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worldwide leaders in **static control**

M E D I C A L .

Air Ionization

Theory & Practice for
Life Science Manufacturing

Static & Particulate Contamination Control Using Ionization Technology



Overview

Anyone who has walked across a carpet and then touched a doorknob has felt the effects of static electricity. The zap from the doorknob may have amounted to 5,000 volts on the person's body and has the potential to melt the conductive pathways on many microchips, such as those in your smartphone.

Static charge can interfere with material and component handling in automated tools, causing stiction and jamming. The production yield loss, re-worked product or returned product due to contamination via static electricity and its effects on quality reaches beyond yield loss and rework costs to customer or market rejection of the contaminated product.

In the case of medical electronic devices, electrostatic discharge (ESD) can easily damage sensitive electronic components in a number of ways. Additionally, electrostatic charge (ESC) attracts airborne and surface particles to product surfaces such as catheters and syringes.

Static electricity affects production rates and product quality, thus reducing profitability. From component to finished product, the possibility of damage due to ESD, particle electrostatic attraction (ESA) or product-handling problems is always present. The cost of these problems increases as a product moves through its manufacturing cycle. For electronic medical products such as pacemakers and diagnostic equipment, the component damage that may not show up during production testing may cause failures in the field where reliability and patient safety are much more critical factors.

Electrostatic charge can be reduced significantly, mitigated and controlled to address particulate contamination of your products and ESD effects on your medical electronic components. The purpose of this booklet is to explain how this control can be achieved.

Static & Particulate Control for Life Science Manufacturing is an overview of the basics of static electricity—what it is, how and why it is a problem, what remedial steps can be taken to counter its effects, and lastly, an examination of why air ionization must be included in any successful program for controlling static charge, ESD and particulate contamination in the workplace.



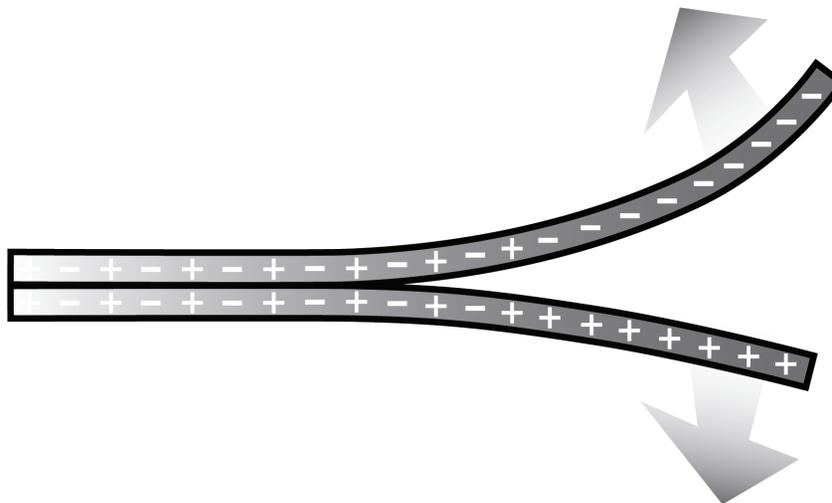
Static Electricity

Static electricity is a familiar but often misunderstood phenomenon associated with stationary electric charge. The laws of nature attempt to maintain a balance of positive and negative charge, and ideally objects would remain neutral with no net charge. Static charging occurs when molecules on the surface of an object become charged or polarized. The charge may be either negative or positive, depending on whether the atoms making up the charged surface have an excess or deficiency of electrons.

Materials that are characterized by their ability to allow movement of an electric charge is commonly referred to as conductive or static-dissipative materials. Non-conductive or insulative materials, by contrast, do not allow an electric charge to move. Tap water and most metals are excellent conductors of electricity, while most types of rubber, plastic, Delrin, Teflon and glass are examples of non-conductors. Any type of material can be charged with static electricity. The most common ways to generate static electricity are by induction and triboelectric charging.

Triboelectric Charging

Whenever two surfaces in contact are separated, one surface loses electrons and becomes positively charged. The other surface gains electrons and becomes negatively charged.



Problems Caused by Static Charge

- Contamination due to electrostatic attraction (ESA) and bonding of particles to charged surfaces
- Destruction of sensitive devices due to an electrostatic discharge (ESD) event
- Equipment lockup and instability due to electrostatic interference
- Product flow or manufacturing problems caused by static charge

Charging Through Induction

Inductive charging occurs when a charged object creates a stationary electrostatic field. It is difficult to charge non-conductors by induction. However, grounding a conductive object when it is in the field, causes it to take on static charge of opposite polarity to the field without having touched the originally charged object.

The electrostatic field from the original object attracts (or induces) opposite polarity charge to the surface of the new object placed within the field. If that object is then isolated from ground and removed from the field, it will hold an electrostatic charge.

