

VERCISE™
Deep Brain Stimulation System

VERCISE™ DIRECTIONAL SYSTEMS*

VERCISE NEURAL NAVIGATOR 2.1 PROGRAMMING TUTORIAL



Rx ONLY CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

*A System that includes the Vercise PC or Vercise Gevia™ IPG and Vercise Cartesia™ Directional Lead(s) form the Vercise Directional System.

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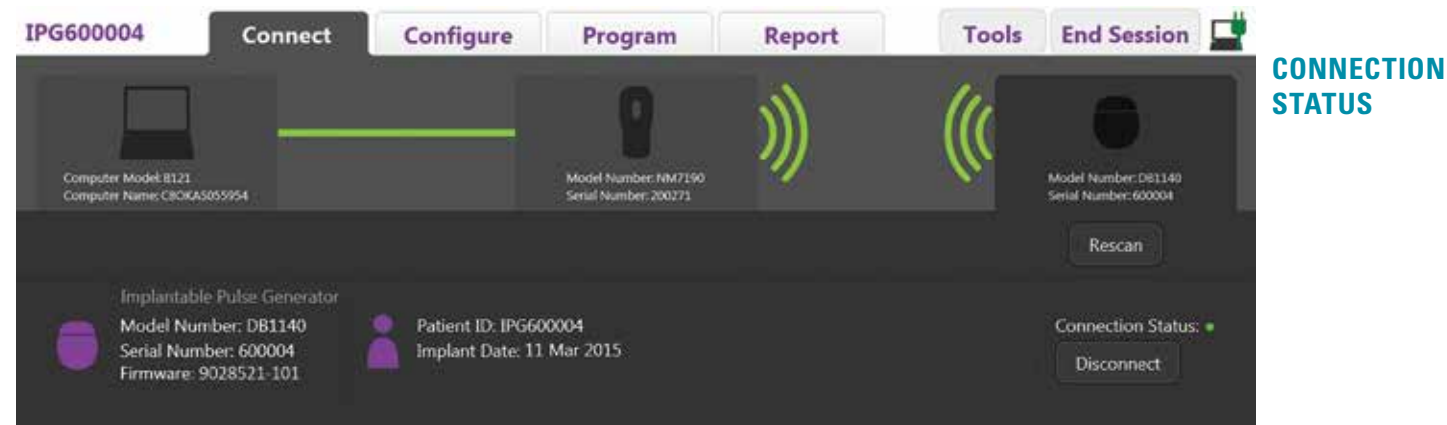
CONNECTING THE PROGRAMMING WAND TO THE CLINICIAN PROGRAMMER (CP)

1. Power ON the CP and log into the ClinicUser account.
2. Plug the Wand into the CP using the provided USB cable.
3. When the Power Light on the Wand turns green, the Wand is ready to use.
4. Place the Wand over the Stimulator.

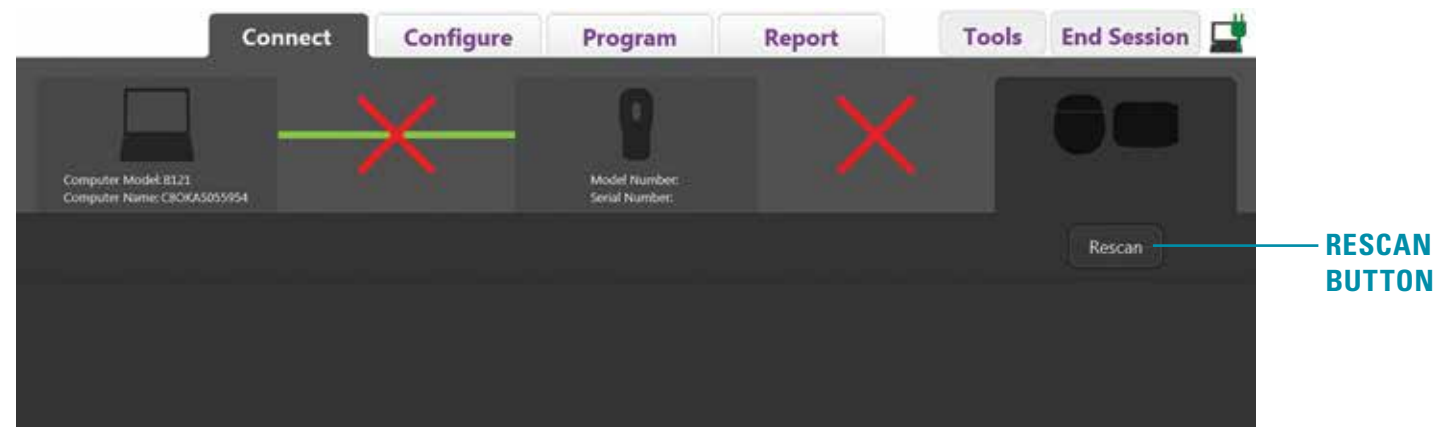


STARTING A PROGRAMMING SESSION

1. Click on the Vercise Launcher icon .
2. Select the Vercise Directional DBS Systems icon  to start Vercise Neural Navigator 2.1.
3. If the Wand is connected, the program will automatically try to connect to a Stimulator.
4. When a connection is established, the following screen is displayed.



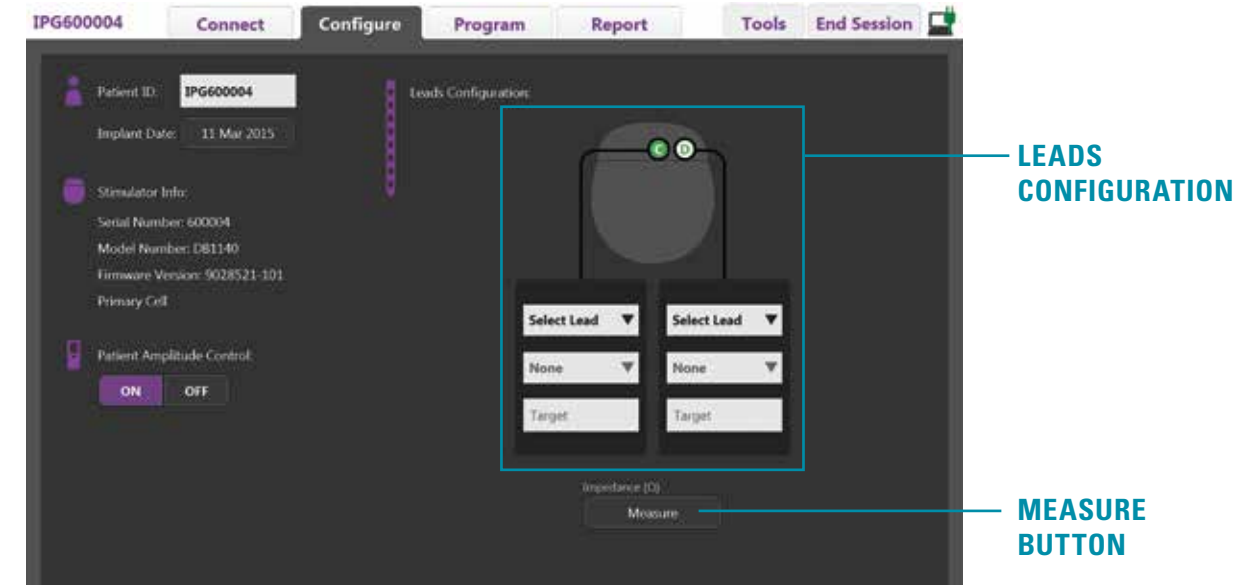
5. If a connection is not established, check the USB connections to the Wand and move the Wand closer to the Stimulator and Rescan.



