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Ionized Air Blow-Off Techniques to Reduce Contamination

When using air blow-off equipment to clean medical plastics (catheters, syringes, vials, etc.) it is critical to include ionization in the process. Ionized air blow-off techniques are substantially more effective in removing unwanted particle contamination on these highly charged materials, as much of the contamination can be held to the surface electrostatically. This article provides data from experiments (conducted with both regular air and ionized air blow-off techniques) that details the increased effectiveness of the ionized approach when blowing off surfaces. In addition, particle count data in typical gowning rooms is provided to document the increased particle burden that personnel carry into clean rooms if ionization techniques are not employed to remove those particles and limit them to the gowning room.

Medical Device Cleaning Operations

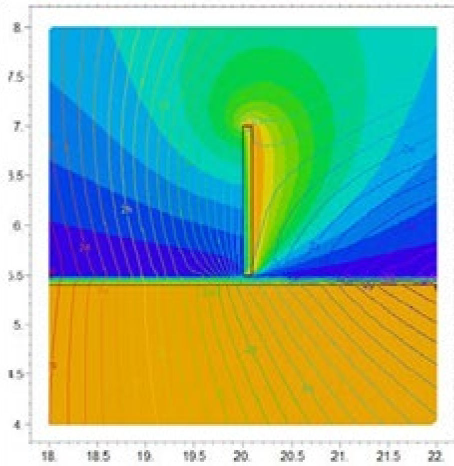
First, two typical cleaning techniques are widely used in medical device manufacturing operations with the goal to eliminate unwanted particles on the surfaces of the device. We discuss the limitations of both:

1. **Alcohol Wipes**: Alcohol wipe downs are commonly used to clean the plastic devices during manufacturing. Once the alcohol wipe-down is conducted (this does remove the static charge on the product temporarily), the product then "dries" and can regenerate its charge from the subsequent evaporation and final rubbing action of the cloth wipe. This "re-charged" product now rapidly attracts particles again, resulting in regenerated particle contamination. Alcohol wipe-downs should be accomplished under ionized air to eliminate this re-charging effect.
2. **Regular Air Blow-offs**: Medical device products are also commonly cleaned in the industry at various stages of manufacturing by blowing them off with regular air (most commonly accomplished with air guns). Although some particles are removed strictly from the force of the moving air on the surface, many particles stay statically attached to the surface and are not removed. In addition, the product can become even more statically charged than before the air blow-off, as particles moving across the product surface cause triboelectric charging to take place on the surface of the product. As a result, even greater particle attraction forces can be created and can cause the product to be more contaminated after the regular air blow-off than before. Ionized air blow- offs (ionizing air guns, etc.) are far more effective in removing all of the particles on the surface and preventing subsequent particle attraction after the blow-off as the product now remains un-charged at that point.

Attraction of Fibers

An interesting phenomenon occurs with small fibers on statically charged surfaces and is worthwhile to note here, as many in our client base have observed and inquired about it. Specifically, in the presence of a static field on a given surface, small fibers attracted to it via ESA (electrostatic attraction) will tend to "stand up" perpendicular to the surface as shown below. It is a tell-tale sign that static charge is present on the surface.

1 mm fiber standing vertically on a charged surface



FEM for that fiber on a charged surface

In the photo above, a clothing fiber (1 mm in height) is captured in this vertical position on a charged plastic surface. This effect is caused by charge migration from the charged surface to the fiber. As the oppositely charged fiber takes on additional electrostatic charge from the surface, a like-charge repulsion effect lifts the fiber away from the surface. The longer a fiber remains on the charged surface, the greater the charge migration and the more likely this phenomenon will be observed. A Finite Element Model (FEM) can be used as a first-order approximation describing this phenomenon (see FEM plot of the charge distribution above). Shown is a positively charged surface and fiber. The electrostatic field and potential structure shows the repulsion dynamic which makes the fiber lift up from the surface.

What is Ionization? Air ionization is the most effective method of eliminating static charges on non-conductive materials and isolated conductors. Air ionizers generate large quantities of positive and negative ions in the surrounding atmosphere, which serve as mobile carriers of charge into the air. As ions flow through the air, they are attracted to oppositely charged particles and surfaces. Neutralization of electrostatically charged surfaces can be rapidly achieved through the process.

