

Programmable
Valve System for
Hydrocephalus

Procedure Guide

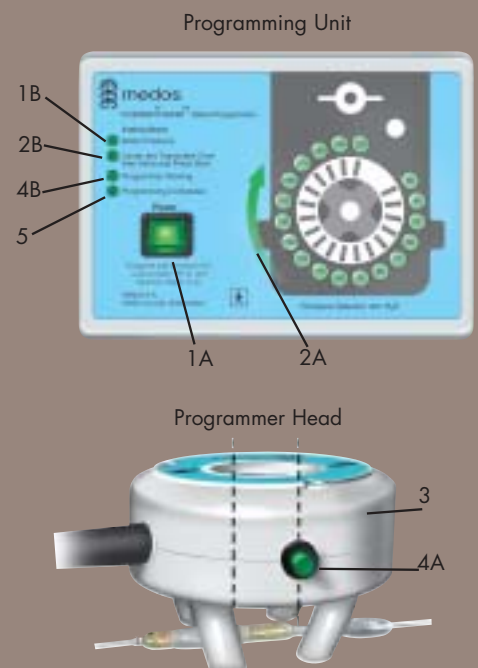
The CODMAN® HAKIM™ Programmable Valve offers the ability to optimize the opening pressure of a shunt system before and after implantation. A shunted patient's condition will often change over the course of their treatment making a fixed pressure shunt no longer optimal. The programmable valve allows a surgeon to non-invasively change the opening pressure between 30 mm H₂O and 200 mm H₂O in 18 steps; negating the need for revision surgery to alter the valve pressure. The programmability of the valve may allow for the development of specialized treatment regimes. The opening pressure of the CODMAN® HAKIM™ Programmable Valve is changed through the use of an externally applied, codified magnetic field. The spring in the ball-spring mechanism of the valve sits atop a rotating spiral cam which contains a stepper motor. Applying a specific magnetic field to the stepper motor will cause the cam to turn slightly, increasing or decreasing the tension on the spring, and changing the opening pressure of the valve. The CODMAN® HAKIM™ Programmable Valve is available in eight basic configurations.

CODMAN HAKIM Programmable Valve Configurations



To program the valve:

1. A) Turn on the programmer unit.
B) The Instruction 1 light on the programmer panel will illuminate.
2. A) Choose the desired pressure on the programmer panel by pressing the corresponding raised button. B) The Instruction 2 light will come on.
3. Place the programmer head over the valve such that the feet of the programmer head straddle the valve mechanism and the arrows on the programmer head align with the direction of CSF flow.
4. A) Press and release the start button on the programmer head while holding the programmer head in place. B) The Instruction 3 light illuminates and C) the pressure selector buttons sequentially light until the valve is finished being programmed.
5. Hold the programmer head in place until the programmer beeps indicating that programming has been completed (approximately 4-8 seconds). The Instruction 4 light will briefly illuminate at the end of the programming cycle.



Valves are supplied without a specific set pressure and must be programmed prior to use. After choosing the desired initial pressure setting, the valve is programmed in its packaging by placing the feet of the transmitter head in the four blister depressions over the valve mechanism and aligning the arrows on the transmitter head with the arrows on the package.

It is acceptable to prime the valve by filling it with lint-free sterile saline or an appropriate antibiotic solution prior to implantation. The valve mechanism should be placed over a bony region and not over an area with an excessive amount of soft tissue. The valve could become embedded in the soft tissue, making it difficult to program postoperatively.