SETTING UP THE STIMULATOR

CONFIGURING THE LEADS

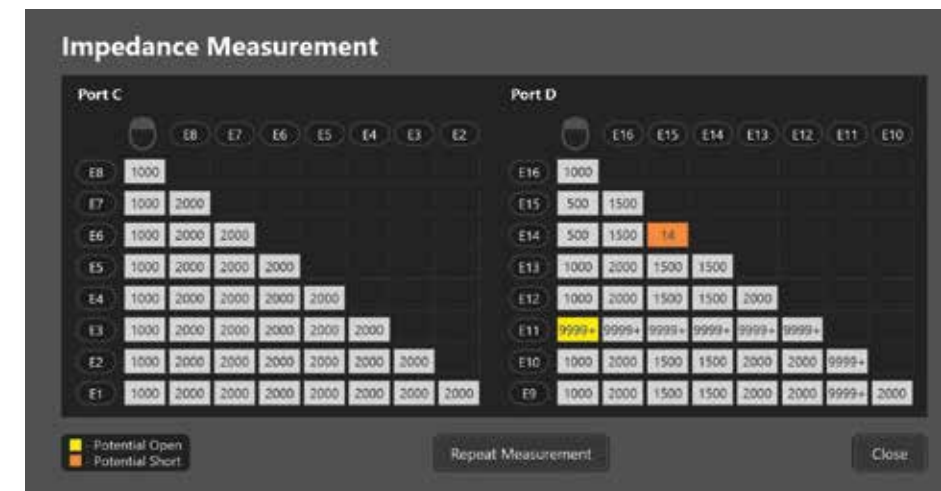
1. Once a connection with the stimulator has been established, switch to the **Configure Tab**.
2. Use arrow keys to access the drop down menus and identify the implanted lead(s) and brain hemisphere. Type in the brain target.



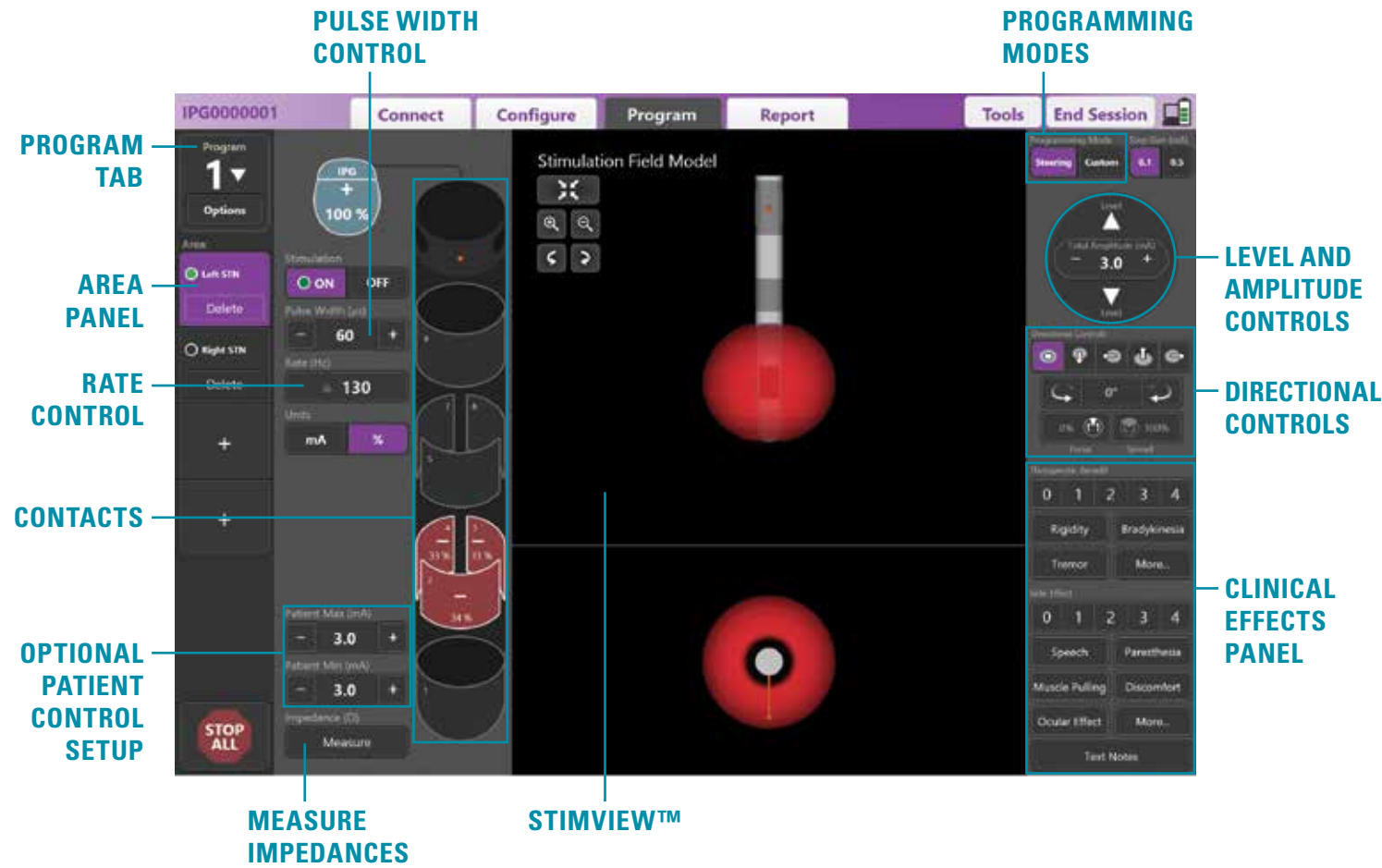
MEASURING IMPEDANCES

Use the **Measure button** on the **Configure** or **Program Tabs** to measure lead impedances. In the Impedance Measurement Window impedances that are greater than 8000 Ω are displayed in yellow and may indicate an open. If values are shown in orange, than impedances are less than 200 Ω and may indicate a short.

