

# Codman®

Hakim®  
Programmable Valve System  
for Hydrocephalus

Utilizing the Codman® Hakim®  
Programmer or Codman® Valve  
Positioning Verification  
(VPV®) System



**Codman®**  
SPECIALTY SURGICAL

A DIVISION OF INTEGRA LIFESCIENCES

### 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<sub>2</sub>O and 200 mm H<sub>2</sub>O 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.

### Operating Codman Hakim Programmer



Programmer Unit #82-3190R, 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.

Transmitter Head



In-Line Valve with SiphonGuard® Anti-Siphon Device

## Preoperative Programming

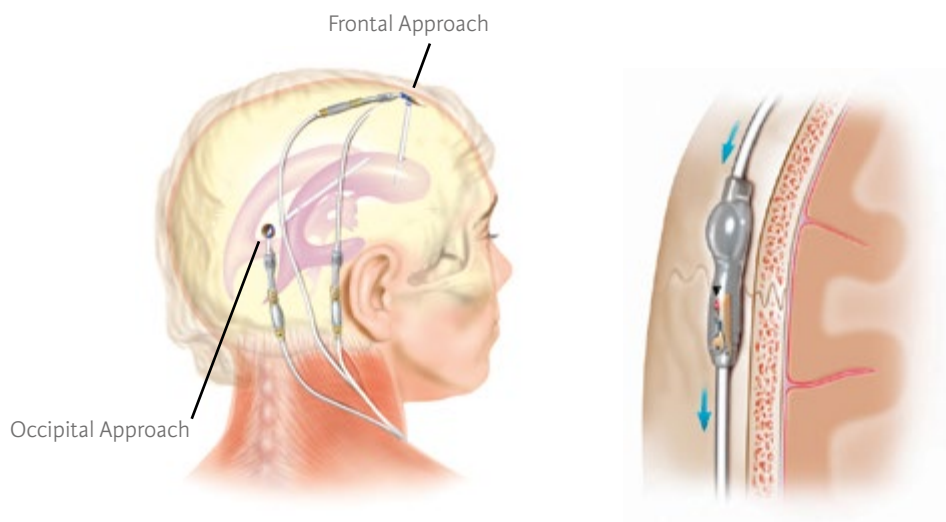
Valves are supplied without a specific setting and must be programmed prior to use. After choosing the desired initial setting, the valve can be programmed in its packaging by placing the four feet of the transmitter head in the four blister depressions over the valve mechanism and aligning the arrows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



