



Manometer Testing of the Codman[→] Hakim[□] Programmable Valve (CHPV/PV) & SIPHONGUARD[→] (ASD) **Prior to Implantation**

Each Codman[→] HakimTM Valve (Precision Valve=PV and Programmable Valve=CHPV) whether with or without SIPHONGUARD[→] is individually tested on a component level to ensure conformance to the advertised performance characteristics. Each Programmable valve is tested at 6 different settings during manufacture for proper dynamic opening pressure over the entire performance curve. Each Precision valve is individually calibrated at its prescribed opening pressure during manufacture.

Each SIPHONGUARD device is individually tested 6 times during manufacture for proper closing flow rate. Finally, each assembly (Valve with/without SIPHONGUARD and distal catheter) is individually leak tested prior to final packaging. For these reasons, we feel as though testing in the operating room prior to implantation is not necessary.

Codman is not alone in its recommendation that manometer testing in the operating room prior to implantation is not a true indicator of a valves performance.

The following Quotation is from "The Shunt Book"

" The pressures needing measurement in shunt testing are very low, given the very low CSF pressure. This creates a challenge as to the choice of a pressure-measuring instrument that will accurately and precisely measure pressure in this low range.

Water manometers are simple, reliable, and inexpensive. However, they are not very responsive and are difficult to make accurate automatic measurement"^{1d}

The following Quotation is from the PS Medical Delta[□] Valve Product Insert

" Verifying the performance characteristics of a valve is an extensive procedure which requires an assembled test apparatus, testing at multiple data points, time to conduct testing, and careful attention not to contaminate the valve.

PS Medical, therefore, does not recommend that the valve be tested for performance characteristics in the operating room.

The performance characteristics of a valve relate to the dynamic performance of a valve throughout the range of physiologic flow rates. It is not possible to verify the dynamic performance characteristics with a static test that can be performed in the operating room"¹²

If the surgeon insists on performing a manometer test for CHPV/PV functionality the results, though poor, will be no different between a standalone CHPV/PV and a CHPV/PV with SIPHONGUARD. This assumes the same test equipment and methods are utilized. Bear in mind that the accuracy of the results could vary from the true opening pressure setting. Differences in the closing pressure results for a CHPV/PV versus a CHPV/PV with SIPHONGUARD will be due to variability in the test method.

It is a common misconception that the manometer test used prior to implantation in the operating room identifies the **opening** pressure of the valve being tested. In fact it is the **closing** pressure that is being measured and not the **opening** pressure. Should the surgeon insist upon performing manometer testing for confirmation of CHPV/PV **closing** pressures, it is possible, but is not recommended. When performed correctly, manometer testing will generate valve **closing** pressure values in the range of the CHPV/PV **opening** pressure setting. However,

closing pressure results will typically vary noticeably from the **opening** pressure setting for the following reasons:

1. The valves are calibrated during manufacture to perform to a specific **opening pressure**. Manometer testing in the operating room confirms **closing pressure**. Although similar, they are not the same.
2. Air bubbles within the manometer assembly or shunt system during manometer testing will lead to increased system resistance and inaccurate results.
3. Manometers come in a variety of inner bore diameters. The smaller the bore, the greater the resistance to flow through the manometer. Higher resistance manometers will require more time to reach a steady state. Even after a steady state is reached, resistances in the test equipment could lead to inaccurate results.

For CHPV/PV with SIPHONGUARD, the system should be allowed more time to reach a steady state due to the fact that the primary pathway of the SIPHONGUARD device may have closed during testing. Closure of the primary pathway is possible during testing if the height of water in the manometer is sufficient to create a flow rate through the SIPHONGUARD which is greater than its closing (activation) flow rate. When this occurs, the flow rate through the system is reduced by a factor of ten. It is for this reason that more time should be allotted for the system to reach steady state. Average manometer test time for verification of closing pressure of a CHPV/PV with SIPHONGUARD will be on the order of 3-5 minutes. This does not include the time required to flush the system of air bubbles.

Flushing Procedure (Required)

If the surgeon prefers not to perform functional testing prior to implantation, as recommended by Codman, it is not necessary to flush the system. Air bubbles within the system will be flushed out by CSF or will be resorbed by it after implantation.