It is noted here that insulative materials such as plastics, glass, rubber, ceramic, etc. ***will not dissipate their charge when connected to ground***. Only bringing air ions close to their surface via ionization equipment removes the charge. Ionization “loosens” the particles on the surface of the device to be cleaned by eliminating the attraction force and a great majority of the previously adhered particles can then be removed with the air flow.

Particle Count Experiments with Both Regular and Ionized Air Blow-offs: Experiments were performed in a laboratory environment to investigate the difference in particles removed with regular and ionized air blow-off techniques. A clean, 6” x 6” piece of regular plastic material was rubbed and charged to over 20 Kv and was placed in close proximity to a dusty surface. Oppositely charged particles from that dusty surface were statically attracted to the plastic surface as a result (see Figure 1 below, which encompasses a 3” x 3” area of the plastic surface). We note here that all the accumulated particles on the plastic surface were thus electrostatically attracted to that surface.

The surface was then blown off for 4 seconds with regular air from a standard air gun (set to 22 psi and positioned approximately 18 inches away from the target surface) into the collection bowl of a particle counter that recorded the number of all the particles collected above 1 micron in size. It was visually obvious at the end of the 4 second blow- off that only approximately half of the particles were removed from the surface (see Figure 2). All these remaining particles were not removed totally due to the electrostatic attraction which was still in effect. We note here that we could not remove these remaining particles even with much longer additional regular air flows (20 seconds and more). By 4 seconds, we had reached the point of diminishing returns.

An ionized air gun was then used to blow off the plastic surface again for 4 seconds. Visually, it was obvious that the surface was dramatically cleaner (virtually spotless) as a result. The ionized airflow, with the same pressure, distance from the surface, and time of application, broke the electrostatic bonds and the remaining particles were removed from the surface (see Figure 3).

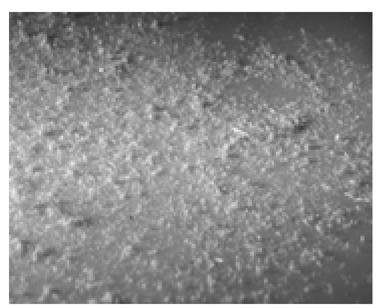


Fig.1: Before air blow-offs

Fig.2: After regular air blow-off

Fig.3: After ionized air blow-off

Data from a Met One Laser Particle Counter reflects the same information we observed visually. Two separate runs were accomplished as detailed below:

- Run 1:
  - Particles removed with regular air: 6,304
  - Additional particles subsequently removed with ionized air: 8,927
- Run 2:
  - Particles removed with regular air: 6,912
  - Additional particles subsequently removed with ionized air: 7,054

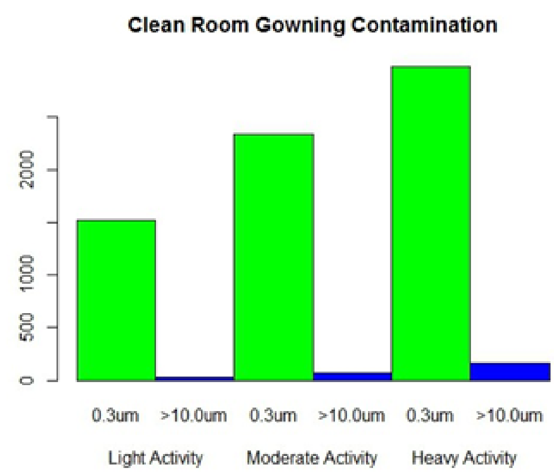
Taking the liberty to extrapolate these results to personnel walking into a gown up area of their manufacturing facility, the roughly 14,000 particles (1 um and above) that we eliminated via ionization in our experiments above per 6″x6″ area of the plastic surface would correlate to between 500,000 and 1 million particles on the entire surface area of the person's body and clothing in this extrapolation. And that result is for one person!

These particles can and should be removed via ionization in the gown up room, and hence, not be transported into the clean room.

Typical Particle Counts with Personnel in Gown-up Rooms: Particle count measurements were performed in a typical medical device facility gowning room (without ionization) before entrance into their Class 1,000 clean room, and provide a typical example of how much of a particle burden (for that class clean room) is introduced by personnel in street clothes. The positioning of the particle counter was 6 feet above the floor both inside the street entrance and entrance to the cleanroom in these experiments, and does not reflect values anywhere close to the total number of particles introduced by the personnel. The particle counts taken during personnel activity were of staff removing clean room clothing, and it can be assumed that similar counts would be taken for staff changing into clean room clothing. In the experiments, 9 particle count readings were taken as personnel came through the gowning room during a break time.

