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Consistency as the True Measure of Cleanroom Wiper Quality

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Abstract

Cleanroom wipers have long played an indispensable role in managing contamination in controlled environments. From wiping residues on hard surfaces to applying cleaning solutions, wipers perform a variety of tasks that help maintain the cleanliness levels desired in a given cleanroom environment. This makes the selection of cleanroom wipers a critical decision in any controlled environment. One common way to distinguish between cleanroom wipers of similar structural design is to compare test results across a variety of criteria, according to recommended practices by organizations such as the IEST. However, these results are typically listed as single data points for a given test and are meant to indicate either "typical values," or even target specifications, in some instances. This approach is inherently limited and ineffective in assessing the true levels of cleanliness of a given wiper product. In this study, we review the test methods that are used to evaluate cleanroom wipers and present a new and improved approach by which users can evaluate their cleanliness. We provide a framework by which the consistency of the cleanliness of cleanroom wipers can be assessed in a statistically relevant manner. Finally, we demonstrate the value of using consistency of test results rather than a singular test result as the true measure of wiper quality.

Keywords

Wiper Evaluation, Wiper Comparison, Cleanroom, Clean Room, Box and Whisker Charts, Consistency Charts, Consistency, Wiper Quality

Introduction

Cleanrooms are designed to control contamination, either by keeping contamination at low levels within the environment, or preferably by keeping contamination outside the controlled environment.

Different industrial areas may be variably sensitive to different sources of contamination in their operations. A pharmaceutical company may consider only large fibers to present a significant risk to their aseptic process for a parenteral drug product, whereas even trace levels of particular elemental contamination can severely impact certain processes in semiconductor wafer fabs.

Wipers are used widely in several industries as part of cleaning protocols prescribed in the maintenance of the controlled environment. Wipers are used to clean hard surfaces, equipment, chambers, and tools; to clean up spills; and to serve as a work surface. Given that wipers serve such integral functions within cleanrooms, a strong emphasis is placed on their cleanliness. Wipers with lower levels of cleanliness can themselves serve as sources of contamination. It is therefore critical that wiper quality and cleanliness levels be adequately measured and comparably evaluated.

Methods to Assess Wiper Quality

The quality of a cleanroom wiper is typically evaluated across a range of performance characteristics including fabric substrate and micro-structure, sorption capacity and rate, particulate burden of various sizes, bioburden, ions, metals and non-volatile residues (NVR), among others. Personnel responsible for the controlled environment typically make an informed judgment about which of these attributes are more critical to them compared to others. Test protocols exist in order to provide common methods to evaluate wipers using the test results.

IEST-RP-CC004.3, *Evaluating Wiping Material Used in Cleanrooms and Other Controlled Environments*[1], describes the different types of contamination related to wiper cleanliness. The three major types of contamination described are particles and fibers, ions, and non-volatile extractable matter.

Particles and Fibers

IEST-RP-CC004.3, Section 6 describes two methods for particle and fiber enumeration. The overall process for particle and fiber counting is first to extract the particles into solution and then to count the extracted particles. The testing solution can be pure water or water with an additive to lower the surface tension of the solution. Some type of motion is used to move particles from the wiper into the extraction solution. The intensity of motion varies the number of particles available for counting. The more intense the motion, the more particles are available for counting. Typical motion generators are orbital (less intense) or biaxial (more intense) shakers. Two methods of particle counting are described in the recommended practice: liquid particle counting (LPC), which is a light-scattering process, and scanning electron microscopy (SEM). Once the particles are in solution, the number of particles is assessed in the form of particle counts.

When the motion is generated by an orbital shaker, a surfactant can be used, since the extraction solution is filtered for analysis by optical and scanning electron microscopy. A more detailed explanation of this extraction and measuring test method is presented in ASTM Standard E2090, *Standard Test Method for Size-Differentiated Counting of Particles and Fibers Released from Clean Room Wipers Using Optical and Scanning Electron Microscopy*[2].

When the motion is generated by biaxial shaker, the wiper is extracted using water only. The typical instrument for small particle analysis (>0.2 µm or >0.5 µm) is a liquid particle counter. An LPC operates by light scattering, so using a surfactant would generate bubbles which could interfere with the particle counting.

