

## Integrity Testing LifeASSURE™ PSA020 and PSA010 Series Filter Cartridges and Capsules

### SAFETY INFORMATION

Read, understand, and follow all safety information contained in these instructions and the instructions provided with the original filtration system, prior to installation and use. Retain for future reference.

### INTRODUCTION

The integrity test is the End User’s method to confirm the structural integrity of a LifeASSURE™ PSA series filter before and after use. It is a non-destructive test that has been correlated to bacteria retention and validates the performance of the filter cartridge. An “in specification” result confirms the porosity of the filter membrane and that the cartridge is structurally integral.

Three integrity test methods can be employed to integrity test hydrophilic (water wettable) LifeASSURE PSA series filters. These methods are:

1. Forward Flow Integrity Test (FFIT)
2. Bubble Point Test (BPT)
3. Pressure Hold Test (PHT)

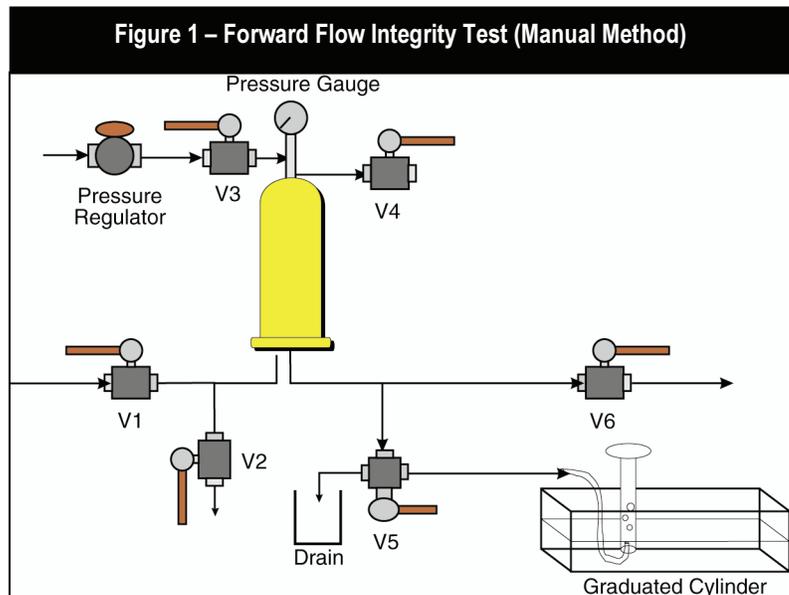
All three Integrity tests can be performed manually or with the CUNOCheck™ 2 Automated Integrity Tester. For more information about using the CUNOCheck 2 tester to perform an integrity test, refer to the CUNOCheck 2 Operator Manual (LITCCK2OPS).

### FORWARD FLOW INTEGRITY TEST

#### Definition

According to Fick’s Law of Diffusion, when a differential gas pressure exists across a wetted membrane, the gas molecules will “diffuse” through the water filling the pores of the membrane. The rate of passage is proportional to the solubility of the gas in the wetting fluid, the surface tension of the wetting fluid, the differential pressure, the thickness of the membrane, the pore size, and the surface area of the membrane. The diffusion rate is measured at a pressure below the membrane bubble point pressure. If no bulk

flow exists, there are no pores large enough to compromise the filter’s integrity. The Forward Flow Integrity Test (FFIT) may be employed with a multi-cartridge housing.



## Procedure 1. Forward Flow Integrity Test (Manual Method – Figure 1)

### WARNING

#### To reduce the risk associated with burn or system burst related injuries:

- Do not exceed maximum operating pressure or temperature limits.
- Do not use product for continuous service with compressed gases.
- Do not use with or expose this product to hot liquids (104 °F) or pressurized steam.

### CAUTION

#### To reduce the risk associated with exposure to contaminants:

- Always use appropriate personal protective equipment (PPE) when installing, operating or changing the product as per your standard operating procedure.
- Ensure that inlet/outlet valves are closed and all system pressure has been relieved prior to opening the system to atmosphere.

