

VERCISE™
Deep Brain Stimulation System

**Boston
Scientific**
Advancing science for life™

PROGRAMMING GUIDE

Accurate Targeting. Precise Control.



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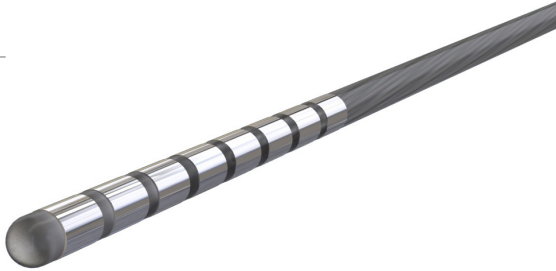
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OVERVIEW

ACCURATE TARGETING

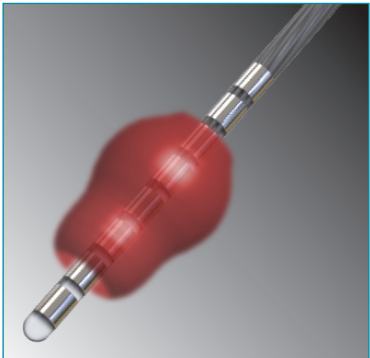
With a dedicated power source for each of the 8 electrodes on the lead, the Vercise™ DBS System enables highly accurate targeting to minimize the side effects of unwanted stimulation and maintain therapy over time.



PRECISE CONTROL

Our Multiple Independent Current Control technology (MICC) generates precise control to refine the size and shape of the stimulation field, designed to customize therapy for individual patients.

The Vercise DBS System offers the lowest pulse width settings (10 – 450 us)¹ and the ability to have a different frequency on each lead (2- 225 Hz).²



PATIENT FOCUS

The Vercise™ DBS System provides an IPG with the smallest footprint, gentle contours and a durable 25-year battery life—all of which are designed to enhance the patients’ quality of life. With Zero-Volt™ battery technology, the battery can be discharged completely or for long periods of time without substantial loss in capacity or battery failure, and with a prolonged battery life, patients are less likely to endure the worry or risks associated with battery replacement surgery.




1) The use of lower pulse widths than established (60-450 µsec) is the sole responsibility of the user.
2) The rate is limited to 255 Hz for a given area.

LINKING A REMOTE CONTROL TO A STIMULATOR



To link a Remote Control that has been previously linked to a different stimulator, you must first de-link the Remote Control from the original Stimulator (see De-linking a Remote Control from a Stimulator below) and then link the Remote Control to the new Stimulator.

To link a Remote Control to a Stimulator:

1. Press and hold the **P** button to unlock the Remote Control. The Remote Control will ask if you want to link it to a Stimulator.
2. Position the Remote Control within 18 inches (45 cm) of the Stimulator and orient the large surface of the Remote Control parallel to large surface of the Stimulator.
3. Press the **P** button to link the Remote Control with the Stimulator or cancel by pressing the button.
4. Confirm the link by pressing the **P** button or cancel by pressing the  button.

DE-LINKING A REMOTE CONTROL FROM A STIMULATOR

To de-link a Remote Control from a Stimulator:

1. Press and hold the **P** button to unlock the Remote Control.
2. Enter the Clinician's screen on the Remote Control by pressing and holding both the  and **P** buttons simultaneously.
3. Scroll down to "Clear Link" and select "Clear Link" by pressing the **P** button.
4. Confirm that you want to clear the link by pressing the **P** button or cancel by pressing the  button.
5. Enter the password **A-B-C**.


NOTE: To re-link the Remote Control, see Linking a Remote Control to a Stimulator above.

SETTING UP

To connect the remote Control to the Clinician Programmer:

1. Plug the USB to Serial Cable into an USB port on the Clinician Programmer
2. Plug the serial end of the USB to Serial Cable into the matching end of the IR Interface
3. Insert the IR Interface and Remote Control into the plastic holder to keep the IR windows aligned, as shown below:



4. Enter the Clinician's screen on the Remote Control by pressing and holding the  and **P** buttons simultaneously.
5. Press the **P** button to select "CP Mode."
• The Remote Control will inform you that it is ready to communicate with the Clinician Programmer.

CREATING A NEW PATIENT

To create a new patient:

1. Click the down arrow on the right side of the Patient drop-down menu.
2. Select New Patient.
• The Profile Screen will automatically be displayed.
3. Fill in the patient's information
4. Required fields are denoted by bold text.
5. Click Finish to save the information.
6. Click the down arrow on the right side of the Reason for Visit drop-down menu.
7. Select the appropriate reason for the visit.

