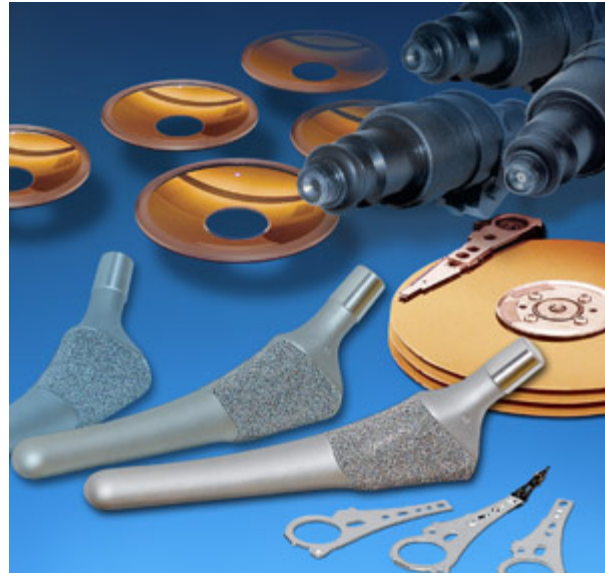


Parts Cleanliness Testing for the Medical Device Industry

In the medical device industry, it is becoming increasingly critical to ensure that parts are clean. Infections or rejections due to inadequate or improper cleaning can result in serious health problems, major litigation, and, in some cases, business failure.

While a rigorous cleaning method is important, it is also necessary to quantify that the cleaning method was effective. That is, after being cleaned, parts need to be checked to see if particles remain. While there are particle scanning devices to check the cleanliness of flat surfaces, medical devices are complex in shape and do not lend themselves to this technology. Different particle counting methods need to be used for testing complex parts. When testing the cleanliness of an irregularly shaped part (and therefore testing the effectiveness of the cleanliness method), all methods follow two steps. The first is to extract the particles from the device into a liquid; the second is to test how many particles the liquid now contains. This article reviews the most common techniques used to test irregularly shaped devices and discusses the advantages and disadvantages of each.



Methods of Particle Extraction

The first step in testing the cleanliness of irregularly shaped parts is particle extraction. There are three common methods:

- High pressure spray
- Sloshing or swirling
- Ultrasonic extraction

High-pressure spray

In many cases, removing contamination is accomplished by a simple spray wash. A solvent/aqueous solution is sprayed from a high-pressure nozzle onto the surfaces of a part. The effluent is captured as it runs off the part into a clean container. This method is

traditionally used when the contamination of interest is of relatively large size (>50 microns) or when the size of the part is exceptionally large.

For this method to be effective, it is imperative to know that both the cleaning solution and the collection vessel are clean. Even if using an exceptionally clean fluid such as ultrapure water, there is a risk of receiving a contaminated batch from the supplier or of a failure in the delivery mechanics contaminating the fluid. The particulate cleanliness of test fluid must be verified frequently enough to ensure its adequacy for the test.

The second concern is the cleanliness of the effluent collection vessel. The collection vessel must be cleaned and checked before each test. Since the particle size of concern for this application is typically large, it is relatively easy to clean the test apparatus to produce the low background values necessary for a successful test. However, if the vessel cleanliness is not verified before testing the part, a breakdown in the pre-test cleaning process will go unnoticed. The particles in the dirty test vessel will increase the counts recorded during the actual part test. This could cause a perfectly cleaned part to be rejected when, in fact, it should be accepted.

Another results concern is technique. As an example, suppose that one testing operator's interpretation of his job is to try to get as many particles off the part as possible. This individual painstakingly covers every millimeter of the part with slow deliberate strokes. Another operator believes that the number of parts tested during the day is the most important indicator of job performance. This individual attempts to cover every millimeter with rapid strokes, believing that as long as the entire part is wet, a representative sample of the particles will be collected. Both of these operators have valid beliefs.

The first operator will remove more particles from the part. The second operator will process more parts. As long as each operator maintains consistent technique, both will generate data that is representative of the cleanliness of the parts. In other words, when parts are dirtier than normal, both will show data with higher particle counts. The problem comes when trying to compare the data produced by the two operators.

In general, the data will be randomly mixed together making it less obvious that the differences can be attributed to operator technique. This, combined with statistical variation in the cleanliness of the parts themselves, will create the appearance that the parts have a relatively wide variation in cleanliness, even though both sets of data may show that the cleanliness of the part is within required specifications. The fact that most of the parts are acceptable means that the upper control limit will necessarily be quite high. This may allow for parts that are actually outside of acceptable levels to be passed on to manufacturing as good parts.

