

**CODMAN NEURO**

 **DePuy Synthes**

**CODMAN® HAKIM®  
Programmable Valves**

EC REP

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# ENGLISH

## IMPORTANT INFORMATION

Please Read Before Use

## CODMAN® HAKIM® Programmable Valves

STERILE EO



### Description

The CODMAN HAKIM Programmable Valve includes a valve mechanism (Figures 1 & 2) that incorporates a flat 316L stainless steel spring in which the calibration is accomplished by a combination between a pillar and a micro-adjustable telescoping fulcrum. The valve chassis is made of titanium. The ball and cone are manufactured from synthetic ruby. Intraventricular pressure is maintained at a constant level by the ball and cone valve seat design.

The pressure setting of the spring in the inlet valve unit is noninvasively adjusted by the use of an external programmer, which activates the stepper motor within the valve housing. The programmer transmits a codified magnetic signal to the motor allowing eighteen pressure settings, ranging from 30 mm to 200 mm H<sub>2</sub>O (294 to 1960 Pa) in 10 mm (98 Pa) increments. These are operating pressures of the valve unit and have been determined with a flow rate of 15–25 mL H<sub>2</sub>O per hour.

The valve is classified by its working pressure with a specified flow rate and not by the opening and closing pressures. The pressure that a valve sustains with a given flow is the parameter that reflects the working pressure of the valve once it is implanted. Before shipment, each valve is calibrated with special equipment: Duplication of these test procedures cannot be accomplished in the operating room.

The valve is marked with an x-ray detectable direction-of-flow indicator.

### Indications

The CODMAN HAKIM Programmable Valves are implantable devices that provide constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

### Contraindications

The CODMAN HAKIM Programmable Unitized Valve Systems are not recommended for atrial placement. Use the nonunitized versions for this procedure.

These devices are contraindicated in patients receiving anticoagulants or known to have a bleeding diathesis.

Avoid shunt implantation if infection is present within the body. Delay the shunt procedure when infections such as meningitis, ventriculitis, peritonitis, bacteremia, and septicemia are present.

### WARNINGS

**Subjecting the valve to strong magnetic fields may change the setting of the valve.**

- The use of Magnetic Resonance (MR) systems up to 3 T will not damage the valve mechanism, but may change the setting of the valve. Confirm the valve setting after an MRI procedure. See *Programming the Programmable Valve*.
- Common magnets greater than 80 gauss, such as household magnets, loudspeaker magnets, and language lab headphone magnets, may affect the valve setting when placed close to the valve.
- Magnetic fields generated from microwaves, high-tension wires, electric motors, transformers, etc., do not affect the valve setting.

Read *MR Information* before performing an MRI procedure on a patient implanted with the programmable valve.

The SIPHONGUARD® device is intended to reduce the rapid flow of CSF. It also reduces the ability to prime the shunt system during implantation to a rate of approximately 0.5 mL/minute.

### MR Information



Do not use the programmer in the MR suite.

The CODMAN HAKIM Programmable Valve is considered "MR Conditional" according to ASTM F 2503. The valve demonstrates no known hazards when an MRI is performed under the following conditions:

- MRI can be performed at any time after implantation
- Use an MR system with a static magnetic field of 3 T or less
- Use an MR system with a spatial gradient of 720 gauss/cm or less
- Limit the exposure to RF energy to a whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes
- Verify the valve setting after the MRI procedure (see *Programming the Programmable Valve*)

In non-clinical testing, the valve produced a temperature rise of 0,4°C at a maximum whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3 T EXCITE® General Electric MR scanner.

MR image quality may be compromised if the area of interest is relatively close to the device. Distortion may be seen at the boundaries of the artifact. Therefore, optimization of the MR imaging parameters may be necessary.

The following chart provides a comparison between the signal void and imaging pulse sequence at 3 T:

Signal Void	Pulse Sequence
1590 mm <sup>2</sup>	T1-SE
1022 mm <sup>2</sup>	T1-SE
2439 mm <sup>2</sup>	GRE
2404 mm <sup>2</sup>	GRE

### Precautions

**The programmable valves are supplied without a specific programmed pressure and must be programmed prior to use.**

Inspect the sterile package carefully. Do not use if:

- the package or seal appears damaged,
- contents appear damaged, or
- the expiry date has passed.

This is an adjustable valve and the surgeon must take that into account when evaluating patients. It is important to verify the current pressure setting as part of any treatment plan.

Do not allow the programming unit or transmitter unit to remain in environmental extremes.

After exposure of the programming unit or the transmitter unit to environmental extremes, such as those found in transport or storage, allow the unit to come within operating range before operating.

Do not program the valve on a metal surface, such as a Mayo stand.

While becoming familiar with valve programming, it is recommended that the pressure setting of the implanted valve be changed in increments of no more than  $\pm 40$  mm H<sub>2</sub>O (392 Pa) in a 24-hour period. Patients whose pressure setting has been changed should be carefully monitored during the first 24 hours post programming. It is recommended that x-rays be taken to confirm the changes made to valve pressure setting.

Before use, check the programming unit and transmitter unit connections, settings, and function (see *Preimplantation Programming Familiarization Procedure*).

Use only Codman branded programmers to program the pressure of the CODMAN HAKIM Programmable Valve.

Unauthorized modifications to the programming unit or transmitter unit may cause a malfunction that could result in serious patient injury or death.

Electrical shock hazard: Do not open the programming unit or transmitter unit. Refer servicing to qualified service personnel.

Explosion hazard: Do not use the programming unit in the presence of flammable materials; i.e., anesthetics, solvents, cleaning agents, and endogenous gases.

Before turning on the 100/120, 220/240 VAC programming unit (catalog no. 82-3121 or 82-3190), verify that the supply voltage selector on the rear of the unit is set to the correct voltage for the electrical outlet.