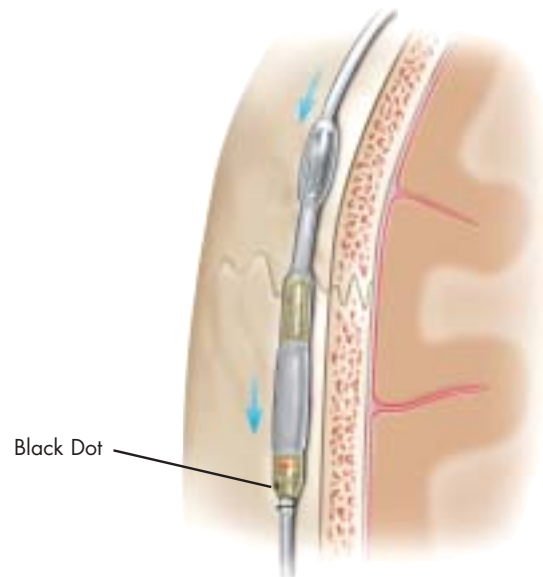
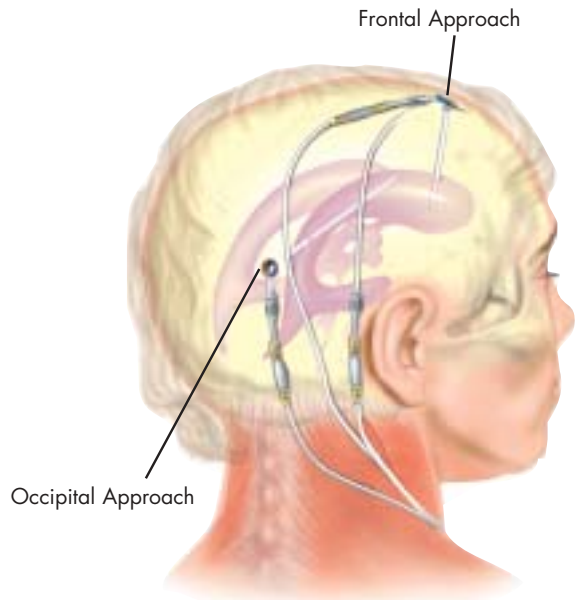
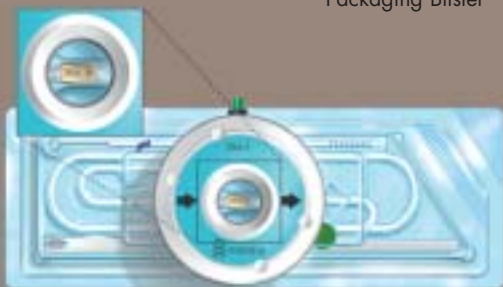
The valve must be oriented with the valve mechanism facing up towards the scalp and in the correct direction for CSF flow. The standard housings, with and without prechamber, have a black dot indicating which side should face upwards. The Micro Valve, Inline, and Right Angle housings have a flat bottom that should rest against the skull, insuring that the mechanism is facing up.

Programming Unit

Programmer Head



Packaging Blister

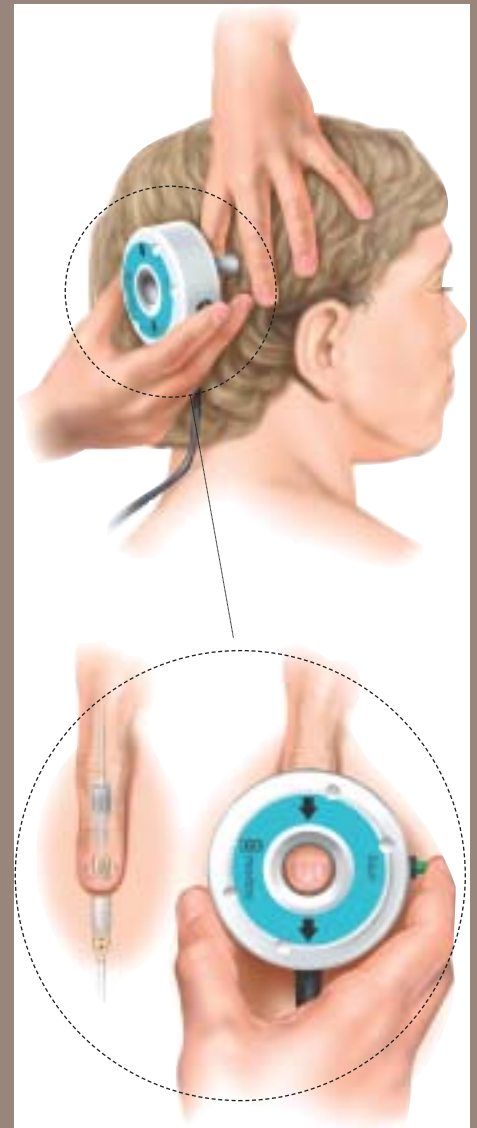


The new pressure setting of the valve should be determined taking into account all of the patient's clinical symptoms and the surgeon's own experience. It is advisable not to increase the pressure setting of the valve by more than 40 mm H₂O in a 24 hour period. Palpate the scalp to locate the implanted valve, then locate the valve mechanism based on the type of housing that has been implanted.



