Designation: F2638 – 12ε1

Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier[1]

This standard is issued under the fixed designation F2638; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε[1] NOTE—The research report designation was added editorially in November 2016.

1. Scope

1.1 This test method measures the aerosol filtration performance of porous packaging materials by creating a defined aerosol of 1.0 µm particles and assessing the filtration efficiency of the material using either single or dual particle counters.

1.2 This test method is applicable to porous materials used to package terminally sterilized medical devices.

1.3 The intent of this test method is to determine the flow rate through a material at which maximum penetration occurs. The porous nature of some materials used in sterile packaging applications might preclude evaluation by means of this test method. The maximum penetration point of a particular material could occur at a flow rate that exceeds the flow capacity of the test apparatus. As such, this test method may not be useful for evaluating the maximum penetration point of materials with a Bendtsen flow rate above 4000 mL/min as measured by ISO 5636–3.

1.4 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

2.2 *ISO Standard:*[3]

ISO 5636–3 Paper and Board—Determination of Air Permeance (Medium Range)—Part 3: Bendtsen Method

3. Terminology

3.1 *Definitions:*

3.1.1 *challenge aerosol*—a sufficient quantity of aerosolized 1.0 µm particles that enable effective particle counting in the filtrate aerosol.

3.1.2 *filtrate aerosol*—particles that remain aerosolized after passage through the test specimen.

3.1.3 *maximum penetration*—the highest percent concentration of particles in the filtrate aerosol when a specimen is tested over a range of pressure differentials or air flow rates.

3.2 *Abbreviations and Symbols:*

Symbol	Unit	Description
C_S	n	Average particle count of the challenge aerosol when using a single particle counter (Method A).
C_F	n	Average particle count of the filtrate aerosol.
C_C	n	Average particle count of the challenge aerosol.
C_{LR}	N	Average particle count of the filtrate aerosol prior to correction for dilution.

[1] This test method is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.15 on Chemical/Safety Properties.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

Symbol	Unit	Description
R	%	Percentage of particles from the challenge aerosol that remain in the filtrate aerosol.
R_M	%	The calculated maximum of R.
P_1	cm WC	Pressure differential across a test specimen due to the air flow required by the particle counter.
P	cm WC	Pressure differential across a test specimen.
F	L/m/cm^2	Air flow rate through the test specimen.
F_1	L/m/cm^2	Air flow rate required by the particle counter when measuring the filtrate aerosol.
F_M	L/m/cm^2	Air flow rate at which maximum penetration occurs.

4. Safety

4.1 The waste and the vacuum venturi vents for the test equipment described in this test method emit an aerosol of polystyrene particles and salt residues. These aerosols should be exhausted from any enclosed environment or collected and filtered to remove all particles.

5. Summary of Test Method

5.1 A porous packaging material test specimen is placed in a sample holder in such a way as to create a filter between the challenge and filtrate aerosols. On the challenge side of the sample holder, an aerosol of particles is presented to the surface of the test specimen. An air flow is generated through the test specimen. A laser particle counter is used to monitor the particle concentrations in the challenge and filtrate aerosols. Particle concentrations will be measured over a range of flow rates in order to measure the percent penetration over the range of flow rates and determine the point of maximum penetration.

5.2 This test uses an aerosol of polystyrene latex particles (PSL) with a geometric mean particle diameter of 1.0 μm and a standard deviation of less than 0.05 μm.

5.2.1 A single particle counter may be used to sequentially measure the challenge and filtrate aerosols or two particle counters may be used to measure them continuously. When using a single particle counter the challenge and filtrate aerosols will be sequentially measured for each test flow rate. The filtrate aerosol concentration is reported as the average concentration of the filtrate aerosol over a time period of 45 to 60 s, beginning no sooner than 1 min from the start of the filtrate aerosol measurement. The challenge aerosol concentration is reported as the average concentration of the challenge aerosol over a time period of not less than 45 s, beginning no sooner than 1 min from the start of the challenge measurement. Challenge concentrations measured immediately before and after each filtrate concentration measurement are averaged to determine the challenge concentration for a given flow rate.

5.2.2 When using two particle counters, the challenge and filtrate aerosols are counted continuously by dedicated particle counters. The challenge and filtrate aerosol concentrations are reported as the average concentration of the challenge or filtrate aerosol over a time period of not less than 45 s, beginning no sooner than 1 min after a change in flow rate.

5.3 At the pressures used in this test, pressure differential across the sample and flow rate through the material are directly proportional. Pressure will be varied over a range that will ideally have at least two measurements at flow rates that are higher and lower than the flow rate that demonstrates the maximum penetration.

5.4 The reported results are the maximum penetration and the flow rate at which it occurs.

6. Significance and Use

6.1 This test method has been developed as a result of research performed by Air Dispersion Limited (Manchester, UK) and funded by the Barrier Test Consortium Limited. The results of this research have been published in a peer-reviewed journal.[4] This research demonstrated that testing the barrier performance of porous packaging materials using microorganisms correlates with measuring the filtration efficiency of the materials.

6.2 This test method does not require the use of microbiological method; in addition, the test method can be conducted in a rapid and timely manner.

6.3 When measuring the filtration efficiency of porous packaging materials a typical filtration efficiency curve is determined (see Fig. 1). Since the arc of these curves is dependent upon the characteristics of each individual material, the appropriate way to make comparison among materials is using the parameter that measures maximum penetration through the material.

6.4 The particle filtration method is a quantitative procedure for determining the microbial barrier properties of materials using a challenge of 1.0 μm particles over range of pressure differentials from near zero to approximately 30 cm water column (WC). This test method is based upon the research of Tallentire and Sinclair[4] and uses physical test methodology to allow for a rapid determination of microbial barrier performance.

7. Apparatus

7.1 *Test Fixture*—This consists of a base with associated valves, tubing, sample holder and clamps necessary to perform the test. Dimensioned drawings and arrangement of all components will be available in a future research report. Dimensions of the sample holder (Fig. 2) and schematics of the single particle counter (Fig. 3) and dual particle counter (Fig. 4) are shown. The significant components of the text fixture include:

7.1.1 *Sample Holder*—This consists of two assemblies, which form identical upper and lower manifolds and sample cavities that deliver a uniform flow of the aerosol or sweep air to the periphery of the test specimen while extracting it from the center.

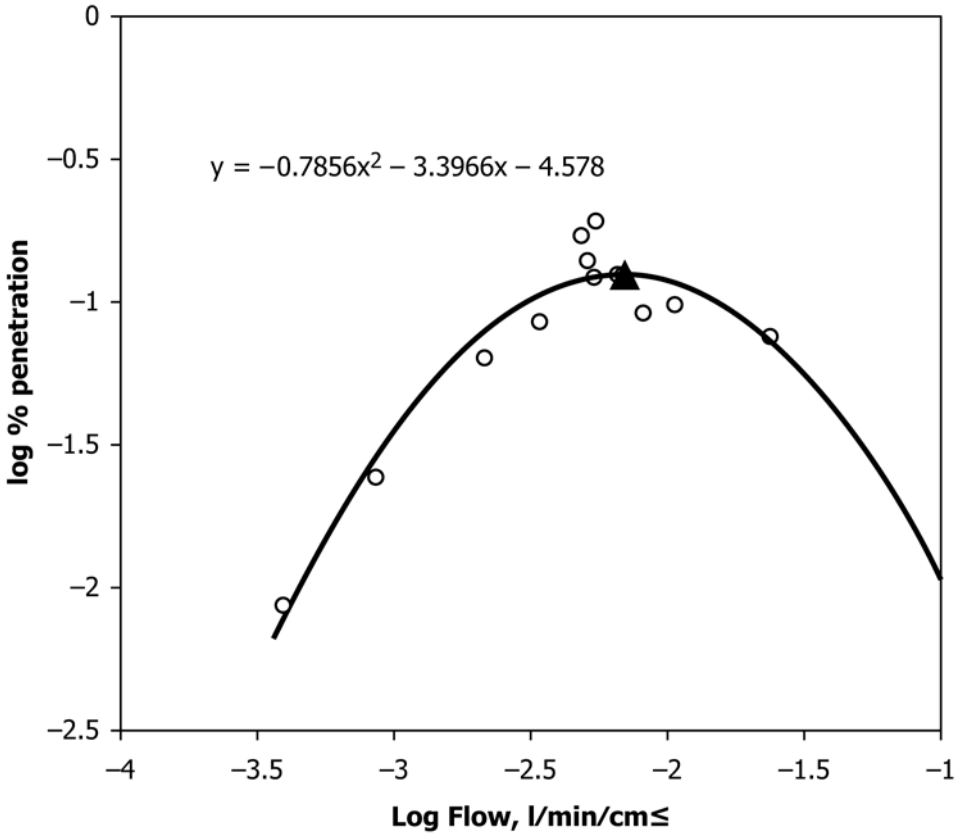
7.1.2 *Normal Flow Range Needle Valve,* 500 μm diameter maximum orifice.

