highly developed using a camera to observe and record the scattered light from projection of the laser light as a sheet to cover the area of the clean zone under investigation.

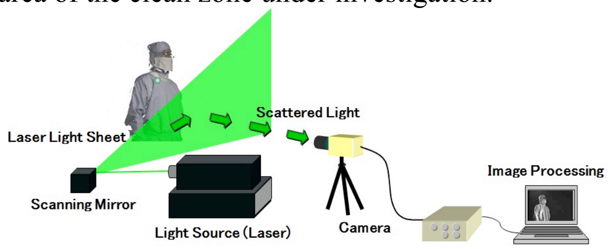

Fig.1 Diagram showing the principle components of the visualization technology.

This system makes it possible to visualize airborne particles and air flow in real time.
The laser light sheet is created by using a laser source and a scanning mirror, and if particles are on the laser light sheet, they scatter the light, and scattered light is detected by the camera. The image can be viewed as a still or moving image to visualized particles. Each white spot is particle.

Fig.2 A cleanroom environment showing the airborne contaminant particles reflected in the laser light.

2. Development of the technology for particle visualization.

The business driver to develop the laser sheet technology came from the microelectronics industry where the technique was developed to try to resolve contamination problems specifically affecting product yield in display screen manufacturing in 2005. This of course is very different to those industries driven by cleanliness requirements defined by compliance objectives, but the technique could be equally applied to a regulated industry.

The technique was developed to provide a method of tracking and controlling contamination dissemination in a manufacturing or research environment. The cleanroom user needed to find a quick and effective technique for both identifying source of particles, and then understanding how they were conveyed to the product component, potentially leading to quality failure due to surface particle contamination. It is usually extremely difficult to identify the particle source that has actually led to the contamination of a product or component, and often even more difficult to observe precisely the mechanisms for transfer. Traditional airborne particle counters can count particles at a point (specific sample locations), but are ineffective for tracking the route from source to target. Detection of particles on the product surface similarly does not immediately tell us what the source was and how they got there. We frequently use an aerosol source to look at the flow of air through visualization. This is often called smoke pattern assessment. Once again this technique has significant limitations, and whilst it can tell us about the airflow, turbulence, and the potential for particle transfer, it doesn't tell us about the actual particles generated by a real process.

3. The technology for airflow visualization

A natural extension of the use of the technology to monitor the generation and transmission of actual particles is the use of the system for tracing airflow using an artificial aerosol source. An ethanol-based aerosol is the preferred agent to use for visualization because first it generates an aerosol that scatters light effectively, and secondly any residue of the aerosol on the surface of equipment evaporates rapidly and leaves no deposit. Good examples of where visualisation is helpful are the investigation of airflow uniformity in cleanrooms, and the containment effectiveness in devices such as class II microbiological safety cabinets. In both these cases, the visualisation can of course be recorded and retained as a record for qualification purposes using this technique. In order to set up a visualisation simulation, the selected critical boundary must be illuminated using the laser sheet source, and the challenge aerosol liberated in order to demonstrate the nature of the airflow across the plane being investigated. Time-lapse photograph can also be used to generate a cumulative still image recording comparisons of particles across the test plane (see fig.4).

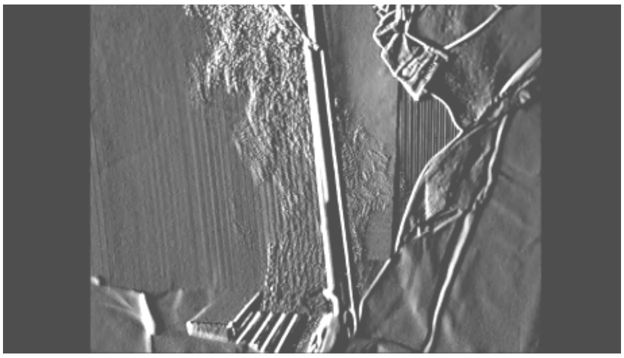

Fig.3 Airflow visualization for a Class II microbiological safety cabinet.

Fig.4 Time-lapse image showing particle concentration comparison across a test plane.