The position of the valve mechanism may be marked by your fingertip. Place the transmitter head over that fingertip so that it is centered directly under the transmitter head. The feet of the transmitter head should straddle the valve mechanism and touch the patient's skin. The transmitter head has an arrow on it indicating the direction of CSF flow, which must align with the CSF flow through the valve.

It is imperative that the transmitter head remain centered over the valve mechanism with the feet of the transmitter head touching the scalp during the entire programming cycle. If the transmitter head is not aligned properly with the valve, or if it moves during the programming cycle, incorrect programming will occur.

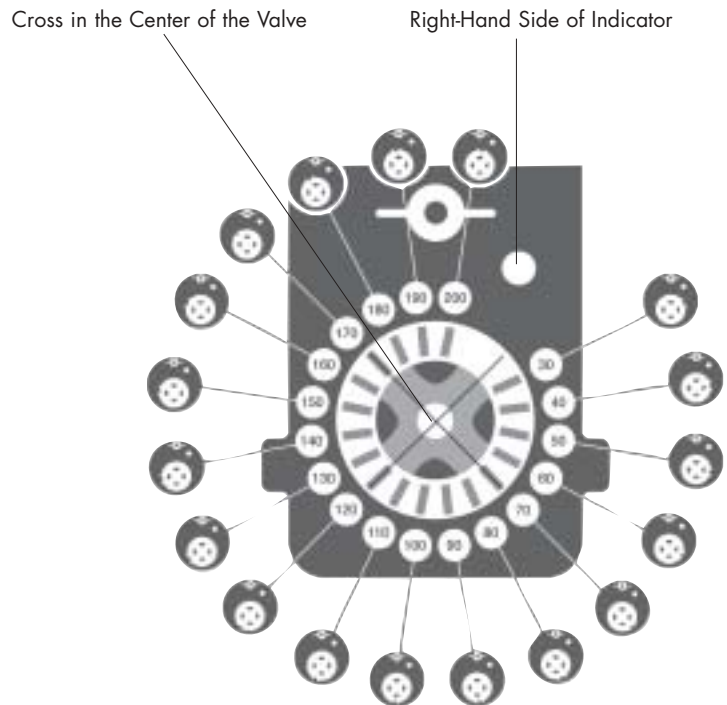
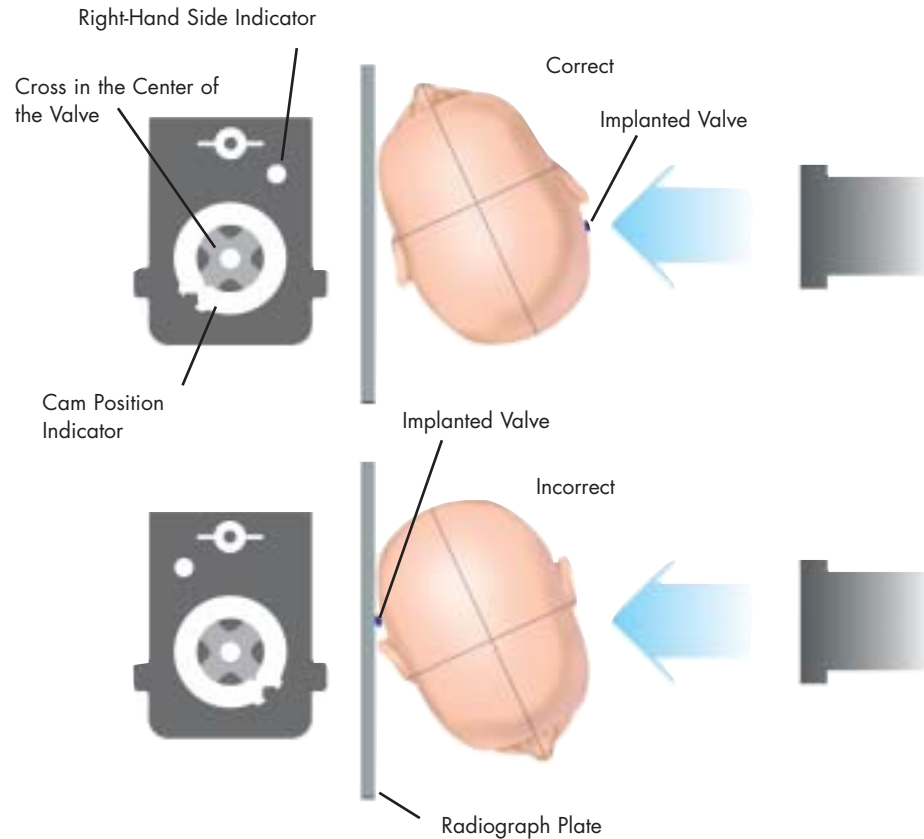


