Vercise™
Neural Navigator 3
Programming Manual

Directions for Use
How to Use This Manual

This manual describes the usage of the Boston Scientific Vercise Neural Navigator Software. Read all instructions carefully before using the DBS Systems.

For indications for use, contraindications, warnings, precautions, adverse events, sterilization, component disposal, and storage and handling, refer to the Information for Prescribers DFU for your Boston Scientific DBS System as listed in your DBS Reference Guide. 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 in your DBS Reference Guide.

Guarantees

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Drawings are for illustration purposes only.

Trademarks

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Contacting Boston Scientific

There are no user serviceable parts. If you have a specific question or issue, please contact your sales representative or call (833) DBS-INFO or (833) 327-4636.

Product Model Numbers

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>*DB-7161</td>
<td>Vercise™ DBS Clinician Programmer</td>
</tr>
<tr>
<td>*DB-7161-R</td>
<td>Vercise DBS Clinician Programmer (refurbished)</td>
</tr>
<tr>
<td>*NM-7161</td>
<td>Clinician Programmer</td>
</tr>
<tr>
<td>*NM-7161-R</td>
<td>Clinician Programmer (refurbished)</td>
</tr>
<tr>
<td>DB-7105-N31</td>
<td>Vercise Neural Navigator Software 3.1 Installer</td>
</tr>
<tr>
<td>DB-7190 and NM-7190</td>
<td>Programming Wand</td>
</tr>
<tr>
<td>DB-7162 and NM-7162</td>
<td>Keyboard</td>
</tr>
<tr>
<td>NM-4512</td>
<td>USB Splitter</td>
</tr>
</tbody>
</table>

*Applicable after installation of Vercise Neural Navigator 3.1 (Software version 9028429-310).
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Introduction

The Boston Scientific Vercise™ Neural Navigator software is used to program the Vercise™ PC and Vercise Gevia™ Deep Brain Stimulation (DBS) Systems.

A programming session may include the following activities:

1. Starting Vercise Neural Navigator
2. Connecting to the Stimulator
3. Configuring the Stimulator and Leads
4. Testing different Stimulation Settings

This manual will provide instructions on how to accomplish these steps and perform additional functions, such as exporting reports and backing up data.

If you have any issues, contact Boston Scientific Technical Support.

Note: Screens depicted in this manual may differ slightly from the screens on your Vercise Neural Navigator software.

Intended Use

Vercise Neural Navigator is a software program that is used to set and adjust stimulation parameters for the Vercise PC and Vercise Gevia DBS Systems.

Connecting the Programming Wand to the Clinician Programmer

The Clinician Programmer (CP) communicates with the Stimulator via a Programming Wand (Figure 1). The Programming Wand uses a radiofrequency (RF) link to communicate with the Stimulator.

CAUTION: Use only Vercise PC or Vercise Gevia DBS System components with the Vercise Neural Navigator software. Failure to do so may result in the inability to program the Stimulator.

CAUTION: The CP is not equipment for the patient environment as defined by IEC 60601-1. The CP and the person using the CP should not be in contact with the patient while programming.

Connecting the Programming Wand to the CP:

1. Plug the CP into a power source.
2. Power ON the CP.
3. Log in as ClinicUser. You will be prompted to setup a password the first time you log into the CP.
   Note: Be sure to make note of the ClinicUser password.
4. Connect the Programming Wand to the CP using the USB cable provided with the Programming Wand.
   (a). Plug the Mini USB end of the USB Cable into the USB Port on the side of the Programming Wand.
   (b). Plug the Standard USB end of the USB Cable into the USB Port on the CP.
5. Wait for the Wand to perform a self-test. At the end of the self-test, the Wand will beep.
6. If the Power Light on the Wand is green, place the Wand over the Stimulator.
   (a). If the Power Light on the Wand remains red, contact Technical Support.
Starting a Programming Session

Starting Vercise Neural Navigator

1. Power ON the CP and log in as ClinicUser.
2. Select the Vercise Launcher icon on the desktop.
3. Select to start Vercise Neural Navigator.
   \textbf{Note:} Multiple softwares should not be run simultaneously on the same CP.
   \textbf{Note:} Vercise Neural Navigator can also be launched in Demo Mode using the Vercise Launcher. Demo Mode is used for demonstration purposes only (Figure 2).