Sloshing or Swirling

This method is typically used for smaller parts or to test containers for cleanliness. To test small parts, a clean container is filled with a carefully measured volume of clean solvent/aqueous cleaning fluid. The parts are added, and the operator then swirls the

container of fluid for a designated interval of time. The number of particles added to the testing fluid determines the cleanliness of the part.

The sloshing/swirling method of extraction suffers from the same shortcomings as the high-pressure spray method. All of the test materials must be verified clean before each test. Because this method is often used for smaller particles, the extraction technique must be more rigorous and carefully followed if reasonable backgrounds are to be achieved (<1% of expected contamination by part).

Once again, operator technique will influence the results. An operator with a more vigorous swirling/sloshing technique will produce greater numbers of particles. In one application, the slosh test showed that no cleaning of parts during manufacturing passed just as many products as ones that had been through three cleaning steps, due to operator variance. An alternative conclusion is that the cleaning process was entirely ineffective.

Some users of the sloshing method have been known to standardize on one operator to perform the test. Both of the above situations produce significant questions on the value of this method. If the test method cannot tell the difference between a part that has been cleaned and one that has not been cleaned, how can any useful decisions be made about the cleanliness of the part? If only one operator can perform the test, what happens to the data when that operator is no longer available? Answers to these questions must be addressed if this method is to become the primary qualification tool for the company's products.

Ultrasonic Extraction

This method can be used for almost all materials, part sizes, and cleanliness levels. The procedure is to immerse the part into a bath containing a solvent/aqueous cleaning fluid. The bath has transducers bonded to the surface, which produce ultrasonic energy in the cleaning fluid.

The ultrasonic energy imparts significant cleaning power to the surface of the part, which is effective at removing even strongly bonded particles. Because the extraction force is constant, more reliable and repeatable particle removal can be obtained. As with the previous two methods, the cleanliness of the test apparatus is critical. There must be a method for testing the cleanliness of the



test container complete with its test fluid. An important consideration is the need to make this background measurement after exposing the test container and fluid to the ultrasonic energy.

Combining the more efficient cleaning of ultrasonic energy with careful flushing of the container can achieve significantly lower background levels for the test. By achieving a lower background the data will track the part's true level of contamination more accurately. This is critical to the performance of any of these methods. Inadequate background preparation will produce results difficult to analyze.

A somewhat less obvious fault in this test (and the swirl/slosh test above) is the time for extraction. Most parts cleanliness tests use extraction intervals of <2 minutes that require the operator to manually time the generator (sloshing).

Anything longer than thirty seconds seems to be beyond the attention span of a typical operator, and a conversation between coworkers or other thoughts about the day will usually intervene, occasionally producing longer than expected extraction times. This variation will provide added variability in the data, increasing the standard deviation. Automation of any kind can improve the results in this part of the test. At the very least, recurrent training is necessary to insure the operators maintain good technique and follow procedures closely to reduce data errors.

Summary of Extraction Methods

Table one summarizes the common extraction methods. Of the three methods described, only the ultrasonic method is highly repeatable, accurate, and precise.

Human error is the greatest cause of error in all methods; the more hands-on time in the procedure, the more room for error.

Extraction Method	Applications	Advantages	Disadvantages
High Pressure Spray	Large particles (> 50 microns) and/or large parts	<ul style="list-style-type: none"> • Low initial investment 	<ul style="list-style-type: none"> • Time consuming • Expensive in payroll time • Inconsistent results due to <ul style="list-style-type: none"> ○ cleanliness of fluid used ○ cleanliness of collection container ○ operator technique
Sloshing or Swirling	Small particles, small devices.	<ul style="list-style-type: none"> • Low initial investment 	<ul style="list-style-type: none"> • Time consuming • Expensive in payroll time • Inconsistent results due to operator method
Ultrasonic	Large or small particles. Large or small devices.	<ul style="list-style-type: none"> • Precise • Fast • Repeatable Results 	<ul style="list-style-type: none"> • High initial investment • Dependant upon operator

Table 1: Summary of Methods of Particle Extraction

Methods of Sample Analysis

After the particles have been extracted from the test part, they must be counted and sized, and then the results must be recorded for evaluation. To do this, the liquid that contains the extracted particles is now analyzed. It is this analysis that provides information to help us know if the cleaning method was effective. Once again, there are several methods for counting the particles.

Gravimetric Analysis

Gravimetric analysis requires the use of a previously weighed membrane filter. The test fluid is then pulled through the filter. The filter is dried, and re-weighed. The additional mass of the filter is presumed to be from the particles extracted from the part. Further, it is assumed that the particles are of the same density and size distribution as the original tests that were used to set acceptable mass levels.

