Integrity Testing of Gas Permeable Silicone Filters

Sponsor: Dr. Thomas Lazzara with Meissner Filtration

A Senior Project
Presented to
the Faculty of the Biomedical Engineering Department
California Polytechnic State University, San Luis Obispo

In Partial Fulfillment
of the Requirements for the Degree
Biomedical Engineering

By

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Statement of Work

Executive Summary

This Statement of Work will outline the details surrounding the necessary research and engineering to design and build a device capable of integrity testing the permeable silicone membrane filter* for a variety of applications. The design team's attempt to accomplish this will be heavily documented, including all communication with the sponsor, Dr. Lazzara and his team of engineers. Existing designs, patents, technical literature, and the applicable industry standards will be investigated thoroughly for reference throughout the design process.

The design team's specific objectives will be clearly outlined in this document including the problem statement, boundary definition, and customer needs. These three criteria shall be discussed and agreed upon with Dr. Lazzara within the first stage of the project. Other objectives that will drive the design process include the product specification matrix, measurable design specifications and a discussion of high-risk specifications. Understanding the filters capability and specifications will be integral to the progress and success of the project.

The design team's project management will also be clearly outlined in this Statement of Work. A description of the overall design process including a table of the key deliverables and the project timeline will be included to keep all team members accountable. A discussion of the next steps will outline immediate actions to be taken within the next 4-6 weeks following the agreement of this document.

Introduction

Over the course of the next eighteen weeks, the design team will investigate the most reasonable, cost efficient, and reliable ways to integrity test the filter for potential future biomedical and pharmaceutical applications. The goal of our project is to create a fixture that a pharmaceutical company can use to quickly and reliably test the integrity of the filter. We will initially establish a variety of methods that test the integrity of the filter, then after a series of quantitative tests, establish which method meets the requirements most thoroughly. Following a strict schedule outlined in the Project Management section of this document and close communication and mentoring from Dr. Lazzara, the design team hopes to have a reliable way for medical professionals to test the integrity of the filters.

Background

There are a series of integrity tests designed to establish whether or not a filter is reliable for further use; however, these integrity tests are not all applicable for the project. The integrity tests that currently exist and are commonly used in industry include Forward Flow Integrity Test (FFIT), Bubble Point Test (BPT), Pressure Hold Test (PHT), and Water Intrusion Test (WIT). Although these tests (see Table I) are not directly applicable to the design, they do introduce the

*vague language used for discretion

useful methods that can be, in some ways, incorporated into the final design. These integrity tests were taken from a Technical Brief compiled by CUNO, Fluid Purification and provided to us by Dr. Lazzara from Meissner Filtration Products.

The Forward Flow Integrity Test takes advantage of Fick's Law of Diffusion and the properties associated with a wetted membrane. Essentially the rate of passage of the gas molecules through the wetting fluid in the filter membrane will determine the diffusion rate of the gas. Knowing the diffusion rate of gas across the membrane will allow the user to determine if the recorded diffusion rate is acceptable for further use of the filter. The Bubble Point Test analyzes "the minimum gas pressure required to overcome the surface tension holding a wetting fluid in a membrane filter's largest pore" (Cuno Filter Purification, Microfluor II Filter Cartridge Integrity Testing). Pressure is applied to wetting fluid in order to form bubbles on the other side of the filter membrane. At the completion of this integrity test, the administrator can compare the measured Bubble Point value against the accepted Bubble Point value for the filter. Similar to the FFIT test, the Pressure Hold Test uses a sensitive pressure gauge to "measure the decay of pressure in a closed volume on the upstream side of the membrane as the gas diffuses through the membrane". The measured Pressure Hold value can then be compared to the acceptable pressure hold value for the filter. The Water Intrusion Test measures the pore size of the filter by forcing water through the hydrophobic filters. The pressure that is able to push the water through the filter is inversely proportional to the size of the pore. This last test described is the only one described that does not involve the use of a wetting fluid. The lack of wetting fluid eliminates the chance of contamination of the product, eliminates flammability issues, and reduces the time of the test because no drying time is required.

Table I: Summary of existing integrity tests

Test	**Limitation**	**Wetting Fluid Required?**	**Specification Required**
FFIT*	Limited sensitivity	YES	Diffusion rate (mL/min)
BPT	10" cartridge filter or smaller	YES	Bubble Point Pressure (bar)
PHT	Requires sensitive pressure gauge	YES	Pressure (bar)
WIT	Hydrophobic filters only	NO	Diffusion rate (mL/min)

**Preferred test method*

Current patents from the manufacturer were researched to better understand the filters. This information has been omitted from the report due to proprietary reasons.

The design team found technical literature that supports the existing integrity test methods that "characterize and analyze the surface pore size distribution" (Calvo, Pore Size Distributions in Microporous Membranes). Calvo explains the theory behind the Bubble Point Methods and why the design team feels comfortable using this method for future analysis. Direct specifications were stated in the Capillary Flow Porometer manual created by Porous Materials, Inc. These specifications will give the design team a starting point and point of reference for future integrity test specifications. Among the important information provided by this manual includes pressure accuracy, flow rates, maximum pore size detectable (Capillary Flow Porometer, PMI Ink.). Measuring membrane pore size distributions will be aided by the work of Dr. Survain and the data collected in her research (Survain, Filtration+Separation). The additional information provided by the various journals mentioned previously can be applied to the pharmaceutical industry as explained by Geoffrey Blanc (Blanc, Pharmaceutical Bioprocessing).

Due to the nature of this project, there are no industry codes, standards, or regulations strictly applicable to the design. The design team will, however, use statistical analysis to establish appropriate and justifiable data based on an agreed upon confidence interval. The integrity test method and corresponding experiment set up is not considered a medical device, but will need to follow the US Food and Drug Administration regulations for Current Good Manufacturing Practice (cGMPs) regulations. The testing fixture and procedure will also follow International Standards Organization (ISO) regulations as well. Some of the cGMPs we will follow are listed in Table II.

Table II: Resource for identifying maintenance codes

cGMP Section	**Description**
Sec. 211.65a Equipment Construction	Materials should not alter the drug product beyond established requirements.
Sec. 211.67a Equipment Cleaning and Maintenance	Equipment and utensils will be cleaned and sterilized at appropriate intervals to prevent contamination.
Sec. 211.67b Equipment Cleaning and Maintenance	Written procedures shall be established and followed for cleaning and maintenance of equipment that include the following: 1. Assignment of cleaning responsibility 2. Maintenance and cleaning schedule 3. Methods, equipment and materials used in cleaning and maintenance operations. Any required disassembly and reassembly also need proper methods 4. Removal of previous batch

	identification 5. Protection of clean equipment from contamination prior to use 6. Inspection for cleanliness before use
Sec. 211.67c Equipment Cleaning and Maintenance	Records shall be kept for maintenance, cleaning, sanitizing, and inspection.

The design team will create a system of steps to follow using equipment already provided by the sponsor. The design team is not responsible for the equipment used, including the filter.

Objectives

The design team aims to compile three methods for testing the integrity of a gas permeable silicone filter. The accessories of the integrity test will include the filter support and peripheral components to execute flow measurements. The integrity tests created will be used to determine if the filter is acceptable for use and the filter's applicability in the field. The design team anticipates the test methods will primarily be used by pharmaceutical companies; however, the language and structure of the tests could be easily executed by other professionals in related fields. The design team will rationalize the choice for the best candidate method then, using that method, test the reliability of the method using simulated defects to correlate defect size. The final proposal will include the optimal test method to analyze the integrity of the filter and demonstrate the filter's sensitivity and robustness. Operational changes will be tested including size of defect and operating temperatures.

The end user needs to be able to determine if the filter is reliable. This is the design team's main product specification; however, other factors will play a role. Other specifications include readability of the test method, accessibility of the test method, fixture reasonability, and material accessibility. Readability of the test method is important because the end user must be able to understand the steps within the test. A poorly written test method can result in improper execution of the test and inaccurate results. Accessibility of the test method is essential to the success of the project because if the methods are not readily available the likelihood of this method being used in the field is limited. Similarly, the materials used must be easily accessible for a wide population. Obscure, hard to acquire materials will discourage the use of the test method. Fixture reasonability describes the simplicity of the experiment setup. A complex fixture assembly increases the possibility for misuse and decreases the possibility for success. A complete list of customer wants, and needs is shown in Appendix B1.

The customer needs and the needs of the sponsor, Dr. Lazzara, are not necessarily aligned. Although Dr. Lazzara also expects the specifications mentioned above, he also expects technical requirements. These technical requirements include tubing material, wetting fluid, color of the wetting fluid, operational methods, flow rate measurements, testing conditions, and fixture connections. There are variations within each of these specifications that will be decided

and defined further in the design process. A list of these design requirements is listed in Appendix B2.

The details for measuring each specification are to be determined and added to this document upon completion. Generally, each specification will be ranked from most important to least important by our customer, in this case, Dr. Lazzara. Ranking of the specifications will give the design team insight into the qualities most important to the customer; therefore, which specifications to focus on during the design process. The more specific design specifications such as measuring fluid flow and operational temperature will be measured using simulations such as COMSOL and estimated as accurately as possible before beginning quantitative measurements.

High risk specifications include the method for measuring fluid flow because it will affect other aspects of the integrity test. Other high-risk specifications include the nondestructive nature of the test. This is an essential detail to the design, that cannot be negotiated. The integrity test method fails if the filter gets destroyed in the process.

Project Management

The design team has created an initial Network Diagram (see Appendix A1 and A2) illustrating the intended project path throughout the entirety of the project. This pictorial description of the design process will serve as a guide not a document to follow strictly, and is subject to change. Any change of this document will be accompanied by a detailed description of the change and justification for the change. The Network Diagram provides the design team with a critical path, drawing attention to aspects of the design process that are critical to the success of the project.

The design process will start with in-depth research of existing integrity tests for filters similar to the filter in question. Research and a thorough understanding of the filter will allow the team to establish project requirements and specifications. The accuracy of the project requirements and specifications will drive the success and timeliness of the project as a whole. This will allow the team to come up with several conceptual prototypes, which will eventually lead to a functional prototype. A functional prototype will be used to establish quantitative data that can be compared to the specifications and project requirements.

Along the timeline there are milestones in the process that will produce key deliverables. All key deliverables will be presented to our sponsor, Dr. Lazzara, for approval and review before proceeding in the design process. These deliverables will be a series of design goals, established by the team, and produced as a series working towards the final goal. Such deliverables include, but are not limited to, design specifications, methods for measuring flow rate, method for inserting the filter in the fixture, test prototypes, fixture characteristics, and the final written test procedure.

Table III: Summary of deliverables and proposed submit date and approval date

Deliverables	**Proposed Submit Date**	**Proposed to be Approved By**
Design Specification	10/16	10/23
Flow Rate Measurement	10/25	11/1
Filter Insertion Method	10/25	11/1
Bill of Material	10/25	11/1
Fixture Characteristic	12/6	12/13
Final Written Procedure	2/19	2/20

The immediate next steps in the design process will be to continue researching background information and gaining knowledge of the filter. The design team will then agree upon design specifications related to the filter. The first conceptual methods for the integrity test will be created based on the test methods that already exist for gas filtration systems. Alterations to these existing methods will be made as necessary based on the unique characteristics of the filter.

The compilation of the design specifications will be the most pressing step in the design process over the next two weeks; however, the Network Diagram illustrates the critical path in our design. The critical path consists of tasks that will alter the timeline of the project if not completed on time. The critical path is seen in RED (see Appendix A2). The red indicates the importance of the task and serves as a reminder to focus more energy and resources into its completion.

Conclusion

This document will serve as a contract between the design team and Dr. Lazzara on behalf of Meissner Filtration Products. It is both party's responsibility to communicate efficiently, provide deliverables when appropriate and formally document all aspects of the design. The project statement, customer needs, product specifications, deliverables, and timeline must be agreed upon before continuation of the design process. Upon approval, the design team will continue with next steps outlined in the Network Diagram, primarily defining design specifications and, with Dr. Lazzara's guidance, assign numerical values to each.

References

Blanc, Geoffrey, et al. “Defining the Implementation of Single-Use Technology: a Comparative Evaluation of a Single-Use Bioreactor with a Stainless-Steel Bioreactor.” *Pharmaceutical Bioprocessing*, 2013, pp. 341–349.

Calvo, J I, et al. “Pore Size Distributions in Microporous Membranes.” *JOURNAL OF COLLOID AND INTERFACE SCIENCE*, vol. 176, 1995, pp. 467–478.

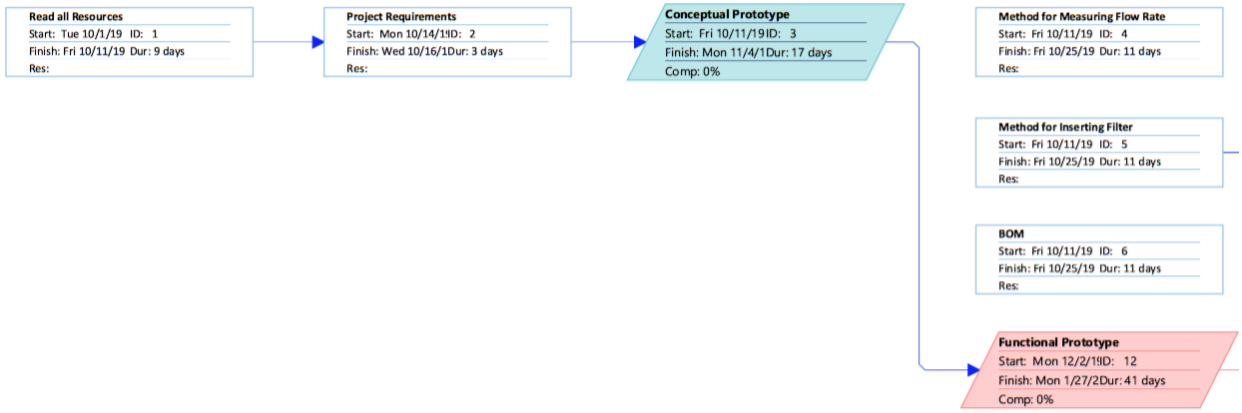
Capillary Flow Porometer. *Capillary Flow Porometer*, Porous Materials, Inc., 2011.