- Configure the system as shown in Figure 1.
- Install the filter in the housing and wet with clean, ambient temperature, filtered water at a flow rate of 3 GPM (11 liters/min) per 10" equivalent for ten minutes or more with a minimum of 5 psid back pressure.
- Close inlet V1 and outlet valve V6 to isolate the housing. Drain all the water from the upstream side of the filter by positioning V5 to direct flow to drain. Adjust the pressure regulator to deliver 3 – 5 psig of air or nitrogen (DO NOT USE CO<sub>2</sub>). Slowly open V3. Close V3 when water discharge is no longer evident.
- Connect one end of a flexible tube to the outlet port V5 and submerge the other end in a container of water. Position V5 to direct flow to the container of water.
- Open V3 and slowly adjust the pressure regulator to pressurize the system to the specified FFIT pressure value and allow the system to equilibrate for a minimum of one minute, or until steady bubbling is seen from the submersed end of the tube.
- Place the opening of the tube under an inverted graduated cylinder or burette (calibrated in milliliters or cubic centimeters) of an appropriate size filled with and submersed under sterile water.
- Measure the air flow for 5 minutes. Calculate the diffusion rate in cc/min.
- When the test is complete, compare the result to the cartridge FFIT specification.
- After the test is complete, drain the water from the housing and place the cartridge back in service.
- If the diffusion rate is higher than the specification, consider following questions and re-test if necessary:
  - Was the filter completely wetted out?
  - Was the correct pore size filter installed?
  - Was the temperature of the water and filter ambient?
  - Was the stabilization time adequate?
  - Was the test time adequate?
  - Was the filter seated correctly in the housing; were the o-rings undamaged?

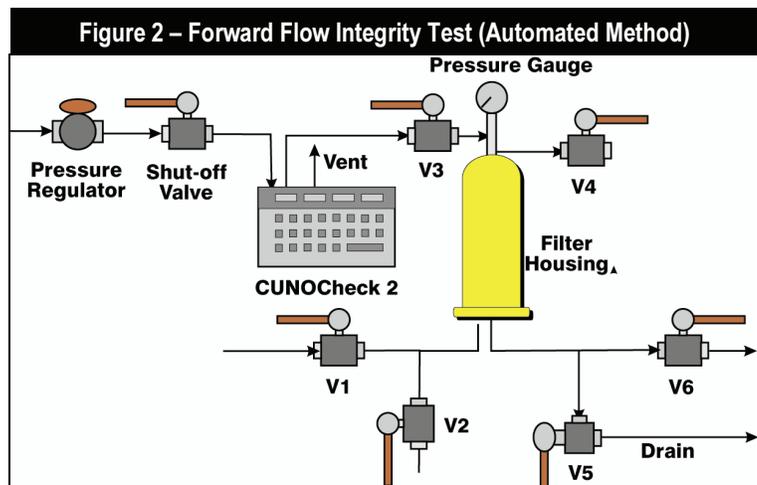
LifeASSURE™ PSA series	Test Pressure psi (bar)	Maximum Diffusion Flow – cc/min		
		10" cartridge/capsule	5" mini-cartridge/capsule	2.5" mini-cartridge/capsule
PSA010	70 (4.83)	<18	<6.3	<3.0
PSA020	35 (2.41)	<13.1	<4.3	<2.1
<b>It is important to make an aseptic connection and to close the outlet port immediately after the system has been integrity tested to prevent contamination</b>				

Procedure 2. Forward Flow Integrity Test (Automated Method - Figure 2)

<b>⚠ WARNING</b>
<p><b>To reduce the risk associated with burn or system burst related injuries:</b></p> <ul style="list-style-type: none"> <li>• Do not exceed maximum operating pressure or temperature limits.</li> <li>• Do not use product for continuous service with compressed gases.</li> <li>• Do not use with or expose this product to hot liquids (104 °F) or pressurized steam.</li> </ul>

<b>⚠ CAUTION</b>
<p><b>To reduce the risk associated with exposure to contaminants:</b></p> <ul style="list-style-type: none"> <li>• Always use appropriate personal protective equipment (PPE) when installing, operating or changing the product as per your standard operating procedure.</li> <li>• Ensure that inlet/outlet valves are closed and all system pressure has been relieved prior to opening the system to atmosphere.</li> </ul>

- A. Configure the system as shown in Figure 2.
- B. Install the filter in the housing and wet with clean, ambient temperature, filtered water at ambient temperature at a flow rate of 3 GPM (11 liters/min) per 10" equivalent for ten minutes or more with a minimum of 5 psid back pressure.
- C. Close inlet V1 and outlet valve V6 to isolate the housing.