Contacts with impedances outside the acceptable range are marked with an Ω symbol.



PROGRAMMING SCREEN OVERVIEW



SETTING STIMULATION PARAMETERS

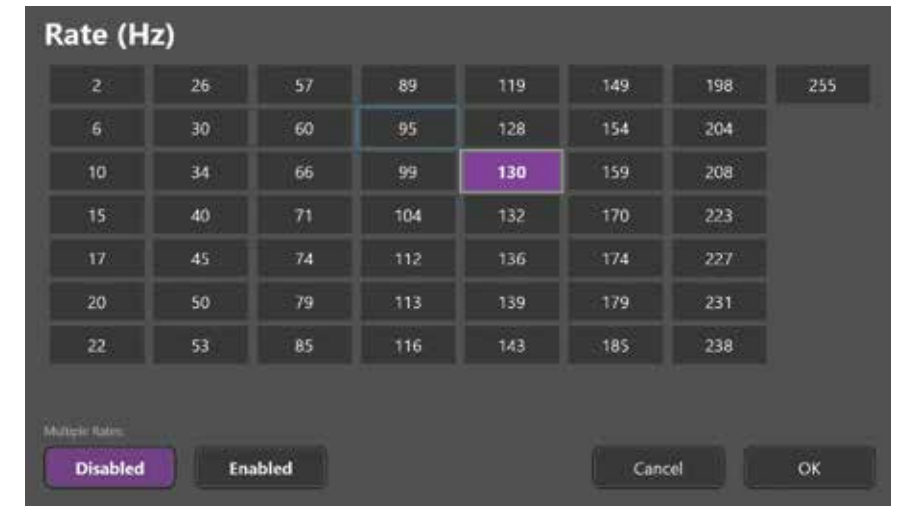
PULSE WIDTH AND RATE

Increasing and decreasing the Pulse Width

The default setting for Pulse Width is 60 μ S and the range is 20-450 μ S. Use the **+** and **-** buttons labeled Pulse Width to increase or decrease Pulse Width in 10 μ S steps.

Increasing and Decreasing the Rate

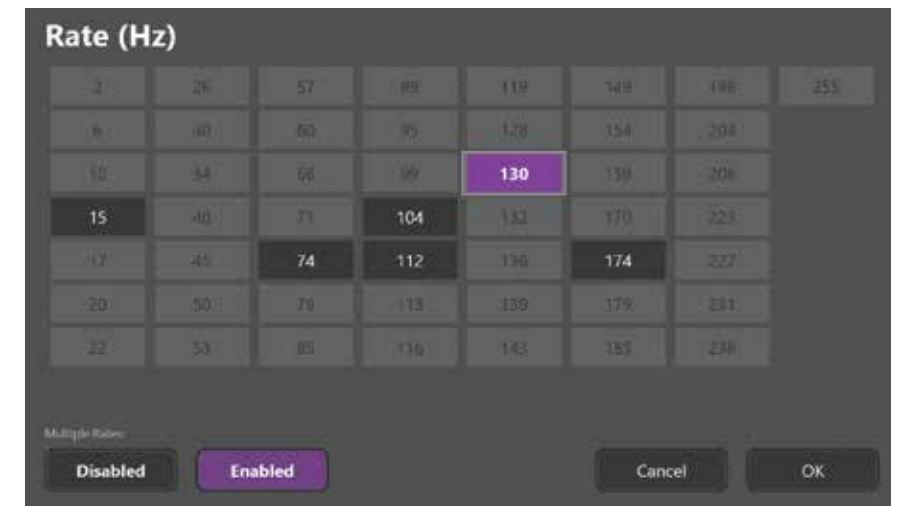
The default setting for Rate is 130 Hz and the range is 2-255 Hz. Select the **Rate Button** and choose the desired Rate from the table. Incompatible rates are greyed out.



Note: Areas that are assigned to the same Lead Port cannot have rates that sum up to greater than 255 Hz.

