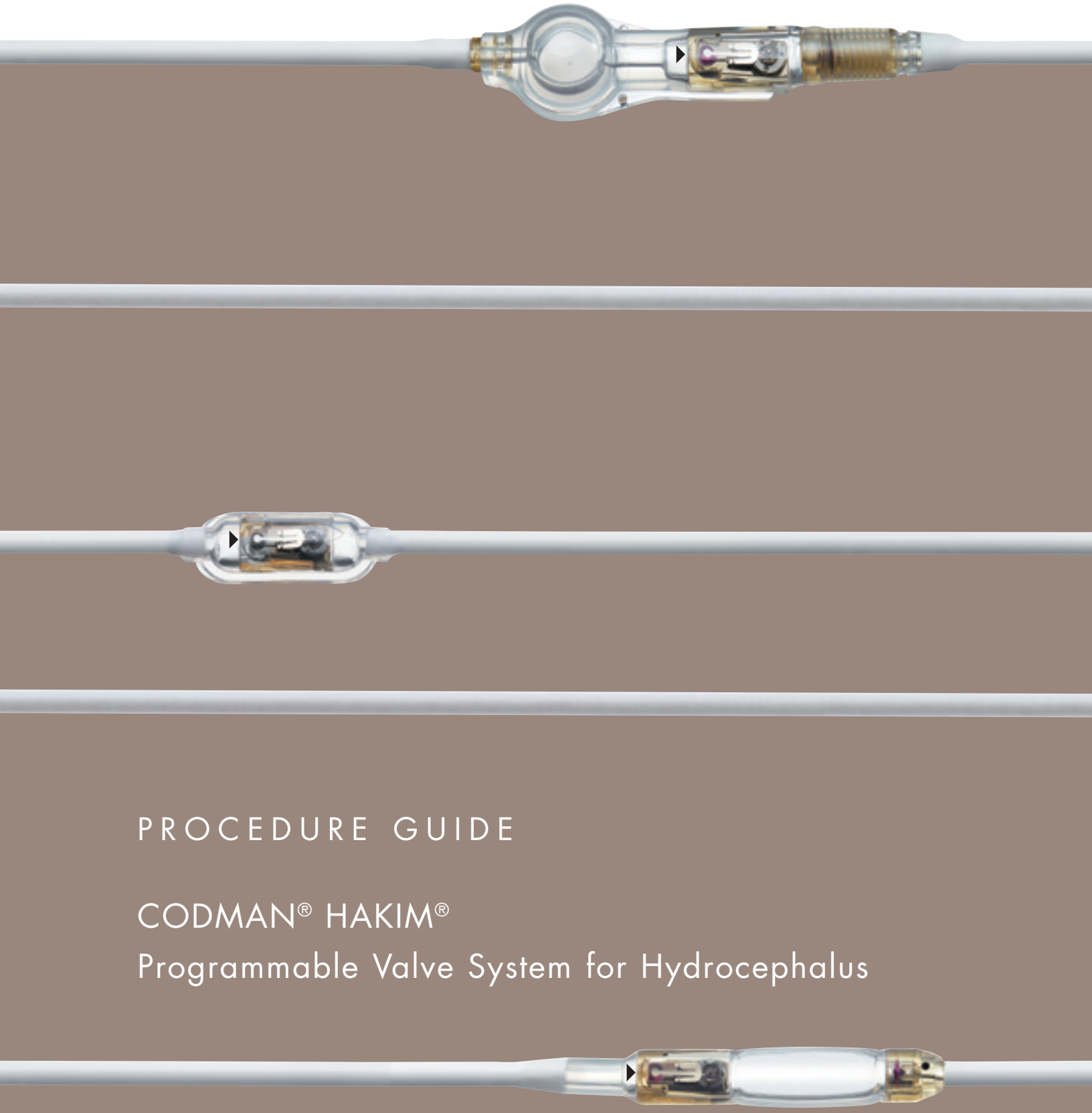

PROCEDURE GUIDE

CODMAN® HAKIM®
Programmable Valve System for Hydrocephalus

Codman
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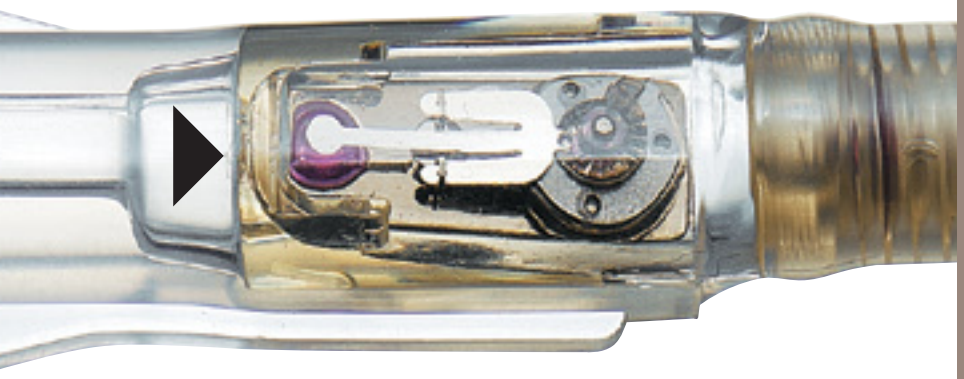
Utilizing the CODMAN HAKIM Programmer or
CODMAN Valve Positioning Verification (VPV™) System

CODMAN® HAKIM® PROGRAMMABLE VALVE FUNDAMENTALS

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 pressure changes necessary. The programmable valve allows a surgeon to non-invasively change the opening pressure between 30 mm H_2O and 200 mm H_2O 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 regimens. The setting 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.