Do not move the transmitter unit during programming.

Never immerse the programming unit or the transmitter unit in any liquid.

Do not sterilize the programming unit or the transmitter.

Use only with components compatible with the dimensions shown in the *Device Description* section.

Aseptic technique is necessary in all phases of the use of this product.

Silicone has a low cut and tear resistance; therefore, exercise care when placing ligatures so as not to tie them too tightly. The use of stainless steel ligatures on silicone rubber is not recommended.

Do not use sharp instruments when handling the silicone valve or catheter; use shod forceps. Cuts or abrasions from sharp instruments may rupture or tear the silicone components.

Do not fold or bend the valve during insertion. Incorrect insertion may cause rupture of the silicone housing.

To better stabilize the position of the valve underneath the scalp, proper valve placement is required. Place the flat underside of the valve against the bone, with the round top surface facing upward.

Verify proper placement and integrity of ligatures at all tubing junctions to prevent obstruction of the catheter lumen and tears or abrasions of the silicone tubing.

Do not fill, flush, or pump the valve with fluid in which cotton, gauze, or other lint-releasing material has been soaked.

Exercise extreme care to prevent the silicone components of the system from coming in contact with bare fingers, towels, drapes, talc, or any linty or granular surfaces. Silicone rubber is highly electrostatic and, as a result, attracts airborne particles and surface contaminants that could produce tissue reaction.

After implantation, avoid unnecessary pumping of the prechamber and pumping chamber to prevent rapid alteration of the intraventricular pressure.

**Cylindrical Valves only:** Before closing the scalp incision (or mastoid incision, if a two-step passage technique is employed), confirm that the direction-of-flow arrow on the valve faces up.

#### Adverse Events

Devices for shunting CSF may have to be replaced at any time due to medical reasons or failure of the device.

Keep patients with implanted shunt systems under close observation for symptoms of shunt failure.

Complications of implanted shunt systems include mechanical failure, shunt pathway obstruction, infection, foreign body (allergic) reaction to implants, and CSF leakage along the implanted shunt pathway.

Clinical signs such as headache, irritability, vomiting, drowsiness, or mental deterioration may be signs of a nonfunctioning shunt. Low-grade colonization, usually with *Staph. epidermidis*, can cause, after an interval from a few days to several years, recurrent fevers, anemia, splenomegaly, and eventually, shunt nephritis or pulmonary hypertension. An infected shunt system may show redness, tenderness, or erosion along the shunt pathway.

Accumulation of biological matter (i.e. blood, protein accumulations, tissue fragments, etc.) in the programming mechanism can cause inability of the device to be reprogrammed.

Clogging of the programmable valve with biological matter can cause the valve to become unresponsive to attempts to change the pressure setting.

Do not use excessive force if attempting to remove the catheter(s). Excessive force can cause the catheter to break, leaving part of the catheter within the body.

Excessive CSF drainage can cause subdural hematomas, slit-like ventricles, and in infants, sunken fontanelles.

Particulate matter such as blood clots, brain fragments, or other tissue particles can obstruct the ventricular catheter. Also, the ventricular catheter can become obstructed by excessive reduction of ventricle size.

If not properly located in the lateral ventricle, the catheter can become embedded in the ventricular wall or choroid plexus.

Fibrous adhesions can bind the catheter to the adjacent choroids plexus or to the ventricular wall. Gentle rotation may free the catheter. DO NOT REMOVE THE CATHETER FORCEFULLY. If the catheter cannot be removed without force, it is recommended that it remain in place, rather than risk intraventricular hemorrhage.

The ventricular catheter can be withdrawn from, or lost in, the lateral ventricles of the brain if it becomes detached from the shunt system.

Blunt or sharp trauma to the head in the region of implant or repetitive manipulation of the valve during implant may compromise the shunt. Check valve position and integrity after occurrence.

#### Device Description

##### Programmable Valve Operating Pressure

30 to 200 mm H<sub>2</sub>O (294 to 1960 Pa) programmable in steps of 10 mm H<sub>2</sub>O (98 Pa)

##### Programmable Valve Configurations

In-line with SIPHONGUARD Device

In-line with SIPHONGUARD Device and Platform with Proximal Tube

In-line

Right Angle with SIPHONGUARD Device

Right Angle

Cylindrical with Prechamber

Cylindrical with RICKHAM® Reservoir

Cylindrical

Micro with RICKHAM Reservoir

Micro

**CODMAN HAKIM In-line and Right Angle Valves** include a programmable valve with a low profile and flat bottom, and an in-line or right angle integral reservoir with or without SIPHONGUARD.

**CODMAN HAKIM Cylindrical Valves** include a programmable valve, a pumping chamber, and an outlet valve available with a prechamber, without a prechamber, or with a RICKHAM reservoir.

**CODMAN HAKIM Micro Valves** include a programmable valve with or without an integral RICKHAM reservoir.

All programmable valve configurations are designed for use with components having the following dimensions:

Component	Inner Diameter	Outer Diameter
Ventricular Catheter	1,4 mm	2,7 mm
Drainage Catheter	1,0 mm	2,2 mm

### SIPHONGUARD Device

CSF flows through the inlet valve and enters the SIPHONGUARD Device, where it flows into two internal passages. Under normal conditions, the majority of CSF flows through a central ruby ball and cone valve, and exits directly out of the distal port of the SIPHONGUARD Device. The remaining CSF travels through a spiral passage that surrounds the central passage, and joins the fluid passing through the central passage, distal to the ball and cone valve.