4. The technology for particle counting

The next stage in the development of the technology is to add image processing to count particles in a visualized zone in a completely different way compared with traditional airborne particle counting. In the case of the traditional airborne particle counter approach, we select a sample location (for monitoring or classification), place the probe (iso-kinetically for uni-directional airflow (UDF)), and collect a defined sample and transport it to the measurement instrument. Within the instrument, laser light is scattered, and the instrument counts numbers of particles by number of flashes, and size of particles by the intensity of the flash (see fig.8). The laser sheet technology enables a completely different approach to counting particles in the air. First a critical plane in the clean-zone is identified, and the laser sheet is established across this plane. Camera vision is then used to observe the particles passing through the plane. The images are taken at the rate of 30 per second, and the particles present in the image counted. The difference in particle numbers between frames gives a measure of the particles that have passed through the plane. Knowledge of the area of the plane under evaluation can then be used to give a measurement of the particle concentration. Depending on the acuity of the camera used, it is possible to discriminate particles of different sizes. In order to satisfy the specific requirements of the pharmaceutical and life sciences world, as well as common practice in many other industries, the system has been developed to evaluate particles ≥0.5 and 5.0 microns.

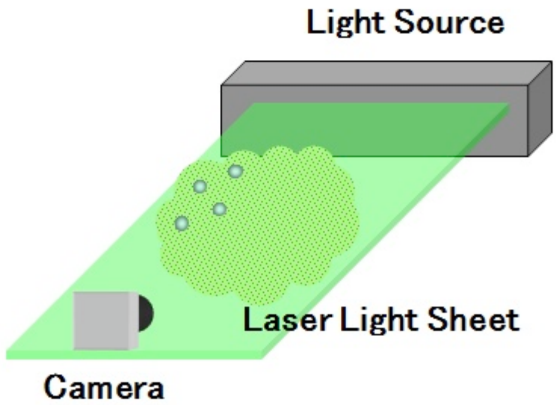

Fig.5 Diagram of laser light sheet and camera vision used to count particles passing through the plane.

The particles counted can be displayed numerically and graphically as shown in fig.6..

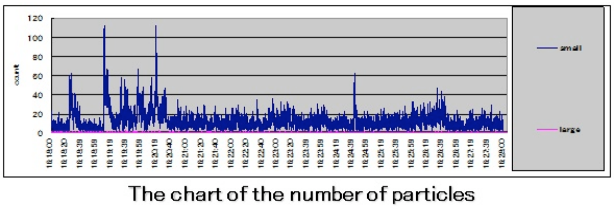

Fig.6 Graphical representation of particle concentration.

4. Applications of the technology

The technology is highly flexible, and can be applied to virtually any kind of cleanroom or clean air device. For any selected device, the technology can be used for tracking particle sources and their dissemination, airflow visualisation, particle counting, and real-time particle monitoring at critical zones and locations. In each case, the major advantage of the technology is that it is able to visualize particles in a critical zone or region of a clean air device. This compares with the airborne particle counter which is only able to count particles at a particular location, and has no capability for tracking and tracing particle sources and their dissemination. In the current state of development, the technology would only be used for clean zone classification if there was a specific agreement between customer and supplier to accept the use of this novel technology. The technology is young and therefore much experience with application has mainly been for detective work, seeking out contamination sources that have or might cause product quality problems.

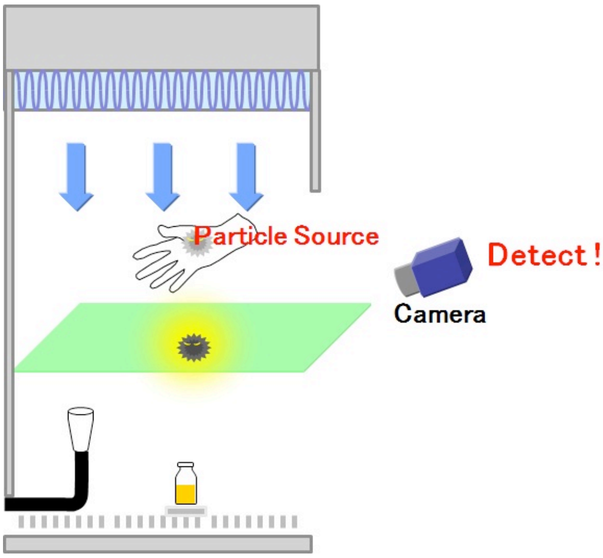

Fig.7 Illustration of the laser sheet evaluation of a critical plane, compared to an airborne particle counter isokinetic probe.