7.1.3 *Low Flow Range Critical Orifice,* 40 μm orifice.

7.2 *Aerosol Generator*—A conventional vertical style medical nebulizer is the preferred aerosol generator for use in a single counter system (Particle Measuring Systems PG100 or equivalent).

NOTE 1—Atomizer style nebulizers are not recommended unless used with a dual particle counter system as they exhibit sudden, unpredictable

[4] "Definition of a Correlation Between Microbiological and Physical Particulate Barrier Performances for Porous Medical Packaging Materials," *PDA J Pharm Sci Technol*, Vol 56, No. 1, 2002, Jan-Feb, 11-9.



NOTE 1—The point of maximum penetration is indicated by the upward pointing triangle.

FIG. 1 A Typical Curve Showing Penetration as a Function of Flow Rate

changes in aerosol concentration.

7.3 *Particle Counter*—The particle counter required for this test method must be capable of distinguishing between the residue from water droplets and the polystyrene latex (PSL) particles (Particle Measuring Systems Lasair series of counters or equivalent). The particle counter should have a flow demand that approximates the flow through the test specimen at maximum penetration. If the particle counter sorts particles by size, it must be determined in which size ranges the PSL particles reside.

7.4 *Data Logging*—The elapsed test time, the pressure differential, the total challenge particles, and/or the total filtrate particles shall be recorded every 6 s. When using the Lasair particle counters, the 1.0 µm PSL particles are counted in both the 0.7 to 1.0 µm and the 1.0 to 2.0 µm size ranges. Therefore, both counts shall be recorded and totaled.

7.5 *Manometer*—A precision manometer with a minimum range of 0 to 5 cm (0 to 2 in.) WC and an accuracy of 0.005 cm (0.002 in.) WC to monitor the pressure difference across the sample.

7.6 *Pressure Regulator*—Precision regulator capable of delivering 1.0 standard litre per minute at pressures up to 3 bar.

7.7 *ULPA Filter*—Required to remove ambient particles.

7.8 *Buna N or Nitrile Rubber SAE Standard AS 568A Size–345 O-rings*—Provide a seal between the challenge and filtrate sides of the test.

8. Materials

8.1 Particle free, dry compressed air.

8.2 Tween 20 or sodium dodecylsulfate (SDS).

8.3 Concentrate suspension of 1 µm PSL particles (Duke Scientific 3K1000, 5100A, and G0100 have all been found satisfactory).

8.4 Distilled water sufficiently free of dissolved material.

8.5 Porous packaging material.

9. Apparatus Preparation

9.1 Apparatus should be assembled as seen in Fig. 3 (single particle counter) or Fig. 4 (dual particle counter).

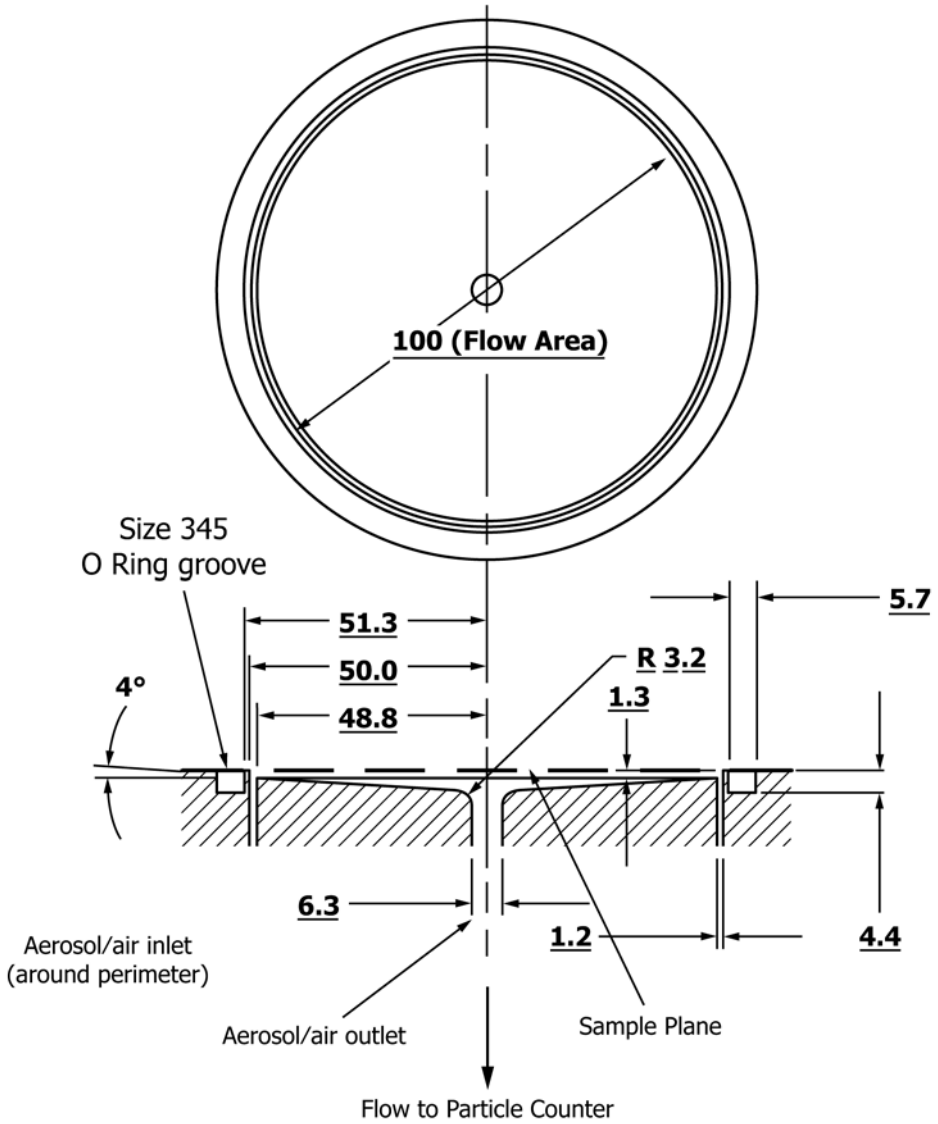
9.2 *Material Preparation:*

9.2.1 *Surfactant Solution:*

9.2.1.1 Prepare a 0.02 % v/v solution of surfactant (Tween 20, SDS, or equivalent) in distilled water daily.

9.2.1.2 Aerosolize the surfactant solution and determine the particle size distribution of this solution by measuring the challenge aerosol. Ideally there should be no particles over 0.7 µm in diameter detected. The aim is no more than 2 such particles detected within any 6-s period. Monitor surfactant solution for 1 min.

9.2.1.3 Table 1 is an example of the size distribution of surfactant solution suitable for use, each row being a 6-s counting interval.



NOTE 1—Dimensions of the cavity in mm. The configuration of the top and bottom cavity is identical.

FIG. 2 Dimensions of the Sample Cavity

9.2.2 *Particle Suspension:*

9.2.2.1 Prepare a suspension of 1 μm PSL particles in the surfactant solution described above.

NOTE 2—This solution is to be made fresh daily. When making the suspension from a highly concentrated source (such as Duke Scientific 5100A) some of the particles will have agglomerated into aggregates consisting of multiple particles. To ensure the aerosol consists of particles having only one PSL particle, place the bottle containing the solution in an ultrasonic bath for 15 s. This will disassociate the particles.

9.2.2.2 Check for particle concentration by monitoring counts in particle counter for 1 min without any sample in sample holder. The resulting challenge aerosol particle concentration must be within the range of 200 to 8000 particles per cc (this is equal to 600 to 24 000 counts per 6-s interval in a Lasair 1003).

9.2.2.3 Check for instrument bias by measuring the challenge counts with the test specimen in place. Then remove the specimen and measure filtrate results. Check that the counts differ by no more than 3 %.

NOTE 3—If concentrations higher than 8000 particles per cc are used, there will be significant errors due to coincidence (counting two particles as a single particle) in the particle counter detector.

10. Sample Preparation

10.1 Cut a sample of porous barrier material no less than 120 mm (the area of the sample exposed to the aerosol is 100 mm in diameter) in any dimension so that it completely covers the O-ring in the lower half of the sample holder. The sample must cover the entire circumference of the seal O-ring. Critical dimensions of the exposure chamber are shown in Fig. 2.

11. Test Procedures

11.1 *Method A Single Particle Counter*—Procedure when using a single particle counter. Fig. 5 shows an example of the particle count results of a typical single measurement with readings every 6 s.