For those who do wish to perform functional testing, **it is extremely important that a CHPV/PV with or without SIPHONGUARD be flushed of all air bubbles prior to testing for proper SIPHONGUARD operation or manometer testing.** The presence of air bubbles within the CHPV/PV or SIPHONGUARD device can lead to inaccurate manometer test results. The presence of air bubbles can reduce the cross-sectional area of the flow path, increasing system resistance, and impeding the flow of water through the system during pre-implantation testing.

Equipment Required:

1. Sterile 50-60 cm manometer graduated in mm, with a bore diameter of 2.5-4 mm
2. 4-way stopcock
3. Sterile Syringe, 5 cc
4. Sterile 5 mm Syringe Filter
5. Sterile Tubing Adapters
6. Sterile Silicone Tubing
7. Sterile Saline Solution

To flush the system (non-unitized versions only):

1. Assemble syringe, manometer, filter, stopcock and tubing as shown in figures 1& 2.



Figure 1

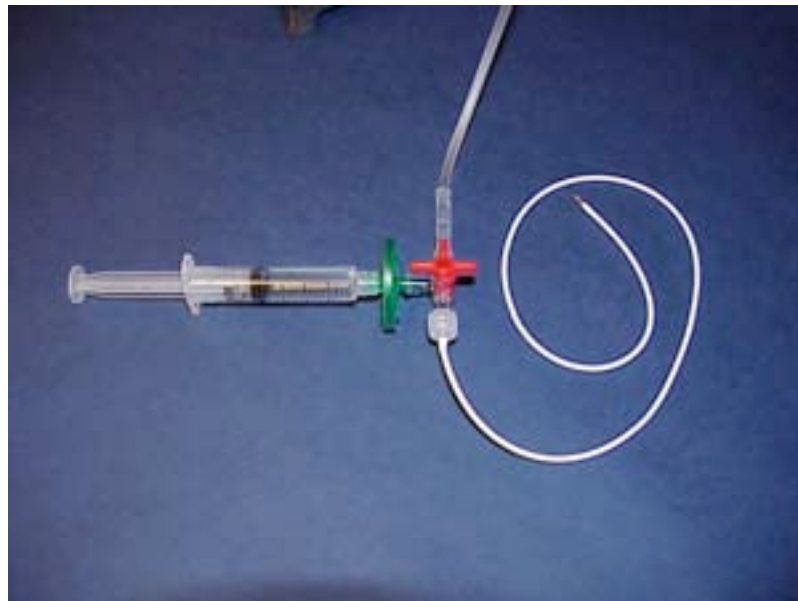


Figure 2 showing proper setup of syringe, filter and 4-way stopcock

2. Fill syringe and remove trapped air bubbles. Reattach to syringe filter.
3. Set opening pressure of valve to 30 mm H₂O.
4. Connect only the valve assembly to the manometer. **Do not attach the distal catheter at this time.**
5. Position the stopcock of the manometer assembly in such a way as to connect the syringe to the valve assembly.
6. Position the CHPV/PV/ASD assembly vertically upward so as to allow flow through the assembly in an upward direction (figure 3). This orientation will aid in flushing air bubbles from the system quicker.

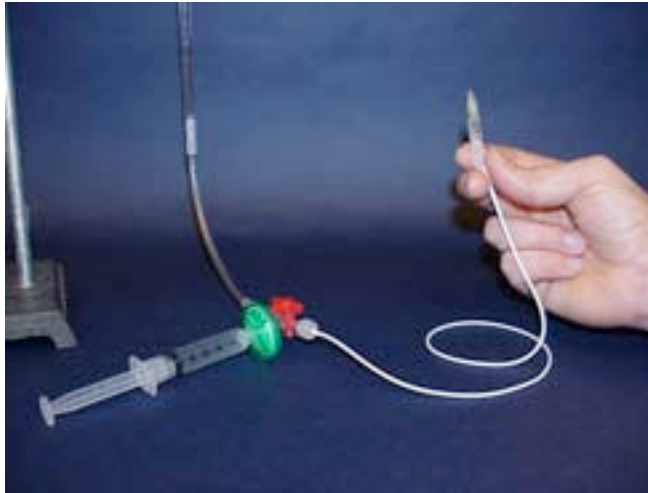


Figure 3

7. Gently flush the system using the syringe while simultaneously gently depressing the prechamber to rid the system of air bubbles (figure 4-next page). It is important that the prechamber be free of bubbles. Bubbles of any size in this area can impede flow through the system.