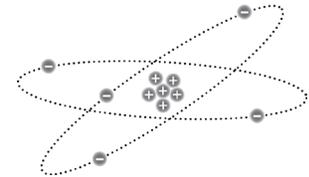
Triboelectric or Friction Charging

Friction is the primary means of generating static electricity. Whenever two surfaces in contact are separated, one surface loses electrons and becomes positively charged while the other surface gains the same electrons and becomes negatively charged. The total charge on the two materials remains the same and may even be zero. After separation, however, each surface retains its positive or negative charge, unless the surface is conductive and a path to ground is provided.

Any material (solid, gas or fluid) whether a conductor or a nonconductor can be charged triboelectrically. The magnitude and polarity of the charge depending on the characteristics of the two materials and are affected by several factors. The factors include surface condition, the

size of the area that is being rubbed or separated, the pressure between the surfaces and the speed of separation or rubbing. Generally, smoother surfaces, larger surfaces and increased speed or pressure between surfaces generate higher levels of electrostatic charge.

Triboelectric charging occurs when rubbing or other physical forces cause electrons to leave their orbit and move from the surface of one material to the surface of another.





The Triboelectric Series, as shown in the chart to the left, is a ranking of materials in order of their likelihood of becoming positively or negatively charged. If two materials are rubbed together, the one higher on the list tends to become positively charged while the lower one tends to take on a negative charge. The better the insulator, the more easily it is charged by friction. Non-conductive materials such as Plexiglas® or Teflon charge readily and can generate large amounts of static charge—sometimes in excess of 25,000V.

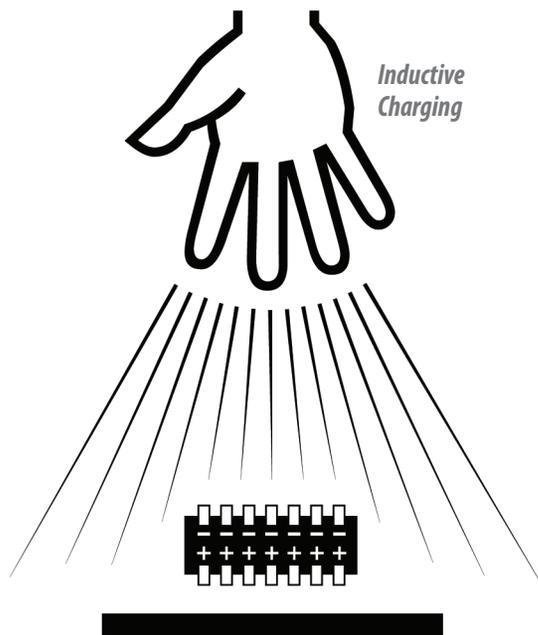
An insulator can be charged triboelectrically by contact and separation with a conductor, even if the conductor is grounded. The conductor, if it is isolated from ground, can be charged by separation from the non-conductor.

Triboelectric Series

Positive

- Air
- Human hands
- Water
- Glass
- Mica
- Human hair
- Nylon
- Wool
- Lead
- Aluminum
- Paper
- Cotton
- Steel
- Wood
- Hard rubber
- Nickel and copper
- Brass and silver
- Gold and platinum
- Acetate rayon
- Polyester
- Polyurethane
- Polyethylene
- PVC (vinyl)
- Silicon
- Teflon

Negative



Inductive charging occurs when a charged object creates a stationary electrostatic field. If you place a conductive object within the field, it will take on a static charge without having touched the original charged object.

Why is Static Charge a Problem?

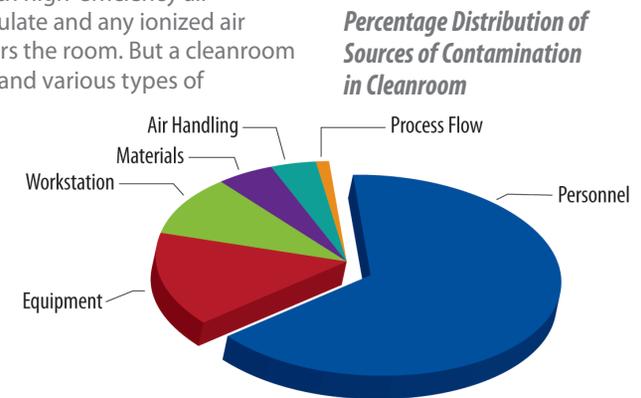
Anything and everything, including movement of people, the moving parts of machinery and the flow of fluids, can generate a static charge. If the presence of static is so extensive, why then is it such a problem?

When a static charge builds up on a sensitive product, a work surface, equipment or a person, the result can be destructive. Products will be contaminated, processes may become degraded and a long list of other—sometimes-mysterious—problems may occur.