Fluid Purification, Cuno. “Microfluor ®II Filter Cartridge Integrity Testing.” *Www.cuno.com*, Apr. 3AD.

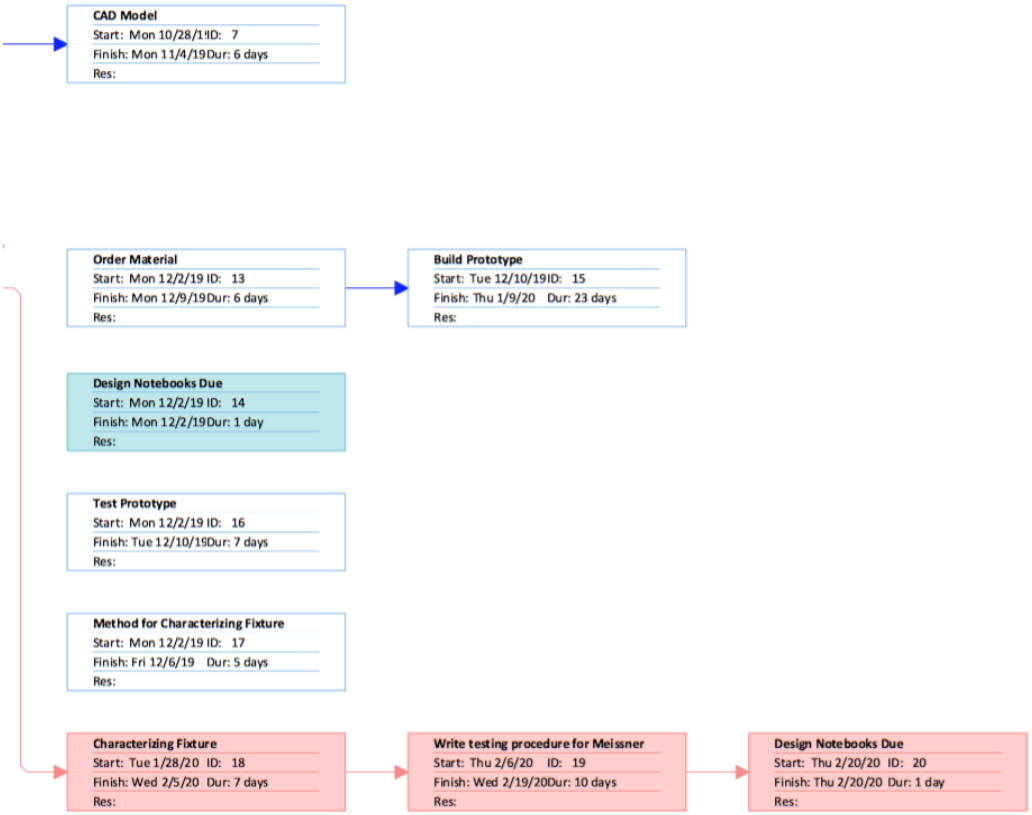
Sirvain, Marie Andree. “Accurate Measuring of Membrane Pore Size Distributions.” *Filtration Separation* , 2015.

APPENDIX

Appendix A1: Network Diagram from October 11th to December 2nd.



Appendix A2: Network Diagram from December 9th to February 20th.



Appendix B1: Complete list of customer wants/needs in no particular order.

Customer Requirements:
a. Filter reliability
b. Readability of the test method
c. Accessibility of the test method
d. Fixture reasonability (complexity)
e. Material accessibility
f. Cost of test method access
g. Time for test method completion
h. Accuracy of test method
i. Diverse application of test method

Appendix B2: Complete list of sponsor wants/needs in no particular order.

Sponsor Specific Requirements:
a. Tubing Material
b. Wetting Fluid
c. Operating Method
d. Flow Measure Method *
e. Testing Conditions
f. Connection
g. Nondestructive*

*High Risk Specifications

Network Diagram

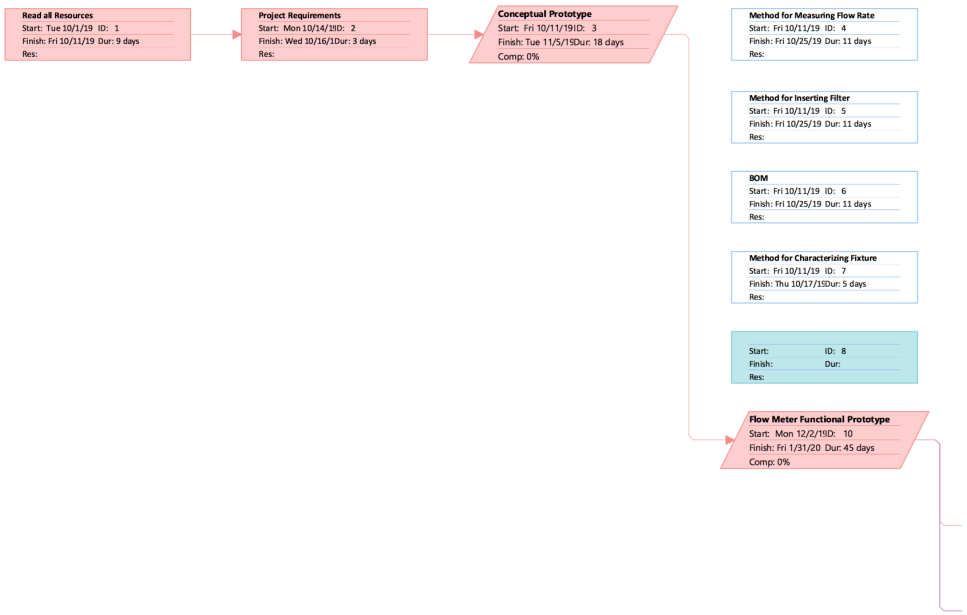


Figure 1: Updated Network Diagram from October 11th to January 31st.

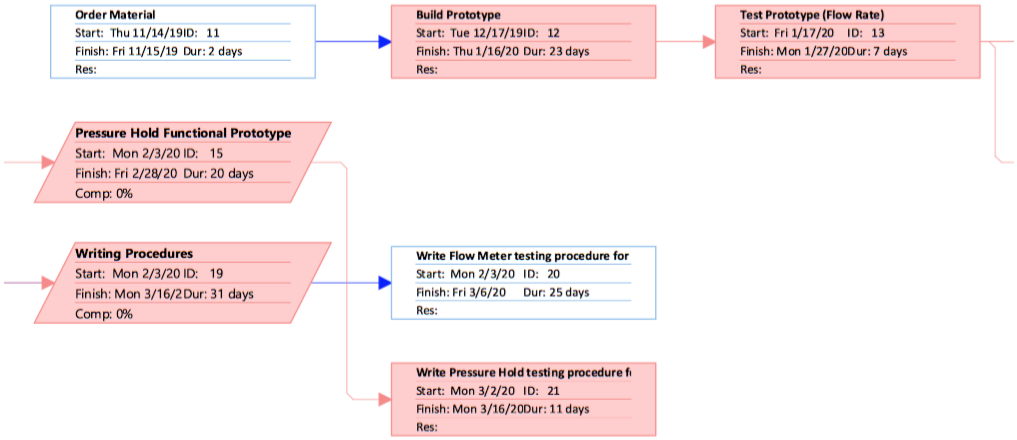


Figure 2: Updated Network Diagram from November 11th to March 16th.

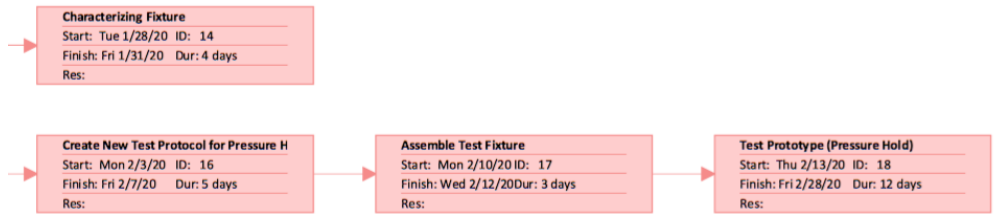


Figure 3: Updated Network Diagram from January 31st to February 28th.

The design team has created an initial Network Diagram illustrating the intended project path throughout the entirety of the project. This pictorial description of the design process will serve as a guide not a document to follow strictly and is subject to change. Any change of this document will be accompanied by a detailed description of the change and justification for the change. The Network Diagram provides the design team with a critical path, drawing attention to aspects of the design process that are critical to the success of the project.

Indications for Use

The testing apparatus and procedures developed here are indicated for the integrity testing of silicone gas permeable filters. The testing is non-destructive and identifies whether the gas diffusion properties adhere to the standards set upon manufacture of the filter.

The testing apparatus is indicated for use by Meissner Filtration's pharmaceutical clients before and after use of the silicone gas permeable filters. Testing is required both before and after to ensure the proper performance throughout use of the filter.

Budget

Table IV: Project budget spreadsheet for traceability

Item Description	Product # (From McMaster)	Purpose	Associated task	Qty	Cost/Unit	Total Cost	Notes
Vacuum	4396K21	Creating "negative" pressure for diffusion	Degassing Test	1	$423.67	$423.67	Provided by Meissner
Pressure Gauges	3834K111	Measuring pressure through filter	Functional Prototype	1	$171.89	$171.89	Provided by Meissner
Valves	4677K51	Controlling fluid and gas flow	Functional Prototype	5	$127.22	$636.10	Provided by Meissner
Tubing	5233K57	Rubber tube for substance flow	Functional Prototype	25	$0.48	$12.00	Provided by Meissner
Pressure Regulator	66325A42	creating controlled test conditions	Flow/Bubble Point Test	1	$190.47	$190.47	Provided by Meissner
Gas Chamber	7822A11	Performing testing away from professional facility	Flow/Bubble Point Test	1	$131.35	$131.35	Provided by Meissner

The design team's current projected budget is $1,045.08. The design team is aware that this number is well above our allotted budget from Cal Poly. The team has discussed this with the sponsor, and they have agreed to supply most of the items on this list, including some of the more expensive ones. Meissner has offered to supply the team with the vacuum, pressure gauges and regulators, and high precision valves if applicable. With the contributions from Meissner, the design team believes that they can finish this project under budget.

Customer Requirements

Table V: Customer Requirements

Customer Requirements:
j. Filter reliability
k. Readability of the test method
l. Accessibility of the test method
m. Fixture reasonability (complexity)
n. Material accessibility
o. Cost of test method access
p. Time for test method completion
q. Accuracy of test method
r. Diverse application of test method

Table VI: Sponsor Specific Requirements

Sponsor Specific Requirements:
h. Tubing Material
i. Wetting Fluid
j. Operating Method
k. Flow Measure Method*
l. Testing Conditions
m. Connection
n. Nondestructive*

*High Risk Specifications

Specification Development

Table VII: Specifications

Specifications:
a. Test pressure < 2 bar
b. Sterilized test fluids
c. Detect orifices down to 7 microns
d. Medical tubing non permeable to gasses, potential in polyurethane
e. Mostly stainless-steel tubing
f. <5% difference between test results before and after
g. Use of nitrogen gases (N_2)

TAM and Competitive Advantage

Benefit:

The team is creating a test that is not currently available to pharmaceutical companies who use these filters. This test will allow these companies to test the integrity of the filters before and after use. To make the test better than others, the team will strive to create an easy to use fixture, a simple and straightforward procedure, and reliable results. The test will offer accurate data while efficiently testing the filters to save customers' time.

Target market:

The target market is all of Meissner's current and future pharmaceutical clients who use the gas permeable filters. This fixture and test procedure will allow current customers to check the integrity of their filters. If the assembly is better than any other competitors, it may be used in sales pitches for future clients.

Competition:

There are several other companies that also distribute gas permeable filters. These other companies also require integrity testing and are the more appropriate competitors. As more companies distribute these filters, the number of competitors will increase. Several other companies manufacture and sell integrity testing units. One company, Pall Emflon, sells two different testing units for their pharmaceutical filters. These units can run multiple tests on a single filter, including measure flow, bubble point and pressure decay tests. To make the test competitive on the market, the design team will strive to match or exceed these filter's reliability, accuracy and ease of use.

Intellectual Property Assessment

Table VIII: Current Issued Patents Related to Silicone Membrane Filters and Integrity Testing

Issued Patents	Example Claims	Remedy
9,095,801: *Filter device test apparatus, filter integrity testing method and computer program product*	A test apparatus (1) for automatically carrying out an integrity test on a filter device	The testing will be done manually
10,376,844: Interface module for filter *integrity testing*	The first and/or second valves are pneumatically controllable	The valves will be manually operated
5,232,600: *Hydrophobic membranes*	Use of hydrophobic membranes.	The testing will use similar methods mentioned in this patent but apply them to hydrophilic membranes.

Table IX: Pending Patent Applications Related to Silicone Membrane Filters and Integrity Testing

Patent Applications	Example Claims	Remedy
20,180,333,680: *METHOD OF LIQUID FILTER WETTING*	The wetting fluid is an aqueous solvent or alcohol	The claim made here is extremely broad, and it seems to be unavoidable where a wetting fluid is necessary for testing
20,030,159,977: *Filter integrity testing system and method, and water purification system comprising same*	Source of the pressure is a pump.	The integrity testing will have gravity as a pressure source.
20,170,252,703: *Interface Module for Filter Integrity Testing*	The first flowpath comprises a vertical section and the check valve is disposed of in the vertical section.	The design will incorporate a valve system in the horizontal sections. Avoiding a vertical check valve will eliminate the possibility of gravity having an effect on the pressure through the valve.