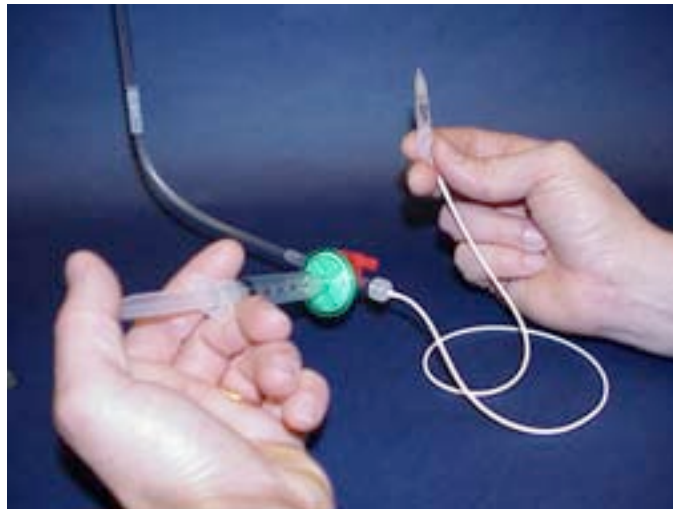


Figure 4

8. Once all air bubbles have been removed, attach the distal catheter and continue to flush the system using the syringe until water exits the end of the distal catheter. Note that an excessive flow rate (> 0.75 ml/min) caused by rapid movement of the syringe plunger will activate the SIPHONGUARD device and create the impression that the valve is distally occluded. In reality, flow has been diverted to the high resistance secondary pathway.
9. The device is now ready for SIPHONGUARD functional testing as well as CHPV/PV manometer testing.

Comments:

- **Extreme care must be taken when flushing any valve as it is possible to damage the unit when excessive flow rates are used. It is recommended that a flow rate no greater than 0.5 ml/min be used for flushing.**

- **At a rate of 0.5 ml/minute, unitized versions will require 2-3 minutes for complete flushing to occur. This is the time required for water to fill the valve and exit the distal catheter. Additional time should be allotted to ensure the system is free of entrapped air bubbles.**
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Functional test of SIPHONGUARD

This test is to be performed immediately after the flushing procedure has been completed. It is designed to provide visual confirmation that the Siphonguard Device is functioning properly.

1. Using the syringe attached to the filter and 4-way stopcock, fill the manometer to the top.
2. Turn the stopcock to isolate the syringe from the CHPV/PV/ASD.
 - Note that the distal catheter will be attached at this time.
3. Bring the distal tip of the distal catheter level with the water level in the manometer (figures 5 & 6-next page).
 - The CHPV/PV with ASD should be resting on a sterile surface and remain undisturbed for the duration of the test.