5. Limitations and constraints of the technology

There are of course limitations to the capability of the technology. The principle ones are the difficulty in determining direct comparability with traditional airborne particle counting, and the other is the physical constraint for location of the laser sheet source and camera in order to be able to generate the laser light sheet across the critical zone under evaluation and at the same time observe reflection of light due to particles using the camera vision technology. Fig.5 illustrates the importance of the physical relationship between the light source and camera.

The first of these limitations is considered in more detail. It is difficult to compare particle counting concentrations with those obtained by traditional airborne particle counters because the techniques are quite different. For clean-zone classification this new counting method is not specified in the reference cleanroom standard. The cleanliness classification by small airborne particles in the range ≥ 0.5 and 5.0 microns is defined within ISO 14644-1: 1999(2). This standard specifies not only the particle concentrations in different classes, but also the method for determining particle concentration using an airborne particle counter specified and calibrated in accordance with ISO 21501-4:2007(3). Because the standard for classification and the associated ISO classes 1 to 9 actually define the type of particle counter, it is not be possible to use the technology as a basis for classification at the moment.

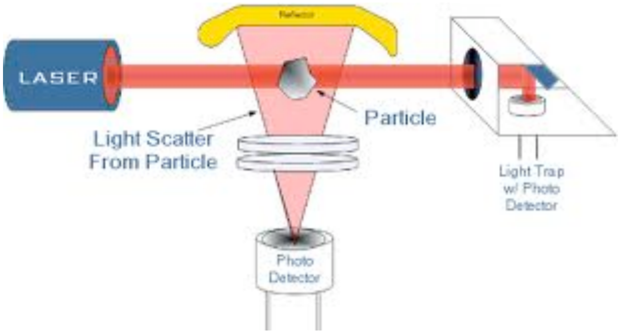

Fig.8 Diagram of a conventional airborne particle counter showing the detection of scattered laser light within the instrument.

It is possible, within the scope of ISO 14644-1 for a customer and supplier to agree to use the laser sheet alternative method as the basis for a cleanliness classification test. However, as a technique for real-time monitoring there is no such restriction, and a real opportunity exists for the use of the technology for improving process knowledge. There will of course be some parties, particularly those requiring to meet the expectations within various guides to good manufacturing practices for sterile medicinal products[4], who will want to determine some level of equivalence with traditional airborne particle counting methods. Future research will be needed to demonstrate equivalence.

4. Conclusions

This new technology using a laser sheet and camera vision provides us with an exciting technique for better understanding the performance of our critical controlled environments. Real-time visualisation and counting of fine particles is a specific requirement of regulated industries, such as the pharmaceutical industry, and a need for those industries that need to control and manage the cleanliness of critical process areas. The technology also allows us to produce visual image evidence of the environment we are testing or monitoring for cleanliness. Probably the major advantage over traditional particle counting is the ability of the technique to allow us to see actual particles generated from the process, and to determine whether they are swept away harmlessly or have an adverse impact on the product or process. This means that this analytical tool has a real value in assessing an understanding the real risks in a critically controlled environment. It is important to recognise that was the technology has been developed significantly over the last five years, it is still very young, and we are learning every day more about its refinement and opportunities to apply it monitoring operations of process improvement.

References

(1) The system is called "VIEST ™", and has been developed by Shin Nippon Air Technologies in Japan. Need to add comment about patent here.

(2) ISO 14644-1:1999. Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness.

(3) ISO 21501-4:2007. Determination of particle size distribution – Single particle light interaction methods – Part 4: Light scattering particle counter for clean spaces.

(4) Guides to good manufacturing practices for sterile medicinal products.

The Rules Governing Medicinal Products in the European Union. Volume 4 EU Guidelines to Good Manufacturing Practice. Medicinal Products for Human and Veterinary Use. Annex 1 Manufacture of Sterile Medicinal Products (corrected version). 25 November 2008.

Guidance for Industry. Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Office of Regulatory Affairs (ORA). September 2004, Pharmaceutical CGMPs.