11.1.1 When only a single particle counter is in use, it must be switched between the challenge and filtrate aerosol.

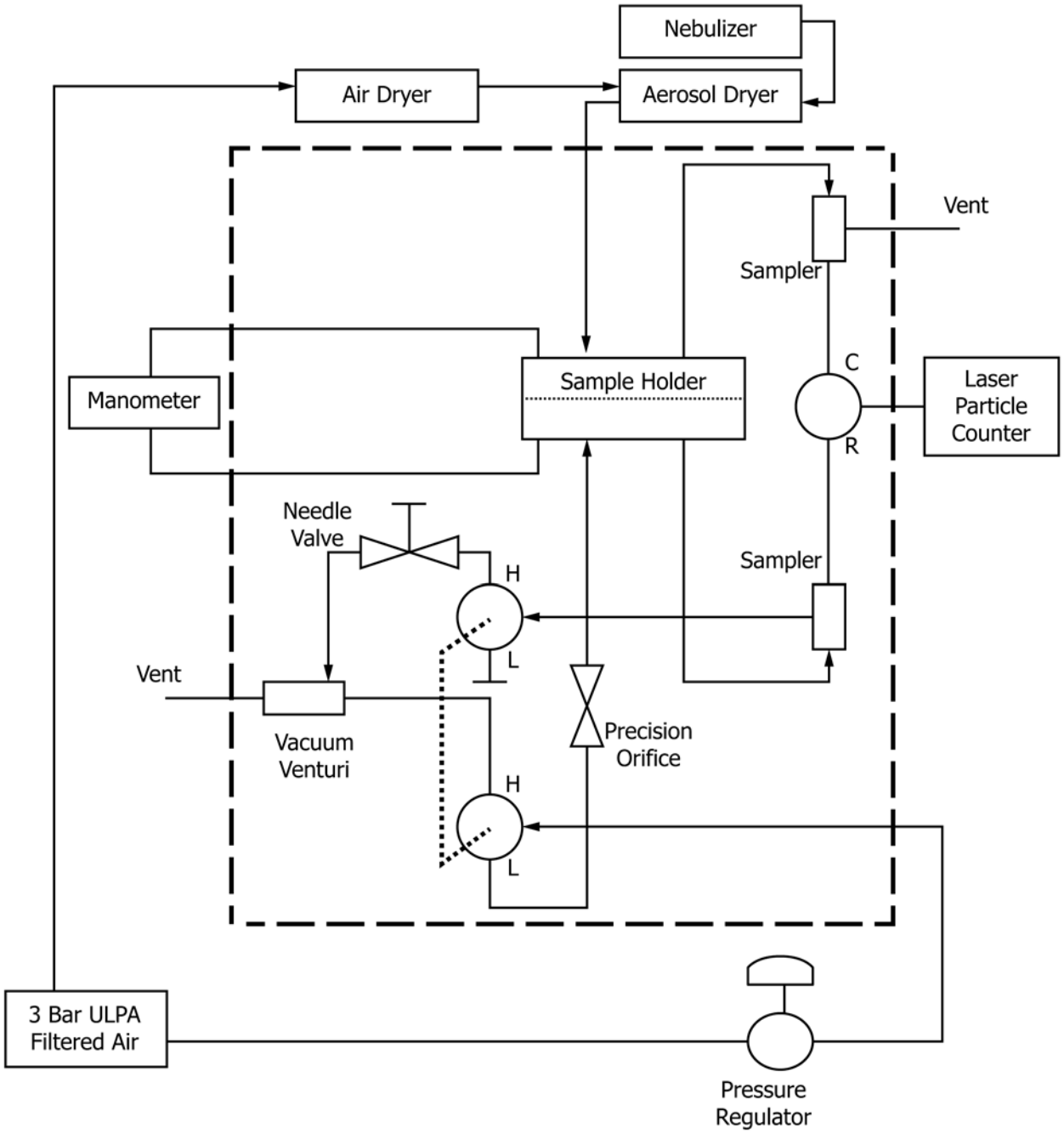


FIG. 3 Equipment Configuration for a Single Particle Counter—Method A

Therefore, an estimate must be made of the challenge aerosol concentration at the time of the filtrate measurement.

11.1.2 Set up equipment for 1 particle counter mode, use 0.7 to 1.0 µm and 1.0 to 2.0 µm bin data, record Lasair and manometer data every 6 s. Record pressure drop across sample during each 6-s sample length while counting particles in filtrate stream.

11.1.3 Test distilled water/surfactant to ensure water is clean as described in 9.2.1.

11.1.4 Prepare appropriate concentration (200 to 8000 particles/mL) of PSL suspension and confirm that the particle counts are within 3 % as described in 9.2.2.3.

11.1.5 Open sample holder and place sample in the sample holder.

11.1.6 Select High Flow Range.

11.1.7 Start aerosol flow, set Particle Counter to count Challenge.

11.1.8 Close the venturi needle valve and increase inlet air pressure to 3 bar, open the needle valve until pressure differential across the sample is 2 cm WC. Allow system to stabilize for at least 1 min before collecting challenge counts for no less than 45 s (45 to 60 s). Set the particle counter to Filtrate. Allow the system to stabilize for at least 2 min before collecting filtrate counts for no less than 45 s (45 to 60 s) and record

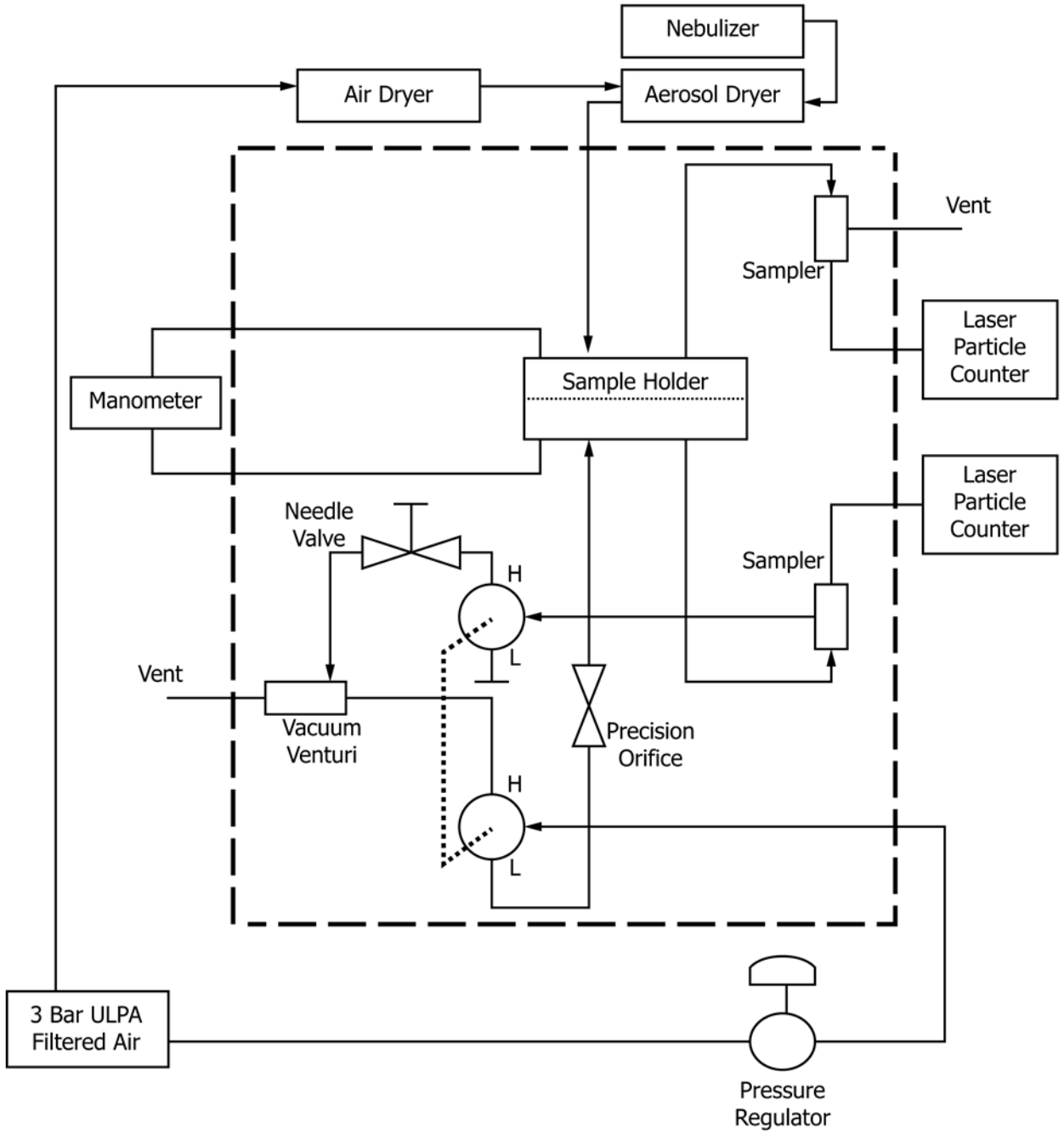


FIG. 4 Equipment Configuration for Dual Particle Counters—Method B

TABLE 1 Example of Particle Counts Generated from 0.02 % Surfactant in Acceptably Clean Distilled Water

0.1 µm	0.2 µm	0.3 µm	0.4 µm	0.5 µm	0.7 µm	1.0 µm	2.0 µm
852	176	36	19	4	0	0	0
879	179	45	15	2	1	0	0
808	155	38	12	1	0	0	0
802	176	37	14	2	0	0	0
828	178	37	14	1	0	0	0

pressure. Set the particle counter back to Challenge, allow the system to stabilize for at least 1 min before collecting challenge counts again for no less than 45 s (45 to 60 s).