Conjoint Analysis

Table X: Conjoint Analysis Factors and Levels

Factor	**Level 1**	**Level 2**
Tubing	Stainless Steel	Medical
Wetting Fluid	DI Water	Saline
Fluid Color	Clear	Pink
Operated Method	Manual	Automated
Measure Method	Flow Rate	Pressure
Testing Condition	90% of Spec	80% of Spec
Connections	Threaded	Adhesive

Table XI: Listing of the Conjoint Cards

Card No.	**Tubing**	**Wetting Fluid**	**Fluid Color**	**Operating Method**	**Measure Method**	**Testing Condition**	**Connections**
1	Stainless Steel	DI Water	Clear	Manual	Flow Rate	90% of Spec	Threaded
2	Stainless Steel	DI Water	Clear	Automated	Pressure	80% of Spec	Adhesive
3	Stainless Steel	Saline	Pink	Manual	Flow Rate	80% of Spec	Adhesive
4	Stainless Steel	Saline	Pink	Automated	Pressure	90% of Spec	Threaded
5	Medical	DI Water	Pink	Manual	Pressure	90% of Spec	Adhesive
6	Medical	DI Water	Pink	Automated	Flow Rate	80% of Spec	Threaded
7	Medical	Saline	Clear	Manual	Pressure	80% of Spec	Threaded
8	Medical	Saline	Clear	Automated	Flow Rate	90% of Spec	Adhesive

SUMMARY OUTPUT								
Regression Statistics								
Multiple R	0.362							
R Square	0.131							
Adjusted R Square	0.111							
Standard Error	2.163							
Observations	312.000							
ANOVA								
	df	*SS*	*MS*	*F*	*Significance F*			
Regression	7.000	215.077	30.725	6.564	3.13598E-07			
Residual	304.000	1422.923	4.681					
Total	311.000	1638.000						
Factors	*Coefficients*	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	4.923	0.346	14.211	0.000	4.241	5.605	4.241	5.605
Tubing	-0.923	0.245	-3.768	0.000	-1.405	-0.441	-1.405	-0.441
Wetting Fluid	0.462	0.245	1.884	0.061	-0.021	0.944	-0.021	0.944
Fluid Color	-0.077	0.245	-0.314	0.754	-0.559	0.405	-0.559	0.405
Operating Method	-1.167	0.245	-4.763	0.000	-1.649	-0.685	-1.649	-0.685
Measure Method	0.064	0.245	0.262	0.794	-0.418	0.546	-0.418	0.546
Testing Condition	0.449	0.245	1.832	0.068	-0.033	0.931	-0.033	0.931
Connections	0.346	0.245	1.413	0.159	-0.136	0.828	-0.136	0.828

Figure 4: Statistical Analysis of Multivariate Regression Model

Discussion:

The factors that have a statistically significant effect on customer attraction are determined based upon the P-Values provided by the ANOVA regression model. If the P-Values are less than 0.05 then the factor is considered to be significant. Through this, we determined that tubing and operating method are important factors. The design team will also consider wetting fluid and testing conditions because these P-Values were also close to the cut-off value. Factors that proved to be less important than the others include the fluid color and measuring method.

Morphology

Table XII: Morphology

Morphology					
Product: Integrity Testing for Gas Permeable Silicone Filters		Organization Name: Meissner Filtration			
Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Testing Gas	Oxygen, O_2	Nitrogen, N_2	Carbon Dioxide CO_2	Argon, Ar	Helium, He
Testing Method	Fluid Flow Rate on Either Side of Filter	Pressure Drop Over Time	Degassing of a liquid with a vacuum	N/A	N/A
Motion	Moving Gas	Moving Liquid	Moving Liquid and Gas	N/A	N/A
Wetting Fluid	Filtered and Sterilized Water	70% IPA	No Wetting Fluid	N/A	N/A
Team member: Kevin Yerina, Patrick Humann, and Maggie Baker			Prepared by: Kevin Yerina, Maggie Baker, and Patrick Humann		

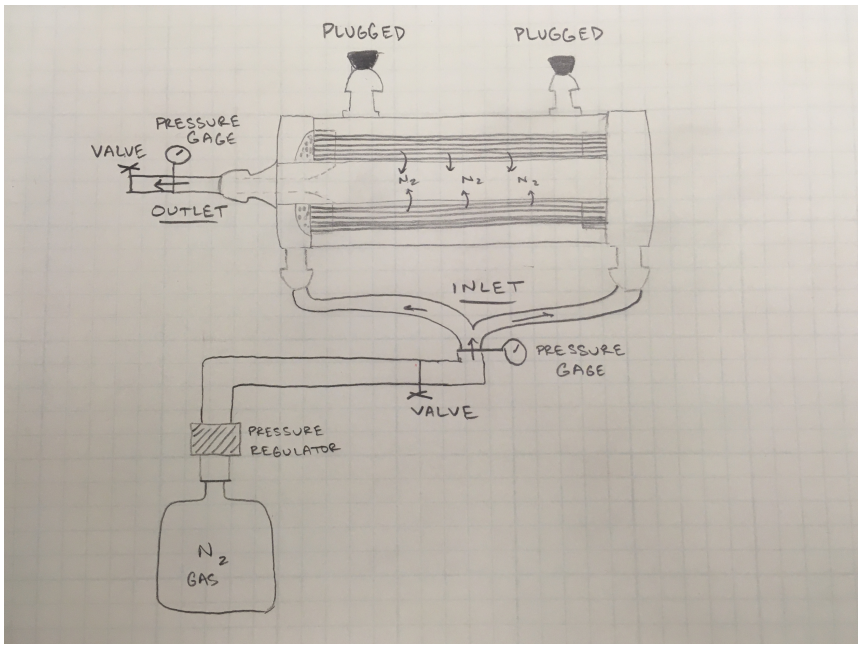
Concept Evaluation

Concept 1

This would be the least expensive and simplest test that has been produced thus far. Nitrogen is an ideal gas for economic purposes because it occupies approximately 78% of normal air and is therefore inexpensive. It is also relatively non-reactive in its diatomic form leading to a low contamination rate of the filter.

The pressure drop over time test is also a simple test as far as materials are concerned. The required materials would include the same or similar tubing and valves to that of the other the other test methods. The specific components required would be a pressure regulator for gas input, and a continuously recording pressure gage at the input and output. Gas would be fed initially to a certain pressure reading with the output closed. Once the desired pressure is released, the input valve would be closed, and output would be opened. Pressure values at the input and output would be recorded until they return to a constant value. Integral and non-integral filters would both be tested and ideally the difference in the rates of pressure drops would be significant enough to identify a flawed filter.

For the other components of the test, the fluid used would just be gas. No liquid would be utilized in the filter in this case. There would also be no wetting fluid used for the testing initially to allow for maximum simplicity. If a wetting fluid is found to assist in the test, then the test procedure will be altered.



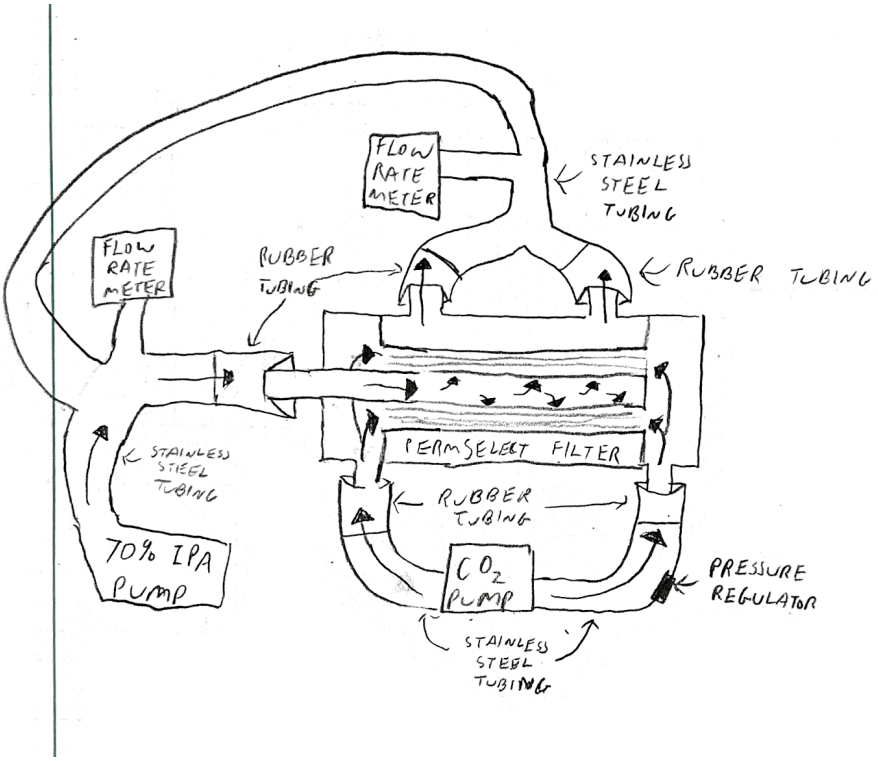
Concept Summary

- Nitrogen
- Pressure drop over time
- Moving gas
- No wetting fluid

Figure 5: Concept I Sketch

Concept 2

70% IPA will be pumped into the end port of the filter. The IPA will flow through the membranes and out of the top ports. The flow rate will be measured before the IPA has entered and after the IPA has exited the filter. CO_2 will be pumped through the bottom ports of the filter and travel between the hollow tubes of the membrane. Testing will need to be done to determine an acceptable range of measurements for the recorded flow rates. Measuring flow rates will indicate if the liquid is able to move through the filter correctly.



Concept Summary:

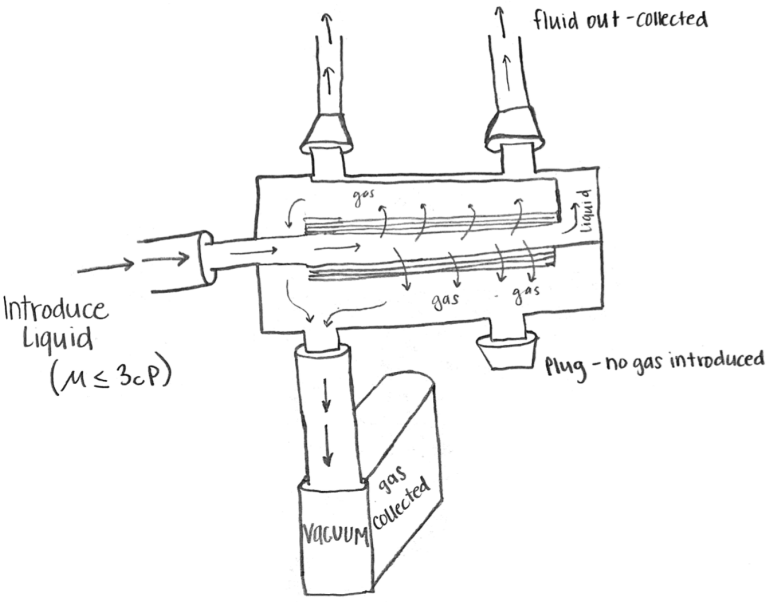
- Carbon Dioxide
- Fluid Flow Rate
- Moving Liquid
- 70% IPA

Figure 6: Concept II Sketch

Concept 3

In preparation for this concept, a liquid, free of all gases, is injected with Helium. It is necessary to know the exact amount of gas injected into the liquid for comparison later on in the concept. The liquid itself does not have to be of a specific type, as long as it can move through the filter freely with a viscosity similar to water.

The liquid will be fed through the filter to separate the gas from the liquid. A vacuum will be attached to the output of the filter, collecting the gas that was separated by the filter. With the gas collected from the output, it can then be measured and compared to the amount of Helium that was initially injected into the liquid. The amount of Helium recorded from the filter will determine how accurately the filter separates the gas from the liquid.



Concept Summary:

- Helium, He
- Degassing of a liquid with a vacuum
- Moving liquid and gas
- No wetting fluid

Figure 7: Concept III Sketch

Table XIII: Results of the Pugh Chart

Methods	**Totals**
Pressure drop over time	145
Fluid Flow Rate	0
Degassing with a vacuum	-45

Conceptual Model

Description of the Model

This model is based on the measurement of the flow rate of nitrogen through the filter based on a controlled pressure input. On the left side is a pressurized container filled with nitrogen connected to a pressure regulator so the design team can control the outward flow. This is connected to stainless steel tubing up until a short amount of polyurethane tubing to connect to the barbs on the filter. As little polyurethane tubing as possible is used in order to minimize gas diffusion from the system. This is especially important on the input end due to the pressurized characteristics of the gas (up to 2 bar).

Connected to the outlet of the filter is polyurethane tubing which is then connected to possibly two different test apparatus. The one shown in Figure 7 is an inverted graduated cylinder filled with water. The gas flowing through the filter will collect in the graduated cylinder and flow rate can be measured based upon volume of nitrogen collected and the duration of our measurement. The other option is the connection of a flow meter to measure the flow in a more precise way. The third option includes connecting the flow meter on the inlet end of the apparatus in between the stainless steel and polyurethane tubing. The results gathered from each option should be similar, and each will be used during testing to provide the team with as much data as possible to compare for accuracy. The method that is found to have the most precision will be used when establishing the final test procedure.