Ions

Extractable or leachable ions can remain as contaminants after the fabric is processed. Typical cations are sodium, potassium, calcium, magnesium, and ammonium. Typical anions are chloride, fluoride, nitrate, nitrite, sulfate and phosphate. It is important to accurately estimate the ionic burden that the wiper carries with it into the cleanroom. The ion levels are typically determined by ion chromatography (IC). Other analytical techniques may include inductive coupled plasma mass spectrometry (ICP-MS) and inductive coupled plasma optical emission spectrometry (ICP-OES).

To extract the ions, a wiper is soaked in water at a given temperature for a specified time. The extraction temperature and time are varied, to derive different information about the wiper. The extraction temperature can be ambient or elevated (80°C is common). The extraction time, which ranges from 15 minutes to 24 hours, varies with the temperature. Extractions performed at elevated temperature and for a short time estimate the maximum ion contamination that the wiper contains. Extractions performed at ambient temperature are targeted to estimate the quantity of ions that may be extracted during use.

Extractable Matter

Trace amounts of finishing oils and other additives used in fabric manufacturing can remain as extractable or leachable contaminants after the fabric is processed. To find the amount of extractable matter, a wiper is soaked in a solvent at a given temperature for a specified time. The amount of extractable matter for a given solvent depends on the time and temperature of the extraction. Typically, the solvent is chosen because the wiper will be used with the solvent. Extracting the wiper at or near the solvent's boiling point will remove more material. Extracting with the solvent at room temperature will estimate how much material the wiper will leave behind.

The wiper is extracted with an excess of solvent at a given time and temperature. The solution is dried and the amount of extracted material is determined gravimetrically. The results are reported as a percent or through multiplication of the basis weight of the wiper, in grams per square meter.

Wiper Testing and Statistical Process Control

As part of any statistical process control program, wiper manufacturers generate relevant data to monitor the cleaning process; for example, the particle burden carried by a processed wiper. Statistical methods are used to analyze these data, in order to measure the inherent variability in the cleaning process. The goal is usually to maintain statistical control and improve the cleaning process capability to produce a wiper with low particle counts and low variability. As the variability is reduced, a more consistent process is established, which in turn results in a more consistent wiper product.

To acquire these data, a representative sample, e.g., one bag in a lot, may be analyzed for its particulate level. Over time, several lots of this product are manufactured, and the particulate level is measured for each lot. The data are trended, resulting in a chart as shown in Figure 1.