A sudden increase in CSF flow will close the ball and cone valve and the entire volume of CSF will be forced through the longer spiral passage, effectively slowing the rate at which CSF is shunted from the brain. Once the flow rate entering the SIPHONGUARD Device decreases, the ruby ball separates from the valve seat, opening the central passage. As long as CSF continues to be shunted from the ventricles, flow through the spiral passage of the SIPHONGUARD Device never stops, regardless of the patient's position.

**Note:** The SIPHONGUARD Device will not activate at low CSF flow rates.

The SIPHONGUARD Device has a rigid enclosing shell of polyethersulfone to prevent inadvertent closure (and subsequent reduction or blockage of CSF flow) caused by externally applied pressure.

### How Supplied

The **Valve** includes a programmable valve, instructions for use, straight connector(s)\*, introducer\*\*, and priming adapter\*\*\*.

The **Valve System** includes a programmable valve, 14 cm ventricular catheter, 120 cm peritoneal catheter, instructions for use, right angle adapter, and priming adapter\*\*\*.

The **Valve System, Unitized**, includes a programmable valve, 14 cm ventricular catheter, 85 cm slit\*\*\*\* or 120 cm unitized peritoneal catheter, instructions for use, straight connector(s)\*, introducer\*\*, right angle adapter, and priming adapter\*\*\*.

\*Straight connectors provided with Cylindrical, Micro, and In-line with SIPHONGUARD and Platform with Proximal Tube versions only.

\*\*Introducers provided with Cylindrical versions only.

\*\*\*Priming adapter provided with In-line, Right Angle, and Micro versions only.

\*\*\*\*85 cm slit catheter packaged with 82-3853 only.

### Components and Accessories

#### Valve Programmer

The valve programmer, available in 100/120 or 220/240 VAC, is supplied with a transmitter head, transmitter cord, and carrying case. The programmer is sold nonsterile and available separately. The programmer is required for changing the pressure setting of the valves.

#### Ventricular Catheter (Figure 3)

The ventricular catheter is a 14 cm straight ventricular catheter molded of radiopaque silicone elastomer with x-ray detectable dots and a preassembled stainless steel introducing stylet.

#### Right Angle Adapter (Figure 4)

The right angle adapter, made of PROLENE® Material, allows 90 degree bending of the ventricular catheter at the burr hole site.

#### Priming Adapter (Figure 5)

The priming adapter, provided with the In-line, Right Angle, and Micro Valves, facilitates preimplantation irrigation to the valve and catheters.

#### Straight Connector

The straight connector joins the proximal and distal catheters to the valve.

#### Valve Introducer

A disposable polyethylene valve introducer is supplied to aid in passing the valve and drainage catheter from the burr hole site to a mastoidal incision, when a two-step passage technique is used. Because of the malleability of this introducer, it can be preformed to a desired curvature prior to valve placement.

### Sterility



The CODMAN HAKIM Programmable Valve Systems are intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Codman & Shurtleff will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

Codman Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminants such as Creutzfeldt-Jakob Disease. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality. (THIS STATEMENT APPLIES TO NON-IMPLANTABLE COMPONENTS ONLY.)

As long as the individual package is not opened or damaged, the product is sterile.

The following components have been tested and were determined to be nonpyrogenic:

Valve, In-line with SIPHONGUARD Device  
Valve, In-line with SIPHONGUARD Device and Platform with Proximal Tube  
Valve, In-line  
Valve, Right Angle with SIPHONGUARD Device  
Valve, Right Angle  
Valve, Cylindrical with Prechamber  
Valve, Cylindrical with RICKHAM Reservoir  
Valve, Cylindrical  
Valve, Micro with RICKHAM Reservoir  
Valve, Micro  
Peritoneal Catheter  
Ventricular Catheter  
Priming Adapter  
Right Angle Adapter  
Straight Connector

#### **Preimplantation Performance Testing**

Each CODMAN HAKIM Programmable Valve is individually tested on a component level to ensure conformance to the advertised performance characteristics. Each valve is dynamically tested at six different settings for proper dynamic opening pressure over the entire performance range.

Performing a manometer test is not recommended, as it is susceptible to environmental factors. Manometer testing yields a result that is not physiologic in nature and for which manufacturers do not specify performance ranges. If the surgeon insists upon performing manometer testing for confirmation of CODMAN HAKIM Valve closing pressures, it is possible, but is not recommended. When performed correctly, manometer testing generates valve closing pressures similar to the CODMAN HAKIM Valve opening pressure setting. However, closing pressure results will typically vary noticeably from the opening pressure setting.

For those surgeons who wish to perform functional testing, please see *Preimplantation Performance Testing* in the Appendix.

#### **Programming the Programmable Valve**

##### **Programmer Information**

**WARNING: The CODMAN HAKIM Programmable Valves are supplied without a specific programmed pressure and must be programmed prior to implantation.**

Programming must be performed prior to implantation through the nonsterile outer package. Perform programming postoperatively as needed.

The programmer consists of two parts, the programming unit and the transmitter unit. The programming unit control panel (Figure 6) features a power switch, programming instructions, and a representation of the programmable portion of the valve system as it appears when x-rayed. This representation also incorporates the 18 pressure selection buttons. Eighteen LEDs, corresponding to the position of the valve pressure indicator when viewed on x-ray, confirm the pressure setting chosen.

After depressing the desired pressure selector button, an LED lights in the programming unit. The lighted LED corresponds exactly with the position of the pressure indicator on the valve. When programming begins, the transmitter unit emits a sequentially coded electromagnetic signal. The stepper motor of the valve detects the signal and rotates the cam assembly, which, in turn adjusts the tension of the spring to the selected pressure setting.

##### **Transmitter Information**

**Note:** This Transmitter Information is for the CODMAN HAKIM Programmers **ONLY**. When using another Codman programmer, please refer to the instructions for use packaged with your programmer.

