

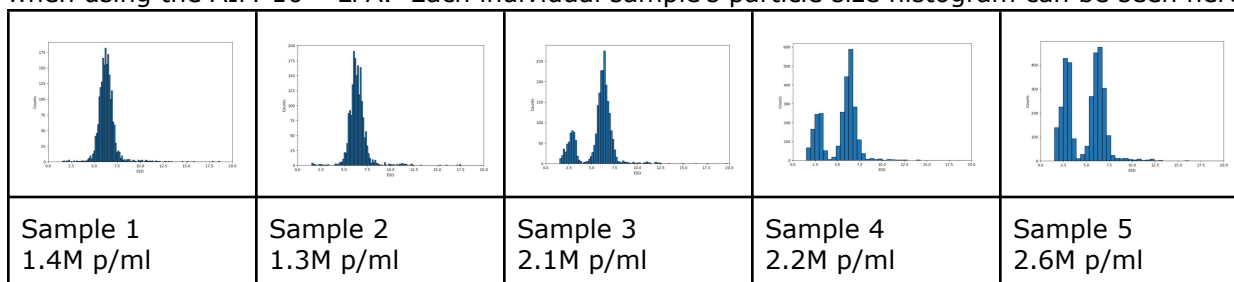
Using the AIM-10™ System's Test Plan Feature to Support Standard Procedures (SOPs)

One of the defining aspects of the AIM-10™ System is the ability for the operator to use the Test Plan feature and program the AIM-10™ to mimic steps from your existing protocols. The creation of a Test Plan is very straightforward through the Test Plan interface. The operator has the ability to enter in the step-by-step instructions from an existing SOP. After a Test Plan is created, it can be recalled at any time in the future and executed directly from the main screen. At the completion of the Test Plan a summary of the results is displayed for review. That summary can also be reopened and reviewed in the future.

Here is an example of the AIM-10™ System's Test Plan functionality based on a real world scenario: A biotech manufacturer must monitor its filling line performance for dispensing a reagent into a reagent bottle. The diluent used in the reagent is passed through a membrane filter to remove particles less than 4 μm while the intended particles in the mixture are between 5 and 7 μm with a concentration range of 1.1M/ml - 1.5M/ml. The sampling plan is intended to ensure the integrity of the filter and prevent contaminants from entering the reagent. An existing sampling plan is already in place and the historical measurement system has been replaced with Sebago Scientific's AIM-10™ Liquid Particle Analyzer. Five samples are selected across the bottling lot with each sample measured for concentration, particle size, and the presence of contaminant particles.



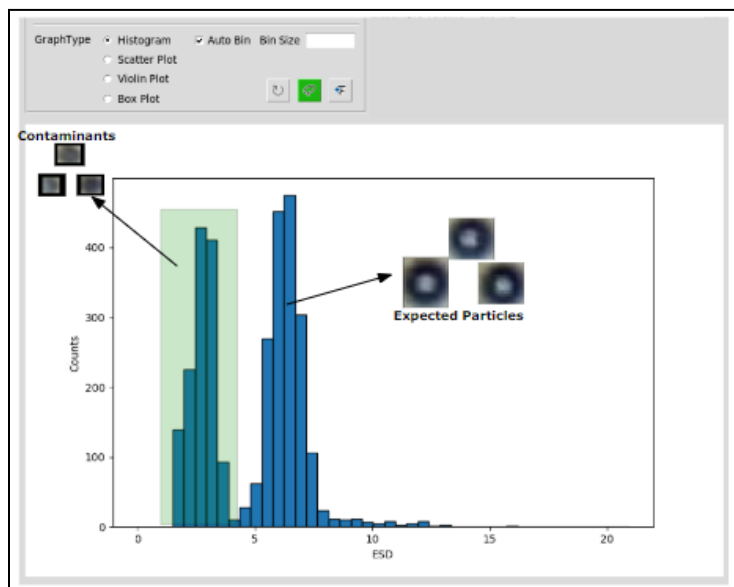
To mimic this testing process, a Test Plan was created that analyzes 5 consecutive samples and pulls a summary together to determine the characteristics of each sample. A properly filled bottle should have a single particle peak at approximately 6 μm with greater than 85% of the particulates between 5 μm and 7 μm . The Test Plan was executed after the filling process was complete, and the analysis for all 5 samples took approximately 25 total minutes when using the AIM-10™ LPA. Each individual sample's particle size histogram can be seen here:



Sample #1 was taken at the start of the filling process, Sample #5 was taken at the end, and the other 3 samples were spaced at equal time intervals throughout the fill. By looking at the histograms, it is apparent that at some time point between Sample #2 and Sample #3 there was a change in the filling system. A second population of particles around 2.5 microns appeared in this time frame and slowly increased for the remainder of the filling event.

It was hypothesized that the increased concentration observed from sample bottles 3 through 5 indicate a foreign substance has been detected in the bottles. The presence of these contaminants is confirmed by using the AIM-10™ to review the concentration of particles from

the 5 um to 7 um range. That particle concentration remained constant throughout the filling event with a range of 1.2M/ml - 1.4M/ml. These potential contaminants can be visualized through the AIM-10™ System's interactive graph screen. By selecting the area of interest on the graph, all the particles in that selection can be viewed individually.

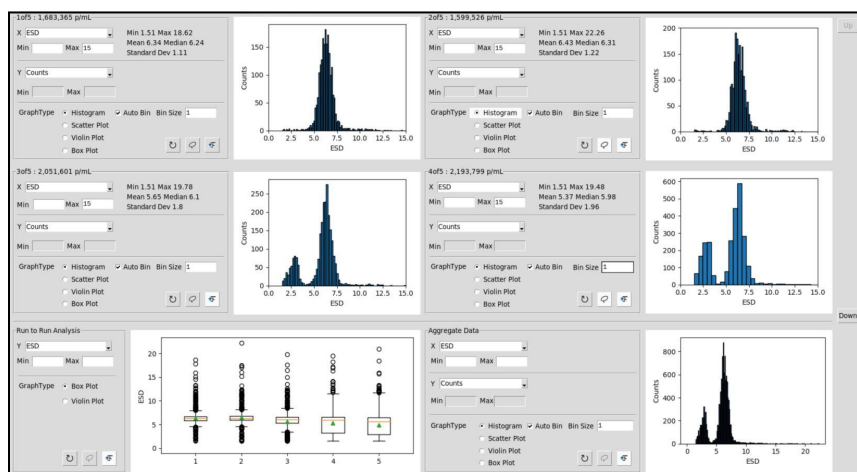


The screen capture of the graph to the left clearly indicates the difference between the smaller contaminate particles and the expected particles. This method of analysis and data review gives you a visual confirmation of the presence of contaminants.

Another way to analyze this data is to use the 'Data Review' feature from Test Plans. This window, seen below, is a summary of all the runs completed in the Test Plan. There are three sections within the review window that groups the runs individually (at the top), compared Run to Run (bottom left) and finally in aggregate (bottom right). For this example, the Run to Run analysis

also indicates a change in the filling performance between runs #2 and #3. The box plots show how the interquartile range of runs #1 and #2 are consistent, and starting with run #3 the range grows larger as a result of the 2.5 micron contaminants passing through the membrane filter.

In conclusion there were three ways to determine the presence of contaminants in this sample process by using the AIM-10™ system. Each way provides a unique perspective on the



characteristics of the filling line's performance.

The consistency of the Test Plan system, as well as the speed at which the results are produced, makes the AIM-10™ System a powerful tool for both SOP execution and advanced interrogation of the particle data.

Contact Sebago Scientific Inc today to see how we can help you find the solution you need.