Particulate Contamination

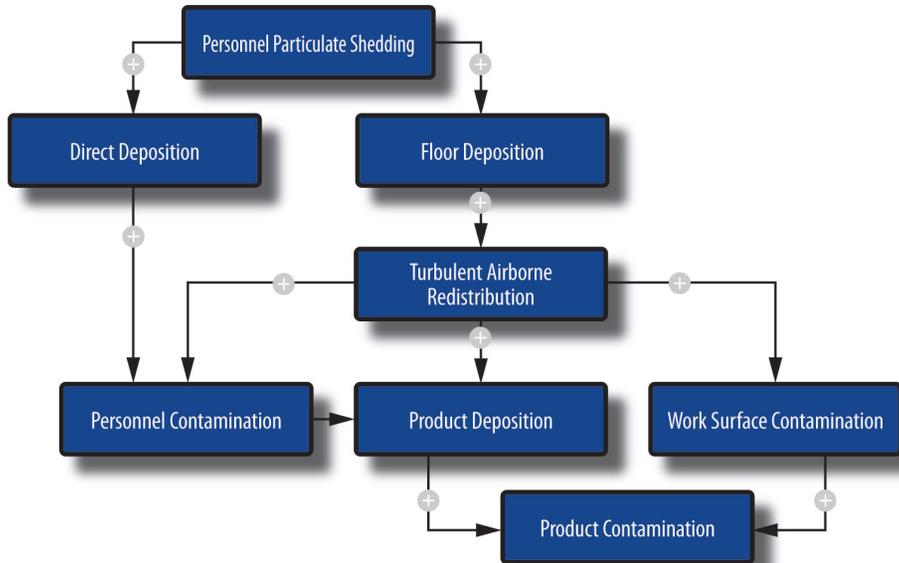
A cleanroom is not entirely what its name implies. A cleanroom is a work area in which high-efficiency air filtration systems remove particulate and any ionized air molecules from the air as it enters the room. But a cleanroom also contains people, machines and various types of process equipment—each contributing contamination to the environment.

Materials typically used in Life Science cleanrooms—plastics, gloves, ceramics, glass and silicone—are good insulators and become charged easily. Air ions present in the air are typically filtered in a similar way to small particulates in cleanroom air filtration systems, thereby losing its static-dissipative qualities. Thus, modern cleanrooms foster higher levels of static charge that remain on objects for long periods of time. The very nature of the cleanroom and the need for products to be as clean as possible makes it difficult to apply antistatic measures because most surface treatments and many static-dissipative materials are not medical grade and compatible with medical products.



Source: Managing Particulates in Cell Therapy: Guidance for best practice, Cytotherapy, 2016, Clark et al.

For most cleanroom operations, the major contamination source comes from personnel. An enormous amount of particulate is imported into the manufacturing process by personnel entering the cleanroom from the world outside. Aside from the considerable range of particulate burden that humans produce naturally (et al., skin and hair shedding), street clothing brings in fibers which are transferred to cleanroom bunny suits and smocks. Floor particulate sampling illustrates this dramatically. The diagram below illustrates the basic model for this contamination pathway into manufacturing.



Considerable research was performed in the late 1980's and early 1990's by key semiconductor researchers dealing with the phenomenon of the attraction of particles to charged surfaces. Even though this may not appear, at first glance, to be related to Life Science Applications, the data and principles are applicable to any clean environment.

At the Institute of Environmental Sciences (IES) technical meeting in 1991, Roger Welker of IBM, San Jose, concluded that "use of air ions results in a significant decrease in surface contamination rates versus identical test conditions without air ions." In the cleanroom where the testing took place, the background airborne particle counts were quite low, only 2.0 particles 0.5 µm and larger per cubic foot.

In a paper published by Masanori Inoue ("Aerosol Deposition on Wafer," Inoue, et al., 1988) and presented at the 1988 IES technical meeting, Inoue demonstrated that **electrostatic charge in a cleanroom is the most important factor causing surface contamination** by particles approximately 0.3 microns in size. Additionally, under his test conditions, he observed that **electrostatic charge was a 1000 times greater factor than diffusion or gravity in causing particle deposition on surfaces.**

A study was done by D.W. Cooper, "Deposition of Submicron Aerosol Particles During Integrated Circuit Manufacturing: Experiments" (Cooper et al., 1988), supports the observation made by Inoue.

Cooper reviewed experiments in which wafers tend to become charged in an operating cleanroom, and found that electrostatic effects can be the dominant particulate deposition mechanism for particles between 0.1 and 1.0 microns in diameter.

Another paper by Michael Yost, "Electrostatic Attraction and Particle Control" Yost et al., 1986), explores the physics of the attraction. The electrostatic forces holding a particle to a charged surface are very strong when compared to gravity or aerodynamic forces such as an air jet. The results clearly demonstrate that the **static charge found in the cleanroom causes surfaces to become contaminated and difficult to clean.** An equipment-related paper by Long, Peterman and Levit (Long et al., 2006) demonstrated that removing the static charge from surfaces significantly improved the cleaning efficiency of those surfaces.