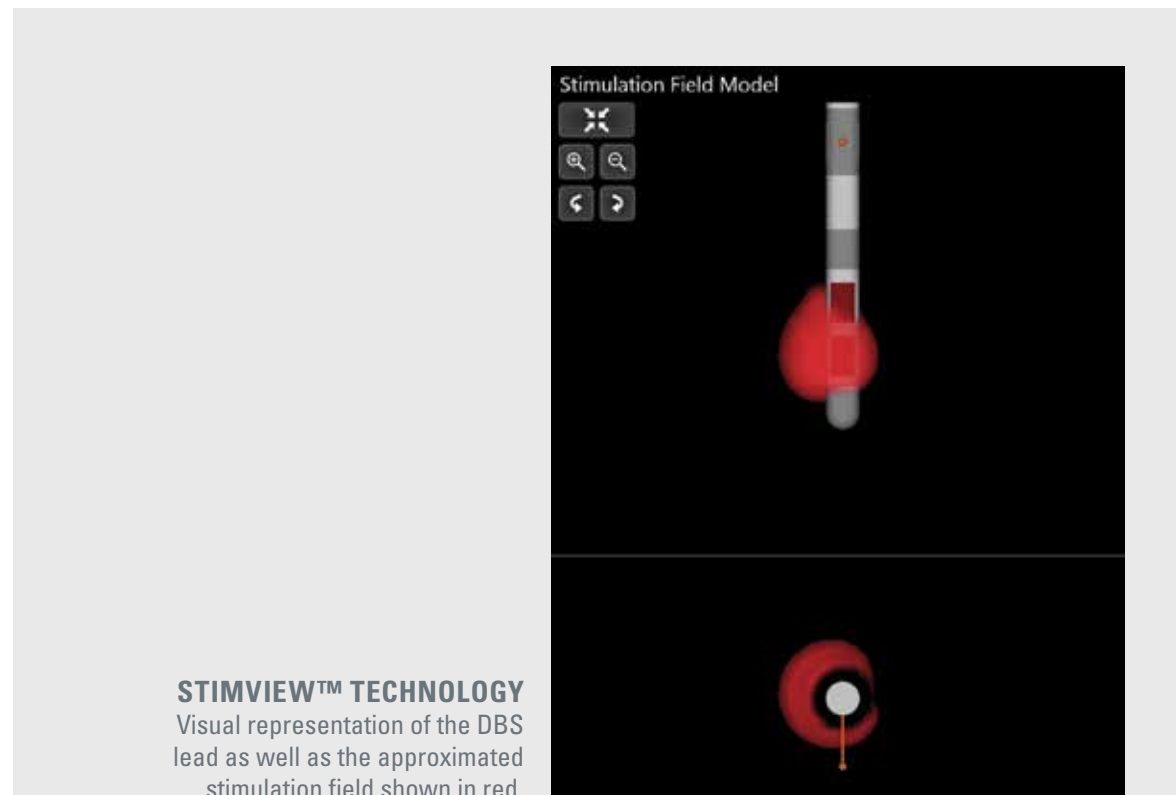
Programming with Different Rates

The Vercise Directional DBS systems allow different Areas to be programmed with different rates. By default, the Multiple Rate option is Disabled. When you enable Multiple Rates, only the rates that are compatible with the rates and pulse widths from the other active Areas are available.



Note: Modifying the rate of an Area will alter the available rates for the other Areas.

Note: If you disable Multiple Rates, the rate for all Areas will be reset to the rate selected for the current Area.




STIMVIEW™ TECHNOLOGY
Visual representation of the DBS lead as well as the approximated stimulation field shown in red.

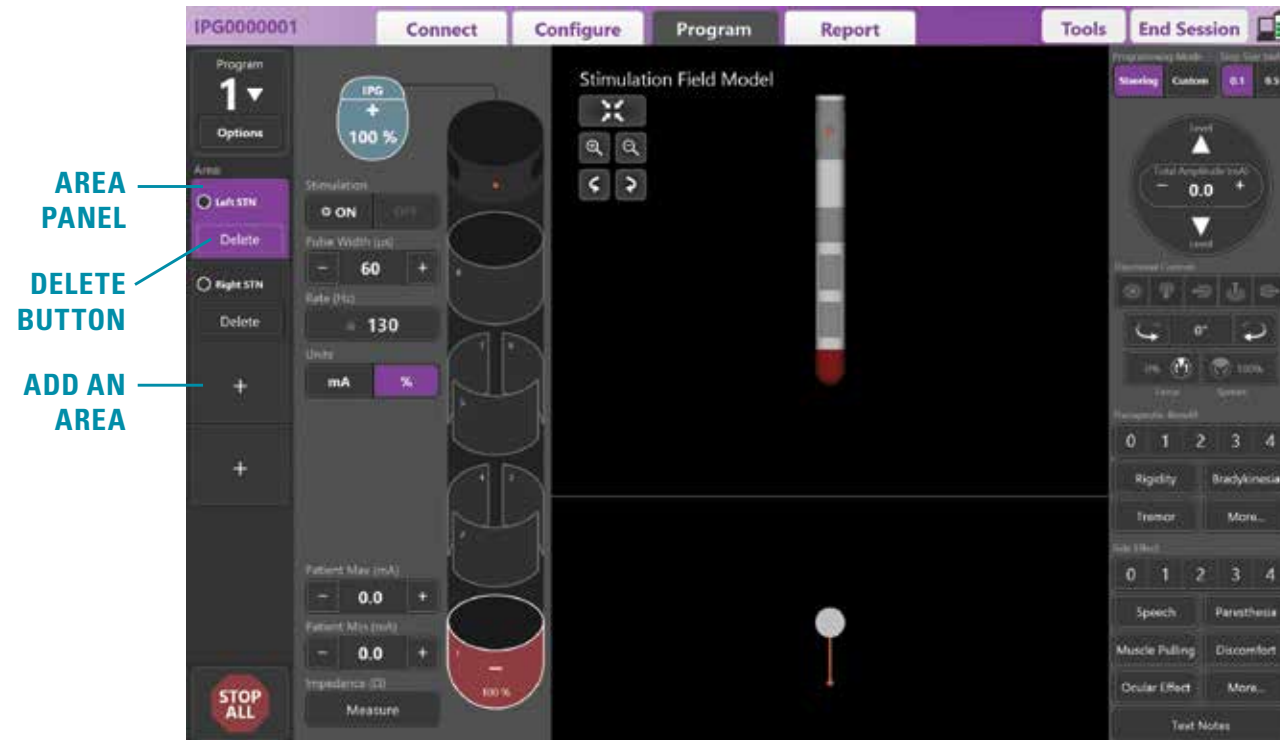
PROGRAMMING THE VERCISE™ DBS SYSTEM

PROGRAMMING THE CARTESIA™ LEAD

SELECTING STIMULATION AREAS




With a new Program, an Area will be assigned to each Lead Port based on the Target and brain hemisphere selected in the **Configure Tab**.

