

STANDARDIZED PROCEDURE
Programming Codman Hakim and PS Medical STRATA
Programmable Shunt Valves (Adult, Peds)

I. Definition

The Codman Hakim Programmable Valve and PS Medical STRATA Valve Systems were developed in response to the known shortcomings of classic fixed pressure shunts. These valves are precise mechanical devices that have the ability to subtly change the opening pressure of the shunt system non-invasively after implantation. The programmable shunt valve systems are implantable devices that provide constant intraventricular pressure and drainage of cerebrospinal fluid (CSF) for the management of hydrocephalus and other conditions in which CSF flow and absorption is impaired. It allows practitioners to optimize the opening pressure of the shunt both pre- and post-implantation, eliminating the need to determine the ideal pressure setting prior to implantation and the need for revision surgery to change the shunt pressure.

II. Background Information

A. Setting: The setting (inpatient vs outpatient) and population (adults vs pediatrics) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form. If the procedure is being done on a Pediatric patient, make sure Child Life is involved and use age appropriate language and age appropriate developmental needs with care of children, as appropriate to the situation.

B. Supervision: The necessity of this protocol will be determined by the Advanced Health Practitioner in collaboration with the supervising physician or his/her designee. Designee is defined as another attending physician who works directly with the supervising physician and is authorized to supervise the Advanced Health Practitioner.

Direct supervision will not be necessary once competency is determined, as provided for in the protocol. The Advanced Health Practitioner will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance to the procedure
2. Bleeding that is not resolved
3. Outcome of the procedure other than expected

C. Indications

Programming the adjustable valve is to be performed only by those AHPs who have been trained by qualified MD's and manufacturer's representatives.

D. Precautions/Contraindications

Precaution should be used when patients undergo magnetic resonance imaging (MRI) as the magnet can move the valve setting in either direction, inadvertently changing the valve pressure. Shunt valve system setting verification must be

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checked post-MRI to evaluate for any deviation from known prior setting before imaging.

With respect to the Codman Hakim Programmable Valve System, X-ray confirmation must be obtained prior to making any adjustment to the valve system if valve setting uncertain at programming session.

In Codman Hakim Programmable Valve Systems, X-ray confirmation must be obtained after making adjustments to the valve.

Consider the following risks associated with programmable valve systems:

1. Overshunting: subdural hematoma
2. Undershunting/Shunt Valve Failure: hydrocephalus

III. Materials

1. Codman Hakim programmer and PS Medical STRATA Valve Adjustment Kit provided by manufacturer.
2. Access to radiology department.

IV. Programming Codman Hakim/PS Medical STRATA Valve Systems

A. Pre-Treatment Evaluation

1. Assess mental status, pain score, medication record, activity record, associated symptoms (nausea, vomiting, visual changes), baseline neurological exam, and evaluation of most recent CT/MRI scans.
2. Confirm current setting of programmable valve.
 - a. Codman Hakim: Evaluate prior X-ray. If setting unknown, obtain baseline single view skull X-ray (see procedure below).
 - b. STRATA valve: Confirm current setting using indicator tool (see procedure below).
3. Determine new pressure setting based on signs and symptoms, recent scans and physician consultation.
 - a. Codman Hakim: Do not increase/decrease valve setting more than 40 mm H₂O.
 - b. STRATA valve: Do not increase/decrease more than 2 pressure level settings.

B. Set-Up

1. Properly functioning Codman Hakim programmer or PS Medical STRATA Valve Adjustment Kit.
2. Comfortable, private environment for patient and practitioner to complete programming session.

C. Prepare Patient

1. Perform a time-out in order to check two patient identifiers and check for allergies.

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2. Describe procedure to patient and support persons.
3. Discuss goals of procedure, time frame for expected results.