Electrostatic Attraction (ESA)

If a critical product surface becomes charged, as it often does during the production process, and if the charge isn't removed, the surface attracts airborne particulates in the cleanroom. Regardless of the filtration system, personnel, machinery and processes can introduce particulates into the air. The ESA affecting these particles is surprisingly strong. Once bonded to a charged surface, it is very difficult to remove the contamination. Cleanroom airflow will not have enough force to remove it. Contamination of this nature is the major contributor to product contamination and rejection in Life Sciences product manufacturing.

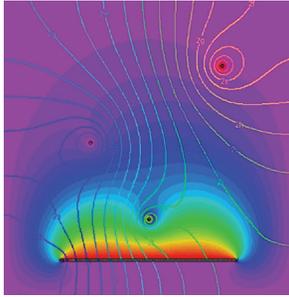
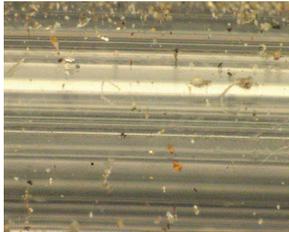
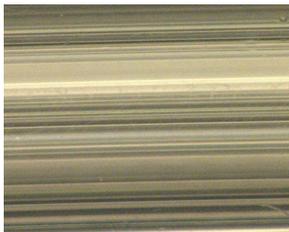


Diagram of charged surface and charged particle Electrostatic Attraction (ESA).



Photograph of a charged catheter after exposure near a cleanroom surface with particulate contamination.



Photograph of an uncharged catheter exposed near a cleanroom surface for five minutes.

Airborne particles are charged through constant collisions with other particles and objects in the cleanroom. Each collision exchanges electrons which create particles with either positive or negative electrostatic charges. The larger the particle, the greater the electron exchange and the higher the charge.

The graph to the left illustrates the electrostatic field structure which forms the attractive force between charged particles and a charged product surface. Particles can move at high velocities and adhere with high binding energies, making them difficult to remove. In fact, for particles at the lower end of the visual size range, usually removing particles cannot be done without first eliminating the electrostatic forces binding them.

The photos on the left demonstrate a typical catheter material exposed to a normal cleanroom environment. The top photograph shows a catheter that has a typical charge present on it, while the bottom photograph shows a catheter in the same environment but with ionization in the cleanroom.

Electrostatic Discharge (ESD)

From decades of working in the high tech electronics industries, it is well known that ESD causes electronic device failure during the production, packaging and testing processes. For medical device products with critical electronic components, damage during manufacturing from electrostatic forces can introduce metrology errors and latent errors where devices fail with customers once the product is in use. Since many new products are using very sensitive electronic assemblies with active sensors, the possibility of latent failures is growing. As the critical dimensions and tolerances of components and circuits become progressively smaller, they become less tolerant to ESD. In circuits designed to operate at lower and lower voltages, minute levels of charge can result in damage or destroy a device.

Typical Charge Levels Found in the Cleanroom

Many objects common to the cleanroom can hold highly destructive levels of electrostatic charge.

Catheters	5-25 kV
Syringes	2-15 kV
Web Films	10-30 kV
Tubing	3-15 kV
Tool Covers	4-18 kV

When failed devices are examined under a scanning electron microscope, the catastrophic effects of ESD become visible. Shorts due to oxide failures and vaporized metal lines are only two of the effects observed.

Recent studies have shown that static discharge can cause even more serious problems than just lowering overall yields. Device degradation due to static discharge may not show up in component testing. If a device fails later in an assembly, it results in additional cost to rework or replace.

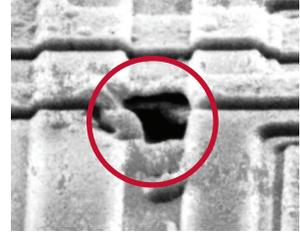
But when a device fails in the field, the cost of repairing or replacing it can easily become 100 times more expensive than if it were detected during manufacture. According to industry estimates, for every ESD-related defect found in manufacturing, there are an additional two to five failures that occur in the field. Not only does ESD cost millions of dollars in downtime and product loss, but it is diminishing valuable user confidence. In a worst-case scenario, the failure of a critical device in a medical application could be fatal.

Material Handling

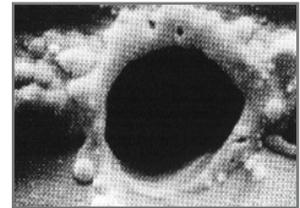
Static charge causes difficulty in handling a countless number of materials and can create problems in feeder tools for product assembly and web tools producing medical sheet products. Electrostatically charged components in feeder bowls can lead to stiction problems as parts are moved to assembly points in tools.

Thin materials that are processed in sheets or on webs and moved over surfaces can create high levels of electrostatic charge. For example, the plastic film used in surgical products is susceptible to what is commonly referred to as "static cling." As an example, medical product assembly tools which have feeder bowls are also susceptible to jamming from the buildup of electrostatic charges.