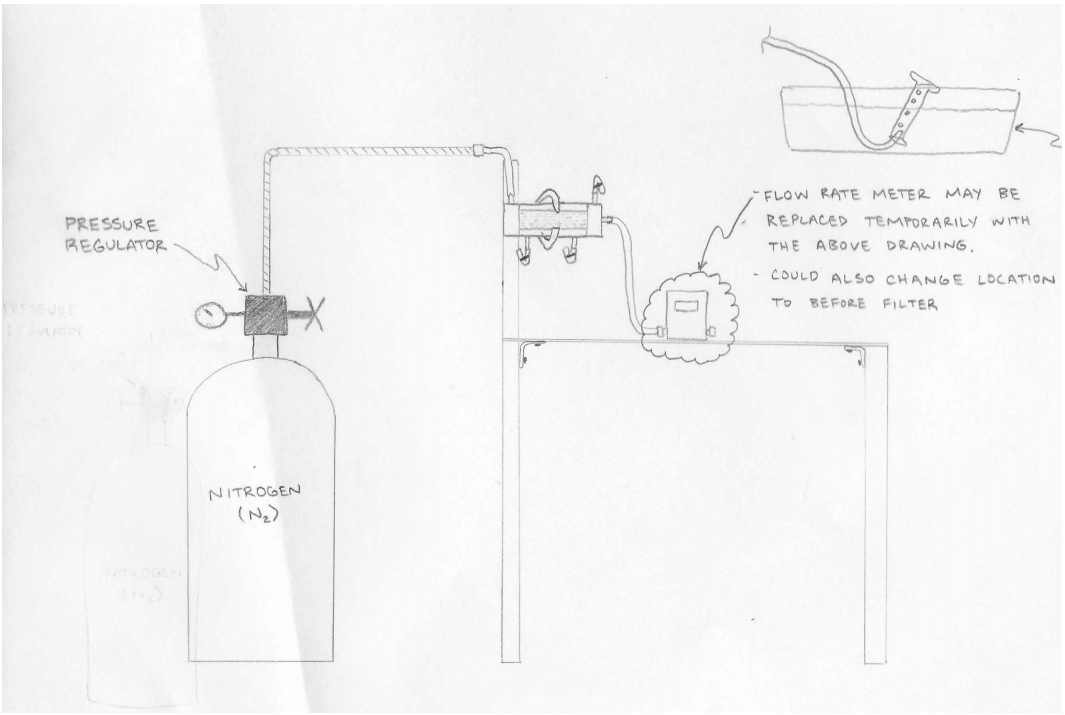


Figure 8: Sketch showing the set up as described in detail above

Analysis Performed

The sketch in Figure 8 shows a method similar to one that the team's sponsor uses to test a comparable filter. Similar to Meissner's method, the team will control gas pressure in and measure gas flow out. Keeping the test similar to an existing method will make creation and implementation of the testing procedure more straightforward and easier to follow. Using similar techniques for creating a fixture and analyzing data will allow the team to use equipment that is easily accessible from the Meissner facility, which is both convenient and cost effective.

The team anticipates collecting data in the form of milliliters of nitrogen in the inverted cylinder. The milliliters of nitrogen will be the volume element of the flow rate. The amount of flow that will be measured over time will vary depending on how fast the nitrogen flows out of the filter. Increasing the run time of the operation will improve the accuracy of the measurement.

Measurements with the flow meter will provide flow rate data directly. It will be important to allow the flow of nitrogen to run for a period of time in order to increase the possibility of recording accurate results with more data points over time.

Lessons Learned

From the model development, the team has a better understanding of how they will collect the measurements. The team will test several data collection methods and compare them before selecting a final method for data collection. Along with necessary tests to gather data, they will also become more comfortable working with the filters. The team will learn how to handle and assemble the filter fixture without damaging it or themselves. With better sketches and analysis, they have also learned which methods will be more challenging or impossible based on filter geometry and function. Writing the steps for each method emphasized the length of certain concepts, helping to keep in mind which methods are more efficient than others.

Data Collection

The team will use equipment from the Meissner Research and Development center in Camarillo including a pressure gauge, mass flow meter, and graduated cylinder. The pressure gauge will be located at the output of the nitrogen tank in order to regulate the amount of pressure introduced to the system. It will be critical to measure the pressure to ensure it does not exceed the maximum allowed pressure for the filter as well as providing an extra layer of protection for the test operator. The mass flow meter can be located at the input of the pressure valve or at the flow rate output. Theoretically, both locations should read the same results. The inverted graduated cylinder is collecting the amount of nitrogen expelled by the filter. This cylinder will provide the team with a volume reading and function as a control for the procedure.

Location of Data Collection

Data can be measured in two places. It can be measured before the nitrogen gas enters the filter or when the nitrogen flows out of the filter. Both locations will be tested to observe if there are any differences in measurement location. The more optimal location will allow the team to choose the more consistently accurate reading, improving the data collection.

Future Developments

Initial testing is required for further development of the design. The team will test the different measurement methods to determine which is the most accurate and repeatable. Once a final measurement method is determined, the fixture will undergo characterization testing. Data will be collected to create an acceptable range of values for integral filters. Calibrated orifices will also be used to determine if the fixture is robust enough to detect flaws down to seven microns in diameter.

Detailed Design

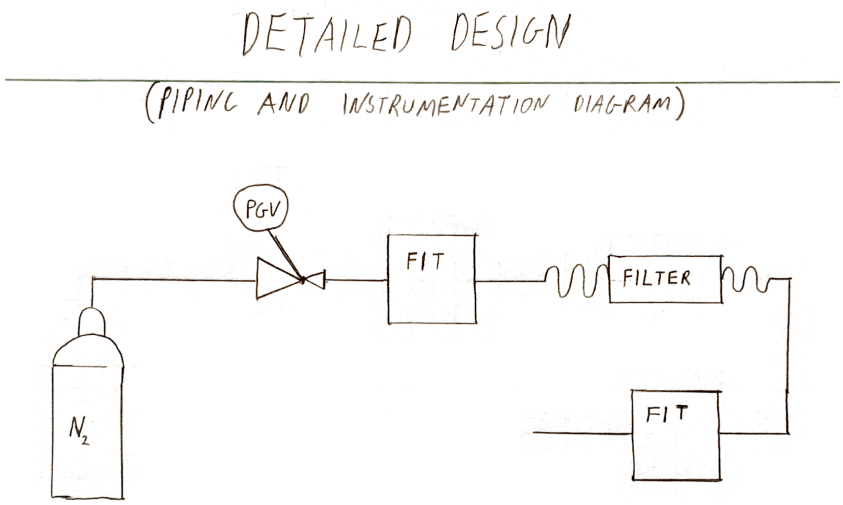


Figure 9: Test Fixture Piping and Instrumentation Diagram

The detailed design is displayed above. The nitrogen gas will travel through stainless steel tubing to a pressure regulator. This will allow the user to have a more precise control over the pressure. The nitrogen will then travel through a flow meter. The tubing will then change to polyurethane tubing to connect to the hose barb fittings on the filter. The polyurethane tubing is shown with the wiggly line in the design above. The nitrogen will then pass through the filter and then another flow meter. Based on the results of testing, one of the flow meters may be removed. Testing will be done with a flow meter before the filter, after the filter, and with a flow meter before and a flow meter after the filter.

Prototype Manufacturing Plan

The prototype is assembled in Meissner's MAARC facility in San Luis Obispo. The frame of the prototype is made from 80/20 extruded aluminum. The tubing is almost entirely stainless steel with short segments of rubber tubing around the filter. Polyurethane tubing will be used to attach to the hose barb fittings of the filter. Polyurethane was chosen because of its gas impermeable qualities. All equipment is located at the MAARC facility for manufacturing.

Prior to assembly, the nitrogen tank should be checked to ensure that it is fully closed, and no gas is flowing. The flow meter should also be connected to power to allow it to equilibrate prior to testing. To set up the prototype for testing, the nitrogen tank must be properly connected to the inlet port of the pressure regulator. A section of tubing must then be properly connected to the outlet port of the pressure regulator and a T-split. One of the T-split openings will connect to a segment of tubing that will transition to polyurethane before connecting to the filter. Polyurethane tubing will connect to the filter outlet before transitioning back to stainless steel tubing. The stainless-steel then connects to another T-split. The other remaining opening of

the first T-split will connect to a shut-off valve. A calibrated orifice will then be connected distal to the shut-off valve. This line will then reconnect to the second T-split that is positioned after the filter and before the flow meter. Once the filter and calibrated orifice lines reconnect at the second T-split, a section of stainless steel tubing will connect to the inlet port of the flow meter. Once all the fittings are connected, a leak test should be performed to ensure the system is sealed. An end cap should be placed at the outlet of the flow meter to close the system. A mixture of soap and water should be applied to each fitting connection. The gas should be gradually added to the system. Each connection should be inspected for the presence of bubbles. If bubbles are present, the connection should be tightened to prevent any leaks. Once there are no leaks the end cap can be removed, and the system is ready for testing.

Before testing, the pressure regulator should be fully closed. The nitrogen tank should then be opened a quarter turn. The pressure regulator should then be slowly opened until the desired pressure is displayed on the pressure gauge. The tubing should be checked for any leaks. A timer should be set for the testing time span. The timer should be started,, and the number displayed by the flow meter should be recorded. The ambient temperature in the testing environment should also be recorded.

Test Protocols

Flow Meter Position Testing

Testing was done with the flow meter positioned before and after the filter to determine the optimal position. The input pressure of Nitrogen gas was recorded, and flow was recorded. The pressure was then incrementally increased and flow rates were recorded. The pressure was then decreased at the same increment and flow rates were recorded. The data collected with the flow meter before the filter was then compared to the data collected with the flow meter positioned after the filter.

Hysteresis Testing

This testing was done to determine if there was hysteresis in the filter, or whether or not there was a difference in test results depending on whether or not the filter membrane was expanding or constricting. To test this, nitrogen gas was introduced into the filter at a known pressure and the flow rate output was measured. The pressure started low and was then gradually increased at set increments. The flow rates were recorded at each pressure and then the pressure was gradually decreased in the same increments. The flow rates were recorded at each pressure again. The data was then plotted separately as pressure increasing versus pressure decreasing. Comparisons were made to determine any differences.

Temperature Testing

Testing was done at different temperatures to see if there was a significant effect to filter performance. To test this, nitrogen gas was introduced into the filter at a known pressure and the

flow rate output was measured. The pressure started low and was then gradually increased at set increments. The flow rates were recorded at each pressure and then the pressure was gradually decreased in the same increments. The flow rates were recorded at each pressure again. The temperature in the testing environment was also recorded so it could be compared to other trials. Data was taken over several days at various ambient temperatures. A hair dryer was then used to heat the filter during testing. The filter temperature was estimated by heating a thermometer and reading the resulting temperature. The data was then plotted and compared to determine the effect of temperature on the filters.

Flow Rate at Various Pressures

The primary test the team performed is that which the set up is shown in the detailed design. It includes the measurement of flow rates through the filter at various pressure inputs. The testing was done with the testing fixture setup shown below in Figure 9.

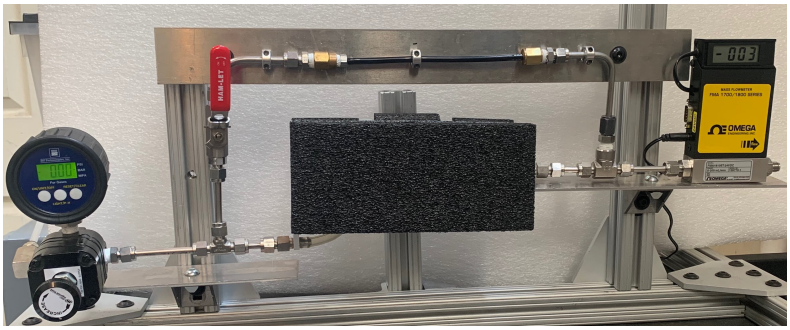


Figure 10: The flow meter test assembly. Components from left to right: pressure regulator, bifurcation to either the orifice or the filter, flow meter.

The gas was fed into the filter at a gage pressure range of 0.10 to 1.50 bar. Pressure was changed in 0.05 bar increments from 0.10 bar up to 1.50 bar and then back down to 0.10 bar. After the team conducted the testing, they narrowed the test down to 5 pressures that end users should test. These five different pressures were set based on the accuracy and consistency of the flow meter. The flow meter utilized had a measurement range of 0-200 mL/min. This flow meter was used for testing integral filters without calibrated orifices. Testing was performed with a flow meter connected after the filter. Initial testing was performed just on the standard filter. Two filters were used to set standard baseline values.

Once baseline values at various pressures were determined, calibrated orifices were placed in parallel with the filter to mimic a defect. Variously sized orifices were utilized to see if it is possible to detect different defect sizes. The smallest orifice the design team was able to use mimics a defect of .0016 inches in size. The same test procedure was done on just the filter and were performed with each of the calibrated orifices in place. The data gathered was used to characterize what the flow rates measured should look like for integral and non-integral filters.

For flow rate testing, flow rate was plotted over the various pressures. The slopes of the lines were determined. The slopes were compared between the integral filter and the calibrated orifice tests.

Pressure Decay Over Time

While flow rate is what the design team have picked as the optimal test method, pressure drop over time was also tested. This involved the application of a certain pressure with no allowed release. Once a specific pressure had been established, gas input was stopped. Gas was then immediately released through the outlet. Pressure recordings were made initially and again every 10 seconds until it reached 0.20 bar. Just like in the flow test, 5 tests were performed for each filter at each pressure. The testing was done with the fixture setup shown below in Figure 10.

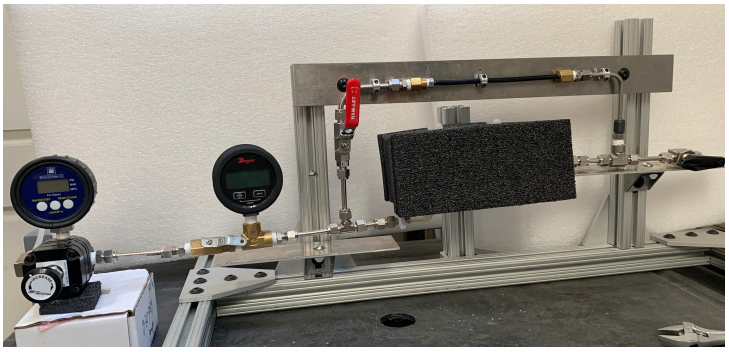


Figure 11: The pressure decay test assembly. Components from left to right: pressure regulator, valve one, pressure gauge, filter, valve two.

Similar to flow rate testing, baseline values were first determined with just the filter connected. Following these tests, the calibrated orifices were once again connected and different sizes were tested. The data gathered in this test were used to characterize the pressure decay rates of integral and non-integral filters.

Destructive Testing

Once the flow rate testing and the pressure drop over time were tested, the destructive testing was conducted. The filters were tested at pressures higher than recommended by the manufacturer. This is likely a defect style that is commonly executed by the end user. Bursting the filter at high pressures was the end goal of the destructive testing, but the design team ran into difficulties reaching pressures higher than 2 bar without other components of the assembly breaking. The destructive testing was inconclusive surrounding the ultimate pressure the filter could sustain.