The data is summarized below:

- Light personnel activity: (>0.3 micron particles) = 1523, (>10.0 micron particles) = 28
- Moderate personnel activity: (>0.3 micron particles) = 2337, (>10.0 micron particles) = 68
- Heavy personnel activity: (>0.3 micron particles) = 2976, (>10.0 micron particles) = 165



[Equipment was Lighthouse Solair 3100 with isokinetic sampling probe on tripod 6ft above floor level. Sampling was three (3) sets of three (3) each 60 second sampling intervals. Locations were just inside fab entrance door and gowning room entrance door.]

In such gowning rooms as the example above, ceiling ionization can be used to discharge clothing and personnel, as well as airborne particles. And as many medical manufacturers use Class 100,000 rated cleanrooms (not the cleaner Class 1,000 clean room detailed in this example), those typical counts above increase dramatically when ionization is present (into the tens of thousands of particles in the same measurement locations) in the gowning room and consequently decrease dramatically in the clean room areas.

Though many particles are produced during the gowning/un-gowning function, ionization eliminates the electrostatic attraction of particles, clothing and personnel, leaving only the standard particle diffusion and gravity deposition models for particles presented to surfaces. With a strong air shower following gowning, the particles on clean room clothing can be removed prior to clean room entry since the electrostatic forces have been removed. It is also critically important to provide an ionized shower for operating personnel in their street clothes as they enter the gowning room as well, to eliminate as many particles as possible from them before they start the gowning process.

It is important to remember that effective contamination control through ionization requires that both clean room access points (gowning rooms) and workstations where product is processed openly need to be concurrently ionized1, 2. Ionization employed in only the production areas can result in increased particle contamination when operating personnel consequently shed particles (due to the local ionization at the workbench) onto exposed product at that location.

Summary: Ionization is a crucial component for the most effective air blow-off techniques to remove particle contamination. In the examples shown, only about 50% of the particles were removed from a statically charged surface when a regular air blow-off gun was employed. Similarly, ionization in the form of both ceiling mounted systems and overhead blowers at an entrance and at an exit of a gowning room provides vastly increased particle removal from personnel before they enter the production clean rooms.

References

1. R.J. Peirce, "Confronting Static Attraction in Medical Plastics Manufacturing," MD&DI, August, 2011.
2. R.J. Peirce, "R educing Particle Contamination via Ionization in Gown-Up and Product Transfer Rooms", MD&DI, November 2013.

About the Authors

Mark Hogsett is currently the Application Engineering Manager for Simco-Ion Technology Group, an ITW company, with over 17 years of experience in applied electrostatics. This group provides electrostatic product and consulting services to the Semiconductor, Flat Panel, Disk Drive, Medical and Electronics industries, as well as collaborative research and product development studies with major corporations. Mr. Hogsett regularly gives technical presentations and seminars on particle contamination for the various industries. He is also currently an active member of the SEMI standards organization, the SEMI ESD Task Force, the Electrostatic Discharge Association (ESDA), Electrostatic Society of America (ESA), IEEE, and the International Society for Bayesian Analysis (ISBA). Mr. Hogsett is a graduate of the University of California at Berkeley. (mhogsett@simco-ion.com)

Roger J. Peirce has been Manager of Technical Services since 2006 for Simco-Ion Technology

Group, an ITW Company. Previously, he provided ESD/ESA consulting services for 20 years to the semiconductor, medical device, and electronics manufacturing communities for ESD

Technical Services – a consulting company he founded in 1986. He co-founded Voyager

Technologies in 1983 to design innovative ESD test equipment, and started his 13-year career at

Bell Labs in Murray Hill, NJ in 1970. He holds 10 US patents and has authored and published more than 20 technical papers on ESD/ESA. Mr. Peirce is a graduate of Fairleigh Dickinson University.

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SIMCO ION™
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Simco-Ion, Technology
1141 Harbor Bay Pkwy, Ste 201
Alameda, CA 94502
Tel: +1 800.367.2452 (in USA)
Tel: +1 510.217.0600
ioninfo@simco-ion.com
www.simco-ion.com