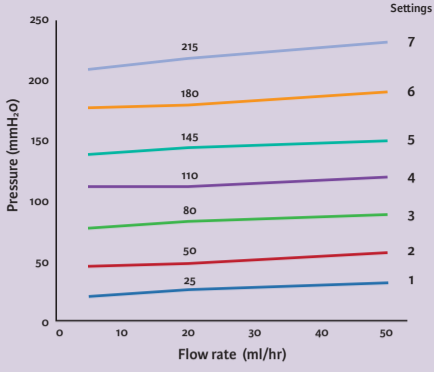


Codman® CERTAS™ Plus Programmable Valve

Performance Setting



The valves perform within a tolerance range of the average pressure as shown here regardless of gravitational orientation:

Settings 1, 2, 3	±20 mm H ₂ O
Setting 4	±25 mm H ₂ O
Settings 5, 6, 7	±35 mm H ₂ O
Setting 8	is intended to limit flow through the valve and has a minimum pressure of 400 mm H ₂ O

Codman Certas® Plus Programmable Valves were made available after March 2015

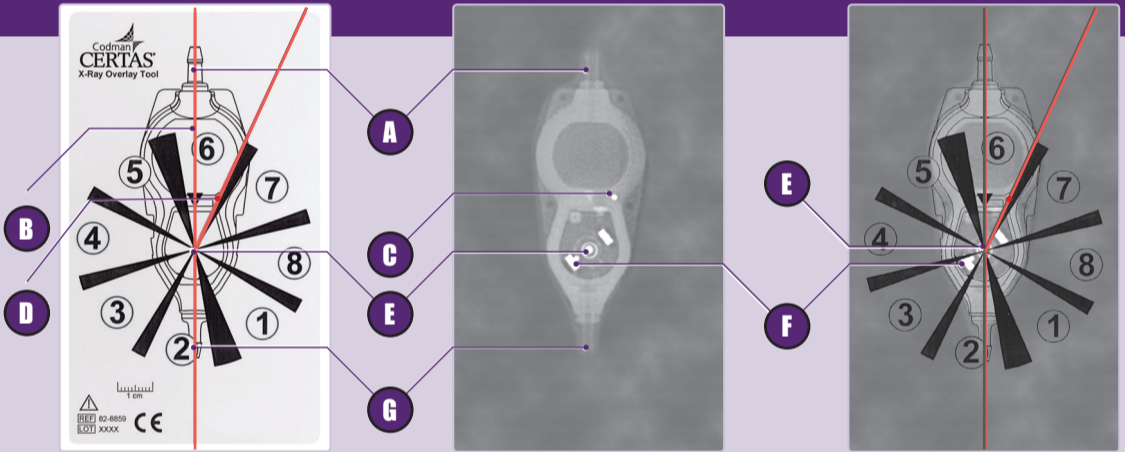
Codman® CERTAS™ Plus Programmable Valve

Reading the Valve Setting with the X-Ray Overlay Tool

Note: Position the X-Ray Overlay Tool flush against the x-ray image.

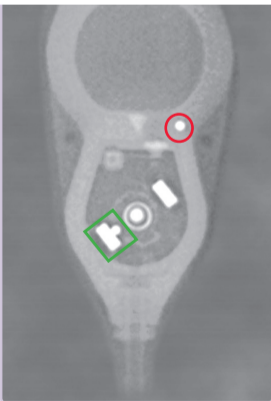
- Align the **RED** centerline of the valve on the overlay with the centerline of the valve x-ray under review. This can be accomplished by aligning the proximal and distal connectors of the x-ray image with those on the overlay.
- Ensure that the numbers on the Overlay Tool that depict the performance settings are properly oriented for viewing. In this orientation the right hand side (RHS) marker red line extends to the right of the **RED** centerline. This ensures proper overlay orientation.
- Align rotating construct (RC) center dot on overlay with the center of the RC of the x-ray image.
- Ensure RHS marker red line containing red dot is aligned with the RHS marker of the x-ray image (if present).
- The valve setting is determined by identifying the region of the overlay that contains the majority of the image of the magnet that has the tantalum ball adjacent to it.

- A** PROXIMAL CONNECTOR
- B** RED CENTERLINE OF VALVE
- C** RIGHT HAND SIDE (RHS) MARKER
- D** RHS MARKER RED LINE (CONTAINS RHS DOT)
- E** ROTATING CONSTRUCT (RC)
- F** MAGNET WITH TANTALUM BALL (SETTING INDICATOR)
- G** DISTAL CONNECTOR



Codman® CERTAS™ Plus Programmable Valve

X-Ray Performance Setting



- Right Hand Side (RHS) X-Ray Marker
- Setting Indicator



INDICATIONS The Codman® CERTAS™ Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus. The Codman CERTAS® Tool Kit allows the noninvasive reading or adjustment of the valve setting for the CODMAN CERTAS and CERTAS Plus Programmable Valves.