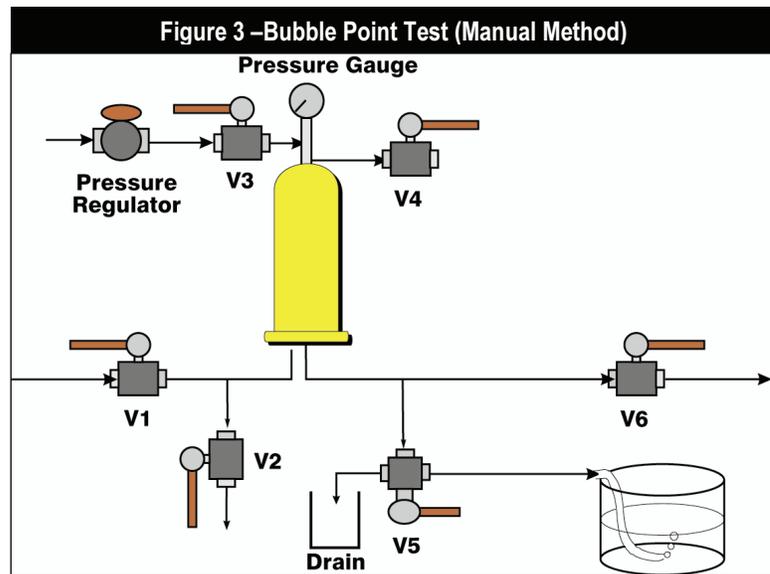
- D. Drain all the water from the upstream side of the filter by positioning V5 to direct flow to drain. Adjust the pressure regulator to deliver 3 – 5 psig of air or nitrogen (DO NOT USE CO<sub>2</sub>). Slowly open V3. Close V3 when water discharge is no longer evident.
- E. Close the housing inlet valve V1 and connect the CUNOCheck™ 2 Automated Integrity Tester at V3 and initiate the automated forward flow integrity test protocol.
- F. When the test is complete, compare the measured forward flow integrity value against the acceptable limit for the filter cartridge under test.
- G. After the test is complete, drain the water from the housing and place the cartridge back in service.

## BUBBLE POINT TEST (Refer to Figure 3)

### Definition

The bubble point is the minimum gas pressure required to overcome the surface tension holding water in a membrane filter's largest pore. The bubble point pressure measurement is only recommended for single 10-inch cartridge filters or smaller. When more filter area is on line, it becomes difficult to distinguish diffusion flow from the true bulk flow which occurs at the bubble point pressure. For setups with 2 or more 10-inch equivalent cartridges, Forward Flow or Pressure Hold measurements are recommended.

The CUNOCheck™ 2 Automated Integrity Tester can be used to perform a bubble point test. When using the CUNOCheck 2 tester, follow the installation instructions for connecting the unit to the upstream valve as shown in Figure 4. Consult 3M Purification Inc. document 70-0201-8848-1 for the filter cartridge bubble point value for the filter cartridge to be used and program this value into the CUNOCheck 2 tester when requested during the test set-up.



### Procedure 1. Bubble Point Test (Manual Method - Figure 3)

#### ⚠ WARNING

To reduce the risk associated with burn or system burst related injuries:

- Do not exceed maximum operating pressure or temperature limits.
- Do not use product for continuous service with compressed gases.
- Do not use with or expose this product to hot liquids (104 °F) or pressurized steam.

#### ⚠ CAUTION

To reduce the risk associated with exposure to contaminants:

- Always use appropriate personal protective equipment (PPE) when installing, operating or changing the product as per your standard operating procedure.
- Ensure that inlet/outlet valves are closed and all system pressure has been relieved prior to opening the system to atmosphere.

- A. Configure the system as shown in Figure 3.
- B. Install the filter in the housing and wet with clean, ambient temperature, filtered water at a flow rate of 3 GPM (11 liters/min) per 10" cartridge for 10 minutes or more with a minimum of 5 psid back pressure.
- C. Close inlet V1 and outlet valve V6 to isolate the housing. Drain all the water from the upstream side of the filter by positioning V5 to direct flow to drain. Adjust the pressure regulator to deliver 3 – 5 psig of air or nitrogen (DO NOT USE CO<sub>2</sub>). Slowly open V3. Close V3 when water discharge is no longer evident.