CSF Flow →

OPERATING CODMAN HAKIM PROGRAMMER

PROGRAMMER #82-3190
To program the valve:

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

Programmer Unit #82-3190

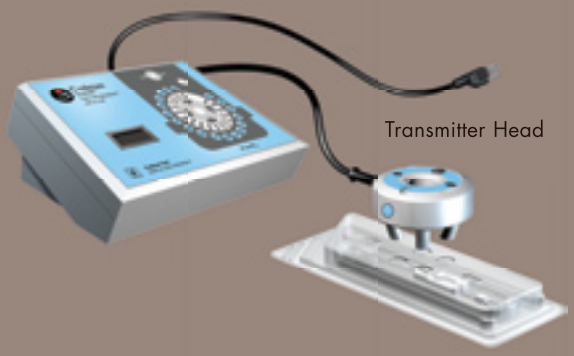
Transmitter Head

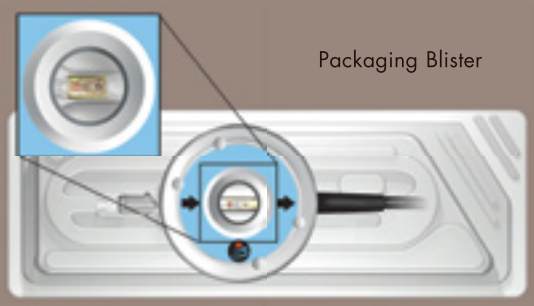
In-Line Valve with
SIPHONGUARD® Anti-Siphon Device

PREOPERATIVE PROGRAMMING

Valves are supplied without a specific setting and must be programmed prior to use. After choosing the desired initial setting, the valve can be programmed in its packaging by placing the four 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.