In addition, the very high electrostatic charges often associated with web processing tools leads to correspondingly high levels of attracted contamination from the surrounding area. Where web sheets are in close proximity to floors under tools, visible floor contamination can be pulled to the sheets.



200x



5000x

Damage Due to ESD

A single ESD event can cause fatal damage to sensitive medical electronic devices during the manufacturing process. The red circle in the top photo shows the site of ESD damage on a semiconductor. The second photo provides a detailed view of the metal bridge that has been formed between the two metal lines by the ESD event.

SEM photos courtesy of 3M.



Gowning Rooms

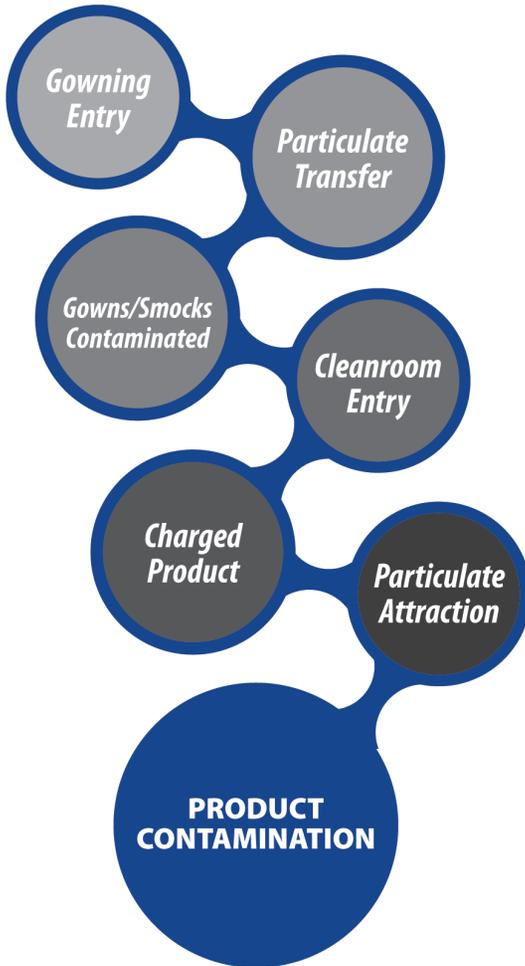
Gowning rooms are the main entry point for contamination entering cleanrooms. Personnel bring contamination from outside the clean room which is then distributed throughout the production facility and onto the exposed product. The transfer will occur between street clothes and smocks or bunny suits when the contamination-laden clothing is in the vicinity of the gowns through the static attraction. An appropriate ionization system in the gowning area can remove upwards of 1 million particles 0.5 um and greater which is then prevented from entering the manufacturing environment.



WITHOUT IONIZATION
PARTICLE ATTRACTION



WITH IONIZATION
PARTICLES FALL TO GROUND



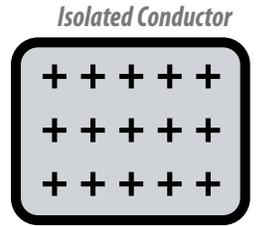
Static Control Methods

It is usually challenging to eliminate static electricity from production environments completely, but with proper use of equipment and remedial procedures, most static problems can be controlled. Many approaches to controlling static charge have been tried over the years.

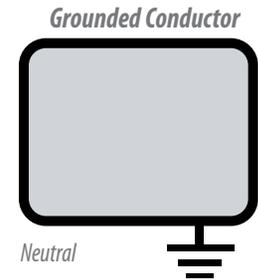
An important consideration in selecting the proper method is whether the charged material is a conductor or an insulator. Static on a conductor can be easily controlled if the object can be grounded. Grounding simply provides a path so that charge can migrate to or from the ground. When a conductor is grounded all of its charges is neutralized and it remains at ground potential. But because the charge does not migrate on insulators, grounding does not work. Grounding an insulator neither removes the charge nor affects the ability of the insulator to become charged as shown in the illustrations on the right.

Providing they follow a strict routine, personnel can be grounded through the use of static-dissipative suits, smocks, gloves and wrist/heel straps. Workstations can be protected by static-dissipative table tops and mats and conductive floors. Materials and devices can be transported in protective bags, bins and boxes made of conductive or static-dissipative materials. These "passive" procedures cannot always be employed and are subject to human error. Many objects used in production are made of materials such as Teflon, quartz or Lexan™. These materials are good insulators for which there is no "antistatic" substitute.

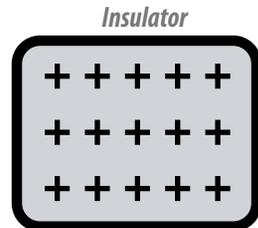
Antistatic or dissipative materials often contain additives that migrate to the surface of the material and attract a thin layer of water. This thin water layer makes the surface of the material conductive, allowing a static charge to move from the surface to the ground. If the water layer is lost, the antistatic properties are lost, and the material behaves as an insulator. Other static-dissipative materials are made by mixing conductive particles like carbon with non-conductive materials. However, these materials often suffer shredding and cause contamination problems.