11.1.9 Adjust the venturi needle valve to reduce the pressure differential across the sample by a factor of 2. If challenge particles have not just been counted, collect data for no less than 45 s (45 to 60 s). Set the particle counter to Filtrate. Allow the system to stabilize for at least 2 min before collecting filtrate counts for no less than 45 s (45 to 60 s) and record pressure. Set the particle counter back to Challenge, allow the system to stabilize for at least 1 min before collecting challenge counts again for no less than 45 s (45 to 60 s). Continue to

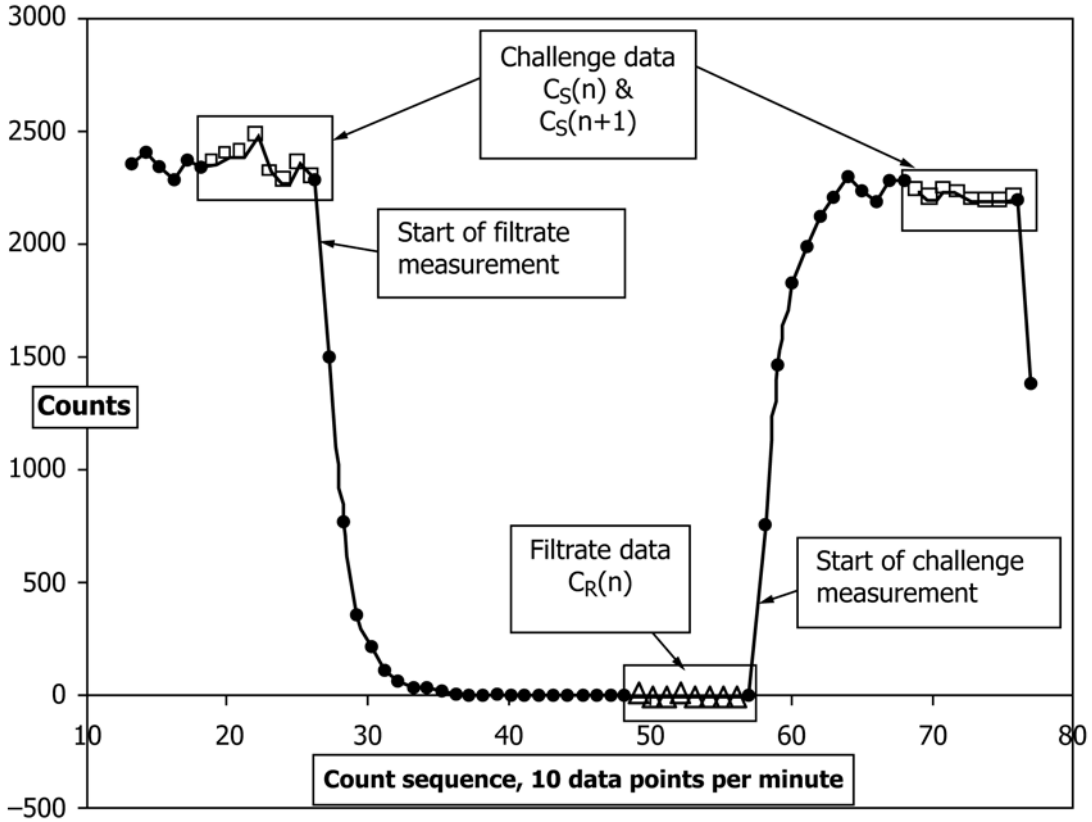


FIG. 5 Example of Data Produced from a Single Measurement Utilizing a Single Particle Counter

reduce pressure differential by a factor of 2 until a maximum penetration value has been detected or the venturi needle valve is closed. The pressure differential may be adjusted to the next value during the second count of challenge particles. If maximum penetration value has not been reached, record pressure differential (P_1) with the venturi needle valve closed prior to switching to the Low Flow Range.

11.1.10 Increase the venturi/sweep flow pressure until pressure differential across the sample is at the next test point. If challenge particles have not just been counted, collect data for no less than 45 s (45 to 60 s). Set the particle counter to Filtrate. Allow the system to stabilize for 2 min before collecting filtrate counts for no less than 45 s (45 to 60 s) and record pressure. Set the particle counter back to Challenge, allow the system to stabilize for at least 1 min before collecting challenge counts again for no less than 45 s (45 to 60 s). Continue to reduce pressure differential by a factor of 2 by increasing the sweep flow pressure and collect data until average filtrate count is less than 5 in 6 s or the pressure differential will not remain stable.

11.1.11 Analyze the data; correct the Low Flow Range results using P_1 to account for dilution from the sweep air. The value taken as the challenge aerosol concentration is the average of the two challenge data sets immediately adjacent to the filtrate data.

11.1.12 When a measurement series is complete, there will be a number of data sets, each data set consisting of a start challenge aerosol concentration, a filtrate aerosol concentration, an end challenge aerosol concentration, and the pressure at which the test measurement was conducted. The end challenge aerosol concentration may be used as the start challenge aerosol concentration for the subsequent measurement.

NOTE 4—Inspect count data for sudden drops in particle counts indicative of depletion of the PSL sphere suspension. Any such anomaly voids the measurement in which it occurred.

11.1.13 C_S is the average challenge concentration taken immediately before and after the filtrate measurement. Calculate the challenge concentration for filtrate measurement n:

$$C_c(n) = (\text{Average of } CS(n) + \text{Average of } CS(n+1))/2 \quad (1)$$

11.2 *Method B Dual Particle Counter*—Procedure when using dual particle counters. Fig. 6 shows an example of the particle counts generated when taking three successive measurements at three different pressures.

11.2.1 The challenge and filtrate data are continuously monitored when using dual particle counters. Concurrent challenge and filtrate data points are used to evaluate barrier performance, for example, in Fig. 6 $C_C(1)$ will be used as the challenge count data for $C_F(1)$.

11.2.2 Set Up Equipment for 2 Particle Counter Mode, use 0.7 µm and 1.0 µm bin data, record Lasair and pressure data continuously.

11.2.3 Test distilled water/surfactant to ensure water is clean as described in 9.2.1.

11.2.4 Prepare appropriate concentration (200 to 8000 particles/ml) of PSL suspension and confirm that the particle counts are within 3 % as described in 9.2.2.3.