Testing Data and Analyses

Flow Meter Position Testing

Filter 2 was tested with the flow meter before and after the filter. Both data sets were plotted on the same graph, see Figure 12, and linear trend lines were set to the data. The linear equations are shown in Table XIV in the form of y = mx, where m represents the slope of the linear line. The intercept was set to 0 because there should be 0 flow with 0 pressure. As seen in Table XIV, the two data sets have very similar slopes and R^2 values. This means that the data is very linear and there does not appear to be a significant change in data. The design team has decided to continue further testing with the flow meter after the filter. The data is similar but as seen in Figure 9, placing the flow meter after the filter will allow the team to test at higher pressures. When the flow meter was positioned before the filter, the flow meter was unable to converge to a single value at pressures above 1 bar of pressure (~14.5 psig is about 1 bar). When the flow meter was positioned after the filter, the flow meter was able to converge to a single value at pressures up to 1.5 bar (~21 psig is about 1.5 bar)

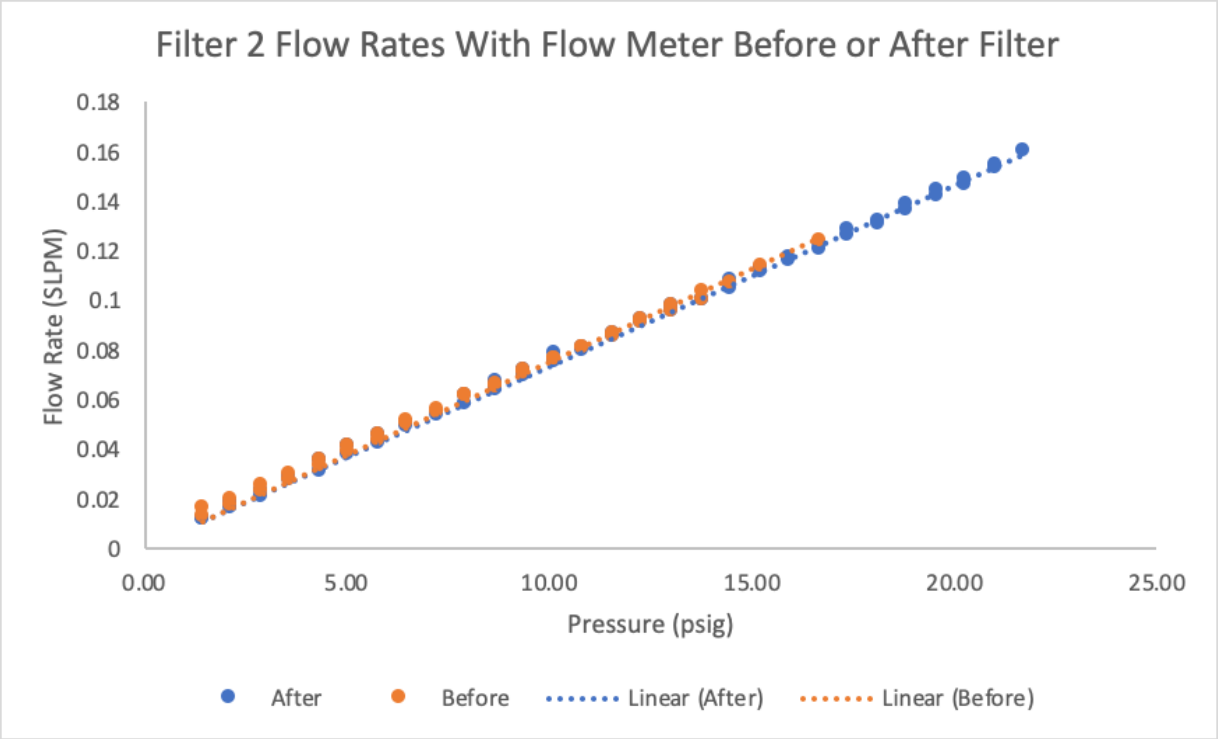


Figure 12: Flow Rates of Filter 2 with Flow Meter Before and After the Filter

Table XIV: Filter 2 Flow Rate Equations with Flow Meter Before or After the Filter

Data Set	Linear Equation	R^2 Value
After	y = 0.0073x	0.9985
Before	y = 0.0075x	0.9964

Hysteresis Testing

Flow rates were plotted over pressure as two separate data sets, increasing and decreasing pressure. Linear trend lines were fit with intercept values of 0 to determine linearity and if there were any signs of hysteresis. The lines are in the form of y = mx where m represents the slope of flow rate over pressure. This testing was done two times with Filter 2. The plots are shown below as Figures 13 and 14. The linear fit equations are shown in Table XV. All of the tests have very similar slopes and R^2 values close to 1. This shows that the data is very linear and that there is almost no hysteresis effect.

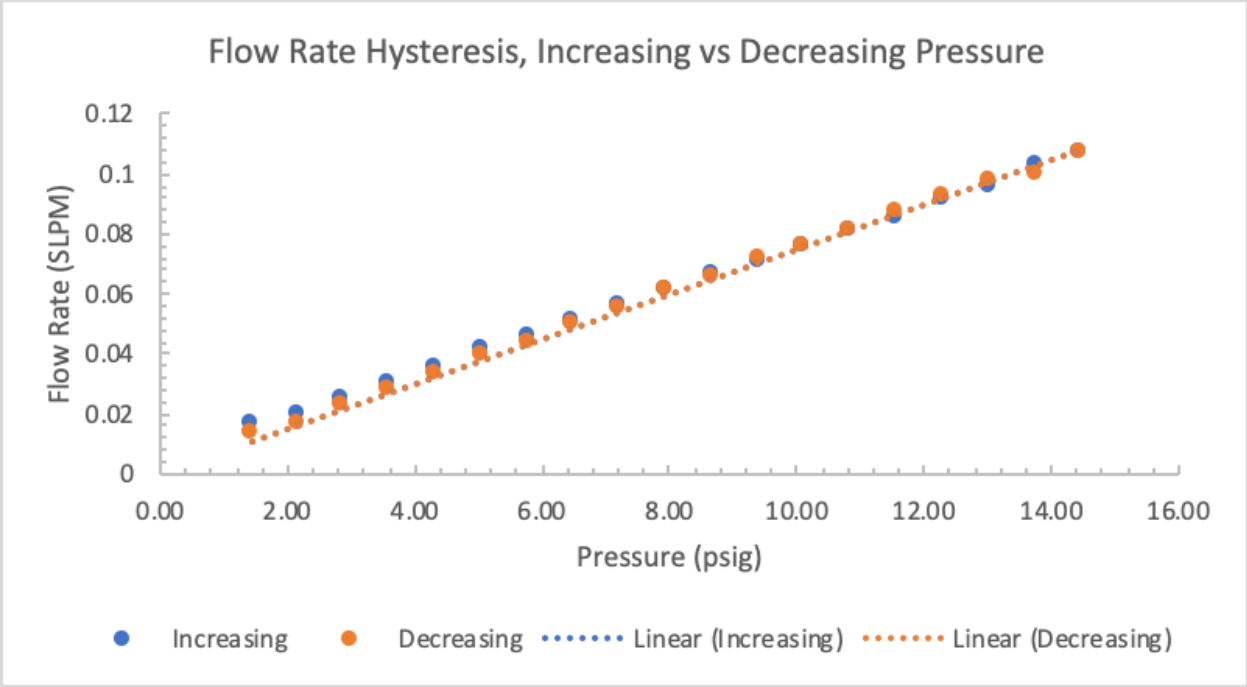


Figure 13: Hysteresis Test 1, Filter 2 Flow Rates

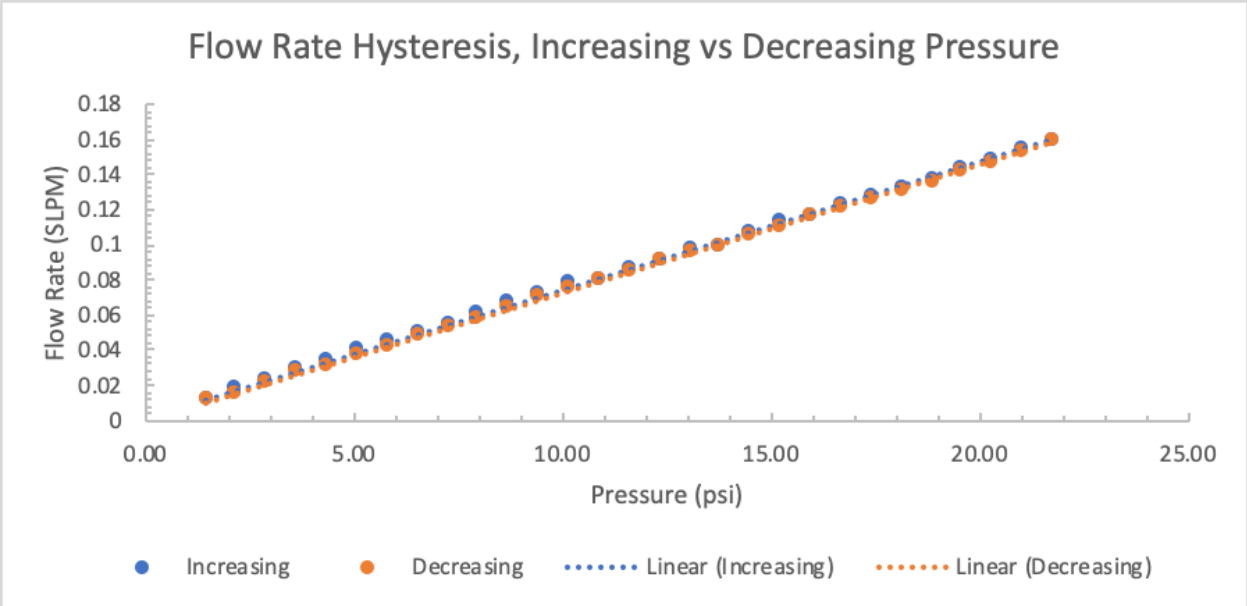


Figure 14: Hysteresis Test 2, Filter 2 Flow Rates

Table XV: Linear Trend Lines from Hysteresis Plots

Test Name	Linear Equation	R^2 Value
Test 1, Increasing	y = 0.0075x	0.9932
Test 1, Decreasing	y = 0.0075x	0.9983
Test 2, Increasing	y = 0.0074x	0.9982
Test 2, Decreasing	y = 0.0073x	0.9996

Temperature Testing

The testing showed that temperature can affect filter performance. In Figure 15, the flow rates will increase, and the data remains linear regardless of temperature. Table XVI shows the linear equations and R^2 values of the data sets. The linear equations show an increase in slope as temperature increases. The R^2 values are all close to a value of 1, indicating that the data is very linear and remains linear even at a higher temperature. It appears that temperature is something we should be aware of but if the data is collected at similar temperatures, it should affect the data too much. As long as this testing is done in controlled environments, then temperature should not be an issue for our end users.

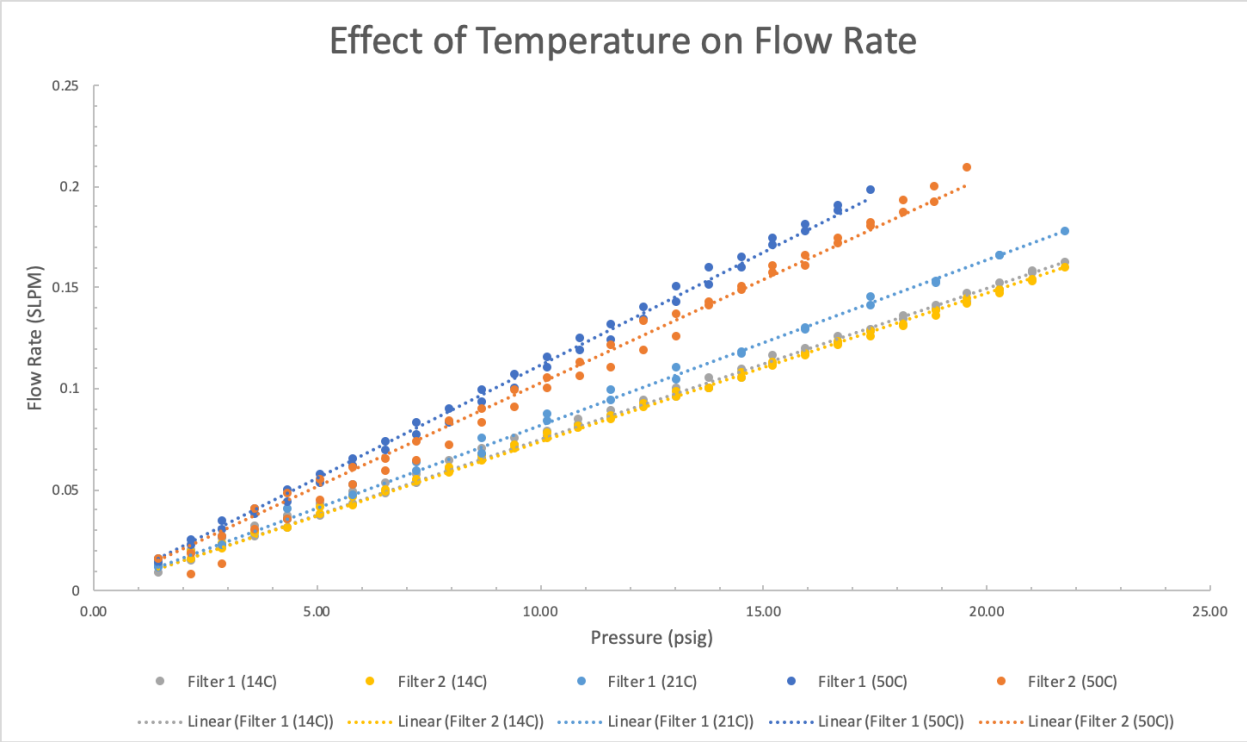


Figure 15: Flow Rate Over Pressure at Various Temperatures (°C)

Table XVI: Linear Trend Lines and R^2 Values from Temperature Testing

Filter (Temperature)	Linear Equation	R^2 Value
Filter 1 (14°C)	y = 0.0075x	0.9967
Filter 2 (14°C)	y = 0.0073x	0.9985
Filter 1 (21°C)	y = 0.0082x	0.9976
Filter 1 (50°C)	y = 0.0112x	0.9968
Filter 2 (50°C)	y = 0.0103x	0.9896

Flow Rate at Various Pressures

The data from the flow rate testing was plotted with linear fit lines. The intercepts were all set to 0. Figure 16 shows flow rate in SLPM over pressure in psig for Filter 1 and Figure 17 shows the data for Filter 2. Figure 18 shows the data for both filters plotted on the same graph. The linear fit equations can be seen in Table XVII. Based on the data, it appears that integral filters should have a linear slope of about 0.0075 SLPM/psig. The flow rate slopes were then plotted over orifice diameter to observe any relationship. Figure 19 and Table XVIII show these results. It appears that there is a linear relationship between flow rate and orifice diameter.