The transmitter unit (Figure 7) incorporates an illuminated center hole and directional arrows to aid in proper positioning over the valve. It connects to the programming unit via a pronged plug and is activated by the START button.

#### **Preimplantation Programming Familiarization Procedure**

To become familiar with valve programming, perform the following preimplantation programming procedure while the valve remains in the blister package.

1. Insert the pronged plug from the transmitter unit into the receptacle at the back of the programming unit.
2. Plug the power cord from the programming unit into an appropriate power source.

**Note:** The instructions contained in steps 3 through 6 are for the CODMAN HAKIM Programmers **ONLY**. When using another Codman programmer, please refer to the instructions for use packaged with your programmer.

3. Press the programming unit's power button to the ON position. Both the ON button and Instruction 1 on the panel will illuminate. Press the desired pressure selection button; Instruction 2 illuminates.
4. Place the transmitter unit's four prongs in the four depressions in the blister around the inlet valve. Point the arrow on the transmitter unit in the same direction as the arrow on the blister (the direction of flow). Look through the illuminated center hole of the transmitter unit.

**CAUTION: Do not move the transmitter unit during programming.**

5. Push the transmitter unit's START button. Instruction 3 on the control panel illuminates. During programming, the pressure selector buttons light sequentially until the selected pressure setting is attained.
6. When programming is completed (approximately five seconds), Instruction 4 on the panel illuminates momentarily and a buzzer sounds.

#### Postimplantation Programming Procedure

1. Insert the pronged plug from the transmitter unit into the receptacle at the back of the programming unit.
2. Plug the power cord from the programming unit into an appropriate power source.
3. Prior to programming, it is advisable to take an x-ray of the patient's head to verify the valve's pressure setting and position.

**Note:** The instructions contained in steps 4 through 11 are for the CODMAN HAKIM Programmers **ONLY**. When using another Codman programmer, please refer to the instructions for use packaged with your programmer.

4. Press the programming unit's power button ON. The ON button and Instruction 1 on the panel illuminate. Press the desired pressure selection button; Instruction 2 on the programmer panel and the center hole of the transmitter unit will illuminate.
5. **Note:** It is not necessary to shave the scalp for this procedure. Palpate the scalp to locate the implanted valve, specifically, the inlet valve, located distal of the reservoir. A fluoroscopic screen may assist in this process. Place the tip of the left forefinger precisely over the inlet valve, keeping the index finger parallel to the valve system and pointing in the direction of flow (Figure 8).
6. Place the transmitter unit's four prongs around the inlet valve so that the prongs are sitting on the scalp. The arrows on the transmitter unit should be parallel to the forefinger and pointing in the direction of flow (Figure 9).
7. Center the transmitter unit so that the illuminated opening is directly above the nail of the index finger (Figure 10).
8. Remove finger from the valve and push the transmitter unit's START button (Figure 11). Instruction 3 on the control panel illuminates, indicating that the valve is programming.

**CAUTION: Do not move the transmitter unit during programming.**

9. During programming, the pressure selector buttons light sequentially until the selected pressure setting is attained.
10. When programming is completed (approximately five seconds), Instruction 4 on the panel illuminates momentarily and a buzzer sounds.
11. Verify the valve pressure setting with an x-ray.

#### X-Raying the Valve

**Note:** The instructions contained in *X-Raying the Valve* are for the CODMAN HAKIM Programmers **ONLY**. When using another Codman programmer, please refer to the instructions for use packaged with your programmer.

It is advisable to x-ray the complete system immediately after implantation to have a permanent record of component placement and to verify valve pressure. It is also advisable to x-ray the valve whenever valve pressure is reprogrammed.

Use an x-ray with intensifying TV screen, or an x-ray plate to confirm proper valve pressure. When documenting the valve pressure with x-rays, take care when positioning so that:

- the nonimplanted side of the head rests on the plate (the implanted side is uppermost from the plate), and,
- the inlet valve is parallel to the x-ray plate.

Viewing the x-ray, the white marker on the valve indicates the right-hand side of the valve. The pressure indicator on the white ring indicates the chosen pressure setting (Figure 12).

There is a direct correlation between the position of the programming unit control panel pressure selector buttons and the position of the pressure indicator on the valve as seen when x-rayed. Note that when the valve is programmed to 70, 120, or 170, the pressure indicator aligns with the "X" in the center of the valve (Figure 13).

#### Programming Procedure in Case of an Inverted Valve

**Note:** The instructions contained in *Programming Procedure in Case of an Inverted Valve* are for the CODMAN HAKIM Programmers **ONLY**. When using another Codman programmer, please refer to the instructions for use packaged with your programmer.

An inverted valve can be diagnosed on x-ray; the white marker will appear on the left side of the valve, instead of the right side. Programming the inverted valve requires a "double programming" to obtain the desired pressure setting.

1. Program the valve with the valve programmer at the 200 valve pressure setting.
2. Calculate the following: 210 (constant) minus the desired pressure setting equals the programming pressure setting. For example, where 70 is the desired pressure setting:  $210 - 70 = 140$ .
3. Push the button for the programming pressure setting (in this example, 140) on the programmer; hold the transmitter in place for approximately 5 seconds until the confirmation tone is heard. If the surgeon is unsure whether the reprogramming took place, he or she must repeat the complete process, Steps 1 through 3, otherwise the programming will be incorrect.

**Note:** When the valve is inverted, pressure settings of 190 and 200 are not possible to program.

### Surgical Procedure

There are a variety of surgical techniques, which can be used to place the CODMAN HAKIM Programmable Valves. The surgeon should choose in accordance with his or her own clinical experience and medical judgment.