4. Upon starting Vercise Neural Navigator, the screen will show the \textbf{Connect Tab} and the software will automatically attempt to connect to a Stimulator (Figure 3).
   (a). If no Stimulator is found, move the Wand closer to the Stimulator that you are trying to connect to and select the \textbf{Rescan} button.
   \textbf{Note:} The CP cannot connect to the Vercise Gevia\textsuperscript{TM} Stimulator when the Stimulator is in MRI Mode. Exit MRI Mode using the Remote Control and rescan to connect. For instructions on exiting MRI Mode, refer to the Remote Control Manual as listed in your DBS Reference Guide.

\begin{table}[h]
\centering
\begin{tabular}{|c|c|}
\hline
\textbf{#} & \textbf{Feature} & \textbf{Description} \\
\hline
1 & Connect Tab & Displays the connection status between the CP, Wand, and Stimulator. \\
2 & Configure Tab & Configure Leads and edit patient profile. \\
3 & Program Tab & Adjust the Stimulator program settings. \\
4 & Data Tab & Generate, print and export reports, and export or delete selected patient(s) data. \\
5 & Tools Tab & Delete patient data. \\
6 & End Session Tab & Disconnect from the Stimulator or exit the application. \\
7 & Battery Indicator & Displays the battery status of the CP. \\
\hline
\end{tabular}
\end{table}
5. Once a connection has been established between the CP and the Stimulator, the following screen will appear (Figure 4).

![Figure 4. Connection Established Between CP and Stimulator](image)

### Table 2: Description of the Connect Tab

<table>
<thead>
<tr>
<th>#</th>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient ID</td>
<td>Displays the Patient ID number.</td>
</tr>
<tr>
<td>2</td>
<td>Connection Status</td>
<td>Displays the connection status between the CP, Wand, and Stimulator along with the Model and Serial Number of each of the devices.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><img src="image" alt="Connection Status" /></td>
</tr>
<tr>
<td>3</td>
<td>Rescan Button</td>
<td>Scan for available Stimulators. Disabled if the CP is already connected to the Stimulator.</td>
</tr>
<tr>
<td>4</td>
<td>Connection Status</td>
<td>Displays a green filled circle if the Stimulator is connected to the CP.</td>
</tr>
<tr>
<td>5</td>
<td>Connect or Disconnect Button</td>
<td>Connect or disconnect from a Stimulator. When a Stimulator is not connected, this button reads 'Connect'. When a Stimulator is connected, this button reads 'Disconnect'.</td>
</tr>
</tbody>
</table>
Programming the Stimulator

Configuring the Leads

Once a connection has been established between the CP, Wand, and Stimulator, switch to the **Configure Tab** to configure the Leads that are connected to the Stimulator (Figure 5).

**Note:** During an initial programming session, Lead Configuration must be completed prior to navigating to the **Program Tab**. Once a Stimulator has been initially configured, you can directly switch to the **Program Tab** after connection has been established from the **Connect Tab**.

![Figure 5. Configuring Leads](image)

<table>
<thead>
<tr>
<th>#</th>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Leads Configuration</td>
<td>For each Lead, select the Lead type, Stimulator Port to which the Lead is connected, and brain hemisphere. Enter the target Area. For Directional Leads, select the Directional Marker orientation.</td>
</tr>
<tr>
<td>2</td>
<td>Measure Button</td>
<td>Measure Impedances. See the “Measuring Impedances” section of this manual for more information.</td>
</tr>
<tr>
<td>3</td>
<td>Patient Amplitude Control</td>
<td>Turn ON/OFF the patient’s ability to change stimulation Amplitude. The range of Patient Amplitude Control is adjusted in the <strong>Program Tab</strong>.</td>
</tr>
<tr>
<td>4</td>
<td>Stimulator Information</td>
<td>Displays the Stimulator Information including Serial number, Model number, Firmware Version and type of Stimulator.</td>
</tr>
<tr>
<td>5</td>
<td>Implant Date</td>
<td>Displays the date on which a CP first connects to a new Stimulator. The Implant Date can be adjusted by selecting the Implant Date button.</td>
</tr>
<tr>
<td>6</td>
<td>Patient ID</td>
<td>The Patient ID automatically defaults to the Stimulator serial number. The Patient ID can be edited by typing into the Patient ID field.</td>
</tr>
</tbody>
</table>

Measuring Impedances

Impedances can be measured using the Measure button on the **Configure** or **Program Tabs**. The impedances of each Contact may be used to verify electrical integrity. When an impedance measurement is taken, impedances are assessed between a Contact and the Stimulator Case (monopolar), and between pairs of Contacts (bipolar). Impedances over 8000 Ω may be the result of open or unconnected wires and are displayed in yellow on the Impedance Measurement window. Impedances less than 200 Ω may be the result of short circuits and are displayed in orange. Contacts that have impedances outside the acceptable range are marked with a symbol on the programming screen. The most recent set of impedance measurements are included in a report that can be printed or exported from the **Data Tab**.
The Programming Screen

Once the Leads have been configured, select the **Program Tab** to begin programming. The Programming screen is divided into the following sections and features as shown in Figure 6. Programming features specific to the Directional Lead and Programming a Directional System are shown in Figure 7. STIMVIEW™, or the Stimulation Field Model (SFM), shown in Figure 7, and the Clinical Effects Map, shown in Figure 6, can be viewed for both a Standard Lead and a Directional Lead.