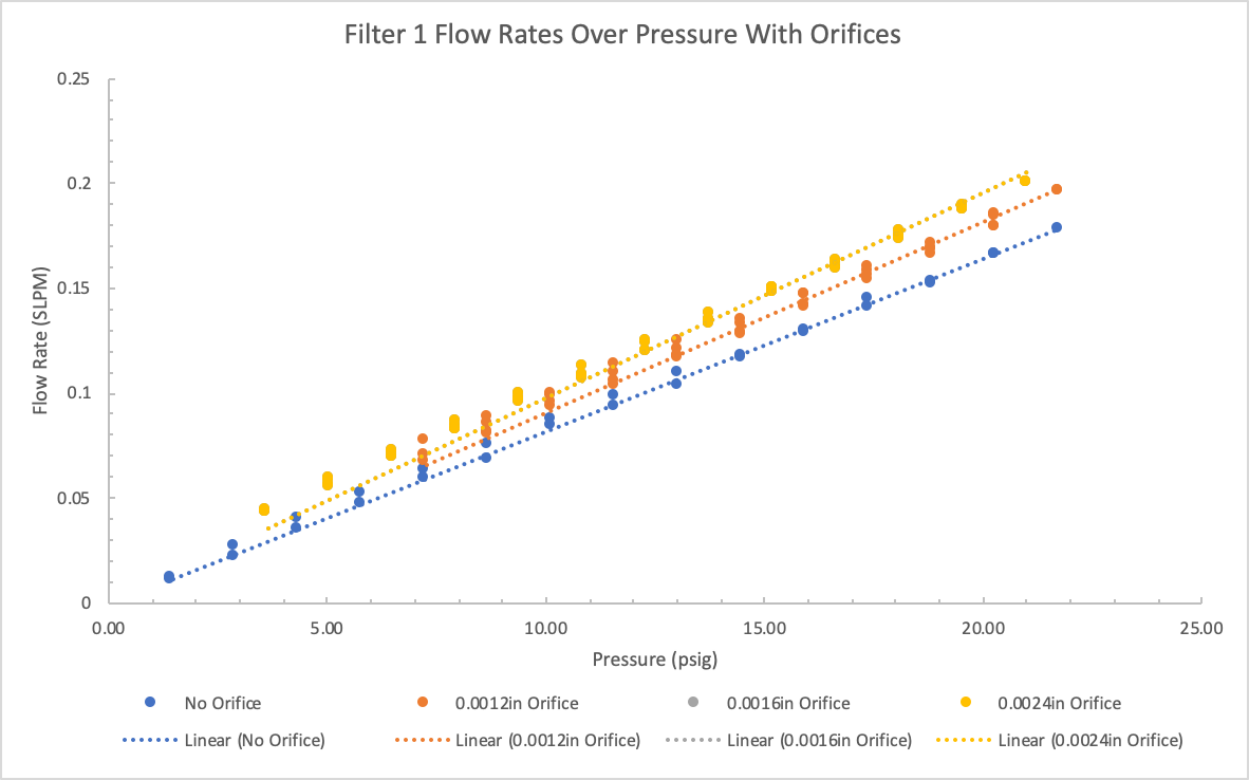


Figure 16: Filter 1 Flow Rates with Orifices

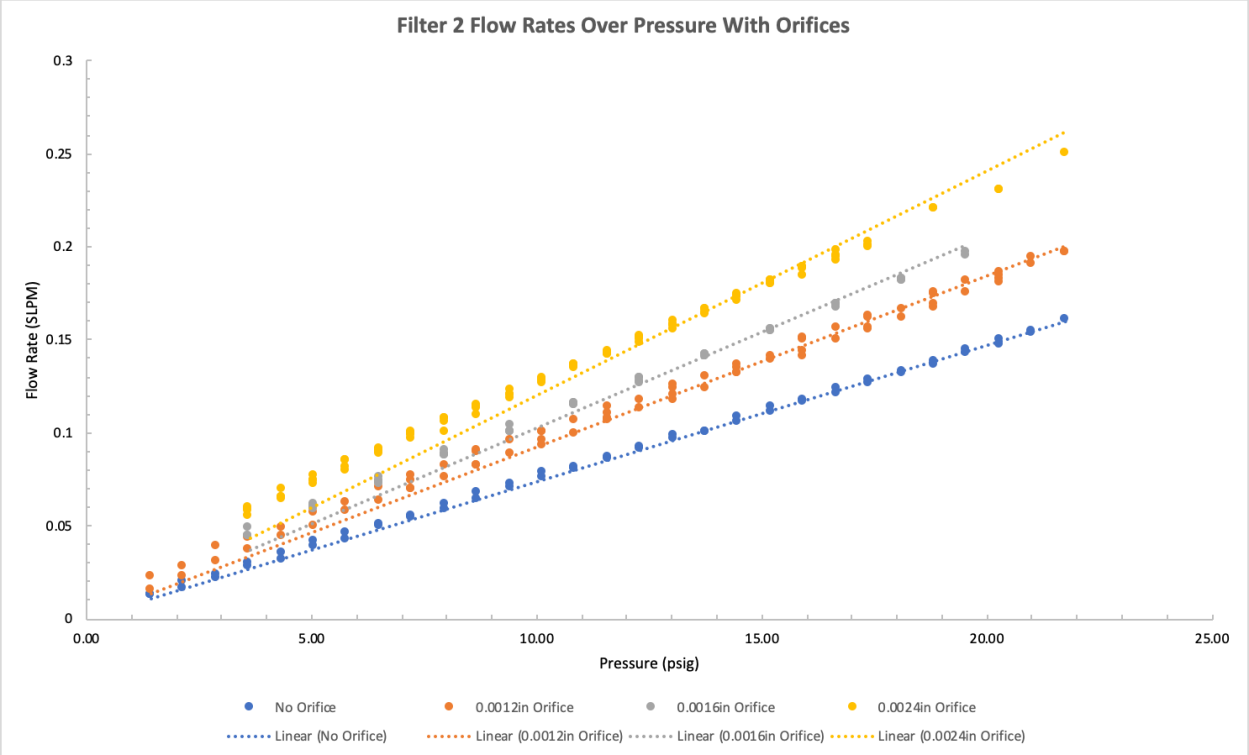


Figure 17: Filter 2 Flow Rates with Orifices

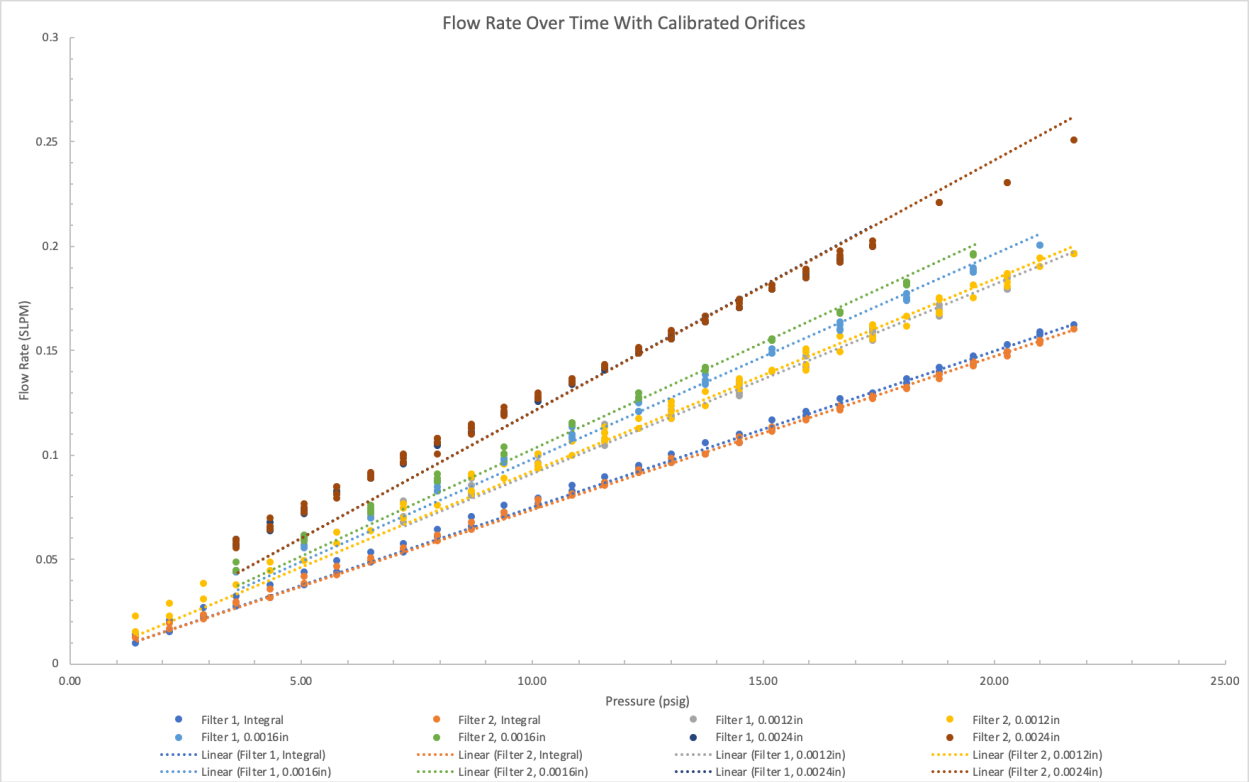


Figure 18: Filter 1 and Filter 2 Flow Rates with Orifices

Table XVII: Linear equations and R^2 values for the flow meter data

Test Name	Linear Equation	R^2 Value
Filter 1, Integral	y = 0.0075x	0.9967
Filter 2, Integral	y = 0.0073x	0.9985
Filter 1, 0.0012in	y = 0.0091x	0.9866
Filter 2, 0.0012in	y = 0.0092x	0.9899
Filter 1, 0.0016in	y = 0.0098x	0.9892
Filter 2, 0.0016in	y = 0.0103x	0.9876
Filter 1, 0.0024in	y = 0.0121x	0.9679
Filter 2, 0.0024in	y = 0.0121x	0.9690

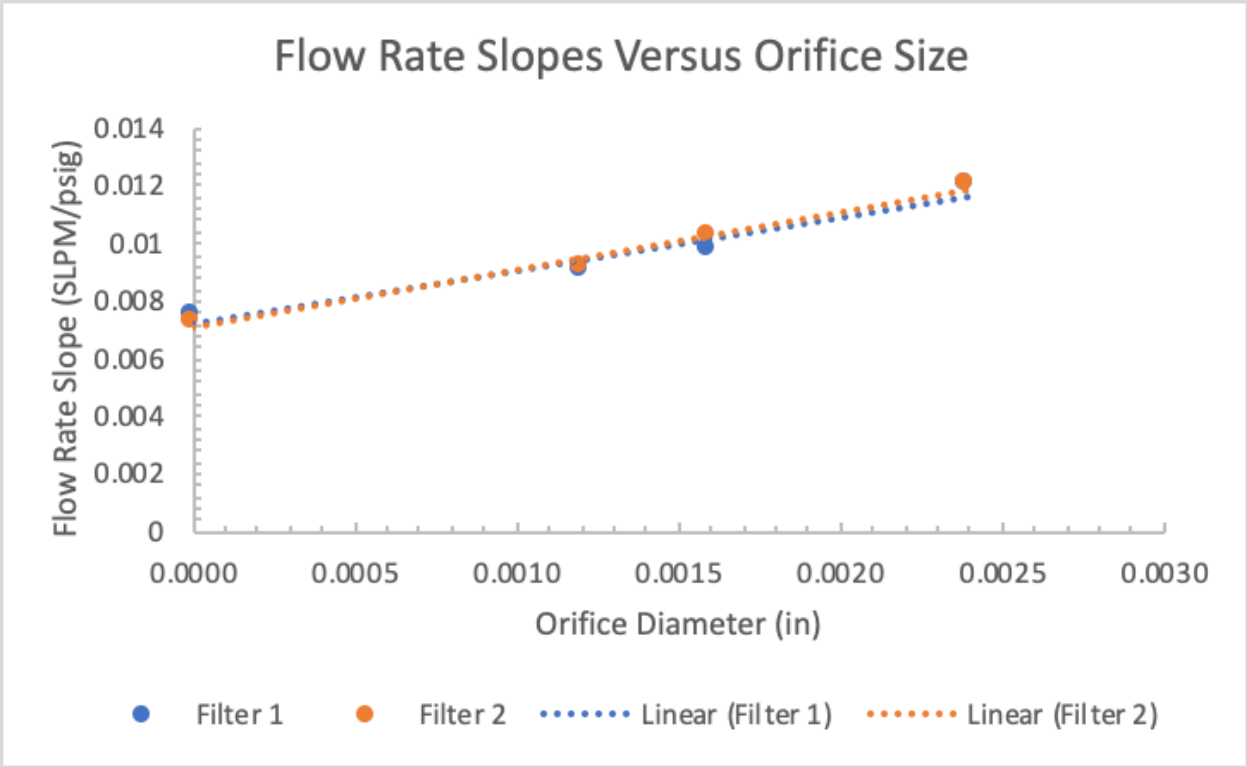


Figure 19: Flow Rate Slopes Over Orifice Diameters for Filters 1 and 2

Table XVIII: Linear Equations for Flow Rates Versus Orifice Diameter

Filter	Linear Equation	R^2 Value
Filter 1	y = 1.8633x + 0.0072	0.9515
Filter 2	y = 1.9967x + 0.0071	0.9862

Pressure Decay Over Time

The recorded pressures were plotted over time and fit to exponential equations. The exponential equations have the form of y = A*e^(Bx), where B is the exponential decay rate. The plots, below, show the pressure in psig plotted over time in seconds. Figure 20 shows the pressure decay data for Filter 1, Figure 20 shows the data for Filter 2 and Figure 21 shows the data for both Filters 1 and 2. For all of this data the initial pressure was about 1 bar. The exponential equations can be seen in Table XIX, below. The data shows that the integral filters had an exponential decay less than 0.023 when the initial pressure is 1 bar. This test does not appear to be able to determine defects as accurately as the flow rate testing because the integral and non-integral test results are very similar, but it seems that this test can be improved by increasing the initial pressure.