The CERTAS Plus Electronic Tool Kit allows the non-invasive reading or adjustment of the valve setting for the CERTAS and CDERTAS Plus Programmable Valves. At end of Warnings section after MRI valve discussion, add: CAUTION: Do NOT use the Certas Plus Electronic Tool Kit in the MR suite.

CONTRAINDICATIONS These devices are contraindicated in patients receiving anticoagulants or known to have 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. The BACTISEAL® Catheters are contraindicated in patients with known hypersensitivity to rifampin or clindamycin hydrochloride.

WARNINGS •Choose an implant site for the valve where the tissue over the valve is not too thick (i.e. tissue thickness <10 mm). Otherwise locating, reading, and adjusting the valve with the tool kit may be difficult (i.e.: multiple attempts maybe required) or impossible. If unable to adjust the valve, the valve will maintain a constant operating pressure and the patient should be informed of this risk (see Tool Kit Instructions for Use for more information). •As with all programmable valves, the magnets within the CERTAS Plus valve will cause an image artifact on CT and MRI imaging. As a result, the implantation site should be chosen so that the artifact will be minimized in areas of significant clinical interest, such as a tumor, that may require repeated future imaging assessment. •Testing shows that the valve mechanism is resistant to unintended changes in the

setting in a 3 Tesla MRI. However, the clinician should confirm the valve setting after a magnetic resonance imaging (MRI) procedure. •The valve setting is adjusted with the application and manipulation of strong magnets. A change to the valve setting is unlikely to occur under normal circumstances. However, magnetic fields should not be placed near the valve due to the possibility of an unintentional setting change. •Read MRI information before performing an MRI procedure on a patient implanted with the valve. •Any magnet may experience a degradation of magnetic field strength as a consequence of exposure to the significantly stronger magnet field induced in an MRI procedure. •Based on the coercivity of the CERTAS Plus magnet material, the valve is resistant to magnetic degradation in a 1.5T MRI. •Testing of the CERTAS Plus valve following exposure to simulated MRI procedures at 3T indicates there is no substantial demagnetization or significant reduction in programmability. Please refer to the Tool Kit IFU if any difficulty in programming occurs.

- 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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Adjustment Tool

Locator Tool

1. Power On



Press and hold the purple button until the screen turns on. CERTAS™ Plus logo will appear, followed by the calibration screen.

2. Calibrate



Tap the purple button to complete calibration. After calibrating, the device is ready for use.



System-ready screen = Calibration completed



Note: If the above screen is shown, remove the Adjustment Tool and place it 60 cm (24 in) away from the Locator Tool.

3. Palpate



Palpate and determine the flow direction of the valve.

*Note: System is unable to detect valve orientation.

4. Locate



Place the Locator Tool over the implanted valve. The concave section of the base should be in contact with the patient.

Move the device so that the locating dot will align into the circle within the valve. Move the device in a linear direction parallel to the valve.

5. Indicate Setting



Once centered, the locating dot will illuminate in white with a checkmark and the current valve setting appears.

6. Adjust Setting



Insert the Adjustment Tool into the Locator Tool so that the line on the Adjustment Tool is pointing toward the current setting.

Turn the Adjustment Tool directly to the desired setting.

7. Confirm Setting



Withdraw the Adjustment Tool in a straight, upward motion. Keep the Adjustment Tool at a minimum distance of 60 cm (24 in) from the Locator Tool.

8. Turn Off

Once the desired setting has been achieved, switch off the Locator Tool by pressing and holding the purple button until the screen turns off.

9. Clean and Store

Disinfect the Tool Kit components and return both tools to their proper locations in the storage case.

The storage case includes:



The storage case includes:

- Locator Tool
- Adjustment Tool
- Quick reference card
- Instructions for use
- X-ray overlay
- Spare batteries (CR123A)
- Screw driver

Troubleshooting: If the Locator Tool shows these screens...



Remove the Locator Tool from the patient and repeat the procedure after confirming the valve orientation. If there is difficulty confirming a valve indication, repeat calibration with the Locator Tool a minimum of 10 cm (4 in) above the valve while keeping it aligned and parallel to the valve. Confirm that the Adjustment Tool is a minimum distance of 60 cm (24in) away from the Locator Tool. If difficulties persist, use fluoroscopy or x-ray to determine the setting.

Between the settings



If the display shows >10 mm, it means the bottom of the device is >10 mm away from the valve but it can provide valve location. If the device is not providing indication after multiple attempts, take fluoroscopy or x-ray.

> 10mm



If the display shows the low battery reminder icon, the system has less than 4 minutes of power remaining before battery power runs out and the system shuts down. Replace the batteries using the screwdriver stored inside of the zipped pocket of the Tool Kit.

Low battery reminder



System Error

Contact your local sales representative as the device is damaged.



Screwdriver is stored inside of the zipped pocket.