**Figure 6. Programming Screen**

**Figure 7. Directional Lead Programming Screen**

<table>
<thead>
<tr>
<th>#</th>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Program Button</td>
<td>Select the Program that you would like to set up or adjust.</td>
</tr>
<tr>
<td>2</td>
<td>Program Options Button</td>
<td>• View battery longevity estimate for non-rechargeable Stimulators.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• View battery recharge estimate for rechargeable Stimulators.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Delete and copy Programs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Change ramp and cycle times for Programs.</td>
</tr>
<tr>
<td>3</td>
<td>Area Panel</td>
<td>Select the Area within a Program that you would like to set up or adjust.</td>
</tr>
<tr>
<td>4</td>
<td>Area Options Button</td>
<td>Delete an Area within a Program.</td>
</tr>
</tbody>
</table>
| 5  | +                        | Add an Area. Select from one of the Stimulator Ports defined in the **Configure Tab**.
<table>
<thead>
<tr>
<th>#</th>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Stimulation ON/OFF Button</td>
<td>Turn stimulation OFF for the Area selected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Note:</strong> When the Amplitude is at 0 mA, increase the Amplitude to turn ON stimulation.</td>
</tr>
<tr>
<td>7</td>
<td>Pulse Width Button</td>
<td>Adjust the Pulse Width.</td>
</tr>
<tr>
<td></td>
<td>Default</td>
<td>Range</td>
</tr>
<tr>
<td></td>
<td>60 μS</td>
<td>20 μS – 450 μS</td>
</tr>
<tr>
<td>8</td>
<td>Rate Button</td>
<td>Adjust the Rate.</td>
</tr>
<tr>
<td></td>
<td>Default</td>
<td>Range</td>
</tr>
<tr>
<td></td>
<td>130 Hz</td>
<td>2 Hz – 255 Hz</td>
</tr>
<tr>
<td>9</td>
<td>Units Button</td>
<td>Select the Units in which Amplitude is displayed on Contacts and Stimulator Case.</td>
</tr>
<tr>
<td></td>
<td>Default</td>
<td>Alternative</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>mA</td>
</tr>
<tr>
<td>10</td>
<td>Patient Amplitude Buttons</td>
<td>Adjust Maximum and Minimum Patient Amplitude.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Note:</strong> The Patient Amplitude buttons are only displayed if the Patient Amplitude Control has been set to ON from the configuration screen.</td>
</tr>
<tr>
<td>11</td>
<td>Stop All Button</td>
<td>Turns off all stimulation.</td>
</tr>
<tr>
<td>12</td>
<td>Contact and Stimulator Case Configuration</td>
<td>Displays percentage of anodic (+) or cathodic (-) energy assigned to the Lead Contacts and Stimulator Case for a given Area. See the “Selecting Contacts” section of this manual for more information.</td>
</tr>
<tr>
<td>13</td>
<td>Measure Button</td>
<td>Measures impedances of the Contacts.</td>
</tr>
<tr>
<td>14</td>
<td>Programming Modes</td>
<td>Select Steering or Custom Programming modes.</td>
</tr>
<tr>
<td>15</td>
<td>Step Size</td>
<td>Select the step size for Amplitude adjustments: 0.1 mA or 0.5 mA.</td>
</tr>
<tr>
<td>16</td>
<td>Level Up and Down Buttons</td>
<td>Steer stimulation focus along the Lead.</td>
</tr>
<tr>
<td>17</td>
<td>Total Amplitude</td>
<td>Increase or decrease the total Amplitude delivered for a given Area.</td>
</tr>
<tr>
<td>18</td>
<td>Clinical Effects Panel</td>
<td>Make note of the Therapeutic Benefits and/or Side Effects for the current Stimulation settings.</td>
</tr>
<tr>
<td>19</td>
<td>Text Notes</td>
<td>Capture text notes for a given Lead (up to 250 characters per Lead Port).</td>
</tr>
<tr>
<td>20</td>
<td>Clinical Effects Map</td>
<td>Graphical summary of assigned Therapeutic Benefits and/or Side Effects at a given position along the DBS Lead array and a stimulation Amplitude.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Note:</strong> Clinical effects data is captured and listed in reports but not plotted on the Clinical Effects Map for configurations not possible in Steering Mode and for Directional Lead settings that are not 100% focused or spread.</td>
</tr>
<tr>
<td>21</td>
<td>Display Drop-down</td>
<td>View control to switch between the Clinical Effects Map, 3D Overview, or 3D Split View of the stimulation field.</td>
</tr>
<tr>
<td>22</td>
<td>Reference Head</td>
<td>The reference head demonstrates the relationship of the Lead currently being programmed to the position of the patient head.</td>
</tr>
<tr>
<td>23</td>
<td>Clinical Effects Legend</td>
<td>The level of therapeutic benefit is indicated by the saturation of the dot.</td>
</tr>
<tr>
<td>24</td>
<td>STIMVIEW™ or Stimulation Field Model (SFM)</td>
<td>Visual representation of the estimated stimulation field for the currently programmed stimulation parameters.</td>
</tr>
<tr>
<td>25</td>
<td>Directional Presets</td>
<td>Select the one touch buttons to adjust the stimulation field. The directional presets will steer the fully focused stimulation field in one of four orthogonal directions or put the stimulation field into “ring mode.” Ring Mode generates, from a segmented Contact Level, stimulation fields equivalent to those generated by a standard “ring” or cylindrical Contact.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Note:</strong> Only applies to DB2202-Directional Lead.</td>
</tr>
<tr>
<td>26</td>
<td>Rotate Buttons</td>
<td>Steer the stimulation focus circumferentially around the Lead.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Note:</strong> Only applies to DB2202-Directional Lead.</td>
</tr>
<tr>
<td>27</td>
<td>Spread/Focus Buttons</td>
<td>Radially spread or focus the stimulation field.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Note:</strong> Only applies to DB2202-Directional Lead.</td>
</tr>
</tbody>
</table>
Table 4: Description of the Program Tab