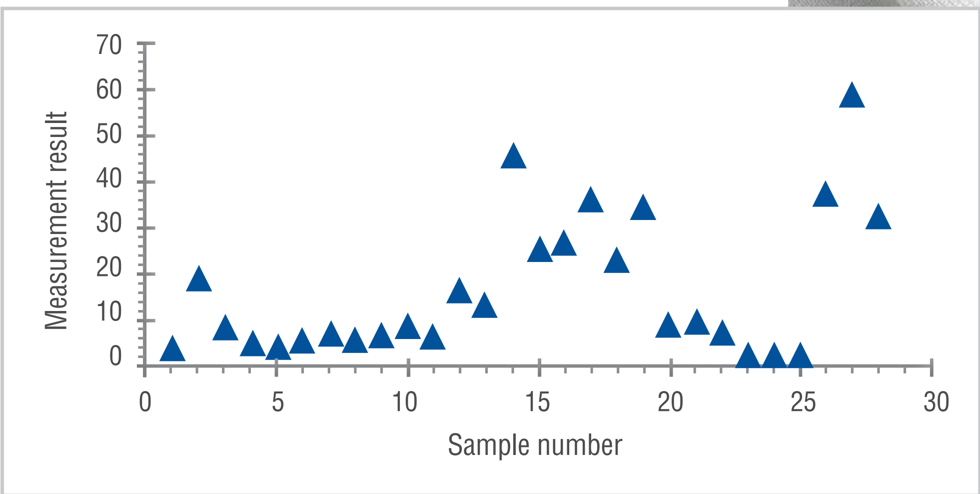
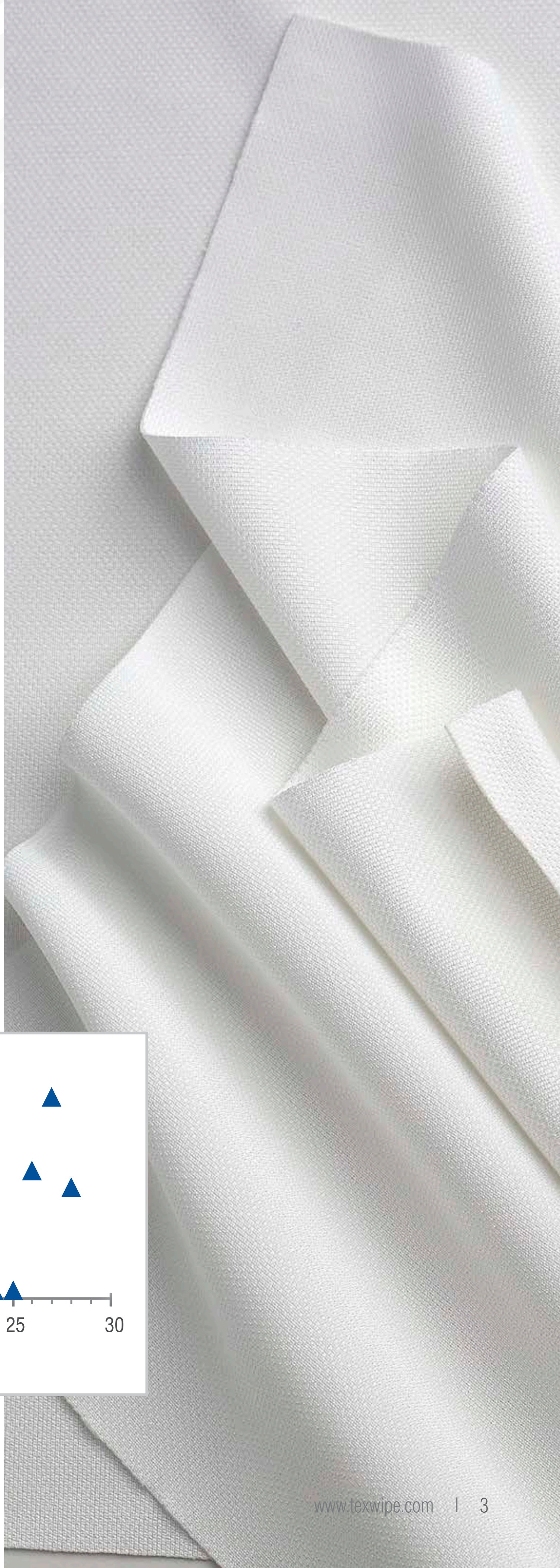


Figure 1. A typical control chart of wiper testing results over manufactured lots.



Statistical Treatment

Now let us assume that the cleaning process being analyzed was changed. How many data points must be generated to determine if a change in the wash process has affected its output significantly (is the wipe cleaner)? To answer this question, a statistical discussion is necessary[3]. The answer is affected by the difference of the means (average, or the sum of the values divided by the number of points) of the data sets, the variability (standard deviation, or the average distance of each data point from the mean) in the data set, and the acceptable level of risk for determining whether the change made a difference or not. The cost and time for acquiring the necessary information also are impacts, but are not part of the statistical treatment of data.

Note that this discussion is applicable to any variable. The t-distribution in the t test introduced in the following paragraphs is dimensionless. The statistical treatment can be applied to compare different extraction processes for metal ion levels (hot water vs. cold water), extraction processes for particle levels (orbital vs. biaxial shake), or extraction solvents for non-volatile residue levels (acetone vs. isopropyl alcohol). This statistical treatment also can be used to determine if different technicians are getting different testing results or to evaluate the output of different manufacturing lines making the same product. The number of data points needed in each data set is a function of the difference of the data set means and overall standard deviation of these data sets.

The operating equation is the result of the t-test[1]

$$t = \frac{|\mu_a - \mu_b|}{S_p(\mu)}$$

where the vertical bars indicate the absolute value of the difference in means, μ, μ_a and μ_b are the means of the data and before and after the change, respectively, and $S_p(\mu)$ is the pooled standard deviation of the means.