Pressure Setting Verification

The pressure setting of the CODMAN® HAKIM™ Programmable Valve must be verified after implantation through the use of x-rays or fluoroscopy.

A proper radiograph will be generated when the film is shot perpendicular to the plane of the valve with the non-implanted side of the patient's head resting on the plate. The film must be taken in relation to the valve and not the patient's anatomy.

The pressure setting of the valve can be determined by comparing the position of the radiopaque maker on the valve cam to the fixed position of the radiopaque right-hand side indicator on the baseplate of the valve. Comparing the patient radiographs to the diagram on the programming unit panel will indicate what pressure setting the valve is at. Note that settings of 70, 120 and 170 mm H₂O align with the cross in the center of the valve.

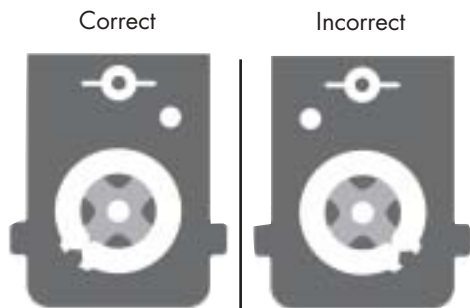


Note: Remember to verify valve pressure setting after an MRI.

Prior to following the procedure to program a rotated valve, review the section on pressure setting verification to insure that the radiographs were taken and read in the proper orientation. An upside-down valve will program incorrectly. It can be determined that the valve is upside-down by examining properly taken radiographs of the valve. A properly oriented valve will appear in a radiograph with its small right-hand side indicator on the right-hand side of the larger, central marker of the valve. By contrast, a rotated valve will have its small right-hand side indicator on the left-hand side of the radiograph.

An upside-down valve is programmed using a two step process. **The valve is first programmed to a setting of 200 mm H₂O**, then is programmed to a setting of 210 mm H₂O minus the desired setting. For example, if a 70mm H₂O setting is desired, the calculation would yield: $210 - 70 = 140$ mm H₂O

Note that if a valve becomes rotated it will no longer be possible to obtain opening pressures of 190 or 200 mm H₂O.



To Obtain this Pressure in the Inverted System	Pressure Formula	Program this Pressure on the Programmer
30 mm H ₂ O	$210 - 30 = 180$	180 mm H ₂ O
40 mm H ₂ O	$210 - 40 = 170$	170 mm H ₂ O
50 mm H ₂ O	$210 - 50 = 160$	160 mm H ₂ O
60 mm H ₂ O	$210 - 60 = 150$	150 mm H ₂ O
70 mm H ₂ O	$210 - 70 = 140$	140 mm H ₂ O
80 mm H ₂ O	$210 - 80 = 130$	130 mm H ₂ O
90 mm H ₂ O	$210 - 90 = 120$	120 mm H ₂ O
100 mm H ₂ O	$210 - 100 = 110$	110 mm H ₂ O
110 mm H ₂ O	$210 - 110 = 100$	100 mm H ₂ O
120 mm H ₂ O	$210 - 120 = 90$	90 mm H ₂ O
130 mm H ₂ O	$210 - 130 = 80$	80 mm H ₂ O
140 mm H ₂ O	$210 - 140 = 70$	70 mm H ₂ O
150 mm H ₂ O	$210 - 150 = 60$	60 mm H ₂ O
160 mm H ₂ O	$210 - 160 = 50$	50 mm H ₂ O
170 mm H ₂ O	$210 - 170 = 40$	40 mm H ₂ O
180 mm H ₂ O	$210 - 180 = 30$	30 mm H ₂ O
190 mm H ₂ O	N/A	N/A
200 mm H ₂ O	N/A	N/A

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