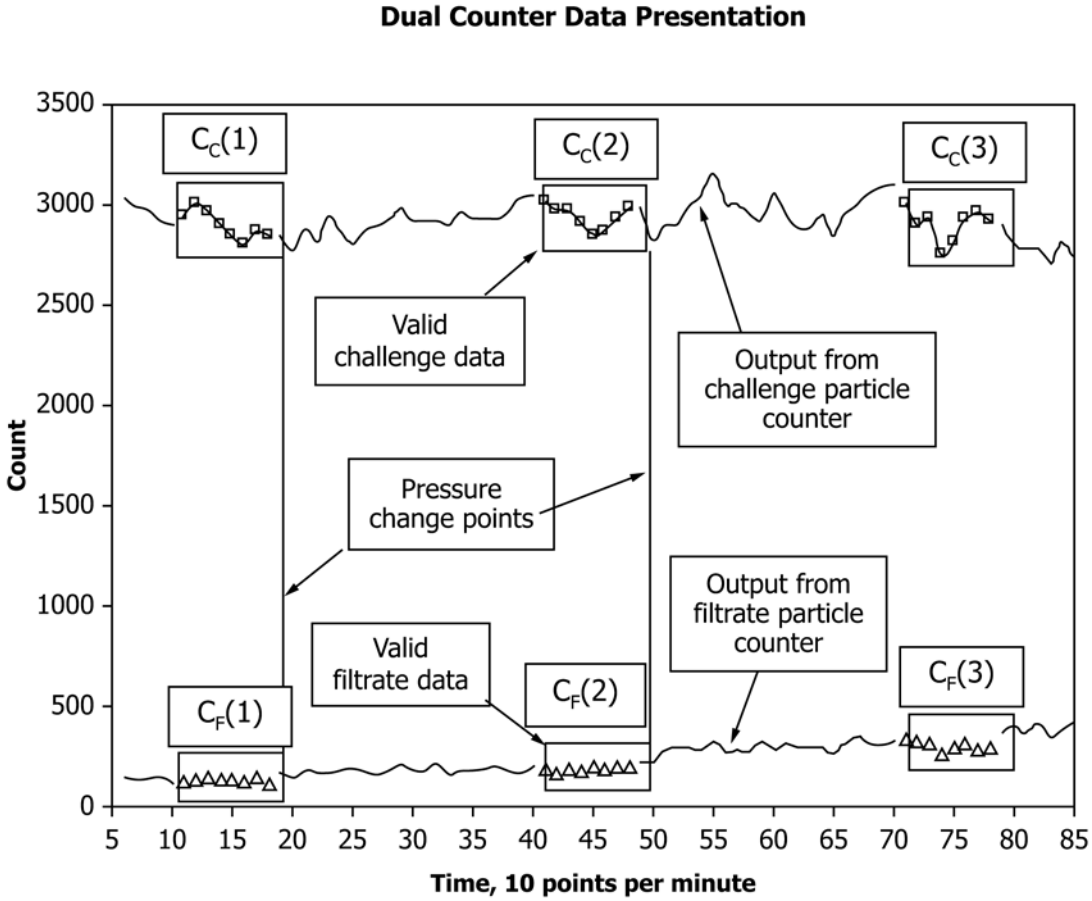


FIG. 6 Example Data Produced Using Dual Particle Counters

11.2.5 Cut sample and place in the sample holder as described in 10.1.

11.2.6 Select High Flow Range.

11.2.7 Start aerosol flow and allow Challenge count to stabilize.

11.2.8 Close the venturi needle valve and increase inlet air pressure to 3 bar, open the needle valve until pressure differential across the sample is 2 cm WC, wait 1 min to stabilize, count challenge and filtrate particles until 50 filtrate particles are detected (or for a minimum of 45 s), record pressure, challenge and filtrate counts.

11.2.9 Adjust venturi needle valve (or decrease venturi/sweep air pressure) to reduce the pressure differential across the sample by a factor of 2, Wait 2 min to stabilize, count challenge and filtrate particles until 50 filtrate particles are detected, record pressure differential, challenge and filtrate counts. Continue to reduce pressure differential by a factor of 2 until a maximum penetration value has been detected (or needle valve is closed or venturi/sweep pressure is zero). If maximum penetration value has not been reached, record pressure differential (P_1) with the needle valve closed (or zero venturi/sweep pressure) prior to switching to the low flow range.

11.2.10 If required, set the venturi/sweep pressure to 0 bar, select low flow range.

11.2.11 Increase the venturi/sweep flow pressure until pressure differential across the sample is at the next test point, wait 2 min to stabilize, count challenge and filtrate particles until 50 filtrate particles are detected, record pressure, challenge and filtrate counts. Continue to reduce pressure differential by a factor of 2 and collect data until average result count is less than 25 in 60 s or the pressure differential will not remain stable.

11.2.12 Analyze data, use challenge counts during period required to accumulate 100 filtrate counts, correct the low flow range results.

11.2.13 The fractional penetration for a given pressure differential is the average of the filtrate data divided by the average of the corresponding challenge data.

12. Data Analysis

12.1 The data is best analyzed in a spreadsheet application. See Appendix X2 for an example.

12.2 Calculate the resulting penetration values as a percent of the challenge particle count.

$$R(n) = C_F(n)/C_C(n)\cdot 100 \quad (2)$$

12.3 Data analysis for a series of pressure differentials.

12.3.1 Determine the flow rate at each test pressure based on the calibrated flow of the particle counter (F_1) and the pressure it generates across the sample (P_1).

$$F(n) = F_1 \cdot P(n)/P_1 \quad (3)$$

12.3.2 Graph the data with x = Log F and y = Log R, and determine the line of best fit. This line of best fit will be a quadratic equation in the form of:

$$\text{Log } R = A \cdot (\text{Log } F)^2 + B \cdot \text{Log } F + C \quad (4)$$

where:

A, B, and C = coefficients for the line of best fit.

12.3.3 Determine the apex of the line of best fit (maximum penetration) and the flow rate for this point. This can be done graphically or using the equations:

12.3.3.1 For flow at maximum penetration:

$$\text{Log } F_M = -B/2A \text{ or } F_M = 10^{-B/2A} \quad (5)$$

12.3.3.2 For maximum percent penetration:

$$\text{Log } R_M = A\ (\text{Log } F_M)^2 + B\ \text{Log } F_M + C \quad (6)$$

where:

A, B, and C = coefficients from the line of best fit.

13. Report

13.1 The report shall include the following:

13.1.1 Specify the method used (Method A or Method B),

13.1.2 Description/identification of the material tested including the basis weight (g/m^2),

13.1.3 Maximum percent penetration,

13.1.4 Flow rate and/or pressure differential at maximum penetration, and

13.1.5 Flow rate demanded by the particle counter and the pressure differential at that flow rate.

14. Precision and Bias

14.1 The precision of this test method is based on intralaboratory studies conducted in 2004 for the single counter method, additional studies conducted in 2006 for the dual counter method and an interlaboratory study conducted in 2012 for the single counter method. In the 2004 study, a total of 27 tests were conducted by three (3) operators. This testing consisted of each operator performing three (3) replicate tests on samples of three (3) different porous packaging materials. A summary of data from this testing is exhibited in Table 2. The 2006 testing was conducted using the same basic test system modified to accommodate a second particle counter so that particles in the challenge aerosol and the filtrate aerosol could be enumerated simultaneously. The testing consisted of one (1) operator testing seven (7) samples from the same material on seven (7) different days during the course of one (1) month. These data are exhibited in a log reduction format in Fig. 7. In the 2012 study, two (2) laboratories analyzed four (4) different porous packaging materials on a total of six (6) test units. One (1) laboratory housed one (1) test unit and the remaining five (5) test units were located at the other laboratory. A total of five (5) operators, each with varying levels of experience conducting the test method, were used for the study. Every test result represents an individual determination, and each lab was asked to report triplicate results for each material. Practice E691 was followed for the design and analysis of the data; the details are given in ASTM Research Report No. F02-1030.[5]

TABLE 2 Maximum Penetration Points

Sample Code	Mean Maximum % Penetration Point	Standard Deviation for Max % Penetration
P	0.32	0.0290
R	0.01	0.0058
T	1.77	0.2160

14.1.1 *Repeatability*—The results of the two independent intralaboratory tests conducted demonstrate that the method is repeatable in either the single or dual counter configuration. Analysis of variance (ANOVA) was conducted on the 2004 test results. ANOVA results are displayed in Fig. 8. In the 2012 interlaboratory study, repeatability limit (r) was determined.

14.1.1.1 *Repeatability Limit (r)*—Two test results obtained within one laboratory shall be judged not equivalent if they differ by more than the "r" value for that material; "r" is the interval representing the critical difference between two test results for the same material, obtained by the same operator using the same equipment on the same day in the same laboratory.

14.1.1.2 Repeatability limits are listed in Table 3.

TABLE 3 Maximum Penetration (%)

Material ID	Average[A]	Repeatability Standard Deviation	Reproducibility Standard Deviation	Repeatability Limit	Reproducibility Limit
	$\bar{x}$	s_r	s_R	r	R
A	27.970	5.137	6.108	14.385	17.102
B	12.602	2.131	2.708	5.968	7.583
C	4.359	0.552	1.647	1.547	4.611
D	0.070	0.078	0.086	0.220	0.242

[A] The average of the laboratories' calculated averages.

14.1.2 *Reproducibility Limit (R)*—Two test results shall be judged not equivalent if they differ by more than the "R" value for that material; "R" is the interval representing the critical difference between two test results for the same material, obtained by different operators using different equipment in different laboratories.

14.1.2.1 Reproducibility limits are listed in Table 3.

14.1.3 The above terms (repeatability limit and reproducibility limit) are used as specified in Practice E177.

14.1.4 Any judgment in accordance with statements 14.1.1 and 14.1.2 would have an approximate 95% probability of being correct.

14.2 *Bias*—At the time of the study, there was no accepted reference material suitable for determining the bias for this test method, therefore no statement on bias is being made.

[5] Supporting data have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:F02-1030. Contact ASTM Customer Service at service@astm.org.