The t-distribution is an estimate of the normal distribution (a parametric distribution which is defined by two parameters, the mean, μ, and the standard deviation, σ) when the sample size is small and the population standard deviation is not known. The t-distribution is affected by number of degrees of freedom, typically, the number of data points minus one, n-1, used to calculate the $S_p(\mu)$ value. The t-distribution has a different distribution for each number of data points. As the number of data points approaches infinity, the t-distribution approaches the normal distribution. The values of the t-distribution can be found in standard tables and are referenced as Table 6.1 in Volk[3] and referenced in Table 1, below. Values in this table are determined by the number of degrees of freedom and the significance value, α, the significance level of the test.

	α, the significance level of the test			
n-1	0.5	0.1	0.05	0.01
10	0.700	1.812	2.228	3.169
20	0.687	1.725	2.086	2.845
Infinity	0.674	1.645	1.960	2.576

Table 1. Sample table of t-distribution values.

The null hypothesis, H_o, is defined as the two means are the same, $\mu_a = \mu_b$. The t value calculated in Equation 1 is used to accept or reject this hypothesis. When the hypothesis is accepted, i.e., the means are the same, the t value is less than the t value in the table. When the null hypothesis is rejected, i.e., the means are different, the calculated t value is larger than the one found in Table 1.

Two types of errors can occur from this test.

1. A Type I error, a false positive, is the false rejection of equal means. The means are the same, but the information from the data indicates that they are different. As the value of α is decreased, the risk of a false positive decreases.
2. The other error is a Type II error, a false negative. This error is the false rejection of means that are different. The means are different, but the data indicate that the means are the same. The probability of this error occurring is defined as β. The quantity, $1 - \beta$, is defined as the power of the test.

α and β are related to each other. As the value of α is decreased, which assures that a false positive does not occur, the risk of a false negative increases. With a fixed value of α, β can only be decreased by increasing the number of data points.

The preceding discussion is summarized in Table 2.

	Reality: H_o is true, $\mu_a = \mu_b$	Reality: H_o is false, $\mu_a \neq \mu_b$
Data set comparison indicates rejecting H_o	Type I error False positive	Correct outcome True positive
Data set comparison indicates not rejecting H_o	Correct outcome True negative	Type II error False negative

Table 2. Comparison of reality with the results of data analysis that will yield Type I and Type II errors.

An example of a Type I error (false positive) is diagnosing a patient with cancer when the patient is free of cancer. An example of Type II error (false negative) is assuming analytical equipment is giving correct results when in fact the equipment is broken, and the results are meaningless.

The minimum number of points needed to determine if the means of two data sets are different is determined by the difference in means of the data sets, the variability in the data set, and the level of risk of Type I and Type II errors that is acceptable from the values of α and β chosen. See Table 3, which is based on Volk[3] Table 6.10. "The Number of Observations Needed in a *t* Test of the Significance of a Mean, In Order to Control the Probabilities of Errors of Types I and II at α and β, Respectively." The number of observations or points needed in a data set is the intersection of value of $|\mu_a - \mu_b|/S_p(x)$ and the combined values of α and β. If the difference between the means and the standard deviation are the same ($|\mu_a - \mu_b|/S_p(x) = 1$) and the values for α and β and are chosen to be 0.05, the minimum number of points required to distinguish between two means is 16, i.e., at least 16 data points are needed in each data set. If more risk is acceptable, and α and β and are 0.10, a minimum of 11 data points in each data set is required.

As the standard deviation of the data decreases, i.e., the values in the data set are closer to each other, the minimum number of data points in each data set required decreases. For example, if the standard deviation is half the difference in means ($|\mu_a - \mu_b|/S_p(x) = 2$) and α and β and are set to 0.05, the minimum number of data points is six, or ten fewer data points.

	Significance value, $\alpha = 0.05$	Significance value, $\alpha = 0.10$
$\lvert\mu_a - \mu_b\rvert / S_p(x)$ value	$\beta = 0.05$	$\beta = 0.10$
1.00	16	11
2.00	6	——

Table 3. Sample table for determining the minimum number of data points for controlling Type I and Type II errors.