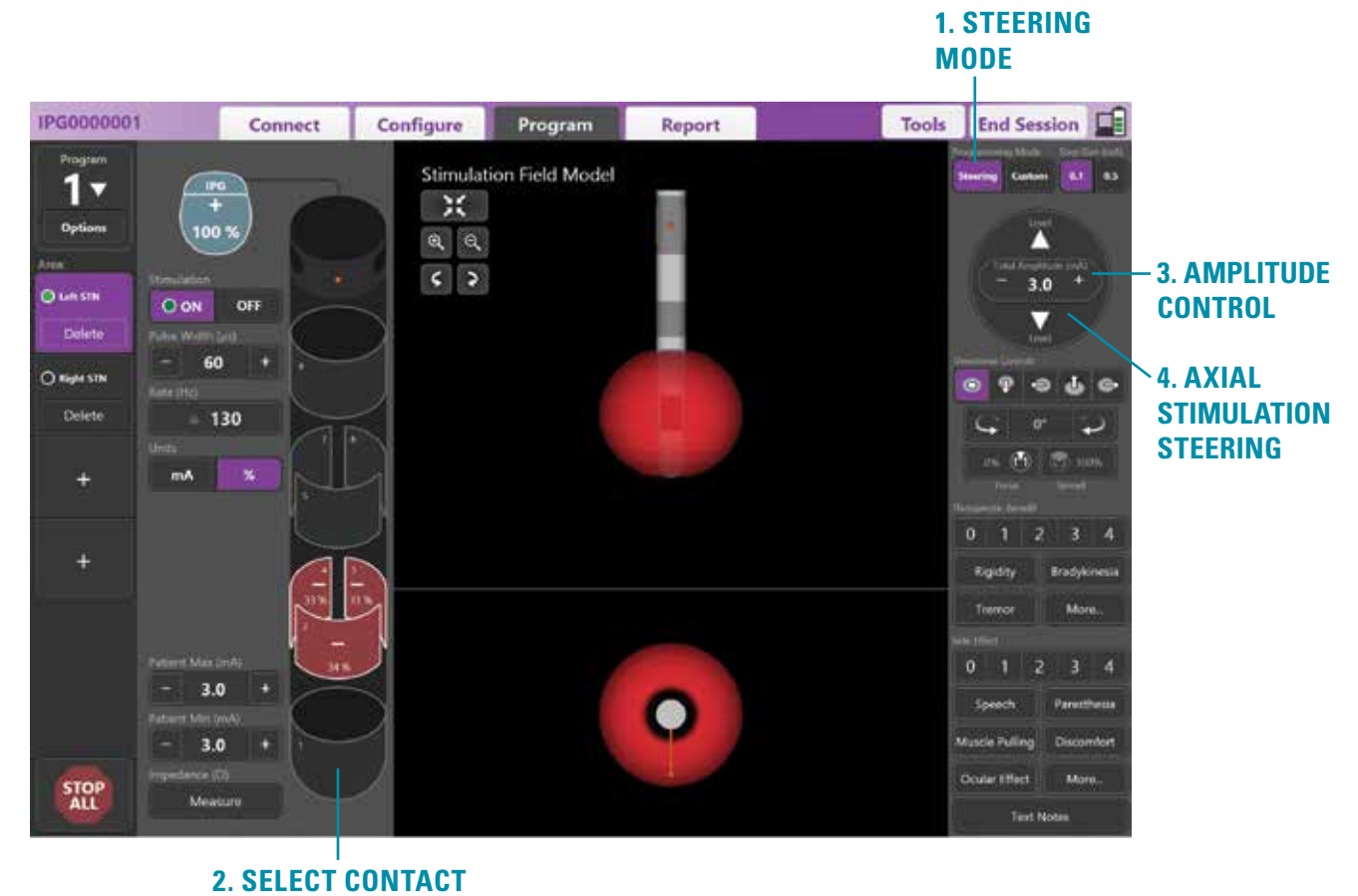
- Add an additional Area by selecting an empty Area  and choosing a Lead Port configuration.
- To reassign an Area select the Delete Button and choose a different Lead Port configuration.
- Configure up to four independent areas of stimulation per program.



PROGRAMMING THE CARTESIA™ LEAD

PROGRAMMING IN RING MODE

1. Select **Steering Mode**.
2. Select contact(s) or level* that you want to program.
3. Increase **Total Amplitude** with the  buttons.
4. Use the  and  buttons to incrementally steer stimulation up and down or axially along the length of the lead.



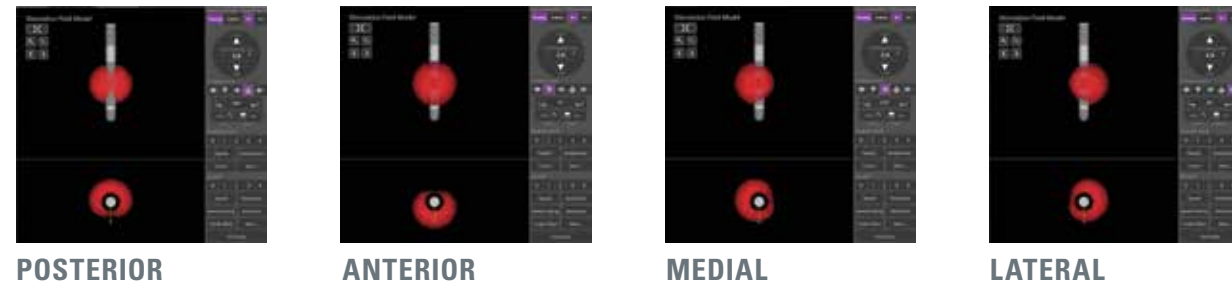
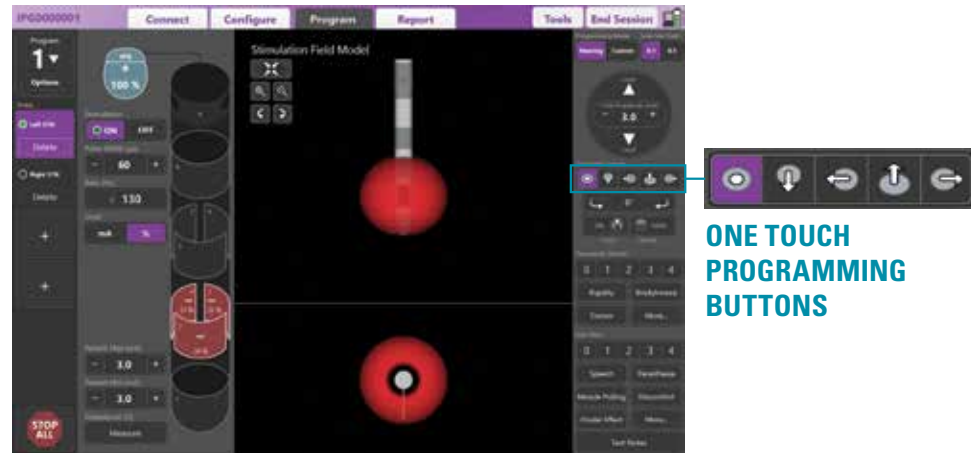
*Level refers to the focal point of stimulation along the axial plane of the lead.

PROGRAMMING THE CARTESIA™ LEAD

SIMPLY ADVANCED PROGRAMMING

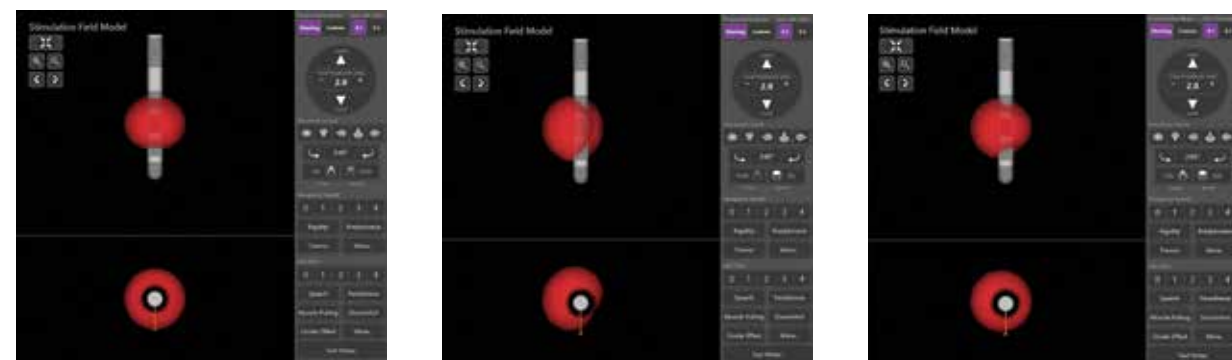
One Touch Programming

Use **One Touch Programming** buttons to quickly steer stimulation into one of four orthogonal directions or put the stimulation field into "ring mode."