<table>
<thead>
<tr>
<th>#</th>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
</table>
| 28 | Directional Indicator | Visual indicator of the orientation of the radiopaque Directional Marker band on the Directional Lead. The orange line and dot correlate to the center of the radiopaque Directional Marker.  
**Note:** Only applies to DB2202-Directional Lead. |
| 29 | STIMVIEW™ View Controls | Adjust the view of the SFM using Zoom, Rotate, Panning Control, or Reset to the original view. Both the Lateral and Axial views of the SFM will adjust in unison using these controls when in 3D Split View, but must be adjusted in the Lateral view. |
| 30 | Virtual Contact        | Dotted ring illustrating the axial location of stimulation along the Lead. The arrow indicator illustrates the rotational orientation of stimulation around the Lead. The dotted ring and arrow indicator together form the Virtual Contact. |

Creating or Modifying a Program

To create a new Program or modify an existing Program, select the Program button and choose one of the four Programs from the drop-down menu. The system allows you to configure up to four Programs on a Stimulator.

For a given Program, you can view and/or adjust several options via the Program Options button. The Program Options include the following:

Table 5: Program Options

<table>
<thead>
<tr>
<th>#</th>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1 | Battery | For a non-rechargeable Stimulator, the Energy Use Index for the current Program is displayed. This value is used to provide an estimate of battery longevity for the current Program on a new non-rechargeable Stimulator. See the “Energy Use Index” section of this manual for more information.  
For a rechargeable Stimulator, an Estimated Charge Time for the current Program is displayed. This value provides an estimate of the duration and frequency of charging necessary to maintain stimulation. |
| 2 | Ramp    | Time to gradually increase the stimulation from zero to the programmed Amplitude when stimulation is turned ON.  
**Default** Options Range  
ON ON/OFF 1 sec - 10 sec |
| 3 | Cycle   | The cycled on and off duration of stimulation delivery.  
**Default** Options Range  
OFF ON/OFF 1 sec - 90 min |
| 4 | Copy to | Copy the current Program settings to another Program. |
| 5 | Delete  | Delete the settings for the current Program. |

Selecting Stimulation Areas

For a given Program, you may configure up to four Areas. With a new Program, an Area will be automatically assigned to each Lead Port and named based on the defined Target and side of the brain selected in the Configure Tab. You may add an additional Area by selecting an empty Area (+) and choosing a Lead Port configuration (e.g. Left STN). You may reassign an Area by first selecting Options for that Area and then choosing Delete Area. You may then select a different Lead Port configuration.