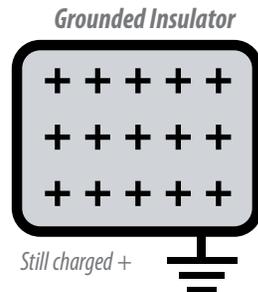
Charged +



Neutral



Charged +



Still charged +

Many of these methods have limitations when applied to the operations of a typical cleanroom facility. The manufacturing process often requires a great deal of movement of people and product between workstations, making the use of wrist straps impractical. Most antistatic or dissipative materials have additives that lead to contamination of the cleanroom and product.



Air Ionization— Conductive Air

Air ionization is increasingly being used to control or neutralize static charge found in critical cleanroom environments. Ionizers actually make the air sufficiently conductive to dissipate the static charge on both insulators and isolated conductors.

Air Ions and the Ionization Process

Air ions are air molecules that have lost or gained an electron. Ions are present in normal air but are “stripped” out when the air is subject to filtration and conditioning. They are produced by radioactive emission or by a phenomenon called “corona discharge” where a high voltage is applied to a sharp point.

All air ionization systems work by flooding the atmosphere with positive and negative ions. When ionized air comes in contact with a charged surface, the charged surface attracts ions of the opposite polarity. As a result, the static electricity that has built up on products, equipment and surfaces are neutralized.

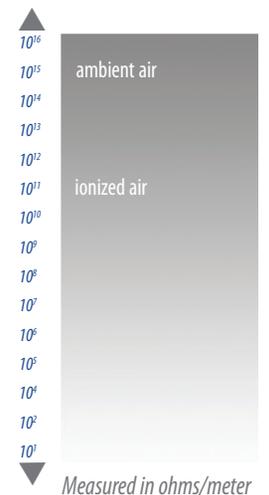
Typically, air is very insulative with a resistivity exceeding 10¹⁵ ohms/meter. By increasing the number of ions in the air it is possible to lower the resistivity of the air to 10¹¹ ohms/meter, thereby making the air more conductive. Conductive air can neutralize static charge on every surface that it contacts. The field from a charged surface attracts ions of the opposite polarity until the charge on the surface is neutralized.

How Does Air Ionization Actually Work?

All air ionization systems work by flooding the atmosphere with positive and negative ions. When the ionized air comes in contact with a charged surface, the surface attracts ions of the opposite polarity. As a result, the static electricity that has built up on products and equipment is neutralized.

Continuum of Resistivity

By using ionization, the resistivity of ambient air is decreased by four orders of magnitude, thereby making the air more conductive.





Bipolar Ionization

Ions of both polarities are required because both positive and negative charges are created in the work area. There are numerous ways to create and deliver bipolar air ionization, and there may be no single "best" method of ionizing for all situations. Deciding which method is best for a specific application depends on the environment, the problem to be solved, and the nature of the work being done in the area. Ions move by field and by air flow, and the effectiveness of a system depends on various environmental conditions.

Over the years, a number of systems have been developed to generate ions. A primary factor that distinguishes one from another is whether or not the system utilizes high voltage AC, DC, pulsed DC current, nuclear or X-ray elements to create ions. These five types of systems vary in efficiency. Sometimes, problems with ion recombination and hot spots (areas with ion imbalance) need to be solved before a system works properly.

The following is a short description of the differences in ionizing technologies and a few examples of where each technology has been used.

Alternating Current (AC)

High voltage is applied to a number of closely-spaced emitter points, which cycle alternately-negative and positive-at the line frequency (50/60 Hz). AC technology is used in grids, ionizing blowers, guns and bars. Due to fast cycling and resultant ion recombination, AC systems must have high levels of airflow to blow ions away from emitter points.

Steady-state DC

With this method, separate emitter points are provided for each polarity. Positive high voltage is continually applied to one-half of the emitter points while negative high voltage is continuously applied to the other half. Steady-state DC is used in room systems, laminar flow hoods, ionizing blowers and ionizing blow-off guns. Steady-state DC work with low

as well as high airflow providing the emitter points is spaced far enough apart to reduce ion recombination, without creating hot spots.

Pulsed DC

Positive and negative emitter points are alternately turned on and off, creating clouds of positive and negative ions. Pulsed DC can be used in non-cleanrooms, as well as cleanrooms and laminar flow hoods. It is generally not used in ionizing blowers or ionizing blow-off guns.

The advantage of this system is its flexibility and versatility, as cycle timing can be adjusted to the specific airflow conditions. For example, in areas of low airflow, a longer time may be required to overcome ion recombination and to allow the ions to reach the work area. In certain kinds of environments, a greater proportion of one polarity might be needed over the other. Pulsed DC allows either polarity to be left on as long as necessary. Some systems feature adjustable off times where neither polarity is on, thus permitting more effective dispersion of ions.