This outcome makes clear that analyzing just one or a few lots (data points) is insufficient to determine if a change has impacted a process or to distinguish between two similar processes or products. In order to make a more reasonable and statistically valid assessment of the impact of such changes, one must analyze a sufficiently large number of data points. Process changes or differences between two similar processes or products are more easily distinguished when the variability is lower.

Anatomy of a Consistency Chart

A statistically unbiased method (no distribution or parameters are assumed) to evaluate many large sets of data is through the use of a consistency chart also referred to as a "box and whisker chart."[4] These charts represent data sets pictorially. The components of the box and whisker in a consistency chart are determined using the individual data points from the data set. A key advantage of a consistency chart is that, because it is defined by five points instead of two (mean and standard deviation), it communicates more information regarding the data set.

The components of the box and whiskers in a consistency chart are determined through the data points themselves. They are:

- **Line** – represents the median or middle value of a ranked data set. (Extreme values do not affect the median value as much as a mean could be affected.)
- **Box** – represents the range of values in which 50% of the data lie. If the median line is closer to one end of the box, the data are skewed toward that end. A smaller box indicates that the values inside the box are more similar.
- **Whisker** – the line at each end of the box, expresses a range of values in which 25% of the data set lie. A short whisker indicates that values within the whisker range are similar to each other.
- **Outlier** – indicates points that are significantly different than the rest of the data set.

Consistency charts are constructed through the following steps.

1. The data set values are ranked from highest to lowest.
2. The ranked data are divided into quartiles.
3. The box is constructed using the first and third quartile values.
4. The whisker ends are defined

$$W_u = Q3 + 1.5 * IQR \qquad (2)$$

$$W_l = Q1 - 1.5 * IQR \qquad (3)$$

   where
   W_u and W_l are the upper and lower whisker values, respectively,
   $Q1$ and $Q3$ are the first and third quartile values, respectively,
   and IQR is Intra-Quartile Range, the difference between $Q3$ and $Q1$.

5. The outliers, which are any values beyond the whisker values, are determined and are indicated by an asterisk.

Once assembled from an adequate number of data points, a consistency chart constitutes a statistically unbiased representation of the available data for any given wiper. Lower medians, smaller boxes, and shorter whiskers taken together indicate a cleaner and more consistent wiper. In contrast to simply reading a mean value and perhaps a standard deviation, a consistency chart represents the true quality of a cleanroom wiper in full measure as it relates to the particular performance attribute being measured.

How to Evaluate a Cleanroom Wiper

1. Comparative assessment of cleanroom wipers

It is customary to evaluate technical specifications in comparing cleanroom wipers across a range of performance test measurements. Often, these are represented by "typical values." However, such test values are nothing more than singular data points from one particular manufactured lot that may be completely unrepresentative of the wipers actually used in the cleanroom. The most unbiased assessment of the cleanliness of a cleanroom wiper would be through consistency charts for all the tested performance parameters over a period of time. This would represent a statistically relevant sampling of test data (minimum of 11 samples depending on data variability) and indicate how variable these data are over a period of time. Ultimately, what matters most to a user in a cleanroom is that any wiper withdrawn from any bag or any lot of the product is as close as possible to any other wiper of that product in terms of cleanliness. Greater variation as evidenced by larger boxes and longer whiskers would indicate a larger variability in wiper cleanliness levels that would place at high risk the process and products that rely on the stated levels of cleanliness. More consistent quality wipers provide a greater assurance to the user that any given wiper from any given bag or lot of that product is very much like every other as regards to test results.

Figure 2 shows a comparison of the data sets for four wipers. The data were obtained by the method described in IEST-RP-CC004.3, Section 6, biaxial shake, >0.5µm LPC (liquid particle counting) analysis of wipers.