Selecting Contacts

You can manually assign anodes and cathodes in Custom Mode or incrementally steer a stimulation field along the Lead in the Steering Mode. Steering Mode is limited to a monopolar configuration of either a single cathode or adjacent cathodes. You may assign the Stimulator Case and all the Contacts as anode or cathode individually in Custom Mode. The External Trial Stimulator (ETS) is limited to Custom Mode since the Stimulator Case cannot be assigned as an anode.

**Note:** Switching from Custom Mode to Steering Mode will clear the Contact and Stimulator Case assignments.

Steering Mode

Steering Mode is a simplified programming mode where the Contact(s) act as the cathode(s) and the Stimulator Case acts as the anode. This mode allows you to steer a monopolar cathode along the Lead, eliminating the need to turn ON and OFF individual Contacts. Steering Mode incrementally shifts a percentage of the cathodic current to the adjacent Contact(s) using current steering technology to create smooth transitions between Contacts.

The DB2201-Standard Lead has eight Contacts per Lead, labeled 1-8 on each Lead.
To Steer along the DB2201-Standard Lead:

1. Select **Steering Mode**.
2. Select a Contact to assign it as a 100% cathode.
3. Use the \( \uparrow \) and \( \downarrow \) buttons to incrementally steer the stimulation focus along the length of the Lead. The amount of cathodic current will shift in 10% increments.

**Note:** You may also adjust directly from one Contact (Level) to another. The Amplitude for the selected Area will drop to 0 mA when another Contact is selected, but not when steering in 10% increments.

The DB-2202 Directional Lead has a total of eight Contacts per Lead, labeled 1-8 on each Lead. Contacts 1 and 8 are the distal and proximal Contacts, respectively, while Contacts 2-7 are the small directional Contacts (segments) for each Lead.

To Steer along the DB2202-Directional Lead:

1. Select **Steering Mode**.
2. Select a Contact to assign it as a cathode. You may create an equal spread of current across a Level of Contacts ("ring mode") by selecting anywhere within that Level, then selecting the center button. To assign a single directional segment as the cathode, select anywhere within that Level, then select the corresponding button (Figure 8).

![Figure 8. Directional Contact Selector](image.png)

3. Use the \( \uparrow \) and \( \downarrow \) buttons to incrementally steer the stimulation focus along the length of the Lead.
4. Select one of five preset directions for the stimulation field. The directional presets will steer the fully focused stimulation field in one of four orthogonal directions or put the stimulation field into "ring mode."

The following steps can be used to refine the applied directional preset or selected directional segment.

5. Use the \( \uparrow \) and \( \downarrow \) buttons to rotate and steer the stimulation focus circumferentially around the Lead.
6. Use the \( \uparrow \) and \( \downarrow \) buttons to radially spread or shrink the focus of the stimulation field.
7. To choose another starting point or to steer on another Contact, select another Contact. To select a segmented Directional Contact, select the Level, then select one of the three labeled segmented Contacts around the circumference of the center button on the Directional Contact Selector.

**Note:** The total Amplitude for the selected Area will drop to 0 mA when another Contact is selected.

**Note:** Stimulation using multiple independent current control and the DB-2202 Directional Lead is referred to as Cartesia 3D.

Custom Mode

Custom Mode allows you to assign a percentage of anodic or cathodic current to individual Contacts and the Stimulator Case.

To program the DB2201-Standard Lead and the DB2202-Directional Lead in Custom Mode:

1. Select **Custom Mode**.
2. Select the Stimulator Case or Contact that you want to adjust. If it was selected, one tap will assign it as an anode (+). Another tap will reassign it as a cathode (-). Another tap will reassign it as OFF (blank). Tapping on a Contact will first select it without changing the polarity.

**Note:** Changing the Contact polarities will reset the Amplitude to zero.

3. Select the \( + \) and \( - \) buttons for the Contact to adjust the percentage of anodic or cathodic current assigned to the selected Contact.

**Note:** When using the External Trial Stimulator (ETS), monopolar configurations are not possible since the ETS "case" cannot be assigned as a cathode or anode.

**Note:** When using the ETS, Clinical Effects data is recorded but not plotted on the CEM.
Turning Stimulation OFF for Individual Areas

To turn stimulation OFF for Individual Areas:

1. Make sure the Area you wish to turn OFF is selected by clicking on the appropriate Area on the Area Panel.
2. Press the Stimulation OFF button to turn Stimulation OFF.

Note: When the Amplitude is at 0 mA, increase the Amplitude to turn ON stimulation.