Nuclear

Designed for use in ionizing bars, guns and blowers; nuclear ionizers usually contain polonium 210 as their radioactive source. The radioactive decay of polonium emits alpha particles that ionize the air.

Nuclear ionizers are available only on a lease basis as federal regulations prohibit the outright sale of radioactive devices.

X-ray

Designed for use inside production equipment, X-ray or photon, ionizers use low energy X-rays (4.9-9 keV) to ionize the air. As the X-ray passes through the air inside a production tool, it ionizes the air along a path of about one meter. No airflow is required to disperse the ions throughout the equipment ionizer. Federal regulations requiring shielding and electrical interlocks must be followed when applying these types of ionizers when their power is greater than 5 keV.

Pulsed DC Ionization

Pulsed DC systems use positive and negative emitter points that are turned on and off alternately to create clouds of positive and negative ions. Cycle timing and polarity can be adjusted to provide the required balance and level of static control needed in a specific environment.



Ceiling Emitter



Pulsed DC systems create clouds of positive and negative ions

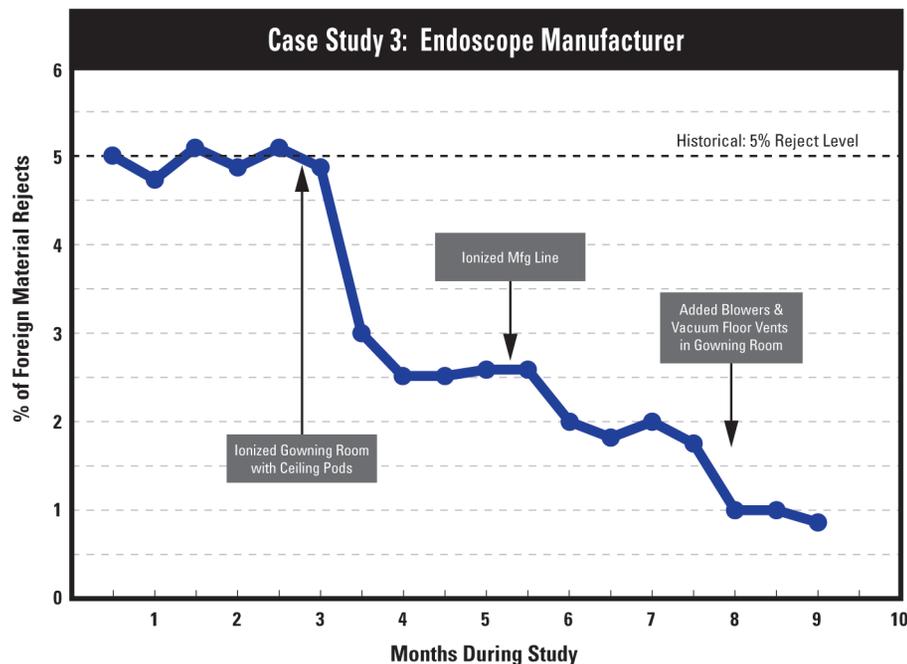
Types of Air Ionization

- Alternating Current (AC)
- Steady-state DC
- Pulsed DC
- Nuclear
- X-ray



Yield Improvement

The following graph demonstrates a typical reduction in production yield rates at a major medical device manufacturer as ionization is implemented step-wise. This manufacturer had been rejecting approximately 5% of their product. Once the garment change room was ionized, this was reduced by about half. As ionization was added to the production area, and further improvements were made (providing for removal of contamination from the environment), the reject rate was reduced to below 1%.



Application Engineering

Dealing effectively with static charge can be a rather complex problem that requires a variety of solutions. When choosing an air ionization system, there are a number of important factors to take into consideration.

Airflow

Some ionization devices require airflow to operate properly while others do not. If ionizers that require airflow are chosen, they must depend on available airflow or include fans in their design. It must be determined whether fans for distributing air ions are compatible with the work environment. Compressed gas ionizers will require a gas source (usually air or nitrogen) and filtration compatible with their use area.

Power Distribution and Control

Self-contained ionizers require 120 VAC power and provisions must be made for supplying this power to each ionizer. Larger systems distribute power from a central controller using either low or high voltage cabling. Control requirements vary with the application. Less critical situations may be satisfied with factory control settings or a single adjustment of an entire area by a central controller. In critical applications, or in areas that lack uniform conditions, the creation of small zones by fine-tuning each emitter point can provide accurate control of both ion balance and level. Feedback sensors provide monitoring and control in critical applications, such as those in the disk drive industry.

Emitter Point Materials

For the wide variety of ionizer applications, it is important that a variety of emitter point materials be available. The sensitivity of the manufacturing environment should always be considered when selecting emitter point materials. For general Life Sciences applications, titanium or tungsten emitter point materials are usually advised.