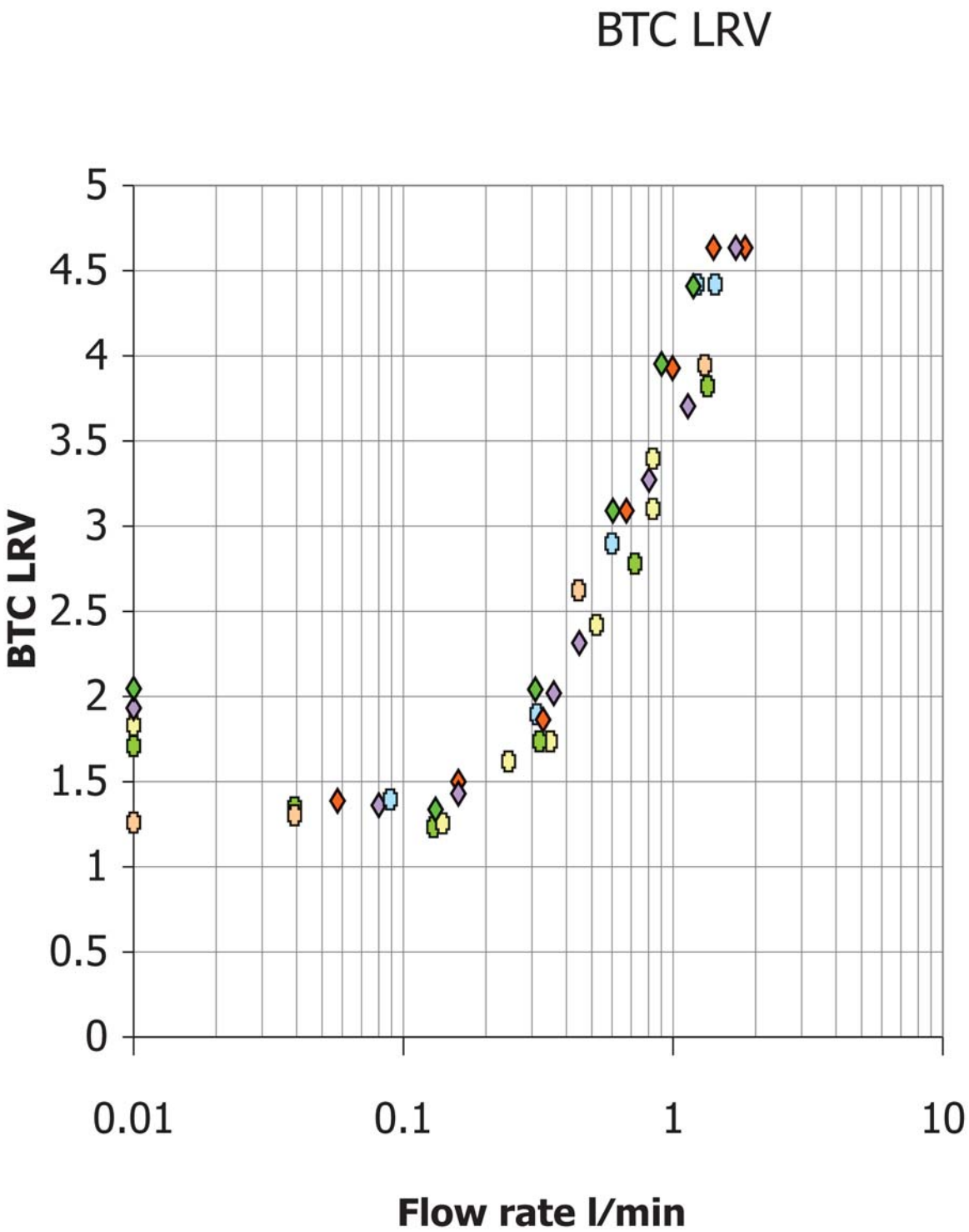


FIG. 7 Log Reduction of Penetration versus Flow

14.3 The precision statement was determined through statistical examination of 72 results, submitted by two laboratories, on four different materials, described below:

Sample A: Medical Grade Coated Paper
Sample B: Synthetic Fiber Reinforced Coated Paper
Sample C: 55# Medical Grade Coated Paper
Sample D: Flashspun High-Density Polyethylene

15. Keywords

15.1 filtration efficiency; medical packaging; microbial barrier; microbial challenge; particulate barrier; porous packaging; sterile barrier; sterile packaging

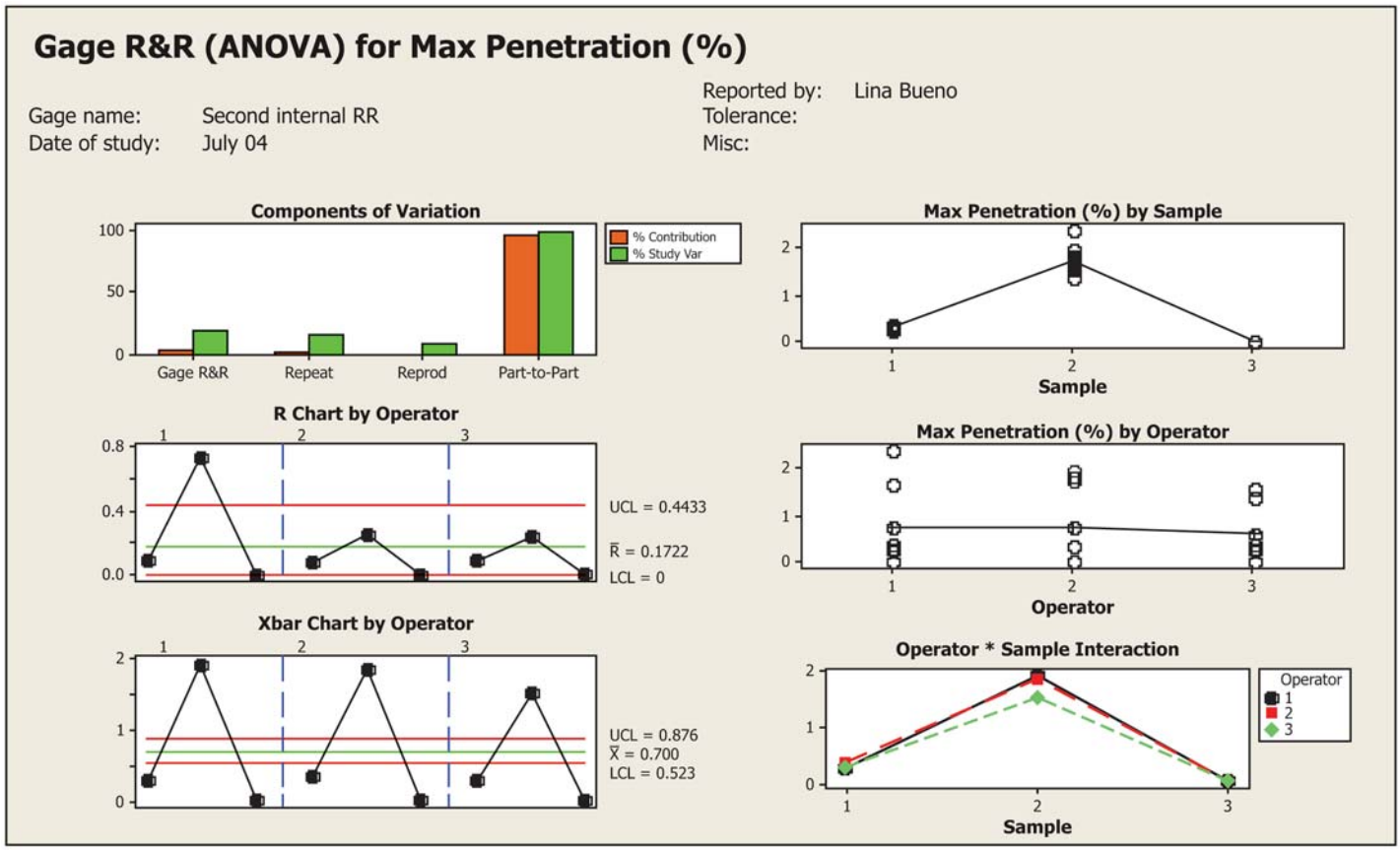


FIG. 8 ANOVA Results

APPENDIXES

(Nonmandatory Information)