Programming Unit #82-3190

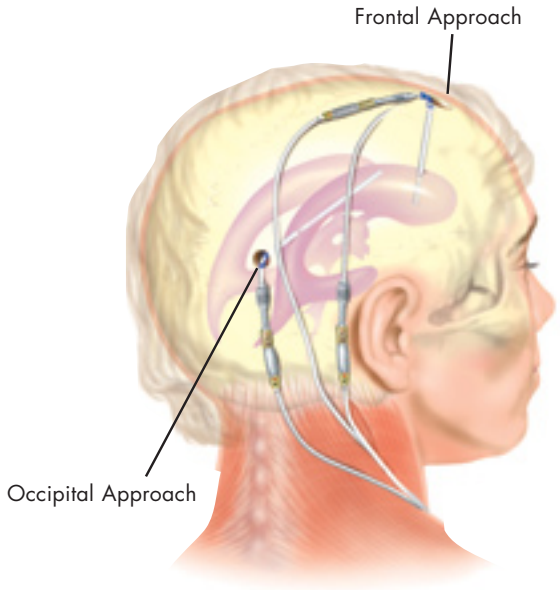


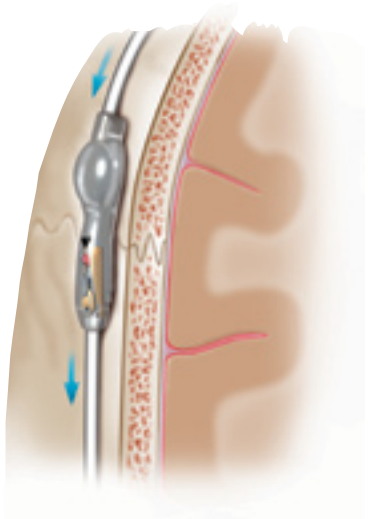


VALVE IMPLANTATION

It is acceptable to prime the valve by filling it with lint-free sterile saline or an appropriate antibiotic solution prior to implantation. If the valve housing includes SIPHONGUARD, priming the system must be reduced to a rate of approximately .5cc/minute. 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 MIcro Valve, in-Line, and Right angle housings have a flat bottom that should rest against the skull, insuring that the mechanIsm Is facIng up.

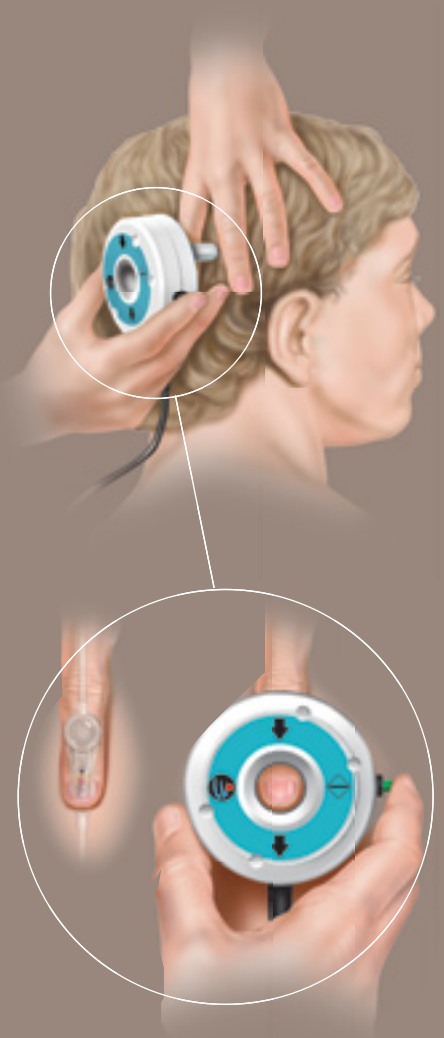




The new setting of the valve should be determined taking into account all of the patient's clinical symptoms and the surgeon's own experience. It is advisable not to increase the setting of the valve by more than 40 mm H_2O in a 24-hour period. Palpate the scalp to locate the implanted valve, then locate 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.