Engineering

Dealing efficiently with static charge can be a complex problem that requires a variety of solutions. When choosing an air ionization system there are a number of important issues that must be examined.

- Airflow characteristics
- Power distribution
- Emitter point materials
- Installation considerations
- Reliability and maintenance
- Testing and evaluation
- Service and warranty
- System cost

Installation Considerations

The methods used for mounting and wiring the ionization device are important considerations and must be compatible with all safety codes and facility requirements. If the installation is done in an operating cleanroom, it must not interfere with ongoing production or compromise the integrity of the environment.

Reliability and Maintenance

All ionization devices require periodic maintenance. Typically, maintenance consists of a simple emitter point cleaning procedure performed every three to twelve months. The frequency of such maintenance depends on the emitter point tip material, its geometry, the operating parameters, and most importantly, the concentration of airborne molecular contaminants (AMCs) in the air. This maintenance can be performed by end users or by the manufacturer's personnel. Long-term reliability and stability are essential for equipment that is in constant use.

A key element for quality systems in life science applications is the ability of personnel to confirm that the system is performing on an ongoing basis. Thus a reliable method to verify that the system is operating within normal parameters is essential. Feedback to a facility monitoring system (FMS) is also beneficial in some instances.

Testing and Evaluation

Often an evaluation system in the actual work area is the only way to determine required performance levels and to establish specifications. It is critical to choose a manufacturer who will assist in writing meaningful specifications for a particular application.

Service and Warranty

Manufacturers must provide assistance in specifying air ionization, on-site installation of an evaluation system, performance certification and calibration upon completion of installation and follow-up service and maintenance if required.

Most ionization equipment is covered by a factory warranty. Always determine warranty length, what it covers, and what is required to keep it in force.

Cost

The user should compute the total cost of ownership when comparing ionization systems. The total cost of ownership includes the equipment, installation, operation and maintenance costs. It is also important to examine the value of not installing an air ionization system. Often the cost of product loss due to static-related problems is many times greater than the actual cost of the system. In the case of medical devices, contamination can cause product rejection, customer complaint, product returns and even subsequent market loss.

Standards

Both the ESD Association and the Institute of Environmental Sciences and Technology have drafted ionization standards that specify a methodology for comparing air ionization systems. Using a charged plate monitor (CPM), the time required to reduce a 1000V charge to 10% of its initial value can be measured accurately.



Ionization Standards

Both the ESD Association (ESDA) and the Institute of Environmental Sciences and Technology (IEST) have standards for the performance of air ionization. These standards, ANSI/ESD STM3.1, ANSI/ESD SP3.3, ANSI/ESD SP3.4 and IEST RP-CC-022, specify a methodology for comparing different systems or the same system over time. The key instrument used is known as a charge plate monitor (CPM). The CPM has an isolated conductive plate that can be charged to a known voltage. It then measures the time required for the ionizer to reduce the charge to 10% of its initial value. Generally, measuring the discharge time is performed by charging the plate to 1000 volts and determining the time it will take for the voltage to drop to 100 volts. In normal air at 60% relative humidity, the decay rate is approximately 12 hours. An ionization system can typically accomplish the same results under a laminar hood in <15 seconds; <60 seconds in a cleanroom and <300 seconds in an open room with minimal air conditioning. In the case of point-of-use air ionization, blowers can achieve the same results in <10 seconds and ionizing air guns may take only a second or two.

Ionization is a requirement for controlling static charge in any effective static control program. The ESDA promulgates the ANSI/ESD S20.20 static control program, which defines the performance of ionizers needed to protect 100V Human Body Model ESD-sensitive devices and 125V Charged Device Model ESD-Sensitive devices. Air ionization is essential to achieving the levels recommended in these standards. The FDA has recognized ANSI/ESD S20.20 as an industry standard that should be considered by medical device manufacturers.

Standards

Both the ESD Association and the Institute of Environmental Sciences and Technology have drafted ionization standards that specify a methodology for comparing air ionization systems. Using a charged plate monitor (CPM), the time required to reduce a 1000V charge to 10% of its initial value can be measured accurately.



Charge Plate Monitor

Conclusion

The risk of damage due to static charge increases with the technological sophistication and miniaturization of products and processes. The Life Sciences market is undergoing a progressive sophistication in available metrology devices and medical technology. This advance is taking Life Sciences manufacturing closer to the problems and issues faced by semiconductor manufacturing decades ago. Scientific research has demonstrated that failure in electronic devices is often the direct result of electrostatic discharge. Air ionization along with "static awareness," personnel training and proper grounding techniques can achieve remarkable results in reducing loss due to ESD and product contamination. In the cleanroom as well as in other critical production areas, air ionization may be the single most critical factor in eliminating the ESD and particulate contamination problems associated with static charge. From product molding operations to product assembly and packaging, static control using air ionization can translate into cost savings, increased yields, and higher quality products. In an increasing number of high technology manufacturing facilities, successful production is impossible without air ionization.



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