Changes in particle density, or size distribution will produce data that could be extremely misleading. For instance, if stainless steel particles are present in one test and nylon particles are present in another test the gravimetric results will be quite different. Is the lighter nylon contaminated part cleaner than the stainless steel part? Is the nylon contamination less important than the stainless steel contamination? The answer to both questions is probably no. Additionally, with each sample transfer, care must be taken not to contaminate the test fluid or the membrane filter. Tests must be performed on the filters periodically to ensure that the drying process does not contaminate the test membrane. One careless action can ruin the entire test.

Optical Inspection

Optical inspection requires the use of a clean membrane filter. The test fluid is pulled through the filter. The filter is then placed on a microscope stage and inspected for particles larger than a specific dimension. Due to the magnification provided by the microscope, it is typical that only a small region of the filter is inspected.

In situations where parts are truly clean, there may only be a few killer (i.e., damaging) particles anywhere on the filter. How can one be assured that the location of these particles is included in the inspection region? Problems also occur in this method when particles are not uniform in shape. Particles can be measured over the longest dimension, average size, length of x-axis, etc. Different inspectors may use different methods, or simply see the size differently resulting in additional data variability. Again, with each sample transfer, care must be taken not to contaminate the test fluid or the membrane filter. One careless action can ruin the entire test.

Optical Particle Counter

An optical particle counter can also be used to sample the test fluid. Advantages of this method include rapid sampling capability, excellent sample-to-sample repeatability that results in confidence in each test, accurate sizing information, and elimination of operator subjectivity and errors.

However, optical particle counters are not an absolute measure of particle size. They measure the equivalent optical size of the particle, reporting a value equivalent to a calibration particle. If the particle is similar to a fiber i.e. long and thin, then orientation in the sample cell can produce different results. These limitations result in relatively little to no variation in the test results when compared to the possible variations produced during the extraction process.

Summary of Analysis Methods

The three methods of analysis described in this paper are summarized below. Of the three, only the optical particle counter method eliminates human error and provides accurate, repeatable results.

Method	Advantages	Disadvantages
Gravimetric	<ul style="list-style-type: none"> • Low initial investment 	<ul style="list-style-type: none"> • Easy to contaminate the results • Human error likely
Optical	<ul style="list-style-type: none"> • Low initial investment 	<ul style="list-style-type: none"> • Difficult to find particles • Human error likely
Optical Particle Counter	<ul style="list-style-type: none"> • Fast • Repeatable • Accurate 	<ul style="list-style-type: none"> • Only measures equivalent particle size • High initial equipment cost

Table 2: Summary of Methods of Analysis

Efficiency and Accuracy

A significant factor in each of the extraction and evaluation methods is time and labor. An operator is involved in each step of the test. They must clean the sample test chambers, perform background checks, extract the particles, and measure the contribution by the test part.

As the cleanliness requirements increase, measurements at smaller particle sizes will be necessary, which increases the time required to clean the apparatus. Because of the labor and time requirement, these tests are typically limited to laboratory checks.

Parts are removed from the cleaning system and sent to the lab for testing. The results of these tests may not be available for a day to a week later, depending on workload in the lab. For this reason, many industries only use these methods when experiencing a major problem in yield. Some opt to skip the testing completely in favor of shotgun servicing of the cleaning equipment. The rationale is that by the time the results point to the actual problem, enough productivity will be lost to merit the more expensive but rapid equipment maintenance.

These limitations produce extremely expensive repercussions in the manufacturing process when parts must be recalled or re-examined to prevent reliability problems as the customers utilize the product. Also, at best, these methods offer a very small sample of

the overall control in the cleaning process without requiring a very large, full time laboratory dedicated to the testing.

New automated technology that incorporates ultrasonic extraction and particle counter technology makes it possible to move testing out of the laboratory onto the manufacturing floor. This technology incorporates automation that reduces or eliminates the occurrence of human errors inherent in the manual versions described, and it helps maintain high throughput. Additionally, many advantages are realized by performing the testing right in the manufacturing area, when the parts exit the cleaning system.

Foremost, with this new technology, contaminated parts can be prevented from reaching the final stages of manufacturing. This will reduce or eliminate product recall/rework due to contamination failures. Additionally, increased information is available about the performance of the cleaning system. Filter changes, bath changes, and major maintenance can be performed only when necessary, all of which increase the cleaning tool's up-time and utilization rate. Changes to the cleaning chemistry or routine can be immediately verified for benefit/detriment to the overall cleaning process. Permanently implementing changes that benefit the cleaning process leads to better results in manufacturing.

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