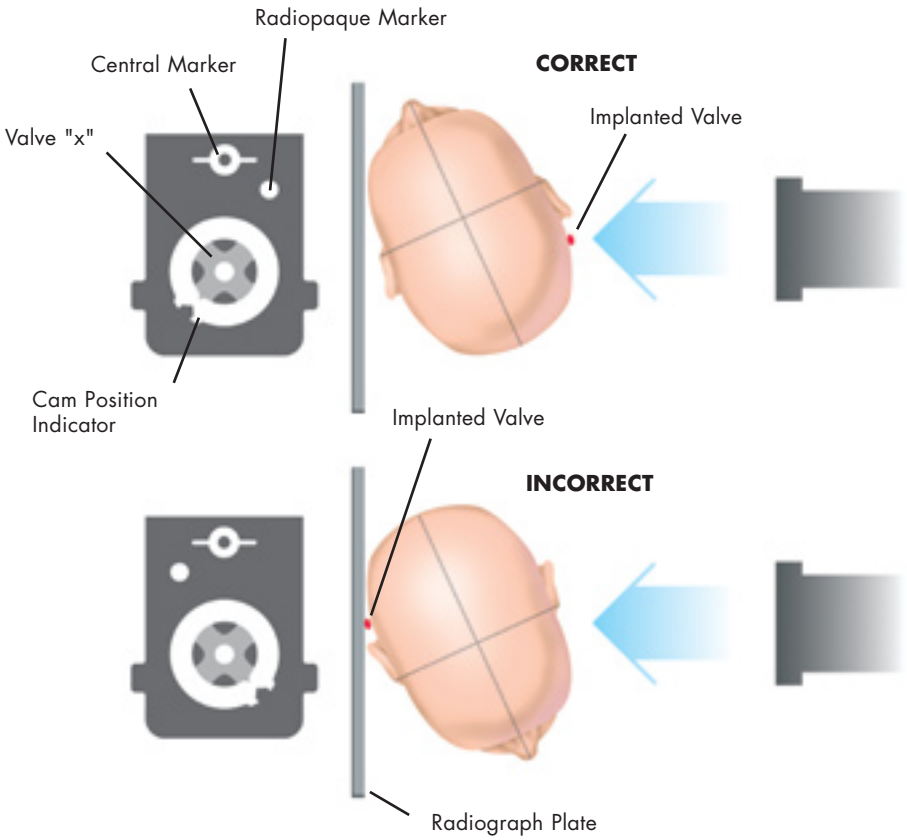
It is imperative that the transmitter head remain centered over the valve mechanism with the feet of the transmitter head touching the scalp during the entire programming cycle. If the transmitter head is not aligned properly with the valve, or if it moves during the programming cycle, incorrect programming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



PRESSURE SETTING VERIFICATION

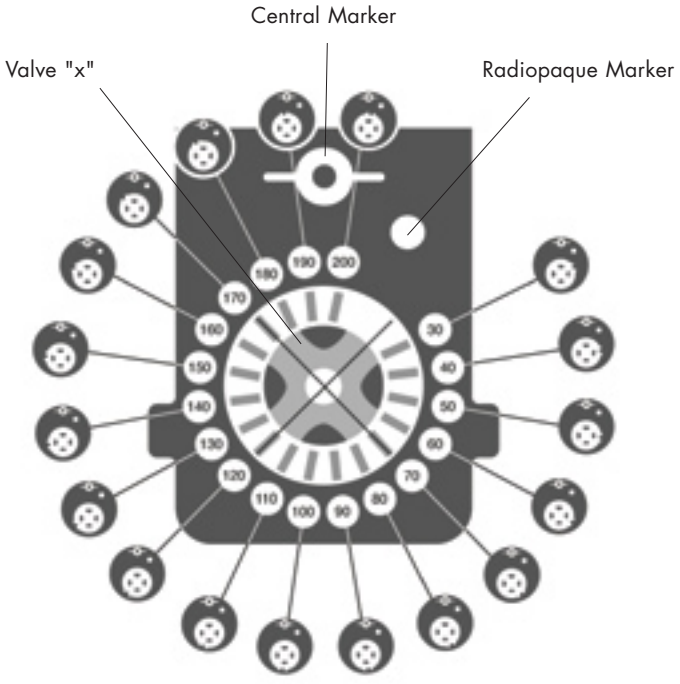
It is advisable to x-ray the complete system immediately after implantation to have a permanent record of component placement and to verify valve pressure. It is also advisable to x-ray the valve whenever valve pressure is reprogrammed or if the patient undergoes an MRI.