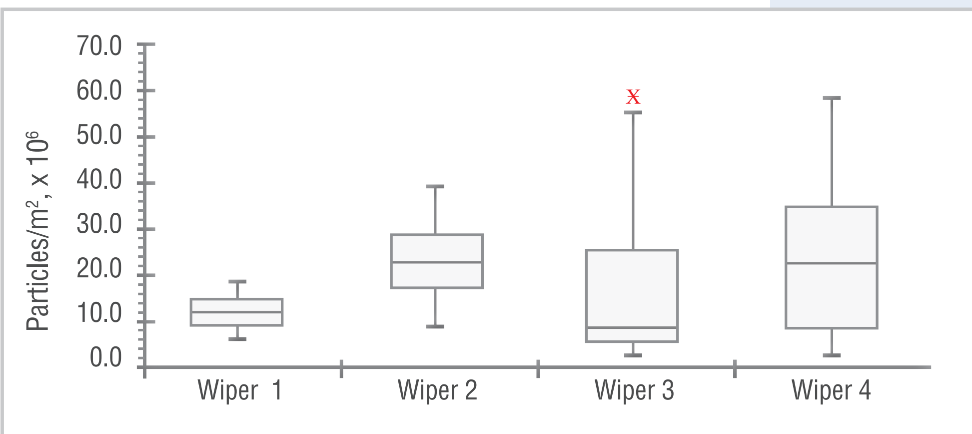


Figure 2. Consistency chart comparing IEST-RP-CC004.3, Section 6, biaxial shake, >0.5µm LPC (liquid particle counting) analysis data sets for four wipers.

Observations

The following observations can be made from Figure 2:

- Wiper 1 has the smallest box and the shortest whiskers. Wiper 3 has an outlier value as shown by the asterisk above the whisker and the longest whisker.

What truly matters in a critical cleaning operation is that each wiper from a bag, each bag within in a lot and each lot of a given wiper product is delivered to the end user with the highest assurance of the expected quality.

Consistency charts offer the most unbiased representation of the consistency of cleanroom wipers from within a bag or lot, over an extended period of time.

- Of the test results for Wiper 3, 25% are lower than those for Wiper 1. The data set for Wiper 1, or the whole box and whisker diagram, lies within the box for Wiper 3.
- Wiper 2 and Wiper 4 have similar medians; Wiper 3 has the lowest median.
- Wiper 4 has the largest box and the largest range in the data.

Summarizing these observations, Wiper 1 is the best wiper because it has a smaller box and shorter whisker. Wiper 3 does have a lower median; however, Wiper 1 is the most consistent wiper at the cleanliness levels claimed.

2. Effect of Automation on Consistency of Cleanroom Wipers

Figure 3 shows a consistency chart comparison of two wipers. The data were obtained by the method described in IEST-RP-CC004.3, Section 6, biaxial shake, >0.5μm LPC (liquid particle counting) analysis of wipers. The product identified as "Fully automated" is manufactured in a fully automated micro-environment free from human contact. The product identified as "Conventional laundry" is made in a conventional cleanroom laundry using manual handling.

Automation is known to reduce variability in a process. Since human beings carry high particulate burdens of various sizes, removing human contact has the effect of reducing particulate levels found in a wiper. When a "hands free" environment is combined with an automated cleaning process that removes the particles from the wipers, a cleaner and more consistent wiper can be produced.