## Valve Implantation

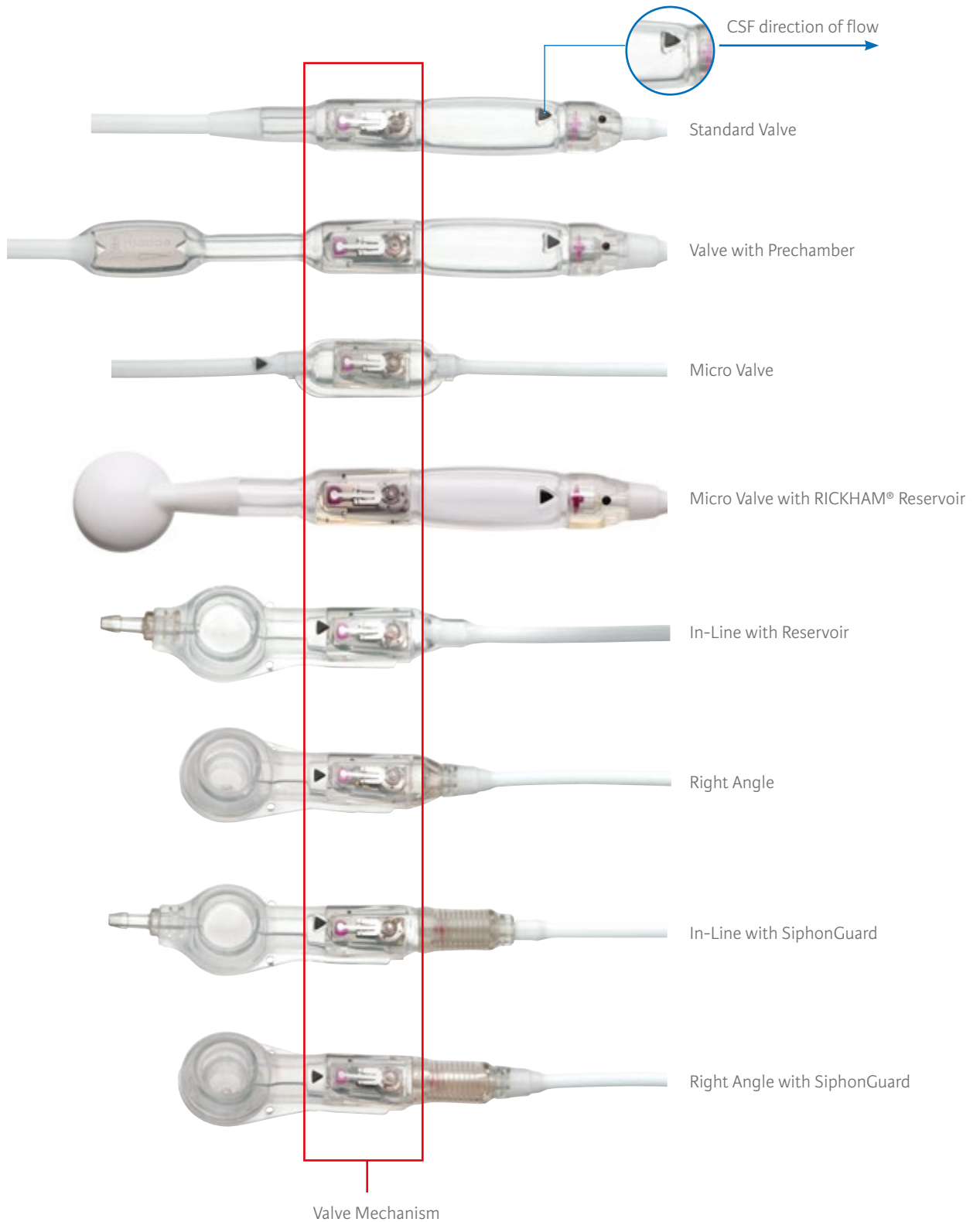
It is acceptable to prime the valve by filling it with lint-free sterile saline or an appropriate antibiotic solution prior to implantation. If the valve housing includes SiphonGuard® Anti-siphon Device, priming the system must be reduced to a rate of approximately 0.5cc/minute. The valve mechanism should 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 standard housings, with and without prechamber, have a black dot indicating which side should face upwards. 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.



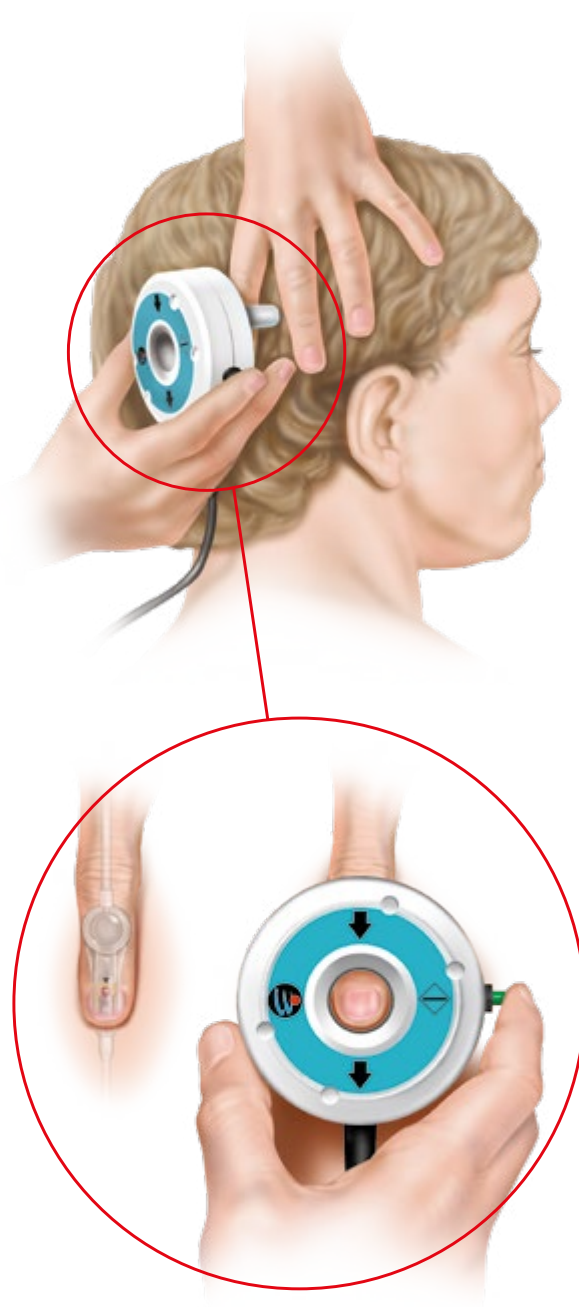
### Postoperative Programming

The new setting of the valve should be determined by 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<sub>2</sub>O 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 direction of flow through the valve.