Focus and Spread

Spread stimulation across multiple contacts or narrow the focus to a single one.



100% SPREAD (0% FOCUS) MEANS RING MODE STIMULATION

100% FOCUS (0% SPREAD) MEANS ALL THE STIMULATION IS PLACED ON A SINGLE CONTACT

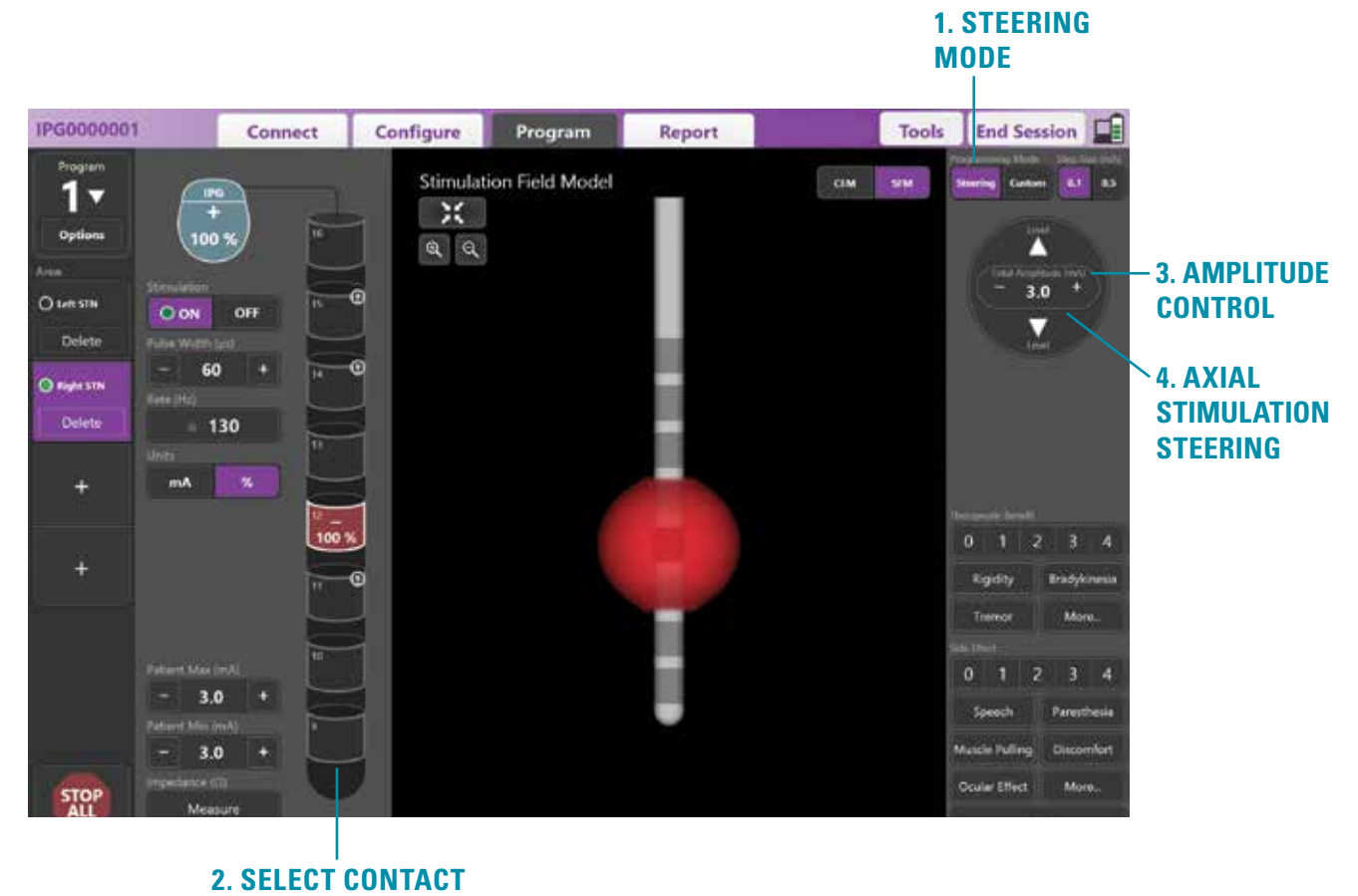
50% FOCUS (50% SPREAD)

Rotational Steering

Rotate stimulation around the lead in 30° increments with the buttons.

PROGRAMMING THE VERCISE STANDARD LEAD

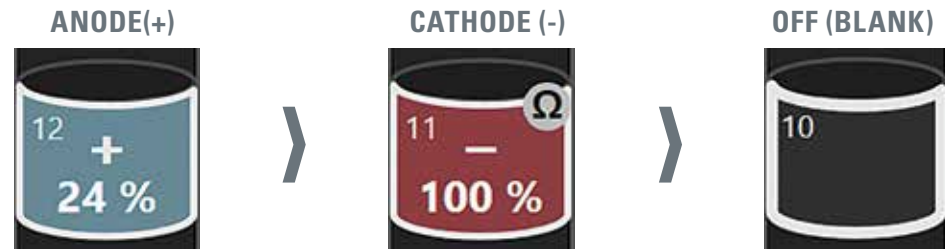
1. Select **Steering Mode**.
2. Select contact that you want to program.
3. Increase **Total Amplitude** with the buttons.
4. Use the buttons to incrementally steer stimulation up and down or axially along the length of the lead.