Turning All Stimulation OFF

Selecting the button will stop stimulation for all active Areas. This function is only meant for turning all Stimulation OFF. To turn Stimulation ON, select each Area that you want to turn ON and select the Stimulation ON/OFF switch.

Increasing and Decreasing the Amplitude

Amplitude is measured in milliamperes (mA). The default setting for Amplitude is 0 mA and the range is 0-20 mA. The maximum Amplitude for a single Contact is 12.7 mA.

To increase or decrease the Amplitude:

1. Use the + and – buttons labeled Total Amplitude to increase or decrease Amplitude.
2. The default step size for Amplitude changes is 0.1 mA. You can change the step size to 0.5 mA using the Step Size buttons.

Note: High stimulation levels can cause permanent tissue damage. A message will pop-up notifying you if you attempt to exceed a stimulation limit and settings that exceed this limit are not allowed.

Increasing and Decreasing the Pulse Width

The Pulse Width of the stimulation is the length of time a burst of energy is applied per pulse. The Pulse Width is measured in microseconds (μS). The default setting for Pulse Width is 60 μS and the range is 20-450 μS.

To increase or decrease the Pulse Width:

1. Select the Pulse Width button.
2. Select the desired Pulse Width from the options provided.

Note: High stimulation levels can cause permanent tissue damage. A message will pop-up notifying you if you attempt to exceed a stimulation limit and settings that exceed this limit are not allowed.

Note: Increasing the Pulse Width by more than 10 microseconds (μS) at a time will cause the total Amplitude to be reset to 0 mA.

Increasing and Decreasing the Rate

The pulse rate of the stimulation, often called the Rate or the Frequency, dictates how many stimulation pulses are delivered in a second, measured in Hertz (Hz) or pulses per second (pps). The default setting for Rate is 130 Hz and the range is 2-255 Hz.

To increase or decrease the Rate:

1. Select the Rate button.
2. Select the desired Rate from the table of available Rates. 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 Multiple Areas with Different Rates

The Vercise PC and Vercise Gevia DBS Systems allow 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 with be reset to the Rate selected for the current Area.

Selecting Patient Amplitude Range

By default, patients do not have the ability to adjust the Amplitude of their stimulation.

However, in some cases, you may want to give a patient the ability to adjust the Amplitude of their stimulation using the Remote Control. To give patients Amplitude Control, first turn ON the Patient Amplitude Control in the Configure Tab. Once the Patient Amplitude Control is turned ON, you can set the allowable Amplitude range in the Program Tab for each Area by setting a Minimum and Maximum.

Note: High stimulation levels can cause permanent tissue damage. A message will pop-up notifying you if you attempt to exceed a stimulation limit and settings that exceed this limit are not allowed.
Viewing the Stimulation Field Model

The Stimulation Field Model (SFM), called STIMVIEW, is a visual representation of the estimated stimulation field for the currently programmed stimulation parameters. The SFM includes both a visual representation of the DBS Lead as well as the approximated stimulation field shown in the color red (Figure 7). As programming parameters are adjusted and the stimulation is steered along the Lead, the SFM will adjust accordingly.

You may switch between two different views by selecting either 3D Overview or 3D Split View from the Display drop-down (Figure 9). 3D Overview presents a three-dimensional view within which you can zoom, rotate, and pan. The 3D Split View provides a dual pane view centered on the Lead. The top pane is in-line with the Lead and the bottom pane is on an axis perpendicular to the Lead.

Adjust the view of the SFM using to Zoom, to Rotate, to Pan, or to Reset the original view. When in 3D Split View, both the Lateral and Axial views of the SFM will adjust in unison using these controls. These controls will not affect or adjust any programming parameters.

Figure 9. Display Drop-down
Mapping the Patient’s Clinical Effects of Stimulation

For a given stimulation setting, you may make note of a 0-4 rating for each therapeutic benefit and a 0-4 rating for each side effect by selecting the button labeled with the symptom or side effect, then selecting the appropriate numerical rating. If selection of a numerical rating is not desired, select anywhere outside of the Therapeutic Benefit and/or Side Effect rating box to close. To remove your Therapeutic Benefit and/or Side Effect selection, select the Therapeutic Benefit or Side Effect that you want to remove, and then select the Therapeutic Benefit or Side Effect from within the pop-up to remove the highlighted section. Each button that is selected is captured as data associated with that stimulation setting for that patient.