X1. ARRANGEMENT OF CONTROL VALVES

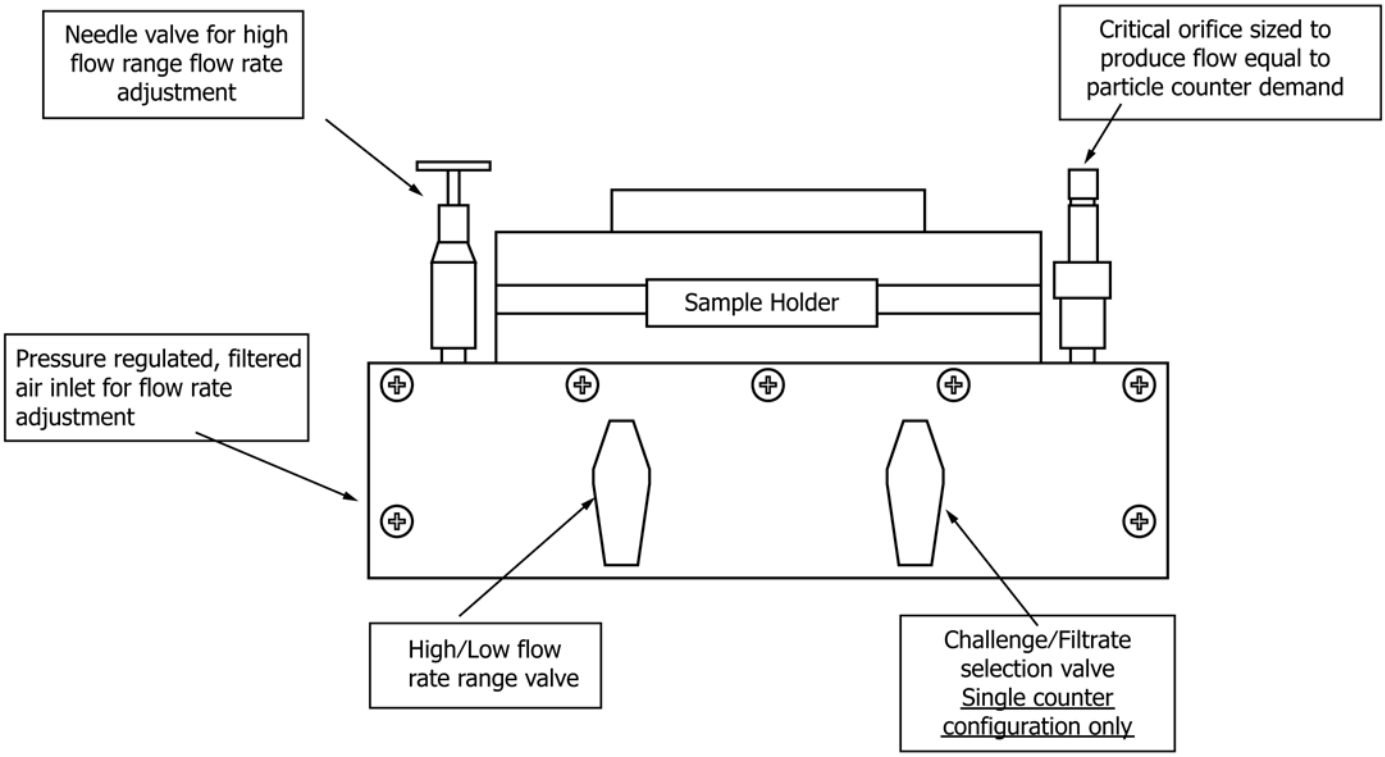


FIG. X1.1 Arrangement of Control Valves

X2. ANALYSIS OF A TYPICAL DATA SET

X2.1 The following analysis was performed using Microsoft Excel. Other spreadsheet applications have similar functionality but may use a different command structure.

X2.2 Each reading from the Lasair particle counter will contain the information shown in Table X2.1. It can be formatted as single comma delineated text string followed by a line feed and carriage return character, which allows it to be easily, imported directly into most spreadsheet applications.

X2.3 Fig. X2.1 shows the average of the leading (sequence 80 to 87) and trailing challenge (sequence 128 to 135) counts are 979.6 and 1150.2. These are averaged to obtain an average challenge count of 1064.9. Handling the challenge data in this manner eliminates potential problems when the number of readings in the leading challenge and trailing challenge are unequal. The average filtrate count (sequence 108 to 115) is 484.9 resulting in a percent penetration of 45.5 %. The pressure differential (dP) across the sample during this measurement was recorded separately as 0.724 cm WC.

TABLE X2.1 Data Provided by the Lasair Series of Particle Counters

NOTE 1—Data displayed vertically for ease of labeling.

Typical Data	Field Name	Test Method Requirement
LASAIR1003	Instrument name	
3/6/2004	Date	Optional
8:03:36	Time	Required
6	Measurement interval, seconds	
0.0001 V6.3-SP	Software version	
0	Instrument performance data	
0	”	
0	”	
1	”	
2754	0.1–0.2 µm bin counts	
292	0.2–0.3 µm bin counts	
55	0.3–0.4 µm bin counts	
17	0.4–0.5 µm bin counts	
5	0.5–0.7 µm bin counts	
33	0.7–1.0 µm bin counts	Required
25	1.0–2.0 µm bin counts	Required
0	>2.0 µm bin counts	
8.84	Laser voltage	
0.001	Instrument performance data	
0	”	
0	”	
0	”	
0	”	
0	”	
234f	”	

X2.4 Table X2.2 shows the results of a series of measurements made on the same specimen. The last three measurements were made in the low flow range. On this material it is not necessary to make measurements in the low flow range to determine the maximum penetration, but it is done to illustrate the technique. The flow demand of the particle counter is 28 mL/min and generated a pressure differential of 0.042 cm WC. Lower pressure differentials were obtained by adding a stream of particle free air to the filtrate side of the specimen. The counts obtained in the Low flow Range (C_{LR}) were corrected for dilution to obtain the filtrate count. For example from Table X2.2:

$$171.1 = 93.7 \cdot 0.042 / 0.023$$

X2.5 In Table X2.3 the pressure differentials have been converted to flow rates. The surface area is 78.54 cm^2. The flow rate is based on 28 mL/min creating a pressure differential of 0.042 cm WC. The logarithms of the flow and percent penetration are calculated, and the second order equation of best fit is determined as shown in Fig. X2.3.

X2.6 From the equation of best fit:

$A = -0.4884$
$B = 0.3258$
$C = 1.6616$

X2.7 The log of the flow rate at the apex of the curve is calculated as:

$$\text{Log } F_M = -B/2A, \text{ or in this example}$$
$$0.333 = -0.3258 / (2 \cdot -0.4884)$$

X2.8 The log of the maximum penetration is:

$$\text{Log } R_M = A \cdot (\text{Log } F_M)^2 + B \cdot \text{Log } F_M + C \text{ , or in this example}$$
$$1.716 = -0.4884 \cdot 0.333^2 + 0.3258 \cdot 0.333 + 1.6616$$

X2.9 The flow at which maximum penetration occurred (F_M) and the maximum penetration (R_M) for this specimen are:

$$F_M = 10^{(\text{Log } F_M)} = 10^{0.333} = 2.155 \text{ mL/cm}^2\text{/min}$$
$$R_M = 10^{(\text{Log } R_M)} = 10^{1.716} = 51.9 \text{ \%}$$

X2.10 This point is marked in Fig. X2.3 by the upward pointing triangle.

X2.11 Additional specimens must be tested to assure statistical validity. Fig. X2.4 shows the results of testing three additional specimens in addition to the above specimen.

Sequence Data No.	Data Stream (total of .7 – 1.0 micron and 1.0 – 2.0 micron counts)	Transition Data	Challenge Leading Data	Challenge Trailing Data	Filtrate Data	Time Increment (sec)	Cumulative Sampling Time (sec)	
78	968	968				6		
79	961	961				6		
80	977		977			6	6	
81	943		943			6	12	
82	974		974			6	18	
83	1052		1052			6	24	>45 sec Challenge Data Collection
84	967		967			6	30	
85	984		984			6	36	
86	977		977			6	42	
87	963		963			6	48	
88	649	649				6		6
89	380	380				6		12
90	430	430				6		18
91	451	451				6		24
92	412	412				6		30
93	459	459				6		36
94	429	429				6		42
95	476	476				6		48
96	476	476				6		54
97	453	453				6		60
98	492	492				6		66
99	469	469				6		72
100	478	478				6		78
101	475	475				6		84
102	466	466				6		90
103	460	460				6		96
104	526	526				6		102
105	535	535				6		108
106	528	528				6		114
107	485	485				6		120
108	460				460	6	6	
109	467				467	6	12	
110	469				469	6	18	
111	524				524	6	24	>45 sec Filtrate Data Collection
112	533				533	6	30	
113	429				429	6	36	
114	506				506	6	42	
115	491				491	6	48	
116	299	299				6		6
117	554	554				6		12
118	802	802				6		18
119	973	973				6		24
120	1065	1065				6		30
121	1139	1139				6		36
122	1169	1169				6		42
123	1171	1171				6		48
124	1223	1223				6		54
125	1233	1233				6		60
126	1188	1188				6		66
127	1184	1184				6		72
128	1131			1131		6	6	
129	1174			1174		6	12	
130	1160			1160		6	18	
131	1182			1182		6	24	>45 sec Challenge Data Collection
132	1128			1128		6	30	
133	1136			1136		6	36	
134	1121			1121		6	42	
135	1170			1170		6	48	
136	689	689				6		
137	441	441				6		
		Averages	980	1150	485			