D. Perform Procedure

1. Codman Hakim Valve System
 - a. confirm exact location of valve mechanism under scalp (direct palpation, prior X-ray if necessary).
 - b. properly position the programmer head over the valve mechanism. The arrows on the programmer head should face the same direction as CSF flow through the valve. Make sure the feet of the programmer head are touching the patient's skin.
 - c. Select the desired pressure on the programmer unit. Press and release the button on the programmer head while holding it over the valve. Wait until the unit beeps (approx. 4-8 seconds) before moving the programmer head.
2. PS Medical STRATA Valve
 - a. Confirm exact location of valve mechanism under scalp (direct palpation, prior X-ray if necessary).
 - b. Confirm current setting of programmable valve. Position the "locator tool" over the valve with the blue arrow facing the direction of CSF flow through the valve. Keeping the "locator tool" in position set the "indicator tool" into the "locator tool" while aligning the red bands on the tools. The blue triangle on the "indicator tool" will point to the valve's current pressure setting.
 - c. The "indicator tool" may give false pressure readings unless it is centered over the valve mechanism.
 - d. Make sure the "adjustment tool" is at least 18 inches away from the "indicator tool" to avoid magnetic influences on the settings.
 - e. Keep the "locator tool" in position while removing the "indicator tool". Set the "adjustment tool" into the "locator tool" with the blue triangle facing the current pressure setting. Rotate the "adjustment tool" to the desired pressure setting.
 - f. Holding the "locator tool" in place, remove the "adjustment tool". (Keep at least 18 inches away from valve). Set the "indicator tool" into the "locator tool" while aligning the red bands on the tools. The blue triangle will point to the new pressure setting.

E. Post Procedure

Codman Hakim Valve System

1. Verify the new pressure setting with proper radiograph of valve system. The X-ray must be shot perpendicular to the valve with the non-implanted side of the patient's head resting on X-ray plate. The angle of the X-ray should be parallel with the angle of the plate. (See Codman Hakim manual for further details.

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2. Interpretation of X-ray: Valve has a pressure indicator wheel that is notched and visible on X-ray. Compare the location of the notch with the pocket card showing a matching wheel and associated pressure settings. Make sure the white marker dot on the valve (seen on X-ray) is on the right-hand side.
3. Repeat X-ray if notch and white marker are not visible.
4. Repeat reprogramming if notch is not positioned at desired pressure setting. Confirm with repeat X-ray.

PS Medical STRATA Valve

1. If there is uncertainty about the pressure setting, repeat step 2 of procedure or obtain skull X-ray. (Use same approach as Codman Hakim System). See Medtronic manual for interpretation of X-ray.
2. Follow-Up Treatment
 - a. Instruct patient/ family to call for any neurological changes or problems at any time
 - b. Follow-up clinic appointment if no symptomatic improvement within 2 weeks after reprogramming.
 - c. Educate patients that strong magnetic fields such as MRI scans can change the valve pressure setting.

V. Documentation

A. Documentation is in the electronic medical record

1. Documentation of the pretreatment evaluation and any abnormal physical findings.
2. Record the time out, indication for the procedure, procedure, new shunt valve setting and verification by X-Ray if indicated. Confirmation of valve setting by X-Ray following MRI is also to be documented. The outcome, how the patient tolerated the procedure, medications (drug, dose, route, & time) given, complications, and the plan in the note, as well as any teaching and discharge instructions should be documented.

B. Abnormal Findings are reviewed with supervising physician.

VI. Competency Assessment

A. Initial Competence

1. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
2. The Advanced Health Practitioner will demonstrate knowledge of the following:
 - a. Medical indication and contraindications of Programming Codman Hakim and PS Medical STRATA programmable shunt valves

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- b. Risks and benefits of the procedure
 - c. Related anatomy and physiology
 - d. Consent process (if applicable)
 - e. Steps in performing the procedure
 - f. Documentation of the procedure
 - g. Ability to interpret results and implications in management.
2. Advanced Health Practitioner will observe the supervising physician perform each procedure three times and perform the procedure **three** times under direct supervision.
 3. Supervising physician will document Advanced Health Practitioner's competency prior to performing procedure without supervision.
 4. The Advanced Health Practitioner will ensure the completion of competency sign off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

B. Continued proficiency

1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.
2. Each candidate will be initially proctored and signed off by an attending physician. Advanced Health Practitioner must perform this procedure at least **three** times per year. In cases where this minimum is not met, the attending, must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner will be signed off after demonstrating 100% accuracy in completing the procedure.
3. Demonstration of continued proficiency shall be monitored through the annual evaluation.
4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted.

VII. RESPONSIBILITY

Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at 353-4380.

VIII. HISTORY OF PROCEDURE

Revised Sept 2012 by the Subcommittee of the Committee for Interdisciplinary Practice

Reviewed Sept 2012 by the Committee on Interdisciplinary Practice

Prior revision October 2008

Approved Sept 2012 by the Executive Medical Board and the Governance Advisory Council.

This procedure is intended for use by UCSF Medical Center staff and personnel and no representations or

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