### Irrigation

Hold the valve vertically with the outlet end pointing upward. Using a syringe, or the action of the pumping chamber (if applicable), slowly and gently fill the entire valve system (Figure 14) with pyrogen-free, sterile saline solution or appropriate antibiotic solution. **Note:** A priming adapter with inlet tubing is provided with the In-line, Right Angle, and Micro versions to facilitate irrigation (Cylindrical Valves incorporate a pumping chamber for this purpose).

**CAUTION: Do not fill, flush, or pump the valve with fluid in which cotton, gauze, or other lint-releasing material has been soaked.**

Once fluid flows from the outlet end of the drainage catheter, occlude the inlet tubing of the valve system with shod forceps close to the ventricular end, and remove the syringe and priming adapter (if applicable).

**CAUTION: Avoid any unnecessary pumping of the system to prevent overdrainage of the ventricles. Over irrigation of the valve system may damage the internal mechanism.**

Please record the valve lot number on the patient's chart.

### Clearing Obstructions

(Cylindrical with Prechamber Valves only)

To check the patency of the ventricular catheter, occlude the tubing between the prechamber and the valve unit with finger pressure (Figure 15). Press the prechamber. If the prechamber does not compress easily and does not return immediately to its original shape, or if the prechamber compresses easily but does not refill immediately, the ventricular catheter may be occluded. To correct this situation, first allow the prechamber to refill. Then, occlude the tubing between the prechamber and the valve unit with finger pressure and press the prechamber firmly. This forces fluid back through the ventricular catheter, helping to remove the obstruction. If necessary, repeat this procedure.

In some circumstances, the use of a syringe (with 25-gauge HUBER®-point needle) is necessary to remove the obstruction. Occlude the tubing between the prechamber and the valve unit with finger pressure. Using light pressure, inject sterile, nonpyrogenic saline solution into the prechamber (Figure 16).

To test the patency of the tubing between the prechamber and the valve unit, occlude the tubing between the prechamber and the valve unit with pressure. Press and release the prechamber. If the prechamber immediately returns to its original shape after compression, remove finger from the tubing and press the pumping chamber. If the pumping chamber compresses readily but does not immediately return to its original shape, there may be an obstruction between the prechamber and valve unit. To remedy this situation, occlude the tubing between the prechamber and the ventricular catheter (Figure 17). Firmly press the prechamber with the adjoining finger to force fluid forward through the valve unit and drainage catheter. If necessary, repeat.

Occasionally, it may be necessary to use a syringe with 25-gauge HUBER®-point needle to dislodge the obstruction. Occlude the tubing proximal to the prechamber. Using light pressure, inject sterile, nonpyrogenic saline solution into the prechamber (Figure 18).

To test the patency of the valve outlet or drainage catheter, press on the pumping chamber. If the pumping chamber resists compression, the valve outlet or drainage catheter may be obstructed. To dislodge the obstruction, press the valve unit forcefully, then release it to permit the prechamber to refill.

### Reservoir Injection

**These instructions apply to the following valve configurations:**

In-line with SIPHONGUARD Device  
 In-line with SIPHONGUARD Device and Platform with Proximal Tube  
 In-line  
 Right Angle with SIPHONGUARD Device  
 Right Angle  
 Cylindrical with Prechamber  
 Cylindrical with RICKHAM Reservoir  
 Micro with RICKHAM Reservoir

To inhibit coring of the reservoir cap, use a HUBER®-point needle (24- or 26-gauge) to penetrate the dome. Insert the needle at an oblique angle to achieve the greatest yield of CSF and to prevent the needle point from piercing the ventricular catheter (Figure 19).

### Troubleshooting

If valve function is adversely affected by accumulations of biological matter, it may be possible to dislodge the material and restore proper function through one of the following methods:

- Flushing and/or pumping the valve (only for those valves without SIPHONGUARD)
- Multiple programming attempts

If these remedial steps fail to rectify the problem, replace the valve.