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 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 base plate of the valve.

Comparing the patient radiographs to the diagram on the programming unit panel will indicate the valve setting. Note that settings of 70, 120 and 170 mm H_2O align with the cross in the center of the valve.



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

OPERATING PROCEDURES FOR VALVE POSITIONING VERFICATION (VPV™) SYSTEM #82-3192
Valve Adjustment: Implanted Valve Mode

1. Turn on the VPV Programmer Unit. The implanted valve icon illuminates.
2. The program unit beeps and the LED panel displays the following message: IMPLANTED VALVE PLEASE SELECT PRESSURE.
3. Press the appropriate setting selection key. The program unit beeps; the corresponding LED illuminates. At the same time, the display changes to: IMPLANTED VALVE, POSITION TRANSMITTER HEAD, and PRESS START.
4. Palpate the scalp to locate the shunt and the implanted valve. Gently palpate the valve to locate the hard inlet portion, approximately 10mm long. Place your fingertip on the scalp directly over the inlet portion.
5. Part any hair with fingertips. Apply a pea-sized amount of ultrasound gel, approximately 2mm thick, to the patient's scalp. Alternate method: apply ultrasound gel to the entire bottom surface of the center rod to a thickness of approximately 2mm.
6. Before placing transmitter on the scalp, ensure that the arrow on the transmitter is in line with the direction of fluid flow through the shunt.
7. Place the transmitter on the scalp so the center rod is directly over the hard inlet portion of the valve and the transmitter's feet contact the patient's scalp. The center rod may recede slightly and the gel will compress. Hold Transmitter in place until adjustment is complete (approximately 3 seconds). Eliminate or minimize ambient noise. Excessive noise can interfere with the acoustic monitoring process.
8. Press the transmitter's blue start button. The program unit beeps once and the LCD display changes to: ADJUSTING VALVE PLEASE WAIT.
9. During the adjustment, the setting selection keys light sequentially and the program unit emits a series of clicks until the selected setting command has been issued to the valve.
10. When the adjustment is complete (approximately 3 seconds), the program unit emits on long beep and the display changes to: ADJUSTMENT COMPLETE PRESS A KEY.

    NOTE: If the acoustic monitoring feature did not receive an expected response, the program unit will emit three beeps and one of the two messages will be displayed.

    REPEAT ADJUSTMENT or NO SIGNAL REPEAT ADJUSTMENT PRESS A KEY.

    After the "ADJUSTMENT COMPLETE" message is displayed press any key to clear. The LCD panel will change to the original message: IMPLANTED VALVE PLEASE SELECT PRESSURE.

    The VPV Programmer provides confirmation of the valve adjustment **without the need for radiographic imaging when the "ADJUSTMENT COMPLETED" message is displayed.**

The CODMAN VPV™ system has two modes of operation: packaged valve mode and implanted valve mode.

Implanted Valve Icon

Implanted Valve Mode
The implanted valve mode is used when adjusting the setting of a valve postoperatively when the patient's scalp is intact. When the implanted valve mode is selected, the acoustic monitoring feature is active.

CENTER ROD

Acoustic Monitoring
When the implanted valve mode is selected, a sensor contained within the transmitter detects valve vibration as the setting of the valve is changed.

Packaged Valve Mode
The packaged valve mode is used when adjusting the setting of a valve in the package before implantation and when adjusting the setting of a recently implanted valve when the patient skin integrity requires a sterile barrier. When the packaged valve mode is selected, the acoustic monitoring feature is not active.

This technique guide is not intended to replace the "Instructions for Use" for the CODMAN VPV System. Refer to I.F.U. for further instructions if needed.