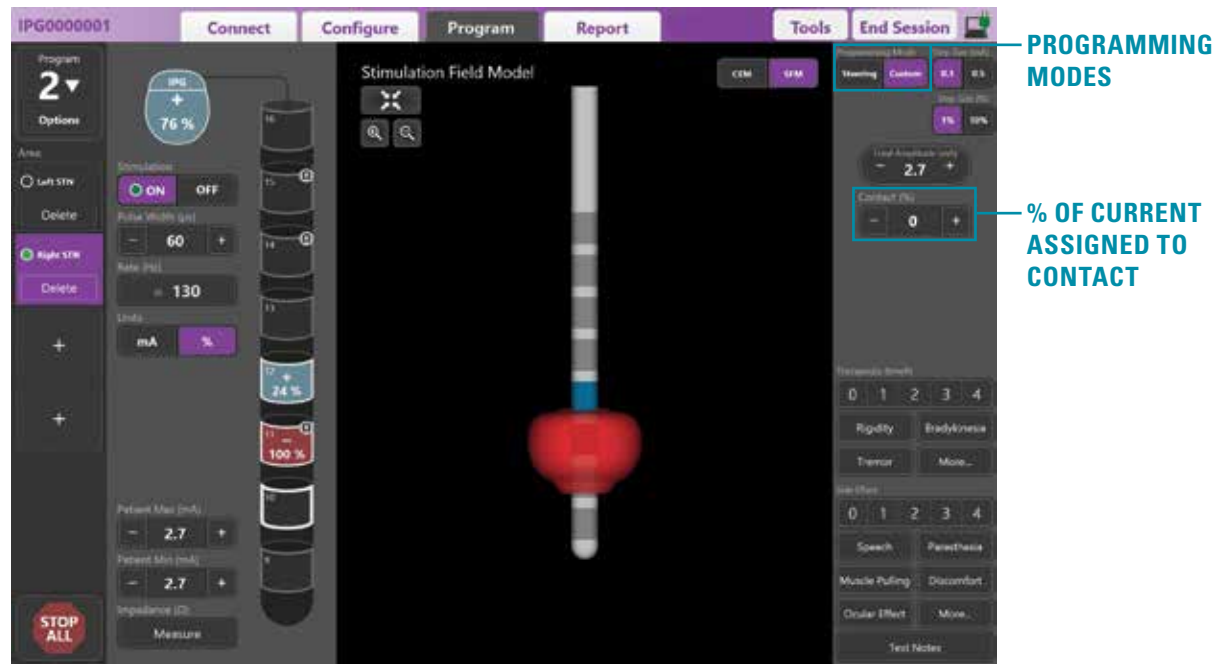
CUSTOM MODE

Custom Mode allows you to assign anodic or cathodic stimulation to individual contacts and case.

1. Select **Custom Mode**.
2. Select the case or contact that you want to adjust.
3. The first tap will select the contact or case and each subsequent tap will cycle through the following assignments:



4. Use the **+** and **-** buttons to adjust the percentage of anodic or cathodic stimulation on the selected contact.

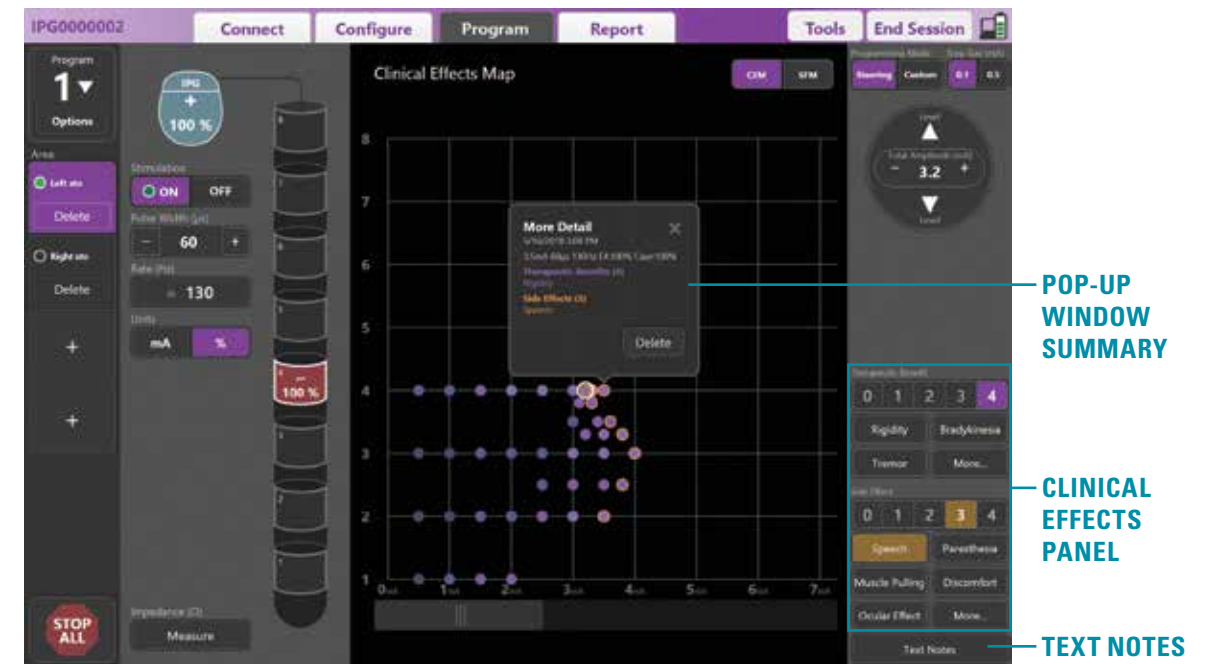


MAPPING THE PATIENT'S CLINICAL EFFECTS OF STIMULATION

The Clinical Effect Panel allows you to note a therapeutic benefit and/or side effect at a given lead position and amplitude on a 0 (no effect) – 4 (strongest effect) scale. Selecting a score for a therapeutic benefit and/or side effect plots a dot on the Clinical Effects Map at the lead position and amplitude. The color of the dot reflects the strength of the therapeutic benefit with 0 displayed as no color and 4 shown as a dark solid purple. Side effects are displayed as an orange ring around the dot.

Selecting a dot will display a pop-up window containing the date and time at which the dot was captured along with the stimulation setting and effect details.

You may also select the Text Notes button to enter and save up to 250 characters of text associated with each lead port.



Note: Clinical effects data and associated settings are saved on the Stimulator and are available for review in the reports tab. The Clinical Effects Map is only available when programming the Vercise Standard Lead.