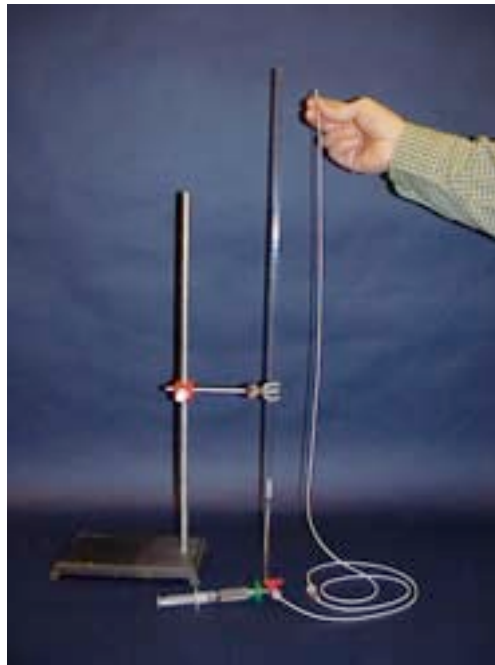


Figure 5

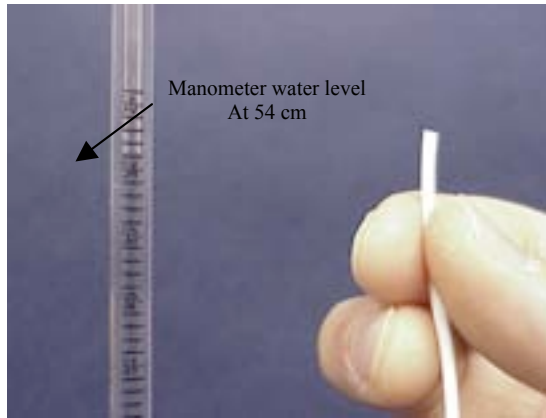


Figure 6

4. Hold the catheter tip adjacent to the manometer and slowly lower the end of the distal catheter until the water level in the manometer begins to drop.
5. Continue to lower the catheter tip at a rate that exceeds the drop rate of the water level in the manometer. As you do so, you will note a corresponding increase in the rate of descent of the water level in the manometer.
6. A point will be reached where the rate of descent of the water level in the manometer will dramatically **decrease** but will NOT stop. This is the point at which the SIPHONGUARD device primary pathway closes and flow is diverted to the higher resistance secondary pathway confirming proper operation.
7. Steps 3 through 6 may be repeated as necessary to re-verify SIPHONGUARD operation.
8. Remove distal catheter for manometer testing of CHPV/PV.

It will not be possible to determine the exact flow rate at which the SIPHONGUARD device closes using the above test. This test is designed only as a functional test for the SIPHONGUARD device.

Test for proper CHPV/PV operation (Manometer Testing)

Equipment Required

1. The test apparatus used for the ASD functional test can also be used for CHPV/PV closing pressure confirmation. The only additional piece of equipment required is a sterile water bath.

Equipment Setup

1. Disconnect the valve from the tubing leading to the manometer. Perform this procedure while the valve is submerged in the water bath. Be sure not to expose the entry and exit ports of the valve to atmosphere, as this will reintroduce air into the system.
2. Place the tip of the tube leading from the manometer into the water bath. Avoid touching the sides of the bath with the tip of the tube as this could alter the test results.
3. Arrange the water bath so that the zero level of the manometer and the fluid level in the water bath are at the same level.
4. Refill the syringe. Reattach the syringe to the 5 mm filter and test apparatus.
5. Refill the manometer using the 5 cc syringe.

Zeroing of the Manometer

1. After refilling the syringe, turn the stopcock to isolate the syringe from the manometer.

2. Allow the water column in the manometer to fall.
3. The water column should stop at the zero level of the manometer (figure 7).

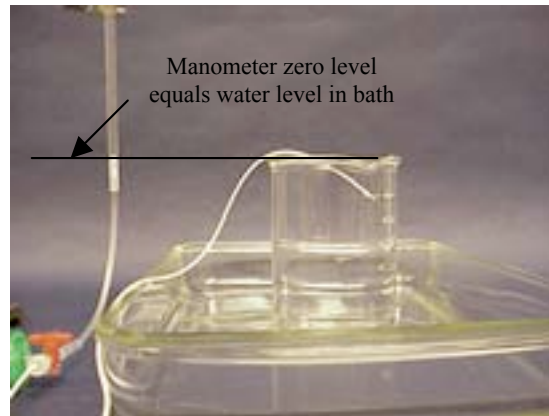


Figure 7

4. If necessary, adjust the height of the manometer to bring the water level in the manometer to the zero mark.

Test Procedure

1. Reconnect the sterile valve to the sterile test apparatus. It is recommended that this step be performed under water in the water bath to prevent the introduction of air bubbles into the valve.
 - Do NOT reattach distal catheter at this time.
2. The attachment of a distal catheter could alter the test results as well as increase test time. This is not possible with unitized versions of the CHPV/PV. Additional time should be allotted for testing of unitized versions.
3. Set the opening pressure of the CHPV/PV to 120 mm H₂O. Laboratory testing has shown that the best correlation between manometer closing pressure and true opening pressure is at a setting of 120 mm H₂O.
4. Submerge the valve completely in the water bath.
 - For the unitized version, the outlet of the distal catheter must be submerged in the water bath in order to obtain accurate results. Confirm that there are no bubbles attached to the tip of the distal catheter and that the tip of the catheter is not resting against the side of the water bath (Figure 8 & 9).