This test was recorded a second time with an initial pressure of 1.5 bar because the values were very similar in the previous test. Figure 23 shows the test data for Filter 1 with an initial pressure of 1.5 bar. Figure 24 shows the data for Filter 2 and Figure 25 shows the data for both

Filters 1 and 2 when the initial pressure was 1.5 bar. Exponential equations were fit to the data again and can be seen in Table XX, below. At first it appeared that increasing the initial pressure improved the data as there were greater differences in decay rate between the integral and orifice tests. Once all the testing was completed this test revealed as false positive as one of the orifice tests had a lower decay rate than the integral filters. This result proves that this test is not adequate for detecting filter integrity and that flow rate testing should be used for integrity testing.

Exponential decay rate was then compared to orifice size to determine any relationship. The data was plotted in Figure 26 and linear trend lines were fit to the data with R^2 values. This data is shown in Table XXI. Each test had a different R^2 value and some were not close to 1. This shows that there is only a weak relationship between decay rate and orifice size, further supporting the conclusion that flow rate testing is the better option.

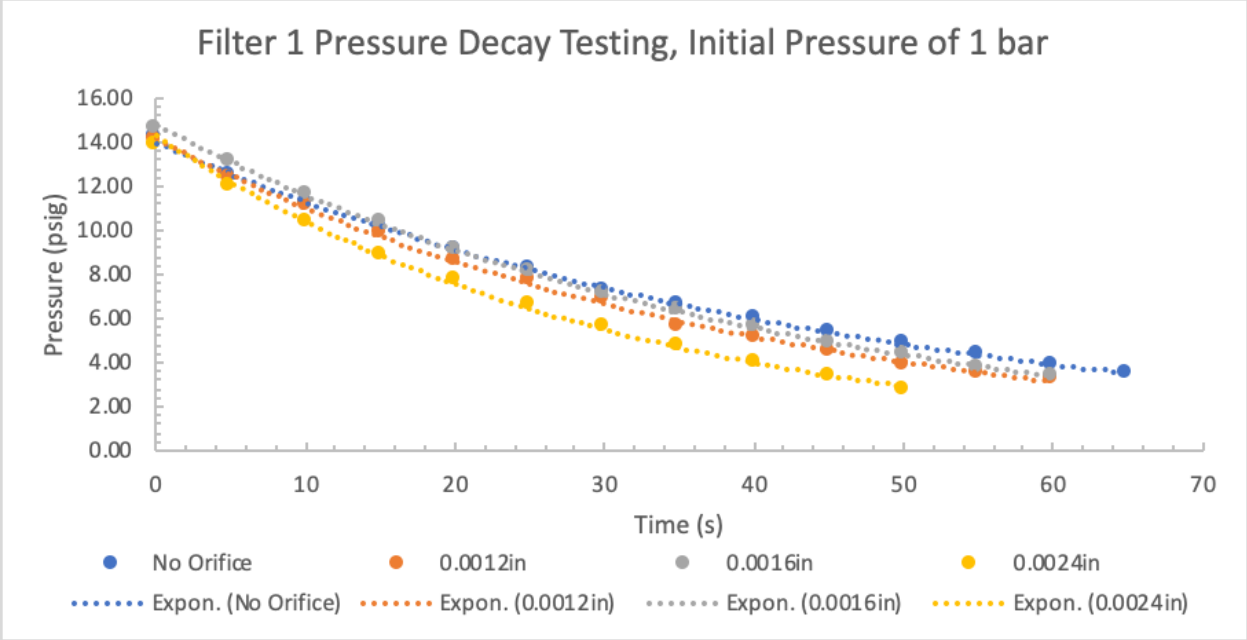


Figure 20: Filter 1 Pressure Decay Data with Orifices

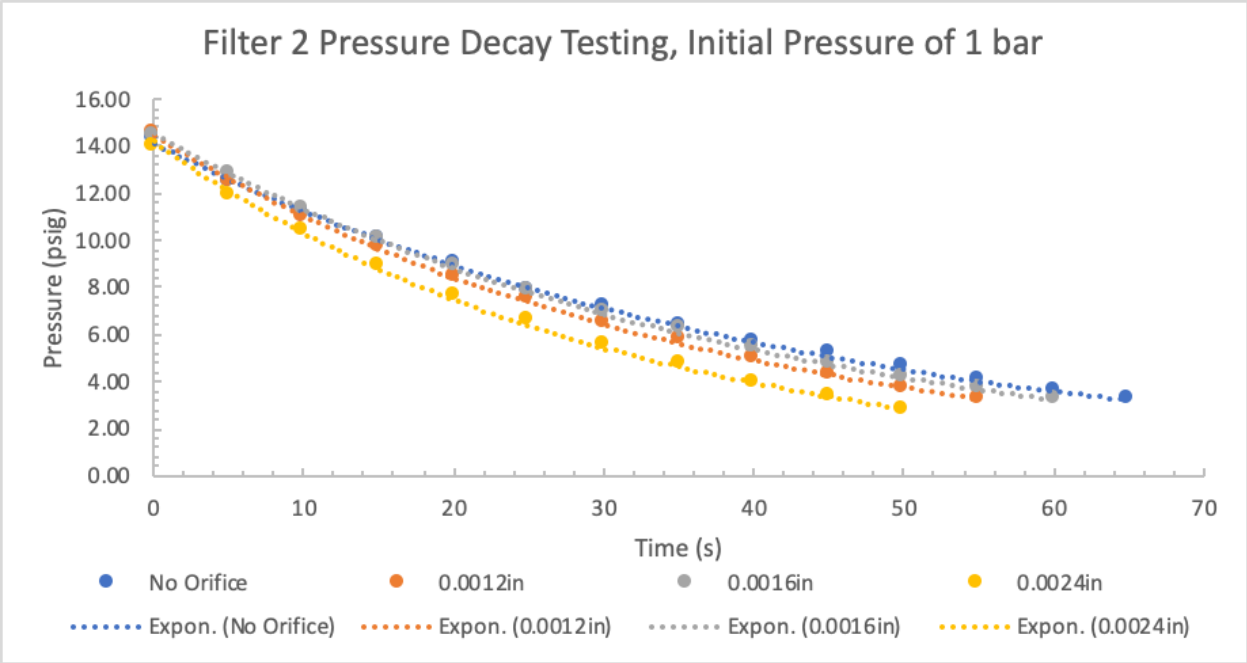


Figure 21: Filter 2 Pressure Decay Data with Orifices

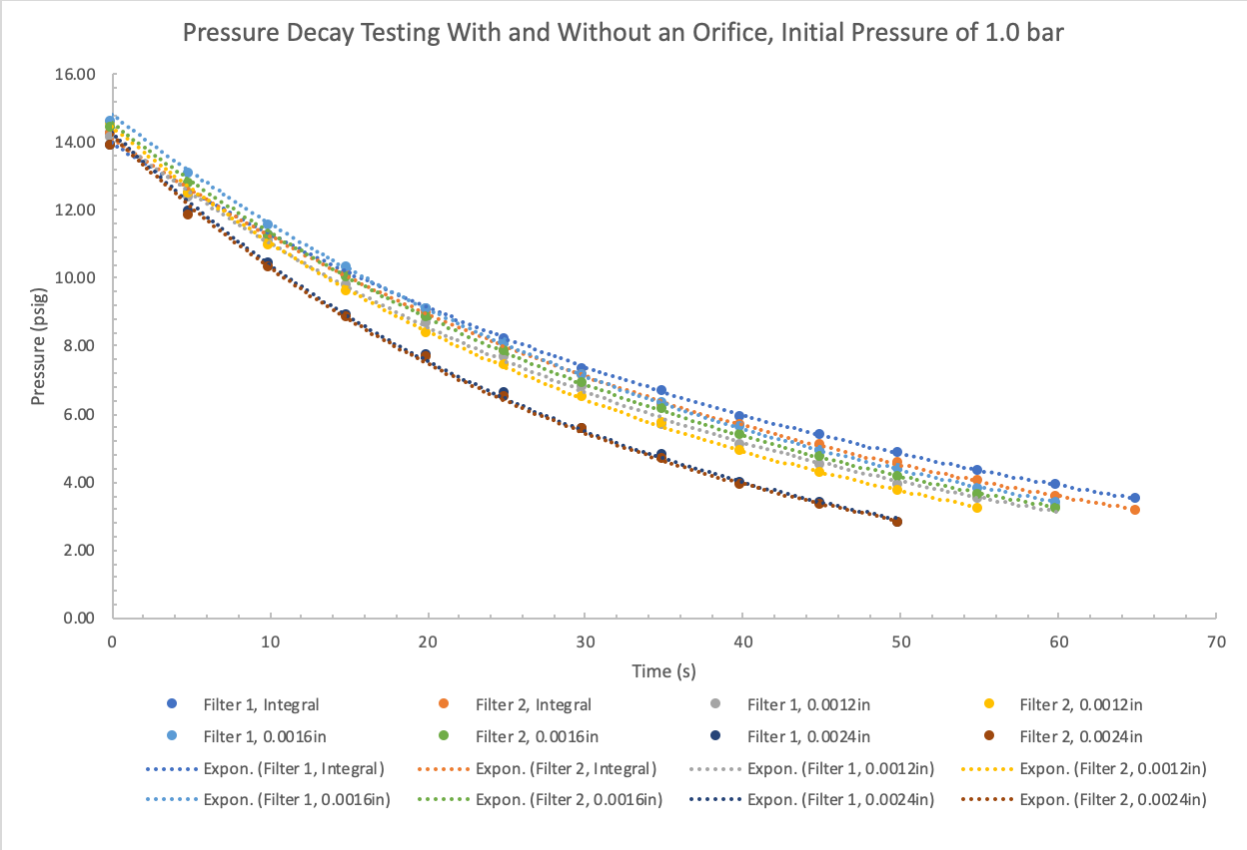


Figure 22: Pressure Decay Data for Filters 1 and 2

Table XIX: Exponential Equations for Pressure Decay Test with Initial Pressure of 1 bar

Test Name	Exponential Equation	R^2 Value
Filter 1, Integral	$y = 13.969e^{-0.021x}$	0.9997
Filter 2, Integral	$y = 14.11e^{-0.023x}$	0.9997
Filter 1, 0.0012in	$y = 14.171e^{-0.025x}$	0.9980
Filter 2, 0.0012in	$y = 14.467e^{-0.027x}$	0.9995
Filter 1, 0.0016in	$y = 14.816e^{-0.024x}$	0.9997
Filter 2, 0.0016in	$y = 14.56e^{-0.025x}$	0.9997
Filter 1, 0.0024in	$y = 14.289e^{-0.032x}$	0.9984
Filter 2, 0.0024in	$y = 14.196e^{-0.032x}$	0.9988