It is imperative that the transmitter head remains centered over the valve mechanism, the direction of flow arrow on the transmitter head aligns with the valve's direction of flow 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.

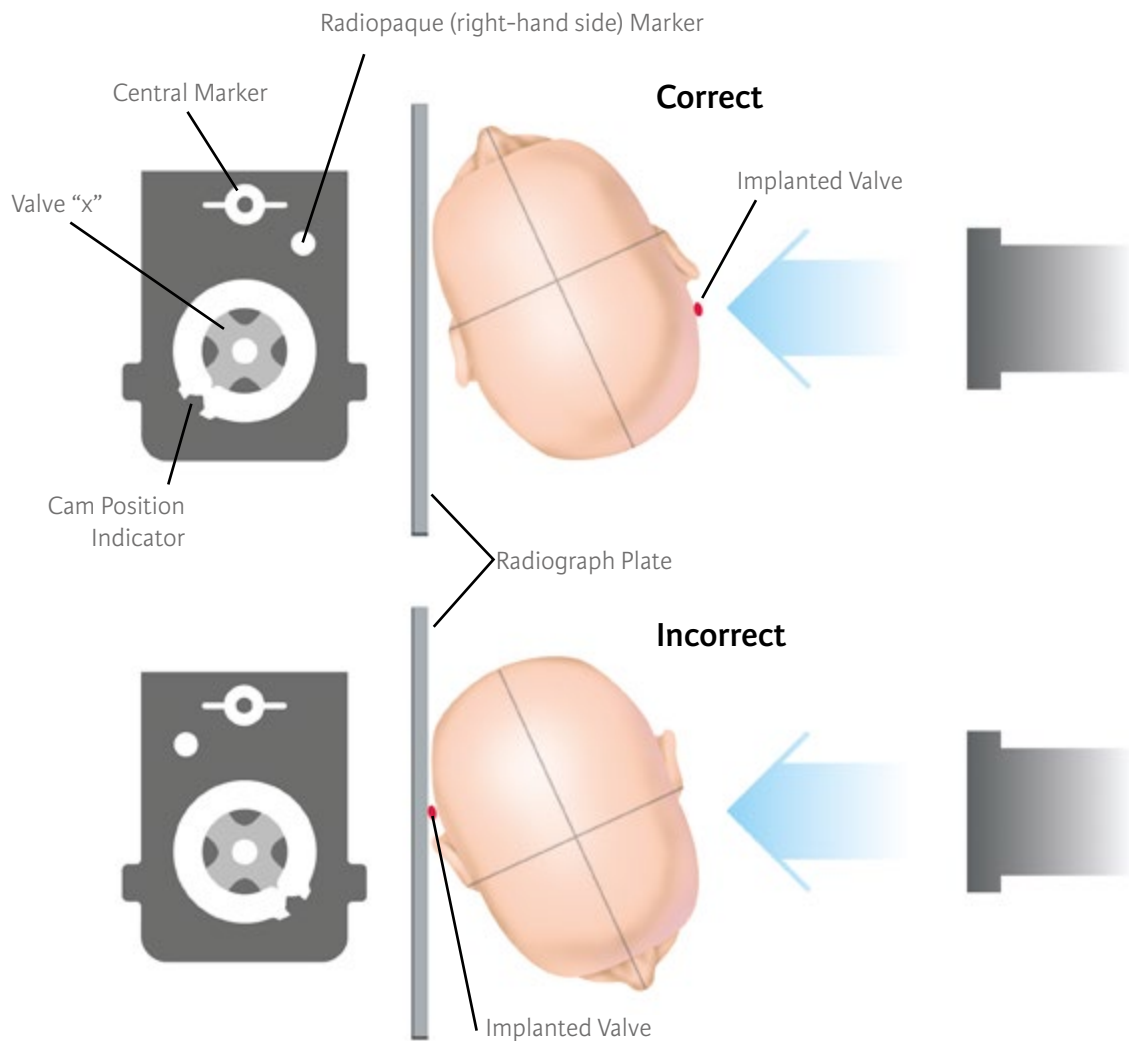


This technique guide is not intended to replace the “Instructions for Use” for the Codman Hakim Programmer System. Refer to the corresponding IFU for further instructions, if needed.