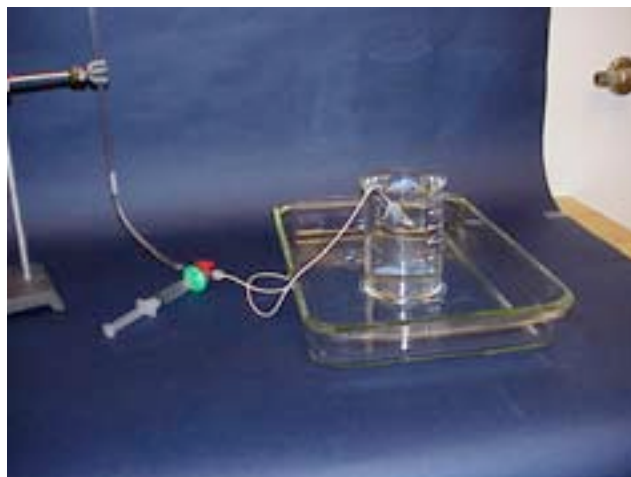


Figure 8



Figure 9

5. Refill the manometer to a height that is equal to the opening pressure setting of the CHPV/PV plus 100 mm. If the CHPV/PV is programmed to an opening pressure of 120 mm H₂O, the height of the water in the manometer should be 120 mm + 100 mm = 220 mm. This procedure will minimize the possibility of inadvertently closing the ASD during manometer testing.
6. Turn stopcock to isolate the manometer from the syringe.
7. The water column in the manometer should start to fall. Depending upon the height of the initial water column, flow from this point on could be through either the primary or secondary pathway of the SIPHONGUARD device. An extended test time is recommended in order to compensate for the possibility of flow only through the secondary pathway of the SIPHONGUARD device.
8. Allow the water column to drop for 3-5 minutes or until a steady state is reached.
9. Read the resultant pressure.
 - Variations in test results from the programmed CHPV/PV opening pressure should be expected. Variations of as much as +/- 25 mm H₂O from the opening pressure setting of the valve are possible based upon the test method being utilized. See figure 10 below.

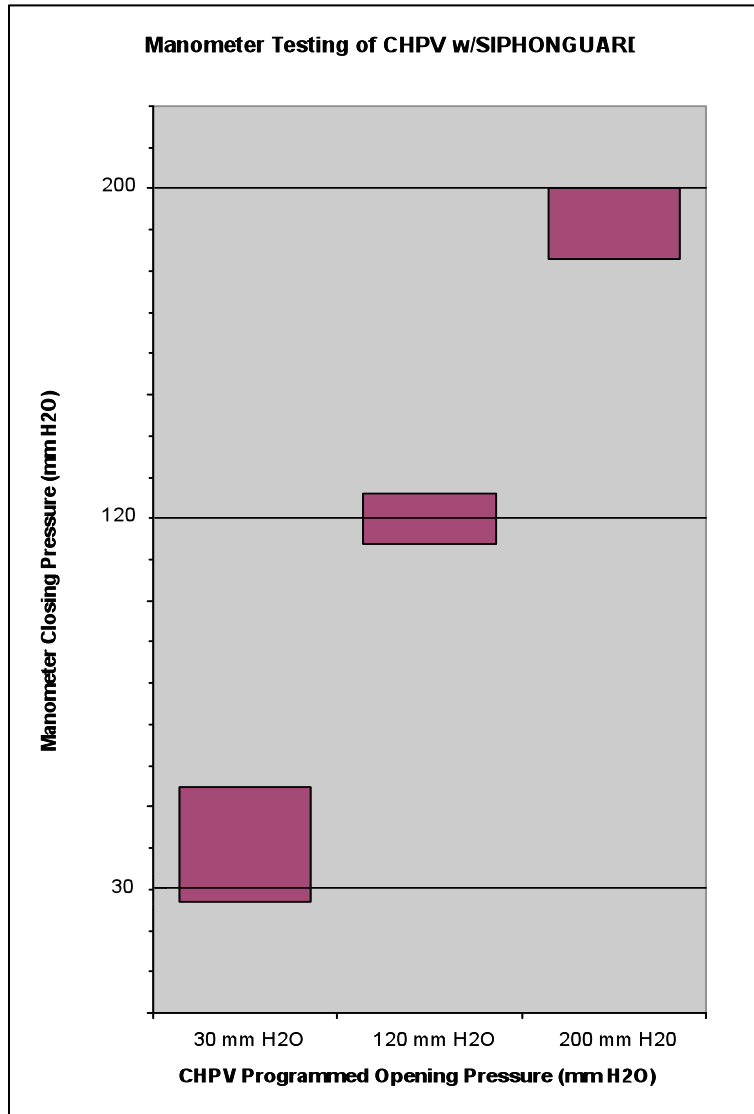


Figure 10

Bibliography

1. The Shunt Book
James M. Drake, Christian Sainte-Rose, 45-46, 1995
2. PS Medical, Delta Valves and Shunt Assemblies, Instructions for use, 16, 1992