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

When capturing Clinical Effects in Steering Mode, a dot is plotted on the CEM at the Axial Lead position and Amplitude. When programming directionally, the CEM switches to a polar grid. A new CEM will be created for programming settings at different Levels (axial positions along the Lead). The rating scale of the therapeutic benefit determines the color saturation of the center of dot. A visual key indicating color saturation for a score appears at the bottom of the CEM when programming in ring mode (100% spread). If a side effect is selected, an orange ring is displayed. 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 effects details (Figure 10).

All of this data is saved on the Stimulator and available for export in the Reports Tab.

**Note:** Clinical effects data is captured and listed in reports but not plotted on the CEM for configurations that are not possible in Steering Mode.

**Note:** The reference head in the CEM view highlights the hemisphere in which you are currently programming.

**Note:** A Clinical Effects Map is only displayed at 100% focus or 100% spread (ring mode).
**Data**

Within the **Data Tab**, you may generate reports for the current programming session, or for patients that have been previously programmed using the same Clinician Programmer.

To generate a report for the current programming session, select the **Data Tab** (Figure 11). A Report may be printed and exported as a PDF or Excel file.

![Figure 11. Data Tab](image)

Select on the **Data Tab** and select the desired information you want to include in the report by checking on any of the following check boxes:

- Programs
- Configuration
- Clinical Effects Maps
- Clinical Effects Details
- Anonymize Patient Data

You can also view reports for all Stimulators that were connected to the CP. Reports can be viewed when the CP is not connected to a Stimulator.

To view reports when the CP is not connected to a Stimulator (Figure 12):

1. Select the **Data Tab**.
2. Select the patient whose report you would like to view and select **View**.

![Figure 12. Viewing Reports When CP Is Not Connected to Stimulator](image)
Export Data

The Export feature allows you to backup a single patient's data or the entire patient database on the CP to a specified location. The backup location can be a folder on the CP or an external storage drive (for example, USB flash drive). This feature can be accessed from the Data Tab.

To create a backup of a single patient's data or the entire patient database (Figure 13):

**Note:** If exporting the data of multiple patients, you must disconnect from all Stimulators.

1. Select the Data Tab.
2. Select the checkbox next to each patient record that you would like to export.
3. Select Export.
4. If desired, select Anonymize Patient Data.
5. Select Browse to choose a backup location.
6. Select Backup to perform the backup function.

**Note:** After the backup is completed, a pop-up window will confirm the location of the file and indicate if the backup was successful.
Tools

The **Tools Tab** allows you to delete patient data.

Data Management

Patient data can be managed under the **Data Management Tab**.

Deleting Clinical Effects Data

All the Clinical Effects Data for a patient can be deleted from the **Tools Tab** under the **Clinical Effects Data Tab**.

**Note:** This feature is available only when the CP is linked to a Patient’s Stimulator.

![Figure 14. Delete All Clinical Effects Data](image)

To delete the Clinical Effects Data (Figure 14):

1. Go to the **Tools Tab**.
2. Select the **Clinical Effects Data Tab** and select **Delete**.
3. Select **Continue**.
Additional Information

Stimulator Programmable Characteristics

If two Leads are implanted, the stimulation parameters are independent such that stimulation of two different brain targets can have different Amplitudes, Pulse Widths, Stimulation Rates, and Contact configurations. It is possible to configure one Lead as monopolar, and one as multipolar. It is also possible to configure a single Lead with both monopolar and multipolar Areas.

The programmable parameter ranges for the Stimulator are shown below.

<table>
<thead>
<tr>
<th>#</th>
<th>Parameter</th>
<th>Parameter Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Waveform</td>
<td>Charge balanced, asymmetric biphasic</td>
</tr>
<tr>
<td>2</td>
<td>Pulse Shape</td>
<td>Rectangular</td>
</tr>
<tr>
<td>3</td>
<td>Current or Voltage Regulated</td>
<td>Current</td>
</tr>
<tr>
<td>4</td>
<td>Amplitude¹</td>
<td>0.1 mA - 20 mA</td>
</tr>
<tr>
<td>5</td>
<td>Rate²</td>
<td>2 Hz - 255 Hz</td>
</tr>
<tr>
<td>6</td>
<td>Pulse Width</td>
<td>20 μs - 450 μs</td>
</tr>
<tr>
<td>7</td>
<td>Cycle On/Off</td>
<td>1 sec - 90 minutes</td>
</tr>
<tr>
<td>8</td>
<td>Ramp On</td>
<td>1 - 10 seconds</td>
</tr>
<tr>
<td>9</td>
<td>Contact Connections</td>
<td>16</td>
</tr>
<tr>
<td>10</td>
<td>Independent Areas of Stim (4 Programs with 4 Areas per Program)</td>
<td>16</td>
</tr>
<tr>
<td>11</td>
<td>Current Path Options</td>
<td>Unipolar, Bipolar, Multipolar</td>
</tr>
</tbody>
</table>

¹ The programmable coverage for each individual Contact is limited to 12.7 mA. A programming interlock is enforced to limit the total output current to 20 mA or less per coverage Area. For example, a maximum current output of 12.7 mA on one Contact would limit the total summed current output on the remaining Contacts to 7.3 mA within one coverage Area.