### Pressure Setting Verification

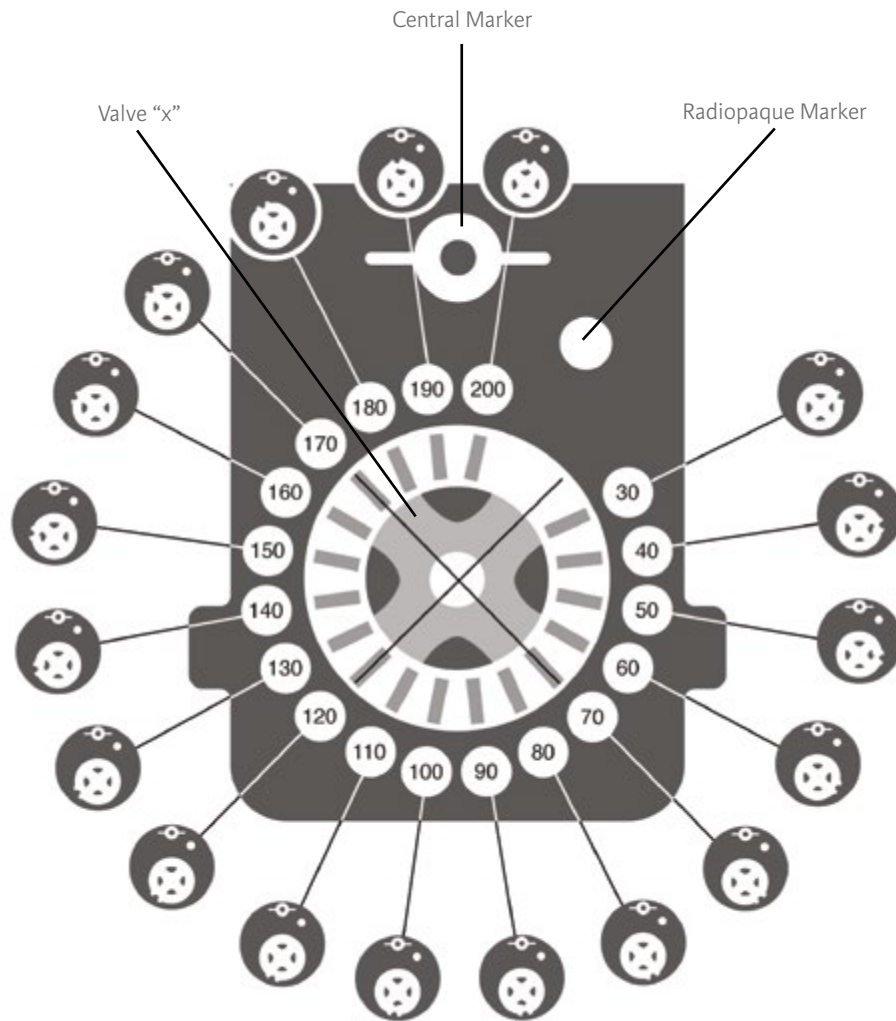
It is advisable to x-ray the complete system immediately after implantation to have a permanent record of component placement and to verify valve pressure. It is also advisable to x-ray the valve whenever valve pressure is reprogrammed or if the patient undergoes an MRI.

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.

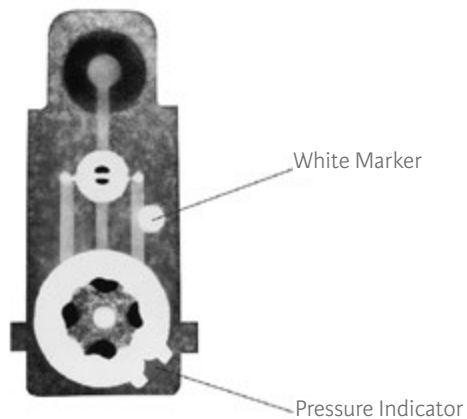


The setting of the valve can be determined by comparing the position of the radiopaque marker on the valve cam to the fixed position of the radiopaque right-hand side indicator on the base plate of the valve.

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<sub>2</sub>O align with the cross in the center of the valve.