SELECTING AN EXISTING PATIENT

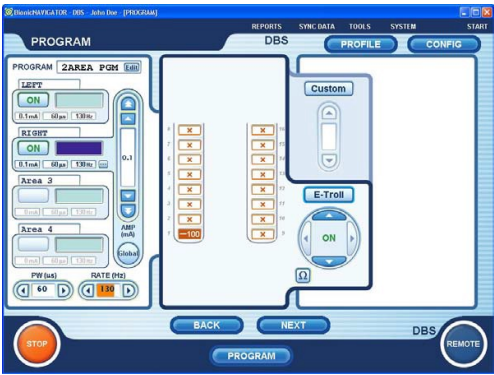
The Clinician Programmer will automatically recognize a patient if you have previously linked to Clinician Programmer to the patient’s hardware.


To select an existing patient:

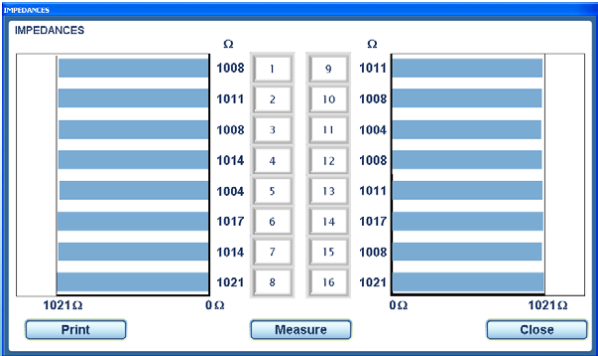
- 1. Click the down arrow on the right side of the Patient pull-down menu
- 2. Select an appropriate patient from the alphabetized list.
- 3. Click the down arrow on the right side of the Reason for Visit pull-down menu.
- 4. Select the reason for patient visit.

PROGRAMMING THE PATIENT

- 1. To get to the Programming screen, select **PROGRAM** at the bottom center of any screen.

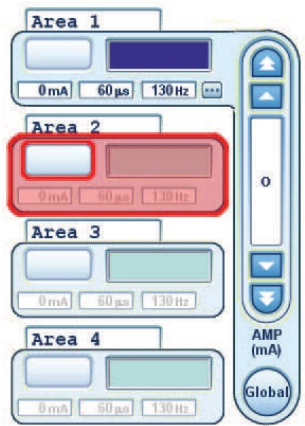




- 2. To check the Lead impedances:
 - 1. Click  while in the Program screen
 - NOTE: All measured impedances are saved into the Clinician Programmer database.



- 2. To exit, click **Close**

- 3. To select an Area:
 - 1. Click on the desired Area control box on the left of the Programming screen, as highlighted in the image below.



- 4. To name an Area:
 - 1. Make sure the Area you wish to name is selected.
 - 2. Click on the Area’s name.
 - 3. Edit the text.
 - Area names may not exceed eight characters in length.
 - 4. Click  to save the changes or  to exit without saving your changes




SELECTING CONTACTS

You may program the patient either by manually selecting anodes and cathodes in Custom Mode or automatically trolling the stimulation field along the lead in E-Troll Mode.

E-TROLL MODE


E-Troll Mode is an enhanced way of conducting a monopolar review.




To E-Troll along the lead:

1. Switch to E-Troll mode by clicking  in the middle of the screen.
2. Select a contact to assign it as a cathode and adjust the amplitude.
3. Use the  and  buttons in the E-Troll panel to incrementally steer the stimulation focus.

CUSTOM MODE


Custom Mode allows you to manually select contacts to be anodes or cathodes.

1. If necessary (i.e., to switch to Custom Mode from E-Troll Mode), press the  button at the top of the middle panel on the Programming screen.
2. Click on the contact to select that contact.
3. Click on the selected contact to turn the contact into an anode.
Click on the selected contact again to turn the contact into a cathode.
Click on the selected contact again to turn the contact OFF (blank).
Contact polarity options include anode (+), cathode (-), and OFF (blank).
4. Repeat steps 2-3 until all desired contacts are selected.


Click...	to...
	Increase the percentage of total cathodic or anodic current on the selected contact.
	Decrease the percentage of total cathodic or anodic current on the selected contact.
	Equalize the percentages of current on all contacts of the selected contact type (anode or cathode).

TURNING STIMULATION ON AND OFF FOR INDIVIDUAL AREAS

To turn ON stimulation for an Area:

1. Make sure the Area you wish to turn on is selected
NOTE: To initially turn on stimulation for an area, that area must first be configured with at least one cathode.
2. Click the  button of the selected area to turn stimulation ON.





To turn OFF stimulation for an Area:

1. Make sure the Area you wish to turn off is selected.
2. Click the  button of the selected Area to turn stimulation OFF.



INCREASING AND DECREASING THE AMPLITUDE

To increase or decrease the amplitude of the selected area:

1. To increase the amplitude, click the up arrows above the AMP label on the Programming screen.
2. To decrease the amplitude, click the down arrows above the AMP label.

Click...	to...
	Increase the amplitude quickly.
	Increase the amplitude slowly.
	Decrease the amplitude slowly.
	Decrease the amplitude quickly.