Challenge Average ((Leading + Trailing)/2): 1065

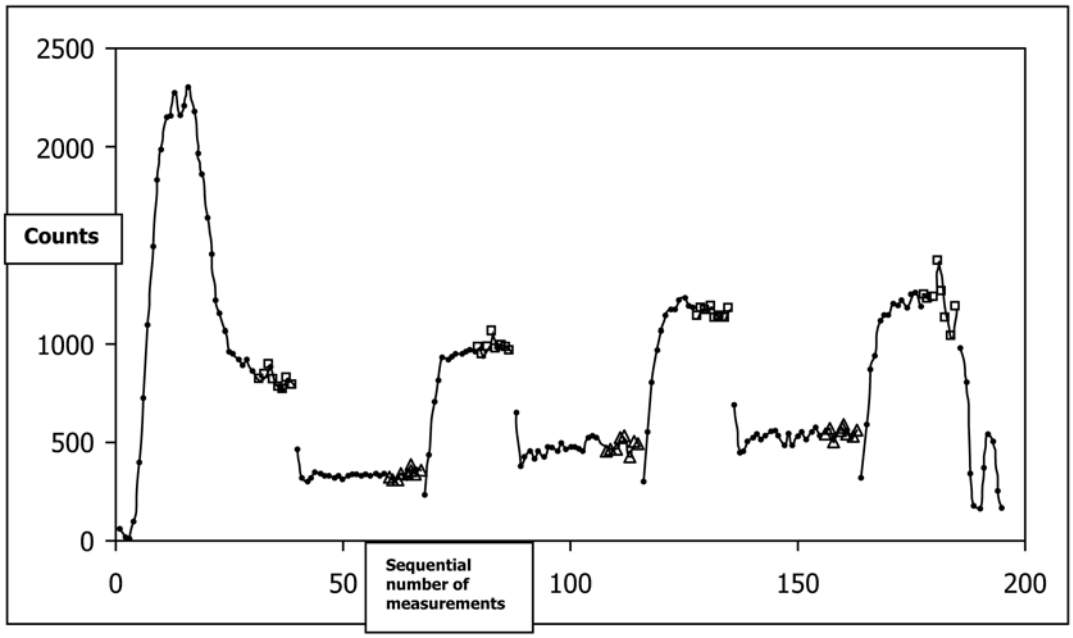
Percent Penetration (Filtrate/Avg Challenge): 45.5%

2 minutes for transition from Challenge to Filtrate

72 sec for transition from Filtrate to Challenge

NOTE 1—The sum of the 0.5 to 0.7 µm bin and the 1.0 to 2.0 µm (33+25 in Table X2.1) bin are used to generate the data in Fig. X2.2.

FIG. X2.1 Example of Formatted Data Set and Explanation of Collected Data



NOTE 1—Measurements were taken at 6-s intervals. The horizontal axis is the sequential number of the measurement.

FIG. X2.2 A Series of 3 Barrier Measurements Made with a Single Particle Counter

TABLE X2.2 Average Challenge and Filtrate Counts of 9 Measurements Made on a Single Specimen

dP	% Pen	Challenge	Filtrate	C_{LR}
0.907	37.7	897.2	338.4	
0.724	45.5	1064.9	484.9	
0.514	46.6	1181.9	551.3	
0.286	41.6	609.1	253.6	
0.105	46.9	771.6	362.1	
0.042	23.8	1072.8	255.1	
0.023	17.3	989.3	171.1	93.7
0.011	8.1	1226.7	99.3	26.0
0.007	2.7	1147.5	31.2	5.2

TABLE X2.4 Logarithms of the Pressure Differential

Flow	% Pen	Log Flow	Log % Pen
7.70	37.72	0.89	1.58
6.15	45.53	0.79	1.66
4.36	46.64	0.64	1.67
2.43	41.64	0.39	1.62
0.89	46.93	–0.05	1.67
0.36	23.78	-0.45	1.38
0.20	17.30	–0.71	1.24
0.09	8.10	–1.03	0.91
0.06	2.70	–1.23	0.43

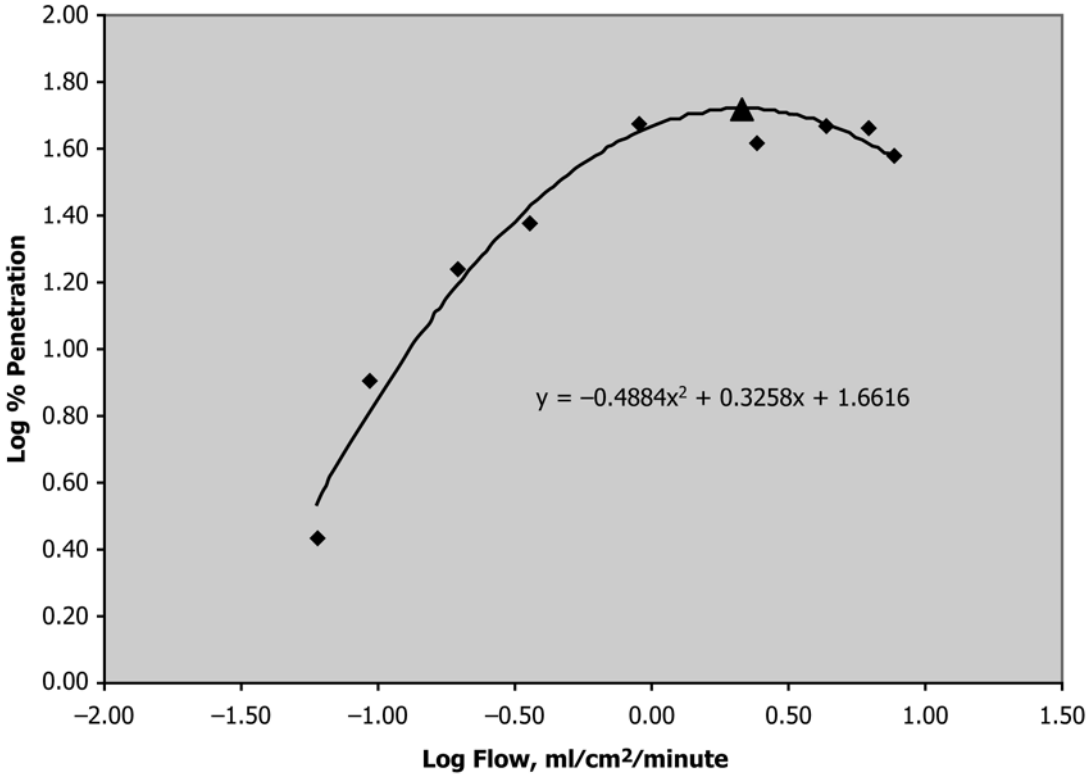


FIG. X2.3 The Plotted Results from Table X2.3, the Equation of Best Fit, and the Point of Maximum Penetration

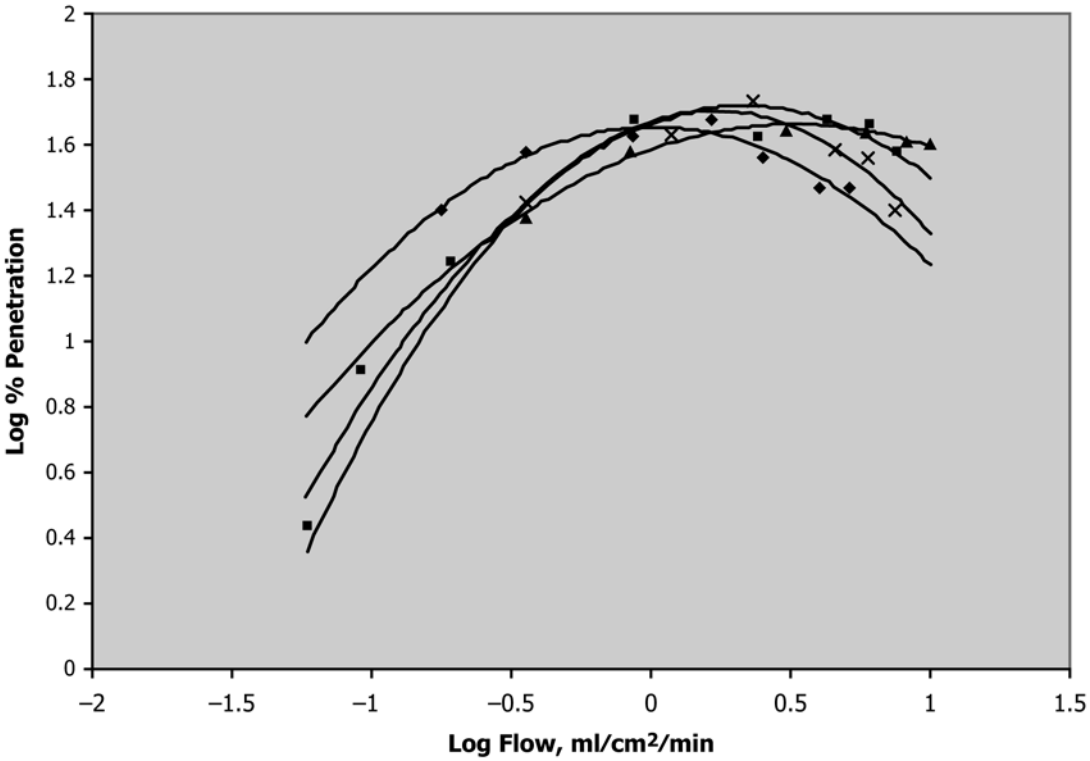


FIG. X2.4 Data from Three Other Specimens in Addition to the Original with Their Associated Trend Lines