**NOTE:** Remember to verify valve pressure setting after an MRI.



## Postoperative Programming



### Operating Procedures for Valve Positioning Verification

(VPV®) System #82-3192R, 82-3192

#### Valve Adjustment: Implanted Valve Mode

1. Turn on the VPV Programmer Unit. Select “implanted valve” mode by pressing the corresponding raised button situated above the LCD display. The implanted valve icon illuminates.
2. The programmer unit beeps and the LED panel displays the following message: IMPLANTED VALVE PLEASE SELECT PRESSURE.
3. Press the appropriate setting selection key. The programmer 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 2 mm 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 2 mm.

**CAUTION: Avoid contact between the gel and the feet of the transmitter. This can distort the acoustic signal and cause a “REPEAT ADJUSTMENT” message to be displayed.**

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 to a size equal or slightly larger than the center rod to create an air-free area.

**CAUTION: Hold the transmitter in place until Step 10 is complete. Movement can interfere with the acoustic monitoring process.**

**CAUTION: Eliminate or minimize ambient noise, such as talking, during the adjustment process. Excessive noise can interfere with the acoustic monitoring process.**

8. Press the transmitter’s blue start button. The programmer 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 programmer unit emits one 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.**

## Programmer Unit Mode Selections



Implanted  
Valve Icon



Center Rod



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

### 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.

### 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 IFU for further instructions, if needed.

Transmitter Head (side)



Transmitter Head (bottom)



## Inverted Valve Adjustment: Codman Hakim Programmer

Programming Unit #82-3190R, 82-3190



Prior to following the procedure to perform adjustment of an inverted valve, review the section on setting verifications 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 (82-3190R, 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 82-3190R, 82-3190. See pressure calculation table below.

### Pressure calculation for an inverted valve

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

## Inverted Valve Adjustment & Confirmation: VPV Programmer



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 programmer 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 version number). 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.

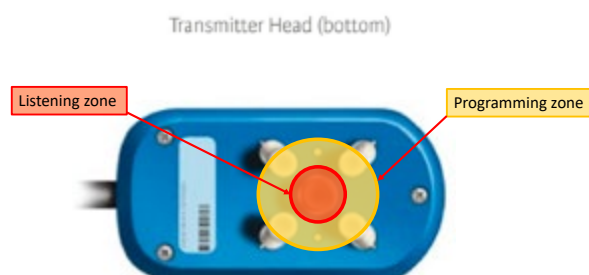
The VPV Programmer provides confirmation of the valve adjustment **without the need for radiographic imaging when the ADJUSTMENT COMPLETED message is displayed.**

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

Recommendations for successful programming of implanted Codman Hakim Programmable Valve valves with the Codman VPV programmer:

- Test the central rod of the transmitter (acoustic element) that its spring mount mechanism is moving freely.
- After locating the valve mechanism under the skin (hard rectangular part of the device), identify it by placing a mark on the skin with a skin marker.
- Always use ultrasound gel to benefit from the acoustic functionality of the transmitter.
- Make sure not to exceed the recommended pea-sized amount of gel.
- Make sure there is no gel on the transmitter feet.
- Transmitter works best when its feet are resting on patient's skin.
- Make sure that the center rod is not fully depressed should the patient have an exceptionally thick skin.
- Avoid ambient unnecessary noise as it would interfere with the acoustic device detection performance.
- After each use and before storage, clean the transmitter and specifically the center rod with a damp cloth and a mild detergent.
- Codman VPV programmer would be able to confirm programming only if the valve mechanism is within the "listening zone" and there is no major ambient noise interference. See image below.
- Cranial defects can affect the orientation of the transmitter. Position the transmitter parallel to the valve plane rather than rely on the feet sitting on the scalp to produce the correct parallel orientation.
- If thick and abundant hair causes an air gap between the center rod and skin, fill the gap completely with ultrasound gel.

The above are recommendations based on expert users experiences, they do not replace the instructions included in the VPV programmer's. Instructions for use document. Please see the Codman VPV programmer instructions for use for more details.



### Codman Hakim Programmable Valve

#### 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 non-unitized 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.

### Codman Hakim Programmer

#### Indications and Usage

The HAKIM Programmer and Transmitter are designed for use only with CODMAN® HAKIM Programmable Valves in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain.

### Codman VPV Programmer

#### Indications

The System is designed for use only with CODMAN® HAKIM® Programmable Valves in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. It is used to noninvasively adjust the CODMAN HAKIM Programmable Valve to the selected setting and provides confirmation of the valve adjustment, without the need for radiographic imaging when an "Adjustment Complete" message is displayed.

#### Contraindications

There are no known contraindications for the use of the CODMAN VPV System.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.

Products mentioned in this document are CE class I, IIb and III devices. Contact Integra should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED".

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