² The Rate is limited to 255 Hz for a given Area. The global Rate limit for each Lead is also 255 Hz.
Stimulation Output at Maximum Parameters vs. Impedance

Figure 15 displays the maximum output current when stimulation settings are set to the maximum values on a Ring or Directional electrode (Amplitude Max = 12.7 mA; PW = 450, 240, 120, 30 µs; Rate Max = 255 Hz). Please note that for typical parameters (PW = 60 µs, Rate = 130 Hz, Amplitude = 3 mA), these limits are not expected to be reached.
**Charge Density**

**Figure 16. Charge Density Limits for Boston Scientific DBS Leads**

Figure 16 displays the recommended maximum charge density for different combinations of Amplitude (mA) and Pulse Width (μs). The solid black line (Limit: 6 mm²) refers to all Contacts on DB2201-Standard Lead and the proximal and distal Contacts of DB2202-Directional Lead. The dashed black line (Limit: 1.5 mm²) refers to the small directional contacts of DB2202-Directional Lead. These estimates of charge density are only for the Boston Scientific DBS Leads.

**WARNING:** Patients may have the ability to change the Amplitude with the Remote Control. The physician should set and verify the maximum and minimum Amplitude levels allowed by the Remote Control to ensure that current levels remain safe.
Energy Use Index

The Energy Use Index applies to non-rechargeable Stimulators only. The Energy Use Index gives you an estimate of longevity of the battery life on the Program selected. After the optimal settings have been identified for a Program, from the Program Tab, select Program Options and then select Battery to obtain the Energy Use Index.

Use Figure 17 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 Boston Scientific rechargeable system.

![Longevity Estimates 24 hours/day](image)

**Figure 17. Longevity Estimates Based on 24 Hour Per Day Usage**

Estimated Charge Time

The Estimated Charge Time applies to rechargeable Stimulators only. The Estimated Charge Times provides an estimate of the duration and frequency of charging necessary to maintain stimulation for the selected Program. After the optimal settings have been identified for a Program, from the Program Tab, select Program Options and then select Battery to obtain the Estimated Charge Time.

Elective Replacement Indicator (ERI) Message

You will not be able to connect to a non-rechargeable Stimulator that is nearing the end of its battery life. The CP will display the Stimulator with an ERI message and the Stimulator battery voltage as shown in Figure 18 on the Connect Tab. During the ERI period, the Stimulator will continue to provide stimulation; however, no changes can be made to the Stimulator setting.

**Note:** The ERI Message applies to non-rechargeable Stimulators only.

![ERI Message Displayed on Connect Tab](image)

**Figure 18. ERI Message Displayed on Connect Tab**

End of Service (EOS) Message

When the Stimulator has reached its end of service, stimulation will no longer be provided. The CP will display the message as shown in Figure 19 on the Connect Tab.

**Note:** The EOS Message applies to non-rechargeable Stimulators only.

![EOS Message Displayed on Connect Tab](image)

**Figure 19. EOS Message Displayed on Connect Tab**
Ending a Programming Session

To end a Programming Session on the CP:

1. Select the **End Session Tab**.
2. Select **Exit Application** to end the programming session and close the application.
3. Alternatively, select **Disconnect from Stimulator** to end the programming session and disconnect from the patient’s Stimulator. This will take you back to the **Connect Tab**.

All Programs and programming data are automatically saved in real-time during the programming session. No step to actively “save” is required. The Patient’s Remote Control automatically syncs with the Stimulator to which it has been linked.

Adjusting CP Time and Date

If system startup or hibernation is detected, the CP provides a notification to verify that the system time and date is correct.

If the Time and Date are correct, select **Verify** to dismiss the notification bar.

If the Time and Date are incorrect select **Adjust** to modify the time and date and select **OK** to confirm changes, as shown in Figure 20.

**CAUTION:** Do not change the date format.

![Date and Time Screens](image)

**Figure 20. Date and Time Screens**

**Note:** You can also select the **Time and Date icon** on the Desktop to launch the time and date adjustment window.