- D. Connect a tube from the outlet port V5 to a container of water. PLEASE NOTE: It is important to make an aseptic connection and to close the outlet port immediately after the system has been integrity tested to prevent contamination.
- E. Open V3. Using the pressure regulator, slowly pressurize the system with air or nitrogen (DO NOT USE CO<sub>2</sub>), raising the pressure 5 psi (0.34 bar) per minute. When within 5 psi (0.34 bar) of the expected bubble point pressure, make only very gradual 1 psi (0.07 bar) increases allowing 5 - 10 seconds between pressure increases to observe evidence of bubbling.
- F. Observe any air flow from the tube connected to the downstream port. A modest flow of small bubbles is diffusion flow only. When a continuous flow of large bubbles appears, the filter's bubble point has been reached.
- G. When the test is complete, compare the measured bubble point value against the acceptable limit for the filter cartridge under test.
- H. After the test is complete, drain the water from the housing and place the cartridge back in service.
- I. If the bubble point is less than the recommended value, consider the following consider following questions and re-test if necessary:
- Was the filter completely wetted out?
  - Was the correct pore size filter installed?
  - Was the temperature of the water and filter ambient?
  - Was the stabilization time adequate?
  - Was the filter seated correctly in the housing and were the o-rings undamaged?

LifeASSURE™ PSA series	Minimum Bubble Point Pressure – psi (bar)		
	10" cartridge/capsule	5" mini-cartridge/capsule	2.5" mini-cartridge/capsule
PSA010	74	74*	74*
PSA020	38	38	38

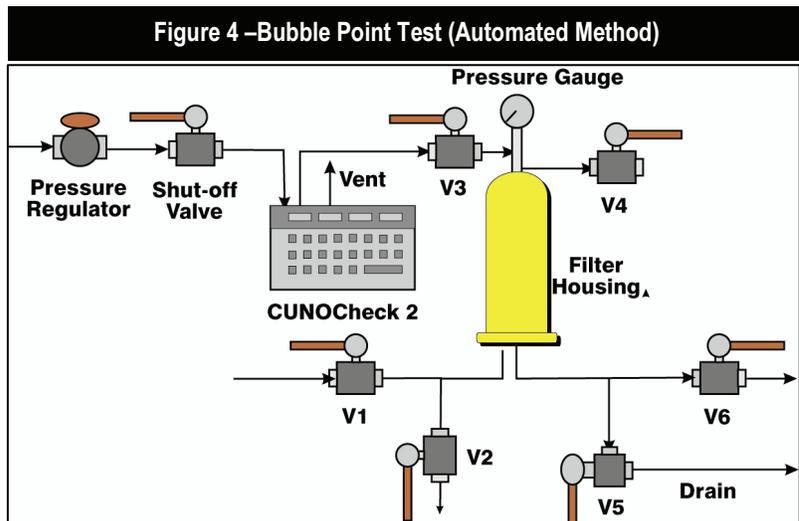
\*The bubble point pressure test is not recommended for PSA010 grade filters in the capsule format. Please use either the Forward Flow Integrity Test or the Pressure Hold Test. It is important to make an aseptic connection and to close the outlet port immediately after the system has been integrity tested to prevent contamination.

Procedure 2. Bubble Point Test (Automated Method - Figure 4)

<b>⚠ WARNING</b>
<p><b>To reduce the risk associated with burn or system burst related injuries:</b></p> <ul style="list-style-type: none"> <li>• Do not exceed maximum operating pressure or temperature limits.</li> <li>• Do not use product for continuous service with compressed gases.</li> <li>• Do not use with or expose this product to hot liquids (104 °F) or pressurized steam.</li> </ul>

<b>⚠ CAUTION</b>
<p><b>To reduce the risk associated with exposure to contaminants:</b></p> <ul style="list-style-type: none"> <li>• Always use appropriate personal protective equipment (PPE) when installing, operating or changing the product as per your standard operating procedure.</li> <li>• Ensure that inlet/outlet valves are closed and all system pressure has been relieved prior to opening the system to atmosphere.</li> </ul>

- A. Configure the system as shown in Figure 4.
- B. Install the filter in the housing and wet with clean, ambient temperature, filtered water at a flow rate of 3 GPM (11 liters/min) per 10" cartridge for 10 minutes or more with a minimum of 5 psid back pressure.
- C. Close inlet V1 and outlet valve V6 to isolate the housing. Drain all the



- water from the upstream side of the filter by positioning V5 to direct flow to drain. Adjust the pressure regulator to deliver 3 – 5 psig of air or nitrogen (DO NOT USE CO<sub>2</sub>). Slowly open V3. Close V3 when water discharge is no longer evident.
- D. Disconnect the water supply line and allow the water to drain from the housing. Leave V5 or V6 open to atmosphere.
- E. Close V1 and connect the CUNOCheck™ 2 Automated Integrity Tester at V3 and initiate the automated bubble point test protocol.
- F. When the test is complete, compare the measured bubble point value against the acceptable limit for the filter cartridge under test.
- G. After the test is complete, drain the water from the housing and place the cartridge back in service.
- H. Disconnect the CUNOCheck 2 Automated Integrity Tester from the housing.