INCREASING AND DECREASING THE PULSE WIDTH

- 1. To increase the pulse width, click the  button below the **PW** label
- 2. To decrease the pulse width, click the  button below the **PW** label

INCREASING AND DECREASING THE RATE

- 1. To increase the rate, click the  button below the **RATE** label
- 2. To decrease the rate, click the  button below the **RATE** label

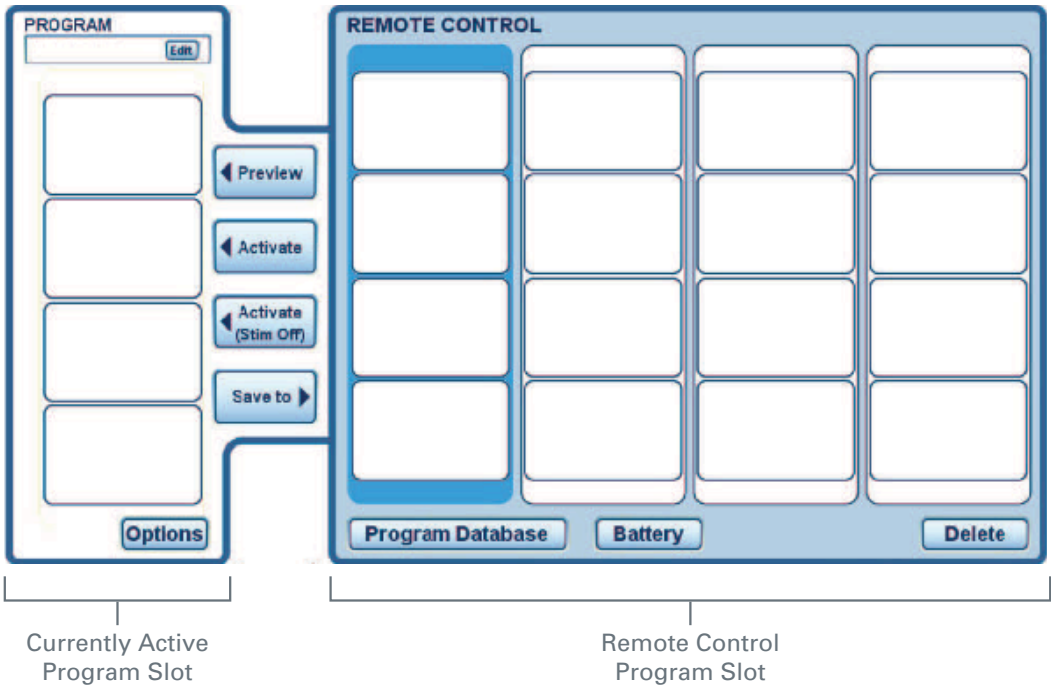
MANAGING PROGRAMS

To get to the Remote Control screen:

- 1. Click  from the Programming screen

UNDERSTANDING THE PROGRAM SLOTS


The program currently running on the stimulator is displayed on the left panel. On the right side of the screen, the four program slots are displayed.



SAVING A PROGRAM


The currently active program can be saved to one of the four program slots.

To save a program to the Stimulator:

- 1. Name the program by clicking **“Edit”** at the top of the left panel, typing a program name, and selecting the **“check mark”**.
- 2. Click a program slot on the right of the screen to which you want to save the program. You can select a blank slot to save a program to, or you can select a slot that already has a program to overwrite it.
- 3. Click .

The currently active program will be saved to the selected program slot.

NOTE: the  symbol in the Remote Control panel indicates last activated or saved program.

- 4. Click  to end programming session.

INNOVATION IN MIND. IMPROVEMENT IN LIFE.

From the very beginning, we've been committed to innovation.

Boston Scientific's Deep Brain Stimulation (DBS) Technology is unlike any other, having its roots in cochlear implant technology, which delivers highly refined and precise stimulation.

The Vercise™ DBS System is designed to offer accurate targeting and precise control to help manage movement disorder symptoms for improved patient quality of life.

References

1. Boston Scientific calculations. Data on file.
2. Boston Scientific Physician Manual.

Please note that this guide is not intended as a substitute for the provided VERCISE™ DBS Programming Manual (9055947). Please contact your Boston Scientific Representative or consult the Programming Manual for information on how to program the Vercise DBS System.

Prescriptive Information. All cited trademarks are the property of their respective owners. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

The Vercise™ Deep Brain Stimulation (DBS) System is indicated for use in unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of levodopa-responsive Parkinson's disease which is not adequately controlled with medication and also for treatment of intractable primary and secondary Dystonia, for persons 7 years of age and older.

Thalamic stimulation using the Boston Scientific Vercise™ DBS System is indicated for the suppression of tremor not adequately controlled by medications in patients diagnosed with Essential Tremor or Parkinson's disease.