### Bibliography

- Adams RD, Fisher M, Hakim S, Ojemann RG, Sweet WH: Symptomatic occult hydrocephalus with "normal" cerebrospinal fluid pressure. *New Eng J Med* 273: 117–126, 1965.
- Bayston R: Serological surveillance of children with CSF shunting devices. Supplement 35: 104–110, 1975, to *Develop Med Child Neurol* 17.
- Bayston R, Swinden J: Aetiology & prevention of Shunt Nephritis. *Zeitschrift für Kinderchirurgie* 28: 377–384, 1979.
- Black P McL, Hakim R, Bailey NO: The Use of the Codman-Medos Programmable Hakim Valve in the Management of Patients with Hydrocephalus: Illustrative Cases. *Neurosurgery* 34: 6, 1994.
- Black P McL: Idiopathic normal-pressure hydrocephalus. Results of shunting in 62 patients. *J Neurosurg* 53: 371–377, 1980.
- Black P McL, Tzouras A, Ojemann RG: CSF shunts for dementia, gait disturbance, and incontinence, *Clinical Neurosurgery*.
- Cohen SJ, Callaghan RP: A syndrome due to bacterial colonisation of Spitz-Holter valves. A review of 5 cases, *Brit Med J* 2: 677–680, 1961.
- Drake JM, Kestle JRW, Milner R, et al: Randomized Trial of Cerebrospinal Fluid Shunt Valve Design in Pediatric Hydrocephalus. *Neurosurgery* 43: 2, 1998.
- Fager CA: Complicated and unusual neurosurgical problems, *Surg Clin N Am* 48: 637–642, 1968.
- Guthrie TC, Dunbar HS, Karpell B: Ventricular size and chronic increased intracranial venous pressure in the dog. *J Neurosurg* 33: 407–414, 1970.
- Hakim C: The physics and physiopathology of the hydraulic complex of the central nervous system (The Mechanics of Hydrocephalus and Normal Pressure Hydrocephalus), Ph.D. Thesis, Massachusetts Institute of Technology, 1985.
- Hakim S, Zuluaga A, Cabrera O: Derivación ventriculoatrial para el tratamiento de la hidrocefalia por medio de la válvula de Hakim. Tesis de grado, Facultad de Medicina, Universidad Javeriana, Bogotá, Colombia, 1964.
- Hakim S, Adams RD: The special clinical problem of symptomatic hydrocephalus with normal cerebrospinal fluid pressure, Observations on cerebrospinal fluid hydrodynamics. *J Neurol Sci* 2: 307–327, 1965.
- Hakim S, Adams RD, Fisher CM: Occult hydrocephalus. *New Eng J Med* 274: 466, 1966.
- Hakim S: Observations on the physiopathology of the CSF pulse and the prevention of ventricular catheter obstruction in valve shunts, Hydrocephalus and Spina Bifida. Supplement 20: 42–48, 1970, to *Develop Med Child Neurol*.
- Hakim S: Biomechanics of hydrocephalus, in Harbert JC (ed): Cisternography and Hydrocephalus, Charles C. Thomas, Springfield, IL, 25–55, 1972.
- Hakim S, Duran de la Roche F, Burton JD: A critical analysis of valve shunts used in treatment of hydrocephalus. *Develop Med Child Neurol* 15: 230–255, 1973.
- Hakim S: Algunas observaciones sobre la presión del L.C.R. Síndrome hidrocefálico en el adulto con presión normal del L.C.R. (Presentación de un nuevo síndrome.) Tesis de grado. Facultad de Medicina, Universidad Javeriana, Bogotá, Colombia, 1964. Available in English as: Some observations on CSF pressure, Hydrocephalic syndrome in adults with "normal" CSF pressure. (Recognition of a new syndrome.)
- Hakim S, Venegas JG, Burton JD: The physics of the cranial cavity, hydrocephalus, and normal pressure hydrocephalus: mechanical interpretation and mathematical model. *Surg Neurol* 5: 187–210, 1976.
- Hakim S, Hakim C: A biomechanical model of hydrocephalus and its relationship to treatment, Hydrocephalus, edited by K Shapiro, A Marmarou, and H Portnoy. 143–160. Raven Press, New York, 1984.
- Hammock MK, Milhorat TH, Earle K, DiChiro C: Vein of Galen ligation of the primate. *J Neurosurg* 34: 77–83, 1971.
- Leheta F: Erfahrungen mit dem Cordis-Hakim-Ventil. *Zbi Neurochir* 33: 69–74, 1972.
- Mori K: Management of Idiopathic Normal Pressure Hydrocephalus: A Multi Institutional Study Conducted in Japan. *J Neurosurg* 2: 95, 2001.
- Nulsen FE, Spitz EB: Treatment of hydrocephalus by direct shunt from ventricle to jugular vein, *Surg Forum* 2: 399–403, 1952.
- O'Brien M, Parent A, Davis B: Management of ventricular shunt infections. *Child's Brain* 5: 304–309, 1979.
- Ojemann RG: Initial experience with the Hakim valve for ventriculovenous shunt. *J Neurosurg* 28: 283–287, 1968.

Ojemann RG: Normal pressure hydrocephalus. *Clin Neurosurg* 18: 337–370, 1971.

Ojemann RG, Black P McL: Evaluation of the patient with dementia and treatment of normal pressure hydrocephalus. In: Wilkins RH, Regachary SS (eds), *Neurosurgery*. McGraw Hill, 1984.

Penn RD, Bacus JW: The brain as a sponge: a computed tomographic look at Hakim's Hypothesis. *Neurosurgery* 14: 670–675, 1984.

Raimondi AJ, Yashon D, Matsumoto S, Reyes C: Increased intracranial pressure without lateralizing signs, the "midline syndrome." *Neurochirurgia* 10: 197–209, 1967.

Rayport M, Reiss J: "Hydrodynamic Properties of certain shunt assemblies for the treatment of hydrocephalus, Part I: Report of a case of communicating hydrocephalus with increased cerebrospinal fluid production treated by duplication of shunting device." Part II: Pressure-flow characteristics of the Spitz-Holter, Pudenz-Meyer, and Cordis-Hakim shunt systems. *J Neurosurg* 30: 455–467, 1969.

Reinprecht A, Dietrich W, Bertalanffy A, Czech T: The Medos Hakim Programmable Valve in the Treatment of Pediatric Hydrocephalus. *Childs Nerv Syst* 13: 588–594, 1997.

Zemack G, Romner B: Seven-year clinical experience with the CODMAN HAKIM programmable valve: a retrospective study of 583 patients. *Neurosurg Focus* 7: 4, 1999.

## APPENDIX

### Preimplantation Performance Testing

Although Codman does not recommend functional testing, some surgeons may choose to do so. Before testing, it is extremely important that a CODMAN HAKIM Valve with or without SIPHONGUARD Device be flushed of all air bubbles. Air bubbles within the CODMAN HAKIM Valve or SIPHONGUARD Device produce inaccurate manometer test results. The presence of air bubbles can reduce the cross-sectional area of the flow path, increase system resistance, and impede the flow of fluid through the system during testing.

### SIPHONGUARD Device Functional Testing

**Equipment Required** (use all sterile equipment, perform testing under sterile conditions)

One manometer, wide-bore (e.g. 3.5 mm), graduated in mm (available in lengths from 38 to 60 cm)  
One 4-way stopcock  
One syringe, 5 mL  
One syringe filter, 5  $\mu$ m  
Tubing adapters  
Silicone tubing  
One male luer connector with 1/16 in. barb  
Saline solution

### Flushing Procedure

**Note:** At a rate of 0.5 mL/minute, unitized versions require 2–3 minutes to complete flushing. This is the time required for fluid to fill the valve and exit the distal catheter. Allot additional time to ensure the system is free of air bubbles.