## **PRESSURE HOLD TEST**

### Definition

A variation of the FFIT is the Pressure Hold Test (PHT). Instead of measuring the diffusion rate of gas across the membrane, the PHT 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. PHT values are dependent on the volume of the specific filter housing employed, less the volume of the installed cartridges. Therefore, they must be determined on a case by case basis. Please contact 3M Purification Technical Service for assistance, if necessary.

The CUNOCheck™ 2 Automated Integrity Tester can be used to perform a pressure hold test. When using the CUNOCheck 2 tester, follow the installation instructions for connecting the unit to the upstream valve as shown in Figure 6. Consult the appropriate 3M Purification literature for the test pressure and PHT value for the filter cartridge to be used and program these values into the CUNOCheck 2 tester when requested during the test set-up.

The following equation can be used to calculate the PHT value:

$$\frac{\Delta P}{T} = \frac{D(P_a)}{V_{hsg}}$$

D=Manufacturer's maximum allowable diffusion rate for all the installed filters in cc/min (see DFT specifications)

T=Time (typically 5 minutes)

P<sub>a</sub>=Atmospheric pressure

V<sub>hsg</sub>=Upstream housing volume (cc) less the volume occupied by the cartridge(s)

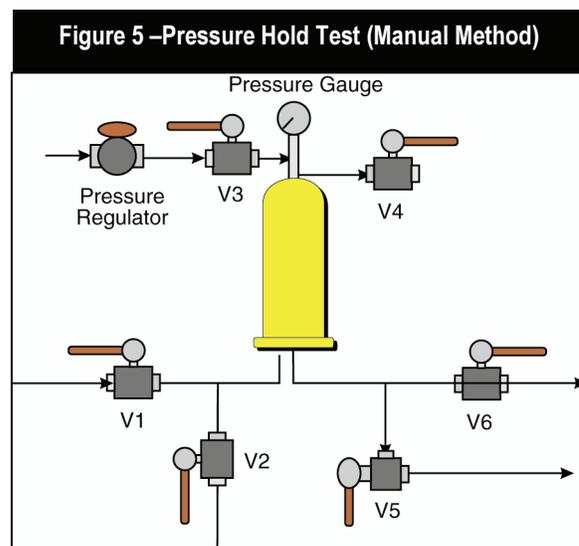
ΔP=Allowable pressure loss

### Procedure 1. Pressure Hold Test (Manual Method– Figure 5)

<b>⚠ WARNING</b>
<p><b>To reduce the risk associated with burn or system burst related injuries:</b></p> <ul style="list-style-type: none"> <li>• Do not exceed maximum operating pressure or temperature limits.</li> <li>• Do not use product for continuous service with compressed gases.</li> <li>• Do not use with or expose this product to hot liquids (104 °F) or pressurized steam.</li> </ul>

<b>⚠ CAUTION</b>
<p><b>To reduce the risk associated with exposure to contaminants:</b></p> <ul style="list-style-type: none"> <li>• Always use appropriate personal protective equipment (PPE) when installing, operating or changing the product as per your standard operating procedure.</li> <li>• Ensure that inlet/outlet valves are closed and all system pressure has been relieved prior to opening the system to atmosphere.</li> </ul>

- A. Configure the system as shown in Figure 5.
- B. Install the filter in the housing and wet with clean, ambient temperature, filtered water at a flow rate of 3 GPM (11 liters/min) per 10" equivalent for ten minutes or more with a minimum of 5 psid back pressure.
- C. Close inlet V1 and outlet valve V6 to isolate the housing. Drain all the water from the upstream side of the filter by positioning V5 to direct flow to drain. Adjust the pressure regulator to deliver 3 – 5 psig of air or nitrogen (DO NOT USE CO<sub>2</sub>). Slowly open V3. Close V3 when water discharge is no longer evident.
- D. Disconnect the water supply line and allow the water to drain from the housing. Leave V5 or V6 open to atmosphere.
- E. Open V3 and slowly adjust the pressure regulator to pressurize the system to the specified PHT pressure value and allow the system to equilibrate for a minimum of two minutes.
- F. Using a stopwatch, measure the pressure decay for 10 minutes. Calculate the pressure decay over the 10 minute period in psi/min.