COLLECTING CLINICAL EFFECTS DATA

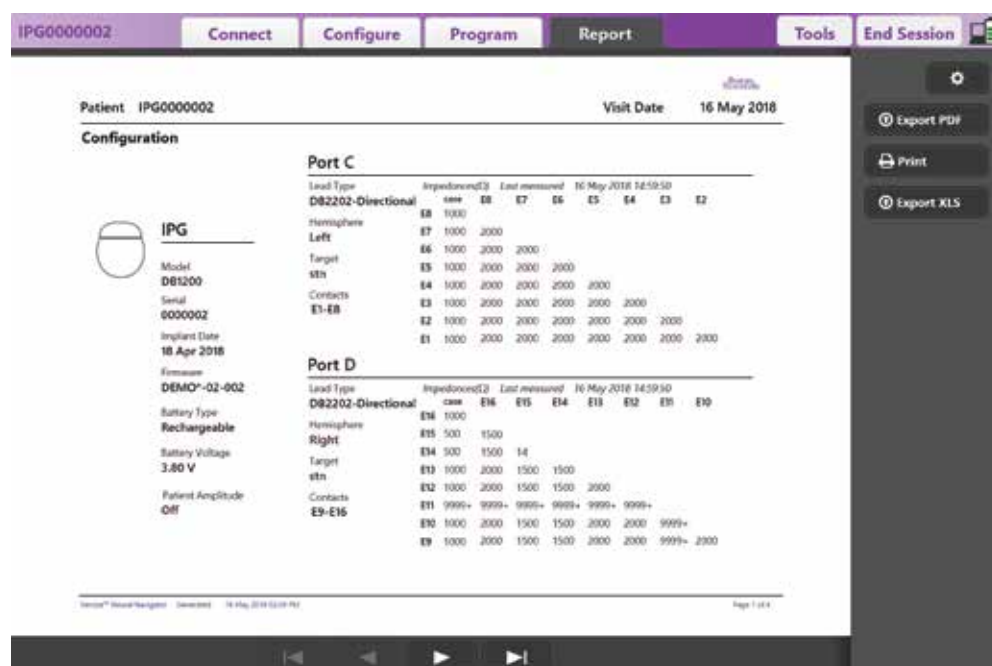
GENERATING REPORTS

To generate a report for the current programming session, click on the Report Tab. A Report may be printed or exported as a pdf or csv file.

Report options include:

- Program Settings
- Configuration
- Clinical Effects Maps
- Clinical Effects Details

The user is able to select the desired information they want to include in the report. You can view reports for all Stimulators that were connected to the CP. Reports can also be viewed when the CP is not connected to a Stimulator.



ENDING A PROGRAMMING SESSION

The Patient's Remote Control Automatically syncs with the Stimulator that it has been linked to. No additional steps need to be performed to copy programs to the Remote Control.

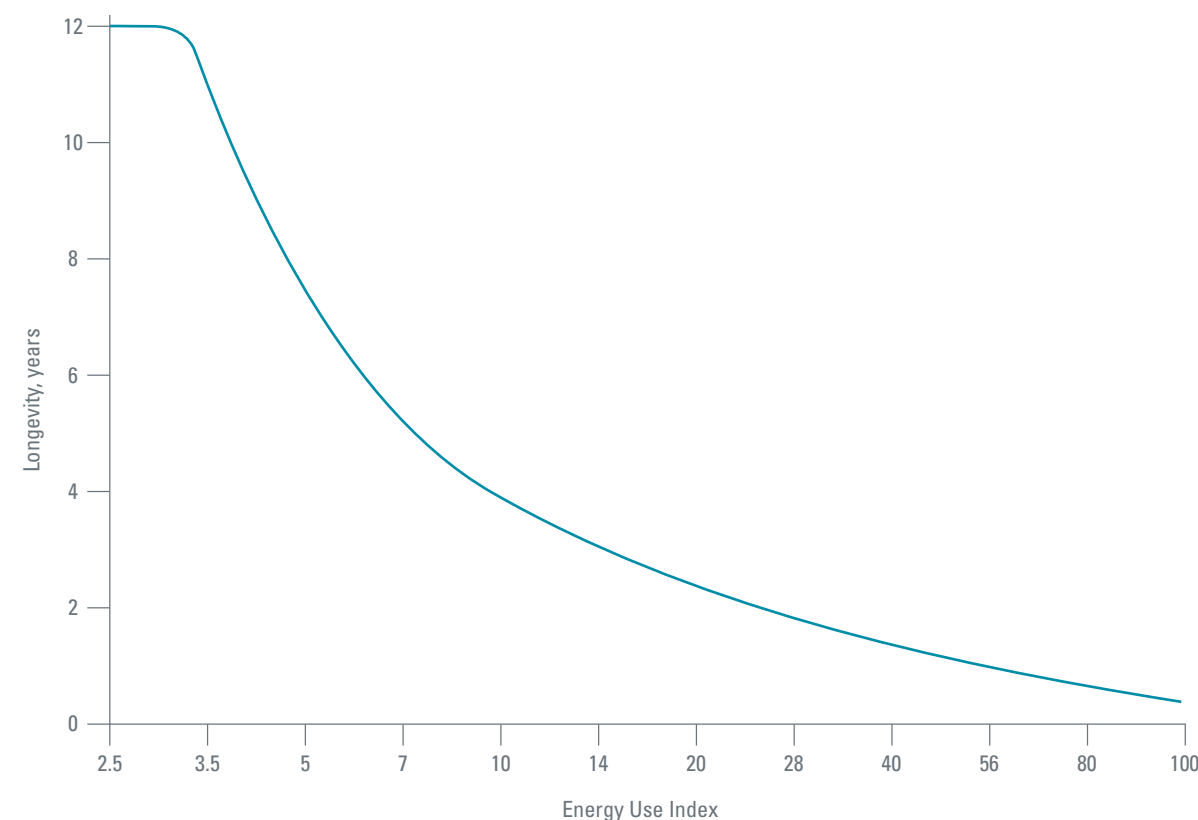
To end a Programming Session on the CP:

1. Select the **End Session** button.
2. Select **Disconnect from Stimulator** to end the programming session and disconnect from the patient's stimulator or select **Exit Application**.

ESTIMATING BATTERY LIFE

The Energy Use Index gives you an estimate of battery longevity for the selected program. After the optimal settings have been identified for a program, click on **Battery** in the **Programs Options** menu on the **Program Tab** to obtain the Energy Use Index.

Use the Longevity Estimate Chart to identify the longevity that corresponds to this Energy Use Index. The figure takes into account nominal non-therapy power consumption, including shelf-life and patient remote control use. If the estimate for longevity obtained is below 12 months, consider evaluating a Vercise Gevia™ DBS System.



GUARANTEES

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ADDITIONAL INFORMATION

For indications, contraindications, warnings, precautions, adverse events summary, sterilization, component disposal and storage and handling, refer to the *Information for Prescribers DFU* for your Boston Scientific DBS System. For other device specific information not included in this manual or labeling symbols, refer to the appropriate DFU for your Boston Scientific DBS System as listed on your *DBS Reference Guide*.

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