1. Assemble manometer, stopcock, syringe, and tubing (Figure A-1).

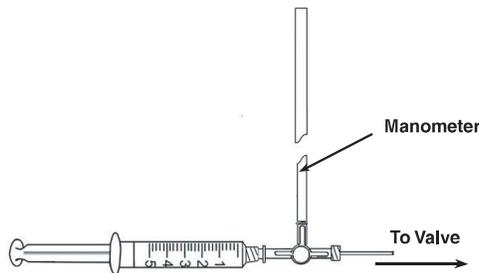
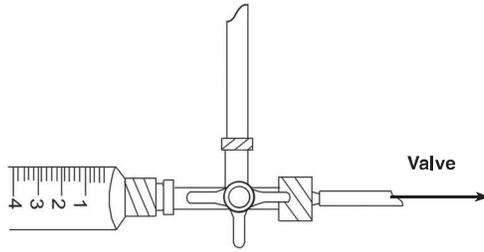


Figure A-1

2. Detach syringe from assembly and fill the syringe with sterile saline solution using the 5  $\mu$ m filter in-line. Detach the filter after filling the syringe.
3. Set the valve opening pressure to 30 mm H<sub>2</sub>O (294 Pa) while the valve remains in its sterile package.
4. Remove valve from the sterile package, and connect the valve to the manometer/syringe assembly.  
**Note:** Do not attach the distal catheter at this time.

- Adjust the stopcock to connect the syringe to the valve assembly (Figure A-2).



**Figure A-2**

- Position the valve vertically to direct the flow of saline upward through the assembly. This orientation aids in flushing air from the system.
- Using the syringe, gently flush saline through the system while gently depressing the prechamber to purge air bubbles from the valve assembly.
- Attach the distal catheter and continue to flush the system using the syringe until saline solution exits the end of the distal catheter.

**Note:** An excessive flow rate ( $>0.75$  mL/min) activates the SIPHONGUARD Device and creates the impression that the valve is distally occluded. In reality, flow is being diverted to the high resistance secondary pathway.

- The device is now ready for *SIPHONGUARD Device Functional Test* or *Manometer Testing*.

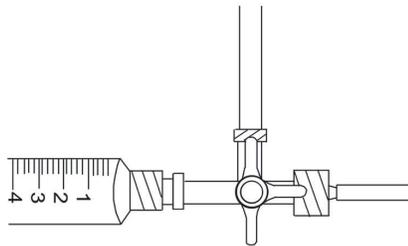
**Note:** All valves are susceptible to damage due to excessive flow rate during testing. Take extreme care when flushing a valve as damage can occur when excessive flow rates are used. It is recommended to use a flow rate of no greater than 0.5 mL/min.

#### SIPHONGUARD Device Functional Test

**Note:** This procedure applies only to valves with an integrated SIPHONGUARD Device.

**Note:** Perform this procedure immediately after completing the flushing procedure. This procedure is designed to provide visual confirmation of proper functioning of the SIPHONGUARD Device.

- Use a full syringe of saline solution attached to the 4-way stopcock to fill the manometer to the top.
- Turn the stopcock to connect the manometer to the CODMAN HAKIM Valve and SIPHONGUARD Device (Figure A-3).

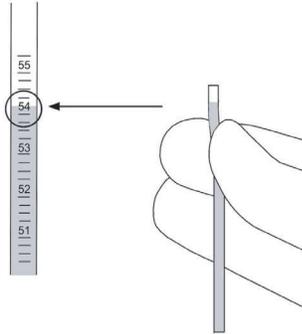


**Figure A-3**

**Note:** Attach the distal catheter at this time, flushed free of air bubbles.

- Bring the end of the distal catheter level with the fluid level in the manometer (Figure A-4).

**Note:** The CODMAN HAKIM Valves with SIPHONGUARD Device must lie on a sterile surface and remain undisturbed for the duration of the test.



**Figure A-4**

- Hold the catheter distal tip adjacent to the manometer and slowly lower the end of the distal catheter until the fluid level in the manometer begins to drop.
- Continue to lower the catheter tip at a rate that exceeds the drop rate of the fluid level in the manometer. As you do so, you will note a corresponding increase in the rate of descent of the fluid level in the manometer.
- A point will be reached where the rate of descent of the fluid level in the manometer dramatically decreases, but does NOT stop. This is the point at which the SIPHONGUARD Device primary pathway closes and flow diverts to the higher resistance secondary pathway. This confirms proper functioning of the SIPHONGUARD Device.
- Repeat Steps 3 through 6 as necessary to reconfirm SIPHONGUARD Device function.
- Remove distal catheter for manometer testing of valve.

#### Manometer Testing

**Note:** Performing a manometer test is not recommended as this test is susceptible to environmental factors and yields a result that is not physiologic in nature and for which manufacturers do not specify performance ranges.

**Note:** Perform this test only on devices that have been prepared according to Steps 1 through 8 in *Flushing Procedure*.

**Equipment Required** (use all sterile equipment, perform testing under sterile conditions)

- One manometer, wide-bore (e.g. 3,5 mm), graduated in mm (available in lengths from 38 to 60 cm)
- One 4-way stopcock
- One syringe, 5 mL
- One syringe filter, 5 µm
- Tubing adapters
- Silicone tubing
- One male luer connector with 1/16 in. barb
- Saline solution

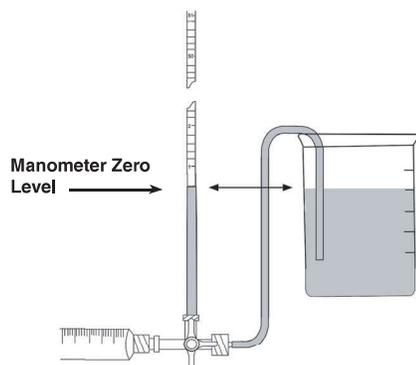
#### Flushing Procedure

Prepare the valve following Steps 1 through 8 in *SIPHONGUARD Device Functional Testing, Flushing Procedure*.