Transmitter Head (side)

Transmitter Head (bottom)

PRESSURE SETTINGS

To Obtain this Pressure in the Inverted System	Pressure Formula	Program this Pressure on the Programmer
30 mm H_2O	210 - 30 = 180	180 mm H_2O
40 mm H_2O	210 - 40 = 170	170 mm H_2O
50 mm H_2O	210 - 50 = 160	160 mm H_2O
60 mm H_2O	210 - 60 = 150	150 mm H_2O
70 mm H_2O	210 - 70 = 140	140 mm H_2O
80 mm H_2O	210 - 80 = 130	130 mm H_2O
90 mm H_2O	210 - 90 = 120	120 mm H_2O
100 mm H_2O	210 - 100= 110	110 mm H_2O
110 mm H_2O	210 - 110 = 100	100 mm H_2O
120 mm H_2O	210 -120 = 90	90 mm H_2O
130 mm H_2O	210 - 130 = 80	80 mm H_2O
140 mm H_2O	210 - 140 = 70	70 mm H_2O
150 mm H_2O	210 - 150= 60	60 mm H_2O
160 mm H_2O	210 - 160= 50	50 mm H_2O
170 mm H_2O	210 -170 = 40	40 mm H_2O
180 mm H_2O	210 - 180 = 30	30 mm H_2O
190 mm H_2O	N/A	N/A
200 mm H_2O	N/A	N/A

INVERTED VALVE ADJUSTMENT: CODMAN HAKIM PROGRAMMER

#82-3190

Prior to following the procedure to perform adjustment of an inverted valve, review the section on setting verfications in the Instructions for Use to insure that the radiographs were taken and read in the proper orientation.

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 setting.

1. Program the valve with the valve programmer (82-3190) 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 1-3, otherwise the programming will be incorrect.

Note: When the valve is inverted, pressure settings of 190 and 200 are not possible to program with 82-3190. See instructions for 82-3192 below.

INVERTED VALVE ADJUSTMENT & CONFIRMATION: VPV PROGRAMMER

#82-3192

An inverted valve can be diagnosed on x-ray: the white marker appears on the left side of the valve, instead of the right side. When an inverted valve has been diagnosed, use the inverted valve adjustment cycle to adjust the valve to **any** of the 18 settings. This optional command is in effect for one adjustment cycle only. Follow the steps below to enable this feature.

1. If the program unit power is on, turn it off. Turn power on. The title screen displays for 3 seconds. The display changes to: CODMAN VPV VERSION 1.27 (or other).

   While the title screen is displayed, press the “70” key on the program unit front panel. The display changes to: ADJUST INVERTED VALVE? 30 = YES 40 = NO.

2. Press the “30” key to set the next adjustment cycle for an inverted valve, or press “40” to exit. When you press “30,” the display changes to: ADJUST INVERTED VALVE? PLEASE CONFIRM 80 = YES 40 = NO.

3. To confirm that the next adjustment cycle is for an inverted valve, press “80”; or press “40” to cancel and exit. When you press “80,” the display changes to: IMPLANTED VALVE INVERTED VALVE PLEASE SELECT PRESSURE.

   The VPV Programmer provides confirmation of the valve adjustment **without the need for radiographic imaging when the "ADJUSTMENT COMPLETED" message is displayed.**

   Proceed as usual, following the steps in Valve Adjustment: Implanted Valve Mode. At the end of the adjustment cycle, the program unit returns to the normal adjustment cycle.

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The CODMAN® HAKIM® Programmable Valve is considered to be "MRI Conditional" according to ASTM F2503. 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 MRI System with a static magnetic field of 3 tesla or less
- Use an MRI System with a spatial gradient of 720 Guass/cm or less
- Limit the exposure to RF energy to a whole-body-averaged specific absorption rate (SAR) of W/kg for 15 minutes
- Verify the valve setting after the MRI procedure (see 'Programming the Valve')

In non-clinical testing, the CHPV produced a temperature rise of 0.4°C at a maximum whole body averaged specific absorption rate (SAR) of 3.0W/kg for 15 minutes of MR scanning in a 3-Tesla Excite® General Electric MR scanner.

For more information, contact your Codman Sales Representative

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For product information, call (800) 225-0460 • www.codman.com

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