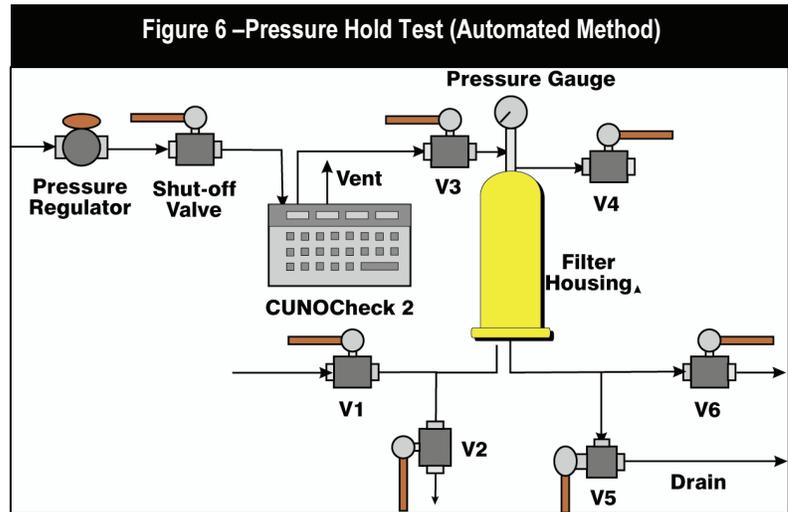


- G. When the test is complete, compare the result to the cartridge PHT specification.
- H. After the test is complete, drain the water from the housing and place the cartridge back in service.
- I. If the pressure decay is higher than the specification, consider following questions and re-test if necessary:
  - Was the filter completely wetted out?
  - Was the correct pore size filter installed?
  - Was the temperature of the water and filter ambient?
  - Was the stabilization time adequate?
  - Was the filter seated correctly in the housing and were the o-rings undamaged?

Procedure 2. Pressure Hold Test (Automated Method- Figure 6)

<b>⚠ WARNING</b>
<p><b>To reduce the risk associated with burn or system burst related injuries:</b></p> <ul style="list-style-type: none"> <li>• Do not exceed maximum operating pressure or temperature limits.</li> <li>• Do not use product for continuous service with compressed gases.</li> <li>• Do not use with or expose this product to hot liquids (104 °F) or pressurized steam.</li> </ul>
<b>⚠ CAUTION</b>
<p><b>To reduce the risk associated with exposure to contaminants:</b></p> <ul style="list-style-type: none"> <li>• Always use appropriate personal protective equipment (PPE) when installing, operating or changing the product as per your standard operating procedure.</li> <li>• Ensure that inlet/outlet valves are closed and all system pressure has been relieved prior to opening the system to atmosphere.</li> </ul>

- A. Configure the system as shown in Figure 6.
- B. Install the filter in the housing and wet with clean, ambient temperature, filtered water at a flow rate of 3 GPM (11 liters/min) per 10" cartridge for 10 minutes or more with a minimum of 5 psid back pressure.
- C. Close inlet V1 and outlet valve V6 to isolate the housing. Drain all the water from the upstream side of the filter by positioning V5 to direct flow to drain. Adjust the pressure regulator to deliver 3 – 5 psig of air or nitrogen (DO NOT USE CO<sub>2</sub>). Slowly open V3. Close V3 when water discharge is no longer evident.
- D. Disconnect the water supply line and allow the water to drain from the housing. Leave V5 or V6 open to atmosphere.



- E. Close V1 and connect the CUNOCheck™ 2 Automated Integrity Tester at V3 and initiate the pressure hold test protocol.
- F. When the test is complete, compare the measured pressure hold value against the acceptable limit for the filter cartridge under test.
- G. After the test is complete, drain the water from the housing and place the cartridge back in service.
- H. Disconnect the CUNOCheck 2 Automated Integrity Tester from the housing.

**Important Notice:**

The test results described in this literature are accurate to the best of our knowledge. A variety of factors, however, can affect the performance of the product(s) in a particular application, some of which are uniquely within your knowledge and control. **INFORMATION IS SUPPLIED UPON THE CONDITION THAT THE PERSONS RECEIVING THE SAME WILL MAKE THEIR OWN DETERMINATION AS TO ITS SUITABILITY FOR THEIR USE. IN NO EVENT WILL 3M BE PURIFICATION INC. RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION.**

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