#### Equipment Setup

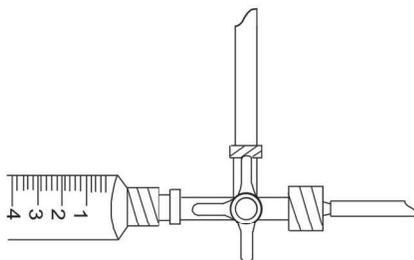
- Disconnect the valve from the tubing leading to the stopcock. Perform this step with the valve submerged in a water bath so as not to reintroduce air into the valve.
- Place the end of the tubing leading from the stopcock into the water bath. Position the tubing so that the end does not come into contact with the sides of the bath.

- Adjust the manometer height so that the zero level of the manometer and the fluid level in the water bath are at the same level (Figure A-5).



**Figure A-5**

- Fill the syringe with saline solution using the syringe filter.
- Disconnect the filter from the syringe and reconnect the syringe to the stopcock.
- Turn the stopcock to isolate the valve from the manometer assembly, connecting the syringe to the manometer (Figure A-6).

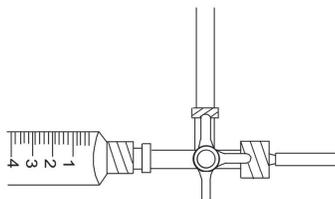


**Figure A-6**

- Refill the manometer using the 5 mL syringe.

**Zeroing the Manometer**

- After refilling the manometer, turn the stopcock to connect the manometer with the bath (Figure A-7).



**Figure A-7**

- Allow the water column in the manometer to fall. The water column should stop at the zero level of the manometer (Figure A-5).
- If necessary, adjust the height of the manometer to bring the water level in the manometer to the same level as the fluid in the water bath.

**Test Procedure**

- Set the opening pressure of the CODMAN HAKIM Valve to 120 mm H<sub>2</sub>O (1176 Pa). [Laboratory testing using ASTM test F647 has shown that the best correlation between manometer closing pressure and dynamic opening pressure is at a setting of 120 mm H<sub>2</sub>O (1176 Pa)].
- 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 reintroduction of air bubbles into the valve.

3. Remove the distal catheter at this time.

**Note:** The attachment of a distal catheter can alter the test results as well as increase test time. This is not possible with unitized versions of the CODMAN HAKIM Valve. Allot additional time for testing of unitized versions.

4. Submerge the valve completely in the water bath. For the unitized version, submerge the outlet of the distal catheter in the water bath to obtain accurate results. Confirm that there are no bubbles attached to the tip of the distal catheter and that the water bath does not obstruct the tip of the catheter.
5. Adjust the stopcock to connect the syringe to the manometer (Figure A-6 above) and refill the manometer to a height equal to the opening pressure setting of the CODMAN HAKIM Valve plus 50 mm. If the CODMAN HAKIM Valve is programmed to an opening pressure of 120 mm H<sub>2</sub>O (1176 Pa), the height of the fluid in the manometer is 120 mm + 50 mm = 170 mm (17 cm) (1176 Pa + 490 Pa = 1666 Pa). This procedure minimizes the possibility of inadvertently activating the SIPHONGUARD Device during manometer testing.
6. Turn the stopcock to connect the manometer to the valve (Figure A-7 above).
7. The water column in the manometer will start to fall. Allow the water column to drop for 3–5 minutes or until a steady state is reached. *A steady state is defined as a change of less than 2 mm H<sub>2</sub>O (20 Pa) in a 2-minute period.*
8. For valves with SIPHONGUARD Device, an extended test time is recommended in order to compensate for the possibility of a decreased flow rate due to SIPHONGUARD Device activation. Allow the water column to drop for 5–7 minutes or until a steady state is achieved.
9. Read the resultant pressure.

Variations between the manometer closing pressure test result and the CODMAN HAKIM Valve setting of as much as ±25 mm H<sub>2</sub>O (248 Pa) are possible based upon the test method utilized. Expect the same device to produce opening pressure results within ±10 mm H<sub>2</sub>O (98 Pa) of the valve setting utilizing an industry standard test method such as ASTM F647 or ISO 7197.

#### WARRANTY

Codman & Shurtleff, Inc. warrants that this medical device is free from defects in both materials and workmanship. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.**

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## FRANÇAIS

### INFORMATIONS IMPORTANTES

À lire avant utilisation

### Valves programmables CODMAN® HAKIM®

STERILE EO



#### Description

Les valves programmables CODMAN HAKIM comprennent un mécanisme d'ouverture (figures 1 & 2) qui intègre un ressort plat en acier inoxydable 316L et dans lequel l'étalonnage s'effectue au moyen d'un montant et d'un pivot télescopique micro-réglable. Le châssis de la valve est en titane. La bille et le cône sont fabriqués en rubis synthétique. La pression intraventriculaire se maintient à un niveau constant grâce à l'appui de la bille sur le cône de la valve.

Le réglage de pression du ressort dans la valve d'admission est ajusté sans invasion chirurgicale par l'intermédiaire d'un programmeur externe qui active le moteur pas à pas dans le logement de la valve. Le programmeur transmet au moteur un signal magnétique codé permettant 18 réglages de pression, allant de 30 mm à 200 mm de H<sub>2</sub>O (294 à 1960 Pa) par paliers de 10 mm (98 Pa). Les pressions opératoires de l'unité de valve ont été déterminées pour un débit compris entre 15 et 25 ml de H<sub>2</sub>O par heure.