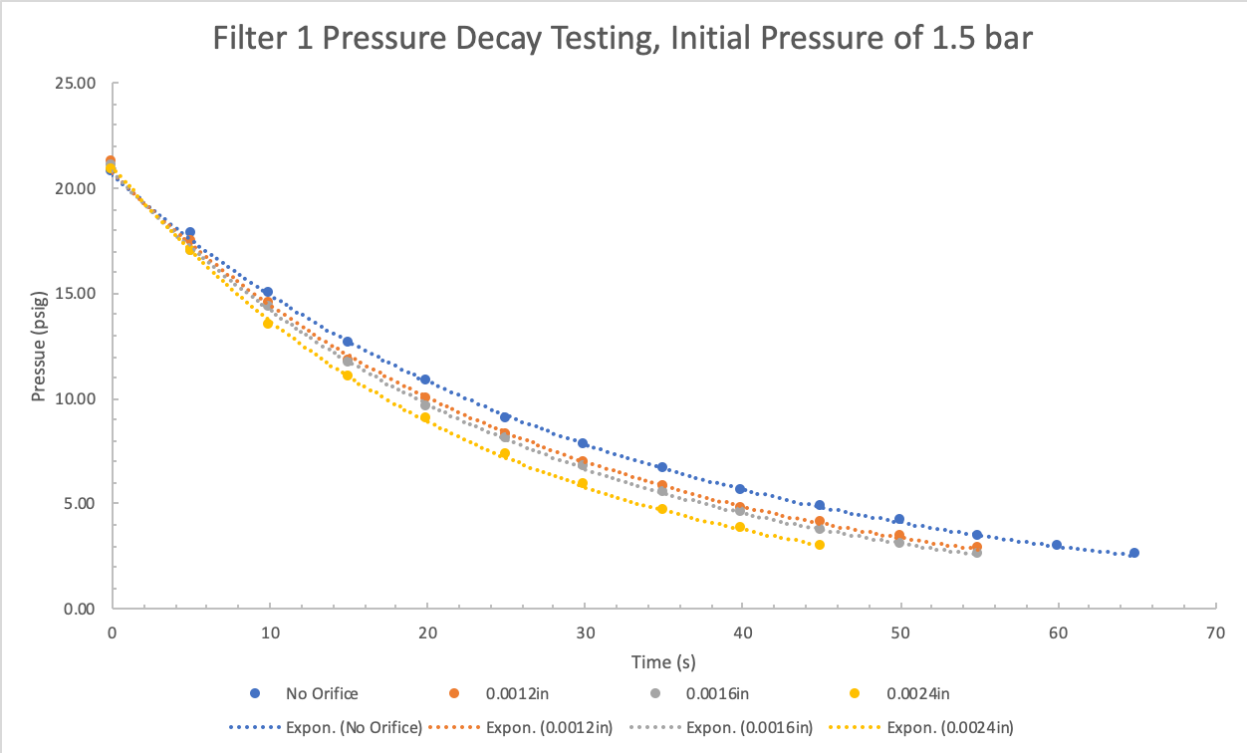


Figure 23: Filter 1 Pressure Decay Data with Orifices

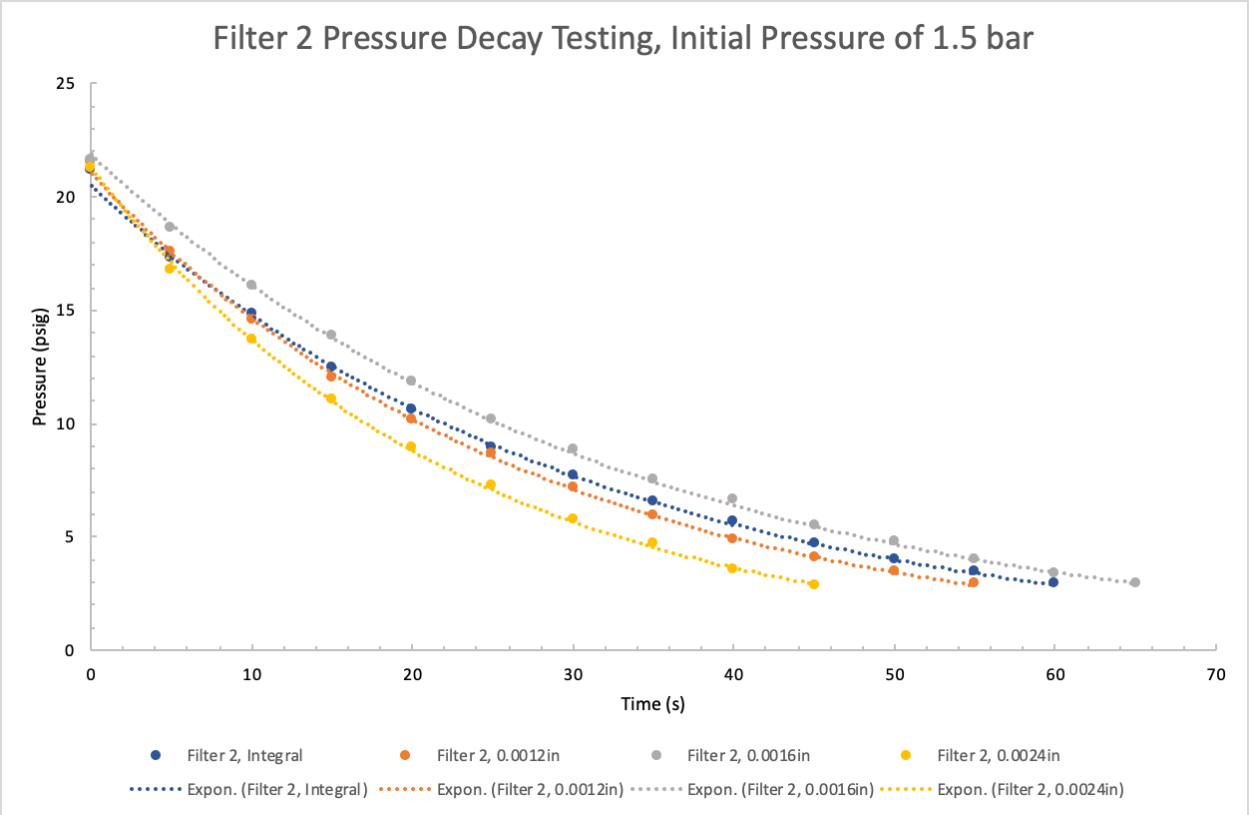


Figure 24: Filter 2 Pressure Decay Data with Orifices

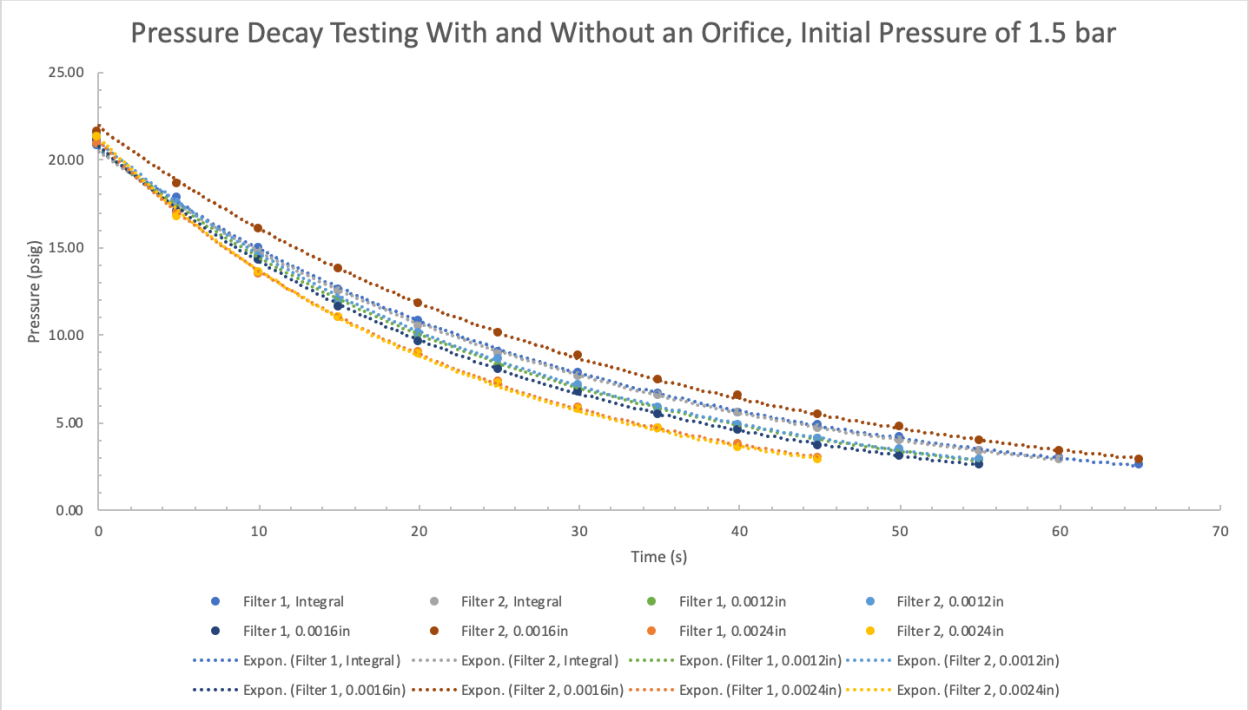


Figure 25: Pressure Decay Data for Filters 1 and 2

Table XX: Exponential Equations for Pressure Decay Test with Initial Pressure of 1.5 bar

Test Name	Exponential Equation	R^2 Value
Filter 1, Integral	$y = 20.619e^{-0.032x}$	0.9996
Filter 2, Integral	$y = 20.503e^{-0.033x}$	0.9996
Filter 1, 0.0012in	$y = 20.758e^{-0.036x}$	0.9995
Filter 2, 0.0012in	$y = 21.049e^{-0.036x}$	0.9996
Filter 1, 0.0016in	$y = 20.773e^{-0.038x}$	0.9998
Filter 2, 0.0016in	$y = 21.907e^{-0.031x}$	0.9996
Filter 1, 0.0024in	$y = 21.044e^{-0.043x}$	0.9994
Filter 2, 0.0024in	$y = 21.306e^{-0.044x}$	0.9994

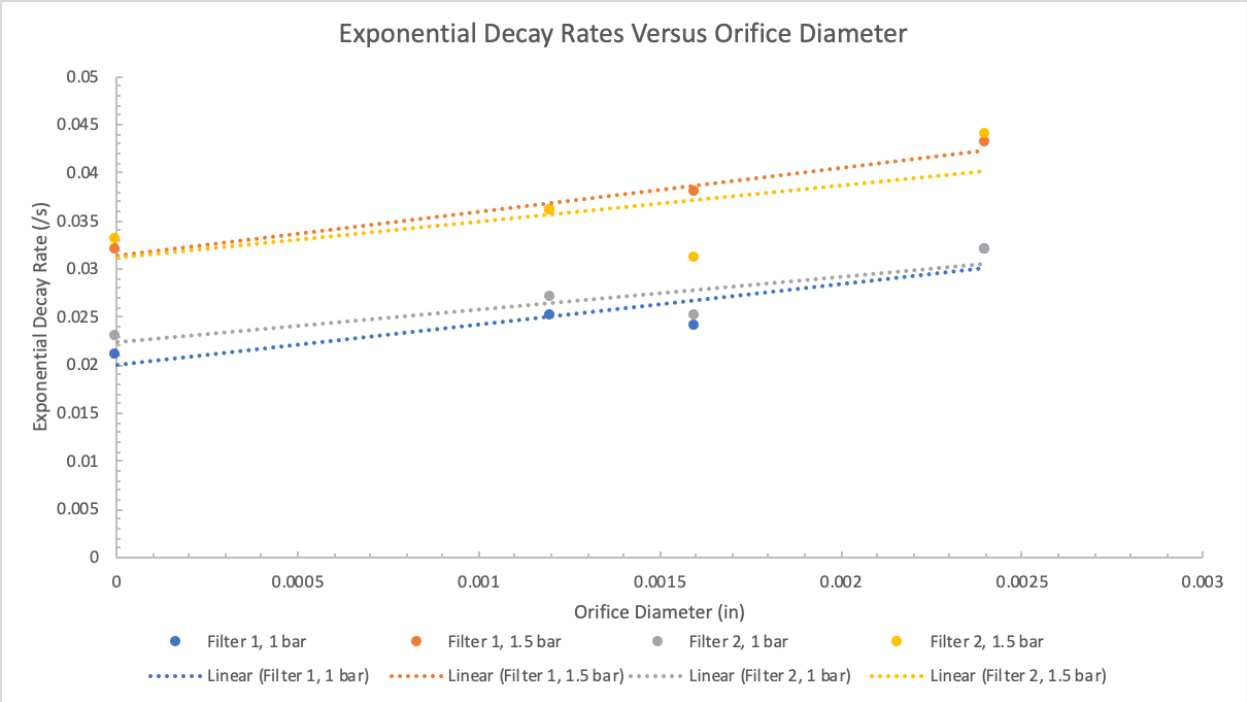


Figure 26: Exponential Decay Rates for Filters 1 and 2 Over Orifice Diameter

Table XXI: Linear Equations Comparing Pressure Decay Rates to Orifice Diameter

Filter, Pressure	Linear Equation	R^2 Value
Filter 1, 1 bar	y = 4.2x + 0.02	0.8142
Filter 1, 1.5 bar	y = 4.5x + 0.0314	0.9681
Filter 2, 1 bar	y = 3.3667x + 0.0224	0.7599
Filter 2, 1.5 bar	y = 3.8333x + 0.0313	0.4967

Destructive Testing

The filter has a maximum operating pressure of 2 bar. The team remained well under 2 bar for all of the prior testing; however, destructive testing took place at 2 bar and above. The goal of destructive testing was to determine the pressure at which the filter began to fail. To test this the team started at a pressure of 1.5 bar (the highest pressure we have introduced to the filter previously) then increased the pressure by .25 bar until the team reached 2 bar. From 2 bar the team began to increase pressure by 0.1 bar increments. As the team reached 2.1 bar, they began to see (and hear) failure in the polyurethane tubing connected to the filter. With multiple attempts to replace and seal the leaks, they determined that the other components surrounding the filter will always fail before the filter fails. This did not allow them to get the failure pressure of the filter, but it allowed them to determine an upper operating limit.

Conclusions

The design team feels confident to conclude the following:

- Flow reading are more accurately and efficiently collected with the flow meter placed after the filter (Figure 12)
- Little to no hysteresis was recorded with either filter (Figure 13, 14)
- Flow rate increased with temperature (Figure 15), resulting in an operating temperature of 21℃
- Flow meter testing proved to be sufficient and accurate to determine if either gas permeable filter is integral both before and after use (Figure 16, 17)
- Flow rate increases with orifice diameter (Figure 19)
- Pressure decay testing can not determine filter integrity with as much confidence as flow meter testing (Figure 22)

Discussion

After multiple test runs to collect data, the design team determined that the flow meter was able to stabilize much faster with it placed after the filter. The data collected with the flow meter placed before the filter was unable to gather data higher than about 16 psig. The flow

meter after the filter, however, was able to collect data up to about 22 psig with a stable flow reading.

Hysteresis was determined by comparing the flow meter value going up in pressure to the flow meter value at the same pressure points on the way down. If pressure values were different on the way down than they were on the way up, the design team would conclude that hysteresis was affecting the flow data, that was not the case. Hysteresis was not found in either filter.

Flow rate as an effect of temperature was recorded by increasing the heat of the filter and running the tests. When the filter was heated, the design team predicted that the filter membrane expanded to allow more flow through. This is consistent with the increased flow rate with increased temperature.

The flow meter testing proved to be the most accurate and easy to use test method because the results were intuitive. The data points were easy to collect, taking less than 15 minutes to gather and the data resulted in no false positives. When flow rate versus pressure was plotted, the slope of the line increased as the orifice diameter increased, which means as the defect grows, the data will stray more severely from the "baseline" or integral filter.

The team has come to the conclusion that the pressure decay test is not sufficient for testing the integrity of the filter because both the integral filter and the filter with a calibrated orifice recorded similar results using the pressure decay test. This risks the possibility of potential false positives and illustrates why the pressure decay test is not an option for determining filter integrity accurately.

Executive Summary

Further testing is required to establish a robust acceptance window for flow rate slopes. Based on the current data, a slope of about 0.0075 SLPM/psig indicates an integral filter. More filters should be tested with smaller orifices to determine a usable acceptance window. Since the design team was unable to complete destructive testing, this is another option for further study. Destructive testing may be done in the future to better characterize the filters.

The flow rate test method was able to meet the design team's requirements. This test method was able to accurately determine a difference between integral filters and filters with a simulated defect. The equipment required for this testing can also be added in line to a company's existing filtration system to make the testing more time efficient. The equipment can also be automated to make the test faster and easier for workers to complete.