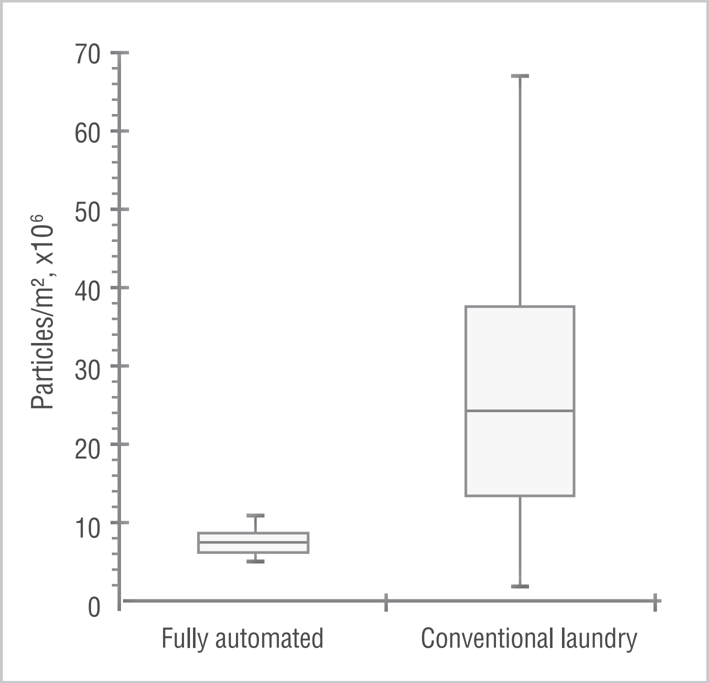


Figure 3. Consistency chart, which compares the IEST-RP-CC004.3, Section 6, biaxial shake, >0.5μm LPC (liquid particle counting) analysis test results for two wipers. The product identified as "Fully automated" is manufactured in a fully automated micro-environment free from human contact. The product identified as "Conventional laundry" is made in a conventional cleanroom laundry.

Figure 4 shows a comparison of data sets for two wipers. The data were obtained by the method described in IEST-RP-CC004.3, Section 6, biaxial shake, >0.5µm LPC (liquid particle counting) analysis of wipers. The wiper identified as "Semi-automated" is manufactured using a process where humans have intermittent contact with the product. The product identified as "Conventional laundry" is made in a conventional cleanroom laundry where each wiper is exposed to humans and the environment. Even a partially automated process reduces the variability in a product.

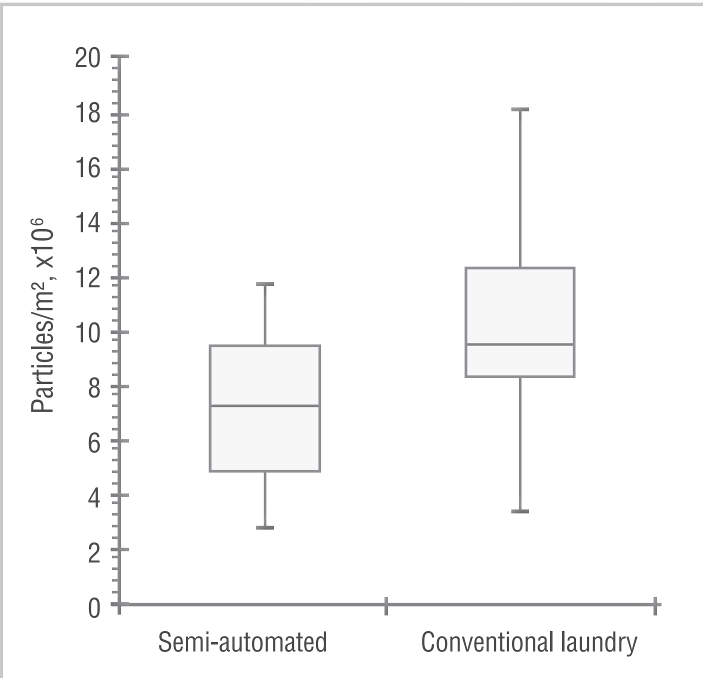


Figure 4. Consistency chart, which compares the IEST-RP-CC004.3, Section 6, biaxial shake, >0.5µm LPC (liquid particle counting) analysis test results for two wipers. The same fabric, both 100% polyester with the same knit structure, manufactured through different cleaning processes. The product labeled "Semi-automated" has intermittent human contact. The product labeled "Conventional laundry" is processed through a typical cleanroom laundry.

Conclusions

Selecting the best cleanroom wiper for a particular application requires the most unbiased scientific assessment of the available data for any given wiper. Comparing consistency charts for cleanroom wipers allows for a quick determination of which process or wiper better meets the user's needs. A more consistent wiper gives a user more confidence in the wiper's performance because of the consistency of its cleanliness over time.

The quality of a cleanroom wiper should therefore be evaluated not merely through a typical or mean value, but more importantly, through a statistically valid assessment of how consistently that typical value is attained in practice over an extended period of time using a given process.

As more automation is used in a wiper manufacturing process, the contamination level and the variability decrease.

What truly matters in a critical cleaning operation is that each wiper from a bag, each bag within in a lot and each lot of a given wiper product is delivered to the end user with the highest assurance of the expected quality. Consistency charts offer the most unbiased representation of the consistency of cleanroom wipers from within a bag or lot, over an extended period of time.

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